

## MTN-025 Data Communiqué #10 - February 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

#### Database Updates

The MTN-025 clinical database was updated on 12 February 2018. The main purpose of updating the clinical database was to add, update, and correct multiple system queries. The goal of system queries is to provide real-time feedback in order to ensure clean data at the point of data entry. Please note that some of these system queries will trigger retrospectively on forms that have already been submitted within Medidata. As a reminder, system queries with the marking group “Site from System” do not count in the Query Rate per the Data Management Quality metrics.

#### CRF COMPLETION GUIDELINES (CCGs)

The CRF Completion Guidelines have been updated to v1.9 (dated 12 February 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. Specimen Storage – Participant declined hair collection after counseling

If a participant declines hair collection, item 1f “Reason hair collection was not done - participant declined hair collection after counseling” should be checked and the reason specified within the text field in item 1f1 “Participant declined hair collection after counseling; specify reason”.

#### 2. Vaginal Ring Tracking Log – Ring not Returned

If a ring(s) was expected to be returned at the visit, but the participant does not return a vaginal ring(s), then the item “Ring not returned” should be checked and the reason the ring not returned should be specified in the text field provided. All remaining Ring Returned items should be blank. If the participant returns the ring at a later date/visit, then update the Ring Returned information with the applicable information: Date ring returned, Visit ring returned, Ring Storage, and the participant-reported questions if applicable. In addition, update the item “Ring not returned” so that it is no longer checked and remove the reason specified within the text field if the ring was returned.

#### 3. Follow-up Visit Summary Completion at Interim Visits

The Follow-up Visit Summary form is a required form at interim visits. In addition, when completing the Follow-up Visit Summary CRF at an interim visit, the item “Is this an interim visit?” should be documented as ‘Yes’ and the reason(s) for the interim visit should be checked.

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#### **4. Follow-up Visit Summary – PrEP**

If the item “Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?” is ‘No’, then the item “Was oral or topical PrEP used” should not be completed.

#### **5. Family Planning Log Completion**

If the participant stops a particular family/planning method during follow-up, then the item “Ongoing” should be updated so that it is no longer checked, the Date Regimen Stopped completed, and then the “Reason(s) for changing or stopping the family planning method” should be completed. If the participant changes her contraceptive/family planning method during follow-up, a new log line should be completed on the Family Planning Log within the V2 – Enrollment folder to document the new contraceptive/family planning method, as applicable.

#### **6. Ring Collection and Insertion and Pharmacy Ring Dispensation**

The number of rings dispensed per the Pharmacy Ring Dispensation form should align with the item on the Ring Collection and Insertion form, specifically the item “Did the participant accept to receive the ring(s) on a quarterly schedule”, which is completed at Month 3, Month 6, and Month 9 only. For example, if the participant was dispensed 3 rings at the first quarterly visit (Month 3) per the Pharmacy Ring Dispensation form, this should align with the item “Did the participant accept to receive the ring(s) on a quarterly schedule?” (e.g. the response to this item should be ‘Yes’). However, if the participant was dispensed 1 ring at the Month 3 quarterly visit per the Pharmacy Ring Dispensation form, the response to item 4 should be ‘No’.

#### **7. Concomitant Medications and Adverse Event Log**

If an Adverse Event is linked on the Concomitant Medications Log, (e.g. the applicable Adverse Event is selected via the dynamic search list), the item 7b “Medication(s)” should also be checked on the applicable Adverse Event Log.

#### **8. Eligibility Criteria**

If the participant did not return to the clinic to complete all screening procedures within the 56-day screening window, this should be documented as ‘Participant did not complete all screening procedures’ for the item “Why was the participant not enrolled?” rather than IoR discretion. In addition, the item “Does the participant meet all eligibility criteria?” should be selected as ‘No’.

### **REMINDERS**

#### **1. Responding to Medidata Rave System and Manual Queries**

If a data point needs to be updated on an eCRF within Medidata Rave, please remember to use the pencil icon to edit the field, make the applicable changes to the data entry field, and re-save the page. Do not input the updated data in the query response field as this may result in a re-query. The query response field should only be used to document any additional clarifying information regarding the data point, request additional guidance on query resolution, or confirm the data has been updated appropriately.

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## **2. Non-Conformant Data on Dynamic Search Lists**

If an Adverse Event has been selected with dynamic search list functionality (e.g. Clinical Product Hold/Discontinuation Log eCRF or Concomitant Medications Log eCRF), and original data on the AE description field or Onset Date has been updated, the AE search list will become non-conformant. Please re-select the corresponding AE field by re-selecting the applicable AE from the dynamic search list to correspond with the latest data so that it is no longer non-conformant.