

MTN-026 Data Communiqué #1 - January 29, 2018

This is official study documentation for MTN- 026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-026 SSP manual.

UPDATES

1. Database Updates

System Queries

As part of the MTN-026 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. Forms with updated system queries include:

- Hematology: The Hematology form has been updated to accommodate “Data entered is out of range” per site normal reference ranges for those analytes that are **not** graded per the DAIDS Toxicity Table. Analytes that are graded per the DAIDS Toxicity Table based on absolute ranges or are not gradable per the DAIDS Toxicity Table will not have their associated site reference ranges visible to sites. All analytes on the Hematology eCRF will no longer have ranges visible at the bottom of the Hematology form.
- STI Tests: The STI Tests form has been corrected so that a system query does not trigger when ‘No’ is selected for Rectal HSV-1 and Rectal HSV-2 at Screening.
- Physical Exam: The system query for Item “Head, Eye, Ear, Nose, and Throat” was corrected so that ‘Not Done’ can be selected and “If abnormal, specify” can be blank.
- Specimen Storage and Cervical Specimen Storage: Queries have been corrected so that they will only trigger if a sample is not collected but expected at the applicable visit per protocol.
- Timed Specimen Storage: The system queries that compare the Plasma PK pre-dose with the Plasma PK post-dose draw time have been broadened on both sides of specimen collection time. The system queries triggering on the collection times for rectal samples were updated so that the system queries will trigger only if sample collection is not within one hour of the post-dose blood draw.

Visit Calendar

The visit calendar on the subject homepage has been updated so that the date will be updated with the actual visit date once it has occurred instead of the target, projected date. If a visit has not yet occurred, the target date will continue to appear but will be grayed out. Once the visit has been completed and the Follow-up Visit Summary form submitted with the Visit Date, then the date will be updated and appear in black.

Visit	Date
V1.0 - Screening	01 Jan 2018
V2.0 - Enrollment	22 Jan 2018
V3.0 - Dosing (1)	29 Jan 2018
V4.0 - 24 hr PK (1)	30 Jan 2018
V5.0 - 48 hr PK (1)	31 Jan 2018
V6.0 - 72 hr PK (1)	01 Feb 2018
V7.0 - Dosing (1)	15 Feb 2018

Actual Visit Date

Target Visit Date

2. CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to v1.2 (dated 29 January 2018) and are posted on the MTN-026 Atlas webpage (<https://atlas.scharp.org/cpas/project/MTN/026/begin.view?>) for download.

3. Reports

The MTN-026 Retention Report is posted and available for viewing on the MTN-026 Atlas webpage, located under the MTN-026 Open Reports. The Retention Report lists by site and by visit the number of expected participants who have completed the visit, the number of participants who have not completed the visit, including the number of participants who missed a visit and the number of participants who terminated early, and the number of participants not expected is listed.

No sign-in or password is required to access this report.

CLARIFICATIONS

No updates

REMINDERS

Medidata Rave reports are available for internal site data cleaning and review and are available on the site-specific Medidata homepage. The following reports are available:

- Productivity Report
- Query Details Report
- Query Summary Report
- Comprehensive Page Status Report