

## MTN-033 Data Communiqué #3 - August 10, 2018

This is official study documentation for MTN-033. Please circulate it among relevant staff for their review, print it, and place it in your MTN-033 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-033 SSP manual.

### UPDATES

#### Database Updates:

The MTN-033 Medidata clinical database was migrated on August 10, 2018 to include the following updates:

#### Adverse Event Log CRF

The Adverse Event log was updated to include additional response options for serious adverse events according to the ICH criteria as requested by DAIDS. The updated question and response options are:

“Is this a serious adverse event according to ICH/GCP or protocol guidelines?”

*If “No”, go to “Has or will this AE be reported as an EAE?” If “Yes”, check all that apply.”*

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

Review and update any completed Adverse Event log CRFs entered into the study clinical database and update, as needed.

#### Dose Administration CRF

The field format for “Estimated amount of gel inserted” was updated to allow for values with data up to 2 decimal places. 2 decimal points.

**If the participant has already completed the dosing visit with the coital simulation device (Visit 3 or Visit 5 depending on the randomly assigned sequence), the site should review the source documentation and update the Dose Administration form, as appropriate.**

For example, if the estimated amount of gel inserted at Visit 3 for a given participant was entered as 2g, and the source documentation for the gel amount indicates that that gel amount was 2.3g, then update “Estimated amount of gel inserted” on the Dose Administration form to 2.3g

#### Rave System Queries

As part of the MTN-033 clinical database migration, some 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.

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CRFs with updated system queries include:

- STI Tests Results: HSV-1 and HSV-2 rectal swabs that are not collected at screening will no longer trigger a query as they are not required at screening.
- Anorectal Exam: Selecting “not done” for “sigmoidoscopy findings” at the screening visit will no longer trigger a query as it is not required at screening.
- Timed Anorectal Specimen Storage: The allowable visit window for rectal biopsies has been corrected to allow for +/- 30 minutes from the participant’s assigned biopsy collection time (1 hour or 4 hours).
- Concomitant Medications Log: “Dose” and “Dose units” are no longer required fields in the event that “dose unknown” is selected.
- Dose Administration: The field “Did the participant report having a bowel movement after use of gel/coital simulation device” has been corrected to allow for this item to be left blank, per form skip instructions.
- Follow-up Visit Summary: The date check for “Was study product use permanently discontinued (scheduled early) at this visit” was corrected to check against “date study product use discontinued for this study period” on the Product Discontinuation CRF.
- Demographics: The allowable age range was corrected to 18 and older (inclusive) per protocol inclusion criteria
- Specimen Storage: The system query has been corrected so that it will no longer trigger if an entry was changed from “No” to “Yes” regarding sample collection.

An updated complete set of MTN-033 eCRFs has been posted to the MTN-033 ATLAS webpage (<https://atlas.scharp.org/cpas/project/MTN/033/begin.view?>). This version of the MTN-033 Rave eCRFs should be used moving forward for back-up data collection purposes.

**CLARIFICATIONS** - None

**REMINDERS** - None