

Section 13. Study Reporting Plan

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Table 13-1 MTN-023/IPM 030 SDMC Reports Distributed via Email

Table 13-2 MTN-023/IPM 030 SDMC Reports Posted on Atlas

The purpose of this reporting plan is to describe the reports that the MTN SDMC (SCHARP) plans to generate for MTN-023/IPM 030.

The specific purposes of this plan are:

- To identify the purpose and content of each report;
- To identify those responsible for the preparation and distribution of each report;
- To identify who should review the reports so that follow-up (if necessary) is taken; and
- To ensure the Protocol Team approves the plan prior to study initiation.

This reporting plan was prepared by the MTN-023/IPM 030 SDMC Project Manager in collaboration with other MTN-023/IPM 030 SDMC staff.

MTN-023/IPM 030 Statistical and Data Management Center (SDMC) Staff

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13.1 Study Reports

Table 13-1 lists the reports the SDMC will produce and distribute via email. Table 13-2 lists the reports the SDMC will produce and make available via the Atlas website, <https://atlas.ssharp.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 13-1: MTN-023/IPM 030 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Monthly, or as needed	<ul style="list-style-type: none"> • SDMC Project Manager • Site Staff as designated by each site
Clinical Data Quality Control (CQC)	As needed (as queries are identified)	<ul style="list-style-type: none"> • SDMC Project Manager • Site Staff as designated by each site
Subset of New Clinical Queries	Weekly	<ul style="list-style-type: none"> • SDMC Project Manager • PSRT members
Unresolved Adverse Experiences (AE) Listing	Monthly	<ul style="list-style-type: none"> • SDMC Project Manager • Site Staff as designated by each site
Unresolved Product Holds	Monthly	<ul style="list-style-type: none"> • SDMC Project Manager • Site Staff as designated by each site
LDMS Specimen Monitoring	Monthly	<ul style="list-style-type: none"> • SDMC Project Manager • Site Staff as designated by each site • Site LDMS Lab Staff • Network Lab Representative

Table 13-2: MTN-023/IPM 030 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Procedures Completion	Monthly	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Missed Visit Listings and Summary	Daily	Unsecure
Protocol Deviations Listing and Summary	Daily	Secure

Protocol Safety Review Team (PSRT)	One week prior to PSRT call	Secure
Study Monitoring Committee (SMC)	As determined by the SMC	Secure

13.1.1 Data Quality Control (QC) Report

Purpose: To identify missing and inconsistent data.

Components: Quality control notes, overdue visit reminders, missing page reminders.

13.1.2 Clinical Data Quality Control (CQC) Report

Purpose: To identify inconsistencies/questions identified in safety or clinical data.

Components: Queries containing clinically-based questions about safety and clinical data.

13.1.3 Subset of New Clinical Queries

Purpose: To monitor a specific subset of AEs and product holds

Components:

- All Grade 3 or higher AEs including the lab events regardless of relationship
- All SAEs and AEs requiring an expedited report to DAIDs
- Any product hold CRF received with reason indicated

13.1.4 Unresolved Adverse Experiences (AE)

Purpose: To identify AEs which have been continuing for 90 or more days (per the AE Log CRF) so that AE status updates are made as needed.

Components: Listing of AEs that have had a “continuing” status for more than 90 days.

13.1.5 Unresolved Product Holds

Purpose: To identify clinical product holds which have been continuing for 30 or more days (per the PH 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.

13.1.6 LDMS Specimen Monitoring Report

Purpose: To identify inconsistencies in specimen storage data between information in LDMS and data recorded on CRFs.

Components: Site-specific listing of specimens with inconsistencies between the PTID, collection date, or visit month information in LDMS and the 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.

13.1.7 Screen Out Report

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.

13.1.8 Enrollment

Purpose: To report participant accrual as reflected by data received and entered at the SDMC.

Components: Accrual data are presented by site, activation date, date 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, percentage of site target enrolled.

13.1.9 Retention Report

Purpose: To report participant visit retention as reflected by data received and entered at the SDMC.

Components: By site and by visit, the number of expected participants who have completed the visit; who have not completed the visit; and have missed a required visit; the number of participants not expected.

13.1.10 Procedures Completion Report

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).

13.1.11 Data Management Quality Report

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

Components: By site and overall, for cumulative and previous month time periods, the total number of CRF pages received, total number of QCs created, QC rate per 100 CRF pages, % QCs resolved (cumulative report only), % CRFs received within 7 days, and mean days to fax in AE Log.

13.1.12 Data Summary Report

Purpose: To summarize 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 monthly and cumulative data management quality data.

13.1.13 Missed Visit Listings and Summary

Purpose: To provide site-specific cumulative listings of all missed visits reported for the study, as well as summary reports (cumulative and for the past month) showing the total number of missed visits by site and for all sites total

Components: Site-specific cumulative listing of missed visits. A visit is considered missed if a Missed Visit CRF has been completed for that visit and the visit window has closed.

13.1.14 Protocol Deviations Listing and Summary

Purpose: To summarize reported protocol deviations reported at each site for a subset of the Protocol Team.

Components: Listing, by site, of reported protocol deviations as reported on the Protocol Deviation Log CRFs received at SCHARP. Frequency, by site, of the type of protocol deviations reported on the Protocol Deviation Log CRFs received at SCHARP.

13.1.15 Protocol Safety Review Team (PSRT) Report

Purpose: To help the Protocol Safety Review Team monitor study participant safety as reflected by adverse experiences reported to the SDMC.

Components: Cumulative AE, product hold, and pregnancy outcome data reported to SCHARP.

13.1.16 Study Monitoring Committee (SMC) Report

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.