

Section 16. Data Communiqués

SCHARP uses “Data Communiqués” to document and communicate data and database decisions and procedures that are made or revised during the study.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is distributed, please circulate it among relevant staff for their review and file as appropriate. Consider each Data Communiqué an official part of the SSP.

Each Data Communiqué may consist of three sections: a Reminders section, used to remind sites of specific data collection or forms completion procedures; a Clarification section, used to clarify data collection or form completion procedures; and an Updates section, used to communicate things such as new database procedures, a revised form, or form instructions.

HPTN083 Data Communiqué #1

10 May 2019

This is official study documentation for the HPTN083 trial. Please print and circulate among relevant staff for review, and file it with your HPTN083 SSP Manual. This document is considered part of the SSP manual.

CLARIFICATIONS

1. Email randomization alerts: The time stamp on all email alerts is in UTC (formerly known as GMT) and not in the local site time zone.

2. Screening data in Medidata Rave: Only the Inclusion/Exclusion and Specimen Storage forms are expected in Medidata Rave prior to the enrollment visit and are coded V1.0 – Screening. Any forms submitted at an interim visit prior to Enrollment will be queried for inactivation. If a participant needs to be re-screened they should receive a new participant ID.

3. V5.0 – Week 5 data entry: The Week 5 folder is used only for the first injection of Step 2 regardless of when it occurs. Any Missed Visit forms entered in Week 5 or any other Step 2 folder for participants who have not received the first injection will be queried for inactivation.

4. INSTRUCTIONS FOR ‘LOST TO FOLLOW-UP’ PARTICIPANTS

- a. Step 1 Participants who have had a Week 4 visit with > 50% adherence** and are currently lost to follow-up: submit a *temporary* product hold form:

On Product Hold form enter:

Date of last oral study product use: Leave blank and respond with UNK.

Visit Code where hold was initiated: Week 4

Reason for hold: ‘Participant request – participant is unwilling or unable to comply with required study procedures’

Hold date: Date site determined participant is currently lost to follow-up

Will the participant resume study product? Yes

Date participant resumed study product – leave blank; answer query with “to be determined”

DO NOT SUBMIT MISSED VISIT FORMS FOR STEP 2 VISITS; LEAVE STEP 2 FOLDERS BLANK.

- b. Step 1 Participants who have not had a Week 4 visit and have passed 120 days from enrollment:** submit a *permanent* product hold form:

On Product Hold form:

Date of last oral study product use: Enter the date that is 120 days past enrollment.

Visit Code where hold was initiated: enter visit code of last visit attended or last Missed Visit (must be a Step 1 visit code)

Reason for hold: ‘Participant request – participant is unwilling or unable to comply with required study procedures’

Hold date: Enter the date that is 120 days past enrollment

Will the participant resume study product? Mark No – permanently discontinued

On Date of Visit or Interim Visit Form of last attended or missed Step 1 visit

Is the participant moving to yearly visits? Yes

Is the participant moving to Step 2? No

- c. **Step 2** Participants who have had at least one injection and then are lost to follow-up for > 6 months: submit a *temporary* product hold form:

On Product Hold form:

Date of last oral study product use: Leave blank and respond with UNK.

Visit Code where hold was initiated: Visit code of the first completed Missed Visit form

Reason for hold: 'Participant request – participant is unwilling or unable to comply with required study procedures'

Hold date: Target date of first missed injection

Will the participant resume study product? Yes

Date participant resumed study product – leave blank; answer query with “to be determined”

SUBMIT MISSED VISIT FORMS FOR STEP 2 VISITS AS EACH WINDOW CLOSES.

5. STEP 3 DAY 0 Visits: All future Step 3 Day 0 visits will be combined with the participant's last Step 2 visit. This applies to participants who transition early to open label TDF/FTC as well as those still in Step 2 when study-wide unblinding occurs.

All empty/unused Step 3 Day 0 folders will be removed from the database during the next database revision. Data already entered in a Step 3 Day 0 folder will remain in that folder.

a. INSTRUCTIONS FOR STEP 2 PARTICIPANTS MOVING TO OPEN LABEL TDF/FTC (EARLY STEP 3) DURING A STEP 2 VISIT:

If, during a Step 2 study visit, it is determined that the participant will transition to open label TDF/FTC that same day AND an injection has not been given, that Step 2 visit will be considered Day 0 of Step 3. ***However, the data should be entered in the Step 2 study visit folder and not in the Step 3 Day 0 folder.*** Entering the data as a Step 2 visit will allow completion of all Step 2 visit requirements and for the visit to be included in Step 2 retention.

- On Date of Visit form mark 'Yes' to “Is the participant ready to move to Step 3?”
- If STI testing has not occurred within 3 months prior to this visit, add the STI form to the folder and enter STI data.

In Step 3 Day 0 folder, Date of Visit form mark 'No' to “did the participant complete this visit?” and submit a Missed Visit form.

- On Missed Visit form, for “Reason visit was missed,” mark 'other', then in “Other, specify”, enter “Transitioned at Step 2 visit.”
- Although “No” is being marked, this final Step 2 visit is also considered the Step 3 Day 0 visit. After the next database update this step will no longer apply.

The next visit will be Step 3 Week 12.

b. INSTRUCTIONS FOR PARTICIPANTS IN STEP 2 AT THE TIME OF STUDY-WIDE UNBLINDING:

After study-wide unblinding occurs, schedule an interim visit within 8 weeks of the last injection.

On the Interim Visit Summary form mark 'Yes' to "Is the participant ready to move to Step 3?"

On the Interim Visit Summary form select the required forms for Step 3 Day 0 visit according to Appendix IC in the protocol:

HIV Test Results Form

Specimen Storage

STI (If testing has not occurred in the past 3 months)

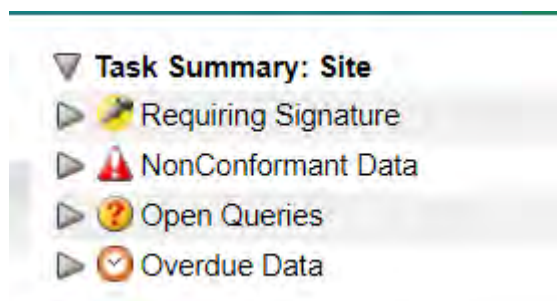
The next visit will be Step 3 Week 12.

6. REQUESTING NEW CASI IDS: If you anticipate running out of CASI IDS please contact SCHARP and allow 2 weeks for the new PTIDs to be created and programmed.

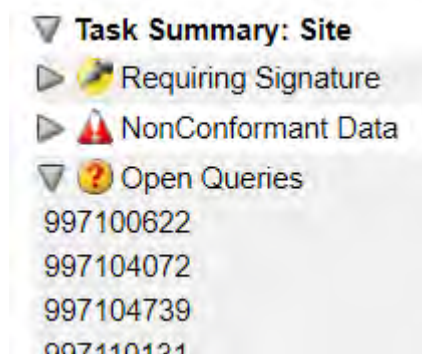
REMINDERS

To ensure that the data contained in the Medidata Rave database is complete and accurate it is important for sites to routinely review and enter or correct data in Rave. Following are some tools available to facilitate the process:

1. The Task Summary in Medidata Rave:



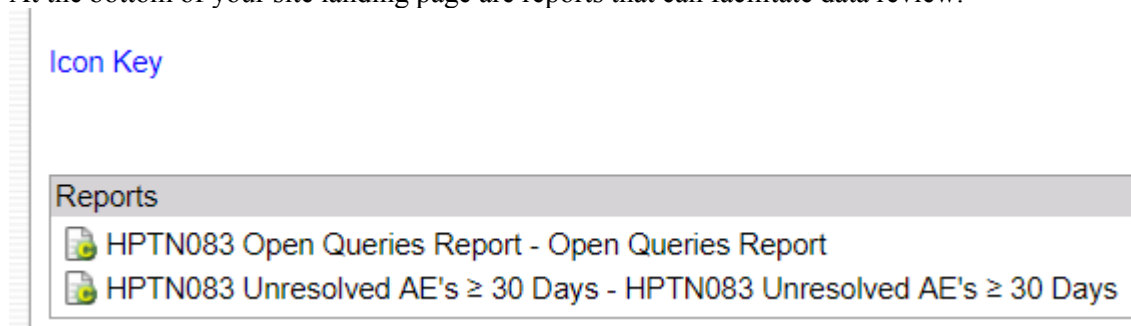
Clicking on any of the arrows under Task Summary: Site will show all PTIDs that fall into that category;



Clicking on a PTID takes you directly to the item(s) needing review or correction.

2. Reports in Rave

At the bottom of your site landing page are reports that can facilitate data review:





HPTN083 Data Communiqué #2 - Corrected

19 June 2019

This is official study documentation for the HPTN083 trial. Please print and circulate among relevant staff for review, and file it with your HPTN083 SSP Manual. This document is considered part of the SSP manual.

1. REMINDER

Syphilis test results: Per the protocol, any reactive syphilis result (treponemal or non-treponemal) must be referred to the CMC for adjudication, accompanied by any prior testing and treatment results. This requirement is irrespective of any previous reporting to the CMC; that is, every test that results as reactive or positive during study conduct must be referred to the CMC. Sites are also required to mark a “yes” or “no” response in MediData Rave to the question, “Did the CMC designate an incident Syphilis infection at this visit?” if a reactive result has been recorded at that visit. The response to this question should be consistent with the CMC’s response to the site’s adjudication request email.

2. UPDATE

Participant Transfers: When initiating a participant transfer to another site please copy the alias ‘sc.083cdm@scharp.org’. Data managers included on the alias will facilitate the process within MediData Rave. Please also allow 2-3 business days after the Transfer form has been completed and the IoR has signed off on all forms for the participant casebook to be transferred to the receiving site. Appendix IV of the SSP - ‘Participant Transfer and Receipt Process within Medidata Rave - has been updated to reflect this addition.

HPTN083 Data Communiqué #3

5 July 2019

This is official study documentation for the HPTN083 trial. Please print and circulate among relevant staff for review, and file it as appropriate.

SUMMARY

The following updates are being made to the clinical database in response to 1) an FDA-required request to collect vital signs retrospectively for all participants, 2) the need to code concomitant medications, 3) the study team decision to remove empty or unused Step 3 Day 0 folders. In addition, updates are being made to correct identified issues in the data collection system and to add or fix several edit checks. The database migration will occur on the afternoon of 5 July 2019.

UPDATES

1. New Vital Signs eCRF

Per FDA requirement, blood pressure, weight, and pulse will be collected for all participants at designated visits. The form will be added during the database migration to each required visit folder and will show as overdue in the Task Summary for all past visits.

SITE ACTION REQUIRED: Complete this form retrospectively for all participants at Enrollment, Weeks 2 and 4, all injection visits, and all Step 3 visits. Important note: this form will not be included in the calculations for the Data Management Quality report.

2. Concomitant Medications eCRF

Concomitant Medications will be coded at SCHARP using WHO drug codes, similar to Adverse Event coding. Sites may receive queries over time asking for clarification or corrections to complete the coding process.

3. Removal of empty Step 3 Day 0 folders

As documented in Data Communiqué #2, all future Step 3 Day 0 visits will be combined with the participant's last Step 2 visit. All empty/unused Step 3 Day 0 folders will be removed from the database during this database migration. Data already entered in a Step 3 Day 0 folder will remain in that folder.

4. Participant Transfer eCRF

The item 'Visit Code of last completed contact with participant' now includes "interim visit" as a selection. A new item, 'Interim Visit Code', has been added.

5. Product Hold eCRF

a) The option "low oral adherence (<75%)" has been replaced with 'low oral adherence' to accommodate different allowable adherence levels found in versions 1 and 2 of the protocol.

b) The item "If product hold was associated with an Adverse event, select the applicable AE" has been revised to allow up to 3 AEs to be linked to one product hold.



6. HIV Test eCRF

The item “Mark if specimen drawn for confirmatory testing” has been removed from all completed and unused forms. The data for all previously checked items is preserved in the database but not visible in Rave. Existing data is still viewable by sites in the audit trail.

7. Injection Site Reaction eCRF

Onset date and outcome date now allow for unknown dates. If full date is not known, “UN” can be entered in the day portion of the date.

8. Hepatitis Test Results eCRF

The item “Anti-Hepatitis C Antibody (anti-HCV)” now has an option for “not done”. Sites do not need to retroactively select this item for completed forms.

9. Demographics eCRF (Argentina sites only)

Race categories have been updated to include site-approved options.

SITE ACTION REQUIRED (Argentina sites only): Update Race selection for all participants who have a completed Demographics form by selecting appropriate response and re-save form.

10. Miscellaneous

Additional system queries have been programmed to complement the mentioned form changes and to further assist with cleaning data.

Several misfiring system queries have either been fixed or removed.

HPTN083 Data Communiqué #4

09 January 2020

This is considered an official study document for the HPTN083 trial. Please print and circulate among relevant staff for review, and file as appropriate.

SUMMARY

The following updates are being made to the clinical database in response to the release of Protocol Version 3.0. In addition, updates are being made to correct identified issues in the data collection system and to add or fix several edit checks. The database update is expected to occur on the afternoon of 10 January 2020 (PST).

UPDATES

1. Capping the duration of follow-up

1a. Removal of Injection Administration eCRF at Week 153/ Visit 43.0

In accordance with protocol version 3.0, participants who complete 3 years on blinded study product will be transitioned to Step 3 and provided open-label TDF/FTC. This timeframe coincides with Week 153 / Visit 43.0, an injection visit. To avoid confusion, the Injection Administration form has been removed from all untouched (unused) Visit 43.0 folders. Note: Because this is an expected transition to Step 3 a Product Hold form is NOT required. However, it is still required to mark “yes” to “Moving to Step 3?” on the Date of Visit form at the last Step 2 visit.

SITE ACTION REQUIRED: If your site does not yet have IRB approval of protocol V3.0 and a participant is scheduled for visit 43.0, contact the 083 CDM alias (sc.083cdm@scharp.org) to request the injection form be re-added for this participant.

1b. Removal of all untouched (unused) Step 2 visit folders from Week 155 / V44.0 onward

All untouched (unused) Step 2 visit folders from Week 155 / V44.0 onward have been removed. Any visit folders with data present will remain in the database.

SITE ACTION REQUIRED: If your site does not have IRB approval of protocol V3.0 and a participant is scheduled for a Step 2 visit 44.0 or greater, contact the 083 CDM alias (sc.083cdm@scharp.org) to request the folder be added for this participant.

2. Supplemental HIV Test Results eCRF

This new eCRF documents HIV 1 / 2 discriminatory and DNA test results as well as the Lab interpretation. The eCRF can be added as needed to any visit folder by marking the box under “Additional Forms or Procedures” on the Date of Visit or Interim Visit Summary eCRF.



Statistical Center for HIV/AIDS
Research and Prevention

SCHARP
at FRED HUTCH



Form: Supplemental HIV Results

Generated On: 16 Dec 2019 17:53:52

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done ☐

OR

Specimen Collection Date

Assay Result

Assay result not provided ☐

HIV Negative ☐

HIV-1 Positive ☐

HIV-2 Positive ☐

HIV-2 Positive with HIV-1

Cross-Reactivity ☐

HIV-1 Positive, Untypable ☐

HIV-1 Indeterminate ☐

HIV-2 Indeterminate ☐

HIV Indeterminate ☐

Other ☐

Other assay result:

Comments (max. 200 characters)

Laboratory Reported HIV Interpretation

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported ☐

OR

Interpretation

HIV Negative ☐

HIV-1 antigen and HIV-1/HIV-2

antibodies were not detected. ☐

No laboratory evidence of HIV

infection. ☐

HIV-1 antibodies were not
confirmed and HIV-1 RNA was
not detected. ☐

HIV-1 Positive ☐

HIV-2 Positive ☐

HIV-2 Positive - This result is

distinct from HIV Positive, ☐

Untypable. ☐

HIV Positive ☐

Acute HIV-1 Positive ☐

HIV-1 Negative, HIV-2

inconclusive ☐

Inconclusive ☐

Other ☐

Other interpretation:

Comments (max. 200 characters)

HIV DNA



Statistical Center for HIV/AIDS
Research and Prevention

SCHARP
at FRED HUTCH



Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:

Not performed/Not reported by Lab (add comment) ☐

OR

Specimen Collection Date

DNA Result

Detectable DNA result (record below) ☐

Detectable DNA, but below limit of detection (<4.09 copies per million cells) ☐

Detectable DNA, above the reportable range of the assay (>100 copies per million cells) ☐

Undetectable DNA, below limit of detection (<4.09 copies per million cells) ☐

Detectable DNA result:

Fixed Unit: copies per million cells

Comments (max. 200 characters)

SITE ACTION REQUIRED: All available past test results must be entered in Medidata Rave in the appropriate visit folder. Note: this form is not included in the calculations for the Data Management Quality (DMQ) report and new data will not be counted as late entries.

3. Vital Signs eCRF

Height has been added to the Vital Signs eCRF and is required at the enrollment visit for all participants, past or current.

SITE ACTION REQUIRED: Complete the height item retrospectively for all participants at the Enrollment visit only. This item can remain blank for all other visits where Vital Signs are collected. Note: To facilitate completion of this item a query for missing data will appear for all participants on the Enrollment Vital Signs form until the data is entered:

Height (Complete at Enrollment only)

? Height is required at enrollment. Please review.
Opened To Site from System (08 Jan 2020)



Please enter Height and save the form *without* responding to the system query (example above); doing so will automatically resolve the query. Note: This is a system-generated query and will not be counted in the DMQ metrics.

4. HIV Test Results eCRF Revised

‘Indeterminate’ has been added to the “HIV 4th or 5th Gen Ag/Ab” as a result option:

Page: HIV Test Results

Specimen Collection Date	<input type="text"/>	...	<input type="text"/>
Mark if specimen drawn for confirmatory testing	<input type="checkbox"/>		
HIV Rapid 1	<input type="radio"/> Non-reactive/Negative <input type="radio"/> Reactive/Positive		
HIV Rapid 2	<input type="radio"/> Non-reactive/Negative <input type="radio"/> Reactive/Positive <input type="radio"/> Not Done		
HIV 4th or 5th Gen Ag/Ab	<input type="radio"/> Non-reactive/Negative	<input type="radio"/> Reactive/Positive	<input checked="" type="radio"/> Indeterminate
HIV-1 RNA Qualitative	<input type="radio"/> Non-reactive/Negative <input type="radio"/> Reactive/Positive <input type="radio"/> Not Done		

SITE ACTION REQUIRED: All past HIV 4th/5th results previously reported to the site as indeterminate should be entered into Rave.

5. Local Lab Results eCRF

The following instruction has been added below the Glucose Severity item:

Glucose Severity Grade
If participant is fasting at any visit, please mark ‘yes’ for “Did the participant fast for at least 8 hours prior to blood collection?” in Lipid Profile section.

Marking this fasting item will ensure that severity grade programming uses the correct ranges to compare to the site-entered severity grade.

SITE ACTION REQUIRED: On existing lab grade queries for Glucose, please review chart notes to confirm whether the participant was fasting at a non-fasting visit and mark the fasting item as appropriate.

6. Date of Visit eCRF and Interim Visit Summary eCRF

6a. In the “mark any additional forms” section the following label has been *removed*:

Mark at Step 3 visits as needed:
HIV Test Results
Interviewer Administered: Follow Up 1
Study Medication Satisfaction Questionnaire (SMSQs)

6b. The option to add Supplemental HIV Results or Vital Signs eCRFs to a folder has been added on the Date of Visit form. On the Interim Visit Summary, the option for Supplemental HIV Results only has been added.

HIV Test Results

Interviewer Administered: Follow Up 1

Study Medication Satisfaction Questionnaire (SMSQs)

→ Supplemental HIV Results

→ Vital Signs

SITE ACTION REQUIRED: None.

6c. The below question:

Did the participant exit/terminate the study at this visit?

→ Is the participant confirmed HIV infected? ?

Is the participant ready to move to Step 3? ?

has been revised to read,

Did the participant exit/terminate the study at this visit?

→ Is participant moving to infected visit schedule? ?

Is the participant ready to move to Step 3? ?

This change accommodates those participants who have not yet been confirmed infected but for whom sites have been instructed to move to the infected schedule. This box should be marked only at the first visit where the participant has been moved to the infected schedule.

SITE ACTION REQUIRED: None.

7. Injection Site Reaction instructions corrected

The SAE section of the Injection Site Reaction form has been corrected to match the wording found on the AE form:

Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?
If "No", go to following question.

If "Yes", check all that apply.

SITE ACTION REQUIRED: None.

8. Missed Yearly Visits

The Yearly Visit Summary form has been updated to include the following item:

Page: **Yearly Visit Summary - Yearly Visit (1)**

Did the participant complete this visit?

☒ Yes ☐ No

SITE ACTION REQUIRED: If a participant on the yearly visit schedule will not be attending a yearly visit, please create a new yearly folder and mark “no” to the new item. This should also be done retroactively for participants that have already missed a yearly visit. Marking “no” will generate a Missed Visit form in the same folder.

9. Product Hold for open-label Truvada (Step 3 study product)

The Product Hold form has been revised to include the following item:

Mark if this hold is for Step 3 open-label product: ☐

Some participants may not initiate open-label Truvada or it may be held or permanently discontinued; in those cases, a Product Hold form is required.

SITE ACTION REQUIRED: Any form previously completed for an open-label Step 3 study product hold or permanent discontinuation must be re-entered with the new box marked.

10. ART eCRF revised

For consistency with Concomitant Medications, the item, “Or mark if continuing at end of study” has been added:

Date Stopped

Or mark if continuing at end of study ☐

A response to either Date Stopped or ‘continuing at end of study’ is required when a participant taking ART terminates.

SITE ACTION REQUIRED: Please update the ART form by marking the new box for any participant who was on non-study provided ART at the time of termination.

11. Interim Visit Summary eCRF

The Interim visit code can now accommodate up to two decimals (xx.xx) if needed. This is needed for participants who have more than nine interim visits between two protocol-required visits. Please note that interim visit codes are based on the previous visit code, not the previous week.

Visit date

Interim visit code

SITE ACTION REQUIRED: None.

Miscellaneous

Additional system queries have been programmed to complement the mentioned form changes and to further assist with cleaning data. Some misfiring system queries have either been fixed or removed.

HPTN083 Data Communiqué #5

02 April 2020 (**Corrected Version**)

This is considered an official study document for the HPTN083 trial. Please print and circulate among relevant staff for review and file as appropriate.

SUMMARY

Per regulatory guidance, the following data conventions have been developed to identify and track COVID-19 related data issues with respect to study visit conduct. These general guidelines have been established to record study assessments and/or visits that are incomplete or missed. If more specific data questions or more complicated scenarios arise that are not covered in this communiqué please contact the Clinical Data Management (CDM) alias, sc.083cdm@scharp.org, for further guidance.

UPDATES

1. Missed visit:

The following guidance applies when an entire study visit is missed due to COVID-19 restrictions/issues. This applies to visits in all Steps of the study.

CRF COMPLETION REQUIREMENTS:

Missed Visit CRF: Select “Other” for the reason visit was missed and enter “COVID” in the Other, specify field.

Note: *the text “COVID” must be recorded consistently in order to be identified programmatically.*

2. Phone/video visit (video via Skype or similar platform):

Record as Interim visit.

CRF COMPLETION REQUIREMENTS:

Interim Visit Summary CRF: Mark any forms or procedures performed and submit data accordingly. Also ensure the ongoing log forms are updated as appropriate, including but not limited to AE, Con Meds, Product Hold/Discontinuation. Any assessment that requires a visit code must be consistent with the interim visit code.

3. Minimal/partial visit

Participant is seen and only minimal assessments are performed that do not include HIV testing, lab testing, and/or specimen collection and storage (any other assessment(s) beyond these will be considered a minimal/partial visit). Record as Interim visit in the same manner as item 2.

4. Normal study visit/ most assessments complete (must include HIV/Specimen collection and storage):

The following guidance applies if some expected assessments are missed within a normal study visit. This applies to visits in all Steps of the study.

CRF COMPLETION REQUIREMENTS:

For CRFs with “Not Done” responses, complete the forms accordingly. For those where this is not an option, save the CRF with missing data and respond to the first query with “COVID”; the SCHARP CDM team will cancel any remaining queries.

If an entire CRF is missed and does not have a lead-in Yes/No question, save the form blank. Respond as indicated above to the first query that fires; the SCHARP CDM team will cancel any remaining queries.

5. Product Holds:

For all product holds due to COVID-19:

CRF COMPLETION REQUIREMENTS:

Product Hold/Discontinuation CRF: Select “Other clinical reason” for the reason product was held and enter “COVID” in the Other, specify field.

Step 2 participants who temporarily hold injections and receive PrEP from outside the study will remain in Step 2; enter the medication on the Concomitant Medications CRF, including start and stop dates to the extent possible.

CLARIFICATIONS

1. **Adverse Event reporting of COVID-19.** If a participant is suspected or confirmed to have COVID-19, report “COVID-19” in Rave as the event term and/or if it meets the ICH seriousness criteria please submit an EAE report to DAIDS. Refer to the DAIDS functional table to determine grade.
2. System queries may fire due to missed or inconsistent data. Answer queries by responding with “COVID”.
3. CASI surveys must only be administered in the clinic during a regular visit.
4. **Protocol Deviation reporting:** In accordance with the Division of AIDS, additional guidance will be issued regarding reporting deviations that meet the definition of reportable per Section 3.4 of the HPTN 083 Study Specific Procedures (SSP) Manual. In the meantime, the instructions included in Section 3.4 of the SSP Manual should be followed to the extent possible, given site-specific circumstances. Deviations that result specifically due to the COVID-19 situation should be documented accordingly.
5. **Data Management Quality Reports:** Production and posting of this report on Atlas will be suspended until further notice; study leadership will determine how to exclude COVID-19 related delays in CRF submission and query resolution. SCHARP continues to review and clean data which may result in new queries. Sites should do their best whenever possible to submit CRFs and resolve queries in a timely manner, however, it is recognized that this may not be possible in many situations.

HPTN083 Data Communiqué #6

13 April 2020

This is considered an official study document for the HPTN083 trial. Please print and circulate among relevant staff for review, and file as appropriate.

SUMMARY

The following update is being made to the clinical database. The database update is expected to occur on 15 April 2020 at 2 pm PST.

Revision to the Interim Visit Summary form:

Due to the COVID-19 pandemic and related clinic service interruptions, many sites are conducting partial visits and submitting them as interim visits. The Interim Visit Summary form now has the option to select one or more behavioral surveys or assessments as needed for an interim visit:

Mark any forms or procedures completed at this visit.	
CD4/viral load	<input type="radio"/> Yes
Hematology	<input type="radio"/> Yes
Hepatitis Test Results	<input type="radio"/> Yes
HIV Test	<input type="radio"/> Yes
Electrocardiogram	<input type="radio"/> Yes
Local Laboratory Results	<input type="radio"/> Yes
Participant Receipt	<input type="radio"/> Yes
Participant Transfer	<input type="radio"/> Yes
Sexually Transmitted Infections	<input type="radio"/> Yes
Specimen Storage	<input type="radio"/> Yes
Log Form	<input type="radio"/> Yes
Supplemental HIV Results	<input type="radio"/> Yes
Interviewer Administered: Follow Up 1	<input type="radio"/> Yes
Interviewer Administered: Follow Up 2	<input type="radio"/> Yes
Study Medication Satisfaction Questionnaire (SMSQs)	<input type="radio"/> Yes
Post-injection Exercise Assessment	<input type="radio"/> Yes

HPTN083 Data Communiqué #7

05 June 2020

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

SUMMARY

The following updates are being made to the clinical database in response to the release of LoA#1, dated 19 May 2020 to V3.0 of the study protocol, dated 31 October 2019. The database update is expected to occur on the afternoon of 5 June 2020 (PST).

UPDATES

1. Participant Unblinding eCRF

This new form documents the date a participant is informed of their study arm assignment and should be completed for all enrolled participants, including those who have terminated. Complete when unblinding occurs or, if a participant is lost to follow up, do not complete until the end of study participation.

Page: Participant Unblinding

Only complete this form when participant has been contacted, or deceased. Otherwise, wait until the end of study follow-up to complete this form.

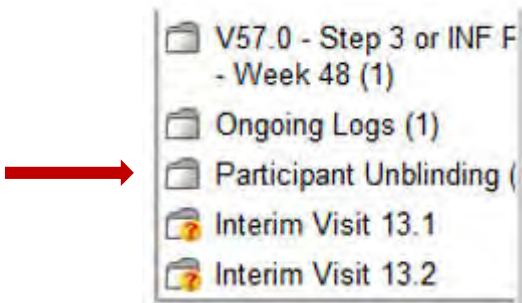
Was the participant informed of their study arm assignment (that is, active CAB or active Truvada)? ☐ Yes ☐ No

If yes, enter date / /

If no, mark reason ☐ Lost to Follow-up ☐ Other

Other, specify

The Participant Unblinding eCRF appears in the new Participant Unblinding folder, which is found below the Ongoing Logs folder for all enrolled participants.



2. Safety visits combined with Injection visits

Upon implementation of LoA #1, separate safety visits for all participants in Step 2 will no longer be conducted; safety procedures and evaluations will be performed at injection visits only. As part of the required safety evaluations, the Post-injection Exercise Assessment should now be done at all injection visits when an injection was given at the previous injection visit by marking the new box on the Date of Visit form; the SMSQs should be done one final time after participant unblinding and can be added by marking the existing box on the Date of Visit form.

If a participant unblinding visit coincides with a safety visit, it is up to investigator discretion whether to perform the safety visit procedures. If the safety visit procedures are done, record the visit and visit code as you normally would. If the safety visit procedures are not done, submit an Interim Visit Summary form to record the visit where unblinding occurred and leave the Safety Visit folder empty/untouched. At a future date SCHARP will remove unused Safety visit folders.

3. Date of Visit eCRF

A new check box has been added for the Post-Injection Exercise Assessment form. This allows sites to add the eCRF to injection visits as needed.

Mark any additional forms or procedures that took place at this visit

CD4/Viral Load	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Hepatitis Test Results	<input type="checkbox"/>
Electrocardiogram	<input type="checkbox"/>
Local Laboratory Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Sexually Transmitted Infections	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Interviewer Administered: Follow Up 1	<input type="checkbox"/>
Study Medication Satisfaction Questionnaire (SMSQs)	<input type="checkbox"/>
Supplemental HIV Results	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Post-Injection Exercise Assessment	<input type="checkbox"/>

4. Injection Administration eCRF

4a. A new check box has been added to indicate, after participant unblinding, that the injection being given is active CAB LA.

Page: Injection Administration

Reminder: All HIV test results from previous visits and at least one HIV test result from the current visit negative/nonreactive prior to injection of study product.

Was an injection given at this visit? ☐ Yes ☐ No

If injection was given:

→ Open label injection (active CAB LA) ☐

Injection Date ...

Needle Size

☐ 21 G x 1 ½ in (0.8mm x 40mm)
☐ 21 G x 2 in (0.8mm x 50mm)
☐ 23 G x 1 ½ in (0.6mm x 40mm)
☐ 23 G x 2 in (0.6mm x 50mm)
☐ 25 G x 1 ½ in (0.5mm x 40mm)
☐ 25 G x 2 in (0.5mm x 50mm)
☐ Other size

If other marked, record needle size

4b. A new reason has been added to document that an injection was not given because the participant is unblinded and no longer receiving placebo injections.

If injection was not given:

Indicate if injection was missed, refused, or permanently discontinued

Printable Version Icon Key

CRF Draft 65 - Page Generated: 02 Jun 2018

Injection missed
Injection refused
Injection schedule permanently discontinued
Unblinded active Truvada participant (no longer receiving placebo injection)

Note: A Product Hold/Discontinuation form should not be completed for participants who stop placebo injections.

5. Behavioral Questionnaires

For all participants, the interviewer-administered questionnaires and computer-assisted self-interviewing surveys (CASI) will be completed one last time at the next scheduled visit at which these assessments are scheduled to occur. Following that visit, these assessments will no longer be administered.

SMSQs

This survey is only required at safety visits. Since safety visits will be combined with injection visits, the survey can be done one last time at any Step 2 visit on or after participant unblinding by marking the box on the Date of Visit or Interim Visit summary to add it to the visit folder.

CASI

Complete a final CASI at the next scheduled visit where it is expected to occur.

Interviewer Administered Follow-up 1 and Interviewer Administered Follow-up 2

Complete *either* a final Follow-up 1 or Follow-up 2 at the next scheduled visit where it is expected to occur. For example, if Follow-up 1 is expected at the next scheduled visit, do not also administer Follow-up 2 at a later visit, and vice versa.

For any visits where a behavioral assessment automatically appears in a visit folder after the final survey was completed, do either of the following:

1. Mark the 'Survey not done' box at the top of the form:

Survey not done



2. Or, if the 'not done box' is not present, save the survey blank and respond only to the first query with a comment, "survey not done". Any remaining queries will be cancelled by SCHARP.

HPTN083 Data Communiqué #8

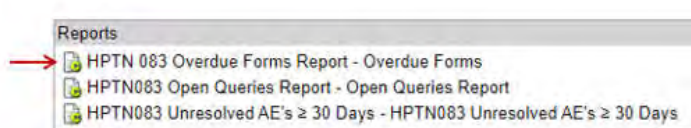
10 July 2020

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

UPDATES

- Overdue Forms Report** Sites now have access to this report on their dashboard below the list of PTIDs:

[Icon Key](#)



Forms Overdue

Site Name	Subject Name	Instance Name	Data Page Number	Is Touched	Is Overdue	Overdue	No. of days overdue
US SCHARP	997503790	V5.0 - Week 5: HIV Test Result		0	1	2/8/13	2,707
US SCHARP	997503790	V5.0 - Week 5: Injection Adm		0	1	2/8/13	2,707
US SCHARP	997503790	V5.0 - Week 5: Interviewer Ar		0	1	2/8/13	2,707

This tool can help sites identify forms that are expected but not yet completed. The report is sorted by PTID and includes Visit, Form Name, Overdue 'as of' date, and number of days the form is overdue. This report can be run as needed and exported to Excel for sorting and filtering. Forms are not shown as overdue until at least 14 days have passed since the target. Date of Visit forms are not included in these reports but should be part of site review for overdue visits.

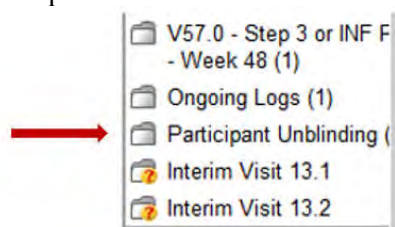
- Unresolved ISRs ≥ 30 Days Report** Sites will soon have access to this report on their dashboard below the list of PTIDs and is similar to the **Unresolved AEs ≥ 30 Days Report**. This tool can help sites review and close out Injection Site Reactions that have no Outcome Date; if an Outcome Date is added to the ISR log line it will be removed from future reports. This report can be run as needed and exported to Excel for sorting and filtering.

CLARIFICATIONS

- Transitioning to Step 3:**
 - Per Version 3.0 of the protocol, participants who reach Step 2 Week 153 will transition to Step 3 at that visit. A product hold form is not required, but "Moving to Step 3" should be answered 'yes' on the Date of Visit form.

- b. If Week 153 is missed and the visit window has closed, complete any Day 0 requirements at the next visit if they are not already required for that visit (e.g., Step 3 Week 12).
- c. When a participant transitions *early* to Step 3 (i.e., at any Step 2 visit prior to Week 153), data for that visit should be entered in the appropriate Step 2 folder as follows:
 - i. If a Step 2 visit window has opened, that visit folder should be used to record procedures required for that Step 2 visit as well as the Step 3 day 0 procedures.
 - ii. If a Step 2 visit has recently occurred and a new window has not yet opened, create an interim visit folder to record the Step 3 Day 0 procedures.
 - iii. A product hold form is required for any early transition to Step 3.

REMINDER Complete a Participant Unblinding form as soon as a participant is informed of their study arm assignment. The Participant Unblinding eCRF was added to the Rave database on 05 June 2020 and appears in the new Participant Unblinding folder, which is found below the Ongoing Logs folder for all enrolled participants.



When a terminated participant is contacted for unblinding complete only the Unblinding form; do not create an interim visit.

HPTN083 Data Communiqué #9

20 August 2020

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

UPDATES

1. Terminations

If a participant has relocated where there is no participating site or has been lost to follow-up for 6 months or more, it is at the discretion of the site investigator whether to keep the participant active in the study or to submit a Termination form. If a Termination form is submitted, the Unblinded Participant eCRF should also be completed.

In cases where a participant is unblinded and refuses further study medication, the site investigator may use their discretion to determine whether the participant should be terminated.

2. Safety Visit Folders

Once a participant is unblinded, Safety folders in Step 2 visits should be left untouched; please do not enter data on the Date of Visit form or save it in any safety visit folders. At a future date SCHARP will remove these unused or untouched Safety visit folders.

To best identify late or overdue forms, the **Overdue Forms Report** on the dashboard is a more efficient method than using the Overdue Data link in the Task Summary. Date of Visit forms are excluded from the Overdue Forms report.

3. Interviewer Follow-Up 1 and 2 eCRFs

Per LOA #1, these forms should only be administered once more after a participant is unblinded. However, these forms are still present in Step 2 Injection folders. If a survey is not administered, please save the form blank, then reply only to the first query indicating the survey was not administered due to participant unblinding.

These forms are reviewed by SCHARP on a regular basis and open queries are canceled; there is no need to write SCHARP to request their removal.

4. Post-Injection Exercise Assessment eCRF

This form is only required if an injection was given at the *previous* visit; it can be added to an Injection visit folder by marking that box on the Date of Visit form. The Post-Injection Exercise Assessment form is no longer required for participants if an injection was not administered for any reason.

5. CASI Surveys

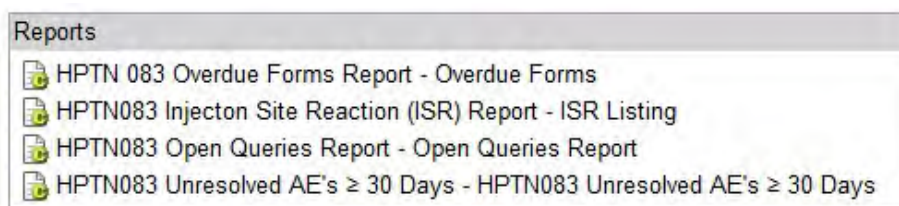
Per LOA #1, CASI surveys only need to be administered once after a participant is unblinded. CASI surveys should only be administered at scheduled visits and not be administered retroactively.

6. Date of Visit eCRF

Pills are no longer dispensed to unblinded participants on the CAB LA regimen. On the Date of Visit form, leave “How many bottles were lost, stolen, or damaged since the last pill dispensation?” blank. Respond to the system query in Rave by entering “unblinded CAB LA participant”. **Data Cleaning Process**
SCHARP is currently doing a thorough data cleaning to ensure the database is complete and accurate. As a result, you may see a rise in the number of queries in Rave and some may be on older data. While all queries need to be addressed, please pay close attention to any query with “Priority” in the text as those corrections may be needed for analyses.

7. Open Queries Report

Sites have access to the Open Queries report on their dashboard below the list of PTIDs:



OPEN QUERIES REPORT-SITE

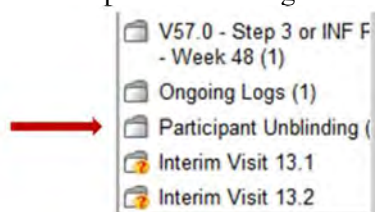
8/19/20

Site Name	PTID	Folder Name	Form Name	Log Number	Query Open Date	Query Status	Query Text
US SCHARP	997100622	Ongoing Logs (1)	Adverse Event	1	10/11/18	Open	Data is required. Please complete.
US SCHARP	997100622	Ongoing Logs (1)	Adverse Event	1	10/11/18	Open	Data is required. Please complete.
US SCHARP	997100622	Ongoing Logs (1)	Adverse Event	1	10/11/18	Open	Data is required. Please complete.

This report is useful in identifying priority queries as part of the data cleaning process (see above). Once the report is exported as an Excel file, it can be sorted by query text to identify queries that begin with “Priority” or by any other column as needed.

REMINDER

The Participant Unblinding form is found in the Participant Unblinding folder for all enrolled participants:



Complete the unblinded form as soon as a participant has been unblinded or if a participant is terminated and lost to follow-up or relocated.

HPTN083 Data Communiqué #10

16 September 2020

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

UPDATES

1. Pill Count – Follow Up

Pill Count CRFs are only mandated by the study at enrollment and weeks 2 and 4, as well as week 5 if not done at the previous visit. Forms that were programmed in error in other follow-up folders have been removed from Rave, including those containing data.

2. Data Freeze

As part of the data cleaning process SCHARP has begun freezing forms in Rave. A frozen form shows the ‘key’ icon checked:



Subject: 993248689
Page: Enrollment - V2.0 - Day 0/Enrollment (1)

Is the participant enrolling in the study?
"Did the participant enroll in the study?" is "Yes" but data items on the Inclusion/Exclusion are blank or indicate participant is not eligible.
Opened To Site from System (18 May 2020)

If participant did not enroll, skip to "Which version of the Sex Pro Tool was used?" and complete remaining items.

Enrollment Date: 1 Feb 2020

Did the participant consent to having blood stored and used for future testing? Yes

Did the participant consent to genetic testing? No

Did the participant consent to participating in the DXA substudy? N/A (slots filled or site not participating)

What is the CASI ID assigned to this participant? XYZ

Did or will the participant complete the enrollment CASI questionnaire? No

Which version of the Sex Pro Tool was used? South America

Record participant's Sex Pro score: 6

Queries may be responded to on a frozen form, but no data can be added or changed. If you need to revise data on a frozen form please contact the SCHARP data management team at sc.083cdm@scharp.org.

CLARIFICATIONS

1. Participant Unblinding at an Interim Visit

For participants who are unblinded outside of a regular protocol visit, an interim visit form is required; this includes unblinding via phone. The only exception to this is terminated participants – no interim form should be completed if unblinding is done after termination.

2. AE alternate etiology

The Adverse Event form contains an alternate etiology item to be completed if the AE has been deemed unrelated to study product. Study leadership confirms that a response to this item is required ONLY IF an alternate etiology is established, otherwise, the item should be left blank. The CRF Completion Guidelines will be updated to reflect this instruction. If the alternate etiology item on a previously entered AE is blank, please DO NOT update the form as doing so will cause the MedDRA coding and review process to be re-initiated, which will interfere with SCHARP's ability to freeze data in a timely manner.

HPTN083 Data Communiqué #11

19 October 2020

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

In preparation of the upcoming data submission for HPTN083, we are working on cleaning the data, freezing and locking the CRFs for all visit data that occurred prior to and including 14May2020.

Below are the timelines for each milestone. At this time, data freeze has been achieved. PI signatures and Data Lock are pending.

MILESTONE	TARGET DATE
Data freeze	14 October 2020
PI Signature	4 December 2020
Data Lock	15 December 2020

Once the data freeze is complete, CRF data cannot be modified. Queries can however be raised and responded to in Rave.

Data lock will occur once the respective data are frozen and PI signatures are complete. Once data lock occurs, there can be no further modification on the respective data items including CRF changes, queries etc.

We understand that the sites are still doing internal QC and monitoring is in process thereby resulting in data update requests. In addition, there are still open queries that have not been completely resolved. Please note we will start unfreezing the CRFs based on site requests. Please ensure to follow the below instructions:

- Request only the specific CRF which needs update instead of the entire PTID or visit.
- Combine your requests on a single email versus multiple emails on the same day.
- Use the data managers alias (sc.083cdm@scharp.org) and do not send requests to individual data managers.

Please ensure all the QC is completed as soon as possible as we will not be able to unfreeze or allow any data change after the data lock deadline.

HPTN083 Data Communiqué #12

9 November 2020

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

1. CASI listing on ATLAS

A CASI listing report is now available on ATLAS. The listing contains details of all surveys submitted into the Illume database (i.e. CASI database). In addition to all submitted surveys, the report also identifies mismatches between Rave and Illume under the column titled “Discrepancy?”.

This report should be used to check for submitted CASI surveys and help you respond to queries posted by SCHARP. Moving forward, please do not use Illume to check whether a survey was submitted. Using Illume for that purpose introduces discrepancies between Rave and Illume and must be reconciled by SCHARP.

Permissions for the report were given to all study coordinators and data managers at sites. The link for the report is below.

<https://atlas.scharp.org/cpas/project/HPTN/083/CASI%20Completion/begin.view?>

2. Preparation for HPTN083 data submission of data for ALL visits that occurred prior/on 14-May-20

- A. **SIGNATURES:** IoR and/or their designees to sign off on by 4-Dec-20.
- B. **DATA CHANGES:** Data requiring revision should be edited as soon as possible. After 15-Dec-20, the data will be locked for editing.
- C. **OPEN QUERIES:** Please answer queries promptly.

MILESTONE	TARGET DATE
IoR/designee Signature	4 December 2020
Data Lock	15 December 2020

HPTN083 Data Communiqué #13

3 February 2021

This is considered an official study document for the HPTN083 trial. Please circulate among relevant staff for review, and file as appropriate.

CASI survey for Visit 43 - Week 153/Step 3 Day 0

For all participants that conduct Visit 43 - Week 153 under protocol version 3, where Visit 43 - Week 153 is combined with Visit Step 3 Day 0, administer the CASI survey for Step 3 Day 0. In Rave, mark “Did or will the participant complete the CASI questionnaire for this visit?” as “Yes” at Visit 43 – week 153.

REMINDER: A premature transition to Step 3 (protocol version 3)

For participants who transition to Step 3 **prematurely**, administer the CASI survey for Step 3 Day 0 at the last Step2 visit, unless the survey was done within the last 4 weeks prior to that visit.