Section 13. Study Reporting Plan

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13.1 Purpose of Study Reporting Plan

The purpose of this reporting plan is to describe the reports that the MTN SDMC (SCHARP) plans to generate for MTN-012/IPM 010.

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-012/IPM 010 SDMC Project Manager in collaboration with other MTN-012/IPM 010 SDMC staff.

13.2 Study Reports

Table 13-1 lists the reports the SDMC will produce and distribute via email. Table13-2 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 which includes the purpose of the report, who will prepare the report, and specific components of the report.

Table 13-1: MTN-012/IPM 010 SDMC reports distributed via e-mail

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Every two weeks, or as needed	• Site Study Coordinators • Site Data Managers • FHI CORE Clinical Research Manager • SDMC Project Manager
Clinical Data Quality Control (CQC) Queries	Every two weeks, or as needed	• Site Study Coordinators • Site Data Managers • FHI CORE Clinical Research Manager • SDMC Project Manager
Site Specimen Monitoring	Monthly	• Site Study Coordinator • Network Lab Representative • SDMC Project Manager
Summary Specimen Monitoring	Monthly	• Network Lab Representative • SDMC Project Manager

Table 13-2: MTN-012/IPM 010 SDMC reports posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment and Retention	Daily	unsecure
Visit Adherence and Procedure Completion	Every two weeks	unsecure
Site Data Management Quality	Monthly	unsecure
Safety (PSRT)	One week prior to each scheduled PSRT call	secure
Network Lab Assay Results	Monthly, once NL results are received at the SDMC	unsecure
Study Monitoring Committee (SMC)	As determined by the SMC	• MTN-012/IPM 010 SMC members and observers • MTN-012/IPM 010 Protocol Chair • MTN-012/IPM 010 Site Investigators

13.2.1 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.

13.2.2 Clinic Data Quality (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.

13.2.3 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.

13.2.4 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 of all discrepancies for all sites between the CRF stored specimen data and LDMS data.

13.2.5 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, includes the number of men (circumcised and uncircumcised) enrolled each week and cumulatively. Retention 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.

13.2.6 Visit Adherence and Completion Report

Purpose: To assess completion of required visit procedures enumerated over all follow-up visits

Prepared by: SDMC Statistical Research Associate

Components: By site and overall:

- distribution of visits, including the number of days between target and actual visit dates and the number of days between sequential follow-up study visits,

- listing of number and percentage of completed key required procedures, which may include specimen collection, safety lab testing, and genital exam completion.

13.2.7 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 for the previous month.

13.2.8 Safety (PSRT) Report

Purpose: To help the Protocol Safety Review Team (PSRT) monitor study participant safety and tolerability as reflected by adverse experiences and product holds reported to the SDMC (via DataFax)

Prepared by: SDMC Reporting Programmer and SDMC Clinical Affairs Safety Associate

Components: Cumulative AE and product hold/discontinuation data reported to SDMC via SCHARP DataFax. Report may include other DataFax data as requested by the PSRT.

13.2.9 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.

13.2.10 Study Monitoring Committee Report

Purpose: To monitor study progress at each site.

Prepared and distributed by: Prepared by SDMC MTN-012/IPM 010 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, and safety/adverse events. Site data management quality, and other components as requested by the SMC.