

## Section 15. Reporting Plan

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### 15.1 Purpose of Reporting Plan

The purpose of this reporting plan is to:

- identify the content of each HPTN084 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 HPTN084 Clinical Data Manager at SCHARP in conjunction with SDMC HPTN084 statisticians and programmers.

### 15.2 Reports

The table below provides detailed information about each report that will be produced for HPTN 084, including the distribution frequency and distribution list. The exact day of the week these reports are distributed will be determined once data collection begins.

| Report Name       | Purpose   | Components  | Distribution Frequency | Responsibility for Preparation                         | Distribution Platform  | Distribution List |
|-------------------|---|---|------------------------|--|--|-------------------|
| <b>Screening</b>  | 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<br><a href="http://ssharp.atlas.org">http://ssharp.atlas.org</a> | Anyone            |
| <b>Enrollment</b> | To monitor participant accrual as reflected by case report form data    | Enrollment data are presented for all sites individually as well as all sites combined.<br><br>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<br><a href="http://ssharp.atlas.org">http://ssharp.atlas.org</a> | Anyone            |
| <b>Retention</b>  | 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.<br><br>Includes the total number participants randomized who 1) completed a visit  | Daily                  | SDMC Statistical Programmer                            | Atlas<br><a href="http://ssharp.atlas.org">http://ssharp.atlas.org</a> | Anyone            |

| Report Name                    | Purpose  | Components   | Distribution Frequency | Responsibility for Preparation | Distribution Platform   | Distribution List |
|--------------------------------|--|--|------------------------|--------------------------------|---|-------------------|
|                                |  | <p>(on time, early or late) and 2) did not complete a visit (visit was missed or ppt was terminated early).</p> <p>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.</p>   |                        |                                |   |                   |
| <b>Data Management Quality</b> | To provide information on site performance with regard to key data management and data quality metrics | <p>Data are presented for all sites individually as well as all sites combined.</p> <p>Cumulative and previous-month statistics including:</p> <ul style="list-style-type: none"> <li>Percentage of CRFs entered within 7 calendar days of study visits</li> <li>Percentage of AEs entered within 3 days of date reported to site</li> </ul> | Monthly                | SDMC                           | <p>Atlas</p> <p><a href="http://atlas.scharp.org">http://atlas.scharp.org</a></p> | Anyone            |

| Report Name                              | Purpose  | Components   | Distribution Frequency | Responsibility for Preparation       | Distribution Platform | Distribution List  |
|--|--|--|------------------------|--------------------------------------|-----------------------|--|
|  |  | <ul style="list-style-type: none"> <li>Total number of data queries (i.e. QCs) that have been manually placed by SDMC staff</li> <li>Number and percentage of queries that have been answered within 7 calendar days after query was opened</li> </ul> |                        |                                      |                       |  |
| <b>Site-Specific Specimen Monitoring</b> | 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,<br>Other site staff as requested,<br>Laboratory Center Representative,<br>SDMC Clinical Data Manager |
| <b>Summary Specimen Monitoring</b>       | To provide the Laboratory Center (LC) with a summary for all sites of  | Summary listing for all sites of all discrepancies between the case report form stored specimen data   | Bi-monthly             | SDMC Lab Data Management (LDM) Group | E-mail                | Laboratory Center Representative,  |

| Report Name                             | Purpose   | Components   | Distribution Frequency  | Responsibility for Preparation  | Distribution Platform  | Distribution List  |
|---|---|--|---|---|--|--|
|   | information contained in the Site-Specific Specimen Monitoring Reports      | and data entered into LDMS.  |   |   |  | SDMC Clinical Data Manager   |
| <b>Study Monitoring Committee (SMC)</b> | To monitor the overall progress of the study and study conduct at each site | Summary by site and overall.<br><br>Report includes information 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, termination, and other study conduct information, as required by the SMC. | 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<br><br><a href="http://scharp.atlas.org">http://scharp.atlas.org</a> | 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 |
|--|--|--|---|--|-----------------------|-------------------|
| <b>Data Safety Monitoring Board (DSMB)</b> | To monitor efficacy and safety as well as to perform an administrative review and/or design review | <u>Open report includes:</u> all components listed for the SMC Open Report.<br><u>Closed report includes:</u> 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 |