

MTN-025 Data Communiqué #8 - September 29, 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. NEW SOCIAL INFLUENCES SUPPLEMENT Y/N and SOCIAL INFLUENCES SUPPLEMENT

SCHARP has issued a new Social Influences Supplement CRF, including a Social Influences Supplement Y/N CRF prompt, dated 08 August 2017.

The Social Influences Supplement CRF will be administered at the scheduled Product Use End Visit (PUEV) and includes questions regarding the strength and structure of each participant's social network per the persons referenced on the Social Influences CRF form.

This CRF does not need to be completed retroactively for participants who have already completed their PUEVs.

The translations for all local languages (Zulu, Shona, Chichewa, Luganda, and Xhosa) of the new Social Influences Supplement CRF are also now available within Medidata Rave. Once your site-specific Source Documentation SOP has been updated and finalized and IRB approval has taken place (if applicable), both the English and local-language version of these eCRFs can be administered to participants while directly entering responses into Rave.

2. CRF UPDATES

The following CRFs have been updated within the clinical database:

Additional Study Procedures Y/N

The Additional Study Procedures Y/N form has been updated to include the capability to add the new Social Influences Supplement Y/N form to the participant's casebook as needed (e.g., at early termination).

Interim Visit Procedures

The Interim Visit Procedures form has been updated to include the capability to add the new Social Influences Supplement Y/N form to the participant's casebook as needed (e.g., at early termination).

3. DATABASE UPDATES

As part of the MTN-025 clinical database migration, multiple system queries have been added, updated and corrected.

Interim Visit Procedures

The CRFs listed on the Interim Visit Procedures form are no longer required fields and system queries will no longer be placed if a response is left blank. Forms that are added can be selected 'Yes'. Responses for other forms can be left blank if they were not completed at the interim visit.

Pregnancy Outcome

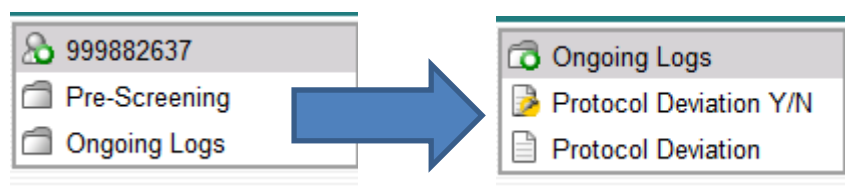
A partial date is now allowed on the Outcome date on the Pregnancy Outcome CRF. At a minimum, a month and year are required.

Social Impact Log

The item "Describe what was done by staff and participant to address social impact" for both participant and staff have been updated to allow up to 600 characters to be entered.

Protocol Deviation Y/N

The Protocol Deviation Y/N is now available immediately right after a PTID has been generated. Any protocol deviations identified prior to Enrollment can be entered into the clinical database. Sites who have completed paper Protocol Deviation Logs should go back and data enter these protocol deviation(s) into Medidata Rave. Sites no longer need to email the paper Protocol Deviation Log CRF to SCHARP.



Demographics

The derived age from the Date of Birth on the Demographics eCRF for main study participants has been updated so that the derived age is calculated based on the Screening Date of Visit, rather than the current date.

Study Exist Assessment

The items "In the past 7 days, how many acts of vaginal sex did you have?" and "In the past 7 days, during how many acts of vaginal sex was a male or female condom used" have been corrected to allow up to 2 digits to be entered.

Laboratory Results

Two digits after the decimal are now allowed for the Creatinine analyte value entered on the Laboratory Results eCRF.

Translations

Translations have been corrected on response items for the following CRFs:

- Social Influences Assessment
- Study Exit Assessment
- Termination

4. CRF COMPLETION GUIDELINES (CCGs)

The CRF Completion Guidelines have been updated to v1.7 (dated 29 September 2017) 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.

4. CRF Paper Updates

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

- Social Influences Supplement, Version 1.0, dated 08 August 2017
- Additional Study Procedures, Version 2.0, dated 29 September 2017
- Interim Visit Procedures, Version 2.0, dated 29 September 2017

An updated Rave eCRF output has been posted as well, Version 14.0, dated 29 September 2017.

5. Reports

The following reports available for internal site data cleaning and review have been corrected on your site-specific Medidata homepage:

- MTN-025 Unresolved Adverse Experiences
- MTN-025 Outstanding Product Holds
- MTN-025 Unresolved Social Impacts