

Welcome and Overview

Scott Solomon, MBA, MSE

Director of Contracts Management and Administration

January 24, 2017



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome



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



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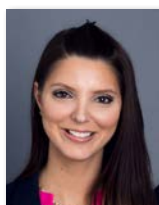
PCORI Staff - Morning Presentations



Scott Solomon
Director,
Contracts
Management and
Administration
(CMA)



Dave Hickam
Program Director,
Clinical Effectiveness
and Decision Science
(CEDS)



Layla Lavasani
Program Officer,
Science, Clinical
Effectiveness
Research (CER)



Parag Aggarwal
Senior Program
Officer, Science,
Addressing
Disparities



Maryan Zirkle
Program Officer,
Research
Infrastructure
Program



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PCORI Staff – Afternoon Presentations



Donna Gentry
Supervisor,
Contracts
Operations
CMA



Yasmeen Long
Program Officer,
Eugene Washington
PCORI Engagement
Awards



Perrinne Kelley
Administrator,
Contracts Operations
CMA



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Housekeeping – Things You Need to Know!

- Registration Desk
- Restrooms
- Helpdesk
- Hotel and Travel Issues



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Housekeeping – Things You Need to Know!

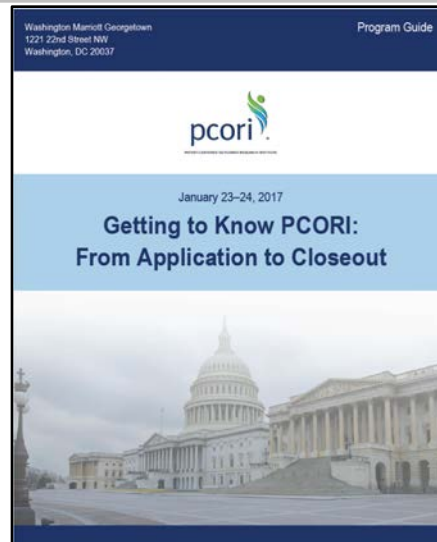
- Morning Break: 11:00 am – 11:15 am
- Lunch: 12:00 pm – 1:00 pm
- Afternoon Recharge: 2:15 pm – 2:30 pm



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Your Guide to What's Happening!



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Mobile Site and Presentations

- Washington PCORI Workshop Mobile Site URL: <http://bit.ly/2jw7oEW>



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Workshop Access Code

Network: **MARRIOTT_CONFERENCE**



PCORIall



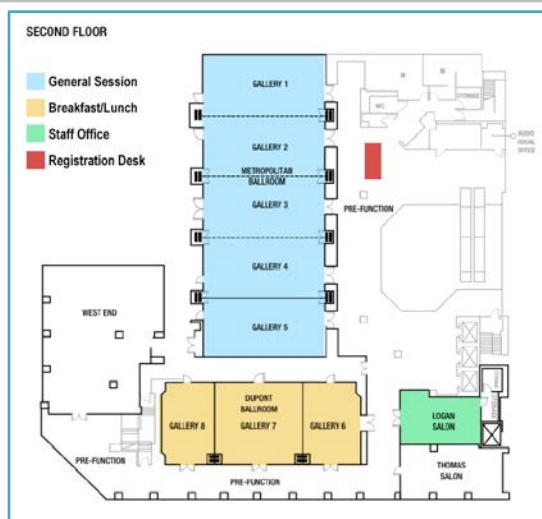
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You Are Here!

January 24th

- Breakfast and Lunch
(Dupont Ballroom
Breakfast 7:30 – 8:45 a.m.
Lunch 12:00 – 1:00 p.m.)
- General Session
(Metropolitan Ballroom,
9:00 a.m. – 12:00 p.m.,
1:00 p.m. – 5:00 p.m.)
- Registration Desk
(Outside the Metropolitan
Ballroom)



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Session Objectives

- Discuss PCORI's history, mission, vision, and organization
- Review PCORI's funding goals, approach, and award activity to date
- Discuss PCORI's unique approach to funding PCOR-Contracts
- 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



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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Overview of PCORI

- **Mandate**
- **Mission**
- **Focus**
- **Goals**
- **PCOR**



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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



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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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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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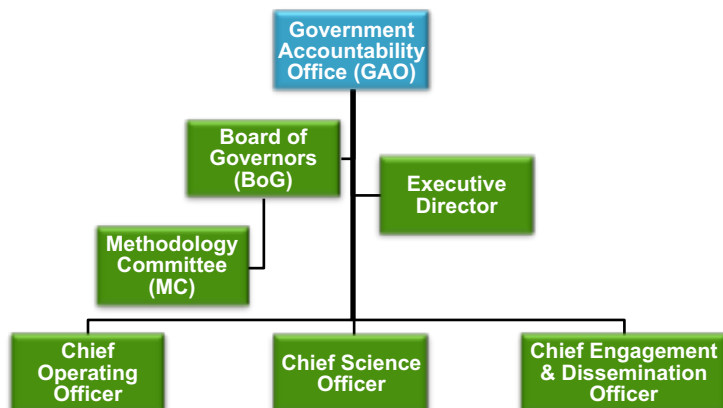
PCORI Emphasizes Engagement for Getting to Practical, Useful Research



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PCORI's Organizational Structure



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Our National Priorities for Research



Assessment of
Prevention, Diagnosis,
and Treatment Options



CER Methods



Improving
Healthcare
Systems



Communication &
Dissemination
Research



Addressing
Disparities



Research
Infrastructure



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Funding Opportunities at PCORI

- **Broads**
- **Pragmatic Clinical Studies (PCS)**
- **Targeted**
- **Research Infrastructure**
- **Engagement**
- **Procurement (Research Support Services)**



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Broads

1. Assessment of Prevention, Diagnosis and Treatment Options (aka CER)
2. Improving Healthcare Systems (IHS)
3. Addressing Disparities (AD)
4. Communication and Dissemination Research (CDR)
5. Improving the Methodology of Comparative Effectiveness Research (aka Methods)

**Funding
per Study**



Up to 2 Million



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Pragmatic Clinical Studies (PCS)

- Large Sample Sizes: Heterogeneity of Treatment Effects
- Topics of special interest from stakeholders, Institute of Medicine, and Agency for Healthcare Research and Quality
- Seeks to produce information that can be directly adopted by providers

Funding per Study  Up to 10 Million



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Targeted

- Targeted funding initiatives; stakeholder-driven topics:
 - Asthma
 - Lower back pain
 - Managing and Reducing Long-Term Opioid Use for Chronic Pain
 - Treatment of Multiple Sclerosis
 - Hepatitis C
 - Sickle Cell Disease
 - Palliative Care

Funding per Study  Up to 10 Million



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Research Infrastructure

- Clinical Data Research Networks (CDRN)
- Patient-Powered Research Networks (PPRN)
- Coordinating Centers

No new
network
opportunities

Front door
research
initiative

Demonstration
projects

Engagement Awards

- Eugene Washington – capacity-building opportunity



up to \$250K

- Pipeline to Proposal (P2P)



\$15K - \$25K - \$50K

Procurement (Research Support Services)

- White papers
- Landscape review
- Evidence synthesis
- RFPs for Operations Support

 **150K to 10 Million**



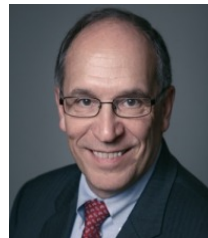
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Our Research Program Directors



David Hickam, MD, MPH
Clinical Effectiveness Research (CER),
Communication and Dissemination Research
(CDR) and Methods



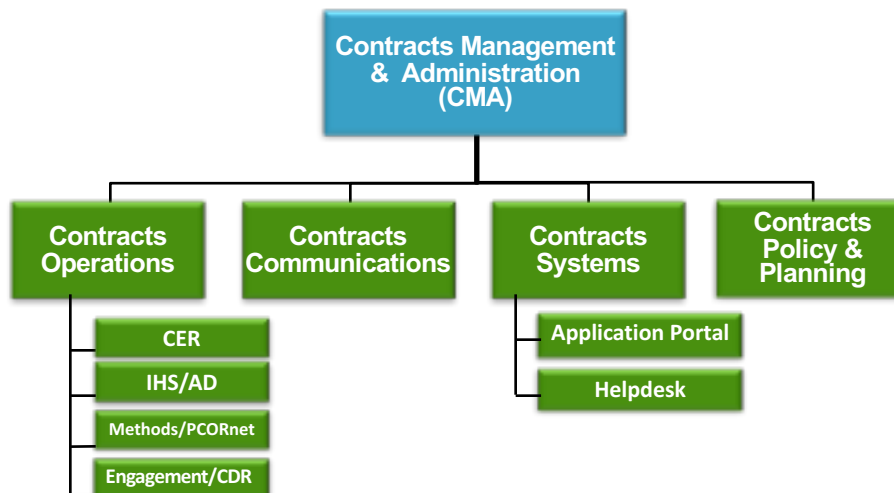
Steven Clauser, PhD, MPA
Improving Healthcare Systems (IHS) and
Addressing Disparities (AD)



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CMA's Organizational Structure



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Building a Patient-Centered Research Community

Find out how you can participate in our work

MORE DETAILS

Session Objectives

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- **Review PCORI's funding goals, approach, and award activity to date**
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Open Opportunities

Our Funding Center contains all of the resources, opportunities, and links to resources for other funding.

Obesity Observational Research Initiatives

Key Deadlines Type

Application: May 27, 2015 Renew

Engagement Award (EAG) Research Meeting

Key Deadlines Type Funds Available Renew

LOI: Not required Program Award

Application: July 1, 2015

PCORI Milestones

Programmatic milestones Administrative milestones Financial milestones

2010

2011

2012

2013

2014

2015



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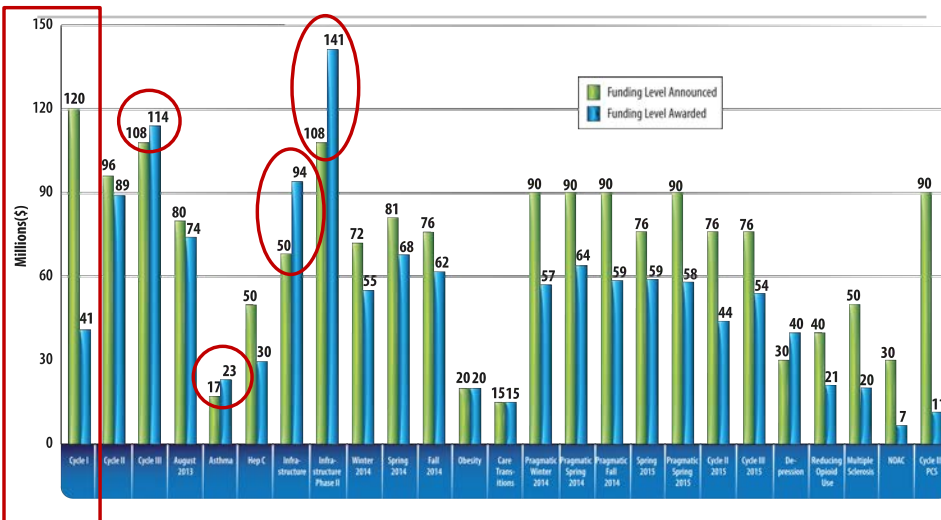
Projected Funding Commitments



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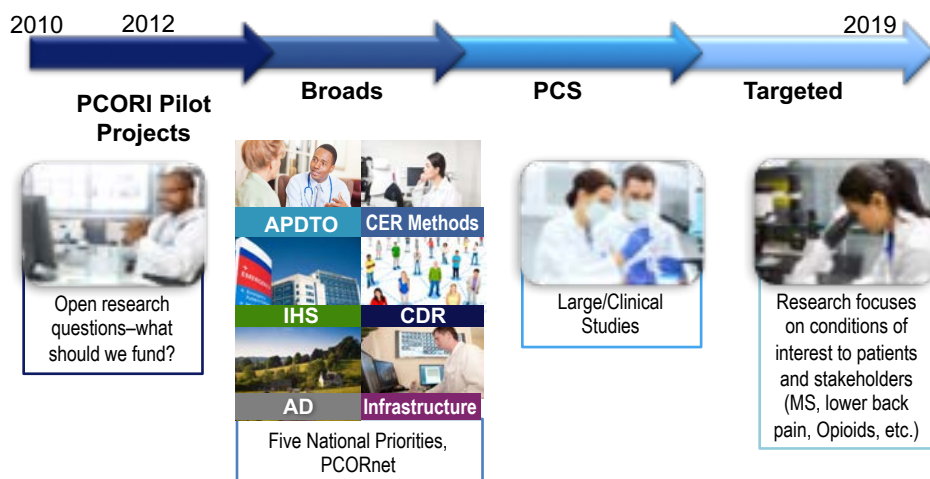
Comparison of Funding Level Announced with Funding Level Awarded



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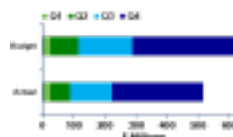
PCORI's Funding Lifecycle



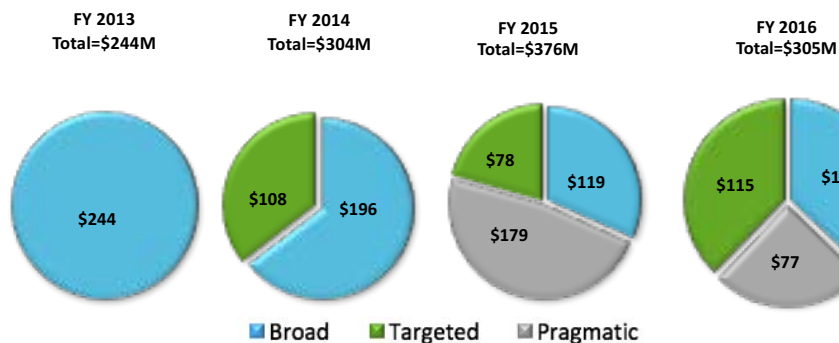
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We are making progress on our Strategic Priority to “Increase the proportion of research funding going to focused and targeted topics”



Funds Committed in Each Fiscal Year by Type of PFA

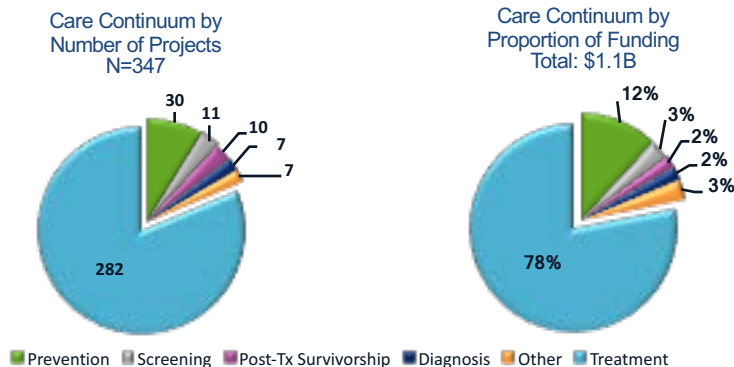


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The majority of our studies focus on treatment and one out of ten projects we fund addresses screening and prevention studies

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



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Snapshot of PI-Initiated Projects: Broads

SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)



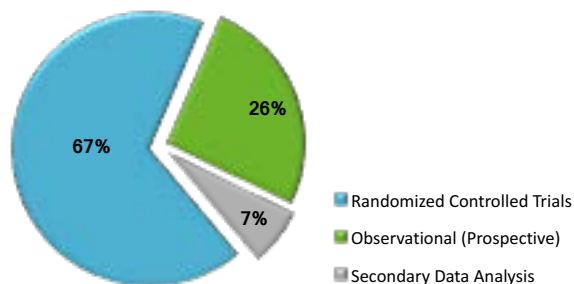
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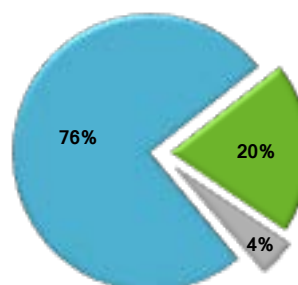
Snapshot of Pragmatic Clinical Studies

Funded Portfolio by Study Design* Cycle I through Spring 2015

Study Design by
Number of Awards
(N=283)



Study Design by
Award Amount (\$)
Total: \$838M



*Does not include Methods projects

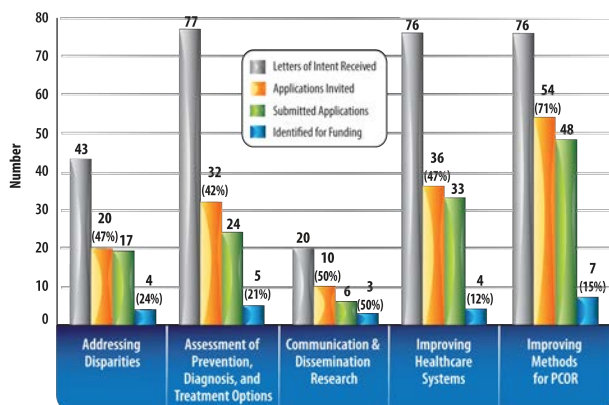


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How do LOIs transition to awards across the National Priorities?

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

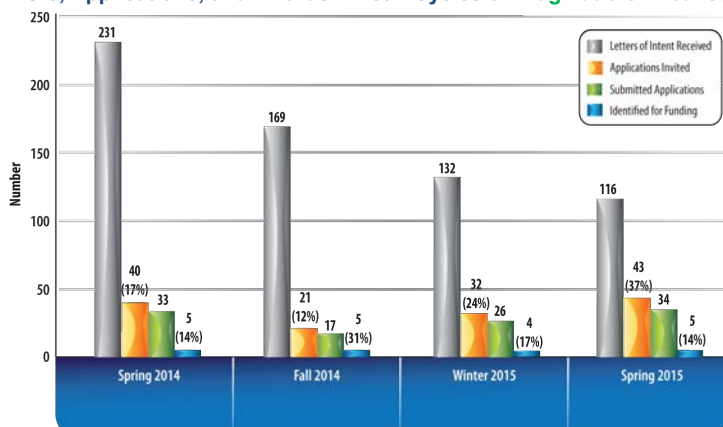


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How do LOIs transition to PCS awards?

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

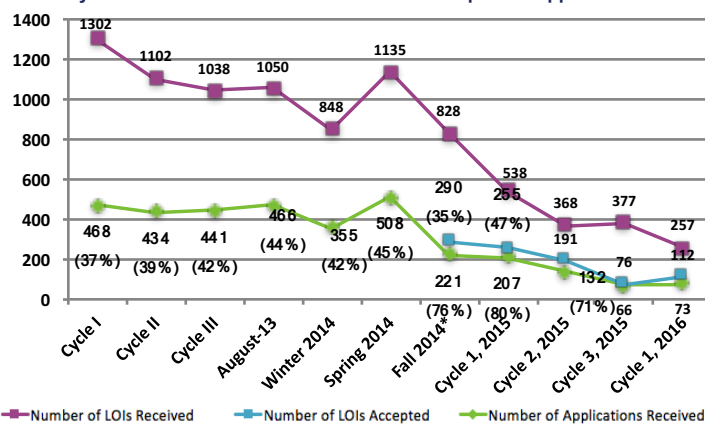


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Declining trends in LOI receipts over cycles for Broad PFAs:

Multicycle Overview of Broad LOIs Received/Accepted to Applications Received

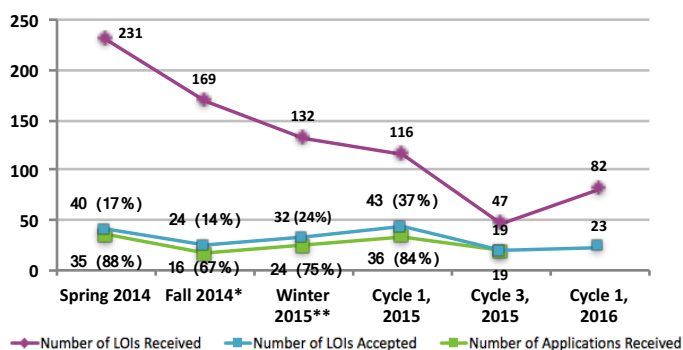


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Declining trends in LOI receipts over cycles for PCS PFAs:

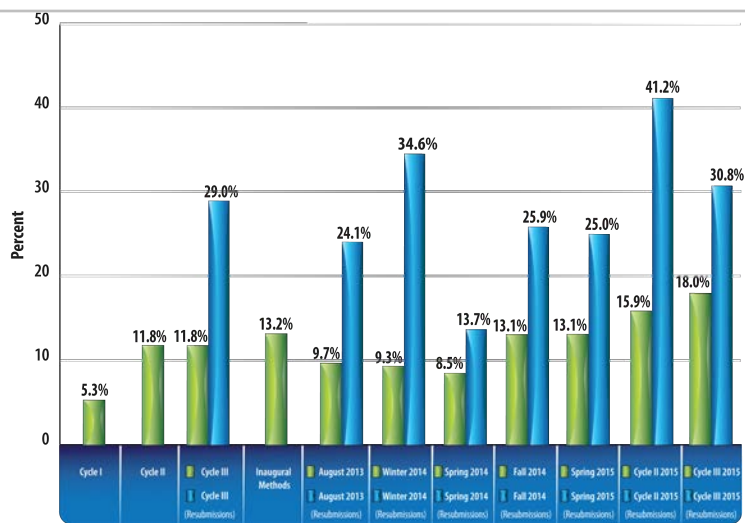
Multicycle Overview of PCS LOIs Received/Accepted to Applications Received



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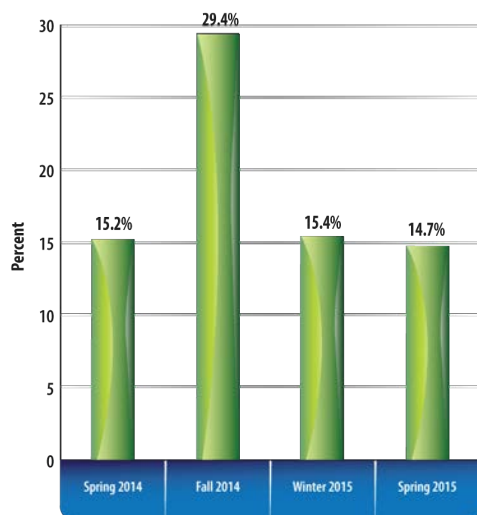
PCORI Funding Rates, to-date



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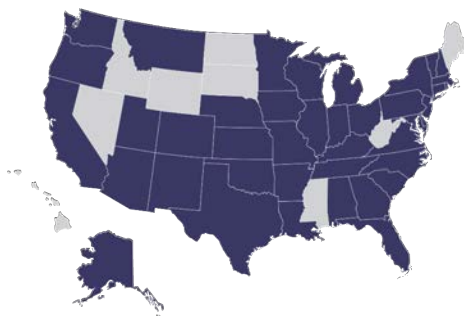
PCORI's Past PCS Funding Rates



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Research Projects Funded, to Date



Total number of research projects awarded: **570***

Total funds awarded: **\$1.61 billion**

Number of states where we are funding research:

41 states (plus the District of Columbia, Canada, Sweden, and Italy)

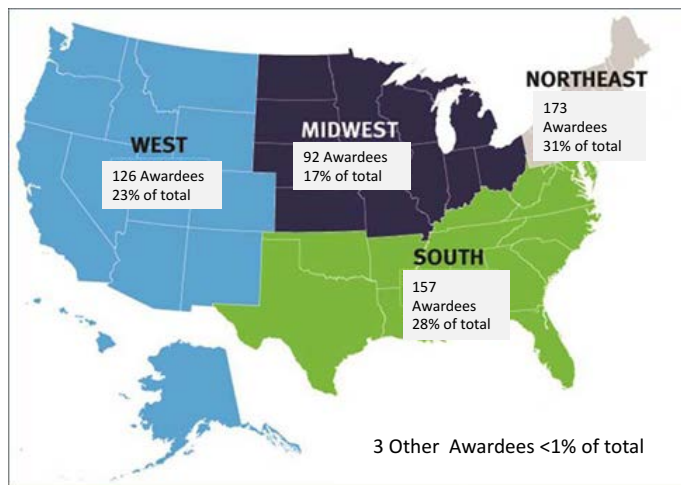
*707 total projects that include engagement, research infrastructure, and coordinating center awards



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Research Funding, by Geographic Distribution



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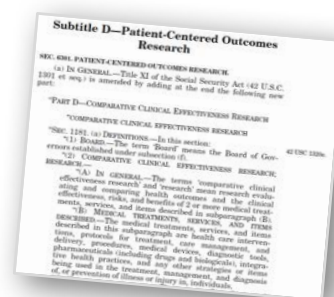
Why Are Awards at PCORI Different?

- The authorizing law (ACA, 2010)
 - Unique terms and conditions
- The need for a research contract vehicle
 - Unique interactions and during-the-award activity



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 **only** from the PCOR Trust Fund
 - 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



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What type of award vehicle best supports PCORI's mission?



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How does a contract impact PCOR?

Fixed-Price Contracts – Cycle 1
Cycle I Expenditures

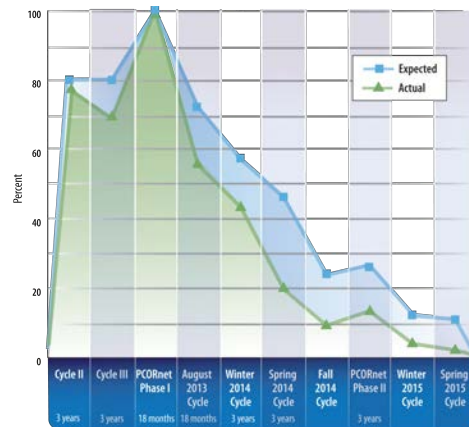


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How does a contract impact PCOR?

Cost-Reimbursable Contracts



*Average Start date is 10/1/2014



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Contracting Goals for PCORI

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

Factors to consider:

- Constantly evolving contract templates
- PCORI is not Federal
- Cost reimbursable contract applied to clinical research



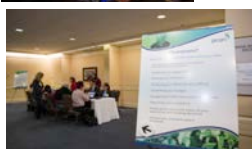
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Reasons for this Workshop

- Disconnect with Applicant Community
- Need to improve/streamline the PCORI online system
- Evolving PCORI Contract Template
- Minimizing Programmatic and Administrative Non-Compliance
- Addressing During-the-Award Performance
 - Realistic budgeting
 - Strategic milestones
 - Recruitment issues

How can PCORI better connect with applicants?

- Improve your understanding of:
 - How to align with PCORI Program and Administrative Requirements
 - LOI and Application success
 - *How* to submit a responsive application
 - Why Patient Engagement is important



Improving/Streamlining the PCORI online system

- Systems over time:
 - NIH/Paper Applications
 - EasyGrants
 - FLUXX
 - FoundationConnect/Salesforce

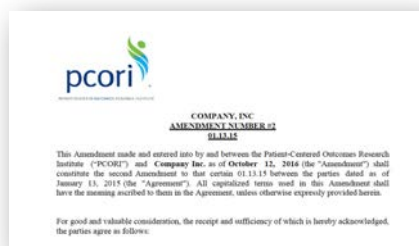


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Evolving PCORI Contract Template

- FFP
- CR8 (Broads, PCS, and Targeted)
- Research Infrastructure
- Engagement
- Procurement



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How are LOIs non-compliant?

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%	--



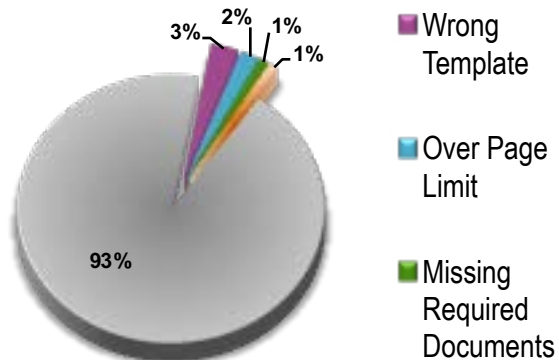
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How are LOIs non-compliant?

More Reasons for Our Workshop—LOI Administrative Non-Compliance

Applications



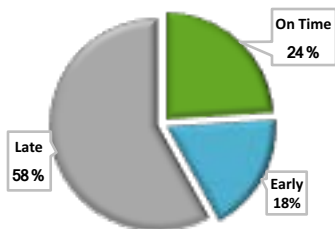
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What is the #1 hurdle to PCORI Research Success? **RECRUITMENT!**

Did Projects Initiate Recruitment on Time?

Timeliness of Recruitment Initiation



Reasons for Delayed Initiation

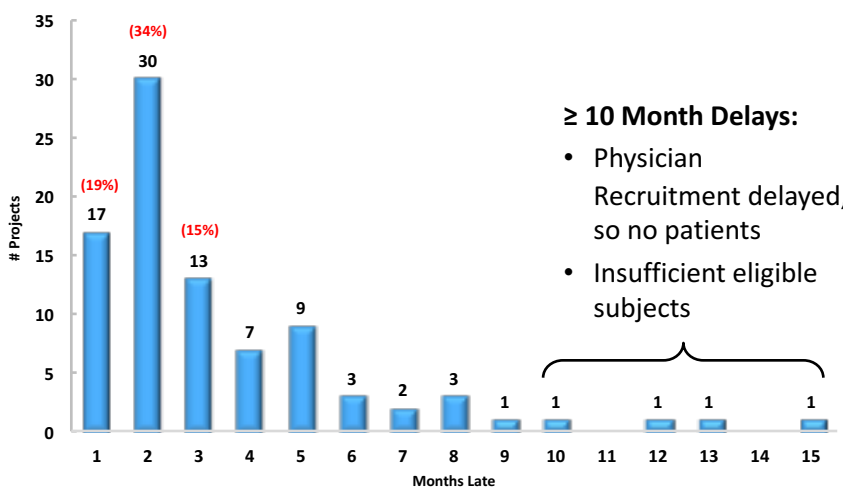
- Delay finalizing intervention
- IRB delays
- Sites withdrawing after randomization
- PI or staff changes, relocations
- Rescheduled or missed appointments
- Restrictive enrollment criteria
- Seasonal issues (asthma symptoms, record snowfall)



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By How Long were Studies Delayed in Initiating Recruitment?



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How are we addressing these issues? The CMA Workshop

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)
- Boston, MA (September, 2016)
- Washington, DC (January, 2017)

NEW

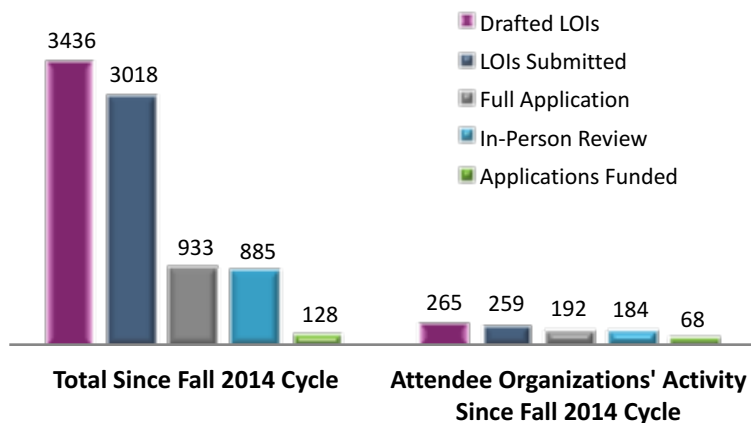
- **Upcoming Chicago (April, 2017)**
— Agenda evolution over time



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



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The Workshop Opportunity



Talk with us!

Questions?

Thank You!

Scott Solomon, MBA, MSE
Director of Contracts Management and
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