Section 16 - Study Reporting Plan

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The MTN-025 Statistical and Data Management Center (SDMC) Staff are listed below.

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16.1 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-025.

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-025 SDMC Clinical Data Manager(s) in collaboration with other MTN-025 SDMC staff.

16.2 Study Reports

Table 16-1 lists the reports that are available within Medidata Rave. Table 16-2 lists the reports that SDMC will produce and distribute via email. Table 16-3 lists the reports the SDMC will produce and make available via the MTN-025 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/025/begin.view?

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

Table 16-1: MTN-025 SDMC Reports Available within Medidata Rave

Report Title	Available to View and Download:
Site-specific Query Details Report	• Site Staff as designated by each site • SDMC Clinical Data Managers
Site-specific Query Summary Report	• Site Staff as designated by each site • SDMC Clinical Data Managers
Site-specific Unresolved Adverse Experiences (AEs)	• Site Staff as designated by each site • SDMC Clinical Data Managers
Site-specific Outstanding Product Holds	• Site Staff as designated by each site • SDMC Clinical Data Managers
Site-specific Unresolved Social Impacts	• Site Staff as designated by each site • SDMC Clinical Data Managers
Site-specific Productivity Report	• Site Staff as designated by each site • SDMC Clinical Data Managers
Site-specific Comprehensive Page Status Report	• Site Staff as designated by each site • SDMC Clinical Data Managers
Audit Trail Report	• Site Staff as designated by each site • SDMC Clinical Data Managers

Table 16-2: MTN-025 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
LDMS Specimen Monitoring	Monthly	• Site LDMS Laboratory Staff • Network Lab Representative • SDMC Clinical Data Managers

Table 16-3: MTN-025 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Retention Report Summary	Daily	Unsecure
Retention Report Graph	Daily	Unsecure
Procedures Completion	Monthly	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Missed Visits Listing	Daily	Unsecure

Missed Visits Summary	Monthly	Unsecure
Protocol Deviations Listing	Daily	Secure
Protocol Deviations Summary	Monthly	Secure
Early Termination	Daily	Secure
PSRT (Safety)	One week prior to PSRT call	Secure
AE listings	One week prior to PSRT call	Secure
SMC	Approximately every 6 months	Secure
Network Laboratory	As needed	Secure
Residual Drug Data	Twice a week	Secure
Adherence Reports	Monthly	Secure

1. Query Details Report (QC Report)

   Purpose: To identify missing and inconsistent data
   Components: Listing of queries by PTID that provides query status, query text, marking group, query response history and query text, resolution status/date

2. Query Summary Report

   Purpose: To provide an overview of query status by site
   Components: Number of open, answered, closed, and cancelled system and manual queries

3. Unresolved Adverse Experiences (AEs)

   Purpose: To identify those AEs that have been continuing for 90 or more days (per the Adverse Experience Log CRF) so that AE status updates are made as needed
   Components: Listing of AEs that have had a “continuing” status for 90 or more days

4. 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

5. Unresolved Social Impacts

   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

6. 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, 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

7. Missed Visits Listing

   Purpose: To identify participants who may have missed their most recent scheduled visit, to help sites focus retention efforts and prevent participants from becoming chronic defaulters
   Components: Site-specific cumulative listing of missed visits per the Missed Visit CRF: includes for each PTID the enrollment date, visit name, visit number, and target visit date

8. Missed Visit Summary

   Purpose: To provide 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

9. Productivity Report

   Purpose: To summarize the user activity for actions completed within the Rave database in the past per site
   Components: Key metrics on Rave user actions (e.g., number of pages entered, number of pages with answered or closed queries)

10. Page Status Comprehensive Report

    Purpose: To summarize the current status per-site of all the CRFs completed
    Components: By site, the number of expected CRFs, number of CRFs entered into Rave, the number of overdue CRFs, the number of CRFs with open and answered queries, the number of CRFs coded, signed by the IoR, and locked by the Data Manager

11. Audit Trail Report

    Purpose: To provide a record listing of all activities made to each data field within the Rave database
    Components: The Rave user, role, action type, date and time, for each data field on CRFs completed per site, based on the user's role.

12. Screen Out

Purpose: To summarize the number of participants screened for the study, the number enrolled, and the reasons participants were not enrolled (Includes the Main Study population and Decliner population)
Components: Number screened, number enrolled, number screened out per reason listed on the Eligibility Criteria CRF.

13. Enrollment

Purpose: To report on participant accrual as reflected by data entered and data submitted into Medidata Rave.
Components: By site, activation date, date 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, percentage of site target enrolled for the MTN-025 study and for the Decliner Population.

14. Retention

Purpose: To report on participant visit retention as reflected by data entered and data submitted into Medidata Rave.
Components: By site and by visit month, 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 missed a visit; the number of participants who terminated early; and the number of participants not expected is listed. Note: Retention is reported through Month 12 only.

15. Retention Report Graph

Purpose: To provide a graphic presentation of the Retention Report.
Components: A line graph containing a line for each site, with the horizontal axis being the Visit Month and the vertical axis the site's retention rate (the % participants retained).

16. Procedure 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 and not completed at follow-up visits. Procedures are expected if the visit was completed (that is, not missed).

17. Data Management Quality Report

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

Components: By site and overall data metrics as specified in the SOP

18. Data Summary Report

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

19. 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.

20. Protocol Deviations Summary Table

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

21. Termination

Purpose: To provide a subset of Protocol Team members with a cumulative summary of all terminations reported for the study, including early terminations.
Components: Site, PTID, Termination Date and Reason for Termination data from the Termination CRF

22. PSRT (Safety) Reports

Purpose: To help the Protocol Safety Review Team monitor participant safety as reflected by adverse experiences, clinical product hold, and social impacts reported to the SDMC.
Components: Cumulative AE, product hold, pregnancy, and social impact data reported to the SDMC.

23. AE Listings

Purpose: To provide the MTN-025 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 Experience Log CRF.

24. Study Monitoring Committee (SMC) Reports

Purpose: To provide information on study conduct and 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, demographics, baseline characteristics, data management quality, protocol deviations, and other components as requested by the SMC

25. Network Laboratory Listings

Purpose: To provide the Network Laboratory (NL) with specimen data so they can determine when site shipments are needed to facilitate timely data transfer between the Network Laboratory and SCHARP
Components: Cumulative number of specimens requiring HIV endpoint confirmatory and QA testing, as well as PK testing, at the Network Labs

26. Residual Drug Data

Purpose: To provide sites with residual drug feedback results on a participant level basis
Components: PDF per-PTID providing individual ring code or quarterly visit with the corresponding protection level

27. Adherence Reports

Purpose: To provide study leadership with a summary of participant choice to use the study ring and quarterly provision of the ring
Components: Summary by site and study month of participant ring choice, and reasons participants choose not the use the ring, ring choice switching behavior, and quarterly ring choice schedule (monthly or quarterly)