Limited PCORI Funding Announcement: Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

Town Hall
Cycle 1 2017

January 25, 2017
Agenda

I. Welcome

II. Background Information

III. Limited Competition PFA Overview
   – Programmatic Requirements
   – Administrative Requirements

IV. Important Changes to PFA

V. Applicant Resources

VI. Questions

Submit questions via the chat function in Meeting Bridge.

Ask a question via phone (an operator will standby to take your questions).
Welcome to the D&I PFA Town Hall

Joanna Siegel, ScD
Director, Dissemination & Implementation
For all the advances it produces, research still has not answered many questions patients face.

People want to know which treatment is best for them.

Patients and their clinicians need information they can understand and use.
Our Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting evidence from research guided by patients, caregivers and the broader health care community.
“The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis...

... and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services...”

-- from PCORI’s authorizing legislation
Using PCORI Research to Improve Healthcare

What is the goal of the D&I Program?

• The D&I Program is charged with heightening awareness of the results of PCORI-funded research, and with advancing efforts to put these findings into practice to improve healthcare delivery and health outcomes.

• *Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results*
Limited Competition PFA Overview: Programmatic Requirements

Chris Gayer, PhD
Program Officer, Communication and Dissemination Research
Purpose and Objectives

**Purpose:** Designed to give PCORI awardee teams an opportunity to

- Propose *investigator-initiated* strategies for disseminating and implementing findings from their PCORI funded studies in the context of existing evidence

- Undertake the **next step(s)** for making their research results more useful, actionable, and accessible to targeted end users

- To promote and facilitate the **effective and timely** use of research evidence in the real world
D&I Activities We Aim to Fund

- We seek to fund projects:
  - designed to **actively** disseminate and implement research results and products
  - using approaches that are informed and guided by established dissemination and implementation models and frameworks
  - in the context of real world settings
1. Develop, demonstrate, and evaluate approaches for incorporating PCORI research results in specific decision-making settings

2. Adapt the content, format, or vehicle for delivering CER research evidence, to improve its use for different populations and across settings.

3. Take results and products found effective “to scale” in diverse settings and populations.

4. De-implement or reduce the use of interventions that are not evidence based, have been prematurely widely adopted, or are harmful or wasteful.

**Note:** All D&I projects must actively disseminate/implement findings to targeted end users and evaluate the success of the dissemination and implementation strategy.
D&I Activities We Do Not Fund

We do not fund projects which:

• Propose to develop or validate a new tool or system for patients or clinicians without the primary purpose of actively disseminating or implementing evidence. Tools and systems previously found to be effective and proposed as the primary mechanism for actively disseminating and implementing evidence will be considered.

• Propose a passive dissemination plan (publications or presentations to heterogeneous audiences) as its primary dissemination method.
D&I Activities We Do Not Fund

We **do not** fund projects which:

- **NEW**: Primarily conduct **new research**, as opposed to disseminating and implementing research findings obtained from already-completed PCORI-funded studies and evaluating the success of those D&I efforts.

- **NEW**: Propose to disseminate and/or implement **findings that are not associated with a PCORI-funded CER or methods study**.

- **NEW**: Propose to **translate and/or adapt a finding** without actively disseminating or implementing it.
Specific Requirements

The overarching objective of this PFA is to promote and facilitate the effective and timely use of research evidence in the real world.

As such, PCORI seeks to fund projects that do all of the following:

1. Propose a logical and feasible next step for D&I of clinically meaningful CER finding(s)
2. Propose to disseminate or implement findings from PCORI CER studies
3. Target end-users who can benefit directly from the use of the evidence, or who are a critical link to achieving changes in health outcomes or health care.
4. Clearly describe key PCORI research study findings
Specific Requirements (Continued)

5. Use an established conceptual model or framework to plan D&I project.

6. Describe how the perspectives and experiences of patients and stakeholders have been incorporated into the project plan.

7. Show commitment and involvement of those required to accomplish the project successfully (i.e. the host delivery systems)

8. Propose an evaluation plan that uses appropriate metrics for measuring success of D&I activities

9. Address the potential of the proposed project to inform future D&I efforts, leading to broader uptake of the PCORI findings.
Merit Review

• Criterion 1. Importance of research results in the context of the existing body of evidence
• Criterion 2. Readiness of the research results for dissemination
• Criterion 3. Technical merit of the proposed dissemination or implementation project (project design, outcomes, and evaluation)
• Criterion 4. Project personnel and environment
• Criterion 5. Patient-centeredness
• Criterion 6. Patient and stakeholder engagement
Limited Competition PFA Overview:
Administrative Requirements
Eligibility

• **Evidence Readiness:**
  – Only projects proposing to disseminate or implement findings from PCORI CER studies that a) tested a research hypothesis and b) evaluated comparative clinical effectiveness of two or more comparators will be responsive to this announcement. (Note: These requirements do not apply to methods studies.)

• **PCORI Research Awardees:**
  – Applications associated solely with PCORI Engagement Awards and Pipeline to Proposal Awards are not eligible

• **Personnel:**
  – The proposed PI’s must either be the PI of the original PCORI-funded project, or if not, then the PI of the current application must include a letter of support from the original PCORI-funded research project PI
Eligibility

• **Timing:**
  – Applicants must submit a DFRR prior to submitting their applications.
    • Applications submitted before DFFRs will be administratively withdrawn
  – Applicants *may* submit the mandatory LOI prior to the submission of their DFRR
  – If a DFRR is judged to be incomplete or otherwise inadequate by PCORI, will be administratively withdrawn
  – Applicants can submit a D&I application for up to two years after the submission of their DFRR
    • Applicants have **one opportunity** for resubmission
Complete a **Mandatory** Letter of Intent (LOI)

- **NEW:** LOIs are **competitive**; only applicants whose LOIs are deemed most responsive to this limited PFA will be invited to submit a full application.

- LOIs are a **mandatory prerequisite** for submission of a full application.
  - Applicants who fail to submit a letter of intent will not be permitted to submit a full application to the corresponding award cycle.

- LOIs **will be screened** by a minimum of two PCORI staff for responsiveness, to ensure compliance with administrative guidelines, and to determine whether the applicant should be invited to submit a full application.
  - Nonresponsive LOIs and those not adhering to administrative guidelines will not be invited to submit a full application.

3 page limit (does not include references)
Complete a **Mandatory** Letter of Intent (LOI)

Address all required sections of the LOI template:

- Title of project
- Original PCORI research award number, title, and name of principal investigator (PI)
- Identification of the evidence gap the original research results fill and the significance of the finding
- Objective and specific aims
- Description of the dissemination setting and end-users
- Description of the approach for disseminating the research results
- Description of D&I evaluation plan, including measurable indicators of success
- Patient and stakeholder engagement in the planning and implementation of this dissemination effort.
NEW:

Total Direct Cost Per Project: $350,000
Maximum Project Period: 2 years
Greater Than Budget/Time Requests

• Greater Than Budget/Time Requests should be used for requesting funding for a project with a budget that exceeds the PFA limits or for a project that exceeds the PFA time limit

• **NEW:** Intention to submit Greater Than request must be indicated at the time of LOI submission
  
  — Justification is required

• **NEW:** If applicant is invited to submit a request, he/she may submit the Greater Than Budget/Time Request form as an attachment to the application

• **NEW:** Collaborative applicants are encouraged to request extra funds or time, as appropriate and commensurate to the scope of the proposed project.
NEW: Collaborations

• Projects involving collaboration to disseminate the results of eligible studies.

• Must involve the partnership of two or more PCORI-funded investigators partnering to disseminate the collective results of two or more eligible studies on a single/closely related condition, population, decision dilemma, or evidence gap

• Use of Greater Than Budget/Time Request is encouraged for collaborative projects

• Must have demonstrated support from PI of each PCORI study being disseminated
Resubmissions

• Applicants can submit a D&I application for up to two years after the submission of their DFRR
• Applicants have one opportunity for resubmission
• Applicants may not resubmit an application until they have received merit review feedback (summary statement) from the initial submission.
• All resubmitted applications require submission of a new LOI
• If invited to submit a full application, applicants must include a Resubmission Letter with their applications.
  – Resubmission Letter must address merit review and programmatic feedback received after the original submission
# Key Information

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<thead>
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<th>Key Information</th>
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<td><strong>Cycle:</strong> Cycle 1 2017</td>
<td><strong>Merit Review:</strong> July 2017</td>
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<td><strong>Full Announcement:</strong> Dissemination and Implementation of Patient-Centered Outcomes Research Institute (PCORI) funded Patient-Centered Outcomes Research (PCOR) Results</td>
<td><strong>Awards Announced:</strong> November 2017</td>
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<td><strong>Online System Opens:</strong> January 17, 2017</td>
<td><strong>Earliest Start Date:</strong> January 2018</td>
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<td><strong>Status:</strong> OPEN</td>
<td><strong>Total Direct Costs:</strong> $350,000</td>
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<td><strong>Applicant Town Hall Session:</strong> January 25, 2017</td>
<td><strong>Funds available up to:</strong> $9,000,000 per year</td>
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<td><strong>Letter of Intent (LOI) Deadline:</strong> February 14, 2017</td>
<td><strong>Maximum Project Period:</strong> 2 years</td>
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<td><strong>Application Deadline:</strong> May 17, 2017</td>
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Summary of Key Changes to PFA for 2017

• More detail and clarity on PCORI’s expectations for successful D&I proposals

• LOI process is now competitive (see pg 7 of PFA for more detail)

• New policy on collaborative submissions (see pg 3 of PFA for more detail)

• Clarification of resubmission policy (see pg 3 of PFA for more detail)

• More detail regarding our expectations around evaluation plans for D&I projects (see pg 5 of PFA for more detail)
Applicant Resources

Arielle Gorstein, MPH
Program Associate, Dissemination & Implementation
Common Pitfalls

- Lack of detail regarding PCORI study findings to be disseminated
- Strength of evidence is not consistent with proposed D&I activity
- Trying to do more than is realistic within the time/budget constraints
- Proposing to develop the dissemination plan as part of the dissemination project
- No indication that key dissemination personnel have D&I experience
- Proposing to develop, test, or validate the tool/product that will be used to perform D&I
- Proposing to perform research
What Can I Do **Now** to Prepare?

1. Review the PFA and begin to develop a D&I plan with your research team and patient/stakeholder partners:  

2. Review the PCORI draft final research reporting instructions; ask your Program Officer if you have any questions:  


4. Email DisseminationQuestions@pcori.org to set up a call with a Program Officer from the D&I team

5. Check out the funded project pages (links on following slide)
Applicant Resources: Where Can I Find Help?

Visit pcori.org/apply, then click on the Limited PCORI Funding announcement link for:

- Application Guidelines
- FAQs
- PCORI Online User Manuals

For technical assistance
- PCORI Helpdesk: pfa@pcori.org

For programmatic assistance
- Disseminationquestions@pcori.org

Funded D&I Projects (for reference)
Q&A

Ask a question via the chat function in Meeting Bridge.

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

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