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

Welcome!

Scott Solomon
Director of Contracts
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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

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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.**

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Strategic Goals

Increase Quantity, Quality, and Timeliness of Research Information

Speed the Implementation and Use of Evidence

Influence Research Funded by Others

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Our National Priorities for Research
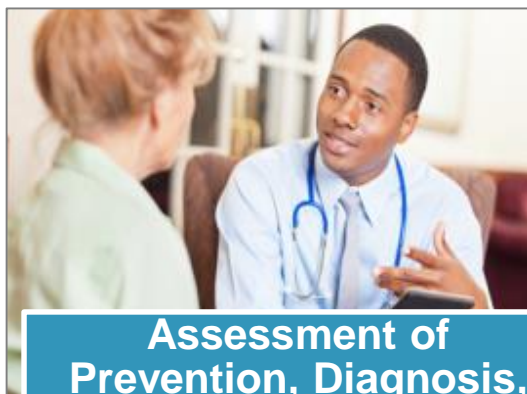
Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication & Dissemination Research

Addressing Disparities

CER Methods and Infrastructure

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OUR GROWING RESEARCH PORTFOLIO
http://www.pcori.org/research-results

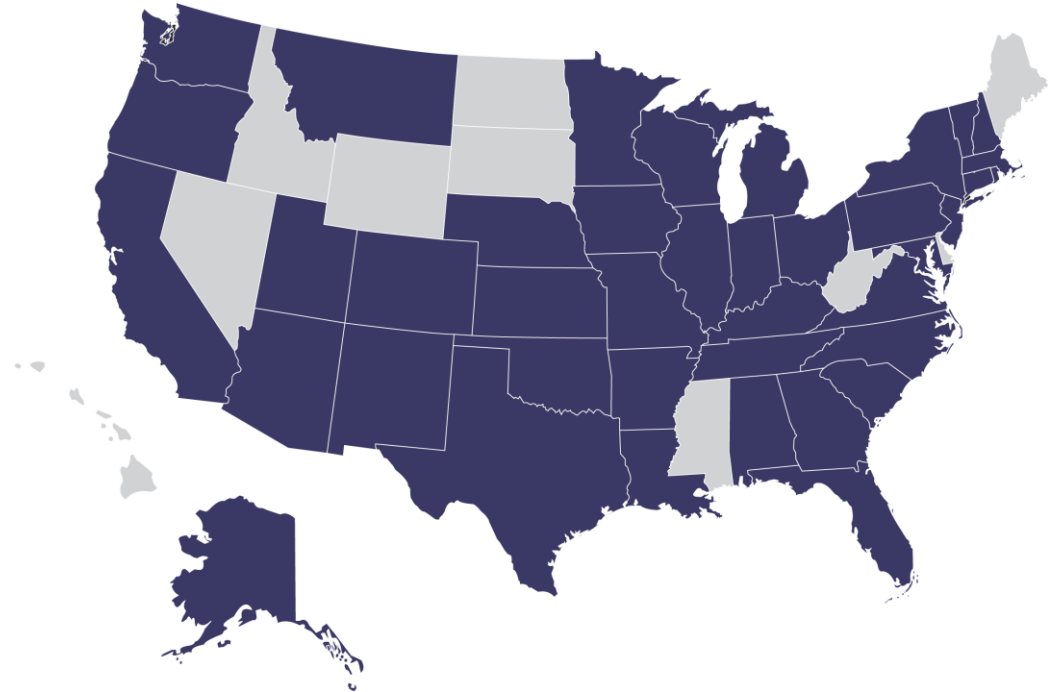PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

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)**

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Snapshot of Funded Projects

SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)

Condition	Count		Condition	Count		Condition	Count
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

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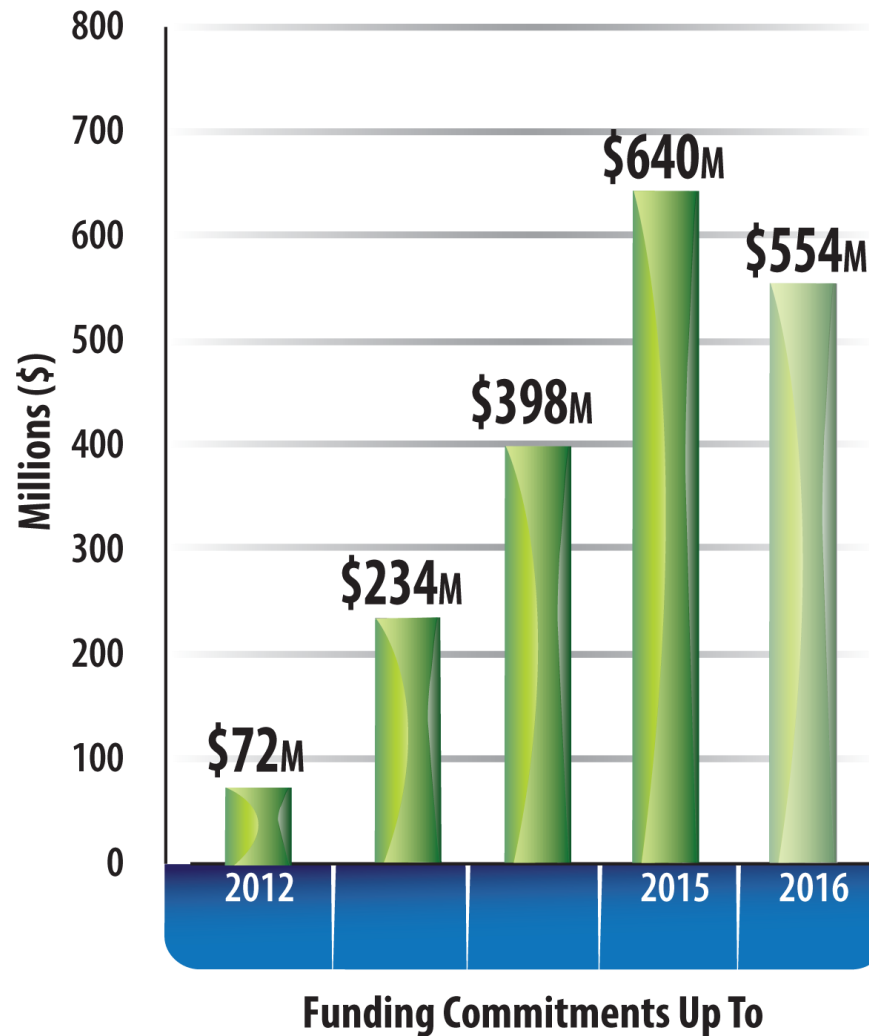
PCORI's Past Funding Rates
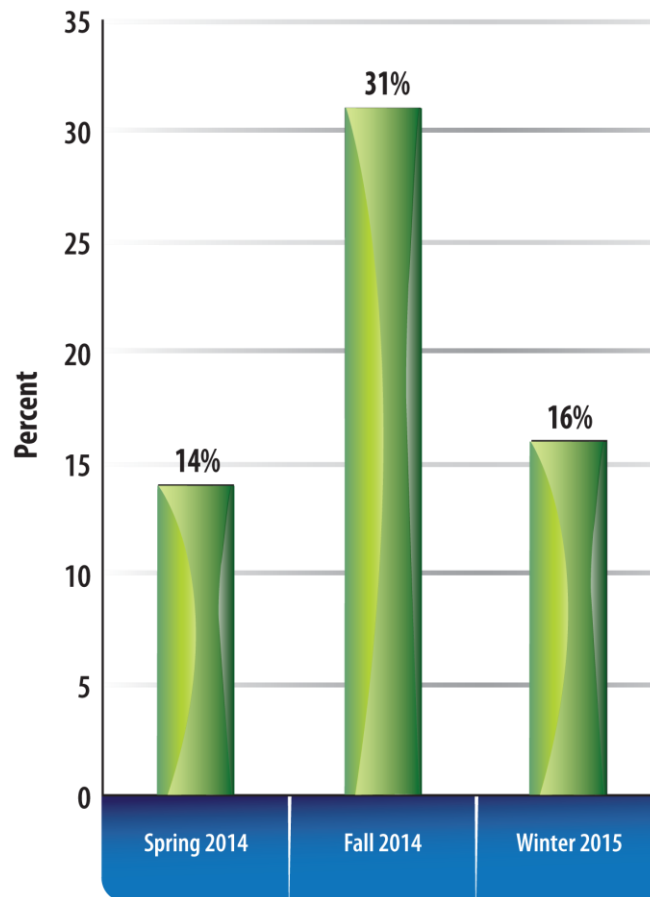
LOIs, Applications, and Awards: First 4 Cycles of Pragmatic Clinical Studies

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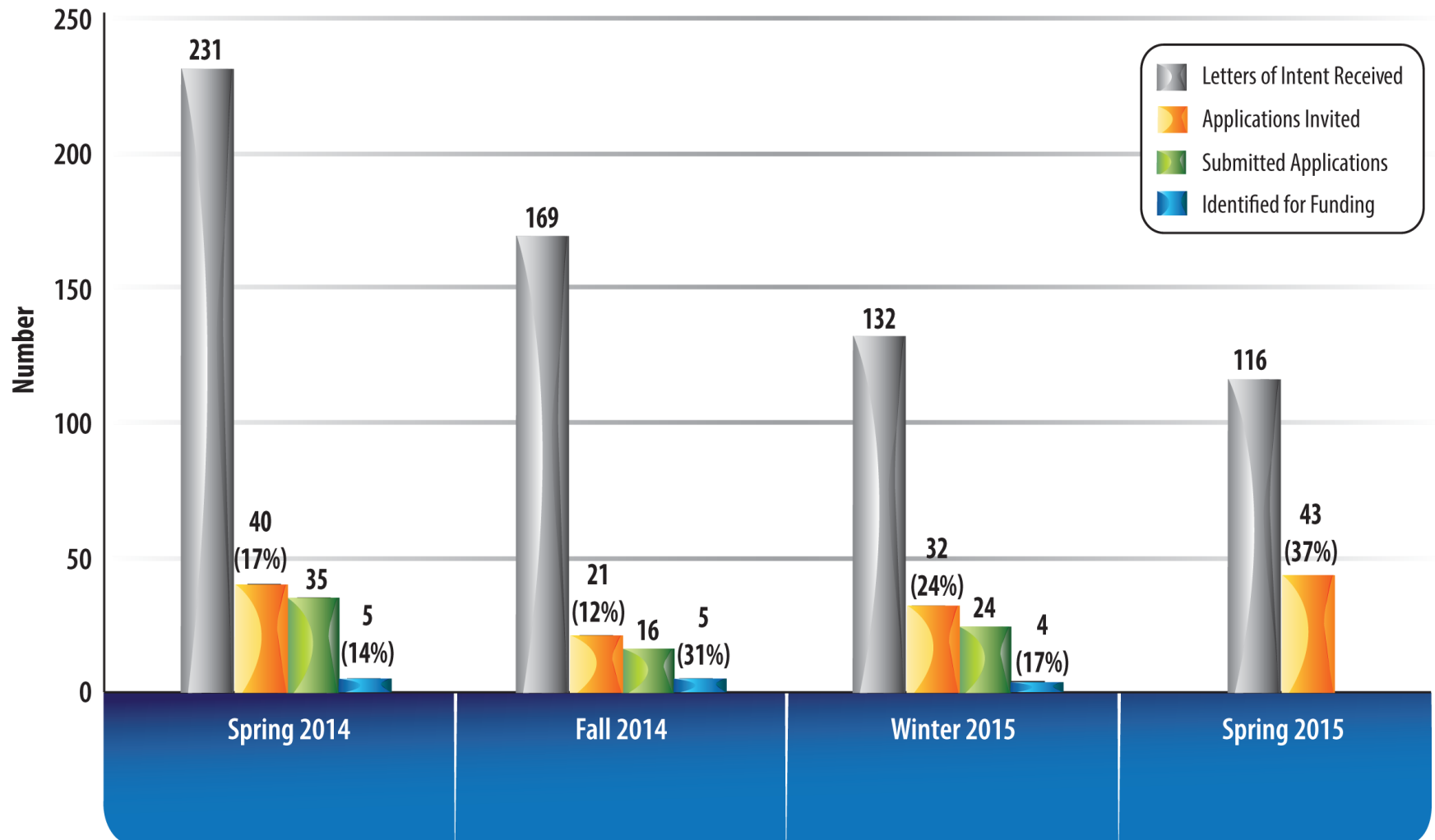
Comparison of Funding Level Announced with Funding Level Awarded

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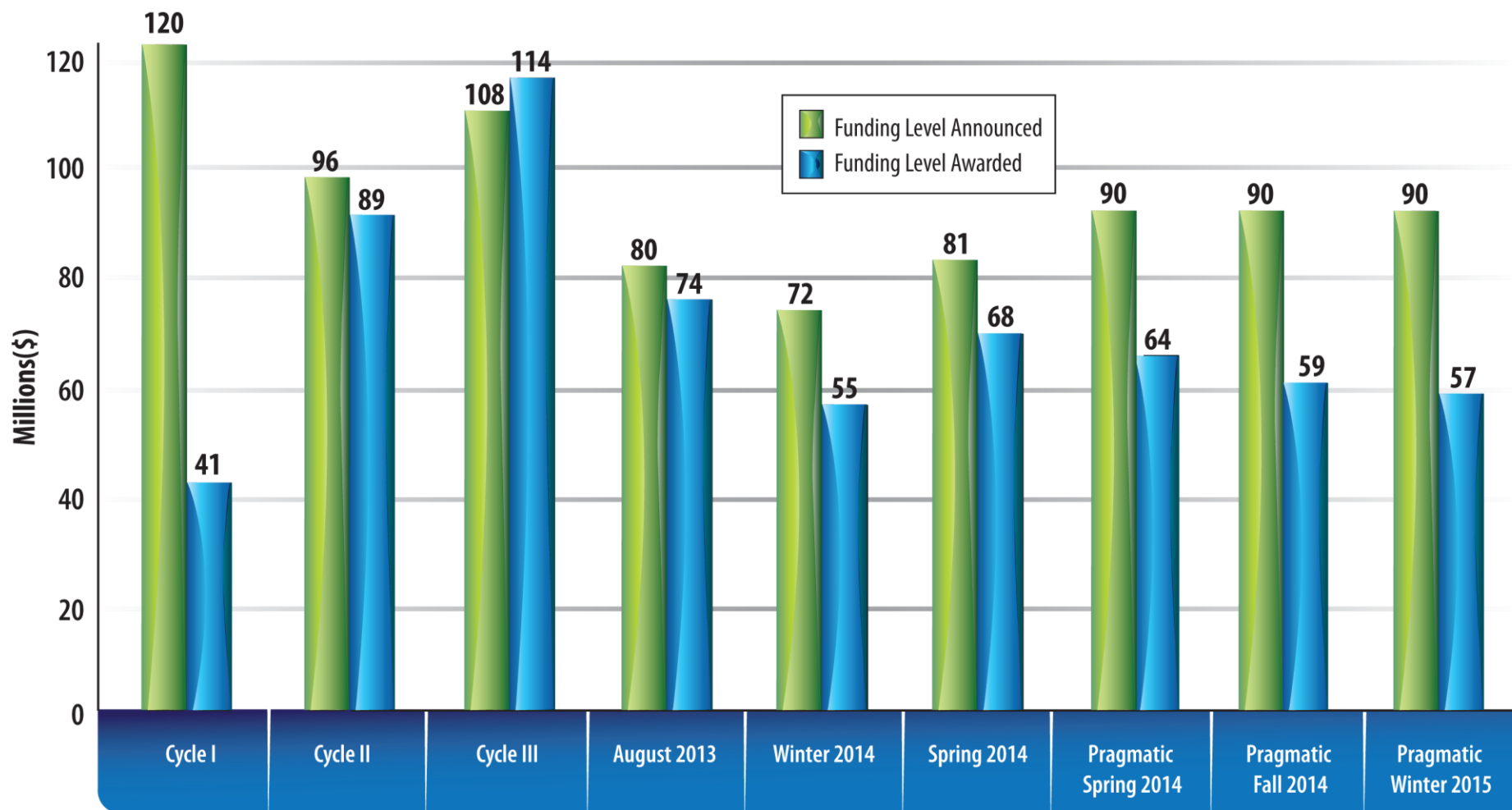
Time from Award to Contract Execution

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
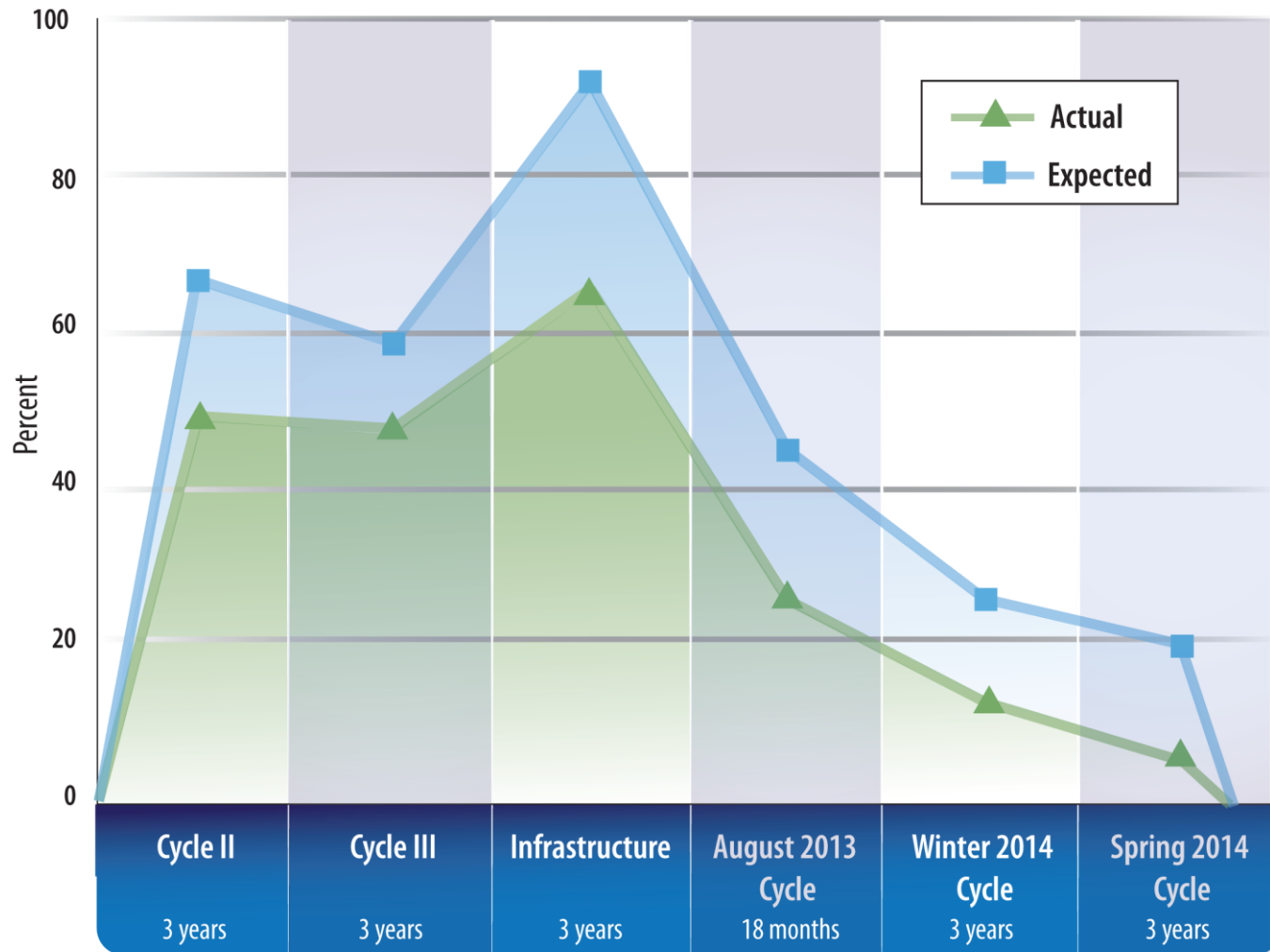
*Average Start date is 10/1/2014

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20

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

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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

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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

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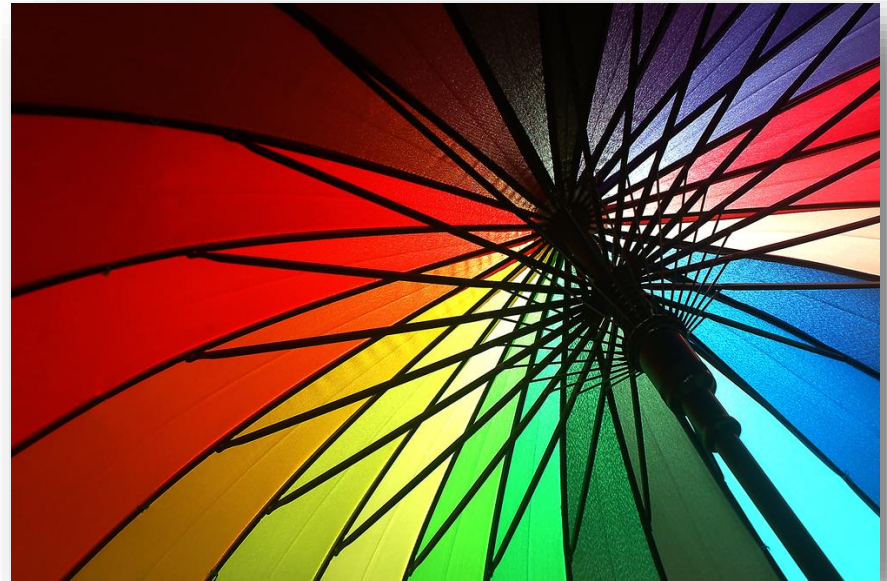
More Reasons for Our Workshop—Administrative Non-Compliance

Applications

Pie chart legend:
- Over Budget/Project Period — 1%
- Over Page Limit — 7%
- Missing Required Documents — 21%
- Administratively Compliant — 71%
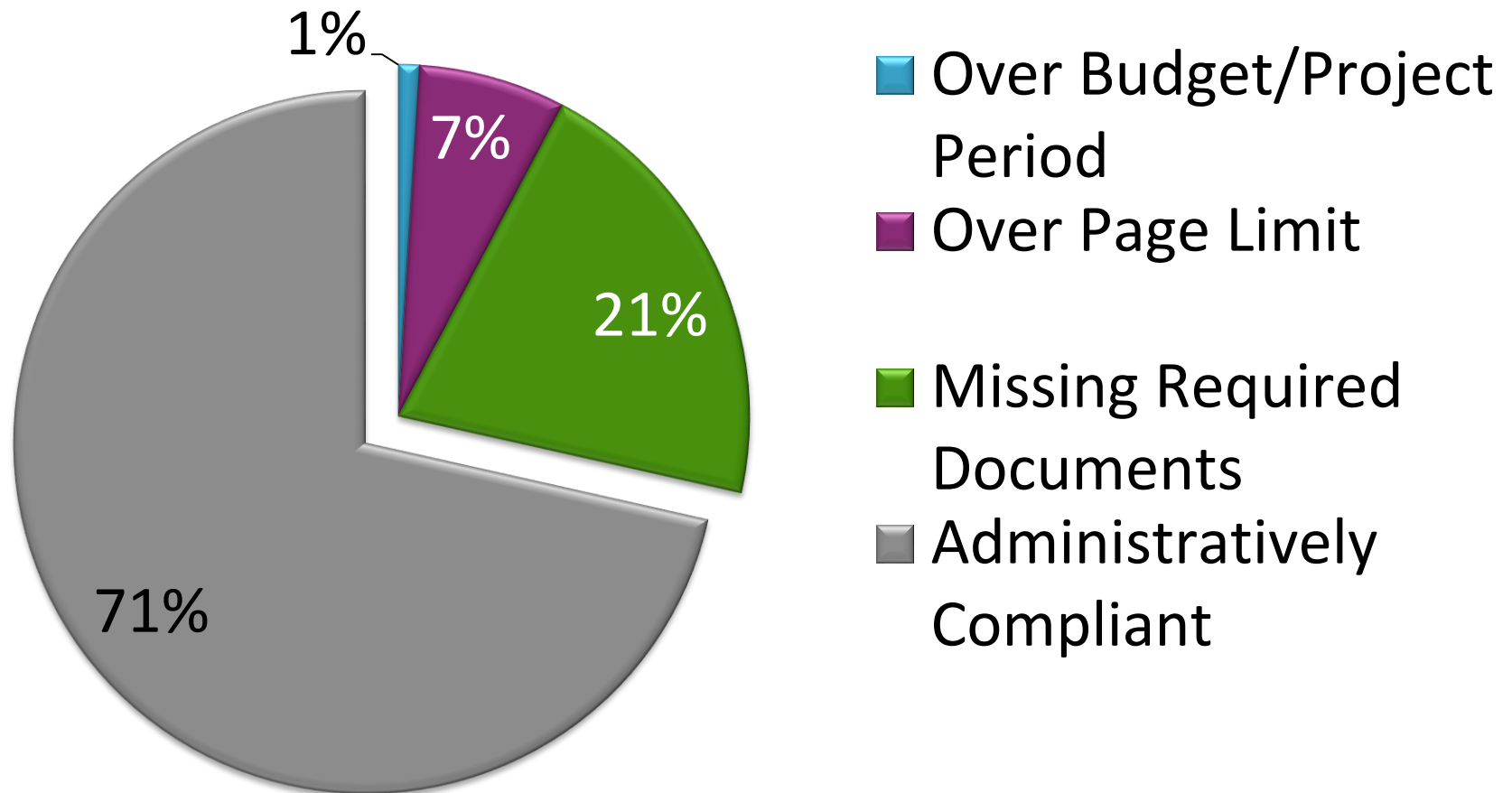
Significant Workshop Statistics

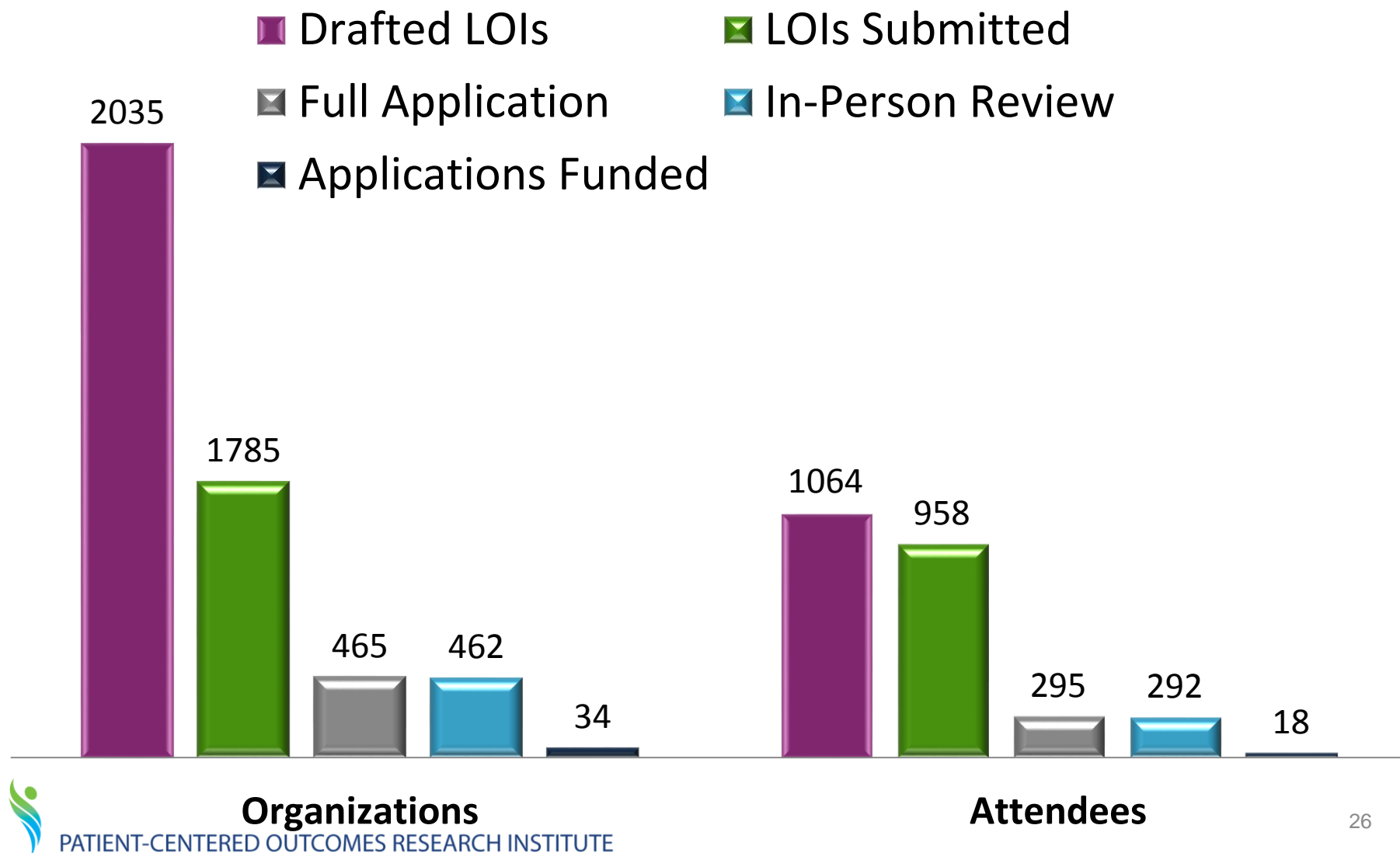Legend:
- Drafted LOIs
- LOIs Submitted
- Full Application
- In-Person Review
- Applications Funded

Organizations
- 2035 (Drafted LOIs)
- 1785 (LOIs Submitted)
- 465 (Full Application)
- 462 (In-Person Review)
- 34 (Applications Funded)

Attendees
- 1064 (Drafted LOIs)
- 958 (LOIs Submitted)
- 295 (Full Application)
- 292 (In-Person Review)
- 18 (Applications Funded)

The Workshop Opportunity

Talk with us!

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Questions?