# Patient-Centered Outcomes Research Institute (PCORI): Mission and Funding Opportunities

## Parag Aggarwal, PhD

Senior Program Officer, Healthcare Delivery and Disparities Research Program

Response Evaluation in Neurofibromatosis and Schwannomatosis (REiNS) Winter Meeting December 4, 2017



# **Agenda**

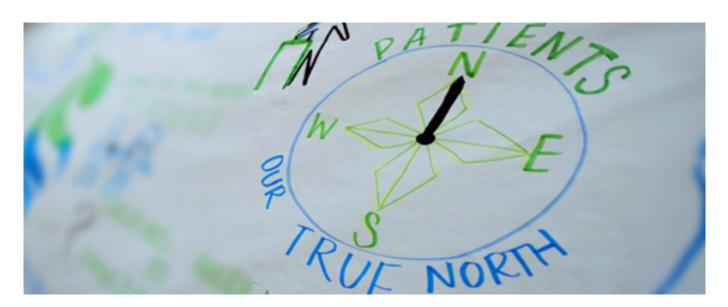
- About PCORI
- PCORI's National Priorities for Research
- PCORI's Funding Opportunities
- PCORI's Funding Process



# **About PCORI**

## Who We Are

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board 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





## **PCORI's Mission and Vision**

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

## **PCORI's Research Focus**

## **Comparative Clinical Effectiveness Research**

- Patient-centered
- Answering questions that matter to patients and other clinical decision makers
- Comparisons of outcomes that matter to patients
- Comparing the effectiveness of two or more interventions with proven efficacy

# 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

# **Better Research Through Engagement**

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



## Who Are Our Stakeholders?

Payers Clinicians

**Caregivers/Family Members** 

**Purchasers** 

**Policy Makers** 

**Patients/Consumers** 

**Industry** 

**Hospitals/Health Systems** 

**Training Institutions** 

**Patient/Caregiver Advocacy Organizations** 



# 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

# **PCORI's National Priorities for Research**

## **Our National Priorities for Research**



Assessment of Prevention, Diagnosis, and Treatment Options











# **Snapshot of PCORI Funded Research Projects**

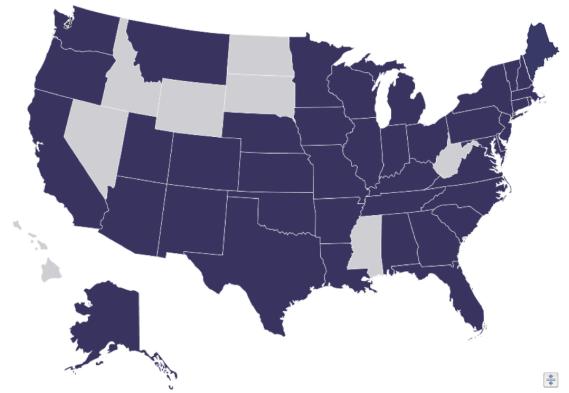
## Number of projects:

More than 600

# Total funds awarded: More than \$2 billion

Number of states where we are funding research: 41 (plus the District of Columbia, Canada, Sweden, and Italy)

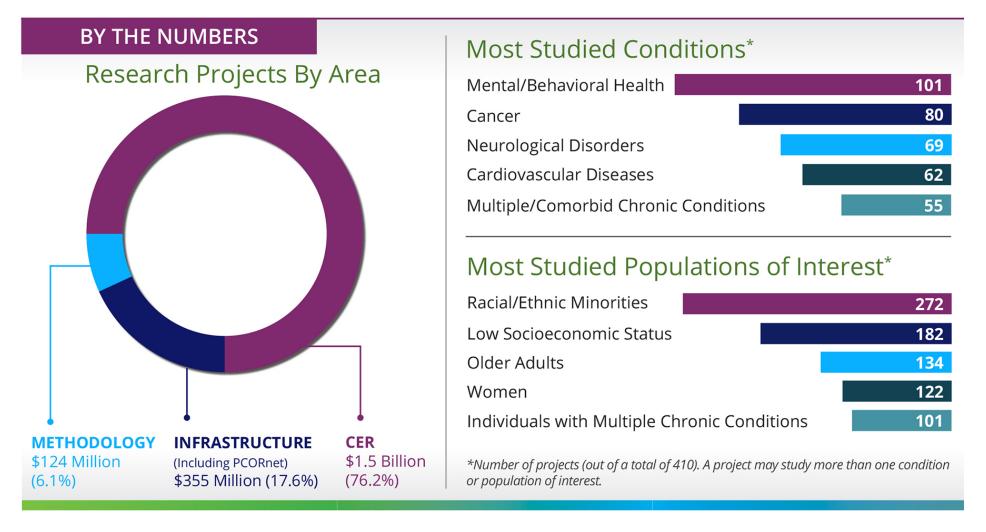
More than 800 total projects that include engagement, research infrastructure, and coordinating center awards



As of November, 2017



## **About Our Research Portfolio**





# **Snapshots of PCORI Research on Specific Topics**

#### **Chronic Pain and Opioids**

Read about our projects on managing chronic pain and addressing opioid use.

### **Dementia and Cognitive Impairment**

Our studies on dementia and cognitive impairment are more important than ever as older adults continue to make up a larger part of the nation's population.

#### **Diabetes**

Learn about our research portfolio on diabetes, the seventh leading cause of death in the United States

### **Kidney Disease**

Read about our research portfolio on kidney disease.

PCORI-funded research on kidney disease examines
what treatments work best for whom, and also which app

what treatments work best for whom, and also which approaches could lead to earlier diagnosis.

#### **Mental Health**

Around one-fifth of American adults suffer from mental illness. Learn how we're studying ways to deal with depression, anxiety, and other mental health issues.

#### **Multiple Chronic Conditions**

Having multiple chronic conditions directly correlates with increased healthcare costs. Read about our PAT...projects aimed at studying nopulations with multiple





See the cardiovascular disease research

spotlight

ONE-FIFTH
of American adults suffer
from mental illness

Source: National Institute of Mental Health

# **Database of Funded Projects**

All projects and corresponding public abstracts for the projects we have funded can be found at:

http://www.pcori.org/research-results

### What We've Funded

SEE A LIST OF COMPLETED PROJECTS WITH RESULTS

Learn more about the key terms on this page ▼

Download these results in CSV format

Displaying 1 - 10 of 997

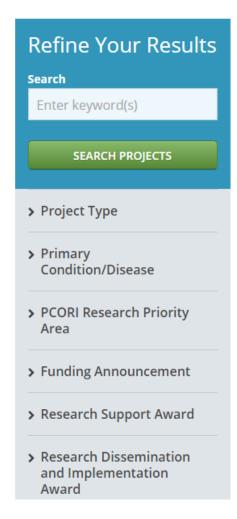
Development of the Arkansas Faith-Academic Initiatives for Transforming Health (FAITH) Network

Organization: University of Arkansas for Medical Sciences

Project Type: Research Support Project

Year Awarded: 2017

Leveraging Patient Partner/Stakeholder



# **PCORI's Funding Opportunities**

# **Funding Opportunities**

- http://www.pcori.org/funding-opportunities
- Engagement Awards: On-going
- Broad Funding Announcement in all 5 Priority Areas
- Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes
- Targeted Funding Announcements



# Eugene Washington PCORI Engagement Award Program

- An engagement funding opportunity -- not research awards
- Support projects that will build a community better able to participate in patient-centered research (PCOR) and comparative clinical effectiveness research (CER), as well as serve as channels to disseminate study results
- Also provide support for symposia, seminars, workshops, and other organized and formal meetings where individuals assemble to exchange information or explore issues or areas of knowledge related to PCOR/CER
- Projects will produce deliverables that are useful to awardees, PCORI, and the broader PCOR community for increasing patient and stakeholder engagement in PCOR and CER



# **Engagement Award Overview**

Engagement Award (EA) projects

 Equip patients and other stakeholders to engage as meaningful partners in PCOR/CER from topic selection to dissemination or implementation of results

 Support organizations to lay groundwork for disseminating and implementing research results or products derived from PCORI Awards of **up to \$250,000** per project,
up to **two years** in
duration

- Funding through an Engagement Award Initiative Notice (EAIN) supports **meetings/conferences** that align with PCORI's mission and strategic plan, and facilitate expansion of PCOR/CER in areas such as:
  - research design and methodology
  - research development
  - dissemination and implementation

Awards of **up to \$50,000**per conference,

up to **one year** in

duration



# A Closer Look at the Funding Opportunity – Projects of Interest (1)

- Support for organizations with strong ties to patients, caregivers, clinicians, and other stakeholders to equip them to be partners in PCOR/CER
- Projects may focus on:
  - increasing the knowledge and competency of patients and other stakeholders to be meaningful partners in all stages of research, from topic selection to dissemination and implementation of results
  - strengthening researchers' skills of partnering with patients and other stakeholders
- Applicants must:
  - clearly explain how the capacity that their proposed award develops will apply to existing or planned PCOR/CER partnership opportunities
  - identify and describe any tools, trainings, or programs that they will use, as well as provide the evidence base underlying such resources
- We encourage applicants to use or adapt available resources whenever possible,
   rather than develop new products and tools



# A Closer Look at the Funding Opportunity – Projects of Interest (2)

 Support organizations with many constituents who view them as trusted sources of health information to strengthen the infrastructure and relationships necessary to D&I research results or products derived from PCORI-funded studies or related research



- Project activities may include:
  - developing, demonstrating, and evaluating the processes, pathways, and mechanisms necessary to provide patients, clinicians, and others in the healthcare community with evidence useful for the decisions they must make
- Applicants must:
  - identify existing or emerging PCOR/CER findings that are highly relevant to its members
  - clearly explain how they intend to sustain the infrastructure and relationships that they develop
  - indicate whether the project has potential to reach beyond the group engaged in the project and whether the project could be a vehicle for D&I additional PCOR/CER findings.

# A Closer Look at Funding Opportunity for Meeting/Conference Support

- The types of meeting/conference themes eligible for support under this EAIN include but are not limited to:
  - Research Design and Methodology—Addresses
    methodological and technical issues of major importance in
    the field of PCOR/CER, or facilitates development of new research
    designs/methodologies.
  - Research Development—Explores or identifies potential topics for PCOR/CER with patients, researchers, or other relevant stakeholders.
     Conference organizers must identify a clear audience for the topic identification exercise, particularly a research funding organization.
  - Dissemination and Implementation—Communicates findings—or emerging findings—from PCORI or related studies to a targeted, essential end-user audience. Conference organizers must address the proposed conference activities as part of an essential strategy for increasing the uptake of findings that have important potential impact on clinical practice, including the important role of the proposed target end-user audience.



## **Research Award PFA Overview**

PCORI Funding Announcement	Funding Per Cycle	Direct Cost Cap	Project Duration
Assessment of Prevention, Diagnosis and Treatment Options	\$32 Million	\$2,000,000	3 Years
Improving Healthcare Systems	\$16 Million	\$5,000,000 (large)	5 Years
		\$2,000,000 (small)	3 Years
Communication and Dissemination Research	\$8 Million	\$2,000,000	3 Years
Addressing Disparities	\$8 Million	\$2,000,000	3 Years
Improving PCORI Methods	\$12 Million	\$750,000	3 Years
Pragmatic Clinical Studies	\$90 Million	\$10,000,000	5 Years



# **PCORI's Broad Funding Announcement**

- Supports research on investigator initiated research topics that address questions of importance to patients and other stakeholders.
- The announcement includes 5
   different types of awards that
   align with PCORI's National
   Priorities for Research

### **Overview**

Awards range from \$750,000 - \$5,000,000 in direct costs per project and are generally 3 years in duration

# **Pragmatic Clinical Studies**

- Addresses critical evidence gaps, including topics of special interest to stakeholders, National Academy of Sciences, Agency for Healthcare Research and Quality
- Seeks to produce information that can be directly adopted by providers
- Often conducted in routine clinical settings
- Though often large, usually less complex protocols than traditional trials

**Overview** 

Awards can be up to \$10 million direct costs per project and are generally 5 years in duration



# **Targeted Funding Announcements**

- Seek research proposals on the highestpriority questions identified through PCORI's topic generation and research prioritization process
- Examples:
  - Clinical Management of Hepatitis C
     Infection
  - Treatment of Multiple Sclerosis
  - Management of Care Transitions for Emerging Adults with Sickle Cell
     Disease

**Overview** 

Budget and project duration vary by funding announcement

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

# **Upcoming Funding Opportunities**

- Engagement Awards
  - Eugene Washington PCORI Engagement Award
    - Letter of Intent: February 1, 2018; June 1 2018
    - Full Application: 40 Days post Review/Approval of LOI
  - Engagement Award (EAIN): Research Meeting and Conference Support
    - No LOI required; Application due February 1, 2018 or June 1, 2018
- Research Awards: Cycle 1 2018
  - Pragmatic Clinical Studies AND Broad Science
    - Letter of Intent: February 13, 2018
    - Full Application: May 16, 2018
    - Merit Review: August 2018



# Help with selecting a PCORI Funding Program

- A list of all open, closed, and upcoming funding announcements can be found here: <a href="http://www.pcori.org/funding-opportunities">http://www.pcori.org/funding-opportunities</a>
- If you are not sure which is best for you, contact the PCORI Helpdesk:
  - Research Awards:
    - Email: <u>sciencequestions@pcori.org</u>
    - Phone: 202-627-1884
    - Online: <a href="http://www.pcori.org/PFA/inquiry">http://www.pcori.org/PFA/inquiry</a>
  - Engagement Awards:
    - Email: ea@pcori.org
    - Phone: 202-370-9312



# **PCORI's Funding Process**

# The PCORI Funding Center



### Contains details about:

- PCORI's Application Process
- Key dates and deadlines
- How to access PCORI's Online Application System and build an application
- PCORI's application guidelines, checklists, and templates
- Access to training webinars



Be sure to download templates for the cycle you are submitting to.



# Research Award Application and Review Process

- **Evaluate Letters of Intent. S**creen Letters of Intent and invite the submission of full applications.
  - Preliminary review of full applications. Reviewers conduct an online review of applications and score them using our review criteria and scoring system.
  - In-person panel review. A subset of applications move forward and are discussed and scored by the full panel. Obtain perspectives of a wide range of reviewers.
    - **Selection Committee Review.** Selection Committee reviews proposed slate of projects; Proposes slate to PCORI's Board of Governors for consideration and approval.



## **Merit Review Criteria**



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 Criterion #2: Potential 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



# **Research Award Tips for Success**

- Adhere to the PFA and Application Guidelines for the funding cycle you are applying to
- Talk to a Program Officer if you have questions
- Start and submit early
- Download <u>PCORI's Online User Manual for Submitting an Online Application</u>
- 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
- Submit the completed application before the due date or on it by 5:00 PM ET



# **Engagement Award Review Process**



- If applying for meeting/conference support, you do not need to submit a Letter of Inquiry (LOI); applicants proceed directly to submitting a full proposal.
- The next funding cycle deadlines for both LOIs and proposals for meeting/conference support is February 1, 2018 and June 1, 2018
- Applications are reviewed by PCORI's Engagement Department, Contracts
   Management and Administration, and other PCORI internal staff, as needed.



# **Tips for Successful Submissions**

- Read FAQs
- Consider projects already awarded summaries and work products available at <a href="http://www.pcori.org/research-results">http://www.pcori.org/research-results</a>
- Review Available Resources
  - Program Guidelines
    - Program summary, award types and list of what we don't fund
  - Application Guidelines
    - Programmatic overview and application requirements
    - Details on how to submit an LOI and application
    - Application checklist
    - Includes a glossary of key terms
    - Allowable and unallowable costs
  - Online User Manual
  - Step-by-step guide to walk through the online application portal
- Use Application Checklist
  - Ensure you've included all required and optional components before hitting submit



# Tips for Successful Submissions (Cont'd)

 While Letters of Support are optional in your submission, we value them and take them into account in the review process.
 If possible, we recommend you submit them as a part of your application.



- Any stakeholder group(s) you are proposing to work with in your proposal should be a part of developing the project concept and ideally, helping to develop your LOI/EAIN. Preliminary engagement work is necessary to develop a strong Engagement Award application.
- For applicants proposing to complete a dissemination-focused project, we expect you to be familiar with PCORI's research portfolio as it pertains to the topic(s), population(s), and/or strategies proposed so that there is a logical connection between your planned project and the content you would ultimately disseminate.
- Engagement Award Program Officers are available to discuss your ideas in advance of, and while you are developing your proposals. Reach out to us at <a href="mailto:ea@pcori.org">ea@pcori.org</a> for support via email or phone.



# **Applications Reviewed Against Six Criteria**

- Program Fit
  - Does the application demonstrate program fit or an innovative idea that supports its mission?
- Project Plan and Timeline
  - Does project plan and timeline seem reasonable?
- Qualifications of Project Lead
  - Do the qualifications of the project lead align with the scope of the project?
- Personnel and Collaborators
  - Is there adequate engagement of patients and other stakeholders? Are collaborations meaningful and appropriate based on interest, expertise and scope of the project?
- Past Performance
  - Does the project team demonstrate sufficient past performance?
- Budget/Cost Proposal
  - Does the budget demonstrate reasonable cost designations?



# Help with selecting a PCORI Funding Program

- A list of all open, closed, and upcoming funding announcements can be found here: <a href="http://www.pcori.org/funding-opportunities">http://www.pcori.org/funding-opportunities</a>
- If you are not sure which is best for you, contact the PCORI Helpdesk:
  - Research Awards:
    - Email: <u>sciencequestions@pcori.org</u>
    - Phone: 202-627-1884
    - Online: <a href="http://www.pcori.org/PFA/inquiry">http://www.pcori.org/PFA/inquiry</a>
  - Engagement Awards:
    - Email: ea@pcori.org
    - Phone: 202-370-9312



## **Thank You**

Parag Aggarwal, PhD

Senior Program Officer, Healthcare Delivery and Disparities Research Program <a href="mailto:paggarwal@pcori.org">paggarwal@pcori.org</a>

