

Understanding PCORI's Pragmatic Clinical Studies Initiative

September 21, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Overview

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September 21, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome!



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?

- 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

“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

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

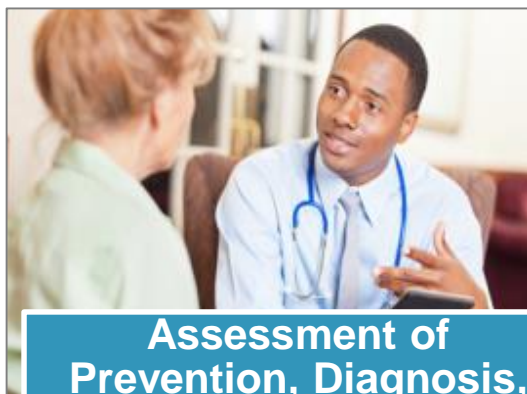


Speed the Implementation and Use of Evidence

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

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Open Opportunities

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

Obesity Observational Research I

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.

PCORI Milestones

1 Engagement-related milestone 2 Leadership-related milestone 3 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 \$60.7 million in awards to fund first 25 primary research projects 2
- 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 \$68.6 million to fund 51 primary research awards 2

JUNE

- Targeted PFA issued for up to \$17 million for studies to improve outcomes in disparities in asthma burden and care 2
- Eugene Washington PCORI Engagement Awards program announced 1
- Winners of first 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 2

SEPTEMBER

- Board approves \$114 million in awards to fund 71 primary research studies 2
- 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 uterine fibroids treatment 3
- Pilot program launched for community-building Pipeline to 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 \$191 million in awards to fund 53 studies, including 8 in response to the asthma PFA, and to build and expand 29 health data networks that will form PCORnet 2
- PCORI announces 30 pilot Pipeline to Proposal awards 1

2014

FEBRUARY

- PFA, including first for large pragmatic clinical studies, issued for up to \$205 million in research project funding 2

MARCH

- Second patient researcher Matchmaking App Challenge launched 1
- Board appoints members of two new advisory panels, on rare disease and clinical trials 1

JUNE

- NIA announces awardee for \$30 million PCORI-funded study on preventing fall-related injuries in older adults 2

JULY

- Board approves topic for first PCORnet clinical trial: assessing optimal dose of aspirin for patients with coronary artery disease 2
- Board approves \$54.8 million in awards to fund 33 primary research studies 2

SEPTEMBER

- Winners of second Matchmaking App Challenge announced 1
- Proposal for peer review and release of primary research findings issued for public comment 1
- Board approves \$102 million in awards for 46 primary research studies 2
- AHRQ announces awardee for \$20 million PCORI-funded study on uterine fibroids treatment 3

PCORI invites public comment on draft PCORI Methodology Report 1

Second round of PFAs issued under first four national priorities for research 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

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.

[MAP OF AWARDS >>](#)

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>

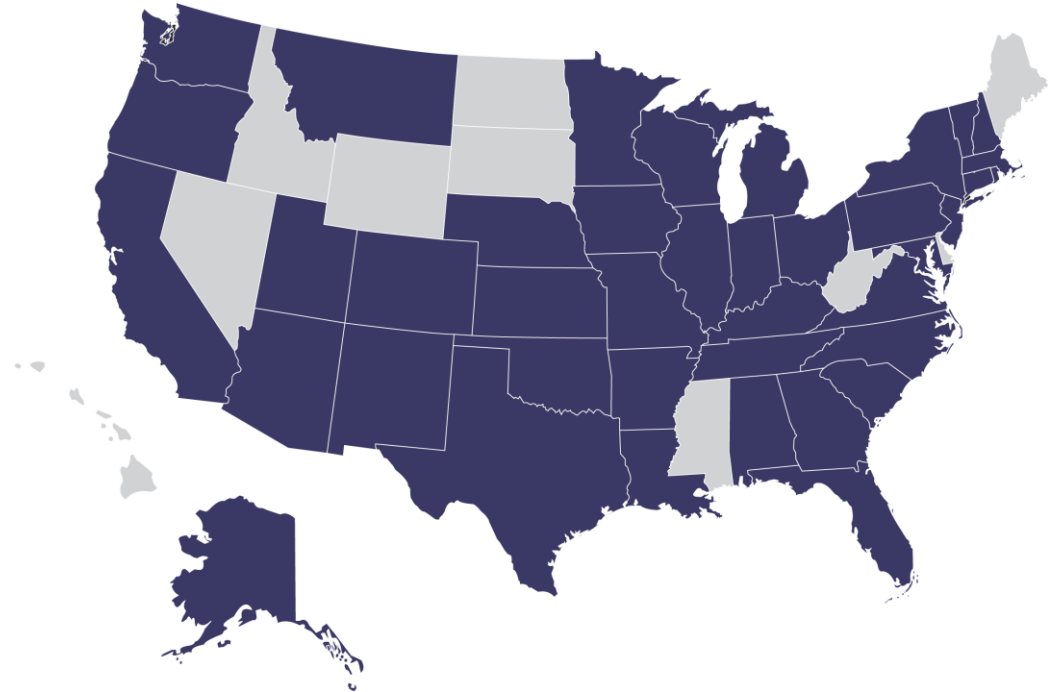


Funded Projects to Date

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)



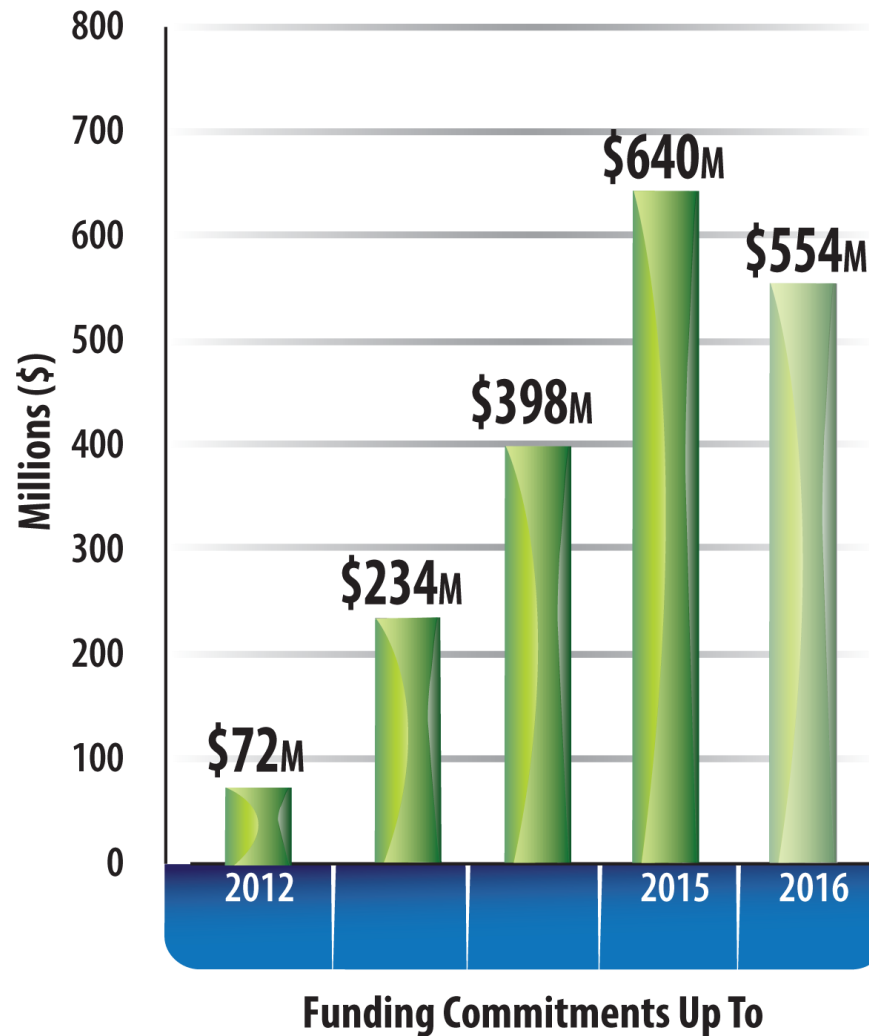
Snapshot of Funded Projects

SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)

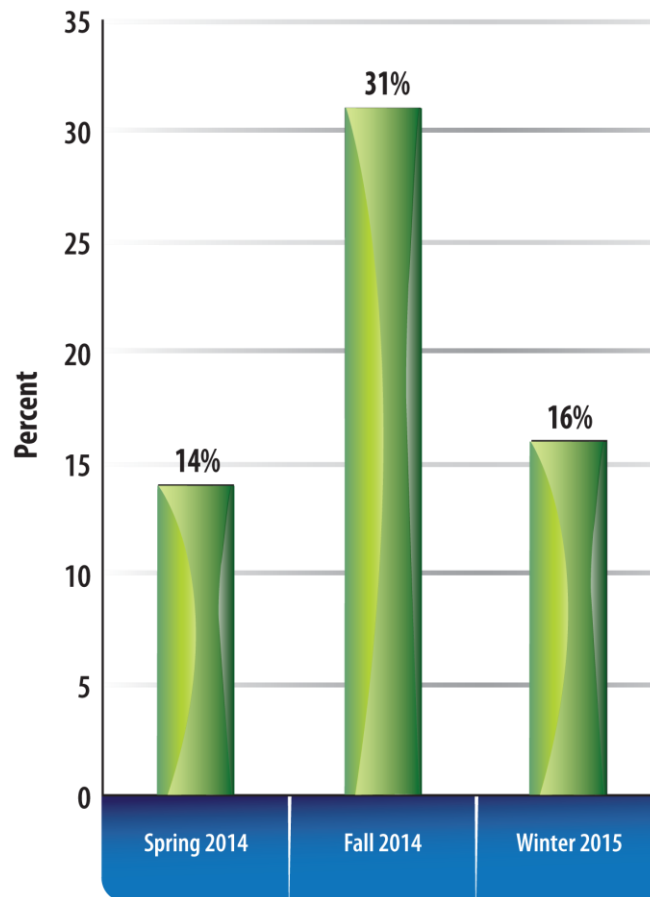
	Mental/Behavioral Health	40		Respiratory Diseases	17		Infectious Diseases	5
	Cancer	38		Multiple/Co-Morbid Chronic Conditions	16		Digestive System Diseases	3
	Cardiovascular Health	23		Trauma/Injury	12		Liver Disease	3
	Nutritional and Metabolic Disorders	19		Reproductive and Perinatal Health	11		Allergies and Immune Disorders	1
	Neurological Disorders	18		Muscular and Skeletal Disorders	10		Skin Disease	1
	Rare Disease	17		Kidney Disease	7		Other/Non-Disease Specific	20



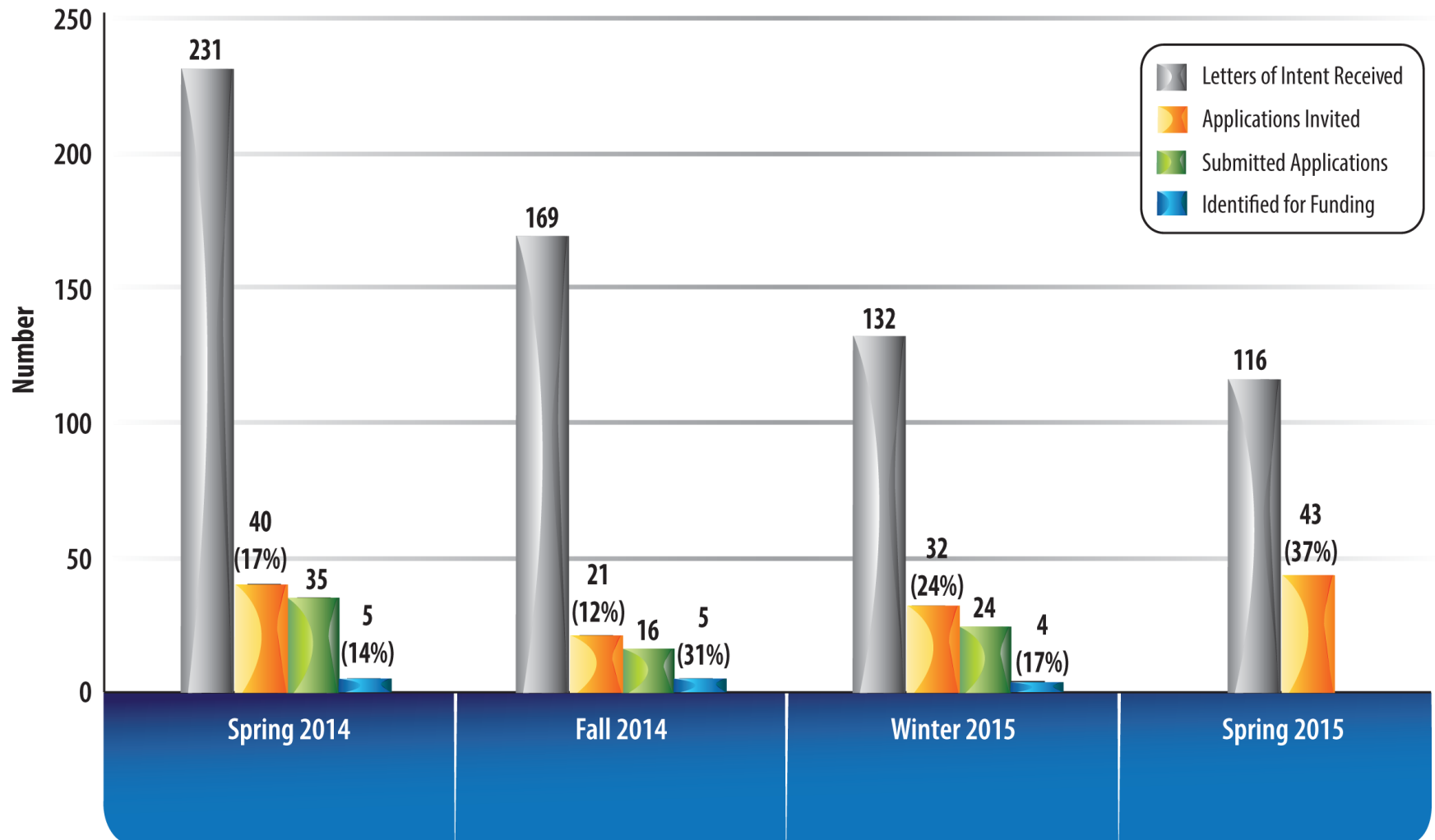
Current Funding Commitments



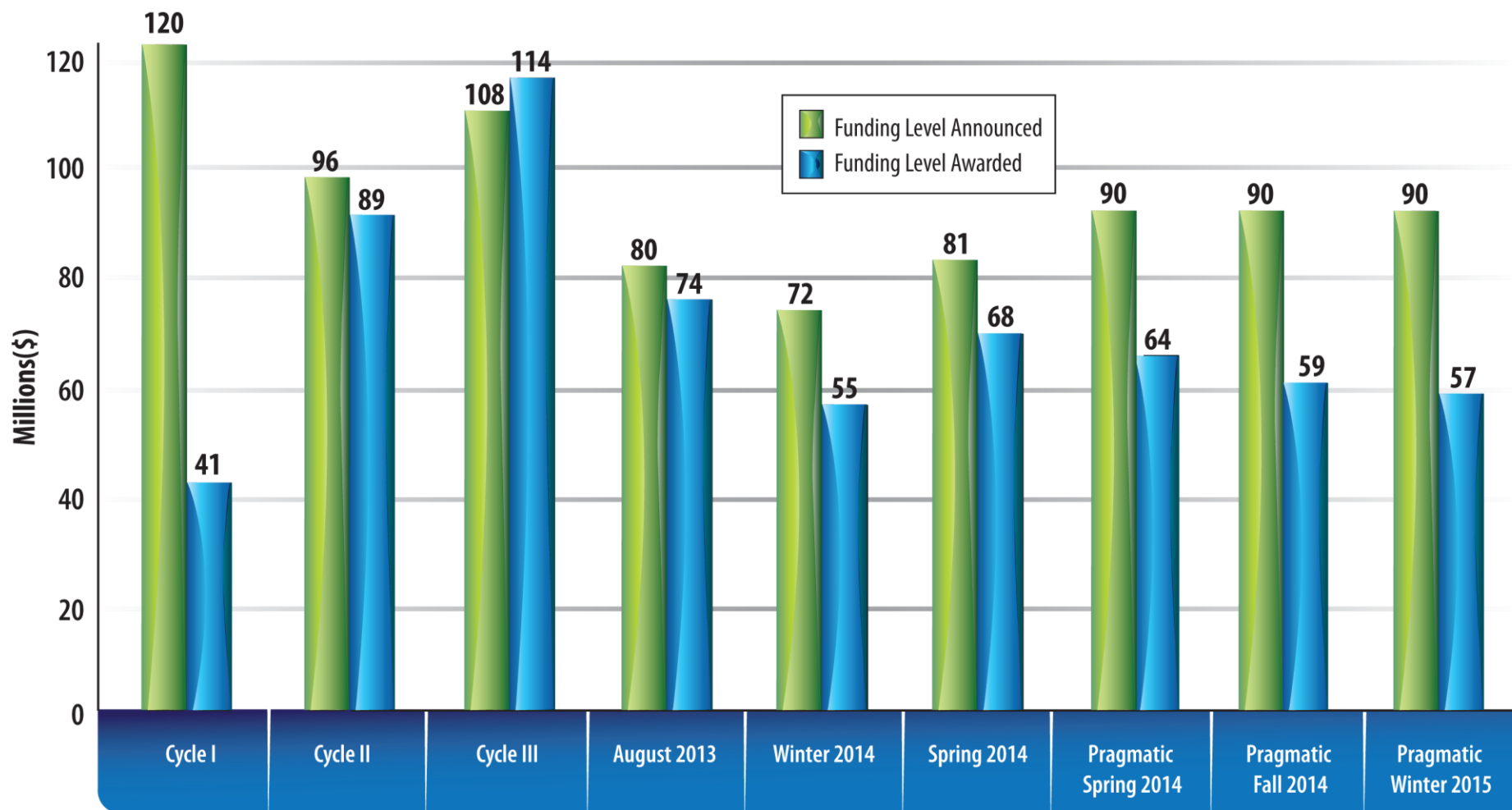
PCORI's Past Funding Rates



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



Comparison of Funding Level Announced with Funding Level Awarded



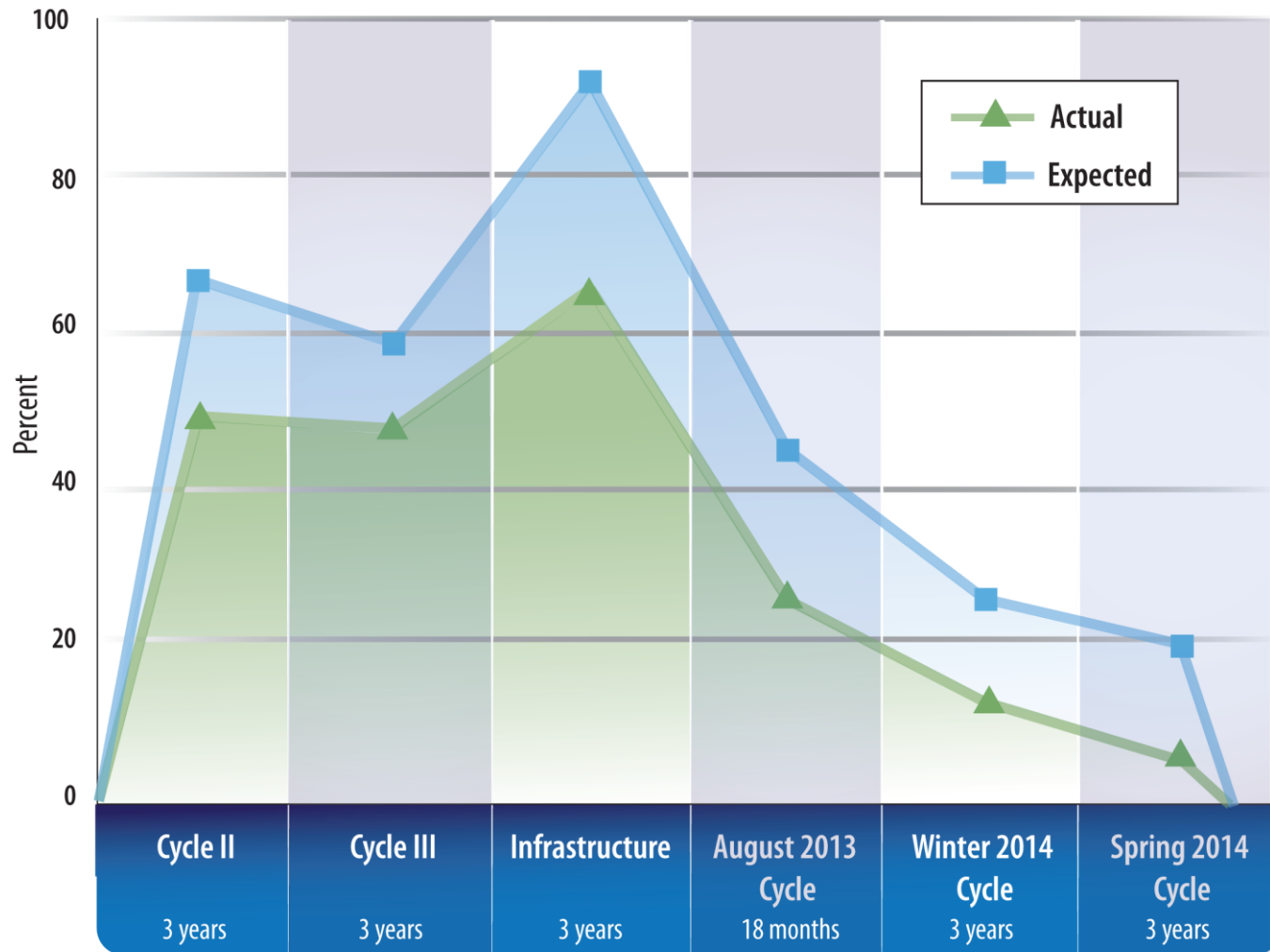
Time from Award to Contract Execution

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?

- 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

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





Session Objectives

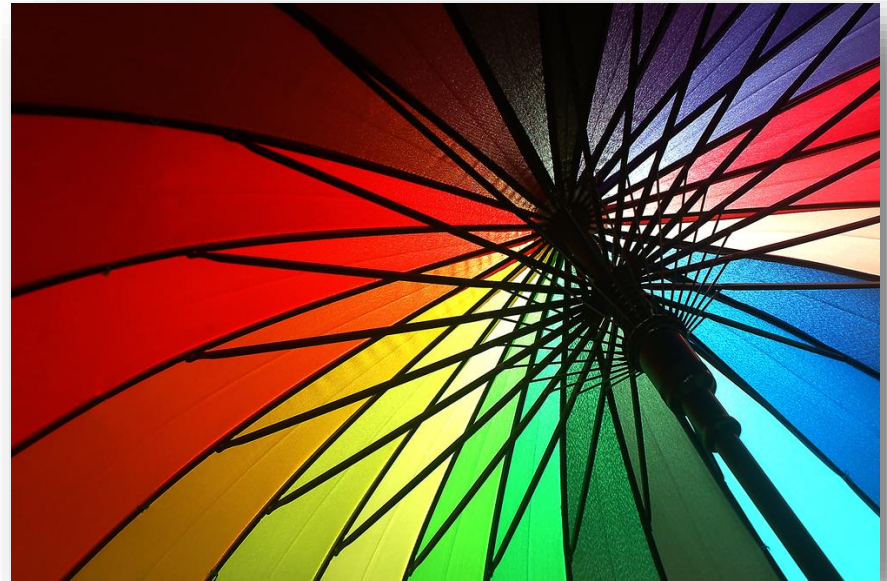
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What We Want To Accomplish

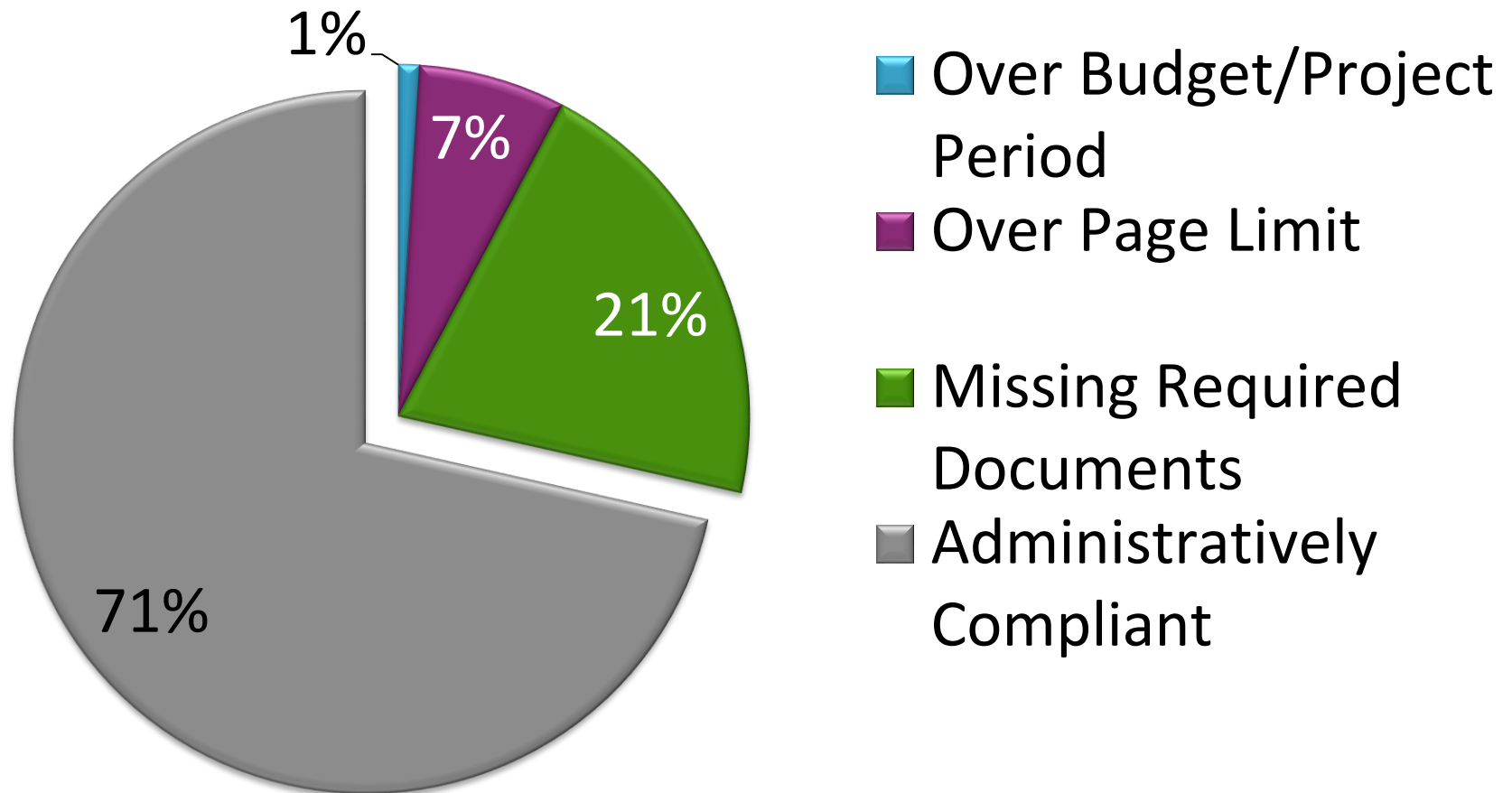
Help you improve your understanding of:

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

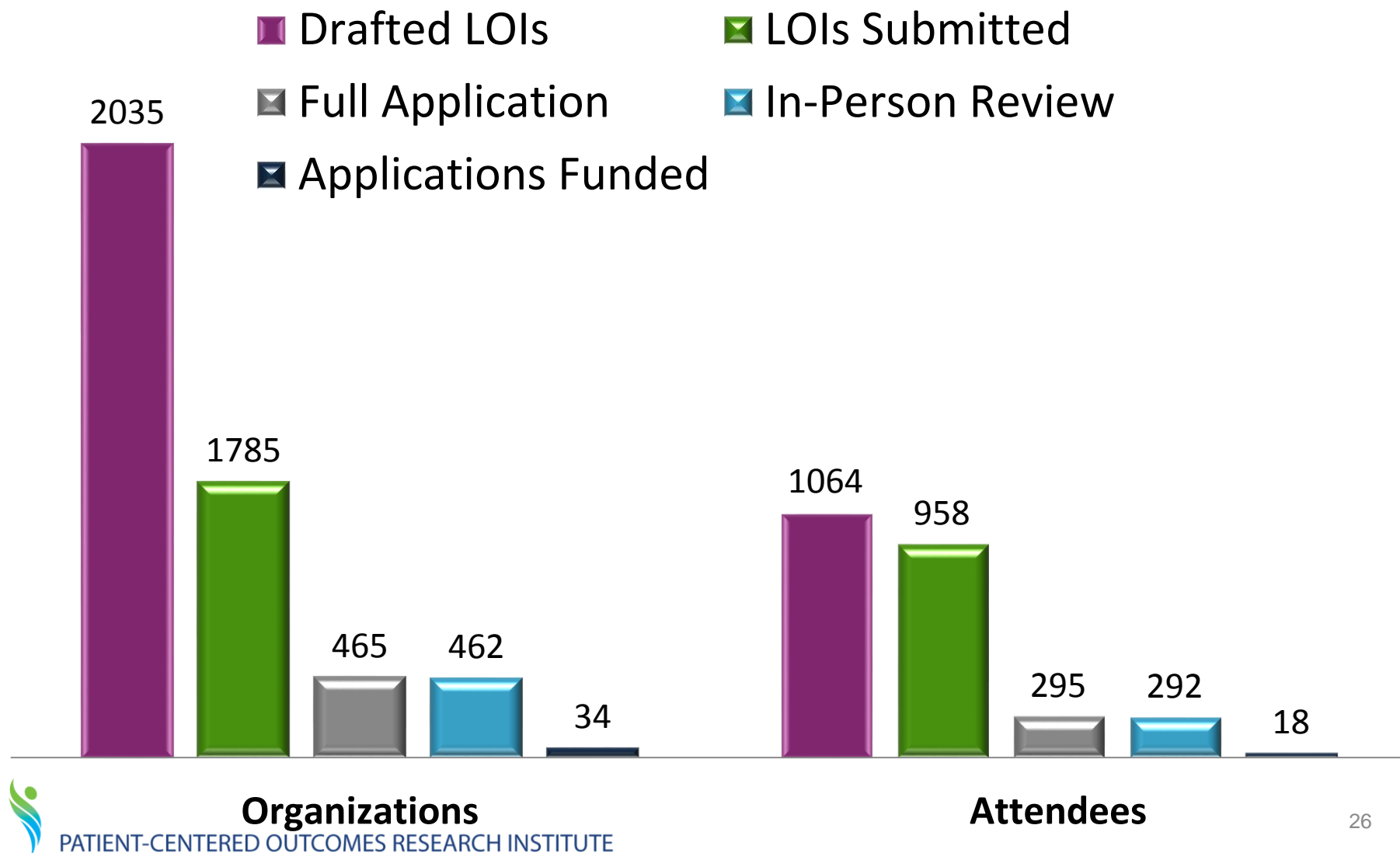


More Reasons for Our Workshop— Administrative Non-Compliance

Applications



Significant Workshop Statistics



The Workshop Opportunity



Talk with us!



Questions?



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