

## 1 INTRODUCTION

### 1.1 PURPOSE OF THIS DOCUMENT

PEDSnet ([pedsnet.org](http://pedsnet.org)) is a network of pediatric institutions and their scientific investigators, patients, parents, clinicians, and health system leaders who collaborate to produce research that improves children's health and healthcare. This document describes the policies that govern actions of individual and institutional collaborators who participate in the creation, development, dissemination, and implementation of PEDSnet and its products.

### 1.2 WHY PEDSNET WAS FORMED

In its current state, the pediatric clinical research system generates evidence too slowly and at too high a cost. Pediatric care often relies on *hand-me-down* evidence from adult studies. Because many health conditions in childhood are uncommon, no single institution has a sufficient number of patients to produce generalizable research that can inform shared clinical decisions that are made by parents, children, and their clinicians for all pediatric health conditions. A persistent challenge is the lack of a national interconnected, multi-institutional infrastructure that can produce the volume of research that is needed to improve children's healthcare. ***PEDSnet was formed to address these challenges.***

The concept for PEDSnet was spawned at a 2009 IOM-sponsored meeting when 25 children's hospital health systems met to discuss advancing children's healthcare through a national learning health system innovation collaborative. As a proof-of-principle, an obesity [study](#) was done using 6 pediatric institutions' EHR data. Data were extracted, mapped to common data standards, and aggregated for analysis. This project paved the way toward the development of a prototype learning health system. In collaboration with the ImproveCareNow network for children with inflammatory bowel disease, PEDSnet secured a grant from the Agency for Healthcare Research and Quality (AHRQ) to build a learning network. The journey from concept to prototype to national scaling was detailed in a 2014 [article](#) published in Health Affairs.

The scaling of PEDSnet is being made possible by two [clinical data research network](#) (CDRN) infrastructure grants from the Patient Centered Outcomes Research Institute (PCORI). The CDRN program has provided PEDSnet with resources to: **(1) build effective leadership and governance** that emphasizes fiscal stewardship, patients' perspectives, and seamless sharing, and creates **policies and procedures** including a **Single Institutional Review Board model** that supports cooperation across institutions for research; **(2) create a community of engaged** patients, families, clinicians, scientists, and health system leaders involved in co-producing knowledge and know-how; **(3) standardize interoperable data** on millions of children that enables data sharing, cohort identification, and research (from proposal concept

to completed studies); **(4)** develop the **capacity to conduct** observational studies and clinical trials rapidly and efficiently using the PEDSnet infrastructure; and, **(5)** design a **sustainability model** that makes PEDSnet highly attractive to funders because of the availability of a range of standardized clinical data, longitudinal data capture, large pediatric populations, and reliable inter-operability with other research networks.

As a CDRN, PEDSnet is a member of [PCORnet](#), which is a consortium of [CDRNs](#), including PEDSnet, and [Patient-Powered Research Networks](#). These Networks are working together to create a national clinical and health services research resource. PEDSnet is the only CDRN within PCORnet focused exclusively on children.

### 1.3 WHAT PEDSNET DOES

#### 1.3.1. MISSION

**Mission Statement:** PEDSnet conducts multi-institutional pediatric research that informs clinical care and contributes to a national learning health system that enhances health for all children.

To accomplish this purpose, PEDSnet makes multi-institutional pediatric clinical research faster and less expensive, engages multiple stakeholders in the research process, and generates new knowledge that informs the decisions that patients, clinicians, and health system leaders make each day to improve the health and healthcare of children and adolescents.

PEDSnet has adopted the learning health system (LHS) model for improving health and healthcare. The essential attributes are:

1. Clinical **communities** of patients, families, front-line clinicians, researchers, and health system leaders who collaborate to produce and use pediatric health care data;
2. Access to extensive electronic health and health care **data**;
3. Observational **research** and clinical trials done in routine clinical care settings; and
4. Quality **improvement** at the point of care brought about by the integration of relevant new knowledge generated through research.

The learning health system is dependent on the active collaboration of all its members, and success is defined by its impact on the health and lives of patients. PEDSnet's focus is on facilitating the conduct of efficient multi-institutional pediatric research, and on research that evaluates alternative approaches for implementing evidence at the point of care.

### 1.3.2 VISION

**2018 Vision Statement:** To be the premier multi-specialty national pediatric clinical network for conducting research in routine healthcare settings.

**2018 Vision Summary:** By the end of 2018, PEDSnet will be recognized as the premier multi-specialty national pediatric clinical network for conducting research in routine care settings. It will be able to access health and healthcare data for several million of the nation's children. Having completed or launched interventional and observational research studies, PEDSnet will have secured a diverse portfolio of federal and private sector funding. It will have created a variety of governance, technical, scientific, and engagement resources that many investigators and institutions have used to conduct efficient pediatric clinical and health services research. PEDSnet will have forged relationships with strategic partners, including several PCORnet Clinical Data Research Networks and Patient-Powered Research Networks that have organized to catalyze the formation of a distributed, national pediatric learning health system. PEDSnet will have transitioned from sole support from the Patient Centered Outcomes Research Institute to a sustainable business model that ensures its long-term sustainability.

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### 1.3.3 STRATEGIC GOALS

PEDSnet will realize its 2018 vision by pursuing five strategic goals, which the PEDSnet Steering Board adopted in November 2015.

1. Develop the most comprehensive and complete pediatric data network in the US;
  2. Become a highly efficient and high throughput pediatric clinical and health services research network;
  3. Attain financial sustainability without additional infrastructure funding from PCORI;
  4. Accelerate the development of an emerging national-scale pediatric learning health system; and
  5. Provide training opportunities for investigators interested in the science of learning health systems.
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