

MTN-036/IPM 047 Data Communiqué #4- August 1, 2018

This is official study documentation for MTN-036/IPM 047. Please circulate it among relevant staff for their review, print it, and place it in your MTN-036/IPM 047 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-036/IPM 047 SSP manual.

1. REMINDERS

None

2. CLARIFICATIONS

None

3. UPDATES

CRF updates

The HIV Confirmatory Test Results form (Version 6.0, dated 30-Jul-2018) has been updated to capture Sample 2 HIV Confirmatory test result and if a sample was stored for testing by the MTN Virology core.

System query updates

As part of the MTN-036 clinical database migration, multiple 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. Please continue to let SCHARP know if there are any system queries that seem to be triggering erroneously.

CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to reflect the changes to the HIV Confirmatory Test Results form. Additional information and instructions can be found in the updated CCGs (CCG v3.0 dated 30-Jul-2018) on the Atlas website here:

https://atlas.scharp.org/cpas/files/MTN/036/_CRFs/%40files/MTN036_CCG.pdf

In addition, a tracked version of all changes has been circulated with this Data Communiqué.

CRF PDF Updates

An updated Rave eCRF output will be posted to Atlas, Version 6.0, dated 30-Jul-2018.