

MTN-025 Data Communiqué #3 - November 23, 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 UPDATES

The following CRFs (listed in alphabetical order) have been updated within the clinical database and/or the paper CRFs:

ACASI Tracking Y/N – Enrollment

The paper form has been updated with a date, 23 November 2016. The PTID and designated visit folder (V2 – Enrollment) were missing in the header on the paper CRF and have been updated accordingly.

Baseline Behavior Assessment

The Baseline Behavior Assessment form has been updated with a date of 23 November 2016. A skip pattern on item 28 and item 30 has been updated from “If only one reason is marked, end of form” to “If all reasons are marked ‘no’, then end of form”.

Baseline Medical History

The paper form has been updated with a date, 23 November 2016. The “Page 1” in the footer of the form has been removed.

Demographics

The Demographics CRF (Version 2.0, dated 23 November 2016) has been updated to include two additional questions:

- “Did the participant become pregnant since the end of ASPIRE?”
 - “If yes, at the time of the pregnancy, was the participant taking any measures to avoid falling pregnant?”

These additional questions will be asked to all participants enrolled into the main study or decliner population starting on 24 November 2016. These items are not required to be completed retroactively for participants who have already completed the Demographics CRF.

Family Planning Log

The Family Planning Log CRF has been updated to V2.0, dated 23 November 2016, and includes the following updates:

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- 'Emergency contraception' has been added as an additional family planning/contraception method for all Family Planning Log forms that are completed starting on 24 November, 2016.
 - At the Enrollment Visit, if the participant reports she is on the same family planning method that was used at her last visit in ASPIRE, an additional required question has been added: 'If yes, was there a break in use of this method for more than 1 month?'. This update will be applied for all Family Planning Log forms that are completed starting on 24 November, 2016 and does not need to be completed retroactively for existing completed log forms.
 - The reasons for changing or stopping the family planning method have been updated to include the following:
 - Interested in long-acting reversible contraception (LARC)
 - Bleeding concerns, including Heavy bleeding, Prolonged bleeding, Intermittent bleeding (e.g. spotting), Less bleeding/no bleeding (e.g. no menses) as sub-response options
 - Break from hormones
 - Difficulty with adherence
 - Weight gain
 - Interested in getting pregnant
 - Became pregnant
 - Contraceptive choice not available
 - Bothered by pain
 - Partner objection
 - Medical contraindication, specify:
 - Other reason, specify:
 - No reason provided

The reason(s) for changing or stopping the family planning method should be asked whenever a family planning/contraception method is stopped (i.e., a date is provided for 'Date Regimen Stopped'). At Enrollment, the reason(s) for changing or stopping the family planning method should be asked if this is *not* the same family planning method that the participant used at her last visit in ASPIRE or if there was a break in her family planning for more than 1 month.

Laboratory Results

The paper Laboratory Results CRF has been updated to v4.0, dated 23 November 2016. The boxes and units have been removed from the paper CRF to accommodate varying site lab analyte values and units. If completing the paper Laboratory Results CRF prior to direct data entry, sites can write in the values and units as needed on the paper CRF or update the paper CRF accordingly to match with their site's units and values.

Ring Collection and Insertion

The Ring Collection and Insertion CRF has been updated to v2.0, dated 23 November 2016. Item 4 on the Ring Collection and Insertion CRF has been updated to the following:

"Did the participant accept to receive the ring(s) on a quarterly schedule?" with Yes/No response options. If 'no', the reason should be specified in the text field provided.

These additional questions will be asked to all participants enrolled into the main study beginning on 24 November 2016 and do not need to be completed retroactively for any completed Ring Collection and Insertion CRFs.

Screening Visit Packet

Space for initials/date was added to the footer on all forms within the Screening Visit packet since these forms will be primarily paper-based across all sites. These forms have been dated 23 November 2016.

2. CRF COMPLETION GUIDELINES

The CRF Completion Guidelines have been updated to v.1.4 (dated 23 November 2016) and are posted onto the MTN-025 Atlas webpage for download. Updates to form completion have been made to the following CRFs:

- Interim Visit Procedures
- Vaginal Ring Tracking Log
- Ring Collection and Insertion
- Pregnancy Outcome
- Family Planning
- Laboratory Results
- Demographics
- Pregnancy Test Result
- Baseline Behavior Assessment

3. DATABASE UPDATES

As part of the MTN-025 clinical database migration, multiple system queries have been updated and corrected. The goal of system queries to provide real-time feedback in order to ensure clean data at the point of data entry. Please continue to let SCHARP know if there are any system queries that seem to be triggering erroneously.

CLARIFICATIONS

1. On the Family Planning log CRF, if 'Sterilization' is reported as the participant's family planning method, the family planning regimen should be marked as "Ongoing". The "Date regimen stopped" should be left blank.
2. On the Demographics form, only the "Date of Birth" **or** "Age (entered by site)" should be completed. Either "Date of Birth" should be recorded and the "Age (entered by site)" should be left blank or vice versa. Medidata Rave derives the age from either the "Date of Birth" or "Age (entered by site)" for analysis. If both of these fields are completed, then the derived age will not be calculated correctly.

REMINDERS

1. The units and reference ranges have been updated as designated by each site's laboratory reference value documentation for the Laboratory Results eCRF within the Rave. No conversions are necessary when entering each analyte result into Medidata Rave. Please enter the laboratory values for each analyte per the source laboratory results documentation.