

Welcome and Overview

James Hulbert

Assistant Director, Policy and Planning
Contracts Management and Administration

September 20, 2016



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome!



James Hulbert,
*Assistant Director,
Policy and Planning*

Contracts Management and
Administration



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PCORI Staff



James Hulbert,
*Assistant Director,
Policy and Planning,
Contracts Management
and Administration*



Scott Solomon,
*Director, Contracts
Management and
Administration*



Steven Clauser,
*Program Director,
Science, Improving
Healthcare Systems*



Lia Hotchkiss
*Director
Eugene Washington
Engagement Awards
Program*



Maryan Zirkle,
*Program Officer,
Research
Infrastructure
Program*



Housekeeping – Things You Need to Know!

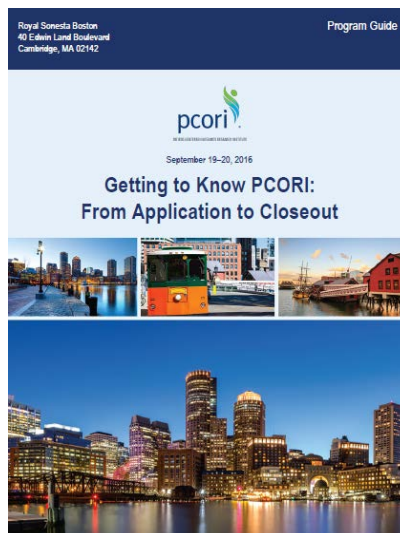
- Registration Desk
- Restrooms



Housekeeping – Things You Need to Know!

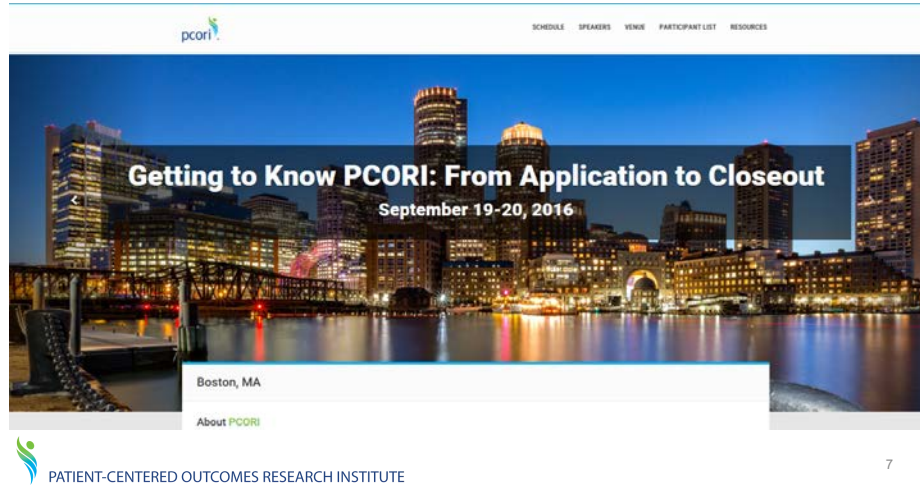
- Morning Recharge: 11:00 am – 11:15 am
- Midday Nourishment: 12:00 pm – 1:00 pm
- Afternoon Recharge: 4:00 pm – 4:15 pm

Your Guide to What's Happening!



Mobile Site and Presentations

- Boston PCORI Workshop Mobile Site URL: <http://bit.ly/2cbJnLR>



Workshop Access Code

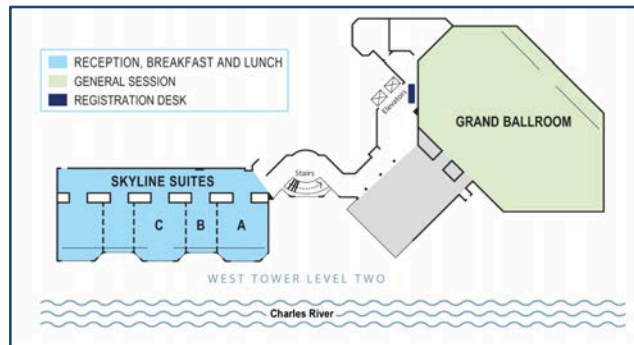


pcori

You Are Here!

September 20

- Breakfast and Lunch (Skyline Suites – West Tower, Level 2, Breakfast 7:30 a.m.–8:45 a.m., Lunch 12:00 p.m.–1:00 p.m.)
- General Session (Grand Ballroom, 9:00 a.m.–12:00 p.m., 1:00 p.m.–5:00 p.m.)
- Registration Desk (Foyer outside Grand Ballroom, 7:00 a.m.–5:00 p.m.)



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

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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



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.**



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



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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?"



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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

Review
Proposals
and Partner
in Research

Reviewing and
Conducting
Research

Tell Us How
We're Doing

Help Us
Share the
Findings

Portfolio
Review

Dissemination
and
Implementation



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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

Open Opportunities

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

Obesity Observational Research

Key Deadlines

Application: May 27, 2015

Engagement Award (EAW): Research Meeting and Conference Support

Key Deadlines	Type	Funds Available	Total Costs
LOE: 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

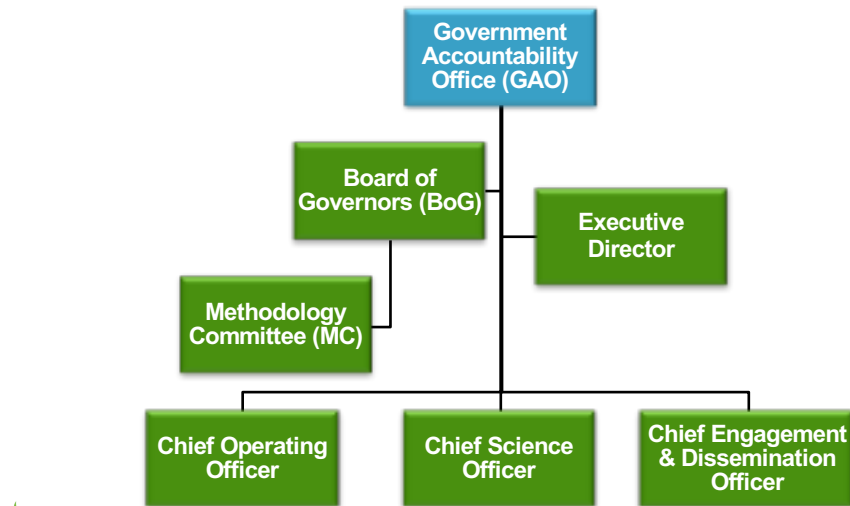
Year	Event
2013	PCORI was established by Congress as an independent agency within the Department of Health and Human Services.
2014	PCORI issued its first Request for Applications (RFAs) for research projects.
2015	PCORI issued its first Request for Proposals (RFPs) for research projects.
2016	PCORI issued its first Request for Proposals (RFPs) for research projects.
2017	PCORI issued its first Request for Proposals (RFPs) for research projects.
2018	PCORI issued its first Request for Proposals (RFPs) for research projects.
2019	PCORI issued its first Request for Proposals (RFPs) for research projects.
2020	PCORI issued its first Request for Proposals (RFPs) for research projects.
2021	PCORI issued its first Request for Proposals (RFPs) for research projects.
2022	PCORI issued its first Request for Proposals (RFPs) for research projects.
2023	PCORI issued its first Request for Proposals (RFPs) for research projects.
2024	PCORI issued its first Request for Proposals (RFPs) for research projects.
2025	PCORI issued its first Request for Proposals (RFPs) for research projects.
2026	PCORI issued its first Request for Proposals (RFPs) for research projects.
2027	PCORI issued its first Request for Proposals (RFPs) for research projects.
2028	PCORI issued its first Request for Proposals (RFPs) for research projects.
2029	PCORI issued its first Request for Proposals (RFPs) for research projects.
2030	PCORI issued its first Request for Proposals (RFPs) for research projects.



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PCORI's Organizational Structure



Our National Priorities for Research



Assessment of Prevention, Diagnosis, and Treatment Options



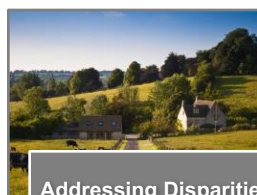
CER Methods



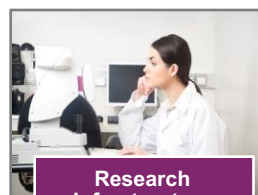
Improving Healthcare Systems



Communication & Dissemination Research



Addressing Disparities



Research Infrastructure



Our Program Directors



Yen-Pin Chiang, PhD (Interim)
Assessment of Prevention,
Diagnosis, and Treatment Options



David Hickam, MD, MPF
CER Methods



Steven Clauser, PhD, MPA
Improving Healthcare Systems



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



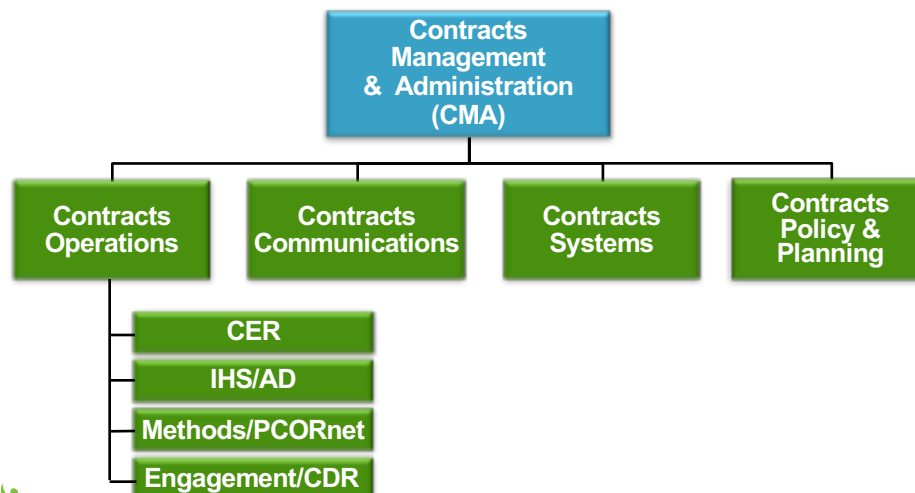
Romana Hasnain-Wynia
MS, PhD
Addressing Disparities



Rachael Fleurence, PhD
Research Infrastructure



CMA's Organizational Structure



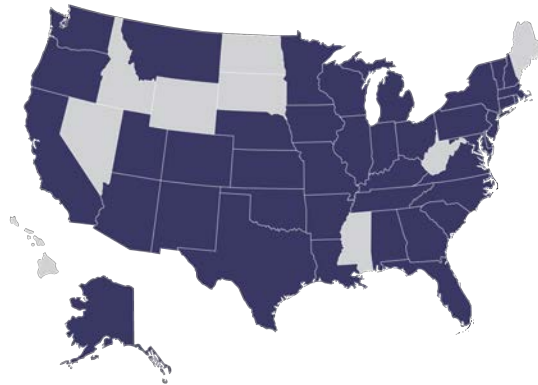
Funded Projects to Date

Total number of research projects awarded: **551***

Total funds awarded: **\$1.55 billion**

Number of states where we are funding research: **41 states (plus the District of Columbia, Canada, Sweden, and Italy)**

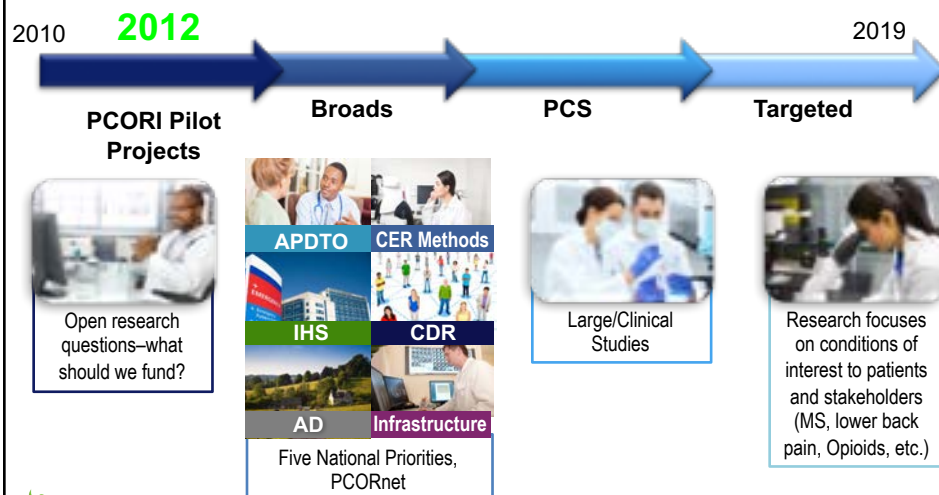
*666 total projects that include engagement, research infrastructure, and coordinating center awards



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PCORI's Funding Lifecycle



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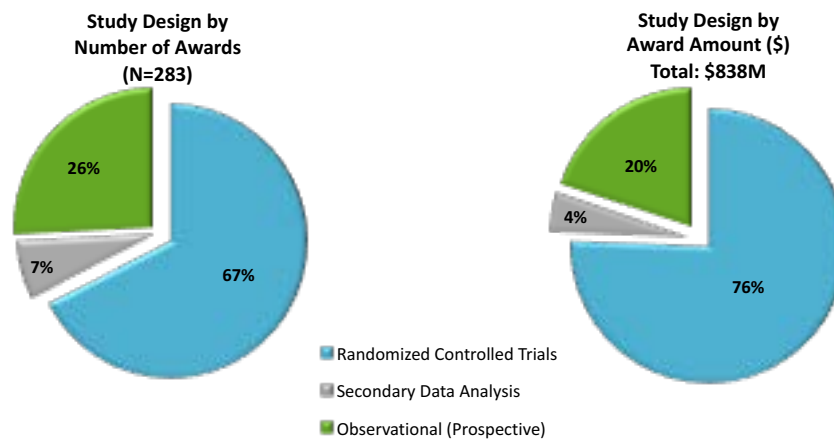
Snapshot of Funded Projects

SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)

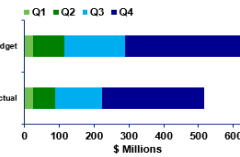
 Mental/Behavioral Health	54	 Other/Non-Disease Specific	22	 Infectious Diseases	11
 Cancer	48	 Respiratory Diseases	22	 Kidney Disease	9
 Cardiovascular Health	32	 Multiple/Co-Morbid Chronic Conditions	18	 Functional Limitations and Disabilities	6
 Neurological Disorders	27	 Reproductive and Perinatal Health	14	 Allergies and Immune Disorders	4
 Nutritional and Metabolic Disorders	26	 Trauma/Injury	14	 Digestive System Diseases	4
 Rare Diseases	23	 Muscular and Skeletal Disorders	12	 Skin Disease	1

The majority of studies in our portfolio are clinical trials

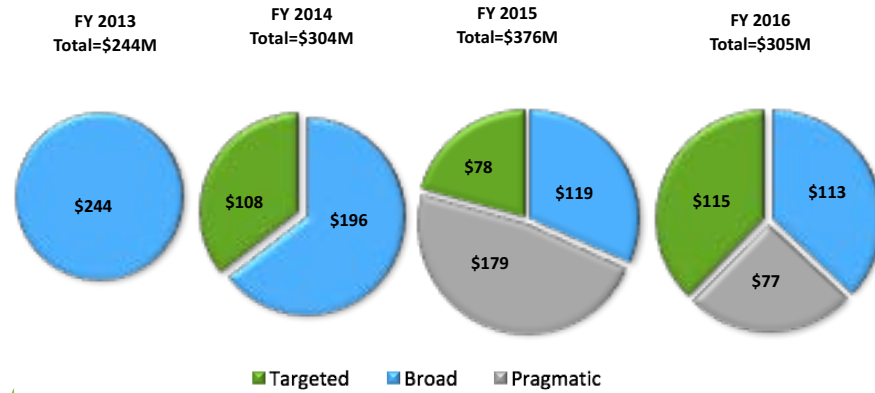
Funded Portfolio by Study Design* Cycle I through Spring 2015



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

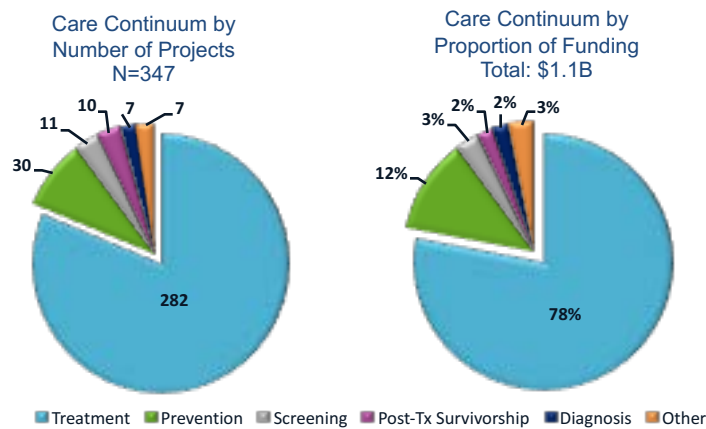


Funds Committed in Each Fiscal Year by Type of PFA



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

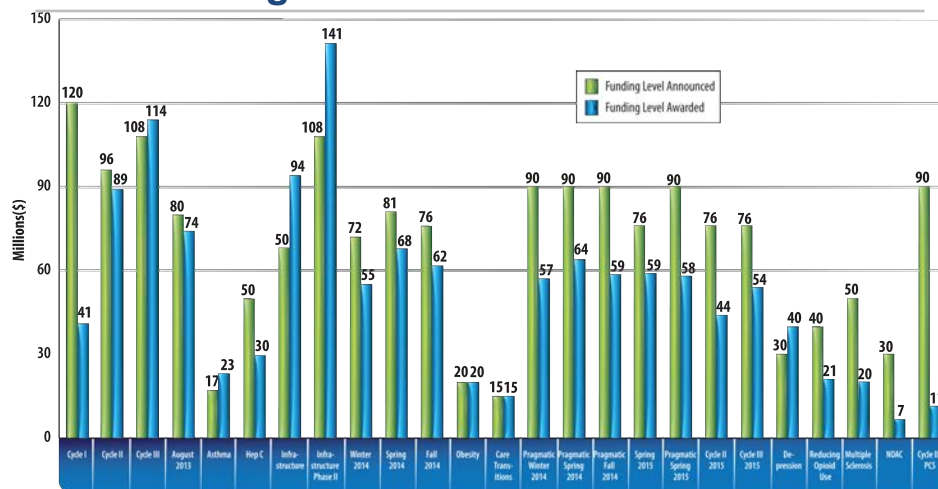
**Funded Portfolio by Care Continuum* **
Cycle 1 through Cycle 3 2015**



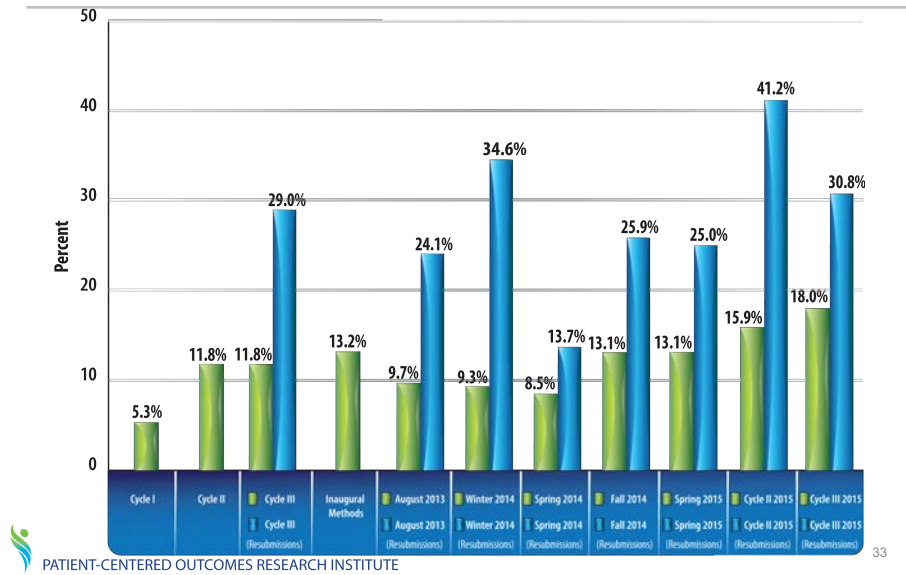
Projected Funding Commitments



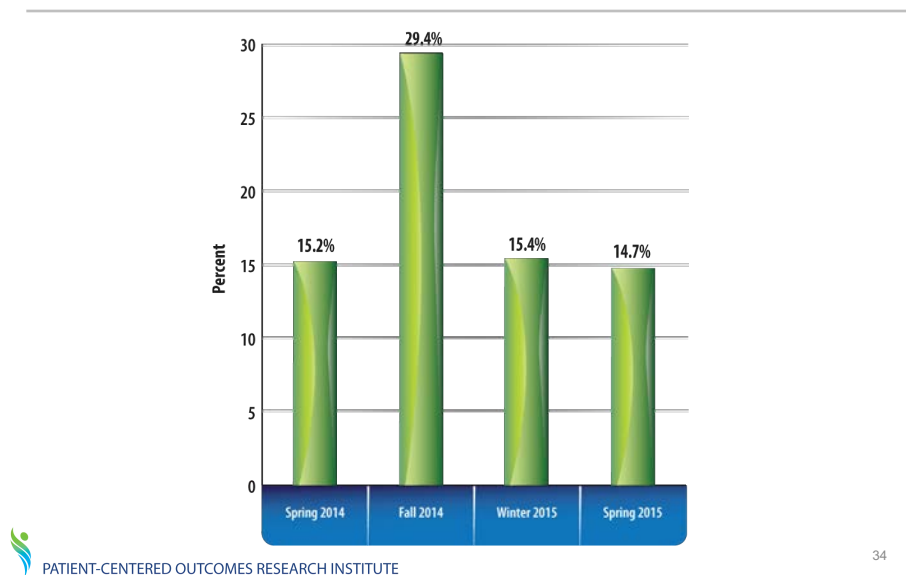
Comparison of Funding Level Announced with Funding Level Awarded



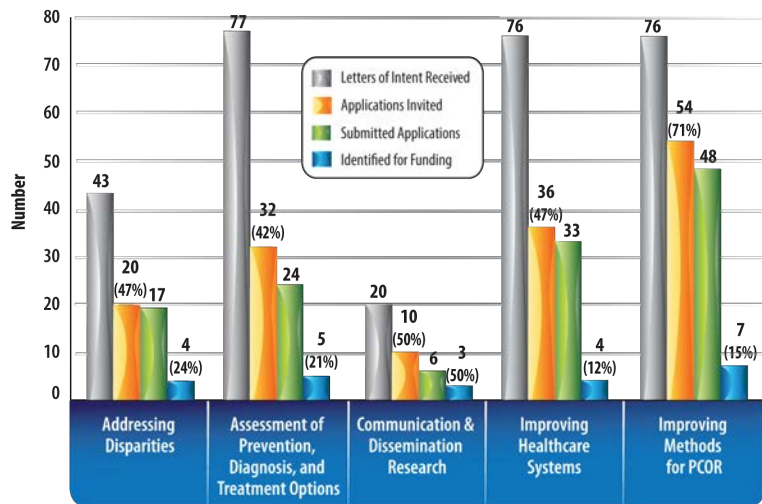
PCORI's Past Funding Lines



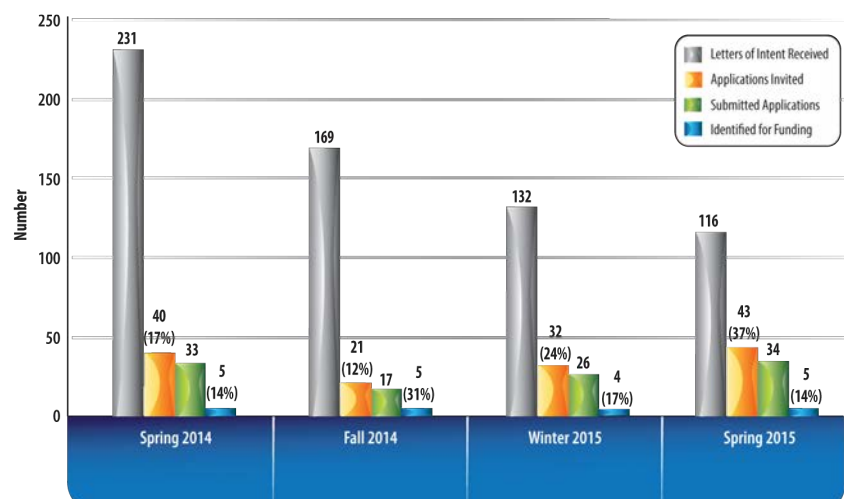
PCORI's Past PCS Funding Rates



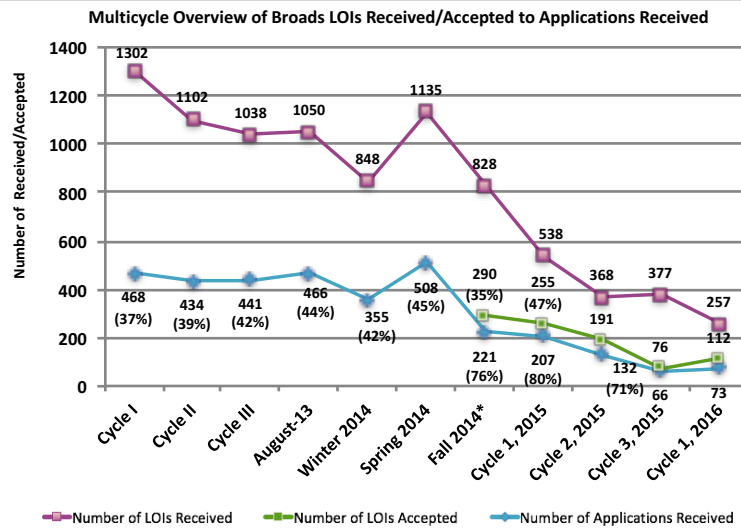
LOIs, Applications, and Awards for Last Funded Cycle (Cycle 3 2015)



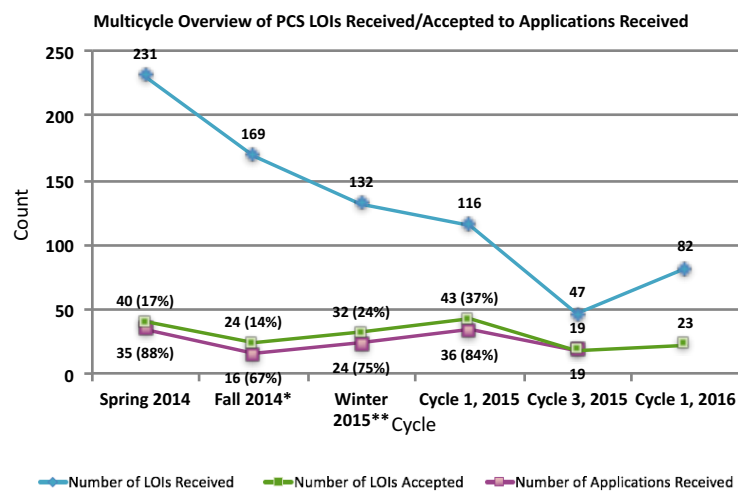
LOIs, Applications, and Awards: First 4 Cycles of Pragmatic Clinical Studies



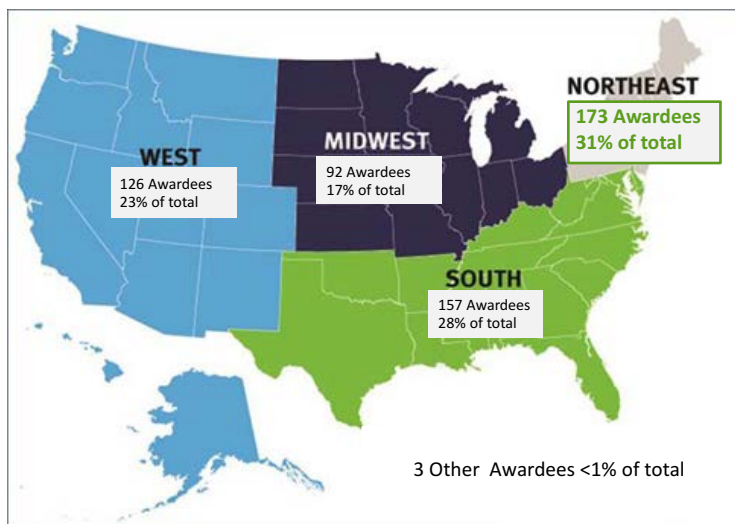
Declining trends in LOI receipts over cycles for Broads PFAs:



Declining trends in LOI receipts over cycles for PCS PFAs:



Funding by Geographic Distribution



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

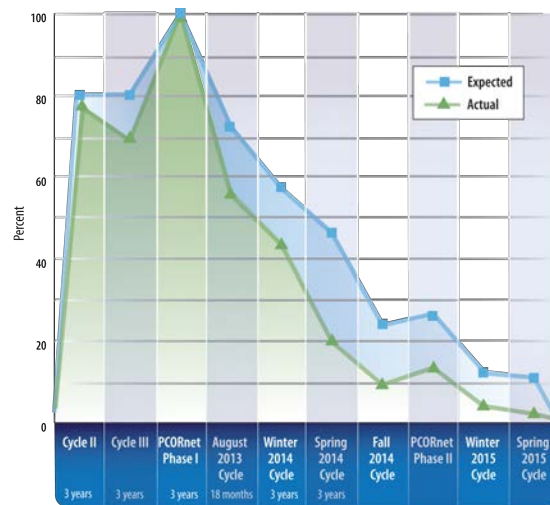


Fixed-Price Contracts – Cycle 1

Cycle I Expenditures



Cost-Reimbursable Contracts



*Average Start date is 10/1/2014



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

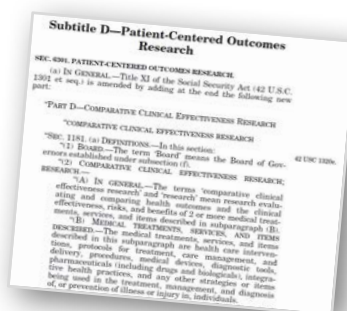


Why Does PCORI Issue Contracts?



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>



Contract Provisions Relating to PCORI's Authorizing Law

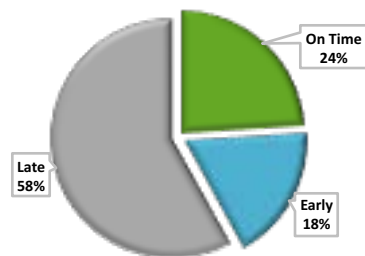
Contracts reflect PCORI's authorizing law

- Adherence to PCORI Methodology Standards
- Consultation with the PCORI Advisory Panels on Clinical Trials and Rare Diseases
- Making Research Findings Publicly Available
- Conflicts of Interest
- Notifications About Publications
- Contract Governing Law
- Indemnification & Insurance
- Intellectual Property Rights in PCORI-Funded Research
- Peer Review of Primary Research
- Data Sharing Plans



Did Projects Initiate Recruitment on Time?

Timeliness of
Recruitment Initiation

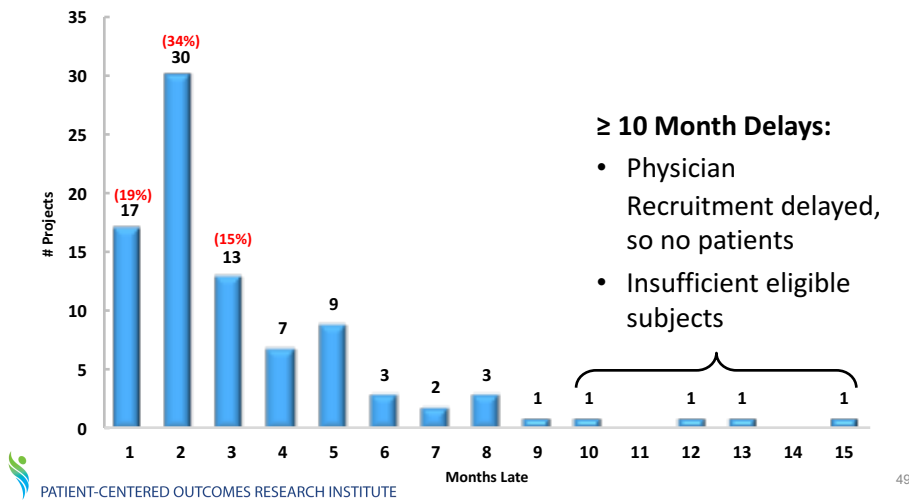


Reasons for Delayed Initiation

- 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?



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:

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

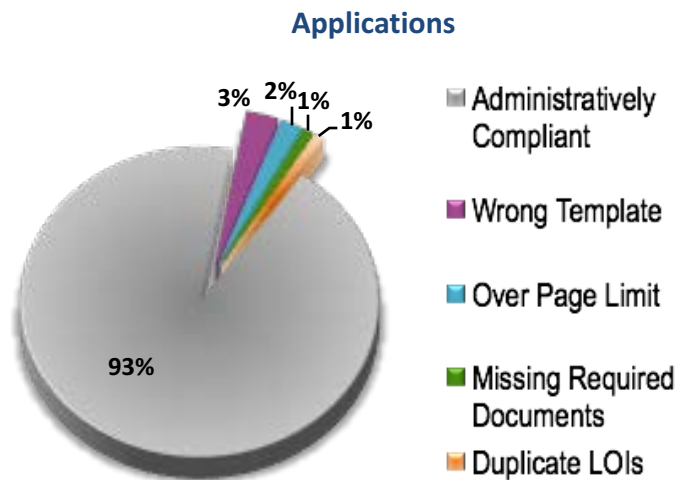


Programmatic Non-Compliance of LOIs

PFA	Spring 2014 LPS	Fall 2014	Winter 2015	Spring 2015	Cycle 2 2015	Cycle 3 2015	Average
AD	--	22.7%	--	26.1%	50.0%	46.5%	36.3%
CDR	--	18.0%	--	24.1%	63.8%	40.0%	36.5%
CER	--	34.5%	--	45.3%	58.6%	50.7%	47.3%
IHS	--	36.0%	--	54.9%	49.4%	47.4%	46.9%
Methods	--	65.3%	--	66.3%	23.5%	27.6%	45.7%
Broads Average	--	34.8%	--	46.8%	47.3%	42.5%	42.9%
PCS	20.1%	14.2%*	24.2%**	--	--	56.5%	28.8%
Average	20.1%	32.2%	24.2%	43.9%	48.8%	44.5%	--



More Reasons for Our Workshop— LOI Administrative Non-Compliance

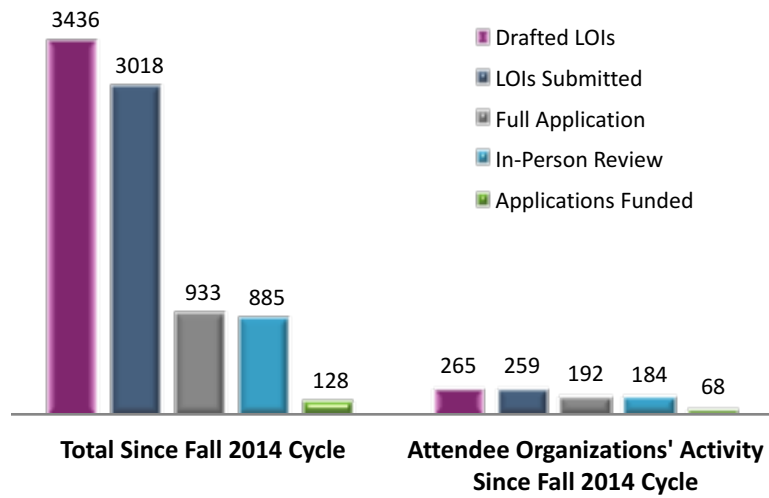


Past CMA PCORI Workshops

- 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



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