

MTN-042 Data Communiqué #2 – April 9, 2020

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

COVID-19 Reporting Updates

Protocol Deviation reporting:

- If a visit is missed (i.e., no part of the visit is completed within the visit window for any reason, e.g., clinic closed, participant cannot make it to the clinic) this is considered a missed visit and should be documented in the database using the Missed Visit CRF. For the reason the visit was missed, choose “Other” and specify that the visit was missed due to COVID-19 in the ‘If, “Other”, specify’ text field.
- If any visit procedures are completed within the visit window and require a CRF to be completed, even if via telephone contact, the visit would not be considered missed. Complete the appropriate CRF(s) for the procedure(s) completed. For the other required CRFs within the visit folder, indicate that the procedure was not performed (if this field is present) or save the blank CRF. If any QCs fire, respond to the query, stating the reason the procedure was not completed (i.e; partial visit, procedure not completed due to COVID-19).
- Any deviation from the protocol (e.g., partial visits or phone contacts instead of clinic visits) should be reported as a protocol deviation on the Protocol Deviation Log. (Note that missed visits will be reported on the Missed Visit CRF and will not be reported as protocol deviations.)
 - o If a visit is conducted in person, but is modified in some way because of COVID-19 (e.g., no physical exam or pelvic exam when both would normally be expected), this should be reported as one protocol deviation. Complete a Protocol Deviation, select “Other” for “Type of Deviation, and in the “Description of deviation” field start the text with “COVID-19:” and explain what occurred during the visit, e.g., “The following procedures were missed: physical exam and pelvic exam.”
 - o If a visit is conducted remotely AND one or more visit procedures were missed due to the participant not being able to come to the clinic, this should be reported as one protocol deviation. Complete a Protocol Deviation, select “Other” for “Type of Deviation, and in the “Description of deviation” field start the text with “COVID-19:” and explain what occurred during the visit, e.g., “remote visit, the following procedures were missed: physical exam and pelvic exam.”
 - o If another Protocol Deviation needs to be reported, unrelated to COVID-19, report as a new Protocol Deviation by clicking “Add a new Log line” to add an additional page for a new deviation to be completed. Categorize ‘type of deviation’ according to normal protocol deviation guidelines.

Adverse Event reporting:

- If a participant is suspected or confirmed to have COVID-19, “COVID-19” should be reported as the AE term. Grade based on the “estimating severity grade” row of the toxicity table. It is not necessary to include details on whether suspected or confirmed in the comments.

Database Updates

The MTN042_C1 (cohort 1) Medidata Rave database was migrated to version 3.0 (1903) on 8 April 2020.

This migration included the addition of one new study case report form:

Infant Feeding Assessment CRF

This form was added to each infant visit folder. The purpose of the form is to do an assessment of the current infant feeding practices since the previous visit and to document any medications the mother has been taking while breastfeeding at the 6 Month and 12 Month Infant Visits. This form should be completed retroactively for any infant visit that has already occurred.

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

Edinburgh Postnatal Depression Scale

The EPDS Score field will now be auto-populated with the EPDS score based on the responses to question 1 – 10. Sites no longer need to calculate and enter this score in the database.

Infant Interim Visit Summary CRF

The Infant Feeding Assessment was added as an option under 'What study procedures were completed at this visit?' to document if that procedure was performed at an infant's interim visit.

Pregnancy Outcome CRF

Two additional delivery facilities for the Zengeza site were added to the response options of 'If "Study designated delivery facility", specify'.

Urine Test Results CRF

A response option of 'Negative' was added to "Leukocyte esterase (LE)". If this form has already been completed, the field must be updated retroactively to select the correct response option.

An updated complete set of blank eCRFs and v3.0 of the MTN-042 CRF Completion Guidelines (CCGs) have been posted to the MTN-042 ATLAS webpage.

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

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.