

PCORnet, the National Patient-Centered Clinical Research Network

Phase I Achievements: Progress in Transforming the Vision and Culture of Clinical Research

[PCORnet](#), the National Patient-Centered Clinical Research Network, is an innovative initiative of the Patient-Centered Outcomes Research Institute (PCORI). It is designed to make it faster, easier, and less costly to conduct clinical research than is now possible by harnessing the power of large amounts of health data and patient partnerships. In the process, it is transforming the culture of clinical research from one directed by researchers to one driven by the needs of patients and those who care for them.

PCORnet is building the means to securely access information on the health experiences of tens of millions of patients and hundreds of health care organizations for research purposes, tapping resources like electronic health records (EHRs), insurance claims, outcomes reported by patients themselves, and other data. PCORnet is engaging thousands of patients and care providers, and hundreds of health systems, in collaborative partnerships to determine how to use the national network's data resources and access to patient populations. Patients are centrally involved in PCORnet's governance.

PCORnet's development began in December 2013 with approval by PCORI's Board of Governors of funding for the initial group of member networks. The 18-month first phase of development began in early 2014 and ran through September 2015. Here are highlights of progress made during Phase I.

Key Achievement: Building a Unique "Network of Networks"

PCORnet's power -- and what sets it apart from other research networks -- is its potential to conduct research using healthcare information and experiences from tens of millions of patients representing the diversity of the American population and "real-world" healthcare settings. This is made possible by the breadth and reach of the member networks that comprised PCORnet during Phase I.

- 11 Clinical Data Research Networks (CDRNs), partnerships among clinics, hospitals, and healthcare systems to develop research-ready data from sources such as electronic health records (EHRs) and insurance claims. Most of these networks involve multiple hospitals, clinics, and other healthcare organizations, extending their reach across many states.
- 18 Patient-Powered Research Networks (PPRNs), partnerships formed by patients, their caregivers and advocates, and research partners with an interest in a particular condition or population, and willing to share information with each other and researchers to improve health outcomes.

Networks joined PCORnet at various stages of their own development. During Phase I, PCORnet supported the further development or expansion of the individual networks and drew them together to advance common goals and shared activities. These goals include building a resource that can be used by researchers nationwide, those affiliated with PCORnet as well as others over time.

Key Achievement: Creating Models for Engagement of Patients, Other Stakeholders

All partner networks have engaged patients and other end-users of research results in all aspects of data collection and use and network governance. In this way, PCORnet is facilitating a shift in clinical research from an investigator-driven model to one more responsive to patients and those who care for them.

Patient engagement:

- Two patient representatives on the PCORnet Executive Committee.
- Eight patient representatives on the PCORnet Steering Committee.
- A PCORnet Patient Council made up of 7 patient representatives from CDRNs and PPRNs.
- Patient principal investigators or co-principal investigators for many CDRNs and all PPRNs.
- All CDRNs and PPRNs conducted robust patient engagement activities at the individual network level, creating models for community engagement to build on research collaborations.

Health system engagement:

- Health Systems Engagement Taskforce organized workshops to engage with leaders of health systems from across the nation, many already affiliated with PCORnet CDRNs.
- Workshops served as the basis for the Health Systems Research Demonstration Project that will be implemented during Phase II.
- PCORnet Advisory Group with representatives of federal and industry partners and others created to help set PCORnet-wide research prioritization agenda.

Key Achievement: Developing a Large Health Data Resource

Phase I CDRNs and PPRNs were selected, in large part, because they had established or potential capacity to access data about patients and engage patients interested in participating in research.

The participating networks made substantial progress in Phase I in enrolling people into their networks, standardizing data, and creating processes for making data useful for research. Although these activities will continue through Phase II, by the end of Phase I, the participating networks had:

- Developed collections of data representing roughly 75 million patients that could be used in research while protecting patients' privacy and security. These collections include:
 - Data from about 60 million patients, with records dating back at least five years, that could be used for observational studies.
 - Access to about 20 million patients who could be invited to participate in interventional research studies.
 - Information on individuals in several categories of conditions important for research:
 - About 16.7 million people who meet obesity criteria
 - About 2.7 million individuals who meet common disease criteria
 - More than 26,000 individuals who meet rare disease criteria.
- Contacted more than 3 million individuals for more in-depth surveys about their conditions, characteristics and interest in participating in future studies.

Key Achievement: Making Health Data “Research Ready” While Protecting Privacy, Security A significant obstacle to harnessing the power of health data to drive more efficient patient-centered

research is that different data sources enter and store data in different formats, based on their individual needs and practices. To realize PCORnet's potential to enable the nation to conduct larger, faster, more impactful studies at lower cost, data must be available in a "common language" so partner networks' data systems can "talk to" each other and the data from one network can be joined with that from another. PCORnet addressed this challenge by developing the [PCORnet Common Data Model](#).

Partner networks also developed the means to use a standard Internet-based tool called [PopMedNet](#) to "ask" each network if its data can help answer research questions. PopMedNet has passed independent security audits and it allows users to conduct data quality checks.

Use of the Common Data Model (CDM) and PopMedNet provide standardization that will:

- Allow PCORnet member networks to provide much faster responses to research questions.
- Allow data to "stay at home" within the individual CDRNs and PPRNs until needed for a specific study, and then only the minimum necessary data elements are shared.
- Ensure security and data quality
- Facilitate collaborations – the CDM and PopMedNet are compatible with and complementary to other widely used CDMs and query approaches.

Key Achievement: Readiness to Conduct Research and Launch of Demonstration Studies

Individual CDRNs and PPRNs were not expected to conduct any research activities during Phase I but to be "research ready" at the start of Phase II. However, several large-scale PCORI-funded demonstration projects were approved during Phase I to test PCORnet's capabilities and answer key research questions:

- [ADAPTABLE \(Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness\)](#), a prospective randomized trial comparing the benefits and harms of a low- and regular-strength daily dose of aspirin to prevent a recurrence of heart attack or stroke in patients with heart disease. The trial will involve 20,000 patients and seven CDRNs, one PPRN and the Coordinating Center.
- [The PCORnet Obesity Observational Study](#) will investigate the effects of antibiotic usage during the first two years of life on children's growth and risk for obesity. The study will use clinical records on 1.6 million children maintained by nine CDRNs representing 42 healthcare systems.
- [The PCORnet Bariatric Study](#), another observational study, comparing the benefits and risks of the three most commonly used types of weight loss surgery, focusing on outcomes that are important to adults and adolescents with severe obesity. It will review records from 60,000 patients who had one of these three procedures in the past 10 years and involve 10 CDRNs, including 53 healthcare organizations.

In addition, PCORI's Board approved a large pragmatic clinical study of treatment options in pediatric Crohn's disease that will use PCORnet resources.

Key Achievement: Building Unique and Productive Partnerships

Phase I saw substantial collaboration among and between PCORnet partner networks, some planned but much that was unanticipated. There were 23 collaborations among CDRNs and 64 between CDRNs and PPRNs. Several of collaborations occurred during Phase I:

- Sharing of engagement and recruitment approaches and tools between networks.
- Shared development of novel data acquisitions tools, such as social networking platforms and remote sensing devices.
- Development and adoption of validated measures, for collecting patient-reported outcomes.

Examples:

- Through a partnership with the [PARTNERS PPRN](#) focused on pediatric arthritis, the [SCILHS CDRN](#) has begun to include patient data on various forms of juvenile arthritic conditions for the first time.
- The [LA CDRN](#) provided the [PI-CONNECT PPRN](#) with summary data on patients diagnosed with Common Variable Immune Deficiency and together the networks developed a manuscript describing the types of specialists within the LA CDRN that treat patients with this condition.
- The [CAPriCORN CDRN](#) has projects under development with the [AR-POWER PPRN](#) and [NYC CDRN](#) to examine the effects on safety of narrow versus open selection of joint replacement devices.
- The [NYC CDRN](#) has been actively collaborating with several PPRNs in areas such as scalable approaches to identify and engage patients and clinicians.

Key Achievement: An Evolving Governance Model to Fit a Maturing Network

As PCORnet matured during Phase I, its governance structure was revised to meet an evolving need for CDRN and PPRN representatives to be more directly involved in day-to-day decision making. A new [Governance Policy](#) laying the groundwork for this approach was developed and adopted by the former PCORnet Steering Committee in August 2015.

Under this policy, the main decision-making body is now the [PCORnet Council](#), which is comprised of one representative from each CDRN and PPRN, and one each from the Coordinating Center and PCORI. The Council replaces the PCORnet Steering Committee, which consisted of the principal investigators of all CDRNs and PPRNs, representatives of the Coordinating Center and PCORI, and representatives from 14 PCORI stakeholders such as relevant government agencies and industry.

In addition, in Phase I, an [Executive Committee](#) formed to address the need for nimble decision-making. In Phase II, an Executive Committee remains and three committees focused on the most crucial activities of Phase II – data, engagement, and research – have replaced the previous 11 task forces from Phase I.