Section 14. Study Reporting Plan

The MTN-039 Statistical and Data Management Center (SDMC) Staff are listed below.

Job Role	Name	Email Address
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14 Study Reporting Plan

The purpose of this reporting plan is to describe the routine reports that the MTN SDMC (SCHARP) plans to generate for MTN-039.

14.1 Purpose of Reporting Plan

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-039 SDMC Clinical Data Manager in collaboration with other MTN-039 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-039 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/039/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-039 SDMC Reports Available in Medidata

Report Title	Permissions List
Site-specific Query Summary	• Site Staff as designated by each site • SDMC Clinical Data Manager
Site-specific Query Details	• Site Staff as designated by each site • SDMC Clinical Data Manager
Site-specific Page Status	• Site Staff as designated by each site • SDMC Clinical Data Manager
Site-specific Productivity	• Site Staff as designated by each site • SDMC Clinical Data Manager
Site-specific AE Listing	• Site Staff as designated by each site • SDMC Clinical Data Manager
Site-specific Page Not Touched	• Site Staff as designated by each site • SDMC Clinical Data Manager

Table 14-2: MTN-039 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Procedure Completion (Visit Adherence)	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
SMC	Approximately every 6 months	Secure

Table 14-3: MTN-039 SDMC Reports Distributed via E-mail

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

1. Query Summary

   Purpose: To provide data query metrics for a given site
   Components: By site, displays a count of the number of Medidata Rave queries that are generated throughout the study - Open, Cancelled, and an overall total grouped by site and marking group

2. Query Details

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

3. Page Status

   Purpose: To provide the current status of CRFs within a specified study, site, participant, folder, and/or form
   Components: By site, provides current status of CRFs by PTID, by visit folder, and by CRF within a visit folder

4. Productivity

   Purpose: To provide key metrics on Rave utilization by Rave user
   Components: By site, provides details on the following activities performed by each Rave user – pages entered, pages verified, pages reviewed, pages entry locked, pages locked, pages with open queries, pages with answered queries, pages with closed queries, pages with cancelled queries, pages coded (Adverse Events and Concomitant Medications), and pages signed

5. Site-specific AE Listing

   Purpose: To provide a listing of all reported AEs for a given site
   Components: By site, provides a cumulative line listing of all AEs reported at each site including: AE term, Date Reported to Site, Visit at which the AE was reported, onset date, whether the AE is ongoing, Severity grade, action taken with study product, status/outcome, SAE/EAE status, whether the AE was a worsening of a baseline medical condition, related to the flexible sigmoidoscopy procedures.

6. Page Not Touched in EDC

   Purpose: To provide a listing of all eCRFs that have never been touched
   Components: By site, provides a cumulative line listing of all eCRFs that have not been touched (i.e. missing or blank pages).

7. 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

8. 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

9. 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

10. 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 protocol-specified reason for ineligibility listed on the Inclusion Exclusion Criteria CRF

11. 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-039 study

12. 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; 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

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

14. 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

15. Data Summary Reports

    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

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 Product Discontinuation CRF

19. AE Listings

    Purpose: To provide the MTN-039 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, demographics, baseline characteristics, data management quality, protocol deviations, and other components as requested by the SMC