Section 16 - Study Reporting Plan

MTN 004 Statistical and Data Management Center (SDMC) Staff

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16.1 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 004.

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
- To ensure the Protocol Team approves the plan prior to study initiation.

This reporting plan was prepared by the MTN 004 SDMC Project Manager in collaboration with other MTN 004 SDMC staff.

16.2 Study Reports

Table 16-1 lists the reports the SDMC will produce and distribute via email.Table16-2 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 16-1: MTN 004 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Every two weeks, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Clinical Data Quality Control (CQC) Queries	Weekly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Study Monitoring Committee (SMC)	As determined by the SMC	• MTN 004 SMC members and observers • MTN 004 Protocol Chair • MTN 004 Site Investigators
Site Specimen Monitoring Report	Monthly	• Site Study Coordinators • Network Lab Representative • SDMC Project Manager
Summary Specimen Monitoring Report	Monthly	• Network Lab Representative • SDMC Project Manager

Table 16-2: MTN 004 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment and Retention	Every Week	Unsecure
Visit Adherence and Procedure Completion	Every 2 Weeks	Unsecure
Site Data Management Quality	Monthly	Unsecure
Safety Report	As determined by the MTN-004 Protocol Safety Review Team (PSRT)	Secure
Network Lab Assay Results Report	Monthly	Unsecure

16.2.1 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

16.2.2 Clinical Data Quality Control (CQC) Queries

Purpose: To identify and help correct inconsistencies/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.

16.2.3 Study Monitoring Committee Report

Purpose: To monitor study progress at each site
Prepared and Distributed by: Prepared by SDMC MTN 004 staff and distributed by SDMC Project Manager
Components: Summary by site and for the study overall of study design and history, accrual, retention, demographics, visit adherence. Site data management quality, and other components as requested by the SMC.

16.2.4 Site Specimen Monitoring Report
Purpose: To monitor storage in LDMS of those specimens marked as "stored" on study CRFs
Prepared by: SDMC Laboratory Programmer
Components: Site-specific listing of all discrepancies between the CRF stored specimen data and LDMS data.

16.2.5 Summary Specimen Monitoring Report
Purpose: To monitor storage in LDMS of those specimens marked as "stored" on study CRFs across all sites
Prepared by: SDMC Laboratory Programmer
Components: Summary listing for all sites of all discrepancies between the CRF stored specimen data and LDMS data.

16.2.6 Enrollment and Retention Report

Purpose: To monitor participant accrual and retention as reflected by data submitted to the SDMC (via DataFax)
Prepared by: SDMC Protocol Programmer
Components: Enrollment, includes the number of women enrolled each week and cumulatively. Retention, by visit. Includes: total 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.

16.2.7 Visit Adherence and Procedure Completion Report

Purpose: To summarize site performance regarding study endpoint data collection
Prepared by: SDMC Statistical Research Associate
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 CASI questionnaire completion.

16.2.8 Site Data Management Quality Report

Purpose: To summarize site performance regarding data management and quality.
Prepared by: SDMC Project Manager
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. Reported cumulatively and for the previous month.

16.2.9 Safety Report

Purpose: To help the Protocol Safety Review Team monitor study participant safety as reflected by adverse experiences reported to the SDMC (via DataFax).
Prepared by: SDMC Reporting Programmer and SDMC Clinical Affairs Safety Associate
Components: Cumulative AE data reported to SCHARP via DataFax.

16.2.10 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 data) along with the number and percentage of results received and processed at SCHARP.