

Welcome and Overview

James Hulbert, Brigitte Scott, and Scott Solomon

Contracts Management and Administration

February 19, 2015



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Welcome!



James Hulbert
Pre-Award Manager



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Housekeeping

- Restrooms
- Food/Reception
- Where to go for help
- Questions



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Help Desk

- Accessing/creating your account in the PCORI Online system
- Updating your application
- Finding your institution
- Assigning your Administrative Official
- Understanding PFA requirements
- Submitting your budget
- Reporting and compliance
- Notifications about the status of your application and funding decisions
- General pre- and post-award processes



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Resources

- Thumb Drive
- WiFi
- PCORI Online
- Tweet using #PCORI
- Questions



**WiFi Access:
SheratonMeetingSpace**



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Welcome!



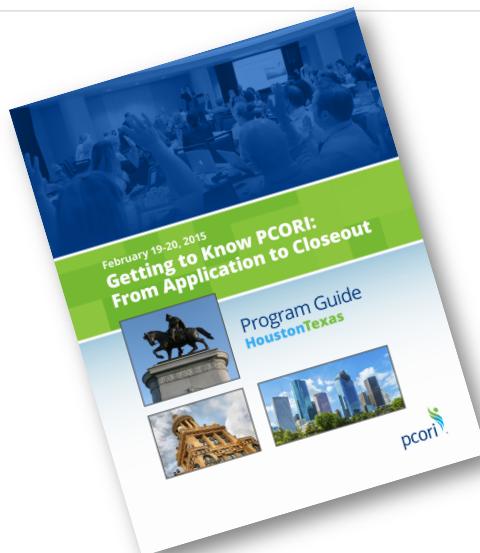
Brigette Scott, MA
Communications Manager,
Contracts Management and
Administration



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Your Program Guide



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Welcome!



Scott Solomon
Director of Contracts
Management and
Administration



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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



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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.



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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



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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 Is Accountable for Changing Practice

“Not less frequently than every 5 years GAO will analyze the **extent to which research findings are used by health care decision-makers**, the effect of the dissemination of such findings on **reducing practice variation and disparities** in health care...”

—from PCORI’s authorizing legislation



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PCORI’s Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from **research guided by patients, caregivers and the broader health care community**.



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Our 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



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Strategic Goals

Increase Quantity, Quality, and Timeliness
of Research Information



Speed the Implementation and
Use of Evidence

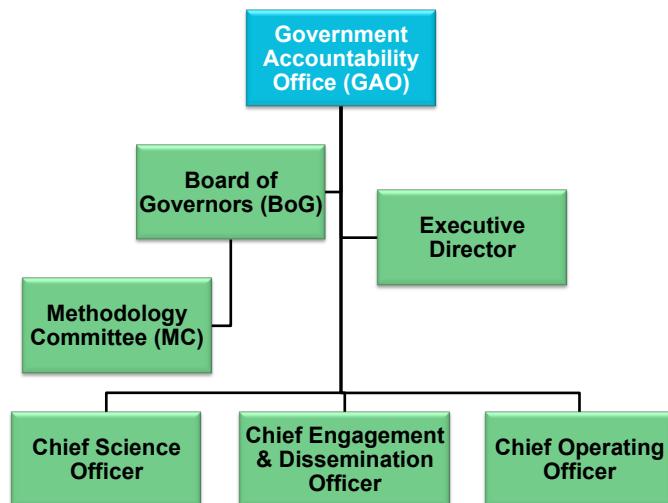
Influence Research Funded by Others



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PCORI's Organizational Structure



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CMA's Organizational Structure



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Our National Priorities for Research



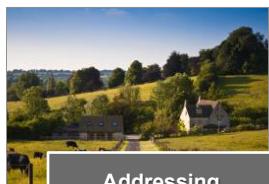
Assessment of Prevention, Diagnosis, and Treatment Options



Improving Healthcare Systems



Communication & Dissemination Research



Addressing Disparities



CER Methods and Infrastructure



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Our Program Directors



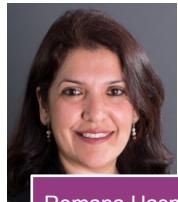
David Hickam, MD, MPH
Assessment of Prevention, Diagnosis, and Treatment Options



Steven Clauser, PhD, MPA
Improving Healthcare Systems



Jean R. Slutsky, PA, MSPH
Communication & Dissemination Research



Romana Hasnain-Wynia
MS, PhD
Addressing Disparities



Rachael Fleurence, PhD
CER Methods and Infrastructure



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Key Features of PCORI Research

Our work answers patients' questions:

"Given my personal characteristics, conditions, and preferences..."

...what should I expect will happen to me?"

...what are my options and what are the potential benefits and harms of those options?"

.. what can I do to improve the outcomes that are most important to me?"

...how can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"



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Key Features of PCORI Research

We engage stakeholders at every step

Advise Us on What to Study

Review Proposals and Partner in Research

Tell Us How We're Doing

Help Us Share the Findings



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PCORI Emphasizes Engagement for Getting to Practical, Useful Research



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Research And Results

Research & Results **What We've Funded**

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 RESEARCH FUNDERS

EVALUATING OUR WORK

PCORI IN THE LITERATURE

360 Research Projects APPROVED **\$671 MILLION Funds Awarded** **39 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), formal calls for projects under our five National Priorities for Research and other funding opportunities. These include funding 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.

Displaying 1 - 50 of 408

Search our awards

State/Province

PCORI Research Priority Area

Award Type: Research

Award Type: Program

Download the award data as an .xls file

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

OUR GROWING RESEARCH PORTFOLIO

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Funded Projects to Date

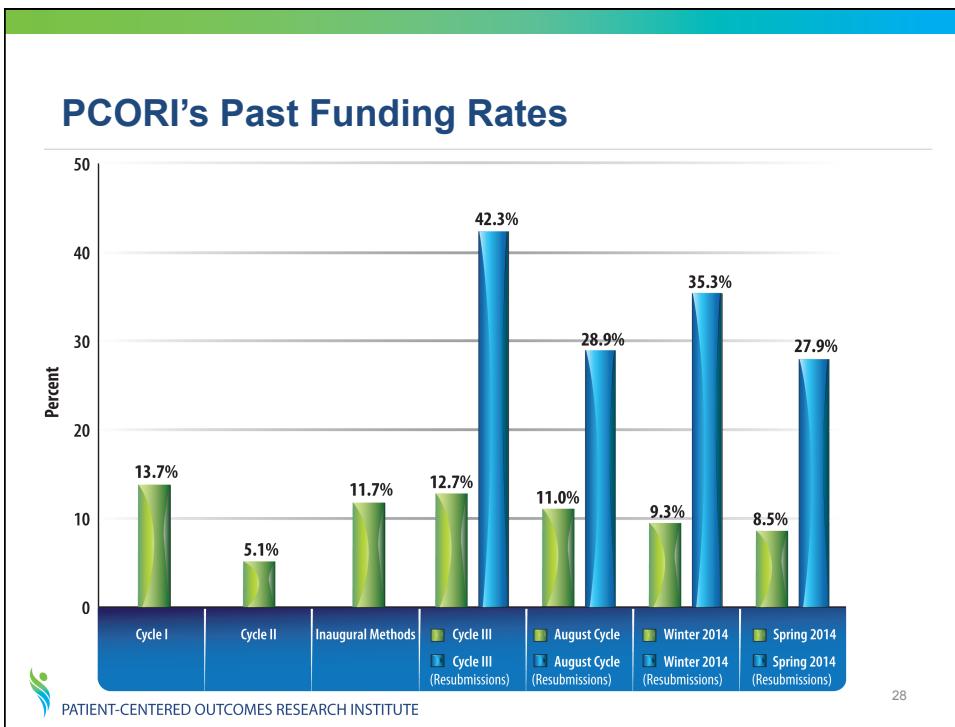
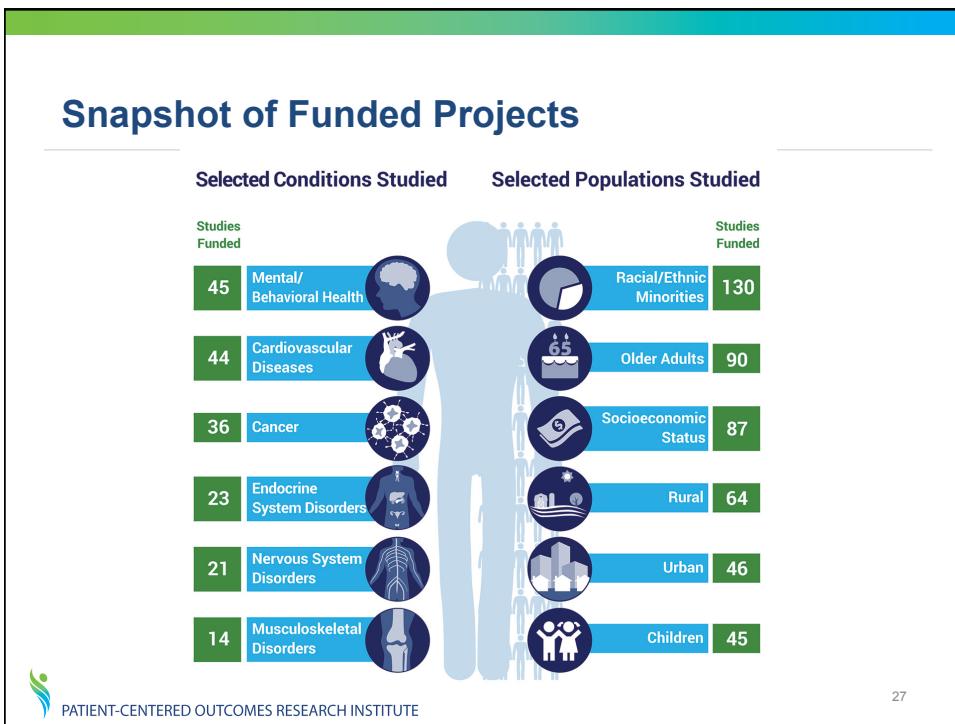
Total number of research projects awarded: **360**

Total funds awarded: **\$671 million**

Number of states where we are funding research: **39 states** (plus the District of Columbia, Quebec and Puerto Rico)

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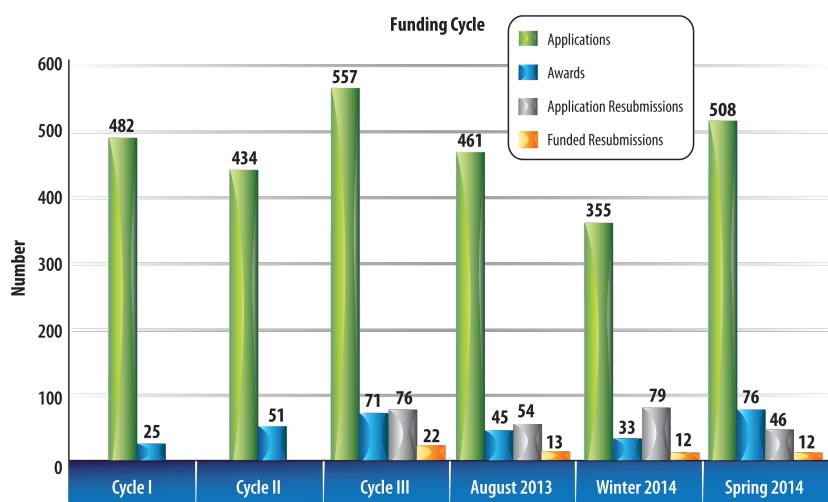
Current Funding Commitments



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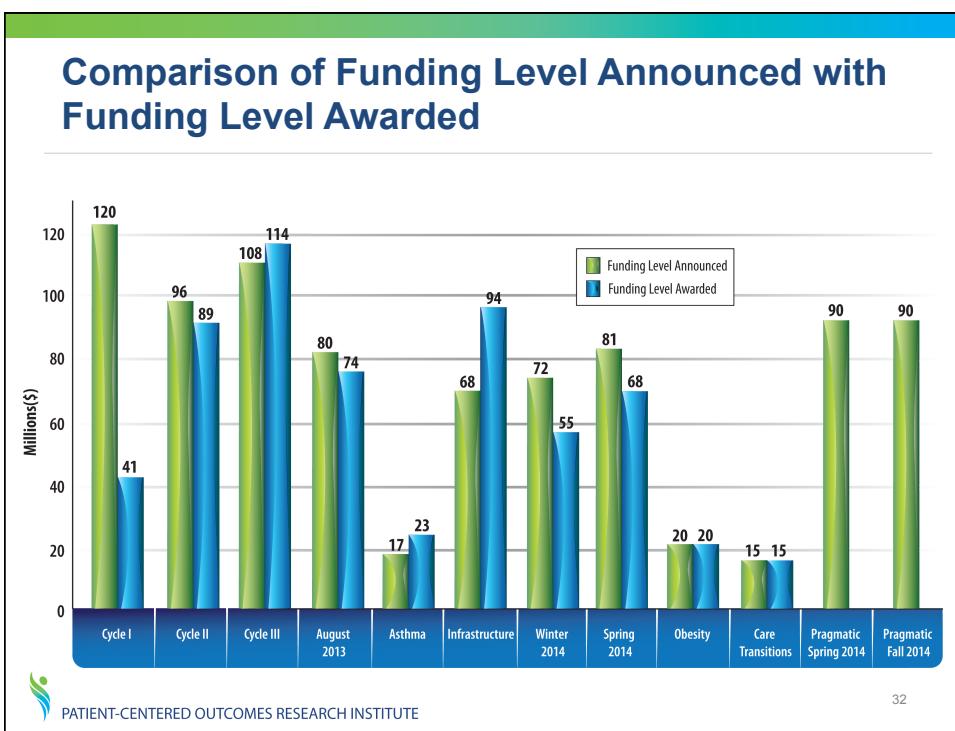
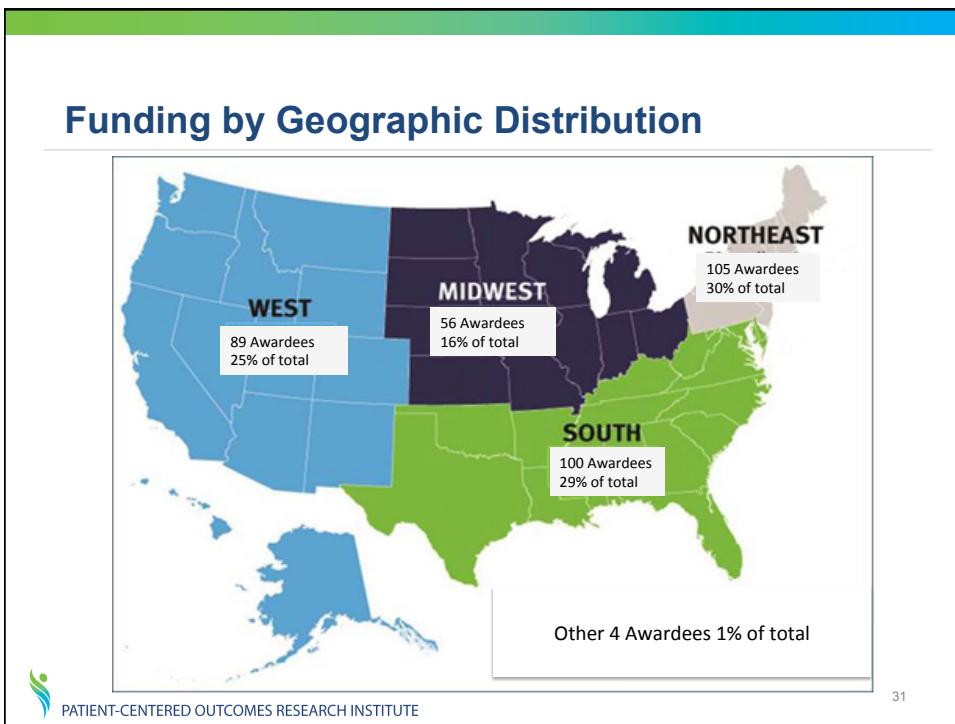
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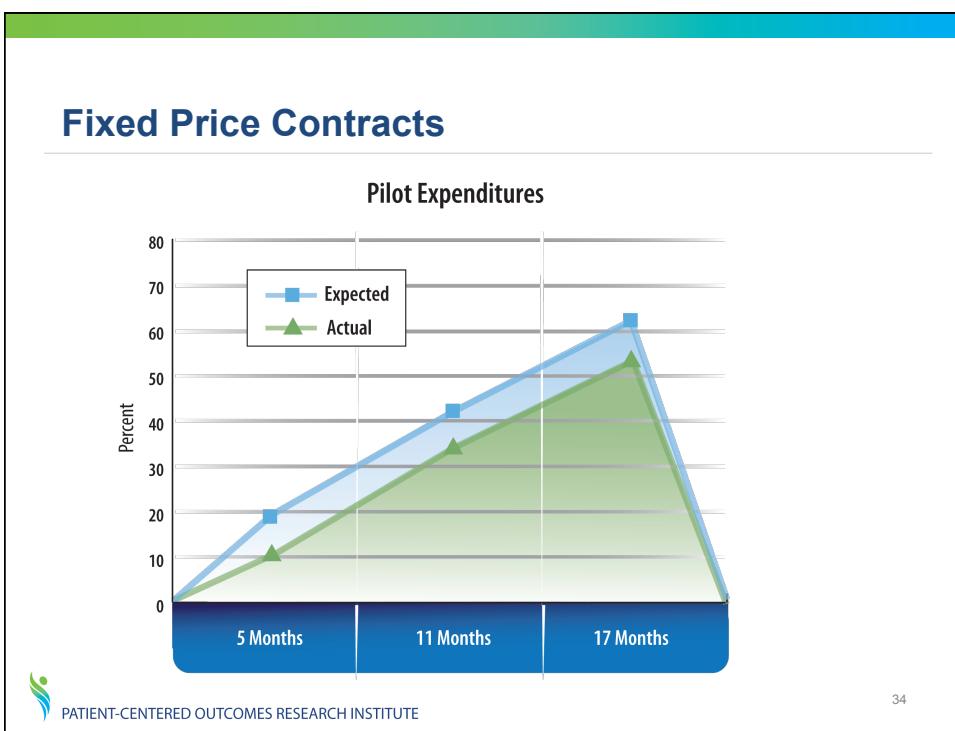
LOIs, Applications, and Awards

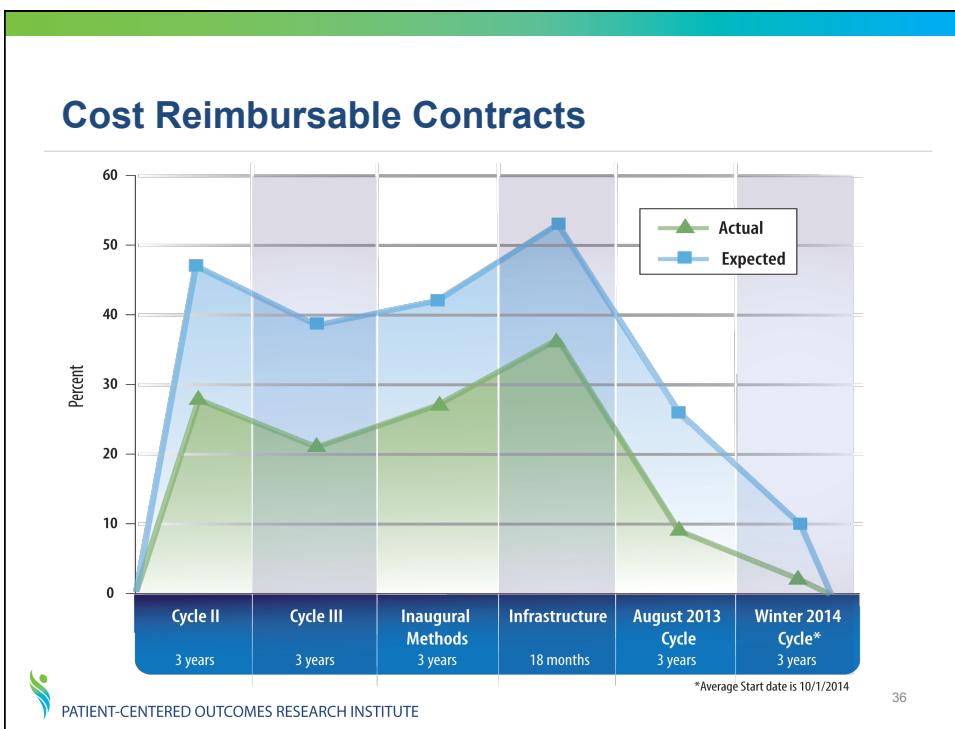
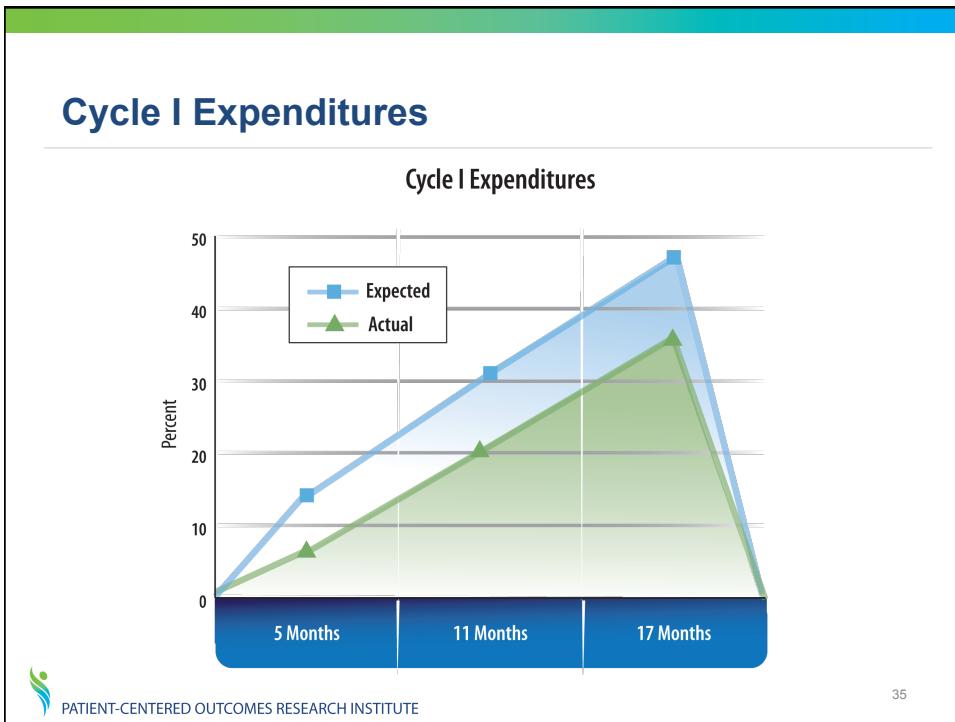


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Why Are Awards at PCORI Different?

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



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Types of Federal Funding Mechanisms



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PCORI Issues Contracts, Not Grants

- PCORI uses contracts to fund and administer meritorious research
- PCORI funding awards are *not grants*



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Why Does PCORI Issue Contracts?

Helps PCORI Meet
Legislative Expectations

Ensures Accountability

Supports Establishment and
Enforcement of Performance
Parameters

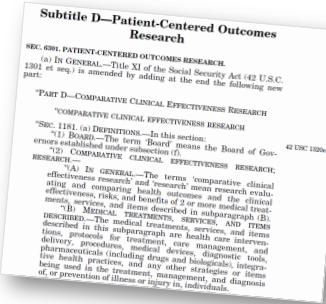


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PCORI's Authorizing Law: Formation

- PCORI is an independent non-profit authorized by Federal law with funding established by Federal law
 - PCORI is NOT a Federal agency or a Federal contractor or grantee
 - Funding is from PCORI Trust Fund and other Federal sources
 - PCORI cannot accept donations or generate revenue



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



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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 Disease
- 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



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Indemnification and Insurance

Since Awardees are responsible for their research:

Awardees are required to indemnify PCORI for claims and costs relating to the research, to the extent permitted by law

Awardees are required to have insurance coverage to cover obligations, to the extent permitted by law



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Session Objectives

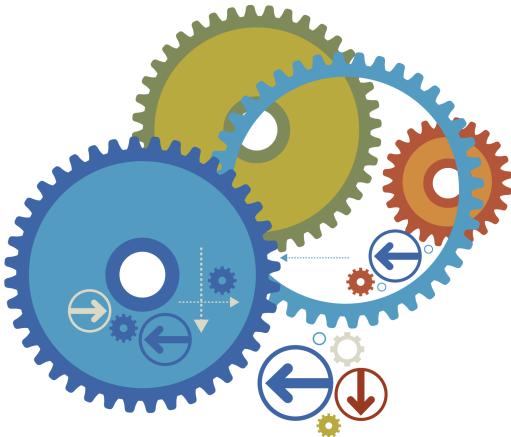
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Our Workshop



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What We Want To Accomplish

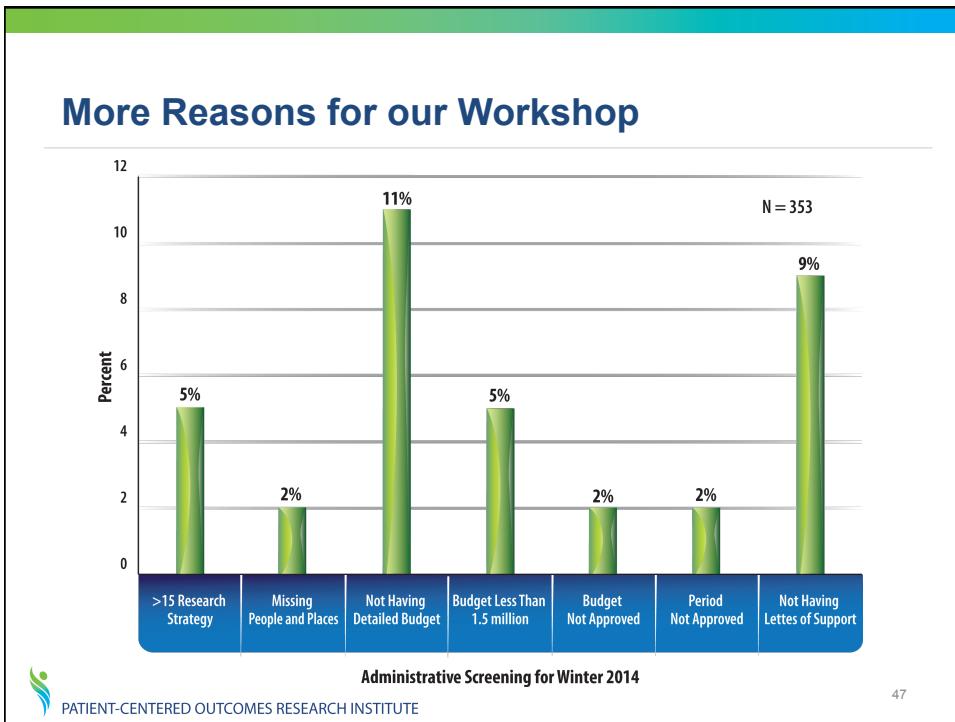
Help you improve:

- Application Quality
- Contract Negotiations
- Award Performance by avoiding:
 - Unrealistic milestones
 - Inability to recruit study subjects
 - Inability to control and manage subcontractors



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Past CMA PCORI Workshops

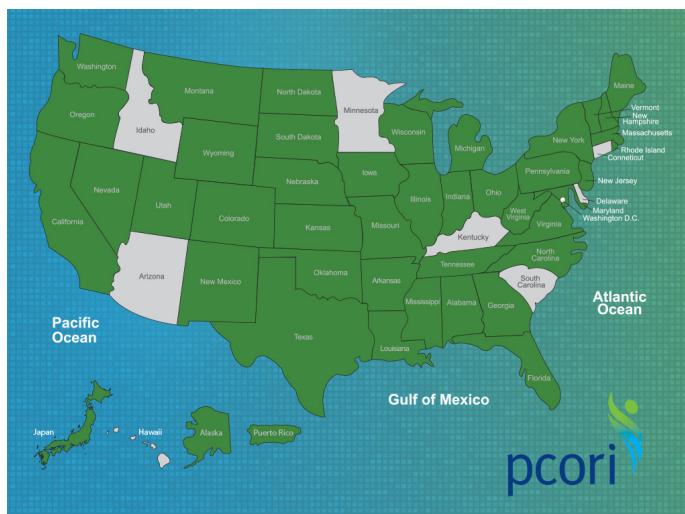
- Washington, DC (July, 2014)
- San Diego, CA (September, 2014)
- Houston , TX (February, 2015)
 - PI and Administrator opportunities to talk with the experts in their field
- Enhancements to this workshop:
 - New Presentations:
 - Program Area Presentations
 - Large Pragmatic Studies
 - Voices of Experience: PI and Research Administrator or Admin office
 - Breakout sessions



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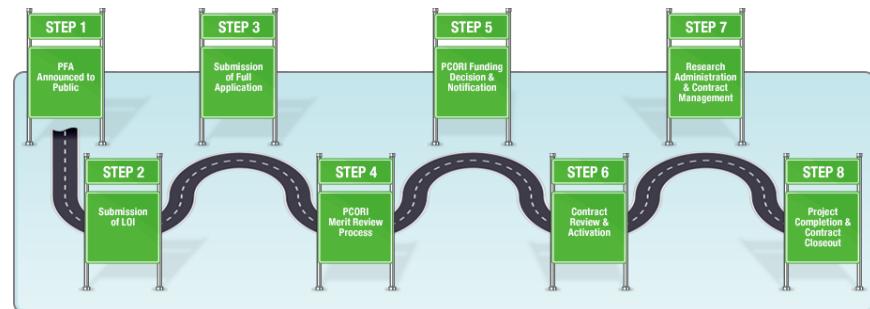
Where are You From?



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The Journey From Application to Closeout



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Questions?



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Thank You!

Scott Solomon

Director of Contracts Management and Administration



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