Section 11 – MTN-009 Study Reporting Plan

MTN-009 Statistical and Data Management Center (SDMC) Staff

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11.1 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-009.

This reporting plan will:

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

This reporting plan was prepared by the MTN-009 SDMC Project Manager in collaboration with other MTN-009 SDMC staff.

11.2 Study Reports

Table 11-1 lists the reports the SDMC will produce and distribute via email. Table 11-2 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 11-1: MTN-009 SDMC Reports Distributed via E-mail

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Distribution Frequency</th>
<th>Email Distribution List</th>
</tr>
</thead>
</table>
| Data Quality Control (QC) Report                       | Every two weeks for the first 3 months of data transmission at a given site, then every month, or as needed | • Site Study Coordinators  
• Site Data Managers  
• CORE Clinical Research Managers  
• SDMC Project Manager |
| Specimen Monitoring Reports (Site-specific and for the study overall) | Monthly                                                                                 | • Site Study Coordinators  
• Network Lab Representative  
• SDMC Project Manager |

### Table 11-2: MTN-009 SDMC Reports Posted on Atlas

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Update Frequency</th>
<th>Atlas Viewing Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Visit Procedure Completion</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Site Data Management Quality</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Study Monitoring Committee (SMC) Report</td>
<td>Within 4-6 months of study initiation, then every 6 months and/or as determined by the SMC</td>
<td>Secure</td>
</tr>
<tr>
<td>Network Lab Assay Results Report</td>
<td>Daily</td>
<td>Secure</td>
</tr>
</tbody>
</table>
11.2.1 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.

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11.2.2 Specimen Monitoring Report

Purpose: To monitor storage in LDMS of those specimens marked as “stored” on study CRFs
Prepared and Distributed by: SDMC Laboratory Programmer
Components: Site-specific and overall study listing of all discrepancies between the CRF stored specimen data and LDMS data.

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11.2.3 Enrollment Report

Purpose: To monitor participant accrual as reflected by data submitted to SCHARP DataFax
Prepared by: SDMC Protocol Programmer
Components: this report includes the number of women enrolled each week and cumulatively.

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11.2.4 Visit Procedure Completion Report

Purpose: To summarize site performance regarding study endpoint data collection
Prepared by: SDMC Statistical Research Associate
Components: Overall and by site, the number and % of required HIV tests completed, Demographics forms completed, ACASI questionnaires completed, and blood specimens collected.

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11.2.5 Site Data Management Quality Report

Purpose: To summarize site performance regarding data management and quality.
Prepared by: SDMC Project Manager or Project Assistant
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. Report includes a table with data from the previous month, and a table with cumulative data since study start.
11.2.6 Study Monitoring Committee (SMC) Report

**Purpose:** To monitor study conduct as outlined by the protocol.
**Prepared by:** SDMC Statistical Research Associate and Protocol Statistician
**Components:** Summary (by site and for the overall study) of study design and history, accrual, participant demographics, ACASI responses, and site data management quality.

11.2.7 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 specimen collection data) along with the number and percentage of results received and processed at SCHARP.