

Section 15 - Study Reporting Plan

For this study, the SDMC (Statistical and Data Management Center) is SCHARP (the Statistical Center for HIV/ AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific time zone. The SCHARP MTN 002 team members, along with their job role and email information, are listed below.

<u>Role on MTN 002</u>	<u>Name</u>	<u>E-mail address</u>
Protocol Statistician	Ben Masse	ben@scharp.org
Project Manager:	Missy Cianciola	missy@scharp.org
Statistical Research Associate:	Karisse Roman	karisse@scharp.org
Protocol Programmer:	Julie Zhou	yzhuo@scharp.org
Data Coordinator:	Suzanne Cullers	scullers@scharp.org
Document Specialist:	Stacie Kentop	stacie@scharp.org
Reporting Programmer	Kate Bader	kate@scharp.org
Laboratory Programmer:	Laura Robins-Morris	lrobins@scharp.org
Clinical Affairs Safety Associate	Molly Swenson	mollys@scharp.org

15.1 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 002.

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 002 SDMC Project Manager in collaboration with other MTN 002 SDMC staff.

15.2 Study Reports

Table 15-1 lists the reports the SDMC will produce and distribute via email. Table 15-2 lists the reports the SDMC will produce and make available via the Atlas website:

<https://atlas.scharp.org/cpas/Project/MTN/begin.view?>

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 15-1: MTN 002 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Every two weeks, or as needed	<ul style="list-style-type: none"> • Site Study Coordinator • Site Data Manager • CORE Clinical Research Manager • SDMC Project Manager
Clinical Data Quality Control (CQC) Queries	Weekly, or as needed	<ul style="list-style-type: none"> • Site Study Coordinator • Site Data Manager • CORE Clinical Research Manager • SDMC Project Manager
Study Monitoring Committee (SMC)	As determined by the SMC	<ul style="list-style-type: none"> • MTN 002 SMC members and observers • MTN 002 Protocol Chair • MTN 002 Site Investigator
Site Specimen Repository Report	Monthly, the 10th of each month	<ul style="list-style-type: none"> • Site Study Coordinator • Network Lab Representative • SDMC Project Manager

Table 15-2: MTN 002 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment and Retention	Daily	Unsecure
Visit Adherence	Monthly, the 1 st of each month	Unsecure
Site Data Management Quality	Monthly, the 5 th of each month	Unsecure
Safety Report	One week prior to each scheduled PSRT call	Secure
Network Lab Assay Results Report	Monthly, the 5 th of each month	Unsecure

15.2.1 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

15.2.2 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.

15.2.3 Study Monitoring Committee Report

Purpose: To monitor study progress at each site.
Prepared and Distributed by: Prepared by SDMC MTN 002 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.

15.2.4 Site Specimen Repository 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.

15.2.5 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 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.

15.2.6 Visit Adherence Report

Purpose: To monitor adherence to the protocol
Prepared by: SDMC Statistical Research Associate
Components: Listing of number and % of required PK blood specimens collected, cervical specimens collected, and administrations of gel use.

15.2.7 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, % of QCs resolved, QC rate per 100 CRF pages, and mean days to fax in CRF pages. Reported cumulatively and for the previous month.

15.2.8 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.

15.2.9 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 at SCHARP.