Section 17 – MTN-003 and MTN-003B Study Reporting Plan

MTN-003 and MTN-003B Statistical and Data Management Center (SDMC) Staff

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17.1 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-003 and MTN-003B.

This reporting plan will:

- 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 corrective action (if necessary) is taken; and
- Ensure the Protocol Team approves the plan prior to study initiation.

This reporting plan was prepared by the MTN-003 and MTN-003B SDMC Project Managers in collaboration with other MTN-003 and MTN-003B SDMC staff.

17.2 Study Reports

Table 17-1 lists the reports the SDMC will produce and distribute via email. Table17-2 lists the reports the SDMC will produce and make available via the Atlas website:

http://atlas.scharp.org

Following the tables is a description of each report that includes the purpose of the report, who will prepare the report, and specific components of the report.

Table 17-1: MTN-003 and MTN-003B SDMC Reports Distributed via E-mail

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC) Report	Every month, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Clinical Data Quality Control (CQC) Queries	Every two weeks for the first 3 months of data transmission at a given site, then every month, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Unresolved Adverse Experiences Listing	Monthly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Managers
Specimen Monitoring Reports (Site-specific and for the study overall)	Monthly	• Site Study Coordinators • Network Lab Representative • SDMC Project Manager

Table 17-2: MTN-003 and MTN-003B SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment and Retention	Daily	Unsecure
Visit Adherence and Procedure Completion	Monthly	Unsecure
Product Adherence	Monthly	Secure
Site Data Management Quality	Monthly	Unsecure
Safety (PSRT) Reports	One week prior to each scheduled PSRT call	Secure
Study Monitoring Committee (SMC) Report	Within 4-6 months of study initiation, then prior to Data Safety Monitoring Board (DSMB) reviews and/or as determined by the SMC	Secure
Data Safety Monitoring Board (DSMB) Report	Up to three weeks prior to scheduled DSMB reviews	Secure
Network Lab Assay Results Report	Daily	Secure

17.2.1 Data Quality Control (QC) Report

Purpose: To identify and help correct missing and inconsistent data
Prepared and Distributed by: SDMC Data Coordinator
Components: Quality control notes, overdue visit reminders, missing page reminders. Report includes quality control notes on MTN-003B data.

17.2.2 Clinical Data Quality Control (CQC) Queries

Purpose: To identify and help correct inconsistencies or questions identified in safety or clinical data
Prepared and Distributed by: SDMC Clinical Affairs Safety Associate
Components: Queries containing clinically-based questions about safety and clinical data

17.2.3 Unresolved Adverse Experiences Listing

Purpose: To identify those AEs that have been marked as "Continuing" for >90 days, to help individual sites monitor AE resolution throughout the study.
Prepared and Distributed by**:** SDMC Reports Programmer and SDMC Clinical Affairs Safety Associate
Components: Site-specific listing of all AEs that have been marked as "Continuing" for >90 days. For each unresolved AE the report lists the PTID, page #, AE text, date reported to site, onset date, severity grade, and visit at which the AE was first reported.

17.2.4 Specimen Monitoring Report

Purpose: To monitor storage in LDMS of those specimens marked as “stored” on study CRFs
Prepared and Distributed by: SDMC Laboratory Programmer
Components: Site-specific and overall study listing of all discrepancies between the CRF stored specimen data and LDMS data. Report includes data collected for MTN-003B.

17.2.5 Enrollment and Retention Report

Purpose: To monitor participant accrual and retention as reflected by data submitted to SCHARP DataFax
Prepared by: SDMC Protocol Programmer
Components: *Enrollment*: this report includes the number of women enrolled each week and cumulatively. *Retention, by visit*: this report includes the total number of women enrolled (broken down by active, inappropriately enrolled, and lost to follow-up); number expected for a given visit; number not expected for a given visit; and total retention by visit calculated as the number of participants who have completed a visit divided by the total number of participants expected for the visit. Separate Enrollment and Retention Reports will be generated for MTN-003 and MTN-003B.

17.2.6 Visit Adherence and Procedure Completion Report

Purpose: To summarize site performance regarding study endpoint data collection
Prepared by: SDMC Statistical Research Associates
Components: Distribution of visits, including the number of days between target and actual visit dates, and the number of days between sequential follow-up visits; listing of number and % of required PK blood specimens collected, genital specimens collected, safety lab tests completed, pelvic exams completed, pregnancy tests completed, and HIV tests completed. Separate reports will be generated for MTN-003 and MTN-003B.

17.2.7 Product Adherence Report

Purpose: To provide information on self-reported product adherence based on CRF pages faxed to SCHARP as well as data collected via ACASI.
Prepared by: SDMC Statistical Research Associates
Components: Summary of product counts and self-reported product use (from CRFs and ACASI), including a summary of qualitative responses to product usage over the past 4 weeks, and a summary of quantitative responses to product usage in the past 7 days

17.2.8 Site Data Management Quality Report

Purpose: To summarize site performance regarding data management and quality.
Prepared by: SDMC Project Managers
Components: Total number of CRF pages faxed to SCHARP, total number of QCs applied, % of QCs resolved, QC rate per 100 CRF pages, and mean days to fax in CRF pages. Report includes a table with data from the previous month, and a table with cumulative data since study start. Report includes CRFs submitted for MTN-003B.

17.2.9 Safety (PSRT) Reports

Purpose: To help the Protocol Safety Review Team (PSRT) monitor study participant safety as reflected by adverse experiences, pregnancies, and social harms reported to the SDMC via SCHARP DataFax.
Prepared by: SDMC Reports Programmer and SDMC Clinical Affairs Safety Associate
Components: Adverse event, pregnancy outcome, and product hold data reported to SDMC via SCHARP DataFax. Report may include other DataFax data as requested by the PSRT.

17.2.10 Study Monitoring Committee (SMC) Report

Purpose: To monitor study conduct as outlined by the protocol.
Prepared by: SDMC Statistical Research Associates and Protocol Statisticians
Components: Summary (by site and for the overall study) of study design and history, accrual, retention, participant demographics, and visit adherence. Report may include site data management quality and other components as requested by the SMC. A similar report will be prepared for MTN-003B for

review along with the MTN-003 SMC report.

17.2.11 Data Safety Monitoring Board (DSMB) Report

Purpose: To monitor the primary safety and effectiveness endpoints of the study, as well as study conduct as outlined in the protocol.
Prepared by: SDMC Statistical Research Associates and Protocol Statisticians
Components: All components listed for the SMC Report, with the addition of adverse event data and HIV-infection data. A report will also be prepared for MTN-003B to include substudy conduct operational characteristics (e.g., accrual and retention) and an assessment of safety, including the onset of osteoporosis and adult non-traumatic fragility fractures or Z-scores < -2.0.

17.2.12 Network Lab Assay Results Report

Purpose: To monitor the receipt of lab assay results from the Network Lab
Prepared by: SDMC Laboratory Programmer
Components: For each specimen analyzed by a Network Lab, the number of results expected (per CRF specimen collection data) along with the number and percentage of results received and processed at SCHARP. MTN-003B data will be included in these reports.