

Section 13. Study Reporting Plan

MTN-014 Statistical and Data Management Center (SDMC) Staff

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13.1 Purpose of Reporting Plan

The purpose of this reporting plan is to describe the reports that the MTN SDMC (SCHARP) plans to generate for MTN-014.

The specific purposes of this plan are:

- To identify the purpose and content of each report;
- To identify those responsible for the preparation and distribution of each report;
- To identify who should review the reports so that corrective action (if necessary) is taken; and

This reporting plan was prepared by the MTN-014 SDMC Project Manager in collaboration with other MTN-014 SDMC staff.

13.2 Study Reports

Table 13-1 lists the reports the SDMC will produce and distribute via email. Table 13-2 lists the reports the SDMC will produce and make available via the MTN-014 Atlas web page:

<https://atlas.scharp.org/cpas/project/MTN/014/begin.view?>

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

Table 13-1: MTN-014 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Biweekly and as needed	<ul style="list-style-type: none"> • Site Staff as designated by each site • SDMC Project Managers
Clinical Queries	As needed (as queries are identified)	<ul style="list-style-type: none"> • Site Staff as designated by each site • SDMC Project Managers
Unresolved Adverse Experiences (AEs)	Monthly	<ul style="list-style-type: none"> • Site Staff as designated by each site • SDMC Project Managers
Unresolved Product Holds	Monthly	<ul style="list-style-type: none"> • Site Staff as designated by each site • SDMC Project Managers
LDMS Specimen Monitoring	Bi-weekly	<ul style="list-style-type: none"> • Site LDMS Laboratory Staff • Network Lab Representative • SDMC Project Managers

Table 13-2: MTN-014 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Procedure Completion	Daily	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Protocol Deviations - Listing	Daily	Secure
Protocol Deviations – Summary	Monthly	Secure
PSRT (Safety)	One week prior to each scheduled PSRT call	Secure
SMC	As requested based on safety concerns	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 30 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 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 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. LDMS Specimen Monitoring

Purpose: To identify stored specimens whose information in LDMS does not match corresponding information collected per the CRFs

Components: Listing of those specimens whose LDMS information does not match the information recorded on CRFs or are listed on CRFs as not having been collected; listing of specimens designated as “collected” per CRF but missing from LDMS; listing of specimens in LDMS from PTIDs who did not enroll

6. 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

7. Enrollment

Purpose: To report on participant accrual as reflected by data received and data entered at the SDMC

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

8. Retention

Purpose: To report on participant retention as reflected by data received and data entered at the SDMC

Components: By site and by visit, the number of participants expected and not expected for the visit. For expected visits, the number and percentage of visits completed not completed will be listed. For the expected visits listed as not completed, the number and percentage of missed visits, and Early Terminations will be provided

9. Procedure Completion

Purpose: To provide information on completion of required study procedures during follow-up

Components: By site, listing of number and percentage of completed key required follow-up visit procedures. Listed procedures may include specimen storage, laboratory assay testing, pelvic and rectal exam completion. This does not include visits that are missed

10. Data Management Quality Report

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

Components: By site, for cumulative and previous month time periods, the total number of CRF pages received, total number of QCs created, QC rate per 100 CRF records, % QCs resolved (cumulative report only), % CRFs received within 5 days, and mean days to fax in AE Log CRFs

11. 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

12. Protocol Deviations Listing

Purpose: To provide MTN Regulatory with a listing of all protocol deviations reported for the study

Components: Each of the fields/data items as listed on the Protocol Deviations Log

13. Protocol Deviations Summary Table

Purpose: To provide MTN Regulatory with a summary table of cumulative protocol deviations.

Components: Cumulative protocols deviations by type of protocol deviation and by site

14. PSRT (Safety) Reports

Purpose: To help the Protocol Safety Review Team monitor participant safety as reflected by adverse experiences and clinical product hold reported to the SDMC

Components: Cumulative AE, product hold data reported to the SDMC

15. Study Monitoring Committee (SMC) Reports

Purpose: To provide information on study conduct and ability to answer study objectives to key Protocol Team members and Site Investigators

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.