

## Section 10. Data Management

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### 10.1 Overview of Section 10

The purpose of this document is to provide site staff with the information needed to complete and submit HPTN091 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 HPTN091, please contact the SCHARP Clinical Data Manager:

**Name: Ian Bell**

**phone: 206.667.7061**

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

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

## **10.2 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 HPTN091 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 HPTN091 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 HPTN091 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

## 10.3 Data Entry/Quality Control

- All entries in Rave must be made in English.
- Once data for an eCRF is completed and saved in the study database, the following may occur:
  - A system query may be automatically triggered in Medidata Rave (e.g., denoting incomplete or inconsistent data).
  - Manual data queries may be placed by the SCHARP Clinical Data Manager (CDM) or Clinical Safety Associate (CSA) after review of entered forms.
  - Data queries may be placed by the site monitor (i.e., PPD) after required review for certain forms and/or fields.
  - Coding queries may be placed by the SCHARP MedDRA coding team to help clarify AE data.
  - Inconsistency queries may be manually placed during AE-EAE reconciliation.

## Query Management and Resolution

- Queries, or QCs, appear in the Medidata Rave Task Summary on the study home page of designated site users (example below). Staff members designated by the site are responsible for routinely checking the Task Summary and correcting/updating study data to resolve any outstanding queries.

Task Summary Example:

▼ 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 'X' is drawn over the first input field, and a red arrow points to the second input field.

When data is entered into the missing field on the right and the form is saved, the auto query will be removed.

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

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 AEs. AEs are expected to be entered within 3 days of site awareness date.

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

AEs Unresolved for ≥ 30 days

US SCHARP

PTID	AE Log Number	Date Reported to Site	Adverse Event	Onset Date	Severity Grade	Visit First 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 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.

## 10.4 eCRF Completion

### 10.4.1 PTID Creation and Screening

Each participant who provides written informed consent to be screened in HPTN091 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 within the site and study it is generated for. It is assigned to a single participant and remains assigned to them even if they transfer to another site during the course of the study. 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 Informed Consent CRF, the Inclusion Exclusion Criteria CRF with the reasons for screening out, Randomization CRF stating that the participant did not enroll (“Is the participant ready to be randomized?” must equal “No”), and the Demographics form. All forms are located in the Screening and Enrollment folders.

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.

### 10.4.2 Enrollment

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

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

### 10.4.3 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 13) 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
- Concomitant Medications Y/N
- Adverse Event Y/N
- Medical History Y/N
- Product Hold Y/N
- Protocol Deviation Y/N
- Social Impact Assessment Y/N

#### 10.4.4 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 10-1.

#### 10.5 Visit Scheduling: Target Days and Visit Windows

Whenever possible, visits should be completed on the target day, (based on the enrollment date for regular schedule visits, GAHT initiation for GAHT Initiation Visit, GAHT Initiation Visit for DHI Day 8 Post Visit, and based on the HIV diagnosis date for visits in the Seroconversion schedule), or within the target visit window.

Reminders for specific visits:

- The Enrollment Visit (V2) must occur within 40 days of screening visit.
- The GAHT Initiation Visit will be scheduled within approximately 10 days but no more than 14 days following the collection of samples for estradiol and total testosterone testing for initiation/re- initiation of GAHT.
- The GAHT Safety Visit will be scheduled one month after GAHT Initiation Visit for participants who are treatment-naïve to spironolactone or cyproterone.

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 following table lists the HPTN091 visit codes, target days and visit windows for each study visit. All windows are listed in days.

**Table 10-1: HPTN091 Visit Codes, Target Days, and Visit Windows**

Week	Visit Code	Target day	Target visit window (± varies days)	Target visit window	Allowable visit window (± varies days)	Allowable visit window
Screening	V1	--	Up to 30days before Day 0	--	--	--
Enrollment/Day 0	V2	0	--	0	0	0
GAHT Initiation Visit	V201	--	--	Within approximately 10 days but no more than 14 days post blood collection for estradiol and total testosterone	+14	--
Week 13	V3	91	-14 / +14	(77, 105)	-14 / +62	(77, 153)
GAHT Safety Visit	V401	--	--	One month after GAHT Initiation Visit	--	--
DHI Day 8 Post Visit (substudy only)	V202	--	--	--	--	--
Week 26	V4	182	-14 / +14	(168, 196)	-28 / +62	(154, 244)
Week 39	V5	273	-14 / +14	(259, 287)	-28 / +63	(245, 336)
Week 52	V6	365	-14 / +14	(351, 379)	-28 / +62	(337, 427)
Week 65	V7	456	-14 / +14	(442, 470)	-28 / +62	(428, 518)
Week 78	V8	547	-14 / +14	(533, 561)	-28 / study closure	(519, study closure)
Seroconversion Termination Visit	V301	--	--	--	--	--



## 10.6 Types of Visits

Please refer to Section 4.3 of the SSP for additional information on each visit type.

### 10.6.1 Scheduled Visits

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

### 10.6.2 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 4.3 of the SSP for further information related to missed visits.

### 10.6.3 Split Visits

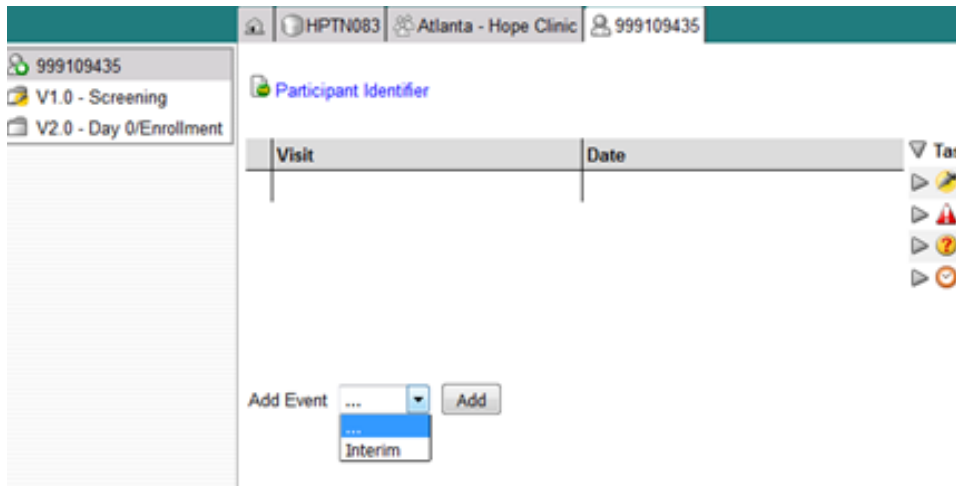
When a participant is not able to complete all required visit evaluations on the same day, the participant may return and complete the remaining evaluations on another day. When such a split visit occurs, case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates). Refer to Section 4.3 of the SSP for further information related to split visits.

### 10.6.4 Interim Visits

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

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

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



An interim visit folder that contains the Interim Visit Summary CRF is then added to the participant’s casebook or set of folders.

#### 10.6.4.1 Interim Visit Codes

Interim visit codes are assigned using the following guidelines:

- To the left of the decimal point, record the 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 their Week 26 visit (visit code = 4) on the target day. They return to the site three days later for additional STI testing. This interim Visit is assigned a visit code of 4.01.

**Example #2:** A participant completes all required study procedures at Visit 6.0 (Week 52 Visit). When the lab results are available later in the week, the site clinician notices the participant has an abnormal lab result that needs to be repeated. The participant returns a week later to get their blood re-drawn. The visit is considered an interim visit because the participant had completed the required study procedures for Visit 6.0. Because this is the first interim visit after visit 6.0 it is assigned visit 6.01.

## 10.7 HPTN091 Schedule of Forms and CASI Surveys

The case report forms are summarized in the HPTN091 Schedule of Forms found at the end of this section. A link to the CASI survey can be found in section 9 of the SSP Manual.

## 10.8 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.

## 10.9 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".
- Concomitant Medications CRF: if a medication is taken for an AE, make sure the linked AE CRF is entered and saved first; then confirm on the Con Meds CRF that the

appropriate, linked AE is selected. Also confirm that ‘Medication’ is marked on the AE CRF.

### **Additional QC Steps for Paper CRFs**

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

- Make sure a response has been recorded for each item, as required per instructions in the CRF Completion Guidelines (CCG) document.
- If a response box with “other” or “specify” line is present, make sure there is text responding to that item.
- Make sure text responses are clearly recorded.
- For paper CRFs that are not source documents, make sure the data recorded on the paper CRFs matches or is consistent with the source documents.

### **Additional QC Steps for Electronic CRFs (eCRF)**

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

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

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

## **10.10 CRF Completion Instructions**

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

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

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

## 10.11 Case Report Forms

The current version of the eCRFs can be found on the HPTN091 Atlas web page:

<https://atlas.scharp.org/cpas/project/HPTN/091/begin.view?>

## 10.12 Schedule of Forms

Visit	Form Name
V1 - Screening	Demographics
	Vital Signs
	Patient Health Questionnaire
	Physical Exam
	Counseling
	Chemistry Panel
	Fasting Lipid Test Results
	Hepatitis Test Results
	HIV Test Results
	CD4 Test Results
	Urinalysis
V2 - Enrollment	Specimen Collection and Storage
	Randomization
	Enrollment
	Inclusion/Exclusion Criteria
	ACASI Tracking
	Vital Signs
	Patient Health Questionnaire
	Physical Exam
	Counseling
	Hepatitis B Vaccination
	Hematology
	HIV Test Results
	CD4 Test Results
	Hormone Tests
	STI Tests
Urinalysis	
Specimen Collection and Storage	

<b>V201 - GAHT Initiation Visit</b>	Date of Visit Missed Visit Counseling Hormone Tests PK Dose Time PK Specimen Collection
<b>V3 - Week 13 Visit</b>	Date of Visit Missed Visit ACASI Tracking Counseling Vital Signs Patient Health Questionnaire Physical Exam Chemistry Panel HIV Test Results CD4 Test Results Hormone Tests STI Tests Specimen Collection and Storage Additional Study Procedures Fasting Lipid Test Results Hematology Hepatitis B Vaccination Hepatitis Test Results Hormone Tests Participant Receipt Participant Transfer Supplemental HIV Results Urinalysis
<b>V4 - Week 26 Visit</b>	Date of Visit Missed Visit ACASI Tracking Counseling Vital Signs Patient Health Questionnaire Physical Exam Chemistry Panel Fasting Lipid Test Results Hematology HIV Test Results CD4 Test Results Hormone Tests STI Tests Specimen Collection and Storage

Additional Study Procedures  
Hepatitis B Vaccination  
Hepatitis Test Results  
Participant Receipt  
Participant Transfer  
Supplemental HIV Results  
Urinalysis

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**V5 - Week 39 Visit**

Date of Visit  
Missed Visit  
ACASI Tracking  
Counseling  
Vital Signs  
Patient Health Questionnaire  
Physical Exam  
Chemistry Panel  
HIV Test Results  
CD4 Test Results  
Hormone Tests  
STI Tests  
Specimen Collection and Storage  
Additional Study Procedures  
Fasting Lipid Test Results  
Hematology  
Hepatitis B Vaccination  
Hepatitis Test Results  
Participant Receipt  
Participant Transfer  
Supplemental HIV Results  
Urinalysis

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**V6 - Week 52 Visit**

Date of Visit  
Missed Visit  
ACASI Tracking  
Counseling  
Vital Signs  
Patient Health Questionnaire  
Physical Exam  
Chemistry Panel  
Hematology  
HIV Test Results  
CD4 Test Results  
Hormone Tests  
STI Tests  
Specimen Collection and Storage  
Additional Study Procedures

Fasting Lipid Test Results  
Hepatitis B Vaccination  
Hepatitis Test Results  
Participant Receipt  
Participant Transfer  
Supplemental HIV Results  
Urinalysis

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**V7 - Week 65 Visit**

Date of Visit  
Missed Visit  
ACASI Tracking  
Counseling  
Vital Signs  
Patient Health Questionnaire  
Physical Exam  
Chemistry Panel  
HIV Test Results  
CD4 Test Results  
Hormone Tests  
STI Tests  
Specimen Collection and Storage  
Additional Study Procedures  
Fasting Lipid Test Results  
Hematology  
Hepatitis B Vaccination  
Hepatitis Test Results  
Participant Receipt  
Participant Transfer  
Supplemental HIV Results  
Urinalysis

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**V8 - Week 78 Visit**

Date of Visit  
Missed Visit  
ACASI Tracking  
Counseling  
Vital Signs  
Patient Health Questionnaire  
Physical Exam  
Chemistry Panel  
Fasting Lipid Test Results  
Hematology  
Hepatitis Test Results  
HIV Test Results  
CD4 Test Results  
Hormone Tests  
STI Tests



	Specimen Collection and Storage Additional Study Procedures Hepatitis B Vaccination Participant Receipt Participant Transfer Supplemental HIV Results Urinalysis
<b>V202 - DHI Day 8 Post Visit</b> (sub study only)	Date of Visit Missed Visit PK Dose Time PK Specimen Collection
<b>V301 - Seroconversion Termination Visit</b>	Date of Visit - Seroconverter Schedule Missed Visit ACASI Tracking Counseling Vital Signs Patient Health Questionnaire Physical Exam Specimen Collection and Storage Additional Study Procedures CD4 Test Results Chemistry Panel Fasting Lipid Test Results Hematology Hepatitis B Vaccination Hepatitis Test Results HIV Test Results Hormone Tests Participant Receipt Participant Transfer STI Tests Supplemental HIV Results Urinalysis
<b>Interim Visit (as needed)</b>	Interim Visit ACASI Tracking CD4 Test Results Chemistry Panel Counseling Fasting Lipid Test Results Hematology Hepatitis B Vaccination Hepatitis Test Results HIV Test Results Hormone Tests

	Participant Receipt
	Participant Transfer
	Patient Health Questionnaire
	Physical Exam
	PK Dose Time
	PK Specimen Collection
	Specimen Collection and Storage
	STI Tests
	Supplemental HIV Results
	Urinalysis
	Vital Signs
	Adverse Event Y/N
	Adverse Event
	Concomitant Medications Y/N
	Concomitant Medications
	Gender Affirming Hormone Therapy Y/N
	Gender Affirming Hormone Therapy Log
	Medical History Y/N
	Medical History
<b>Ongoing logs (as needed)</b>	Peer Health Navigation Tracking Y/N
	Peer Health Navigation Tracking Log
	Pre-exposure Prophylaxis Y/N
	Pre-exposure Prophylaxis Log
	Protocol Deviations Y/N
	Protocol Deviation Log
	Social Impact Assessment Y/N
	Social Impact
<b>Discontinuations</b>	Study Termination
	Date of Visit
	Counseling
	Vital Signs
<b>GAHT Safety Visit</b>	Patient Health Questionnaire
	Physical Exam
	Chemistry Panel
	Social Impact