

# Welcome and Overview

**James Hulbert**

Assistant Director, Policy and Planning

January 29, 2016



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

## Welcome!



**James Hulbert,**  
*Assistant Director,  
Policy and Planning*



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## Housekeeping – Things You Need to Know!

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- PCORI Staff
- Restrooms



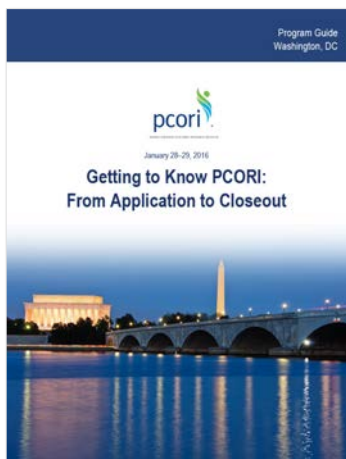
## Housekeeping – Things You Need to Know!

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- Morning Recharge: 11:00 am – 11:15 am
- Midday Nourishment: 12:00 pm – 1:15 pm
- Afternoon Recharge: 3:30 pm – 3:45 pm



## Your Guide to What's Happening!



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## Mobile Site and Presentations

- Washington PCORI Workshop Mobile Site URL: <http://bit.ly/1S6XUd5>



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## Workshop Access Code

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# PCORI@16



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## Connect with Us!

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[contractsworkshop@pcori.org](mailto:contractsworkshop@pcori.org)



# #PCORI



<https://goo.gl/JhzuXA>



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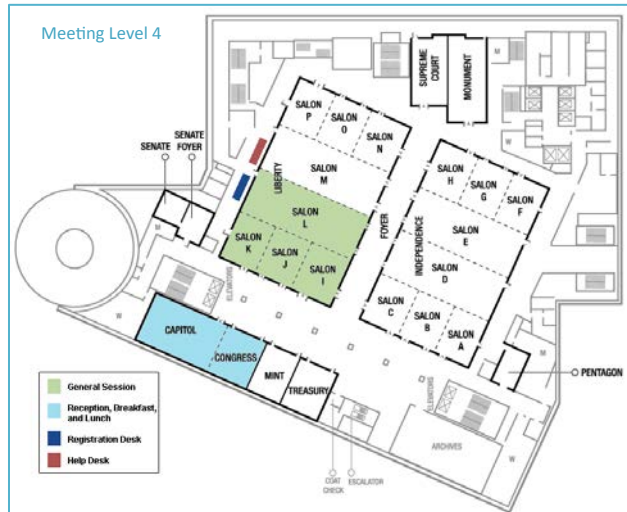
## You Are Here!

### January 28

- Registration Desk (Foyer outside Liberty I-L)
- Helpdesk (Foyer outside Liberty I-L)
- Reception (Capital/Congress)

### January 29

- Breakfast and Lunch (Capital/Congress)
- General Session (Liberty I-L Ballroom)
- Registration Desk and HelpDesk



## 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



# Welcome!



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

A collage of eight photographs showing various activities at a PCORI event. Top row: people at a networking table, a PCORI banner in a hallway, a woman at a laptop, and a group of people. Middle row: a PCORI logo on a screen, a speaker at a podium, and a panel of four people. Bottom row: a large audience in a conference hall, a PCORI banner, and a speaker at a podium with a PCORI logo on the screen.

**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



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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



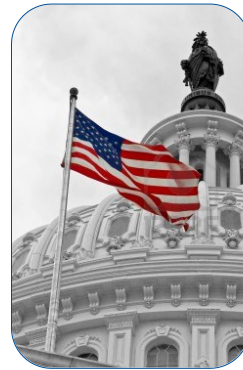
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## PCORI Has a Broad and Complex Mandate

“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’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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## 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**

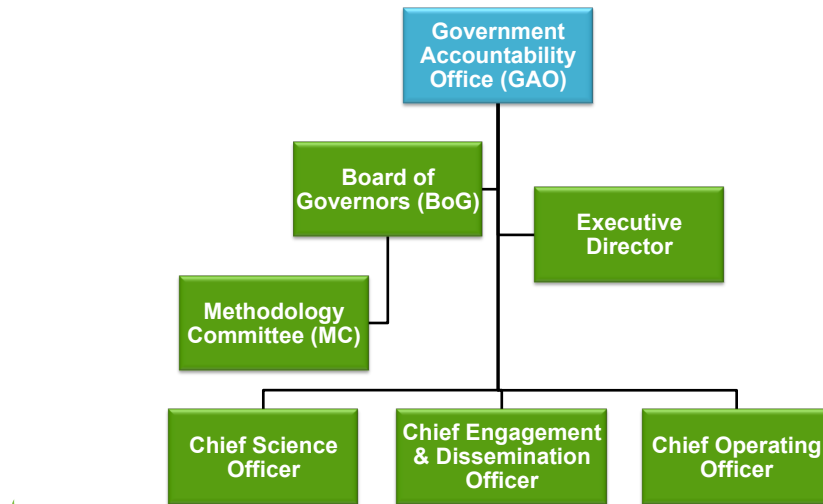


**Speed the Implementation and Use of Evidence**

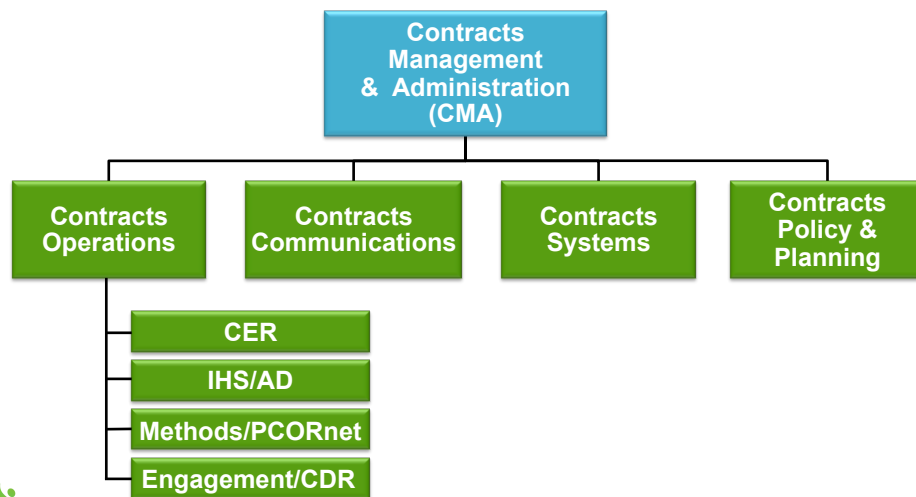
**Influence Research Funded by Others**



## PCORI's Organizational Structure



## CMA's Organizational Structure



## Our National Priorities for Research



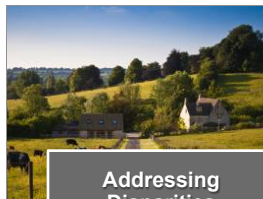
Assessment of  
Prevention, Diagnosis,  
and Treatment Options



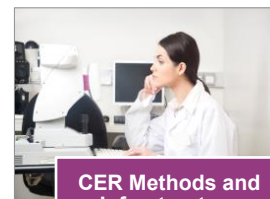
Improving Healthcare  
Systems



Communication &  
Dissemination  
Research



Addressing  
Disparities



CER Methods and  
Infrastructure



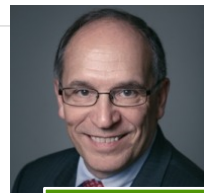
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## Our Program Directors



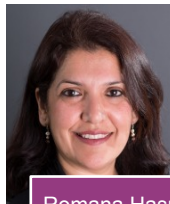
David Hickam, MD, MPH  
Assessment of Prevention, Diagnosis,  
and Treatment Options



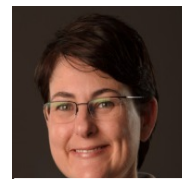
Steven Clauser, PhD, MPA  
Improving Healthcare  
Systems



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  
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**

**2011**

**2012**

**2013**

**2014**

**2015**

### Open Opportunities

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

**Obesity Observational Research Initiative**

**Key Deadlines**

Application: May 27, 2015

**Engagement Award (EAW): Research Meeting and Conference Support**

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



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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

PCORNET: THE NATIONAL PATIENT-CENTERED CLINICAL RESEARCH NETWORK

RESEARCH IN ACTION

COLLABORATING WITH OTHER

### What We've Funded

**476** Research Projects APPROVED

**\$1.25** BILLION Research Funds Awarded

**41** 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>



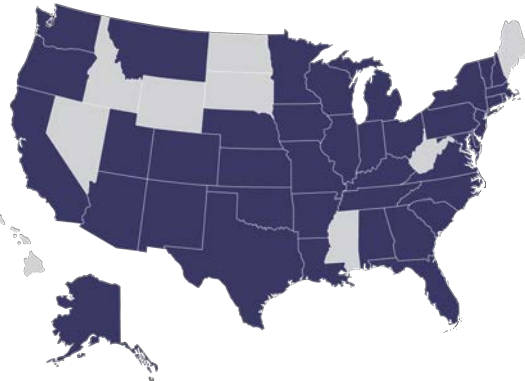
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## Funded Projects to Date

Total number of research projects awarded: **476**

Total funds awarded: **\$1.25 billion**

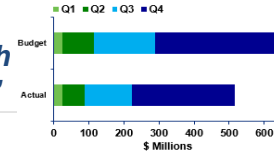
Number of states where we are funding research: **41 states** (plus the District of Columbia and Quebec)



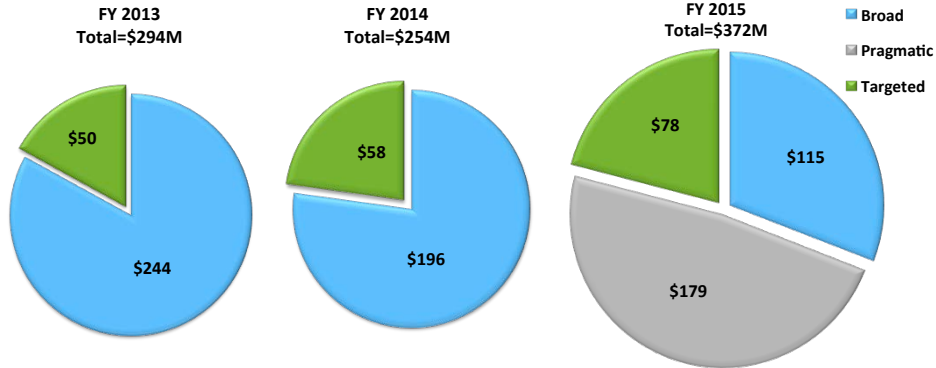
## Current Funding Commitments



We are making progress on our Strategic Priority to “Increase the proportion of research funding going to focused and targeted topics”



### Funds Committed in Each Fiscal Year by Type of PFA

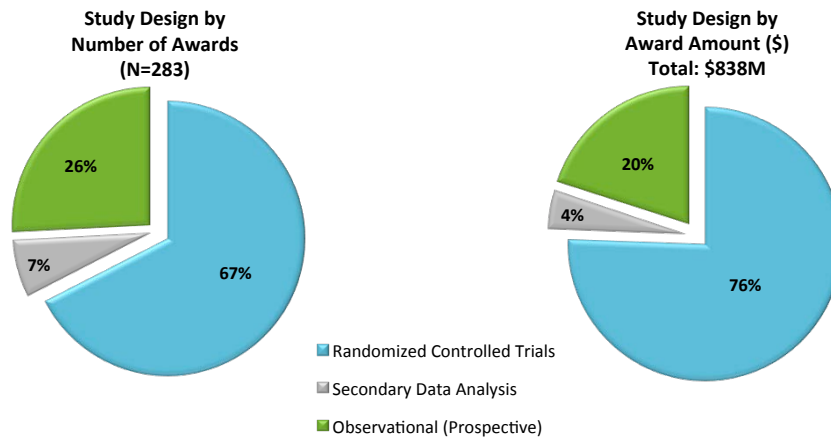


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### The majority of studies in our portfolio are clinical trials

#### Funded Portfolio by Study Design Cycle I through Spring 2015



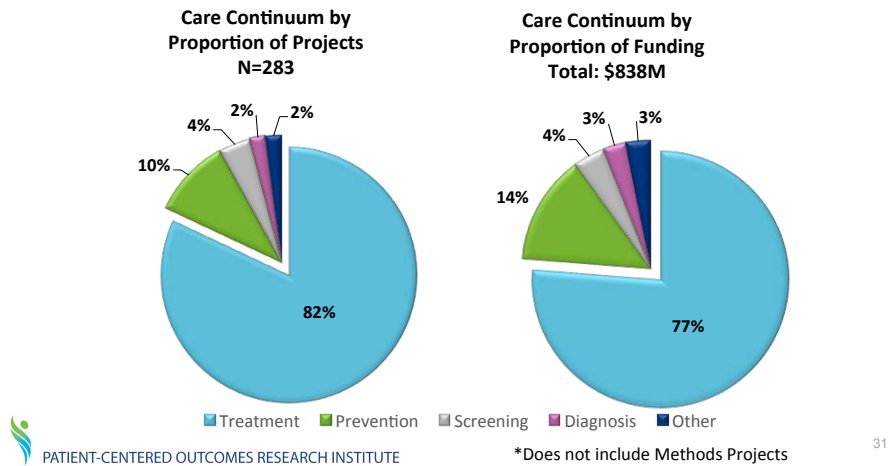
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\*Does not include Methods projects

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The majority of our studies focus on treatment and one out of five projects we fund addresses screening and prevention studies

**Funded Portfolio by Care Continuum**  
Cycle 1 through Spring 2015



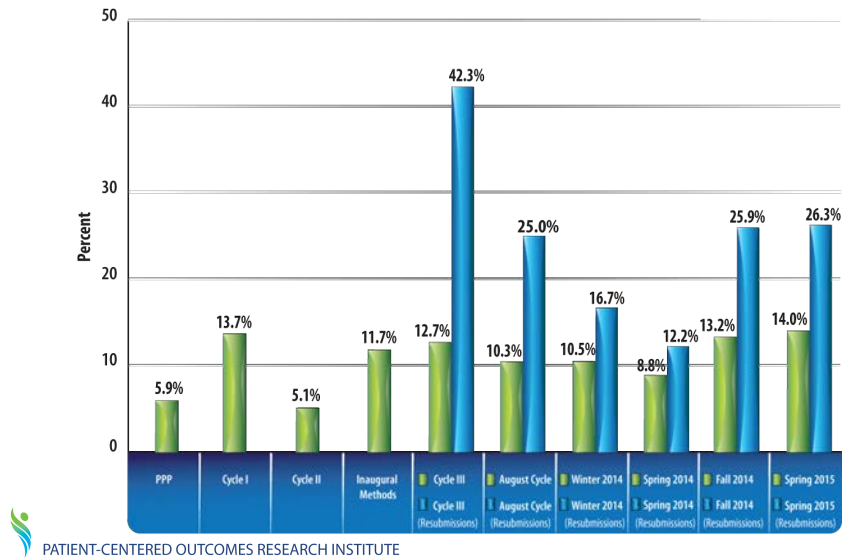
## Snapshot of Funded Projects

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

 Mental/Behavioral Health	44	 Neurological Disorders	20	 Infectious Diseases	10
 Cancer	41	 Respiratory Diseases	19	 Kidney Disease	8
 Cardiovascular Health	26	 Multiple/Co-Morbid Chronic Conditions	16	 Digestive System Diseases	3
 Nutritional and Metabolic Disorders	24	 Trauma/Injury	12	 Allergies and Immune Disorders	2
 Other/Non-Disease Specific	22	 Reproductive and Perinatal Health	12	 Skin Disease	1
 Rare Disease	21	 Muscular and Skeletal Disorders	11		

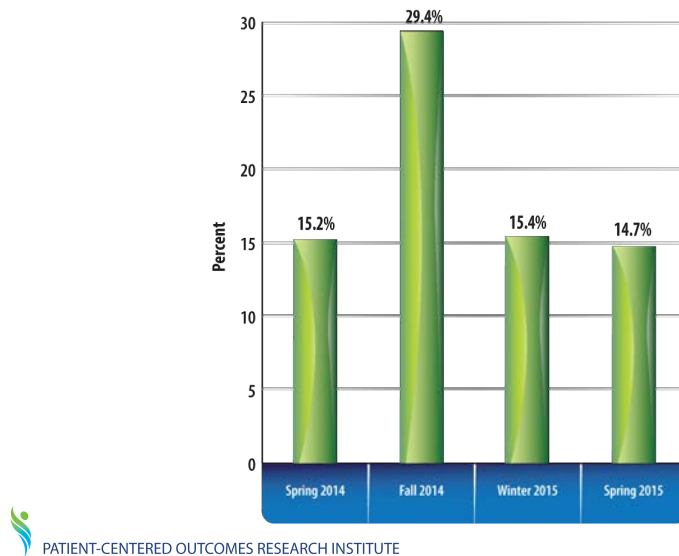


## PCORI's Past Funding Lines



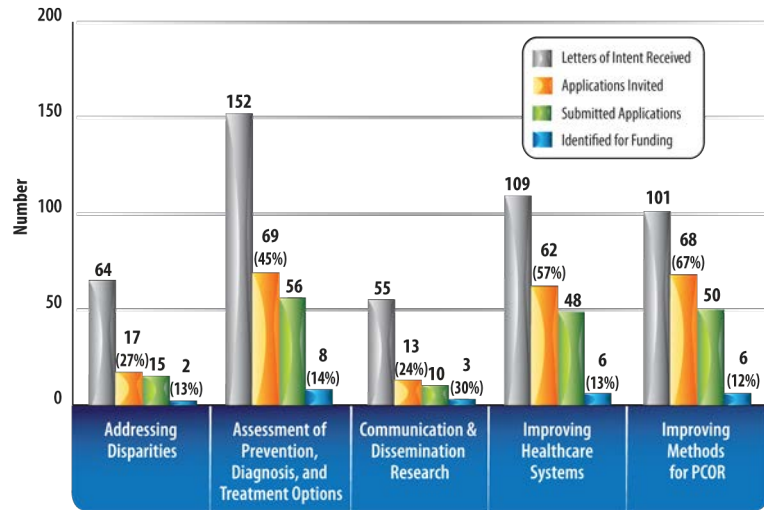
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## PCORI's Past PCS Funding Rates

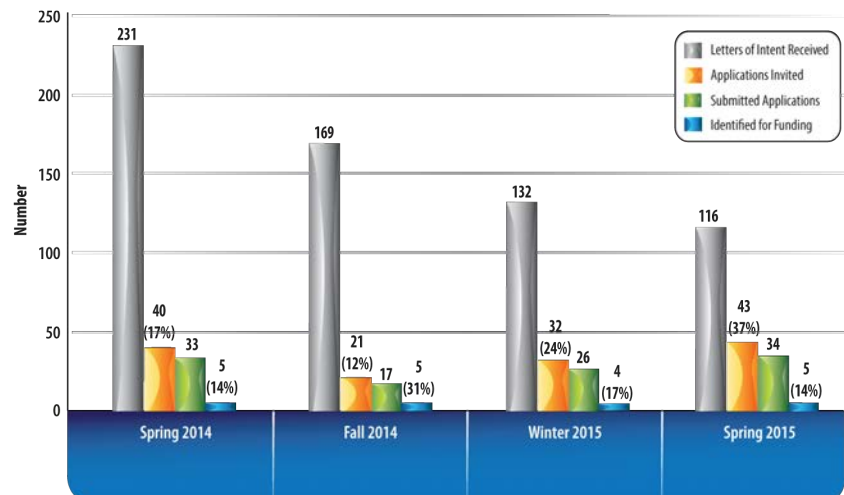


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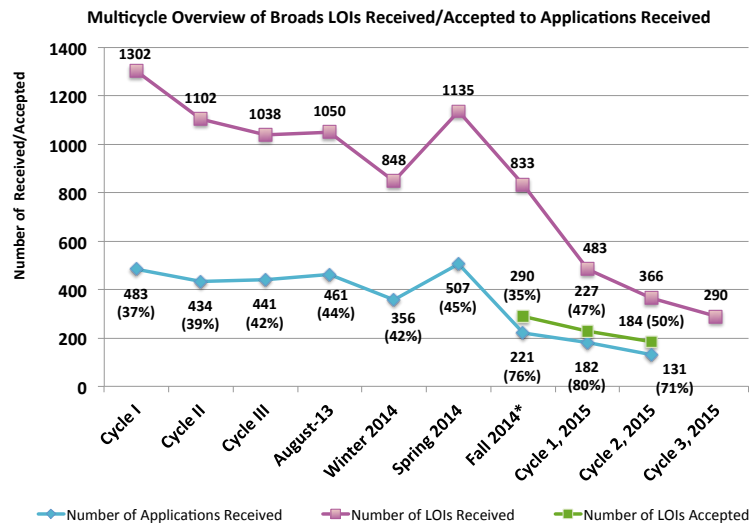
## LOIs, Applications, and Awards for Last Funded Cycle (Spring 2015)



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



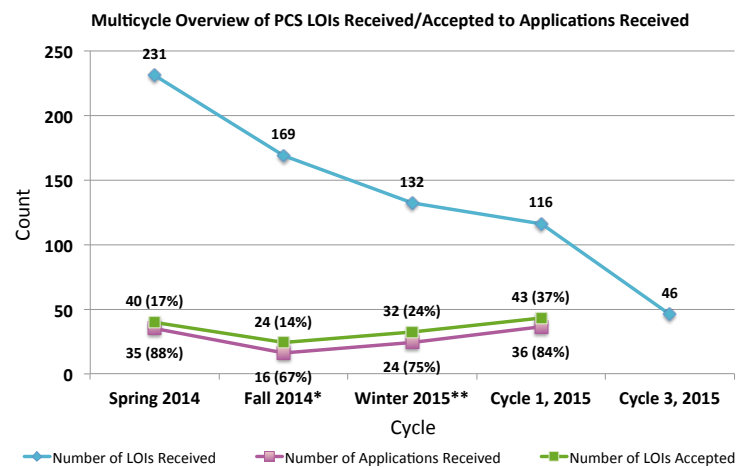
## Declining trends in LOI receipts over cycles for Broads PFAs:



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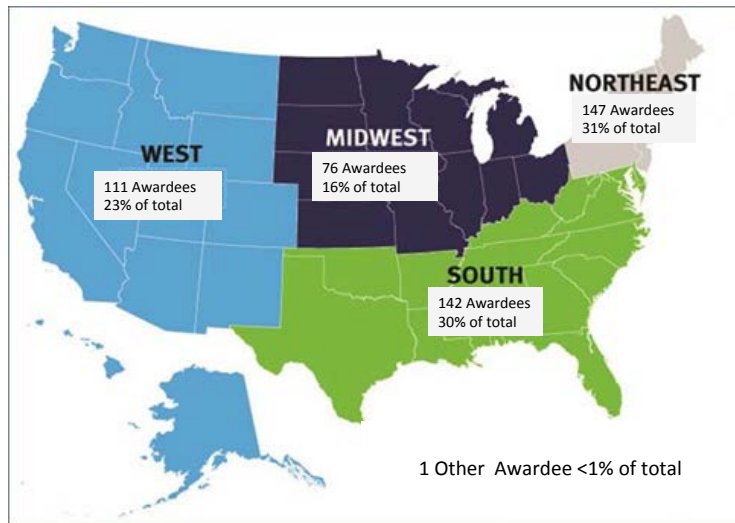
## Declining trends in LOI receipts over cycles for PCS PFAs:



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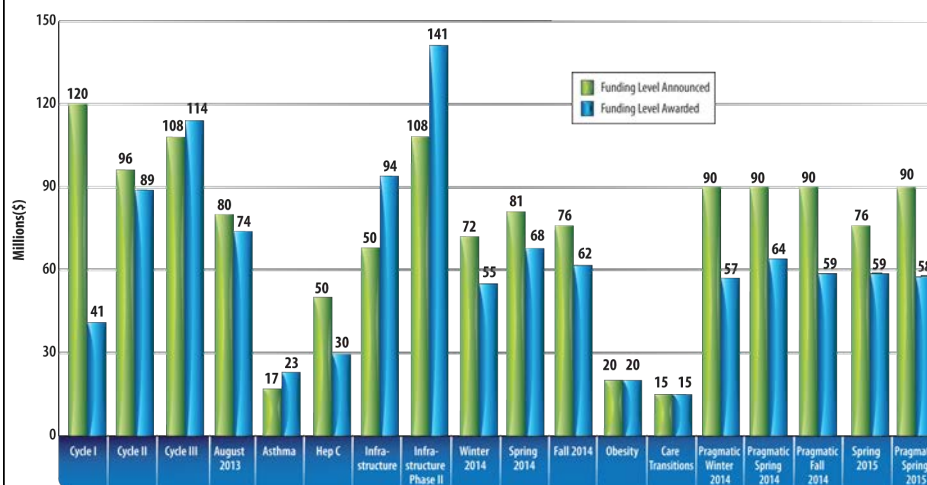
## Funding by Geographic Distribution



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## Comparison of Funding Level Announced with Funding Level Awarded



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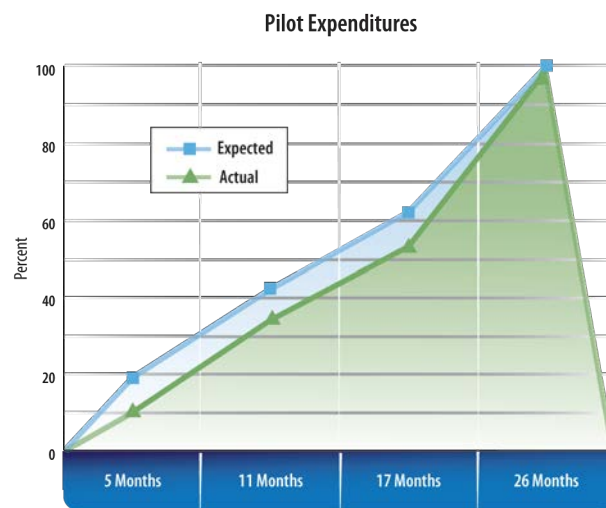
## Time from Award to Contract Execution

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

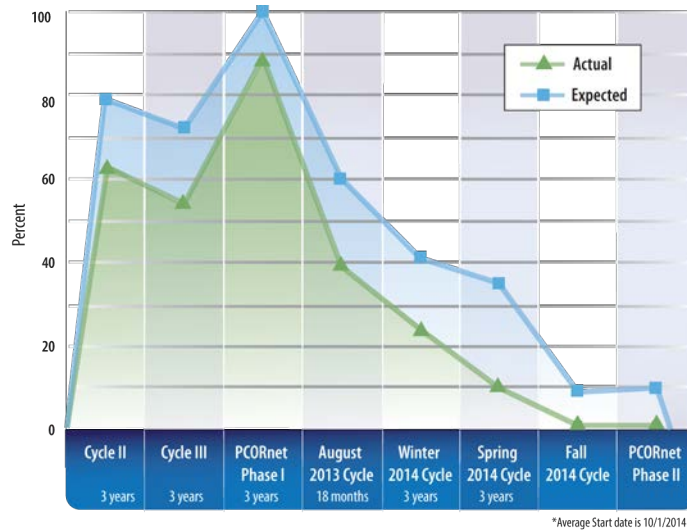
### Factors to consider:

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

## Fixed-Price Contracts



## Cost-Reimbursable Contracts



## Why Are Awards at PCORI Different?

- The authorizing law (HCA)
  - It affects PCORI research projects
- The PCORI research contracting process
  - There is a difference between a research contract and a research grant



## Types of Federal Funding Mechanisms

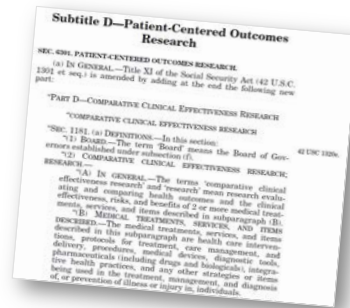


## Why Does PCORI Issue Contracts?



## 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>



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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



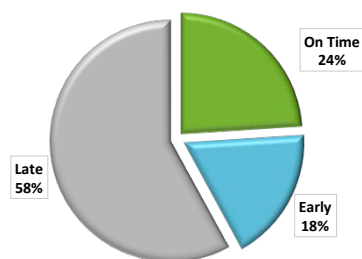
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## Did projects initiate recruitment on time?

Timeliness of Recruitment Initiation

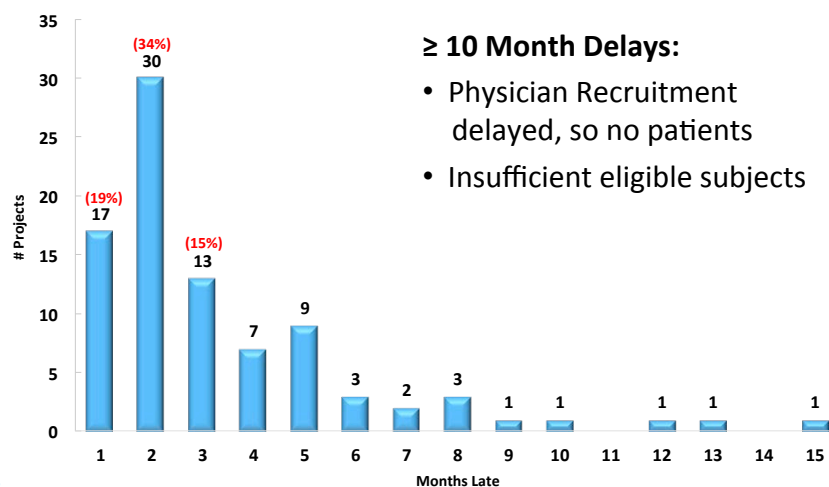


### Reasons for Delayed Initiation

- Delay finalizing intervention
- IRB delays
- Sites withdrawing after randomization
- PI or staff changes, relocations
- Rescheduled or missed appointments
- Restrictive enrollment criteria
- Seasonal issues (asthma symptoms, record snowfall)



## By how long were studies delayed in initiating recruitment?



### ≥ 10 Month Delays:

- Physician Recruitment delayed, so no patients
- Insufficient eligible subjects





**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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## 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

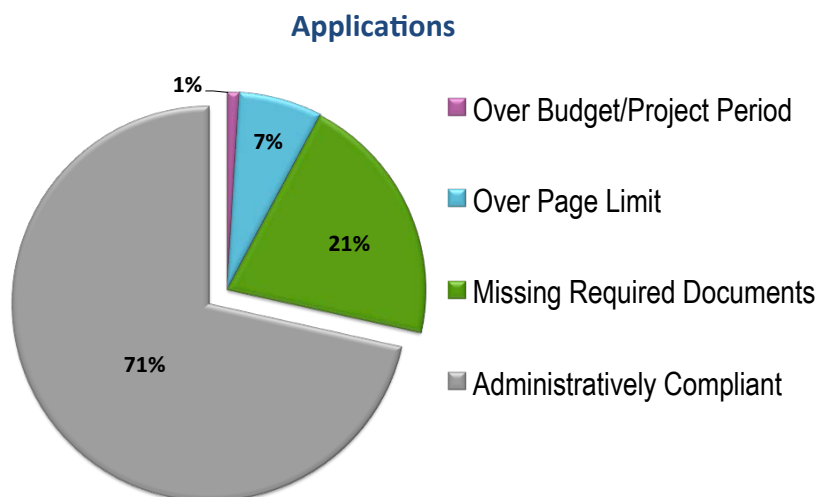


## Programmatic Non-Compliance of LOIs

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 Average	--	34.8%	--	46.8%
PCS	20.1%	14.2%*	24.2%**	--

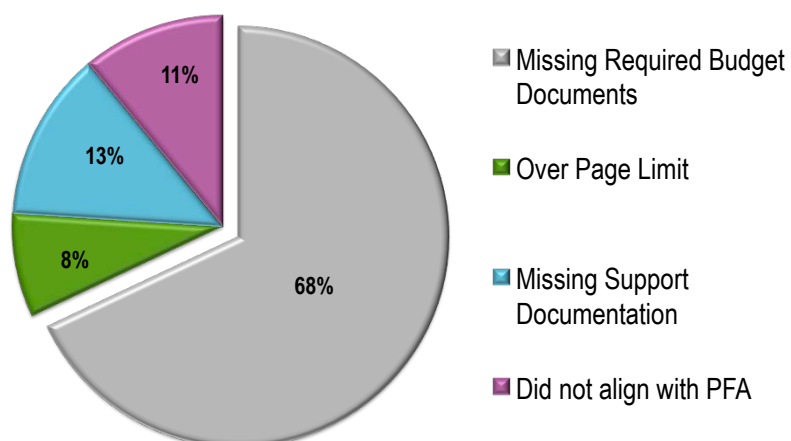


## More Reasons for Our Workshop— Administrative Non-Compliance



## More Reasons for Our Workshop— Administrative Non-Compliance

Spring 2015 Applications

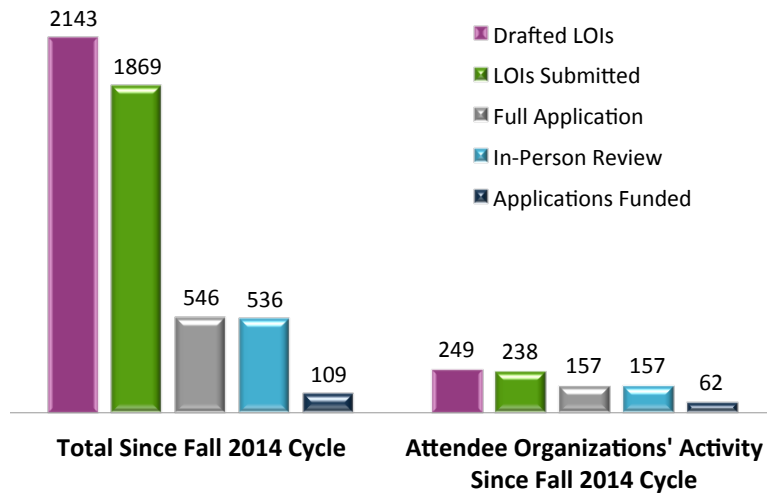


## Past CMA PCORI Workshops

- Washington, DC (July, 2014)
- San Diego, CA (September, 2014)
- Houston, TX (February, 2015)
- Atlanta, GA (June, 2015)
- Portland, OR (September, 2015)
- West Virginia (September, 2015)
- CMA Summit (October, 2015)
- Washington, DC (January, 2016)
  - Agenda evolution over time



## Significant Workshop Statistics: From LOIs Drafted to Applications Funded



## The Workshop Opportunity



Talk with us!

# Questions?

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# Thank You!

**Scott Solomon, MBA, MSE**  
Director of Contracts Management and Administration

January 29, 2016



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