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 083 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 083, please contact the SCHARP Clinical Data Manager alias: **sc.083cdm@scharp.org or the lead CDM:**

Name: Leslie Cottle
phone: 206.667.7405
e-mail: leslie@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 083 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 083 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 083 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 or Concomitant medication 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.

- Queries are expected to be responded to by sites within 7 days of when the query was first added.

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

OPEN QUERIES REPORT-SITE

8/20/18

Site Name	PTID	Folder Name	Form Name	Log Number	Query Open Date	Query Status	Query Text
Test2	821238531	Interim Visit 1	Interim Visit Summary	0	12/5/17	Open	Data is required. Please complete.
Test2	821238531	V2.0 - Day 0/Enrollment	Demographics	0	12/2/16	Open	Data is required. Please complete.
Test2	821238531	V2.0 - Day 0/Enrollment	Demographics	0	12/2/16	Open	Data is required. Please complete.
Test2	821238531	V2.0 - Day 0/Enrollment	Demographics	0	12/2/16	Open	Data is required. Please complete.

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; all log forms and forms containing lab results may take longer to complete as sites may need to wait for data to become available. 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.

This step should only be done when instructed by the SCHARP Clinical Data Manager. Typically this happens pending a transfer, or when sites are nearing closeout. If a data change or query is added to an eCRF that has been signed off, the electronic signature will be broken and the IoR will have to re-sign the form.

13.4 eCRF Completion

13.4.1 PTID Creation and Screening

Each participant who provides written informed consent to be screened in HPTN 083 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.

The Specimen Storage eCRF and the Inclusion / Exclusion form are the only forms entered

into Rave for the Screening Visit. If the participant does not enroll, site staff must complete the Enrollment CRF with this information and the reasons for screening out.

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 and Randomization

Prior to randomization eligibility must be confirmed, which includes a negative rapid HIV test on a sample drawn at the Enrollment visit per LC guidelines. (Note: Sites that conduct split enrollment visits due to physical location constraints (e.g., an off-site pharmacy), can randomize 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 form in the participant's screening folder must be completed before the Enrollment folder is added. Site staff then complete and save the Enrollment eCRF found in the Enrollment folder which will add all required forms for the visit, including the Randomization form.

To randomize a participant, site staff mark 'Yes' to the question, "Is the participant ready to be randomized?" on the Randomization eCRF. Once the page is saved, the database will assign the participant to a treatment arm and the Randomization Date and Time will appear automatically on the Randomization eCRF. Note that Date and Time are in Coordinated Universal Time (UTC). **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 randomizing the participant.

The participant's randomly assigned treatment arm will not appear in the study database, since the study is double-blinded. Rather, DAIDS Pharmaceutical Affairs Branch-approved site pharmacists only (along with the study statisticians) will be provided restricted access to the Medidata Randomization and Trial Supply Management (RTSM) - previously referred to as Medidata Balance to obtain the coded information needed to select and dispense the correct study medication. Each time a participant is randomized select SCHARP and site staff, including the site pharmacist, will receive an email to inform them of a new randomization.

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 Randomization
- o Concomitant Medications Y/N
- o Adverse Event Y/N
- o Pre-existing Conditions Y/N
- o ART Medication Y/N
- o Protocol Deviation 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, which is based on the date of enrollment / Day 0, or within the target visit window. Additionally, as outlined in Section 5.10 of Version 3.0 of the protocol, visits conducted outside of the target visit windows are allowable without restriction.   Allowable visit windows are an extension of the target windows and are contiguous. When necessary, visits may be completed inside the allowable window.

Note: If the participant moves to Step 3, remaining target dates will be based on the combined final Step 2/Step 3 Day 0 visit date.

The following table lists the HPTN 083 visit codes, target days and visit windows for each study visit for scheduling guidance. All windows are listed in days.

Table 13-1: HPTN 083 Visit Codes, Target Days, and Visit Windows

Week	Visit Code	Target day	Target visit window (±varies days)	Allowable visit window (± varies days)	Allowable visit window
Screening	1.0	--	--		
Step 1					
Day 0/Enrollment	2.0	0	(0 , 3)	+6	(0 , 6)
Week 2	3.0	14	(11 , 17)	-7 / +6	(7 , 20)
Week 4	4.0	28	(25 , 31)	-7 / +3	(21 , 31)
Step 2					
Week 5	5.0	35	(32 , 38)	-3 / +3	(32 , 38)
Week 6	6.0	42	(39 , 45)	-3 / +10	(39 , 52)
Week 9	7.0	63	(60 , 66)	-10 / +3	(53 , 66)
Week 10	8.0	70	(67 , 73)	-3 / +24	(67 , 94)
Week 17	9.0	119	(112 , 126)	-24 / +7	(95 , 126)
Week 19	10.0	133	(127 , 140)	-6 / +20	(127 , 153)
Week 25	11.0	175	(168 , 182)	-21 / +7	(154 , 182)
Week 27	12.0	189	(183 , 196)	-6 / +20	(183 , 209)
Week 33	13.0	231	(224 , 238)	-21 / +7	(210 , 238)
Week 35	14.0	245	(239 , 252)	-6 / +20	(239 , 265)
Week 41	15.0	287	(280 , 294)	-21 / +7	(266 , 294)
Week 43	16.0	301	(295 , 308)	-6 / +20	(295 , 321)
Week 49	17.0	343	(336 , 350)	-21 / +7	(322 , 350)
Week 51	18.0	357	(351 , 364)	-6 / +20	(351 , 377)
Week 57	19.0	399	(392 , 406)	-21 / +7	(378 , 406)
Week 59	20.0	413	(407 , 420)	-6 / +20	(407 , 433)
Week 65	21.0	455	(448 , 462)	-21 / +7	(434 , 462)
Week 67	22.0	469	(463 , 476)	-6 / +20	(463 , 489)
Week 73	23.0	511	(504 , 518)	-21 / +7	(490 , 518)
Week 75	24.0	525	(519 , 532)	-6 / +20	(519 , 545)
Week 81	25.0	567	(560 , 574)	-21 / +7	(546 , 574)
Week 83	26.0	581	(575 , 588)	-6 / +20	(575 , 601)
Week 89	27.0	623	(616 , 630)	-21 / +7	(602 , 630)
Week 91	28.0	637	(631 , 644)	-6 / +20	(631 , 657)
Week 97	29.0	679	(672 , 686)	-21 / +7	(658 , 686)
Week 99	30.0	693	(687 , 700)	-6 / +20	(687 , 713)
Week 105	31.0	735	(728 , 742)	-21 / +7	(714 , 742)
Week 107	32.0	749	(743 , 756)	-6 / +20	(743 , 769)

Week	Visit Code	Target day	Target visit window (±varies days)	Allowable visit window (± varies days)	Allowable visit window
Week 113	33.0	791	(784 , 798)	-21 / +7	(770 , 798)
Week 115	34.0	805	(799 , 812)	-6 / +20	(799 , 825)
Week 121	35.0	847	(840 , 854)	-21 / +7	(826 , 854)
Week 123	36.0	861	(855 , 868)	-6 / +20	(855 , 881)
Week 129	37.0	903	(896 , 910)	-21 / +7	(882 , 910)
Week 131	38.0	917	(911 , 924)	-6 / +20	(911 , 937)
Week 137	39.0	959	(952 , 966)	-21 / +7	(938 , 966)
Week 139	40.0	973	(967 , 980)	-6 / +20	(967 , 993)
Week 145	41.0	1015	(1008 , 1022)	-21 / +7	(994 , 1022)
Week 147	42.0	1029	(1023 , 1036)	-6 / +20	(1023 , 1049)
Week 153*	43.0	1071	(1064 , 1078)	-21 / +7	(1050 , 1078)
Week 155	44.0	1085	(1079 , 1092)	-6 / +20	(1079 , 1105)
Week 161	45.0	1127	(1120 , 1134)	-21 / +7	(1106 , 1134)
Week 163	46.0	1141	(1135 , 1148)	-6 / +20	(1135 , 1161)
Week 169	47.0	1183	(1176 , 1190)	-21 / +7	(1162 , 1190)
Week 171	48.0	1197	(1191 , 1204)	-6 / +20	(1191 , 1217)
Week 177	49.0	1239	(1232 , 1246)	-21 / +7	(1218 , 1246)
Week 179	50.0	1253	(1247 , 1260)	-6 / +20	(1247 , 1273)
Week 185	51.0	1295	(1288 , 1302)	-21 / +7	(1274 , 1302)
Week 187	52.0	1309	(1303 , 1316)	-6 / +20	(1303 , 1329)

*After protocol V. 3.0 has received all local and national approvals at a site, Week 153 will serve as the final Step 2 / Step 3 hybrid visit for participants still in Step 2.

Step 3					
Day 0 (Step 3 only) *No longer used*	53.0	<8 weeks from last injection	(0 , 14)	+42	(0 , 42)
Week 12	54.0	84	70, 98	-41 / +42	(43 , 126)
Week 24	55.0	168	154, 182	-41 / +42	(127 , 210)
Week 36	56.0	252	238, 266	-41 / +42	(211 , 294)
Week 48	57.0	336	322, 350	-41 / +42	(295 , 378)
Annual Visits					
Yearly 1	80.0	~52 weeks or 365 days after last Step visit	NA	- 182 / +182	(183, 547)
Yearly 2	81.0	Day 730	NA	- 182 / +182	(548, 912)
Yearly 3	82.0	Day 1095	NA	- 182 / +182	(913, 1277)
Yearly 4	83.0	Day 1460	NA	- 182 / +182	(1278, 1642)

13.6   HPTN 083 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, 33, etc. All injections should be given as close to those intervals as possible, with target windows defined as +/- 3 days for the Week 5 and 9 injection visits, and +/- 7 days for Week 17+ 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:

1. If a participant is late receiving an injection, the site should attempt to provide the injection as soon as possible, not waiting for the next planned injection time/window.

2. If an injection is <u>eight or more weeks late (that is, eight or more weeks later than the target date)</u>, a repeat of the initial 4-week interval series should be administered. That is, the subsequent two injections after 8-week or longer delay should occur four weeks apart.

3. Following a late injection and/or late injection-followed-by-4-week-injection series, the participant should be brought back on the original, planned injection schedule by, if necessary, shortening subsequent injection intervals. Shortened intervals may be used until an injection can be scheduled within the next target injection window. Injection intervals should be no shorter than 6 weeks, and no more than two shortened intervals should be needed to get a participant back on schedule, unless additional delays occur. The "4-week" interval injections should not be shortened to less than 3 weeks apart.

Coding the injection visits

1. Late injection visits should generally be coded based on the injection visit with the most recently opened window. Injection windows for the Week 5 and Week 9 injections open 3 days prior to the target injection date, and windows for the Week 17+ injections open 7 days prior to the target injection date. The first injection must always be coded as Week 5; later injections will receive a visit code as outlined above.

2. If an injection is more than 8 weeks late and a 4-week interval is required (as above), the first injection visit should be coded as the injection with the previously opened window, and the second injection (4-weeks later) should be coded as the injection with the current, most recently opened window.

3. Safety visits should always be coded as the next visit following the code used for the

injection visit.

4. If an injection is missed, and the visit is not needed to accommodate a 4-week interval injection as in (2) above, the injection visit should be entered as a Missed Visit.

Late/Missed Safety Visits

1. 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 HV infection

Coding Safety Visits

1. A late safety visit should be coded according to the earliest missed safety visit following an injection. For example, if the participant receives the week-9 injection and misses the week-11 safety visit, the next safety visit should be coded as "week 11", even if it occurs much later.

2. Discretionary safety visits may be coded as "interim visits"

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.

The only exception to this rule is when an injection visit is split over two days. This occurs when certain procedures are done but the injection is not given on the first day of the split visit. In this case, an interim visit folder must be created to document on the Interim Visit summary the date

oral medication was dispensed. Note that the Injection Administration form will be in the regular visit folder but should have the same date as the Interim Visit Summary if oral medication was dispensed on the same day.

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 after an expected visit

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. Only interim visits that take place after enrollment will be entered into the database.
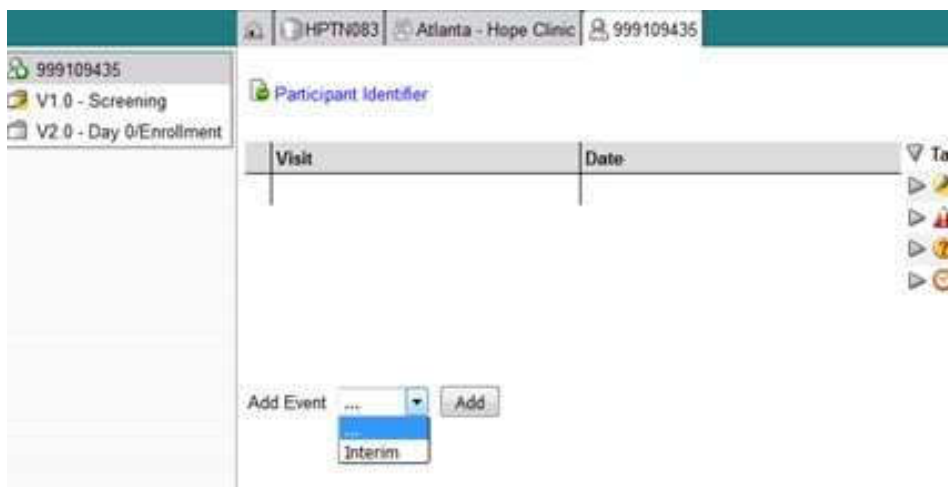
To add an interim visit in Rave, click on 'Add Event' while in the participant's folder and select 'interim'An interim visit folder that contains the Interim Visit Summary CRF is then added to the participant's casebook, or set of folders.

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 required visit,
  - #.2 = the second interim visit after the required visit,
  - #.3 = the third interim visit after the required visit, and so on.
  - If more than 9 visits occur between protocol-required visits, the visits must be coded as

- #.91 – the tenth interim visit,
- #.92- the eleventh interim visit, and so on.

Example #1: A participant completes his Visit 8.0 Week 10 visit 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's last visit was V10 Week 19 and has not been seen since then. The participant arrives in clinic requesting HIV testing only and no other study procedures are done. This interim visit is assigned a visit code of 10.1.

13.7.5 Annual Visits

The first Yearly (Annual) Visit should occur approximately 12 months after the visit where it's determined the participant will move to annual visits.

To add a Yearly visit in Rave, click on 'Add Event' while in the participant's folder and select 'Yearly Visit':

A Yearly visit folder will then be added to the participant's casebook.

If a participant in Step 2 wishes to stop all medications, including Step 3 open label Truvada, but are willing to be seen annually, they must still be moved to Step 3 in the database; all Step 3 visits will be entered as missed. After the target date for Step 3 Week 48 has passed the participant can be transitioned to annual visits.

13.8 Step 3 Transition Visits

Early Transition to Step 3

Early transition to Step 3 can occur at any time during Step 2 as a result of a participant request or clinical event that requires permanent discontinuation of injections.

At the final Step 2 visit where open label Truvada is first administered, mark "Yes" to moving to Step 3 on the Date of Visit or Interim Summary form. Complete all expected Step 2 procedures for the visit and add other CRFs to the visit folder as necessary. For example, the STI form and SMSQs are required for the Step 3 Day 0 visit; if those are not already required at the visit where Step 3 transition is occurring, add the forms to the folder. The next required visit is then Step 3 Week 12.

Transition to Step 3 after completion of Step 2 (Protocol V3.0)
For sites with all local and national approvals in place for protocol V3.0, participants who reach Step 2 Week 153 will transition to Step 3 at that visit; indicate on the form as described above that the participant is moving to Step 3 and add the SMSQs survey into the visit folder.

13.9 HPTN 083 Schedule of Forms and CASI Surveys

The case report forms and surveys required for each study visit are summarized in the HPTN 083 Schedule of Forms. The schedule of forms refers to surveys by specific name, not the more general terms of behavioral and acceptability assessments as mentioned in the protocol.

13.10 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.

13.11 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.

- Concomitant Medications CRF: If a medication is taken for an AE, select the AE in the dropdown list provided. An AE log line must be completed before it can be selected on the Con Meds CRF.Also confirm that 'Medication" is marked on the AE CRF under "Other action(s) takne" with Study Product.

- Local Lab and Hematology CRF: If a test is linked to a reported AE, select the AE in the dropdown list provided. An AE log line must be completed before it can be selected on the Local Lab or Hematology 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.

13.12 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.

13.13 Case Report Forms

The current version of the eCRFs case can be found on the HPTN 083 Atlas web page:
https://atlas.scharp.org/cpas/project/HPTN/083/begin.view