

Section 11 – MTN-009 Study Reporting Plan

MTN-009 Statistical and Data Management Center (SDMC) Staff

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11.1 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-009.

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-009 SDMC Project Manager in collaboration with other MTN-009 SDMC staff.

11.2 Study Reports

Table 11-1 lists the reports the SDMC will produce and distribute via email. Table 11-2 lists the reports the SDMC will produce and make available via the Atlas website:

<https://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 11-1: MTN-009 SDMC Reports Distributed via E-mail

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC) Report	Every two weeks for the first 3 months of data transmission at a given site, then every month, or as needed	<ul style="list-style-type: none"> • Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Specimen Monitoring Reports (Site-specific and for the study overall)	Monthly	<ul style="list-style-type: none"> • Site Study Coordinators • Network Lab Representative • SDMC Project Manager

Table 11-2: MTN-009 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment	Daily	Unsecure
Visit Procedure Completion	Monthly	Unsecure
Site Data Management Quality	Monthly	Unsecure
Study Monitoring Committee (SMC) Report	Within 4-6 months of study initiation, then every 6 months and/or as determined by the SMC	Secure
Network Lab Assay Results Report	Daily	Secure

11.2.1 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.

11.2.2 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.

11.2.3 Enrollment Report

Purpose: To monitor participant accrual as reflected by data submitted to SCHARP DataFax

Prepared by: SDMC Protocol Programmer

Components: this report includes the number of women enrolled each week and cumulatively.

11.2.4 Visit Procedure Completion Report

Purpose: To summarize site performance regarding study endpoint data collection

Prepared by: SDMC Statistical Research Associate

Components: Overall and by site, the number and % of required HIV tests completed, Demographics forms completed, ACASI questionnaires completed, and blood specimens collected.

11.2.5 Site Data Management Quality Report

Purpose: To summarize site performance regarding data management and quality.

Prepared by: SDMC Project Manager or Project Assistant

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.

11.2.6 Study Monitoring Committee (SMC) Report

Purpose: To monitor study conduct as outlined by the protocol.

Prepared by: SDMC Statistical Research Associate and Protocol Statistician

Components: Summary (by site and for the overall study) of study design and history, accrual, participant demographics, ACASI responses, and site data management quality.

11.2.7 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.