

MTN-039 Data Communiqué #1 – April 16, 2020

This is official study documentation for MTN-039. Please circulate it among relevant staff for their review, print it, and place it in your MTN-039 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-039 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.

CLARIFICATIONS

In the event that a Medidata system query (data QC) is placed on data point in error or if the data entered falls outside of the normal parameters for a programmed edit check, note within the query response text box that the data is correct as entered and provide any other applicable information that helps to contextualize the scenario. SCHARP will review the site response text box and close these erroneous system queries, as needed.

REMINDERS - None