Section 17 - Study Reporting Plan

The MTN-020 Statistical and Data Management Center (SDMC) Staff are listed below.

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17.1 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-020.

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-020 SDMC Project Manager in collaboration with other MTN-020 SDMC staff.

17.2 Study Reports

Table 17-1 lists the reports the SDMC will produce and distribute via email. Table 17-2 lists the reports the SDMC will produce and make available via the MTN-020 Atlas web page:

https://atlas.scharp.org/cpas/project/MTN/020/begin.view?

Following the tables is a description of each report that includes the purpose and components of the report.

Table 17-1: MTN-020 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
Data Quality Control (QC)	Monthly and as needed	• Site Staff as designated by each site • SDMC Project Managers
Clinical Queries	As needed (as queries are identified)	• Site Staff as designated by each site • SDMC Project Managers
Unresolved Adverse Experiences (AEs)	Monthly	• Site Staff as designated by each site • SDMC Project Managers
Unresolved Product Holds	Monthly	• Site Staff as designated by each site • SDMC Project Managers
Unresolved Social Harms	Monthly	• Site Staff as designated by each site • SDMC Project Managers
LDMS Specimen Monitoring	Monthly	• Site LDMS Laboratory Staff • Network Lab Representative • SDMC Project Managers
Missed Visits Listing	Monthly	• Site Staff that receive QC Reports • CORE Clinical Research Managers • Protocol Chair/Co-Chair • SDMC Project Managers

Table 17-2: MTN-020 SDMC Reports Posted on Atlas

Report Title	Update Frequency	Atlas Viewing Area
Screen Out	Daily	Unsecure
Enrollment	Daily	Unsecure
Retention	Daily	Unsecure
Retention Report Summary	Daily	Unsecure
Retention Report Graph	Daily	Unsecure
Enrolled PTID	Daily	Unsecure
Procedure Completion	Monthly	Unsecure
Data Management Quality	Monthly	Unsecure
Data Summary	Monthly	Unsecure
Baseline Contraceptives Use	Daily	Unsecure
Follow-up Contraceptives Use	Monthly	Secure
Protocol Deviations Listing	Daily	Secure
Protocol Deviations Summary Table	Monthly	Secure
Early Termination	Daily	Secure

PSRT (Safety)	One week prior to PSRT call	Secure
SMC and DSMB	As determined by the DSMB	Secure
Product Adherence & Ring Collection and Insertion - Cumulative	Daily	Secure
Product Adherence & Ring Collection and Insertion – Past Month	Monthly	Secure
Network Laboratory	As needed	Secure
PPD Reports	Quarterly	Secure
AE Data	Daily	Secure

1. Data Quality Control (QC Report)

   Purpose: To identify missing and inconsistent data
   Components: Quality control notes; overdue visit reminders, missing page reminders

2. Clinical Queries
   Purpose: To identify inconsistencies/questions identified in safety or clinical data
   Components: Queries containing clinically-based questions about safety and clinical data

3. Unresolved Adverse Experiences (AEs)

   Purpose: To identify those AEs that 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 90 or more days

4. Unresolved Product Holds

   Purpose: To identify those clinical product holds that 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

5. Unresolved Social Harms

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

6. LDMS Specimen Monitoring

   Purpose: To identify stored specimens whose information in LDMS does not match corresponding information collected per CRFs
   Components: Listing of those specimens whose LDMS PTID, collection date, or visit month 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

7. Missed Visits Listing

   Purpose: To identify participants who may have missed their most recent scheduled visit in the past month, to help sites focus retention efforts and prevent participants from becoming chronic defaulters
   Components: Site-specific listing of PTIDs who may have missed the most recent scheduled visit in the past month (i.e., a Missed Visit CRF was received, or no CRFs were entered at SCHARP for the visit), along with their total number of consecutive visits missed (cumulative), total number of visits missed, date of the last completed visit, and window end for the next expected visit

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 Eligibility Criteria CRF.

9. Enrollment

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

10. Retention

    Purpose: To report on participant visit retention as reflected by data received and data entered at the SDMC.
    Components: By site and by visit month, 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 is listed.

11. Retention – Summary Table

    Purpose: To provide a summary of visit retention by study site
    Components: By site, a summary of cumulative visit retention over all expected visits overall and for the last three calendar months. Retention rates excluding participants who terminated early is also included.

12. Retention Report Graph

    Purpose: To provide a graphic presentation of the Retention Report.
    Components: A line graph containing a line for each site, with the horizontal axis being the Visit Month and the vertical axis the site's retention rate (the % participants retained).

13. Enrolled PTID Listing

    Purpose: To make enrolled PTID numbers and corresponding enrollment dates available to site monitors.
    Components: By site, a listing of each enrolled PTID along with the enrollment date

14. 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).

15. 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, 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. SCHARP specified goals are included, as applicable.

16. 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.

17. Baseline Contraceptives 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 Baseline Family Planning CRF, the number and percentage of participants reporting use of that contraceptive method.

18. 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 CRF.

19. 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.

20. 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

21. 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

22. PSRT (Safety) Reports

    Purpose: To help the Protocol Safety Review Team monitor participant safety as reflected by adverse experiences, clinical product hold, and social impacts reported to the SDMC.
    Components: Cumulative AE, product hold, and social impact data reported to the SDMC.

23. Study Monitoring Committee (SMC) and Data Safety Monitoring Board (DSMB) Reports

    Purpose: To provide information on study conduct and ability to answer study objectives, and primary endpoint data to SMC and DSMB 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 or DSMB

24. Product Adherence & Ring Collection and Insertion

Purpose: To provide a subset of Protocol Team members with a cumulative and past month data listing of study product adherence data to identify trends and issues that require follow up
Components: Summary by site and overall of data from the Ring Adherence CRF and the Ring Collection/Insertion CRF

25. Network Laboratory Listings

Purpose: To provide the Network Laboratory (NL) with specimen data so they can determine when site shipments are needed to facilitate timely data transfer between the Network Laboratory and SCHARP
Components: Cumulative number of specimens requiring HIV endpoint confirmatory and QA testing, as well as PK testing, at the Network Labs

26. PPD Reports

Purpose: To provide PPD with quarterly listings of study data to conduct the protocol monitoring review plan at the study sites
Components: clinical product hold and Grade 2 and higher AE listings by site

27. AE Data

Purpose: To provide the MTN-020 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 AE-1 log CRF.