The National Patient-Centered Clinical Research Network: Clinical Data Research Networks (CDRN)

*Building a National Data Infrastructure to Advance Patient-Centered Comparative Effectiveness Research (CER)*

**Town Hall for Applicants:** June 2013
Agenda

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Submitting Questions:

Submit questions via the chat function in Meeting Bridge

Ask a question via phone (an operator will standby to take your questions)
Introductions

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Executive Director

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About PCORI
PCORI’s Mission and Vision

- The Patient-Centered Outcomes Research Institute (PCORI) is an independent, non-profit health research organization authorized by the Patient Protection and Affordable Care Act of 2010.

- PCORI funds patient-centered research to assist patients, caregivers, and other stakeholders in making informed health decisions.

**Mission**

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.

**Vision**

Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
PCORI’s National Priorities

PCORI’s funding cycles focus on its National Priorities, which were put forth in PCORI’s authorizing legislation.

These five broad areas comprise PCORI’s National Priorities for Research and encompass the patient-centered comparative clinical effectiveness research PCORI will support.

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication and Dissemination
- Addressing Disparities
- Accelerating Patient-Centered Outcomes Research and Methodological Research
National Patient-Centered Clinical Research Network
The goal of PCORI’s National Patient-Centered Clinical Research Network Program is to improve the nation’s capacity to conduct CER efficiently, by creating a large, highly representative, national patient-centered clinical research network for conducting clinical outcomes research.

The vision is to support a learning US healthcare system, which would allow for large-scale research to be conducted with enhanced accuracy and efficiency.
National Patient-Centered Clinical Research Network

The core components of this network will be:

- Clinical Data Research Networks (CDRNs), which are system-based networks including electronic health records (EHR) data and covering the entire clinical experience of defined populations, and

- Patient-Powered Research Networks (PPRNs), which are groups of patients interested in forming a research network and in participating in research.

Specifically, this program will promote:

- A more comprehensive, complete, longitudinal data infrastructure;

- Broader participation of patients, clinicians, health systems, and payers in governance and use of the network, and

- Data inter-operability between networks to facilitate data sharing as part of research projects.
National Patient-Centered Clinical Research Network: Our Vision

Steering Committee
- Awardees
- PCORI
- AHRQ, NIH, FDA, ONC, CMS

Scientific Advisory Board

Special Expert Group

Coordinating Center Staff
Ideal PCORI CDRN Characteristics
Involvement of multiple (two or more) **health systems**, working toward data standardization and interoperability within the network and across networks to allow for efficient, valid sharing of individual or aggregate data for purposes of data analysis.

Involvement of the **healthcare system leadership** in governance and use of the network to enhance network efficiency, utility, and identification of models for sustainability of the network.

**Capacity and willingness to support large-scale randomized trials**, as well as observational comparative effectiveness studies, with **substantive patient and clinician involvement** in the governance and use of the network.
Ideal CDRN Characteristics: Patients

- **Coverage of a large, diverse, defined population** not selected for a particular disease, condition, or procedure; **ability to capture complete clinical information on this population** over time, including longitudinal information on clinical care, changes in clinical characteristics and conditions, and the occurrence of clinical care or outcomes, within or outside the system.

- The **ability to efficiently contact patients** for the purposes of recruitment; collecting patient-reported information; and maintaining **consistently high levels of participation in research studies**.

- Demonstrated **ability to engage substantial patient populations** with selected conditions, both within and outside their systems, for purposes of generating research questions, participating in network governance, or in appropriate research studies.
Ideal CDRN Characteristics: Administrative

- Willingness to **serve as a part of a national data infrastructure resource** for the conduct of CER by researchers within or outside the network.

- **Capacity to embed research activity within functioning healthcare systems** without disrupting the business of providing health care.

- Alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed studies.

- **Clear, proven policies and track record for maintaining data security, patient privacy, and confidentiality.**

- Ability to collect, store, retrieve, process, or ship biological specimens for research purposes, with appropriate consent, for use by qualified researchers.

- Ability to **streamline subcontracting processes** for research involving multiple sites.
Clinical Data Research Networks (CDRN)

$56 million is available to support up to 8 new or existing CDRNs for 18 months.

COOPERATIVE AGREEMENT AWARD

• At least two health care systems engaged.
• Willingness and capacity to work toward data standardization with other awardees.
• Willingness to participate in collaborative studies with data sharing as part of a national research infrastructure.

18 MONTHS LATER

• > 1,000,000 patients enrolled.
• Data standardized within network and with other awardee networks.
• Patients, system, and clinicians engaged in governance & use.
• Capable of implementing clinical trials.
Under this PFA, PCORI is not interested in providing maintenance funds to support existing work. Rather, we are looking to fund work that will move each network toward becoming an effective component of a national network. Thus, applicant networks may differ on what is proposed as primary tasks.

Reminder: Please refer to the PFA for a detailed description of what PCORI is seeking through this PFA.
Letter of Intent (LOI) Submission
Understanding the Letter of Intent (LOI)

- A LOI is **required** in order to submit an application.
- LOIs will be reviewed and approved within 4 weeks.
- Applicants will receive an invitation to submit an application after submitting a LOI.
- An Investigator can only be listed as a **PI on one LOI**.
- A system may be a participant in no more than two applications.

**Of note:** PCORI encourages applicants to submit their LOI and application before the stated due date. **LOIs and applications are due 5:00 pm EST.**
The CDRN LOI should address the following:

- **Project/network plan**: Describe network composition, size and data sources. Briefly address each of the following:
  - Describe *transformative change or dramatic incremental improvement* for the network, rather than only a continuation of current progress.
  - Capacity of the *network to expand*, including proposed plans for new collaborations with other organizations.
  - *Informatics* capability to link and collaborate with other networks.
  - Plans for identifying and *engaging at least three patient cohorts* within the network: (1) at least one high-prevalence disorder, (2) at least one rare disease or condition, and (3) patients with obesity cohort.
  - *Readiness and potential to address each of the ideal features of the CDRN.*
The CDRN LOI should address the following: (additional information)

- **Leadership and personnel**: Describe qualifications of the PI and key personnel, organizational leadership’s commitment to this work.

- **LOI supporting documentation**: The following items that can be provided as supporting documentation include references, lists of abbreviations and biographical sketches.

- **Additional items**:
  - The LOI 4-page limit applies to text and any figures, tables, graphs, photographs, diagrams, pictures, pictorials, and cartoons.
  - URLs included providing additional information to expand the LOI will not be reviewed.
  - This limit excludes the LOI supporting documentation.
The LOI will be evaluated internally by PCORI based on the project/network plan and on leadership and personnel.

LOIs will be reviewed based on fit of the applicant network with the goals of the Cooperative Agreement and feasibility to complete work within the budget and project period proposed.
Administrative Matters
Funds & Budget

- Funds available: up to $58 Million
- Cooperative Agreement: up to 8
- Maximum $7,000,000 total costs
- Indirect costs: up to 40% of total modified direct costs
- Request for exceptions to funding limit may be made during the LOI submission

Period of Performance

- 18 months
- There are no exceptions for award length

Note: This is one-time announcement. It will not be reissued.
Eligibility Requirements – CDRNs

Applications may be submitted by:

- Any private sector research organization, including any:
  - non-profit organization
  - for-profit organization

- Any public sector research organization, including any:
  - university or college
  - hospital or healthcare system
  - Laboratory or manufacture
  - unit of state or local government

- Only US-based organizations may apply as primary institutions

- Nondomestic Components of Organizations based in the United States

Please Note: Individuals are not eligible to submit applications to PCORI.
### Key Dates: PCORI Funding Announcement

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<th>Action</th>
<th>Dates</th>
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<tr>
<td>System Opening Date</td>
<td>May 15</td>
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<tr>
<td>Letter of Intent (LOI) Due Date</td>
<td>Wednesday, June 19</td>
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<td>Informational Training Programs</td>
<td><strong>CDRN</strong>: Tuesday, June 4th 3:00 PM</td>
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<td></td>
<td><strong>PPRN</strong>: Tuesday, June 4th 3:00 PM</td>
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<td>Notification of LOI status</td>
<td>Wednesday, July 17</td>
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<td>Application Deadline</td>
<td>Friday, September 27</td>
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<td>Merit Review Dates</td>
<td>October - November</td>
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<td>Awards Announced</td>
<td>December 2013</td>
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<td>Earliest Start Date</td>
<td>January</td>
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Can a patient registry apply for CDRN funding?

- No, we do not consider a stand-alone registry as eligible to be a CDRN. However, a registry may be eligible to apply as a PPRN or to partner with a health care system to create one of the target populations within a system in a CDRN application.
Frequently Asked Questions (Administrative)

- **My institution is interested in applying for CDRN funding. Do we need to partner with another group?**
  - A CDRN is defined as a network between two or more health care systems. This partnership may serve to expand the population covered OR to enhance data completeness for the same population. In addition, we expect that at the end of the 18-month Phase One period, all CDRNs will have made substantial progress toward achieving data interoperability and data standardization with other funded CDRNs and PPRNs.

- **Can an organization apply as both a CDRN and a PPRN?**
  - CDRNs and PPRNs are inherently different. CDRNs are healthcare delivery systems, large health plans, and similar types of organizations that cover large, diverse, defined populations unselected for a particular disease, condition, or procedure. In contrast, PPRNs are patient communities linked by a common condition. For the most part, we expect that organizations will not qualify for both funding announcements. The exception might be a large healthcare delivery system that has formed a patient group around a particular condition. In this case, the healthcare delivery system could apply as a CDRN and the affiliated patient group could apply as a PPRN.
Would a regional network be a viable competitor with existing national networks? Will reviewers be encouraged to consider smaller networks?

- Yes, we encourage networks of all sizes to apply. However, PCORI seeks to support new or existing CDRNs that will develop the capacity to conduct comparative effectiveness studies using data from clinical practice in a large, defined population (at least one million people by the end of Phase One for conditions other than rare diseases).

Does my institution need to identify our partner(s) as part of the letter of intent?

- Yes, we ask that you explicitly indicate current partnerships and/or plans to partner with other organizations.
Resources
View training materials through the Quick Links for Applicants bar. Access:

- Application training
- Opportunities for webinars
- Reviewer training

Visit the Funding Center for:

- PFAs
- Templates
- Instructions
- Key dates
- FAQ’s
This is just the beginning…
Questions

Please use this time to ask any question you may have about the PFA or the LOI submission process.

If we are unable to address your question during this time, e-mail the help desk at pfa@pcori.org.

Submitting Questions:

Submit questions via the chat function in Meeting Bridge

Ask a question via phone (an operator will standby to take your questions)