Section 13. Data Management

The purpose of this document is to provide site staff with the information needed to complete electronic Case Report Forms (eCRFs) in MediData Rave.

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

HPTN 084 SDMC Staff

Job Role	**Name**	**Email Address**
Sr. Clinical Data Manager	Stephanie Beigel-Orme	sbeigelo@scharp.org
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**For questions about clinical queries (queries that say “To Site from Safety” or “To Site from Coder”, please contact the SDMC Clinical Safety group: sc.clinsafety@scharp.org

13.1 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 eCRFs by entering data into the Medidata Rave study database. As specified in each site's Source Documentation Standard Operating Procedure (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 study database in Medidata Rave may be accessed at www.imedidata.com.

When using Medidata Rave, the internet browser chosen and internet 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 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 HPTN084 Atlas web page.

https://atlas.scharp.org/cpas/project/HPTN/084/begin.view?

Site staff should contact the study Clinical Data Manager(s) with any questions related to study data collection and management. 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
1-866-MEDIDATA (633-4328)

Direct number
1-973-659-6780

Toll-free fax
1-877-743-2350

Direct fax
1-973-954-5621

Email
helpdesk@mdsol.com

Hours
24 hours a day, 7 days a week

13.2 Data Entry/Quality Control

- 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) and/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 coder to help clarify AE data.
  - Inconsistency queries may be manually placed during AE-EAE reconciliation.
- 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.

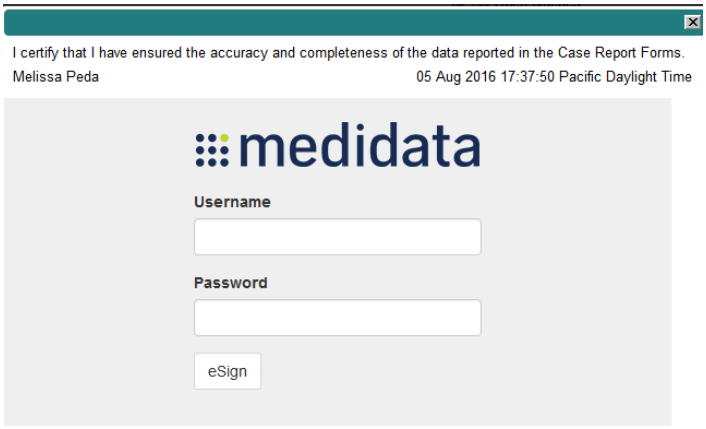
  Task Summary Example:

Task Summary: Site	Subjects
Requiring Signature	16
NonConformant Data	0
Requiring Coding	0
Requiring Translation	0
Open Queries	8
Answered Queries	0

- 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 paper CRFs **must** be entered into the Medidata Rave study database.

Electronic Signatures by Investigators

Each site Investigator of Record 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 EDC Training Manual and/or the Investigator e-Learning module for specific instructions on how to sign off on CRFs.



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. Please note that if an eCRF is signed off and a query is applied to the form or a change to the form occurs during the study, the electronic signature will be broken and the IoR will need to re-sign the form.

13.3 eCRF Completion

13.3.1 Participant Identification number (PTID) Creation and Screening

Each participant who provides written informed consent to be screened in HPTN084 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 EDC Training Manual and the CRF Completion Guidelines (CCGs) 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 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.

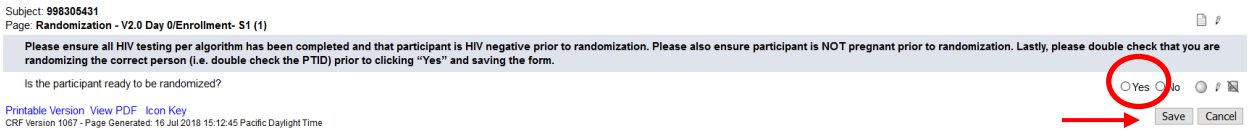
If a participant does not enroll in the study, the following forms are required to document the Screening Visit: Screening Outcome, HIV Test Results, Plasma Storage, and VOICE Risk Score – Modified. Inclusion and exclusion criteria are documented on the Screening Outcome eCRF as well as reasons for not enrolling into the study.

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

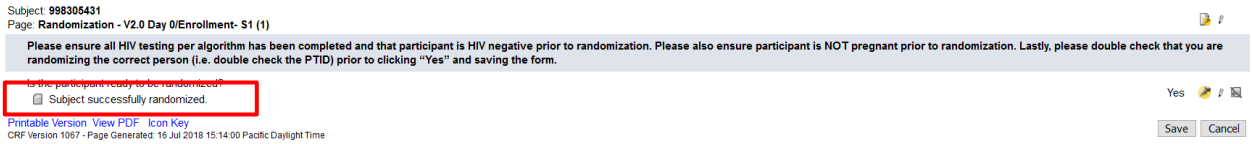
13.3.2 Enrollment and Randomization

Prior to randomization eligibility must be confirmed, which includes a negative HIV test on a sample drawn at the Enrollment visit as well as a negative pregnancy test.

To randomize a participant, site staff mark 'Yes' to the question, "Is the participant ready to be randomized?" on the Randomization eCRF and click the "Save" button (see image below).



Once the Randomization eCRF is saved, a message will appear on the form that reads: "Subject successfully randomized" as shown in the image below. The Medidata Balance module will assign the participant to a treatment arm and the participant is considered successfully randomized. **A participant is considered enrolled in the study once this step takes place**.



Note that the participant's randomly assigned treatment arm will not appear in the clinical study database, since the study is double-blinded. Rather, PAB-approved site pharmacists only (along with the study statisticians) will be provided restricted access to Medidata Balance to obtain the coded information needed to select and dispense the correct study medication.

Each time a participant is randomized an email confirmation will be sent to anyone with a Medidata account who is assigned the role of "CRC', "IoR", "Read only access" or "Pharmacist" to inform them of the new randomization. The randomization confirmation notice will include the following information:

Randomization Alert:
Study: HPTN084
Environment: PROD
Site Number: 12345
Subject ID: 999999990
A Subject has been randomized at 2/9/2018 9:21:17 AM Calendar Date. Pharmacists can log into the www.imedidata.com to view the participant's assigned treatment

All randomization notices should be kept in a secure location.

In the event the randomization confirmation email is not received, please follow the steps detailed below:

- Inform the site pharmacist that a randomization confirmation email for the randomized participant was not received (it does not mean that the participant was not randomized, just that the email did not get through to the site).
- Ask the site pharmacist to confirm the participant was successfully randomized by logging in to Balance.
- When final product preparations are to begin, provide the pharmacist with the PTID of the randomized participant and request that the pharmacist log into Medidata RTSM (Balance), locate the PTID, retrieve the treatment assignment, and prepare study product accordingly.
- Document all steps in the participant chart.
- Do not contact Medidata Support.

13.3.3 General Guidelines for eCRF Completion

- When completing an eCRF, refer to the 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 5 days is acceptable.
- AEs should be entered within 3 days 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 Label (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 all "Y/N" forms that are used as triggers for log forms (e.g. Concomitant Medications Y/N or Adverse Event Y/N):

13.3.4 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). Interim Visit Codes do need to be assigned. For more information see section 13.6.

Please remember: For specimen collection, the visit code and date on the eCRF must match the visit code and date in the Laboratory and Data Management System (LDMS) database.

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

13.4 Visit Scheduling: Target Days and Visit Windows

Table 13-1 lists the HPTN 084 visit codes, target days and visit windows for each study visit. All windows are listed in days.

13.4.1 Target Days

A target date is the day in which a visit should ideally occur. Target dates for Step 1 visits are based on the date of Enrollment into the study; target dates for Step 2 visits are based on the date the Week 5 Visit is completed; and target dates for Step 3 visits on the day that the first Step 3 visit, Day 0, is conducted. Target dates do not change even if a visit in that step takes place before or after the target date. Whenever possible, visits should be completed on the target day for that visit.

13.4.2 Visit Windows

There are two types of visit windows in HPTN084. If a visit cannot be completed on the target date, it should be completed within the the target visit window in order to be counted as "on time" in the Retention Report. If it is not possible to complete the visit on within the target window, the visit still needs to be completed within the allowable (larger) visit window in order to be considered "complete" in the Retention Report. Visits conducted before the target window opens but still within the allowable window are considered "complete" but "early" in the Retention Report. Visits conducted after the target window closes but still within the allowable visit window are considered "complete" but "late" in the Retention Report. If a visit doesn't occur within the allowable window it will be considered "missed" in the Retention Report. Medidata Rave will not query for an overdue visit (i.e. the forms for that visit) until the allowable visit window has closed.

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

Week	Visit Code	Day allowable window opens	Day target window opens	Target Day	Day target window closes	Day allowable window closes
Screening	1.0	--	--	--	--	--
Step 1						
Day 0/Enrollment	2.0	0	0	**0**	3	6
Week 2	3.0	7	11	**14**	17	20
Week 4*	4.0	21	25	**28**	31	31
Step 2*						
Day 0/Week 5*	5.0	0	0	**0**	3	3
Week 6	6.0	4	4	**7**	10	17
Week 9	7.0	18	25	**28**	31	41
Week 13	8.0	42	53	**56**	59	69
Week 17	9.0	70	81	**84**	87	97
Week 21	10.0	98	109	**112**	115	125
Week 25	11.0	126	137	**140**	143	168
Week 33	12.0	169	189	**196**	203	224
Week 41	13.0	225	245	**252**	255	255
Week 42	14.0	256	256	**259**	266	283
Week 49	15.0	284	301	**308**	315	336
Week 57	16.0	337	357	**364**	371	392
Week 65	17.0	393	413	**420**	427	448
Week 73	18.0	449	469	**476**	483	504
Week 81	19.0	505	525	**532**	539	560
Week 89	20.0	561	581	**588**	595	616
Week 97	21.0	617	637	**644**	651	672
Week 105	22.0	673	693	**700**	707	728
Week 113	23.0	729	749	**756**	763	784
Week 121	24.0	785	805	**812**	819	840
Week 129	25.0	841	861	**868**	875	896
Week 137	26.0	897	917	**924**	931	952
Week 145	27.0	953	973	**980**	987	1008
Week 153	28.0	1009	1029	**1036**	1043	1064
Week 161	29.0	1065	1085	**1092**	1099	1120
Week 169	30.0	1121	1141	**1148**	1155	1176
Week 177	31.0	1177	1197	**1204**	1211	1232
Week 185	32.0	1233	1253	**1260**	1267	1288

Week	Visit Code	Day allowable window opens	Day target window opens	Target Day	Day target window closes	Day allowable window closes
Step 3**						
Day 0 (Step 3 only)	33.0	0	0	**<8 weeks from last injection**	14	42
Week 12	34.0	43	70	**84**	98	126
Week 24	35.0	127	154	**168**	182	210
Week 36	36.0	211	238	**252**	266	294
Week 48	37.0	295	322	**336**	350	378

*Please note that the Week 4 and Week 5 Visits must be completed in order for a participant to move to Step 2. If a Week 4 or Week 5 Visit is delayed or missed, contact the CMC for further guidance.

**The target dates for all Step 2 visits are based off of the actual date of the Week 5 Visit. The target dates for all Step 3 visits are based off of the first Step 3 Visit, called "Step 3/Day 0".

Open Label Truvada Schedule						
Week	**Visit Code**	**Day allowable window opens**	**Day target window opens**	**Target Day**	**Day target window closes**	**Day allowable window closes**
Day 0 (date injections permanently discontinue)	V201/or other*	0	0	**0**	14	42
Week 12	202.0	43	70	**84**	98	126
Week 24	203.0	127	154	**168**	182	210
Week 36	204.0	211	238	**252**	266	294
Week 48	205.0	295	322	**336**	350	378

- Day 0 for Open Label Truvada Schedule may be a Step 2 visit code or 201. See Section 13.5 Alternate Visits.

Pregnancy Schedule*						
Week	**Visit Code**	**Day allowable window opens**	**Day target window opens**	**Target Day**	**Day target window closes**	**Day allowable window closes**
Day 0 (First positive Pregnancy Test)	XX.X	0	0	**0**	0	0
4 weeks after first positive pregnancy test	Interim visit XX.X	21	--	**28**	--	35
Quarterly Visit 1 (12 weeks since first positive pregnancy test)	101	43	70	**84**	98	126
Quarterly Visit 2 (24 weeks since first positive pregnancy test)	102	127	154	**168**	182	210
Quarterly Visit 3 (36 weeks since first positive pregnancy test)	103	211	238	**252**	266	294

*Pregnancy schedule is to be followed throughout pregnancy and while participant is breastfeeding.

Yearly/Annual Visits						
Week	**Visit Code**	**Day allowable window opens**	**Day target window opens**	**Target Day**	**Day target window closes**	**Day allowable window closes**
Day 0 (Last visit participant at clinic HIV Test conducted)	XX.X	0	0	**0**	0	0
Yearly Visit 1	50.0	182	358	**365**	372	548
Yearly Visit 2	51.0	547	723	**730**	737	913
Yearly Visit 3	52.0	912	1088	**1095**	1102	1278
Yearly Visit 4	53.0	1277	1453	**1460**	1467	1643
Yearly Visit 5	54.0	1642	1818	**1825**	1832	2008

Seroconverter Schedule						
Week	**Visit Code***	**Day allowable window opens**	**Day target window opens**	**Target Day**	**Day target window closes**	**Day allowable window closes**
HIV Confirmatory Visit	XX.X	0	0	**0**	14	42
Week 12	XX.X	43	70	**84**	98	126
Week 24	XX.X	127	154	**168**	182	210
Week 36	XX.X	211	238	**252**	266	294
Week 48	XX.X	295	322	**336**	350	378

*Due to unblinding considerations, there are no unique visit codes for seroconverters. The visit codes should reflect the next study visits for the participants.

Table 13-2: HPTN 084 Open Label (OL)Visit Codes, Target Days, and Visit Windows

Week	Visit Code	Day allowable window opens	Day target window opens	Target Day	Day target window closes	Day allowable window closes
OLE Transition 1: Steps 4a → 4b-→ 4c						
4a Day 0 (Oral lead in)	55.0	0	0	**0**	3	13
4b Week 4(Loading Dose)	56.0	14	25	28	31	41
4c Day 0*	57.0	42	53	56	59	69
OLE Transition 2: Steps 4b → 4c						
4b Day 0 (Loading Dose)	56.0	0	0	**0**	20	20
4c Day 0*	57.0	21	25	28	31	63
OLE Transition 3: Step 4c						
	CAB / TDF/FTC					
Day 0	57.0 / 64.0	0	0	0	7	28
Week 8	58.0 / 65.0	29	49	56	63	84
Week 16	59.0 / 66.0	85	105	112	119	140
Week 24	60.0 / 67.0	141	161	168	175	196
Week 32	61.0 / 68.0	197	217	224	231	252
Week 40	62.0 / 69.0	253	273	280	287	308
Week 48	63.0 / 70.0	309	329	336	343	364
Step 4d- Pregnant/Breastfeeding Participants						
Day 0	76.0	14	3	**0**	3	13
Week 4	77.0	14	25	**28**	31	41
Week 8	78.0	42	53	**56**	59	69
Week 12	79.0	70	81	**84**	87	97
Week 16	80.0	98	109	**112**	115	125
Week 20	81.0	126	137	**140**	143	153
Week 24	82.0	154	165	**168**	171	181
Week 28	83.0	182	193	**196**	199	209
Week 32	84.0	210	221	**224**	227	237
Week 36	85.0	238	249	**252**	255	265
Week 40	86.0	266	277	**280**	283	293
Delivery (Day 0)		0	0	**0**	3	6
Week 2, pp**	87.0	7	11	**14**	17	20
Week 4, pp	88.0	21	25	**28**	31	31
Week 8, pp	89.0	32	49	**56**	63	84

Week	Visit Code	Day allowable window opens	Day target window opens	Target Day	Day target window closes	Day allowable window closes
Week 16, pp	90.0	85	105	**112**	119	140
Week 24, pp	91.0	141	161	**168**	175	196
Week 32, pp	92.0	197	217	**224**	231	252
Week 40, pp	93.0	253	273	**280**	287	308
Week 48, pp	94.0	309	329	**336**	343	364
Step 5						
Week	**Visit Code**	**Day allowable window opens**	**Day target window opens**	**Target Day**	**Day target window closes**	**Day allowable window closes**
Day 0 (Day 0 no later than 8 weeks after the last injection	71.0	0	0	**0**	14	42
Week 12	72.0	43	70	**84**	98	126
Week 24	73.0	127	154	**168**	182	210
Week 36	74.0	211	238	**252**	266	294
Week 48	75.0	295	322	**336**	350	378

*Proceed with Step 4c

**post-partum visit

13.5 Types of Visits

Scheduled Visits

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

Missed Visits

A scheduled visit is considered missed if it is not completed within its allowable visit window. Missed Visits are documented by completing a Missed Visit eCRF. Do not completed a Missed Visit CRF until you are sure that the visit has been missed (i.e. once the allowable window has closed and the participant has not returned to the clinic for that visit).

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, as

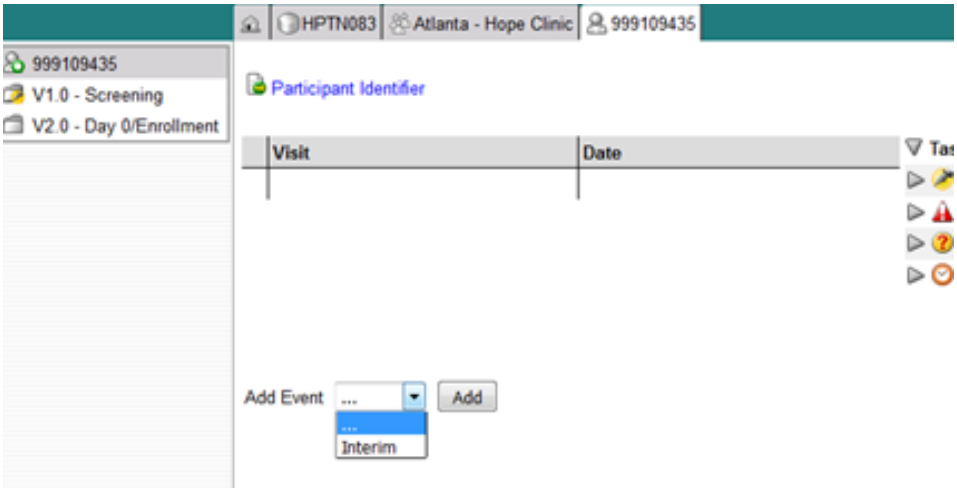
long as all evaluations for that visit are completed within the same allowable visit window for that visit. When such a split visit occurs, case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates).

If a form contains a place to record a visit date, and a visit is split, record the date of the first visit associated with the split visit. The exception is the Week 5 Visit. **If a Week 5 Visit is split, the date of visit will always be considered the date that the first injection was given.**

Interim Visits

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 Medidata Rave CRF, the interim visit is assigned an interim visit code (visit number ending in something other than ".0") and the Interim Visit eCRF is used to document the visit. All phone contacts that result in at least one newly-completed Rave CRF 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 CRF is then added to the participant's casebook, or set of folders.

13.6 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: A participant completes all required study procedures at Week 6 (visit code =6.0). 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 a few days later to get her blood re-drawn. The second visit is considered an interim visit because the participant had already completed the required study procedures for visit 6.0. Since this is the first interim visit after visit 6.0, it is assigned visit code 6.1.

If participant is on alternate schedule, the interim visit code should reflect that. For example if she is on the Pregnancy Schedule and comes in after visit 102, the interim visit code should be 102.1.

13.7 HPTN 084 Schedule of Forms

The case report forms required for each study visit are summarized in Appendix 13A at the end of this SSP section.

13.8 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.

13.9 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. 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 is newly completed at a visit that is not an interim visit, make sure the corresponding "Y/N" CRF is marked "yes" for the visit. For example, if the Adverse Event CRF is 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 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.

13.10 Form-Specific Completion Instructions

Detailed form completion instructions for each form are provided in the Case Report Form Completion Guidelines (CCGs) document. The instructions document skip patterns, required items, formats of variables, 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 may not see all forms or form items listed in the CCG, but rather only those items needing detailed explanation.

13.11 Case Report Forms

The current version of the eCRFs can be found on the HPTN084 Atlas web page.

Appendix 13A: HPTN084 Schedule of Forms

STEP	VISIT	FORM
1	**Screening**	Screening Outcome*****
	Visit 1.0	Hematology
		Hepatitis B Test Results
		Hepatitis C Test Results
		HIV Test Results*****
		Medical History
		Plasma Storage*****
		Pregnancy Test Results
		Screening Chemistries
		Screening Liver Function Test Results
		VOICE Risk Score - Modified*****
	****All Screening forms are required if a participant enrolls in the study. In addition, the Conmeds and Contraception CRFs must be completed. If a participant does not enroll in the study, please complete only those forms identified with an *.***	
1	**Enrollment/Day 0**	Chemistry Testing
	Visit 2.0	Counseling
		Demographics
		Enrollment Visit
		Fasting Lipid Test Results
		Hematology
		Hepatitis B Test Results
		HIV Test Results
1	**Enrollment/Day 0**	Liver Function Test Results

STEP	VISIT	FORM
	Visit 2.0	Pill Count – Enrollment
		Plasma Storage
		Pregnancy Test Results
		Randomization
		STI Test Results
		Urinalysis
		Whole Blood Storage
	Update the Concomitant Medications Log and Medical History Log at this visit as appropriate.	
1	**Week 2**	Chemistry Testing
	Visit 3.0	Counseling
		Date of Visit – Step 1 Only
		Hematology
		HIV Test Results
		Pill Count – Step 1
		Plasma Storage
		Pregnancy Test Results
1	**Week 4**	Chemistry Testing
	Visit 4.0	Counseling
		Date of Visit – Step 1 Only
		DBS Storage
		Hematology
		HIV Test Results
		Liver Function Test Results
		Pill Count – Step 1

STEP	VISIT	FORM
		Plasma Storage
		Pregnancy Test Results
2	**Week 5**	Chemistry Testing
	Visit 5.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 6**	Chemistry Testing
	Visit 6.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Liver Function Test Results
		Plasma Storage
		Pregnancy Test Results
	Complete the Injection Site Reaction Log if needed.	
2	**Week 9**	Chemistry Testing
	Visit 7.0	Counseling
		Date of Visit

STEP	VISIT	FORM
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 13**	Chemistry Testing
	Visit 8.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Liver Function Test Results
		Plasma Storage
		Pregnancy Test Results
	Complete the Injection Site Reaction Log if needed.	
2	**Week 17**	Chemistry Testing
	Visit 9.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3

STEP	VISIT	FORM
		Plasma Storage
		Pregnancy Test Results
2	**Week 21**	Chemistry Testing
	Visit 10.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Liver Function Test Results
		Plasma Storage
		Pregnancy Test Results
	Complete the Injection Site Reaction Log if needed.	
2	**Week 25**	Chemistry Testing
	Visit 11.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 33**	Chemistry Testing
	Visit 12.0	Counseling
		Date of Visit

STEP	VISIT	FORM
		Dried Blood Spot Storage
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
2	**Week 41**	Chemistry Testing
	Visit 13.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 42**	Chemistry Testing
	Visit 14.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results

STEP	VISIT	FORM
		Liver Function Test Results
		Plasma Storage
		Pregnancy Test Results
	Complete the Injection Site Reaction Log if needed.	
2	**Week 49**	Chemistry Testing
	Visit 15.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 57**	Chemistry Testing
	Visit 16.0	Counseling
		Date of Visit
		Dried Blood Spot Storage
		Fasting Lipid Test Results
		Hematology
		Hepatitis C Test Results
		HIV Test Results
		Injection Administration
		Liver Function Test Results

STEP	VISIT	FORM
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
		Urinalysis
2	**Week 65**	Chemistry Testing
	Visit 17.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 73**	Chemistry Testing
	Visit 18.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage

STEP	VISIT	FORM
		Pregnancy Test Results
2	**Week 81**	Chemistry Testing
	Visit 19.0	Counseling
		Date of Visit
		Dried Blood Spot Storage
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
2	**Week 89**	Chemistry Testing
	Visit 20.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 97**	Chemistry Testing

STEP	VISIT	FORM
	Visit 21.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 105**	Chemistry Testing
	Visit 22.0	Counseling
		Date of Visit
		Dried Blood Spot Storage
		Fasting Lipid Test Results
		Hematology
		Hepatitis C Test Results
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
		Urinalysis

STEP	VISIT	FORM
2	**Week 113**	Chemistry Testing
	Visit 23.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 121**	Chemistry Testing
	Visit 24.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 129**	Chemistry Testing
	Visit 25.0	Counseling
		Date of Visit

STEP	VISIT	FORM
		Dried Blood Spot Storage
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
2	**Week 137**	Chemistry Testing
	Visit 26.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 145**	Chemistry Testing
	Visit 27.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results

STEP	VISIT	FORM
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 153**	Chemistry Testing
	Visit 28.0	Counseling
		Date of Visit
		Dried Blood Spot Storage
		Hematology
		Hepatitis C Test Results
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
		Urinalysis
2	**Week 161**	Chemistry Testing
	Visit 29.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results

STEP	VISIT	FORM
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
2	**Week 169**	Chemistry Testing
	Visit 30.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
	Week 177	Chemistry Testing
	Visit 31.0	Counseling
		Date of Visit
		Dried Blood Spot Storage
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3

STEP	VISIT	FORM
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
2	**Week 185**	Chemistry Testing
	Visit 32.0	Counseling
		Date of Visit
		Hematology
		HIV Test Results
		Injection Administration
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
	Step 3/Day 0	Counseling
	Visit 33.0	Date of Visit
		HIV Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
3	**Step 3/Week 12**	Counseling
	Visit 34.0	Date of Visit
		HIV Test Results
		Pill Dispensation – Step 2 and 3

STEP	VISIT	FORM
		Plasma Storage
		Pregnancy Test Results
3	**Step 3/Week 24**	Chemistry Testing
	Visit 35.0	Counseling
		Date of Visit
		Dried Blood Spot Storage
		HIV Test Results
		Liver Function Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
		STI Test Results
3	**Step 3/Week 36**	Counseling
	Visit 36.0	Date of Visit
		HIV Test Results
		Pill Dispensation – Step 2 and 3
		Plasma Storage
		Pregnancy Test Results
3	**Step 3/Week 48**	Chemistry Testing
	Visit 37.0	Date of Visit
		Dried Blood Spot Storage
		HIV Test Results
		Liver Function Test Results
		Plasma Storage

STEP	VISIT	FORM
		Pregnancy Test Results
		STI Test Results
4a	**V 55.0 Day 0**	Date of Visit - OLE
4a	**V 55.0 Day 0**	Counseling
4a	**V 55.0 Day 0**	HIV Test Results Y/N
4a	**V 55.0 Day 0**	Pregnancy Test Results - OLE
4a	**V 55.0 Day 0**	Hematology
4a	**V 55.0 Day 0**	Chemistry Testing
4a	**V 55.0 Day 0**	Liver Function Tests
4a	**V 55.0 Day 0**	Fasting Lipid Test Results
4a	**V 55.0 Day 0**	Plasma Storage
4a	**V 55.0 Day 0**	Dried Blood Spot Storage
4a	**V 55.0 Day 0**	Contraception -OLE
4b	**V 56.0: Day 0**	Date of Visit - OLE
4b	**V 56.0: Day 0**	Counseling
4b	**V 56.0: Day 0**	HIV Test Results
4b	**V 56.0: Day 0**	Pregnancy Test Results - OLE
4b	**V 56.0: Day 0**	Hematology
4b	**V 56.0: Day 0**	Chemistry Testing
4b	**V 56.0: Day 0**	Liver Function Tests
4b	**V 56.0: Day 0**	Fasting Lipid Test Results
4b	**V 56.0: Day 0**	Plasma Storage
4b	**V 56.0: Day 0**	Dried Blood Spot Storage
4b	**V 56.0: Day 0**	Injection Administration
4b	**V 56.0: Day 0**	Contraception -OLE

STEP	VISIT	FORM
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Date of Visit - OLE
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Counseling
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	HIV Test Results Y/N
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Pregnancy Test Results - OLE
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Hematology
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Chemistry Testing
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Liver Function Tests
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	STI Test Results
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Urinalysis
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Plasma Storage
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Dried Blood Spot Storage

STEP	VISIT	FORM
4c	**57 CAB-LA or V 64.0: TDF/FTC WK 0**	Contraception -OLE
4c	**57 CAB-LA**	Injection Administration
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	Date of Visit - OLE
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	Counseling
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	HIV Test Results Y/N
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	Pregnancy Test Results - OLE
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	Plasma Storage
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	Dried Blood Spot Storage
4c	**58 CAB-LA or V 65.0: TDF/FTC WK 8**	Contraception -OLE
4c	**58 CAB-LA**	Injection Administration
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	Date of Visit - OLE
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	Counseling

STEP	VISIT	FORM
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	HIV Test Results Y/N
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	Pregnancy Test Results - OLE
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	Plasma Storage
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	Dried Blood Spot Storage
4c	**59 CAB-LA or V 66.0: TDF/FTC WK16**	Contraception -OLE
4c	**59 CAB-LA**	Injection Administration
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Date of Visit - OLE
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Counseling
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	HIV Test Results Y/N
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Pregnancy Test Results - OLE
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Hematology

STEP	VISIT	FORM
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Chemistry Testing
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Liver Function Tests
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	STI Test Results
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Urinalysis
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Plasma Storage
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Dried Blood Spot Storage
4c	**V60:CAB-LA or V67: TDF/FTC WK24**	Contraception -OLE
4c	**V60:CAB-LA**	Injection Administration
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	Date of Visit - OLE
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	Counseling
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	HIV Test Results Y/N

STEP	VISIT	FORM
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	Pregnancy Test Results - OLE
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	Plasma Storage
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	Dried Blood Spot Storage
4c	**V61 CAB-LA or V68: TDF/FTC Week 32**	Contraception -OLE
4c	**V61 CAB-LA**	Injection Administration
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	Date of Visit - OLE
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	Counseling
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	HIV Test Results Y/N
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	Pregnancy Test Results - OLE
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	Plasma Storage
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	Dried Blood Spot Storage
4c	**V62.0 CAB-LA or V69.0: TDF/FTC**	Contraception -OLE
4c	**V62.0 CAB-LA**	Injection Administration
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Date of Visit – OLE

STEP	VISIT	FORM
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Counseling
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	HIV Test Results Y/N
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Pregnancy Test Results - OLE
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Hematology
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Chemistry Testing
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Liver Function Tests
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Fasting Lipid Test Results
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	STI Test Results
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Urinalysis
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Plasma Storage
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Dried Blood Spot Storage

STEP	VISIT	FORM
4c	**V63.0 CAB-LA or V70.0: TDF/FTC WK48**	Contraception -OLE
4c	**V63.0 CAB-LA**	Injection Administration
4d Pregnancy Infant Sub-study	**V76.0 WK 0**	Date of Visit - Pregnancy OLE
4d	**V76.0 WK 0**	Counseling
4d	**V76.0 WK 0**	Injection Administration
4d	**V76.0 WK 0**	HIV Test Results Y/N
4d	**V76.0 WK 0**	Hematology
4d	**V76.0 WK 0**	Chemistry Testing
4d	**V76.0 WK 0**	Liver Function Tests
4d	**V76.0 WK 0**	STI Test Results
4d	**V76.0 WK 0**	Urinalysis
4d	**V76.0 WK 0**	Plasma Storage
4d	**V76.0 WK 0**	Dried Blood Spot Storage
4d	**V76.0 WK 0**	Contraception -OLE
4d	**V77.0 WK 4**	Date of Visit - Pregnancy OLE
4d	**V77.0 WK 4**	Counseling
4d	**V77.0 WK 4**	HIV Test Results Y/N
4d	**V77.0 WK 4**	Plasma Storage
4d	**V77.0 WK 4**	Dried Blood Spot Storage
4d	**V77.0 WK 4**	Plasma Storage
4d	**V77.0 WK 4**	Dried Blood Spot Storage
4d	**V77.0 WK 4**	Contraception -OLE
4d	**V78.0 WK 8**	Date of Visit - Pregnancy OLE

STEP	VISIT	FORM
4d	V78.0 WK 8	Counseling
4d	V78.0 WK 8	Injection Administration
4d	V78.0 WK 8	HIV Test Results Y/N
4d	V78.0 WK 8	Plasma Storage
4d	V78.0 WK 8	Dried Blood Spot Storage
4d	V78.0 WK 8	Contraception -OLE
4d	V79.0 WK 12	Date of Visit - Pregnancy OLE
4d	V79.0 WK 12	Ultrasound - OLE
4d	V79.0 WK 12	Counseling
4d	V79.0 WK 12	HIV Test Results Y/N
4d	V79.0 WK 12	Plasma Storage
4d	V79.0 WK 12	Dried Blood Spot Storage
4d	V79.0 WK 12	Contraception -OLE
4d	V80.0 WK 16	Date of Visit - Pregnancy OLE
4d	V80.0 WK 16	Counseling
4d	V80.0 WK 16	Injection Administration
4d	V80.0 WK 16	HIV Test Results Y/N
4d	V80.0 WK 16	Plasma Storage
4d	V80.0 WK 16	Dried Blood Spot Storage
4d	V80.0 WK 16	Contraception -OLE
4d	V81.0 WK 20	Date of Visit - Pregnancy OLE
4d	V81.0 WK 20	Counseling
4d	V81.0 WK 20	HIV Test Results Y/N
4d	V81.0 WK 20	Plasma Storage
4d	V81.0 WK 20	Dried Blood Spot Storage
4d	V81.0 WK 20	Contraception -OLE

STEP	VISIT	FORM
4d	V82.0 WK 24	Date of Visit - Pregnancy OLE
4d	V82.0 WK 24	Counseling
4d	V82.0 WK 24	Injection Administration
4d	V82.0 WK 24	HIV Test Results Y/N
4d	V82.0 WK 24	Hematology
4d	V82.0 WK 24	Chemistry Testing
4d	V82.0 WK 24	Liver Function Tests
4d	V82.0 WK 24	STI Test Results
4d	V82.0 WK 24	Urinalysis
4d	V82.0 WK 24	Plasma Storage
4d	V82.0 WK 24	Dried Blood Spot Storage
4d	V82.0 WK 24	Contraception -OLE
4d	V83.0 WK 28	Date of Visit - Pregnancy OLE
4d	V83.0 WK 28	Counseling
4d	V83.0 WK 28	HIV Test Results Y/N
4d	V83.0 WK 28	Plasma Storage
4d	V83.0 WK 28	Dried Blood Spot Storage
4d	V83.0 WK 28	Contraception -OLE
4d	V84.0 WK 32	Date of Visit - Pregnancy OLE
4d	V84.0 WK 32	Counseling
4d	V84.0 WK 32	Injection Administration
4d	V84.0 WK 32	HIV Test Results Y/N
4d	V84.0 WK 32	Plasma Storage
4d	V84.0 WK 32	Dried Blood Spot Storage
4d	V84.0 WK 32	Contraception -OLE
4d	V85.0 WK 36	Date of Visit - Pregnancy OLE

STEP	VISIT	FORM
4d	V85.0 WK 36	Counseling
4d	V85.0 WK 36	HIV Test Results Y/N
4d	V85.0 WK 36	Hematology
4d	V85.0 WK 36	Chemistry Testing
4d	V85.0 WK 36	Liver Function Tests
4d	V85.0 WK 36	Urinalysis
4d	V85.0 WK 36	Plasma Storage
4d	V85.0 WK 36	Dried Blood Spot Storage
4d	V85.0 WK 36	Contraception -OLE
4d	V86.0 WK 40	Date of Visit - Pregnancy OLE
4d	V86.0 WK 40	Counseling
4d	V86.0 WK 40	Injection Administration
4d	V86.0 WK 40	HIV Test Results Y/N
4d	V86.0 WK 40	Contraception -OLE
4d	V87.0 WK 2 PP	Date of Visit - Pregnancy OLE
4d	V87.0 WK 2 PP	Specimen Collection - Breast Milk
4d	V87.0 WK 2 PP	HIV Test Results Y/N
4d	V87.0 WK 2 PP	Plasma Storage
4d	V87.0 WK 2 PP	Infant Specimen Collection - Plasma
4d	V87.0 WK 2 PP	Contraception -OLE
4d	V87.0 WK 2 PP	Date of Visit - Pregnancy OLE
4d	V87.0 WK 2 PP	Specimen Collection - Breast Milk
4d	V87.0 WK 2 PP	HIV Test Results Y/N
4d	V87.0 WK 2 PP	Plasma Storage
4d	V87.0 WK 2 PP	Dried Blood Spot Storage
4d	V87.0 WK 2 PP	Infant Specimen Collection - Plasma

STEP	VISIT	FORM
4d	V87.0 WK 2 PP	Contraception -OLE
4d	V88.0 WK 4 PP	Date of Visit - Pregnancy OLE
4d	V88.0 WK 4 PP	Specimen Collection - Breast Milk
4d	V88.0 WK 4 PP	HIV Test Results Y/N
4d	V88.0 WK 4 PP	Plasma Storage
4d	V88.0 WK 4 PP	Dried Blood Spot Storage
4d	V88.0 WK 4 PP	Infant Specimen Collection - Plasma
4d	V88.0 WK 4 PP	Contraception -OLE
4d	V89.0 Week 8 PP	Date of Visit - Pregnancy OLE
4d	V89.0 Week 8 PP	Specimen Collection - Breast Milk
4d	V89.0 Week 8 PP	Counseling
4d	V89.0 Week 8 PP	Injection Administration
4d	V89.0 Week 8 PP	HIV Test Results Y/N
4d	V89.0 Week 8 PP	Pregnancy Test Results - OLE
4d	V89.0 Week 8 PP	Hematology
4d	V89.0 Week 8 PP	Chemistry Testing
4d	V89.0 Week 8 PP	Liver Function Tests
4d	V89.0 Week 8 PP	STI Test Results
4d	V89.0 Week 8 PP	Urinalysis
4d	V89.0 Week 8 PP	Plasma Storage
4d	V89.0 Week 8 PP	Dried Blood Spot Storage
4d	V89.0 Week 8 PP	Infant Assessment
4d	V89.0 Week 8 PP	Infant Breastmilk Feeding Assessment
4d	V89.0 Week 8 PP	Infant Specimen Collection - Plasma
4d	V89.0 Week 8 PP	Contraception -OLE
4d	V90.0 Week 16 PP	Date of Visit - Pregnancy OLE

STEP	VISIT	FORM
4d	V90.0 Week 16 PP	Specimen Collection - Breast Milk
4d	V90.0 Week 16 PP	Counseling
4d	V90.0 Week 16 PP	Injection Administration
4d	V90.0 Week 16 PP	HIV Test Results Y/N
4d	V90.0 Week 16 PP	Pregnancy Test Results - OLE
4d	V90.0 Week 16 PP	Plasma Storage
4d	V90.0 Week 16 PP	Dried Blood Spot Storage
4d	V90.0 Week 16 PP	Infant Breastmilk Feeding Assessment
4d	V90.0 Week 16 PP	Infant Specimen Collection - Plasma
4d	V90.0 Week 16 PP	Contraception -OLE
4d	V91.0 Week 24 PP	Date of Visit - Pregnancy OLE
4d	V91.0 Week 24 PP	Specimen Collection - Breast Milk
4d	V91.0 Week 24 PP	Counseling
4d	V91.0 Week 24 PP	Injection Administration
4d	V91.0 Week 24 PP	HIV Test Results Y/N
4d	V91.0 Week 24 PP	Pregnancy Test Results - OLE
4d	V91.0 Week 24 PP	Plasma Storage
4d	V91.0 Week 24 PP	Dried Blood Spot Storage
4d	V91.0 Week 24 PP	Infant Breastmilk Feeding Assessment
4d	V91.0 Week 24 PP	Infant Specimen Collection - Plasma
4d	V91.0 Week 24 PP	Contraception -OLE
4d	V92.0 Week 32 PP	Date of Visit - Pregnancy OLE
4d	V92.0 Week 32 PP	Counseling
4d	V92.0 Week 32 PP	Injection Administration
4d	V92.0 Week 32 PP	HIV Test Results Y/N
4d	V92.0 Week 32 PP	Pregnancy Test Results - OLE

STEP	VISIT	FORM
4d	V92.0 Week 32 PP	Plasma Storage
4d	V92.0 Week 32 PP	Contraception -OLE
4d	V93.0 Week 40 PP	Date of Visit - Pregnancy OLE
4d	V93.0 Week 40 PP	Counseling
4d	V93.0 Week 40 PP	HIV Test Results Y/N
4d	V93.0 Week 40 PP	Pregnancy Test Results - OLE
4d	V93.0 Week 40 PP	Plasma Storage
4d	V93.0 Week 40 PP	Contraception -OLE
4d	V94.0 Week 48 PP	Date of Visit - Pregnancy OLE
4d	V94.0 Week 48 PP	Counseling
4d	V94.0 Week 48 PP	Injection Administration
4d	V94.0 Week 48 PP	HIV Test Results Y/N
4d	V94.0 Week 48 PP	Pregnancy Test Results - OLE
4d	V94.0 Week 48 PP	Hematology
4d	V94.0 Week 48 PP	Chemistry Testing
4d	V94.0 Week 48 PP	Liver Function Tests
4d	V94.0 Week 48 PP	STI Test Results
4d	V94.0 Week 48 PP	Urinalysis
4d	V94.0 Week 48 PP	Plasma Storage
4d	V94.0 Week 48 PP	Infant Assessment
4d	V94.0 Week 48 PP	Infant Specimen Collection - Plasma
Step 5	V71.0 Day 0	Date of Visit - OLE
Step 5	V71.0 Day 0	Counseling
Step 5	V71.0 Day 0	HIV Test Results Y/N
Step 5	V71.0 Day 0	Pregnancy Test Results - OLE

STEP	VISIT	FORM
Step 5	**V71.0 Day 0**	Chemistry Testing
Step 5	**V71.0 Day 0**	Liver Function Tests
Step 5	**V71.0 Day 0**	STI Test Results
Step 5	**V71.0 Day 0**	Plasma Storage
Step 5	**V71.0 Day 0**	Dried Blood Spot Storage
Step 5	**V71.0 Day 0**	Contraception -OLE
Step 5	**V72.0 Week 12**	Date of Visit - OLE
Step 5	**V72.0 Week 12**	Counseling
Step 5	**V72.0 Week 12**	HIV Test Results Y/N
Step 5	**V72.0 Week 12**	Pregnancy Test Results - OLE
Step 5	**V72.0 Week 12**	Plasma Storage
Step 5	**V72.0 Week 12**	Dried Blood Spot Storage
Step 5	**V72.0 Week 12**	Contraception -OLE
Step 5	**V73.0 Week 24**	Date of Visit - OLE
Step 5	**V73.0 Week 24**	Counseling
Step 5	**V73.0 Week 24**	HIV Test Results Y/N
Step 5	**V73.0 Week 24**	Pregnancy Test Results - OLE
Step 5	**V73.0 Week 24**	Chemistry Testing
Step 5	**V73.0 Week 24**	STI Test Results
Step 5	**V73.0 Week 24**	Plasma Storage
Step 5	**V73.0 Week 24**	Dried Blood Spot Storage
Step 5	**V73.0 Week 24**	Contraception -OLE
Step 5	**V74.0 Week 36**	Date of Visit - OLE
Step 5	**V74.0 Week 36**	Counseling

STEP	VISIT	FORM
Step 5	**V74.0 Week 36**	HIV Test Results Y/N
Step 5	**V74.0 Week 36**	Pregnancy Test Results - OLE
Step 5	**V74.0 Week 36**	Plasma Storage
Step 5	**V74.0 Week 36**	Dried Blood Spot Storage
Step 5	**V74.0 Week 36**	Contraception -OLE
Step 5	**V75.0 Week 48**	Date of Visit - OLE
Step 5	**V75.0 Week 48**	HIV Test Results Y/N
Step 5	**V75.0 Week 48**	Pregnancy Test Results - OLE
Step 5	**V75.0 Week 48**	Chemistry Testing
Step 5	**V75.0 Week 48**	Liver Function Tests
Step 5	**V75.0 Week 48**	STI Test Results
Step 5	**V75.0 Week 48**	Plasma Storage
Step 5	**V75.0 Week 48**	Dried Blood Spot Storage
Step 5	**V75.0 Week 48**	Contraception -OLE

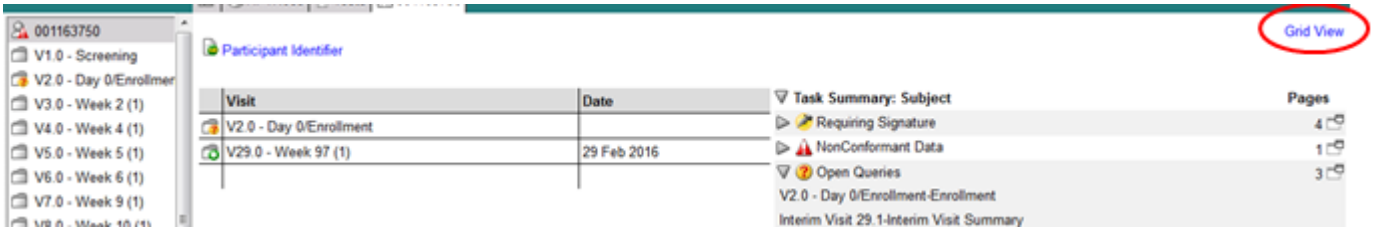
NOTE: Some as-needed forms, such as the Adverse Event Log and the Product Hold/Discontinuation Log, can be found in the "Ongoing Logs" folder in the participant's casebook. Other as needed forms, such as forms related to a participant's pregnancy or early unblinding, can be added using the "Add Event" feature of Rave. Please see the CCGs for more information. The alternate schedules, Pregnancy and Open Label Truvada are not listed here. In addition the Product Choice CRF, which marks the start of the OL portion of the study is not listed.

Appendix 13B: Participant Transfer and Receipt Process in Rave

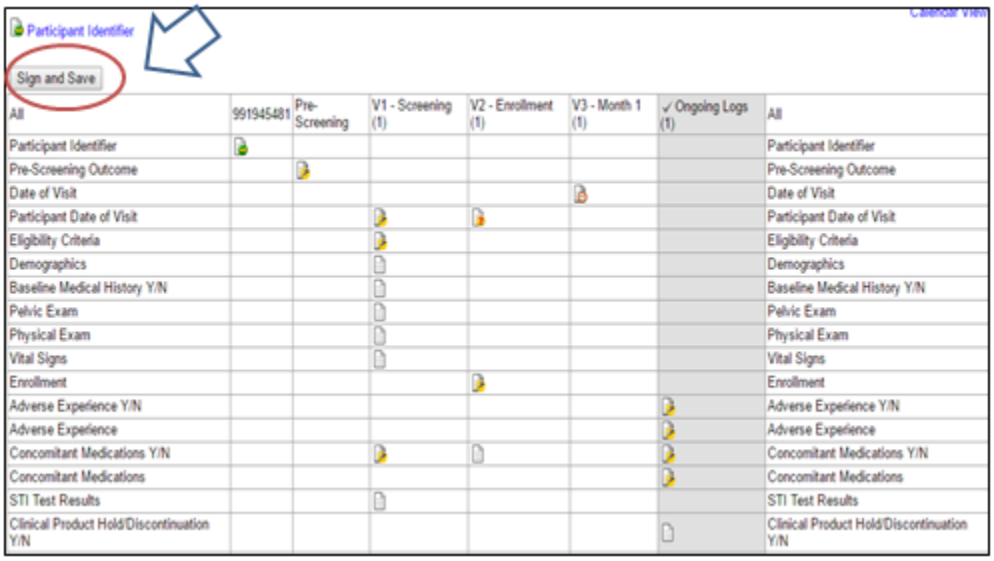
Transferring Site:

1. When initiating a participant transfer to another site please contact the CDM alias 'sc.084cdm@scharp.org'. Data managers included on the alias will facilitate the transfer process within Rave.
2. On the appropriate DOV CRF, indicate additional procedures were required to populate the Additional Procedures CRF. Then mark 'Participant Transfer' to populate that CRF.
3. Complete and save the Transfer form.
4. Ensure and all required eCRFs have been completed all data queries are resolved.
5. Investigator of Record (IOR) or designee must verify the data is complete and accurate by signing off on the participant's eCRFs as follows:

    a. IoR (or designee) logs into Medidata and selects transferring PTID. On the Participant page, select "Grid View":

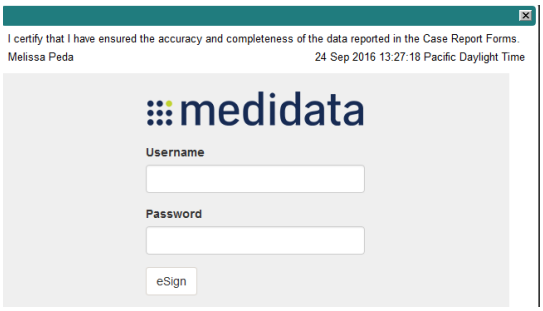


    b. Grid View lists all forms completed and expected for a participant.
    c. To sign off on all completed forms for the PTID, select "All" forms while in Grid View and then click "Sign and Save".



,

d. A signature prompt will display alongside a user ID and password text box. This serves as your electronic signature:



Note: The time that it takes for Medidata Rave to apply the IoR signature to all completed eCRFs will depend on the number of completed CRFs within the participant's casebook. If there are a large number of completed eCRFs, the application of eSignatures may take up to several minutes.

IMPORTANT: When this step is complete please contact the SCHARP Clinical Data Manager so that the transfer can be completed within Rave. Please allow 1-2 days to complete this step.

Receiving Site:

1. Prior to the participant's first scheduled visit at your site, confirm that the participant's casebook is accessible within the Medidata Rave database from your site homepage. Note that the participant retains their original PTID.
2. When participant arrives for the first visit at your site, navigate to the participant's Medidata casebook.
3. On the scheduled DOV CRF, indicate additional procedures were required to populate the Additional Procedures CRF. Then mark 'Participant Receipt' to populate that CRF.
4. Complete and save the Participant Receipt form.
5. Proceed with study visits in Rave.