

MTN-036/IPM 047 Data Communiqué #1 - January 25, 2018

This is official study documentation for MTN- 036/IPM 047. Please circulate it among relevant staff for their review, print it, and place it in your MTN-036/IPM 047 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-036/IPM 047 SSP manual.

UPDATES

1. CRF updates

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

Pelvic Exam

The Pelvic Exam form (Version 3.0, dated 25-Jan-2018) has been updated to change the “Abnormal blood or bleeding; describe” field to a text box. If “Abnormal blood or bleeding” was selected on a form that has already been completed, and a description of the abnormal blood or bleeding is available within source documentation, update this item. If this information is not available in source documentation, provide this information in the query response.

Physical Exam

The Physical Exam form (Version 3.0, dated 25-Jan-2018) has been updated to remove the “Oral mucosa” and “if abnormal, specify:” fields. These items are not required to be updated retroactively for participants who have already completed a Physical Exam.

Ring Adherence

The Ring Adherence form (Version 3.0, dated 25-Jan-2018) has been updated to allow multiple responses for “What are the reason(s) why the vaginal ring came out on its own?” This item is not required to be updated retroactively for participants who have already completed the Ring Adherence form.

The form has been updated to add clarifying text “(or since the ring was inserted if Visit 8/Day 28)” to multiple questions that ask “Since the ring was inserted...” When completing these questions at Visit 8, indicate if the activity in question has occurred since enrollment. When completing these questions at Visit 9 or Visit 10, indicate if the activity in question has occurred since the previous visit.

Ring Insertion and Removal

The Ring Insertion and Removal form (Version 3.0, dated 25-Jan-2018) has been updated to allow multiple responses for “If very difficult or difficult, why? (Choose all that apply)”. This item is not required to be updated retroactively for participants who have already completed the Ring Insertion and Removal form.

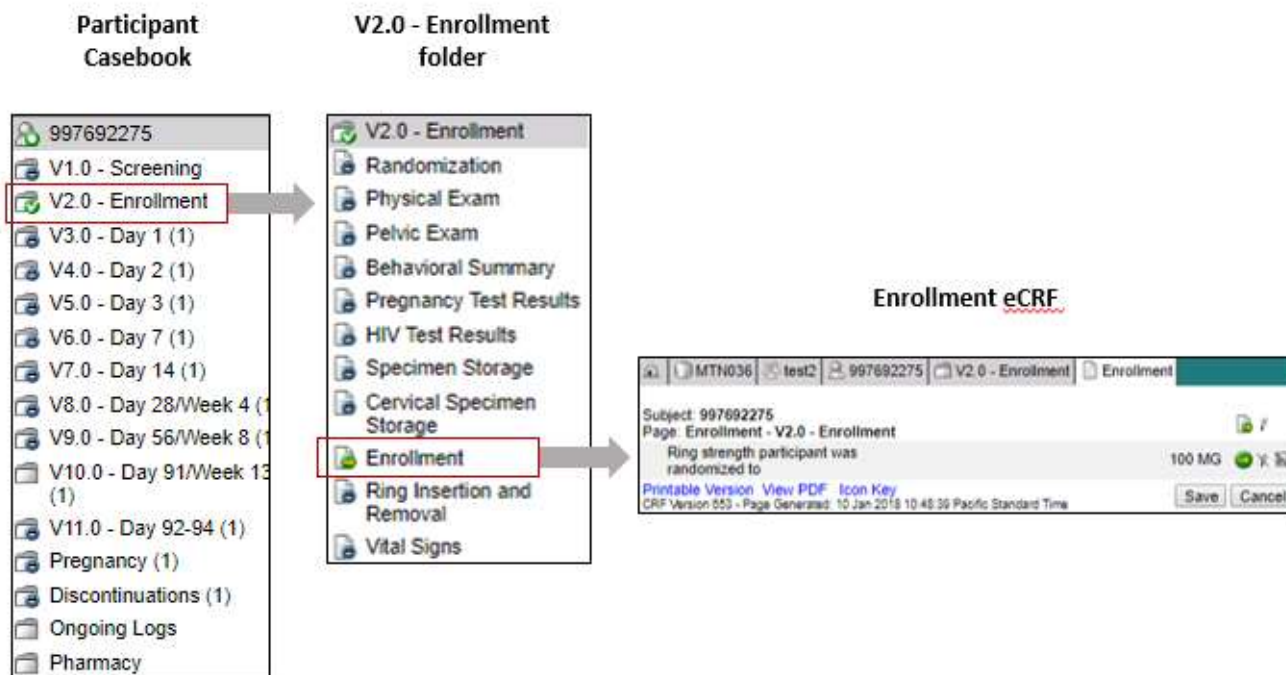
2. Updates

As part of the MTN-036 clinical database migration, multiple system queries have been updated and corrected. The goal of system queries is 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.

Rave Pharmacist Role

The Pharmacist role within the MTN-036 Medidata Rave database has been updated to allow the Site Pharmacists to view the “Ring strength participant was randomized to” field on the Enrollment eCRF in the Enrollment folder. Site Pharmacists will also retain the ability to access, enter data, and resolve data queries on the Pharmacy Dispensation eCRF in the Pharmacy folder, and the Protocol Deviations Summary and Protocol Deviations Log eCRFs in the Ongoing Logs folder.

After selecting the participant, the Pharmacist can navigate to the Enrollment eCRF by first selecting the V2.0 – Enrollment folder, and then selecting the Enrollment eCRF within the Enrollment folder. Here is an example of a participant’s casebook, Enrollment folder, and Enrollment eCRF when logged into Medidata with the Pharmacist user role:



CRF Completion Guidelines (CCGs) – Randomization CRF

The CRF Completion Guidelines have been updated to state that the Randomization CRF in the Enrollment folder must be completed for **ALL** participants, including those who screen fail. Additional information and instructions can be found in the updated CCGs (CCG v1.1 dated 25-Jan-2018) on the Atlas website here:

https://atlas.scharp.org/cpas/files/MTN/036/CRFs/%40files/MTN036_CCG.pdf

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

CRF PDF Updates

An updated Rave eCRF output will be posted to Atlas, Version 3.0, dated 25-Jan-2018.

3. CLARIFICATIONS

Eligibility Criteria eCRF completion

The Eligibility Criteria eCRF must be completed for each screening attempt. If a participant is ineligible after the first screening attempt, complete the Eligibility Criteria eCRF and enter the eligibility status based on the first screening attempt. If a second screening attempt will not take place, alert the SCHARP MTN-036 Clinical Data Manager. System queries placed on the screening and enrollment CRFs will be canceled or closed with the exception of the Eligibility Criteria eCRF, in the Screening folder. Any queries placed on the Eligibility Criteria eCRF must be resolved for all study participants.

If the participant attempts a second screening, all previously completed screening forms should be updated with data from the second screening attempt and the Eligibility eCRF should be updated to reflect the participant's current eligibility status.