Section 15. Reporting Plan

15.1 Purpose of Reporting Plan

The purpose of this reporting plan is to:

- identify the content of each HPTN 083 report;
- identify those responsible for production and distribution of each report;
- identify who should receive and review the reports so corrective action (if necessary) is taken.

The reporting plan is prepared by the HPTN 083 Clinical Data Manager at SCHARP in conjunction with SDMC HPTN 083 statisticians and programmers.

15.2 Reports

The table below provides detailed information about each report that will be produced for HPTN 083, including the distribution frequency and distribution list.

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
Screening	Summarizes screening at each site as reflected by case report form data	The number of participants screened, number enrolled, and reasons not enrolled for all sites individually as well as all sites combined.	Daily	SDMC Protocol Programmer and/or Statistical Programmer	Atlas http://scharp.atlas.org	Open to all
Enrollment	To monitor participant accrual as reflected by case report form data	Enrollment data are presented for all sites individually a well as all sites combined. Includes site activation date, dates of first enrollments, duration of accrual, and the number of participants enrolled each week compared with weekly enrollment targets.	Daily	SDMC Protocol Programmer and/or Statistical Programmer	Atlas http://scharp.atlas.org	Open to all
Retention	To monitor participant retention as reflected by case report form data	Retention data are presented for all sites individually as well as all sites combined. Includes the total number participants randomized who 1) completed a visit	Daily	SDMC Statistical Programmer	Atlas http://scharp.atlas.org	Open to all

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
		(on time, early or late) and 2) did not complete a visit (visit was missed or ppt was terminated early). Total retention is calculated as the number of enrolled participants who completed follow-up visits divided by the total number of participants expected for a visit.				
Data Management Quality	To provide information on site performance with regard to key data management and data quality metrics	Data are presented for all sites individually as well as all sites combined. Cumulative and previous-month statistics including: • Percentage of CRFs entered within 7 calendar days of study visits • Percentage of AEs entered within 3 days of date reported to site	Monthly	SDMC	Atlas http://atlas.scharp.org	Open to all

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
		(Grade 1 AEs are not included) • Total number of data queries (i.e. QCs) that have been manually placed by SDMC staff • Number and percentage of queries that have been answered within 7 calendar days after query was opened				
Site-Specific Specimen Monitoring	To identify stored specimens whose information in LDMS does not match corresponding information collected on case report forms	Site-specific listings of all discrepancies between specimens listed as "stored" in case report forms and data entered into LDMS as well as LDMS data entry errors.	Bi-monthly	SDMC Lab Data Operations (LDO) Group	E-mail	Site Study Coordinator, Other site staff as requested, Laboratory Center Representative, SDMC Clinical Data Manager

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
Summary Specimen Monitoring	To provide the Laboratory Center (LC) with a summary for all sites of information contained in the Site-Specific Specimen Monitoring Reports	Summary listing for all sites of all discrepancies between the case report form stored specimen data and data entered into LDMS.	Bi-monthly	SDMC Lab Data Management (LDM) Group	E-mail	Laboratory Center Representative, SDMC Clinical Data Manager
Study Monitoring Committee (SMC)	To monitor the overall progress of the study and study conduct at each site	Summary by site and overall. Report includes in-formation on trial design and SMC history, accrual, baseline characteristics of participants, enrollment/randomization, and retention of participants, social harms/impacts, protocol deviations, completion of Computer-Assisted Self Interviewing (CASI) data,	Will occur after ~ 4 months of enrollment and every 6 months thereafter	SDMC Statistical Research Associates (SRAs) and Protocol Statistician, with assistance from SCHARP study team	Atlas http://scharp.atlas.org	SMC (open and closed reports), Protocol Chairs (open report only), Selected members of HPTN LOC, SDMC, LC, DAIDS and Site IoRs, (open report only)

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
		termination, and other study conduct information, as required by the SMC.				
Data Safety Monitoring Board (DSMB)	To monitor efficacy and safety as well as to perform an administrative review and/or design review	Open report includes: all components listed for the SMC Open Report. Closed report includes: all components listed for the SMC report by treatment arm, with the addition of adverse event data and HIV-infection data.	Every 6 months or as determined by the DSMB	SDMS Statistical Research Associates and Protocol Statistician, with assistance from SCHARP study team	Mail or E-mail	DSMB members only