Section 13 - Study Reporting Plan

The MTN-030 Statistical and Data Management Center (SDMC) Staff are listed below.

<table>
<thead>
<tr>
<th>Job Role</th>
<th>Name</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Statistician</td>
<td>Barbra Richardson</td>
<td><a href="mailto:barbrar@u.washington.edu">barbrar@u.washington.edu</a></td>
</tr>
<tr>
<td>Statistical Research Associate</td>
<td>Colin O'Rourke</td>
<td><a href="mailto:corourke@scharp.org">corourke@scharp.org</a></td>
</tr>
<tr>
<td>Clinical Data Manager</td>
<td>Melissa Peda</td>
<td><a href="mailto:mapeda@scharp.org">mapeda@scharp.org</a></td>
</tr>
<tr>
<td>Clinical Programmer</td>
<td>Craig Chin</td>
<td><a href="mailto:craig@scharp.org">craig@scharp.org</a></td>
</tr>
<tr>
<td>Clinical Safety Associate</td>
<td>Ning Jiang</td>
<td><a href="mailto:njiang2@scharp.org">njiang2@scharp.org</a></td>
</tr>
</tbody>
</table>

13.1 Purpose of Reporting Plan

The purpose of this reporting plan is to describe the routine reports that the MTN SDMC (SCHARP) plans to generate for MTN-030.

The specific purposes of this plan are to:

- 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 follow-up (if necessary) is done.

This reporting plan was prepared by the MTN-030 SDMC Clinical Data Manager in collaboration with other MTN-030 SDMC staff.

13.2 Study Reports

The reports listed in Table 13-1 are available within the Medidata web-based environment and can be run by designated site users (based on user permissions) at any time to include the most current data available in the Medidata Rave study database.

Table 13-2 lists the reports the SDMC will produce and make available via the MTN-030 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/030/begin.view?

Table 13-3 lists the reports the SDMC will produce and distribute via e-mail.

Following the tables is a description of each report that includes the purpose and components of the report.
Table 13-1: MTN-030 SDMC Reports Available in Medidata

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Permissions List</th>
</tr>
</thead>
</table>
| Site-specific Data Quality Control (QC) notes (i.e., data queries) | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |
| Site-specific Query Summary                                      | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |
| Site-specific Query Details                                      | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |
| Site-specific Page Status                                        | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |
| Site-specific Enrollment                                         | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |
| Site-specific Retention                                          | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |
| Site-specific Missed Visit Listing                               | • Site Staff as designated by each site
|                                                                  | • SDMC Clinical Data Manager                         |

Table 13-2: MTN-030 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>Screen Out</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Enrollment</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Retention</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Procedure Completion</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Data Management Quality</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Data Summary</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Missed Visit Listing</td>
<td>Daily</td>
<td>Secure</td>
</tr>
<tr>
<td>Missed Visit Summary</td>
<td>Monthly</td>
<td>Secure</td>
</tr>
<tr>
<td>Protocol Deviations Listing</td>
<td>Daily</td>
<td>Secure</td>
</tr>
<tr>
<td>Protocol Deviations Summary Table</td>
<td>Monthly</td>
<td>Secure</td>
</tr>
<tr>
<td>PSRT (Safety)</td>
<td>One week prior to PSRT call</td>
<td>Secure</td>
</tr>
<tr>
<td>AE listings</td>
<td>One week prior to PSRT call</td>
<td>Secure</td>
</tr>
<tr>
<td>SMC</td>
<td>Approximately every 6 months</td>
<td>Secure</td>
</tr>
</tbody>
</table>
Table 13-3: MTN-030 SDMC Reports Distributed via E-mail

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Distribution Frequency</th>
<th>E-mail Distribution List</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDMS Specimen Monitoring</td>
<td>Monthly</td>
<td>• Site LDMS Laboratory Staff&lt;br&gt;• MTN Laboratory Center Representative(s)&lt;br&gt;• SDMC Clinical Data Managers</td>
</tr>
</tbody>
</table>

1. Data Quality Control (QC Report)

   **Purpose:** To identify data that is missing, inconsistent, and/or in need of additional clarification
   **Components:** Data quality control notes and clinical queries

2. Query Summary

   **Purpose:** To provide data query metrics for a given site
   **Components:** By site, displays a count of the number of Medidata Rave queries that are generated throughout the study - Open, Answered, Closed, Cancelled, and an overall total grouped by site and role

3. Query Details

   **Purpose:** To provide detailed information on data queries for a given site
   **Components:** By site, displays for each data query the query status, query user, marking group, field, form, folder, subject, site group, and site

4. Page Status

   **Purpose:** To provide the current status of CRFs within a specified study, site, participant, folder, and/or form
   **Components:** By site, provides current status of CRFs by PTID, by visit folder, and by CRF within a visit folder

5. LDMS Specimen Monitoring

   **Purpose:** To identify stored specimens whose information in LDMS does not match corresponding information collected per study CRFs
   **Components:** Listing of those specimens whose LDMS PTID, visit code, and/or collection date information does not match the information recorded on CRFs; specimens that are stored per CRF but not present in LDMS; specimens that are present in LDMS but not stored per CRF; specimens in LDMS from PTIDs who did not enroll

6. Missed Visit Listing

   **Purpose:** To identify participants who have missed scheduled study visits, to help sites focus retention efforts and prevent participants from becoming chronic defaulters and/or meeting criteria for replacement
   **Components:** Site-specific listing of cumulative missed visits per the Missed Visit
CRF; includes, for each PTID, the enrollment date, visit name, start and end of visit window

7. Missed Visit Summary

**Purpose:** To provide a subset of Protocol Team members with a cumulative summary of all missed visits for the study

**Components:** Overall and by site, the number and percentages of missed visits reported for the study

8. Screen Out

**Purpose:** To summarize the number of participants screened for the study, the number enrolled, and the reasons participants were not enrolled

**Components:** Number screened, number enrolled, number screened out per reason listed on the Inclusion/Exclusion Criteria CRF

9. Enrollment

**Purpose:** To report on participant accrual as reflected by data entered into the study database

**Components:** By site, activation date, dates of first and last enrollments, duration of accrual, enrollment target, total number screened, total number enrolled, screening to enrollment ratio, average number of enrollments per week, and percentage of site target enrolled for the MTN-030 study

10. Retention

**Purpose:** To report on participant visit retention as reflected by data entered into the study database

**Components:** By site and by visit, the number of expected participants who have completed the visit; the number of participants who have not completed the visit; the number of visits missed; the number of participants who missed a visit, but had product available; the number of participants who have terminated early; the number of participants, excluding early terminators, who have completed the visit; and the number of participants not expected

11. Procedure Completion

**Purpose:** To provide information on completion of required study procedures during follow-up, and serve as an indication as to the amount of missing data from completed visits

**Components:** Overall and by site, listing of number and percentage of required (“expected”) study procedures that were completed at follow-up visits. Procedures are expected if the visit was completed (that is, not missed).

12. Data Management Quality Report

**Purpose:** To provide information on site performance with regard to key data management and data quality metrics.

**Components:** By site and overall data metrics

13. Data Summary Reports

**Purpose:** To provide summary information on site performance regarding data
management quality, enrollment, retention, and selected procedure completion. 
Components: Cumulative enrollment and retention data, cumulative procedure 
completion data for selected study procedures, and cumulative and monthly data 
management quality data

14. Protocol Deviations Listing

Purpose: To provide a subset of Protocol Team members with a cumulative listing of 
all protocol deviations reported for the study.
Components: Each of the fields/data items as listed on the Protocol Deviations Log CRF.

15. Protocol Deviations Summary Table

Purpose: To provide a subset of Protocol Team members with a cumulative 
and past month summary of all protocol deviations for the study
Components: Overall and by site, the number and percentages of protocol 
deviations reported for the study

16. PSRT (Safety) Reports

Purpose: To help the Protocol Safety Review Team (PSRT) monitor participant safety 
as reflected by adverse events and study product discontinuations reported to the 
SDMC.
Components: Cumulative AE and study product discontinuations reported to the 
SDMC on the AE Log CRF and Treatment Discontinuation CRF.

17. AE Listings

Purpose: To provide the MTN-030 Safety Physicians with a cumulative listing of all 
adverse events in order to monitor participant safety.
Components: Cumulative listing of all adverse events reports to the SDMC per the 
Adverse Event Log CRF

18. Study Monitoring Committee (SMC) Reports

Purpose: To provide information on study conduct, ability to answer study objectives, 
and primary endpoint data to SMC members as required in preparation for scheduled 
reviews
Components: Summary by site and overall of study design and history, accrual, 
retention, demographics, baseline characteristics, data management quality, protocol 
deviations, and other components as requested by the SMC