

MTN-034 Data Communiqué #5 – February 14, 2020

This is official study documentation for MTN-034. Please circulate it among relevant staff for their review, print it, and place it in your MTN-034 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-034 SSP manual.

UPDATES

The MTN034 Medidata Rave database was migrated to version 8.0 (1823) on 14 February 2020.

The migration included changes to study case report forms and Rave System Queries:

Study Case Report Forms:

Adverse Event Log CRF

Two new fields were added to the AE log CRF.

One field was added to document which product is the AE thought to be related to; DPV vaginal ring or Oral Truvada. For any AEs that have already been reported and are marked 'related', clinicians should re-assess and retroactively select the checkbox they believe the AE is thought to be related to.

A second field was added to document if Dapivirine vaginal ring relatedness is attributed to the device or drug. If an AE is thought to be related to the DPV vaginal ring, and the AE is related to study product, the "If "related" to the DPV vaginal ring, is the AE related to the drug (dapivirine) or device (ring itself or ring insertion)?" field must be completed to document if the clinician thinks the AE is related to the drug, device, or if they cannot distinguish between the drug and device components. For any AEs that have already been reported, sites should review and, if related to DPV vaginal ring, complete the new field retroactively.

For ease of finding previously reported related AEs, we have retrospectively added QCs to appear in your task list for all AEs that were marked 'related'. You can use this task list to complete the newly added fields, as applicable, and re-sign off on each of the log lines. These are 'Site to System' queries and will NOT be counted in the DMQ Report

Vital Signs CRF

Three new fields were added to the Vital Signs CRF.

Blood Pressure Severity Grade: This field will be completed going forward from the date of this migration. If there is a severity grade that needs to be reported after SCHARP reviews the CRF data that has already been submitted, a clinical QC will be placed to update this item. ***It is not necessary to go back to existing data and update this item, unless a QC is placed.***

Blood Pressure adverse event, if applicable: If there is a reportable AE for the Blood pressure, use the drop-down menu to select the corresponding AE.

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- Not reportable as an adverse event: if the Blood pressure is not reportable as an AE, mark this box. A query will fire if both are left blank and the Vital signs were done. ***It is not necessary to go back to existing data and update this item, unless a QC is placed.***

Local Laboratory CRF

The WBC field was updated to allow for an additional digit to be entered to correct the non-conformant queries appearing for some PTIDs.

Rave System Queries

As part of the MTN-034 clinical database migration, some system queries have been updated or 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:

Adherence counseling CRF: Amended queries due the Clarification memo #1

Ring Insertion and Removal CRF: Added additional queries for data completeness

Prep Provision and Returns CRF: Added additional queries for data completeness

Pharmacy Dispensation CRF: Added additional queries for data completeness

Adverse Event CRF: Added additional queries for the newly added fields related to relatedness

Vital Signs CRF: Added additional queries for the newly added fields related to Blood Pressure Severity grade/AE reporting

An updated complete set of blank eCRFs and v4.0 of the MTN-034 CRF Completion Guidelines (CCGs) have been posted to the MTN-034 ATLAS webpage.

<https://atlas.ssharp.org/cpas/project/MTN/034/begin.view?>