Section 14 - Study Reporting Plan

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14.1 Purpose of Reporting Plan

The purpose of this reporting plan is to describe the reports that the MTN SDMC (SCHARP) plans to generate for MTN-015.

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 corrective action (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-015 SDMC Project Manager in collaboration with other MTN-015 SDMC staff.

14.2 Study Reports

Table 14-1 lists the reports the SDMC will produce and distribute via email. Table 14-2 lists the reports the SDMC will produce and make available via the Atlas website:

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

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 14-1: MTN-015 SDMC Reports Distributed via Email

Report Title	Distribution Frequency	Distribution List
Data Quality Control (QC)	Monthly	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Manager • SDMC Project Manager
Site Specimen Monitoring Report	Monthly	• Site Study Coordinators • Network Lab Representative • SDMC Project Manager
Summary Specimen Monitoring Report	Monthly	• Network Lab Representative • SDMC Project Manager

Table 14-2: MTN-015 SDMC Reports Posted on Atlas

Report Title	Update Frequency	MTN-015 Atlas Viewing Area
Enrollment – VOICE Participants Only	Weekly	Unsecure
Enrollment – All Participants	Weekly	Unsecure
Retention– VOICE Participants Only	Weekly	Unsecure
Retention – All Participants	Weekly	Unsecure
Visit Adherence – All Participants – Days Between Target and Actual Visits	Weekly	Unsecure
Visit Adherence - All Participants – Procedure Completion	Weekly	Unsecure
Site Data Management Quality	Monthly	Unsecure
HIV/AIDS-associated Events	Monthly	Secure
ART Medications	Monthly	Secure
ART Monitoring Report	Monthly	Secure
Interim Study Review (ISR)	Prior to each ISR Review	Secure
Protocol Deviations Listings	Daily	Secure
Protocol Deviations-Summary Table	Monthly	Secure

14.2.1   Data Quality Control (QC) Report

Purpose: To identify missing and inconsistent data.
Prepared and Distributed by: SDMC Data Coordinator
Components: Quality control notes and missing page reminders

14.2.2   Site Specimen Monitoring Report
Purpose: To monitor storage in LDMS of those specimens marked as "stored" on study CRFs.
Prepared by: SDMC Laboratory Programmer
Components: Site-specific listing of all discrepancies between the CRF stored specimen data and LDMS data.

14.2.3   Summary Specimen Monitoring Report
Purpose: To monitor storage in LDMS of those specimens marked as "stored" on study CRFs.
Prepared by: SDMC Laboratory Programmer
Components: Summary listing of all discrepancies between the CRF stored specimen data and LDMS data, across all study sites. Listing of new discrepancies between the CRF stored specimen data and LDMS data, across all study sites.

14.2.4   Enrollment – VOICE Participants Only
Purpose: To present enrollment data for participants whose parent protocol is VOICE.
Prepared by: SDMC Reporting Programmer
Components: Number of eligible participants enrolled, time from seroconversion to enrollment (all participants), and time from ART initiation to enrollment (participants enrolled as ART participants only).

14.2.5   Enrollment – All Participants
Purpose: To present enrollment data for all participants enrolled in the study, regardless of parent protocol.
Prepared by: SDMC Reporting Programmer
Components: % of eligible participants enrolled, time from seroconversion to enrollment (all participants, listed in %s), and time from ART initiation to enrollment (participants enrolled as ART participants only, listed in %s).

14.2.6   Retention – VOICE Participants Only
Purpose: To present retention data for participants whose parent protocol is VOICE.
Prepared by: SDMC Reporting Programmer
Components: For each follow-up visit, the number and % of participants who are expected for the visit, have completed the visit (retained), have missed the visit, have terminated early/LFU, or who have completed the visit prior to being expected. Presented first by non-ART participants, then ART participants.

14.2.7   Retention – All Participants
Purpose: To present retention data for all participants, regardless of parent protocol.
Prepared by: SDMC Reporting Programmer
Components: % of participants who have completed each follow-up visit, by non-ART track, then ART track participants.

14.2.8   Visit Adherence – All Participants – Days Between Target and Actual Visits
Purpose: To monitor adherence to target follow-up visit dates.
Prepared by: SDMC Reporting Programmer
Components: For each follow-up visit, the % of participants who have completed the visit, the mean number of days between the actual visit date and the target visit date, along with the median, min, max, and 25th and 75th percentiles. Presented first for non-ART participants, then for ART track participants.

14.2.9   Visit Adherence – All Participants – Procedures Completion
Purpose: To monitor completion of protocol-required laboratory procedures during follow-up.
Prepared by: SDMC Reporting Programmer
Components: Listing of the number and % completion of various laboratory procedures during follow-up, overall and by site.

14.2.10 Site Data Management Quality Report
Purpose: To summarize site performance regarding data management and quality.
Prepared by: SDMC Project Manager
Components: Total number of CRF pages faxed to SCHARP, total number of QCs applied, % of QCs resolved, QC rate per 100 CRF pages, and mean days to fax in CRF pages. Reported cumulatively (since study start) and for the previous month.

14.2.11 HIV/AIDS-associated Events Report
Purpose: To provide data on HIV/AIDS-associated and AIDS-defining illnesses reported on the study
Prepared by: SDMC Reporting Programmer
Components: For each event reported, the event description, visit code at which it was reported, date started, date stopped, whether the event is an AIDS-defining illness, and whether the clinical diagnosis is confirmed, probable, or unknown.

14.2.12 ART Medications Report
Purpose: To provide data on ART medication use.
Prepared by: SDMC Reporting Programmer
Components: By participant, for each ART medication reported, a listing of the medication name, start date, stop date (when present), stop reason, and dose/frequency.

14.2.13 ART Monitoring Report
Purpose: To provide list of participants with AIDS defining illnesses not on ART.

Prepared by: SDMC Reporting Programmer
Components: By participant, for each reason why the participant is not on ART, visit number, collection date and absolute CD 4+ count.

14.2.14 Interim Study Review Report

Purpose: To monitor study progress at each site.
Prepared and Distributed by: Prepared by SDMC MTN-015 staff
Components: Summary by site for the accrual, retention, demographics, and visit adherence. Also includes information on site data management quality and other components as requested by the ISR.

14.2.15 Protocol Deviations Listings Report

Purpose: To provide a subset of Protocol Team members with a cumulative listing of all protocol deviations reported for the study.
Prepared and Distributed by: Prepared by SDMC MTN-015 staff
Components: Each of the fields/data items as listed on the Protocol Deviations Log CRF.

14.2.16 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.
Prepared and Distributed by: Prepared by SDMC MTN-015 staff
Components: Overall and by site, the number and percentages of protocol deviations reported for the study