

Section 13. Reporting Plan for HPTN 046

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13.1 Purpose of Reporting Plan

This Reporting Plan describes the procedures and reports that SCHARP plans to use to monitor data collection, data quality, participant safety and trial conduct for HPTN046. During the study, SCHARP activities will include: 1) ongoing review of all study data, checking for completeness and accuracy; 2) production of reports for monitoring of study enrollment, retention rates, safety and study results; and 3) monitoring adherence to key protocol requirements

The purposes of this plan are:

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

13.2 Procedures

This reporting plan has been prepared by the Project Managers at SCHARP in conjunction with SCHARP statisticians and programmers. The dates in this monitoring plan are estimates since some analyses are event-driven rather than time-driven. Therefore, this plan will be modified as necessary.

13.3 Reports

The schedule table below lists the various reports that SCHARP will produce and the frequency of distribution. Following the table is a description of each report that includes the purpose, who will prepare the report, the distribution frequency, who will receive the report, the method of distribution, and specific components of the report. The exact day of the week these reports are distributed will be determined once data collection begins. The first Site Data Management Quality Report will be produced once an adequate amount of data is in DataFax. Thereafter, these reports will be produced on a monthly basis based on the date of the first report.

Table 13-1: Reporting Schedule

Report	Distribution Frequency	Distribution List
13.3.1 Enrollment/Retention	Updated daily	Posted on SCHARP web site: http://www.scharp.org/HPTN/PTN046/046.html
13.3.2 Data Quality Control (QC)	Monthly, or as needed	<ul style="list-style-type: none"> - Site Study Coordinators - Site Data Manager - CORE Clinical Research Monitor(s) - SCHARP Project Manager
13.3.3 Clinical Queries (CQC)	As needed	Staff designated by site
13.3.4 Site Data Management Quality Report	Monthly, or as needed	Protocol Team
13.3.5 Protocol Safety Review Team (PSRT)	Bi-Monthly, or as needed	Protocol Safety Review Team: <ul style="list-style-type: none"> - Protocol Statistician - Protocol Chair - NIAID Medical Officer - NICHD Medical Officer - SCHARP Clinical Staff - SCHARP Project Manager - Designated Site Clinicians
13.3.6 Study Monitoring Committee (SMC)	Every 6 months just prior to DSMB review, or as determined by the SMC	SMC Protocol Team Others, as needed
13.3.7 Data Safety Monitoring Board (DSMB)	Every 6 months, or as determined by the DSMB	To receive a Closed Report: <ul style="list-style-type: none"> - DSMB members - Protocol Statistician - Protocol Statistical Research Associates - SCHARP HPTN Deputy Director To receive Open Report only: <ul style="list-style-type: none"> - CORE Protocol Specialist - Site PIs - Investigators of Record - SCHARP Project Manager - DAIDS Medical Officer - SMC Others, as needed

In general, routine reports generated from the SCHARP database (e.g., QC Reports, Enrollment/Retention Reports) will include data submitted by sites up to 10 calendar days prior to the date of the report. Other reports, such as DSMB Reports, will have a scheduled data submission cut-off date communicated to sites before the report is generated.

13.3.1 Enrollment and Retention Report

Purpose: To monitor participant accrual and retention by site as reflected by data submitted to SCHARP DataFax.

Responsibility for Preparation: • SCHARP HPTN046 SAS Programmers

Responsibility for Distribution: • SCHARP HPTN046 SAS Programmers

Frequency: Weekly, for the first 6 months, then monthly

Distribution List: Distributed by e-mail to Protocol Team, CORE Clinical Research Managers, and Project Manager.

Components:

- Enrollment: For all sites individually and combined, the number of infants enrolled/randomized.
- Retention: For all sites individually and combined by visit. Includes: Total enrolled (broken down by active, inappropriately enrolled, lost to follow-up and deceased status), expected for next visit (including percentage of visits conducted on time and late), not expected for next visit and total retention calculated as the number of participants who have completed a visit divided by total number of participants expected for a visit.

13.3.2 Data Quality Control (QC) Report

Purpose: To identify and help correct missing and inconsistent data in the database.

Responsibility

for Preparation:

- SCHARP HPTN046 Data Coordinator
- SCHARP HPTN046 SAS Programmers
- SCHARP HPTN046 Project Manager
(to review prior to distribution)

Responsibility

for Distribution: SCHARP HPTN046 Data Coordinator

Frequency: Monthly, or as needed

Distribution List: Distributed by e-mail to Site Study Coordinators, Site Data Managers, CORE Protocol Specialist, and Project Manager.

Components:

- Fax/Refax list (missing pages, overdue visits, missing data, inconsistent data)
- Questions and Answers (more complex problems)

13.3.3 Clinical Quality Control (QC) Report

Purpose: To identify and reconcile clinical and laboratory issues and inconsistencies to study data.

Responsibility for Preparation: • SCHARP HPTN046 Clinical Affairs Safety Associate

Responsibility for Distribution: • SCHARP HPTN046 Project Manager

Frequency: As needed

Distribution List: Site staff designated by site and CORE Protocol Specialist

Components: • Participant-specific, clinically based questions regarding lab and/or clinical data.

13.3.4 Site Data Management Quality Report

- Purpose:** To summarize site performance regarding data management and quality.
- Responsibility for Preparation:** • SCHARP HPTN046 Project Manager
- Responsibility for Distribution:** • SCHARP HPTN046 Project Manager
- Frequency:** Monthly, or as needed
- Distribution List:** Distributed by e-mail to Protocol Team
- Components:**
- Total Records: The total number of CRF (DataFax) pages received by site, and for all sites combined.
 - Total QCs: The total number of quality control errors identified on the pages included in Total Records. Data is presented by site, and for all sites combined.
 - QC Rate/100 Pages: The average number of quality control errors identified (per the description of Total QCs above) for every 100 pages of data received by SCHARP. Data is presented by site, and for all sites combined.

13.3.5 Protocol Safety Review Team (PSRT) Report

Purpose: To monitor study adverse experiences and laboratory toxicities on a regular basis

Responsibility for Preparation:

- SCHARP HPTN046 SAS Programmer
- SCHARP HPTN046 Clinical Specialist

Responsibility for Distribution:

- SCHARP HPTN046 SAS Programmer
- SCHARP HPTN046 Project Manager

Frequency: Every 2 weeks, or as determined by the HPTN046 PSRT

Distribution List: Distributed by e-mail to HPTN046 Protocol Safety Review Team

Components:

- Frequency of AEs by body system and severity
- Frequency of AEs by body system and relationship to study drug
- Grade 2 and higher hepatic clinical and laboratory abnormalities
- Grade 2 and higher rashes
- Grade 3 and higher clinical and laboratory events/abnormalities
- AEs reported as Expedited AEs to RCC

13.3.6 Study Monitoring Committee (SMC) Report

Purpose: To monitor study progress at each site.

Responsibility

for Preparation:

- SCHARP HPTN046 Data Coordinators
- SCHARP HPTN046 SAS Programmers
- SCHARP HPTN046 Statistical Research Associates
- SCHARP HPTN046 Project Manager
- SCHARP HPTN046 Technical Document Specialist
- SCHARP HPTN046 Statistician (to review prior to distribution)

Responsibility

for Distribution:

- SCHARP HPTN046 Technical Document Specialist
- SCHARP HPTN046 Statistical Research Associates

Frequency: Every 6 months just prior to the DSMB review, or as determined by the HPTN SMC

Distribution List: Distributed by e-mail to HPTN SMC members, the Protocol Team, and others as needed.

Components: Summary by site, and overall, of:

- Trial Design and History
- Screening
- Accrual
- Retention
- Demographics
- Adherence to Study Drug
- Site Performance
- Availability of primary and secondary endpoint data
- Other information, as requested by the SMC

13.3.7 Data Safety Monitoring Board (DSMB) Reports

- 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:**
- SCHARP HPTN046 Data Coordinators
 - SCHARP HPTN046 SAS Programmers
 - SCHARP HPTN046 Statistical Research Associates
 - SCHARP HPTN046 Project Manager
 - SCHARP HPTN046 Technical Document Specialist
 - SCHARP HPTN046 Statistician (to review prior to distribution)

- Responsibility for Distribution:**
- SCHARP HPTN046 Technical Document Specialist
 - SCHARP HPTN046 Statistical Research Associates

- Frequency:** * Every 6 months, or as determined by the NIAID VPDSMB

Distribution List:

- Open Report**
- NIAID VPDSMB Members
 - CORE Protocol Specialist
 - Site PIs
 - Investigators of Record
 - SCHARP Project Manager
 - SCHARP HPTN046 Statistician
 - SCHARP HPTN046 Statistical Research Associates
 - NIAID Medical Officer
 - NICHD Medical Officer
 - HPTN Study Monitoring Committee

Distribution List:

- Closed Report**
- NIAID VPDSMB Members
 - SCHARP HPTN Principal Investigator
 - SCHARP HPTN Deputy Director, as needed
 - SCHARP HPTN046 Statistician
 - SCHARP HPTN046 Statistical Research Associates
 - Others, as needed

Components:

- Open Report**
(Data not reported by arm)
- Trial Design and History
 - Accrual, Eligibility, and Adherence
 - Baseline Characteristics
 - Participant Status and Retention

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- Data Quality and Timelines
 - Summary and Recommendations

Components:

Closed Report

*(Data reported
by blinded arm)*

- Trial Design and History
- Accrual, Eligibility, and Adherence
- Baseline Characteristics
- Participant Status and Retention
- Adverse Experiences
- Efficacy (after six months)
- Data Quality and Timeliness
- Summary and Recommendations
- Other information, as requested by the DSMB