MTN-025 Data Communiqué #6 - April 21, 2017

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

1. CRF UPDATES

The following CRFs have been updated within the clinical database:

Baseline Behavior Assessment and Behavior Assessment

The Baseline Behavior Assessment has been updated to include an additional item 15a:

- In the past 12 months, has anyone (not including current or past sexual partners) ever forced you to have sex by holding you down or hurting you?

The Behavior Assessment has been updated to include an additional item 13a:

- In the past 3 months, has anyone (not including current or past sexual partners) ever forced you to have sex by holding you down or hurting you?

These questions should be asked to all participants enrolled into the main study or decliner population starting on 24 April 2017. These items should not be completed retroactively for participants who have already completed the Baseline Behavior Assessment or Behavior Assessment.

Study Exit Assessment

Item 8 on the Study Exit Assessment has been updated to remove the implication the participant used the ring and is now worded as the following:

- In the future, if a vaginal ring similar to the one used in this study becomes widely available for HIV prevention, would you be interested in using it for HIV prevention?

Concomitant Medications

The Concomitant Medications Log has been updated to include three additional drop-down menus to specify the associated AE term and onset date in the case that a medication is provided for more than one AE.

If a Concomitant Medications Log eCRF has already been completed and there is more than 1 associated AE, sites should update the existing Concomitant medications Log eCRF to link the applicable AE(s).

HIV Test Results

The kit type for Rapid HIV Test 1 and Rapid HIV Test 2 now includes an additional item "If Not applicable, specify". If "Not applicable" is selected, then specify in this field the specific kit used. For example, if the back-up kit Alere Determine was used, select 'Not applicable' for Rapid HIV Test 1 and then specify "Alere Determine" in the "If Not applicable, specify" text field.

Laboratory Results – Selection of Site Laboratory

Sites will no longer need to select the site laboratory at the top of the eCRF in order to populate lab-specific analyte reference ranges and units. This will automatically be defaulted to your local site lab so that the ranges and units of measurement for each analyte at the bottom of the form populate.

2. DATABASE UPDATES

As part of the MTN-025 clinical database migration, multiple system queries and fields have been updated and corrected. The following updates have occurred within the clinical database:

Additional Study Procedures Y/N

The CRFs listed on the Additional Study Procedures Y/N are no longer required fields and system queries will no longer be placed if a response is left blank. Forms that are added for 'as indicated' procedures can be selected 'Yes'. All other forms can be left blank if they were not completed at the study visit. For example, if only a pelvic exam was performed (clinically indicated), select 'Yes' for "Pelvic Exam" and leave all other items blank. Once the form is saved, the Pelvic Exam eCRF will dynamically add to the associated visit folder to be completed.

Partial Dates

Partial dates are now allowed on the following forms and fields:

- Adverse Experience Log: Outcome date (month and year are required)
- Ring Collection and Insertion: When was a ring last in place? (month and year are required)

Visit Code Notation

The visit code assigned to each study visit should be in the format 'X.XX' on the following forms:

- Vaginal Ring Tracking Log
- Social Benefit Log
- Social Impact Log

If the visit code is not entered in the correct format, a non-conformant query will be placed to update the visit code into the appropriate format.

Laboratory Results

The number of digits on the Laboratory Results eCRF has been updated to accommodate sites reference ranges and values. When entering the lab value for each analyte, no rounding is required and the lab value can be entered directly from the site local lab report.

Concomitant Medications

The dose field on the Concomitant Medications Log eCRF has been updated to allow for characters. If a participant reports a combination drug, a '/' or '-' can be used (e.g. 5/500) to distinguish the different doses. If the dose is unknown, enter 'Unknown'.

Adverse Experience Log

The Comments field on the Adverse Experience Log has increased to allow for up to 400 characters to be entered.

3. CRF COMPLETION GUIDELINES (CCGs)

The CRF Completion Guidelines have been updated to v1.6 (dated 21 April 2017) and are posted on the MTN-025 Atlas webpage for download. In addition, a tracked version of all changes have been circulated with this Data Communique.

4. CRF Paper Updates

The paper versions of the following forms have been updated and are posted on the MTN-025 Atlas webpage:

- Baseline Behavior Assessment, Version 4.0, dated 05 January 2017 (English)
- Behavior Assessment, Version 4.0, dated 05 January 2017 (English)
- Study Exit Assessment, Version 2.0, dated 05 January 2017 (English)
- Concomitant Medications Log, Version 2.0, dated 21 April 2017
- Ring Collection and Insertion, Version 2.0, dated 21 April 2017
- HIV Test Results, Version 3.0, dated 21 April 2017

CLARIFICATIONS

1. Ring Collection and Insertion CRF

Item 4, "Did the participant accept to receive the ring(s) on a quarterly schedule?" on the Ring Collection and Insertion CRF should be completed only for those participants who choose to use a new ring at the visit (Item 3). If the participant has been placed on clinical product hold at the time of this visit or has been permanently discontinued from study product (i.e., if the response to Item 3 is "NA"), item 4 and 5 should be skipped. If the participant does not choose to use a ring at the visit (i.e., if the response to Item 3 is "No"), Item 4 should be skipped.

REMINDERS

1. The translations for all local languages (Zulu, Shona, Chichewa, Luganda, and Xhosa) of the interviewer-administered eCRFs are now available within the clinical database. Once your site-specific Source Documentation SOP has been updated and finalized, both the English and local-language versions of these eCRFs can be administered to participants while directly entering responses into Rave.

2. If an Adverse Event or a Concomitant Medication has been selected with dynamic search list functionality (e.g. Pelvic Exam eCRF or Concomitant Medications Log eCRF), and original data on the medication or AE description field or Onset Date/Date Started has been updated or if the log line was inactivated, the AE or CM search list will become non-conformant. Rave will request that you update the corresponding AE or CM field by re-selecting from the dynamic search list to correspond with the latest data so that it is no longer non-conformant.