19 NETWORK EVALUATION

The HPTN is committed to excellence in all aspects of its research as well as Network governance. The Performance Evaluation Committee (PEC) is charged with directing the internal Network evaluation. The evaluation documents the success of the Network and its components in meeting evaluation standards developed by the PEC.

The PEC is responsible for overseeing a continuous, comprehensive evaluation of the HPTN. This includes the Clinical Trials Units (CTUs) and Clinical Research Sites (CRSs) as well as other grantee organizations and entities that are also part of the HPTN—Leadership and Operations Center (LOC), Laboratory Center (LC), Statistical and Data Management Center (SDMC), and standing committees. Performance evaluation serves primarily to ensure that groups are contributing effectively to those protocols they have undertaken and to elicit closer scrutiny and corrective action where successful and timely completion of studies is in jeopardy. The goal of the evaluation is to provide data to assist in leadership decisions about changes necessary within the Network to improve overall functioning.

The PEC reviews evaluation reports and data, adjusts performance measures as needed, and reports evaluation findings to the Executive Committee (EC) for review and action.

Membership
The PEC Chair is appointed by the EC and reports the results of the Network Performance Evaluation at an in-person meeting. The membership of the PEC should include the PEC Chair, Evaluation Coordinator from the LOC, representatives from the SDMC, LC, LOC, HPTN investigators and study coordinators, community and the Division of AIDS (DAIDS).

19.1 Network Evaluation Plan and Performance Measures

To develop the evaluation plan for each component of the HPTN, the PEC uses the following approach for each area. This plan is reviewed and revised by the PEC on an annual basis.

- Objectives, and the activities necessary to achieve them, are identified to fully describe the function of each component of the HPTN being evaluated. These are based on the Network approved processes
- For each activity, the PEC identifies an indicator (or indicators) to be used to determine if objectives are being satisfactorily met. These measures are re-evaluated each year to determine their appropriateness and relevance to the performance of the Network
- The performance indicators are disseminated to the Network members before the start of the evaluation period
- A web-based questionnaire is sent annually to a representative sample of Network members. Results of this evaluation are used by the PEC to assess perceptions of Network functioning across groups and committees. The data collected from this exercise yields important information about the various functions of the Network
- The PEC submits an evaluation report to the EC at in-person meetings with recommendations for improvement
- Results of the evaluation are also sent to CTU Principal Investigators (PIs), protocol teams and committee chairs as well as the PIs of the LOC, SDMC and LC
- Network entities are requested to respond to findings and recommendations of the PEC

19.2 Performance Criteria for CRSs

The PEC reviews performance both by site per protocol and by protocol across sites. Performance measures for the CRSs include the following:

- *Study implementation:* Accrual rate, retention, adherence to protocol/protocol violations, data management, specimen results reporting
- *Community participation:* Development of and adherence to a site-specific community involvement plan, evidence of Community Advisory Board (CAB) participation and input, participation of site community representatives and community educators in HPTN activities as well as at regional and national conferences and meetings
- *General site/research management:* Adequate site and study staffing (coverage and experience); staff training (for physicians, nurses, quality assurance/quality control (QA/QC) coordinators, laboratory personnel, etc.)

19.3 Performance Indicators

The LOC is responsible for providing leadership and coordination of various functions of the Network, including the protocol development and implementation, Network's Scientific Committees (SCs), Working Groups, Network Communications, Community program and community involvement within the Network, and Network Evaluation. Specifically, the LOC provides technical expertise and administrative support through personnel and resources.

The SDMC and the LC are charged with providing statistical, data management, and laboratory support and expertise to the Network's Scientific Committees, Protocol Teams, and CRSs. Their specific activities, although varied, are all conducted to ensure that statistical and laboratory activities of the Network support the aims of the studies and are timely, reliable, and valid.

The performance indicators used for the evaluation include:

Activity	Measure	Standard	Source
Executive Committee (EC)			
EC meeting attendance	Percentage of voting EC members at each meeting	90% of voting members in attendance	Meeting minutes
Individual attendance at EC meetings for voting members	Proportion of EC members who attended 75% of meetings	100% of members attend 75% of meetings	Meeting minutes
Concept activity	Number of concepts reviewed and approved by the EC	1 annually	LOC (PRISM)
Concept review activity	Timeliness of concept review	Timely review with full feedback within 4 weeks of concept submission	LOC (PRISM)
Concept to protocol	Timeliness to SRC	16 weeks to SRC	LOC (PRISM)
Manuscript Review			

Activity	Measure	Standard	Source
Committee (MRC)			
Manuscript review timeliness	Average number of days for manuscript review Abstract Poster Presentations	5 working days 1 working day 2 working days 1 working day	Manuscript tracking system (in development)
Science Review Committee (SRC)			
Review cycle of protocols	Average number of days	5 working days	SRC/LOC
Protocol approval	Number of protocols approved	No standard but tracked	LOC (PRISM)
Protocol review timeliness	Average number of days for feedback to team	5 working days	SRC summary
Leadership and Operations Center (LOC)			
Science Generation	Concept to protocol version 0.1 to SRC	16 weeks	LOC
Science Generation	Response to SRC review	15 working days	LOC
Science Generation	Response to PSRC review	15 working days	LOC
Publications	Number of manuscripts / presentations that have coauthors from LOC	No standard but tracked	LOC
Protocol implementation	Time from protocol version 1.0 to site activation	120 days (domestic) 240 days (international)	LOC (PRISM)
Trainings at Site	Number of trainings conduced at sites	No standard but tracked	LOC
Assessment Visits	Number of assessment visits at sites	At least once per site for each study	LOC
Laboratory Center			

Activity	Measure	Standard	Source
(LC)			
Concept development	Percentage of concept reviews provided	100%	LOC
Concept to Protocol (first draft) version 0.1 to SRC	Timeliness of concept to protocol version 0.1 to SRC	16 weeks Extensions may be granted	LOC
Protocol design and implementation expertise	% of protocols with an HPTN LC QC representative on the protocol team	100%	LOC
Protocol design and implementation expertise	% protocol teams with additional HPTN LC investigators on the protocol team (e.g. virologist)	No standard but tracked	LOC
Response to SRC review	Timeliness of response to SRC	15 working days	LOC
Response to Prevention Science Review Committee (PSRC) review	Timeliness of response to PSRC	15 working days	LOC
Site monitoring	Number of sites / External Quality Assurance (EQA) panels monitored	No standard but tracked	LC
Coordinator support	Number of QA/QC coordinators onsite	No standard but tracked	LC
Assay development	Number of new assays developed and evaluated for use in HPTN trials	No standard but tracked	LC
Publications	Number of manuscripts / presentations related to new assay development/ evaluation and pathogenesis- or transmission-based studies	No standard but tracked	LC

Activity	Measure	Standard	Source
QC testing volume	Approximate number of QC tests performed (e.g. duplicate testing of enrollment and endpoint samples)	No standard but tracked	LC
Protocol testing at the LC	% of HPTN protocols supported by testing at the LC	No standard but tracked	LC
Participation in cross-network committees	Number of committees with HPTN LC members	No standard but tracked	LC
Statistical and Data Management Center (SDMC)			
Statistical leadership	Percentage of leadership calls and meetings with SDMC representation	100% of leadership calls and meetings	Meeting Minutes
Science Generation	Concept to protocol version 0.1 to SRC	16 weeks	LOC
Science Generation	Response to SRC review	15 working days	LOC
Science Generation	Response to PSRC review	15 working days	LOC
Protocol development support	Number of protocols input provided	No standard but tracked	SDMC
Protocol development support	Number of protocol Case Report Forms (CRFs) developed	No standard but tracked	SDMC
Protocol development support	Time to completion of additional data collection tools (i.e., ACASI)	≤120 days	SDMC
Protocol development support	Time from final protocol version 1.0 to protocol activation (i.e., English database readiness)	≤120 days	SDMC
Sites			
Enrollment	Percentage of expected participants enrolled during evaluation period	Meet the protocol specified goal	SDMC/LOC

Activity	Measure	Standard	Source
Retention	Percentage of protocol expected retention rate during evaluation period	Meet the protocol specified goal	SDMC/LOC
Adherence	Percentage of treatment schedules adhered to by site	The site should adhere to 100% to treatment schedules	SDMC
Case Report Forms (CRF) faxed to SDMC	Average number of days to fax CRF to SDMC	Average of 5 days to fax CRF to SDMC	SDMC
QC resolved within 28 days	Percentage of QC reports resolved in 29 days	% of QC resolved in 28 days are compared per site within each protocol	SDMC