



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Summary of Responses from a Request for Information: Input on Research Networks

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About PCORI

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization and is charged with helping patients, clinicians, purchasers, and policy makers make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.” It does this by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI’s strong patient-centered orientation directs attention to individual and system differences that may influence research strategies and outcomes. PCORI is charged with producing useful, relevant clinical evidence through the support of new research and the analysis and synthesis of existing research.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work.

DISCLAIMER

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Patient-Centered Outcomes Research Institute
1828 L St., NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700
Fax: (202) 355-9558



Email: info@pcori.org

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INTRODUCTION

The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients and their providers make more informed decisions. As part of this mission, PCORI is committed to supporting the creation of a robust, sustainable National Patient-Centered Clinical Research Network (NPCCRN) to improve the nation's capacity to conduct comparative effectiveness research (CER) quickly and efficiently.

In November 2012, PCORI issued a Request for Information (RFI) about Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs), the two core components that will comprise the NPCCRN. This RFI invited stakeholders from the broad healthcare community to provide us with their input about existing health and healthcare data networks, and the potential for these research data networks to provide opportunities for conducting efficient and effective PCOR.

In April 2013, PCORI released two funding announcements committing \$68 million to facilitate the development of this network:

- **Clinical Data Research Networks (CDRNs)** link clinical, patient-level data on diagnoses, treatments, covariate information, bio-physiologic measures and clinical outcomes from multiple healthcare delivery systems or data sources. Data sources may include data archived from electronic health records, claims, referrals and other computerized sources of patient-level information. PCORI seeks to leverage the prior experience of existing CDRNs and to encourage newer networks that meet certain criteria to advance the vision of a sustainable national research infrastructure.
- **Patient-Powered Research Networks (PPRNs)** are groups of patients and caregivers that are linked by a common condition, who have assembled virtually or through some other means, to provide their own patient-reported data and facilitate patient-generated healthcare research. PPRNs allow patients to share data on their health-related experiences, address questions raised by network members, and participate in formal research studies. In order to be considered for funding, PCORI requires that these groups be governed by the participating patients. PPRNs are intended to further explore patient-centered approaches to network governance, research topic selection, research recruitment and participation, and inclusion of broad, diverse, activated patient communities. It is expected that their participation in the PCORI Research Infrastructure Program will prove useful for increasing participation of patients covered within CDRNs, and for addressing specific challenges including governance and data use, recruitment and informed consent, and collection of patient reported data.

This document summarizes the input received from respondents to PCORI's RFI. The input that was provided by respondents helped to inform PCORI's PPRN and CDRN funding announcements.



EXECUTIVE SUMMARY

The Request for Information (RFI)—Input on Research Networks, yielded responses from 36 organizations including clinical networks, patient networks, and registries. Key findings from the RFI have been helpful to PCORI as it developed its infrastructure funding announcements to support a robust, sustainable National Patient-Centered Clinical Research Network (NPCCRN). These responses have provided PCORI with information about what is both realistic and feasible as we support the growth of these networks beyond their current infrastructures. Additionally, the information received from the RFI respondents will help PCORI create evaluation criteria that will support the contract awardees in making substantial improvements in their networks for PCOR, but will also provide a helpful framework by which awardees will be monitored and held accountable for the final product.

CDRNs and PPRNs are looking for ways to achieve a stronger, more sustainable platform for PCOR, and there is a clear opportunity for these groups to partner to build together. PPRNs bring the power of activated patients interested in using data to improve their own health outcomes, and CDRNs can provide the infrastructure to collect, process and evaluate data to drive patient-centered outcomes. A common thread among CDRN and PPRN respondents was that engaging patients was seen as important, but will require time and resources to achieve successfully.

This summary report provides a brief overview of the findings from the RFI responses and is organized as follows:

- **RFI Respondents:** includes acknowledgements of all RFI respondents, and an overview of the characteristics of the responding networks
- **Patient Involvement in Governance:** describes the current capacity and opportunity for networks to involve patients in network governance and decision making
- **Network Capabilities and Budget Considerations:** details the budget, size, and capabilities of CDRNs; there is no cost data for PPRNs, however a separate assessment of their network capabilities is available for comparison with CDRNs
- **Informed Consent:** describes the work that select CDRNs are engaged in to streamline processes related to ethical issues and informed consent

Limitations of this assessment draw mostly from the small sample size of voluntary respondents. For the full list of questions asked in the RFI, please see page 6 of the original [RFI](#).



RFI RESPONDENTS

PCORI would like to thank the 36 respondents who provided information about their networks. Information about each respondent has been de-identified throughout this summary. We have provided a list of responding networks below to publicly acknowledge their much appreciated efforts and assistance:

- Adult Congenital Heart Association
- American Orthotic & Prosthetic Association (AOPA) Association
- Association of Asian Pacific Community Health Organizations
- Association of Departments of Family Medicine
- CERTAIN Washington State
- Childhood Arthritis and Rheumatology Research Alliance Registry Network (CARRAnet)
- Clinico-Genomic Data Networks: eMERGE, PAGE Consortium, PGRN, IMSGC, IIBDGC, COGENT, CCGCRN, PHGEN, SHRINE
- Colorado Associated Community Health Information Enterprise
- Community Health Applied Research Network (CHARN)
- Comparative Effectiveness Research through Collaborative Electronic Reporting (CER2)
- Connecticut Center for Primary Care, Inc. (CCPC/ProHealth)
- High Value Health Care Collaborative
- HMORN
- HOMERuN
- Informed Medical Decisions Foundation: A Shared Decision Making Learning Collaborative
- Large Urology Group Practice Association
- Learning Networks Core at Cincinnati Children's Hospital Medical Center (CCHMC)
- Mental Health Services Oversight and Accountability Commission, California
- MURDOCK Study Community Registry and Biorepository (Duke)
- Northern New England Perinatal Quality Improvement Network and OBNeT LLC
- OCHIN-PBRN
- Patients Like Me
- Pediatric Emergency Care Applied Research Network
- PHIS+: Augmenting the Pediatric Health Information System with Clinical Data (Children's Hospital of Philadelphia)
- PopMedNet (PMN) Networks
- PPRNet/Medical University of South Carolina (MUSC)
- PrimeRESEARCH/Greenway
- PRISE Research Network (University of Utah)
- Research Match (CTSA)
- Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI)
- The Children's Hospital of Philadelphia Research Consortium
- The Dartmouth Institute
- The Schizophrenia and Related Disorders Alliance of America (SARDAA)
- Upstate New York Practice-based Research Network (UNYNET) and Patient Voices Network (PVN)
- Wisconsin Network for Health Research



- WWAMI (Washington, Wyoming, Alaska, Montana, and Idaho) Region Practice and Research Network (WPRN) and DataQue

Type of network: Of these 36 respondents, the vast majority, (27 networks) were categorized as CDRNs, two respondents were categorized as PPRNs, and three were established organizations that could not be categorized as either CDRNs or PPRNs, but offer specialized services in the field of research. The four remaining respondents consisted of networks that are not yet established but have plans for development.

Geographic reach: The respondents included patient representation from 47 states across the United States. A number of respondent networks included patients from several states; for example, one network with a pediatric focus includes hospitals and pediatric centers from 43 states in the US, as well as three provinces in Canada. The states not represented by the responding networks are Kentucky, South Dakota and Rhode Island.

Clinical condition focus of the responding networks: Respondents were asked to provide information about the specific conditions of patients covered within their networks. While 25 of the 36 respondents (69%) maintain networks with no specific disease focus, it is worth noting that five of the 36 total responding networks (14%) focus exclusively on pediatric patients—both the general pediatric population, and specific condition(s). Conditions commonly covered by the networks include cardiovascular, oncology, metabolic, pulmonary, neurological, mental health, bone and joint and gastrointestinal conditions. Cardiovascular conditions include, but are not limited to, hypertension, heart failure, and coronary heart disease. Metabolic conditions include obesity, diabetes, high cholesterol and thyroid conditions. Pulmonary conditions include asthma, chronic obstructive pulmonary disease, lung disease, and cystic fibrosis. Mental health conditions primarily include depression, autism, schizophrenia and ADHD, while neurological conditions included multiple sclerosis, Alzheimer’s disease and stroke. Bone and joint conditions included arthritis (in adults and in children), osteoporosis, back pain and child rheumatic conditions. Gastrointestinal conditions primarily included inflammatory bowel disease, Crohn’s disease and urological conditions. Other, less common conditions indicated in the RFI responses include surgical site infections, and conditions associated with orthotics and prosthetics.

Years of existence of responding networks: The table below provides the distribution of the number of years the responding networks have been in existence. The majority of networks were established within the last five years. Because the question related to the age of the network was interpreted in multiple ways, the years included below correspond to the onset of patient enrollment within the network (when this information was reported). Some respondents reported the age of smaller networks within the larger/umbrella network, so the total sample for the table below exceeds 36, the total number of respondents to the RFI. Additionally, respondents that do not yet have an established network were excluded from this assessment.



Distribution of Age of Respondent Networks

Year network was Established	Total Number of Responding Networks Established in this Timeframe	Percent of Total Responding Networks Established in this Timeframe
2007 - 2012	17	42.5%
2001 - 2006	9	22.5%
1995 - 2000	1	2.5%
1989 - 1994	0	0%
1983 - 1988	2	5%
1982 - 1987	1	2.5%
NA/No response	10	25%
	Total = 40	Total = 100%

Size of responding networks: The table below provides the distribution of the size of the responding networks. One of the responding PPRNs falls into the size category of 100,000 – 499,999 individuals, and the other responding PPRN falls into the size category of 1,000 to 19,999 individuals. Some respondents reported the size of smaller networks within the larger/umbrella network, which is reflected in the table below. Respondents that do not yet have an established network were excluded from this assessment.

Distribution of Size of Respondent Networks

Size of Network (Number of Individuals Included)	Total Number of Responding Networks of this Size	Percent of Total Responding Networks of this Size
>1M (largest network is 5 million individuals)	7	23.3%
500,000 - 999,999	2	6.7%
499,999 - 100,000	5	16.7%
99,999 - 50,000	1	3.3%
49,999 - 10,000	2	6.7%
9,999 - 1,000	2	6.7%
<1,000	3	10%
NA/No response	8	26.7%
	Total = 30	Total = 100.1% (with rounding error)

PATIENT INVOLVEMENT IN GOVERNANCE

Patient involvement in governance and decisions about the uses of network data is necessary in order to maintain a patient-centered focus for research. Involving patients in the governance structure ensures that patients' voices are heard, that data is being used in the interest of the patients, and that patient-centered outcomes are achievable. The RFI inquired about the current involvement of patients in the governance of these research data networks.



Of the twenty-nine currently operating networks that responded to the RFI, only two of the networks engage patients in a full decision-making capacity. While the majority of networks did not include patients in broad governance roles, they did report involving patients in advisory panels, or in other one-time projects to inform policies and procedures. PPRN respondents did not provide information regarding the the level of patient involvement in the governance of their networks. Many respondents that did not have patients involved in governance noted the importance of engaging patients more deeply in future network decisions.

PATIENT ENGAGEMENT IN NETWORK GOVERNANCE, KEY ACTIVITIES

Level of Involvement in Patients in Governance of the Network	Total Number of Networks Engaged in this Level of Governance (n = 29)	Percent of Total (n = 29)
Total patient involvement in governance (patient/consumer Board members)	2	7%
Patients/consumers involved through Advisory Panels, and other structured feedback roles*	6	21%
Ad hoc patient involvement**	4	14%
Patients not involved	9	31%
Information not available	8	28%
	Total = 29	Total = 101% (with rounding error)

*Examples include Patient Advisory Panels and Research Advisory Groups that regularly perform structured activities to provide advocacy and a voice for all patients, in addition to stakeholder groups that provide feedback through mechanisms, such as web forums; while networks included in these categories do not have a governance structure that includes patients, networks with patients involved in Advisory Groups and Panels have emphasized in their responses that patient feedback is seriously considered in major decisions

**Ad hoc patient involvement includes patient voices in projects and planning on a case-by-case basis, but without the additional structure to ensure regularity and the voice of a decision maker

NETWORK BUDGETS

Fourteen network respondents answered questions regarding the following budgetary considerations:

- Cost to maintain the network
- Total annual budget for research operations

In comparing the costs to maintain each network with the number of individual patients included in the network, there is large variation among networks in dollars spent per individual. This could be due to differences in the overall capacity and complexity of the networks, or the level of efficiency at which each network operates.



Assessment of Network Capabilities: CDRNs Only

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Cost to maintain network	\$9M for 3 years	Varies	\$170K /year	\$425K /year	\$241K	\$5.28M / year	\$245K /year	\$500 to \$20K	\$800K	NA	\$800K /year (2012)	\$666K /year	See below*	\$6.8M NIH grant to est. network
Total annual budget for research operations	\$2.9M	\$400K	\$15M	\$2M	\$2M	\$5M	\$367K	\$650K	\$800K	\$1M	\$800K	\$250-350K	See below*	Varies
Year network was established	2010	2002	2001	2007	2002	2001	2001	2003	2009	2012	2009	1987	2007	2009
Approximate number of individual patients included in the network ((except for where respondent indicated number of procedures)	> 1M	350,000	450,000	5M	200,000	1.2M	1.2M	60,000 procedures	50,000	800,000	50K	N/A	See below*	<10,000
Capacity to follow patients, track meaningful changes over time	Yes	Yes	Information not provided	Yes	Yes	In development	Yes (for patients at select clinics)	Yes, but limited	Not yet	Yes	Not yet	Yes	Yes, all but one network*	Yes
Use of mobile	Informa	In	No	Experi	Yes -	Yes	Plans in	Yes	No	Yes	Looking	Looking	Piloting	Pilot



	1	2	3	4	5	6	7	8	9	10	11	12	13	14
devices, technologies for improving collection, analysis, application of patient-reported data?	-tion not provided	development		menting with partners	Patient Portal	(early stages)	place to develop				at options	at options	capture via SMS tools	phase
Potential to grow on current infrastructure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Network linked to/working in collaboration with larger system(s)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Exploring possibility with payers	No	Yes	Exploring possibilities	Yes	Yes	No, but has capacity
Policies in place to share data with other systems and groups	Yes	Yes	Limited	Yes	Yes	Yes	Yes	Limited	No	No	No	Limited	Limited (usually not shared outside of network)	Yes



Capacity to randomize data and populations to be included in RCTs/cluster trials	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not done yet, but has potential			
Capacity to store genetic data or biomarkers, and apply this information for purposes of PCOR?	No	No	No	No	Yes	Yes	Yes, if data stored in EHR	Yes	No	One member network can do this	No, but has the potential to do so with right partner			Yes
Reusability of network resources	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
Involvement in QI and clinical care delivery	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not yet

Assessment of Network Capabilities: Smaller Network within Larger/Umbrella Network (listed above as network # 13)

	13 a	13 b	13 c	13 d	13 e
Cost to maintain network	\$1.2M/year	\$350-400K/year	\$320K/year	\$2M/year	\$600K/year
Total annual budget for research operations	\$2M/year	NA	\$52,394/year	NA	NA
Number of individual patients included in the network (general population, unless condition indicated)	15,000 pediatric patients over 50 sites, 27 states, and one site in England	772 pediatric patients with one rare disease over 46 sites, 27 states	845 pediatric patients with one rare disease over 10 sites, 9 US cities, 1 Canadian city	Network of eight children's hospitals which saved an est'd 3,576 children from harm	Volume unclear, but goal to collect data on 140K annual births in state of Ohio

NETWORK CAPABILITIES

The following table presents the level of achievement of specific network capabilities, by proportion of total CDRN respondents. One note of interest is that 100% of the networks cite reusability of network resources, demonstrating potential for efficiency and sustainability. Potential opportunities for CDRNs include increasing the capacity to store genetic data or biomarkers for use in PCOR studies, and increasing the use of mobile devices and other emerging technologies for patient-reported data.

Assessment of CDRN Capabilities

CDRN Capability	Yes	In development/ planning	No/Not Yet	Information not available/not provided
Capacity to follow patients, track meaningful changes over time	71%	7%	14%	7%
Use of mobile devices, technologies for improving collection, analysis, application of patient-reported data?	29%	50%	14%	7%
Potential for infrastructure to be scalable	100%	0%	0%	0%
Network linked to/working in collaboration with larger system(s)	71%	14%	14%	0%
Policies in place to share data with other systems and groups	50%	29% (Limited policies/data not usually shared outside network)	21%	0%
Capacity to randomize data and populations to be included in RCTs/cluster trials	64%	0%	36%	0%
Capacity to store genetic data or biomarkers, and apply this information for purposes of PCOR?	43%	0%	0%	57%
Reusability of network resources	100%	0%	0%	0%
Involvement in QI and clinical care delivery	86%	0%	14%	0%

The following table has been provided to illustrate the capabilities of the responding PPRNs. The data indicates that both responding PPRNs are able to reuse the data they collect for subsequent studies. A potential opportunity for PPRNs moving forward will be the ability to harness the complementary capabilities that CDRNs and other PPRNs offer in order to create synergies and additional efficiencies. Due to the fact that only two PPRNs responded to this RFI, the data presented in this table is presented specifically for each PPRN respondent, as compared to the CDRN table above which presents capabilities by proportion of respondents.

Assessment of PPRN Capabilities

PPRN Capability	1	2
Cost to maintain network	NA	NA
Total annual budget for research operations	NA	NA
Number of individual patients included in the network (general population, unless condition indicated)	5000 consumers; 4500 of which have the same/similar conditions	170,000 consumers; more than 1500 conditions
Capacity to follow patients, track meaningful changes over time	NA	Yes
Use of mobile devices, technologies for improving collection, analysis, application of patient-reported data?	Yes	NA
Potential to grow on current infrastructure	No	NA
Network linked to/working in collaboration with larger system(s)	No	NA
Capacity to randomize data and populations to be included in RCTs/cluster trials	No	NA
Capacity to store genetic data or biomarkers, and apply this information for purposes of PCOR?	No	NA
Year network was established	2008	2004
Reusability of network resources	Yes	Yes
Involvement in QI and clinical care delivery	No	NA

INFORMED CONSENT

Informed consent and ethical considerations are critical to any network working with human subjects participating in research. However, the way in which a network manages these issues holds implications for the efficiency and scalability of the network. For example, streamlined policies and centralized functions may enable consent to be acquired only once. The following list describes the ways that some of the responding networks are looking at becoming more efficient with informed consent in order to enroll patients more quickly and with fewer barriers, while still ensuring that patient rights are being protected.

- One network asks patients to sign a consent at the time of enrollment that covers the use of data provided through the questionnaire, annual contact, release by providers of medical information, provision of basic vital signs, collection of blood and urine for samples, and contact up to four times per year to request participation in additional research studies.
- One network was in the process of developing a statewide human subject research protection review.
- One network created a community IRB comprised of members of Community Health Clinics, their patients, and academic researchers experienced in conducting research with the network population.
- One network developed a federated IRB that includes provisions for transferring data from legacy patients based on local IRB review. This network is in the process of developing an option for web-based consent to be rolled out soon.
- One network has an IRB subcommittee that convenes regularly, has established procedures for reviewing all study proposals and workgroup requests to ensure that local Community Health Clinic, population/patient interests, and IRB issues are covered prior to final version of document submitted. Any proposed studies that involve patient contact in the future will be vetted through the central IRB subcommittee.