Section 14 - Study Reporting Plan

14. Introduction

The MTN-034 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 Statisticist</td>
<td>Elizabeth Brown</td>
<td><a href="mailto:ebrown@uw.edu">ebrown@uw.edu</a></td>
</tr>
<tr>
<td>Statistical Research Associate</td>
<td>Daniel Szydlo</td>
<td><a href="mailto:dszydlo@scharp.org">dszydlo@scharp.org</a></td>
</tr>
<tr>
<td>Lead Clinical Data Manager</td>
<td>Jennifer Schille</td>
<td><a href="mailto:jens@scharp.org">jens@scharp.org</a></td>
</tr>
<tr>
<td>Clinical Programmer</td>
<td>Chun Zou</td>
<td><a href="mailto:czou@scharp.org">czou@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>

14.1 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-034.

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-034 SDMC Clinical Data Manager in collaboration with other MTN-034 SDMC staff.

14.2 Study Reports

The reports listed in Table 14-1 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 14-2 lists the reports the SDMC will produce and make available via the MTN-034 Atlas web page: [https://atlas.scharp.org/cpas/project/MTN/034/begin.view](https://atlas.scharp.org/cpas/project/MTN/034/begin.view)?

Table 14-3 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 14-1: MTN-034 SDMC Reports Available in Medidata

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Permissions List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Query Details Report (site-specific)</td>
<td>• Site Staff as designated by each site SDMC Clinical Data Manager</td>
</tr>
<tr>
<td>Unresolved Adverse Events (site-specific)</td>
<td>Site Staff as designated by each site SDMC Clinical Data Manager</td>
</tr>
<tr>
<td>Unresolved Product Holds (site-specific)</td>
<td>Site Staff as designated by each site SDMC Clinical Data Manager</td>
</tr>
<tr>
<td>Unresolved Social Harms (site-specific)</td>
<td>Site Staff as designated by each site SDMC Clinical Data Manager</td>
</tr>
<tr>
<td>Enrolled PTID Listing (site-specific)</td>
<td>Site Staff as designated by each site SDMC Clinical Data Manager</td>
</tr>
</tbody>
</table>

Table 14-2: MTN-034 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>Retention Report Graph</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Retention Report – COVID-19</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Retention Graph – COVID-19</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Procedure Completion</td>
<td>Monthly</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Procedures Completion Report – COVID–19</td>
<td>Daily</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>Baseline Contraceptive Use</td>
<td>Daily</td>
<td>Unsecure</td>
</tr>
<tr>
<td>Enrollment by Age</td>
<td>Daily</td>
<td>Secure</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>Missed Visit Report – COVID-19</td>
<td>Daily</td>
<td>Unsecure</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>Protocol Deviations Listing – COVID-19</td>
<td>Weekly</td>
<td>Unsecure</td>
</tr>
</tbody>
</table>
Table 14-3: MTN-034 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</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MTN Laboratory Center Representative(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SDMC Clinical Data Managers</td>
</tr>
</tbody>
</table>

1. Query Details

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

2. Unresolved Adverse Events (AEs)

**Purpose:** To identify those AEs that have been continuing for 90 or more days (per the Adverse Event Log CRF) so that AE status updates are reviewed and updates are made, as needed  
**Components:** Listing of ongoing AEs that have been continuing for 90 or more days

3. Unresolved Product Holds

**Purpose:** To identify those clinical product holds that have been continuing for 30 or more days (per the Clinical Product Hold/Discontinuation Log CRF) so that product status updates are made as needed  
**Components:** Listing of product holds that have been ongoing for 30 or more days

4. Unresolved Social Harms

**Purpose:** To identify social harms that have been ongoing for 30 or more days (per the Social Impact CRF) so that status updates are made as needed  
**Components:** Listing of social harms that have been ongoing for 30 or more days

5. Enrolled PTID Listing

**Purpose:** To provide all enrolled PTIDs for MTN-034 to aid in data management at the site  
**Components:** Site-specific cumulative listing of all enrolled PTIDs per the Randomization CRF

6. 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 Eligibility Criteria CRF

7. 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-034 study

8. 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

8a. Retention Report - COVID-19 Purpose: Same as the Retention Report, however, this report only includes visits completed on or after 26 MARCH 2020.

9. Retention Report Graph

Purpose: To provide a graphic representation of the Retention Report

Components: A line graph containing a line for each site, with the horizontal axis being the Visit Month and vertical axis the site’s retention rate (the % of participants retained).

9a. Retention Graph - COVID-19. Purpose: Same as the Retention Report Graph, however, this report only includes visits completed on or after 26 MARCH 2020.

10. 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).

10a. Procedures Completion Report - COVID-19. Purpose: Same as the Procedures Completion report, however this report only includes those visits completed or expected to be completed on or after 26 MARCH 2020.

11. Data Management Quality

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

Components: By site and overall data metrics

12. Data Summary

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

13. 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.

**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.

14. 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.

14a. Missed Visit Report - COVID-19, **Purpose:** Same as the Missed visit Summary report, however this report only includes those missed visits where the last date of the visit window is on or after 26 March 2020.

15. Baseline Contraceptive Use

**Purpose:** To identify the types of contraceptives used by participants as reported at the Enrollment Visit.

**Components:** Overall and by site, for each contraceptive listed on the Family Planning Log CRF, the number and percentage of participants reporting use of that contraceptive method.

16. 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 CRF.

16a. Protocol Deviation Listing - COVID-19, **Purpose:** Protocol Deviations related specifically to COVID-19 only.


17. 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.

18. Early Termination

**Purpose:** To provide a subset of Protocol Team members with a cumulative listing of all early terminations reported for the study.

**Components:** Site, PTID, Termination Date and Reason for Termination data from the Termination CRF.

1. PSRT (Safety) Reports

**Purpose:** To aid the Protocol Safety Review Team (PSRT) monitor participant safety as reflected by adverse events and study product holds or discontinuations reported to the SDMC.
Components: Cumulative AE and study product holds and discontinuations reported to the SDMC on the AE Log CRF, Product Hold, and Product Discontinuation CRF

2. AE Listings

Purpose: To provide the MTN-034 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

3. 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

4. Adherence Reports

Purpose: To provide drug summary information to study leadership as part of ongoing review of adherence data during the study
Components: Summaries of drug adherence strategies, and participant product choice.

5. Follow-up Contraceptives Use

Purpose: To identify the types of contraceptives used by participants as reported at follow-up visits occurring during the past month.
Components: Overall and by site, the number and percentage of participants reporting use of each contraceptive method listed on the Family Planning Log CRF.

6. 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