


# PCORI Funding Announcement: Improving Infrastructure for Conducting Patient-Centered Outcomes Research

# The National Patient-Centered Clinical Research Network (PCORnet): Initiative on Health Plan/System Data Partnerships (A Stepwise Approach to Collaboration)

Published October 13, 2015
Updated December 18, 2015

This limited PCORI Funding Announcement applies to the funding opportunity that closes on February 17, 2016, at 5 p.m. (ET). Application guidelines, templates, and other resources are available at www.pcori.org/pcornet-initiative-health-plan-system-data.

**About PCORI**

The Patient-Centered Outcomes Research Institute (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. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by our authorizing legislation, is to help 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."



**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**

**Follow us on Twitter: @PCORI**

# Overview

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| Published | October 13, 2015 |
| Letter of Intent Due | December 1, 2015, by 5 p.m. (ET)<br><br>Letters of Intent (LOIs) will be screened for responsiveness to this PCORI Funding Announcement (PFA) and fitness to program goals. Only those selected will be invited to submit full applications. Notification of invitation to submit full applications will occur no later than December 10, 2015. |
| Summary | The Patient-Centered Outcomes Research Institute (PCORI) seeks to fund up to two health plans as part of advancing the completeness of the National Patient-Centered Clinical Research Network (PCORnet). Beginning in 2014, PCORI provided initial infrastructure development funds (Phase I) for PCORnet. Funds were awarded for the development of 11 Clinical Data Research Networks (CDRNs), 18 Patient-Powered Research Networks (PPRNs), and one Coordinating Center (CC). Phase I infrastructure development concluded in September 2015, 18 months from its launch in April 2014. Phase II of PCORnet begins in October 2015 and seeks to expand the infrastructure built during Phase I. Applicants should familiarize themselves with the Phase II solicitations for CDRNs and PPRNs. More information on current PCORnet activities and structure can be found at www.pcornet.org.<br><br>A critical element for many of the anticipated uses of PCORnet is the availability of complete, longitudinal data on populations receiving health care within the CDRNs and PPRNs. PCORnet's current CDRNs are working to capture complete, longitudinal healthcare data on their populations, including electronic health record (EHR) data from both ambulatory and in-patient care in the delivery system, and claims information or other records representing care received outside participating delivery systems. Their efforts include individual outreach to health plans with which their systems do substantial amounts of business, and outreach to the Centers for Medicare and Medicaid Services (CMS). A list of current PCORnet CDRNs is available online. PPRNs are working to create active communities of engaged patients willing to generate questions for research and participate in research studies. An ability to partner with the health plans that cover their member patients will also be necessary for PPRNs. A list of current PCORnet PPRNs is also available online.<br><br>PCORI has determined that a supplemental approach to advancing the availability of complete, longitudinal data, spanning time and care setting and addressing the many challenges of such data linkages, would be for PCORI to directly fund major US health plans that cover significant numbers of patients in one or more of the PCORnet CDRNs. These health plans would engage in data linkage governance and technical activities in a comprehensive, stepwise approach toward successful linkages of claims and EHR data for use in conducting comparative clinical effectiveness research (CER). Successful applicants will also be expected to link with one or more PPRNs for enrollees who are also members of the PPRN(s).<br><br>This announcement describes the scope of work for funding of up to two health plans to partner with PCORnet CDRNs and PPRNs for establishing the governance framework and subsequent implementation of linkage of longitudinal healthcare claims data with these CDRNs and PPRNs to support PCORnet Demonstration Studies (Year One), and then for establishing the governance and subsequent implementation for linkage of longitudinal healthcare data in CDRNs and PPRNs to support construction of multipurpose linked data sets for use in additional research studies funded by PCORI and other funders in the future (Years Two and Three). The emphasis is fundamentally on claims data relating to the care experience of members enrolled in health plans who also have records of receiving care in |

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|---|---|
| | one or more health systems participating in a PCORnet CDRN or PPRN. |
| Applicant Resources | See www.pcori.org/pcornet-initiative-health-plan-system-data. |
| Key Dates | Online System Opens: October 13, 2015<br>LOI Deadline: December 1, 2015, by 5 p.m. (ET)<br>LOI Status Notification: December 10, 2015<br>Application Deadline: February 17, 2016, by 5 p.m. (ET)<br>Merit Review: April 2016<br>Awards Announced: June 2016<br>Earliest Project Start Date: August 2016 |
| Maximum Project Budget (Direct Costs) | $3 million |
| Budget/Time Limits | Applicants must submit a Greater Than Time/Budget Request by 5:00 PM EST on December 17, 2015 if the proposed project's budget or duration exceeds limits specified in this announcement. |
| Maximum Project Period | Three years |
| Funds Available | Up to $6 million direct costs for up to two health plans |
| Eligibility | Applications may be submitted by any insurance company, insurance administrator, or insurance organization (including a health system such as a health maintenance organization) that provides or pays the cost of medical care for enrolled members who also have records of receiving care in one or more health systems participating in a PCORnet CDRN or PPRN.<br><br>The Internal Revenue Service (IRS) must recognize all applicant organizations. Organizations may submit multiple applications for funding. Individuals are not permitted to apply. |
| Review Criteria | 1. Population Overlap with One or More CDRN Populations<br>2. Approach to Governance and Oversight<br>3. Technical Merit of Proposed Approach to Data Linkage Activities<br>4. Engaging in and Sustaining a Collaborative Research Network |
| Contact Us | For programmatic inquiries, please email (sciencequestions@pcori.org), phone (202-627-1884), or contact us online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days of receiving an inquiry but will not guarantee the same response time for inquiries received three days prior to an LOI or application deadline.<br><br>For administrative, financial, or technical inquiries, please email (pfa@pcori.org). PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. Applicants may call the Helpdesk (202-627-1885) for technical or administrative support. It is the applicant's responsibility to submit the application on or before the application deadline. |
| Other | Deadlines are at 5 p.m. (ET). If a deadline falls on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday. |

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# I. Introduction

### Summary of Program

Beginning in 2014, PCORI provided initial infrastructure development funds (Phase I) for the National Patient-Centered Clinical Research Network (PCORnet). Funds were awarded to develop the capacity of 11 CDRNs, 18 PPRNs, and one CC to participate in a national network for conducting CER. Phase I infrastructure development concluded in Fall 2015, 18 months from its launch. Phase II funding awards for both CDRNs and PPRNs were announced on July 21, 2015. More information on current PCORnet activities and structure can be found at www.pcornet.org.

PCORnet is intended to be a large, representative national network for conducting CER. It is envisioned that PCORnet will support a range of study designs, including large longitudinal observational studies, large pragmatic clinical trials conducted within delivery systems, rapid-cycle research in concert with health systems and plans, and surveillance studies across geographic areas and over time.

PCORI has recently funded three PCORnet Demonstration Studies to support research on important unanswered clinical questions faced by patients and their clinicians, using PCORnet's Distributed Research Network (DRN) and associated processes and programs to formally test and evaluate the capacity of PCORnet's data infrastructure and the functionalities of the DRN, and to provide an early opportunity for CDRN and PPRN investigators, patients, and other stakeholders to organize and collaborate in a multisite study and develop an efficient, collaborative process to do so.

A critical element for many of these existing demonstration studies and anticipated uses of PCORnet is the availability of complete, longitudinal data on populations receiving health care within the institutions that comprise the CDRNs and PPRNs. PCORnet's current CDRNs are working to capture complete, longitudinal healthcare data on their populations, including electronic health record (EHR) data from both ambulatory and inpatient care in the delivery system, and claims information or other records representing care received outside the delivery system. Their efforts include individual outreach to health plans with which their systems do substantial amounts of business, as well as outreach to CMS. A list of current PCORnet CDRNs is available online. PPRNs are working to create active communities of engaged patients willing to generate questions for research and to participate in research studies. An ability to partner with the health plans that cover their member patients will also be necessary. A list of current PCORnet PPRNs is available online. Some plans will have large numbers of covered enrollees in multiple CDRN or PPRN populations. PCORI recognizes that the linkage of complementary data from CDRNs, PPRNs, and health plans is necessary to optimize and enhance CER; however, there are many challenges associated with the governance and technical activities necessary to link these data across a distributed data network, such as PCORnet.

PCORI has determined that a supplemental approach to advancing the availability of complete, longitudinal data, spanning time and care setting and addressing the many challenges of such data linkages, would be for PCORI to directly fund major US health plans that cover significant numbers of patients in one or more of the PCORnet CDRNs and PPRNs to engage in data linkage governance and technical collaboration activities in an incremental approach toward successful linkages of claims and clinical data for use in conducting CER. The health plan/system data linkage collaborations will include a

stepwise, or incremental, approach to ensure that governance and technical issues are appropriately addressed prior to implementation of data linkages to support PCORnet Demonstration Studies and to support additional research projects and multipurpose linked data sets for use in future research studies. The vision of these CDRN- or PPRN-health plan partnerships is that either a CDRN, PPRN, or a health plan site could serve as the primary site in a funded research study in the future. Requests for linkage and data might originate with the CDRN, the PPRN, or the health plan. They may result from inquiries or funding opportunities offered by outside funders, from within the healthcare delivery systems of a CDRN or PPRN, or from the participating health plan. The long-term vision for PCORnet is of a collaborative research network (1) that is sustained by funding from multiple sources, (2) that will continue to grow and involve more delivery systems and health plans, and (3) that advances the vision of learning healthcare systems and increases the recognition of research questions that are of particular importance to both health systems and health plans.

This solicitation is directed to health plans with enrolled members who also have records of receiving care in one or more health systems participating in a PCORnet CDRN and/or PPRN. Applicants should familiarize themselves with the solicitations for CDRNs, PPRNs, the PCORnet Demonstration Studies: ADAPTABLE and the two Obesity Observational Studies, the current lists of CDRNs and PPRNs, the current list of networks affiliated with each of the PCORnet Demonstration Studies: ADAPTABLE and the Obesity Observational Studies, and most specifically, the geographic and institutional locations of the populations captured by these CDRNs (see Table 1) and PPRNs. PPRN coverage is variable; therefore, applicants should refer to the list of funded PPRNs to reach out to the PPRN prime applicant site for up-to-date population coverage.

**Table 1: Geographic Coverage Captured by the Participating CDRNs**

| Clinical Data Research Network (CDRN) | Prime Site Location | Geographic Coverage |
|---|---|---|
| **ADVANCE** | Portland, Oregon | Alaska, California, Florida, Georgia, Hawaii, Indiana, Kansas, Maryland, Massachusetts, Minnesota, Montana, Missouri, Nevada, New Mexico, North Carolina, Ohio, Oregon, Rhode Island, Texas, Utah, Washington, Wisconsin |
| **CAPriCORN** | Chicago, Illinois | Chicago |
| **GPC** | Kansas City, Kansas | Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, Texas, Wisconsin |
| **REACHnet** | New Orleans, Louisiana | Louisiana and Texas |
| **LHSNet** | Rochester, Minnesota | Arizona, Florida, Iowa, Michigan, Minnesota, Ohio, Texas, Utah, Wisconsin |
| **MidSouth** | Nashville, Tennessee | Arkansas, North Carolina, South Carolina, Tennessee, Virginia, Mississippi |
| **NYC CDRN** | New York City, New York | New York, New Jersey, Connecticut |
| **OneFlorida** | Gainesville, Florida | Florida |
| **PATH** | Pittsburgh, Pennsylvania | Maryland, Pennsylvania, Utah |
| **PEDSnet** | Philadelphia, Pennsylvania | Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Washington D.C., Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming |
| **PORTAL** | Pasadena, California | California, Colorado, District of Columbia, Hawaii, Iowa, Maryland, |

| Clinical Data Research Network (CDRN) | Prime Site Location | Geographic Coverage |
|---|---|---|
| | | Minnesota, Oregon, Virginia, Washington, Wisconsin |
| **pSCANNER** | San Diego, California | California |
| **SCILHS** | Boston, Massachusetts | Massachusetts, Missouri, Ohio, New York, Texas, Washington |

Anticipated key funded activities for the stepwise approach of the Health Plan/System Data Partnerships are as follows:

### Year One: Linkage to support PCORnet Demonstration Studies

- **Activities related to the linkage of data to support PCORnet Demonstration Studies**
    - Describe the extent of overlap (i.e., the numbers) of individuals for whom there are records in the EHR data or enrollment data of one or more CDRNs and/or PPRNs, respectively, and also in the enrollment and claims data of the plan.
    - Develop and implement governance policies along with standard operating procedures (SOPs) for efficiently obtaining Institutional Review Board (IRB) review, executing appropriate Data-Sharing/Data-Use Agreements, development and implementation of standardized Business Associate Agreements (BAAs) (as appropriate), and conducting of linkages at both the individual patient and organizational levels for the PCORnet demonstration projects: ADAPTABLE, where individual consent is required, and for each of the two Obesity Observational Studies, where waivers of consent will be obtained. Ensure that all policies and procedures comply with applicable privacy, security, and human subject research laws.
    - Develop and implement a process that allows for use of follow-up data for consented participants in the PCORnet Demonstration Studies: ADAPTABLE and the Obesity Observational Studies.
    - Ensure that the relevant data for the three PCORnet demonstration projects are mapped to the PCORnet Common Data Model (CDM), which is modeled closely upon the Sentinel Initiative's data model, in which several major US health plans already participate.
    - Work closely with the PCORnet CC to conduct the linkage of data required for these studies.

### Years Two and Three: Linkages with PCORnet CDRNs and PPRNs for additional research projects and for development of multipurpose linked data sets

Funding for Years Two and Three is contingent upon successful completion of Year One activities. Specifically, awardees must have developed the governance policies and accompanying procedures and demonstrated capacity for linkage of health plan data with EHR data from CDRNs or from data collected by PPRNs to support PCORnet Demonstration Studies.

- **Activities related to the linkage of data with PCORnet CDRNs and PPRNs for additional research projects and for development of multipurpose linked data sets**
    - Develop and implement any additional governance policies and SOPs as needed to support additional research studies from a variety of potential funding sources and for development of a multipurpose linked data set; determine if previous governance and oversight efforts from Year One are appropriate for work in Years Two and Three (e.g., mapping to the PCORnet CDM and responding to queries); if not, develop or modify any additional governance policies and processes to support additional research studies that either obtain written informed consent or are conducted under waivers of informed consent, as well as processes to support development of multipurpose linked data sets.
    - Develop a process for responding to queries from the PCORnet CC that is rapid, efficient, and does not require IRB approval.

**Years One–Three: Engaging in and sustaining a collaborative research network**

- **Activities related to engaging in and sustaining a collaborative research network**
    - Engage in discussions about proposed research activities with interested CDRNs and PPRNs.
    - Share and explore approaches to data linkage and assessment of population overlap with PCORnet networks.
    - Participate in PCORnet workgroups related to data linkage and other topics deemed relevant by the PCORnet Council and/or the Data Committee.

Applicants should be aware that anticipated work and funding for Years Two and Three of this award are contingent upon successful completion of Year One milestones and may be subject to negotiation.

Applicants should also be aware that the milestones and deliverables agreed upon for this contract are subject to change at PCORI's request, with the awardee's consent, during the period of the award, in order to ensure that PCORnet can continue to develop and evolve throughout Phase II so that it best meets its overall goals, including long-term sustainability. Thus, applicants should indicate and ensure that they have the operational flexibility to make changes to their proposed work plans, deliverables, and timelines during the three-year award period if deemed necessary and appropriate by PCORI and the awardees.



# II. Guidance for Responding to Solicitation

Applicants should describe specific plans and procedures within the proposed health plan/system data partnership for achieving the requirements for Years One, Two, and Three as described below. Provide examples of past efforts in each area as appropriate.

## Year One

During Year One of the Health Plan/System Data Partnership award, it is expected that funded health plans will engage in the following activities:

*ACTIVITIES RELATED TO THE LINKAGE OF DATA TO SUPPORT PCORnet DEMONSTRATION STUDIES*

**Describe the estimated extent of overlap (i.e., the numbers) of individuals for whom there are records in the EHR data or enrollment data of one or more CDRNs and/or PPRNs, respectively, and corresponding data on enrollment and claims with the plan.**

Describe proposed approaches to performing data linkages to CDRN and PPRN data, as determined to support the three PCORnet Demonstration Studies and in compliance with applicable privacy, security, and human subject research laws.

PCORI currently anticipates that there are several approaches for linking health plan data with CDRN clinical data for activities beyond the initial overlap assessment and aggregate data tables. Applicants should describe the approaches they propose and any additional agreements between health plans and participating CDRNs and PPRNs that may be needed to perform IRB-approved linkages in support of both the ADAPTABLE and Obesity PCORnet Demonstration Studies.

In order to conduct research that characterizes the full healthcare experience over time and across different care settings, it is anticipated that clinical and self-reported data from CDRNs and PPRNs and claims data from health plans will need to be linked in a systematic way at both the organizational level and at the level of the individual patient. Applicants should describe their prior experience conducting such linkages, describe the approaches they believe are feasible (e.g., using identified or de-identified data, or both) to accomplish the work described above, and describe their health plan leadership's willingness to participate in these efforts. Specifically, applicants must describe how they will address the challenges related to sharing of individual-level data to accomplish linkages in a way that results in a high degree of certainty that the clinical and claims data are associated with the same individual, in compliance with applicable laws. A concrete indication of organizational willingness to collaborate with and share data with the healthcare delivery systems of PCORnet CDRNs and with the individual patients of PCORnet PPRNs must be included in the application.

Note that implementation of the approaches will require linkage that identifies, with a high degree of accuracy, individual patients who have records in both a CDRN or a PPRN and the applicant health plan. The product of this activity should be aggregate tables of numbers of patients, by age and gender, with records in both data sources, along with information on length of enrollment in the health plan and nature of care received in the delivery system.

**Develop and implement governance policies along with SOPs for efficiently obtaining IRB review, executing appropriate Data-sharing/Data-use agreements, development and implementation of standardized BAAs (as appropriate), and conducting of linkages at both the individual patient and organizational levels for the PCORnet demonstration projects: ADAPTABLE, where individual consent is required, and for each of the two Obesity Observational Studies, where a waiver of consent will be obtained. Ensure that all policies and procedures comply with applicable privacy, security, and human subject research laws.**

Develop and implement efficient and legally compliant policies in collaboration with CDRN member delivery systems and PPRN members that protect research participants and recognize the characteristics and attendant relevant risks of most PCOR studies.

Applicants should describe the requisite agreements with identified CDRNs and related health systems and PPRNs (e.g., BAAs, Data-Use/Data-Sharing Agreements) and how these agreements will be pursued and completed in the most efficient possible manner. Describe anticipated challenges and proposed solutions.

Describe proposed approaches for obtaining IRB review and approval and, as appropriate, waivers of informed consent and HIPAA authorization, including previous successes for similar activities.

Applicants should describe past experience with data linkages, including use-case-based linkages as described above, as well as experience with broader, more complex linkages via a registry or cohort of patients. Such descriptions should include details of how the health plan addressed legal and technical challenges, including establishing trust between data-providing entities.

Applicants should provide current and planned policies and procedures for protecting the privacy, security, and confidentiality of claims data in multinetwork studies, including in-place or planned policies, practices, and agreements to protect data during acquisition, linkage, storage, analysis, and transmission, in compliance with applicable legal requirements.

**Develop and implement a process that allows for use of follow-up data for consented study participants in the PCORnet Demonstration Studies: ADAPTABLE and Obesity Observational Studies.**

It is envisioned that PCORnet will be an efficient infrastructure that facilitates recruitment, randomization, and follow-up of subjects enrolled in both individual-level and cluster randomized trials on a range of topics. While the CDRNs are well suited to implement clinical trials in their delivery systems and conduct observational studies, if a patient receives care outside of the delivery system, the potential exists that data on his/her follow-up clinical experiences may not be available, having an impact on the robustness of the trial data. Given that this "loss to follow-up" is an issue in clinical trials, the ability to access patient claims data pursuant to their providing written consent would be of critical value to the efficient conduct and methodological rigor of these trials. Health plans will be required to develop frameworks that will allow them to have patient data available for the PCORnet Demonstration Studies, consistent with applicable legal requirements, and describe approaches and/or past experience with performing such activities.

**Ensure that the relevant data for the three PCORnet demonstration projects are mapped to the PCORnet CDM, which is modeled closely upon the Sentinel Initiative's data model, in which several major US health plans already participate.**

Applicants should maintain their data in the latest version of the PCORnet CDM and should plan to refresh the data at least quarterly. Applicants will be expected to work with the PCORnet CC to perform data quality checking and to respond to issues that arise in this process.

It is essential that the health plan have the Sentinel CDM instantiated and implemented at the onset of Year One. The PCORnet CDM is based on the Mini-Sentinel Common Data Model (www.mini-sentinel.org) and has been informed by other distributed initiatives such as the Health Maintenance Organization Research Network (HMORN), the Vaccine Safety Datalink, various Agency for Healthcare Research and Quality (AHRQ) Distributed Research Network projects, and the Office of the National

Coordinator (ONC) Standards & Interoperability Framework Query Health Initiative. The PCORnet CDM is positioned within healthcare standard terminologies (including ICD, SNOMED, CPT, HCPSC, and LOINC) to enable interoperability with and responsiveness to evolving data standards. It can be accessed here. Effort should be allocated to work with the PCORnet CC to streamline the process for transforming the data into the PCORnet CDM. Applicants will be expected to work in collaboration with the PCORnet Data Committee and the PCORnet CC to share insights and address challenges of DRN activities.

**Work closely with the PCORnet CC to conduct the linkage of data required for these studies.**

Applicants should work with the PCORnet CC, CDRNs, PPRNs, and organizational leaders to establish an acceptable, efficient method for organizing and mapping data on these patients into the PCORnet CDM and to conduct the linkage of data required for these three demonstration projects.

## Years Two and Three

During Years Two and Three of the Health Plan/System Data Partnership award, it is expected that funded health plans will engage in the following activities, contingent upon completion of Year One activities and milestones:

***ACTIVITIES RELATED TO THE LINKAGE OF DATA WITH PCORNET CDRNS AND PPRNS FOR ADDITIONAL RESEARCH PROJECTS AND FOR DEVELOPMENT OF MULTIPURPOSE LINKED DATA SETS***

**Develop and implement any additional governance policies and SOPs as needed to support additional research studies from a variety of potential funding sources and for development of a multipurpose linked data set; determine if the previous governance and oversight efforts from Year One are appropriate for work in Years Two and Three (e.g., mapping to the PCORnet CDM and responding to queries); if not, develop or modify any additional governance policies and processes to support additional research studies, that obtain written informed consent and that are done under waivers of informed consent, and to support the development of multipurpose linked data sets.**

A multipurpose linked data set is defined as a data set that includes extensive linked data from health plans, CDRNs, and PPRNs for all members contained in both health plan and CDRN data sets, without respect to a given study, study population, or hypothesis, and that is intended to be used repeatedly in the conduct of IRB-approved comparative clinical effectiveness research. Applicants should specifically address the willingness of health plan leadership to contribute to such a database and to work with the PCORnet CC to demonstrate the utility of the created enriched data set in conducting comparative effectiveness analysis in the future. Applicants should address the question of where such a database would be housed, how access would be governed, the explicit purposes it could be used for, and whether IRB approval would be needed to construct the database or only for its subsequent use in research.

Develop and implement efficient and legally compliant policies in collaboration with CDRN member delivery systems and PPRN members that protect research participants and recognize the characteristics and attendant relevant risks of most PCOR studies.

Applicants should describe the requisite agreements with identified CDRNs and related health systems

and PPRNs (e.g., BAAs, Data-Use/Data-Sharing Agreements) and how these will be undertaken in the most efficient possible manner.

Processes for obtaining IRB review and approval and, as appropriate, waivers of informed consent and HIPAA authorization, including previous successes for similar activities, should also be documented.

Applicants should provide current and planned policies and procedures for protecting the privacy, security, and confidentiality of claims data in multinetwork studies, including in-place or planned policies, practices, and agreements to protect data during acquisition, linkage, storage, analysis, and transmission, in compliance with applicable legal requirements.

Applicants should describe any past experience with data linkages to support multipurpose data sets for use in future research. Such descriptions should include details of how the health plan addressed legal and technical challenges, including establishing trust between data-providing entities.

Applicants must work with PCORnet CC, CDRNs, PPRNs, and organizational leaders to establish an acceptable, efficient method for linkage of data to support additional research studies and for development of a multipurpose linked data set.

Applicants should attempt to create processes that will scale across all of PCORnet and that will minimize redundancy. To the extent possible, applicants should work toward minimal requirements and a common language in Year One, on behalf of PCORnet, that all parties can agree to and leverage for future work.

Applicants should continue to maintain their data in the latest version of the PCORnet CDM and should plan to refresh the data at least quarterly. Applicants will be expected to work with the PCORnet CC to perform data quality checking and to respond to issues that arise in this process.

**Develop a process for responding to queries from the PCORnet CC that is rapid, efficient, and does not require IRB approval.**

Applicants should work with the PCORnet CC to establish an acceptable, efficient method for responding to queries.

PCORI has planned for an anticipated volume of research queries to be distributed through the PCORnet CC using the PCORnet DRN (see Table 2). Health plans should determine how to work with the PCORnet CC using the PCORnet DRN.

Pre-research queries will originate from the PCORnet CC and will use the PCORnet DRN. New research projects will be funded separately, must be reviewed and approved by an IRB, and will have involvement from CDRN and/or PPRN governing bodies (as governance decisions about participation remain with each CDRN and PPRN). Centralized IRBs will be strongly encouraged for each study; hence the applicant should describe its experience working with central IRBs or other approaches to streamlining IRB review.

**Table 2: Anticipated Volume of PCORnet Research Queries in Phase II**

| Phase II Year | Pre-Research Queries[1] (#) | Observational Studies[2] (#) | Clinical Trials[2] (#) |
|---|---|---|---|
| **Year 1** | 50 | 10 | 5 |

| Phase II Year | Pre-Research Queries[1] (#) | Observational Studies[2] (#) | Clinical Trials[2] (#) |
|---|---|---|---|
| **Year 2** | 100 | 10 | 5 |
| **Year 3** | 200 | 20 | 5 |

[1] Networks will have the capacity to support this volume of pre-research queries in Years One, Two, and Three, respectively.
[2] Networks will have the capacity to support this volume of research. **Funding would be provided through a separate research funding mechanism, not through the PCORI contract awarded under this Funding Announcement.** Please note that PCORI does not commit to supporting this level of research funding alone and it is envisioned that other funders will be involved in supporting research to meet these goals.

Successful health plan applicants will be expected to have the capacity to participate in research queries and research studies using the PCORnet DRN in the future. The use of Statistical Analysis System (SAS) software for execution of the queries is required; applicants should include in their work plan effort for personnel skilled in the use of SAS for sophisticated data queries. Applicants will be expected to work in collaboration with the PCORnet Data Committee and the PCORnet CC to share insights and address challenges of the Distributed Research Network (DRN) activities.

## Years One–Three

***ACTIVITIES RELATED TO ENGAGING IN AND SUSTAINING A COLLABORATIVE RESEARCH NETWORK***

**Engage in discussions about proposed research activities with interested CDRNs and PPRNs.**

PCORnet is being advanced as a collaborative research resource that is open and welcoming to a diverse set of potential research partners. Openness by PCORnet networks to participating in studies proposed by a range of funders—and to possibilities for collaboration and data linkage with other research networks and registries—is also critical to network sustainability. The requirement and opportunity for health plans and delivery systems to engage in discussions about PCORnet research studies is an exciting aspect of this proposal for partnership. The requirement extends to consideration of research ideas proposed by plans and delivery systems jointly, as well as to proposals that they do not initiate, although no health plan or delivery system will be required to participate in a specific study. It is envisioned that health plans will have the opportunity to identify and propose study questions that may be of broad interest to PCORnet partners and that leverage its data capabilities. Applicants should describe how they will engage in discussions about research activities within their plan, in collaboration with specific CDRNs and PPRNs with which they are partnering, the PCORnet CC, and with the broader PCORnet community. Health plan thoughts and concerns regarding ongoing participation in PCORnet, with an aim of becoming a self-sustaining, growing research network, should be discussed.

**Share and explore approaches to data linkage and assessment of population overlap with other PCORnet networks.**

As a collaborative endeavor, PCORnet seeks to harvest the insights and effective practices undertaken by CDRNs, PPRNs, health plans, and the broader research community and use them to support a "PCORnet Commons" that is envisioned as a resource repository that frees others from having to repeat

or reinvent processes. To the extent reasonable and feasible, it is envisioned that health plans engaged in PCORnet will share approaches to data linkage and assessing population overlap, provided sharing these approaches does not compromise the plans' proprietary business concerns.

**Participate in PCORnet workgroups related to data linkage and other topics deemed relevant by the PCORnet Council and/or Data Committee.**

PCORnet's governance structure includes a PCORnet Council and Executive Committee along with three other Committees: Engagement, Data, and Research. In the future there will likely be workgroups established to discuss topics of emerging relevance. Applicants should be willing and able to participate in PCORnet workgroups related to data linkage or other issues of mutual concern, if deemed appropriate by the PCORnet Council and/or Data Committee.

### Staffing and Organizational Capacity Requirements

PCORI requires that each applicant propose at least three co-Principal Investigators (co-PIs), one of whom is the lead PI on the application and is named in the award contract. PCORI requires that two co-PIs be participants from the health plan and at least one co-PI be a participant from a PCORnet CDRN or PPRN. The co-PIs must have the following qualifications:

- One of the three co-PIs must be a senior health plan executive.
- One of the three co-PIs must have primary experience or expertise in health services research or CER and be either a health plan participant (the lead PI) or a PCORnet participant.
- One of the three co-PIs must have primary experience or expertise in large-scale database construction and linkage and health information technology and be either a health plan participant (the lead PI) or a PCORnet participant.

The senior health plan executive PI must contribute a minimum of five percent Full-Time Equivalent (FTE). The Lead PI may contribute up to 40 percent FTE. The designated Health Plan Executive and Lead PI combined must contribute up to 30 percent FTE and must be full-time employees of the prime applicant.

Along with the co-PIs, applicants are required to propose a leadership structure to guide the health plan's engagement in PCORnet with complementary expertise in database development, clinical research, health plan administration, patient engagement, research oversight, and data privacy. To this end, levels of effort for these individuals should take into account broader involvement in activities relating to PCORnet, as well as effort devoted to the applicant's own scope of work.

The query tool used by PCORnet (PopMedNet) performs quality checks and uses SAS code to develop queries. In addition, many analysis programs will use SAS code. Therefore, applicants are expected to purchase or have in place a license and up-to-date SAS software and to budget for an analyst with SAS expertise at a minimum 25 percent FTE.

### Methodological Considerations

All PCORI proposals must adhere to relevant PCORI Methodology Standards,[1] including the Standards for Data Networks as Research-Facilitating Infrastructures.

To help reviewers quickly identify the adherence to a particular standard, applicants should cite each methodology standard within their proposals as the standard is addressed.

### Protection of Human Subjects

The awardee institution or organization bears ultimate responsibility for safeguarding the rights and welfare of human subjects in PCORI-supported activities.

PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see the Section 5 "Human Subjects Research Policy" from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports,[2] issued by the US Department of Health and Human Services (HHS). It is expected that awardees will obtain human subjects review and approval, including appropriate waivers of informed consent and/or HIPAA authorization as determined by the IRB.

### Peer Review and Release of Research Findings

PCORI has a legislative mandate to ensure the scientific integrity of the primary research it supports and to make study findings widely available and useful to patients, clinicians, and the general public within a specific timeframe. The PCORI Board of Governors (Board) adopted the following process for peer review and public release of the results of all funded studies.

Awardee Institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and properly interprets the findings in clinical or other decisional contexts. Subject matter experts, individuals with expertise on research methodology or biostatistics, as well as patients, caregivers, and other healthcare stakeholders, will review the draft final research report. After awardees have responded to reviewers' comments to PCORI's satisfaction, the report will be accepted and considered final. PCORI will then prepare a 500-word abstract summarizing the study results for patients and the general public, which the Awardee Institution will review and approve.

PCORI will post the following materials on its website no later than 90 days after the draft final research report is accepted: a 500-word abstract for medical professionals, a standardized summary of the study's results for patients and the general public, and a link to the study record on ClinicalTrials.gov (as applicable). The final research report, along with anonymized reviewer comments, will be made publicly available on the PCORI website no later than 12 months after its acceptance, except by prior mutual agreement with the Awardee Institution.

[1] See http://www.pcori.org/content/pcori-methodology-report.

[2] See http://grants.nih.gov/grants/funding/424/supplementalinstructions.docx.

### Budget and Project Duration

The maximum budget for any single awardee under this PFA is $3 million direct costs over the three years of PCORnet's Phase II. PCORI does ***not*** consider exceptions to the stated budget or research period of performance limits (three years). If your proposed project has a budget that exceeds the $3 million total direct cost cap and/or has a project period that exceeds the three-year period of research performance, you must submit a Greater Than Time/Budget Request form by December 17, 2015. Applicants may contact PCORI research staff during the application period with any questions related to budget.

Overall, the budget and budget justification must describe, in detail, the resources and associated budgetary costs needed to implement the proposed scope of work. The application should describe any ways in which the applicant plans to leverage existing resources, whether the health plan/system will receive any matching funds or in-kind resources for infrastructure maintenance, and how the health plan/system intends to create synergies between infrastructure maintenance and future research and other internal health plan projects/initiatives (for example, if the health plan is engaged in healthcare improvement activities such as initiatives to reduce the use of low-value healthcare services, improve medication adherence, or predict utilization, how might such initiatives inform the plan's engagement in PCORnet?).

Applicants should budget for travel to Washington, DC for up to three attendees to attend up to eight in-person one-day meetings per project year. These meetings may include, but are not limited to:

- Kickoff Meeting
- PCORnet In-person Collaboration Meetings
- Ad Hoc Meetings (such as workshops convened by PCORI or other bodies and PCORnet Committees)

Funds are not to exceed $1,000 per person, per meeting. Over the course of the three-year budget, PCORI-required travel costs (prime and subcontractor combined) should not exceed $72,000 (the maximum budget allowed would be $1,000 per person for up to three attendees for eight meetings per year). Travel budget requests should be based on competitive estimates and include a detailed breakdown of expenses for each traveler.

The proposed budget should address the following:

- Expenditures (personnel and non-human resources) required over the three-year award that are necessary for developing and maintaining the data infrastructure, as well as the activities required as a PCORnet collaborator
- Plans to leverage existing resources or to obtain matching/in-kind funds from the parent organization and/or other funding sources
- A clear and adequate travel budget for each traveler

# III. How To Submit a Proposal

### Letter of Intent

All applicants are required to submit a Letter of Intent (LOI), which will be reviewed by PCORI program staff for responsiveness to this PFA and application guidelines. Invitations to submit full applications will be sent to selected applicants.

Applicants should download the PCORnet Initiative on Health Plan/System Data Partnerships PFA LOI template from the PCORI Funding Center. They must complete the document and convert it to a PDF with a limit of five pages. LOIs that exceed the page limit (excluding references and required tables) may not be reviewed. All references must be listed at the end of the LOI. Do not upload additional documents—including letters of endorsement or support, relevant publications, or supplemental graphs—as part of your LOI; they are not requested at this stage. Their inclusion will result in LOI rejection without review. Please visit the PCORI Funding Center for additional applicant resources, including the application guidelines and required templates.

Applicants will be notified no later than December 10, 2015 as to whether they have been invited to submit full applications. PCORI will accept full applications only from invited organizations.

### Letter of Intent Review

LOIs will be reviewed by a minimum of two PCORI staff for programmatic fit and responsiveness to the PFA and Application Guidelines. LOIs are screened against the following criteria:

- Overlap with the Phase II CDRN and PPRN populations for the CDRNs and PPRNs for which the health plan intends to work
- Proposed approaches to governance and oversight in support of the PCORnet Demonstration Studies, potential future studies, and multipurpose linked data sets
- Proposed approaches to link data between one or more CDRNs and/or PPRNs and the health plan
- Anticipated ability to organize data into the PCORnet CDM
- Potential to contribute to the PCORnet Commons through the development of shared tools and resources
- Strength of the proposed collaborations with other CDRNs and/or PPRNs
- Expertise and experience of the proposed project team
- Programmatic fit and balance

**Note:** LOIs that show scientific overlap or that appear to be duplicate submissions will be removed during the LOI screening process.

### Submission Dates

LOIs and applications must be submitted in accordance with the published dates and times listed in the

Overview and in the PCORI Funding Center. Refer to PCORI's Policy on the Submission of Research Contract Applications for additional guidance on ensuring an on-time submission.

### PCORI Online

To submit a proposal, you must register with PCORI Online and submit both an LOI and an application for each cycle to which you are applying.

### Applicant Resources

| | |
|---|---|
| **PCORI Funding Center** | www.pcori.org/pcornet-initiative-health-plan-system-data |
| **PCORI Online System** | https://pcori.fluxx.io |
| **PCORI Funding Awards** | www. pcori.org/pfaawards |

## IV. Merit Review

PCORI's merit review process is designed to support the following goals:

- To identify applications that have the strongest potential to help patients, caregivers, clinicians, and other stakeholders make informed decisions to improve patient outcomes
- To implement a transparent, fair, objective, consistent process to identify these applications
- To elicit high-quality feedback that reflects a diversity of perspectives to ensure that the research funded by PCORI reflects the interests and views of patients and those who care for them, and that it meets the criteria for scientific rigor
- To fund projects that fill important evidence gaps and have strong implementation potential
- To regularly evaluate and continually improve merit review process and policies in support of PCORI's mission

PCORI merit review is a multiphase process that includes: PFA development; staff evaluation of LOIs; preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI's Research Priority Area Program staff, based on the preliminary review and program priorities); applicant interviews; Selection Committee recommendation of applications for funding; and finally, Board of Governors (Board) award approval (no later than April 2016).

### Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Applications may be eliminated from the review process for administrative or scientific reasons (e.g., nonresponsiveness). An application may be administratively withdrawn if it is incomplete or submitted past the stated due date and time or

if it does not meet the administrative or formatting criteria (including page limits) outlined in the application guidelines, in the PCORI templates, and in the PCORI Online system. An application may be scientifically withdrawn if it is judged to be nonresponsive to the guidelines provided in this PFA or if it does not meet PCORI programmatic requirements including:

- Overlap with the Phase II CDRN and PPRN populations
- Anticipated ability to organize data into the PCORnet CDM
- Proposed approaches to governance and oversight in support of the PCORnet Demonstration Studies, potential future studies, and multipurpose linked data sets
- Proposed approaches to link data between one or more CDRNs and/or PPRNs and the health plan
- Potential to contribute to the PCORnet Commons through the development of shared tools and resources
- Strength of the proposed collaborations with other CDRNs and/or PPRNs
- Expertise and experience of the proposed project team
- Programmatic fit and balance

PCORI Merit Review Officers (MROs) recruit each panel based on the number of LOIs and topic areas represented by invited LOIs. MROs recruit the panel chair, scientist reviewers who are subject matter experts, patient representatives, and representatives of other stakeholder groups. All panel members receive training during the review cycle to ensure that all understand the programmatic and organizational goals of review. Below are PCORI's merit review criteria. PCORI's merit review panels use these criteria during the preliminary and in-person review phases to evaluate and score all submitted applications:

**Criterion 1: Population Overlap with One or More CDRN Populations**

- To what extent has the applicant demonstrated the potential that the health plan population(s) overlaps with populations cared for by PCORnet CDRNs and PPRNs for each of the three Demonstration Studies, potential future studies, and for a multipurpose data set?
- How well developed are the applicant's collaborations with the CC, CDRNs, PPRNs, and organization leaders? What types of collaborations have been undertaken to date to assess population coverage between the health plan and PCORnet CDRNs and PPRNs?
- To what extent has the applicant previously engaged in similar work to link populations across healthcare settings and timespans with respect to specific IRB-approved research studies and multipurpose data sets?
- Does the proposed team provide the required amount of time and effort (FTEs) and have the necessary expertise to conduct the project?

**Criterion 2: Approach to Governance and Oversight**

- Does the applicant describe an approach for the linkages to support the IRB-approved PCORnet Demonstration Studies, potential future studies, and multipurpose linked data sets that is commensurate with the proposed activities, reflects understanding of human subjects protection requirements, and provides compliant and efficient ways to link multisite data in

compliance with associated IRB, HIPAA, and other applicable requirements?

- Does the applicant describe an approach for efficiently obtaining appropriate Data-Sharing/Data-Use Agreements and the development and implementation of standardized BAAs, as appropriate, for the PCORnet Demonstration Studies, potential future studies, and the multipurpose linked data sets?
- Does the applicant specifically describe how they will address the challenges related to sharing of individual-level data to accomplish linkages in a way that results in a high degree of certainty that the data are associated with the same individual, in compliance with applicable laws?
- Does the applicant provide current and planned practices, as well as specific technical approaches, for protecting the privacy, security, and confidentiality of claims data in multinetwork studies, including in-place or planned policies, practices, and agreements to protect data during acquisition, linkage, storage, analysis, and transmission, in compliance with applicable legal requirements?

**Criterion 3: Technical Merit of Proposed Approach to Data Linkage Activities**

- Does the applicant provide evidence that the overall approaches and methodologies in place to accomplish the data linkage activities can be completed in the specified time frame, with compelling evidence that the proposed data linkages would augment the data already captured at the CDRN or PPRN, and is this supported by their health plan leadership as demonstrated by examples from prior work?
- Does the applicant provide evidence of the policies and procedures already in place for responding to a data breach, including how affected patients, clinicians, and researchers will be notified, how potential harm will be mitigated, and how any negative impact on the capacity of the health plan to conduct research will be minimized?
- Does the applicant provide credible and technically feasible approaches to ensuring non-duplication of patient data between a network and a health plan (e.g., if there were two beneficiaries with the same name, could the health plan reliably determine which one received care at a given health system)?
- Does the applicant have the capacity and a plan to maintain high-quality analysis-ready data sets mapped to the PCORnet CDM (e.g., instantiated and implemented data in the Sentinel data model), including demonstrated ability to ensure that data are complete and consistent and are refreshed quarterly, and that processes are in place for remedying data errors as needed?
- Does the applicant demonstrate the willingness and ability to participate in queries related to the three PCORnet Demonstration Studies and to build the capacity to participate in potential future research studies using the PCORnet DRN?
- Does the applicant describe how the health plan would respond to queries, including the decision-making process for responding to a query; the centralized or federated technical approach to implementing the query response; and the software and personnel to conduct these queries as well as more complex analyses using SAS?

- Does the applicant describe an approach that will allow for use of follow-up data for consenting participants involved in the PCORnet Demonstration Studies?

**Criterion 4: Engaging in and Sustaining a Collaborative Research Network**

- Does the applicant describe how it might engage in discussions about research activities within their plan, in collaboration with specific CDRNs and PPRNs with which they are partnering, the PCORnet CC, and the broader PCORnet community?
- Does the applicant describe its ability and willingness to share knowledge and practices with others by identifying areas of expertise, approaches, tools, and techniques with which the health plan has depth of experience, and by describing policies, mechanisms, and tools to share and disseminate these approaches including via the PCORnet Commons?
- Does the applicant describe its willingness to participate in PCORnet workgroups related to data linkage deemed relevant by the PCORnet Council and/or Data Subcommittee?

### In-Person Review

During preliminary review, all administratively and scientifically compliant applications are evaluated and scored based on PCORI's merit review criteria, including evaluation of adherence to PCORI's Methodology Standards. After the preliminary review is completed, PCORI program staff members evaluate panel scores and critiques to identify a subset of applications to be discussed at the in-person review meeting. Not all submitted applications move forward to in-person review.

During the in-person review, panels meet to discuss applications and to further clarify the merits of the proposed research as well as identify areas for improvement. Additionally, each application is re-scored based on the content of discussion. The chair and PCORI MRO lead the in-person panel meeting and ensure that all applications receive a fair and thorough review informed by the standards outlined in the PFA.

### Applicant Interviews

PCORI may invite select applicants to interview with the PCORI program staff prior to recommending a slate to the Selection Committee.

### Post-Panel Review

After the in-person panel review and applicant interviews, PCORI program staff evaluate merit review scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff members then recommend projects to a Selection Committee, which includes members of PCORI's Board. The Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI's strategic priorities. This slate is then proposed to PCORI's Board for its consideration and approval.

### Summary Statements and Funding Recommendations

Summary statements are provided to applicants approximately two weeks before funding decisions are announced. If an application progresses to in-person discussion, the applicant will receive a summary

statement inclusive of the panel discussion notes, the final average overall score, and preliminary reviewer critiques. Summary statements for applications that do not progress to in-person discussion include only the preliminary reviewer critiques.

Factoring in the total available funds allotted for this announcement, high-scoring applications that fit the programmatic needs and satisfactorily address reviewers' critiques will be considered for funding by the PCORI Board. It is expected that applicants will receive a funding status notification no later than June 2016.

### Terms and Conditions for Funding

Applicants approved by the Board will be expected to agree to PCORI's funding terms and conditions, and they will be expected to agree to the terms and conditions for health plan engagement and collaboration with PCORnet as conditions of final receipt of funding.