Section 15. Study Reporting Plan

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Effective with Version 2.1 of this section, prior references to the HIV Prevention Trials Network (HPTN) have been replaced where applicable with references to the Microbicide Trials Network (MTN).

15.1 Purpose of Reporting Plan

The purpose of this reporting plan is to describe the procedures and reports that the MTN SDMC (SCHARP) plans to use to monitor HPTN 035 data collection, data quality, participant safety, and study conduct.

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 receive and 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 has been prepared by the HPTN 035 SDMC Project Managers in conjunction with HPTN 035 SDMC statisticians, statistical research associates, and programmers.

15.2 Study Reports

Table 15-1 lists the reports the SDMC will produce, the frequency of distribution, and the distribution list for each report. Following the table is a description of each report that includes the purpose of the report, who will prepare the report, and specific components of the report. The exact day of the week reports are distributed will be determined once data collection begins.

Table 15-1: Study Reporting Schedule and Distribution Lists

Report	Distribution Frequency	Distribution List
Enrollment/Retention	Every week for at least the first 6 months, then monthly	• HPTN 035 Protocol Team
Accrual	Monthly, or as needed	• HPTN 035 Protocol Team
Data Quality Control (QC)	Every 2 weeks for the first 3 months of site activity, then monthly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Manager • SDMC Project Managers
Clinical Data Quality Control (CQC) Reports	Weekly, or as needed	• Designated Site Staff • CORE Clinical Research Manager • SDMC Project Managers
Visit Adherence	Monthly, or as needed	• HPTN 035 Protocol Team
Site Data Management Quality	Monthly, or as needed	• HPTN 035 Protocol Team
Unresolved Adverse Experiences Listing	Monthly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Manager • SDMC Project Managers
Safety	Monthly, or as needed	• HPTN 035 Protocol Safety Review Team (PSRT)
Study Monitoring Committee (SMC)	Within 4 months of study initiation, then every 4-6 months or as determined by the SMC	• HPTN 035 SMC members and observers • HPTN 035 Co-Chairs
Data Safety Monitoring Board (DSMB)	Every 8 months, or as determined by the DSMB	Closed and Open Report: • DSMB members • SDMC Protocol Statisticians • SDMC Protocol Statistical Research Associates • SDMC Deputy Director of Statistics Open Report only: • HPTN 035 SMC members and observers • HPTN 035 Co-Chairs • Others, as needed

15.2.1 Enrollment/Retention Report

Purpose: To monitor participant accrual and retention as reflected by data submitted to the SDMC (via DataFax).

Responsibility for Preparation:
- SDMC SAS Programmers

Components:
- Enrollment for all sites individually and combined. Includes the number of women enrolled/randomized each week and cumulatively, and a comparison with the weekly and cumulative enrollment targets.
- Retention for all sites individually and combined, by visit. Includes: total enrolled (broken down by active, inappropriately enrolled, and lost to follow-up); number expected for a given visit; number not expected for a given visit; and total retention by visit calculated as the number of participants who have completed a visit divided by total number of participants expected for the visit.

15.2.2 Accrual Report

Purpose: To summarize monthly site accrual in relation to monthly site accrual targets specified in the protocol (and possibly modified in the course of study progress.)

Responsibility for Preparation:
- SDMC Statistical Research Associates

Components: By site and overall,
- monthly accrual is described as 1) calendar month -- the number of participants enrolled in a given calendar month (January, February, etc.); and 2) study month -- the number of participants enrolled in a monthly period defined by the date of the first enrollment at a clinic or site.

15.2.3 Data Quality Control (QC) Report

Purpose: To identify and help correct missing and inconsistent data.

Responsibility for Preparation:
- SDMC Data Coordinators
- SDMC SAS Programmers
- SDMC Project Managers

Components:
- Fax/Re-fax list - includes listing of missing pages, overdue visits, missing data, and inconsistent data.
- Questions and Answers section - contains more complex questions about submitted data.

15.2.4 Clinical Data Quality Control (QC) Report

Purpose: To identify and help correct inconsistencies/questions identified in clinical data.

Responsibility for Preparation:
- SDMC Clinical Affairs Safety Associate

Components:
- Questions and Answers section - contains clinically-based questions about clinical data.

15.2.5 Visit Adherence Report

Purpose: To summarize site performance regarding study primary and secondary endpoint data collection.

Responsibility for Preparation:
- SDMC Statistical Research Associates

Components: By site and overall,

- distribution of visits, including (1) the number of days between target and actual visit dates and (2) the number of days between sequential monthly visits;
- number and percentage of required pelvic exams completed, and gram stains slides collected;
- number and percentage of required HIV tests completed;
- number and percentage of required pregnancy tests completed;
- number and percentage of required Phase II laboratory tests completed,
- number of participants who missed three or more consecutive visits.

15.2.6 Site Data Management Quality Report

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

Responsibility for Preparation:
- SDMC Project Managers

Components:

- Total Records: the total number of DataFax CRF pages received (including refaxes) at the SDMC listed by site and for all sites combined.
- Total QCs: the total number of quality control (QC) notes placed on data received at the SDMC, listed by site and for all sites combined. This number does not include “Missing Page,” “Overdue,” and “Fax Noise” QCs.
- Total QCs Resolved (%): The percentage of total QCs sent to the site that have been resolved, listed by site and for all sites combined.
- QC Rate /100 Pages: The average number of quality control notes placed per 100 DataFax CRF pages, listed by site and for all sites combined.
- Mean Days to Fax In: Mean number of days that it takes for DataFax CRFs to be sent to the SDMC from the day they were completed, listed by site and for all sites combined.

15.2.7 Unresolved Adverse Experiences Listing

Purpose: To identify and update/resolve incomplete Adverse Experience outcome data.

Responsibility for Preparation:
- SDMC SAS Programmers

Components:
- Summary listing (by participant ID) of all unresolved adverse experiences.

15.2.8 Safety Report

Purpose: To monitor study participant safety as reflected by reported adverse experiences and laboratory toxicities.

Responsibility for Preparation:
- SDMC SAS Programmers
- SDMC Clinical Affairs Safety Associate

Components:
- Selected adverse experiences and laboratory values, listed by site and for all sites combined (see the HPTN 035 Protocol Safety Review Team Monitoring Plan in section 11, Appendix 11-2 of the SSP for more detailed information on HPTN 035 safety reports).

15.2.9 Study Monitoring Committee (SMC) Report

Purpose: To monitor study progress at each site.

Responsibility for Preparation:

- SDMC Data Coordinators
- SDMC SAS Programmers
- SDMC Statistical Research Associates
- SDMC Project Managers
- SDMC Document Specialist
- SDMC Statisticians

Components: Summary by site, and overall, of:

- Study design and history
- Screening
- Accrual
- Retention
- Demographics
- Product Adherence
- Pregnancy and Pregnancy Outcomes
- Other information, as requested by the SMC

The following reports (previously described) will also be included:

- Visit Adherence Report
- Site Data Management Quality Report

15.2.10 Data Safety Monitoring Board (DSMB) Report

Purpose:

- To ensure participant safety with regard to toxicity and efficacy.
- To identify problems regarding data quality, accrual, eligibility, evaluability rates, retention, and adherence.

Responsibility for Preparation:

- SDMC Data Coordinators
- SDMC SAS Programmers
- SDMC Statistical Research Associates
- SDMC Project Managers
- SDMC Document Specialist
- SDMC Statisticians

Open Report Components:

Summary by site, and overall, of:

- Study design and history
- Screening
- Accrual
- Retention
- Demographics
- Product Adherence
- Safety/Adverse Events
- Pregnancy and Pregnancy Outcomes
- Protocol Events

The following reports (previously described) will also be included:

- Visit Adherence Report
- Site Data Management Quality Report

Closed Report Components: *(Data reported by blinded arm)*

In addition to receiving the DSMB Open Report described above, members of the DSMB will receive the Closed DSMB Report that contains a summary, by site and overall, of:

- Effectiveness against HIV
- Effectiveness against Secondary Endpoints
- Summary and Recommendations
- Other information, as requested by the DSMB