Section 17 – MTN-003 and MTN-003B Study Reporting Plan

MTN-003 and MTN-003B Statistical and Data Management Center (SDMC) Staff

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17.1 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-003 and MTN-003B.

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-003 and MTN-003B SDMC Project Managers in collaboration with other MTN-003 and MTN-003B SDMC staff.

17.2 Study Reports

Table 17-1 lists the reports the SDMC will produce and distribute via email. Table17-2 lists the reports the SDMC will produce and make available via the Atlas website:

http://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 17-1: MTN-003 and MTN-003B 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 Managers |
| Clinical Data Quality Control (CQC) Queries| 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 Managers |
| Unresolved Adverse Experiences Listing     | Monthly, or as needed                                                                   | • Site Study Coordinators  
• Site Data Managers  
• CORE Clinical Research Managers  
• SDMC Project Managers |
| Specimen Monitoring Reports (Site-specific and for the study overall) | Monthly                                                                                 | • Site Study Coordinators  
• Network Lab Representative  
• SDMC Project Managers |

Table 17-2: MTN-003 and MTN-003B 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 and Retention</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Visit Adherence and Procedure Completion</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Product Adherence</td>
<td>Monthly</td>
<td>Secure</td>
</tr>
<tr>
<td>Site Data Management Quality</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Safety (PSRT) Reports</td>
<td>One week prior to each scheduled PSRT call</td>
<td>Secure</td>
</tr>
<tr>
<td>Study Monitoring Committee (SMC) Report</td>
<td>Within 4-6 months of study initiation, then prior to Data Safety Monitoring Board (DSMB) reviews and/or as determined by the SMC</td>
<td>Secure</td>
</tr>
<tr>
<td>Data Safety Monitoring Board (DSMB) Report</td>
<td>Up to three weeks prior to scheduled DSMB reviews</td>
<td>Secure</td>
</tr>
<tr>
<td>Network Lab Assay Results Report</td>
<td>Daily</td>
<td>Secure</td>
</tr>
</tbody>
</table>
17.2.1 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. Report includes quality control notes on MTN-003B data.

17.2.2 Clinical Data Quality Control (CQC) Queries

Purpose: To identify and help correct inconsistencies or 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

17.2.3 Unresolved Adverse Experiences Listing

Purpose: To identify those AEs that have been marked as "Continuing" for >90 days, to help individual sites monitor AE resolution throughout the study.
Prepared and Distributed by: SDMC Reports Programmer and SDMC Clinical Affairs Safety Associate
Components: Site-specific listing of all AEs that have been marked as "Continuing" for >90 days. For each unresolved AE the report lists the PTID, page #, AE text, date reported to site, onset date, severity grade, and visit at which the AE was first reported.

17.2.4 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. Report includes data collected for MTN-003B.

17.2.5 Enrollment and Retention Report

Purpose: To monitor participant accrual and retention as reflected by data submitted to SCHARP DataFax
Prepared by: SDMC Protocol Programmer
Components: Enrollment: this report includes the number of women enrolled each week and cumulatively. Retention, by visit: this report includes the total number of women 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. Separate Enrollment and Retention Reports will be generated for MTN-003 and MTN-003B.
17.2.6 Visit Adherence and Procedure Completion Report

**Purpose:** To summarize site performance regarding study endpoint data collection

**Prepared by:** SDMC Statistical Research Associates

**Components:**
- Distribution of visits, including the number of days between target and actual visit dates, and the number of days between sequential follow-up visits;
- Listing of number and % of required PK blood specimens collected, genital specimens collected, safety lab tests completed, pelvic exams completed, pregnancy tests completed, and HIV tests completed.
- Separate reports will be generated for MTN-003 and MTN-003B.

17.2.7 Product Adherence Report

**Purpose:** To provide information on self-reported product adherence based on CRF pages faxed to SCHARP as well as data collected via ACASI.

**Prepared by:** SDMC Statistical Research Associates

**Components:**
- Summary of product counts and self-reported product use (from CRFs and ACASI), including a summary of qualitative responses to product usage over the past 4 weeks, and a summary of quantitative responses to product usage in the past 7 days.

17.2.8 Site Data Management Quality Report

**Purpose:** To summarize site performance regarding data management and quality.

**Prepared by:** SDMC Project Managers

**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.
- Report includes CRFs submitted for MTN-003B.

17.2.9 Safety (PSRT) Reports

**Purpose:** To help the Protocol Safety Review Team (PSRT) monitor study participant safety as reflected by adverse experiences, pregnancies, and social harms reported to the SDMC via SCHARP DataFax.

**Prepared by:** SDMC Reports Programmer and SDMC Clinical Affairs Safety Associate

**Components:**
- Adverse event, pregnancy outcome, and product hold data reported to SDMC via SCHARP DataFax.
- Report may include other DataFax data as requested by the PSRT.

17.2.10 Study Monitoring Committee (SMC) Report

**Purpose:** To monitor study conduct as outlined by the protocol.

**Prepared by:** SDMC Statistical Research Associates and Protocol Statisticians

**Components:**
- Summary (by site and for the overall study) of study design and history, accrual, retention, participant demographics, and visit adherence.
- Report may include site data management quality and other components as requested by the SMC. A similar report will be prepared for MTN-003B for...
review along with the MTN-003 SMC report.

17.2.11 Data Safety Monitoring Board (DSMB) Report

**Purpose:** To monitor the primary safety and effectiveness endpoints of the study, as well as study conduct as outlined in the protocol.

**Prepared by:** SDMC Statistical Research Associates and Protocol Statisticians

**Components:** All components listed for the SMC Report, with the addition of adverse event data and HIV-infection data. A report will also be prepared for MTN-003B to include substudy conduct operational characteristics (e.g., accrual and retention) and an assessment of safety, including the onset of osteoporosis and adult non-traumatic fragility fractures or Z-scores < -2.0.

17.2.12 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. MTN-003B data will be included in these reports.