

MTN-037 Data Communiqué #3 - November 13, 2018

This is official study documentation for MTN-037. Please circulate it among relevant staff for their review, print it, and place it in your MTN-037 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-037 SSP manual.

UPDATES

Database Updates:

The MTN-037 Medidata clinical database was migrated on November 13, 2018 to include the following updates:

Dose Administration CRF

The Dose Administration CRF was updated to fix the “Time gel application administered” field format.

If the participant has already completed the dosing visit(s), the site should review the source documentation and update the Dose Administration form, as appropriate.

Pregnancy Test Results CRF

The Pregnancy Test Results CRF will be automatically populated for visits 3, 5, and 7 if the participant is female.

Visit Folder Population

The mechanism for visit folder population has been corrected and the appropriate visit folders should populate in the correct sequence.

Rave System Queries

As part of the MTN-037 clinical database migration, some 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.

CRFs with updated system queries include:

- Hematology
- Dose administration
- Follow-up Visit Summary
- Demographics
- Anorectal Exam and Sigmoidoscopy
- Local Laboratory Results
- Pelvic Specimen Storage

CLARIFICATIONS

In the event that a Medidata system query (data QC) is placed on data point in error or if the data entered falls outside of the normal parameters for a programmed edit check, note within the query response text box that the data is correct as entered and provide any other applicable information that helps to contextualize the scenario. SCHARP will review the site response text box and close these erroneous system queries, as needed.

REMINDERS - None