Agenda

Programmatic Overview

Administrative Overview

Questions and Answers

Submitting Questions:
- Submit questions via the chat function in Meeting Bridge.
- Ask a question via phone (an operator will standby to take your questions).
Programmatic Overview

Maryan Zirkle, MD, MS, MA
Program Officer, CER
Methods and Infrastructure
PCORnet CDRN-Phase II Webinar PFA
pcori.org/funding/opportunities
PCORnet Phase II: Clinical Data Research Networks (CDRNs)

Objectives of the PFA

- Fund up to 13 clinical data research networks (CDRNs) as part of Phase II of PCORnet. A complementary PFA seeks to fund up to 22 patient-powered research networks (PPRNs).
- Provide infrastructure funding to CDRNs to expand on the infrastructure built during Phase I of PCORnet.
- This PFA seeks both current Phase I CDRNs and new CDRN applicants.

Project period: 3 years

Budget: Up to $6,250,000 million in direct costs
  Year 1: $2.5m
  Year 2: $2.5m
  Year 3: $1.25m
PCORnet: Phase II
Clinical Data Research Networks (CDRNs)
Overview

• In Phase II, PCORnet will be established as a national resource to support multi-network patient-centered observational and interventional research.

• The network will begin to address research queries and answer important clinical research questions as it continues to build additional infrastructure for conducting more efficient and complex clinical research.

• PCORI will be funding up to 13 CDRNs:
  • system-based networks that include hospitals and community based-practices, and that may include health plans.
  • all of which routinely and securely collect individual patient-level data.

• Phase II funding is intended to support the continuity, sustainability, and expansion of critical CDRN resources and operations.
PCORnet: Phase II
Clinical Data Research Networks (CDRNs)
Goals

• **Goal 1.** Highly engaged patients, caregivers, and researchers participate in network governance and research topic generation.

• **Goal 2.** Analysis-ready standardized data, use of the PCORnet Common Data Model, and preserving strong privacy and data-security protections.

• **Goal 3.** An infrastructure for supporting clinical trials embedded within patient communities.

• **Goal 4.** An oversight framework that fosters public trust in research.

• **Goal 5.** A collaborative community that attracts a diverse set of researchers, funders, and other networks.

• **Goal 6.** Sustainable research networks.
PCORnet: Phase II
Clinical Data Research Networks (CDRNs)
Requirements

- Ability and willingness to participate in multi-network PCORnet research (i.e., research projects involving collaboration across multiple CDRNs and PPRNs) on a wide range of study designs, topics, and conditions.

- Full participation in developing PCORnet as a national research infrastructure by demonstrating an openness to respond to external requests for collaborative partnerships and by building the infrastructure needed to facilitate these inquiries and partnerships.

- Develop and maintain data linkages between CDRN data and data from private health plan or health insurance databases.

- Increase the level of collaboration with PPRNs and to have active collaborations—or commitments for collaboration—with a minimum of two PCORnet PPRNs at the time of application.
PCORnet: Phase II
Clinical Data Research Networks (CDRNs)
Applicant Overview

- **Current CDRNs** will apply for continuation of funding in competition with new applicants.
- **New applicants** (i.e., applicants not funded during Phase I) must provide an explicit plan and compelling evidence to demonstrate that, within six months of the date of the initiation of funding, their proposed CDRN will be able to meet the same requirements as Phase I CDRNs.
How are applications reviewed

pcori.org/content/merit-review-process
Applications are reviewed against nine criteria covering the following:

A. Completion of Phase I requirements
   - Current Applicants: Successful completion of Phase I requirements
   - New Applicants: Ability to meet the same requirements for Phase I by, at most, month 6 of Phase II, including prior experience and achievements enrolling participants, collecting patient-generated data, and conducting clinical research

B. Strength of proposed activities to meet Phase II goals

C. Strength of staffing and management plan

D. Proposed budget
Administrative Overview

Donna Gentry, MA
Contracts Administrator,
Pre-Award
Contracts Management
and Administration
Applicant Resources

Refer to PCORI’s Funding Center for the following resources:

- PFA and Application Guidelines
- PCORI Online User Manuals
- PCORI Online: [https://pcori.fluxx.io/](https://pcori.fluxx.io/)
- Research Methodology: [http://www.pcori.org/node/4020](http://www.pcori.org/node/4020)
Budget and Period Limitations

Funds & Budget
- Total Direct costs: CDRN: $6,250,000 direct costs:
  - Year 1: $2.5M, Year 2: $2.5m, Year 3: $1.25m
- Indirect costs: up to 40%
- Institutional base salary up to $200,000
- Indirect costs are capped on subcontracts / sub awards
- The limit for Scientific Travel is $10,000 over the duration of the project. There is no cap on Programmatic Travel.

Period of Performance: Three Years
Putting the application together
pcori.org/apply
Milestones Template- CDRN

• Milestones Template should be completed, saved as a .pdf file

• Use proper naming convention:
  Milestones_PI Last name

• Upload into PCORI Online
Technical Proposal Template

- Technical Strategy
- Protection of Human Subjects
- Consortium Contractual Arrangements
- References
- Optional Appendices
Technical Proposal Template - CDRN

Technical Strategy: Do not exceed 30 pages

Part I: Executive Summary – 1 page

Part II: Technical Proposal

A. Demonstration of Successful Achievement of Phase I Infrastructure Requirements – 6 pages

B. Proposed Plans for the Statement of Work in Phase II
   Goal 1 – 3 pages       Goal 4 – 3 pages
   Goal 2 – 6 pages       Goal 5 – 2 pages
   Goal 3 – 3 pages       Goal 6 – 2 Pages

C. Staffing and Organizational Requirements – 4 pages

D. Proposed Budget – This is addressed in separate Budget Template and Justification
Technical Proposal Template - Continued

• Protection of Human Subjects – 5 pages
• Consortium Contractual Arrangements – As needed
• References Cited – 10 pages
• Appendix (Optional) – 25 pages

All sections of the Technical Proposal should be saved as “TechnicalProposal_PI Last Name” and uploaded into PCORI Online as a single file.
People and Places Template

- 5 pages per individual, no limit on number of individuals
- 15 pages total for all Site(s)/Resources
- You may use the NIH biosketch or PCORI’s format
- Biosketches are required for all key personnel
- List all partners within the Key Personnel section
Budget - Template

• **Three budget sections** must be submitted as part of the online application process:

1. Detailed Budget
2. Budget Summary
3. Budget Justification

**NOTE:**
A detailed budget is needed for each year of the program. Complete each budget section for the prime applicant and any/each subcontractor.
Letters of Support

Demonstrate the commitment of key personnel and/or your organization’s leadership to the research project

- Address letters to the Principal Investigator or institution
- Letters are required from collaborating networks. See the PFA for collaboration requirements
- Not required for research assistants or others who are not contributing in a substantive, measurable way to the project
- Letters from your leadership and/or organizations supporting dissemination and implementation of research findings are strongly encouraged
- Consultants, coordinating center sites, and DSMB should also submit a letter of support.
PCORI Online System
pcori.fluxx.io
Using the PCORI Online System

All application materials must be submitted at [pcori.fluxx.io](pcori.fluxx.io)

- Use Google Chrome or Safari browsers

- Complete required fields -
  - PI and Contact information, Network Information – previously entered as part of LOI
  - Public Abstract (3,000 characters/spaces)
  - Key Personnel – As needed

- Upload –
  - Technical Proposal Template – Page limits as described
  - People and Places Template - Page limits as described
  - Milestones Template – As needed
  - Budget Template - As needed
  - Letters of Support – As needed
Using the PCORI Online System

All application materials must be submitted at pcori.fluxx.io

- Click the “Save and Review” tab on the left side navigation pane and then “Save and Review” on the main page
- Use the correct naming conventions for all documents and select the correct drop-down options when uploading documents
- Designate the correct individuals to your application
- Refer to our PCORI Online user manual for guidance.

Patient-Centered Outcomes Research Institute
Reminders
<table>
<thead>
<tr>
<th>What</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant Town Halls</td>
<td>February 17, 2015</td>
</tr>
<tr>
<td>Application Deadline</td>
<td>April 7, 2015 by 5:00pm ET</td>
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<tr>
<td>Interviews</td>
<td>June 3-12, 2015</td>
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<tr>
<td>Merit Review Dates</td>
<td>July 2015</td>
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<tr>
<td>Awards Announced</td>
<td>July/August 2015</td>
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<tr>
<td>Earliest Project Start Date</td>
<td>October 2015</td>
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Have a Question?

Research/Programmatic Questions
sciencequestions@pcori.org | (202) 627-1884

Administrative/Financial/Technical Questions
pfa@pcori.org | (202) 627-1885
Thank you!