

MEETING NOTES

PCORI Funding Overview & Research Opportunities

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| Presenter: | Dr. Erin Colligan, PCORI Program Officer |
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| PCORI Link: | https://www.pcori.org |
| Recap By: | OSIRD |

Executive Summary

The session provided an overview of the Patient-Centered Outcomes Research Institute (PCORI), its funding mechanisms, application processes, and the central role of patient engagement in all PCORI-funded research. Dr. Colligan, a program officer specializing in pain management and systems research, walked attendees through the various types of awards, eligibility criteria, and practical advice for submitting competitive applications. A Q&A session followed covering topics such as the definition of "patient," international research eligibility, dissemination grants for non-PCORI studies, structured mentorship, and PCORI's organizational status.

What Is PCORI?

PCORI is an independent, non-governmental nonprofit organization established under the Affordable Care Act. It is funded through a combination of general tax revenue and the Patient-Centered Outcomes Research Trust Fund, which is supported by a tax on insurers. PCORI's mission is to help people make better-informed healthcare decisions by producing high-integrity, evidence-based information guided by patients, caregivers, and the broader healthcare community.

A key distinction emphasized throughout the presentation is that PCORI focuses on patient-centered outcomes rather than payer or health system perspectives. PCORI does not fund cost-effectiveness research; instead, it is agnostic to costs and focused on determining what works best for patients. However, PCORI does welcome the inclusion of patient-centered economic burden measures such as transportation costs, lost wages, copays, and childcare expenses.

Topic Themes & Research Agenda

PCORI's research agenda is shaped by broad stakeholder engagement and comprises evolving topic themes that highlight areas of national significance where research gaps exist. These themes are intersectional and encompass health issues facing large populations in the United States. While PCORI welcomes all investigator-initiated research, the topic themes serve as

guided priorities informed by community partners. Pain management was highlighted as one such priority area, with Dr. Colligan serving as a lead on the pain management work group.

Types of PCORI-Funded Projects

Comparative Effectiveness Research (CER) Awards

CER awards are PCORI's primary funding mechanism. These studies compare two or more treatments, services, or healthcare practices. CER is divided into two tracks:

- Clinical CER: Focuses directly on medications, treatments, and clinical interventions.
- Systems Research: Focuses on care delivery strategies and practice- or health system-level interventions.

Applicants are routed to the appropriate track (clinical vs. systems) based on their topic area after submitting a research idea.

Other Award Types

- Methods Awards: Smaller awards focused on innovations in research methods that can inform CER studies.
- Science of Engagement Awards: Newer awards focused on developing, validating, and testing engagement techniques and measures to advance the science of patient engagement.
- Dissemination and Implementation Awards: Primarily for taking completed PCORI-funded research findings to the next level through broader implementation. Most of these focus on previously funded PCORI projects, though open competition opportunities occasionally arise.
- Engagement Awards: Capacity-building and convening support awards that bring patients, caregivers, and clinicians together to build the infrastructure for patient-informed CER.

Key Funding Mechanisms

Phase Large Awards

These are PCORI's largest awards, featuring an 18-month feasibility phase followed by evaluation and potential advancement to a full-scale study. This mechanism is offered at least annually.

Broad Pragmatic Studies (BPS)

Described as PCORI's "bread and butter," BPS is the primary funding opportunity open to all investigator-initiated research. It offers three budget categories: up to \$5 million, \$5–12 million, and up to \$12 million (using the PCORI map). Letters of intent are three pages. BPS may include

special areas of emphasis aligned with topic themes, but all well-justified research ideas are welcome. PCORI runs approximately three funding cycles per year.

Topical Funding Announcements

Stakeholder-driven announcements addressing issues and questions of national significance. If an application to a topical announcement is not scored well, the applicant can resubmit under BPS incorporating merit review feedback.

PCORnet: Research Infrastructure

PCORnet is a nationwide network of eight clinical research networks providing access to real-world patient care data through a standardized common data model. It draws from approximately 13,000 clinical sites and 47 million demographically representative patients available for recruitment. PCORnet supports observational studies through pragmatic trials. Studies using PCORnet come in under the BPS Category 3, and interested researchers can contact the "PCORnet front door" for logistical support.

Patient Engagement: Foundational Expectations

Patient engagement is central to PCORI's mission. Applications must address six foundational areas of engagement, moving beyond input-only approaches toward meaningful partnership. The key principles discussed include:

- **Representative Involvement:** Ensuring diverse, relevant patient voices are included from the outset.
- **Early and Ongoing Engagement:** Patient involvement from research conception through dissemination of findings.
- **Dedicated Funds for Engagement:** Budgeting for partner compensation is required and closely reviewed.
- **Capacity Building:** Developing teams that include patients as genuine partners.
- **Meaningful Decision-Making Inclusion:** Patients should guide measure selection, methodology, recruitment strategies, and interpretation of results.
- **Ongoing Review and Assessment:** Regular check-ins to evaluate the quality and effectiveness of engagement throughout the project.

Practical Advice on Patient Engagement

Dr. Colligan emphasized that her top piece of advice is to talk to patients before developing your application. She recommended consulting existing patient advisory boards at institutions, working with patient advocacy groups, and including patient quotations in the application to make the case for the decisional dilemma. She shared anecdotes where patient advisors helped solve recruitment challenges by offering practical insights, such as making recruitment letters less formal and displaying recognizable phone numbers so patients would answer calls.

Structured Mentorship Opportunity

PCORI now offers a structured mentorship component under BPS awards. This allows junior or mid-career researchers, or those making a career transition into patient-centered CER, to work with a senior researcher in a formal mentorship role. The goal is to position mentees to independently lead future CER projects. Dr. Colligan shared the example of a physical therapist in her portfolio who is transitioning into CER through this mechanism.

Research Impact Examples

The CODA Study (Clinical CER)

This study compared antibiotics versus surgery for treating acute appendicitis. One month after treatment, patients who received antibiotics had similar health outcomes to those who underwent surgery. The American College of Surgeons incorporated these findings into national clinical guidelines, recognizing antibiotics as an accepted first-line treatment. PCORI also funded a follow-on implementation project to train over 500 clinicians and staff on these treatment options.

The MODEL Study (Systems CER)

This study compared three approaches to improving diabetes self-care among African American adults in low-income areas of the mid-South: a diabetes education guide alone, the guide plus text messages, and the guide plus in-person health coaches. Patients who received text messages reported more days following a healthy eating plan compared to the guide alone, while coaching did not show a significant difference in eating habits. There was no difference across approaches in exercise or medication adherence. The findings help patients and health systems choose the most effective and feasible support strategies.

How to Apply

Eligibility Decision Tree

PCORI provides a flowchart on their FAQ page to determine whether a study qualifies as comparative clinical effectiveness research. The core criteria are:

1. The research must compare two or more healthcare options that have evidence of efficacy or are in widespread use.
2. The research must address a decisional dilemma that could inform patient healthcare decision-making.
3. Patients and other partners must be engaged in the research questions, study design, and outcome selection.
4. Study results must provide evidence that can be readily adopted in real-world settings (scalability).

Contacting PCORI

Researchers are encouraged to submit a brief summary of their research idea to pfa@pcori.org using the PECOTs format (Population, Intervention, Comparator, Outcomes, Timing, and Setting). PCORI does not review full letters of intent in advance of submission deadlines, but a short summary (even a paragraph) helps program officers assess fit and connect applicants with the right expertise.

Q&A Session Highlights

Definition of "Patient"

A question was raised about how PCORI defines "patient" in the context of prevention-focused research (e.g., HIV prevention). Dr. Colligan acknowledged this is a nuanced area and suggested focusing on identifying individuals at higher risk who would benefit most from interventions, and recommended reaching out to the relevant work group for scoping guidance.

International Research

PCORI's congressional mandate specifies a focus on U.S. healthcare and patients. While some studies may include international sites, the research must be primarily U.S.-based, and applicants must demonstrate that findings from other countries are generalizable to the U.S. healthcare system.

Dissemination Grants for Non-PCORI Studies

A question was asked about whether NIH-funded clinical trials could qualify for PCORI dissemination and implementation awards. Dr. Colligan noted that while most such awards go to PCORI-funded studies, open competition opportunities have been available, though their frequency is uncertain.

PI Experience Requirements

PCORI evaluates the researcher and environment as one of its six merit review criteria. PIs are expected to have experience managing studies at the scope of PCORI awards. Junior researchers can serve as co-investigators to build experience before leading future applications.

PCORI's Organizational Status

PCORI is an independent nonprofit, not a federal agency. It was established under the Affordable Care Act and has not been subject to any restrictions affecting federal agencies. PCORI maintains a public policy department that liaises with Congress and has testified before congressional committees.

Pre-Established Community Partnerships

Applicants should have key stakeholder committee members identified by the application phase and should have consulted patients early. Letters of support from partners are helpful. While every detail does not need to be finalized, evidence of meaningful patient consultation and endorsement of the research question strengthens the application.

Key Resources & Contact Information

- General inquiries and research summaries: pfa@pcori.org
- PCORI FAQ and methodology standards: available on the PCORI website
- PCORnet front door: contact for studies using PCORnet infrastructure
- Self-guided trainings on patient-centered CER and engagement are available online
- PCORI newsletter for funding opportunities and research summaries
- Opportunities to get involved: advisory panels, merit reviewers, PCORI ambassadors, peer reviewers

Note: Dr. Colligan indicated she is a point of contact for Broad Pragmatic Studies and welcomes researchers to discuss their ideas.