



MTN-033 Data Communiqué #4 - September 11, 2018

This is official study documentation for MTN-033. Please circulate it among relevant staff for their review, print it, and place it in your MTN-033 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-033 SSP manual.

UPDATES - None

CLARIFICATIONS

If a protocol deviation occurs during a scheduled or interim visit, the Protocol Deviation Log should be completed to include the visit code in the field “description of deviation”.

Example:

At Visit 3.0, a sample was collected outside of the collection window due to a scheduling conflict with the doctor.

If the deviation did not occur during a scheduled or interim visit, do not add a visit code to the “description of deviation”.

REMINDERS - None