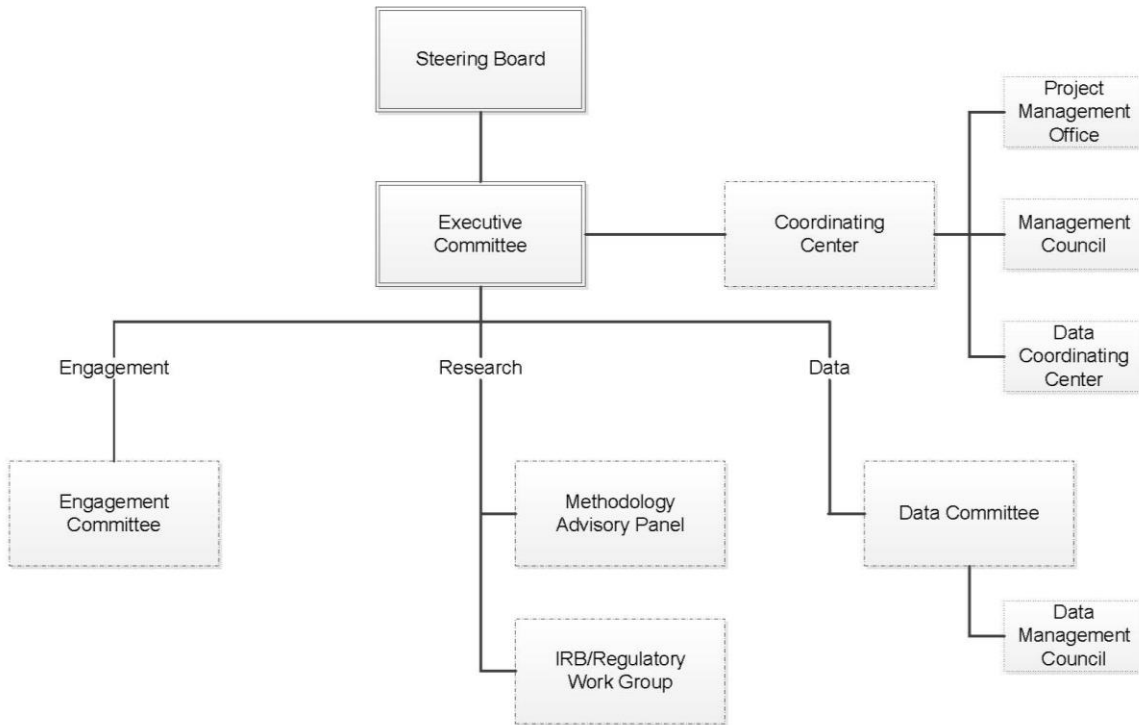


2 PEDSNET ORGANIZATIONAL ARCHITECTURE



PEDSnet is composed of Member Institutions, a Steering Board, an Executive Committee, three subcommittees (Data, Engagement, and the Methodology Advisory Panel), Work Groups, and a Coordinating Center.

2.1 FOUNDING MEMBER INSTITUTIONS

Eight Founding Member Institutions established PEDSnet, as it is currently configured, in 2014. As Founders, these institutions established PEDSnet’s governance, data network, scientific, technical, methodologic, engagement, and organizational expertise. Representatives of the Founding Institutions participate in the Steering Board, Committees, and work groups.

The 8 Founders are:

- Boston Children’s Hospital
- Children’s Hospital Colorado
- Children’s Hospital of Philadelphia
- Cincinnati Children’s Hospital Medical Center
- Nationwide Children’s Hospital

- Nemours Children's Health System
- St. Louis Children's Hospital
- Seattle Children's Hospital

These institutions are academic health centers that provide inpatient, specialty outpatient, emergency, and primary care services and programs and support large research infrastructures. With regional catchment areas extending across 11 states, and a national and international specialty referral base, PEDSnet Founding Member Institutions annually provide care for >2.1 million unique patients, about 3% of all children in the U.S., from diverse demographic, geographic, and socioeconomic backgrounds.

2.2 STEERING BOARD

The Steering Board serves as the overall governing body for PEDSnet. It ensures that PEDSnet is true to its mission, pursues its vision and strategic goals, and update vision as new opportunities, trends, and challenges present themselves. Responsibilities include:

- Oversight of PEDSnet's network, data, research, and engagement operations;
- Commissioning and approving PEDSnet's strategic plans;
- Defining new strategic directions;
- Ratifying policies; and,
- Providing institutional leadership in support of PEDSnet's mission and vision.

Steering Board Membership

The PEDSnet Steering Board has 10 voting members, one institutional leader who represents their Institution, and 2 parents. Each Founding Member Institution also has an Alternate Board Member. Voting members may choose to delegate voting authority to their Alternate if they are unable to vote, because of travel, illness, or other circumstances. Each institution is allowed one vote. Members and Alternates serve two-year terms, which can be renewed at the discretion of their Institution. Each institution identifies its Steering Board Member and an Alternate. Both individuals attend Steering Board meetings, receive Steering Board meeting materials, and attend PEDSnet face-to-face meetings. The institutional PEDSnet Site Principal Investigator, who also serves as a representative to the Executive Committee, will submit nominees from their Institution to the Chair and Vice Chair of the Steering Board. Addition of new members to the PEDSnet Steering Board will require a two-thirds majority of voting members to approve the nomination. Members may resign by providing written notice to the Chair of the Steering Board.

Steering Board Chair and Vice Chair

An elected Chair from among the 10 voting members will lead the PEDSnet Steering Board. The Chair will serve a two-year term, renewable for one additional term. The PEDSnet Executive Director will serve as the Vice Chair of the PEDSnet Steering Board, and in this role, will provide managerial support to the Chair of the Steering Board and will be a non-voting member.

Steering Board Meetings

The PEDSnet Steering Board Chair will chair these meetings. In his or her absence, the Vice Chair will lead the meeting. In cases when both individuals are absent, the Vice Chair will appoint a member of the PEDSnet Executive Committee to serve in this role. In general, meetings will be held via teleconference and webinar. One meeting each year will be held face-to-face. The Steering Board will approve summaries of Steering Board meetings within 45 days of a meeting. Once approved, the summaries will be made publicly available on the PEDSnet web site.

2.3 EXECUTIVE COMMITTEE

The Executive Committee (EC) will oversee PEDSnet research, data, engagement, and network operations, and will provide a forum for member institutions to communicate with one another. Responsibilities include:

- Ensure efficient and effective operations of the Network;
- Oversee the Coordinating Center, Data, Engagement, and Methods Advisory Panel Committees;
- Develop policies for ratification by the Steering Board;
- Approve changes to the Common Data Model;
- Approve requests for PEDSnet collaboration; and,
- Approve requests for PEDSnet Study Approval.

Executive Committee Members

There will be 8 voting members of the Executive Committee. Each Founding Institution will appoint one individual to serve as the Institutional PEDSnet Site Principal Investigator, and these 8 individuals will be the voting members of the Executive Committee. The PEDSnet Executive Director will serve as the Chair of the Executive Committee. The Director of the Data Coordinating Center and the Director of PEDSnet Operations, both in the Coordinating Center, will serve as non-voting members. EC members will serve two-year terms, which can be renewed at the discretion of their institution. Members may resign by providing written notice to the Chair of the Executive Committee.

Strategic Planning

At the discretion of the Steering Board, the Executive Committee will develop and submit for Steering Board review and ratification a PEDSnet strategic plan. Once the Steering Board ratifies this, the Executive Committee will develop operational plans for executing the strategic plan, monitoring and reporting on progress towards achieving strategic goals and objectives, and ensuring the network's performance is optimized for quality and efficiency.

Executive Committee Meetings

The Executive Committee will meet on a biweekly to weekly basis, depending on the volume of activity it must handle. The PEDSnet Executive Director will chair meetings. In his or her absence, another member of the PEDSnet Executive Committee will be designated to serve in this role. In general, meetings will be held via teleconference and webinar. Summaries of Executive Committee meetings will be produced by the Coordinating Center and approved by the Executive Committee within 30 days of a meeting.

2.4 DATA COMMITTEE

The role of the Data Committee is to oversee PEDSnet's data network and to develop data governance policies. Responsibilities include:

- Develop policies for managing the Data Network;
- Develop data governance policies;
- Develop policies for responding to requests for data queries or data-sets;
- Stimulate informatics innovations that advance PEDSnet's mission and goals; and,
- Make recommendations to the EC regarding expansion of the PEDSnet Common Data Model.

Data Committee Members

There will be 8 voting members of the Data Committee. Each Founding Member Institution will appoint one individual to serve as the PEDSnet Institutional Informatics Leader. These individuals will be the voting members of the Data Committee. The PEDSnet Director of the Data Coordinating Center will serve as the Chair of the Data Committee. Data Committee members will serve two-year terms, which can be renewed. Members may resign by providing written notice to the Chair of the Executive Committee.

Data Committee Meetings

The Data Committee will meet on a frequency commensurate with the volume of activity it must handle. The PEDSnet Director of the Data Coordinating Center will chair meetings. In his or her absence, another member of the PEDSnet Data Committee will be designated to serve in this role. In general, meetings will be held via teleconference and webinar.

2.5 ENGAGEMENT COMMITTEE

The role of the Engagement Committee is to stimulate, strengthen, and oversee engagement of institutions, networks, and individuals in PEDSnet. Responsibilities include:

- Development and oversight of PEDSnet's membership model;
- Development and oversight of PEDSnet's approach to outreach;
- Identification and dissemination of effective patients, parent, and clinician engagement methods for research projects; and,
- Development and oversight of the PEDSnet engagement services.

Engagement Committee Members

There will be 8 voting members of the Engagement Committee. Each Founding Member Institution will appoint one individual to serve on the Engagement Committee. The Executive Director will select an individual to chair the Engagement Committee. Engagement Committee members will serve two-year terms, which can be renewed. Committee members may resign by providing written notice to the Chair of the Executive Committee.

Engagement Committee Meetings

The Engagement Committee will meet on a frequency commensurate with the volume of activity it must handle. The PEDSnet Engagement Committee chair will lead meetings. In his or her absence, another member of the PEDSnet Engagement Committee will be designated to serve in this role. In general, meetings will be held via teleconference and webinar.

2.6 METHODOLOGY ADVISORY PANEL (MAP)

The purpose of the MAP, a sub-committee of the Executive Committee, is to assist investigators in developing high quality protocols that will result in actionable results for health care providers and patients or changes in practice. Responsibilities include:

- Development and implementation of the PEDSnet Study Approval process
- Provision of constructive feedback to research proposals

MAP Membership

The MAP members will be chosen so as to provide particular expertise in research designs and methods, such as those highlighted in the PCORI Methodology Report and Standards. In addition, some MAP members will have expertise in the use of patient-reported child health outcome measures. The MAP members will be nominated by Institutional Site Principal

Investigators and will be approved by the PEDSnet Director of Research. Each PEDSnet site will have, at minimum, one funded methodologist (generally doctoral-level statisticians, epidemiologists, clinical trial experts, and social scientists) on the MAP.

MAP Meetings

The MAP will meet on a frequency commensurate with the volume of activity it must handle. The PEDSnet Director of Research will appoint a chair or co-chairs to lead the meetings. In general, meetings will be held via teleconference and webinar.

2.7 COORDINATING CENTER

The PEDSnet Executive Director leads the Coordinating Center (CC). The CC includes a PEDSnet Management Office (PMO), Data Coordinating Center (DCC), and a PEDSnet Management Council (PMC).

2.7.1 PEDSNET EXECUTIVE DIRECTOR

Responsibilities for this individual include:

- Ensure successful execution of the PEDSnet strategic and operational plans;
- Provide leadership to the Coordinating Center; and,
- Serve in the following roles:
 - Network liaison to PCORnet;
 - Vice Chair of the PEDSnet Steering Board; and,
 - Chair of the PEDSnet Executive Committee.

The PEDSnet Executive Director is appointed by and reports to the Steering Board.

2.7.2 PEDSNET MANAGEMENT OFFICE (PMO)

The PMO provides logistical and project management support to Network operations and research projects. Responsibilities include:

- Communication within the Network;
- Outreach activities under the direction of the Engagement Committee;
- Management of the PEDSnet web site and access to PEDSnet resources;
- Project management for research projects; and,
- Logistical support to the Steering Board, Committees, and Working Groups.

The PMO is led by the PEDSnet Director of Operations, who is appointed by and reports to the PEDSnet Executive Director.

2.7.3 DATA COORDINATING CENTER (DCC)

The DCC develops, maintains, and operates the PEDSnet data network under the guidance of the Data Committee. Responsibilities include:

- Implement the PEDSnet data sharing infrastructure;
- Maintain Network data standards;
- Manage submission of data extracts;
- Perform data quality assessments of the data network;
- Ensure the data security;
- Perform data linkages with external data sources;
- Document procedures;
- Provide monthly reports on uses of the data network;
- Develop reusable tools for management and use of the data network;
- Archive study data and results; and,
- Respond to data requests for queries and data sets to support research studies.

The DCC is led by the PEDSnet Informatics Director, who is appointed by and reports to the PEDSnet Executive Director.

2.7.4 PEDSNET MANAGEMENT COUNCIL (PMC)

The PMC will be responsible for overseeing the day-to-day operations of the Network. It will ensure that the operational plans approved by the Executive Committee are executed efficiently and effectively. It will produce standard processes for review and approval by the Executive Committee. The members of the PMC will include the PEDSnet Director of Operations, Informatics Director, Research Director, Engagement Director, and Executive Director.

Research Director

The Research Director will be responsible for developing policies, processes, and procedures that facilitate development of research projects and their implementation. The Research Director will promote research partnerships, oversee the assignment of PEDSnet Study Approval to individual projects, and oversee the development of policies for IRB oversight for PEDSnet studies. The Research Director may develop working groups to manage some of these activities, such as an IRB/Regulatory work group to develop and oversee a Single IRB framework for the Network. The Research Director will be appointed by and report to the Executive Director.

Engagement Director

The Engagement Director will be responsible for designing, continuously improving, and overseeing the formation and engagement of PEDSnet's communities of patient, clinician, and network participants, management of the PEDSnet membership program, and the identification and development of engagement resources and tools for research projects. The Engagement Director may develop working groups to manage some of these activities. The Engagement Director will be appointed by and report to the Executive Director.

Informatics Director

The Informatics Director will provide operational leadership for PEDSnet's data network and data governance, lead DCC operations, will chair the Data Committee, and stimulate informatics innovations that advance the goals of PEDSnet. The Informatics Director may develop working groups to manage some of these activities. The DCC Director will be appointed by the PEDSnet Principal Investigator.

PMC Meetings

The PMC will meet on a weekly basis. Meetings will be chaired by the Director of Operations.

2.8 INSTITUTIONAL TEAMS

Each Founding Member Institution will assemble several individuals to form an Institutional Team. These individuals will represent the Institution in various PEDSnet Committees and Work Groups, and will conduct the business of PEDSnet within their own institution. The composition of Institutional Teams and the role of team members is as follows:

Steering Board Member

Serves on the Steering Board as a voting member

Steering Board Alternate

Serves on the Steering Board as a non-voting member

Site Principal Investigator

Oversees PEDSnet activities within his or her Institution; serves as primary scientific liaison for institutional investigators who wish to work with PEDSnet; approve requests for their institution to serve as a PEDSnet sponsor institution; approves PEDSnet study concept submissions to the Methods Advisory Panel; serves on the PEDSnet Executive Committee;

Site Informatics Lead

Oversees data extraction, transformation, and loading into data network; supervises informatics staff; and, serves on Data Committee

Informatics Staff

Execute data extraction, transformation, and loading of data into data network; maintain local PEDSnet data mart; manage re-identification of patients for PEDSnet research studies; and, provide informatics support to conduct of PEDSnet research at their institution

Parent Partners

Participate in PEDSnet Committees and work groups; participate in PEDSnet Studies as parent partners

Project Manager

Provides administrative and project management support to Institutional Team; serves as institutional representative to PMO

IRB Representative

Serves on the Regulatory Working Group, representing the institution's regulatory interests

Legal Representative

Provides legal expertise to ad hoc PEDSnet working groups

Sponsored Project Office Representative/s (including Research Business/Finance)

Participate in ad hoc working groups related to contracting, and grant preparation and management; implement streamlined grant preparation, management (including budget), and contractual processes to increase the efficiency of PEDSnet administrative operations