

## MTN-025 Data Communiqué #5 - April 14, 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

None

### CLARIFICATIONS

#### Responding to and Resolving Rave System and Manual Queries

In the event of discrepant or missing data on a given data point within an eCRF, a Medidata Rave system query will be placed on the data point to alert the Rave user that the item requires review and correction. System queries will close automatically after saving the form if the data point is entered or corrected - no response to the query is necessary.

However, if a response to a system query is provided when updating the data point field, the query will need to be reviewed and manually closed by SCHARP. A response to a query only should be used to document any additional clarifying information regarding the data point or to request additional guidance from SCHARP on query resolution.

When a manual query is placed by SCHARP or a monitor, both a response to the query and an update to the data entry field is required. There may be exceptions when a response to a manual query is not required; in these instances a response field will not be present for a Rave user to complete. All manual queries that have been addressed by the site will need to be reviewed in order to close the query.

#### Entered Data in Medidata Rave for Ineligible Participants

With the exception of the Pre-Screening Outcome and Participant Date of Visit within the Screening folder, eCRFs should only be completed within the Medidata Rave database once it has been determined that the participant is eligible to enroll into the study. The Eligibility Criteria eCRF should be completed once it is confirmed the participant will enroll or screens out for the study.

If screening or enrollment data has been entered erroneously for ineligible participants, the applicable eCRFs should not be retained within the clinical database and data provided on the eCRFs should be removed. Please alert the SCHARP Clinical Data Manager in the event that this occurs.

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### Concomitant Medications Log: guidance on copper IUCD dose and dose units

When recording Intrauterine Contraceptive Devices (IUCD) on the Concomitant Medications Log CRF, indicate the dose as “1”, the dose unit as ‘other’, and indicate ‘device’ in the “Other, specify” text field.

### Vital Signs CRF – Weight Item

When entering the weight value on the Vital Signs eCRF, round to the nearest kilogram as this value should be entered as a whole number.

### Pregnancy Outcome

When reporting a pregnancy outcome, complete the Pregnancy Outcome eCRF within the visit folder at which the pregnancy was reported (i.e., The Pregnancy Report and History and Pregnancy Outcome eCRFs should be documented at same study visit. ) For example, if a pregnancy is reported at the V5 – Month 3 visit, a Pregnancy Report and History eCRF should be completed at Month 3. When the pregnancy outcome is known, select ‘Yes’ for “Pregnancy Outcome” on the “Additional Study Procedures Y/N” form and complete the eCRF

### Adverse Experience Log – Comments field

A clinical rationale for the AE relationship to study product is required to be provided within the Comments field on each AE log CRF, regardless of relatedness. Ensure that for every reportable AE, a rationale whether the AE is judged to be ‘related’ or ‘not related’ to study product is provided.

## **REMINDERS**

### **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

For example, the visit code for the V2 – Enrollment visit should be recorded as 2.00 (not 02.0 or 2.0). Leading 0’s should not be entered as part of the visit code and 2 digits should be entered after the decimal.

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## **Materials on MTN-025 ATLAS webpage**

- Medidata Rave Materials are available on the MTN-025 ATLAS website (<https://atlas.scharp.org/cpas/project/MTN/025/begin.view?>), including training materials presented at the 2016 MTN Regional Meeting, 2017 MTN Annual Meeting, and SCHARP site visits in February 2017.
- A Medidata Rave Icon Key PDF that can be used for site reference when reviewing the status of eCRFs completed within the clinical database is posted on ATLAS.
- When completing paper CRFs, as needed, please ensure you are using the most recent CRF visit packets currently posted on the MTN-025 Atlas website.

## **Rave Reports**

Medidata Rave reports are available for internal site data cleaning and review and available on your site-specific Medidata homepage. As a reminder, site staff that have access to these reports will need to complete the Rave Reporter e-Learning. The following reports are available:

- MTN-025 Unresolved Adverse Experiences
- MTN-025 Outstanding Product Holds
- MTN-025 Unresolved Social Impacts
- Audit Trail Report
- Productivity Report
- Query Details Report
- Query Summary Report
- Comprehensive Page Status Report