

MTN-025 Data Communiqué #1 - September 19, 2016

This is official study documentation for MTN- 025. Please circulate it among relevant staff for their review, print it, and place it in your MTN-025 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-025 SSP manual.

UPDATES

CRF Updates (in order by CRF title) - The following CRFs have been updated to v2.0 (dated 07 September 2016) within the clinical database and/or the paper CRFs:

1. Baseline Behavior Assessment and Behavior Assessment

Minor wording updates have been made to items 11c1 on the Baseline Behavior Assessment and item 8c1 on the Behavior Assessment from “If yes, please specify” to only “Specify” to be consistent with translations. In addition, an instruction within the form has been updated to correct the specific items referenced (“Complete items 21-26 at PUEV or Early Termination visit only”).

2. Clinical Product Hold/Discontinuation Log

The “Date of last study product use” item on the Clinical Product Hold/Discontinuation Log CRF has been updated to include an additional response, “Participant never used the ring”. If a participant has never used the vaginal ring during HOPE and is placed on clinical product hold or permanently discontinued by a study clinician, leave the date field for this item blank and check the “Participant never used ring” box.

3. HIV Test Results

The Rapid HIV Test kit type item on the HIV Test Results CRF has been updated to include a ‘Not applicable’ response option. If a 4th generation test is not available and a 3rd generation test was used, select the “Not applicable” response for the applicable rapid HIV test kit type and contact the MTN Laboratory Center for further guidance.

4. Laboratory Results

The Laboratory Results CRF has been updated to include an additional item to specify the associated AE term and onset date for an abnormal value that meets AE reporting criteria. This “specify AE” item has been added to the Hemoglobin, Platelets, WBC, Neutrophils, Lymphocytes, AST (SGOT) and ALT (SGPT) items for completion during follow-up, as indicated.

5. Participant Transfer

The item “Last completed visit with participant” has been removed from the Participant Transfer CRF as this administrative question is no longer required within Medidata Rave. The Participant

Transfer CRF should be added to the last completed study visit at the transferring site within the Rave database by selecting this form within the Additional Study Procedures CRF (or the Interim Visit Procedures form if the last completed study visit is an interim visit).

6. Pharmacy Ring Dispensation

The Pharmacy Ring Dispensation CRF has been updated to remove the “Time vaginal ring(s) dispensed” item as it has been determined that the time at which each ring has been dispensed is not needed within the clinical database. In addition, the updated CRF allows for up to three vaginal rings to be dispensed at a study visit (i.e., the “Vaginal Ring #4” items have been removed from this CRF). Please refer to SSP section 9.1 for further guidance on ring dispensation.

7. Pelvic Exam

Two optional text fields have been added to the item “Were any new pelvic finding AEs reported at this visit?” in the event that more than one associated AE has been reported. Note that if a new pelvic finding AE is reported at a study visit (i.e., if this item is marked “Yes”), at least one AE term and onset date must be specified. For example, if a pelvic finding of cervical erythema is reported at a study visit and documented on the Pelvic Exam CRF, specify the associated AE within the first line provided and leave the two additional fields blank.

8. Seroconverter Laboratory Results

An erroneous item within the T CELL subsets item with response options ‘positive’ and ‘negative’ has been removed from the Seroconverter Laboratory Results CRF.

9. Social Benefit Log

The item “How many people did this benefit involve?” has been removed from the log form as this administrative question is no longer needed. If the reported social benefit involves someone other than the participant, select the type of relationship the social benefit involved for up to three persons (Person 1, Person 2, and/or Person 3).

10. Specimen Storage

The item requesting a reason when plasma is not ‘stored/not required’ at a study visit has been updated to be required only when plasma is ‘not stored’ at expected visits. If plasma storage is not required at a given visit, per protocol, a reason plasma is not required does not need to be specified and this item can be left blank.

11. Vaginal Ring Tracking Log

Additional rows have been added to the paper Vaginal Ring Tracking Log CRF to provide additional space in documenting the provision and receipt of vaginal rings throughout the study prior to data entry into the Rave database.

12. CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to v1.2 and is posted onto the MTN-025 Atlas webpage for download. Updates to form completion have been made to the following CRFs:

- Social Benefit Log
- Participant Receipt
- Pharmacy Ring Dispensation
- Vaginal Ring Tracking Log
- Physical Exam
- Vital Signs
- Family Planning Log
- Specimen Storage

A general note regarding completion of text fields in English has been added to interviewer-administered form completion guidance.

CLARIFICATIONS

1. Ring Adherence CRF completion at Interim Visits

Note that the Ring Adherence CRF is not completed at interim visits; this form should be completed at the required Monthly, Quarterly, Semi-Annual, and PUEV visits only. If a participant returns a vaginal ring at an interim visit, complete the applicable row on the Vaginal Ring Tracking Log to document ring return and per-participant reported ring use, and complete the Ring Adherence CRF at the participant's next scheduled study visit.

REMINDERS

1. Case Report Form (CRF) pdf files and CRF Completion Guidelines for printing on Atlas

The CRF visit packet pdf files and the current version of the CRF Completion Guidelines are available on the MTN-025 Atlas webpage for sites to print and complete, as needed, prior to data entry into the Rave study database, as specified in site specific Source Documentation SOP.

Click on the “+” to the left of each heading to expand the section.

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Visit Packets and Individual CRFs

Case Report Forms		
Document:	Language:	Page size:
Complete Set (Alphabetical)	English	A4
MTN-025 CRF Completion Guidelines	English	A4

Visit Packets		
Document:	Language:	Page size:
Pre-Screening	English	A4
Decliner Population Screening/Enrollment	English	A4
V1 - Screening Visit	English	A4
V2 - Enrollment Visit	English	A4
V3 & V4 - Month 1 and Month 2 Visits	English	A4
V5, V6 & V7 - Month 3, Month 6, and Month 9 Visits	English	A4
V8 - Month 12/PUEV	English	A4
V9 - Study Exit Visit	English	A4
Early Termination Visit	English	A4

To open the pdf, click on “A4” under the “Page size” column.

2. MTN Data Request Form

The MTN SCHARP Data Request Form is available on the MTN-025 “Study Implementation Materials” study webpage (<http://www.mtnstopshiv.org/node/7330>) and should be completed for any ad hoc data requests such as site IRB/regulatory submissions during the study. Please complete this form and email it to the HOPE Clinical Data Managers and Statistical Research Associates.