

MTN-042 Data Communiqué #6 – April 18, 2021

This is official study documentation for MTN-042. Please circulate it among relevant staff for their review, print it, and place it in your MTN-042 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-042 SSP manual.

UPDATES

Database Updates

The MTN042_C1 (cohort 1) Medidata Rave database was migrated to version 6.0 (2720) on 16-April-2021.

The migration included changes to the following study case report forms:

Inclusion/Exclusion Criteria

A new field was added to capture the date it was determined that a participant would not enroll in the study: “Date participant was found ‘Eligible/Not Enrolled,’ ‘Ineligible,’ or ‘Incomplete screening’”.

This field should be completed retroactively for all individuals who were screened but did not enroll.

Infant Inclusion/Exclusion

A new field was added to capture the date it was determined that an infant would not enroll in the study: “If “No”, date determined”.

This field should be completed retroactively for all infants who were assigned a PTID but did not enroll.

Informed Consent

New fields were added to capture “Consent type” and “Consent version”, and to capture information about any additional consent forms that were signed.

For all participants who were assigned a PTID, this form should be updated retroactively to record consent type and consent version. For all participants who signed more than one consent form, this form should also be updated to record every consent form that was signed.

In addition to form changes, 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.