

# 12. Data Management

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## 12.1 Overview of Section 12

The purpose of this document is to provide site staff with the information needed to complete and submit HPTN094 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 HPTN094, please contact the SCHARP Clinical Data Manager:

**Name: Melissa Cummings**

**phone: 206.667.1232**

**e-mail: [mcumming@scharp.org](mailto:mcumming@scharp.org)**

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

## **12.2 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 HPTN094 study database in Medidata Rave may be accessed at [www.imedidata.com](http://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 HPTN094 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 HPTN094 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](mailto: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

<b>Toll-free</b>	<b>Direct number</b>
1-866-MEDIDATA (633-4328)	1-973-659-6780

<b>Toll-free fax</b>	<b>Direct fax</b>
1-877-743-2350	1-973-954-5621

**Email**  
[helpdesk@mdsol.com](mailto:helpdesk@mdsol.com)

**Hours**  
24 hours a day, 7 days a week

## 12.3 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 SAE data.
  - Inconsistency queries may be manually placed during SAE-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:

▼ 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 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:

What is the CASI ID assigned to this participant?  
? Data is required. Please complete.  
Opened To Site from System (02 Dec 2016)

A red arrow points to the empty input field on the right.

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).

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; exceptions include all log forms, forms containing lab results, and SAEs. SAEs are expected to be entered within 3 days of site awareness date.

- **Unresolved SAEs ≥ 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 Reporter	# 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 SAEs that have no Outcome Date; if an Outcome Date is added to the SAE 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 SAEs 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.

## 12.4 eCRF Completion

### 12.4.1 PTID Creation and Screening

Each participant who provides written informed consent to be screened in HPTN094 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.

### 12.4.2 Enrollment and Randomization

Prior to enrollment, eligibility must be confirmed.

To enroll a participant, site staff mark “Eligible and enrolled” to the question “Eligibility status” and enter the “Enrollment date” on the Screening and 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.

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).

Subject: 998305431  
Page: Randomization - V2.0 Day 0/Enrollment- S1 (1)

Please ensure all HIV testing per algorithm has been completed and that participant is HIV negative prior to randomization. Please also ensure participant is NOT pregnant prior to randomization. Lastly, please double check that you are randomizing the correct person (i.e. double check the PTID) prior to clicking "Yes" and saving the form.

Is the participant ready to be randomized?

Yes  No

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

CRF Version 1067 - Page Generated: 16 Jul 2018 15:12:45 Pacific Daylight Time

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.

Subject: 998305431  
Page: Randomization - V2.0 Day 0/Enrollment- S1 (1)

Please ensure all HIV testing per algorithm has been completed and that participant is HIV negative prior to randomization. Please also ensure participant is NOT pregnant prior to randomization. Lastly, please double check that you are randomizing the correct person (i.e. double check the PTID) prior to clicking "Yes" and saving the form.

Is the participant ready to be randomized?  
 Subject successfully randomized.

Printable Version View PDF Icon Key  
CRF Version 1067 - Page Generated: 16 Jul 2018 15:14:00 Pacific Daylight Time

Yes

Save Cancel

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: HPTN094  
Environment: PROD  
Site Number: 12345  
Subject ID: 999999990  
Arm:

The arm of study that the participant has been randomized to will also appear on the Screening and Enrollment CRF.

### 12.4.3 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.
- SAEs 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 26) 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:

- Participant Identifier
- Medical History Y/N
- Navigation Session Y/N
- Protocol Deviation Y/N
- Serious Adverse Event Y/N

### 12.4.4 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).

**Please remember:** 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 12-1.



## **12.5 Visit Scheduling: Target Days and Visit Windows**

Whenever possible, visits should be completed on the target day (based on the date of enrollment for regular scheduled visits) or within the target visit window.

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.

The HPTN 094 visit codes are:

- Screening – V1.0
- Enrollment – V2.0
- Week 26 – V3.0
- Week 52 – V4.0

Refer to Protocol Section 6.8 for additional information about study visit windows.

## **12.6 Types of Visits**

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

### **12.6.1 Scheduled Visits**

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

### **12.6.2 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.

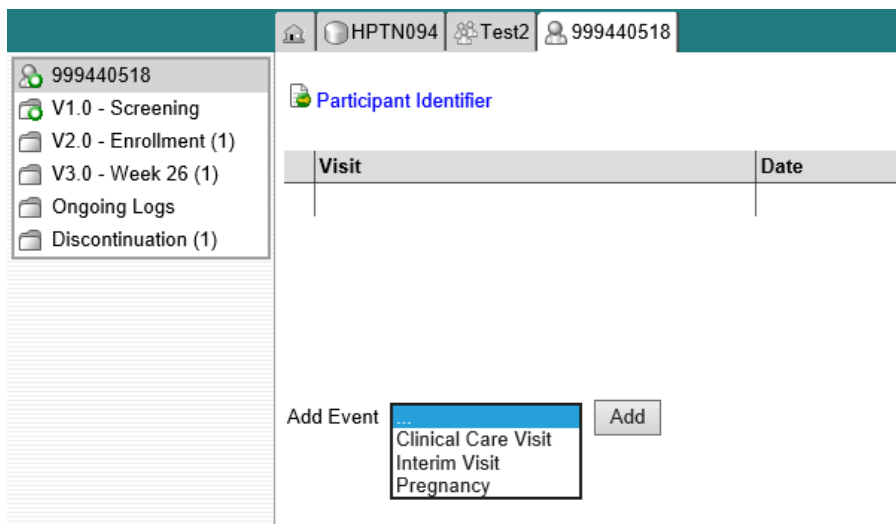
### **12.6.3 Split Visits**

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 4.3 of the SSP for further information related to split visits.

### **12.6.4 Clinical Care Visits**

Participants will be seen in the mobile unit as needed to provide medication and to manage adherence to MOUD and ART or PrEP, and to address other participant health needs. These will be considered “Clinical Care” visits. Clinical Care visits take place between the Enrollment Visit and the week 26 visit for participants in the active treatment arm.

To add a Clinical Care visit in Rave, click on ‘Add Event’ while in the participant’s folder and select ‘Clinical Care’:



A Clinical Care visit folder is then added to the participant’s casebook.

#### 12.6.4.1 Clinical Care Visit Codes

The first Clinical Care visit is considered 201.0, the next is 202.0 and so on. This coding will differentiate them from regular scheduled visits (1.0, 2.0, 3.0, etc) and interim visits (3.01, 3.02, 3.03 etc.)

#### 12.6.4 Interim Visits

An interim visit is an “extra” visit that occurs after procedures for a required visit are completed. Participants in either arm may have an interim visit, though in the intervention arm, visits after enrollment but before the Week 26 visit will be clinical care visits. See further discussion about interim visits in SSP Section 5.

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.

#### 12.6.4.1 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:
  - #.01 = the first interim visit after the most recently-required visit,
  - #.02 = the second interim visit after the most recently-required visit,
  - #.03 = the third interim visit after the most recently-required visit, and so on.

**Example #1:** A participant completes his Week 26 visit (visit code = 3.0) on the target day. He returns to the site later for additional STI testing. This interim Visit is assigned a visit code of 3.01.

**Example #2:** A participant completes all required study procedures at Week 52 visit (visit code = 4.0). 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 to get his blood re-drawn. The return visit is considered an interim visit because the participant had completed the required study procedures for Visit 4.0. Because this is the first interim visit after visit 4.0 it is assigned visit 4.01.

### 12.7 HPTN094 Schedule of Forms and CASI Surveys

The case report forms are summarized in the HPTN 094 Schedule of Forms found at the end of this section. A link to the CASI survey can be found in Section 13 of the SSP Manual (CASI).

### 12.8 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.

### 12.9 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. (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 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”.

### **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.

## **12.10 CRF Completion Instructions**

Detailed form completion instructions for each form are provided in the CRF Completion Guidelines (CCG) document. The instructions document 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.

## **12.11 Case Report Forms**

The current version of the eCRFs can be found on the HPTN094 Atlas web page:  
<https://atlas.scharp.org/cpas/project/HPTN/094/begin.view?>

**12.12 Schedule of Forms** (R=Required at this visit; X=May or may not apply at this visit)

Visit Code:	Screening - V1.0	Enrollment - V2.0	Care visits	Week 26 - V3.0	Week 52 - V4.0	Interim visit
<b>Visit Day:</b>		0				
<b>Week:</b>		0		26	52	
<b>Form Name</b>	SCR					
Date of Visit				R	R	
Antiretroviral Treatment Regimen Log		R	X	R	R	X
Behavioral Questionnaire		R		R	R	
CASI Tracking		R		R	R	
CD4 Test Results/Viral Load		R	X	R	R	X
Chemistry Panel		R	X	X	X	X
Clinical Care Visit			R			
Couple Tracking		R				
Demographics	R					
Hematology		R	X	X	X	X
Hepatitis Test Results		R	X	R	R	X
HIV Test Results	R	R				
Informed Consent	R					
Interim Visit						R
Medical History	X	X				
Medication for Opioid Use Disorder Log		R	X	R	R	X
Missed Visit				X	X	
Navigation Session Log		X	X			X
OUD Test Results	R	R	X	R	R	X
Participant Receipt			X	X	X	X
Participant Transfer			X	X	X	X
Pre-exposure Prophylaxis Log		R	X	R	R	X
Pregnancy Outcome			X	X	X	X
Pregnancy Report			X	X	X	X
Pregnancy Test Results		R	X	X	X	X
Protocol Deviations Log		X	X	X	X	X
Randomization		R				
Receipt of Community Services				R	R	

Screening and Enrollment	R					
Serious Adverse Event Log		X	X	X	X	X
Specimen Collection	R	R	X	R	R	X
STI Test Results		R	X	R	R	X
Study Co-Enrollment				R	R	
Study Termination			X	X	R	X