



# **2019 ANNUAL MEETING**

OCTOBER 19 - 23

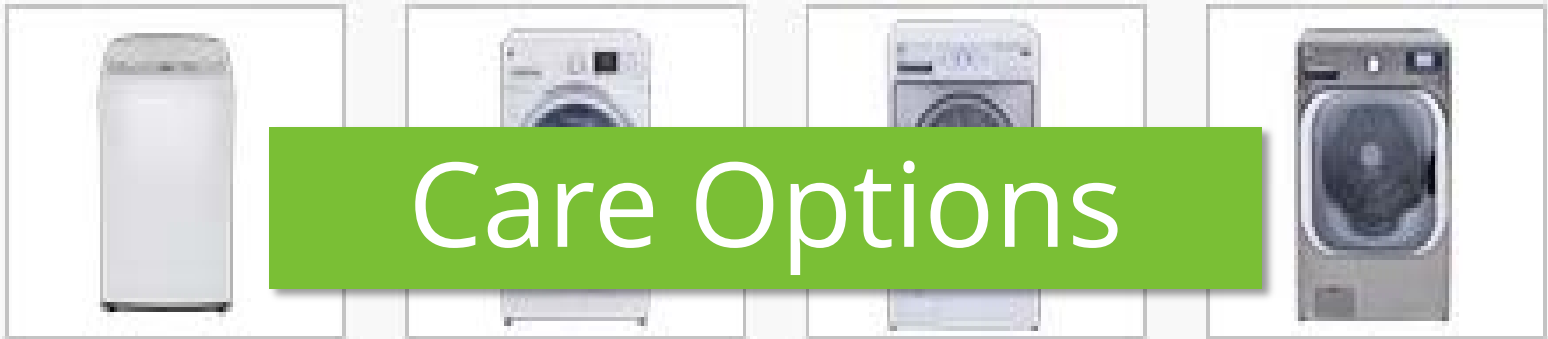
## **An Introduction to the Patient- Centered Outcomes Research Institute**

---

James Hulbert, MS, Associate Director, Patient-Centered Outcomes Research Institute  
Washington, D.C., U.S.A.

# Imagine if Healthcare was like Consumer Reports

ConsumerReports.org<sup>®</sup>



Preference		Overall score	52	Good	71	Very Good	71	Very Good	72	Very Good
										
			60		80		60		75	
										
										
										
										
										
										

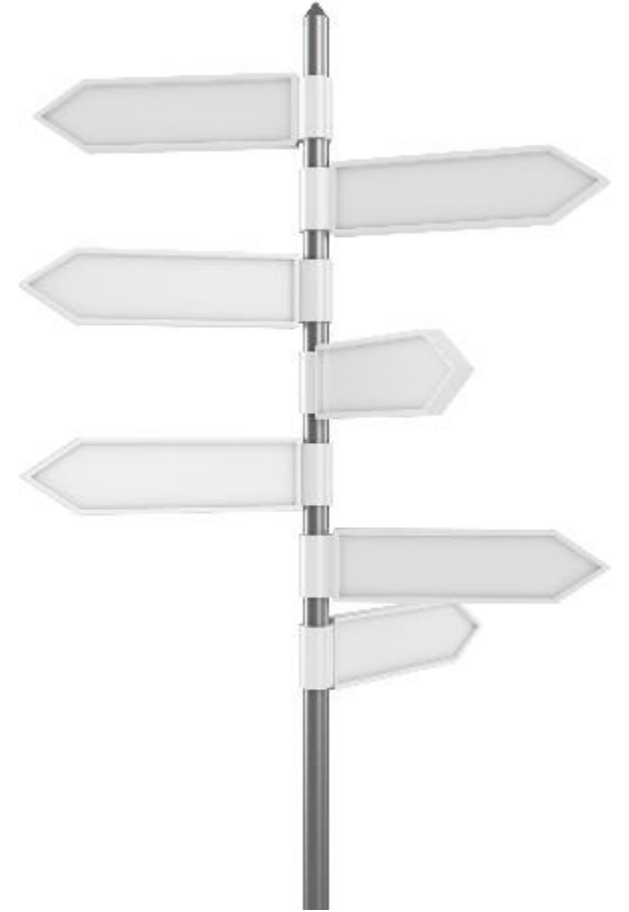
# About Us

- 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



# Why Is Our Work Needed?

- For all the advances it produces, traditional healthcare research has not answered many questions patients face.
- People want to know which preventive, diagnostic, or treatment option is best for them.
- Patients and their clinicians need information they can understand and use.





# How Is Our Work Different?

- We fund research on which care options work, for whom, under which circumstances.
- We focus on answering questions most important to patients and those who care for them.
- We aim to produce evidence that can be easily applied in real-world settings.
- We engage patients, caregivers, clinicians, insurers, employers, and other stakeholders throughout the research process.
- This makes it more likely we'll get the research questions right and the study results will be useful and taken up in practice.






# Our Mission and Strategic Goals



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.**

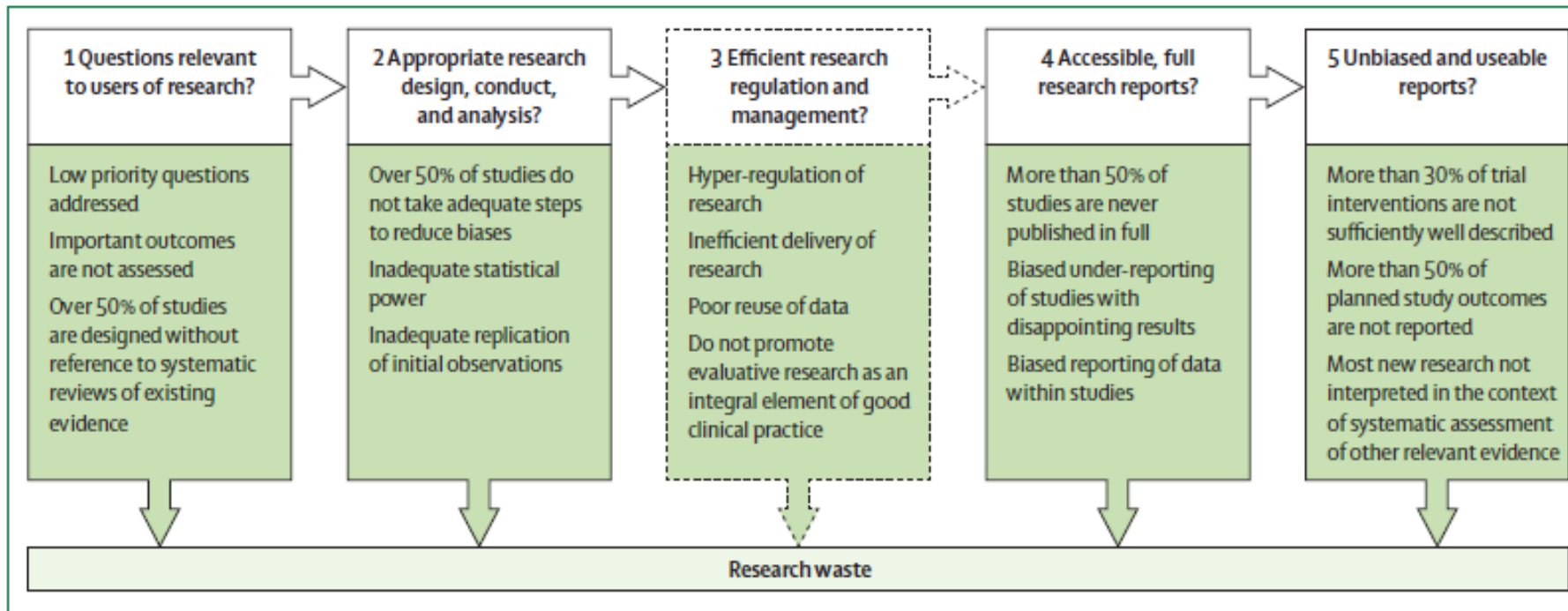
## Our Strategic Goals:

-  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

# Making Research Results Useable

In 2009, thought leaders estimated that **85% of biomedical research is avoidably wasted** [Chalmers and Glasziou, Lancet 2009]

- Series of papers followed in the Lancet in 2014 which included 17 recommendations for improvement across all stages of research production



Increasing value and reducing waste in biomedical research: who's listening? Moher D, et al. *Lancet* 2015; Online: Sept.28

# Relevance to PCORI



Many of the recommendations made in the 2014 Lancet series for reducing waste align with PCORI's strategic goals and commitment to transparency:

1. Substantially **increase the quantity, quality, and timeliness of useful, trustworthy information** available to support health decisions.
2. **Speed the implementation and use** of patient-centered outcomes research evidence.
3. **Influence** clinical and healthcare research funded by **others to be more patient-centered.**

With this in mind, PCORI began self-assessment of current practice against Lancet recommendations in 2016, with major effort in 2017

# How are we doing? A view from the outside

- External assessment by Nasser et al in 2017 found that **PCORI is one the few major health funders** internationally (N=12) which:
  - **Involve the public in setting priorities** and **is transparent** about the priority-setting process (1 of 3 funders)
  - **Require citation of a systematic review** in applications for funding (1 of 2 funders)
  - **Require trial registration** at the point of award (1 of 3 funders)
  - Dedicate **funding for methods** research (1 of 3 funders)

How priorities are set? Are patients and public involved?

UK	NIHR
Netherlands	ZonMw
USA	PCORI
UK	MRC
Norway	RHA
Australia	NHMRC
Canada	CIHR
USA	NIH
France	FMoH
France	ANR
Germany	DFG
Denmark	DR

Prioritisation process is transparently and patients are partners in the decision making

Some information on the plan for a prioritisation process but not on implementation

Patients involvement is very limited

No patient involvement in the priority setting process

No information on how priorities are set

Nasser et. al, What do funders do to increase value and reduce waste in research? World Conference on Research Integrity, 2017. Amsterdam

# How are we doing? A view from the inside

- Performed **self-audit of practice and policies against Lancet recommendations** to benchmark our current practice and identify areas for improvement



Whitlock EP, Selby JV, Dunham KM, Fernandez A, Forsythe LP, Norquist G. Examining the role of funders in ensuring value and reducing waste in research: An organizational case-study of the Patient-Centered Outcomes Research Institute [version 1; peer review: awaiting peer review]. F1000Research 2019, 8:288

- **PCORI has at least some level of policy or practice for 85% of the sub-recommendations** (28 of 33), with ample room for additional improvement
  - **Areas of strength:** engaging end users in research prioritization, requiring design and conduct standards, requiring and supporting complete reporting, promoting integration of research in clinical practice
  - **Areas of growth:** rewarding research replication and reproducibility, improving policies on data sharing, making study protocols publicly available

2.

---

## Our Research Focus

# We Fund Comparative Clinical Effectiveness Research (CER)



- Generates and synthesizes evidence comparing benefits and harms of at least two different methods to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits 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*

Adapted from *Initial National Priorities for Comparative Effectiveness Research*, Institute of Medicine of the National Academies



# We Fund Patient-Centered Outcomes Research

## PCOR is a relatively new form of CER that....

- Considers patients' needs and preferences, and the outcomes most important to them
- Investigates what works, for whom, under what circumstances
- Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options



# We Fund Research That...



## Meets these criteria:

### 1. Potential for the study to fill critical gaps in evidence

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

### 2. Potential for the study findings 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(s) and environment

The proposed project has a team with appropriate investigators (e.g. qualifications and experience), as well as an environment with sufficient capacity (e.g. resources, facilities, and equipment)

### 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

# What We Mean By...

## **“Patient-centeredness”**

- The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
- Research questions and outcomes should reflect what is important to patients and caregivers



## **“Patient and stakeholder engagement”**

- Patients are partners in research, not just “subjects”
- Active and meaningful engagement between scientists, patients, and other stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought-out plan

# Focus on High-Priority Conditions

- Affecting large numbers of people across a range of population
- Placing a heavy burden on individuals, families, specific populations, and society
- Including rare diseases, which are difficult to study



# Pays Particular Attention to Specific Populations

- Racial and ethnic minorities
- Older adults
- Low-income
- Residents of rural areas
- Women
- Children
- Patients with low health literacy/numeracy and limited English proficiency
- Lesbian, gay, bisexual, transgender (LGBT) persons
- Veterans and members of the armed forces and their families
- Individuals with special healthcare needs, including individuals with disabilities, individuals with multiple chronic diseases, individuals with rare diseases, and individuals whose genetic makeup affects their medical outcomes



# We Also Work to Improve Research Methodology

In any study, methods matter. That's why we've developed methodology standards that patient-centered CER should follow, at a minimum.

## Methodology Standards: 16 Broad Categories

- Formulating Research Questions
- Patient-Centeredness
- Data Integrity and Rigorous Analyses
- Preventing/Handling Missing Data
- Heterogeneity of Treatment Effects
- Data Registries
- Complex Interventions
- Mixed Methods Research
- Data Networks
- Causal Inference
- Adaptive and Bayesian Trial Designs
- Studies of Medical Tests
- Systematic Reviews
- Research Designs Using Clusters
- Qualitative Methods
- Individual Participant-Level Data Meta-Analysis

3.

---

## Our Growing Research Portfolio



# Snapshot of Funded Projects

## Number of funded awards:

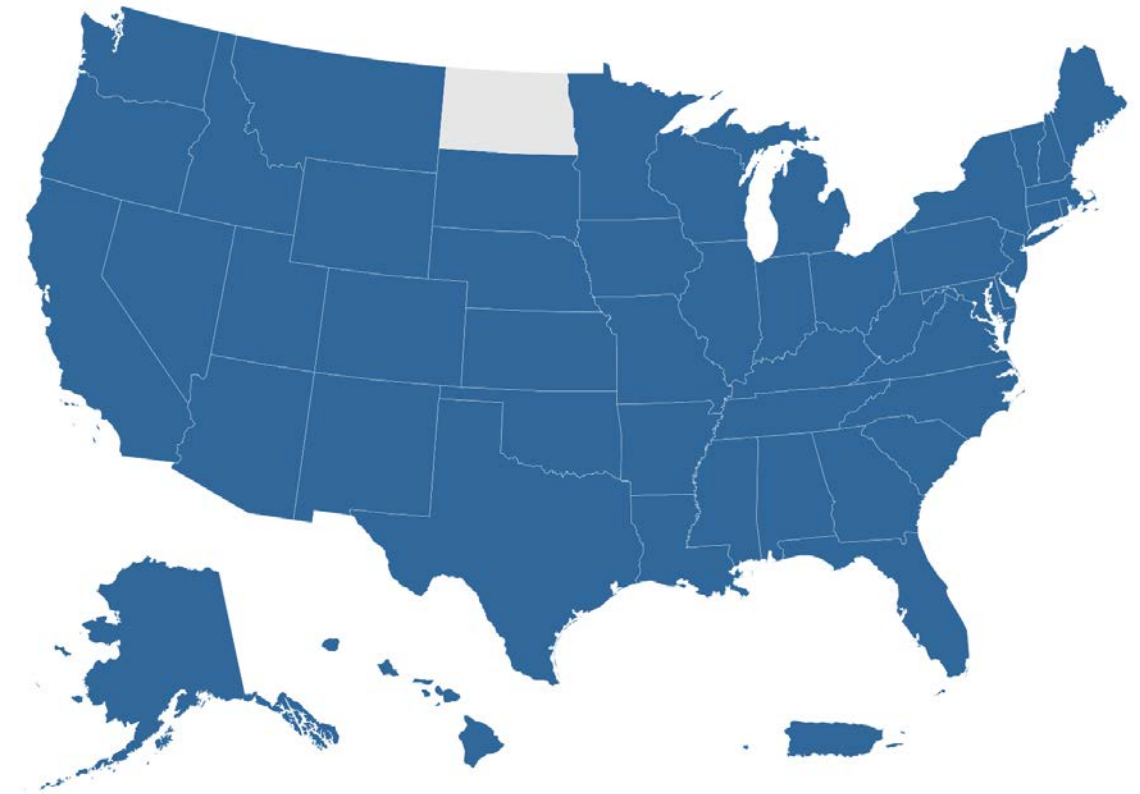
More than 1,400

## Amount awarded:

More than \$2.4 billion

## Number of states where we are funding projects:

49 (plus the District of Columbia and Puerto Rico)



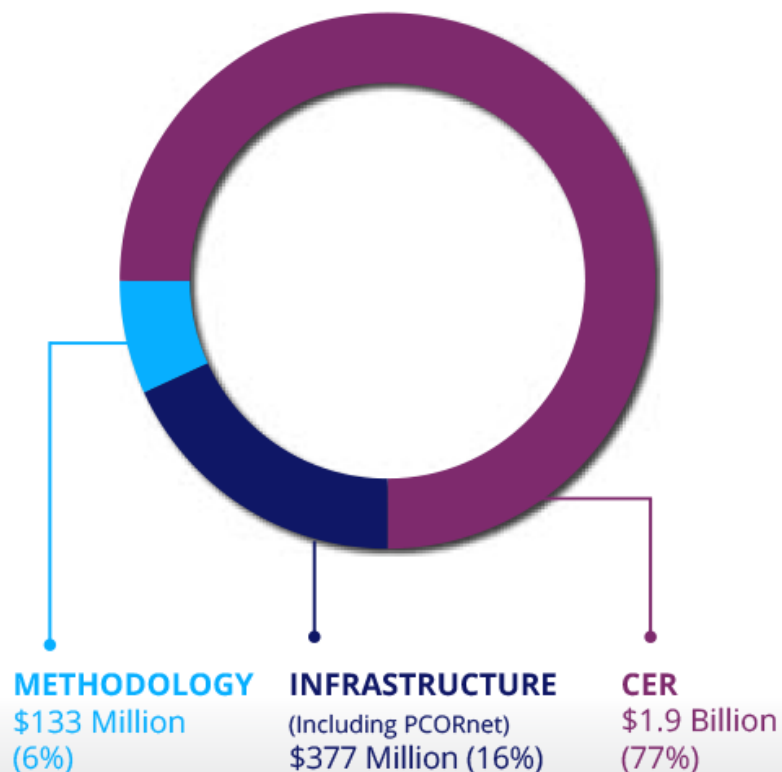
AS OF MARCH 2019  
All awards



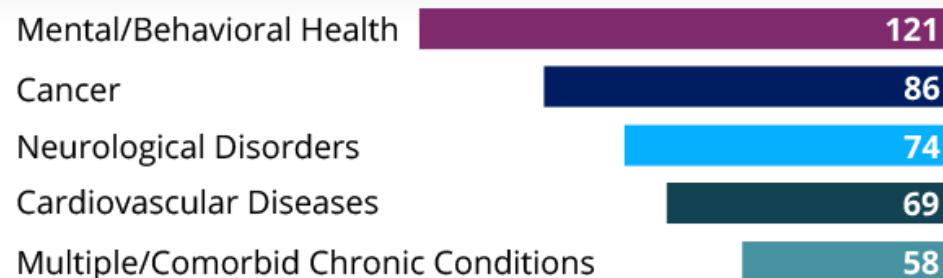
# About Our Research Portfolio

## BY THE NUMBERS

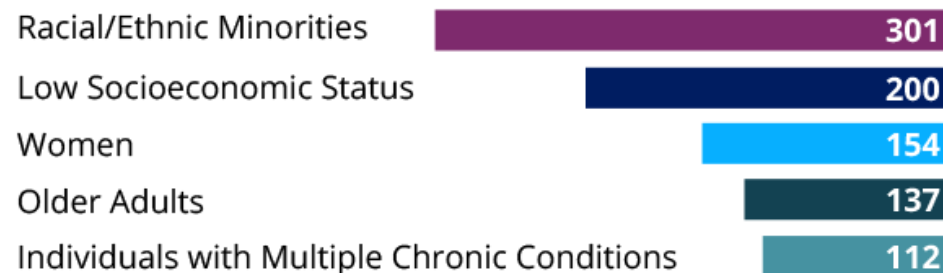
### Research Projects By Area



### Most Studied Conditions\*



### Most Studied Priority Populations\*



\*Number of projects (out of a total of 455). A project may study more than one condition or priority population.

# PCORI Funds Research on High-Cost, High-Impact Health Conditions



National Per Capita Expenditure	Condition	Number of PCORI Studies	PCORI Investment
\$32,027	Stroke	15	\$63 M
	Heart Failure	15	\$70 M
	Hepatitis (Chronic Viral B and C)	9	\$60 M
	Chronic Obstructive Pulmonary Disease	17	\$89 M
	Schizophrenia/Other Psychotic Disorders	11	\$22 M
	Chronic Kidney Disease	18	\$72 M
	Asthma	16	\$51 M
	Atrial Fibrillation	5	\$8 M
	Alzheimer's Disease/Dementia	13	\$78 M
	Depression	44	\$173 M
	Cancer	83	\$322 M
	Ischemic Heart Disease	21	\$101 M
	Osteoporosis	1	\$14 M
	HIV/AIDS	7	\$16 M
	Arthritis	15	\$50 M
	Diabetes	31	\$73 M
	Hypertension	12	\$54 M
	Hyperlipidemia	7	\$27 M
\$8,285	Autism Spectrum Disorders	2	\$4 M

PCORI has funded **256** studies determining what works best in care for the 19 highest cost conditions in the United States.

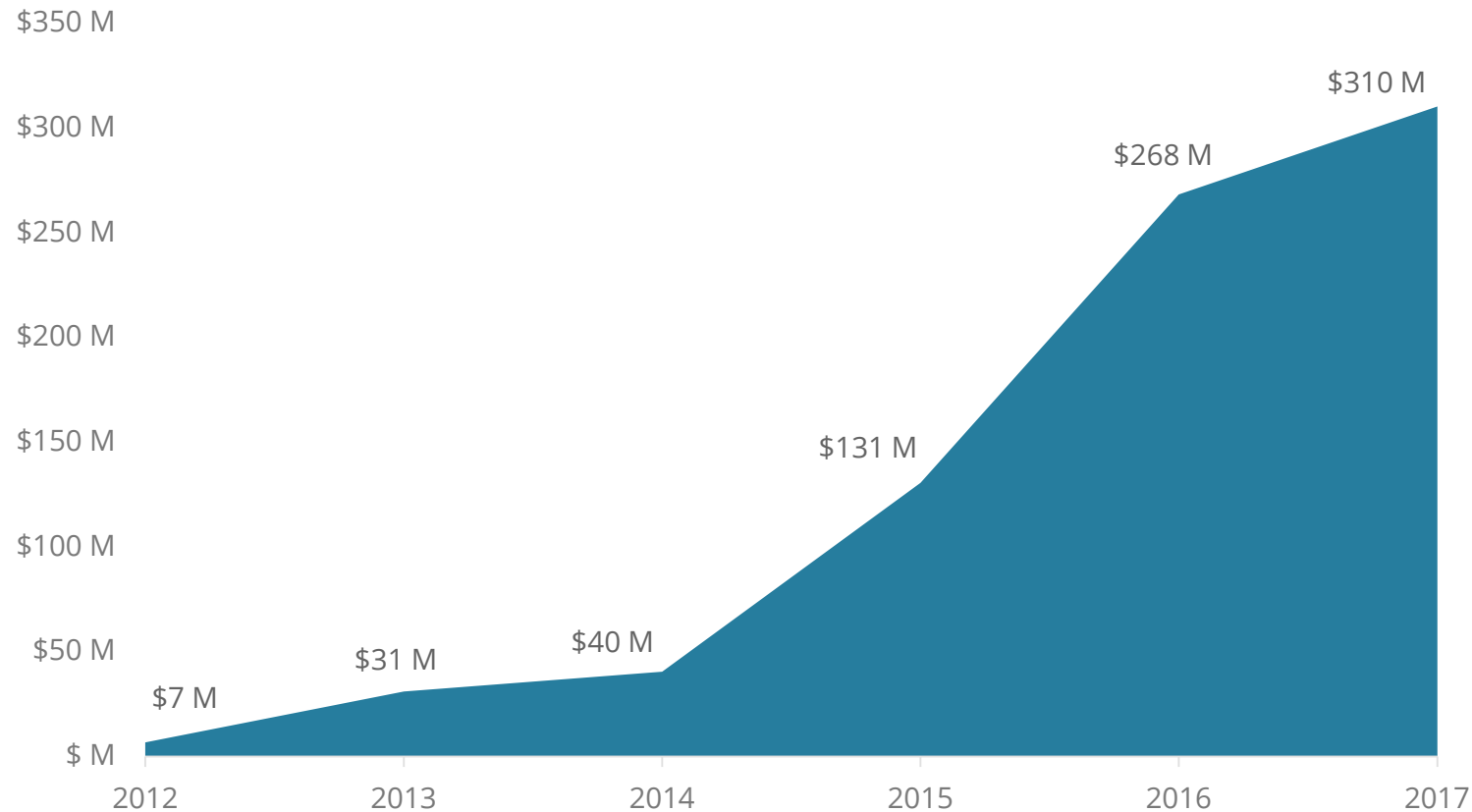
High-cost clinical conditions identified by the Centers for Medicare and Medicaid Services for 2015.

The PCORI CER portfolio includes 440 active/completed CER studies as of August 2018. Analysis excludes Methods, Pilots, PPRNs, CDRNs, and Engagement Awards.

# PCORI's Funding of Prescription Drugs CER Studies



PCORI has funded **61** CER studies that involve the use of prescription drugs as a compared intervention, representing an investment of \$310 million.



# Assessment of Prevention, Diagnosis, and Treatment Options

## Seeks to fund research that:

- Compares the effectiveness of two or more options that are known to be effective but have not been adequately compared in previous studies
- Among compared population groups, investigates factors that account for variation in treatment outcomes that may influence those outcomes

# Improving Healthcare Systems

## Seeks to fund research on effects of system changes on:

- Patients' access to high-quality support for self-care and coordination across healthcare settings
- Decision making based on patients' values
- Experiences important to patients and caregivers, e.g., overall health, functional ability, quality of life, stress, and survival
- Efficiency of healthcare delivery, as measured by the amount of ineffective, duplicative, or wasteful care provided to patients

# Communication and Dissemination Research

## Seeks to fund research in:

- Clinician engagement with CER
- Research translation, decision support interventions, and risk communication
- Distribution of CER to patients, caregivers, and providers

# Addressing Disparities

## Seeks to fund research that:

- Compares interventions to reduce or eliminate disparities in patient-centered outcomes
- Identifies/compares promising practices that address contextual factors and their impact on outcomes
- Compares healthcare options across different patient populations
- Compares and identifies best practices within various patient populations for information sharing about outcomes and research

# Improving Methods for Conducting Patient-Centered Outcomes Research



**Seeks to fund investigator-initiated research that addresses gaps in methodological research to benefit all healthcare stakeholders.** Focuses on:

- Methods for patient and other stakeholder engagement in research
- General analytic methods
- Design-specific analytic methods
- Analytics for data networks
- Usability, interpretability, and clinical meaningfulness of patient-reported outcomes
- Issues related to human subjects protections
- Improving methods of recruitment and retention of participants into PCOR/CER



# Pragmatic Clinical Studies

## **Seek to produce information that can be directly adopted by providers:**

- Compares two or more options for prevention, diagnosis, treatment, or management of a disease or symptom
- Addresses critical clinical choices faced by patients, caregivers, clinicians, and systems
- 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

4.

---

## Better Research Through Engagement

# Why Engage?

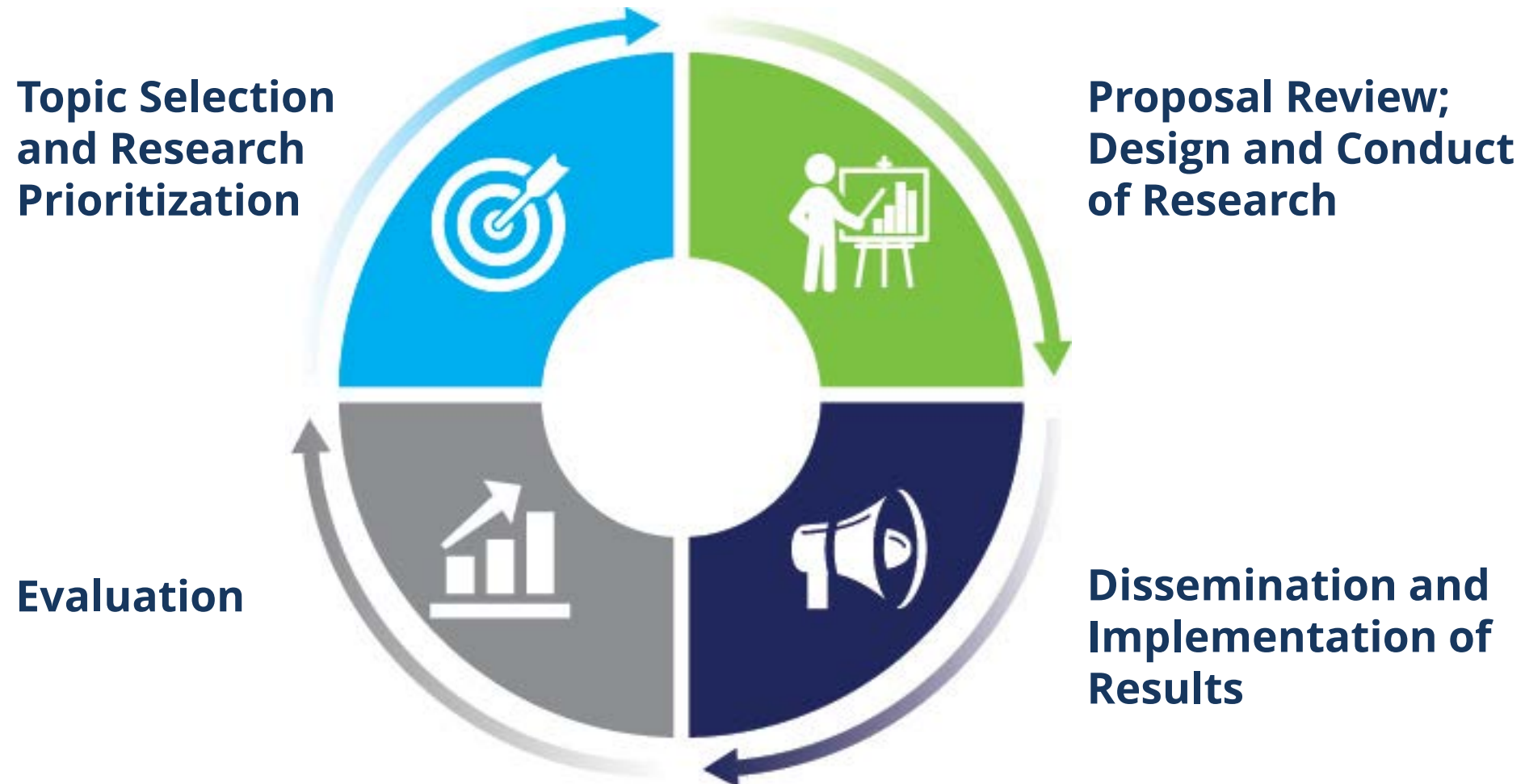
- To influence research to be patient-centered, relevant, and useful
  - To establish trust and a sense of legitimacy in research findings
    - To encourage successful uptake and use of research results



# Engagement Helps with Dissemination & Adoption



# Engagement as a Path to Useful, High-Quality Research



# Our Engagement Rubric— A Valuable Resource



Provides practical guidance to applicants, merit reviewers, awardees, and engagement/program officers on effective engagement in research

- **Planning the Study:** How patient and stakeholder partners will participate in study planning and design
- **Conducting the Study:** How patient and stakeholder partners will participate in the conduct of the study
- **Disseminating the Study Results:** How patient and stakeholder partners will be involved in plans to disseminate study findings and ensure that findings are communicated in understandable, usable ways
- **PCOR Engagement Principles:** Reciprocal relationships, co-learning, partnership, trust, transparency, honesty

# Engagement in Health Research Literature Explorer

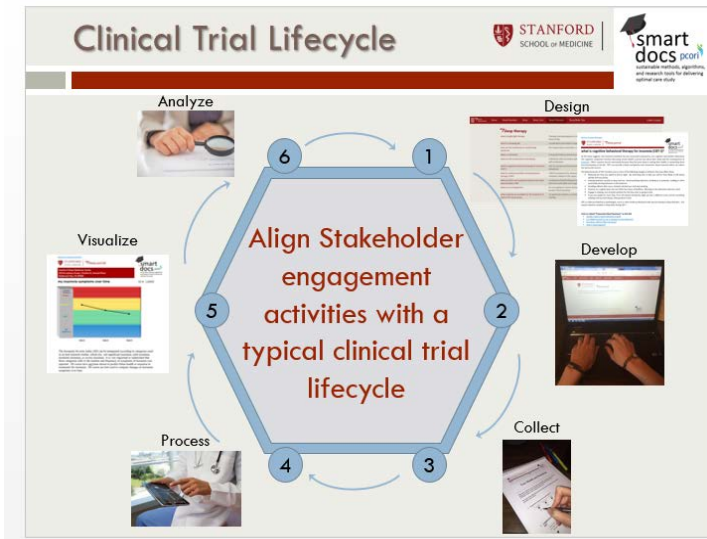
This searchable, catalogued resource for peer-reviewed literature can help identify **publications about engagement**

- It contains over 1,000 articles that include:
  - Examples of engagement in health research
  - Evaluations of engagement in health research
  - Syntheses of engagement methods and impacts
  - Frameworks, editorials, and commentaries on engagement in health research
- Articles can be filtered by communities that were engaged, phase of research engagement (e.g., study design, recruitment, etc.), and publication year

Link: [Engagement in Health Research Literature Explorer](#)

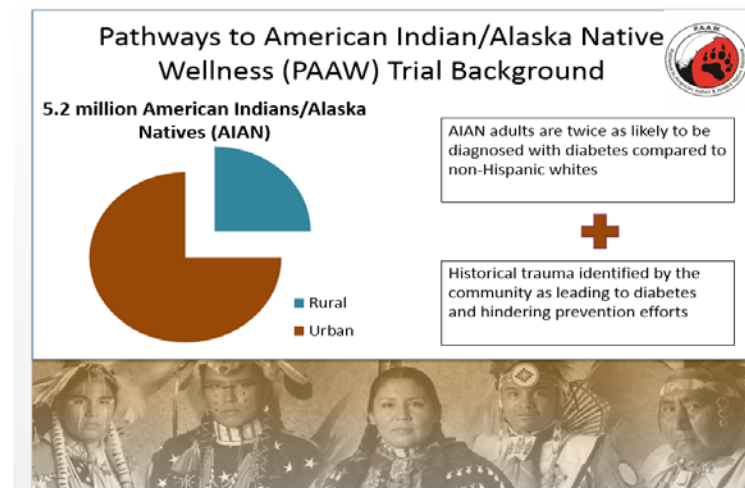
Refine Your Results
<div>^ Topic</div> <div>Example of Engagement in Health Research (528)</div> <div>Detailed Description of Engagement in Health Research (357)</div> <div>Framework, Editorial, Commentary (310)</div> <div>Evidence for Engagement (164)</div>
<div>v Stakeholder Involvement</div>
<div>v Phases of Research Engagement</div>
<div>v Year</div>

# Webinar Resources



- “Leveraging Patient & Stakeholder Engagement to Facilitate Study & Research Network Recruitment: Stories of Impact from PCORI Funded Projects”
- “Emerging Approaches for Structuring Multi-Stakeholder Engagement in PCOR Projects”

- “Patient and Stakeholder Engagement in Research: Strategies for Initiating Research Partnerships”
- “Community Engagement in Research: Practical Tips for Researchers & Community-based Organizations”
- “Getting Physicians involved in Patient-Centered Research: Showcasing Involvement of Medical Specialty Societies in PCORI Awards”





# Building a PCOR Community Nationwide



Our Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards are not research awards but opportunities to build patient-centered outcomes research capacity.

**Number of  
awards:**

**351\***

**Amount  
awarded:**

**\$71 million**

**States with funded  
projects:**

**46** (plus DC and  
Puerto Rico)

---

These awards support projects that promote meaningful involvement by patients, caregivers, clinicians, and other healthcare stakeholders in comparative clinical effectiveness research (CER).

\*AS OF FEBURARY 22, 2019

# Engagement Award Funding Opportunities



**Up to  
\$300,000  
2 years**

## **Engagement Award: Dissemination Initiative**

Objective: Actively disseminate PCORI-funded research findings  
Next Letter of Intent due date: May 31, 2019

**Up to  
\$50,000  
1 year**

## **Engagement Award: Conference Support**

Objective: Convene stakeholders and communicate PCORI-funded research finding to a targeted end-user audience  
Next Application due date: May 31, 2019

**Up to  
\$250,000  
2 years**

## **Engagement Award: Capacity Building**

Objective: Develop infrastructure and partnerships for dissemination and implementation of PCORI-funded research findings  
Next Letter of Intent due date: May 31, 2019

# What DON'T Engagement Awards Fund?

## Out of Scope for an Engagement Award project:

- Projects solely intended to increase patient engagement in health care or health care systems rather than health care research
- Projects to design or test health care interventions
- Activities that involve the use of a drug or medical device
- Development of clinical practice guidelines or care protocols
- Projects to recruit and enroll patients for clinical trials
- Projects that only involve patients as subjects (individuals enrolled into a study as participants)
- Research studies including randomized controlled trials, observational studies and pragmatic clinical studies
- Development or maintenance of a registry, or recruitment to participate in a registry
- Projects designed solely to validate tools or instruments
- Writing research proposals or completing grant applications, grantmaking
- Projects focused on social determinants of health, with no focus on patient-centered outcomes research, or comparative clinical effectiveness research
- Planning for dissemination or dissemination initiatives without including PCORI-funded research or related products
- Conferences that are scheduled to occur less than 6 months from the application due date
- Projects or meetings without a clear focus on patient-centered outcomes research, or comparative clinical effectiveness research



5.

---

## Information for Applicants

# Who Can Apply?

## **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 there is a clear benefit to the US healthcare system and patient-centered research efforts

**Note: Individuals may not apply**

# PCORI Funding Opportunities



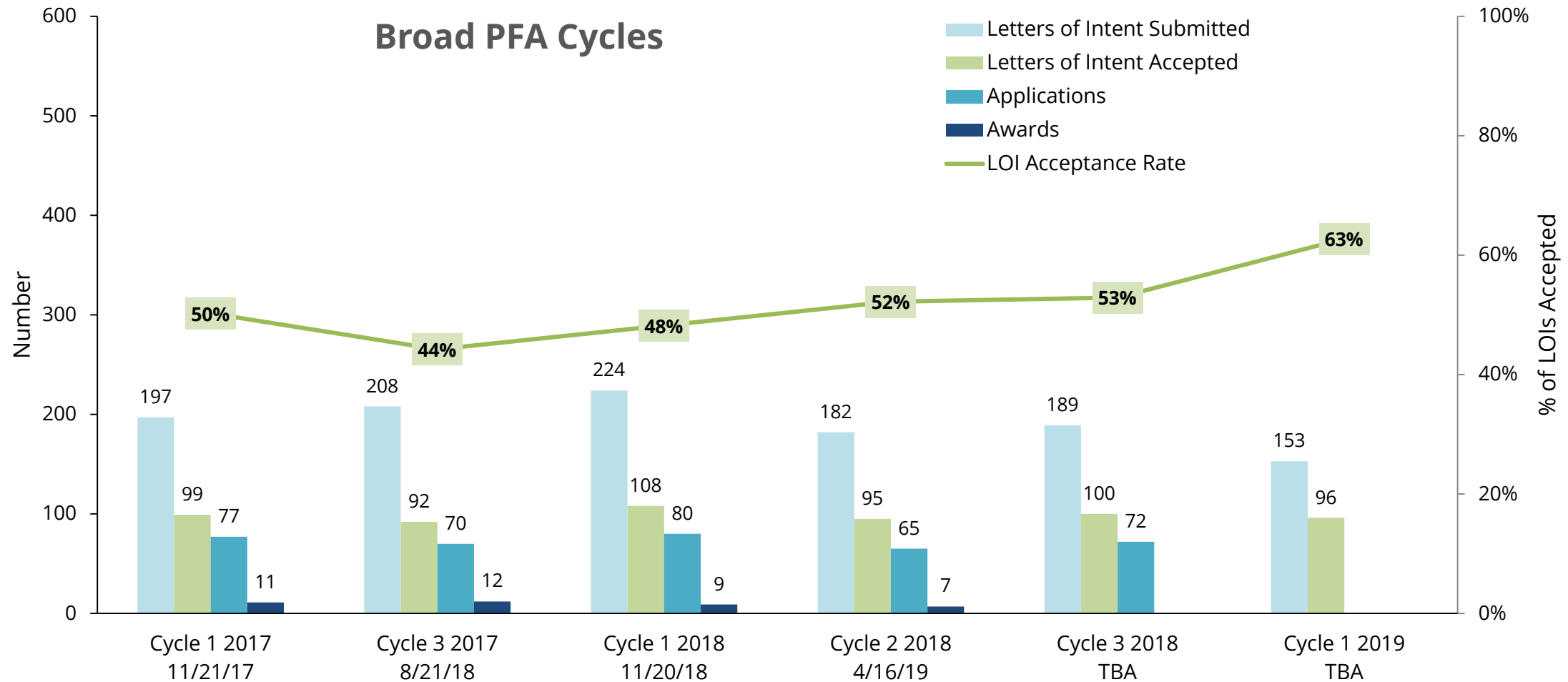
Our research funding is awarded through PCORI Funding Announcements.

Open opportunities are posted at [pcori.org/apply](https://pcori.org/apply).

A screenshot of the PCORI website's "Funding Opportunities" page. The page has a blue header with the PCORI logo and navigation links: BLOG, CAREERS, NEWSROOM, SUBSCRIBE, and CONTACT. Below the header is a teal navigation bar with links: ABOUT US, FUNDING OPPORTUNITIES (highlighted), RESEARCH &amp; RESULTS, GET INVOLVED, and MEETINGS &amp; EVENTS. The main content area has a teal background with the title "Funding Opportunities". On the left, there is a sidebar with links: Funding Opportunities, WHAT &amp; WHO WE FUND, HOW TO APPLY, APPLICANT TRAINING, WHAT WE MEAN BY ENGAGEMENT, MERIT REVIEW PROCESS, PROGRAMMATIC FUNDING, and AWARDEE RESOURCES. The main text area explains that most funding is awarded through PCORI Funding Announcements (PFAs) and lists other opportunities like Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards. Below this is a filter bar with three tabs: OPEN (selected), UPCOMING, and CLOSED. The "Open Opportunities" section states that the PCORI Online Application System is open for the Spring 2015 funding cycle.

# LOIs, Applications, and Awards

## Broad PFA Cycles



Cycle dates indicate approval by the Board; Only 6 most recent Broad PFAs cycles shown; All Broad cycles shown had a competitive LOI process

# Letter of Intent (LOI): Requirements

- Submit your LOI through PCORI Online
- An LOI is required and must be submitted prior to the deadline
- To submit an LOI, download **the PFA-specific Letter of Intent Template** from the [Funding Center](#) to begin your LOI
- You must answer all questions
- Do not upload additional documents as part of your LOI- letters of endorsements or support are not accepted at this stage
- Only those LOIs deemed most responsive (programmatically and administratively) to this PFA will be invited to submit a full application





# Tips on Preparing a Letter of Intent (LOI)

- Show the importance, relevance, and justification of the research question as evidenced by critical gaps identified by clinical guideline developers and/or a recent relevant systematic review
- Provide evidence of a compelling decisional dilemma for clinicians or patients
- Support the known efficacy of the intervention(s) and comparator(s)
- Provide clear and credible responses to the LOI questions, such as **well-described comparators**, clear research methods (e.g., study design, sample size, effect size)
- Support the feasibility of what you propose to do
- Programmatic fit and balance



# Invited to Apply: Tips for Success



- Adhere to the Application Guidelines for the appropriate PFA and funding cycle
- Start and submit application early
- Have a copy of your approved LOI readily accessible
- Ensure that all team members can see the application in the system (check during the LOI stage)
- Inform your AO of your intent to submit
- **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
- Justify your power calculations based on prior evidence of anticipated effect sizes
- **Clearly demonstrate the feasibility of the study**
  - Show that have the team to do this and you are the right team
  - Define and support your recruitment and retention plan
  - Document that sites are already committed to participating
  - Include realistic timelines for site start-up, IRB approval, and recruitment
- Submit the completed application on/before the due date by **5:00 PM ET**

# Early results from our initial cohorts indicate that PCORI-funded studies are doing better on recruitment than available benchmarks

Through literature searches and working with other funders, we identified *points of reference for research projects*:



**Primary Reference:** Tufts Center for the Study of Drug Development. **89% of Trials Meet Enrollment, but Timelines Slip, Half of Sites Under-enroll.** *Tufts CSFDD Impact Reports.* January/February 2013, Vol. 15 No. 1.

# Recruitment Status of PCORI Projects as of Q3-18

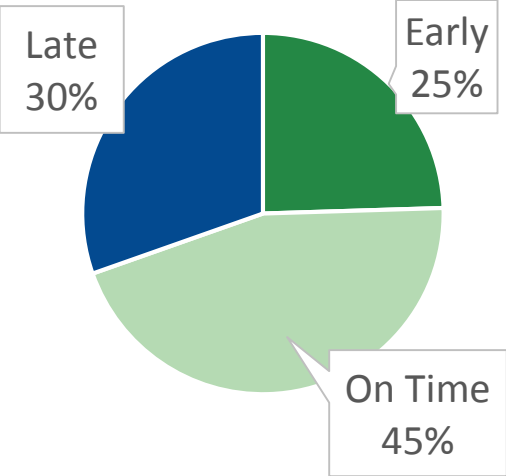


366 Projects: 75% Broad, 10% PCS, 15% Targeted

Most PCORI-funded studies complete recruitment early or on time, and majority of those completed late take 3 or fewer additional months to complete it

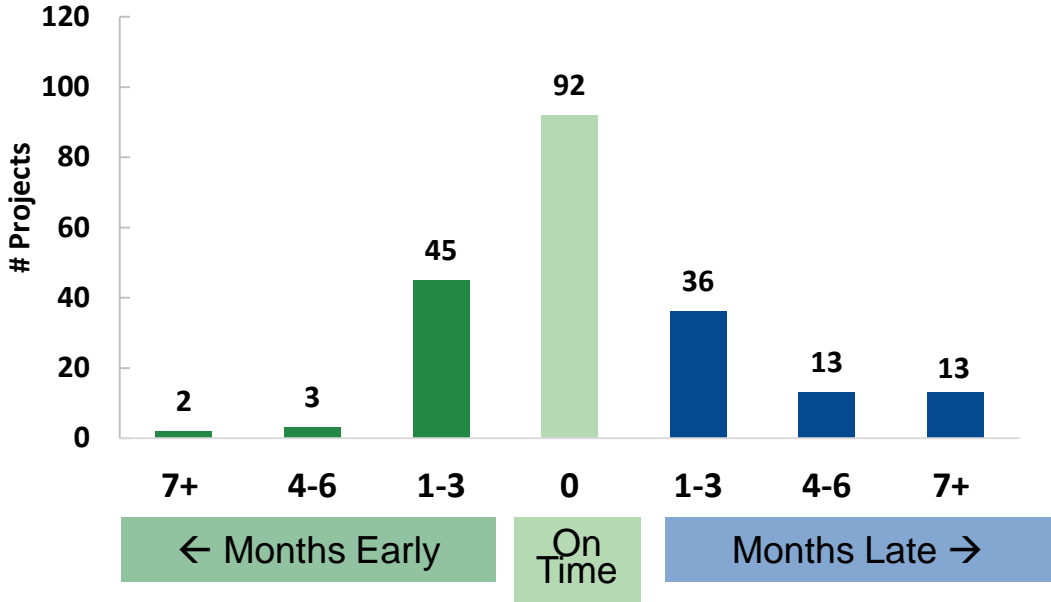


Timeliness of Recruitment Completion  
(N=204)



**70%** Completed on time or early

Timeliness of Recruitment Completion



# Many PCORI-funded studies require modest extensions of their recruitment timelines

## To what extent do studies need to **modify recruitment timeline** to complete recruitment?



**82/204** (40%) of studies that have completed recruitment have extended planned recruitment time by >1 month

- Median recruitment extension: 6.1 months (Average 7.1 m)
- 7% (N=6) did not need the extension- completed on time with original timeline
- 73% (N=60) completed recruitment on time with new deadline
- 20% (N=16) completed recruitment late, even with new deadline

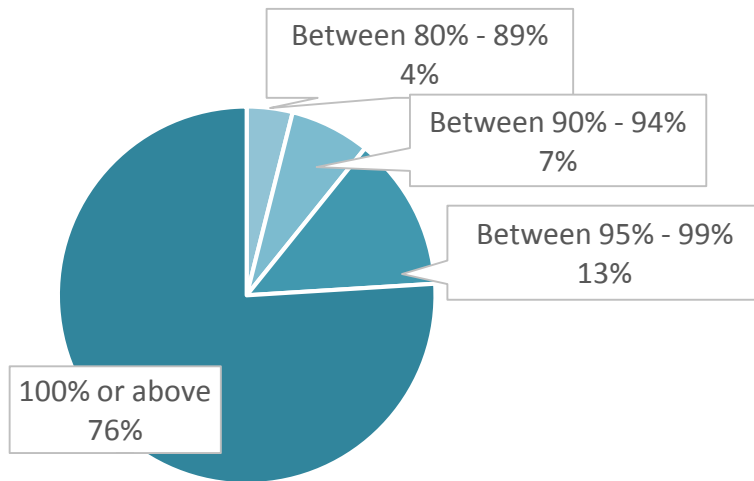
Among all completed studies, the average time to complete recruitment was 138% of the original planned recruitment timeline (median 110%)

PCORI Average: 138% of planned enrollment time, vs. Point of Reference: 194% (Tufts 2013)

# Almost all PCORI-funded studies achieve at least 90% of their enrollment targets, and more than half of them meet or exceed it

Proportion of Enrollment  
Target Achieved

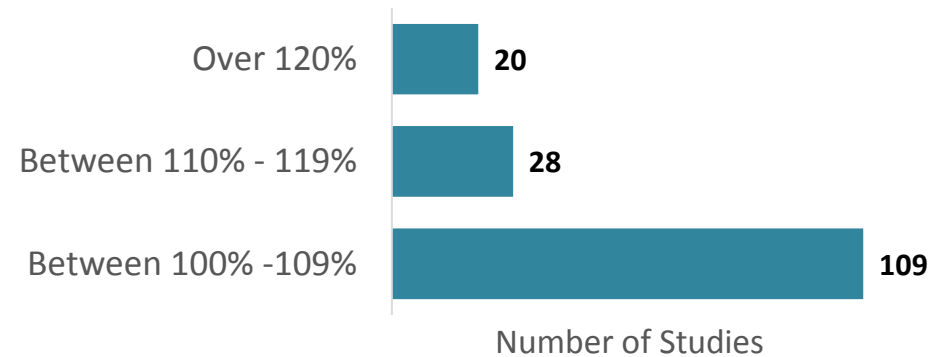
N=204



**96%** achieved >90% of enrollment target

Details on Enrollment  
of 100% of Target or Higher

Percent of Target Enrollment, N=124

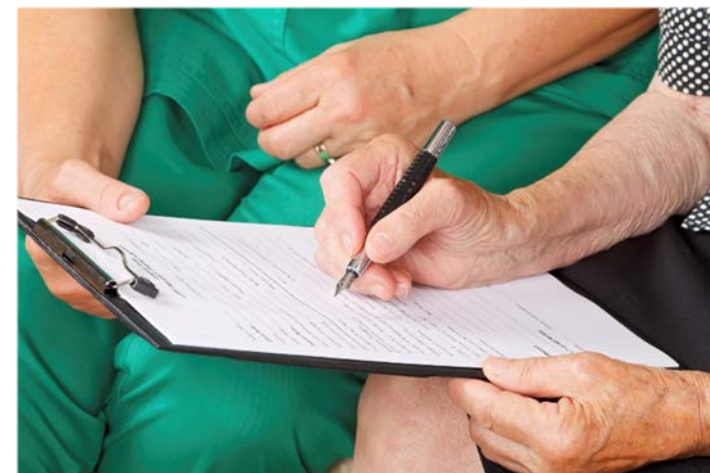


**10%** of PCORI studies that have completed recruitment achieved >120% of enrollment target

PCORI: 72% met or exceeded enrollment, vs. Point of Reference: 52% (Tufts 2013)

# Commonly Cited Reasons for Delays in Recruitment

- IRB delays (40% of studies that start recruitment late cite an IRB delay)
- Site activation (multi-site trials)
- Staffing issues
- Changes to PI or institution
- Contract or subcontract negotiations
- Extreme weather/holiday seasons
- Unexpected challenges with eligibility criteria
- Delays obtaining stakeholder input
- Delays obtaining payor coverage for clinical services





# Changes After LOI Approval

- Full application are invited based on the information provided in the LOI
- Changes to the following require PCORI approval:
  - Principal Investigator
  - Institution
  - Research question(s)
  - Specific aims
  - Study design
  - Comparators
  - Budget/periods of performance



# Application Components and Templates (Broad PFAs)

- Project Information (abstracts)
- Budget
- Milestones\*
- People and Places\*
- Research Plan Template\*
- Methodology Standards\*
- Subcontractor Detailed Budget\*
- Budget Justification\*
- Letters of Support\*
- Resubmission Letter\*

\* Indicates an uploaded document



# Application Components: Budget & Justification



- In PCORI Online, for the Budget tab complete the following sections:
  - Detailed Research Project Budget for Each Year of the Research Project Period
  - Detailed Peer-Review Budget for Peer-Review-Related Costs
  - Budget Summary for Entire Project
- In the Templates and Uploads tab, upload the **Budget Justification Template** for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer-Review Budget for all research and peer-review-related costs. Include the federally negotiated or independently audited indirect cost rate letter (prime contractor) and fringe benefit rate policy verification document (prime contractor).

# Application Components: Milestones/Deliverables

- Milestones
  - Significant events, deliverables, tasks, and/or outcomes that occur over the course of the project that mark progress toward the project's overall aims (e.g., IRB approval, initial enrollment, etc.)
- Deliverables
  - Measurable and verifiable outcomes or products that a project team must create and deliver according to the contract terms



*See Appendix 1 of the Application Guidelines for Sample Milestone Schedule*

# Application Components: People & Places



- **Leadership Plan (if applicable): 5 pages**
  - Required for Dual-PI Applications
- **Project/Performance Site(s) and Resources: 15 pages**
  - Provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and availability to the project.
- **Professional Profile/Biosketch: 5 pages per individual**
  - NIH formatted biosketch is permissible
- **Patient/Stakeholder Partner Profile/Biosketch: 5 pages per individual**
  - PCORI provides a template

# Application Components: People & Places Template (cont.)

- **Leadership Plan Template (Dual PI Applications only)**

- Describe the governance and organizational structure of the leadership team and the research project;
- Delineate the administrative, technical, scientific, and engagement responsibilities for each PI and the rationale for submitting a dual-PI application;
- Discuss communication plans and the process for making decisions on scientific and engagement direction;
- Describe the procedure for resolving conflicts.



Note: If this template is applicable, it should be uploaded as the first section of the People and Places Template

# Application Components: Research Plan

- **Research Strategy: 12 pages**
  - Provide all the information requested, as outlined in the template:
    - Specific Aims
    - Background
    - Significance
    - Study Design or Approach
- **Research Team & Environment: 2 pages**
  - Describe the research team's capabilities to accomplish the goals of the proposed research project and the appropriateness of the research environment to conduct the study.
- **Dissemination & Implementation: 1 page**
  - Describe how you will make study results available to study participants after you complete the analyses, and possible barriers to disseminating and implementing the results of this research in other settings.
- **Protection of Human Subjects: 5 pages**
  - Describe the protection of human subjects in your research and estimate the final racial/ethnic and gender enrollment.





# Application Components: Research Plan (cont.)



- **Consortium Contractual Arrangements: 5 pages**
  - Describe the proposed components of the research project that will be performed by subcontracted organizations.
  - Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.
- **References Cited: 10 pages**
  - Follow scholarly citation practice and list the source material cited in your Research Plan
- **Appendices: 10 pages (optional)**
  - Applicants can include additional materials that they believe are useful, but reviewers are not required to review the appendix materials in evaluating the application.
- **Methodology Standards Checklist: No page limit**
  - Applicants must complete each column of this checklist, as appropriate, and include it with the Research Plan PDF upload



# A Strong Research Team Matters

- Is the PI the right fit?
  - Complexity of the project
  - Time commitments
  - Experience
- Have a complimentary team that offers different skills and perspectives
- Show/explain how the team will work together
- Include subject matter experts



# Key Considerations When Developing an Engagement Plan

- Structure
- Budget
- Level of involvement
- “Representativeness”
- Training
- Maintaining engagement through the study
- Evaluation
- Dissemination



# Budgeting for Engagement

## Things to Consider:

- Financial compensation of partners
- Expenses of partners (transportation, childcare, caregiver)
- Budgeting for program staff dedicated to engagement tasks
- Costs of engagement meetings and events (travel, food, audio visual)
- Additional time and resource to incorporate partner feedback into various project process



*Refer to PCORI's compensation framework for guidance*

# Application Components: Letters of Support

- Letters of support should be addressed to the PI to demonstrate the commitment of key personnel and supporting organizations to the proposed project.
- Letters of support should be organized in the following manner:
  - Letters of organizational support
  - Letters of collaboration
  - Letters confirming access to patient populations, data sets, and additional resources



6.

---

## Building a Budget

# Budgeting: Embrace Your Inner Accountant

Follow these three points when building a budget:

- **Be realistic**
  - Do you really need to request the maximum budget cap?
  - Avoid the danger of wanting to “stretch every penny”
- **Be detailed**
  - Breakout the cost by category
  - Include quotes & estimates
- **Justify your costs**
  - Explain what funds will be used for
  - Tie the costs to the scope of work
  - Note any abnormal requests






# Indirect Costs

- Indirect costs are calculated at up to **40%** of the allowable direct costs
- If you do not have an audited indirect cost, you may request up to 10% indirect costs
  - Must be noted in the Budget Justification
- Foreign organizations may request up to 10% indirect costs
- You may assess indirect costs on the first \$25,000 of each subcontractor





# Frequently Rejected Costs

-  DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)
-  DOCKING STATIONS
-  DOUBLE MONITORS
-  ELECTRONICS PROTECTION PLANS
-  OFFICE FURNITURE
-  REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD

Review



## PCORI Cost Principles

Description of Allowable Direct Costs under a PCORI Award

Published October 14, 2016  
Updated August 14, 2017

Version 2



7.

---

## How We Review Research Proposals

# Our Merit Review Process

- 1 Evaluate Letters of Intent.** At least two PCORI staff review each Letter of Intent and a committee of staff members determines which will be invited to submit full applications. Information in the Letters of Intent drives the recruitment of patients, clinicians, scientists, and other members of the healthcare community who have the appropriate expertise to serve on merit review panels.
- 2 Preliminary review of full applications.** Reviewers conduct a preliminary review of applications, providing written critiques and scores for the applications based on our review criteria and scoring system.



# Our Merit Review Process



**3 In-person panel review.** Following the preliminary review, a subset of applications move forward and are discussed and scored by the full panel of merit reviewers at an in-person meeting. The perspectives of a wide range of reviewers help us choose projects that are important, practical, and relevant to the audiences who will use the results of our work.

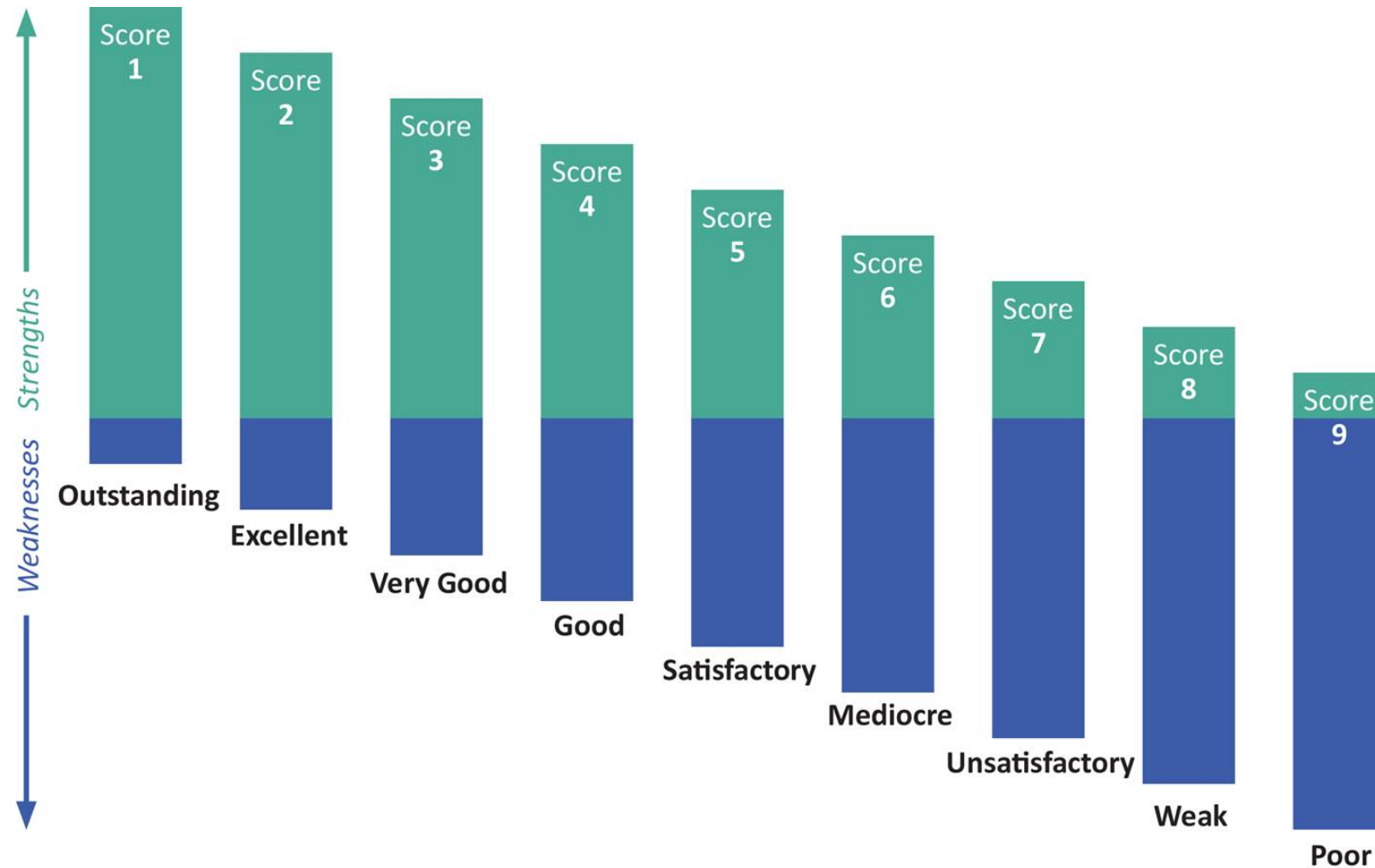
**4 Selection Committee Review.** Program staff recommend projects to a Selection Committee that includes members of PCORI's Board of Governors. The committee identifies a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI's strategic priorities.

This slate is proposed to PCORI's Board for consideration and approval.

# Our Merit Review Process

	Patient/Other Stakeholder Reviewers	Scientist Reviewers
Criterion 1: Potential for the study to fill critical gaps and generate actionable evidence		✓
Criterion 2: Potential for the study findings to be adopted into clinical practice and improve delivery of care	✓	✓
Criterion 3: Scientific merit (research design, analysis, and outcomes)		✓
Criterion 4: Investigator(s) and environment	✓	✓
Criterion 5: Patient-centeredness	✓	✓
Criterion 6: Patient and stakeholder engagement	✓	✓

# Scoring Range



# Resources on Merit Review

## Merit Review

<http://www.pcori.org/funding-opportunities/merit-review-process>

- Overview of Merit Review Process
- Merit Review Criteria for funding programs



8.

---

## Notes on Post Award

# You Have a Contract, Now What?

- Confirm your contract details!
  - Effective start and end dates
  - Project title
  - Final budget
  - Milestone schedule
- Introductory e-mail sent upon contract execution
- Kickoff call
  - Team introductions
  - Manage expectations
  - Let us know what's new
    - Staff changes
    - Subcontractor changes
    - Organization calendar changes
- Financial Account Setup





# Period of Performance

- Milestones and deliverables ensure that the funded project is completed on-time
- Efficient project management strategies will place you ahead of the curve
- We want to see the study end on-time ... no automatic no-cost time extensions



# Monitoring and Reporting

- Effective monitoring helps ensure:
  - Contract Compliance
  - Consistency with Project Work Plan
  - Completion of Contract Milestones
  - Adjustments during the Award
  - Modifications
    - \$
    - Milestones



# Types of Reporting

- Interim Progress Report
- Special Progress Report
- Notification of Publication Acceptance
- COI Reporting
- Final Reports – Progress and Financial
  - Final Research Report (Peer Reviewed)
  - Final Progress Report
  - Expenditure Report



# Invoicing

- PCORI reviews project invoices and spending to ensure the following:
  - Charges are allowable, allocable, reasonable, and consistent
  - Funds are spent in accordance with the approved budget
  - Work is progressing
- Requirements
  - No less than every 90 days
  - Labor Detail
  - Meets PCORI's invoice template requirements
  - Receipts where applicable
  - Submitted through PCORI Online



9.

---

## Getting the Word Out

# Dissemination and Implementation (D&I) of Results

**We are planning a strong effort to encourage the healthcare community's use of important results from the research that we fund.**

We are committed to:

- Enhancing awareness of evidence useful to people and organizations as they make health decisions
- Speeding the integration of this evidence into practice



- **Context:** Evidence, audience, and setting must be considered in planning activities.
- **Engagement:** Efforts will not succeed without ongoing patient and other stakeholder engagement to provide context and build interest in evidence.
- **Evaluation:** Evaluation of activities is vital to identifying the most effective processes.



# Contact Information

**Jim Hulbert:** Associate Director, Financial Compliance

 202.827.7705

 jhulbert@pcori.org

 [www.pcori.org](http://www.pcori.org)

 @pcori

 /PCORInstitute

 PCORI

 /pcori



# Thank You!

---