19 CLINICAL RESEARCH SITES (CRS) AND NETWORK CENTRAL RESOURCES EVALUATION

The evaluation of the HPTN is divided into two components: 1) The evaluation of Clinical Research Sites (CRSs); and 2) the evaluation of the central resources of the network (Leadership and Operations Office (LOC); Laboratory Center (LC); and the Statistical and Data Management Center (SDMC)).

19.1 CRS Evaluation

A Performance Evaluation Committee (PEC) has been established with the sole charge of directing the evaluation of CRSs currently conducting trials in the HPTN. A PEC Chair is appointed by the Executive Management Committee. The membership of the PEC will include the PEC Chair; representatives from the LOC, SDMC, and LC; site representatives, including an investigator, a study coordinator, and a community representatives; Division of AIDS (DAIDS) staff; and others as needed.

The evaluation serves primarily to ensure that CRSs are contributing effectively to the studies that they have undertaken, both within a single site and across studies across sites. Sites will be evaluated by the PEC at least annually, with reports provided to the HPTN Leadership and DAIDS that may include funding recommendations. Examples of site performance indicators are outlined below in Table 1.

Table 1

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
Study-specific enrollment demographics are being met, as applicable (for studies with specific demographic targets)	Study-specific measures for sex assigned at birth, gender identity, ethnicity, race, age	Mainly reference measurements only (e.g., for race, Black, White, Asian, Other, etc.; Ethnicity – Hispanic or non-Hispanic). Sex assigned at birth is protocol-specific	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	90% within 7 days for EDC studies	SDMC reports
Quality of data submitted (number of queries)	Per MediData	Per MediData	SDMC reports
QC Query resolution	Percentage of queries resolved within 7 days	80% resolved $\leq$7 days	SDMC reports
Timely submission of AEs	Percentage of adverse events submitted within 3 days of site awareness	90% of AEs submitted $\leq$3 days	SDMC reports
Quality of specimen handling/ shipment	Number of shipments received within the specified timeframe with little to no errors	90% received within timeframe with <10% errors	LC reports
Response to Queries from Site Monitoring reports	Response to queries	Response within 21 days	NCRMS

19.2 Evaluation of the Network

As a group, the leadership members of the LOC, SDMC and LC will be responsible for directing the evaluation of the Network for protocol development and protocol implementation (including confirmation of adequate funding to implement the protocol), and publication of results. Study teams will be charged with creating an implementation timeline that includes these milestones. Examples of performance criteria are outlined in Table 2:

Table 2

Example of Performance Criteria
Adequate resources in a timely manner to implement a protocol
Meeting agreed-upon timelines for protocol and study-specific manual development; timeliness for submission of and response to Division of AIDS (DAIDS) protocol review process; timeliness for study activation
Meeting agreed upon timelines for study-specific primary and other endpoint testing and QC testing volume
Meeting agreed-upon level of support and timeliness to data management during study implementation; timeliness of provision of primary analysis data tables relative to the last participant/last visit; timeliness of data produced for manuscript development
Meeting review timelines for abstracts and manuscripts
Timeliness for publication of results

19.3 Resolution of Performance Issues

The Network leadership will ensure that the HPTN perform at the highest standard. As such, the EMC will be responsible for ensuring that performance problems are identified in a timely manner and addressed and resolved.

In all such cases of site or central resource performance issues, the EMC will be notified of the issue along with the corrective action plan. For cases related to sites, DAIDS will be informed and consulted in the resolution process.