18 NETWORK EVALUATION

The IMPAACT Network is committed to excellence in all aspects of its research. The Management Oversight Group (MOG) is responsible for overseeing a comprehensive process for evaluation of the network with both ongoing and periodic components. The purpose of the evaluation process is to ensure that IMPAACT-affiliated NIAID-funded and NICHD-funded clinical research sites and other network entities are functioning appropriately and contributing to successful development, execution, oversight, completion, and publication of studies and other activities that advance the IMPAACT research agenda. The evaluation serves to document the success of network entities in meeting evaluation standards and identifies areas for improvement. It informs leadership decisions about changes that may be necessary to improve functioning and performance while ensuring participant safety and data integrity. It also provides information needed to facilitate appropriate allocation of network resources.

The overall scientific direction and leadership of the network, including the work of the Scientific Committees (SCs), may be evaluated periodically by an external scientific advisory group. The MOG evaluates the performance of the Operations Center, Statistical and Data Management Center (SDMC), and Laboratory Center (LC); the LC evaluates the specialty laboratories. The performance of sites is evaluated approximately annually. A Network Evaluation Group (NEG), chaired by the IMPAACT vice chair and supported by a Network Evaluation Coordinator from the Operations Center, is responsible for developing and carrying out a network evaluation program that achieves the aims stated above. Other members of the NEG include representatives from the Operations Center, SDMC, LC, and network sponsors.

The NEG develops performance metrics for the various network entities and, as each evaluation is completed, the NEG develops an evaluation report that is submitted to the IMPAACT MOG. Evaluation reports are shared with the entities whose work was evaluated and with network sponsors, as appropriate. A primary component of network evaluation is the Site Performance Report. This report focuses on critical aspects of study implementation at the site level, such as participant accrual and retention, data quality, laboratory performance, and regulatory issues. Site community engagement programs will be evaluated separately as determined by the IMPAACT Community Advisory Board (ICAB) in consultation with the MOG. At the request of the MOG, the NEG may evaluate and report on other network entities in a similar manner.

Ongoing Evaluation

On an ongoing basis, the MOG reviews the progress of network studies through review of monthly Study Operations Reports and Accrual and Retention Reports generated by the Operations Center and SDMC, respectively; ad hoc reports from the LC; and information from other sources, with recommended actions identified and communicated to sites, study teams, and network committees or groups. The SDMC also provides monthly accrual, retention, data management quality, and laboratory data and specimen management reports to sites. The LC closely monitors the performance of specialty and site laboratories. As needed, problems and deficiencies are reported to the MOG. This ongoing review permits rapid identification of problems and therefore enables study sites, teams, and other entities to take early corrective action.

Periodic Evaluation

On behalf of the MOG, the NEG oversees periodic evaluations of all IMPAACT-affiliated sites, as described in the remainder of this section. A comprehensive evaluation report is generated and submitted to the MOG for review and action.

18.1 Network Evaluation Plan and Performance Measures

The approach described below is followed for each periodic evaluation:

- Objectives, and the activities necessary to achieve them, are identified, reviewed, and adjusted as needed prior to each periodic evaluation by the NEG to determine their appropriateness and relevance to the performance of the Network at the time of the review.
- For each activity, the NEG identifies indicator(s) of whether objectives are being satisfactorily met; see Table 18-1. These are reviewed and adjusted as needed prior to each periodic evaluation to determine their appropriateness and relevance to the performance of the Network at the time of the review.
- Indicator data are compiled to determine the extent to which objectives are being met; see Table 18-1.
- Based on the compiled data, the NEG submits an evaluation report to the MOG, highlighting successes and making recommendations for improvement.
- Evaluation reports are also sent to NIAID clinical trials unit (CTU) principal investigators (PIs) and CRS leaders (for their site), NICHD site PIs (for their site), the network sponsors, and the network Operations Center, SDMC, and LC.
- Sites are provided the opportunity to confirm the accuracy of their evaluation results and are requested to respond to the NEG's findings and recommendations, as needed. Responses are reviewed by the NEG and recommendations for any follow-up actions are provided to the MOG. See Section 18.4 for a description of follow-up actions and possible outcomes.

18.2 Performance Criteria for IMPAACT-affiliated NIAID-funded Clinical Research Sites

Site performance within each study and across studies is reviewed for the period of evaluation (a twelve-month time period, generally), with consideration of the number and stage of studies in which each is participating, recency of site engagement, and external factors that may impact site readiness and accumulation of sufficient data for meaningful evaluation. Site performance measures include the following, as determined by the NEG:

- Protocol implementation timelines
- Participant accrual and retention
- Clinical data management, including data timeliness, data quality, and query responsiveness
- Laboratory data and specimen management, including LDMS export timeliness, lab query responsiveness, and BRI repository shipment evaluations
- Laboratory quality assurance, including safety testing, VQA test performance, IQA test performance, and PBMC cryopreservation
- Outstanding laboratory critical action items
- Protocol deviations

Site performance measures and standards are specified in Table 18-1 below, except where in development.

Table 18-1. Performance Measures and Standards for NIAID Clinical Research Sites

Criterion	Measure(s)	Standard	Source
Protocol Implementation Timeline	Time to enrollment once site receives the final protocol for submission to the IRB/EC and other regulatory entities: • Date protocol distributed to site • Date of protocol registration approval • Date of study-specific activation • Date of first enrollment at site Note: Includes protocols finalized for implementation during the evaluation period	Informational only	Operations Center, NIAID CRMS, SDMC
Participant Accrual	• Number of participants enrolled across the life of the study and within past 12 months compared to site-specific accrual target for study Note: Includes studies currently enrolling (or open to accrual) and studies closed to accrual during the evaluation period	Projected number versus actual number (projected number is based on site-provided goals); goal is >90% over the study accrual period for studies that have closed to accrual in the evaluation period Note: For NIAID-funded sites: DAIDS may consider discontinuing core funding for sites with <5 new enrollments or <3 in complex or high-priority studies	SDMC (with projections provided by the sites through the Operations Center)
Participant Retention	• Number of participants on study for the past 12 months • Number of participants reported to the data management center (DMC) as lost to follow-up for any reason (e.g., participant withdrawal, participant did not return/could not be located by the site) in past 12 months and over life of the study Note: Includes studies currently enrolling (or open to accrual) and studies closed to accrual during the evaluation period	>90% overall retention or as per protocol	SDMC

Table 18-1. Performance Measures and Standards for NIAID Clinical Research Sites

Criterion	Measure(s)	Standard	Source
Clinical Data Management	Composite score of data timeliness, data quality, and query responsiveness	≥ 70 composite score	SDMC
	• Data timeliness: – Percentage of expected data submitted – Average time (in weeks) to submit data based on expected data submission timeline	Score range: 0 – 16 0 – 16	SDMC
	• Data quality: Reported as site data error rate compared to overall IMPAACT error rate. The data error rate compares the total number of errors to the number of transactions submitted, which may be form data entry, form correction or form deletion.	Score range: 0 – 18	SDMC
	• Query responsiveness: – Percentage of total potential errors resolved – Average time (in weeks) to resolve potential errors – Percentage of total queries answered – Average time (in weeks) to respond to queries	Score range: 0 – 8 0 – 10 0 – 16 0 – 16	SDMC
Laboratory Data and Specimen Management	• LDMS Export Timeliness: Export LDMS data and retrieve deploys once a week	≥ 80%	SDMC
	• Lab Query Responsiveness: Respond to queries within two weeks	≥ 90%	SDMC
	• BRI Repository Shipment Evaluations: Overall resolution and responsiveness to shipment problems based on the total number of shipments. See Shipment Evaluation SOP.	≥ 90 composite score	SDMC
Laboratory Quality Assurance	• Safety Testing (50% of score) • VQA Test Performance (25% of score) • IQA Test Performance (12.5 % of score) • PBMC Cryopreservation (12.5 % of score)	≥ 90% composite score	LC
Outstanding Laboratory Critical Action Items	• Resolution of critical action items within 90 days of notification	≤ 90-day resolution	LC
Protocol Deviations	• Listing of reportable protocol deviations per site (see Section 12)	No protocol deviations	SDMC

18.3 Overall Network Productivity

Overall network function and productivity are evidenced in a number of ways including but not limited to development, review, and approval of new study proposals (capsules, concept sheets, data analysis concept sheets [DACS], new works concept sheets [NWCS]) and protocols; initiation of new studies and completion of ongoing studies; results reporting, presentation, and publication; and evidence of impact on public health policy and/or product licensure or labeling changes. The NEG will report on these outcomes periodically as requested by the MOG as part of the comprehensive network annual evaluation.

18.4 Outcomes and Actions

As noted above, each network entity evaluated will be provided an opportunity to review evaluation findings and confirm their accuracy.

Sites with below-standard performance measures will generally have 30 days to provide the NEG with a written plan for corrective action in the relevant performance areas. The NEG may offer technical assistance and guidance and may recommend actions to facilitate improvement. Improvement must be demonstrated within six months or reasons provided for why this cannot be achieved. In such cases, an alternate time period must be agreed to by the NEG.

If a site fails to meet a standard for a specific measure(s) in two or more consecutive periodic evaluation cycles, the NEG may recommend to the MOG specific actions such as temporary closure of enrollment screens, pending review of site or laboratory procedures in that area(s).

A site is unable to meet the network's performance requirements in two consecutive comprehensive evaluation cycles – or by an earlier timepoint as determined by the MOG – may result in the withdrawal of protocol funds and/or a recommendation that network affiliation with the site be terminated, with appropriate close-out activities to be completed. A site that is not meeting performance standards and is at risk of losing network affiliation is provided the opportunity to summarize any extenuating circumstances that they would like considered before a final decision is made. The final decision on the site status with the network will be determined by the MOG in consultation with the sponsors after considering the recommendations made by the NEG.

Network sponsors' requirements and/or cross-network evaluation of site performance and contributions – including determination of whether the site is needed to support the scientific agenda of one or more networks – may result in a change in funding status, irrespective of the network's evaluation.