

Welcome and Overview

Scott Solomon, MBA, MSE

Director of Contracts Management and Administration

April 11, 2017



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome



Scott Solomon, MBA, MSE

*Director of Contracts
Management and Administration*



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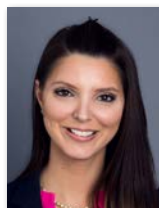
PCORI Staff – Morning Presentations



Scott Solomon
Director,
Contracts
Management and
Administration
(CMA)



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



Layla Lavasani
Program Officer,
Science, Clinical
Effectiveness and
Decision Science
(CEDS) Program



Maryan Zirkle
Program Officer,
Research
Infrastructure
Program



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PCORI Staff – Afternoon Presentations



Lia Hotchkiss
Director,
Eugene Washington
Engagement Awards
Program



Iris Giggetts
Administrator, Contracts
Operations



Mari Kimura
Merit Review Officer



Scott Solomon
Director, Contracts
Management and
Administration (CMA)



James Hulbert
Assistant Director,
Finance Compliance



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Housekeeping – Things You Need to Know!

- Registration Desk
- Restrooms
- Hotel and Travel Issues



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Housekeeping – Things You Need to Know!

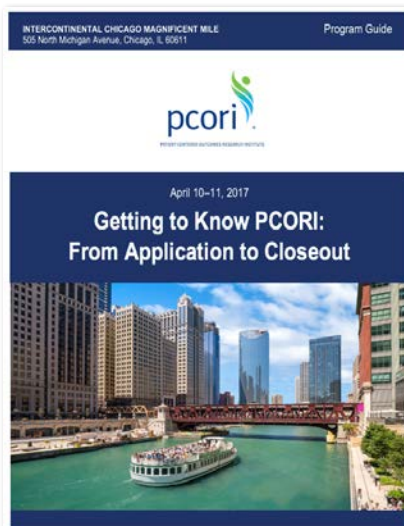
- Morning Break: 11:00 am – 11:15 am
- Lunch: 12:00 pm – 1:15 pm
- Afternoon Recharge: 3:15 pm – 3:30 pm



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Your Guide to What's Happening!

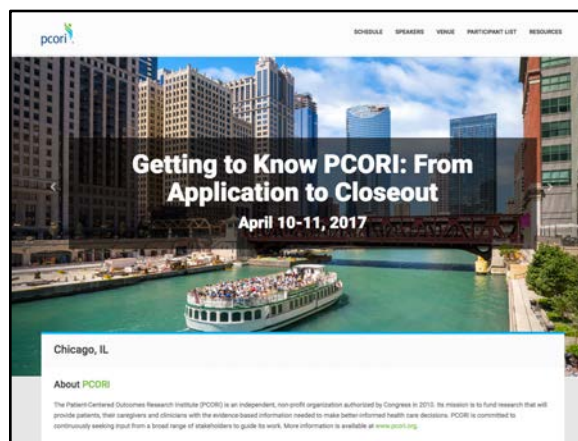


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Mobile Site and Presentations

- Chicago PCORI Workshop Mobile Site URL: <http://bit.ly/2oDHW3l>



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Workshop Access Code



Network: **PCORI**

Password: **Workshop17**



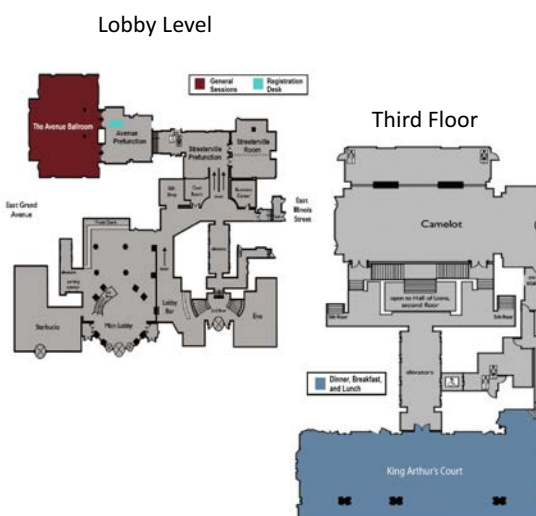
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You Are Here!

April 11

- Breakfast and Lunch (King Arthur Court, Breakfast 7:30 a.m.–8:45 a.m., Lunch 12:00 p.m.–1:15 p.m.)
- General Sessions (Avenue Ballroom, 9:00 a.m.–12:00 p.m., 1:15 p.m.–5:00 p.m.)
- Registration (Outside Avenue Ballroom Foyer, 7:00 a.m.–5:00 p.m.)



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Session Objectives

- Explain PCORI's history, mission, vision, and organization
- Identify PCORI's funding goals, approach, and award activity to date
- Describe PCORI's unique approach to funding PCOR-Contracts
- Explain 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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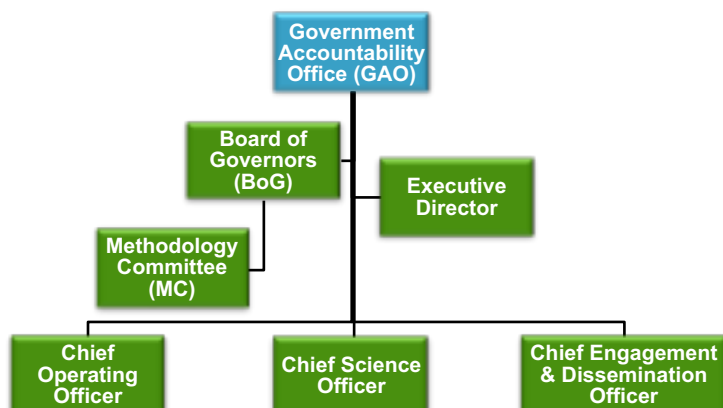
PCORI Emphasizes Engagement for Getting to Practical, Useful Research



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PCORI's Organizational Structure



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Our National Priorities for Research and PCORnet



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



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Engagement Awards

- Eugene Washington – capacity-building opportunity



up to \$250K

- Pipeline to Proposal (P2P)



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



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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 and Decision Science
(CEDS) Program



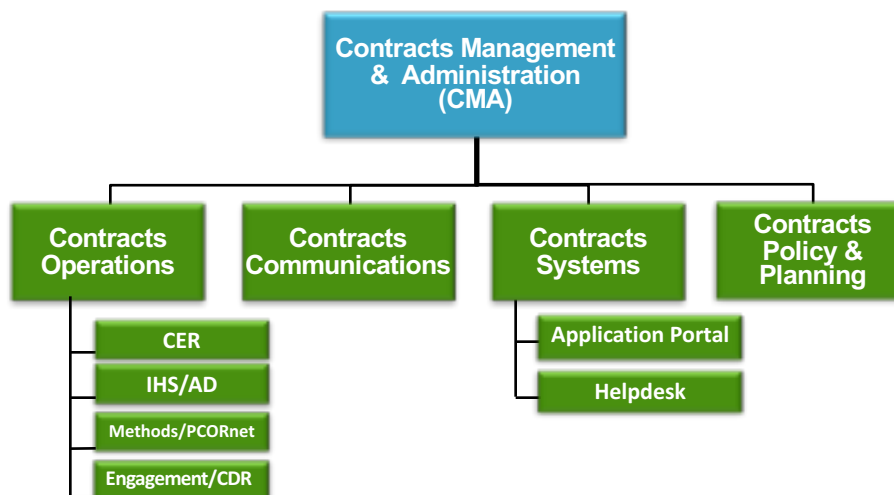
Steven Clauser, PhD, MPA
Healthcare Delivery and Disparities
Research



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CMA's Organizational Structure



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PCORI's Funding Goals



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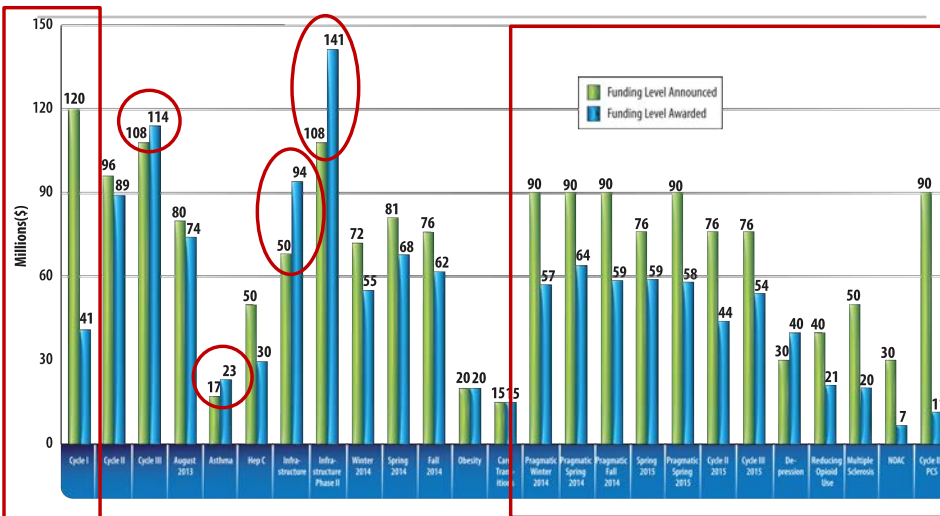
Projected Funding Commitments



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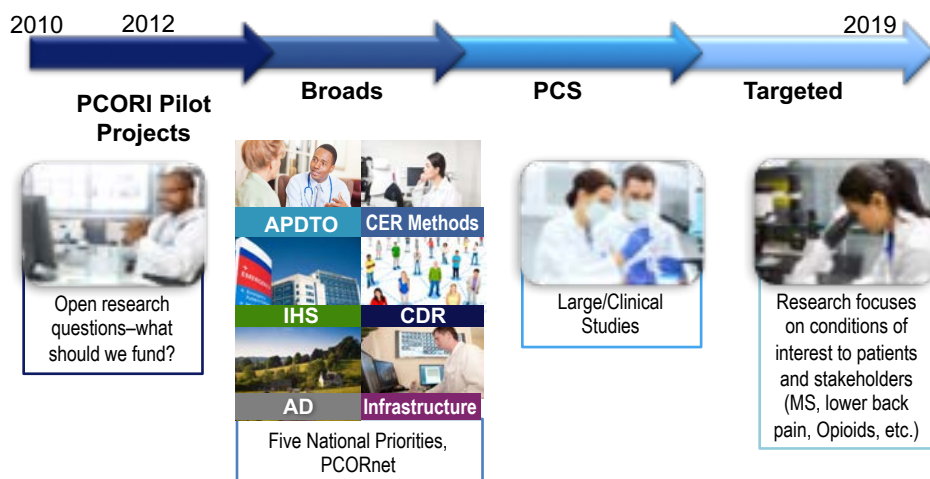
Comparison of Funding Level Announced with Funding Level Awarded



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PCORI's Funding Lifecycle



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

Funded Portfolio by Care Continuum*
Cycle I through Cycle 2 2016



7 other projects representing a \$37.8M investment are not specific to a continuum stage

*Categories are not mutually exclusive.
The PCORI CER portfolio includes 365 projects funded through March 2017.
Analysis excludes Methods projects, PPRN, CDRN and Pilot projects.

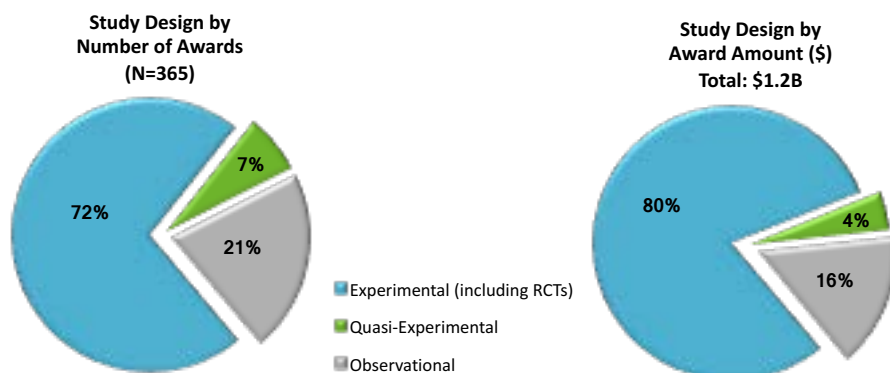



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The majority of studies in our portfolio are clinical trials

Funded Portfolio by Study Design*
Cycle 1 through Cycle 2 2016

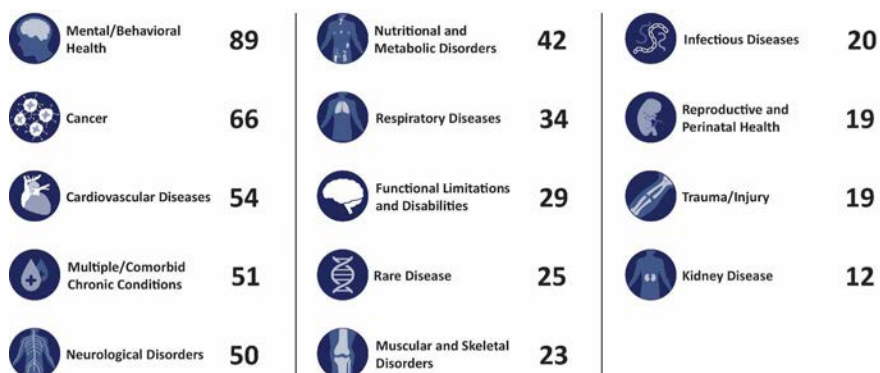


*Does not include Methods projects.
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Snapshot of PI-Initiated Projects: Broads

SNAPSHOT OF FUNDED RESEARCH PROJECTS (BY MEDICAL CONDITION)

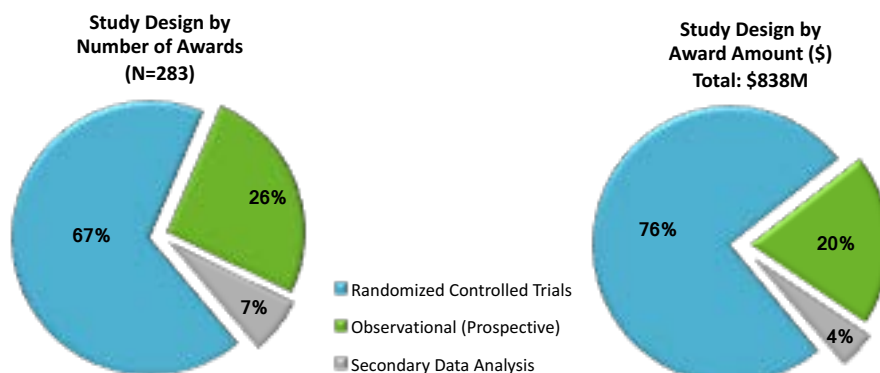


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Snapshot of Pragmatic Clinical Studies

Funded Portfolio by Study Design* Cycle I through Spring 2015



*Does not include Methods projects

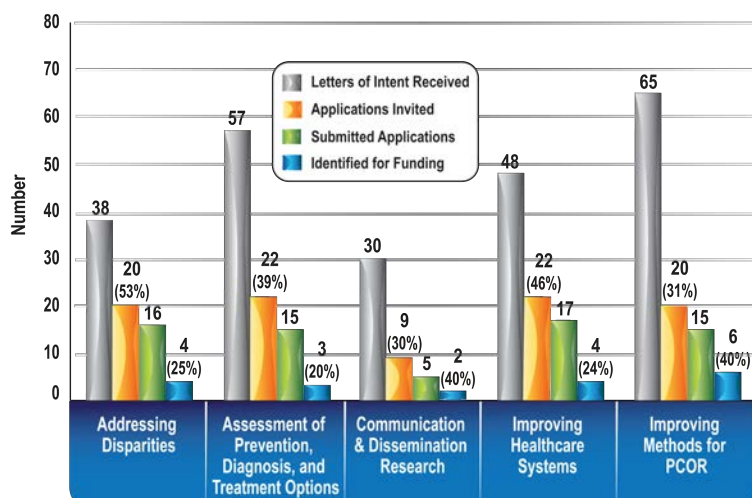


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How do LOIs transition to awards across the National Priorities?

LOIs, Applications, and Awards for Funded Cycles in FY 2016 (Cycles 1 & 2 2016)

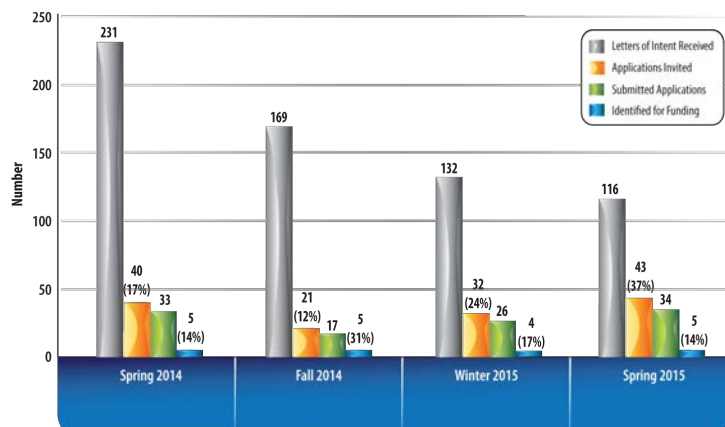


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How do LOIs transition to PCS awards?

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

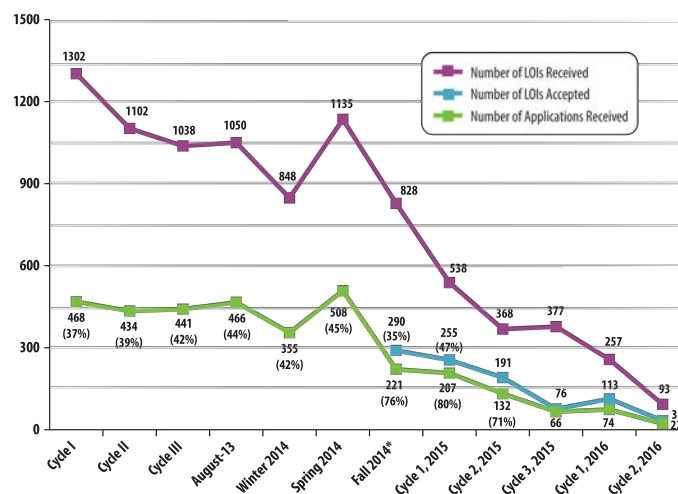


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Declining trends in LOI receipts over cycles for Broad PFAs:

Multicycle Overview of Broad LOIs Received/Accepted to Applications Received

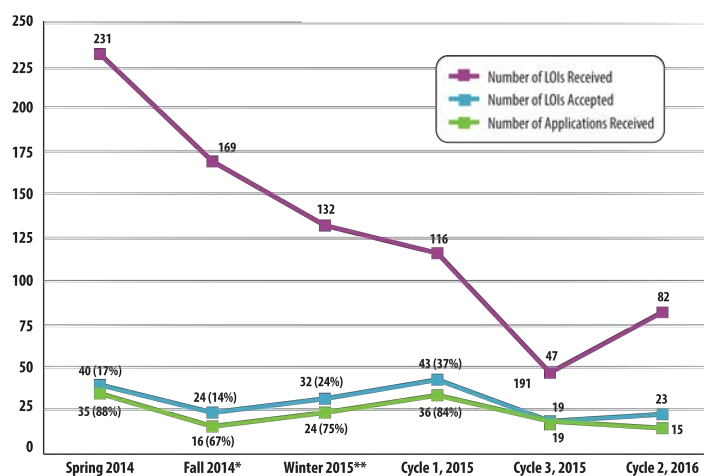


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Declining trends in LOI receipts over cycles for PCS PFAs:

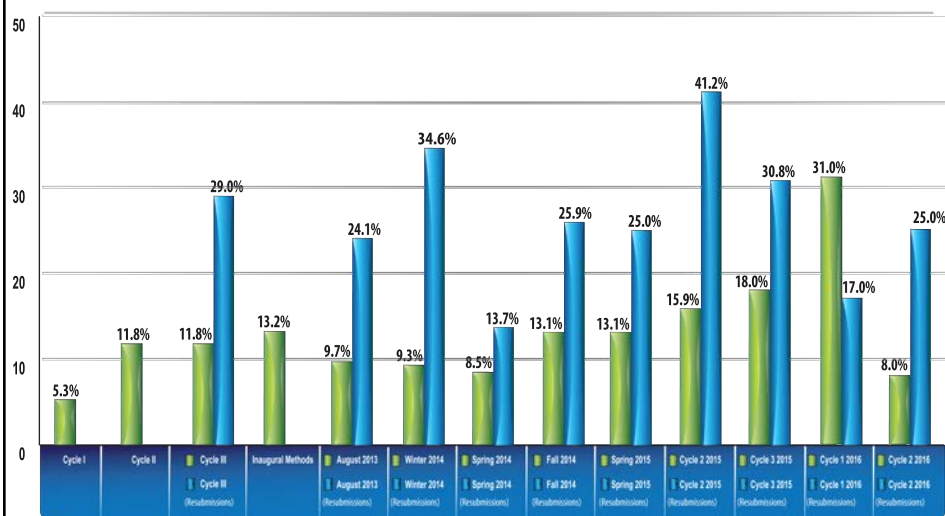
Multicycle Overview of PCS LOIs Received/Accepted to Applications Received



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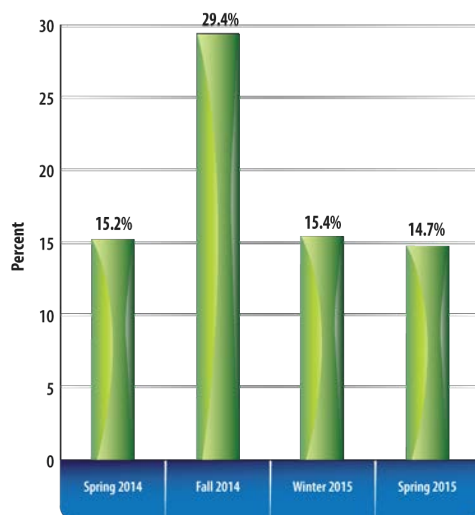
PCORI Funding Rates, to Date



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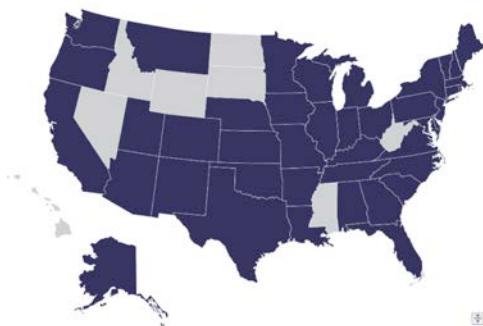
PCORI's Past PCS Funding Rates



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Research Projects Funded to Date



Total number of research projects awarded: **440***

Total funds awarded: **\$1.6 billion**

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

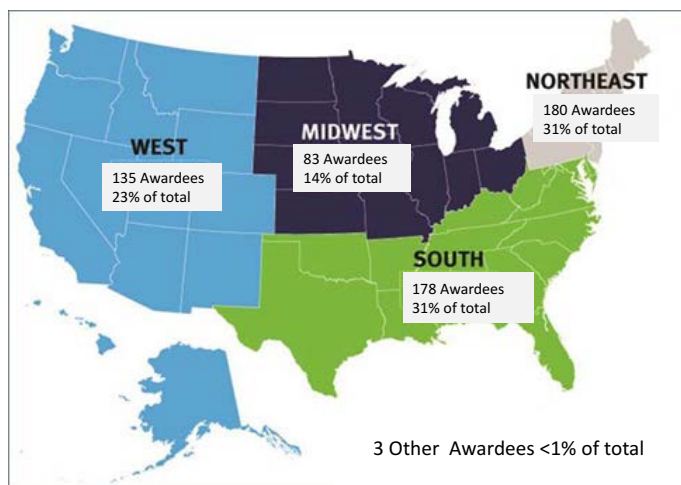
*784 total projects that include engagement, research infrastructure, and coordinating center awards



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Research Funding, by Geographic Distribution



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PCORI Funded Contracts



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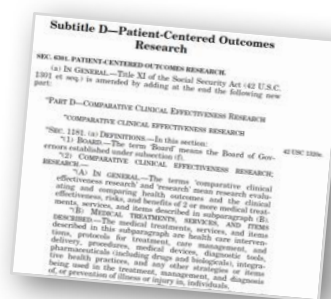
Why Are Awards at PCORI Different?

- 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

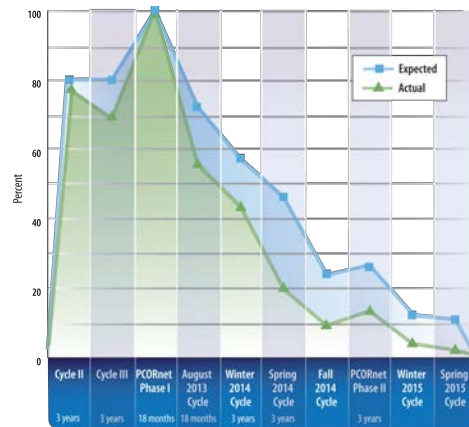


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How does a contract impact PCOR?

Cost-Reimbursable Contracts



*Average Start date is 10/1/2014

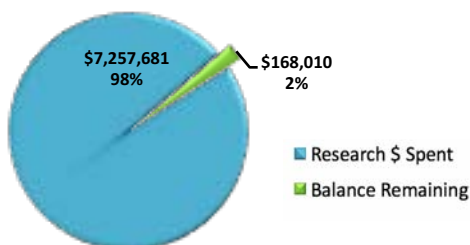


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After research period invoices are processed, awardees spent 98% of their research budget

Research Period Projects
Ending June 2016
Cost Reimbursable Budget:
\$7,425,691



Research Period Projects
Ending June 2016
Fixed Reimbursable Budget:
\$15,347,711



- Expect the PO and CMA administrator to work with you to negotiate a realistic budget; if you “pad” we will come back and ask you to cut
- Don’t over inflate the budget
- Our awards, as evident by the 2% remaining, shows that we are getting it right



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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



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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



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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



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Improving/Streamlining the PCORI online system

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

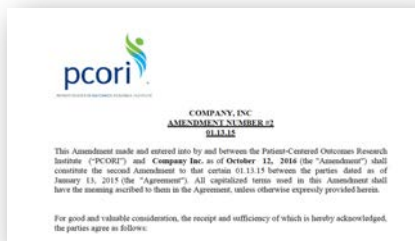


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Evolving PCORI Contract Template

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



How are LOIs non-compliant?

Programmatic Non-Compliance of LOIs

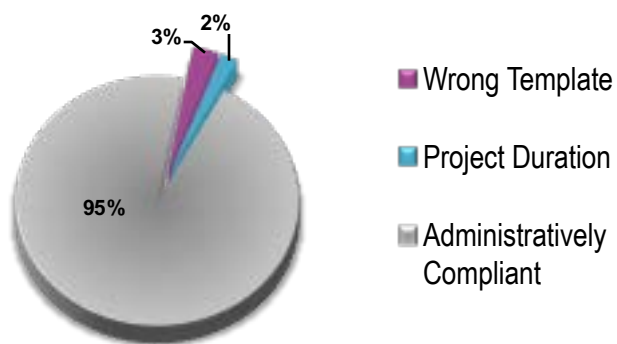
| PFA | Fall 2014 | Winter 2015 | Spring 2015 | Cycle 2 2015 | Cycle 3 2015 | Cycle 1 2016 | Average |
|----------------|-----------|-------------|-------------|--------------|--------------|--------------|---------|
| AD | 22.7% | -- | 26.1% | 50.0% | 46.5% | 3.0% | 29.7% |
| CDR | 18.0% | -- | 24.1% | 63.8% | 40.0% | 70.0% | 43.2% |
| CER | 34.5% | -- | 45.3% | 58.6% | 50.7% | 45.0% | 46.8% |
| IHS | 36.0% | -- | 54.9% | 49.4% | 47.4% | -- | 46.9% |
| Methods | 65.3% | -- | 66.3% | 23.5% | 27.6% | 3.0% | 37.1% |
| Broads Average | 34.8% | -- | 46.8% | 47.3% | 42.5% | 30.3% | 40.3% |
| PCS | 14.2%* | 24.2%** | -- | -- | 56.5% | -- | 28.8% |
| Average | 32.2% | 24.2% | 43.9% | 48.8% | 44.5% | 30.3% | -- |



How are LOIs non-compliant?

More Reasons for Our Workshop—LOI **Administrative** Non-Compliance

Applications



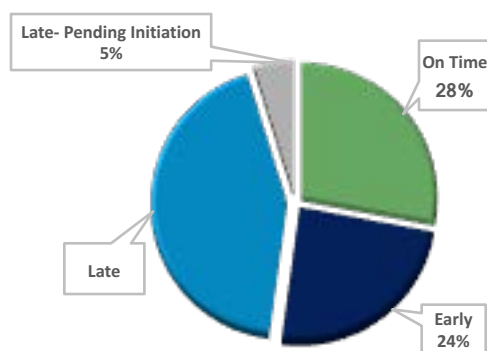
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What is the #1 hurdle to PCORI Research Success? **RECRUITMENT!**

Did Projects Initiate Recruitment on Time?

Timeliness of Recruitment Initiation



Reasons for Delayed Initiation

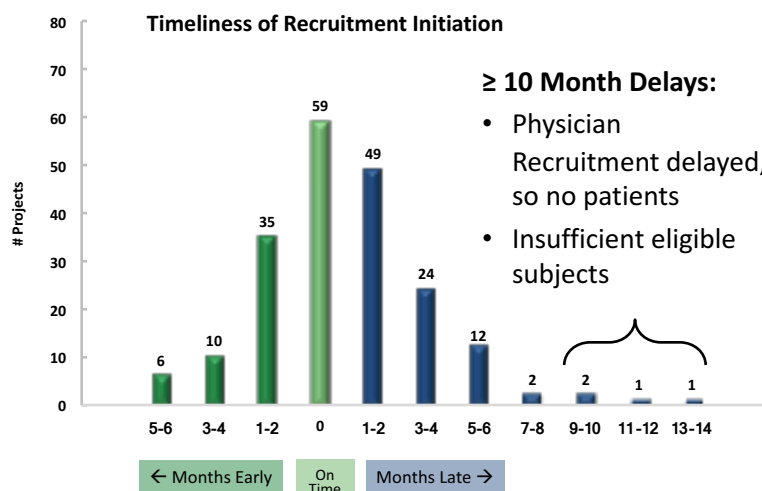
- Subcontract negotiation
- IRB Approval
- Staff turnover



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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)
- Chicago, IL (April, 2017)

NEW

Upcoming Washington, DC (July, 2017)

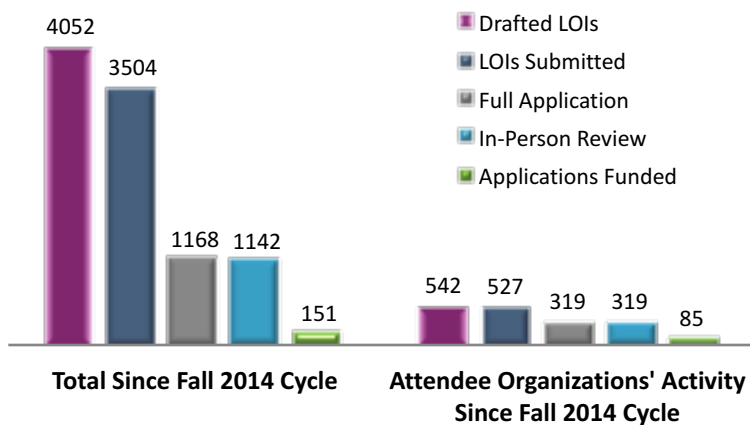
— Agenda evolution over time



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Significant Workshop Statistics: From LOIs Drafted to Applications Funded



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The Workshop Opportunity



Talk with us!



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Questions?

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Thank You!

Scott Solomon, MBA, MSE
Director of Contracts Management and
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