Section 13. Study Reporting Plan

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13.1 Purpose of Reporting Plan

The purpose of this reporting plan is to describe the reports that will be generated for MTN-029.

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;

This reporting plan was prepared by the MTN-029 SDMC Project Manager in collaboration with other MTN-029 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-029 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/029/begin.view?

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

Table 13-1: MTN-029 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Biweekly	• Site Staff as designated by site • SDMC Project Manager
LDMS Specimen Monitoring	Monthly	• Site LDMS Laboratory Staff • Laboratory Center Representative • SDMC Project Manager

Table 13-2: MTN-029 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
Missed Visit	Daily	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Protocol Deviations - Listing	Daily	Secure
Protocol Deviations – Summary	Monthly	Secure
AE Listing	Daily	Secure
PSRT (Safety)	One week prior to each scheduled PSRT call	Secure
SMC	Every 6 months and as needed	Secure

1. Data Quality Control (QC Report)

   Purpose: To identify missing and inconsistent data, including inconsistencies/questions identified in safety or clinical data
   Components: Quality control notes; overdue visit reminders, missing page reminders, and queries containing clinically-based questions about safety and clinical data

2. 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; listing of specimens in LDMS with unexpected or missing specimen information

3. 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

4. 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

5. 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

6. Procedure Completion

   Purpose: To provide visit adherence information on completion of required study procedures during follow-up
   Components: By site, listing of number and percentage of completed required follow-up visit procedures. Listed procedures may include specimen storage, laboratory assay testing, and pelvic exam completion. This does not include visits that are missed

7. Missed Visit Report

   Purpose: To provide a summary, cumulative and by site, of missed visits
   Components: a site-specific listing of missed visits (cumulative and within the past month). A visit is considered missed if a Missed Visit CRF has been completed for that visit and the visit window has closed.

8. 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

9. Data Summary Report

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

10. 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

11. 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

12. AE Listing

    Purpose: To provide the MTN-029 Safety Physicians with a cumulative listing of all adverse events in order to monitor participant safety.
    Components: Cumulative listing of all adverse events reported to the SDMC per the AE Log CRF

13. PSRT (Safety) Report

    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

14. Study Monitoring Committee (SMC) Report

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 baseline characteristics, data management quality, protocol deviations, accrual, retention, completion of primary and main secondary endpoint assessments, study or lab issues, safety data, and other components as requested by the SMC