

PCORnet, the National Patient-Centered Clinical Research Network

Plans for Phase II: Leveraging Resources and Building on Progress

[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 healthcare 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. PCORnet is being expanded in a second phase of development launched in fall 2015. Following are highlights of plans for strengthening PCORnet during its three-year Phase II, which runs through September 2018.

Key Goal: Strengthen Member Networks and PCORnet-Wide Diversity

PCORnet's power—and what sets it apart from other research networks—is its potential to conduct clinical 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 comprise PCORnet in Phase II.

The 33 individual networks funded under Phase II include most of those that participated in Phase I. Six additional established networks, with the capacity to quickly integrate into PCORnet, were funded to be part of PCORnet in Phase II. These six complement those whose funding was renewed and include two focused on specific populations—under-resourced groups with behavioral healthcare needs and gender and sexual minority groups—rather than conditions. PCORnet is now comprised of:

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

Through these partner networks, PCORnet can provide health data on more than 150 conditions and diverse population needs and potentially offer access to millions of patients interested in research.

Key Goal: Conduct a Range of Research Projects, Demonstrate PCORnet's Capabilities

Even in the case of well-established and mature research networks, PCORnet continues to stimulate and support new areas of collaboration and research, such as new or enhanced methods of engagement with patients, clinicians and healthcare systems administrators, and the addition of new types of research data, such as patient-reported outcomes focused on the needs of specific patient populations.

Three major PCORI-funded studies approved during Phase I are being conducted during Phase II, using PCORnet's assets to answer key patient-centered questions and test the network's capabilities to conduct both interventional and observational studies. These include:

- A randomized trial focused on daily aspirin for people with cardiovascular disease.
- Two observational studies focused on weight loss surgical procedures and the association between antibiotics and childhood obesity, respectively.

PCORI has funded or plans to fund several additional research projects to further test PCORnet's capabilities and answer key questions. These include:

- Participation in the Natural Experiments Network, a joint CDC-NIH initiative, will enable CDRNs to participate in population health research on the impact of policies and other changes in societal conditions that can affect health.
- PPRN Demonstration Projects will focus on patient-identified research questions on conditions important to the PPRN community and accelerate collaborations among PPRNs.
- Health Plan/System Data Partnership, which will strengthen partner networks' ability to capture complete healthcare data on their populations, spanning longer time periods and care settings, by forging data-linking partnerships with health insurance plans.
- PCORnet Health Systems Demonstration Projects, which will enable member networks and health systems leaders to jointly identify and prioritize a set of data-driven research activities of high interest to health systems and clinicians.

Key Goal: Streamline Processes to Promote Efficient Research

During Phase II, PCORnet will implement and test a range of tools and procedures that aim to streamline the process of conducting clinical research and fulfill its potential to support faster, less costly studies.

These include:

- PCORnet Master Contract – As part of conducting the demonstration studies, PCORnet will test the use of master contracts that will reduce administrative burden on the networks.
- PCORnet Commons – PCORnet will expand this collection of shared tools, knowledge, expertise, and processes generated by the CDRNs and PPRNs.
- PCORnet-Wide Institutional Review Board (IRB) and Uniform Contracting Processes – PCORnet will leverage member networks' experiences in developing approaches for streamlining IRB and contracting processes and offer such processes for PCORnet-wide use.

Key Goal: Increase Collaborations within PCORnet and with the Wider Research Community

Based on the substantial levels of collaboration among PCORnet partner networks during Phase I, all networks are fostering increased collaboration efforts in Phase II. PCORI and the governance of PCORnet is supporting these efforts, which include interactions among CDRNs and PPRNs and between CDRNs and NIH-sponsored Clinical and Translational Science Award (CTSA) recipients, among others. Continuing or newly proposed collaborations include:

- CDRN-PPRN partnerships to:
 - Develop and share tools that facilitate input from patients and other stakeholders in the prioritization of research questions
 - Engage and co-enroll patients, including those with rare diseases
 - Develop research proposals for submission to PCORI and other funding organizations.
 - Develop, validate, and implement data de-duplication mechanisms.
- PPRN interactions to share messages and techniques to increase recruitment.

PCORnet aims to be a resource for studies funded by public and private agencies and foundations, healthcare delivery systems, health insurance plans, and pharmaceutical and medical device industries. It also aims to broker partnerships between these research customers and PCORnet researchers.

To facilitate use of PCORnet as a national resource, PCORnet will establish an institutional “front door” by which researchers not affiliated with partner networks can propose research questions and topics.

Key Goal: Continue to Expand Data Resources

During Phase II, PCORnet member networks will continue to add data and data categories to the PCORnet Common Data Model. Significant efforts are under way to engage with America’s Health Insurance Plans (AHIP), FDA’s Sentinel program, and the Centers for Medicare and Medicaid Services (CMS), to prepare networks for high-quality observational studies and clinical trials, as many of their proposed methods are being tested for the very first time.