

MTN-034 Data Communiqué #6 – March 27, 2020

This is official study documentation for MTN-034. Please circulate it among relevant staff for their review, print it, and place it in your MTN-034 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-034 SSP manual.

Due to the ongoing COVID-19 pandemic, a Protocol Deviation CRF will need to be completed when there is a deviation from the protocol for a visit. 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 or any other deviation from the protocol due to this pandemic. **This will be effective as of March 26th, 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 does 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 does 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.
Description of deviation	Begin the description of the deviation with COVID-19 and then add additional details of what procedure(s) were missed, if it was a partial visit, if the visit was completed over the phone, etc. This will allow us to filter out these specific deviations. It will also document when a procedure was missed due to COVID-19 and help alleviate future QCs.
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.
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.

Field	Instructions
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.