

# Understanding PCORI's Pragmatic Clinical Studies Initiative

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September 21, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# Welcome and Overview

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Director of Contracts Management and Administration

September 21, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# Welcome!

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**Scott Solomon**  
Director of Contracts  
Management and  
Administration





## Session Objectives

- **Discuss PCORI's history, mission, and vision**
- Brief overview of PCORI's research portfolio and unique approach to funding research
- Describe the reason for this workshop



# About Us

- An independent research institute authorized by Congress in 2010; 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



# Why PCORI?

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- Research has not answered many questions patients face
- People want to know which treatment is right for them
- Patients need information they can understand and use



# PCORI Has a Broad and Complex Mandate

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**“assist patients, clinicians, purchasers, and policy-makers in making informed health decisions...through research and evidence synthesis...and the dissemination of research findings”**

—from PCORI’s authorizing legislation



<http://www.pcori.org/assets/PCORI-Authorizing-Legislation-032310.pdf>

# PCORI's Mission

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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.**



# Strategic Goals

**Increase Quantity, Quality, and Timeliness  
of Research Information**



**Speed the Implementation and  
Use of Evidence**

**Influence Research Funded by Others**



# Our National Priorities for Research



**Assessment of  
Prevention, Diagnosis,  
and Treatment Options**



**Improving Healthcare  
Systems**



**Communication &  
Dissemination  
Research**



**Addressing  
Disparities**



**CER Methods and  
Infrastructure**



# Building a Patient-Centered Research Community

Find out how you can participate in our work

MORE DETAILS

## Open Opportunities

Our Funding Center contains all of the opportunities, and links to resources for

## Obesity Observational Research Initiative

### Key Deadlines

Application: May 27, 2015

## Engagement Award (EAIN): Research Meeting and Conference Support

Key Deadlines	Type	Funds Available	Total Costs
LOI: Not required Application: July 1, 2015	Program Award		One-time award total costs must not exceed \$50,000 and multi-year award total costs may not exceed \$250,000.

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**PCORI Milestones**

Engagement related milestone Leadership related milestone Research-related milestone

NOVEMBER  
• First PFA issued under fifth national priority for research (advancing PCORI methods) ①  
• Board adopts revised PCORI Methodology Standards ①  
• Board approves creation of first four multi-stakeholder advisory panels ①

DECEMBER  
• Board approves \$40.7 million in awards to fund first 25 primary research projects ①  
• First patient researcher Matchmaking App Challenge announced ①

2013  
JANUARY  
• Applications invited for first four advisory panels ①

MARCH  
• Eighty-four individuals named to serve on advisory panels ①

APRIL  
• Advisory panels hold first meetings ①  
• PCORI announces plan for PCORnet, the National Patient-Centered Clinical Research Network ①

MAY  
• Board approves \$60.6 million to fund 51 primary research awards ①

JUNE  
• Targeted PFA issued for up to \$17 million for studies to improve outcomes in disparities in asthma burden and severity ①  
• Eugene Washington PCORI Engagement Awards program announced ①  
• Second patient researcher Matchmaking App Challenge announced ①

JULY  
• PCORI and National Institute on Aging invite applications for up to \$30 million for a study on preventing fall-related injuries in older adults ①

SEPTEMBER  
• Board approves \$14 million in awards to fund 71 primary research studies ①  
• PCORI announces large pragmatic clinical studies initiative ①

OCTOBER  
• PCORI and the Agency for Healthcare Research and Quality (AHRQ) invite applications for a registry and studies on urine臊nia treatment ①  
• Pilot program launched for community-building PCORI Proposal Awards ①

NOVEMBER  
• Board adopts revised PCORI Methodology Report ①  
• Board creates two new multi-stakeholder advisory panels, on rare disease and clinical trials ①

DECEMBER  
• Applications invited for Advisory Panels on Clinical Trials and Rare Disease ①  
• Board approves \$101 million in awards to fund 53 studies, including 8 new trials and expand 29 health care networks that will form PCORnet ①  
• PCORI announces 30 pilot Pipeline to Proposal awards ①

2014  
FEBRUARY  
• PFAs, including first for large pragmatic clinical studies, issued for up to \$205 million in research project funding ①

MARCH  
• Second patient researcher Matchmaking App Challenge launched ①  
• PCORI announces two new advisory panels, on rare disease and clinical trials ①

JUNE  
• NIH announces award for \$10 million PCORI-funded study preventing fall-related injuries in older adults ①

JULY  
• Board approves topic for first PCORnet clinical trial: assessing optimal dose of aspirin for patients with coronary artery disease ①  
• Board approves \$54.8 million in awards to fund 33 primary research studies ①

SEPTEMBER  
• Workforce of second Matchmaking App Challenge announced ①  
• Proposal for peer review and release of primary research findings issued for public comment ①  
• PCORI announces \$10 million in awards for 48 primary research studies ①  
• AHRQ announces award for \$20 million PCORI-funded study on uterine fibroids treatment ①





# Research And Results

## Research & Results

OUR PROGRAMS

RESEARCH WE SUPPORT

HOW WE SELECT RESEARCH  
TOPICS

RESEARCH METHODOLOGY

PCORNET: THE NATIONAL  
PATIENT-CENTERED CLINICAL  
RESEARCH NETWORK

RESEARCH IN ACTION

COLLABORATING WITH OTHER

## What We've Funded

**440** Research Projects  
APPROVED

**\$1.08 BILLION**  
Research Funds Awarded

**40 STATES**  
With Research Funded

[MAP OF AWARDS >>](#)

PCORI awards funding for research and other programmatic initiatives in several ways. Our primary research funding is awarded through PCORI Funding Announcements (PFAs), broad calls for projects under our five National Priorities for Research and Research Agenda as well as "targeted" announcements on specific high-priority topics, and special one-time funding opportunities. We also offer the Eugene Washington PCORI Engagement Awards and Pipeline to Proposal awards; these are not research awards but are designed to better integrate patients and other stakeholders into the research process.

*Tips: Enter search terms to search the title, researchers, and abstracts. You may also filter by the categories listed below. Select desired terms from the drop-down lists and then click the GO button to view the results.*

# OUR GROWING RESEARCH PORTFOLIO

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

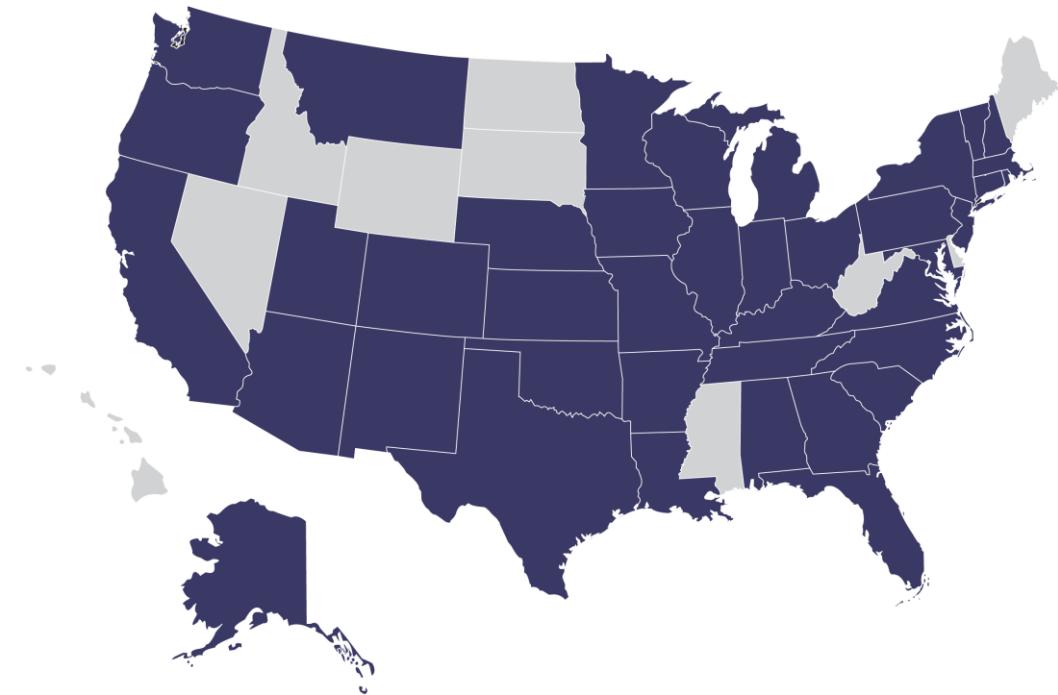


# Funded Projects to Date

Total number of research projects awarded: **440**

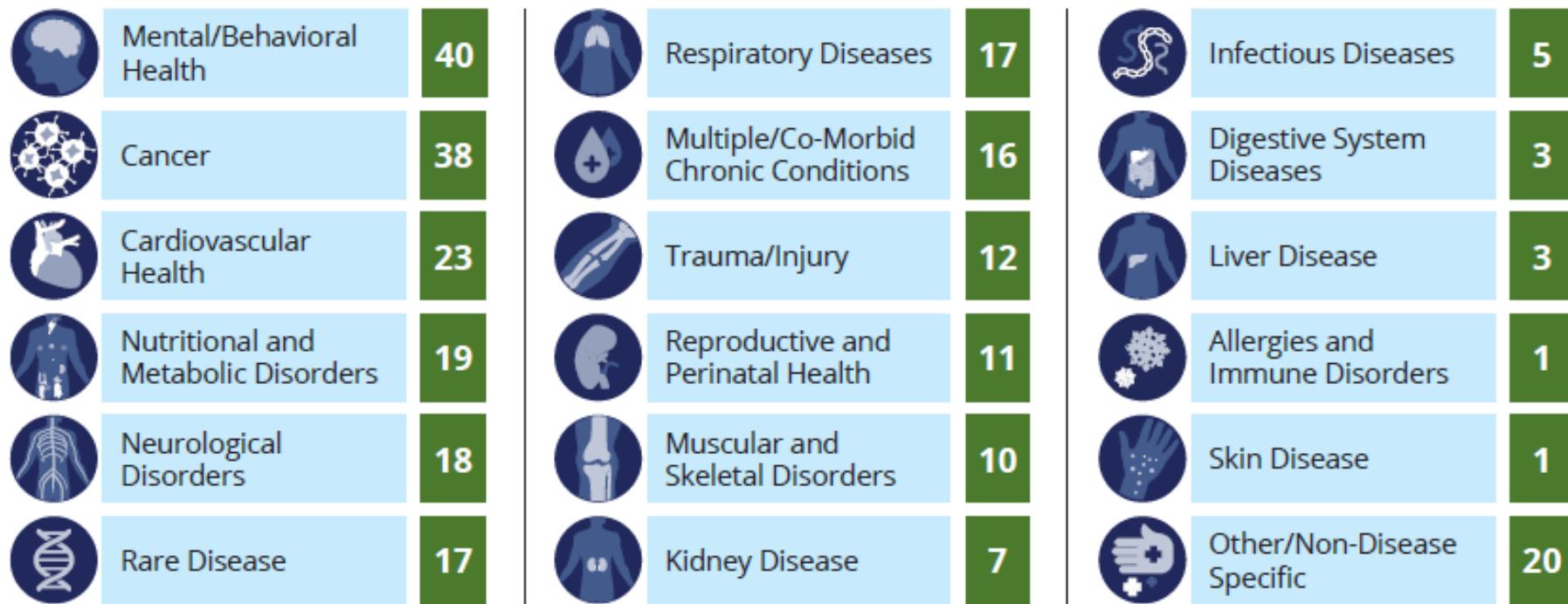
Total funds awarded:  
**\$1.08 billion**

Number of states where we are funding research:  
**40 states** (plus the District of Columbia and Quebec)

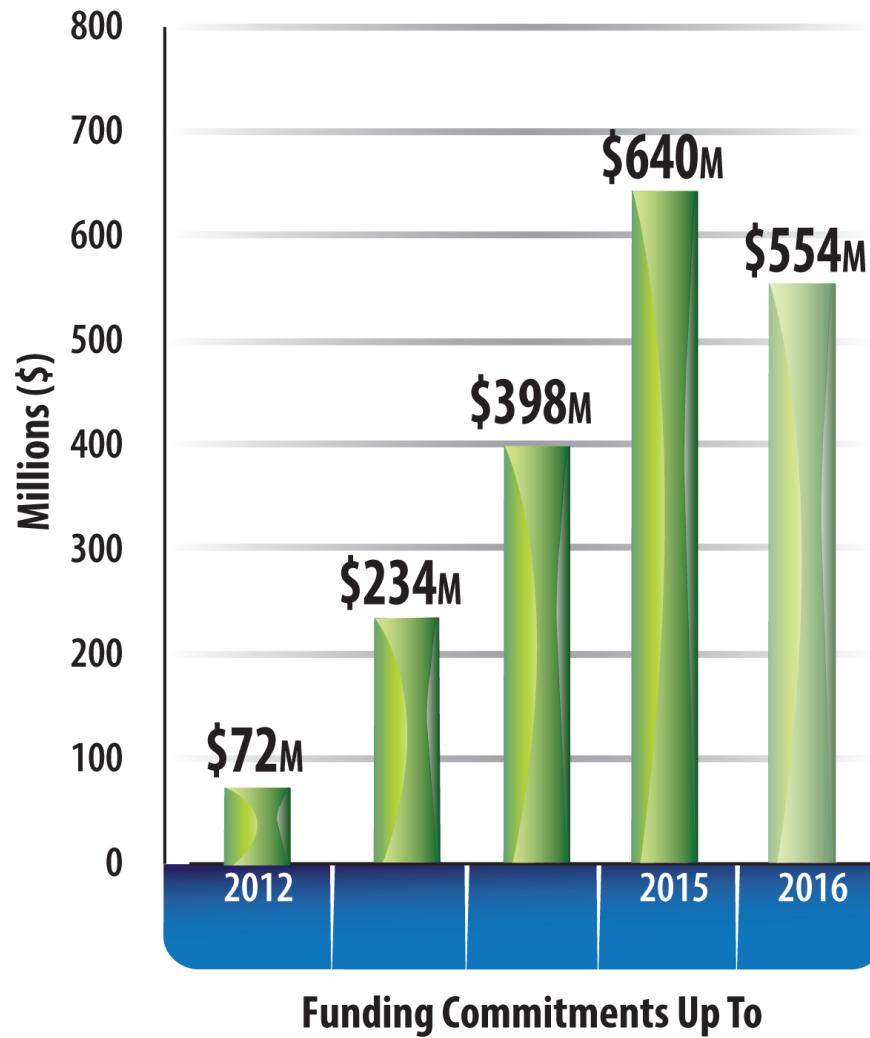


# Snapshot of Funded Projects

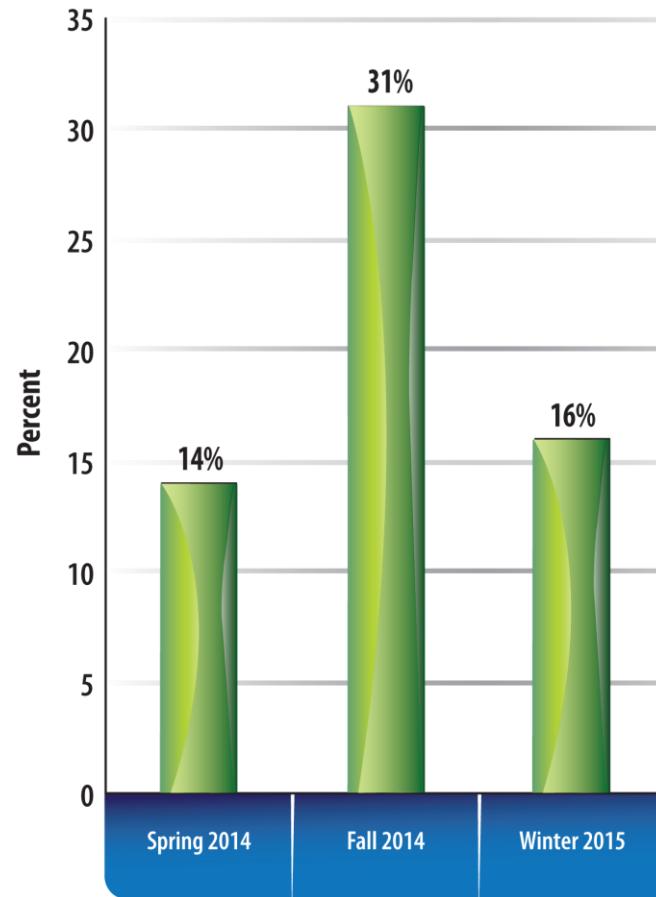
## SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)



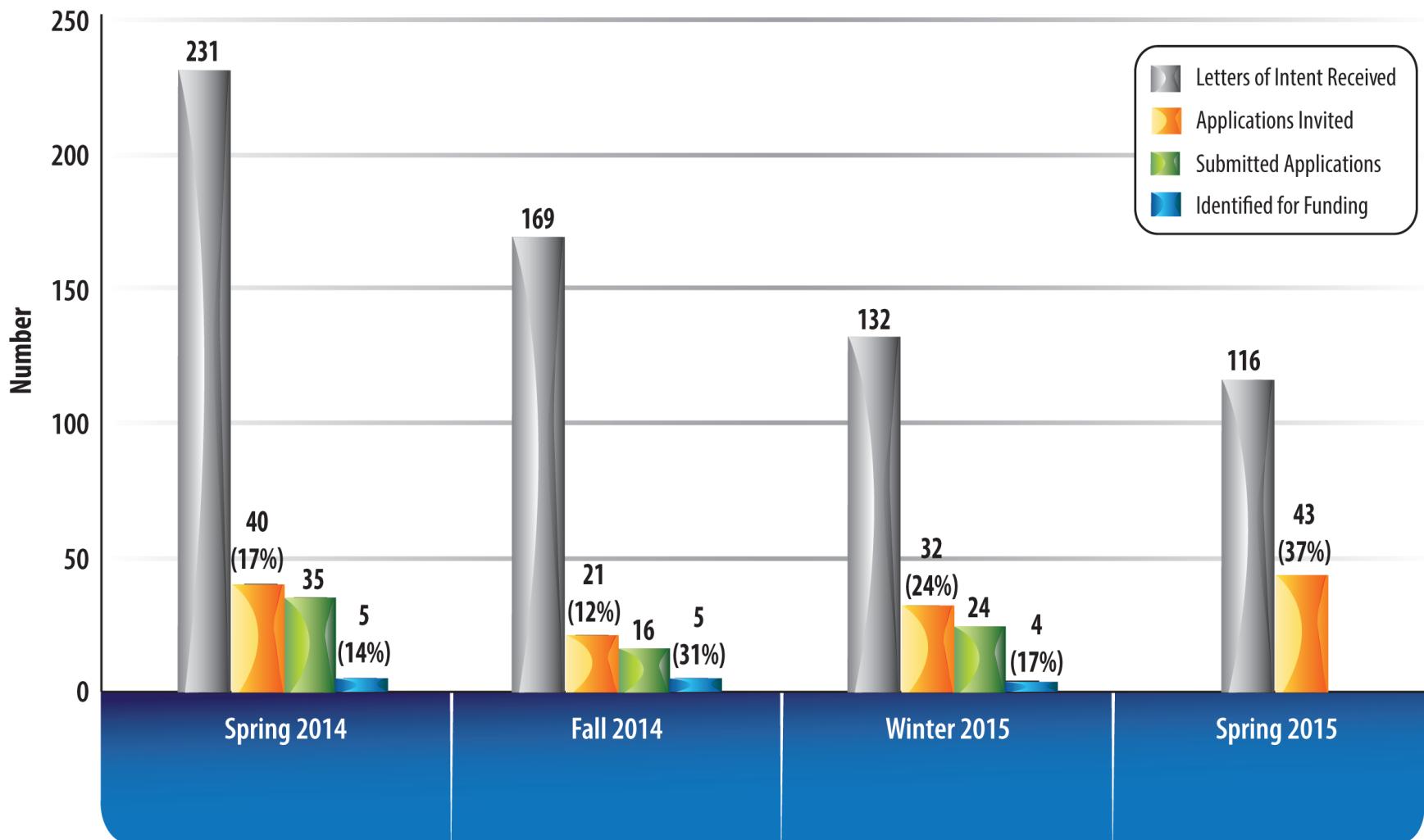
# Current Funding Commitments



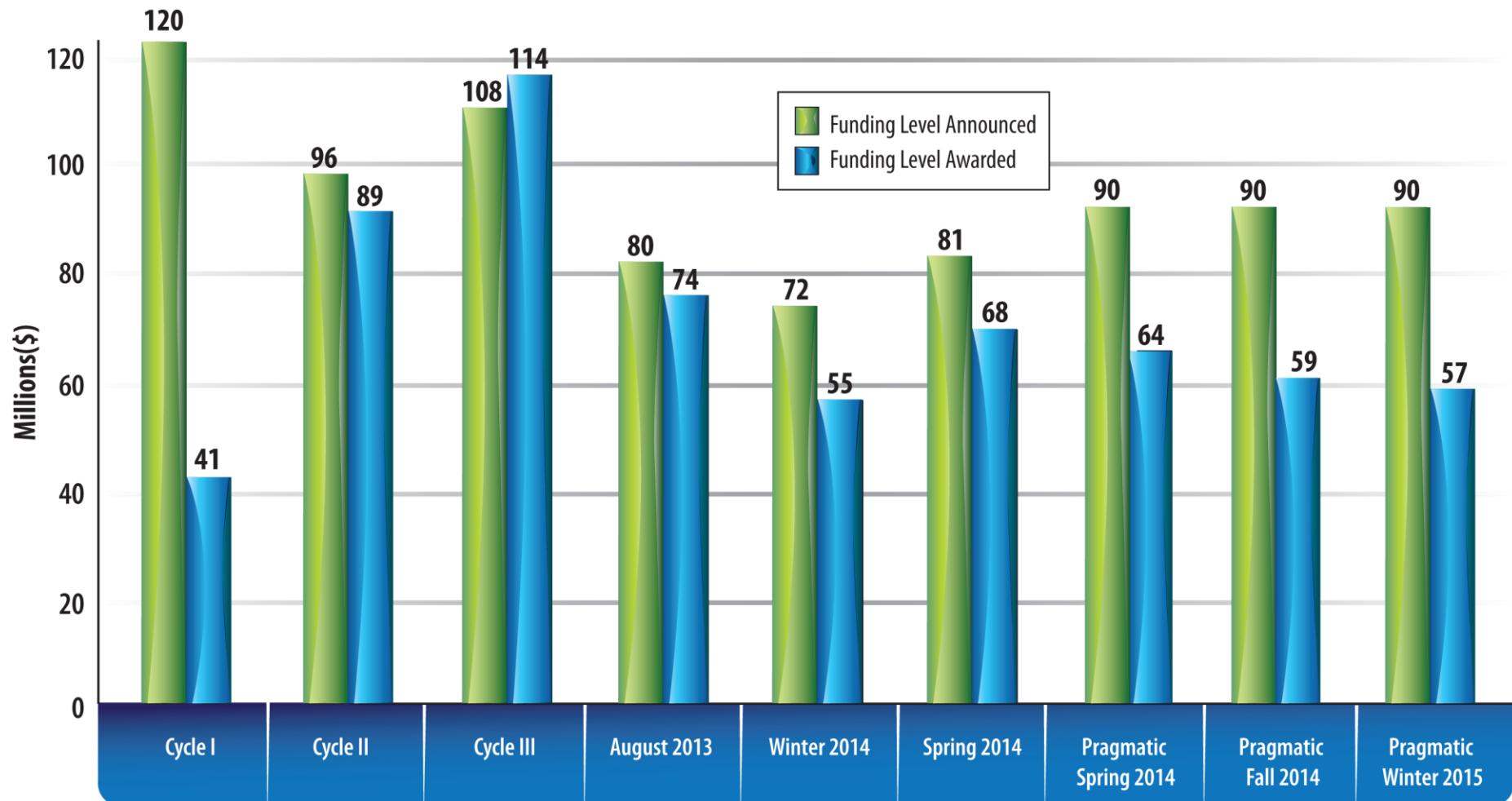
# PCORI's Past Funding Rates



# LOIs, Applications, and Awards: First 4 Cycles of Pragmatic Clinical Studies



# Comparison of Funding Level Announced with Funding Level Awarded



# Time from Award to Contract Execution

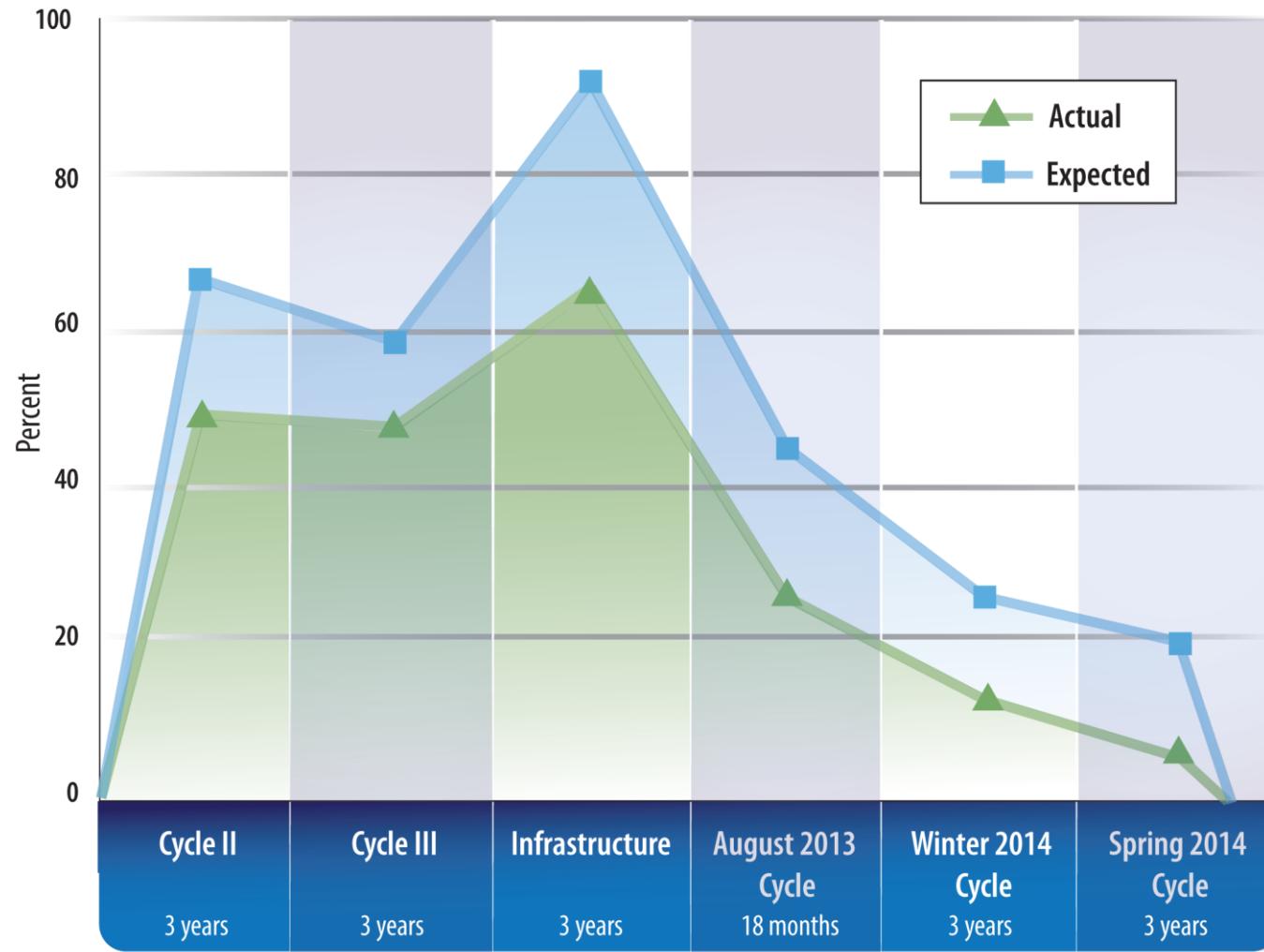
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**CMA has an operational goal of executing 75% of each Cycle's contracts within 90 days of Board approval**

- Constantly changing contract templates
- PCORI is NOT Federal
- Cost reimbursable procurement contract applied to clinical research



# Cost-Reimbursable Contracts



\*Average Start date is 10/1/2014



# Why Are Awards at PCORI Different?

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- PCORI research contracting process
  - What is the difference between a research contract and a research grant?
- The authorizing law
  - How it affects PCORI research projects



# Contract Provisions Relating to PCORI's Authorizing Law

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## Contracts reflect PCORI's authorizing law

- Adherence to PCORI Methodology Standards
- Consultation with the PCORI Advisory Panels on Clinical Trials and Rare Diseases
- Peer Review of Primary Research
- Making Research Findings Publicly Available
- Conflicts of Interest
- Notifications About Publications
- Indemnification & Insurance
- Intellectual Property Rights in PCORI-Funded Research
- Contract Governing Law
- Data Sharing Plans





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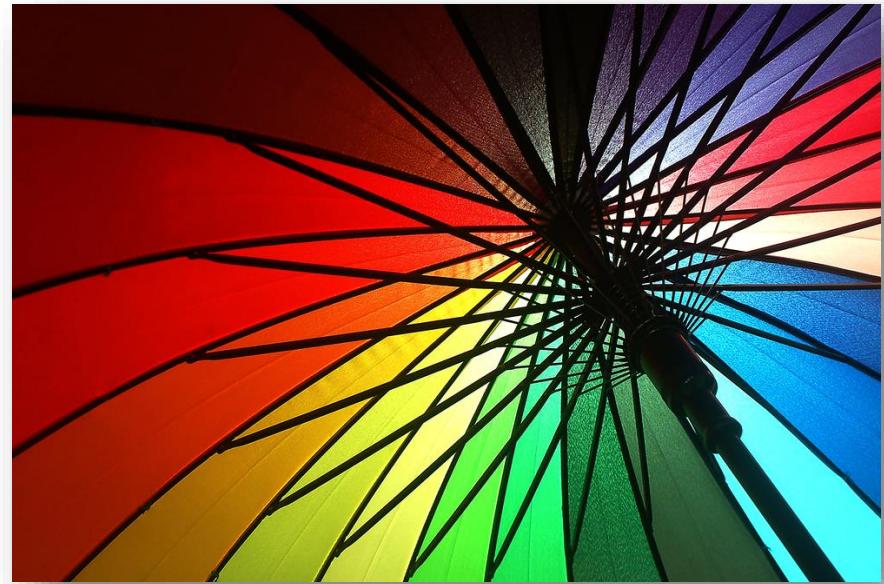


# What We Want To Accomplish

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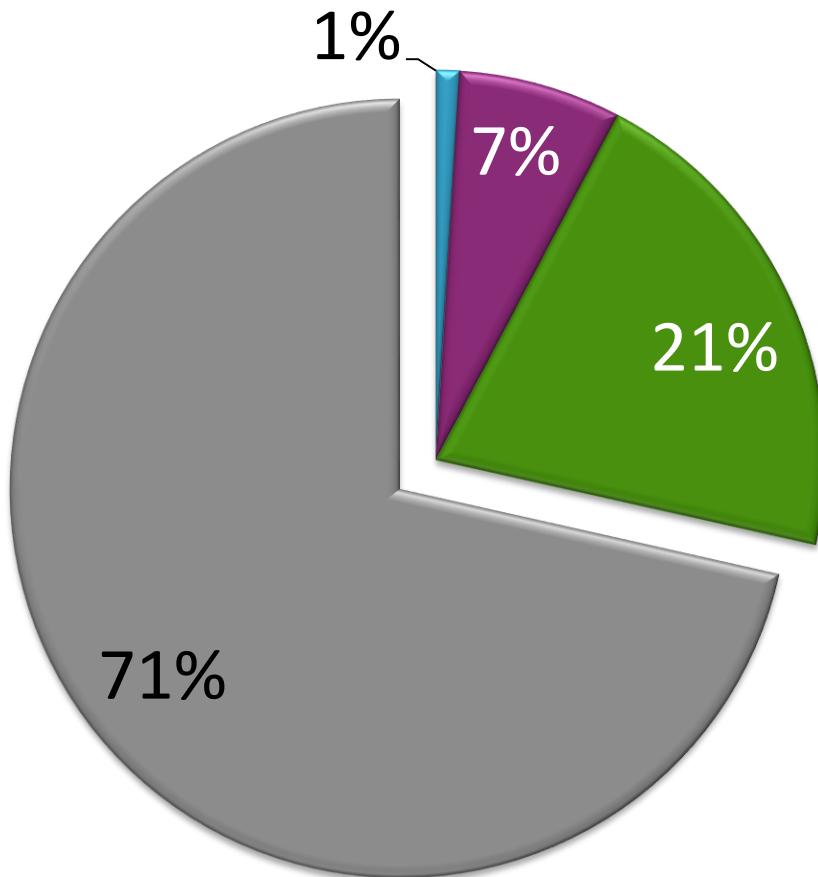
Help you improve your understanding of:

- Patient Engagement
- How to align with PCORI Program Requirements
- LOI success
- How to submit a responsive application



# More Reasons for Our Workshop— Administrative Non-Compliance

## Applications



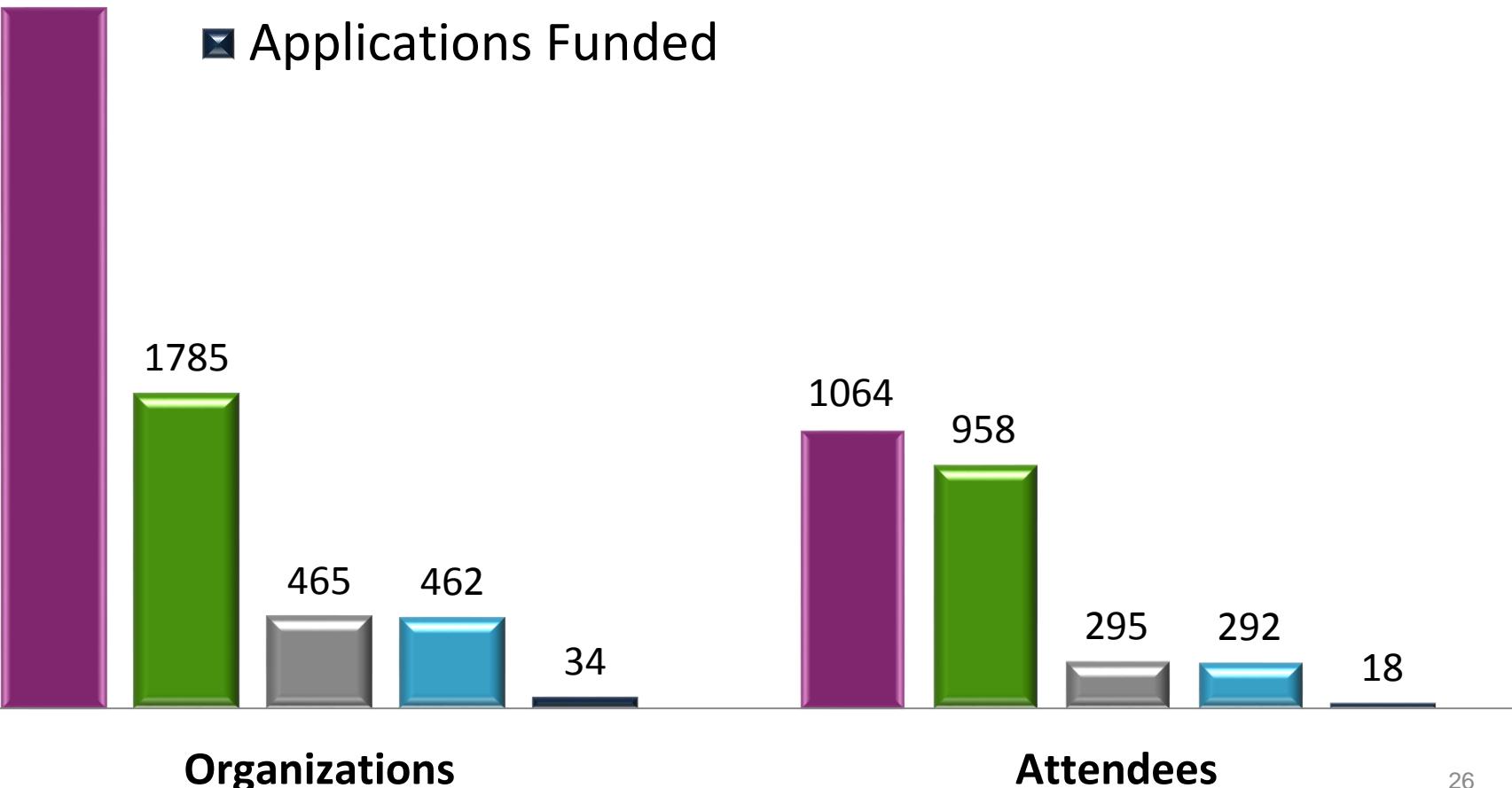
- Over Budget/Project Period
- Over Page Limit
- Missing Required Documents
- Administratively Compliant



# Significant Workshop Statistics

- Drafted LOIs
- Full Application
- Applications Funded
- LOIs Submitted
- In-Person Review

2035



# The Workshop Opportunity

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Talk with us!



# Questions?

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