

MTN-035 Data Communiqué #1 – September 5, 2019

This is official study documentation for MTN-035 (DESIRE). Please circulate it among relevant staff for their review, print it, and place it in your MTN-035 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-035 SSP manual.

UPDATES

The MTN-035 Medidata Rave database was migrated to version 3.0 (1491) on 05 September 2019. This migration fixed queries that were misfiring on various forms. In addition, changes were made to the following case report forms (CRFs):

Inclusion/Exclusion Criteria CRF

The help text, “If Eligible and enrolled” or “Incomplete Screening”, end of form’ was moved to appear below the question, “Was the participant enrolled into MTN-035?”.

The question, “Was the participant enrolled into MTN-035?” requires an answer for all sites.

Randomization CRF

Both the Investigator as well as CRC staff are now able to view sequence assignments after randomization on the Enrollment CRF.

An updated complete set of blank eCRFs and v2.0 of the MTN-035 CRF Completion Guidelines (CCGs) have been posted to the MTN-035 ATLAS webpage:

<https://atlas.scharp.org/cpas/project/MTN/035/begin.view?>

CLARIFICATIONS

Discontinuation of Study Product CRF

This form is present within the “Discontinuations” folder. Complete this form when a participant completes a given product use period (i.e. at each PUEV)”, or when study product is discontinued for any other reason.

Pharmacy Dispensation CRF

Record the exact day, month and year study product was dispensed from the pharmacy. The time frame, documentation and date product is provided to the participant should be in accordance with site-specific pharmacy dispensation SOPs.

The CCGs V2.0 have been updated in accordance with the above.

REMINDERS

Behavioral Assessment Summary CRF

The question "Was a conjoint analysis assessment completed at this visit?" should be left blank, unless at Visit 8.