



20 NETWORK EVALUATION

The IDCRC LG is committed to excellence in all aspects of its research. The Executive Management Team (EMT) is responsible for overseeing a comprehensive process for evaluation of the network with both ongoing and periodic components. This process will monitor implementation of clinical research conducted by the VTEUs and evaluate the operational performance of the overall network and each element within the IDCRC. Evaluation will occur in domains associated with the overall aims of the network with metrics assessed on a regular basis, varying by unit being evaluated and the priorities of the network. Domains identified are 1) leadership direction in support of NIAID's research priorities, 2) oversight of protocol implementation, 3) communication, 4) fiscal oversight, 5) transparency of procedures, and 6) personnel proficiency and training.

The evaluation process ensures that IDCRC-affiliated NIAID-funded clinical research sites (VTEUs) and other consortium entities are functioning appropriately and contributing to successful development, execution, oversight, completion, and publication of studies and other activities that advance the IDCRC research agenda. It serves to document the success of consortium entities in meeting evaluation standards and identify areas for improvement. This 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 IDCRC resources.

The Co-Directors of the LOC are responsible for developing and carrying out a network evaluation program that achieves the aims stated above. At a consortium level this process is managed via the Performance and Quality Assurance Evaluation KFC (chaired by one of the LOC Co-Directors). This KFC membership includes investigators and coordinators from VTEUs, other LG Unit representatives, and DMID. A member of the LOC Administrative Core and/or FHI 360 will provide administrative support.

The Performance Evaluation and Quality (PEQ) KFC develops performance metrics for the various consortium entities and, as each evaluation is completed, the LOC develops an evaluation report that is submitted to the IDCRC EMT. Evaluation reports are shared with the entities whose work was evaluated and with network sponsors, as appropriate. Metrics are consistently reviewed for appropriateness based upon the current needs of the IDCRC in meeting objectives.

The evaluation will be executed by various groups depending upon the group that is being evaluated. The External Advisory Board, established in the IDCRC's first year, will periodically evaluate the overall scientific direction and leadership of the IDCRC, including the work of the Expert Working Groups (EWGs) and Key Function Committees (KFCs). The EMT evaluates the performance of the Leadership Operations Center (LOC), Clinical Operations Unit (COU), Statistical and Data science Unit (SDSU), and Laboratory Operations Unit (LOU); the LOU evaluates the VTEU laboratories and specialty laboratories. The performance of sites is evaluated approximately annually utilizing metrics compiled from multiple sources. Study level performance is monitored on a monthly basis by the COU.

Ongoing Evaluation

On an ongoing basis, the COU reviews the progress of consortium studies through review of monthly Study Operations Reports and Accrual and Retention Reports generated by the Protocol Operations



Center, SDMC/SDSU. The data centers provide protocol specific reports via their individual portals. The LOU closely monitors the performance of specialty and site laboratories. As needed, problems and deficiencies are reported to the EMT. 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 EMT, the LOC oversees periodic evaluations of the network overall, network units and all IDCRC-affiliated sites, as described in the remainder of this section. A comprehensive evaluation report is generated and submitted to the EMT for review and action.

20.1 Network Evaluation Plan and Performance Measures

The approach described below is followed for each periodic evaluation:

- Objectives of the evaluation, and the activities necessary to achieve them, are identified, reviewed, and adjusted as needed prior to each periodic evaluation by the LOC to determine their appropriateness and relevance to the performance of the consortium at the time of the review.
- For each activity, the LOC identifies indicator(s) of whether objectives are being satisfactorily met. These are reviewed and adjusted as needed prior to each periodic evaluation to determine their appropriateness and relevance to the performance of the consortium at the time of the review.
- Indicator data are compiled to determine the extent to which objectives are being met.
- Based on the compiled data, the LOC submits an evaluation report to the EMT, highlighting successes and making recommendations for improvement.
- Evaluation reports are also sent to NIAID DMID VTEU principal investigators (PIs), the network sponsors, and the IDCRC units (COU, LOU and SDSU).

VTEUs are provided the opportunity to confirm the accuracy of their evaluation results and are requested to respond to the LOC's findings and recommendations, as needed. Responses are reviewed by the LOC and recommendations for any follow-up actions are provided to the EMT. See Section 20.7 for a description of follow-up actions and possible outcomes.

20.2 Performance Criteria for the IDCRC Leadership Group

The IDCRC LG will undergo regular evaluation of activities overall with regards to the specific aims of the network. Evaluation will be conducted by 1) an External Advisory Board (EAB) that will monitor the objectives and success of the LG's activities overall, 2) by the LOC, COU, LOU, SDSU, EWG and Key Function Committee Chairs, and VTEU PIs, through annual in-person discussions and by a brief survey delivered online, and 3) through systematically elicited feedback from DMID/NIAID colleagues. The domains of this review will use metrics organized around the major IDCRC LG goals and are outlined in Table 5 which also describes the categories and processes to be evaluated; the metric; acceptable standard, and the individual or group with oversight responsible for each aspect of evaluation.



Table 5. Domains and example metrics for Overall IDCRC LG Evaluation

Domain	LG Aim	Example Evaluation Metrics
Leadership Direction	Organize execution of NIAID's research priorities through operations with VTEU sites	<ul style="list-style-type: none"> Completed studies Publications
Oversight of Protocol Implementation	Efficiently implement study protocols at VTEU sites	Time from protocol concept to study implementation
Communication	Optimize communication with collaborating partners, VTEUs, and NIAID	Scheduled video conferences, distribution of eNewsletters, timely meeting minutes, annual survey of partners
Fiscal Oversight	Support timeliness of flow-through funds	Time from award made to LG & subcontract sent to sites for approval
Transparency of Procedures	Support availability of protocols, SOPs, instruments to the ID research community	Proportion of study documents posted online and accessed by users
Personnel Proficiency & Training	Ensure competence of the workforce performing LG oversight	Documentation of appropriate training & Certification
Mentoring of Junior Investigators	Support career development of young investigators in ID clinical research	Career development (or similar) awards to young investigators; participation on committees

20.3 Performance Criteria for the LOC

The IDCRC Leadership Operations Center (LOC) is responsible for overall administrative leadership for the LG, and the oversight and evaluation of all LG activities including refining of the research agenda, prioritizing research concepts, protocol development, timely publication and communication of results, and responding to infectious diseases public health emergencies. The LOC leadership coordinates the activities of the EMT, Key Function Committees and EWGs. The LOC is responsible for the for day-to-day operations, implementing research concepts, communications and the timely publication and dissemination of study results. Evaluation metrics will be determined by the IDCRC Co-PIs with input sought from 1) the External Advisory Board (EAB), 2) the COU, LOU, SDSU, EWG and Key Function Committee Chairs, and VTEU PIs, through annual in-person discussions and by a brief survey delivered online, and 3) through systematically elicited feedback from DMID/NIAID colleagues. These efforts will be facilitated by COU/FHI360 members of the PEQ KFC.

Domain	LOC Aim	Example Evaluation Metrics
Leadership Direction	Organize execution of NIAID's research priorities through operations with VTEU sites	<ul style="list-style-type: none"> Completed studies Publications
Oversight of Protocol Implementation	Facilitate innovative study and trial designs, including innovation in laboratory and statistical techniques	<ul style="list-style-type: none"> Time from concept submission to approval Number of protocols implemented Number of EWG meetings held
Communication	Ensure an active and engaged b-directional exchange of information to support learning, sharing of progress and dissemination of research findings.	<ul style="list-style-type: none"> Establishment and maintenance of an up-to-date website Create and manage listservs Annual meeting held
Fiscal Oversight	Oversee cost-effective management of IDCRC resources	<ul style="list-style-type: none"> Time from award made to LG & subcontract sent to sites for approval Number of standing awards to ensure rapid implementation of study activities



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Transparency of Procedures	Develop and incorporate policies, methods and approaches for monitoring the implementation and the quality (including risk assessment and mitigation strategies) of research conducted by the VTEUs and the operational performance of the overall IDCRC	<ul style="list-style-type: none"> • Proportion of study documents posted online and accessed by users • Availability of SOPs and policies on-line
Personnel Proficiency & Training	Ensure competence of the workforce performing IDCRC activities	<ul style="list-style-type: none"> • Number of VTEU evaluations conducted by the PEQ KFC • Documentation of appropriate trainings and certifications
Mentoring of Junior Investigators	Establish and operate a mentoring, career development and training platform to train and cultivate the IDCRC science workforce and leadership of the future	<ul style="list-style-type: none"> • Participation of junior members in EWGs • Number of junior investigators participating in protocols • Establishment of a mentoring committee

20.4 Performance Criteria for the COU

The COU functions to ensure the performance of studies at a high level by providing leadership on protocol development and implementation planning, and is responsible for site selection, qualification, and management of protocol- specific sites. Quality, efficiency, ethics, reliability and flexibility are emphasized. Function and productivity are evidenced in a number of ways including but not limited to review of protocols; initiation of new studies and completion of ongoing studies. The COU ensure that appropriate quality control and quality assurance activities are in place to identify and address areas for site improvement. Evaluation will be on a regular basis and overseen by the Performance and Quality Assurance Evaluation KFC, with regular review and updates of the metrics to best fit with the current goals and needs of the IDCRC.

Domain	COU Aim	Example Evaluation Metrics
Leadership Direction	Provide effective operational support, management and oversight for the IDCRC clinical research	<ul style="list-style-type: none"> • Number of completed studies • Number of approved studies
Oversight of Protocol Implementation	Efficiently implement study protocols at VTEU sites	<ul style="list-style-type: none"> • Review of quality management plans • Time from protocol development to implementation
Communication	Optimize communication with study investigators and IDCRC units	Monthly reports on study activities
Fiscal Oversight	Ensure fiscal responsibility of study sites	<ul style="list-style-type: none"> • Development of a master study budget • Annual survey of budget costs • Analysis of actual study costs vs estimated
Transparency of Procedures	Support availability of protocols, SOPs, instruments to the IDCRC	Proportion of study documents posted online and accessed by users
Personnel Proficiency & Training	Provides specialized training for clinical trials, related laboratory procedures, and data management for IDCRC staff in support of IDCRC activities	Number of trainings administered
Mentoring of Junior Investigators	Provide opportunities for young Investigators in the conduct of clinical research	# of early career investigators involved in IDCRC studies

20.5 Performance Criteria for the LOU

The LOU serves as the central point of implementation, oversight and coordination of IDCRC lab research activities, working to ensure the consistency and integrity of the clinical specimens and laboratory data supporting the IDCRC clinical research studies. Evaluation will be on a regular basis and overseen by the Performance and Quality Assurance Evaluation KFC, with regular consideration and updates of the metrics to best fit with the current goals and needs of the IDCRC.



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Domain	LOU Aim	Example Evaluation Metrics
Leadership Direction	Identify, design and implement laboratory research plans with the IDCRCLG and NIAID, and develop and conduct ancillary studies to support IDCRC research and clinical activities	<ul style="list-style-type: none"> • Implementation of new assays • Involvement in secondary research • Leadership and oversight of lab-based protocols
Oversight of Protocol Implementation	Implement an overarching laboratory quality management program (QMP) that will ensure the consistency and integrity of the clinical specimens and laboratory data supporting the IDCRC clinical research studies.	<ul style="list-style-type: none"> • # of Central Assay Plans written • Evaluation of lab processes completed - # of summary reports prepared and submitted to the IDCRC • Documentation of lab compliance for GCLP standards • Ongoing evaluation of protocol-specific measures by sites
Communication	Form strong linkages to the VTEU laboratories, study groups, NIAID, and other IDCRC units	<ul style="list-style-type: none"> • Participations in leadership calls • Participation in study calls • Submission of quarterly written reports
Fiscal Oversight	Ensure fiscal responsibility of study sites	Annual survey of lab capabilities and assay costs
Transparency of Procedures	Ensure awareness of VTEU-associated labs regarding the measures that they will be judged upon	<ul style="list-style-type: none"> • Availability of SOPs on quality management • Availability of results from QC management
Personnel Proficiency & Training	Harmonize lab procedures across sites and to perform QA monitoring of processing procedures, ensuring a uniform quality of lab specimens	<ul style="list-style-type: none"> • Number of trainings administered • Number of standardized SOPs developed for lab harmonization
Mentoring of Junior Investigators	Mentor, train and foster the career development of the next generation of laboratory scientists across the consortium and VTEUs at the interface of basic and clinical infectious disease research	<ul style="list-style-type: none"> • # of early career investigators involved in IDCRC studies • Participation in an LOU junior lab investigator working group • Pilot funding secured for junior investigators based on IDCRC data

20.6 Performance Criteria for the SDSU

The objectives of the SDSU are to implement and oversee data collection and management for successful implementation of proposed IDCRC clinical trials and other clinical studies, monitor safety data in a timely fashion, deliver statistical leadership in monitoring and reporting on clinical trials and provide scientific leadership in statistics and data science to further our understanding of clinical trial and cohort results. Evaluation of fulfillment of these objectives will be on a regular basis and overseen by the Performance and Quality Assurance Evaluation KFC, with regular consideration and updates of the metrics to best fit with the current goals and needs of the IDCRC.

Domain	SDSU Aim	Example Evaluation Metrics
Leadership Direction	Provide statistical leadership and data management to support IDCRC research activities and to develop and implement innovative statistical and data science approaches to improve scientific understanding of infectious diseases	<ul style="list-style-type: none"> • Participation in study proposals • # of independent analyses proposed • Did all protocols undergo SDSU review? • # of protocols with stats section written by SDSU
Oversight of Protocol Implementation	Provide statistical leadership and support throughout the protocol development and implementation process, including design, monitoring and primary and secondary analysis	<ul style="list-style-type: none"> • # of ECPs reviewed • Time to review ECPs • # of stats consultations for ECPs • # of publications participated in • # of protocol specific databases constructed • Number of DSMB/SMC reports completed.
Communication	Form strong linkages to the study groups, NIAID, and other IDCRC units	<ul style="list-style-type: none"> • Participations in leadership calls • Participation in study calls • # of regular SDSU calls
Fiscal Oversight	Ensure fiscal responsibility of SDSU funds	<ul style="list-style-type: none"> • Provide regular budget reports to the IDCRC • Timeliness of invoice submission
Transparency of Procedures	Clear understanding of SCHARP processes by IDCRC partners	<ul style="list-style-type: none"> • Availability of SCHARP SOPs to investigators • Compliance with industry guidelines • Maintenance of SOPs – frequency of review and updates
Personnel Proficiency & Training	Provide data management training for network-affiliated clinical research sites (CRSs) investigators and laboratory staff, where a CRS refers to both VTEUs as well as protocol-specific sites	<ul style="list-style-type: none"> • # of trainings held
Mentoring of Junior Investigators	Mentor, train and foster the career development of junior investigators in statistical and data management	<ul style="list-style-type: none"> • # of SDSU junior investigators involved in IDCRC studies • # of secondary research studies initiated by SDSU junior investigators • Participation in the mentoring committee

20.7 Performance Criteria for IDCRC-affiliated NIAID-funded Clinical Research Sites

Site performance within each study and across studies is reviewed for the period of evaluation (generally a twelve- month time period), 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. The COU will monitor the sites on protocol-specific performance measures, including the following, as determined by the LOC:

- 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

Data for these metrics will be provided by the LOU and either Emmes or the SDSU, depending upon the protocol. Site performance measures and standards are specified in Table 20-1 below, except where in development.

VTEU Overall Performance Measures

The PEQ KFC will evaluate overall performance of the VTEUs on a regular basis, generally yearly, on their overall participation in the IDCRC and overall metrics from the IDCRC protocols that they participate in.

IDCRC VTEU Metrics DRAFT (10Sept2021)		
Category	Metric	Frequency
Scientific Output	# Masthead Authored Publications	Every six months;
Scientific Leadership	Participation in EWGs (membership and attendance ?)	Look at membership and attendance - annually
	Participation in KFCs (membership and attendance ?)	Look at membership and attendance - annually
	Participation in Protocols as Chair	Annual metric
Scientific Contribution and Capacity	Protocol participation (# and type of protocols)	Quarterly or every 6 months
	Participant census (# subjects enrolled per site)	Quarterly or every 6 months
Communication /	Collaboration (participation in SC calls)	Every six months or annually



Reporting	Timeliness of progress report as relevant (prime vs. subsite)	Annual metric
	VTEU site representation on Friday calls (TBD)	Every six months or annually
Site Preparation	Readiness for NIAID/ Monitors' Site Visit	
	Approval by NIAID/ network	
	Activation for first network protocol	
Site Management	Time for regulatory approvals	Quarterly
	Time to site activation	Quarterly
	Achievement of enrollment goals	Quarterly
	Data quality issues	Quarterly
	Specimen quality issues	Quarterly
	CQMP compliance	Quarterly
	Site Monitoring Reports	Quarterly
Community Engagement	Community Engagement Activities (types of recruitment activities, community outreach)	
	CAB functionality - Meetings	
	CAB Retreat - Occurrence	
Personnel	Network required trainings / certifications	Quarterly
	IATA Certification - documentation of completion	

20.8 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 COU with a written plan for corrective action in the relevant performance areas. The COU 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 COU.

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



The inability of a site to meet the network’s performance requirements in two consecutive comprehensive evaluation cycles – or by an earlier timepoint as determined by the EMT – 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 EMT in consultation with the sponsors after considering the recommendations made by the LOC.

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.