MTN-034 Data Communiqué #2 – March 13, 2019

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

Randomization CRF

As part of a migration to the study Medidata database, the Randomization CRF has been updated to allow for the Randomization ID field to be visible to the CRC and Investigator roles. This field should be used in order to randomize participants to the Serial IDI group. Please refer to the Section 11.3.1.1 of the MTN-034 SSP for guidance on Serial IDI randomization and selection.

Pharmacy Dispensation CRF

The Tablet Lot Number #1 and Tablet Lot Number #2 fields were updated with the database migration to allow for up to 9 characters and numbers to be entered by the site pharmacists. For those Pharmacy Dispensation CRFs completed prior to the migration for those participants receiving Truvada, SCHARP will send applicable sites a listing of fields that will need to be updated with the specified lot numbers.

The Vaginal Ring lot number #1 and #2 fields have been updated to allow for both numbers and letters to be entered by the site pharmacists.

An updated complete set of blank eCRFs, version 6.0_PROD_13MAR2019 (1291), and v2.0 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?

CLARIFICATIONS

Adherence Counseling CRF

Indicate the study product that the participant was randomized to receive at that visit when answering the question "Is the participant currently using the ring or tablets?". The intent of this question is to indicate the study product that the participant was assigned to and was provided at each study visit. The response "Neither" should only be marked if the participant chooses to not use product or if the participant has been placed on clinical product hold.

Demographics CRF

For item 11 "What is the highest level (class/form/standard/grade/year) she completed at that level?", enter the number indicating the highest year the participant completed in within the level of schooling answered in question 10.

For example, secondary school, fourth form should be recorded as '4'. Primary school, year three should be recorded as '3'. Secondary school, grade ten should be recorded as '10'.

These instructions and instructions for other items on the Demographics CRF have been included in version 2.0 of the CCGs.

Pharmacy Dispensation CRF

The "Study Product Sequence" field on the Pharmacy Dispensation CRF must be completed by pharmacy staff using the study prescription received from the site clinic. The "Study Product Sequence field (auto-populated from Medidata Balance)" field will not appear on the Pharmacy Dispensation CRF **until the form is saved** as this field is a QC check to ensure that data entry of the study product sequence and study product is accurate on the CRF. Site staff should leave this field blank when completing the form. Once the form is saved, ensure that this field is the same as the "Study Product Sequence" selected by site staff.

CRF Source Data Upload Fields

A number of CRFs within the Medidata Rave database include a "Source Data Upload Field" that should be used in the event that PPD monitors conduct remote monitoring during study implementation. These fields should be left blank (i.e., sites should not upload source data to these fields) unless otherwise specified by SCHARP.

REMINDERS

None