

Welcome and Overview

Gray Norquist, Brigitte Scott, and Scott Solomon
Contracts Management and Administration

June 22, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

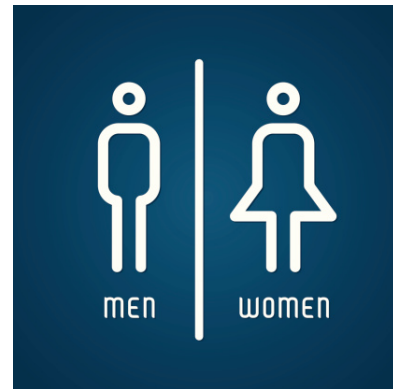
Welcome!



Brigitte Scott, MA
Communications Manager,
Contracts Management and
Administration

Housekeeping – Things You Need to Know!

- PCORI Staff
- Restrooms

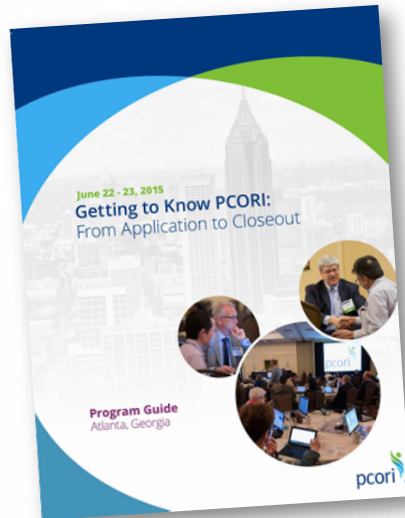


Housekeeping – Things You Need to Know!

- Morning Recharge: 9:45 am – 10:00 am
- Midday Nourishment: 12:00 pm – 1:30 pm
- Afternoon Recharge: 3:30 pm – 3:45 pm



Your Guide to What's Happening!



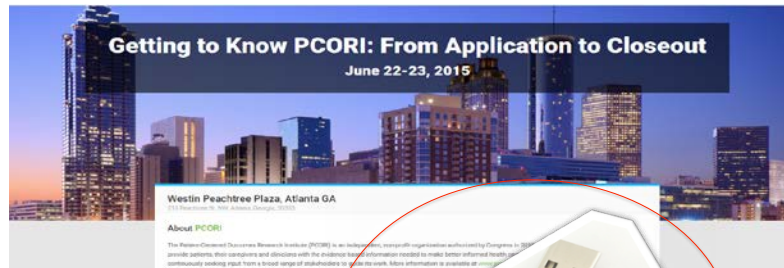
OMG – I Need to Check My Email! Workshop Access Code



pcori2015

Mobile Site and Presentations

- Atlanta PCORI Workshop Mobile Site URL: <http://goo.gl/OwKHGI>



Connect with Us!



contractsworkshop@pcori.org



#PCORI

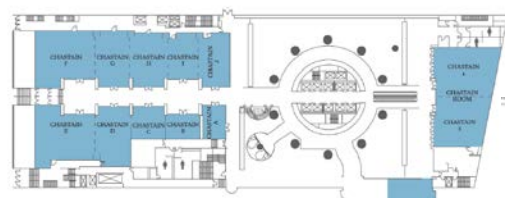


<https://goo.gl/JhzuXA>

You Are Here!

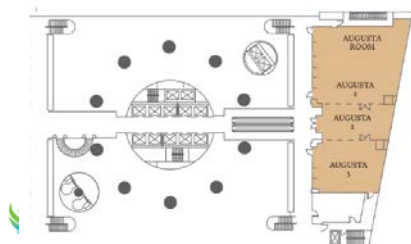
6TH FLOOR

Breakout Sessions



7TH FLOOR

Breakfast and Lunch



General Sessions - 10th Floor



9

Questions: Help Desk!

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



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

10

Welcome!



Scott Solomon
Director of Contracts
Management and
Administration

A collage of eight photographs showing various activities from a PCORI workshop. The photos include: a man speaking at a podium; a woman at a laptop; a group of people at a round table; a man and woman shaking hands; a man speaking at a podium; a group of people at a round table; a man speaking at a podium; and a group of people at a round table. The PCORI logo is visible in the background of several photos.

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



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

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

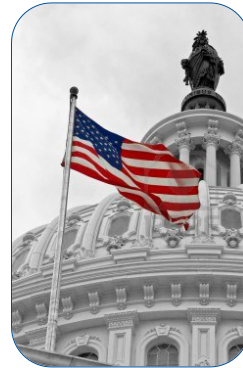


PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

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>



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

15

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.**



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

16

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

Strategic Goals

Increase Quantity, Quality, and Timeliness of Research Information

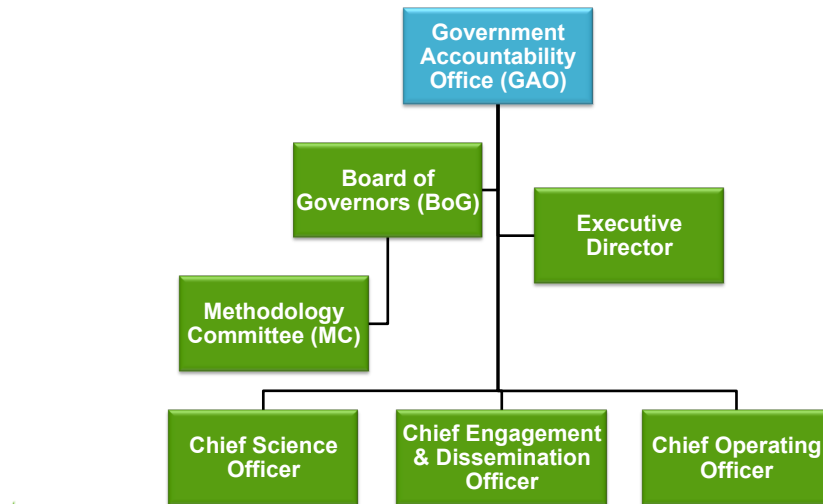


Speed the Implementation and Use of Evidence

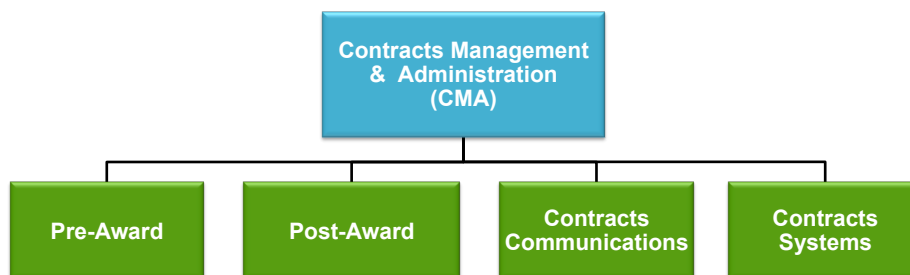
Influence Research Funded by Others



PCORI's Organizational Structure



CMA's Organizational Structure



Our National Priorities for Research



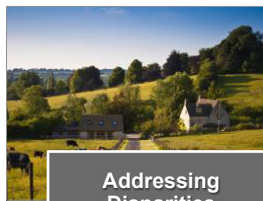
**Assessment of
Prevention, Diagnosis,
and Treatment Options**



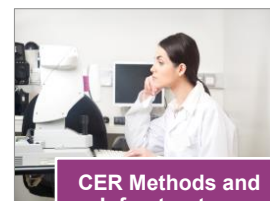
**Improving Healthcare
Systems**



**Communication &
Dissemination
Research**



**Addressing
Disparities**



**CER Methods and
Infrastructure**



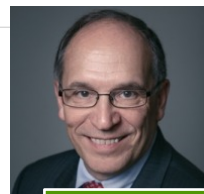
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

21

Our Program Directors



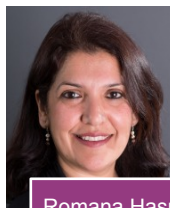
David Hickam, MD, MPH
Assessment of Prevention, Diagnosis,
and Treatment Options



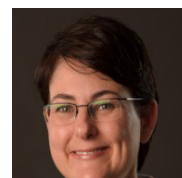
Steven Clauser, PhD, MPA
Improving Healthcare
Systems



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



**Romana Hasnain-Wynia
MS, PhD**
Addressing Disparities



Rachael Fleurence, PhD
CER Methods and
Infrastructure



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

22

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
health care?"



PCORI Emphasizes Engagement for Getting to Practical, Useful Research

We engage stakeholders at every step

Generating and
Prioritizing
Research
Questions

Advise Us
on What To
Study

Reviewing and
Conducting
Research

Review
Proposals
and Partner
in Research

Portfolio
Review

Tell Us How
We're Doing

Dissemination
and
Implementation

Help Us
Share the
Findings



Building a Patient-Centered Research Community

Find out how you can participate in our work

MORE DETAILS

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

PCORI Milestones

1. Programmatic milestones 2. Leadership milestones 3. Research milestones

2010
PCORI was established by Congress as an independent federal agency within the U.S. Department of Health and Human Services. The agency's mission is to fund research that will improve the health of patients and the lives of the people who care for them.

2011
PCORI released its first Funding Priorities for Research and Research Agenda, which outlined the agency's focus on patient-centered research. The agency also released its first Request for Proposals (RFP) for research funding.

2012
PCORI awarded its first research grants. The agency also released its first Request for Proposals (RFP) for research funding.

2013
PCORI awarded its first research grants. The agency also released its first Request for Proposals (RFP) for research funding.

2014
PCORI awarded its first research grants. The agency also released its first Request for Proposals (RFP) for research funding.

Open Opportunities

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


Obesity Observational Research Initiative

Key Deadlines

Applications: May 27, 2015

Engagement Award (EAW): Research Meeting and Conference Support

Key Deadlines	Type	Funds Available	Total Costs
LOI: Not required Applications: 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.	



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

25



pcori Patient-Centered Outcomes Research Institute

[BLOG](#)
[CAREERS](#)
[NEWSROOM](#)
[SUBSCRIBE](#)
[CONTACT](#)

[HOME](#)
[ABOUT US](#)
[FUNDING OPPORTUNITIES](#)
[RESEARCH & RESULTS](#)
[GET INVOLVED](#)
[MEETINGS & EVENTS](#)

Research And Results

Research & Results

OUR PROGRAMS

RESEARCH WE SUPPORT

HOW WE SELECT RESEARCH TOPICS

RESEARCH METHODOLOGY

PCORINET: THE NATIONAL PATIENT-CENTERED CLINICAL RESEARCH NETWORK

RESEARCH IN ACTION

COLLABORATING WITH OTHER

What We've Funded

400 Research Projects APPROVED

\$868.6 MILLION Research Funds Awarded

39 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>



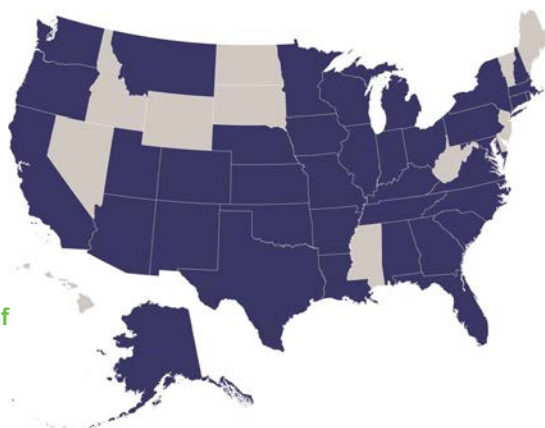
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Funded Projects to Date

Total number of research projects awarded: **400**

Total funds awarded: **\$868.6 million**

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



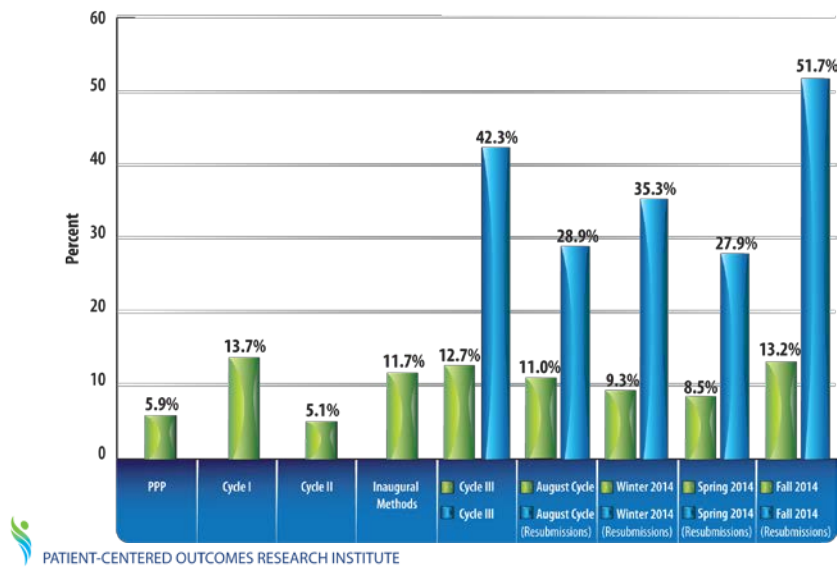
Snapshot of Funded Projects

SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)

 Cancer	38	 Respiratory Diseases	17	 Infectious Diseases	5
 Mental/Behavioral Health	38	 Multiple/Co-Morbid Chronic Conditions	16	 Liver Disease	3
 Cardiovascular Health	22	 Trauma/Injury	12	 Digestive System Diseases	2
 Neurological Disorders	18	 Reproductive and Perinatal Health	11	 Allergies and Immune Disorders	1
 Nutritional and Metabolic Disorders	17	 Muscular and Skeletal Disorders	9	 Skin Disease	1
 Rare Disease	17	 Kidney Disease	7	 Other/Non-Disease Specific	20

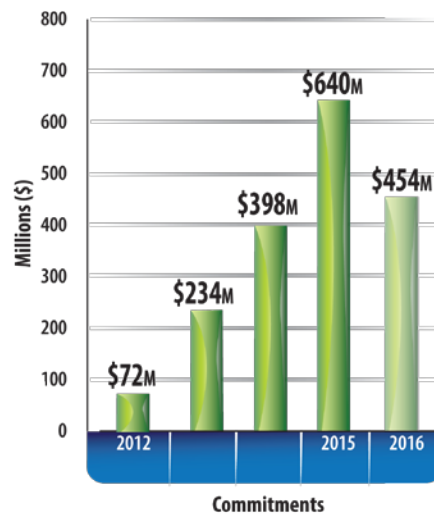


PCORI's Past Funding Lines



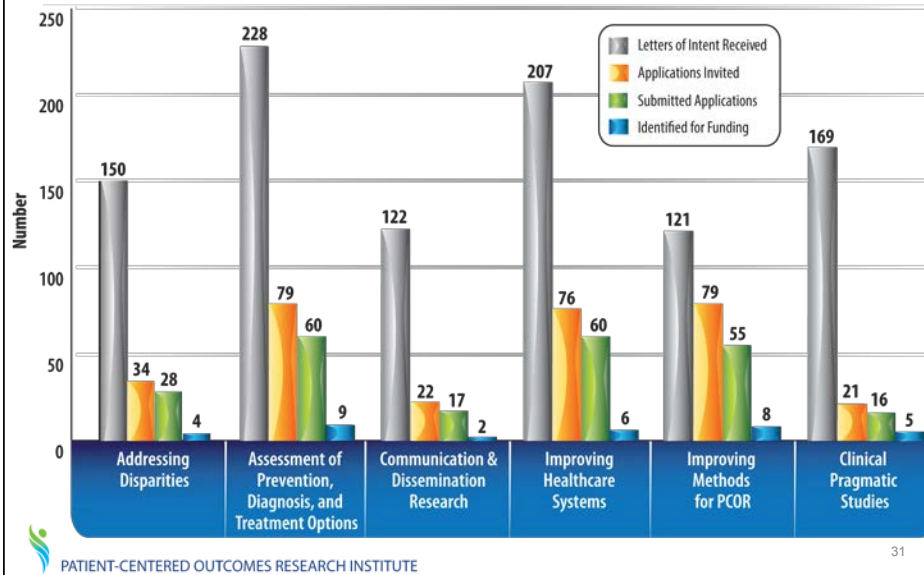
29

Current Funding Commitments



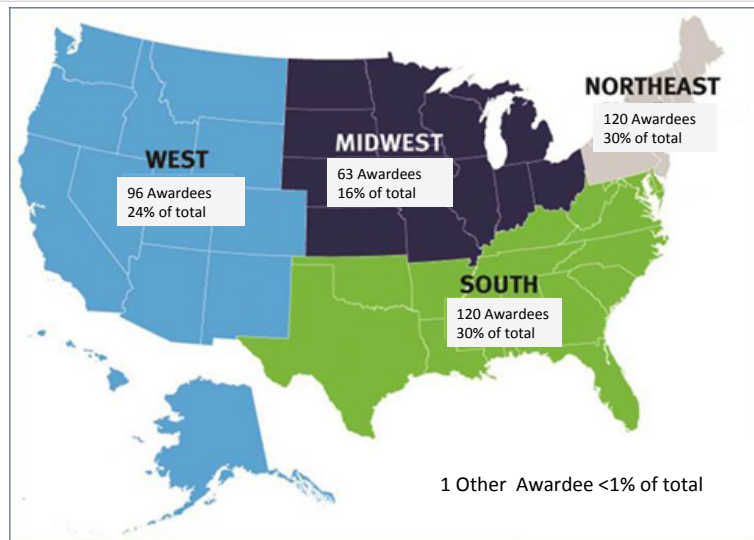
30

LOIs, Applications, and Awards



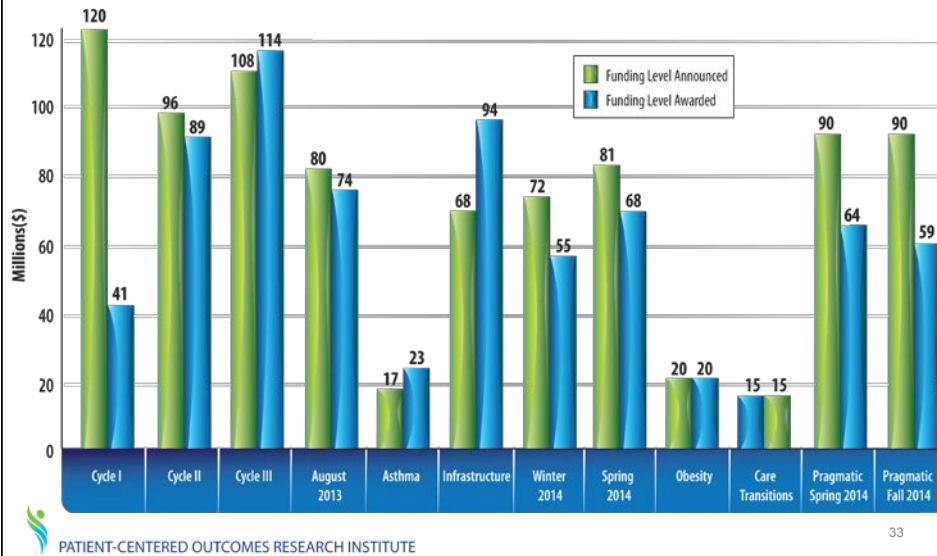
31

Funding by Geographic Distribution



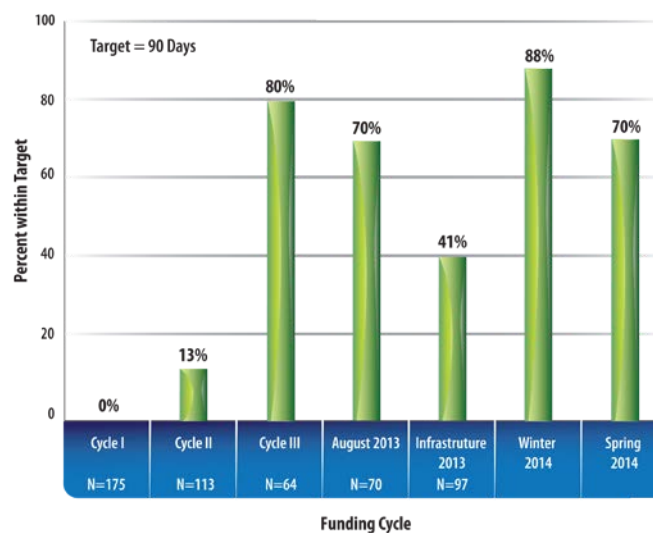
32

Comparison of Funding Level Announced with Funding Level Awarded



33

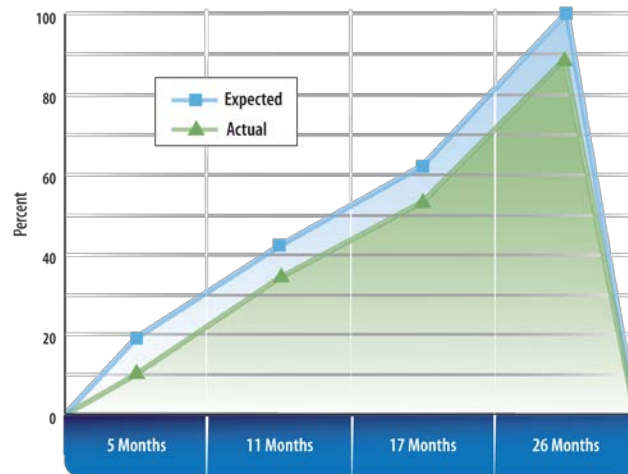
Time from Award to Contract Execution



34

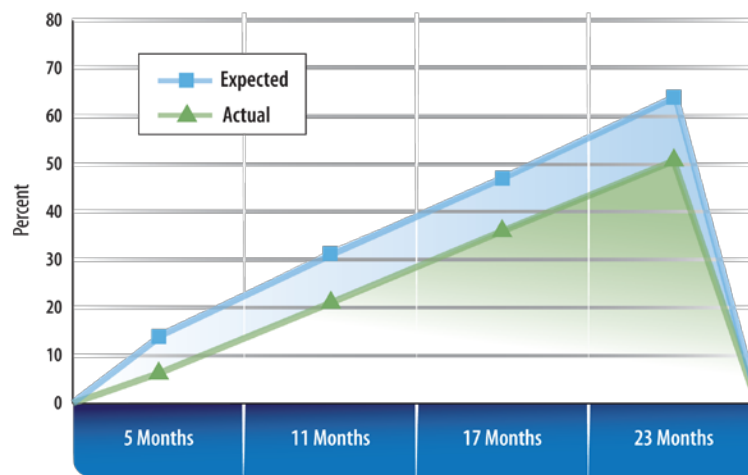
Fixed-Price Contracts

Pilot Expenditures

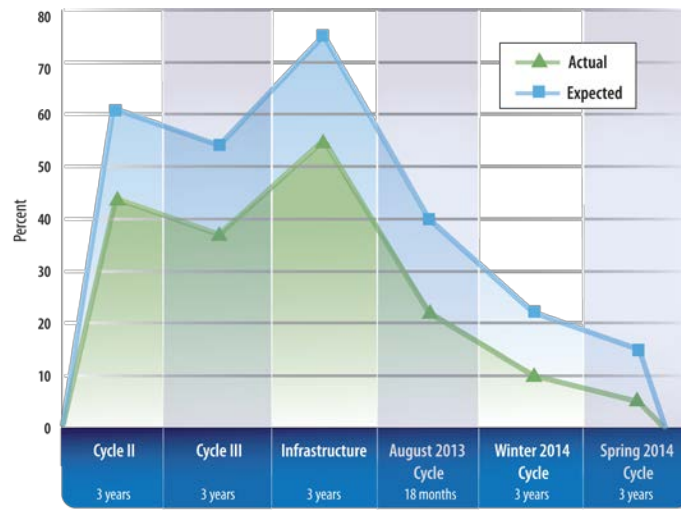


Fixed-Price Contracts

Cycle I Expenditures



Cost-Reimbursable Contracts



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



Types of Federal Funding Mechanisms

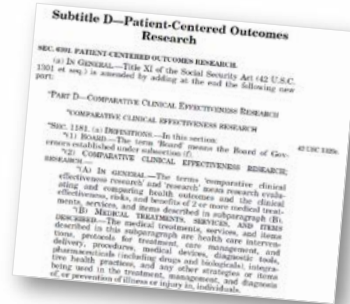


Why Does PCORI Issue Contracts?



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 the PCOR Trust Fund and other federal sources
 - PCORI cannot accept donations or generate revenue



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

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

- 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**

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

43

What We Want To Accomplish

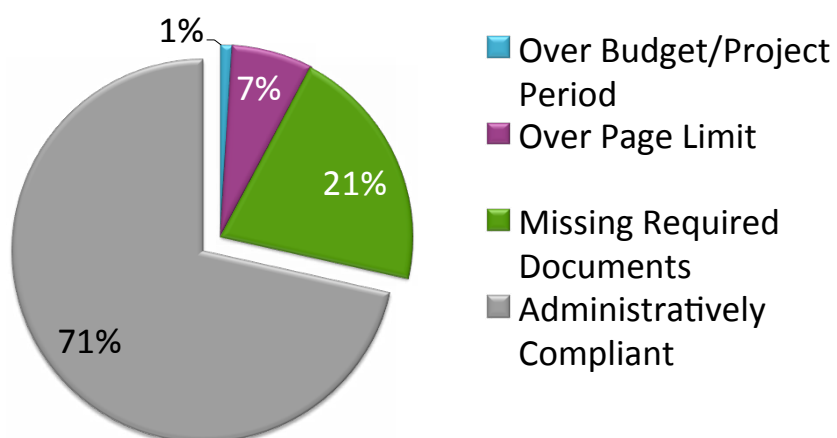
Help you improve:

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



More Reasons for Our Workshop— Administrative Non-Compliance

Applications



Programmatic Non-Compliance

PFA	Spring 2014 LPS	Fall 2014	Winter 2015	Spring 2015
AD	--	22.7%	--	26.1%
CDR	--	18.0%	--	24.1%
CER	--	34.5%	--	45.3%
IHS	--	36.0%	--	54.9%
Methods	--	65.3%	--	66.3%
Broads Total	--	34.8%	--	46.8%
LPS	20.1%	14.2%*	24.2%**	--



Past CMA PCORI Workshops

- Washington, DC (July, 2014)
- San Diego, CA (September, 2014)
- Houston, TX (February, 2015)
- Atlanta, GA (June, 2015)
 - Improvements to this workshop include:
 - Breakout Sessions directed at specific roles
 - A Pragmatic Studies track
 - More time and staff available for one-on-one sessions



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

47

Where are You From?

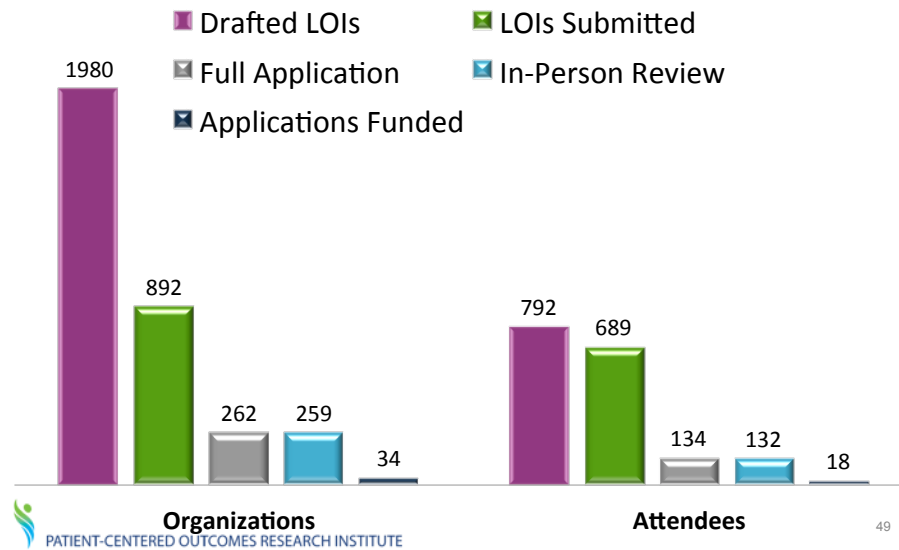
- Atlanta Workshop 2015 attendees represent **33 states** and **Puerto Rico**
- Attendees from states without current PCORI awards: **Mississippi, New Jersey, Delaware, and West Virginia**
- In less than one year, 593 PIs and Research Administrators have attended a CMA Workshop



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

48

Significant Workshop Statistics

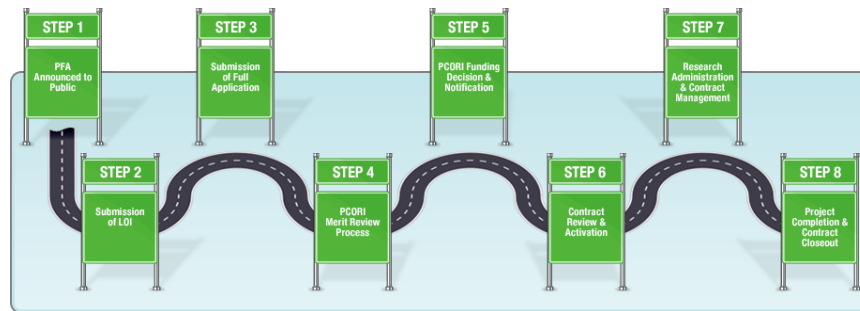


The Workshop Opportunity



Talk with us!

The Journey From Application to Closeout



Questions?



Thank You!

Scott Solomon

Director of Contracts Management and Administration



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE