Section 15. Study Reporting Plan

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15.1 Purpose of Reporting Plan

The purpose of this reporting plan is to describe the procedures and reports that the HPTN SDMC (SCHARP) plans to use to monitor HPTN 059 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 059 SDMC Project Manager in conjunction with the HPTN 059 SDMC Statistician, Statistical Research Associate, Programmers, Data Coordinator, and Clinical Affairs Safety Associate.

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 every two weeks	• HPTN 059 Protocol Team
Data Quality Control (QC)	Every 2 weeks for the first 3 months of site activity, then every 3 weeks (or as needed).	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Clinical Data Quality Control (CQC)	Weekly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager
Visit Adherence	Monthly, or as needed	• HPTN 059 Protocol Team
Site Data Management Quality	Monthly, or as needed	• HPTN 059 Protocol Team
Unresolved Adverse Experiences	Monthly, or as needed	• Site Study Coordinators • Site Data Managers • CORE Clinical Research Managers • SDMC Project Manager • SDMC Clinical Affairs Safety Associate
Safety	As determined by the HPTN 059 Protocol Safety Review Team (PSRT)	• HPTN 059 Protocol Safety Review Team (PSRT)
Study Monitoring Committee (SMC)	Within 4 months of study initiation, then as determined by the SMC	• HPTN 059 SMC members and observers • HPTN 059 Protocol Chair • HPTN 059 Protocol Co-Chairs • HPTN 059 Site Investigators
Specimen Repository Report: All Sites	Monthly	• HPTN 059 Central Laboratory • SDMC Project Manager
Specimen Repository Report: Site-specific	Monthly	• Site LDMS/Lab Data Managers • SDMC Project Manager

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 Data Quality Control (QC) Report

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

Responsibility for Preparation:
- SDMC Data Coordinator
- SDMC SAS Programmers
- SDMC Project Manager

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.

15.2.3 Clinical Data Quality Control (CQC) Report

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

Responsibility for Preparation:
- SDMC Clinical Affairs Safety Associate

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

15.2.4 Visit Adherence Report

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

Responsibility for Preparation:
- SDMC Statistical Research Associate

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;
- number and percentage of required pregnancy tests completed;
- number and percentage of required laboratory tests completed,
- number of participants who missed three or more monthly visits in a row.

15.2.5 Site Data Management Quality Report

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

Responsibility for Preparation:
- SDMC Project Manager

Components:
- Total Records: the total number of DataFax CRF pages received (does not include 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” QCs.
- 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.

15.2.6 Unresolved Adverse Experiences Report

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.

15.2.7 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 059 Protocol Safety Review Team Monitoring Plan in section 10 of this SSP for more detailed information on HPTN 059 safety reports).

15.2.8 Study Monitoring Committee (SMC) Report

Purpose: To monitor study progress at each site.

Responsibility for Preparation:

- SDMC Data Coordinator
- SDMC SAS Programmers
- SDMC Statistical Research Associate
- SDMC Project Manager
- SDMC Technical Document Specialist
- SDMC Statistician

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
- Other information, as requested by the SMC

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

- Visit Adherence Report (as necessary)
- Site Data Management Quality Report

15.2.9 Specimen Repository Report: All Sites

Purpose: To monitor collection of stored specimens across all study sites, and to ensure that the number and type of specimens marked as collected in the SDMC database (CRF data) match the number and type of specimens entered into the Laboratory Data Management System (LDMS) database

Responsibility for Preparation:
- SDMC Lab Programmer

Components:
- Summary listing of all existing discrepancies between the SDMC data and the LDMS data (across all study sites)
- Listing of new discrepancies between the SDMC data and the LDMS data since the last report was generated

15.2.10 Specimen Repository Report: Site-specific

Purpose: To monitor collection of stored specimens at each study site, and to ensure that the number and type of specimens marked as collected in the SDMC database (CRF data) match the number and type of specimens entered into the Laboratory Data Management System (LDMS) database

Responsibility for Preparation:
- SDMC Lab Programmer

Components:
- Site-specific summary listing of all existing discrepancies between the SDMC data and the LDMS data