14. Study Reporting Plan

The purpose of this reporting plan is to describe the reports that the MTN SDMC (SCHARP) plans to generate for MTN-011.

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-011 SDMC Project Manager in collaboration with other MTN-011 SDMC staff.

MTN-011 Statistical and Data Management Center (SDMC) Staff

Job Role	Name	Email Address
Protocol Statistician	Cliff Kelly	cwkelly@scharp.org
Project Manager	Corey Miller	corey@scharp.org
Statistical Research Associate	Karen Liu	cliu2@scharp.org
Protocol Programmer	Rick Westcott	rwestcot@scharp.org
Reporting Programmer	Kate Bader	kate@scharp.org
Data Coordinator	Debbie Lands	dlands@scharp.org
Document Specialist	Lori Filipcic	lorif@scharp.org
Lab Programmer	Della Wilson	della@scharp.org
CASI Programmer	Rick Westcott	rwestcot@scharp.org
Clinical Affairs Safety Associate	Jill Zeller	jzeller@scharp.org

14.1 Study Reports

Table 14-1 lists the reports the SDMC will produce and distribute via email. Table 14-2 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 14-1: MTN-011 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC) Report	Every two weeks, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Clinical Data Quality Control (CQC) Report	Weekly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Unresolved Adverse Experiences (AE) Listing	Monthly	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Specimen Monitoring Report	Monthly	• Site Study Coordinators • Network Lab Representative • SDMC Project Manager

Table 14-2: MTN-011 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment and Retention Report	Daily	Unsecure
Visit Adherence and Procedure Completion Report	Monthly	Unsecure
Site Data Management Quality Report	Monthly	Unsecure
Data Summary Report	Monthly	Unsecure
Protocol Safety Review Team (PSRT) Report	One week prior to each scheduled PSRT call	Secure
Network Lab Assay Results Report	Monthly, once NL results are received at the SDMC	Unsecure
Study Monitoring Committee (SMC) Report	As determined by the SMC	• MTN-011 SMC members and observers • MTN-011 Protocol Chair • MTN-011 Site Investigators
Protocol Deviations Report	Daily	Secure

14.2.1 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

14.2.2 Clinical Data Quality Control (CQC) Report

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

14.2.3 Unresolved Adverse Experiences (AE) Listing

Purpose: To identify AEs where the “resolution/outcome” must be updated on the AE Log case report form for female and male participants
Prepared and distributed by: SDMC Clinical Affairs Safety Associate
Components: Listing of AEs that have had a “continuing” status for more than 90 days

14.2.4 Specimen Monitoring Report

Purpose: To monitor specimen storage in LDMS for 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

14.2.5 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 table includes the number of couples enrolled each week and cumulatively
- Retention table includes total number of couples (for couple visits) and 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 couples or women who have completed a visit divided by the total number of couples or women expected for the visit.

14.2.6 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; listing of number and percentage of completed key required procedures, which may include pelvic exam completion, PK specimen collection, CVL specimen collection, CASI questionnaire completion

14.2.7 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, percentage of QCs resolved, QC rate per 100 CRF pages, and mean days to fax in CRF pages; reported cumulatively and monthly (previous month)

14.2.8 Data Summary Report

Purpose: To summarize site performance regarding data management quality, enrollment, retention, and selected procedure completion
Prepared by: SDMC Project Manager
Components: Cumulative enrollment and retention data, cumulative procedure completion data for selected study procedures, and monthly and cumulative data management quality data

14.2.9 Protocol Safety Review Team (PSRT) 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

14.2.10 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

14.2.11 Study Monitoring Committee (SMC) Report

Purpose: To monitor study progress at each site
Prepared by: Prepared by SDMC MTN-011 staff and distributed by SDMC Project Manager
Components: Summary by site and overall of study design and history, accrual, retention, demographics, product adherence, safety/adverse events, pregnancy and pregnancy outcomes; site data management quality and other components (e.g. procedure completion) as requested by the SMC

14.2.12 Protocol Deviations Report

Purpose: To summarize reported protocol deviations at each site
Prepared and distributed by: Prepared by SDMC Protocol Programmer

Components: Listing, by site, of reported protocol deviations as reported on Protocol Deviation Log CRFs received at SCHARP (via DataFax)