Section 13 - Study Reporting Plan

The MTN-017 Statistical and Data Management Center (SDMC) Staff are listed below.

Job Role	Name	Email Address
Protocol Statistician	Barbra Richardson	barbrar@u.washington.edu
Statistical Research Associate	Marla Husnik	marla@fredhutch.org
Statistical Research Associate	Karen Liu	cliu2@scharp.org
Project Manager	Karen Patterson	karenp@fredhutch.org
Project Manager	Melissa Peda	mapeda@fredhutch.org
Protocol Programmer	Katie Weaver	kweaver@scharp.org
Data Coordinator	Stacie Kentop	stacie@fredhutch.org
Lab Operations Programmer	Katie Snapinn	ksnapinn@fredhutch.org
Clinical Affairs Safety Associate	Yevgeny Grigoriev	ygrigori@fredhutch.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-017.

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-017 SDMC Project Manager in collaboration with other MTN-017 SDMC staff.

13.2 Study Reports

Table 13-1 lists the reports the SDMC will produce and distribute via e-mail. Table 13-2 lists the reports the SDMC will produce and make available via the MTN-017 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/017/begin.view?

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

Table 13-1: MTN-017 SDMC Reports Distributed via E-mail

Report Title	Distribution Frequency	E-mail Distribution List
Data Quality Control (QC)	Monthly	• Site Staff as designated by each site • SDMC Project Manager
Clinical Queries	As needed (as queries are identified)	• Site Staff as designated by each site • SDMC Project Manager
Unresolved Adverse Experiences (AEs)	Every 3 months	• Site Staff as designated by each site • SDMC Project Manager
Unresolved Product Holds	Monthly	• Site Staff as designated by each site • SDMC Project Manager
Unresolved Social Harms	Monthly	• Site Staff as designated by each site • SDMC Project Manager
LDMS Specimen Monitoring	Twice a month	• Site LDMS Laboratory Staff • Network Lab Representative • SDMC Project Manager

Table 13-2: MTN-017 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Retention Report Graph	Daily	Unsecure
Procedure Completion	Monthly	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Missed Visits	Daily	Unsecure
Product Adherence	Daily	Secure
Protocol Deviations Listing	Daily	Secure
Protocol Deviations – Summary	Daily	Secure
PSRT (Safety)	One week prior to PSRT call	Secure
SMC	As determined by the SMC	Secure

1. Data Quality Control (QC Report)

   Purpose: To identify missing and inconsistent data
   Components: Quality control notes; overdue visit reminders, missing page reminders

2. Clinical Queries

   Purpose: To identify inconsistencies/questions identified in safety or clinical data
   Components: Queries containing clinically-based questions about safety and clinical data

3. Unresolved Adverse Experiences (AEs)

   Purpose: To identify those AEs that have been continuing for 90 or more days (per the AE 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. Unresolved Product Holds

   Purpose: To identify those clinical product holds that have been continuing for 30 or more days (per the PH 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 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 CRFs
   Components: Listing of those specimens whose LDMS PTID, collection date, or visit month 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. 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 Eligibility Criteria CRF

8. Enrollment

   Purpose: To report on participant accrual as reflected by data received and data entered at the SDMC
   Components: Accrual data is presented 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.

9. Retention

   Purpose: To report on participant visit retention as reflected by data received and data entered at the SDMC
   Components: By site and by visit, the number of expected participants who have completed the visit; the number who have not completed the visit; the number of visits missed; the number of participants not expected

10. 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)

11. 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)

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, for cumulative and previous month time periods, the total number of CRF pages received, total number of QCs created, QC rate per 100 CRF pages,% QCs resolved (cumulative report only), % CRFs received within 7 days, and mean days to fax in AE Log

13. 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

14. Missed Visits

Purpose: To provide site-specific cumulative listings of all missed visits reported for the study, as well as a summary report showing the total number of missed visits by site and for all sites total
Components: Site-specific listing of PTIDs who may have missed the most recent scheduled visit (i.e., a Missed Visit CRF was received, or no CRFs were entered at SCHARP for the visit), date of the enrollment date and expected visit date, and visit window dates for the expected visit

15. Product Adherence

Purpose: To provide members of the MTN-017 Adherence Working Group with a cumulative summary of study product adherence data to identify trends and issues
Components: Summary by site and overall of data from the Product Dispensation and Return CRF, Data Convergence Interview non-DataFax CRF, and the BRWG's final converged rate; data presented by product regimen and visit. In addition, the report includes a listing of participants with negative PK results, presented by site, product regimen, visit, and specimen collection date.

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

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 deviations reported for the study

18. 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, and social impact data reported to the SDMC

19. 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