Section 14 - Study Reporting Plan

The MTN-035 Statistical and Data Management Center (SDMC) Staff are listed below.

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14.1   Purpose of Reporting Plan

The purpose of this reporting plan is to describe the routine reports that the MTN SDMC (SCHARP) plans to generate for MTN-035.

The specific purposes of this plan are to:

- Identify the purpose and content of each report;

- Identify those responsible for the preparation and distribution of each report;

- Identify who should review the reports so that follow-up (if necessary) is done.

This reporting plan was prepared by the MTN-035 SDMC Clinical Data Manager in collaboration with other MTN-035 SDMC staff.

14.2   Study Reports

The reports listed in Table 14-1 are available within the Medidata web-based environment and can be run by designated site users (based on user permissions) at any time to include the most current data available in the Medidata Rave study database.

Table 14-2 lists the reports the SDMC will produce and make available via the MTN-035 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/035/begin.view?

Table 14-3 lists the reports the SDMC will produce and distribute via e-mail.

Following the tables is a description of each report that includes the purpose and components of the report.

Table 14-1: MTN-035 SDMC Reports Available in Medidata

Report Title	Permissions List
Query Details Report (site-specific)	• Site Staff as designated by each site • SDMC Clinical Data Manager
Unresolved Adverse Events (site-specific)	• Site Staff as designated by each site • SDMC Clinical Data Manager
Outstanding Product Holds (site-specific)	• Site Staff as designated by each site • SDMC Clinical Data Manager
Unresolved Social Harms (site-specific)	• Site Staff as designated by each site • SDMC Clinical Data Manager
AE Listing (site-specific)	• Site Staff as designated by each site • SDMC Clinical Data Manager
Enrolled PTID Listing (site-specific)	• Site Staff as designated by each site • SDMC Clinical Data Manager

Table 14-2: MTN-035 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Retention Report (Interim Visits Included)	Daily	Unsecure
Procedures Completion	Monthly	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Missed Visit Listing	Daily	Secure
Missed Visit Summary	Monthly	Secure
Protocol Deviations Listing	Daily	Secure
Protocol Deviations Summary Table	Monthly	Secure
PSRT (Safety)	One week prior to PSRT call	Secure
AE Listings	One week prior to PSRT call	Secure
Study Monitoring Committee (SMC)	Approximately every 4-6 months	Secure
Special COVID-19 specific reports:	Varied	Secure

Table 14-3: MTN-035 SDMC Reports Distributed via E-mail

Report Title	Distribution Frequency	E-mail Distribution List
LDMS Specimen Monitoring	Monthly	• Site LDMS Laboratory Staff • MTN Laboratory Center Representative(s) • SDMC Clinical Data Managers

1. Query Details

   Purpose: To provide detailed information on data queries for a given site
   Components: By site, displays for each data query the query status, query user, marking group, field, form, folder, and subject.

2. Unresolved Adverse Events (AEs)

   Purpose: To identify those AEs that have been continuing for 30 or more days (per the Adverse Event Log CRF) so that AE status updates are made as needed
   Components: Listing of ongoing AEs that have had for 30 or more days

3. Outstanding Product Holds

   Purpose: To identify those clinical product holds that have been continuing for 30 or more days (per the Clinical Product Hold/Discontinuation Log CRF) so that product status updates are made as needed
   Components: Listing of product holds that have been ongoing for 30 or more days

4. Unresolved Social Harms

   Purpose: To identify social harms that have been ongoing for 30 or more days (per the Social Impact Log) so that status updates are made as needed
   Components: Listing of Social Harms that have been ongoing for 30 or more days

5. AE Listing

   Purpose: To provide detailed cumulative listings of all reported Adverse Events per site during the study for clinical and data management
   Components: Cumulative listing of Adverse Events (AEs) reported for each site

6. Enrolled PTID Listing

   Purpose: To provide listing of PTIDs for all participants who have enrolled into the study by site as identified via the Randomization eCRF completion within the Medidata Rave study database.
   Components: Cumulative listing of PTIDs enrolled for each site

7. Screen Out

   Purpose: To summarize the number of participants screened for the study, the number enrolled, and the reasons participants were not enrolled
   Components: Number screened, number enrolled, number screened out per reason listed on the Inclusion/Exclusion Criteria CRF

8. Enrollment

   Purpose: To report on participant accrual as reflected by data entered into the study database

Components: By site, activation date, dates of first and last enrollments, duration of accrual, enrollment target, total number screened, total number enrolled, screening to enrollment ratio, average number of enrollments per week, and percentage of site target enrolled for the MTN-035 study

9. Retention

Purpose: To report on participant visit retention as reflected by data entered into the study database
Components: 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; the number of visits missed; the number of participants who missed a visit, but had product available; the number of participants who have terminated early; the number of participants, excluding early terminators, who have completed the visit; and the number of participants not expected

10. Retention Report (Interim Visits Included)

Purpose: To report on participant visit retention inclusive of interim visits as reflected by data entered into the study database
Components: 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; the number of participants who have completed the visit as an interim visit, the number of visits missed; the number of participants who missed a visit, but had product available; the number of participants who have terminated early; the number of participants, excluding early terminators, who have completed the visit; and the number of participants not expected

11. Procedures Completion

Purpose: To provide information on completion of required study procedures during follow-up, and serve as an indication as to the amount of missing data from completed visits
Components: Overall and by site, listing of number and percentage of required ("expected") study procedures that were completed at follow-up visits. Procedures are expected if the visit was completed (that is, not missed).

12. Data Management Quality

Purpose: To provide information on site performance with regard to key data management and data quality metrics.
Components: By site and overall data metrics

13. Data Summary

Purpose: To provide summary information on site performance regarding data management quality, enrollment, retention (inclusive of interim visits), and selected procedure completion.
Components: Cumulative enrollment and retention data (inclusive of interim visits), cumulative procedure completion data for selected study procedures, and cumulative and monthly data management quality data

14. Missed Visit Listing

Purpose: To identify participants who have missed scheduled study visits, to help sites focus retention efforts and prevent participants from becoming chronic defaulters and/or meeting criteria for replacement
Components: Site-specific listing of cumulative missed visits per the Missed Visit CRF; includes, for each PTID, the enrollment date, visit name, start and end of visit window

15. Missed Visit Summary

   Purpose: To provide a subset of Protocol Team members with a cumulative summary of all missed visits for the study
   Components: Overall and by site, the number and percentages of missed visits reported for the study

16. Protocol Deviations Listing

   Purpose: To provide a subset of Protocol Team members with a cumulative listing of all protocol deviations reported for the study.
   Components: Each of the fields/data items as listed on the Protocol Deviations Log CRF.

17. Protocol Deviations Summary Table

   Purpose: To provide a subset of Protocol Team members with a cumulative and past month summary of all protocol deviations for the study
   Components: Overall and by site, the number and percentages of protocol deviations reported for the study

18. PSRT (Safety) Reports

   Purpose: To help the Protocol Safety Review Team (PSRT) monitor participant safety as reflected by adverse events and study product discontinuations reported to the SDMC.
   Components: Cumulative AE and study product discontinuations reported to the SDMC on the AE Log CRF and Treatment Discontinuation CRF.

19. AE Listing

   Purpose: To provide the MTN-035 Safety Physicians with a cumulative listing of all adverse events in order to monitor participant safety.
   Components: Cumulative listing of all adverse events reports to the SDMC per the Adverse Event Log CRF

20. Study Monitoring Committee (SMC) Reports

   Purpose: To provide information on study conduct, ability to answer study objectives, and primary endpoint data to SMC members as required in preparation for scheduled reviews
   Components: Summary by site and overall of study design and history, accrual, retention, retention (inclusive of interim visits), demographics, baseline characteristics, data management quality, protocol deviations, and other components as requested by the SMC

21. LDMS Specimen Monitoring

   Purpose: To identify stored specimens whose information in LDMS does not match corresponding information collected per study CRFs
   Components: Listing of those specimens whose LDMS PTID, visit code, and/or collection date information does not match the information recorded on CRFs; specimens that are stored per CRF but not present in LDMS; specimens that are present in LDMS but not stored per CRF; specimens in LDMS from PTIDs who did not enroll

22. Special COVID-19 specific reports:
Purpose: In addition, the following special reports will be produced to account for essential data which may be affected due to COVID-19: Missed Visit Report – COVID-19; Procedures Completion Report – COVID-19; Retention Report – COVID-19; Retention Graph – COVID-19.
Components: The components and frequency of production of these reports are identical to original

reports outlined above with the exception of all COVID-19 specific reports including data beginning from March 16, 2020 onwards.