

MTN-042 Data Communiqué #8 – February 22, 2022

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_C2 (cohort 2) Medidata Rave database was migrated to version 3.0 (3623) on 22-February-2022.

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

Pregnancy Outcome

Two fields were added to capture the intergrowth weight-for-age percentile and the associated severity grade. These fields should be completed for every participant with a reported birth weight. These fields should be completed retrospectively for all participants with a reported birth weight.

Two fields were added to document the pregnancy outcome number and infant PTID in cases when multiple pregnancy outcomes (e.g., twins) are reported for one maternal participant. These fields should only be completed when multiple pregnancy outcomes are reported.

Infant Vital Signs

Two fields were added to capture the WHO weight-for-age percentile and the associated severity grade. These fields should be completed for every infant vital signs assessment when the participant is less than 28 days old.

Two additional fields were added to capture the WHO weight-for-length z-score and the associated severity grade. These fields should be completed for every infant vital signs assessment when the participant is greater than or equal to 28 days old.

These fields should be completed retrospectively for all completed infant vital signs assessments.

An updated complete set of blank eCRFs will be posted to the MTN-042 ATLAS webpage.

<https://atlas.scharp.org/cpas/project/MTN/042/begin.view?>