

MTN-039 Data Communiqué #2 – May 19, 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

Missed Visits and Protocol Deviation reporting:

- If a participant's next scheduled visit is a dosing visit (according to the schedule prior to pausing all study activities), do not enter a Missed Visit CRF. Complete a protocol deviation for delayed dosing due to COVID-19. Select "Other" for "Type of deviation" and in the "Description of deviation" field, start the text with "COVID-19" and explain why the dosing was not administered according to schedule. Upon resumption of study activities, complete all visits and required CRFs, as appropriate, for the remainder of the study.

CLARIFICATIONS – None

REMINDERS – None