

MTN-034 Data Communiqué #7 – July 22, 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.

UPDATES

The MTN-034 Medidata Rave database was migrated to Version 9.0 (2136) on 22 July 2020. The main purpose of this migration was to add the COVID-19 Behavioral Assessment (per Clarification Memo #02). In addition, new fields were added to the Ring Insertion and Removal CRF to aid in calculations of the adherence data. Changes are outlined for each CRF below:

COVID-19 Behavioral Assessment CRF

The COVID-19 Behavioral Assessment CRF has been added per Clarification Memo #02 dated May 27th, 2020. This form will be required to be administered at the next scheduled visit for a participant upon site approval, if applicable, and then again around 3 months later.

Since all participants are at different time frames in the study, this CRF has been added to the list of CRFs to choose from on the 'Additional Study Procedures' CRF and 'Interim Visit Summary' CRF as a means to add this CRF to a visit folder. By clicking "Yes" to "Were any additional study procedures or forms completed outside of the scheduled study visit per protocol on the Follow-up visit summary CRF, this will trigger the 'Additional Study Procedures' CRF, the 'COVID-19 Behavioral Assessment' CRF is listed in the study procedures to choose from. By marking this CRF it will populate the CRF in the visit folder for completion. If this is to be completed at an Interim Visit, this CRF is listed on the Interim Visit CRF and can be marked which will trigger the CRF into that interim visit folder.

Most of the items on this CRF require a response, a QC will fire if there is a required item left blank. Please refer to the CCGs for item specific completion.

Ring Insertion and Removal CRF

The following fields were added to the Ring Insertion and Removal CRF to aid in calculating residual drug levels in returned rings:

- Date returned ring #1 was provided to the participant
- Date returned ring #1 was inserted **OR** Unknown
- Date returned ring #1 was removed **OR** Unknown
- Date returned ring #2 was provided to the participant
- Date returned ring #2 was inserted **OR** Unknown
- Date returned ring #2 was removed **OR** Unknown

These questions should be answered depending on how many rings were returned.

An updated complete set of blank eCRFs and v5.0 of the MTN-034 CRF Completion Guidelines (CCGs) have been posted to the MTN-034 ATLAS webpage.

<https://atlas.scharp.org/cpas/project/MTN/034/begin.view?>

Adverse Event Log CRF completion:

Item Specific Instructions:

If a ppt presents to the clinic with COVID-19 symptoms, make sure you enter COVID-19 for the AE term. Since this is not in the DAIDS Tox table, please refer to the below:

Estimating Severity Grade for Parameters Not Identified in the Grading Table

The functional table below should be used to grade the severity of an AE that is not specifically identified in the grading table. In addition, all deaths related to an AE are to be classified as grade 5.

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
Clinical adverse event NOT identified elsewhere in the grading table	Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated	Potentially life-threatening symptoms causing inability to perform basic self-care functions with intervention indicated to prevent permanent impairment, persistent disability, or death