MTN-042 Data Communiqué #9 – April 5, 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 4.0 (3755) on 4-April-2022

As part of the migration, three new case report forms were added:

Infant Participant Transfer

This form was added a part of participant transfer process. This form can be added using "Additional Study Procedures" or "Interim Visit Summary" form and is completed by the transferring site of the infant participant.

Participant Transfer

This form was added as a part of participant transfer process. This form can be added using "Additional Study Procedures" or "Interim Visit Summary" form and is completed by the transferring site of the mother participant.

Participant Receipt

This form was added for sites to be able to participants. This form can be added using "Additional Study Procedures" or "Interim Visit Summary" form and is completed by the receiving site for both mother and infant participant.

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

Additional Study Procedures

"Participant Transfer" and "Participant Receipt" are added as new checkbox options. The two forms can be added in any visit folders of mother participant.

Infant Additional Study Procedures

"Infant Participant Transfer" and "Participant Receipt" are added as new checkbox options. The two forms can be added in any visit folders of infant participant.

Interim Visit Summary

"Participant Transfer" and "Participant Receipt" are added as new checkbox options. The two forms can be added in any interim visit folder.

Infant Interim Visit Summary

"Infant Participant Transfer" and "Participant Receipt" are added as new checkbox options. The two forms can be added in any interim visit folder of infant participant.

In addition to form and visit folder 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.

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?