

## Section 15. Study Reporting Plan

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### 15.1 Purpose of Reporting Plan

During the study, the Statistical and Data Management Center (SDMC) for MTN-016 (SCHARP) will: 1) review all study data on CRFs, checking for completeness and accuracy; 2) monitor data collection, data quality, and study conduct; 3) monitor adherence to key protocol requirements; and 4) produce reports.

The purpose of this reporting plan is to:

- Identify the content of each report;
- Identify those responsible for production and distribution of each report;
- Identify who should receive and review the reports so corrective action (if necessary) is taken;
- Ensure the Protocol Team approves the plan prior to study initiation.

The reporting plan is prepared by the MTN-016 SDMC Project Manager at SCHARP in collaboration with other MTN-016 SDMC staff.

### 15.2 Reports

The table below lists the distribution frequency and distribution list for the reports that will be produced for MTN-016. The sections following this table describe each report in detail.

	<b>Report</b>	<b>Distribution Frequency</b>	<b>Distribution List</b>
15.2.1	<b>Enrollment and Retention</b>	Daily	Posted on Atlas and can be viewed by: - Anyone
15.2.2	<b>Visit Adherence</b>	Monthly	Posted on Atlas and can be viewed by: - Anyone
15.2.3	<b>Data Quality Control (QC)</b>	Every 2 weeks, or as needed	Emailed to: - Site Study Coordinator - Site Data Manager - Other site staff as requested by the site - SDMC PM
15.2.4	<b>Site Data Management Quality</b>	Monthly	Posted on Atlas and can be viewed by: - Anyone
15.2.5	<b>Specimen Monitoring</b>	Monthly	Emailed to: - Site Study Coordinator - Other site staff as requested by the site

			<ul style="list-style-type: none"> <li>- NL Representative</li> <li>- SDMC PM</li> </ul>
15.2.6	<b>Network Lab Assay Results</b>	As needed	Emailed to: <ul style="list-style-type: none"> <li>- NL Representative</li> <li>- SDMC PM</li> </ul>
15.2.7	<b>Interim Review</b>	Yearly or as needed	Posted on Atlas and can be reviewed by: <ul style="list-style-type: none"> <li>- Interim Review Committee</li> <li>- Protocol Chairs</li> <li>- Selected members of MTN Core, FHI360, SDMC, NL and DAIDS</li> </ul>

### 15.2.1 Enrollment and Retention Reports

<b>Purpose</b>	To monitor participant accrual and retention as reflected by case report form data received and entered by the SDMC
<b>Responsibility for Preparation</b>	SDMC Protocol and Reporting Programmers
<b>Frequency</b>	Daily
<b>Distribution List</b>	Posted on Atlas: <a href="http://atlas.ssharp.org">http://atlas.ssharp.org</a> Can be viewed by: <ul style="list-style-type: none"><li>• Anyone</li></ul>
<b>Components</b>	<u>Enrollment Reports</u> include the total number of women and infants enrolled each week and cumulatively. There are separate Enrollment Reports for women and infants whose parent protocol is ASPIRE. <u>Retention Reports</u> , by visit, include: total enrolled; number expected for a given visit; and total retained for the visit, which is calculated as the number of participants who have completed a visit divided by the total number of participants expected for the visit. There are separate Retention Reports for women and infants whose parent study is ASPIRE.

## 15.2.2 Visit Adherence

<b>Purpose</b>	To monitor adherence to the protocol
<b>Responsibility for Preparation</b>	SDMC Statistical Research Associate
<b>Frequency</b>	Monthly
<b>Distribution List</b>	Posted on Atlas: <a href="http://atlas.ssharp.org">http://atlas.ssharp.org</a> Can be viewed by: <ul style="list-style-type: none"><li>• Anyone</li></ul>
<b>Components</b>	By site and overall for woman and infants: - Number and percentage of required woman and infant visit procedures completed.

### 15.2.3 Data Quality Control (QC) Report

<b>Purpose</b>	To identify and correct missing and inconsistent data
<b>Responsibility for Preparation</b>	SDMC Data Coordinator
<b>Frequency</b>	Every 2 weeks
<b>Distribution List</b>	Emailed to: <ul style="list-style-type: none"><li>• Site Study Coordinator</li><li>• Site Data Manager</li><li>• Other staff by request (such as the QA/QC Coordinator)</li><li>• SDMC Project Manager</li></ul>
<b>Components</b>	List of missing pages, overdue visits, missing data, and questions about inconsistent or unclear data.

## 15.2.4 Site Data Management Quality Report

<b>Purpose</b>	To summarize site performance regarding data management and quality
<b>Responsibility for Preparation</b>	SDMC Project Manager
<b>Frequency</b>	Monthly
<b>Distribution List</b>	Posted on Atlas: <a href="http://atlas.scharp.org">http://atlas.scharp.org</a> Can be viewed by: <ul style="list-style-type: none"><li>• Anyone</li></ul>
<b>Components</b>	Cumulative and previous-month statistics including: <ul style="list-style-type: none"><li>• Total number DataFax form pages received</li><li>• Total number of quality control (QC) errors identified in DataFax and sent to the site</li><li>• Percent QCs resolved</li><li>• Rate of QCs sent per 100 pages</li><li>• Mean number of days for sites to fax CRFs to SCHARP Data-Fax</li></ul>

## 15.2.5 Specimen Monitoring Reports

<b>Purpose</b>	To monitor storage in LDMS of those specimens marked as “stored” on case report forms
<b>Responsibility for Preparation</b>	SDMC Lab Data Operations Programmer
<b>Frequency</b>	Monthly
<b>Distribution List</b>	Emailed to: <ul style="list-style-type: none"><li>• Site Study Coordinator</li><li>• Other site staff as requested</li><li>• Network Lab Representative</li><li>• SDMC Project Manager</li></ul>
<b>Components</b>	Site-specific listing of all discrepancies between the case report form stored specimen data and data entered into LDMS as well as LDMS data entry errors.

## 15.2.6 Network Lab Assay Results

<b>Purpose</b>	To monitor the receipt of lab assay results from the Network lab
<b>Responsibility for Preparation</b>	SDMC Lab Data Operations Programmer
<b>Frequency</b>	As needed
<b>Distribution List</b>	Emailed to: <ul style="list-style-type: none"><li>• Network Lab Representative</li><li>• SDMC Project Manager</li></ul>
<b>Components</b>	For each specimen analyzed by a Network Lab, the number of results expected (per CRF data) and the number and percentage of results received at the SDMC



## 15.2.7 Interim Review Report

<b>Purpose</b>	To assess safety according to the primary objectives of this study
<b>Responsibility for Preparation</b>	SDMC Statistical Research Associates, with assistance from MTN-016 SDMC study team
<b>Frequency</b>	Yearly or as needed
<b>Distribution List</b>	Posted on Atlas: <a href="http://atlas.scharp.org">http://atlas.scharp.org</a>  Can be viewed by: <ul style="list-style-type: none"><li>• Interim Review Committee</li><li>• Protocol Chairs</li><li>• Selected members of MTN Core, FHI360, SDMC, NL and DAIDS</li></ul>
<b>Components</b>	Summary by site, and overall: <ul style="list-style-type: none"><li>• Trial Design</li><li>• Pregnancy Report and Outcome data</li><li>• Major Malformation Assessment data</li></ul>