MTN-035 Data Communiqué #2 – April 14, 2020 (UPDATED)

This is official study documentation for MTN-035. Please circulate it among relevant staff for their review, print it, and place it in your MTN-035 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-035 SSP Manual.

This is an updated MTN-035 Data Communiqué #2. Updates are included in **bold** text throughout the document.

A Protocol Deviation CRF will need to be completed when there is a deviation from the protocol for a visit resulting from the ongoing COVID-19 pandemic. This could be when there is a partial visit and only some visit procedures are completed, when a phone visit was conducted when it would normally be an in-clinic study visit, **when study product is dispensed early/multiple study products are dispensed at a visit,** or any other deviation from the protocol due to this pandemic. This will be effective as of 27 March 2020.

Protocol Deviation Log CRF completion:

Item Specific Instructions:

Field	Instructions
Site awareness date	Record the date the site became aware of the deviation. A complete date is required.
Deviation date	Record the date the deviation occurred (start date). A complete date is required.
Has or will this deviation be reported to local IRB/EC?	Select "Yes" or "No". Note: If COVID-19-related PDs do not need to be reported to your local IRB, this can be marked "No".
Has or will this deviation be reported to DAIDS as a critical event?	Select "Yes" or "No". Note: If COVID-19-related PDs do not need to be reported to DAIDS as a critical event, this can be marked "No".
Type of deviation	"Other" should be chosen for deviations occurring due to COVID-19. If there are other deviations unrelated to COVID-19, then add any additional deviations as appropriate.

Field	Instructions
Description of deviation	**Missed procedures:** Begin the description of the deviation with "COVID-19" and then add additional details of what procedure(s) were missed; e.g., if it was a partial visit, if the visit was completed over the phone, etc. This will allow the SDMC to filter out these specific deviations. It will also document when a procedure was missed due to COVID-19 and help alleviate future QCs. **Product dispensed early / multiple products dispensed:** **Begin the description of the deviation with "COVID-19" and then add additional details of what study products were dispensed at the visit. Only one protocol deviation log line is required to cover all products dispensed.**
Plans and/or actions to address the deviation	Use this text field to enter any specific actions you wish to document and have a record of in the database. If multiple products were dispensed, confirm that participants were provided instruction on when to start and end each product use period.
Plans and/or actions to prevent future occurrences of the deviation	Since this is currently unavoidable, you can mark this as NA or Not Applicable.
Deviation reported by	Enter the staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained and kept at the study site.

<u>Pharmacy Dispensation Log CRF completion:</u>

Date study product dispensed: Continue to enter the date study product was dispensed by the pharmacist. **A new log line should be completed for each study product dispensed even if they are dispensed on the same day.** If a site is dispensing more than one study product on a given day, please enter "multiple prescriptions dispensed on same day due to COVID-19" or similar on any date-related queries that fire.

Please note that COVID-19 related protocol deviations are being recorded as deviations for documentation purposes only, and do not count against the site in any way.