MTN-034 Data Communiqué #8 – November 30, 2021

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 MTN-034 Medidata Rave database was migrated to Version 10.0 (3393) on 30 November 2021. The main purpose of this migration was to update a few changes to the database. Changes are outlined for each CRF below:

Eligibility Criteria CRF:

We have added a Date Field: “Date participant was found "Eligible/Not Enrolled" or "Ineligible" or "Incomplete screening" on the Eligibility Criteria CRF. This date will need to be retroactively completed, per DAIDS request. SCHARP will be sending individual sites data listings for the PTIDs that will need this date completed.

HIV Test Result:

We have updated the names of some of the drop-down menu items. This should not affect data entry as we mapped the new names so they correspond with the previously selected choices, however, you may see additional QC s if this is not the case.

Visit Folder V24.0

The Visit 24.0 Visit Folder title was updated to reflect V24.0 - Week 76 rather than V24.0 - Week 73