MTN-025 Data Communiqué #2 - October 21, 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

1. CRF Completion Guidelines (CCGs) Updates

The CRF Completion Guidelines have been updated to v1.3 (dated 20 October 2016) and are posted onto the MTN-025 Atlas webpage for download. Updates to form completion guidance have been made to the following CRFs:

- Laboratory Results

  The section '*Lab Result Units and Rounding'* has been updated to reflect current guidance. The Laboratory Results eCRF within the Rave database contains the proper units next to each numerical lab result, as designated by each site laboratory reference value documentation. The units of measurement do not need to be recorded on the eCRF and no conversions are necessary when transcribing each analyte result into Medidata Rave.

- Concomitant Medications

  Instructions for completion of the field 'Medication Name' have been updated to clarify that the trade or generic medication name can be recorded on the Concomitant Medications Log CRF and should be based on participant report or other source documentation. If a medication is reported with its generic name, document the generic name on the Log CRF. If the trade name of the medication is reported, document the trade name as the medication name on the log CRF. This guidance will help to avoid clinical coding queries and ensure proper coding at SCHARP.

  Instructions have been added on how to record medications when the dosage is unknown. In these cases, the dose units should be recorded as "Unknown" and the dose field should be left blank. A system query will fire indicating this is a missing value once the form is saved. Please indicate the dosage is unknown per participant report in response to the generated query. SCHARP will review and then resolve this query manually.

- Pharmacy Ring Dispensation

  The ring code notation has been corrected to X.X. Refer to Reminder #2 within this Data Communiqué for additional information.

2. CRF Schedule of Forms

For ease of reference, the CRF Schedule of Forms that is located within the MTN-025 Data Collection section of the SPP is now available as a separate PDF document with the "Other Documents" section

of the MTN-025 Atlas webpage for download. The Schedule of Forms should be referenced to ensure completion of all required and as needed CRFs at each study visit.

3. CRF Updates

The paper version of the Laboratory Results CRF has been updated to 3.0 (dated 12 October 2016). The response option "Within normal range" for the severity grade has been updated to 'Not gradable'. This update had been made previously to the Laboratory Results eCRF within the clinical database.

4. Medidata Rave User Account Requests

To request new Medidata Rave user accounts or to request updates to existing user accounts, complete the Medidata Rave User Request Form, available on the MTN-025 Atlas webpage within the "Medidata Study Materials" section, with the following information:

- User: First/last name, email address
- Medidata Rave role/permissions (select from drop down list)
- Site requestor: First/last name, job title, email address

Send the completed spreadsheet to the following SCHARP alias: sc.rave.users.rt@scharp.org. The SCHARP ticketing system will track progress as we proceed with user access administration. Please direct any questions regarding Rave user accounts to: sc.rave.users.rt@scharp.org.

CLARIFICATIONS

1. HIV Test Results CRF Not Required at Screening/Enrollment

The HIV Test Results CRF is not required to be completed at the Screening or Enrollment Visits as the participant must be HIV-negative to enroll into the study. The participant's HIV status is documented on the Enrollment CRF (Item 4 – HIV Status).

2. Laboratory Results CRF – Selection of Site Laboratory

To populate lab-specific analyte reference ranges and units of measurement, the lab performing laboratory testing for a study site must be selected at the top of the Laboratory Results eCRF within the Rave database. If more than one lab is associated with a study site, select the applicable laboratory that completed testing for the participant. Once a laboratory has been selected, the eCRF will update automatically to populate the ranges and units of measurement for each analyte at the bottom of the form. To view the ranges that have been specified for an associated laboratory, click the "View Ranges" link.

<u>Example:</u>

REMINDERS

1. **Paper Case Report Forms (CRFs)**

   Sites are welcome to adapt the paper CRFs available on the MTN-025 webpage to incorporate any formatting changes to items that would be helpful for form completion. Examples of formatting changes include the addition of item completion instructions of which would be helpful for site staff to be aware, the addition of space for site staff initials and date, spacing of items, etc. Changes to existing items or response options <u>should not</u> be made. Please let SCHARP know of any substantive changes made to the paper CRFs.

2. **Vaginal Ring Code Notation**

   The vaginal ring code assigned to each vaginal ring must be in the format 'X.X' on the following forms:

   - Pharmacy Ring Dispensation CRF
   - Ring Collection and Insertion CRF
   - Vaginal Ring Tracking Log CRF
   - LDMS Tracking Sheet

   For example, the ring code for the first ring dispensed and provided to a participant should be recorded as 1.0 (**not** 01.0). Leading 0's should not be entered as part of the ring code. This is to ensure that programmed Medidata Rave edit checks are able to link and to compare data collected across these three forms and within LDMS for each vaginal ring provided to a participant.