Section 13. Data Management

13.1   Overview of Section 13

The purpose of this document is to provide site staff with the information needed to complete and submit HPTN 084-01 case report forms.

The SDMC (Statistical and Data Management Center) for this study is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Time (PT) time zone.

SDMC Contact Information

For information about this section of the SSP or about data management procedures for HPTN 084-01, please contact the SCHARP Clinical Data Manager:

Name: Julie Ngo
phone: +001 206 667 2094
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Phone: +001 206 667 2793
Email: jpease@scharp.org

For questions about clinical queries, please contact the SDMC Clinical Safety group: sc.clinsafety@scharp.org

13.2   Medidata Rave Overview

Medidata Rave is the data management system used by SCHARP to receive and manage study data collected at study sites. Each site completes study electronic case report forms (eCRFs) by entering data into the Medidata Rave study database. As specified in each site's Source Documentation SOP, data may be entered directly into the study database (i.e., electronic CRF is source), collected first on paper CRFs and then entered into the study database, and/or entered into the study database based on other non-CRF source documents (e.g., lab reports, testing logs, chart notes, etc.)

The HPTN 084-01 study database in Medidata Rave may be accessed at www.imedidata.com.

When using Medidata Rave, the internet browser chosen and connectivity quality will be the most critical factors affecting functionality, as Medidata is accessed via a URL using a web browser. Using an outdated browser will result in a warning banner on the log-in page of iMedidata. This warning will inform the user that their browser does not support security features that are being implemented in future iMedidata releases and to upgrade their browser. Users using any of the following browsers will see this banner:

- Internet Explorer – Versions older than 8.0
- Chrome – Versions older than 30.0
- Firefox – Versions older than 24.0
- Safari - Versions older than 7.0
- Opera - Versions older than 17.0

Each site's Data Management SOP designates the site staff members responsible for entering data into the study database. SCHARP grants designated site staff access with specific user permissions to the study database. They are required to complete eLearning modules in Medidata, as assigned by SCHARP, before access is granted and data can be entered into the study database. For more detailed information, see the iMedidata Access Guide, posted on the HPTN 084-01 Atlas webpage.

Detailed guidance on data collection, entry, navigation and general use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is posted

on the HPTN 084-01 Atlas web page.

Site staff should contact the study Clinical Data Manager(s) with any questions related to study data collection and management.

To request new access or to revise access to the study for any of site staff, please send an email sc.access.medidata@scharp.org.

A representative from Medidata Solutions may be contacted (see contact information below) anytime a site has technical questions or problems related to access or use of the Medidata Rave software.

For service in English

Toll-free	**Direct number**
1-866-MEDIDATA (633-4328)	1-973-659-6780
Toll-free fax	**Direct fax**
1-877-743-2350	1-973-954-5621

Email
helpdesk@mdsol.com

Hours
24 hours a day, 7 days a week

13.3 Data Entry/Quality Control

- All entries in Rave must be made in English.

- Once data for an eCRF is completed and saved in the study database, the following may occur:

  - A system query may be automatically triggered in Medidata Rave (e.g., denoting incomplete or inconsistent data).

  - Manual data queries may be placed by the SCHARP Clinical Data Manager (CDM) or Clinical Safety Associate (CSA) after review of entered forms.

  - Data queries may be placed by the site monitor (i.e., PPD) after required review for certain forms and/or fields.

  - Coding queries may be placed by the SCHARP MedDRA coding team to help clarify AE data.

  - Inconsistency queries may be manually placed during AE-EAE reconciliation.

  -

Query Management and Resolution

- Queries, or QCs, appear in the Medidata Rave Task Summary on the study home page of designated site users (example below). Staff members designated by the site are responsible

for routinely checking the Task Summary and correcting/updating study data to resolve any outstanding queries.

Task Summary Example:

- When site staff correct/update study data in response to a manual or coding query, SCHARP staff review the updated data and resolve the query or re-query as needed.

- When site staff correct/update study data in response to a monitoring query, the site monitor (i.e., PPD) reviews the updated data and resolves the query or re-queries as needed.

- If a site utilizes paper CRFs as source documents, any changes to the data recorded on paper CRFs **must** be entered into the Medidata Rave study database.

- If a query "Data is required" is auto-generated (marked "Site from System"), it is not necessary to enter a response in the query field:
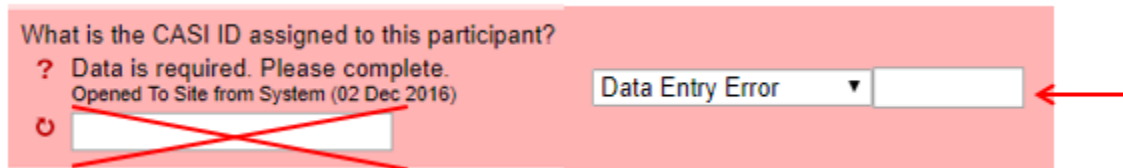
When data is entered into the missing field on the right and the form is saved, the auto query will be removed.

- **Open Queries Report** Sites have access to this report on their dashboard below the list of PTIDs (example below).

This tool can help sites manage and review unresolved queries. The report is sorted by PTID and includes Form Name, Query Open Date, Query Text, and the number of days the query is outstanding. This report can be run as needed and exported to Excel for sorting and filtering.

Most forms are expected to be completed in Rave within 7 days of the date of visit; exceptions include all log forms, forms containing lab results, and AEs. AEs are expected to be entered within 3 days of site awareness date.

- **Unresolved AEs ≥ 30 Days Report** Sites have access to this report on their dashboard below the list of PTIDs (example below).

AEs Unresolved for ≥ 30 days

US SCHARP

PTID	AE Log Number	Date Reported to Site	Adverse Event	Onset Date	Severity Grade	Visit First Reported	# of Days Ongoing
997133882	1	11 MAR 2018	TTT	10 MAR 2018			163
997136190	1	11 JUN 2017	FLABBINESS	10 JUN 2017			436
997269976	1	11 FEB 2018	XYZ TEST	10 FEB 2018	Grade 4 (Potentially life-thr	V4.0 - Week 4	191
997352533	1	16 Jul 2017	XYZ	15 Jul 2017	Grade 1 (Mild)	V6.0 - Week 6	401
997352533	2	16 Jul 2017	ANXIETY	14 Jul 2017	Grade 1 (Mild)	V5.0 - Week 5	402
997472696	1	01 FEB 2017	TESTING	20 JAN 2017	Grade 1 (Mild)	V5.0 - Week 5	577
997737826	1	16 JUN 2017	XYZ	14 JUN 2017	Grade 2 (Moderate)	V8.0 - Week 10	432

This tool can help sites review and close out AEs that have no Outcome Date; if an Outcome Date is added to the AE log line it will be removed from future reports. This report can be run as needed and exported to Excel for sorting and filtering. It is expected that some AEs will be ongoing.

Electronic Signatures by Investigators

Each site investigator or designee must sign off on each participant's complete set of data, or 'case book' to attest that the data has been reviewed and is deemed to be accurate. Their iMedidata login credentials serve as their electronic signature. Please refer to the "Electronic Signature" section of the Medidata Rave Electronic Data Capture (EDC) Training Manual and/or the Investigator e-Learning module for specific instructions.

13.4   eCRF Completion

13.4.1 PTID Creation and Screening

Each participant who provides written informed consent to be screened in HPTN 084-01 will be assigned a Participant Identifier, or PTID. The PTID is created when site staff add a subject within their Medidata home study and site folder. Refer to the "Creating Subjects" section of the Medidata Rave Electronic Data Capture (EDC) Training Manual or the CRF Completion Guidelines (CCG) for specific instructions.

Each PTID is unique. It will be assigned to a single participant only at a given site and not assigned to any other participant at any site or in any study for which SCHARP is the Statistical and Data Management Center (SDMC).

PTIDs are nine digits and formatted as "XXXYYYYYZ". The PTID consists of three parts: the site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The

check digit (Z) is a number generated by SCHARP with the participant number and helps ensure that the correct PTID is recorded and entered.

If the participant does not enroll, site staff must complete the Inclusion Exclusion Criteria CRF with the reasons for screening out and Enrollment CRF stating that the participant did not enroll ("Was the participant enrolled in the study" must equal "No"). Both forms are located in the Enrollment folder.

If a participant returns at a later date to re-screen a new, unique PTID must be assigned and treated as a new participant in the data management system.

13.4.2 Enrollment

Prior to enrollment, eligibility must be confirmed, which includes a negative rapid HIV test on a sample drawn at the Enrollment visit per LC guidelines as well as a negative pregnancy test. (Note: Sites that conduct split enrollment visits due to physical location constraints (e.g., an off-site pharmacy), can enroll prior to completing the rapid HIV testing required at the Enrollment visit; however, these results must be available and confirmed to be negative/non-reactive prior to the administration of study product.) The Inclusion Exclusion Criteria form in the participant's enrollment folder must be completed before the Enrollment CRF.

To enroll a participant, site staff mark 'Yes' to the question, "Was the participant enrolled in the study?" on the Enrollment eCRF. **A participant is considered enrolled in the study once this step takes place**; please confirm that the PTID is correct and that all screening procedures are complete prior to enrolling the participant.

13.4.3 General Guidelines for eCRF Completion

- When completing an eCRF, refer to the CRF Completion Guidelines (CCG) document, posted on ATLAS, for detailed instructions on data collection pertaining to the given form and fields on that form.

- Medidata Rave allows data to be entered directly into the study database (i.e., electronic CRF as source). Any data that is either collected first on paper CRFs or derived from non-CRF source documents (e.g., lab reports) should ideally be entered into Rave within 1-2 business days of the visit, though up to 7 (calendar) days is acceptable.

- AEs should be entered within 3 days of site awareness date and EAEs within 24 hours.

- If some or all of the eCRFs will be completed first as paper CRFs, write the participant's PTID and Visit Week (e.g., Week 6) or Visit code on the paper form.

  Any eCRF that does not collect study data does not need to be completed as a paper form, such as:

  o Participant Identifier

  o Concomitant Medications Y/N

  o Adverse Event Y/N

  o Medical History Y/N

- o Product Hold Y/N

- o Protocol Deviation Y/N

- o Injection Site Reaction Y/N

- o Social Impact Assessment Y/N

13.4.4 Visit Codes

Most eCRFs in the study database are set up within pre-defined study visit folders, so the visit name and code automatically appear (and do not need to be entered for required study visits).

<u>Please remember</u>: For specimen collection, the visit code and date on the eCRF must match the visit code and date in the LDMS database.

Visit codes for required visits are listed in table 13-1.

13.5 Visit Scheduling: Target Days and Visit Windows

Whenever possible, visits should be completed on the target day, (based on the date of enrollment / Day 0 for visits in Step 1, based on the first injection date for visits in Step 2, based on the last injection date for visits in Step 3, based on the HIV diagnosis date for visits in the Seroconversion schedule, and based on the positive pregnancy test date for visits in the Pregnancy schedule), or within the target visit window.

Reminders for specific visits:
- The enrollment visit (V102.0) must occur within 30 days of specimen collection at the screening visit.
- The Step 3 Week +8 (V301.0) visit should be conducted as close to the target date as possible.
- The Pregnancy Week +4 (V501.0) visit should be conducted as close to the target date as possible.

Allowable visit windows are an extension of the target windows and are contiguous. When necessary, visits may be completed inside the allowable window. Visits completed within the allowable window but outside the target window are considered (early/late) for the purpose of assessing on time retention

For HPTN 084 Open Label Extension (OLE) schedules, target days, and windows, please refer to the DM SSP for that protocol.

The following table lists the HPTN 084-01 visit codes, target days and visit windows for each study visit. All windows are listed in days.

Table 13-1: HPTN 084-01 Visit Codes, Target Days, and Visit Windows

Week	Visit Code	Target day	Target visit window (± varies days)	Target visit window	Allowable visit window (± varies days)	Allowable visit window
Screening	101.0	--		--		
Step 1						
Enrollment/Day 0	102.0	0	+3	(0 , 3)	+6	(0 , 6)
Week 2	103.0	14	-3 / +3	(11 , 17)	-7 / +6	(7 , 20)
Week 4	104.0	28	-3 / +3	(25 , 31)	-7 / +3	(21 , 31)
Step 2						
Week 5	201.0	0	+3	(0 , 3)	+3	(0 , 3)
Week 6	202.0	7	-3 / +3	(4 , 10)	-3 / +10	(4 , 17)
Week 9	203.0	28	-3 / +3	(25 , 31)	-10 / +3	(18 , 31)
Week 10	204.0	35	-3 / +3	(32 , 38)	-3 / +24	(32 , 59)
Week 17	205.0	84	-3 / +3	(81 , 87)	-24 / +3	(60 , 87)
Week 18	206.0	91	-3 / +3	(88 , 94)	-3 / +24	(88, 115)
Week 25	207.0	140	-3 / +3	(137 , 143)	-24 / +3	(116,143)
Week 26	208.0	147	-3 / +3	(144 , 150)	-3 / +24	(144, 171)
Week 33	209.0	196	-3 / +3	(193 , 199)	-24 / +3	(172, 199)
Week 34	210.0	203	-3 / +3	(200 , 206)	-3 / +24	(200, 227)
Step 3						
Day 0	-	0 (Date of last injection)	-	-	-	-
Week +8	301.0	56	-7 / +7	(49, 63)	-28/+14	(28, 70)
Week +12	302.0	84	-7 / +7	(77, 91)	-13/+42	(71, 126)
Week +24	303.0	168	-7 / +7	(161, 175)	-41/+42	(127, 210)
Week +36	304.0	252	-7 / +7	(245, 259)	-41/+42	(211, 294)
Week +48	305.0	336	-7 / +7	(329, 343)	-42/+42	(295, 378)
Seroconverter Visits						
Day 0	401.0	0 (the date of HIV confirmation visit)	+7	(0, 7)	+42	(0, 42)
Week 12	402.0	84	-7 / +7	(77, 91)	-41/+42	(43, 126)
Week 24	403.0	168	-7 / +7	(161, 175)	-41/+42	(127, 210)
Week 36	404.0	252	-7 / +7	(245, 259)	-41/+42	(211, 294)
Week 48	405.0	336	-7 / +7	(329, 343)	-41/+42	(295, 378)

Week	Visit Code	Target day	Target visit window (± varies days)	Target visit window	Allowable visit window (± varies days)	Allowable visit window
Pregnancy Visits						
Day 0	-	0 (Date of first positive pregnancy test)	-	-	-	-
Week +4	501.0	28	-7 / +7	(21, 35)	-28/+14	(0, 42)
Week +12	502.0	84	-7 / +7	(77, 91)	-13/+42	(71, 126)
Week +24	503.0	168	-7 / +7	(161, 175)	-41/+42	(127, 210)
Week +36	504.0	252	-7 / +7	(245, 259)	-41/+42	(211, 294)
Week +48	505.0	336	-7 / +7	(329, 343)	-41/+42	(295, 378)

13.6   HPTN 084 -01 Injection Schedule – Late/Missed Injections

Planned Injection Schedule

The planned visit schedule is as follows: first injection at week 5, second injection 4 weeks later at week 9, and all remaining injections 8 weeks apart, at weeks 17, 25, and 33. All injections should be given as close to those intervals as possible, with target windows defined as +/- 3 days for all injection visits.

Late/Missed Injections

If an injection cannot be given on time, the site should attempt to get the participant back on the original injection schedule as quickly as possible.   The following general guidelines should be followed, with consultation and prior approval from the CMC:

1. If a participant is late receiving an injection, the site should attempt to provide the injection as soon as possible within the visit window.
2. Missed injection visit: the CMC must be consulted in advance regarding additional clinical considerations for the timing of injections. **In the case that the CMC has not been contacted, the entire visit should be deferred, not just the injection administration.**

Late/Missed Safety Visits

1. Missed safety visits: the visit can be completed between 5 to 21 days after the injection. If the visit is not conducted during this timeframe AND is out of the target visit window, consult with the CMC for guidance regarding additional clinical considerations for the timing of the visit (only contact the CMC if both conditions have been met). To ensure participant safety, if a participant misses a safety visit following an injection, a safety visit must take place prior to receiving another injection.
2. Additional safety visits can occur based on IoR discretion in the event of suspicion of signs or symptoms consistent with acute HIV infection.

13.7   Types of Visits

Please refer to Section 5.3 of the SSP for additional information on each visit type.

13.7.1 Scheduled Visits

A scheduled visit is a required visit as dictated by the protocol.

13.7.2 Missed Visits

A scheduled visit is considered missed only if it is not completed within its allowable visit window AND the required procedures for that visit are not completed. If a participant is available to complete visit procedures outside of the target window consult with the CMC or the Clinical Data Manager as appropriate to confirm the best approach for documentation. Refer to Section 5.3 of the SSP for further information related to missed visits.

13.7.3 Split Visits

When a participant is not able to complete all required visit evaluations on the same day, the participant may return and complete the remaining evaluations on another day. When such a split visit occurs, case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates). Refer to Section 5.3 of the SSP for further information related to split visits.

13.7.4 Interim Visits

An interim visit is an 'extra' visit that occurs after procedures for a required visit are completed. For example, a participant comes to clinic for additional STI testing.

All interim visits/contacts with the participant should be documented in a chart note. Additionally, if the interim contact results in at least one newly-completed or updated Medidata Rave CRF, the interim visit is assigned an interim visit code (visit number ending in something other than ".0"). All phone contacts that meet interim visit criteria as specified above are also assigned interim visit codes.

To add an interim visit in Rave, click on 'Add Event' while in the participant's folder and select 'interim':
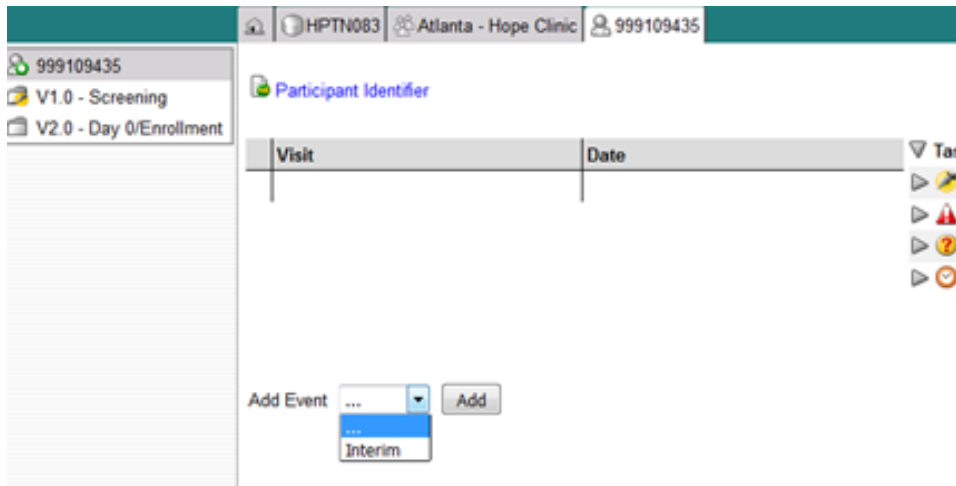
An interim visit folder that contains the Interim Visit Summary CRF is then added to the participant's casebook or set of folders.

13.7.4.1 Interim Visit Codes

Interim visit codes are assigned using the following guidelines:

- To the left of the decimal point, record the two-digit visit code for the most recently required follow-up visit *even if the visit was missed and/or if the participant is within the next visit's window.*

- To the right of the decimal point:
  - #.1 = the first interim visit after the most recently-required visit,
  - #.2 = the second interim visit after the most recently-required visit,
  - #.3 = the third interim visit after the most recently-required visit, and so on.

Example #1: A participant completes his Week 10 visit (visit code = 8) on the target day. He returns to the site three days later for additional STI testing. This interim Visit is assigned a visit code of 8.1.

Example #2: A participant completes all required study procedures at Visit 6.0 (Day 42), post-injection safety visit. When the lab results are available later in the week, the site clinician notices the participant has an abnormal lab result that needs to be repeated. The participant returns on Day 46 to get his blood re-drawn. The visit on Day 46 is considered an interim visit because the participant had completed the required study procedures for Visit 6.0. Because this is the first interim visit after visit 6.0 it is assigned visit 6.1.

13.8   HPTN 084-01 Schedule of Forms and CASI Surveys

The case report forms are summarized in the HPTN 084-01 Schedule of Forms found at the end of this section. A link to the CASI survey can be found in section 14 of the SSP Manual (CASI).

13.9   Completing Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is important that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

13.10   Site Review (Quality Control) of CRFs

As described in the site's Data Management SOP, each site must perform Quality Control (QC) review steps, especially for paper CRFs prior to their data entry into the study database. (If a site is entering all data directly into Medidata then this section does not apply.) While paper CRFs are being reviewed, it is important that they are stored and tracked systematically.

Below are specific review guidelines that should be followed for these QC review steps.

QC Review Step #1

- Review visit checklist to ensure all required procedures were completed

- Review completed paper CRFs and eCRFs based on participant responses to ensure completeness.

QC Review Step #2 procedures for all visits:

- Review visit checklist to ensure all required procedures were completed

- Ensure the PTID is correct, is recorded correctly on all paper source documents (including paper CRFs) and is the same on the paper source documents and the eCRFs for a given participant.

- Confirm that no participant identifiers other than the PTID are present on paper source documents, including paper CRFs.

- Ensure that the assigned visit code is correct, and is consistent between the paper source documents, including paper CRFs, the eCRFs, the LDMS Specimen Tracking Sheet, and LDMS for a given participant visit.

- If a log CRF needs to be completed, make sure the corresponding "Y/N" CRF is marked "yes" in order to populate the first log CRF. For example, if the Adverse Event CRF needs to be completed, the Adverse Event Y/N CRF must be completed and marked "yes".

- Concomitant Medications CRF: if a medication is taken for an AE, make sure the linked AE CRF is entered and saved first; then confirm on the Con Meds CRF that the appropriate, linked AE is selected. Also confirm that 'Medication" is marked on the AE CRF.

Additional QC Steps for Paper CRFs

If some or all CRFs will first be completed on paper, the following review step should occur before forms are data-entered into the study database. Ideally, this review will happen once all lab results are available, so that all forms for a particular visit can be reviewed for consistency across documents. The goal is to correct data inconsistencies/errors prior to entering data into the study database, so that data is accurate, complete, and available at the time of data entry, thus minimizing the likelihood of data queries.

- Make sure a response has been recorded for each item, as required per instructions in the CRF Completion Guidelines (CCG) document.

- If a response box with "other" or "specify" line is present, make sure there is text responding to that item.

- Make sure text responses are clearly recorded.

- For paper CRFs that are not source documents, make sure the data recorded on the paper CRFs matches or is consistent with the source documents.

Additional QC Steps for Electronic CRFs (eCRF)

When data is entered into the study database, and an eCRF is saved, system queries are automatically generated in response to inconsistent or incomplete data. Unlike the paper CRFs, which require manual review, eCRFs have the advantage of having the study database itself provide a real-time QC review to ensure data completeness.

No additional review steps are required for eCRFs that are source (i.e., the data is directly entered into the study database, rather than entered based on a separate paper CRF or other paper source document).

Electronic CRFs that are completed based on other paper source documents (e.g., data entry of paper CRFs or lab reports) should be reviewed to ensure that the data entered matches or is consistent with the source documents. The site's Data Management SOP provides additional details and specifies which staff members will perform the review.

13.11 CRF Completion Instructions

Detailed form completion instructions for each form are provided in the CRF Completion Guidelines (CCG) document. The instructions document skip patterns, form completion of paper CRFs, and include guidance on completion of the eCRF in the study database. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all forms or form items listed in the CCG, but rather only those items needing detailed explanation.

- Patient Health Questionnaire (PHQ): This form is only present at Enrollment. The score is auto-calculated by the system and does not need to be entered by the site staff. For further instructions, please refer to the CCGs. The ranges are listed below:

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

13.12 Case Report Forms

The current version of the eCRFs can be found on the HPTN 084-01 Atlas web page:
https://atlas.scharp.org/cpas/project/HPTN/084-01/begin.view?

13.13 Schedule of Forms

**For the schedule of forms for HPTN084 OLE, please refer to the SSPs for that protocol.*

Step 1 - Visit	Form Name
V1 - Screening	Informed Consent
	Vital Signs
	Specimen Collection and Storage
	Hematology
	Chemistry Panel
	HIV Test Results
	STI Tests
	Hepatitis Test Results
	Counseling
	Contraception-Screening
	Pregnancy Test Results
V2 - Enrollment Visit	Demographics
	Inclusion Exclusion Criteria
	Enrollment
	Behavioral Assessment, CASI Tracking
	Physical Exam
	Vital Signs
	Pill Count - Enrollment
	HIV Test Results
	Specimen Collection and Storage
	Hematology
	Chemistry Panel
	Fasting Lipid Test Results
	Urinalysis
	Hepatitis Test Results

Visit	Form Name
	Patient Health Questionnaire
	Counseling
	Contraception
	Pregnancy Test Results
V3 – Week 2	Date of Visit – Step 1
	Vital Signs
	Pill Count
	Specimen Collection and Storage
	HIV Test Results
	Hematology
	Chemistry Panel
	Counseling
	Contraception
	Pregnancy Test Results
V4 – Week 4	Date of Visit – Step 1
	Vital Signs
	Pill Count
	Specimen Collection and Storage
	HIV Test Results
	Hematology
	Chemistry Panel
	Behavioral Assessment, CASI Tracking
	Counseling
	Pregnancy Test Results
	Contraception
Step 2 - Visit	**Form Name**
W5, W9, W17, W25, W33 – Injection Visits	Date of Visit – Step 2
	Vital Signs
	Behavioral Assessment, CASI Tracking
	Specimen Collection and Storage
	Injection Administration
	HIV Test Results
	Hematology
	Chemistry Panel
	STI Tests (GC/CT only at Week 17 and 33; Syphilis only at Week 33)
	Counseling
	Urinalysis
	Pregnancy Test Results
	Contraception
W6, W10, W18, W26, W34 – Safety Visits	Date of Visit – Step 2
	Vital Signs
	Specimen Collection and Storage

	Hematology
	Chemistry Panel
	Fasting Lipid Test Results (Week 34 only)
	Counseling
	Urinalysis
Step 3 - Visit	**Form Name**
W+8, W+12, W+24, W+36, W+48	Date of Visit – Step 3
	Vital Signs
	Behavioral Assessment, CASI Tracking *(not done at W+8)*
	HIV Test Results *(not done at W+8)*
	Specimen Collection and Storage
	Hematology *(not done at W+8)*
	Chemistry Panel *(not done at W+8)*
	STI Tests (*not done at W+8, Syphilis only at W+36)*
	Counseling
	Urinalysis *(not done at W+8)*
	Pregnancy Test Results *(not done at W+8)*
	Contraception *(not done at W+8)*
Seroconverter Schedule - Visit	**Form Name**
HIV confirmation Visit	Date of Visit - HIV
	Vital Signs
	Specimen Collection and Storage
	HIV Test Results
	CD4/Viral Load
	Counseling
	Supplemental HIV Results
Week 12, Week 24, Week 36, Week 48	Date of Visit – HIV
	Vital Signs
	CD4/Viral Load (W+24 and W+48 only)
	Specimen Collection and Storage
	Chemistry Panel
	Hematology
Pregnancy Schedule	**Form Name**
W+4, W+12, W+24, W+36, W+48	Date of Visit - Pregnancy Schedule
	Vital Signs
	Behavioral Assessment, CASI Tracking
	Chemistry Panel
	Hematology
	Specimen Collection and Storage
	HIV Test Results

	Pregnancy Test Results (W+4 only)
	Urinalysis (W+4 only)
	Counseling

As needed **(Additional Study Procedures/Interim Visits Procedures)**	Interim Visit Summary
	Additional Study Procedures
	HIV Test Results
	CD4/Viral Load
	Chemistry Panel
	Counseling
	CASI
	Pill Count Step 1
	Pregnancy Test Results
	Contraception
	Hematology
	Physical Exam
	Vital Signs
	Specimen Collection and Storage
	STI Test Results
	Missed Visit
	Injection Administration
	Participant Receipt
	Participant Transfer
	Hepatitis Test Results
	Urinalysis
	Product Choice
	Fasting Lipid Test Results
As needed, Ongoing Logs	Adverse Event Y/N
	Adverse Event
	Concomitant Medications Y/N
	Concomitant Medications
	Injection Site Reaction Y/N
	Injection Site Reaction

	Medical History Y/N	
	Medical History	
	Protocol Deviations Y/N	
	Protocol Deviations Log	
	Product Hold Y/N	
	Product Hold Log	
	Social Impact Y/N	
	Social Impact Log	
Pregnancy	Pregnancy History	
	Pregnancy Report	
	Pregnancy Outcome Log	
Discontinuations	Study Termination	
	Discontinuation of Study Product	