Section 14 - Study Reporting Plan

14. Introduction

The MTN-036/IPM 047 Statistical and Data Management Center (SDMC) Staff are listed below.

Job Role	Name	Email Address
Protocol Statistician	Jingyang Zhang	jzhang2@fhcrc.org
Statistical Research Associate	Holly Gundacker	hgundack@scharp.org
Clinical Data Manager	Tanya Harrell	tharrell@scharp.org
Clinical Programmer	Deepika Konatham	dkonatha@scharp.org
Lab Data Coordinator	Sara Aranda	saranda@scharp.org
Clinical Safety Associate	Ning Jiang	njiang2@scharp.org

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-036/IPM 047.

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-036/IPM 047 SDMC Clinical Data Manager in collaboration with other MTN-036/IPM 047 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-036/IPM 047 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/036/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-036/IPM 047 SDMC Reports Available in Medidata

Report Title	Permissions List
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

Table 14-2: MTN-036/IPM 047 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Procedure Completion	Monthly	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Missed Visit Listing	Daily	Unsecure
Missed Visit Summary	Monthly	Unsecure
Protocol Deviations Listing	Daily	Secure
Protocol Deviations Summary Table	Monthly	Secure
PSRT (Safety)	One week prior to PSRT call	Secure
AE listings	One week prior to PSRT call	Secure
SMC	Approximately every 6 months	Secure

Table 14-3: MTN-036/IPM 047 SDMC Reports Distributed via E-mail

Report Title	Distribution Frequency	E-mail Distribution List
LDMS Specimen Monitoring	Monthly	• Site LDMS Laboratory Staff • MTN Laboratory Center Representative(s) • SDMC Clinical Data Managers

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-036/IPM 047 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-036/IPM 047 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