

Section 15. Study Reporting Plan

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-016 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact Corey Miller (corey@scharp.org).

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, WA, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-016 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN-016	Name	E-mail address
Protocol Statistician	Ben Masse	bmasse@scharp.org
Project Manager	Corey Miller	corey@scharp.org
Statistical Research Associate	Sharavi Gandham	sharavi@scharp.org
Protocol Programmer	Shuhuan Zhang	shuhuan@scharp.org
Data Coordinator	Suzanne Cullers	scullers@scharp.org
Document Specialist	Donna Fulcher	donna@scharp.org
Reporting Programmer	Deb Bassuk	dbassuk@scharp.org
Laboratory Programmer	Laura Robins-Morris	lrobin@scharp.org

15.1 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-016.

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-016 SDMC Project Manager in collaboration with other MTN-016 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-016 SDMC reports distributed via e-mail

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
Study Monitoring Committee (SMC)	As determined by the SMC	<ul style="list-style-type: none"> • MTN-016 SMC members and observers • MTN-016 Protocol Co-chairs • MTN-016 Site Investigators
Site Specimen Repository	As determined by the Network Laboratory	<ul style="list-style-type: none"> • Site Study Coordinator • Network Lab Representative • SDMC Project Manager

Table 15-2: MTN-016 SDMC reports posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Enrollment and Retention	Daily	unsecure
Visit Adherence	Monthly, the 5 th day of each month	unsecure
Site Data Management Quality	Monthly, the 5 th day of each month	unsecure
Network Lab Assay Results	Monthly, the 5 th day of each month	unsecure
Adjunct Major Malformation Data	As needed	secure

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 Study Monitoring Committee Report

Purpose: To monitor study progress at each site.

Prepared and distributed by: Prepared by SDMC MTN-016 staff and distributed by SDMC Project Manager

Components: Summary by site and for the study overall of study design and history, accrual, retention, demographics, and visit adherence. Site data management quality, and other components as requested by the SMC.

15.2.3 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.

15.2.4 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 and infants 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.

15.2.5 Visit Adherence Report

Purpose: To monitor adherence to the protocol

Prepared by: SDMC Statistical Research Associate

Components: By site and overall for woman and infants:

- distribution of visits, including (1) the number of days between target and actual visit dates and (2) the number of days between sequential study visits,
- number and percentage of required infant visit procedures completed. For the Month 1, 6, and 12 visit this will include measurements of weight, length, head circumference, and completion of the infant physical exam. At the Month 6 and 12 visits, this will also include completion of the developmental screening exam.

15.2.6 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.

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

15.2.8 Adjunct Major Malformation Data

Purpose: To provide additional infant and maternal clinical and medical history data for infants with a reported eligible Major Malformation for review by the MTN-016 Major Malformation Endpoint Team.

Prepared by: SDMC Statistical Research Associate

Components: Data reported on corresponding Infant Physical Exam form, maternal Concomitant Medications Log form, maternal Genetic Screening History form, and maternal Pregnancy Report and History form.