Section 13 Study Reporting Plan

13 Introduction

The MTN-043 Statistical and Data Management Center (SDMC) Staff are listed below.

Job Role	Name	Email Address
Protocol Statistician	Barbra Richardson	barbrar@uw.edu
Protocol Co-Chair	Jennifer Balkus	jbalkus@uw.edu
Statistical Research Associate	Holly Gundacker	hgundack@scharp.org
Lead Clinical Data Manager	Jillian Zemanek	jzemanek@scharp.org
Clinical Programmer	Jackie Fitzpatrick	jackie@scharp.org
Clinical Safety Associate	Wendy Hou	whou2@scharp.org
Lab Data Coordinator	Dana Tupa	dtupa@scharp.org

13.1 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-043.
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-043 SDMC Clinical Data Manager in collaboration with other MTN-043 SDMC staff.

13.2 Study Reports

The reports listed in Table 13-1 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 13-2 lists the reports the SDMC will produce and make available via the MTN-043 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/043/begin.view?

Table 13-3 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 13-1: MTN-043 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
Query Summary 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
Unresolved 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

Table 13-2: MTN-043 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Mother Screen Out	Daily	Unsecure
Mother - Exclusive Breastfeeding	Monthly	Unsecure
Infant Screen Out	Daily	Unsecure
Mother-Infant Enrollment	Daily	Unsecure
Mother Retention	Daily	Unsecure
Infant Retention	Daily	Unsecure
Mother Procedure Completion	Monthly	Unsecure
Infant Procedure 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 Summary)	One week prior to PSRT call	Secure
Mother AE listings	One week prior to PSRT call	Secure
Infant AE listings	One week prior to PSRT call	Secure
Adherence Reports	Ad hoc (when batch data available)	Secure
Participant Safety History Report	Ad hoc	Secure

EPDS Listing	Weekly	Secure
Weekly Alerts	Weekly	Secure
LDMS Specimen Monitoring	Monthly	Secure

Table 13-3: MTN-043 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: Query status, query user, marking group, field, form, folder, subject, site group, and site for each open data query by site

2. 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, Answered, Closed, Cancelled, and an overall total grouped by site and role.

3. Unresolved Adverse Events (AEs)

Purpose: To identify those AEs that have been continuing for 30 or more days (per the Adverse Event Log and Non-Enrolled Infant Adverse Event Log CRFs) so that AE status updates are reviewed and updates are made, as needed
Components: Listing of ongoing AEs that have been continuing for 30 or more days

4. Unresolved 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 Harms

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

6. Mother Screen Out

Purpose: To summarize the number of mothers 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

7. Mother – Exclusive Breastfeeding

Purpose: To summarize the number and percent of mothers exclusively breastfeeding infants and number and percent of mothers who have completely weaned infants from breastmilk.
Components: Exclusively breastfeed and Completely weaned from breastmilk per site and per visit on the Feeding Assessment CRF

8. Infant Screen Out

Purpose: To summarize the number of infants 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

9. Mother-Infant Enrollment

Purpose: To report on participant accrual of mother-infant pairs as reflected by data entered into the study database
Components: By site, activation date, dates of first and last enrollments, duration of accrual, total number screened, total number enrolled, screening to enrollment ratio, average number of enrollments per week, and percentage of study target (across all sites) enrolled for the MTN-043 study

10. Mother 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 have terminated early; the number of participants, excluding early terminators, who have completed the visit; and the number of participants not expected

11. Infant Retention

Purpose: To report on infant visit retention as reflected by data entered into the study database
Components: By site and by visit, the number of expected infants who have completed the visit; the number of infants who have not completed the visit; the number of infant visits missed; the number of infants who have terminated early; the number of infants, excluding early terminators, who have completed the visit; and the number of infants not expected

12. Mother 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).

13. Infant Procedure Completion

Purpose: To provide information on completion of required infant 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

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

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. 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

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 by participant type,

17. 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

18. 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 CRF

19. 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

20. PSRT (Safety) Reports

Purpose: To aid the Protocol Safety Review Team (PSRT) monitor participant safety as reflected by adverse events and study product holds or discontinuations reported to the SDMC

Components: Cumulative AE, social impacts, study product holds, pregnancy reports/outcome and discontinuations reported to the SDMC on the AE Log CRF, Product Hold, and Product Discontinuation CRF

21. Mother AE Listings

Purpose: To provide the MTN-043 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

22. Infant AE Listings

Purpose: To provide the MTN-043 Safety Physicians with a cumulative listing of all infant adverse events in order to monitor participant safety.
Components: Cumulative listing of all infant adverse events reports to the SDMC per the Adverse Event Log CRFs

23. Interim Safety Review Reports

Purpose: To provide the Interim Review Panel with participant safety data to determine if the study should move forward with enrolling the next cohort
Components: Summary of participants enrolled, and summaries and listings of primary and secondary safety outcomes

24. Adherence Reports

Purpose: To provide drug summary information to study leadership as part of ongoing review of adherence data during the study
Components: Summary of drug adherence and tables of drug level trajectories over time by product arm, site and overall

25. Participant Safety History Report

Purpose: To provide PSRT safety history on mother-infant pairs
Components: Listing Includes participant level data elements: demographics, enrollment, ring insertion/removal, PrEP provisions/returns, product hold, product discontinuation, vital signs/physical exams, lab test results, pregnancy history/tests/report/outcome, AEs, baseline medical condition and concomitant medications. It will include the information for both the mother and the infant.

26. EPDS Listing

Purpose: To provide PSRT data of higher risk EPDS cases
Components: Listing of cases where EPDS score is 10 or greater, or question #10 “The thought of harming myself has occurred to me” is not answered “Never”.

27. Weekly Alerts:

Purpose: To provide PSRT weekly safety alerts
Components: Newly reported or modified grade 3+ AEs/lab results, SAEs, EAEs, product holds, early product discontinuations, pregnancies and pregnancy outcomes.

28. 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