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2 NETWORK GROUPS

The IMPAACT Network comprises a global network of clinical research sites (CRSs), the Leadership and Operations Center (LOC), Laboratory Center (LC), Statistical and Data Management Center (SDMC), IMPAACT Community Advisory Board (ICAB), and other groups and committees charged with the scientific, management, and operational support of the Network. The Network is led by a chair and vice chair(s), who are accountable to the National Institute of Allergy and Infectious Diseases (NIAID) Program Officer. Additional information concerning these entities is provided in this section.

2.1 Network Leadership

The IMPAACT Network is led by the Network chair and vice chair(s) in collaboration with the Scientific Leadership Group (SLG), Scientific Committees (SCs), and Management Oversight Group (MOG). The leadership group is responsible for ensuring the efficient development and implementation of the IMPAACT research agenda as well as managing and coordinating activities across the Network.

2.1.1 Network Chair and Vice Chairs

The Network chair is an investigator with experience reflective of the Network’s scientific agenda and operational scope. They serve as chair of the SLG and MOG. Responsibilities include serving as the LOC principal investigator (PI); overseeing and managing the Network’s finances; directing the Network and executing its plans as determined by the SLG, MOG, and National Institutes of Health (NIH) partners; ensuring collaboration with other research networks and groups, including pharmaceutical companies; and serving as the Network’s executive representative. Other responsibilities include but are not limited to

maintenance of Network policies and procedures, regulatory compliance and performance evaluation, review of publications, and collaboration with the community. The Network chair must commit a minimum level of effort of 50% for the term of service, which is the award period of the IMPAACT Network grant.

The SLG (described in Section 2.1.2) elects the Network chair and vice chair(s). The SLG reviews applicant submissions and SLG voting members elect the chair, after a broad solicitation for individuals with relevant expertise and experience. Applicants need not be associated with an IMPAACT site; however, site leadership experience is considered a strength. Election decisions are generally expected to be based on at least 75% concurrence among voting members. Any current SLG member who applies is recused from the entire review and election process.

As needed, a call for applicants and/or nominations for Network chair typically takes place approximately 15 months before beginning a new Network grant funding cycle so that the elected chair can be named in the application for the new grant. The newly elected chair serves in a transitional capacity as Network chair-elect, participating as a non-voting member of the SLG and MOG, until the new grant is awarded, at which time they assume the duties of Network chair.

If it becomes necessary to replace the Network chair, a special election may be held. One of the vice chairs will serve as chair until the replacement is selected.

The Network vice chair(s) should meet the same requirements as the chair and is/are elected following the same procedures as the Network chair. The primary duties of a vice chair are to assist the Network chair, assume the powers and duties of the Network chair in their absence or, in case of a potential conflict of interest, lead meetings in the absence of the Network chair. The Network vice chair(s) also serve(s) as chair(s) of some Network committees and groups.

2.1.2 Scientific Leadership Group

The SLG sets the overall scientific agenda of the Network. The Network chair serves as the chair of the SLG; other members include the Network vice chairs, SDMC PIs, LC PI, Operations Center Director, Study Monitoring Committee (SMC) chair, ICAB chair, up to four at-large investigators, and NIAID, National Institute of Child Health and Human Development (NICHD), and National Institute of Mental Health (NIMH) representatives. At-large members of the SLG are selected by the MOG to ensure appropriate breadth and depth of scientific expertise and diversity, reflective of the Network's research agenda and geographical scope. *Ex officio* members of the SLG may also serve as voting members.

The primary responsibilities of the SLG are to:

- Set, develop, and execute the overall scientific agenda of the Network, in close collaboration with the SCs and the ICAB
- Prioritize studies across research areas and the overall research portfolio
- Review evolving HIV/AIDS science and determine implications for the Network
- Review new study proposals
- Identify gaps in the Network's research agenda and commission studies to address these
- Liaise with other research networks and groups to foster collaboration

The SLG convenes regularly via conference call and in person, including periodically with the SC chairs and vice chairs and, as needed, with external advisors. When voting is required, SLG members with conflicts of interest (e.g., part of the team developing a proposal) abstain from voting, and decisions are

generally expected to be based on at least 75% concurrence among voting members. Voting members include all listed SLG members above, with one voting representative from each of the three NIH institutes. If decisions are mixed or split, the chair and vice chair(s) may determine next steps, based on the results, and generally include additional follow-up to reach consensus. To ensure coordination and communication, additional representatives of the Operations Center, SDMC, LC, and NIH sponsoring institutes may participate in SLG meetings as observers.

Decisions made by the SLG are communicated in writing to the relevant parties, and updates on plans and activities are provided to SLG members during routine calls or otherwise as needed. Updates to other Network members are provided via email broadcasts, website postings, conference calls, and other means as appropriate. On an ongoing basis, the SLG reviews and prioritizes new study proposals; review is based on scientific merit, potential public health impact, and feasibility and research advantage of Network implementation, as described in Section 9. See Section 6 for details regarding Network meetings and communications.

2.1.3 Management Oversight Group

As described in Section 2.1.2, the SLG focuses on the scientific priorities for the Network, whereas the Network management and oversight functions are the responsibility of the MOG. The MOG is comprised of a subset of SLG members, and the Network chair serves as the chair of the MOG; other members include the Network vice chair(s), SDMC PIs, LC PI, Operations Center Director, and NIAID, NICHD, and NIMH representatives.

The primary responsibilities of the MOG are to:

- Oversee the Network's fiscal matters
- Evaluate and recommend the distribution of resources across Network components
- Review site selection and accrual plans
- Ensure regulatory compliance
- Develop collaboration agreements
- Monitor Network performance and productivity
- Review and approve the Network Manual of Procedures (MOP)
- Conduct other administrative and operational aspects of the Network's business

The MOG convenes regularly via conference calls and in person. When voting is required, MOG members with conflicts of interest (e.g., being part of the team developing a proposal) abstain from voting, and decisions are generally expected to be based on at least 75% concurrence among voting members. Voting members include all listed MOG members above, with one voting representative from each of the three NIH institutes. If decisions are mixed or split, the chair and vice chair(s) may determine next steps, based on the results, and generally include additional follow-up to reach consensus. To ensure coordination and communication, additional representatives of the LOC (including the Finance and Contracts Office at Johns Hopkins University [JHU]), SDMC, LC, and NIH sponsoring institutes may participate in MOG meetings as observers.

Decisions made by the MOG are communicated in writing to the relevant parties, and updates on plans and activities are provided to MOG members during routine calls or otherwise as needed. Updates to other Network members are provided via email broadcasts, website postings, conference calls, and other means as appropriate. See Section 6 for details regarding Network meetings and communications.

2.1.4 Scientific Committees

The IMPAACT Network is committed to conducting high quality clinical trials that advance the prevention and treatment of HIV and its complications for infants, children, adolescents, and pregnant and postpartum people globally. The Network’s research agenda includes four scientific aims, reflecting the following key research areas:

- Treatment
- ART-Free Remission (“Cure”)
- Tuberculosis
- Complications and Co-Morbidities

For each research area, a SC continually reassesses research priorities considering emerging science as well as new ideas and opportunities, seeks collaboration with other research networks and entities, and oversees the development and review of study proposals based on scientific priorities.

The SCs are responsible for:

- Reviewing their respective portfolios of studies in the context of evolving science and standards of care
- Identifying gaps in the science and new interventions for priority populations
- Ensuring that new high priority study proposals are developed for consideration by the SLG

SCs convene regularly via conference call and in person. SC chairs and vice chairs periodically meet with the SLG via conference call or in person. SCs are expected to collaborate on areas of topical overlap and mutual interest, each drawing upon the expertise of others as needed. See Section 6 for details regarding Network meetings and communications.

2.1.4.1 SC Chairs and Vice Chairs

SC chairs and vice chairs are selected by the SLG to ensure appropriate breadth and depth of scientific expertise and diversity, reflective of the Network’s research agenda and geographical scope. Chairs and vice chairs are accountable to the SLG. They are responsible for leading their respective SCs and participating in SLG conference calls and meetings as requested to discuss their SCs’ research agendas and priorities. Each SC also has a designated SLG liaison who is available for Network leadership consultation on an ongoing basis.

2.1.4.2 SC Membership

Each SC is composed of experts in the relevant field and typically includes a chair and vice chair, at-large members, and representatives from the ICAB, SDMC, LC, Operations Center, NIAID, NICHD, and NIMH. At-large members are chosen by the chair and vice chair and confirmed by the SLG after a broad solicitation for individuals with relevant expertise and experience.

When voting is required, SC members with conflicts of interest (e.g., being part of the team developing a proposal) abstain from voting. Voting members include all listed members above, with one voting representative from the ICAB, each of the central resource groups, and each of the three NIH institutes. Voting may be considered completed once at least 60% of at-large members plus the chair and vice chair have voted; if decisions are mixed or split, the chair and vice chair may determine next steps, based on the results.

To ensure coordination and communication with Network leadership, a liaison from the SLG is also selected to participate in each SC; this person is not considered a voting member. To augment or expand existing expertise within a SC or to replace a departing member, the SC chair and vice chair may propose additional individuals for membership, with appointment to be confirmed by the SLG.

2.1.5 Removal of Any IMPAACT Leadership Member

In the unlikely event that any IMPAACT leadership (SLG or SC) member needs to be removed for cause, a written proposal to remove the member must be submitted with support from at least three voting members of the group (SLG or SC). Removal of the member is based on at least 75% concurrence among voting members of the group and requires concurrence from NIAID. Removal of an SC member also requires concurrence from the SLG.

Leadership members include the Network chair, Network vice chairs, at-large SLG members, SC chairs and vice chairs, and all other members of the SLG, except for NIH members.

2.2 Advisory Groups

2.2.1 IMPAACT Community Advisory Board

The IMPAACT Community Advisory Board (ICAB) is responsible for advising the Network leadership, SCs, protocol teams, and other Network groups on issues related to the planning and implementation of the IMPAACT research agenda and for supporting local (site) community programs through training and information exchange. The ICAB also communicates and represents the views of local community programs through participation of its representatives in the SLG, SCs, protocol teams, and other Network groups. The ICAB convenes regularly via conference calls and in person. The ICAB chair is accountable to the Network chair and the MOG.

See Section 5 for additional details on the ICAB.

2.2.2 Scientific Service Cores

Two scientific service cores provide expertise integral to the design, conduct, and analysis of IMPAACT studies, from early planning through protocol development, via a consultative model.

The Social Behavioral Service Core ensures that IMPAACT studies are designed and implemented with appropriate consideration of social-behavioral factors that may influence outcomes of interest or success of the study and that state-of-the-art approaches and measures are used. The core is led by a chair and composed of internationally recognized experts in adherence measurement and analysis, as well as engagement in care, retention, and decision making, with specific emphasis on child, adolescent, and maternal health.

The Pharmacometric Service Core's responsibilities are to provide expertise in the design of pharmacometric studies including developing initial pharmacokinetic (PK) and pharmacodynamic (PD) models, continually updating these models as new information becomes available, and applying statistical methods to optimize study design. They also perform, in collaboration with the LC's Specialty Pharmacology Laboratories and other specialty laboratories, PK analyses of IMPAACT study data, exploratory PK/PD analysis, and PK/pharmacogenetic studies. The core is led by a chair and composed of PK/PD modeling experts in pediatrics, obstetrics, HIV, TB, and other therapies used in IMPAACT

studies. As needed, they work in collaboration with industry sponsors to ensure appropriate utilization of the most up-to-date adult PK and PD characteristics to ensure optimal design of IMPAACT studies.

The chairs of both cores are selected by the SLG; members are chosen by the chair and confirmed by the SLG. The cores are accountable to the SLG.

2.2.3 External Scientific Advisory Group (EAG)

An external scientific advisory group may be convened periodically to provide constructive feedback on the Network's current and planned scientific agenda, including identifying gaps and providing recommendations for prioritization and future directions. The group may convene either via conference call or in person. The group should include diverse expertise and experience relevant to the Network's research agenda, including pediatric HIV therapy, pediatric TB/HIV co-infection, perinatal HIV transmission, pediatric HIV vaccines, pediatric immunology, HIV reservoirs, metabolic/neuropsychiatric complications of HIV and ARV therapy, and behavioral sciences. The group should also include community representation. Members must be currently unassociated with IMPAACT and have no current conflict of interest. The group is directly advisory to the SLG and will be led by a non-voting *ex officio* member of the SLG.

The external scientific advisory function may be fulfilled through alternative means as determined by the SLG.

2.2.4 Electronic Case Report Forms Committee

The Electronic Case Report Form (eCRF) Committee works closely with the SDMC to develop standardized data collection methods and eCRFs that collect the data required for IMPAACT studies in an accurate and efficient manner. The committee develops generic eCRFs for use across studies, promotes efficient data collection and data entry, and reduces collection of nonessential information.

The eCRF Committee is led by representatives of the SDMC and composed of representatives from the SDMC, LC, and Operations Center, as well as site representatives, including study coordinators, data managers, study nurses, and other clinicians. Members review and provide input on the design of new generic eCRFs and provide input on study-specific eCRFs for new studies as needed. Committee activities focus on review of generic eCRFs (done on monthly calls) and study-specific eCRFs (done as needed and by email).

2.3 Central Resources

The central resources of the IMPAACT Network include:

- Leadership and Operations Center (LOC), located at Johns Hopkins University (JHU) and FHI 360
- Statistical and Data Management Center (SDMC), located at the Harvard T.H. Chan School of Public Health and Frontier Science Foundation
- Laboratory Center (LC), located at the University of California Los Angeles (UCLA)

These groups coordinate closely with each other in the development, implementation, and oversight of Network studies and other Network activities.

2.3.1 Leadership and Operations Center

The Leadership and Operations Center (LOC) supports the Network leadership, structure, and functioning and is responsible for helping to shape the Network’s scientific agenda and plays a key role in all phases of science generation and protocol development. Oversight of the LOC is the responsibility of the Network chair. The LOC includes functions across two institutions: the IMPAACT Finance and Contracts Office (at JHU) and the IMPAACT Operations Center (at FHI 360).

The Finance and Contracts Office administers and disperses grant and other funding for support of the Network leadership, protocol chairs, clinical research sites, specialty laboratories, the Operations Center, and other central resources. The Finance and Contracts Office also executes contracts with pharmaceutical companies and other collaborators to support Network studies.

The Operations Center provides a central point of coordination, communications, and support for all aspects of the Network. The Operations Center supports the scientific agenda; coordinates the development, implementation, and reporting of IMPAACT studies; supports all Network groups, committees, and protocol teams; and arranges and supports all Network meetings and leadership travel. The Operations Center Director serves as a voting member of the SLG and MOG.

The LOC’s responsibilities, by functional area, are summarized in Table 2-1.

2.3.2 Statistical and Data Management Center

Through a separate but linked and fully collaborative grant with the LOC and the LC, the Statistical and Data Management Center (SDMC) is responsible for helping to shape the Network’s scientific agenda and plays a key role in all phases of science generation and protocol development. The SDMC also provides comprehensive biostatistical and data management leadership, specifically in the design and implementation of Network studies and in the collection, quality control, and analysis of study data in accordance with study protocols and in collaboration with other team members, following the principles of Good Clinical Data Management Practices (GCDMP) and Good Clinical Practices (GCP).

The SDMC is comprised of a Statistical and Data Analysis Center (SDAC), located at the Center for Biostatistics in AIDS Research at the Harvard T.H. Chan School of Public Health, and a Data Management Center (DMC), located at Frontier Science Foundation. The SDMC PIs have fiscal responsibility for the SDMC grant, are accountable to the NIAID Program Officer and the Network chair, and serve as a voting member (one representative) of the SLG and MOG.

The SDMC’s responsibilities, by functional area, are summarized in Table 2-2.

2.3.3 Laboratory Center

Through a separate but linked and fully collaborative grant with the LOC and the SDMC, the Laboratory Center (LC) is responsible for helping to shape the Network’s scientific agenda and plays a key role in all phases of science generation and protocol development. The LC is also responsible for leadership, oversight, and support of laboratory aspects of Network studies and other activities including NIAID site laboratory preparedness and performance and coordination and oversight of the Network’s specialty laboratories. Westat supports laboratory activities for NICHD sites. The LC plays a leadership role in cross-network activities, updating, harmonizing, and streamlining laboratory procedures used in other networks and groups.

The LC is located at the University of California Los Angeles (UCLA). The LC PI has fiscal responsibility for the LC grant, is accountable to the NIAID Program Officer and the Network chair, and serves as a voting member of the SLG and MOG.

The LC staff maintains regular communication with IMPAACT sites and confirms that sites are able to perform study-required laboratory procedures and tests prior to site activation for the study. The LC staff also visit sites, as necessary, to assess laboratory facilities and procedures.

The LC’s responsibilities, by functional area, are summarized in Table 2-3.

Table 2-1. IMPAACT LOC Operational Responsibilities

Functional Area	Responsibilities
Leadership and governance	<ul style="list-style-type: none"> • Serve on and provide logistical and administrative support to the SLG, MOG, SCs, ICAB, Social Behavioral Service Core, and other Network committees and groups • Participate in the overall management of the Network and development of the IMPAACT scientific agenda • Provide operational leadership to the Network • Coordinate the development and management of the Network MOP • Coordinate and support Network evaluation processes (see Section 18)
Protocol management and support See Section 4 for a full listing of roles and responsibilities for the protocol CRM.	<ul style="list-style-type: none"> • Facilitate the development, review, approval, and tracking of concepts, ancillary studies, and other related study proposals • Assign a clinical research manager (CRM) to each IMPAACT protocol • In collaboration with the protocol chair, plan and manage protocol team business in consultation and with the support of other protocol team members • Facilitate communication between protocol teams, study sites, Network leadership, and other Network and sponsor entities as needed
Technical assistance to sites	<ul style="list-style-type: none"> • Coordinate the development and implementation of study-specific training plans as well as training related to Network policies and procedures • Coordinate and facilitate responses to inquiries from site staff on logistics and procedures for IMPAACT studies in collaboration with protocol team members and other Network entities, as applicable
Coordination of, facilitation of, and participation on oversight committees	<ul style="list-style-type: none"> • Serve as member of and coordinate activities of oversight groups • Facilitate preparation and distribution of relevant review materials; prepare and distribute review outcome reports and associated communications, as applicable
Community engagement See Section 5 for a full description of roles and responsibilities for the Operations Center community program staff.	<ul style="list-style-type: none"> • Facilitate broad community involvement through community representation on key Network committees and groups and, as applicable, by working with sites to develop and enhance the IMPAACT Community Advisory Board (ICAB) • Support the work of the ICAB and IMPAACT CAB Leadership Group (ILG)

Table 2-1. IMPAACT LOC Operational Responsibilities

Functional Area	Responsibilities
<p>Communication and information dissemination</p>	<ul style="list-style-type: none"> • Develop and maintain the IMPAACT website, including relevant information on sites and IMPAACT studies • Support and coordinate Network-level communication through conference calls, in-person meetings, electronic and written materials, announcements, and postings on the IMPAACT website and social media outlets • Support and organize Network meetings • Develop and maintain email groups and directories for the IMPAACT communication system in collaboration with the DMC • Maintain inventory of site- and study-related information and provide requested information to Network leadership and other committees as needed • Support the NIAID Clinical Research Management System (CRMS) and The Division of AIDS (DAIDS) Regulatory Support Center (RSC) by providing current study-specific information and documents in real time
<p>Financial management and support</p>	<ul style="list-style-type: none"> • Evaluate the adequacy of financial resources provided to sites, as necessary • Assist NIH Grants Management Branch (GMB), DAIDS Prevention Sciences Program (PSP), OCSO, and IMPAACT leadership in analysis of site funding requests and all other Network financial matters • Develop an annual funding plan based on the needs of the scientific agenda implemented during the funding cycle • Administer and disperse grant and other funding for support of Network activities • Execute contracts with pharmaceutical companies and other collaborators to support Network studies

Table 2-2. IMPAACT SDMC Operational Responsibilities

Functional Area	Responsibilities
Leadership and governance	<ul style="list-style-type: none"> • Serve on the SLG, MOG, SCs, and other Network committees and groups • Participate in the overall management of the IMPAACT Network and development of the IMPAACT scientific agenda • Provide statistical and data management leadership to the IMPAACT Network • Contribute to the development and management of the Network MOP • Contribute to Network evaluation processes (see Section 18)
Protocol management and support See Section 4 for a full listing of roles and responsibilities for the statistician, PDM, and LDM.	<ul style="list-style-type: none"> • Participate in the review of concepts, ancillary studies, and other related study proposals; track status of analyses being performed by the SDMC • Assign a statistician, a protocol data manager (PDM), and a laboratory data manager (LDM) to each IMPAACT protocol • Participate in the protocol-related groups, as applicable • Design and maintain the study databases • Provide centralized data entry and data management • Provide reports to fulfill Investigational New Drug (IND) reporting requirements, as applicable • Review and provide study data and reporting to pharmaceutical partners under the terms of the Clinical Trials Agreement (CTA), as applicable • Develop and implement data quality control (QC) systems • Provide needed information to the DAIDS Clinical Site Monitor to assist with site-monitoring visits
Technical assistance to sites	<ul style="list-style-type: none"> • Participate in the development and implementation of study-specific training plans • Develop, coordinate, and implement training related to data management for Network members • Respond to inquiries from site staff in collaboration with protocol team members and other Network entities, as applicable • Provide operational assistance to sites, the LC, and protocol teams for specimen tracking and retrieval, including labeling and specimen tracking sheets to facilitate specimen entry into the specimen tracking system, the Laboratory Data Management System (LDMS), and reports of LDMS entry errors and discrepancies between LDMS and CRF databases
Information technology support	<ul style="list-style-type: none"> • Develop and maintain software systems and related procedures for transmitting, receiving, processing, analyzing, and storing study data and meeting reporting requirements • Assist sites in set-up and maintenance of data collection material relay systems
Participation on oversight committees	<ul style="list-style-type: none"> • Serve as a member of oversight groups
Clinical data safety monitoring	<ul style="list-style-type: none"> • Provide clinical review of relevant laboratory and safety data for accuracy, consistency, and completeness • Provide QC and coding of adverse event (AE) data • Verify completeness of expedited adverse event reporting through reconciliation of AEs reported to DAIDS and those reported to the SDMC

Table 2-3. IMPAACT LC Operational Responsibilities

Functional Area	Responsibilities
<p>Leadership and governance</p>	<ul style="list-style-type: none"> • Serve on the SLG, MOG, SCs, and other Network committees and groups • Serve on and provide logistical and administrative support to the Pharmacometrics Service Core • Participate in the overall management of the Network and development of the IMPAACT scientific agenda • Contribute to the development and management of the Network MOP • Contribute to Network evaluation processes (see Section 18)
<p>Protocol management and support See Section 4 for a full listing of roles and responsibilities for the LC representative and LT. See Section 17 for a full listing of roles and responsibilities for the Laboratory Center.</p>	<ul style="list-style-type: none"> • Participate in the review of concepts, ancillary studies, and other related study proposals • Assign a LC representative to each IMPAACT protocol; facilitate assignment of a LT, in consultation with Laboratory Technologist Committee, to each IMPAACT protocol • Review and define appropriate laboratory testing methods and materials to be used in IMPAACT studies • Participate in protocol-related groups, as applicable • Collaborate with other NIH-sponsored HIV clinical trial networks to harmonize laboratory methods and maximize the efficiency of protocol development, implementation, and analysis • Collaborate with IMPAACT specialty labs to perform protocol-specified testing
<p>Technical assistance to sites</p>	<ul style="list-style-type: none"> • Participate in the development and implementation of study-specific training plans • Respond to inquiries from NIAID site staff in collaboration with protocol team members and other Network entities, as applicable (Westat responds to laboratory-related inquiries from NICHD site staff) • Provide operational assistance to sites, the SDMC, and protocol teams for specimen tracking and retrieval, including labeling and tracking specimen sheets to facilitate specimen entry into the specimen tracking system, the LDMS, and reports of LDMS entry errors and discrepancies between LDMS and CRF databases
<p>Participation on oversight committees</p>	<ul style="list-style-type: none"> • Serve as a member of oversight groups

2.4 Oversight Groups

Additional Network groups provide oversight on behalf of the SLG and MOG:

- Multidisciplinary Protocol Review Group (MPRG)
- Study Monitoring Committee(s) (SMC)
- Network Evaluation Group (NEG)
- Publications Review Group (PRG)

These committees have both standing and *ad hoc* members and convene via conference call as needed.

2.4.1 Multidisciplinary Protocol Review Group

The Multidisciplinary Protocol Review Group (MPRG) reviews protocols on behalf of the SLG prior to submission to the NIAID Sciences Review Committees. The purpose of the MPRG review is to ensure IMPAACT protocols are scientifically rigorous, accurate, consistent, complete, and standardized to the extent possible. The MPRG critically reviews protocols for scientific and design integrity; operational feasibility, focusing on key issues such as site participation, infrastructure, and capacity; relevance to the community; and any ethical, logistical, or potential regulatory concerns. The review is multidisciplinary to streamline and avoid multiple sequential review steps. This group has authority to approve protocols, request revision and re-submission, or to disapprove them, based on Network-specified criteria.

See Section 9 for additional details on the MPRG.

2.4.2 Study Monitoring Committee

In support of the management and oversight functions of the MOG, for designated studies a Study Monitoring Committee (SMC) monitors participant safety and the progress and quality of IMPAACT study conduct. The scope of SMC reviews varies across studies, reflective of protocol specifications.

See Section 13 for additional details on the SMC.

2.4.3 Network Evaluation Group

The Network Evaluation Group (NEG) develops and conducts the Network evaluation program on behalf of the MOG. Evaluation reports are shared with the entities whose work was evaluated and with Network sponsors, as appropriate. A primary component of evaluation is the CRS 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. At the request of the MOG, the NEG may evaluate and report on other Network entities in a similar manner.

See Section 18 for additional details on the NEG.

2.4.4 Publications Review Group

The Publications Review Group (PRG) reviews all abstracts and manuscripts reporting on Network studies and related investigations prior to submission to a conference or journal to ensure high quality products and publications and scientific rigor.

See Section 19 for additional details on the PRG.

2.5 Protocol Teams

Protocol teams assume primary responsibility for scientific leadership in the development, implementation, and day-to-day oversight of IMPAACT studies; protocol teams are also responsible for timely dissemination of study results.

See Section 4 for additional details on the composition and functions of protocol teams.

2.6 Clinical Research Sites

IMPAACT studies are conducted at clinical research sites (CRSs) worldwide and are funded by NIAID and NICHD. Investigators and other representatives of these sites, including community representatives, participate in all levels of the Network structure. The active participation of site representatives is critical to IMPAACT's scientific mission. These sites bring extensive clinical trials capacity and a wealth of experience for implementation of the Network's scientific agenda.

IMPAACT sites are experienced in implementing clinical trials, monitoring for and reporting adverse events, achieving high participant retention rates, and rigorously adhering to study protocols. Site staff are skilled in applying the principles of Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) in all aspects of study conduct. These practices include obtaining informed consent and assent; performing clinical, pharmacy, and laboratory study procedures; maintaining study product accountability; performing data management and quality management processes; and collecting, labeling, processing, testing, storing, and shipping biological specimens. In addition, each site obtains community input on the research process through its community advisory board(s), although a site may refer to this structure by another locally chosen name or establish an alternative structure.

Staffing at each site may vary based on the structure of the site, the number and type of studies being conducted, and any local requirements. Some staff members may have general functions that apply across studies and others may have study-specific responsibilities. Site staff often include the following:

- CRS Leader and CRS Coordinator
- Study-specific Investigators of Record (IoR) and sub-investigators
- Study-specific Coordinators
- Pharmacist of Record, study-specific Pharmacists of Record, and other pharmacists and pharmacy technicians
- Research nurses and clinicians
- Data managers and technicians
- Laboratory directors, managers, technologists, and technicians
- Counselors and social workers
- Community educators and liaisons
- Participant outreach, recruitment, and retention staff
- QA/QC staff
- Administrative staff

2.6.1 NIAID Sites

The Division of AIDS (DAIDS) at NIAID funds sites worldwide to participate in Network studies. Each site is part of a Clinical Trials Unit (CTU); CTUs may be comprised of multiple sites. NIAID provides resources to fund research infrastructure and study implementation through cooperative agreements with CTUs and through the LOC.

2.6.2 NICHD Sites

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) funds sites worldwide to participate in Network studies. NICHD provides resources to sites to fund research infrastructure and study implementation through the NICHD coordinating center.

2.6.3 Protocol-Specific Sites

Sites that are not affiliated with the Network through NIAID or NICHD may be engaged and supported to implement specific Network studies if needed to meet the study objectives, such as to reach special populations or expand capacity.

See Section 10 for additional details.