



PCORI, CER, and Funding Opportunities

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PCORI

New Investigators Meeting

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Presentation Objectives

- Introduction to PCORI
- Overview of funding programs and merit review
- PCORI's research portfolio
- Specific CER Alliance award example
- Final tips

About PCORI

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns



Our Mission and Strategic Goals

To help people make informed healthcare decisions, and to improve 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.**

Our Strategic Goals:



Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions



Speed the implementation and use of patient-centered outcomes research evidence



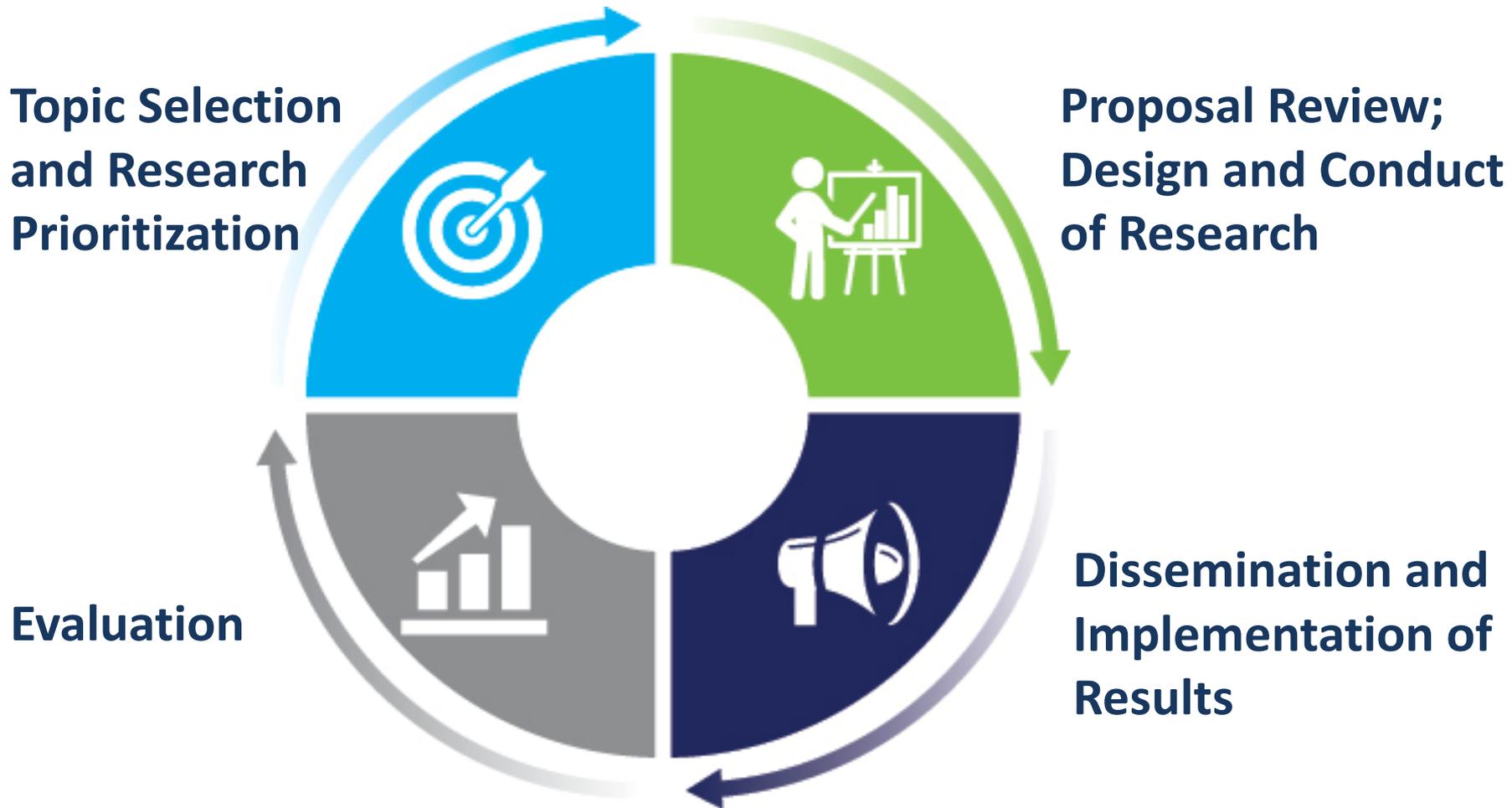
Influence research funded by others to be more patient-centered

We Fund Comparative Effectiveness Research

- Generates and synthesizes evidence comparing benefits and harms of at least two different methods (with established efficacy) to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits and harms in real-world populations
- Describes results in subgroups of people
- Helps consumers, clinicians, purchasers, and policy makers make informed decisions that will improve care for individuals and populations
- Informs a specific clinical or policy decision

Note: We do not fund cost-effectiveness research

Engagement: a Path to Useful, High-Quality Research



OVERVIEW OF FUNDING PROGRAMS AND MERIT REVIEW

Our National Priorities for Research

National Priority	Description of Research Focus
Assessment of Prevention, Diagnosis, and Treatment Options	Research comparing the harms and benefits of alternative interventions to determine which work best for individual patients
Improving Healthcare Systems	Research comparing different health system-level approaches for improving access and care
Communication and Dissemination Research	Research comparing different ways of providing information produced by CER
Addressing Disparities	Research comparing interventions to reduce or eliminate disparities in health and health care
Accelerating PCOR and Methodological Research	Infrastructure and methodological development to support CER

Broad Funding Announcements

Overview

- Topics are investigator initiated, representing the research community's interests
- The announcements include awards that align with PCORI's National Priorities for Research
- Applicants must demonstrate active patient partnerships in proposal

- Project Duration: Generally 3 Years
- Direct Costs per Project: \$750,000 – \$5,000,000
- Competitive LOI Review

Pragmatic Clinical Studies

Seeks to produce information that can be directly adopted by providers:

- Addresses critical clinical choices
- Often conducted in routine clinical settings
- Though often large, usually less complex protocols than traditional trials
- Topics of special interest from stakeholders, Institute of Medicine, Agency for Healthcare Research and Quality

Overview

- Awards per Funding Cycle: Six to Nine
- Maximum Project Duration: 5 Years
- Maximum Direct Costs per Project: \$10 Million
- Competitive LOI Review

Targeted Funding Announcements

Seek research proposals on the highest-priority questions identified through PCORI's topic generation and research prioritization process

Examples:

- Clinical Management of Hepatitis C Infection
- Treatment of Multiple Sclerosis
- Management and Reduction of Opioid Use for Chronic Pain

Overview

- Project Duration: Varies by announcement
- Direct Costs per Project: Varies by announcement
- Competitive LOI Review

<http://www.pcori.org/research-results/how-we-select-research-topics/generation-and-prioritization-topics-funding-4>

What PCORI is not seeking

- Studies of cost-effectiveness
- Natural history studies
- Studies to establish efficacy

“(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”.

Who Can Apply?

PCORI accepts applications from:

- **Any private-sector research organization**, including:
 - Non-profit or for-profit organization
 - Laboratory or manufacturer/industry
- **Any public-sector research organization**, including:
 - University or college (including affiliated clinician group)
 - Hospital or healthcare system (including affiliated clinician group)
 - Units of state, local, or federal government
- **Foreign organizations and nondomestic components of US organizations**, if clear benefit to US healthcare system and patient-centered research efforts

Note: Individuals may not apply

Our Merit Review Process

1. Evaluate letters of intent.
2. Preliminary review of full applications.
3. In-person panel review
4. Selection Committee review.
5. Slate is proposed to PCORI's Board for consideration and approval.

PCORI Funds Research That...

Meets these criteria:

1: Potential for the study to fill critical gaps and generate actionable evidence

Addresses a *clinical uncertainty or decisional dilemma* experienced by patients and other stakeholders

2: Potential for the study to be adopted into clinical practice and improve delivery of care

Has the potential to lead to *improvements in clinical practice and patient outcomes*

3: Scientific merit (research design, analysis and outcomes)

Has a research design of sufficient technical merit to ensure that the *study goals will be met*

4: Investigator and environment

Appropriateness of team and environment's capacity to support proposed project

5: Patient-centeredness

Focuses on improving *patient-centered outcomes* and employs a *patient-centered research design*

6: Patient and stakeholder engagement

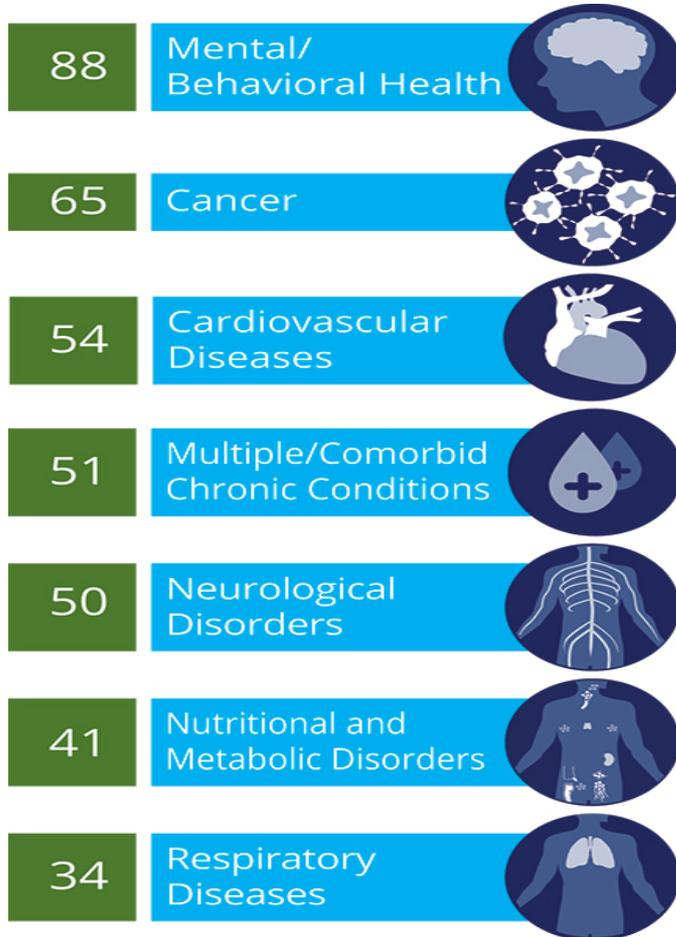
Includes patients and other stakeholders as *partners throughout the entire research process*



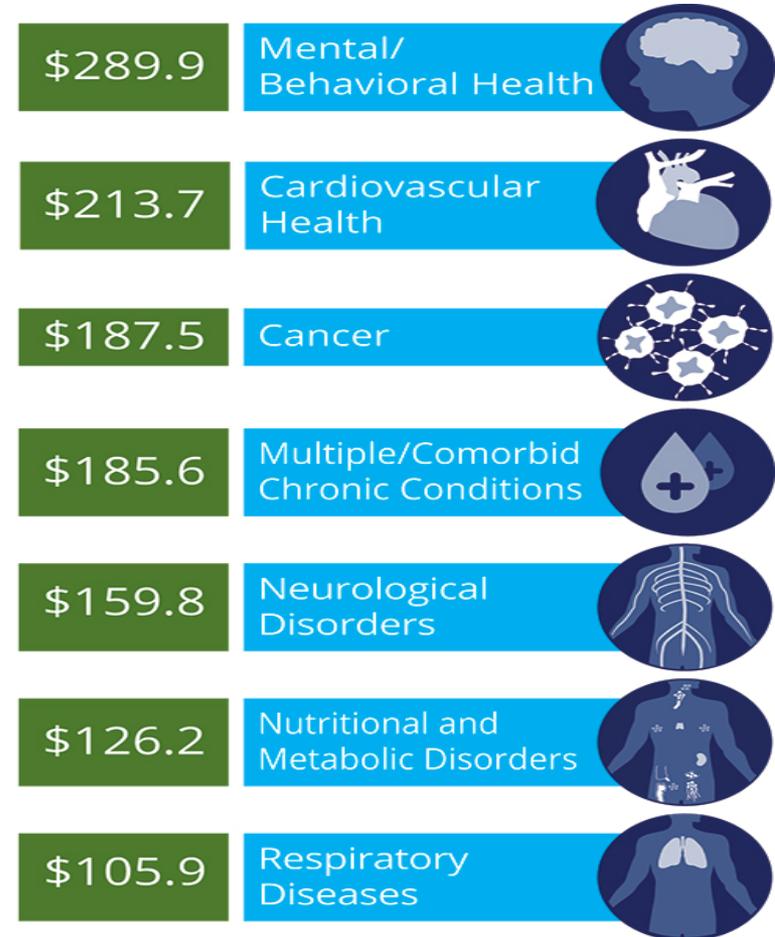
PCORI'S RESEARCH PORTFOLIO AND SPECIFIC ALLIANCE EXAMPLE

PCORI Funded Projects

By number of projects



By amount awarded (in millions)



Comparison of Operative versus Medical Endocrine Therapy (COMET) for Low Risk DCIS (PI, Shelley Hwang)

- **Research Question**

- What are the comparative benefits and harms of managing low-risk DCIS with guideline concordant care compared to active surveillance?

- **Study Design**

- Multi-site non-inferiority randomized controlled trial
- 100 sites within Alliance
- 1192 participants with biopsy-confirmed low-risk DCIS

- **Outcomes**

- 2-year ipsilateral invasive cancer rate
- Health-related QOL at 1 and 2 years
- Anxiety and depression
- Financial burden/employment

FINAL TIPS

Tips for Success

- Clearly describe comparators for the study
- Document evidence of efficacy/effectiveness for the intervention and comparator(s) and/or demonstrate that they are in widespread use
- Provide a sound rationale for why the research question of interest is important to patients
- Clearly demonstrate the feasibility of the study
 - Show you have the team to do what is proposed and you are the right team
 - Describe and justify your recruitment and retention plan
 - Document that sites are already committed to participating
 - Include realistic timelines for site start-up, IRB approval, and recruitment

PCORI Funding Opportunities

Our research funding is awarded through PCORI Funding Announcements. Open opportunities are posted at pcori.org/apply.

The screenshot shows the PCORI website's 'Funding Opportunities' page. At the top, the PCORI logo is on the left, and navigation links for 'BLOG', 'CAREERS', 'NEWSROOM', 'SUBSCRIBE', and 'CONTACT' are on the right. Below the logo is the text 'Patient-Centered Outcomes Research Institute'. A search bar is located on the right side of the header. A blue navigation bar contains links for 'ABOUT US', 'FUNDING OPPORTUNITIES' (which is highlighted), 'RESEARCH & RESULTS', 'GET INVOLVED', and 'MEETINGS & EVENTS'. The main heading 'Funding Opportunities' is displayed in large white text on a blue background. Below this, a sidebar on the left lists various sections: 'Funding Opportunities', 'WHAT & WHO WE FUND', 'HOW TO APPLY', 'APPLICANT TRAINING', 'WHAT WE MEAN BY ENGAGEMENT', 'MERIT REVIEW PROCESS', 'PROGRAMMATIC FUNDING', and 'AWARDEE RESOURCES'. The main content area features a paragraph explaining that most funding is awarded through PCORI Funding Announcements (PFAs) and also offers programmatic funding opportunities like the Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards. Below this text is a horizontal bar with three tabs: 'OPEN', 'UPCOMING', and 'CLOSED'. The 'OPEN' tab is selected. Under the 'Open Opportunities' section, there is a paragraph detailing the resources available to applicants, including the PCORI Online Application System and information about the National Patient-Centered Clinical Research Network Phase II applicants.

Help with Selecting a PCORI Funding Program

- A list of all open, closed, and upcoming funding announcements can be found here:
<http://www.pcori.org/funding-opportunities>
- If you are not sure which is best for you, contact the PCORI Helpdesk:
 - Email: sciencequestions@pcori.org
 - Phone: (202) – 627 – 1884
 - Online: <http://www.pcori.org/PFA/inquiry>

Contact Us



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Thank You

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