

## MTN-025 Data Communiqué #9 - January 17, 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

#### Database Updates

A migration of the MTN-025 clinical database was performed on 16 January 2018. The following updates occurred as part of this migration:

1. Some system queries that were erroneously triggering have been inactivated. These will be updated and corrected at a later time. In the meantime, please ensure your site pays particular attention to the skip patterns outlined in the CRF Completion Guidelines, especially on the Social Influences Assessment form in order to ensure there is no missing data. Specifically, if the relationship is entered as 'Other' or 'Other family member', specify the participant's response in the 'Other or other family member, specify' text field provided.
2. The number of allowable characters has been increased for those items with AE dynamic search list functionality (e.g. Pelvic Exam, Termination, and Laboratory Results eCRF). If any of these items are currently non-conformant, please re-select from the dynamic search list so that the item is *blank*, re-save the page, and then re-select the applicable AE from the dynamic search list so that it is no longer non-conformant.
3. The programming of the derived age has been updated so that the age populates for all participants with an entered Date of Birth.
4. The programming for site monitors to complete source data verification (SDV) has been corrected so that all applicable forms and fields will show as requiring verification.

#### CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to Version 1.8 (dated 17 January 2018) and are posted onto the MTN-025 Atlas webpage for download. Clarifications/updates to form completion have been made to the following CRFs:

- Eligibility Criteria
- Follow-up Visit Summary
- ACASI Tracking
- Ring Collection and Insertion
- Pregnancy Outcome
- HIV Test Results
- Social Influences Assessment

In addition, a tracked version of all changes has been circulated with this Data Communiqué.

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## CRF Paper Updates

There was a versioning error in the formatted Behavioral Packets posted on the MTN-025 Atlas webpage. The paper versions of all behavioral packets (English and locale language) have been replaced with the Rave eCRF output in order to ensure the most current forms are being administered in the event that paper forms need to be used.

## CLARIFICATIONS

### 1. Ring Collection and Insertion Form Completion – Item 3

Note that if item “Did the participant choose to use a new ring at this visit” (Item 3) is ‘Not applicable’, then items 4 “Did the participant accept to receive the ring(s) on a quarterly schedule” and 5 “What are the reasons that the participant opted to not use the ring at this visit” should be left blank. Item 6 “Was a ring provided at this visit” and 6a “Reason ring not provided” should then be completed and remaining items should not be completed. This scenario would apply if the participant is on product hold, has been permanently discontinued from study product, or if this visit is after her expected study product use period (e.g. PUEV or early termination visit).

### 2. Ring Collection and Insertion – Item 4

Item 4 “Did the participant accept to receive the ring(s) on a quarterly schedule?” should only be completed at the Quarterly Visits Month 3, Month 6, and Month 9. This item should not be completed at any other visit, including the PUEV (Month 12) visit or an interim visit.

### 3. Concomitant Medications – If contraceptive

All contraceptives that are dispensed to a participant, regardless of indication, should be recorded on the Concomitant Medications Log with the item “If contraceptive, was it dispensed at research center?” completed. This item should be left blank if the medication is not a contraceptive.

### 4. AE Outcome Date when treatment is indicated

For adverse experiences requiring treatment, record as the outcome date the date when all associated symptoms have resolved (or returned to baseline severity), or the date when treatment is completed, *whichever is later*. An AE is not considered resolved until both symptoms have resolved and treatment has been completed.

*Example:* A participant presents with Grade 2 vaginal discharge on 24 Nov 17 and is prescribed doxycycline on the same date. The participant’s symptoms resolved on 27 Nov 17 and she completes her antibiotic regimen on 05 Dec 17. The Status/Outcome Date (Item 6a) should be recorded as 05 Dec 17 on the corresponding AE log CRF.

### 5. Clinical Product Hold/Discontinuation Log CRF Completion

A Clinical Product Hold/Discontinuation Log should be completed for any **clinical** reason that warrants a product hold or discontinuation by *site staff*, regardless of whether participants choose to use the ring or choose not use the ring during the study. This form should not be completed for non-clinical reasons, including in instances when the participant herself decides herself not use the study vaginal ring. In addition, a Product Hold/Discontinuation Log CRF should not be completed at the PUEV (scheduled or early termination), as all participants are expected to permanently discontinue study product use at the PUEV.

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## 6. Termination CRF

If the “Reason for termination” is ‘scheduled exit visit/end of study’, then this is the end of form and remaining items should be left blank. Specifically, item “Was termination associated with an adverse experience?” should not be completed.

## 7. Open, Blank Log Lines

Any unused blank log line(s) should be inactivated within Medidata Rave. Each blank log line(s) can be inactivated by clicking “Inactivate” at the bottom of the log page and selecting the applicable log line(s) that needs to be inactivated.

## REMINDERS

### 1. Y/N Administrative Prompt Questions

All Yes/No prompt questions should be completed within each visit folder and the Ongoing Logs folder. Specifically, the Protocol Deviation Y/N for participants who only pre-screened should be completed, even if the participant did not screen for the study. If a participant has terminated from the study, please ensure **all** applicable Y/N questions have a response and are closed out.