MTN-042 Data Communiqué #3 – October 29, 2020

This is official study documentation for MTN-042. Please circulate it among relevant staff for their review, print it, and place it in your MTN-042 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-042 SSP manual.

UPDATES

Database Updates

The MTN042_C1 (cohort 1) Medidata Rave database was migrated to version 4.0 (2310) on 29 October 2020.

This migration included the addition of one new study case report form:

COVID-19 Behavioral Assessment CRF

This form was added to the Enrollment and V103 folders. This form should only be completed after a site has approval to implement LoA #2. If these visits are completed prior to LoA#2 approval, contact SCHARP CDM to inactivate this form.

If a participant has already had their enrollment visit, the COVID-19 Behavioral Assessment should be completed at the participant's next visit. The form can be added to any visit folder using the Additional Study Procedures form.

The migration also included updates to the V6.0 - Week 4 bi-weekly visit folder:

The Ring Insertion and Removal, PrEP Provisions and Returns, and Ring Assessment CRFs were added to this visit folder. These were initially excluded from this visit in error. If this visit has been completed for a participant randomized to the DPV vaginal ring group and the Ring Insertion and Removal and/or Ring Assessment CRFs were not completed, please add and complete these forms if the data is available elsewhere (e.g., in source documents) or complete a Protocol Deviation. If this visit has been completed for a participant randomized to the oral Truvada group and the PrEP Provisions and Returns form was not completed, please add and complete this form if the data is available elsewhere (e.g., in source documents) or complete a Protocol Deviation.

The Tablet Assessment CRF was added to this folder per LoA#2. This form should only be completed after a site has approval to implement LoA#2. If this visit is completed prior to LoA#2 approval, contact SCHARP CDM to inactivate this form.

The migration also included changes to the following study case report forms:

Pregnancy Outcome

A new field has been added to the Pregnancy Outcome CRF: "Is the outcome of this pregnancy obtainable?". The purpose of this field is to capture if the pregnancy information was not available. This field should be completed retroactively.

Ring Insertion and Removal

Date fields were added to the Ring Insertion and Removal CRF in order to capture the provision dates of returned rings. These fields should be completed retroactively.

HIV Test Result

Two HIV Rapid kit names were updated in the database to reflect a change in test kit names. AlereTM HIV Combo was updated to Alere/Abbot HIV Combo/Ultra. Alere Determine was updated to Alere/Abbot Determine.

An updated complete set of blank eCRFs and v4.0 of the MTN-042 CRF Completion Guidelines (CCGs) will be posted to the MTN-042 ATLAS webpage.

https://atlas.scharp.org/cpas/project/MTN/042/begin.view?

In addition to form and visit folder changes, multiple system queries have been updated and corrected. The goal of system queries is to provide real-time feedback in order to ensure clean data at the point of data entry. Please continue to let SCHARP know if there are any system queries that seem to be triggering erroneously.

CLARIFICATIONS

Product returned early and prior to V101 – PPO Visit

In cases when a participant's study product is collected early and before the PPO Visit (e.g., site staff collect the used vaginal ring when a participant goes into labor), the product return should be documented as an interim visit and the appropriate forms (Ring Insertion and Removal and Specimen Storage for a returned vaginal ring, or PrEP Provisions and Returns for a returned Truvada pill bottle) should be completed.

Date of product discontinuation

On the Discontinuation of Study Product CRF, the "Date that study product use ended" should match the participant's pregnancy outcome date or the date the participant reaches 41 6/7 weeks gestation (i.e., the last allowable date of study product use). This date may or may not match the date the participant reports last using product or the date the product is returned to the clinic.