

Section 13. Reporting Plan

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13.1 Purpose of Reporting Plan

This reporting plan describes the procedures and reports SCHARP plans to use to monitor HPTN 058 data collection, data quality, and participant safety. During the study, SCHARP activities include: 1) ongoing review of all study data on CRFs, checking for completeness and accuracy; 2) monitoring of data collection, data quality, participant safety, and trial conduct; and 3) monitoring adherence to key protocol requirements.

The purposes of this plan are to:

- identify the content of each report;
- identify those responsible for production and distribution of each report;
- ensure that the protocol team approves and agrees to the types of reports to be generated by SCHARP and the schedule for distributing these reports;
- identify who should receive and review the reports so corrective action (if necessary) is taken.

13.2 Procedures

The reporting plan will be prepared by the HPTN 058 Project Manager at SCHARP in conjunction with SCHARP statisticians and programmers.

13.3 Reports

The table below lists the distribution frequency and distribution list for the reports described in this document. The exact day of the week these reports are distributed will be determined once data collection begins. The first Data Management Quality report will be produced once an adequate amount of data is in the database. The sections following this table describe each report in detail.

Report		Distribution Frequency	Distribution List
13.3.1	Enrollment/Retention	Updated daily and posted on SCHARP Web Portal	NA
13.3.2	Data Quality Control (QC)	Bi-monthly	Site Study Coordinator Site Data Manager
13.3.3	Clinical and Coding Queries	As needed	Clinical Staff designated by site
13.3.4	Data Management Quality	Monthly	Protocol Team, OCSO
13.3.5	Unresolved Serious Adverse Events	Quarterly, or as needed	Site study coordinators Site data managers SCHARP Project Manager
13.3.6	Protocol Safety Review Team	Bi-monthly, or as needed	HTPN 058 Protocol Safety Review Team (PSRT)
13.3.7	Pregnancy	Quarterly, or as needed	PSRT
13.3.8	Study Monitoring Committee (SMC)	Prior to each DSMB review, or as determined by the SMC	SMC Protocol Chairs Observers from HPTN Core, SDMC, NL and DAIDS
13.3.9	Data Safety & Monitoring Board (DSMB)	Yearly, or as determined by the DSMB	DSMB Others, as needed

13.3.1 Enrollment/Retention Report

Purpose	To monitor participant enrollment and retention as reflected by CRF data received by SCHARP.
Responsibility for Preparation	SCHARP Protocol Programmers
Frequency	Updated daily
Distribution List	NA - posted on SCHARP Web Portal (ATLAS)
Components	By site, weekly and cumulative: <ul style="list-style-type: none">• Enrollment: For all sites individually and combined, the number of participants enrolled each week, and a comparison with the weekly 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), expected for visit (including percentage of visits conducted on time and late), not expected for the visit and total retention calculated as the number of participants who have completed study visits divided by total number of participants expected for a visit.

13.3.2 Data Quality Control (QC) Report

Purpose	To identify and correct missing and inconsistent data in the database
Responsibility for Preparation	SCHARP HPTN 058 Data Coordinators
Frequency	Bi-Monthly
Distribution List	Site Study Coordinator Site Data Manager
Components	<ul style="list-style-type: none">• List of missing pages, overdue visits, missing data; questions about inconsistent or unclear data.

13.3.3 Clinical and Coding Queries

Purpose	To identify and reconcile clinical and laboratory issues and inconsistencies in study data
Responsibility for Preparation	SCHARP Clinical Affairs Safety Associate
Frequency	As needed
Distribution List	Clinical Site staff designated by site
Components	<ul style="list-style-type: none">• Contains participant-specific, clinically based questions regarding Adverse experience, lab and/or clinical data

13.3.4 Data Management Quality Report

Purpose	To summarize over time site performance regarding data quality
Responsibility for Preparation	SCHARP HPTN 058 Project Manager
Frequency	Monthly
Distribution List	Protocol Team
Components	Cummulative and past-month statistics: <ul style="list-style-type: none">• Total number DataFax form pages received.• Total number of quality control (QC) errors identified in DataFax and sent to the site.• Percent QCs Resolved• Rate of QCs sent per 100 pages.• Mean number of days for sites to fax forms to DataFax.

13.3.5 Unresolved Serious Adverse Events Report

Purpose	To identify and update/resolve incomplete Serious Adverse Event outcome data
Responsibility for Preparation	SCHARP programmers
Frequency	Quarterly
Distribution List	Site study coordinator, site data manager
Components	<ul style="list-style-type: none">• Summary listing by participant ID of all unresolved serious adverse events

13.3.6 Protocol Safety Review Team Reports

Purpose	To monitor study participant safety as reflected by reported serious adverse events and laboratory toxicities
Responsibility for Preparation	SCHARP Reporting Programmer, Clinical Safety Specialist
Frequency	Bi-monthly
Distribution List	Posted to SCHARP web portal (ATLAS) with pass-word protected access for the HPTN 058 Protocol Safety Review Team (PSRT) members
Components	<ul style="list-style-type: none">• Serious adverse events, pregnancy outcomes, laboratory values (as determined by PSRT), and social impacts, summarized by site and for all sites combined

13.3.7 Pregnancy Report

Purpose	To report the pregnancy test results, pregnancies, and pregnancy outcomes of study participants during the course of the study.
Responsibility for Preparation	SCHARP Programmers
Frequency	Quarterly
Distribution List	HPTN 058 PSRT
Components	<ul style="list-style-type: none">• Summary listing of all pregnancy testing by visit and pregnancy outcomes.

13.3.8 Study Monitoring Committee (SMC) Report

Purpose	To monitor the progress of the study at each site.	
Responsibility for Preparation	SCHARP HPTN 058 Statistical Research Associates, with assistance from SCHARP study team	
Frequency	Every six months just prior to DSMB review, or as determined by the SMC.	
Distribution List	<table border="1"><tr><td>SMC Protocol Chairs Observers from HPTN Core, SDMC, NL and DAIDS</td></tr></table>	SMC Protocol Chairs Observers from HPTN Core, SDMC, NL and DAIDS
SMC Protocol Chairs Observers from HPTN Core, SDMC, NL and DAIDS		
Components	<p>Summary (most information will be pooled by treatment arm) by site, and overall:</p> <ul style="list-style-type: none">• Summary of trial design and SMC history• Accrual of participants• Baseline characteristics• Retention• Termination• Adherence to treatment• Other study conduct information, as requested by the SMC• Issues affecting study conduct, as requested by the SMC	

13.3.9 Data Safety and Monitoring Board (DSMB) Report

Purpose	For one or more of these reasons: To monitor efficacy and safety; administrative review; or design review
Responsibility for Preparation	SCHARP HPTN 058 Statistical Research Associates, with assistance from SCHARP study team
Frequency	Every 6 months or to be determined by the DSMB
Distribution List	Open report: DSMB, Protocol Chairs Closed report: DSMB
Components	<p>Open report (most information will be pooled by treatment arm) will include, at a minimum;</p> <ul style="list-style-type: none">• Summary of trial design and DSMB history• Accrual of participants• Baseline characteristics• Retention• Termination• Adherence to treatment• SAEs and EAEs• HIV/AIDS events• Other follow-up information, as required by the DSMB• Issues affecting study conduct

Closed report will include, at minimum, all information in the open report by treatment arm. In addition, at each formal interim analysis review, analyses of efficacy and safety endpoints by treatment arm will be included.