

MTN-037 Data Communiqué #2 - August 31, 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 August 31, 2018 to include the following updates:

Enrollment CRF

The Enrollment CRF was updated to autopopulate the “48 Hr visit sampling assignment” field after randomization is completed according to the randomization assignment schedule in Balance.

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:

- STI Test Results: HSV-1 and HSV-2 rectal swabs that are not collected at screening will no longer trigger a query as they are not required at screening.

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