



## Patient-Centered Outcomes Research Institute National Patient-Centered Clinical Research Network

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### **The Concept**

The Patient-Centered Outcomes Research Institute (PCORI) seeks to develop a National Patient-Centered Clinical Research Network to improve our capacity to efficiently conduct comparative clinical effectiveness research (CER). The proposed network would unite patients, researchers, and healthcare systems, and support rapid, effective observational and interventional studies with active participation from a broad patient population.

CER can play a significant role in improving the volume and quality of information available to patients, caregivers, clinicians, and other healthcare professionals. A national data-rich infrastructure to support high-quality, efficient CER will benefit all Americans.

PCORI envisions a large, representative, and sustainable national research infrastructure with multiple components, including healthcare systems, Clinical Data Research Networks (CDRN), and Patient-Powered Research Networks (PPRN) with rich clinical data drawn from electronic health records (EHR) and other data sources captured and stored in standardized, interoperable formats. Central to this vision is the participation—in designing and managing the network—of healthcare systems, clinicians, and activated communities of patients, including both those who receive care within the systems and those who might simply wish to participate in research.

Over time, the PPRNs and CDRNs will become more integrated as a result of activating and engaging patients within multiple healthcare systems and obtaining richer clinical data on members who receive their care outside of participating systems.

### **Making the Vision a Reality**

This initiative, which builds on a number of prior efforts to craft large clinical research networks, falls under one of PCORI's five broad National Priorities for Research, "Accelerating Patient-Centered and Methodological Research." To establish the network, PCORI will provide support through funding a broad network of CDRNs and PPRNs, as well as a Coordinating Center, which will provide management support for collaborative projects, technical resources, meeting support, and program evaluation.

The network will be governed by a Steering Committee comprised of PCORI representatives, network members, federal funders of clinical research, data owners and experts, and patients. A Scientific Advisory Board and a Special Expert Group will provide additional support and guidance.

The network's governance structure ensures that the major contributors—health systems, clinicians, and patients—play key roles in governing the direction and uses of this infrastructure, and that the interests of patients remain central in decision making about policies, practices, and uses of the network.

### **Components of the National Patient-Centered Clinical Research Network**

- **Clinical Data Research Networks (CDRN)** are system-based networks (originating in healthcare systems such as hospitals, health plans, or practice-based networks) with the potential to become components of a national electronic network, without structural impediments to conducting research. CDRNs will strive to stimulate broader participation of patients, clinicians, health systems, and payers in developing, governing, and using large databases of clinical information; facilitate rapid, efficient conduct of both randomized trials and observational studies within care delivery systems using the network infrastructure; and promote and support greater collaboration and data sharing between networks based on standardized, interoperable data structures.
- **Patient-Powered Research Networks (PPRN)** are groups of patients interested in forming a research network and in participating in research, both observational and randomized. PPRNs are intended to further explore patient-centered approaches to network governance; research topic selection; research recruitment and participation; inclusion of broad, diverse, activated patient communities; and interoperability with other elements in the national patient-centered clinical research network.
- The **Coordinating Center (CC)** is an organization that connects all CDRNs and PPRNs while implementing and supporting Steering Committee policies and procedures. An organization serving as the Coordinating Center may not receive a CDRN or PPRN award.
- The **Steering Committee (SC)** is an inclusive group that works collaboratively in developing a national research infrastructure. The SC, which includes PCORI leadership, will make decisions on policies, best practices, methods, and standards to assure progress toward the vision of an efficient and interoperable network of CDRNs and PPRNs, with the support of the Coordinating Center.
- The **Scientific Advisory Board (SAB)** consists of PCORI Methodology Committee members and external independent experts in the fields of CER using clinical data, health informatics, epidemiology, biostatistics, and analytic and database methodology. It will provide advice and guidance and oversee the evaluation process for the network.
- The **Special Expert Group (SEG)** will be available to provide advice, as requested, to awardees and those governing the overall initiative. The SEG will consist of representatives of industries with an interest and expertise in informatics, social media, collection of patient-reported outcomes, and the conduct and use of comparative effectiveness and safety research using clinical networks.