

MTN-042 Data Communiqué #7 – December 21, 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_C2 (cohort 2) Medidata Rave database was migrated to version 2.0 (3435) on 21-December-2021.

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

Enrollment

The field label for “Was the participant randomized to participate in IDI (In Depth Interview)?” was changed to “Was the participant purposively selected to participate in IDI (In Depth Interview)?” and the field “Was the participant invited to participate in IDI?” was removed to reflect how participants are being selected and invited in cohort 2.

The migration also included updates to the V101.0 – PPO Visit folder:

The Edinburgh Postnatal Depression Scale CRF and the Post-PO Behavioral Assessment CRF were removed from the visit folder; per the SSP, these assessments are not intended to be completed at this visit.

SCHARP will review all existing V101.0 – PPO Visit folders. If these forms were previously completed at this visit, SCHARP will inactivate the forms in the database.

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?>