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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 evaluation of Clinical Research Sites (CRSs) currently conducting trials in the HPTN. Performance evaluation serves primarily to ensure that CRSs are contributing effectively to those studies 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 DAIDS and network leadership to assist in decisions about CRS funding and affiliation to improve overall functioning.

The PEC reviews and 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. The membership of the PEC should include the PEC Chair, Evaluation Coordinator from the LOC, representatives from the SDMC, LC, LOC, HPTN investigators, community and the [Division of AIDS](#) (DAIDS) and others as needed.

19.1 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, visit completion rate, protocol deviations, data management quality metrics, specimen shipments
- *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

19.2 Performance Indicators

The performance indicators used for the evaluation include:

Activity	Measure	Standard	Source
Sites			
Enrollment	The number enrolled during the evaluation period is compared to expected enrollment for the time period to calculate evaluation period enrollment percentage	Meet the protocol specified goal	SDMC reports

Activity	Measure	Standard	Source
Sites			
Estimated Retention	Visit completion rates at each site are compared to the protocol-specified expectation	Meet the protocol specified goal	SDMC reports
Timely submission of study data	Average number of days to enter data	Data submitted within 5 days for Datafax; 90% within 7 days for EDC studies	SDMC reports
Quality of data submitted (number of queries)	Number of queries/100 pages	<10/100 pages submitted	SDMC reports
QC Query resolution	Percentage of queries resolved within 7 days	80% resolved ≤ 7 days	SDMC reports
Timely submission of AEs	Percentage of adverse events submitted within 3 days of site awareness	90% of AEs submitted ≤ 3 days	SDMC reports
Protocol deviations/violations	Number of protocol deviations/violations reported on CRFs	None	SDMC reports
Quality of specimen handling/ shipment	Number of shipments received within the specified timeframe	90% received within timeframe	LC reports
Response to Queries from Site Monitoring reports	Response to queries	Response within 21 days	