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

The HPTN undergoes a comprehensive annual evaluation. Both the Clinical Research Sites (CRSs) and the Network Central Resource groups (HPTN Leadership and Operations Office (LOC), Laboratory Center (LC); and Statistical and Data Management Center (SDMC)) are assessed.

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 HPTN Executive Committee (EC). The membership of the PEC includes the PEC Chair; representatives from the HPTN LOC, SDMC, and LC; site representatives, including an investigator, study coordinator, and community representative; Division of AIDS (DAIDS) staff; and others as needed.

The evaluation ensures that CRSs are effectively implementing and managing studies they are conducting. CRSs are evaluated by the PEC at least annually. Evaluation reports are provided to the HPTN Leadership and DAIDS. Funding recommendations may be included. Examples of site performance indicators are outlined below in Table 1.

Table 1 – CRS Performance Indicators

Activity	Measure	Standard	Source
Enrollment	The number of participants 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
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 study data	90% of study data submitted within 7 days	SDMC reports
Quality of data submitted (number of queries)	Measured as queries per 100 pages of data submitted	No set standard, study-specific	SDMC reports
QC Query resolution	Percentage of queries resolved within 7 days	80% of queries 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

Activity	Measure	Standard	Source
Monitoring of Laboratory Data Management Standard	Percentage of laboratory and clinic reviews in the Specimen Data Quality Control tool	70% of reviews acted upon or resolved <7 days	LC reports
Quality of specimen handling/shipment	Number of shipments received within the specified timeframe with little to no errors	90% of shipments received within timeframe with <10% errors	LC reports

19.2   Central Resources Evaluation

As a group, leadership members of the HPTN LOC, SDMC, and LC are responsible for directing the evaluation of Central Resource performance.

Central Resource groups are continually evaluated on ongoing processes, such as: protocol development to HPTN Scientific Review Committee timelines, consistent quality of data reports, timeliness of sample processing, and publication of results.

To assist the evaluators, study teams will create and maintain an implementation timeline that includes network-determined milestones. The LC will produce sample processing reports per study. The SDMC will produce data quality reports per study.

Examples of performance criteria are outlined in Table 2:

Table 2 – Central Resources Performance Criteria

Examples 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 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

HPTN leadership will ensure that the HPTN performs at the highest standard. As such, the HPTN EC 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 HPTN EC 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.