

## MTN-035 Data Communiqué #3 – June 9, 2020

**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 4.0 (2029) on 09 June 2020. This migration added three fields to the Discontinuation of Study Product CRF and related edit checks. Changes were made to the following case report forms (CRFs):

#### Discontinuation of Study Product CRF

Added 2 new required fields for “Visit at which study product was discontinued” and “Type of study product discontinued”. These fields will require data entry for all existing and future Discontinuation of Study Product forms. Associated edit checks were also added.

#### Concomitant Medications CRF

Added 2 new dynamic search lists for AEs to be used in the instance a Concomitant Medication is associated with multiple AEs.

#### Pharmacy Dispensation:

A custom function was added to issue a query in the instance "Which product was dispensed at this visit" is "Placebo rectal inserts" and "Date study product dispensed" is after 12 June 2020.

An updated complete set of blank eCRFs and v3.0 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?>