MTN-025 Data Communiqué #11 - April 12, 2018

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

Medidata Database Updates

The MTN-025 clinical database was updated on 12 April 2018. The main purpose of updating the clinical database was to update system queries and ensure all required forms are added to the participant's visit folder.

System Queries

Some of the updated system queries will trigger retrospectively on forms that were submitted within Medidata for completed visits. Please note that specific items were previously hidden after the form was saved based upon form skip instructions. As part of this migration, these fields will no longer be hidden and a system query may trigger if data is discrepant with what is expected. If data was originally entered when it is not required, the data should be removed and the form re-saved. Conversely, if data was not entered when it was expected, then the item should be completed as applicable. However, if this data cannot be obtained (e.g., the form was participant administered), then please include this specific information in the query response field in response to the system query and SCHARP will resolve the query. Please refer to the Clarifications section below for specific forms that have been updated.

Required Forms

The database was updated to ensure all required forms have been added to the participant's visit folder. Please ensure the applicable CRF(s) is completed as a back-up paper CRF should have been completed. However, please contact SCHARP and FHI for guidance if a specific assessment was not completed and a back-up paper CRF and/or source is not available in these instances.

CRF COMPLETION GUIDELINES (CCGs)

The CRF Completion Guidelines have been updated to v2.0 (dated 12 April 2018) and are posted on the MTN-025 Atlas webpage for download. In addition, a tracked version of all changes has been circulated with this Data Communiqué.

CLARIFICATIONS

1. Pre-Screening Outcome

If "Was the participant contacted to participate in HOPE" is 'No', then item "Did the participant conduct a screening visit for HOPE?" should be blank.

If “Was the participant contacted to participate in HOPE” is ‘Yes’, then item “Why was the ASPIRE participant not contacted to participate in HOPE” should be blank.

2. Ring Collection and Insertion

When completing the Ring Collection and Insertion CRF at the Enrolment Visit, all items 1, 1a, 1b, 1b1, and 2 should be left blank.

If “Was a ring in place at the end of the visit” is ‘No’, then a response is required for item “Reason ring not in place at end of visit” (Item 8a).

3. Demographics

If “What is the participant’s religion” is a response other than ‘None’, then a response is required for item “How many times a week does the participant attend religious services”. Conversely, if “What is the participant’s religion” is ‘None’, then “How many times a week does the participant attend religious services” should be left blank.

4. HIV Test Results

If “Was plasma stored for HIV confirmatory testing” is ‘Yes’, then a “Plasma for HIV confirmatory testing collection date” is required.

If both Rapid HIV test 1 and Rapid HIV test 2 are negative, then that is the end of form and all other remaining items (e.g. Geenius HIV-1/2 confirmatory test, Plasma, HIV RNA PCR, CD4, and final HIV status) should be left blank.

5. Pregnancy Test Result

If item 2a is ‘amenorrheic for the past 6 months’ or ‘no menses since participant’s last visit’, then the first day of last menstrual period, last day of last menstrual period, and ongoing items should all be blank.

6. Behavior Assessment

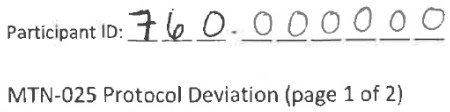
Items 21 – 26 on the Behavior Assessment should be completed at the Product Use End Visit (PUEV) or Early Termination Visit only. If item 22 is ‘not applicable – never used the ring during HOPE’, then item 23 (23a, 23b, 23c) should be skipped. The remaining items 24, 25, and 26, should still be completed as applicable.

7. Protocol Deviation Log completion for deviations not associated with a PTID

If a protocol deviation is not associated with a participant, please use the following PTID format below on the Protocol Deviation Log CRF:

XXX-00000-0

The first 3 digits of the PTID should correspond to your site's Medidata Rave site ID number. All PTIDs for your site start with the same 3 digits, and these 3 digits should be used together with 0's for the last 6 digits) for any Protocol Deviation Log CRFs reporting non-participant related deviations. For example, the Medidata Rave site ID number for the Blantyre CRS is 760, so the PTID should be designated 760-000000 (see example below).



A *paper* Protocol Deviation CRF should be completed in these cases and the paper CRF must be scanned and emailed to the SCHARP CDM for submission as these non-participant specific deviations will be captured outside of the clinical database.

REMINDERS

None