



**CRF Completion Guidelines (CCGs)**  
**Protocol #: HPTN 083**  
**Version 7.0 (23Jun2023)**

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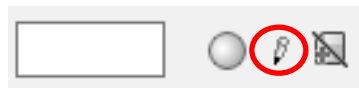
## COMPLETION GUIDELINES FOR STANDARD CRFs

The following instructions are study-specific data completion instructions intended to assist site staff when completing Case Report Forms (CRFs) for HPTN 083 (detailed guidance on general data collection, entry, navigation and use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is posted on the HPTN 083 Atlas web page:

<https://atlas.scharp.org/cpas/project/HPTN/083/begin.view?>

General Guidelines – Medidata Rave forms (electronic CRF completion):

- The Participant ID is automatically assigned by Rave as a 9-digit field, starting with the 3-digit site number followed by a randomly assigned 6-digit participant number.
- All data entered in the electronic form should correspond accurately with source documents.
- Complete all required fields on the screen. Please ensure all entries are in English and are accurate, consistent, complete, and medically logical.
- Ensure there are no missing data in the form. Where requested to “specify” for an item, ensure an entry has been made.
  - Visit dates should be complete and chronological according to the protocol.
  - All date fields are entered as Day/Month/Year (dd/mmm/yyyy) (e.g., 16 APR 2017).
- Use dropdown menus, when available, to select the appropriate response. Do not enter and save text as a response in items with dropdown menus. Such text responses will be flagged as non-conformant data.
- Avoid using abbreviations and symbols wherever possible. Do not use special characters unless explicitly stated, and do not hit the Return key in text fields.
- If corrections are needed, click the “pencil” icon to the right of the field. The field will become editable. Correct the value and give the reason for the change, if needed.



- Data changes can be reviewed in the audit trail. Click the “pen” icon to the right of each field to view its history. If data is modified inadvertently, these changes are also saved in the audit trail.



- System queries may open in response to missing or invalid data entries. System queries close automatically once the form has been re-saved if queried data points have been entered or corrected. System queries do not require a response. Answering a system query prior to updating the data triggers a manual query that must be reviewed and closed by SCHARP.

**Enrollment Date**

? "Did the participant enroll in the study" equals "Yes", yet the "Enrollment Date" is blank.

Please correct.

Opened To Site from System (05 Jul 2017) ←

Data Entry Error
...
?
✎
🗑️

- Log (or repeating) forms allow you to view and enter multiple items on one form, and to switch between portrait and grid views. The following eCRFs are log forms or use the log field format: Pre-existing Condition, Concomitant Medications, Adverse Event, ART Medication, Protocol Deviation, Social Impact, Product Hold/Discontinuation, and Injection Site Reaction.
  - Each log requires a separate form to indicate that one or more entries is required, e.g. Pre-existing Conditions Y/N.
  - The log's first entry will appear as a blank form page. Once filled and saved, this entry appears as a row on the form in the grid view.
  - Click "Add a new Log line" to add a row. You will be redirected to another blank form to enter complete details.
  - Clicking a field on any row opens the form for that row's entry. Existing entries may only be edited from the form page.
  - Log lines can be inactivated by clicking "Inactivate" and specifying the log line number if needed. If a line has been inactivated in error, click to "Reactivate" as appropriate.
- If a scheduled visit was missed, do not enter data on any forms for the visit EXCEPT the Date of Visit form. Mark "No" on the Date of Visit eCRF to the question, "Did the participant complete this visit?" and save this form to add the Missed Visit eCRF to the visit folder for completion.
- The Investigator of Record (IoR) will sign all pages after the participant's data has been reviewed, no further changes or additions to the forms are necessary, and the casebook is frozen by SCHARP. The SCHARP Clinical Data Manager(s) will provide directions for the timing of when the Investigator should perform the final review and sign the form pages.

### Add Event

- The **Add Event** dropdown menu can add select forms and visits to a participant's casebook.
- The following folders can be added to a participant's casebook:
  - Interim Visits (see section on "Interim Visits" below for how to add interim visits to a participant's casebook)
  - Yearly Visits (see section on "Interim Visits" below for how to add visits to a participant's casebook)

### Interim Visits

- Should unscheduled assessments be required for a non-routine visit or procedure, add the visit by clicking on the **Add Event** button. Select "Interim Visit". An Interim Visit folder will appear in the participant's casebook.
- Open the Interim Visit folder to access the "Interim Visit Summary" form. On the Interim Visit Summary form, enter the Interim visit code. Note that the visit code is based on the previous regular visit code (not the week). Enter the visit date as the earliest date visit procedures performed at the visit began.

Select "Yes" for each assessment that was performed. The selected forms will be populated automatically within the applicable Interim Visit folder.

### Yearly Visits

- After a participant transitions to yearly visits, add a yearly visit folder by clicking on the **Add Event** button. Select “Yearly Visit”. A Yearly Visit folder will appear in the participant’s casebook.
- Open the Yearly Visit folder to access the “Yearly Visit Summary” form and select the applicable Yearly visit code from the pull-down menu.
- Select “Yes” for each assessment that was performed. The selected forms will be populated automatically within the applicable Interim Visit folder.
- On the Yearly Visit Summary eCRF, enter the visit date as the earliest date visit procedures performed at the visit began.
- If a participant completely misses a yearly visit, create the expected Yearly visit folder as above and select No to the question “Did the participant complete the visit?” Once the form is saved complete the Missed Visit form that now appears in the folder.

Note: Step 2 participants who no longer receive injections and do not or cannot take Step 3 open label study product must first complete the Step 3 schedule before moving to yearly visits.

### Auto-population of Medidata Rave Forms

- Medidata Rave will dynamically add folders and eCRFs to a visit folder within a participant’s casebook based on specified responses on certain eCRFs. Below are a few examples:
  - Example 1: Enrollment eCRF - Enrollment folder
    - If “Yes” is selected for “Is the participant enrolling in the study?”, all Step 2 and Step 3 folders will be added.
  - Example 2: Date of Visit eCRF
    - If “No” is selected for “Did the participant complete this visit?” the Missed Visit eCRF will be added to the visit folder and required eCRFs for that visit will not appear in the folder.
    - If any additional eCRFs are marked in the “Mark any additional forms or procedures” section, those marked eCRFs will be added to the visit folder. Note: If the eCRF already appears in the folder as a required form do not mark that form on the list.
  - Example 3: Adverse Event Y/N
    - Selecting ‘Yes’ for “Has the participant experienced an Adverse Event during the study?” will dynamically add the Adverse Events Log eCRF to the Ongoing Logs folder.

### Dynamic Search List Functionality

- Dynamic searchlist functionality is used to look up Adverse Events data (*AE log line, onset date, and AE term, e.g. “#001 05JAN2017-FEVER”*).
- Dynamic searchlist functionality is present on the following forms: Concomitant Medications, Hematology, Local Laboratory Results, and Product Hold
- For Example:
  - An AE of “FEVER” started on 05JAN2017 and is reported on the Adverse Events form
  - On the Concomitant Medications form, if a listed medication was used for this AE, a dynamic searchlist can be used to select the applicable AE log line from the dropdown list.

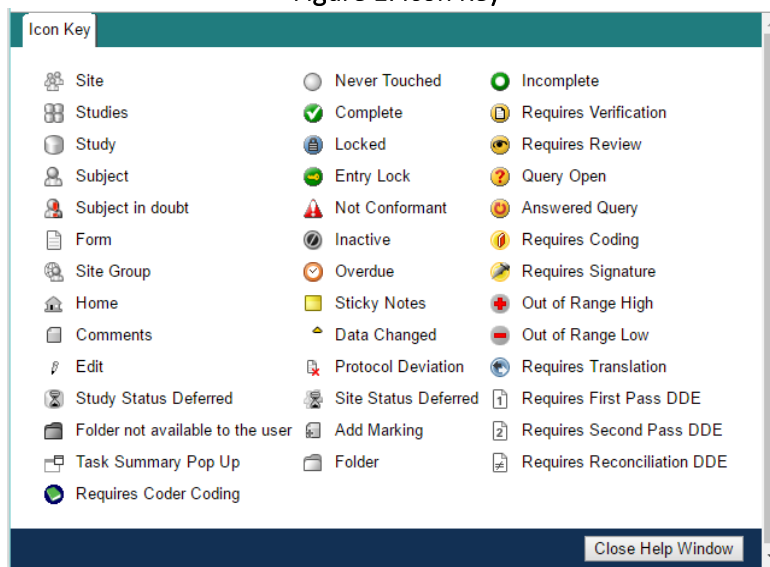
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- The dynamic search list displays “AE log line, onset date, and AE term” once an AE is selected.
- Your selection can be manually deleted by re-selecting the AE if entered in error
  - **Note:** If the original data (e.g., AE term and/or onset date) was revised or the AE log line was inactivated, the previous selection becomes non-conformant (see icon in chart below). You will need to correct the item by re-selecting the AE on the form where the nonconformant icon appears and re-saving that form.. In some cases, it may be necessary to save the form twice: first with no AE selected, then again after the AE has been re-selected

### Icon Key

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

Figure 1. Icon Key

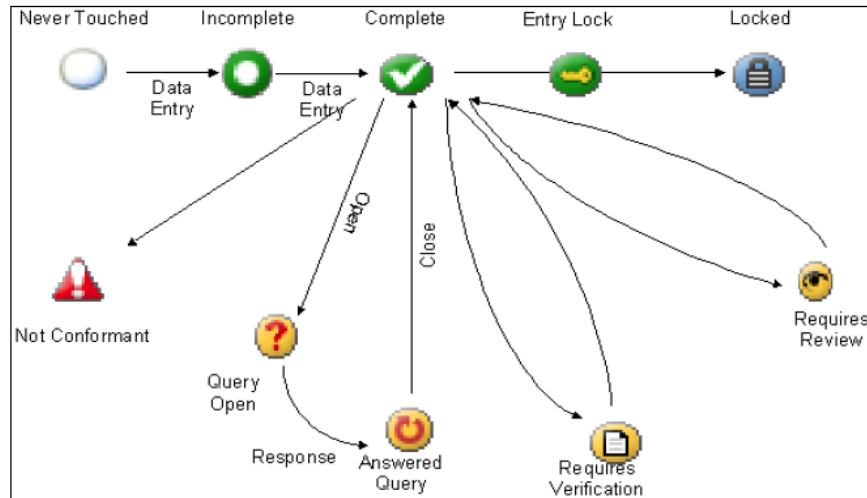


### Icon Progressions

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

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

Figure 2. Icon Progression



**Task Summary**

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

**Figure 3. Site-Level Task Summary**

Task Summary: Site	Subjects
▶ Requiring Signature	8
▶ NonConformant Data	0
▶ Open Queries	8
▶ Overdue Data	0

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

Task Summary: Site	Subjects
▶ Requiring Signature	8
▶ NonConformant Data	0
▼ Open Queries	8
998210855	
998238757	
998313907	
998329818	
998423107	
998549894	
998561588	
998672732	
1	
▶ Overdue Data	0

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

**Figure 5. Participant-Level Task Summary**

<b>Task Summary: Subject</b>	<b>Pages</b>
▶ 📄 Requiring Signature	1 📄
▶ ⚠️ NonConformant Data	0 📄
▼ ❓ Open Queries	3 📄
V1.0 - Screening-Hematology	
<u>V1.0 - Screening-Baseline Medical History Summary</u>	
V1.0 - Screening-Baseline Medical History Log	
1	
▶ 🕒 Overdue Data	0 📄

### How to Record Dates - Electronic and/or Paper

Dates are entered using the “dd MMM yyyy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yyyy” represents the four digits of the year.

The month field must be entered with the three-letter abbreviation in English. Abbreviations are shown below. In the study database, these abbreviations will be selected from a dropdown list in the month field.

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

For example, September 20, 2016 is recorded as:

The screenshot shows a date entry interface with three input fields: a day field containing '20', a month dropdown menu currently showing 'Sep', and a year field containing '2016'. A 'Sav' button is located to the right of the month dropdown. The dropdown menu is open, displaying a list of months: '...', 'Jan', 'Feb', 'Mar' (highlighted in blue), 'Apr', 'May', 'Jun', 'Jul', and 'Aug'.

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

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

### How to Record Time - Electronic and/or Paper

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

24-hour clock

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

**How to Record Numbers (non-dates)**

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

**Data Corrections and Additions - Electronic and/or Paper**

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

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

**How to Handle Missing and Unknown Data**

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

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

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

*mp*  
~~18 AUG 16~~     *don't know exact date*  
 un FEB 14

---

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

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

**LABORATORY FORM GENERAL INSTRUCTIONS****Reporting Severity Grade**

- Record the severity grade at the top of the form by selecting from the dropdown menu for each corresponding lab analyte when applicable. If the analyte does not meet criteria for severity grade 1 or greater per the DAIDS Toxicity table (Version 2.0), select the “Not gradable” option.
- The severity grade options are as follows:
  - Grade 1 – Mild
  - Grade 2 – Moderate

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- 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).
- Record any Grade 1 or higher lab values on the “Pre-Existing Conditions Log” or “Adverse Event Log” form(s) as applicable.
- If an abnormal lab finding meets AE reporting criteria, select the corresponding AE within the dropdown 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.

#### *Lab Result Units and Rounding*

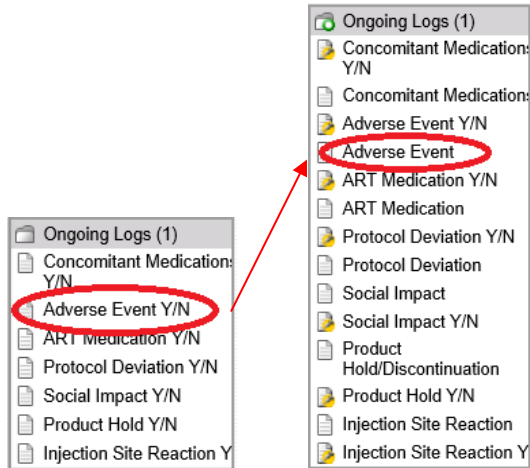
- Results should be documented on the form using the units present on the source laboratory results document so that no conversion is necessary. If the units present on the form do not match your source results report, contact the Clinical Data Manager at SCHARP. Note that the following units are equivalent:

$$\text{IU/L} = \text{U/L}$$

$$\text{I/I} \times 100 = \%$$

$$10^9/\text{L} = 10^3/\text{mm}^3 = 10^3/\mu\text{L}$$

**ADVERSE EVENT Y/N**



**Purpose:**

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

**General Instructions:**

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

**Item-specific Instructions:**

Field	Instructions
<p>Has the participant experienced an Adverse Event during the study?</p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is selected and the form saved, then the “Adverse Event” log form appears in the folder and can be completed.</li> </ul>

# ADVERSE EVENT

Page: Adverse Event - Ongoing Logs (1) ☰

Currently viewing line 2 of 2. Apply to Record   
 Click here to return to "Complete View".

Date reported to site	<input type="text"/> ... ▾ <input type="text"/>	<input type="radio"/> <input type="radio"/>
Adverse Event (AE)	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Onset Date	<input type="text"/> ... ▾ <input type="text"/>	<input type="radio"/> <input type="radio"/>
At which visit was this AE first reported?	... ▾	<input type="radio"/> <input type="radio"/>
Interim visit code, if applicable:	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Is the AE still ongoing?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> <input type="radio"/>
Outcome Date	<input type="text"/> ... ▾ <input type="text"/>	<input type="radio"/> <input type="radio"/>
Severity Grade	... ▾	<input type="radio"/> <input type="radio"/>
Relationship to study product	<input type="radio"/> Related <input type="radio"/> Not Related	<input type="radio"/> <input type="radio"/>
Alternate etiology	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Action Taken with Study Product	... ▾	<input type="radio"/> <input type="radio"/>
Other action(s) taken		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
None		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Medication		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Therapeutic procedure/surgery		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Diagnostic procedure		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Other		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Other, specify	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Status/Outcome <sup>?</sup>	... ▾	<input type="radio"/> <input type="radio"/>
Is this a serious adverse event according to ICH/GCP or protocol guidelines? If "No", go to following question.		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/>
If "Yes", check all that apply.		
Results in death		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Is life-threatening		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Requires inpatient hospitalization or prolongation of existing hospitalization		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Results in persistent or significant disability/incapacity		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Is a congenital anomaly/birth defect		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above		<input type="checkbox"/> <input type="radio"/> <input type="radio"/>
Has or will this AE be reported as an EAE?		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/>
If yes, EAE number	<input type="text"/>	<input type="radio"/> <input type="radio"/>

[Printable Version](#) [View PDF](#) [Icon Key](#) Save Cancel

CRF Version 993 - Page Generated: 01 Aug 2018 11:31:21 Pacific Daylight Time

**Purpose:**

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

**General Instructions:**

Complete one log line for each adverse event (AE). HIV infection should not be reported on this form.

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Only list conditions that start on or after enrollment date, otherwise record conditions as pre-existing. Record increases in severity/frequency as new events with corresponding start/stop dates and add additional log lines by clicking “Add a new Log line”.

**Item-specific Instructions:**

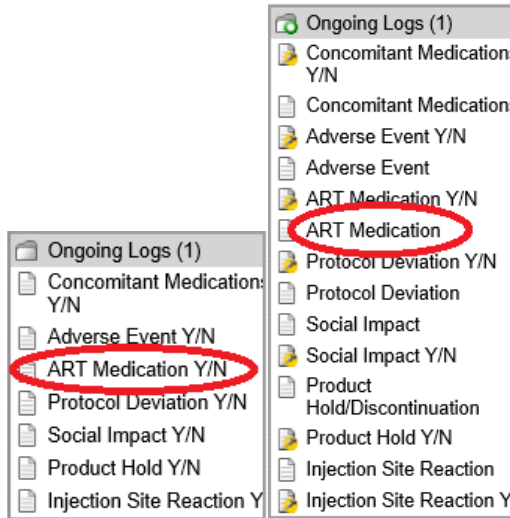
Field	Instructions
Date Reported to Site	<ul style="list-style-type: none"> <li>Record the date the site first became aware of the AE.</li> <li>For lab AEs, record the date the lab result was received.</li> <li>If results are received outside of a regular visit, create an interim visit.</li> <li>This date should correspond to the visit at which AE was first reported (see below).</li> </ul>
Adverse Event (AE)	<ul style="list-style-type: none"> <li>Describe the AE using medical terminology. Record a diagnosis/anatomical location if available.</li> <li>Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate AE log line.</li> <li>For lab abnormalities, reporting format is “increased/decreased [test name]” – for example, “decreased hematocrit” or “increased ALT”.</li> <li>If a cluster of symptoms reported on separate Adverse Experience Log lines is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, inactivate the AE Log lines for the other symptoms with the option “INACT_L – Log line not required.”</li> </ul>
Onset Date	<ul style="list-style-type: none"> <li>At minimum, a month and year are required. If day is unknown, enter “UN” in the day field.</li> <li>Record date participant first experienced symptoms, date of abnormal exam findings, or specimen collection date of abnormal test as appropriate</li> <li>For lab AEs, select the visit the blood draw was done</li> </ul>
At which visit was this AE first reported?	<ul style="list-style-type: none"> <li>Select visit when the site first became aware of the AE from the dropdown list</li> <li>For lab AEs, select the visit the blood draw was done.</li> <li>If Interim visit, enter “Interim Visit”, and record visit number in next field.</li> </ul>

Field	Instructions
Interim visit code, if applicable	<ul style="list-style-type: none"> <li>• Enter interim visit code in space provided</li> </ul>
Is the AE still ongoing?	<ul style="list-style-type: none"> <li>• Select “Yes” if the AE is continuing at the time it is first reported</li> <li>• Select “No” if the condition is no longer present or returned to 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.</li> <li>• If “Yes”, leave Outcome Date blank</li> </ul>
Outcome Date	<ul style="list-style-type: none"> <li>• Record the outcome date for the AE</li> <li>• At minimum, month and year are required. If day is unknown, enter “UN” in the day field.</li> <li>• Outcome date may be date on which participant reports no longer experiencing the AE, or the date of visit or specimen collection date at which it is first noted the AE has resolved or returned to baseline status.</li> </ul>
Severity Grade	<ul style="list-style-type: none"> <li>• Record the severity grade using the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> (including relevant appendices/addendums) <ul style="list-style-type: none"> <li>○ Grade 1 (Mild)</li> <li>○ Grade 2 (Moderate)</li> <li>○ Grade 3 (Severe)</li> <li>○ Grade 4 (Potentially life-threatening)</li> <li>○ Grade 5 (Death)</li> </ul> </li> </ul>
Relationship to study product	<ul style="list-style-type: none"> <li>• Record assessment of the relationship between the AE and the study agent</li> <li>• Mark “Related” if there is a reasonable possibility that the AE may be related to the study agent.</li> <li>• Mark “Not Related” if there is not a reasonable possibility that the AE is related to the study agent.</li> </ul>
Alternate etiology	<ul style="list-style-type: none"> <li>• If AE is not related to study agent, record rationale or alternate etiology.</li> <li>• If an alternate etiology is not established, this response should be blank.</li> </ul>

Field	Instructions
<p><b>Action Taken with Study Product</b></p>	<ul style="list-style-type: none"> <li>• Select “dose not changed” if there is no change to the participant’s planned use (dose, frequency, schedule) of study product as a result of the AE.</li> <li>• “Dose reduced” and “dose increased” do not apply and should not be selected in HPTN 083.</li> <li>• Select “drug withdrawn” if the AE results in permanent discontinuation of study product.</li> <li>• Select “drug interrupted” if AE results in a clinician-initiated product hold.</li> <li>• For multiple AEs, mark “drug withdrawn” or “drug interrupted” for each AE contributing to the permanent or temporary discontinuation. Ensure the Product Hold Y/N and Product Hold/Discontinuation forms are completed.</li> <li>• Select “not applicable” if the AE’s onset date is on or after the date the participant permanently discontinues study product use.</li> </ul>
<p><b>Other action(s) taken</b></p>	<ul style="list-style-type: none"> <li>• Select “None” or check all that apply.</li> <li>• Select “Medication” only if participant reports taking medication. Report medication(s) on the “Concomitant Medications” log form.</li> <li>• Select “Therapeutic procedure/surgery” only if participant reports a procedure or surgery.</li> <li>• Select “Diagnostic procedure” only if a diagnostic procedure is reported.</li> <li>• If “Other”, specify relevant details in the “Other, specify” text field provided.</li> </ul>
<p><b>Status/Outcome</b></p>	<ul style="list-style-type: none"> <li>• Select “recovered/resolved” if AE is no longer present, has returned to baseline severity/frequency, or has increased in severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated.</li> <li>• Select “recovering/resolving” if AE is continuing and has not yet resolved or returned to baseline severity/frequency.</li> <li>• Select “resolved with sequelae” if participant has recovered from the AE, but with remaining effects or impairment. These remaining effects can be temporary but are still present at the time of the report.</li> <li>• Select “not recovered/resolved” if AE is continuing at the time of participant termination from the study.</li> <li>• Select “fatal” only if the severity grade of this AE is Grade 5. Any other AEs continuing at the time of death should be recorded as “not recovered/resolved”.</li> </ul>

Field	Instructions
<p><b>Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No” If “Yes”, check all that apply.               <ul style="list-style-type: none"> <li>○ Results in death</li> <li>○ Is life-threatening</li> <li>○ Requires inpatient hospitalization or prolongation of existing hospitalization</li> <li>○ Results in persistent or significant disability/incapacity</li> <li>○ Is a congenital anomaly/birth defect</li> <li>○ Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above</li> </ul> </li> </ul>
<p><b>Has or will this AE be reported as an EAE?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• For questions about ICH guidelines and EAE reporting, refer to current <i>Manual for Expedited Reporting of Adverse Events to DAIDS</i>.</li> <li>• 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.</li> </ul>
<p><b>If yes, EAE number</b></p>	<ul style="list-style-type: none"> <li>• Enter EAE number in text field provided</li> </ul>

## ART MEDICATION Y/N



**Purpose:**

This form documents whether any ART medications were taken by the participant after HIV infection was confirmed.


**General Instructions:**

This summary form is located within the “Ongoing Logs” folder.

**Item-specific Instructions:**

Field	Instructions
<p>Has the participant started taking any ART medication?</p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is selected and the form is saved, the ART Medication form will appear in the “Ongoing Logs” folder.</li> <li>• If at the time of termination, the participant has not taken any ART medication, mark “No”.</li> </ul>

# ART MEDICATION


 Currently viewing line 1 of 1.  
 Click here to return to "Complete View".

ART Medication Code

Date Started

Date Stopped

Or mark if continuing at end of study

**Purpose:**

To document ART medications taken by the participant after HIV infection is confirmed. These medications should not be documented on the Concomitant Medications form.

**General Instructions:**

This form is located within the "Ongoing Logs" folder. Complete one log line for each medication and add additional log lines by clicking "Add a new Log line".

**Item-specific Instructions:**

Field	Instructions
ART Medication Code	<ul style="list-style-type: none"> <li>Select the appropriate medication from the dropdown list.</li> <li>To move between pages of medications click on the "&lt;&lt;Back" and "Next&gt;&gt;" buttons at the top of the list. You can also type the first letters of the medication and only medications starting with those letters will appear for selection.</li> </ul>
Date Started	<ul style="list-style-type: none"> <li>Enter the date the medication started</li> <li>A complete date is required</li> </ul>
Date Stopped	<ul style="list-style-type: none"> <li>If applicable, enter the date the medication was discontinued</li> <li>A complete date is required</li> <li>At the participant's Study Exit/Termination Visit, either "Date Stopped" OR "Mark if continuing at end of study" box must be marked</li> </ul>

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Field	Instructions
Or mark if continuing at end of study.	<ul style="list-style-type: none"><li data-bbox="630 268 1373 331">• Mark box if medication was continuing at the time of study completion</li></ul>

## CASI - OLE

### HPTN083\_Open Label Extension Questionnaire

▶ Please enter the participant's 9-digit PTID with no hyphens or spaces (for example: 999000111):

▶ Please enter the 5-7 digit CASI ID assigned to this participant (for example EX001):

▶ What visit is this?

*Please select the visit from the drop down menu.*

Log-In

▶ Visit date (DD/MM/YYYY):

Ensure to include both the month and day as 2 digits. For example, if the visit happens on the first of the month, it should be recorded as "01" not "1". Similarly, if the visit happens in May, type "05", not just "5".

▶ Language:

- English
- Vietnamese

Next ▶

#### Purpose:

This survey records participant's sexual behavior throughout the OLE phase of the study.

#### General Instructions:

This is a behavioral survey and **SHOULD NOT** be taken retrospectively or for future visits. A drop-down menu allows for the selection of **any visit code** (i.e. including non-CASI visits) in the OLE phase of the study. The survey Visit code must match the Visit code in Rave.

To see what surveys have already been taken, use the CASI listing on Atlas (Communiqué #12). Do not use Illume to find out whether a survey was taken, as this introduces survey entries with no participant's data that must be removed.

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## Item-specific Instructions:

Field	Instructions
<p><b>Please enter the participant's 9-digit PTID with no hyphens or spaces (for example: 999000111):</b></p>	<ul style="list-style-type: none"> <li>• Enter PTID</li> <li>• CASI ID and PTID must match</li> </ul>
<p><b>Please enter the 5-7 digit CASI ID assigned to this participant (for example: EX001):</b></p>	<ul style="list-style-type: none"> <li>• Enter CASI ID</li> <li>• CASI ID and PTID must match</li> </ul>
<p><b>What visit is this?</b></p> <p><b>Please select the visit from the dropdown menu.</b></p>	<ul style="list-style-type: none"> <li>• Select the visit when participant took the survey</li> <li>• Do not select a future visit</li> <li>• Do not select a past visit</li> </ul>
<p><b>Visit date (DD/MM/YYYY):</b>  <b>Ensure to include both the month and day as 2 digits. For example, if the visit happens on the first of the month, it should be recorded as "01" not "1".</b>  <b>Similarly, if the visit happens in May, type "05", not just "5".</b></p>	<ul style="list-style-type: none"> <li>• Enter today's date</li> <li>• If survey was taken on paper in the past and is transcribed into Illume later, enter the date the survey was taken on paper. This is the only scenario that permits entry of a past date.</li> </ul>

## CD4/VIRAL LOAD RESULTS

<b>CD4</b>	
Was a CD4 done?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="radio"/>
Date of collection:	<input type="text"/> ... <input type="text"/>
Absolute CD4+	<input type="text"/> cells/mm3 <input type="radio"/> <input type="radio"/> <input type="radio"/>
<b>Or</b>	
Unable to analyze	<input type="checkbox"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
<b>Viral Load</b>	
Was a viral load done?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="radio"/>
Date of collection:	<input type="text"/> ... <input type="text"/>
HIV RNA PCR (plasma)	<input type="text"/> viral copies/mL <input type="radio"/> <input type="radio"/> <input type="radio"/>
Or select if undetectable	<input type="checkbox"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
Or select if detected but less than lower limit of detection	<input type="checkbox"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
Lower limit of detection	... <input type="text"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
<a href="#">Printable Version</a> <a href="#">View PDF</a> <a href="#">Icon Key</a> CRF Version 519 - Page Generated: 29 Dec 2017 15:03:23 Pacific Standard Time	
<input type="button" value="Save"/> <input type="button" value="Cancel"/>	

**Purpose:**

To document CD4 and HIV viral load for HIV infected participants.

**General Instructions:**

Complete this form at the HIV Confirmation Visit, V55.0 – Week 24, and V57.0 – Week 48, or when clinically indicated during follow-up. To add this form to a participant’s visit folder, mark “CD4/Viral Load” on the Date of Visit CRF. Once the Date of Visit form is saved, the form appears in the visit folder.

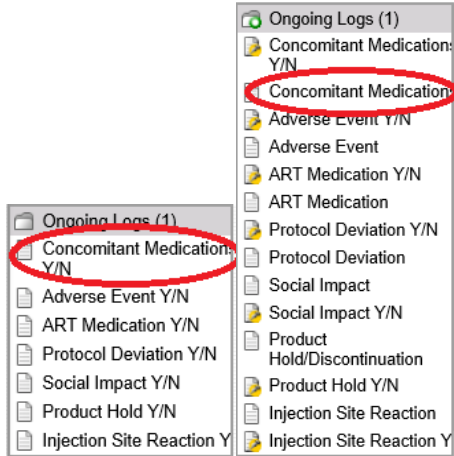
**Item-specific Instructions:**

Field	Instructions
Was a CD4 done?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”</li> </ul>
Date of collection:	<ul style="list-style-type: none"> <li>If CD4 was done, enter the date the sample was collected</li> <li>A complete date is required</li> </ul>

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Field	Instructions
Absolute CD4+	<ul style="list-style-type: none"> <li>Enter the absolute CD4 in units of “cells/mm<sup>3</sup>”</li> </ul>
<b>Or</b>	
Unable to analyze	<ul style="list-style-type: none"> <li>Check if sample was unable to be analyzed</li> </ul>
Was a viral load done?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”</li> <li>If viral load was done on the same specimen used to confirm HIV infection (and recorded on the HIV Test form), enter the RNA results on the HIV Test Results form.</li> </ul>
Date of collection:	<ul style="list-style-type: none"> <li>Enter the date the sample was collected</li> <li>A complete date is required</li> </ul>
HIV RNA PCR (plasma)	<ul style="list-style-type: none"> <li>Enter the result in units of “viral copies/mL”</li> </ul>
Or select if undetectable	<ul style="list-style-type: none"> <li>Select if result is undetectable</li> </ul>
Or select if detected but less than lower limit of detection	<ul style="list-style-type: none"> <li>Select if test result is below the lower limit of detection</li> </ul>
Lower limit of detection	<ul style="list-style-type: none"> <li>Select the lower limit of detection from the dropdown list.</li> </ul>

## *CONCOMITANT MEDICATIONS Y/N*



**Purpose:**

This form documents if any concomitant medications were reported by the participant during the study or within 30 days prior to study enrollment.

**General Instructions:**

This summary form is located within the “Ongoing Logs” folder.

**Item-specific Instructions:**

Field	Instructions
<p style="text-align: center;"><b>Were any concomitant medications taken?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is selected and the form saved, the Concomitant Medications log form appears within the “Ongoing Logs” folder</li> </ul>

# CONCOMITANT MEDICATIONS

Page: Concomitant Medications - Ongoing Logs (1) Apply to Record

Currently viewing line 1 of 1.  
 Click here to return to "Complete View".

Medication Name	<input type="text"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Indication	<input type="text"/>	<input type="radio"/>	<input type="text"/>	<input type="text"/>
Mark if medication taken for cross-sex hormone therapy. <input type="checkbox"/>				
Date Started <sup>?</sup>	<input type="text"/>	...	<input type="text"/>	<input type="text"/>
Date Stopped	<input type="text"/>	...	<input type="text"/>	<input type="text"/>
Or mark if continuing at end of study. <input type="checkbox"/>				
Frequency	<input type="text"/>			<input type="radio"/>
If Other frequency, please specify: <input type="text"/>				
Route	<input type="text"/>			<input type="radio"/>
If Other route, please specify: <input type="text"/>				
Dose	<input type="text"/>			<input type="radio"/>
Dose Units	<input type="text"/>			<input type="radio"/>
If Other dose units, specify: <input type="text"/>				
Taken for a reported AE?				<input type="radio"/> Yes <input type="radio"/> No
Adverse event #1	<input type="text"/>			<input type="radio"/>
Adverse event #2	<input type="text"/>			<input type="radio"/>
Adverse event #3	<input type="text"/>			<input type="radio"/>
Adverse event #4	<input type="text"/>			<input type="radio"/>
Taken for reported Injection Site Reaction?				<input type="radio"/> Yes <input type="radio"/> No
Injection Site Reaction #1	<input type="text"/>			<input type="radio"/>
Injection Site Reaction #2	<input type="text"/>			<input type="radio"/>
Injection Site Reaction #3	<input type="text"/>			<input type="radio"/>
Injection Site Reaction #4	<input type="text"/>			<input type="radio"/>

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CRF Version 993 - Page Generated: 01 Aug 2018 16:40:11 Pacific Daylight Time

**Purpose:**

This log form is used to document all medications taken by the participant, starting up to 30 days prior to the Enrollment Visit. This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive hormonal medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, and naturopathic preparations.

**General Instructions:**

Complete a separate entry in the study database for each reported concomitant medication. Use the "Add a new Log line" button to add an additional concomitant medication.

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**Item-specific Instructions:**

Field	Instructions
<b>Medication Name</b>	<ul style="list-style-type: none"> <li>Record the trade or generic name of the medication</li> <li>A combination medication can be recorded as one entry</li> </ul>
<b>Indication</b>	<ul style="list-style-type: none"> <li>Record the underlying indication for which the medication was taken.</li> <li>For health supplements, such as multivitamins, record “general health”</li> <li>For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”).</li> </ul>
<b>Mark if medication taken for cross-sex hormone therapy.</b>	<ul style="list-style-type: none"> <li>Mark box if medication is being taken for cross-sex hormone therapy</li> </ul>
<b>Date Started</b>	<ul style="list-style-type: none"> <li>Enter the date the medication was initiated</li> <li>If participant is unable to recall exact date of medication initiation, obtain best estimate</li> <li>Year is required at minimum</li> </ul>
<b>Date Stopped</b>	<ul style="list-style-type: none"> <li>Enter the stop date of this medication if known</li> <li>Month and year are required at minimum</li> <li>At the participant’s Study Exit/Termination Visit, the “Date Stopped” must be recorded for each medication OR the “Or mark if continuing at end of study” box must be checked</li> </ul>
<b>Or mark if continuing at end of study.</b>	<ul style="list-style-type: none"> <li>Mark box if medication was continuing at the time of study completion</li> </ul>

<p style="text-align: center;"><b>Frequency</b></p>	<ul style="list-style-type: none"> <li>• Select the frequency from options provided in the dropdown list</li> <li>• <i>Common frequency abbreviations:</i> <ul style="list-style-type: none"> <li>○ PRN: as needed</li> <li>○ QD: every day</li> <li>○ TID: three times daily</li> <li>○ QID: four times daily</li> <li>○ QHS: at bedtime</li> <li>○ ONCE: one time</li> <li>○ BID: twice daily</li> <li>○ Other</li> </ul> </li> <li>• If “Other” is selected, record frequency in the corresponding “If Other frequency, specify” text field provided</li> </ul>
<p style="text-align: center;"><b>Route</b></p>	<ul style="list-style-type: none"> <li>• Select the route from options provided in the dropdown list</li> <li>• <i>Common route abbreviations:</i> <ul style="list-style-type: none"> <li>○ PO: oral</li> <li>○ IM: intramuscular</li> <li>○ IV: intravenous</li> <li>○ TOP: topical</li> <li>○ IHL: inhaled</li> <li>○ VAG: vaginal</li> <li>○ REC: rectal</li> <li>○ SC: subcutaneous</li> <li>○ Other</li> </ul> </li> <li>• If “Other” is selected, specify route in the corresponding “If Other route, specify” text field provided</li> </ul>
<p style="text-align: center;"><b>Dose</b></p>	<ul style="list-style-type: none"> <li>• Enter the dose in the field provided</li> <li>• For combination drugs, use the “/” or “-” to distinguish the different doses (i.e., hydrocodone/acetaminophen 5/500).</li> <li>• If the dose is unknown, enter “Unknown” in the space provided.</li> </ul>
<p style="text-align: center;"><b>Dose Units</b></p>	<ul style="list-style-type: none"> <li>• Select the applicable dose units provided from the dropdown list</li> <li>• If unit of measurement is not known, select the “Unknown” option.</li> <li>• If “Other” is selected, provide a response to the “If Other dose units, specify” text field below</li> </ul>
<p style="text-align: center;"><b>Taken for a reported AE?</b></p>	<ul style="list-style-type: none"> <li>• If the medication was taken for a reported AE, select “Yes”</li> <li>• If taken for an AE, the AE must be linked below</li> </ul>

<b>Adverse event (#1, #2, #3, #4)</b>	<ul style="list-style-type: none"><li>• If the medication was taken for a reported AE, select appropriate AE from the dropdown list.</li><li>• The AE form must be completed before it can be linked on the Concomitant Medications form.</li><li>• Up to 4 adverse events can be entered for each Medication Name.</li></ul>
<b>Taken for a reported Injection Site Reaction?</b>	<ul style="list-style-type: none"><li>• If the medication was taken for a reported ISR, select “Yes”</li><li>• If taken for an ISR, the ISR must be linked below</li></ul>
<b>Injection Site Reaction (#1, #2, #3, #4)</b>	<ul style="list-style-type: none"><li>• If the medication was taken for a reported ISR, select ISR from the dropdown list</li><li>• The ISR form must be completed before it can be linked on the Concomitant Medications form</li><li>• Up to 4 ISRs can be entered for each Medication Name.</li></ul>

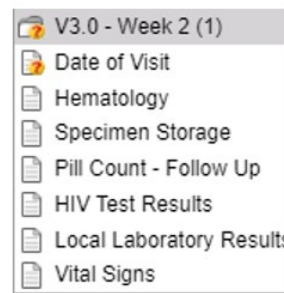


**General Instructions:**

Complete this form in order to generate all other forms related to a specific visit. Additional forms can be added using the checkboxes provided on the Date of Visit form.



After DOV submission →



**Item-specific Instructions:**














Field	Instructions
Did the participant complete this visit?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “No” is selected, a Missed Visit form is generated in the same visit folder.</li> </ul>
Visit Date:	<ul style="list-style-type: none"> <li>• A complete date is required</li> <li>• If visit was missed, skip this field</li> </ul>
<b>How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?</b>	<ul style="list-style-type: none"> <li>• Select the number of bottles from the dropdown list</li> <li>• If no bottles were dispensed, select ‘none’</li> </ul>
How many bottles were lost, stolen, or damaged since the last pill dispensation?	<ul style="list-style-type: none"> <li>• Select the number of bottles from the dropdown list</li> <li>• If no bottles were lost, stolen or damaged, select ‘none’</li> </ul>
Did the participant exit/terminate the study at this visit?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes”, a Termination form will be added to the visit folder and must be submitted.</li> </ul>
Is participant moving to the infected visit schedule?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes”, the remaining Step 2 visit folders are removed from the participant’s casebook.</li> </ul>
Is the participant ready to move to Step 3?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• Select “Yes” at last Step 2 visit before participant moves to Step 3.</li> <li>• At Step 3 visits, leave this question blank.</li> </ul>

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Field	Instructions
	<ul style="list-style-type: none"> <li>• If “Yes”, any Step 3 Day 0 forms not already present in the folder must be added; refer to the schedule of forms. If “Yes”, the remaining Step 2 visit folders are removed from the participant’s casebook.</li> </ul>
<p><b>Is the participant moving to yearly visits?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• Only select “Yes” If participant is in Step 1 and has not had a Week 5 injection OR the participant has completed all Step 3 visits.</li> <li>• If “Yes” is selected during Step 1, the Step 2 and Step 3 visit folders are removed from the participant’s casebook.</li> </ul>
<p><b>Did or will the participant complete the CASI questionnaire for this visit?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> </ul>
<p><b>Record the date and time of the participant’s last dose of Step 1 oral study products.</b></p>	<ul style="list-style-type: none"> <li>• Record a response to this question only once at or prior to the Week 5 visit</li> <li>• Record the date and time of the participant’s last dose of Step 1 oral study products using a 24-hour clock</li> <li>• If time is not known enter “00:00”</li> </ul>
<p><b>Is the participant moving to Step 2?</b></p>	<ul style="list-style-type: none"> <li>• Mark an answer to this question only once at or prior to the Week 5 visit</li> <li>• Select “Yes” or “No”</li> <li>• If “No” is selected the remaining Step 2 visit folders are removed from the participant’s casebook.</li> </ul>
<p><b>Mark any additional forms or procedures that took place at this visit</b></p>	<ul style="list-style-type: none"> <li>• <i>Check all additional forms to be completed at this visit</i></li> </ul>
<p><b>Mark at Step 3 visits as needed:</b></p>	<ul style="list-style-type: none"> <li>• <i>Check all additional Step 3 forms to be completed at this visit</i></li> <li>• <i>Only mark these items if the participant is currently in Step 3.</i></li> </ul>

## DATE OF VISIT – HIV

Subject: Subject  
Page: Date of Visit - HIV

Did the participant complete this visit?	<input type="radio"/> Yes <input type="radio"/> No	 
Visit Date:	<input type="text"/> ... <input type="text"/>	 
Did the participant exit/terminate the study at this visit?	<input type="radio"/> Yes <input type="radio"/> No	 
<b>Mark any additional forms or procedures that took place at this visit</b>		
CD4/Viral Load Results	<input type="checkbox"/>	 
Participant Receipt	<input type="checkbox"/>	 
Participant Transfer	<input type="checkbox"/>	 
Supplemental HIV Results	<input type="checkbox"/>	 

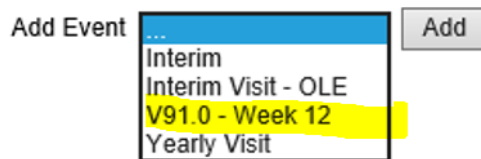
**Purpose:**

This form is used to record visits for HIV-positive participants done **during the open-label extension (OLE) only**.

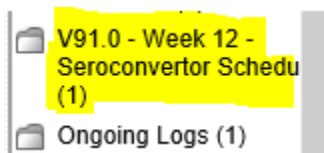
**General Instructions:**

The first visit on the HIV-infected schedule is coded as **V91.0 – Week 12**. Complete the Date of Visit – HIV form to generate all required and additional CRFs required for a specific visit. Additional forms can be added by marking checkboxes provided under the “Mark any additional forms or procedures that took place at this visit” section on the Date of Visit – HIV.

To generate this form, select “**V91.0 – Week 12**” from the participant’s homepage using the “Add Event” dropdown.



Visit 91.0 – Week 12 will appear in the visit menu on the left above “Ongoing logs”.



CONFIDENTIAL DOCUMENT

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Field	Instructions
Did the participant complete this visit?	<ul style="list-style-type: none"><li>• Select "Yes" or "No"</li><li>• If "No" is selected, a Missed Visit form is generated in the same visit folder.</li></ul>
Visit Date:	<ul style="list-style-type: none"><li>• A complete date is required</li><li>• If visit was missed, skip this field</li></ul>
Did the participant exit/terminate the study at this visit?	<ul style="list-style-type: none"><li>• Select "Yes" or "No"</li><li>• If "Yes", a Termination form will be added to the visit folder and must be submitted.</li></ul>
Mark any additional forms or procedures that took place at this visit	<ul style="list-style-type: none"><li>• Check all additional forms to be completed at this visit</li></ul>

## DATE OF VISIT – OLE

Subject: **Subject**  
 Page: **Date of Visit - OLE**



Did the participant complete this visit?	<input type="radio"/> Yes <input type="radio"/> No	
Visit Date:	<input type="text"/> ... <input type="text"/>	
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	<input type="text"/>	
Did the participant exit/terminate the study at this visit?	<input type="radio"/> Yes <input type="radio"/> No	
Did or will the participant complete the CASI questionnaire for this visit?	<input type="radio"/> Yes <input type="radio"/> No	
Is the participant moving to a new step or visit schedule?	<input type="radio"/> Yes <input type="radio"/> No	
If Yes, please indicate which Step or visit schedule?	<input type="text"/>	
<b>Mark any additional forms or procedures that took place at this visit</b>		
CD4/Viral Load Results	<input type="checkbox"/>	
Hepatitis Test Results	<input type="checkbox"/>	
Local Laboratory Results	<input type="checkbox"/>	
Participant Receipt	<input type="checkbox"/>	
Participant Transfer	<input type="checkbox"/>	
Sexually Transmitted Infections	<input type="checkbox"/>	
Supplemental HIV Results	<input type="checkbox"/>	

**Purpose:**

This form is used to record visits for participants done **during the open-label extension (OLE) only**.

**General Instructions**

This form will generate once the Product Choice – OLE form is completed. Complete the Date of Visit – OLE form to generate all required CRFs related to a specific visit. Additional forms can be added by marking checkboxes provided under the “Mark any additional forms or procedures that took place at this visit” section on the Date of Visit – OLE.

**Item-specific Instructions:**

Field	Instructions
<b>Did the participant complete this visit?</b>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “No” is selected, a Missed Visit form is generated in the same visit folder.</li> </ul>
<b>Visit Date:</b>	<ul style="list-style-type: none"> <li>• A complete date is required</li> <li>• If visit was missed, skip this field</li> </ul>
<b>How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?</b>	<ul style="list-style-type: none"> <li>• Select the number of bottles from the dropdown list</li> <li>• If no bottles were dispensed, select ‘0’.</li> </ul>
<b>Did the participant exit/terminate the study at this visit?</b>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes”, a Termination form will be added to the visit folder and must be submitted.</li> </ul>
<b>Did or will the participant complete the CASI questionnaire for this visit?</b>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> </ul>
<b>Is the participant moving to a new step or visit schedule?</b>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• Select “Yes” only if participant is moving to a new step or visit schedule (e.g. Step 5 to Step 4a)</li> <li>• Select “No” when participant follows the step progression per Schedule of Forms (e.g. Step 4a to Step 4b to Step 4c to Step 5)</li> </ul>
<b>If Yes, please indicate which Step or visit schedule?</b>	<ul style="list-style-type: none"> <li>• Select the Step or visit schedule from drop down menu.</li> </ul>
<b>Mark any additional forms or procedures that took place at this visit</b>	<ul style="list-style-type: none"> <li>• Check all additional forms to be completed at this visit</li> </ul>

# DEMOGRAPHICS

What is the participant's date of birth?  ...

Age Years

What was the participant's sex at birth? Male

What is the participant's self-identified gender?

If "self-identify, other" is marked, please specify:

What is the participant's current marital status?

If other, specify

What is the participant's current employment status?

What is the participant's highest level of education?

Does the participant consider him/herself to be Latino/a or of Hispanic origin?  Yes  No

Race

Specify:

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**Purpose:**

This form is used to document a participant’s demographic and socioeconomic information.

**General Instructions:**

This form is completed at the V2.0 – Day 0/Enrollment visit. Responses should reflect the participant’s status at screening and should not be changed after enrollment unless correction is needed.

**Item-specific Instructions:**

Field	Instructions
What is the participant’s date of birth?	<ul style="list-style-type: none"> <li>• Provide the date of birth</li> <li>• A complete date is required</li> </ul>
Age	<i>This is an automatically derived field based on the participant’s date of birth and the date of initial form completion. No data entry is required.</i>

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Field	Instructions
<b>What was the participant's sex at birth?</b>	<i>This field is automatically filled as Male due to the protocol eligibility requirements. No data entry is required.</i>
<b>What is the participant's self-identified gender?</b>	<ul style="list-style-type: none"> <li>• Select the applicable response from the dropdown list.</li> <li>• If "Self-identify, other" is selected, provide a response in the text field provided.</li> </ul>
<b>What is the participant's current marital status?</b>	<ul style="list-style-type: none"> <li>• Select the applicable response from the dropdown list based on the participant's response.</li> <li>• If "Other", provide a response in the text field provided.</li> </ul>
<b>What is the participant's current employment status?</b>	<ul style="list-style-type: none"> <li>• Select the applicable response from the dropdown list.</li> </ul>
<b>What is the participant's highest level of education?</b>	<ul style="list-style-type: none"> <li>• Complete this item based on participant self-report.</li> </ul>
<b>Does the participant consider him/herself to be Latino/a or of Hispanic origin?</b>	<ul style="list-style-type: none"> <li>• Select "Yes" or "No"</li> </ul>
Race	<ul style="list-style-type: none"> <li>• Select race from the dropdown list.</li> <li>• If "Other, specify" is selected, provide a response in the Specify text field provided below.</li> </ul>

## *DXA SCAN*

Did the participant have a DXA scan for this visit?	<input type="text" value="..."/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>		
Date of DXA scan	<input type="text"/>	<input type="text" value="..."/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>

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**Purpose:**

This form is used to document the participant’s DXA scan information.

**General Instructions:**

Complete this form for all participants at specified visits.

**Item-specific Instructions:**

Field	Instructions
Did the participant have a DXA scan for this visit?	<ul style="list-style-type: none"> <li>Select “Yes”, “No”, or “N/A (slots filled or site not participating)”</li> </ul>
Date of DXA scan	<ul style="list-style-type: none"> <li>Provide date of the scan</li> <li>A complete date is required</li> <li>Leave item blank if scan was not performed.</li> </ul>

# ELECTROCARDIOGRAM

Date of ECG	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>
<b>QTC INTERVAL MEASUREMENT</b>		
Not measurable	<input type="checkbox"/>	<input type="radio"/> <input type="radio"/>
<b>Or</b>		
QTc interval	<input type="text"/> ms	<input type="radio"/> <input type="radio"/>
Severity Grade	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Adverse Event	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Reporting method used:	<input type="radio"/> Bazett <input type="radio"/> Fridericia	<input type="radio"/> <input type="radio"/>
<b>OVERALL ECG FINDINGS</b>		
Overall ECG findings	<input type="radio"/> Normal <input type="radio"/> Specific ECG Findings	<input type="radio"/> <input type="radio"/>

**Purpose:**

This form is used to document normal and abnormal findings observed during Lead ECG tests.

**General Information/Instructions:**


This form is completed at protocol-specified visits, and as clinically indicated at any other study visits.

**Item-specific Instructions:**

Field	Instructions
Date of ECG	<ul style="list-style-type: none"> <li>Enter the date the ECG was performed</li> <li>A complete date is required</li> </ul>
<b>QTC INTERVAL MEASUREMENT</b>	
Not measurable	<ul style="list-style-type: none"> <li>Select if the ECG was not measurable.</li> <li>If a result was obtained, leave field unchecked and enter results in fields below.</li> </ul>
<b>Or</b>	
QTc interval	<ul style="list-style-type: none"> <li>Enter ECG result in units of milliseconds (ms)</li> </ul>

Field	Instructions
Severity Grade	<ul style="list-style-type: none"> <li>Select a severity grade (1-4) or “not gradable” from dropdown list</li> <li>If a severity grade is selected, the test result field must not be blank</li> </ul>
Adverse Event	<ul style="list-style-type: none"> <li>If test is linked to a reported AE, select the AE in the search list provided</li> <li>The AE form must be completed before it can be linked on the Electrocardiogram form.</li> </ul>
Reporting method used:	<ul style="list-style-type: none"> <li>Select which reporting method was used, “Bazett” or “Fridericia”</li> </ul>
<b>Overall ECG Findings</b>	
Overall ECG findings	<ul style="list-style-type: none"> <li>Select “Normal” or “Specific ECG findings”</li> <li>If “Specific ECG Findings” is selected, ensure all applicable findings are marked from the items listed below</li> </ul>
<b>SPECIFIC ECG FINDINGS</b>	
Specific ECG findings	<ul style="list-style-type: none"> <li>If specific findings are noted, indicate by checking all findings as applicable</li> </ul>
Other, specify:	<ul style="list-style-type: none"> <li>If any finding does not apply to the specific options provided, specify in text field provided</li> </ul>

# ENROLLMENT

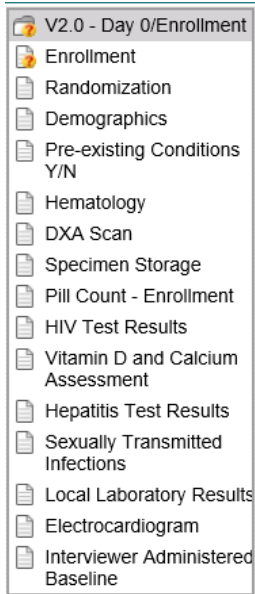
Is the participant enrolling in the study?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>If participant did not enroll, skip to "Record Participant's Sex Pro Score" and complete remaining items.</b>					
Enrollment Date	<input type="text"/>	...	<input type="text"/>	<input type="radio"/>	<input type="radio"/>
Did the participant consent to having blood stored and used for future testing?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did the participant consent to genetic testing?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did the participant consent to participating in the DXA substudy?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A (slots filled or site not participating)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
What is the CASI ID assigned to this participant?	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did or will the participant complete the enrollment CASI questionnaire?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Which version of the Sex Pro Tool was used?	...	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Record participant's Sex Pro score	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Complete the following item only if participant does not enroll. If more than one reason, add additional log lines.</b>					
 Currently viewing line 1 of 1. Click here to return to "Complete View".					
Reason participant was not enrolled in the study:	<input type="text"/>				
<a href="#">Printable Version</a> <a href="#">View PDF</a> <a href="#">Icon Key</a>					
CRF Version 519 - Page Generated: 14 Nov 2017 11:55:12 Pacific Standard Time				<input type="button" value="Save"/> <input type="button" value="Cancel"/>	

**Purpose:**

This form is used to document a participant’s study enrollment and to set target dates for future visits. This form is completed at enrollment for participants who have provided informed consent and who are eligible to participate in the study. This form is also completed for participants who screen for the study but do not enroll.

**General Instructions:**

Complete this form for each participant who signed informed consent for HPTN 083.



After an Enrollment form is submitted indicating a participant is going to be enrolled in the study, other Enrollment forms will be generated.

**Item-specific Instructions:**

Field	Instructions
Is the participant enrolling in the study?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If participant did not enroll, skip to "Which version of the Sex Pro Tool was used?" and complete remaining items.</li> </ul>
Enrollment Date	<ul style="list-style-type: none"> <li>• A complete date is required</li> </ul>
Did the participant consent to having blood stored and used for future testing?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• Update as needed if the participant changes consent during the study.</li> </ul>
Did the participant consent to genetic testing?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> </ul>
Did the participant consent to participating in the DXA substudy?	<ul style="list-style-type: none"> <li>• Select “Yes”, “No”, or “N/A (slots filled or site not participating)”</li> </ul>
What is the CASI ID assigned to this participant?	<ul style="list-style-type: none"> <li>• Enter the CASI ID assigned in the text field provided</li> </ul>

Field	Instructions
<p>Did or will the participant complete the enrollment CASI questionnaire?</p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> </ul>
<p>Which version of the Sex Pro Tool was used?</p>	<ul style="list-style-type: none"> <li>• Select either “South America”, “North America”, or “Not Applicable”</li> </ul>
<p>Record participant’s Sex Pro score</p>	<ul style="list-style-type: none"> <li>• Enter the participant’s Sex Pro score in the field provided</li> <li>• If Sex Pro Tool was not used, leave item blank</li> </ul>
<p>Reason participant was not enrolled in the study:</p>	<ul style="list-style-type: none"> <li>• Select the reason participant was not enrolled from the dropdown list</li> <li>• To move between pages of termination reasons, click on the “&lt; Back” and “Next &gt;” buttons at the top of the list. You can also type the first letters of a key word to show only choices containing those letters.</li> <li>• If more than one reason, add additional log lines.</li> </ul>

# HEMATOLOGY

Page: Hematology - V2.0 - Day 0/Enrollment

Lab



Was a hematology sample collected?  Yes  No

Date of Collection

Hemoglobin severity grade

Hemoglobin Adverse event

Platelets Severity grade

Platelets Adverse event

WBC Severity grade

WBC Adverse event

Was differential done?  Yes  No

Neutrophils Severity grade

Neutrophils Adverse event

Lymphocytes severity grade

Lymphocytes Adverse event

	Data	Range Status	Unit	Range	
Hemoglobin	<input type="text"/>				<input type="radio"/> <input type="text"/>
Hematocrit	<input type="text"/>				<input type="radio"/> <input type="text"/>
MCV	<input type="text"/>				<input type="radio"/> <input type="text"/>
Platelets	<input type="text"/>				<input type="radio"/> <input type="text"/>
WBC	<input type="text"/>				<input type="radio"/> <input type="text"/>
Neutrophils	<input type="text"/>				<input type="radio"/> <input type="text"/>
Lymphocytes	<input type="text"/>				<input type="radio"/> <input type="text"/>
Monocytes	<input type="text"/>				<input type="radio"/> <input type="text"/>
Eosinophils	<input type="text"/>				<input type="radio"/> <input type="text"/>
Basophils	<input type="text"/>				<input type="radio"/> <input type="text"/>
Atypical lymphocytes	<input type="text"/>				<input type="radio"/> <input type="text"/>

Test results are entered in these fields

Units and Ranges will populate when a lab is selected at the top of the form

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**Purpose:**

This form is used to document the participant's hematology test results.

**General Information/Instructions:**

Use this form to report the hematology and differential test results obtained from specimens collected for this visit.

Local Lab reference ranges should automatically appear on lab forms; if that is not the case please contact SCHARP to correct this.










Some lab results are graded based on change from baseline. Note that 'baseline' means tests done at the enrollment visit not the screening visit.

**Item-specific Instructions:**

Field	Data
<i>Test Result</i>	<ul style="list-style-type: none"> <li>• Enter the result of the specified test</li> <li>○ To eliminate the need to round a number, each test result field allows up to 5 digits beyond the decimal point</li> <li>• If test was not performed, leave blank</li> <li>• If result is entered, ensure a severity grade for the result is entered</li> </ul>

Field	Instructions
Was a hematology sample collected?	<ul style="list-style-type: none"> <li>• Select "Yes" or "No"</li> </ul>
Date of collection:	<ul style="list-style-type: none"> <li>• Enter the date the sample was collected</li> <li>• A complete date is required</li> </ul>
<i>Test Severity grade</i>	<ul style="list-style-type: none"> <li>• Select a severity grade (1-4) or "not gradable" from the dropdown list</li> <li>• If a severity grade is selected, the test result field must not be blank</li> </ul>
<i>Test Adverse event</i>	<ul style="list-style-type: none"> <li>• If test is linked to a reported AE, select the AE in the dropdown list provided</li> <li>• An AE form must be completed before it can be selected on the Hematology form.</li> </ul>

# HEPATITIS TEST RESULTS

<b>HEPATITIS C</b>	
Anti-Hepatitis C Antibody (anti-HCV):	<input checked="" type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Not Done   
<b>HEPATITIS B</b>	
Hepatitis B Surface Antibody (HBsAb):	<input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Not Done   
Hepatitis B Core Antibody (HBCoreAb):	<input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Not Done   

**Purpose:**

This form is used to document hepatitis test results and confirmatory results from local lab confirmatory testing.

**General Instructions:**

This form is completed at protocol-specified visits and as clinically indicated at any other visits.

**Item-specific Instructions:**

Field	Instructions
Anti-Hepatitis C Antibody (anti-HCV):	<ul style="list-style-type: none"> <li>Select “Negative”, “Positive”, or “Not Done”</li> </ul>
Hepatitis B Surface Antibody (HBsAb):	<ul style="list-style-type: none"> <li>Select “Negative”, “Positive”, or “Not Done”</li> </ul>
Hepatitis B Core Antibody (HBCoreAb):	<ul style="list-style-type: none"> <li>Select “Negative”, “Positive”, or “Not Done”</li> </ul>

# HIV TEST RESULTS

Specimen Collection Date	<input type="text"/> ... <input type="text"/>				
HIV Rapid 1	<input type="radio"/> Non-reactive/Negative	<input type="radio"/> Reactive/Positive			
HIV Rapid 2	<input type="radio"/> Non-reactive/Negative	<input type="radio"/> Reactive/Positive	<input type="radio"/> Not Done		
HIV 4th or 5th Gen Ag/Ab	<input type="radio"/> Non-reactive/Negative	<input type="radio"/> Reactive/Positive	<input type="radio"/> Indeterminate	<input type="radio"/> Not Done	
HIV-1 RNA Qualitative	<input type="radio"/> Non-reactive/Negative	<input type="radio"/> Reactive/Positive	<input type="radio"/> Not Done		
<b>HIV RNA PCR</b>					
HIV RNA PCR Not Done	<input type="checkbox"/>				
HIV RNA PCR (plasma)	<input type="text"/>	viral copies/mL			
Or select if undetectable	<input type="checkbox"/>				
Or select if detected but less than lower limit of detection	<input type="checkbox"/>				
Lower limit of detection	<input type="text"/>	...			
<b>If HIV testing is incomplete, mark "Additional blood specimen collection required" and save form. Add results from subsequent sample(s) on the new HIV Test Results form added in this visit's folder.</b>					
Final HIV Status from local testing:	<input type="text"/>	...			
Additional blood specimen collection required	<input type="checkbox"/>				

**Purpose:**

This form is used to document HIV test results from local lab testing and results provided by the Lab Center used to confirm HIV infection.

**General Instructions:**

Complete this form at protocol-specified visits and as clinically indicated during follow-up. Record HIV specimen test results on this form as they become available from the local lab.

**Item-specific Instructions:**

Field	Instructions
Specimen Collection Date	<ul style="list-style-type: none"> <li>Enter the date the specimen was collected</li> <li>A complete date is required</li> </ul>
HIV Rapid 1	<ul style="list-style-type: none"> <li>An HIV Rapid test is required each time HIV testing is performed.</li> <li>Select "Non-reactive/Negative" or "Reactive/Positive" as appropriate.</li> </ul>
HIV Rapid 2	<ul style="list-style-type: none"> <li>Select "Non-reactive/Negative", "Reactive/Positive", or "Not Done"</li> </ul>

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Field	Instructions
HIV 4th or 5th Gen Ag/Ab	<ul style="list-style-type: none"> <li>A 4th/5th Gen Combo Antibody and Antigen, EIA/CMIA is required each time HIV testing is performed.</li> <li>Select “Non-reactive/Negative”, “Reactive/Positive”, “Indeterminate”, or “Not Done”</li> </ul>
HIV-1 RNA Qualitative	<ul style="list-style-type: none"> <li>Select “Non-reactive/Negative”, “Reactive/Positive”, or “Not Done”</li> </ul>
<b>HIV RNA PCR</b>	
HIV RNA PCR Not Done	<ul style="list-style-type: none"> <li>Mark checkbox if HIV RNA PCR was not performed</li> <li>If checked, other fields describing HIV RNA PCR test results should be blank</li> </ul>
HIV RNA PCR (plasma)	<ul style="list-style-type: none"> <li>Enter the HIV RNA PCR (plasma) result from the source documents in units of viral copies/mL</li> </ul>
<b>Or select if undetectable</b>	<ul style="list-style-type: none"> <li>Select if RNA PCR test was done but no viral copies were detected; otherwise leave blank.</li> </ul>
<b>Or select if detected but less than lower limit of detection</b>	<ul style="list-style-type: none"> <li>Select if RNA PCR test was done but result was below the lower limit of detection for the test; otherwise leave blank</li> <li>If selected, enter lower limit of detection in subsequent field</li> </ul>
<b>Lower limit of detection</b>	<ul style="list-style-type: none"> <li>Select the lower limit of detection for the test in the drop down list</li> </ul>

Field	Instructions
<b>Final HIV Status from local testing:</b>	<ul style="list-style-type: none"> <li>• Select final HIV Status from local testing</li> <li>• If any Reactive or Positive result is recorded but infection is not yet confirmed, 'Additional HIV Test Results' should be marked as final status. Either an additional HIV Test form should be added to this folder, or confirmatory results should appear in a later visit folder.               <ul style="list-style-type: none"> <li>○ Exception: If HIV ½ Discriminatory Assay or DNA results were used to confirm HIV infection, mark "Positive" as the final result on this form and complete the Supplemental HIV Results form.</li> </ul> </li> </ul>
<b>Additional blood specimen collection required</b>	<ul style="list-style-type: none"> <li>• Check if an additional blood specimen collection is required</li> </ul>
<p>If HIV testing is incomplete, mark "Additional blood specimen collection required" and save form. Add results from subsequent sample(s) on the new HIV Test Results form added in this visit's folder.</p>	

## ***INCLUSION / EXCLUSION***

Date the participant marked or signed the study Screening and Enrollment consent form.	<input type="text"/>	...	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Did participant complete all screening for inclusion and exclusion criteria?					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>The following are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.</b>											
MSM or TGW					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Male at birth					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18 years or older at time of screening					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Willing to provide informed consent for the study					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
At high risk for sexually acquiring HIV infection based on self-report of at least one of the following. <b>Mark all that apply.</b>					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Any condomless receptive anal intercourse in 6 months prior to enrollment (condomless anal intercourse within a monogamous HIV seronegative concordant relationship does not meet this criterion)					<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
More than five partners in 6 months prior to Enrollment					<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Any stimulant drug use in 6 months prior to Enrollment					<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rectal or urethral gonorrhea or chlamydia or incident syphilis in 6 months prior to Enrollment					<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
SexPro score of ≤ 16 (US sites only)					<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-reactive / negative HIV test results. <a href="#">?</a>					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hemoglobin > 11 g/dL					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Absolute neutrophil count > 750 cells/mm3					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Platelet count ≥ 100,000/mm3					<input type="radio"/>	Yes	<input type="radio"/>	No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Calculated creatinine clearance $\geq$ 60 mL/minute using the Cockcroft-Gault equation	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Alanine aminotransferase (ALT) < 2 times the upper limit of normal (ULN)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Total bilirubin < 2.5 times ULN	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Hepatitis B virus (HBV) surface antigen (HBsAg) negative	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
HCV Ab negative	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
No Grade 3 or higher laboratory abnormalities obtained at screening, including tests obtained as part of a panel of tests ordered to obtain the protocol-required laboratory test results.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
No medical condition that, in the opinion of the study investigator, would interfere with the conduct of the study	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Willing to undergo all required study procedures	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
<b>The following are exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.</b>	
One or more reactive or positive HIV test result at Screening	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
A reactive/positive rapid HIV test at Enrollment	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Active or recent use of any illicit intravenous drugs	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Co-enrollment in any other interventional research study or other concurrent studies that may interfere with this study	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Past or current participation in HIV vaccine trial	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Clinically significant cardiovascular disease	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
QTc interval (B or F) > 500 msec	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Inflammatory skin conditions that compromise the safety of IM injections	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Has a tattoo or other dermatological condition overlying the buttock region which may interfere with interpretation of injection site reactions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Current or chronic history of liver disease or known hepatic or biliary abnormalities	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Coagulopathy which would contraindicate IM injection	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Active or planned use of prohibited medications	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Known or suspected allergy to study product components (active or placebo), including egg or soy products	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Surgically-placed or injected buttock implants or fillers, per self-report	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Alcohol or substance use that would jeopardize the safety of the participant on study	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>
History of seizure disorder	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> <input type="radio"/> <input type="checkbox"/>

**Purpose:**

This form is used to confirm participant eligibility prior to randomization. NOTE: The form was introduced into the study on 15 June 2018 and is only required for participants screened on or after that date.

**CONFIDENTIAL DOCUMENT**

Once this form is saved the Enrollment folder will appear in the participant's casebook.

**General Information/Instructions:**



Complete this form at screening prior to randomizing and enrolling the participant.



**Item-specific Instructions**

Field	Instructions
Date the participant marked or signed the study Screening and Enrollment consent form.	<ul style="list-style-type: none"> <li>• Enter the date the consent was signed</li> <li>• A complete date is required</li> </ul>
Did participant complete all screening for inclusion and exclusion criteria?	<ul style="list-style-type: none"> <li>• Select either "Yes" or "No"</li> <li>• If "Yes" is selected, then all inclusion and exclusion items must have a response</li> <li>• If "No" is selected, then enter responses only for those criteria assessed</li> </ul>
Inclusion Criteria	<ul style="list-style-type: none"> <li>• Mark appropriate response for each criterion</li> </ul>
Exclusion Criteria	<ul style="list-style-type: none"> <li>• Mark appropriate response for each criterion</li> </ul>

# INFORMED CONSENT – VERSION 5.0

Page: **Informed Consent - Version 5.0 - Product Choice - OLE (1)**

Did the participant consent for Protocol Version 5.0?  Yes  No   

If Yes, Date of Informed Consent  ...    

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 3750 - Page Generated: 08 Apr 2022 17:13:42 Pacific Daylight Time

**Purpose:**

This form is used to document whether participant consented to study protocol v5.0.

**General Instructions:**



Complete this form at the next visit after your site received v5.0 approval.



**Item-specific Instructions:**

Field	Instructions
<p>Did the participant consent for Protocol Version 5.0?</p>	<ul style="list-style-type: none"> <li>• Select either “Yes” or “No”</li> <li>• “Yes” should only be selected if participant consented to Step 6 visits. Otherwise, enter “No”.</li> <li>• If “Yes” is selected, then enter Date of Informed Consent in the next response</li> <li>• If “No” is selected, then end of form</li> </ul>
<p>If Yes, Date of Informed Consent</p>	<ul style="list-style-type: none"> <li>• Enter the date version 5.0 consent was signed</li> <li>• A complete date is required</li> </ul>

# INFORMED CONSENT – VERSION 6.0

Page: **Informed Consent - Version 6.0 - Product Choice - OLE (1)**

Did the participant consent to Protocol Version 6.0?  Yes  No   

If Yes, Date of Informed Consent  ...    

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 4644 - Page Generated: 18 May 2023 15:16:02 Pacific Daylight Time

**Purpose:**

This form is used to document whether participant consented to study protocol v5.0.

**General Instructions:**

Complete this form at the next visit after your site received v5.0 approval.

**Item-specific Instructions:**

Field	Instructions
Did the participant consent for Protocol Version 6.0?	<ul style="list-style-type: none"> <li>• Select either “Yes” or “No”</li> <li>• “Yes” should only be selected if participant consented to Step 7 visits. Otherwise, enter “No”.</li> <li>• If “Yes” is selected, then enter Date of Informed Consent in the next response</li> <li>• If “No” is selected, then end of form</li> </ul>
If Yes, Date of Informed Consent	<ul style="list-style-type: none"> <li>• Enter the date version 6.0 consent was signed</li> <li>• A complete date is required</li> </ul>

# INJECTION ADMINISTRATION

Subject: **Subject**  
 Page: **Injection Administration**

**Reminder: All HIV test results from previous visits and at least one HIV test result from the current visit must be confirmed negative/nonreactive prior of study product.**

**Was an injection given at this visit?**  Yes  No

**If injection was given:**

Open label injection (active CAB LA)

Injection Date  ..

Needle Size  21 G x 1 ½ in (0.8mm x 40mm)  
 21 G x 2 in (0.8mm x 50mm)  
 23 G x 1 ½ in (0.6mm x 40mm)  
 23 G x 2 in (0.6mm x 50mm)  
 25 G x 1 ½ in (0.5mm x 40mm)  
 25 G x 2 in (0.5mm x 50mm)  
 Other size

If other marked, record needle size

Was complete dose given?  Yes  No

If no, what volume was given?  ml

Location of injection  Right buttock  Left buttock

Time of preparation for injection  :

Time of injection  :

**If injection was not given:**

Indicate if injection was missed, refused, or permanently discontinued.

**Purpose:**

This form is used to summarize information regarding the injection administration at that visit.

**General Information/Instructions:**

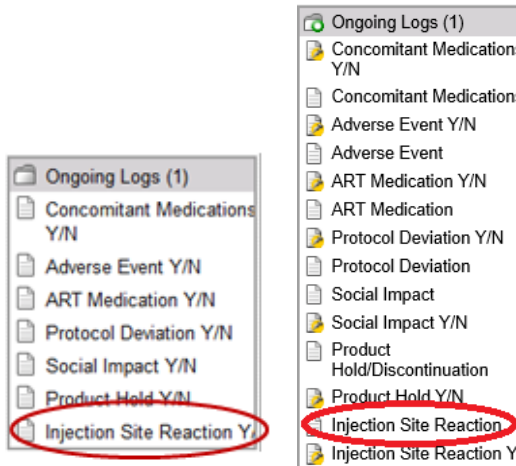
Complete this form at protocol-specified visits after HIV testing has been completed.

**Item-specific Instructions**

Field	Instructions
Was an injection given at this visit?	<ul style="list-style-type: none"> <li>Select either “Yes” or “No”</li> </ul>
If injection was given	
Open label injection (active CAB LA)	<ul style="list-style-type: none"> <li>Mark this box if this injection is for an unblinded CAB participant</li> <li>Mark this box at all OLE visits</li> </ul>

Field	Instructions
Injection Date	<ul style="list-style-type: none"> <li>Enter the date the injection was received</li> <li>A complete date is required</li> </ul>
Needle Size	<ul style="list-style-type: none"> <li>Select the appropriate needle size</li> </ul>
If other marked, record needle size	<ul style="list-style-type: none"> <li>Complete this item if "other size" is marked in the Needle Size item; otherwise leave blank.</li> </ul>
Was complete dose given?	<ul style="list-style-type: none"> <li>Select either "Yes" or "No"</li> <li>If "No" is selected, then enter the volume of study drug administered below.</li> </ul>
If no, what volume was given?	<ul style="list-style-type: none"> <li>If complete dose was given, field should be blank</li> <li>Enter volume of study drug administered in mL</li> </ul>
Location of injection	<ul style="list-style-type: none"> <li>Select either "Right buttock" or "Left buttock"</li> </ul>
Time of preparation for injection	<ul style="list-style-type: none"> <li>Enter a time using a 24-hour clock</li> <li>Time of preparation must precede the time of injection</li> </ul>
Time of injection	<ul style="list-style-type: none"> <li>Enter a time using a 24-hour clock</li> </ul>
If injection was not given:	
Indicate if injection was missed, refused, or permanently discontinued.	<ul style="list-style-type: none"> <li>Select either "Injection missed", "Injection refused", or "Injection schedule permanently discontinued"</li> </ul>

## *INJECTION SITE REACTION Y/N*



**Purpose:**

This form documents whether any injection site reactions (ISRs) were experienced by the participant during the study due to study drug injections and is used to add the Injection Site Reaction form into the Ongoing Logs folder.

**General Instructions:**

This form is located within the “Ongoing Logs” folder and is completed only once, at the time the first ISR is reported.

**Item-specific Instructions:**

Field	Instructions
<p>Has the participant experienced any injection site reactions?</p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is selected, the Injection Site Reaction log form appears in the Ongoing Logs folder and can then be completed.</li> </ul>

## INJECTION SITE REACTION

Date reported to site	<input type="text"/> ... <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Event diagnosis	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Injection site side	<input type="radio"/> Left <input type="radio"/> Right	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Onset Date	<input type="text"/> ... <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
At which visit was this reaction first reported?	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Interim visit code, if applicable:	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is the reaction still ongoing?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Outcome Date	<input type="text"/> ... <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Severity Grade	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Action Taken with Study Product	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Other action(s) taken</b>					
None		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medication		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Therapeutic procedure/surgery		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diagnostic procedure		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other, specify	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Status/Outcome	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?</b> If "No", go to following question.					
		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If "Yes", check all that apply.					
Results in death		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is life-threatening		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Requires inpatient hospitalization or prolongation of existing hospitalization		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Results in persistent or significant disability/incapacity		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is a congenital anomaly/birth defect		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above		<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Has or will this reaction be reported as an EAE?		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If yes, EAE number	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Purpose:**

This form is used to document any injection site reactions to study injections either reported by the participant or observed during the clinic visit.

**General Information/Instructions:**

Injection Site Reactions should only be reported on the ISR form and not on the Adverse Event form - unless the reaction event is not found in the dropdown list of diagnoses. In that case, the reaction should be entered on an AE form.

For every subsequent ISR reported, add a new ISR log line by selecting the “Add a new log line” at the bottom of the form.

**Item-specific Instructions**

Field	Instructions
Date reported to site	<ul style="list-style-type: none"> <li>Enter the date the site first became aware of the reaction.</li> <li>A complete date is required.</li> </ul>
Event diagnosis	<ul style="list-style-type: none"> <li>Select from the dropdown list the type of injection site reaction that occurred</li> </ul>
Injection site side	<ul style="list-style-type: none"> <li>Select “Left” or “Right” for the side on which the injection was given</li> </ul>
Onset date	<ul style="list-style-type: none"> <li>Record the date participant first experienced the reaction</li> <li>At minimum, a month and year are required</li> <li>Date must be on or after the date of study drug injection</li> </ul>
At which visit was this reaction first reported?	<ul style="list-style-type: none"> <li>Select visit the site first became aware of the ISR from the dropdown list</li> <li>If interim visit, mark ‘interim visit’ and record the visit code in the next field.</li> </ul>
Interim visit code, if applicable	<ul style="list-style-type: none"> <li>Enter interim visit code in space provided, if applicable.</li> </ul>
Is the reaction still ongoing?	<ul style="list-style-type: none"> <li>Select “Yes” if the ISR is continuing at the time it is first reported</li> <li>If “Yes”, leave Outcome Date blank.</li> </ul>

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Field	Instructions
<p><b>Outcome Date</b></p>	<ul style="list-style-type: none"> <li>• Enter the date on which the participant no longer experienced the reaction</li> <li>• At minimum, a month and year are required</li> <li>• Date must be on or after the onset date</li> </ul>
<p><b>Severity Grade</b></p>	<ul style="list-style-type: none"> <li>• Record the severity grade using the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> (including relevant appendices/addendums) <ul style="list-style-type: none"> <li>○ Grade 1 (Mild)</li> <li>○ Grade 2 (Moderate)</li> <li>○ Grade 3 (Severe)</li> <li>○ Grade 4 (Potentially life-threatening)</li> <li>○ Grade 5 (Death)</li> </ul> </li> </ul>
<p><b>Action Taken with Study Product</b></p>	<ul style="list-style-type: none"> <li>• Select “dose not changed” if there is no change to the participant’s planned use (dose, frequency, schedule) of study product as a result of the ISR.</li> <li>• “Dose reduced” and “dose increased” do not apply and should not be selected in HPTN 083.</li> <li>• Select “drug withdrawn” if the ISR results in permanent discontinuation of study product.</li> <li>• Select “drug interrupted” if ISR results in a clinician-initiated product hold.</li> <li>• 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/Discontinuation forms are completed.</li> <li>• Select “not applicable” if the ISR’s onset date is on or after the date the participant permanently discontinues study product use.</li> </ul>
<p><b>Other action(s) taken:</b></p>	<ul style="list-style-type: none"> <li>• Select “None” or check all that apply.</li> <li>• Select “Medication” only if participant reports taking medication for the reported reaction. Report medication(s) on the Concomitant Medications log</li> <li>• Select “Therapeutic procedure/surgery” only if participant reports a procedure or surgery.</li> <li>• Select “Diagnostic procedure” only if a diagnostic procedure is reported.</li> <li>• If “Other”, then specify relevant details in the “Other, specify” text field provided.</li> </ul>

Field	Instructions
Status/Outcome	<ul style="list-style-type: none"> <li>• Select “recovered/resolved” if reaction is no longer present, has returned to baseline severity/frequency, or has increased in severity/frequency. Note that if a participant started taking medication once enrolled to control a reaction, the reaction is not considered resolved while the medication is still indicated.</li> <li>• Select “recovering/resolving” if reaction is continuing and has not yet resolved or returned to baseline severity/frequency.</li> <li>• Select “resolved with sequelae” if participant has recovered from the reaction, but with remaining effects or impairment. These remaining effects can be temporary but are still present at the time of the report.</li> <li>• Select “not recovered/resolved” whenever a reaction is continuing at the time of participant termination from the study.</li> <li>• Select “fatal” only if the severity grade of this reaction is Grade 5. Any other AEs or reactions continuing at the time of death should be recorded as “not recovered/resolved”.</li> </ul>
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is selected mark at least one item from the list.</li> </ul>
Has or will this reaction be reported as an EAE?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• For questions about ICH guidelines and EAE reporting, refer to current <i>Manual for Expedited Reporting of Adverse Events to DAIDS</i>.</li> <li>• 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.</li> </ul>
If yes, EAE number	<ul style="list-style-type: none"> <li>• Enter EAE number in field provided</li> </ul>

# INTERIM VISIT SUMMARY

Subject: **Subject**  
Page: **Interim Visit Summary**



Visit date  ...

Interim visit code

How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?

How many bottles were lost, stolen, or damaged since the last pill dispensation?

Did the participant exit/terminate the study at this visit?  Yes  No

Is participant moving to infected visit schedule?  Yes  No

Is the participant ready to move to Step 3?  Yes  No

Is the participant moving to yearly visits?  Yes  No

**Complete only if participant is discontinuing Step 1 before Week 5 visit:**

Record the date and time of the participant's last dose of Step 1 oral study products.  ...   :

Is the participant moving to Step 2?  Yes  No

**Mark any forms or procedures completed at this visit.**

CD4/viral load  Yes

Hematology  Yes

Hepatitis Test Results  Yes

HIV Test  Yes

Electrocardiogram  Yes

Local Laboratory Results  Yes

Participant Receipt  Yes

Participant Transfer  Yes

Sexually Transmitted Infections  Yes

Specimen Storage  Yes

Log Form  Yes

Supplemental HIV Results  Yes

Interviewer Administered: Follow Up 1  Yes

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Interviewer Administered: Follow Up 2

Yes  No  Yes  No  Yes  No

Study Medication Satisfaction Questionnaire (SMSQs)

Yes  No  Yes  No  Yes  No

Post-injection Exercise Assessment

Yes  No  Yes  No  Yes  No

### Purpose:

This form is used to summarize information collected at an interim visit and to record all procedures or assessments the participant received at the interim visit (e.g., confirmatory HIV Test Results).

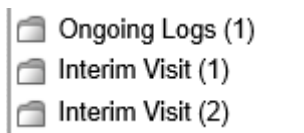
### General Information/Instructions:

Complete this form for each interim visit in which new data was collected for a participant. If no data is collected pertaining to HPTN 083 during the interim visit, this form does not need to be entered.

To add an interim visit, select “Interim Visit” from the participant’s homepage using the “Add Event” dropdown.

Add Event

Interim Visits will generate in numerical order and appear below the Ongoing Logs folder.



Once the Interim Visit Summary form is completed the actual visit code will appear in the list of folders:



Field	Instructions
Visit Date	<ul style="list-style-type: none"> <li>A complete date is required.</li> </ul>
Interim visit code	<ul style="list-style-type: none"> <li>Enter the applicable interim visit code. Note that the code is based on the previous regular visit, not the week.</li> <li>Refer to the Data Collection SSP for more information on interim visit codes</li> </ul>
<b>How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?</b>	<ul style="list-style-type: none"> <li>Select the number of bottles from the dropdown list</li> </ul>
How many bottles were lost, stolen, or damaged since the last pill dispensation?	<ul style="list-style-type: none"> <li>Select the number of bottles from the dropdown list</li> </ul>
Did the participant exit/terminate the study at this visit?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> <li>If "Yes", a Termination form will be added to the visit folder and must be submitted</li> </ul>
Is participant moving to the infected visit schedule?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> <li>If "Yes", the remaining Step 2 visit folders are removed from the participant's casebook.</li> </ul>
Is the participant ready to move to Step 3?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> <li>If "Yes", any Step 3 Day 0 forms not already present in the folder must be added</li> <li>If "Yes", the remaining Step 2 visit folders are removed from the participant's casebook.</li> </ul>
Is the participant moving to yearly visits?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> <li>Only select "Yes" If participant is in Step 1 and has not had a Week 5 injection OR the participant has completed all Step 3 visits.</li> <li>If "Yes" is selected during Step 1, the Step 2 and Step 3 visit folders are removed from the participant's casebook.</li> </ul>

<p><b>Record the date and time of the participant's last dose of Step 1 oral study products.</b></p>	<ul style="list-style-type: none"> <li>Record a response to this question only once, prior to the Week 5 visit</li> <li>Record the date and time of the participant's last dose of Step 1 oral study products using a 24-hour clock</li> <li>If time is not known enter "00:00"</li> </ul>
<p><b>Is the participant moving to Step 2?</b></p>	<ul style="list-style-type: none"> <li>Mark an answer to this question only once, prior to the Week 5 visit</li> <li>Select "Yes" or "No"</li> <li>If "No" is selected the remaining Step 2 visit folders are removed from the participant's casebook.</li> </ul>
<p><i>Mark any forms or procedures completed at this visit</i></p>	<ul style="list-style-type: none"> <li><i>Check all additional forms to be completed at this visit</i></li> <li><i>Marking one or more forms from the list and saving the Interim Visit form will add those specific forms to the interim visit folder.</i></li> </ul>

## INTERIM VISIT - OLE

Subject: Subject

Page: Interim Visit - OLE



Visit date	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>	
Interim visit code	<input type="text"/>	<input type="radio"/>	
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	<input type="text"/>	<input type="radio"/>	
Did the participant exit/terminate the study at this visit?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	
Is the participant moving to a new step or visit schedule?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>	
If Yes, please indicate which Step or visit schedule?	<input type="text"/>	<input type="radio"/>	
<b>Mark any forms or procedures completed at this visit.</b>			
CD4/Viral Load Results	<input type="radio"/> Yes	<input type="radio"/>	
Hematology	<input type="radio"/> Yes	<input type="radio"/>	
Hepatitis Test Results	<input type="radio"/> Yes	<input type="radio"/>	
HIV Test Results	<input type="radio"/> Yes	<input type="radio"/>	
Local Laboratory Results	<input type="radio"/> Yes	<input type="radio"/>	
Participant Receipt	<input type="radio"/> Yes	<input type="radio"/>	
Participant Transfer	<input type="radio"/> Yes	<input type="radio"/>	
Sexually Transmitted Infections	<input type="radio"/> Yes	<input type="radio"/>	
Specimen Storage	<input type="radio"/> Yes	<input type="radio"/>	
Log Form	<input type="radio"/> Yes	<input type="radio"/>	
Supplemental HIV Results	<input type="radio"/> Yes	<input type="radio"/>	

### Purpose:

This form is used to summarize information collected at an interim visit done **during the open-label extension (OLE) only**, and to record all procedures or assessments the participant received at the interim visit (e.g., confirmatory HIV Test Results).

### General Information/Instructions:






Complete this form for each interim visit in which new data was collected for a participant. If no data is collected pertaining to HPTN 083 during the interim visit, this form does not need to be entered.

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To add an interim visit, select “Interim Visit - OLE” from the participant’s homepage using the “Add Event” dropdown.



Interim Visits will generate in numerical order and appear below the Ongoing Logs folder.

-  Ongoing Logs (1)
-  Product Choice - OLE
-  Interim Visit - OLE (1)
-  Interim Visit - OLE (2)
-  Interim Visit - OLE (3)

Once the Interim Visit Summary form is completed the actual visit code will appear in the list of folders:

-  Ongoing Logs (1)
-  Product Choice - OLE (1)
-  Interim Visit - OLE (2)
-  Interim Visit - OLE (3)
-  Interim Visit - OLE 62.1

Field	Instructions
Visit Date	<ul style="list-style-type: none"> <li>A complete date is required.</li> </ul>
Interim visit code	<ul style="list-style-type: none"> <li>Enter the applicable interim visit code. Note that the code is based on the previous regular visit, not the week.</li> <li>Refer to the Data Collection SSP for more information on interim visit codes</li> </ul>
<b>How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?</b>	<ul style="list-style-type: none"> <li>Select the number of bottles from the dropdown list</li> <li>This question is required at all OLE steps and visits. If no bottles were dispensed, select '0'.</li> </ul>
Did the participant exit/terminate the study at this visit?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> <li>If "Yes", a Termination form will be added to the visit folder and must be submitted</li> </ul>
Is participant moving to a new step or visit schedule?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> <li>If "Yes", the next question is required</li> <li>If "No", skip the next question</li> </ul>
If Yes, please indicate which Step or visit schedule?	<ul style="list-style-type: none"> <li>Select one of the following: Oral CAB (Step 4a), Loading Dose CAB (Step 4b), TDF/FTC (Step 5), Seroconverter Schedule</li> </ul>
<i>Mark any forms or procedures completed at this visit</i>	<ul style="list-style-type: none"> <li><i>Check all additional forms to be completed at this visit</i></li> <li><i>Marking one or more forms from the list and saving the Interim Visit form will add those specific forms to the interim visit folder.</i></li> </ul>

## ***INTERVIEWER ADMINISTERED BASELINE***

### **Purpose:**

This form is used to document participant socialization, beliefs, and behaviors at baseline.

### **General Information/Instructions:**

Interview is to be conducted during V2.0 – Day 0/Enrollment

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices

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- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, mark "prefer not to answer" when available or leave field blank and respond to system auto-query with "Unknown" or "Does not wish to answer".

## ***INTERVIEWER ADMINISTERED FOLLOW UP 1***

### **Purpose:**

This form is used to document participant socialization, beliefs, and behaviors during follow-up visits throughout the course of the study.

### **General Information/Instructions:**

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, mark "prefer not to answer" when available or leave field blank and respond to system auto-query with "Unknown" or "Does not wish to answer".

## ***INTERVIEWER ADMINISTERED FOLLOW UP 2***

### **Purpose:**

This form is used to document participant feelings, social support, and feelings about PrEP use during follow-up visits throughout the course of the study.

### **General Information/Instructions:**

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, mark "prefer not to answer" when available or leave field blank and respond to system auto-query with "Unknown" or "Does not wish to answer".

## ***INTERVIEWER ADMINISTERED: OLE***

### **Purpose:**

This form is used to document participant's choices and feelings about using PrEP during follow-ups visits throughout the course of the **OLE** part of the study.

### **General Instructions:**

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices

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- Record the participant’s responses in the fields provided
- When survey is administered ALL questions need to be answered. If the participant does not wish to answer, mark “prefer not to answer”. When a question is not applicable, select “NA”.
- If the entire survey is not done mark the box “Survey not done” on the top of the form.

## LOCAL LABORATORY RESULTS

Page: Local Laboratory Results - V2.0 - Day 0/Enrollment Lab ... ▼ 📄 ✎

**RENAL FUNCTION TESTS**

Was a sample collected for renal function testing?  Yes  No 📄 ✎

Date of collection:  ... ▼  📄 ✎

Creatinine Severity Grade  ... ▼ 📄 ✎

Creatinine Adverse event  ▼ 📄 ✎

Calculated creatinine clearance Severity Grade  ... ▼ 📄 ✎

Creatinine Clearance Adverse event  ▼ 📄 ✎

**LIVER FUNCTION TESTS**

Was a sample collected for Liver function testing?  Yes  No 📄 ✎

Date of collection:  ... ▼  📄 ✎

Alkaline phosphatase Severity Grade  ... ▼ 📄 ✎

Alkaline phosphatase Adverse event  ▼ 📄 ✎

AST (SGOT) Severity Grade  ... ▼ 📄 ✎

AST (SGOT) Adverse event  ▼ 📄 ✎

ALT (SGPT) Severity Grade  ... ▼ 📄 ✎

ALT (SGPT) Adverse event  ▼ 📄 ✎

Total bilirubin Severity Grade  ... ▼ 📄 ✎

Total bilirubin Adverse event  ▼ 📄 ✎

**OTHER CHEMISTRIES**

Was a sample collected for other chemistry testing?  Yes  No 📄 ✎

Date of collection:	<input type="text"/> ... <input type="text"/>		
CPK Severity Grade	...		
CPK (CK) Adverse event			
Glucose Severity Grade	...		
If participant is fasting at any visit, please mark 'yes' for "Did the participant fast for at least 8 hours prior to blood collection?" in Lipid Profile section.			
Glucose Adverse event			
Amylase Severity Grade	...		
Amylase Adverse event			
Lipase Severity Grade	...		
Lipase Adverse event			
Phosphorus (Phosphate) Severity Grade	...		
Phosphorus (Phosphate) Adverse event			
Calcium Severity Grade	...		
Calcium Adverse event			
<b>LIPID PROFILE</b>			
Was a sample collected for the fasting lipid profile?	<input type="radio"/> Yes <input type="radio"/> No		
Date of collection:	<input type="text"/> ... <input type="text"/>		
Did the participant fast for at least 8 hours prior to blood collection?	<input type="radio"/> Yes <input type="radio"/> No		
If participant did not fast do not record lipid results.			
Total cholesterol Severity Grade	...		
Total cholesterol Adverse event			
Triglycerides Severity Grade	...		
Triglycerides Adverse event			
LDL Direct or Calculated?	<input type="radio"/> Direct <input type="radio"/> calculated		
LDL Severity Grade	...		
LDL Adverse event			
<b>URINE TESTS</b>			

Was a sample collected for urine tests?  Yes  No

Date of collection:  ...

Protein (Urine) Severity Grade

Protein (Urine) Adverse event

Glucose (Urine) Severity Grade

Glucose (Urine) Adverse event

	Data	Range Status	Unit	Range	
Creatinine	<input type="text"/>				<input type="radio"/> <input type="text"/>
Calculated creatinine clearance	<input type="text"/>				<input type="radio"/> <input type="text"/>
BUN	<input type="text"/>				<input type="radio"/> <input type="text"/>
Urea	<input type="text"/>				<input type="radio"/> <input type="text"/>
Alkaline phosphatase	<input type="text"/>				<input type="radio"/> <input type="text"/>
AST (SGOT)	<input type="text"/>				<input type="radio"/> <input type="text"/>
ALT (SGPT)	<input type="text"/>				<input type="radio"/> <input type="text"/>
Total bilirubin	<input type="text"/>				<input type="radio"/> <input type="text"/>
CPK (CK)	<input type="text"/>				<input type="radio"/> <input type="text"/>
Glucose	<input type="text"/>				<input type="radio"/> <input type="text"/>
Amylase	<input type="text"/>				<input type="radio"/> <input type="text"/>
Lipase	<input type="text"/>				<input type="radio"/> <input type="text"/>
Phosphorus (Phosphate)	<input type="text"/>				<input type="radio"/> <input type="text"/>
Calcium	<input type="text"/>				<input type="radio"/> <input type="text"/>
25-OH-vit D (Vitamin D)	<input type="text"/>				<input type="radio"/> <input type="text"/>
Total cholesterol	<input type="text"/>				<input type="radio"/> <input type="text"/>
Triglycerides	<input type="text"/>				<input type="radio"/> <input type="text"/>
LDL	<input type="text"/>				<input type="radio"/> <input type="text"/>
HDL	<input type="text"/>				<input type="radio"/> <input type="text"/>
Protein (Urine)	... <input type="text"/>				<input type="radio"/> <input type="text"/>
Glucose (Urine)	... <input type="text"/>				<input type="radio"/> <input type="text"/>

**Test results are entered in these fields**

**Units and Ranges will populate when a lab is selected at the top of the form**

**Purpose:**

This form is used to document the participant’s local lab test results.

**General Information/Instructions:**

Use this form to report test results obtained from specimens collected for this visit.

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Local Lab reference ranges should automatically appear on lab forms; if that is not the case please contact SCHARP to correct this.

Some lab results are graded based on change from baseline. Note that 'baseline' means tests done at the enrollment visit, not the screening visit.

If participant fasted at a non-fasting visit, mark 'yes' to "Did the participant fast for at least 8 hours prior to blood collection" in the Lipid Profile section.

## Item-specific Instructions:

Field	Data
<i>Test Result</i>	<ul style="list-style-type: none"> <li>• Enter the result of the specified test</li> <li>• To eliminate the need to round a number, each test result field allows up to 5 digits beyond the decimal point</li> <li>• If test was not performed, leave blank</li> <li>• If test is entered, ensure a severity grade for the result is entered, if the severity grade field for that result is present on the form</li> </ul>

Field	Instructions
<i>Was a sample collected for testing?</i>	<ul style="list-style-type: none"> <li>• Select "Yes" or "No"</li> </ul>
<i>Date of collection</i>	<ul style="list-style-type: none"> <li>• Enter the date the specimen was collected</li> <li>• A complete date is required</li> </ul>
<i>Test severity grade</i>	<ul style="list-style-type: none"> <li>• Select a severity grade (1-4) or "not gradable" from the dropdown list</li> <li>• If a severity grade is selected, the test result field must not be blank</li> <li>• Only select "Not gradable" if the lab result is normal or not gradable. Do not select if a result is not entered for that lab test</li> </ul>
<i>Test Adverse event</i>	<ul style="list-style-type: none"> <li>• If test is linked to a reported AE, select the AE in the dropdown list provided</li> <li>• An AE form must be completed before it can be selected on the Local Lab Results form.</li> </ul>

# LOG REVISIONS

Page: Log Revisions - Ongoing Logs (1)



Currently viewing line 1 of 1.  
 Click here to return to "Complete View". Apply to Record

Form Name  ✕ 🗑

Event Name  ✕ 🗑

**The below fields should be updated for Adverse Event or Injection site reaction forms only**  Yes  No  ✕ 🗑

Is the AE / reaction still ongoing?

Outcome Date  ...   ✕ 🗑

Status/Outcome  ...  ✕ 🗑

Action Taken with Study Product  ...  ✕ 🗑

**The below fields should be updated for Concomitant Medications or ART Medication forms only**  ✕ 🗑

Date Stopped  ...   ✕ 🗑

Or mark if continuing at end of study   ✕ 🗑

**The below fields should be updated for Product Hold/Discontinuation form only**  ✕ 🗑

Will the participant resume study product?  ...  ✕ 🗑

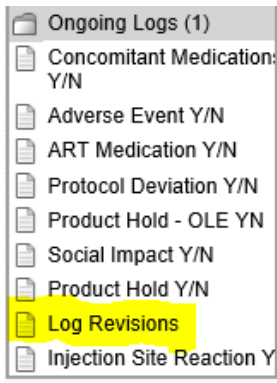
Date participant resumed study product:  ...   ✕ 🗑

**Purpose:**

The Log Revision form is used to update Concomitant Medications, Adverse Event, ART Medication, Product Hold/Discontinuation, and Injection Site Reaction logs (Ongoing Logs) that are **ongoing AND data entry locked** in Rave.

**General Instructions:**

The Log Revision form will be pre-populated with Ongoing logs that are both **ongoing AND data entry locked** in Rave. To update a qualifying Ongoing log, select the log on the Log Revision form and update.



**The below fields should be updated for Adverse Event or Injection site reaction forms only:**

Use this section of the Log Revision form to update Outcome Date, Status/Outcome and Action Taken with Study Product for AEs and ISRs that are ongoing AND are data entry locked in Rave.

**The below fields should be updated for Concomitant Medications or ART Medication forms only:**

Use this section of the Log Revision form to update “Date Stopped” and “Or mark if continuing at the end of study” for ConMed and ART logs that have “Date Stopped” and “Or mark if continuing at the end of study” blank AND are data entry locked in Rave.

**The below fields should be updated for Product Hold/Discontinuation form only:**

Use this section of the Log Revision form to update “Will the participant resume study product?” and “Date participant resumed study product:” for Product Hold/Discontinuations that have “Will the participant resume study product?” marked as “Yes” and the “Date resumed” blank AND are data entry locked in Rave.

Field	Instructions
Form Name	<ul style="list-style-type: none"> <li>This field is pre-populated. Do not complete.</li> </ul>
Event Name	<ul style="list-style-type: none"> <li>This field is pre-populated. Do not complete.</li> </ul>
Log Line Number	<ul style="list-style-type: none"> <li>This field is pre-populated. Do not complete.</li> </ul>
Event Term	<ul style="list-style-type: none"> <li>This field is pre-populated. Do not complete.</li> </ul>
Is the AE / reaction still ongoing?	<ul style="list-style-type: none"> <li>Use only to update Adverse Event or Injection Site Reaction log</li> <li>Select “Yes” or “No”</li> </ul>
Outcome Date	<ul style="list-style-type: none"> <li>Enter full date in DD-MMM-YYYY format if available</li> <li>A partial date UN-MM-YYYY is allowed</li> </ul>
Status/Outcome	<ul style="list-style-type: none"> <li>Refer to Adverse Events or ISR section of CCGs for specific details.</li> </ul>
Action Taken with Study Product	<ul style="list-style-type: none"> <li>Refer to Adverse Events or ISR section of CCGs for specific details.</li> </ul>

<b>Date Stopped</b>	<ul style="list-style-type: none"><li>• Use to update Concomitant Medication and ART Medication</li><li>• Enter full date in DD-MMM-YYYY format if available</li><li>• A partial date UN-MM-YYYY or UN-UNK-YYYY is allowed</li></ul>
<b>Or mark if continuing at end of study</b>	<ul style="list-style-type: none"><li>• Mark box if medication was continuing at the time of study completion</li></ul>
<b>Will the participant resume study product?</b>	<ul style="list-style-type: none"><li>• Use to update Product Hold/Discontinuation only</li><li>• Select “Yes” or “No”</li></ul>
<b>Date participant resumed study product:</b>	<ul style="list-style-type: none"><li>• Enter full date in DD-MMM-YYYY format</li></ul>

# LONG TERM CONSENT UPDATE

Subject: **993686959**

Page: **Long Term Consent Update - Ongoing Logs (1)**



Did the participant change their long term consent since enrollment?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>
<b>If Yes, indicate the current response for each of the below questions:</b>		
Did the participant consent to having blood stored and used for future testing?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>
Date consent updated	<input type="text"/> ... <input type="text"/>	<input type="radio"/>
Did the participant consent to genetic testing?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/>
Date consent updated	<input type="text"/> ... <input type="text"/>	<input type="radio"/>

**Purpose:**

Complete this form if a participant has changed either of their long term consents since enrollment.

**General Information/Instructions:**





To add this form, select “Long Term Consent Update” from the participant’s homepage using the “Add Event” dropdown.

Add Event

**Item-specific Instructions:**

Field	Instructions
Did the participant change their long term consent since enrollment?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is entered, complete both questions below about a change in consent</li> <li>• If “No”, end of form</li> </ul>
Did the participant consent to having blood stored and used for future testing?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes”, enter date in next response</li> </ul>
Date consent updated	<ul style="list-style-type: none"> <li>• Enter date that blood storage consent was updated</li> <li>• A complete date is required</li> </ul>
Did the participant consent to genetic testing?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes”, enter date in next response</li> </ul>
Date consent updated	<ul style="list-style-type: none"> <li>• Enter date that genetic testing consent was updated</li> <li>• A complete date is required</li> </ul>

# MISSED VISIT

Target Visit Date	<input type="text"/> ... <input type="text"/>	  
Reason visit was missed <sup>?</sup>	<input type="text"/>	  
If other, specify	<input type="text"/>	  

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CRF Version 519 - Page Generated: 16 Nov 2017 11:44:10 Pacific Standard Time

**Purpose:**

Complete this form each time an enrolled participant misses a required visit and will not be completing procedures for that visit.

**General Information/Instructions:**

A missed visit form will be added to a visit folder if the response to “Did the participant complete this visit?” on the Date of Visit form is “No”.

**Item-specific Instructions:**

Field	Instructions
Target Visit Date	<ul style="list-style-type: none"> <li>Record the target date of the visit</li> <li>A complete date is required</li> </ul>
Reason visit was missed	<ul style="list-style-type: none"> <li>Select the reason that the participant missed this visit from the dropdown list</li> <li>If the reason is not included in this list, select “other”, and specify the reason in the “If other, specify” text field provided</li> </ul>

# PARTICIPANT RECEIPT

Page: Participant Receipt - V4.0 - Week 4 (1)

Name of receiving study site	<input type="text" value="..."/>	<input type="button" value="v"/>	<input type="button" value="🔍"/>	<input type="button" value="🗑"/>
Name of transferring study site	<input type="text" value="..."/>	<input type="button" value="v"/>	<input type="button" value="🔍"/>	<input type="button" value="🗑"/>
Date informed consent signed at receiving site	<input type="text"/>	<input type="button" value="..."/>	<input type="button" value="v"/>	<input type="button" value="🗑"/>

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CRF Version 148 - Page Generated: 16 Nov 2017 09:33:51 Pacific Standard Time

**Purpose:**

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

**General Instructions:**

This form is completed by the receiving site. Marking “Participant Receipt” under the Additional Forms section on the Date of Visit or Interim Visit form will add the Receipt form to the visit folder.

**Item-specific Instructions:**

Field	Instructions
Name of receiving study site:	<ul style="list-style-type: none"> <li>Select the applicable site from the dropdown list</li> <li>Site should match the name of receiving site on the Participant Transfer form</li> </ul>
Name of transferring study site:	<ul style="list-style-type: none"> <li>Select the applicable site from the dropdown list</li> <li>Site should match the name of transferring site on the Participant Transfer form</li> </ul>
Date informed consent signed at receiving site	<ul style="list-style-type: none"> <li>A complete date is required</li> </ul>

## ***PARTICIPANT TRANSFER***

Name of transferring study site:	<input type="text" value="..."/>			
Name of receiving study site:	<input type="text" value="..."/>			
Visit Code of last completed contact with participant	<input type="text" value="..."/>			
Interim Visit Code	<input type="text"/>			
Date participant records were sent to receiving study site	<input type="text"/>		<input type="text"/>	

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CRF Version 1362 - Page Generated: 27 Jun 2019 15:40:48 Pacific Daylight Time

**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.

**Item-specific Instructions:**

Field	Instructions
Name of transferring study site:	<ul style="list-style-type: none"> <li>Select the applicable site from the dropdown list</li> <li>Site should match the name of transferring site on the Participant Receipt form</li> </ul>
Name of receiving study site:	<ul style="list-style-type: none"> <li>Select the applicable site from the dropdown list</li> <li>Site should match the name of receiving site on the Participant Receipt form</li> </ul>
Visit Code of last completed contact with participant	<ul style="list-style-type: none"> <li>Select the applicable VISIT from the dropdown list</li> <li>If interim visit, select “Interim Visit Code”</li> </ul>
Interim Visit Code	<ul style="list-style-type: none"> <li>Enter interim visit code, if applicable</li> </ul>
Date participant records were sent to receiving study site	<ul style="list-style-type: none"> <li>A complete date is required</li> </ul>

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# PARTICIPANT UNBLINDING

Page: Participant Unblinding



**Only complete this form when participant has been contacted, or deceased. Otherwise, wait until the end of study to complete this form.**

Was the participant informed of their study arm assignment (that is, active CAB or active Truvada)?  Yes  No

If yes, enter date  ...

If no, mark reason  Lost to Follow-up  Other

Other, specify

**Purpose:**

Complete this form when a participant is unblinded after site approval of LOA #3.

**General Instructions:**

This form is completed at the visit where participant is informed of his study regimen. If this contact happens over the phone or in between regular visits, an interim visit should be completed to document this event.

**Item-specific Instructions:**

Field	Instructions
Was the participant informed of their study arm assignment (that is, active CAB or active Truvada)?	<ul style="list-style-type: none"> <li>Enter "Yes" or "No"</li> </ul>
If yes, enter date	<ul style="list-style-type: none"> <li>If participant has been notified of his study regimen, enter the date of contact.</li> <li>A complete date is required</li> </ul>
If no, mark reason	<ul style="list-style-type: none"> <li>If participant terminated and has not been informed of his regimen, enter either "Lost to Follow-up" or "Other"</li> <li>If "Other" is entered, record the reason in "Other, specify" field.</li> </ul>

# PILL COUNT - ENROLLMENT

Page: Pill Count - Enrollment - V2.0 - Day 0/Enrollment



Record the number of pills dispensed at the Enrollment visit:

Cabotegravir (real or placebo)

TDF/FTC (real or placebo)

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CRF Version 519 - Page Generated: 16 Nov 2017 10:38:18 Pacific Standard Time



**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
Cabotegravir (real or placebo)	<ul style="list-style-type: none"> <li>Enter the number of cabotegravir (<b>real or placebo</b>) pills that were dispensed in the field provided</li> </ul>
TDF/FTC (real or placebo)	<ul style="list-style-type: none"> <li>Enter the number of TDF/FTC (<b>real or placebo</b>) pills that were dispensed in the field provided</li> </ul>

## PILL COUNT – FOLLOW UP

Page: Pill Count - Follow Up - V3.0 - Week 2 (1) ☰ ↕

Did the participant bring in any pills at this visit? If yes, record the number of pills brought in at this visit.  Yes  No

Date of Pill Count  ...

Cabotegravir (real or placebo)

TDF/FTC (real or placebo)

Was the participant dispensed any additional pills at this visit? If yes, record the number of pills dispensed at this visit.  Yes  No

Cabotegravir (real or placebo)

TDF/FTC (real or placebo)

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CRF Version 519 - Page Generated: 16 Nov 2017 10:53:29 Pacific Standard Time

**Purpose:**

This form is used to document the participant’s pill dispensation through week 4.

**General Instructions:**

Complete this form at Visit 3.0 - Week 2 and 4.0 - Week 4.

**Item-specific Instructions:**

Field	Instructions
Did the participant bring in any pills at this visit? If yes, record the number of pills brought in at this visit.	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “No” is selected, move to the pill dispensation section below</li> </ul>
Date of Pill Count	<ul style="list-style-type: none"> <li>• A complete date is required</li> </ul>
Cabotegravir (real or placebo)	<ul style="list-style-type: none"> <li>• Enter the number of cabotegravir (real or placebo) pills that were returned in the field provided</li> </ul>
TDF/FTC (real or placebo)	<ul style="list-style-type: none"> <li>• Enter the number of TDF/FTC (real or placebo) pills that were returned in the field provided</li> </ul>

Field	Instructions
<p>Was the participant dispensed any additional pills at this visit? If yes, record the number of pills dispensed at this visit.</p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• Mark “Yes” only if <i>new</i>, complete bottles are dispensed. Do not include pills counted and returned to participant.</li> <li>• If “No” is selected, remaining fields should be blank.</li> </ul>
<p>Cabotegravir (real or placebo)</p>	<ul style="list-style-type: none"> <li>• Enter the number of new cabotegravir (real or placebo) pills dispensed in the field provided</li> <li>• Do not record pills already counted and returned to the participant.</li> </ul>
<p>TDF/FTC (real or placebo)</p>	<ul style="list-style-type: none"> <li>• Enter the number of new TDF/FTC (real or placebo) pills dispensed in the field provided</li> <li>• Do not record pills already counted and returned to the participant.</li> </ul>

# POST-INJECTION EXERCISE ASSESSMENT

Page: Post-injection Exercise Assessment - V6.0 - Week 6 (1)

Since the participant's last injection, did the participant perform any vigorous activities?  Yes  No   

What type of activities?    

For how long? Record total combined time in hours.   hours   

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CRF Version 519 - Page Generated: 16 Nov 2017 11:21:32 Pacific Standard Time

**Purpose:**

This form is used to document the participant's level of physical activity.

**General Information/Instructions:**

This form is required at V6.0 – Week 6 and every other subsequent visit in Step 2 of the study.

**Item-specific Instructions:**

Field	Instructions
Since the participant's last injection, did the participant perform any vigorous activities?	<ul style="list-style-type: none"> <li>Select either "Yes" or "No"</li> </ul>
What type of activities?	<ul style="list-style-type: none"> <li>Briefly describe activities in text field provided</li> </ul>
For how long? Record in total combined time, in hours and minutes.	<ul style="list-style-type: none"> <li>Enter the total number of hours and minutes the participant engaged in vigorous activities.</li> <li>Record partial hours using a decimal.</li> </ul>

## PRE-EXISTING CONDITIONS Y/N

Page: **Pre-existing Conditions Y/N - V2.0 - Day 0/Enrollment**



Does the participant have any pre-existing conditions to report?

Yes  No

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CRF Version 519 - Page Generated: 14 Nov 2017 12:08:37 Pacific Standard Time

**Purpose:**

To document whether any pre-existing medical conditions/events were reported at the Screening visit or recalled by the participant during follow-up.

**General Instructions:**


This form appears in the Visit 2.0/Day 0 visit. Note that this form is not present within the "Ongoing Logs" folder.

**Item-specific Instructions:**

Field	Instructions
Does the participant have any pre-existing conditions to report?	<ul style="list-style-type: none"> <li>• Select either "Yes" or "No"</li> <li>• If "Yes" is marked and the form saved, the "Pre-existing Conditions" log form appears in the Enrollment folder and can then be completed.</li> </ul>

## PRE-EXISTING CONDITIONS

Page: **Pre-existing Conditions - V2.0 - Day 0/Enrollment** ☰ ✎

 Currently viewing line 1 of 1.  
Click here to return to "Complete View". Apply to Record

Date medical history collected	<input type="text"/> ... <input type="text"/>	<input type="radio"/> ✎ ✕
Description of medical history condition/event	<input style="width: 100%;" type="text"/>	<input type="radio"/> ✎ ✕
Is condition/event gradable?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> ✎ ✕
Toxicity (Severity) Grade	<input style="width: 100%;" type="text"/> ... <input type="text"/>	<input type="radio"/> ✎ ✕
Date medical condition/event started	<input type="text"/> ... <input type="text"/>	<input type="radio"/> ✎ ✕
Is the condition ongoing at time of assessment?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> ✎ ✕
Date medical condition/event ended/resolved	<input type="text"/> ... <input type="text"/>	<input type="radio"/> ✎ ✕

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 519 - Page Generated: 14 Nov 2017 12:37:09 Pacific Standard Time

**Purpose:**

This form is used to document the participant’s pre-existing medical conditions, including but not limited to: history of hospitalizations, surgeries, allergies, any condition that required prescription medication, and acute or chronic conditions ongoing at screening and/or that occur between screening and enrollment.

If, during follow-up, a pre-existing condition resolves or increases in severity or frequency from baseline, this must be documented, but not on the Pre-Existing Conditions CRF, which is intended to remain a snapshot of the participant’s medical history at enrollment.

This form will appear in the V2.0 – Day 0/Enrollment folder after the “Pre-existing Conditions” prompt has been answered as “Yes”. Use the “Add a new Log line” button to add an additional baseline medical history condition/event.

**General Instructions:**

- Record any relevant medical conditions. This includes conditions and symptoms reported by the participant as well as any conditions identified via physical exam or laboratory testing.
- If needed, record any pre-existing medical conditions identified during follow-up. Write a chart note to explain why the entry was added after the Enrollment Visit.
- Complete a separate entry (e.g. log line) for each pre-existing condition/event when entering into the study database.

## Item-specific Instructions:

Field	Instructions
Date medical history collected	<ul style="list-style-type: none"> <li>• Record the date medical history was collected</li> <li>• A complete date is required</li> </ul>
Description of medical history condition/event	<ul style="list-style-type: none"> <li>• Briefly describe event</li> <li>• Whenever possible, provide a diagnosis instead of listing a cluster of symptoms</li> <li>• If no diagnosis is identified, each symptom must be recorded as a separate log line</li> <li>• If an abnormal lab value is reported at the Enrollment visit, record the lab assay with the direction (i.e., increased or decreased) of the abnormality <i>ex: "decreased hematocrit" or "increased ALT"</i></li> <li>• Additional information on the frequency and duration of chronic condition outbreaks can also be provided within this description</li> </ul>
Is condition/event gradable?	<ul style="list-style-type: none"> <li>• Select "Yes" or "No"</li> <li>• If a condition is not gradable (below Grade 1), select "No"</li> </ul>
Toxicity (Severity) Grade	<ul style="list-style-type: none"> <li>• This item is required if "Is condition/event gradable?" is "Yes".</li> <li>• If the item improves in severity or resolves during the study, then the Toxicity Grade should remain unchanged on this CRF</li> <li>• Record the severity grade using the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> (including relevant appendices/addendums) <ul style="list-style-type: none"> <li>○ Grade 1 (Mild)</li> <li>○ Grade 2 (Moderate)</li> <li>○ Grade 3 (Severe)</li> <li>○ Grade 4 (Potentially life-threatening)</li> </ul> </li> </ul>

Field	Instructions
Date medical condition/event started	<ul style="list-style-type: none"> <li>Record the date the medical condition was first diagnosed or the date the surgery/procedure was performed as applicable.</li> <li>If the participant is unable to recall the exact date, obtain best estimate. At a minimum, a year is required.</li> <li>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.</li> </ul>
Is the condition ongoing at time of assessment?	<ul style="list-style-type: none"> <li>Select "Yes" for chronic conditions, as well as any other conditions that are currently ongoing at the time of assessment (i.e. at Screening and/or Enrollment).</li> <li>If the condition resolves during follow-up, this item should remain unchanged on this CRF.</li> </ul>
Date medical condition/event ended/resolved	<ul style="list-style-type: none"> <li>This item is only required if "Is the condition ongoing?" is "No" at the time of enrollment.</li> <li>At a minimum, a year is required.</li> <li>Record the date the medical condition was considered resolved.</li> <li>For surgeries/procedures, record the date the surgery/procedure was completed.</li> </ul>

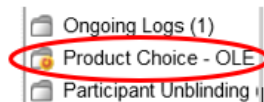
## PRODUCT CHOICE - OLE

### Purpose:

This form should be completed at the first visit after approval of protocol v4.0 when the participant decides whether or not to continue in the open-label extension (OLE). It records the participant’s decision, as well as the participant’s choice of product if participant is moving to the open-label extension (OLE).

### General Instructions:

This form is located below the Ongoing Logs folder on the left navigation bar.



Form: Product Choice - OLE

Generated On: 18 Nov 2021 02:38:39

Will participant move to Open Label Extension (OLE)? Yes   
 No

Date decision was made on whether to move to Open-label extension?

If No, Reason (end of form)

- Study participation too burdensome
- Already accessed TDF/FTC through another mechanism
- Prefer to take TAF/FTC
- Relocating to area where study is not offered
- Prefer not to answer
- Prefers TDF/FTC but not eligible for study-provided TDF/FTC
- Other

Other, specify \_\_\_\_\_

If Yes, Date of Informed Consent \_\_\_\_\_

Select OLE Regimen CAB   
 TDF/FTC   
 Seroconverter schedule – continuing from Version 3.0 of the protocol   
 Open Label Truvada Schedule – continuing from Version 3.0 of the protocol

If CAB, specify introductory regimen (mark only one):  
 Oral CAB (Step 4a)   
 Loading Dose (4-week interval) CAB-LA (Step 4b)   
 Standard Dose (8-week interval) CAB-LA (Step 4c)

If CAB regimen selected, Reason  
 Prefer injections and/or don't like pills   
 CAB was shown to be superior to Truvada for HIV prevention   
 Want to avoid potential side effects of Truvada   
 Other

Other, specify \_\_\_\_\_

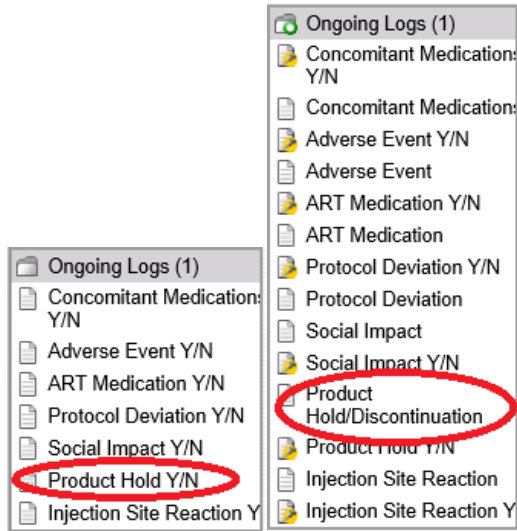
If TDF/FTC regimen selected, Reason  
 Don't like injections and/or prefer pills   
 The potential side effects of Truvada are better understood than those of Cabotegravir   
 Concerned about resistance if injectable PrEP fails   
 Other

Other, specify \_\_\_\_\_

Item-specific Instructions:

Field	Instructions
Will participant move to Open Label Extension (OLE)?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”.</li> </ul>
Date the decision was made on whether to move to Open-label extension?	<ul style="list-style-type: none"> <li>Enter the date the decision was made on whether or not to move to open-label extension.</li> <li>This response is required for all participants who are offered the open-label extension.</li> </ul>
If No, Reason (end of form)	<ul style="list-style-type: none"> <li>If participant chooses not to move to open-label extension, select the reason.</li> <li>If “Other” is selected, enter reason in “Other, specify” field.</li> <li>If site has LOA #3 approval, complete termination procedures in v60 – Exit Visit folder, including Termination form.</li> <li>If site does not yet have LOA #3 approval, complete termination procedures in a v3.0 interim visit, based on the last visit attended or missed.</li> </ul>
If Yes, Date of Informed Consent	<ul style="list-style-type: none"> <li>Enter the date participant signed consent for open-label extension.</li> <li>If participant chooses not to move to open-label extension, leave this date blank.</li> </ul>
Select OLE Regimen	<ul style="list-style-type: none"> <li>Select “CAB”, “TDF/FTC”, “Seroconverter schedule”, or “Open Label Truvada schedule”</li> </ul>
If CAB, specify introductory regimen (mark only one):	<ul style="list-style-type: none"> <li>If participant chooses CAB, select either “Oral CAB (Step 4a)”, “Loading Dose (4-week interval) CAB-LA (Step 4b)”, or “Standard Dose (8-week interval) CAB-LA (Step 4c)”.</li> </ul>
If CAB regimen selected, Reason	<ul style="list-style-type: none"> <li>If participant chooses CAB, select the reason.</li> <li>If “Other” is selected, enter reason in “Other, specify” field.</li> </ul>
If TDF/FTC regimen selected, Reason	<ul style="list-style-type: none"> <li>If participant chooses TDF/FTC, select the reason.</li> <li>If “Other” is selected, enter reason in “Other, specify” field.</li> <li>If “OLE Regimen” is “Open Label Truvada Schedule – continuing from Version 3.0 of the protocol”, this response should be blank.</li> </ul>

## *PRODUCT HOLD Y/N*



**Purpose:**

This form documents whether a participant’s study product is temporarily or permanently discontinued.

**General Instructions:**

This form is located in the “Ongoing Logs” folder. Complete this form once when study product use is temporarily or permanently discontinued.

**Item-specific Instructions:**

Field	Instructions
<p>Is there a product hold or discontinuation to report?</p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”.</li> <li>• If “Yes” is selected and the form saved, the Product Hold/Discontinuation log form appears in the folder and can then be completed.</li> </ul>

## *PRODUCT HOLD/DISCONTINUATION*

Date of last oral study product use	<input type="text"/> ... ▼ <input type="text"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Date of last injection:	<input type="text"/> ... ▼ <input type="text"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Date when this study product hold or discontinuation was initiated:	<input type="text"/> ... ▼ <input type="text"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
At what visit was this product hold/discontinuation initiated?	... ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Interim visit code	<input type="text"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Why is the study product being held or discontinued?	... ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
If Other marked, specify: <sup>?</sup>	<input type="text"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Mark if this hold is for Step 3 open-label product:	<input type="checkbox"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
If product hold was associated with an Adverse event, select the applicable AE(s):	<input type="text"/> ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Adverse Event #1		
Adverse Event #2	<input type="text"/> ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Adverse Event #3	<input type="text"/> ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	<input type="text"/> ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s).	<input type="text"/> ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Will the participant resume study product?	... ▼	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>
Date participant resumed study product:	<input type="text"/> ... ▼ <input type="text"/>	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/>

### Purpose:

This form documents a participant's temporary or permanent discontinuation of study product use.

### General Instructions:

This form is present within the "Ongoing Logs" folder. Complete this form for each enrolled participant when study product use is temporarily or permanently discontinued.

A Product Hold form is expected in the following circumstances:

- A participant in Step 1 moves to Yearly visits prior to first injection
- A participant in Step 2 moves to Step 3
- A participant in Step 3 discontinues use of open-label daily oral TDF/FTC

This log is not completed if a participant finishes study product as required per protocol, if a participant terminates the study early, or to document adherence issues.

**CONFIDENTIAL DOCUMENT**

If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete a separate Product Hold/Discontinuation log line for each reason. The same visit code should be used on each entry.

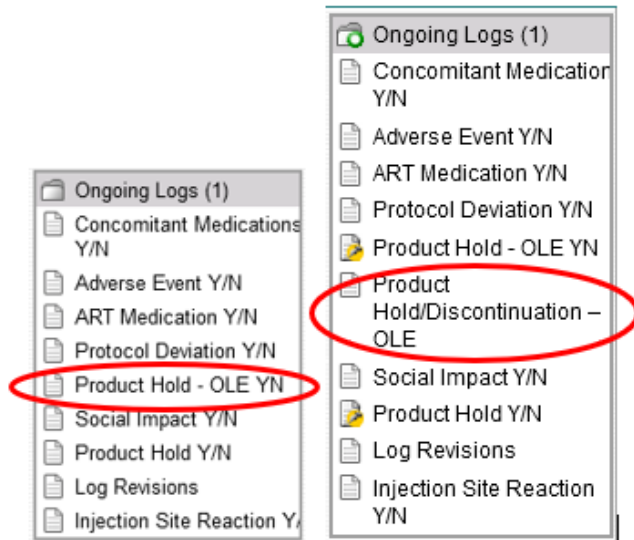
**Item-specific Instructions:**

Field	Instructions
<b>Date of last oral study product use</b>	<ul style="list-style-type: none"> <li>Enter the date of the last use of oral study product</li> <li>Month and year are required; if the day is unknown enter UN</li> </ul>
<b>Date of last injection:</b>	<ul style="list-style-type: none"> <li>Enter the date of the last injection of study product</li> <li>A complete date is required</li> <li>If participant did not reach Step 2, leave field blank; in response to query enter 'did not reach Step 2'</li> </ul>
<b>Date when this study product hold or discontinuation was initiated:</b>	<ul style="list-style-type: none"> <li>Record the date when the participant was temporarily or permanently discontinued from study product</li> <li>A complete date is required</li> </ul>
<b>At what visit was this product hold/discontinuation initiated?</b>	<ul style="list-style-type: none"> <li>Select the visit at which study product hold/discontinuation began</li> <li>If hold occurred at an interim visit, select 'interim visit' from the drop-down menu and record interim visit number in field below</li> </ul>
<b>Interim visit code</b>	<ul style="list-style-type: none"> <li>If hold occurred at an interim visit, enter interim visit code</li> </ul>
<b>Why is the study product being held or discontinued?</b>	<ul style="list-style-type: none"> <li>Select the primary reason from the dropdown menu</li> <li>If "Clinical AE (protocol mandated)" or "Laboratory AE (clinical mandated)" is marked, select the appropriate AE(s) from the dropdown lists below</li> <li>If the primary reason is 'Other clinical reason' or 'Other participant request', provide additional details in the "If Other marked, specify" text field provided</li> </ul>
<b>Mark if this hold is for Step 3 open-label product</b>	<ul style="list-style-type: none"> <li>Mark this box if the reported Product Hold/Discontinuation is for Step 3 open-label study product</li> </ul>
	<ul style="list-style-type: none"> <li>Select related adverse event(s) from the dropdown list</li> </ul>

CONFIDENTIAL DOCUMENT

<p>If product hold was associated with an Adverse event, select the applicable AE(s):</p>	<ul style="list-style-type: none"> <li>Up to 3 adverse events can be selected.</li> </ul>
<p>If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:</p>	<ul style="list-style-type: none"> <li>Select any related injection site reactions from the drop-down list</li> </ul>
<p>If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s):</p>	<ul style="list-style-type: none"> <li>Select any medication entered on the CM form that was added as a result of product hold</li> </ul>
<p>Will the participant resume study product?</p>	<ul style="list-style-type: none"> <li>Select either "Yes", "No (permanently discontinued)", "No (hold continuing/ permanently discontinued for another reason)</li> </ul>
<p>Date participant resumed study product:</p>	<ul style="list-style-type: none"> <li>Enter the date the participant resumed taking study drug</li> <li>A complete date is required</li> </ul>

## *PRODUCT HOLD OLE - Y/N*



**Purpose:**

This form documents whether a participant’s study product is temporarily or permanently discontinued during the open-label extension (OLE) only.

**General Instructions:**

This form is located in the “Ongoing Logs” folder. Complete this form once when study product use is temporarily or permanently discontinued.

**Item-specific Instructions:**

Field	Instructions
<p><b>Is there a product hold or discontinuation to report?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”.</li> <li>• If “Yes” is selected and the form saved, the Product Hold/Discontinuation - OLE log form appears in the folder and can then be completed.</li> </ul>

## PRODUCT HOLD/DISCONTINUATION - OLE

Is this hold for oral study product or CAB injection?	<input type="radio"/> Oral product <input type="radio"/> CAB injection	<input type="radio"/> <input type="radio"/>
Date of last oral study product or CAB injection	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>
Date when this study product hold or discontinuation was initiated:	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>
At what visit was this product hold/discontinuation initiated?	...	<input type="radio"/> <input type="radio"/>
Interim visit code	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Why is the study product being held or discontinued?	...	<input type="radio"/> <input type="radio"/>
If Other marked, specify: <sup>?</sup>	<input type="text"/>	<input type="radio"/> <input type="radio"/>
<b>If product hold was associated with an Adverse event, select the applicable AE(s):</b> Adverse Event #1	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Adverse Event #2	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Adverse Event #3	<input type="text"/>	<input type="radio"/> <input type="radio"/>
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	<input type="text"/>	<input type="radio"/> <input type="radio"/>
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s).	<input type="text"/>	<input type="radio"/> <input type="radio"/>
<b>Complete this section only if participant has either resumed or permanently discontinued study drug.</b>	...	<input type="radio"/> <input type="radio"/>
Has the participant resumed study product?		
Date participant resumed study product:	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>
Date participant <b>permanently</b> discontinued study product:	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>

**Purpose:**

This form documents a participant’s temporary or permanent discontinuation of study product use **during the open-label extension (OLE) only.**

**General Instructions:**

This form is present within the “Ongoing Logs” folder. Complete this form for each enrolled participant when study product use is temporarily or permanently discontinued. This form should also be completed when a participant switches regimens during the OLE.

CONFIDENTIAL DOCUMENT

This log is not completed if a participant finishes study product as required per protocol, if a participant terminates the study early, or to document adherence issues.

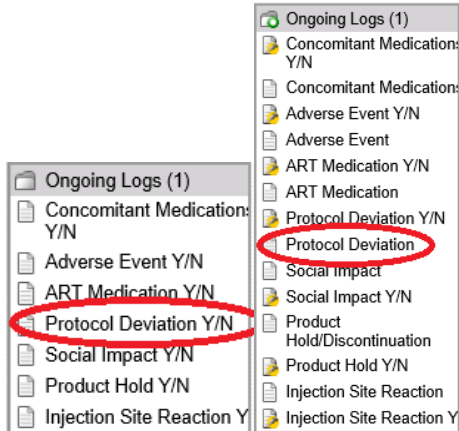
If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete a separate Product Hold/Discontinuation log line for each reason. The same visit code should be used on each entry.

**Item-specific Instructions:**

Field	Instructions
Which study product is being held?	<ul style="list-style-type: none"> <li>Mark "Oral CAB", "CAB-LA injection", or "TDF/FTC"</li> </ul>
Date of last oral study product or CAB injection	<ul style="list-style-type: none"> <li>Enter the date of the last use of oral study product or CAB injection <i>in the current Step</i> (i.e. open-label extension).</li> <li>Month and year are required; if the day is unknown enter UN</li> </ul>
Date when this study product hold or discontinuation was initiated:	<ul style="list-style-type: none"> <li>Record the date when the participant was temporarily or permanently discontinued from study product</li> <li>A complete date is required</li> </ul>
At what visit was this product hold/discontinuation initiated?	<ul style="list-style-type: none"> <li>Select the visit at which study product hold/discontinuation began</li> <li>If hold occurred at an interim visit, select 'interim visit' from the drop-down menu and record interim visit number in field below</li> <li>Visit code must match the Step of the product being held.</li> </ul>
Interim visit code	<ul style="list-style-type: none"> <li>If hold occurred at an interim visit, enter interim visit code</li> </ul>
Why is the study product being held or discontinued?	<ul style="list-style-type: none"> <li>Select the primary reason from the dropdown menu</li> <li>If the primary reason is 'Other clinical reason' or 'Other participant request', provide additional details in the "If Other marked, specify" text field provided</li> </ul>
If product hold was associated with an Adverse event, select the applicable AE(s):	<ul style="list-style-type: none"> <li>Select related adverse event(s) from the dropdown list</li> <li>Up to 3 adverse events can be selected.</li> </ul>

	<ul style="list-style-type: none"> <li>• If “Clinical AE (protocol mandated)” or “Laboratory AE (clinical mandated)” is marked, select the appropriate AE(s) from the dropdown lists below.</li> <li>• An AE may also be selected if “CMC recommendation based on a clinical event” or “CMC recommendation based on a laboratory value” is marked.</li> </ul>
<b>If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:</b>	<ul style="list-style-type: none"> <li>• Select any related injection site reactions from the drop-down list</li> </ul>
<b>If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s):</b>	<ul style="list-style-type: none"> <li>• Select any medication entered on the CM form that was added as a result of product hold</li> </ul>
<b>Has the participant resumed study product?</b>	<ul style="list-style-type: none"> <li>• Complete this question only if participant has either resumed or permanently discontinued study product; OR if participant has terminated.</li> <li>• Select either “Yes”, “No (permanently discontinued)”, “No (hold continuing/ permanently discontinued for another reason).</li> <li>• If participant has not resumed study product at termination, update this form by selecting “No (permanently discontinued)”.</li> </ul>
<b>Date participant resumed study product:</b>	<ul style="list-style-type: none"> <li>• Enter the date the participant resumed taking study drug</li> <li>• A complete date is required</li> <li>• If participant has not resumed study product, leave this date blank.</li> </ul>
<b>Date participant <i>permanently</i> discontinued study product:</b>	<ul style="list-style-type: none"> <li>• Enter the date the participant permanently discontinued study drug.</li> <li>• A complete date is required.</li> <li>• If participant has not resumed study product at termination, update this form by entering termination date here.</li> </ul>

## *PROTOCOL DEVIATION Y/N*



**Purpose:**

This form documents 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
<p><b>Have any protocol deviations occurred?</b></p>	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes” is selected, then the Protocol Deviation log form appears in the Ongoing Logs folder and can then be completed</li> </ul>

# PROTOCOL DEVIATION

Page: Protocol Deviation - Ongoing Logs (1) Print

Currently viewing line 1 of 1.  
Click here to return to "Complete View". Apply to Record

**Prior to completing this form contact the protocol deviations alias to confirm reporting requirements.**

Site awareness date  ...

Deviation date  ...

Has or will this deviation be reported to local IRB/EC?  Yes  No

Has or will this deviation be reported to DAIDS as a critical event?  Yes  No

Type of deviation

Description of deviation:

Plans and/or action taken to address the deviation:

Plans and/or action taken to prevent future occurrences of the deviation:

Deviation reported by (staff name):

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CRF Version 993 - Page Generated: 07 Aug 2018 15:14:16 Pacific Daylight Time

**Purpose:**

This form documents reportable protocol deviations identified for study participants during the implementation of HPTN 083.

**General Information/Instructions:**

Prior to completing a deviation form contact the [083pd@hptn.org](mailto:083pd@hptn.org) alias to confirm whether an event is considered a reportable deviation.

Complete this form each time a reportable protocol deviation is identified. Complete one page per protocol deviation when entering in the study database. To add an additional deviation within Medidata Rave, clicking "Add a new Log line" will add an additional page for a new deviation to be completed.

Reportable protocol deviations are defined by the HPTN 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	<ul style="list-style-type: none"> <li>Record the date the site became aware of the deviation</li> <li>A complete date is required</li> </ul>
Deviation date	<ul style="list-style-type: none"> <li>Record the date the deviation occurred (start date)</li> <li>At a minimum, the Year is required.</li> </ul>
Has or will this deviation be reported to local IRB/EC?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> </ul>
Has or will this deviation be reported to DAIDS as a critical event?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> </ul>
Type of deviation	<ul style="list-style-type: none"> <li>Select the applicable deviation from the search list.</li> <li>The first few letters of the description can be typed in the 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 "&lt;&lt;Back" and "Next&gt;&gt;" buttons at the top of the list.</li> <li><i>Please see table below for the types of deviations.</i></li> </ul>
Description of deviation	<ul style="list-style-type: none"> <li>Use text field to briefly describe specific details of deviation</li> </ul>
Plans and/or action taken to address the deviation	<ul style="list-style-type: none"> <li>Use text field to provide a brief description of plans to address deviation</li> </ul>
Plans and/or action taken to prevent future occurrences of the deviation	<ul style="list-style-type: none"> <li>Use text field to provide a brief description of plans to prevent similar deviations in the future</li> </ul>
Deviation reported by (staff name):	<ul style="list-style-type: none"> <li>Enter name of staff member that reported the deviation</li> </ul>

PROTOCOL DEVIATION CODE LIST
Description
<b>Inappropriate enrollment:</b> The participant enrolled and not all eligibility requirements were met.
<b>Failure to follow trial randomization or blinding procedures:</b> Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
<b>Study product management deviation:</b> The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
<b>Study product dispensing error:</b> The wrong study product was dispensed to a participant, or study product was dispensed to a participant who permanently discontinued study product use.
<b>Conduct of non-protocol procedure:</b> A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice.
<b>Breach of confidentiality:</b> 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.
<b>Physical assessment deviation:</b> 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).
<b>Lab assessment deviation:</b> 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).
<b>Use of non-IRB/EC-approved materials:</b> Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
<b>Informed assent/consent process deviation:</b> Examples include failure to accurately execute and/or document any part of the informed consent process.
<b>Failure to complete eligibility assessment prior to randomization / incomplete assessment of</b>

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<b>eligibility prior to enrollment:</b> Examples include failure to complete any required assessment within 45 days of screening specimen collection.
Other

## ***RANDOMIZATION***

Is the participant ready to be randomized?  Yes  No

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**Purpose:**

The Randomization form will randomize the participant within Medidata.

**General Instructions:**

Prior to entering this form, confirm the correct PTID has been selected for randomization and the participant is eligible for the study.

One randomization is complete, a confirmation will appear on the form stating “Subject successfully randomized.”

**Item-specific Instructions:**

Field	Instructions
Is the participant ready to be randomized?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”</li> </ul>

# SEXUALLY TRANSMITTED INFECTIONS

**Syphilis screening test**

Was a sample collected for syphilis testing?  Yes  No

Date of collection:  ...

Mark algorithm used  Traditional  Reverse

Treponemal test  Non-reactive/Negative  Reactive/Positive

Non-Treponemal test  Non-reactive/Negative  Reactive/Positive

Titer if indicated

**Or**

N/A

Second Treponemal test  Non-reactive/Negative  Reactive/Positive

Did the CMC designate an incident Syphilis infection at this visit?  Yes  No

**GC/CT NAAT**

Was a sample collected for NAAT for GC/CT?  Yes  No

Date of collection:  ...

N. gonorrhea – URINE  Negative  Positive

C. trachomatis – URINE  Negative  Positive

N. gonorrhea – RECTAL  Negative  Positive

C. trachomatis – RECTAL  Negative  Positive

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CRF Version 993 - Page Generated: 07 Aug 2018 15:17:28 Pacific Daylight Time  
[Printable Version](#) [View PDF](#) [Icon Key](#)  
CRF Version 148 - Page Generated: 15 Nov 2017 14:51:37 Pacific Standard Time

**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 indicated during the study.

If an STI is diagnosed during screening, record STI diagnoses in Pre-existing Conditions form.

**Item-specific Instructions:**

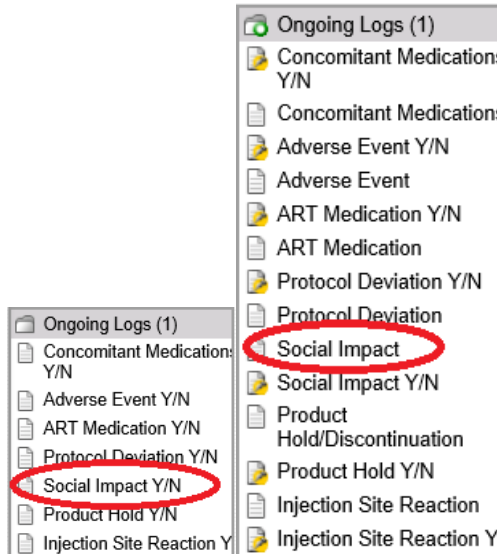
Field	Instructions
Was a sample collected for syphilis testing?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> </ul>
Date of collection:	<ul style="list-style-type: none"> <li>A complete date is required</li> </ul>

Field	Instructions
Mark algorithm used	<ul style="list-style-type: none"> <li>Select "Traditional" or "Reverse"</li> <li>If "Traditional", a result is required for "Non-Treponemal test"</li> <li>If "Reverse", a result is required for "Treponemal test"</li> </ul>
Treponemal test	<ul style="list-style-type: none"> <li>Select "Non-reactive/Negative" or "Reactive/Positive"</li> </ul>
Non-Treponemal test	<ul style="list-style-type: none"> <li>Select "Non-reactive/Negative" or "Reactive/Positive"</li> <li>If response is "Reactive/Positive" then "Titer if indicated" is required.</li> </ul>
Titer if indicated	<ul style="list-style-type: none"> <li>Enter titer if it is indicated</li> </ul>
Or	
N/A	<ul style="list-style-type: none"> <li>Mark if Titer is not indicated</li> </ul>
Second Treponemal test	<ul style="list-style-type: none"> <li>Select "Non-reactive/Negative" or "Reactive/Positive"</li> </ul>
Did the CMC designate an incident Syphilis infection at this visit?	<ul style="list-style-type: none"> <li>Select "Yes", "No", or "IoR designated incident syphilis infection" in accordance with CMC communication.</li> <li>A response to this question is required at all visits if any test result is "Reactive/Positive".</li> <li>At OLE visits only, enter "IoR designated incident syphilis infection" if IoR deemed a new infection after a positive result.</li> <li>Select "Yes" or "IoR designated incident syphilis infection" only once for the same event regardless of multiple reactive results.</li> </ul>
GC/CT NAAT	
Was a sample collected for NAAT for GC/CT?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> </ul>
Date of collection:	<ul style="list-style-type: none"> <li>A complete date is required</li> </ul>
N. gonorrhoea – URINE	<ul style="list-style-type: none"> <li>Select "Negative" or "Positive"</li> </ul>
C. trachomatis – URINE	<ul style="list-style-type: none"> <li>Select "Negative" or "Positive"</li> </ul>

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Field	Instructions
N. gonorrhoea – RECTAL	<ul style="list-style-type: none"> <li>Select “Negative” or “Positive”</li> </ul>
C. trachomatis – RECTAL	<ul style="list-style-type: none"> <li>Select “Negative” or “Positive”</li> </ul>

## ***SOCIAL IMPACT Y/N***



**Purpose:**

This form documents 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 reported a social impact during the study?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”</li> <li>If “Yes” is selected, then the Social Impact log form appears in the Ongoing Logs folder and can then be completed</li> </ul>

## ***SOCIAL IMPACT***

Page: Social Impact - Ongoing Logs (1) Apply to Record

Currently viewing line 1 of 1.  
Click here to return to "Complete View".

Date reported

Concisely describe social impact

Onset date

Social impact type

If other, specify

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CRF Version 519 - Page Generated: 16 Nov 2017 14:45:24 Pacific Standard Time

**Purpose:**

It is possible that participants' involvement in the study could become known to others, and that a social impact may result (i.e., because participants could be perceived as being HIV-infected or at risk or "high risk" for HIV infection). This form documents social impacts that the participant thinks are related to participation in the study.

**General Instructions:**

Complete this form on an as-needed basis.

**Item-specific Instructions:**

Field	Instructions
Date reported	<ul style="list-style-type: none"> <li>Enter the date the social impact was reported to the site</li> <li>A complete date is required</li> </ul>
Concisely describe social impact	<ul style="list-style-type: none"> <li>Describe the social impact</li> </ul>
Onset date	<ul style="list-style-type: none"> <li>Enter the date on which the impact began</li> <li>A complete date is preferred, if day or month is unknown, use UN or UNK respectively.</li> </ul>
Social impact type	<ul style="list-style-type: none"> <li>Select appropriate social impact type from the dropdown list</li> <li>If "Other – Had other problems not covered in the codes above" is selected, specify social impact type in "If other, specify" text field</li> </ul>





Field	Instructions
Time plasma sample collected	<ul style="list-style-type: none"> <li>Record the time the specimen(s) was collected using a 24-hour clock</li> </ul>
Was plasma stored?	<ul style="list-style-type: none"> <li>Select "Stored" or "Not Stored"</li> </ul>
Was a dried blood spot collected?	<ul style="list-style-type: none"> <li>Select "Yes" or "No" <ul style="list-style-type: none"> <li>Select "No" if participant did not consent to genetic testing.</li> </ul> </li> <li>If "Yes", enter the date/time of collection and whether or not sample was stored</li> </ul>
Specimen collection date	<ul style="list-style-type: none"> <li>Record the date the specimen(s) was collected</li> <li>A complete date is required</li> </ul>
Time Dried Blood Spot collected	<ul style="list-style-type: none"> <li>Enter time of sample(s) collection using a 24-hour clock</li> </ul>
Was Dried Blood Spot stored?	<ul style="list-style-type: none"> <li>Select "Stored" or "Not Stored"</li> <li>If sample was not collected, leave this response blank.</li> </ul>
(Complete only for Enrollment Visit) Was a whole blood sample collected for storage?	<ul style="list-style-type: none"> <li>Select "Yes" or "No" at Enrollment visit only.</li> <li>At all other visits, leave blank.</li> <li>If "Yes", enter the date/time of collection and whether or not sample was stored</li> </ul>
Specimen collection date	<ul style="list-style-type: none"> <li>Record the date that the specimen(s) was collected</li> <li>A complete date is required</li> </ul>
Time Whole Blood collected	<ul style="list-style-type: none"> <li>Enter time of sample(s) collection using a 24-hour clock</li> </ul>
Was Whole Blood stored?	<ul style="list-style-type: none"> <li>Select "Stored" or "Not Stored"</li> </ul>

Field	Instructions
Was a cell pellet collected?	<ul style="list-style-type: none"><li>• Select "Yes" or "No"</li><li>• If "Yes", enter the date/time of collection and whether or not sample was stored</li></ul>
Specimen collection date	<ul style="list-style-type: none"><li>• Record the date that the specimen(s) was collected</li><li>• A complete date is required</li></ul>
Was a cell pellet stored?	<ul style="list-style-type: none"><li>• Select "Stored" or "Not Stored"</li></ul>
Additional blood specimen collection required	<ul style="list-style-type: none"><li>• Select "Yes" or "No"</li><li>• If "Yes" selected and the form is saved, an additional Specimen Storage form is added in the visit's folder where additional information can be entered.</li></ul>

## ***STUDY MEDICATION SATISFACTION QUESTIONNAIRE (SMSQs)***

**Purpose:**

This form is used to document participant satisfaction with the study medication.

**General Information/Instructions:**

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, leave field blank and answer system auto-query with "Unknown" or "Does not wish to answer" to confirm
- If the entire survey is not done mark the box "Survey not done"

## ***STUDY MEDICATION SATISFACTION QUESTIONNAIRE CHANGE (SMSQc)***

**Purpose:**

This form is used to document changes in participant satisfaction with the study medication during the preceding weeks.

**General Information/Instructions:**

This form is required at V10.0 – Week 19 of the study.

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, leave field blank and answer system auto-query with "Unknown" or "Does not wish to answer" to confirm
- If the entire survey is not done mark the box "Survey not done"

## ***STUDY MEDICATION SATISFACTION QUESTIONNAIRE: OLE***

**Purpose:**

This form is used to document changes in participant satisfaction with the study medication during the preceding weeks during the OLE part of the study.

**General Information/Instructions:**

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer, select "Prefer not to answer" where available, otherwise, select "NA". If participant does not know or question is not applicable, select "NA".
- If the entire survey is not done mark the box "Survey not done" on top of the form

# SUPPLEMENTAL HIV TEST RESULTS

**Form: Supplemental HIV Results**

**Generated On: 16 Dec 2019 17:53:52**

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done

OR

Specimen Collection Date \_\_\_\_\_

- Assay Result
- Assay result not provided
  - HIV Negative
  - HIV-1 Positive
  - HIV-2 Positive
  - HIV-2 Positive with HIV-1 Cross-Reactivity
  - HIV-1 Positive, Untypable
  - HIV-1 Indeterminate
  - HIV-2 Indeterminate
  - HIV Indeterminate
  - Other

Other assay result: \_\_\_\_\_

Comments (max. 200 characters) \_\_\_\_\_

Laboratory Reported HIV Interpretation \_\_\_\_\_

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported

OR

- Interpretation
- HIV Negative
  - HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.
  - HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.
  - HIV-1 Positive
  - HIV-2 Positive
  - HIV-2 Positive - This result is distinct from HIV Positive, Untypable.
  - HIV Positive
  - Acute HIV-1 Positive
  - HIV-1 Negative, HIV-2 inconclusive
  - Inconclusive
  - Other

Other interpretation: \_\_\_\_\_

Comments (max. 200 characters) \_\_\_\_\_

HIV DNA \_\_\_\_\_

Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:

Not performed/Not reported by Lab (add comment)

---

OR

Specimen Collection Date \_\_\_\_\_

DNA Result

Detectable DNA result (record below)

Detectable DNA , but below limit of detection (<4.09 copies per million cells)

Detectable DNA, above the reportable range of the assay (>100 copies per million cells)

Undetectable DNA, below limit of detection (<4.09 copies per million cells )

---

Detectable DNA result: \_\_\_\_\_ Fixed Unit: copies per million cells

---

Comments (max. 200 characters) \_\_\_\_\_

**Purpose:**

This form is used to document all HIV 1/2 discriminatory results and DNA test results.

**General Instructions:**

Complete this form any time specimens are drawn for HIV 1/2 or DNA testing.

Marking the response next to this form name on the Date of Visit, Interim, or Yearly Summary form will add the Supplemental HIV form to that visit folder.

**Item-specific Instructions:**

Field	Instructions
HIV 1/2 Discriminatory Assay	<ul style="list-style-type: none"> <li>• Mark 'Not Done' if test was not performed</li> <li>• If 'Not Done' is marked, the Specimen Collection Date and Assay Result should be blank</li> </ul>
Specimen Collection Date	<ul style="list-style-type: none"> <li>• Enter the date the specimen was collected</li> <li>• A complete date is required</li> </ul>
Assay Result	<ul style="list-style-type: none"> <li>• Select the appropriate result</li> <li>• If result not provided, mark 'Assay result not provided'</li> <li>• If the result does not appear on the list of options, mark 'Other' and report assay result in the field below</li> </ul>
Other assay result	<ul style="list-style-type: none"> <li>• If result does not appear on the list of options, mark 'Other' in the item above and record result.</li> </ul>

<b>Comments</b>	<ul style="list-style-type: none"> <li>Record any additional comments that may help describe the assay result.</li> <li>Assay results should only be recorded in the Assay Result or Other Assay Result field.</li> </ul>
<b>Laboratory Reported HIV Interpretation</b>	<ul style="list-style-type: none"> <li>Mark 'Not Reported' if not provided by testing lab Or mark interpretation.</li> <li>If 'Not Reported' is marked, other fields describing Lab Reported HIV Interpretation should be blank</li> </ul>
<b>Interpretation</b>	<ul style="list-style-type: none"> <li>Select the appropriate interpretation</li> <li>If the appropriate interpretation does not appear on the list of options, mark 'Other' and report interpretation in the field below</li> </ul>
<b>Other interpretation</b>	<ul style="list-style-type: none"> <li>If result does not appear on the list of options, mark 'Other' in the item above and record result.</li> </ul>
<b>Comments</b>	<ul style="list-style-type: none"> <li>Record any additional comments that may help describe the result interpretation.</li> <li>Result interpretations should only be recorded in the Interpretation or Other interpretation field.</li> </ul>
<b>HIV DNA</b>	<ul style="list-style-type: none"> <li>Mark 'Not performed/not reported by Lab' if not provided by testing lab or complete appropriate result field.</li> <li>If 'Not performed/not reported by Lab' is marked, other fields describing HIV DNA should be blank</li> </ul>
<b>Specimen Collection Date</b>	<ul style="list-style-type: none"> <li>Enter the date the specimen was collected</li> <li>A complete date is required</li> </ul>

---

<b>DNA Result</b>	<ul style="list-style-type: none"><li>• Select the appropriate result</li><li>• If result is detectable and in range enter the result in the field below</li></ul>
<b>Detectable DNA Result</b>	<ul style="list-style-type: none"><li>• Enter detectable DNA result; otherwise leave item blank</li></ul>
<b>Comments</b>	<ul style="list-style-type: none"><li>• Record any additional comments that may help describe the results.</li><li>• Results should only be recorded in the DNA Result field</li></ul>

## TERMINATION

Termination date	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>
Reason for termination	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Date of death	<input type="text"/> ... <input type="text"/>	<input type="radio"/> <input type="radio"/>
Specify <sup>?</sup>	<input type="text"/>	<input type="radio"/> <input type="radio"/>
Was termination associated with an adverse event?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> <input type="radio"/>
If yes, please specify AE	<input type="text"/>	<input type="radio"/> <input type="radio"/>

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CRF Version 519 - Page Generated: 16 Nov 2017 11:48:25 Pacific Standard Time

**Purpose:**

This form is used to document a participant’s exit from the study (i.e. study termination).

**General Instructions:**

Complete this form for each enrolled participant at either the scheduled exit/end of study visit or when the participant is confirmed to no longer be participating in the study.

Participants cannot be terminated for relocating or considered lost to follow up until the end of the study. During the study, those participants who are currently lost to follow up or relocated must have a Missed Visit form completed for all missed visits.

The Termination form is added to the visit folder (protocol or interim visit) for the visit at which the site determines the participant to be terminating. Marking “Yes” to “Did the participant exit/terminate the study at this visit?” on either the Date of Visit or Interim Visit Summary form and saving the form will add the Termination form to that visit folder.

**Item-specific Instructions:**

Field	Instructions
Termination date	<ul style="list-style-type: none"> <li>A complete date is required</li> </ul>
Reason for termination	<ul style="list-style-type: none"> <li>Select the reason for termination from the study from the dropdown list.</li> <li>If “linkage to local CAB” is selected, complete a ConMed log to record outside CAB injection.</li> </ul>

<b>Date of death</b>	<ul style="list-style-type: none"><li>• If “Death” is selected, record date of death</li></ul>
<b>Specify</b>	<ul style="list-style-type: none"><li>• If reason for termination is “Death” or “other”, provide additional details in the text field provided, including cause of death if applicable.</li></ul>
<b>Was termination associated with an adverse event?</b>	<ul style="list-style-type: none"><li>• Select “Yes” or “No”</li></ul>
<b>If yes, please specify AE</b>	<ul style="list-style-type: none"><li>• If the participant terminated from the study due to an AE, choose the applicable AE from the dropdown list</li><li>• An AE form must be completed for the event before it can be selected in the dropdown list</li></ul>

# UN-TERMINATION

Page: **Un-termination - V3.0 - Week 2 (1)**

Un-termination date	<input type="text"/>	...	<input type="text"/>
Reason for Un-termination	<input type="radio"/> Participant has requested to participate in the open label extension (OLE). <input type="radio"/> Other		
If Other marked, specify:	<input type="text"/>		






















**Purpose:**

This form is used to re-activate terminated participants back into the study after site acceptance of protocol v4.0.

**Item-specific Instructions:**

Field	Instructions
Un-termination date	<ul style="list-style-type: none"> <li>• Enter date participant was re-activated into the study.</li> <li>• A full date is required.</li> </ul>
Reason for Un-termination	<ul style="list-style-type: none"> <li>• Select either 'Participant has requested to participate in the open label extension (OLE) or 'Other'.</li> <li>• If 'Other' is selected, enter reason in 'If other marked, specify'.</li> </ul>

## VITAL SIGNS

Were vital signs done?	<input type="radio"/> Yes <input type="radio"/> No	  
Date of assessment	<input type="text"/> ... <input type="text"/>	  
Systolic blood pressure	<input type="text"/> mmHg	  
Diastolic blood pressure	<input type="text"/> mmHg	  
Weight	<input type="text"/> kg	  
Height (Complete at Enrollment only)	<input type="text"/> cm	  
Pulse	<input type="text"/> beats/min	  



### Purpose:




This form is used to document a participant's blood pressure, weight, pulse, and Height (enrollment only).




### Item-specific Instructions:




Field	Instructions
Were vital signs done?	<ul style="list-style-type: none"> <li>Select "Yes" or "No"</li> </ul>
Date of assessment	<ul style="list-style-type: none"> <li>A complete date is required</li> </ul>
Systolic blood pressure	<ul style="list-style-type: none"> <li>Enter the systolic blood pressure in units of "mmHG"</li> </ul>
Diastolic blood pressure	<ul style="list-style-type: none"> <li>Enter the diastolic blood pressure in units of "mmHG"</li> </ul>
Weight	<ul style="list-style-type: none"> <li>Enter the weight in units of "kg"</li> <li>Up to one decimal place can be entered</li> </ul>
Height	<ul style="list-style-type: none"> <li>Enter the height in units of "cm"</li> <li>This item is required only at the enrollment visit</li> <li>Up to one decimal place can be entered</li> </ul>
Pulse	<ul style="list-style-type: none"> <li>Enter the pulse in units of beats/minute</li> </ul>




# VITAMIN D AND CALCIUM ASSESSMENT




Page: **Vitamin D and Calcium Assessment - V2.0 - Day 0/Enrollment (1)**  

Was assessment done?  Yes  No   

Any change from previous assessment of daily intake?  Yes  No   

Record the total daily calcium intake  mg   

Record the total daily Vitamin D intake  IU   

Comments    

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 993 - Page Generated: 07 Aug 2018 15:34:18 Pacific Daylight Time

**Purpose:**

This form is used to document a participant’s calcium and Vitamin D intake as well as any changes from previous assessments.

**Item-specific Instructions:**

Field	Instructions
Was assessment done?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”</li> </ul>
Any change from previous assessment of daily intake?	<ul style="list-style-type: none"> <li>Select “Yes” or “No”</li> </ul>
Record the total daily calcium intake	<ul style="list-style-type: none"> <li>Enter the daily calcium intake in units of “mg”</li> </ul>
Record the total daily Vitamin D intake	<ul style="list-style-type: none"> <li>Enter the daily Vitamin D intake in units of “IU”.</li> </ul>
Comments	<ul style="list-style-type: none"> <li>Enter any additional comments as needed</li> </ul>

# YEARLY VISIT SUMMARY

Page: Yearly Visit Summary



Did the participant complete this visit?	<input type="radio"/> Yes <input type="radio"/> No		
Visit Date:	<input type="text"/> ... <input type="text"/>		
Yearly visit code	<input type="text"/>		
Did the participant exit/terminate the study at this visit?	<input type="radio"/> Yes <input type="radio"/> No		
Is the participant confirmed HIV infected?	<input type="radio"/> Yes <input type="radio"/> No		
<b>Mark any forms or procedures completed at this visit.</b>			
Hematology	<input type="radio"/> Yes <input type="radio"/> No		
Hepatitis Test Results	<input type="radio"/> Yes <input type="radio"/> No		
Electrocardiogram	<input type="radio"/> Yes <input type="radio"/> No		
Local Laboratory Results	<input type="radio"/> Yes <input type="radio"/> No		
Participant Receipt	<input type="radio"/> Yes <input type="radio"/> No		
Participant Transfer	<input type="radio"/> Yes <input type="radio"/> No		
Sexually Transmitted Infections	<input type="radio"/> Yes <input type="radio"/> No		
Supplemental HIV Results	<input type="radio"/> Yes <input type="radio"/> No		

**Purpose:**

This form is used to summarize information collected at a yearly visit and to record all procedures or assessments the participant received at the interim visit (e.g., HIV Test Results).

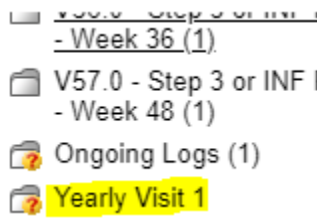
**General Information/Instructions:**

Complete this form for each expected yearly visit.

To add a “yearly visit” folder, select “Yearly Visit” from the participant’s homepage using the “Add Event” dropdown.

Add Event

Yearly Visits will generate in numerical order and appear below the Ongoing Logs folder.



**Item-specific Instructions:**

Field	Instructions
Did the participant complete this visit?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• Selecting “No” will generate a Missed Visit form</li> </ul>
Visit Date	<ul style="list-style-type: none"> <li>• A complete date is required.</li> </ul>
Yearly visit code	<ul style="list-style-type: none"> <li>• Select the appropriate visit code from the drop-down list</li> </ul>
Did the participant exit/terminate the study at this visit?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• If “Yes”, a Termination form will be added to the visit folder and must be submitted</li> </ul>
Is the participant confirmed HIV infected?	<ul style="list-style-type: none"> <li>• Select “Yes” or “No”</li> <li>• </li> </ul>
<i>Mark any forms or procedures completed at this visit</i>	<ul style="list-style-type: none"> <li>• <i>Check all additional forms to be completed at this visit</i></li> <li>• <i>Marking one or more forms from the list and saving the Interim Visit form will add those specific forms to the interim visit folder.</i></li> </ul>

## Document History

Summary of Changes to CRF Completion Guidelines

Version		Summary of Revisions
Number	Date	
01.0	24 Jan 2018	Original version
02.0	15 July 2019	<ul style="list-style-type: none"> <li>• New form – Inclusion/Exclusion New form – Inclusion/Exclusion</li> <li>• New form – Vital Signs</li> <li>• New form – Yearly Visit Summary</li> <li>• Updated screen shots of forms:                             <ul style="list-style-type: none"> <li>○ Adverse Event</li> <li>○ Concomitant Medications form</li> <li>○ Date of Visit form</li> <li>○ Hepatitis Test Results</li> <li>○ HIV Test Results</li> <li>○ Injection Administration</li> <li>○ Injection Site Reaction</li> <li>○ Participant Transfer</li> <li>○ Product Hold/Discontinuation</li> <li>○ Sexually Transmitted Infections</li> <li>○ Specimen Storage</li> <li>○ Vitamin D and Calcium Assessment</li> </ul> </li> <li>• Moved general instructions and description of database functionality from appendix to the top of document</li> <li>• Added or updated instructions for CRFs modified in migration or those needing further clarification:                             <ul style="list-style-type: none"> <li>○ Adverse Event</li> <li>○ Concomitant Medications</li> <li>○ Date of Visit</li> <li>○ Local Lab Results (allow up to 5 digits beyond decimal)</li> <li>○ Hematology Results</li> <li>○ Hepatitis Test Results</li> <li>○ HIV Test Results</li> <li>○ Injection Administration</li> <li>○ Interim Visit Summary</li> <li>○ Local Lab Results</li> <li>○ Participant Transfer</li> <li>○ Pre-Existing Conditions</li> <li>○ Product Hold/Discontinuation</li> <li>○ Protocol Deviation</li> <li>○ Sexually Transmitted Infections</li> <li>○ Specimen Storage</li> <li>○ Vital Signs</li> <li>○ Vitamin D and Calcium Assessment</li> </ul> </li> </ul>

CONFIDENTIAL DOCUMENT

Version		Summary of Revisions
Number	Date	
03.0	25 Mar 2021	<ul style="list-style-type: none"> <li>○ New item added to Yearly Visit Summary to allow for missed yearly visit.</li> <li>○ Instructions added regarding dynamic search lists where selection of an AE becomes nonconformant due to data being revised on original AE log line.</li> <li>○ Updated screen shots of forms and added or updated instructions:                             <ul style="list-style-type: none"> <li>○ ART Medication</li> <li>○ Date of Visit</li> <li>○ Interim Visit</li> <li>○ HIV Test Results</li> <li>○ Product Hold/Discontinuation</li> <li>○ Vital Signs</li> <li>○ Yearly Visit Summary</li> </ul> </li> <li>○ New form – Supplemental HIV Test Results</li> <li>○ Added instructions to Local Lab Results to mark fasting item if participant fasted at a non-fasting visit.</li> <li>○ Updated instructions to Pre-existing Conditions so that conditions are not updated on this form after enrollment</li> <li>○ New form – Participant Unblinding</li> <li>○ New forms:                             <ul style="list-style-type: none"> <li>○ Date of Visit – OLE</li> <li>○ Date of Visit – HIV</li> <li>○ Interim Visit – OLE</li> <li>○ Product Hold – OLE Y/N</li> <li>○ Product Hold/Discontinuation – OLE</li> <li>○ Product Choice – OLE</li> <li>○ Log Revisions</li> <li>○ Interviewer Administered – OLE</li> <li>○ SMSQ – OLE</li> <li>○ Un-termination</li> </ul> </li> </ul>
04.0	14Jan2022	<ul style="list-style-type: none"> <li>○ New form – Long Term Consent Update</li> <li>○ New screenshot and options added to Product Choice-OLE</li> <li>○ New instructions added to Interviewer Administered – OLE to indicate that a response is required at all visits</li> <li>○ New instructions added to Interviewer Administered – OLE to indicate that a response is required at all visits</li> <li>○ New instruction added to Sexually Transmitted Infections form to indicate that a response is always required after a positive result for “Did the CMC designate a syphilis infection?” even in v4.0.</li> </ul>

Version		Summary of Revisions
Number	Date	
05.0	20May2022	<ul style="list-style-type: none"> <li>○ New form: Informed Consent – Version 5.0</li> <li>○ New instruction added to Sexually Transmitted Infections form to indicate which test is used for Traditional and Reverse algorithms.</li> <li>○ New instructions added to Product Choice to clarify which visit to use for terminating participants who do not move to the OLE.</li> <li>○ New instruction added to Product Choice to clarify that participants moving from Step 3 to Step 5 should not have a reason entered in “If TDF/FTC regimen selected, Reason”.</li> </ul>
06.0	29Jul2022	<ul style="list-style-type: none"> <li>○ New response option on Termination form, “Reason for termination”: “linkage to local CAB”.</li> <li>○ New response option on Sexually Transmitted Infections form, “Did CMC designate an incident syphilis infection”: “IoR designated incident syphilis infection (OLE visits only)”.</li> <li>○ New instruction added to Sexually Transmitted Infections form to only enter “IoR designated incident syphilis infection” at OLE visits.</li> <li>○ New instruction added to Injection Administration form to mark “Open label injection (active CAB LA)” at all OLE visits.</li> </ul>
07.0	20Jun2023	<ul style="list-style-type: none"> <li>○ New form: Informed Consent – Version 6.0</li> <li>○ New instruction added to AE form for visit code.</li> <li>○ New instruction added to AE form for alternate etiology.</li> <li>○ New instruction added to Product Hold-OLE form for visit code.</li> <li>○ New instruction added to Informed Consent – Version 5.0 for date entry.</li> <li>○ New instruction added to Long Term Consent Update for date entry.</li> </ul>