Board of Governors Meeting
via Teleconference/Webinar

September 28, 2015

10:15am-6:00 pm ET

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Joe Selby, MD, MPH
Executive Director

Time	Agenda Item
10:15-10:30	Welcome, Call to Order, and Consent Agenda
10:30-11:15	Executive Director's Report and Q3 Dashboard Review
11:15-11:45	Consider for Approval: Annual Budget FY 2016
11:45-12:15	Consider for Approval: Slate of Spring 2015 Broad Awards
12:15-1:15	Break
1:15-2:00	Stakeholder Perspectives: Health Plans *Moderator: Kerry Barnett, JD, Board Member* • *Lewis Sandy, MD:* Senior Vice President, Clinical Advancement – UnitedHealth Group • *Sam Nussbaum, MD:* Executive Vice President, Clinical Health Policy – Anthem, Inc.
2:00-2:30	Consider for Approval: Slate of Hepatitis C Awards
2:30-3:15	Consider for Approval: Targeted PCORI Funding Announcements (PFA) Development
3:15-3:30	Break
3:30-4:00	Methodology Committee Update
4:00-4:45	Evaluation Update: Results of Applicant Analyses
4:45-5:30	PCORnet Phase II
5:30-6:00	Public Comment
6:00	Wrap Up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Motion for Consent Agenda Items

- Approve minutes from August 18, 2015 Board meeting
- Approve nomination by the Governance Committee for Robin Newhouse, PhD, RN, to serve as Chair, and Steve Goodman, MD, MHS, PhD to serve as Vice-Chair of the Methodology Committee, each for a second term

Robin Newhouse, PhD, RN

Steven Goodman, MD, MHS, PhD

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent Agenda
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Executive Director's Report

Joe Selby, MD, MPH
Executive Director

Thank You, CSO Bryan R. Luce, PhD, MBA

- PCORI's first Chief Science Officer!
- Led PCORI through the growth of our science department, development of PCORI's targeted approaches to funding CER, and began PCORI's Strategic Portfolio Initiative
- Recognized the exciting opportunity we have at PCORI and brought that excitement to all he worked with
- His entire career (thus far!) has advanced the field of outcomes research and the application of reason and science to health services allocations and personal decisions

Thanks, Bryan!

Welcome to PCORI's new CSO

- We are honored to welcome Evelyn P. Whitlock, MD, MPH, as PCORI's new Chief Science Officer!
- Dr. Whitlock currently serves as Senior Investigator at the Center for Health Research and Senior Director of the Evidence-Based Practice Center at Kaiser Permanente Northwest
- Her career thus far shows tremendous commitment to evidence-based practice, clinical decision-making in preventative services, and furthering research in translational science
- We are confident Dr. Whitlock will be an invaluable leader towards PCORI's mission. We are excited to begin work with her in January 2016!


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IV or Oral Antibiotics for Children After Hospitalization for Serious Infections?
See how PCORI-funded research could help doctors and parents make more informed choices
READ MORE

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 RESEARCH FUNDERS

PCORI in the Literature

This collection of articles and opinion pieces provides insights into PCORI's work to advance patient-centered comparative clinical effectiveness research. The collection includes papers, articles, and commentaries written by researchers working on PCORI-funded projects and by PCORI staff, members of our Board of Governors and Methodology Committee, and others who are following our work.

PCORI is committed to the principle of transparency and openness in all of our work, including the sharing of information about our activities and the dissemination of research findings. We encourage authors to make their articles available without a subscription. In the list below, we provide links when articles are available without charge.

Results from PCORI-Funded Research Studies

Improving Lung Cancer Outcomes by Improving the Quality of Surgical Care

Raymond U. Osarogiagbon and Thomas A. D'Amico, "Improving Lung Cancer Outcomes by Improving the Quality of Surgical Care," *Translational Lung Cancer Research* 4(4) (August 2015).

View PCORI Study

Hypertension Disparities Reduction Awards

- ***A collaboration between the NIH (NHLBI, NINDS) and PCORI's Addressing Disparities program***
- Partnership Goals:
  1. Solicit comprehensive comparative effectiveness studies testing multi-level and multi-component interventions
  2. Promote strong patient and stakeholder engagement
  3. Identify effective approaches for reducing hypertension disparities in racial and ethnic minorities, low SES populations, and/or rural populations
- Total Funds Awarded: $23.5M

Awardees:

- ***Monika Safford, MD (University of Alabama):*** *"Collaboration to Improve Blood Pressure in the US Black Belt –Addressing the Triple Threat"*
- ***Lisa Cooper, MD (Johns Hopkins University):*** *"Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities"*

PCORI's Inaugural Annual Meeting:

"Progress in Building a Patient-Centered Comparative Clinical Effectiveness Research Community"

- **Dates**: October 6 - 8, 2015
- **Location**: Crystal Gateway Marriott Hotel, Arlington, VA
- Bringing together more than one thousand members of the PCORI community to update our stakeholders on research portfolio, discuss early results of completed studies, and address key issues in the dissemination / implementation of PCOR

Highlights

Tuesday, October 6	Wednesday, October 7	Thursday, October 8
• **Special Joint Session on Dissemination -** PCORI, AHRQ, AcademyHealth	• **Opening Plenary Session**: *The State of PCOR/CER Keynote Address*	• **Plenary Session**: *Data Access in Open Science*

See full schedule at: http://www.pcori.org/events/2015/pcori-annual-meeting

Dashboard Review
Third Quarter of FY 2015

Joe Selby, MD, MPH

Executive Director

Michele Orza, ScD

Senior Advisor to the Executive Director

Board of Governors FY2015 Dashboard – Q3 (As of 6/30/2015)

Increasing Useful Information

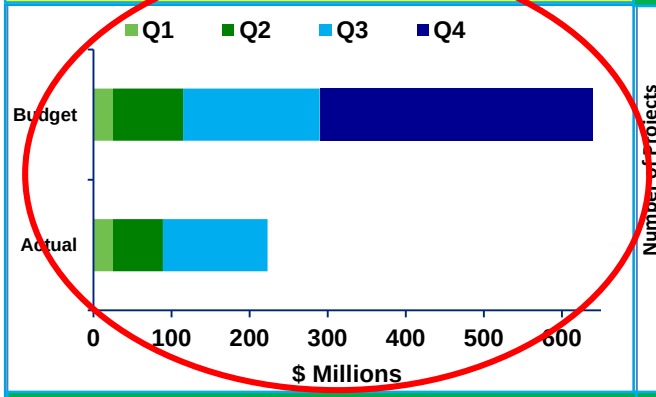
Results from 3 PCORI-funded studies: improving stroke outcomes important to patients, individualizing diabetes treatment, and less-invasive care for children with serious infections.

Our Goals: Increase Information, Speed Implementation, and Influence Research

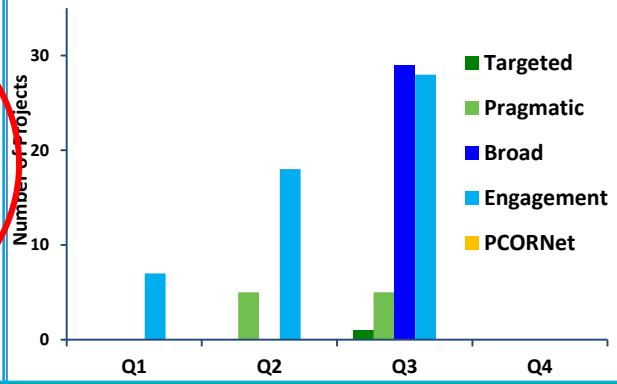
Legend

- On Target
- Off Target
- Needs Attention
- NA=Not Applicable
- Q4=Q4 2014
- Q1=Q1 2015
- Q2=Q2 2015
- Q3=Q3 2015

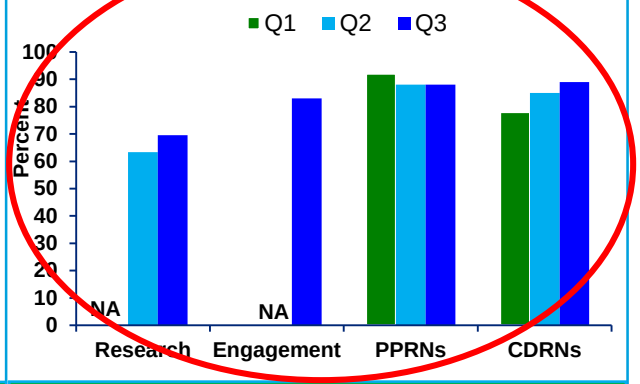
Funds Committed to Research – up to $640M



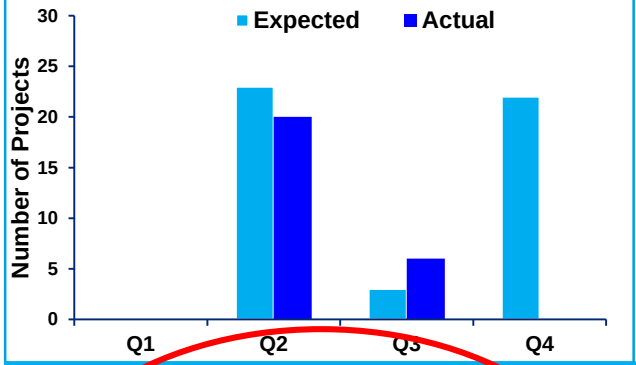
Projects Awarded



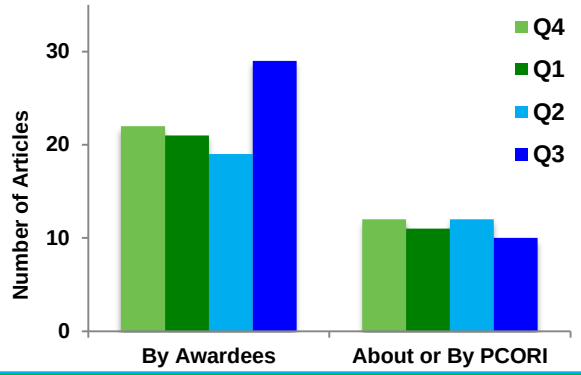
Percent of Projects on Track



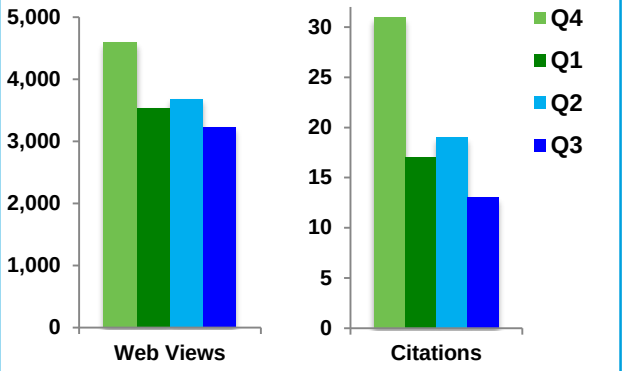
Projects Completed as Expected



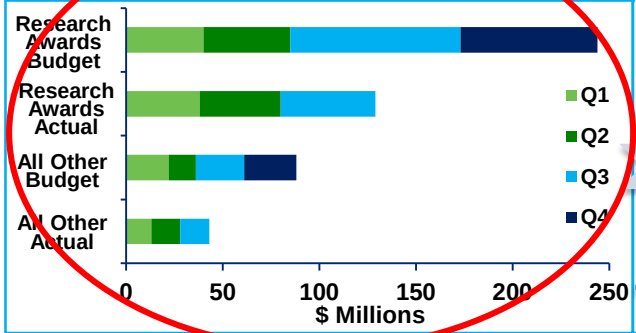
Journal Articles Published



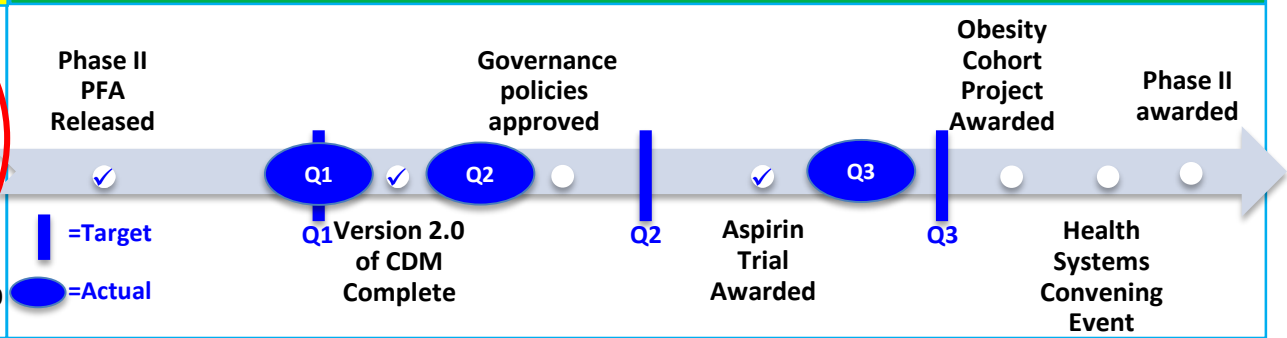
Uptake of Methodology Standards



Expenditures – Total Budget, up to $362M



Progress of PCORnet – Completion of Phase I



Demonstrating PCORI's Mission: Three Highlighted Studies

1. Assessing the Benefits and Harms of Alternative Approaches to Treatment

2. Individualized Prediction of Benefit – What Works for Whom?

3. Impact of Involving Patients on the Research Team

PCORI Study: Assessing Benefits/Harms of Alternative Treatments

Comparative Effectiveness of Intravenous v. Oral Antibiotic Therapy for Serious Bacterial Infections

Keren et al. JAMA Pediatr. 2015 Feb;169:120-8.

Ron Keren, MD, MPH

Children's Hospital of Philadelphia

PCORI Study: Assessing Benefits/Harms of Alternative Treatments

2012, Cycle 1, Assessment of Prevention, Diagnosis and Treatment Options award

Comparative effectiveness research of oral antibiotics vs. intravenous antibiotics via intravenous (PICC) line at hospital discharge for three different infections: (a) ruptured appendicitis, (b) complicated pneumonia, and (c) osteomyelitis.

Osteomyelitis Results: Antibiotic therapy with oral and PICC were equally effective for curing the primary infection, but PICC lines were associated with more adverse events (16% vs. 0%). Despite concerns about treating younger (<5) children or those with MRSA infections with oral antibiotics, stratified analysis showed that treatment failure rates were not meaningfully different.

"We found no advantage of the more invasive PICC route. Given the magnitude and gravity of the PICC-related complications, clinicians should reconsider… prolonged IV therapy when an effective oral alternative exists."

PCORI Study: Individualized Prediction of Benefit What Works for Whom?

Improving diabetes prevention with benefit based tailored treatment: risk-based re-analysis of Diabetes Prevention Program

Sussman JB et al. BMJ 2015:350: Feb. 19th

David Kent, MD, MS
Tufts University Medical Center
Sackler School of Graduate Biomedical Sciences

PCORI Study: Individualized Prediction of Benefit

2012, Pilot Project

Re-analysis of the Diabetes Prevention Program, a large randomized trial which showed that both lifestyle interventions and metformin lowered the risk for developing Type 2 diabetes in persons judged to be at increased risk for developing diabetes.

Results: The benefits of metformin were seen almost exclusively in patients in the topmost quarter of risk of diabetes; no benefit in lowest risk quarter. By contrast, the lifestyle intervention provided meaningful protection in all 4 quarters of risk.

"Patients at high risk for diabetes have substantial variation in their likelihood of receiving benefit from diabetes prevention treatments. Using this knowledge could decrease overtreatment and make prevention of diabetes far more efficient, effective, and patient centered."

PCORI Study: Impact of Involving Patients

Real world effectiveness of warfarin among ischemic stroke patients with atrial fibrillation: observational analysis from Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER) study.

Y Xian et al., BMJ 2015; 351:h3786

Adrian Felipe Hernandez, MD, MS

Duke University

PCORI Study: Impact of Involving Patients

Sept 2013, Cycle 3, Assessment of Prevention, Diagnosis and Treatment Options award

A set of observational comparative effectiveness studies to improve decision-making and patient-centered stroke outcomes in three therapeutic areas: statins, anti-coagulants and anti-depressants in elderly persons who have had an ischemic stroke.

Outcomes: Patient involvement shifted the primary outcome from typical cardiovascular endpoints to "home time: days spent at home during follow-up," quality of life, and death; secondary outcomes include all-cause readmission and disease-specific readmissions.

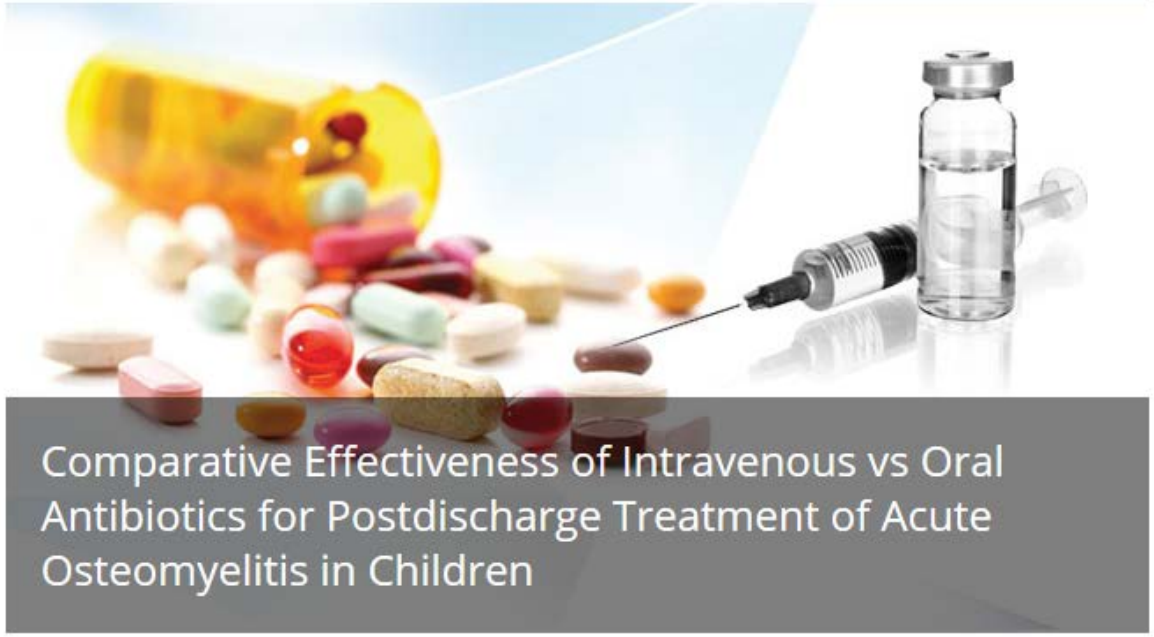
Results: Among 12,553 patients with atrial fibrillation after a stroke, those started on warfarin before discharge enjoyed 47 more days at home during up to two years of follow-up, as well as lower rates of recurrent stroke, MI, death.

"These findings support the routine use of warfarin for eligible ischemic stroke patients with atrial fibrillation, including those over 80 years of age, women, those with more severe strokes, and those with comorbid conditions."

Goal 2 Results: Early Indicators of Uptake of Information about Less-invasive Treatment of Serious Infections in Children

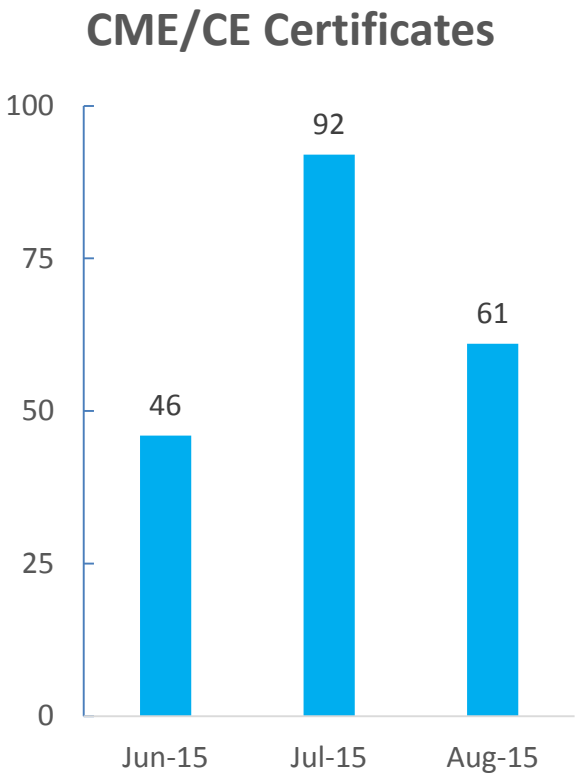
PCORI-Funded Continuing Education

First CME/CE program, launched Mid-June



This program is accredited for: Physicians, Physician Assistants, Nurse Practitioners, Pharmacists, Nurses, Case Managers, and Certified Health Education Specialists

Activity Type: Online | **Release Date:** May 26, 2015 | **Expiration Date:** June 14, 2016



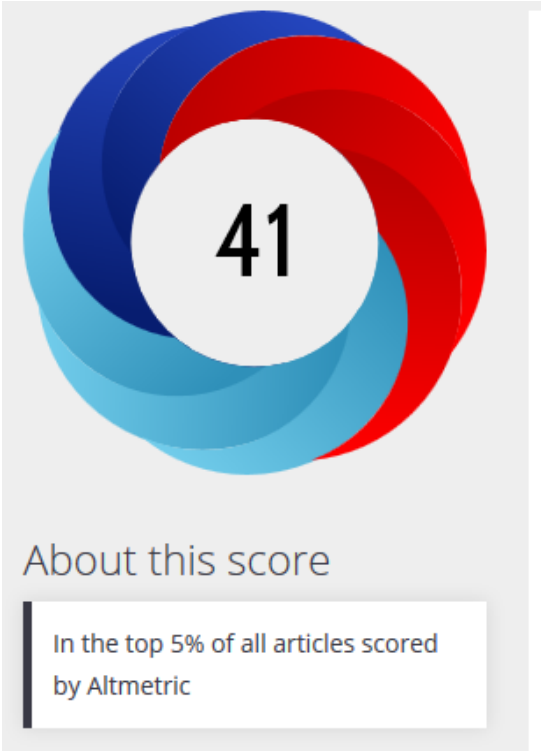
Ongoing Tracking to Include:
-CME/CE completion by specialty and subspecialty
-Enrollment by CME/CE activity

Example of Tracking Uptake and Use of Information: Less-invasive Treatment of Serious Infections in Children

Uptake: Altmetrics

Total Views	
9,974	7,190 Pageviews
	2,784 PDF Downloads

Since 12/1/2014



"Altmetric has tracked ***4,198,162 articles*** across all sources so far. Compared to these this article has done particularly well."

Use

According to the study's lead author, Dr. Ron Keren, the ***Pediatric Infectious Diseases Society*** is preparing a new practice guideline on bone and joint infections and is ***considering the findings of the PCORI study in developing its recommendations***.

We are following the development of these guidelines and other potential uses of the results of this study.

Goal 3 Results: Increased Support for PCOR at the University of Texas Health Science Center at San Antonio

At UTHSC San Antonio, PCORI is credited with motivating:*

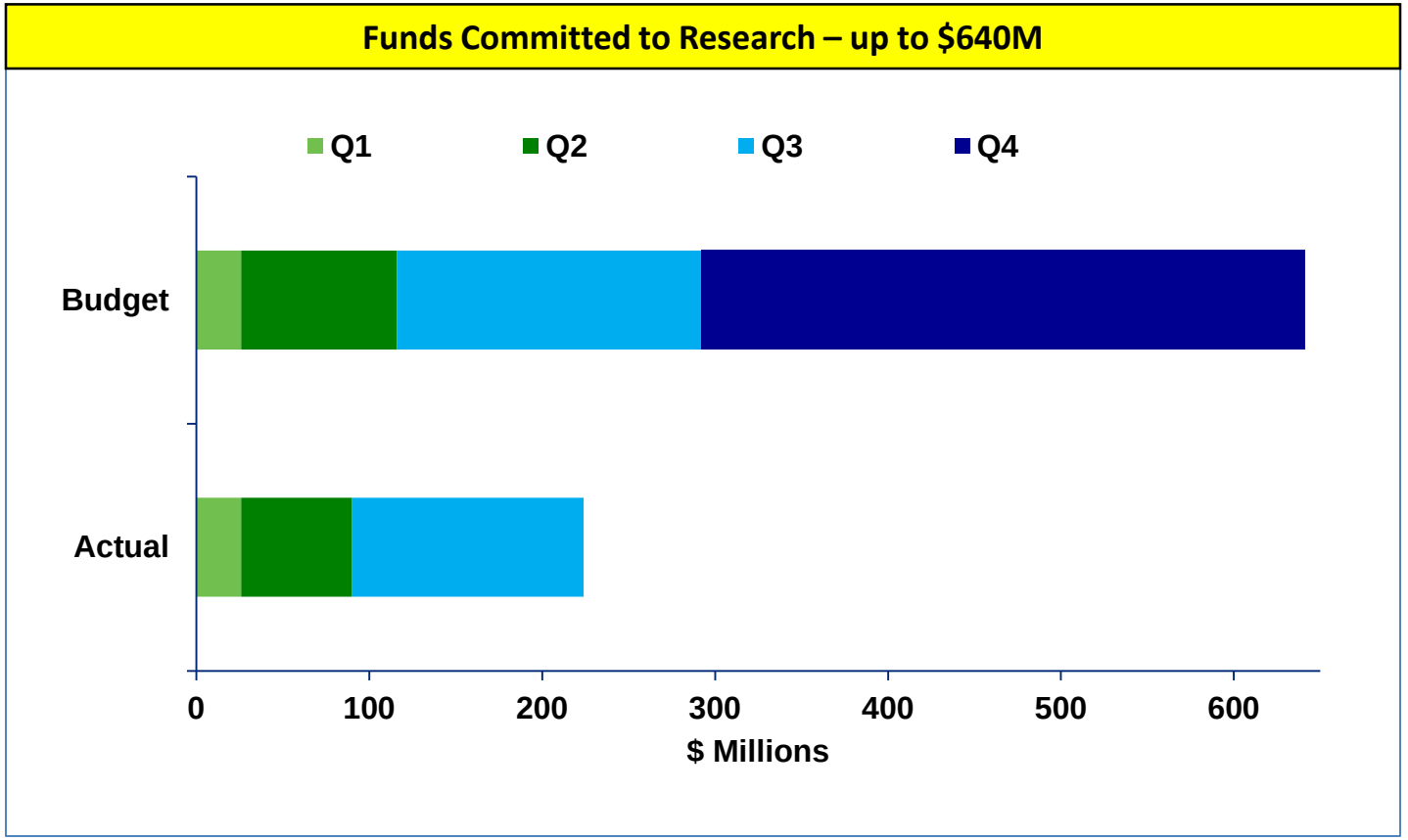
- **Workshops** on PCORI that resulted in
  - Listserv
  - Working group focused on PCORI applications (~130 investigators)
  - Day-long in-service on grant writing
- Clinical Investigator **Kick-start (CLIK) awards**
  - $50K, one year
  - Fund meaningful engagement with partners to increase knowledge about and skills in research engagement
- **New policies** to permit hiring patient or stakeholder partners as experts on university pay roll
- **Patient-centered approaches** to applications for research to other funders

"[PCORI's approach] has changed everything about the way the university thinks about research – a ripple effect I would not have anticipated."

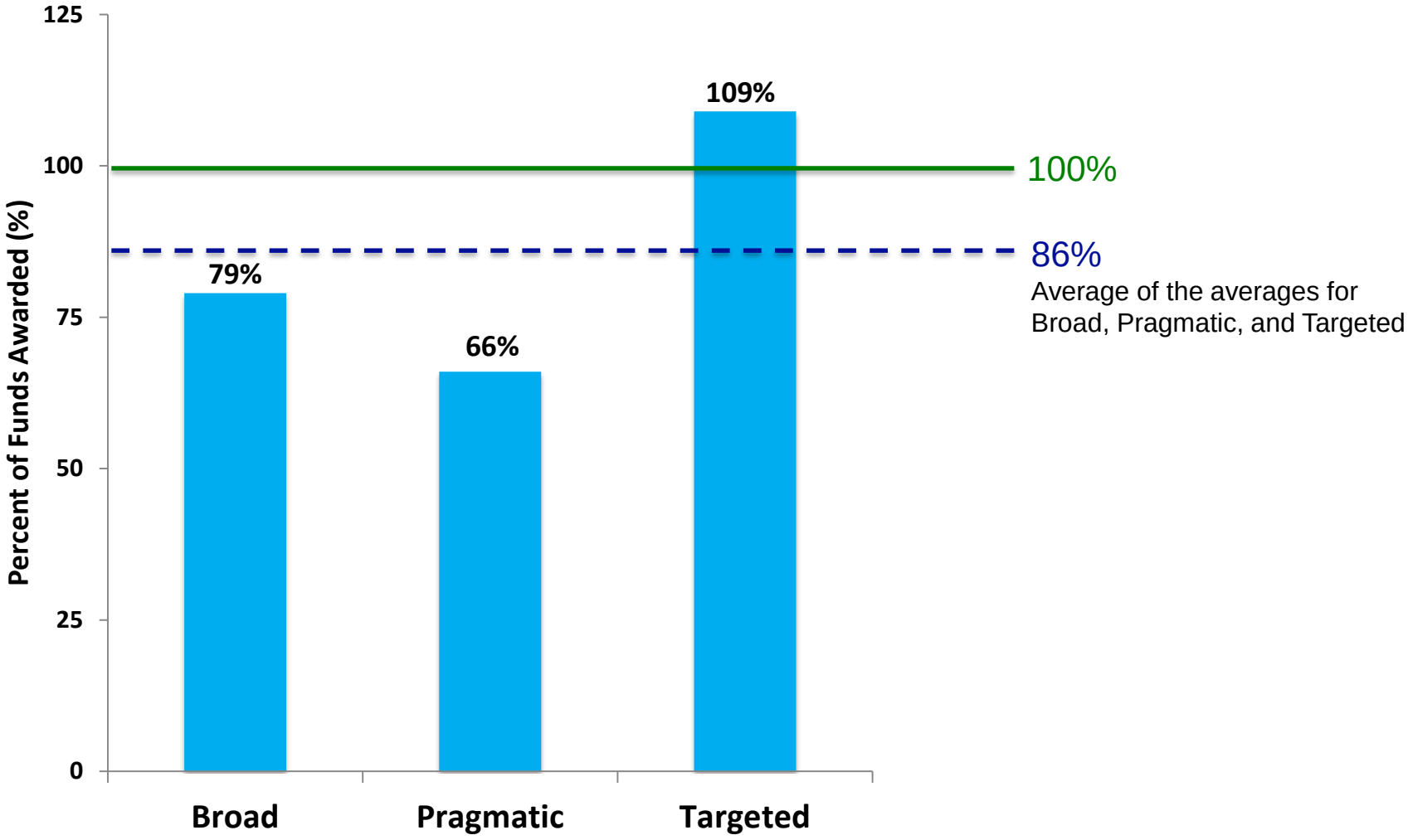
Dawn Velligan, PhD, MA, Professor and Chief of Community Recovery Research and Training

**Jennifer Potter, PhD, MPH, Assistant Dean for Research and Student Programs*

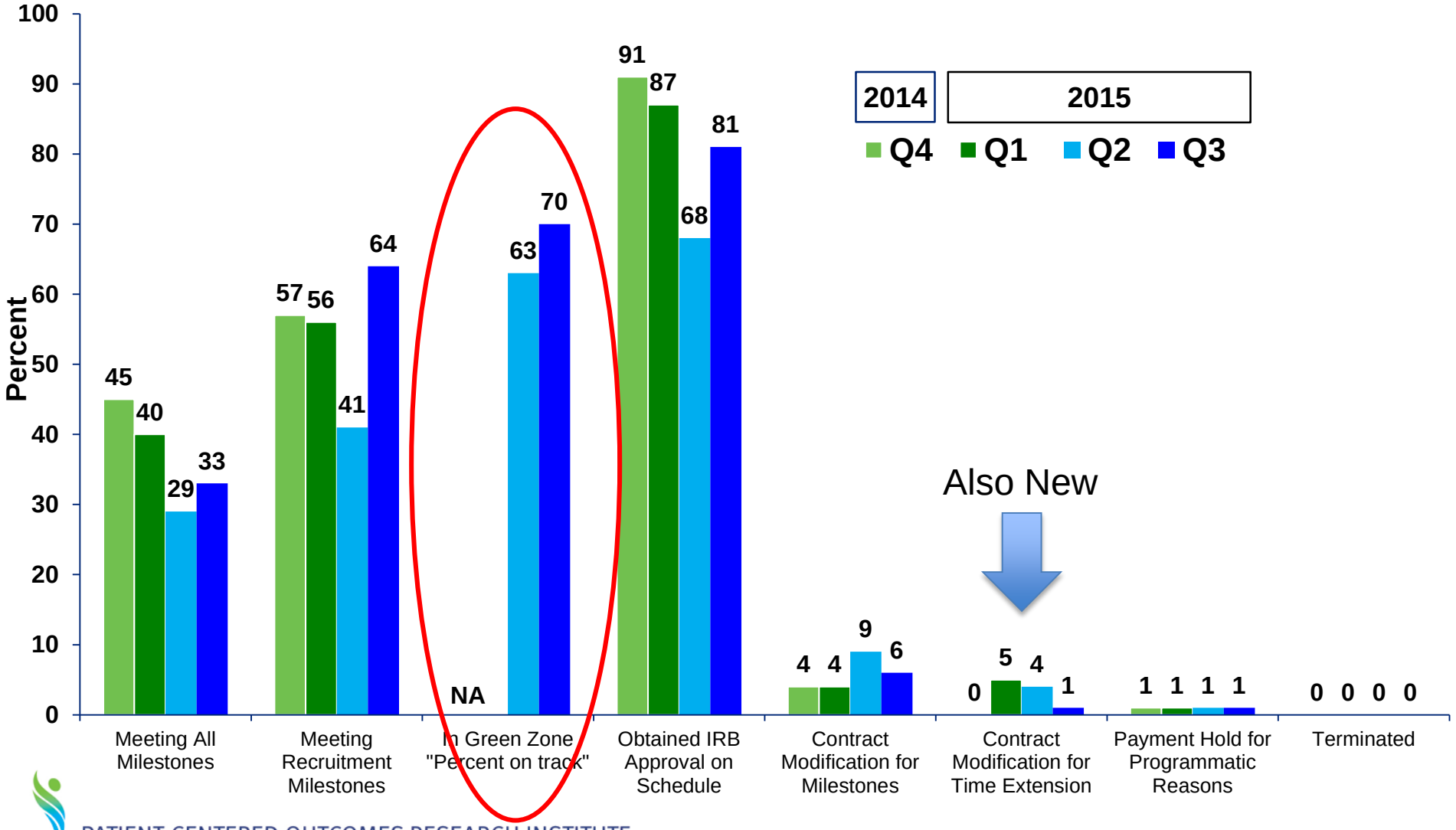
Funds Committed to Research and Research Infrastructure Projects: Q3 2015



Our Funding History: For Broad and Pragmatic studies, we award on average less funds than we announced in the PFA, for Targeted studies we award on average a bit more



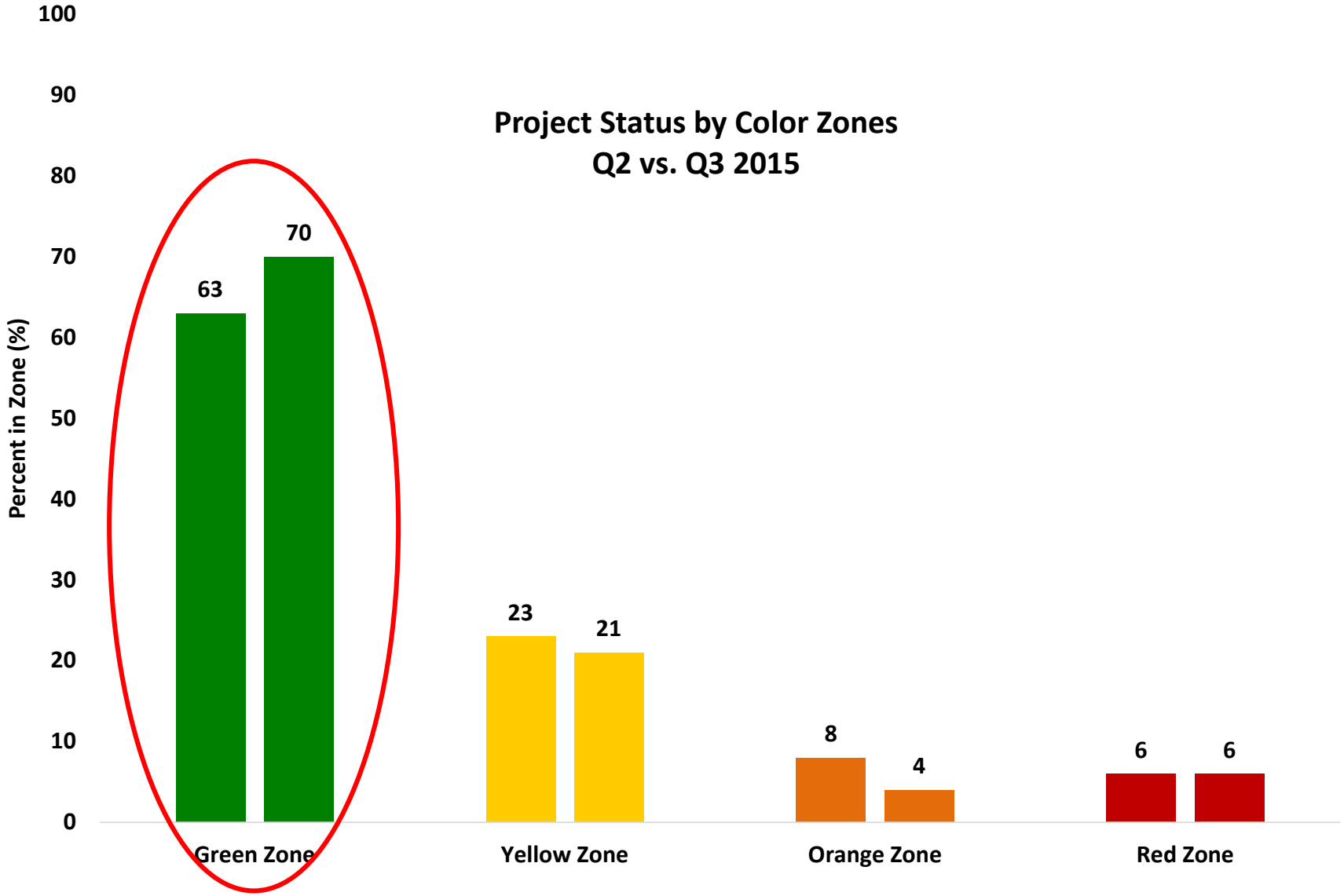
Measures of the Progress of Research Projects



New Metric in Development for Progress of Projects

GREEN	YELLOW	ORANGE	RED
≥75% Recruitment target	***<75% and ≥50% Recruitment***	***<50% and ≥25% Recruitment***	***<25%* Recruitment target**
-AND-	***-OR-***	***-OR-***	**-OR-**
≥ 85% All Milestones	**<85% and ≥65% Milestones**	**<65% and ≥50% Milestones**	**<50% All Milestones**
-AND-	***-OR-***	***-OR-***	**-OR-**
PO has confidence in project	PO has some concerns about project.	PO has serious concerns; Modifications to the Milestone Schedule are likely required.	PO has significant concerns; Major modifications to Milestone Schedule are required.
Next Steps			
Continue monitoring	**Increase communication**	**Pursue Modifications;** Increased communication	**Place project under review;** Draft Project Remediation Plan

New on Our Dashboard:
Percent of Projects on Track = Percent in Green Zone

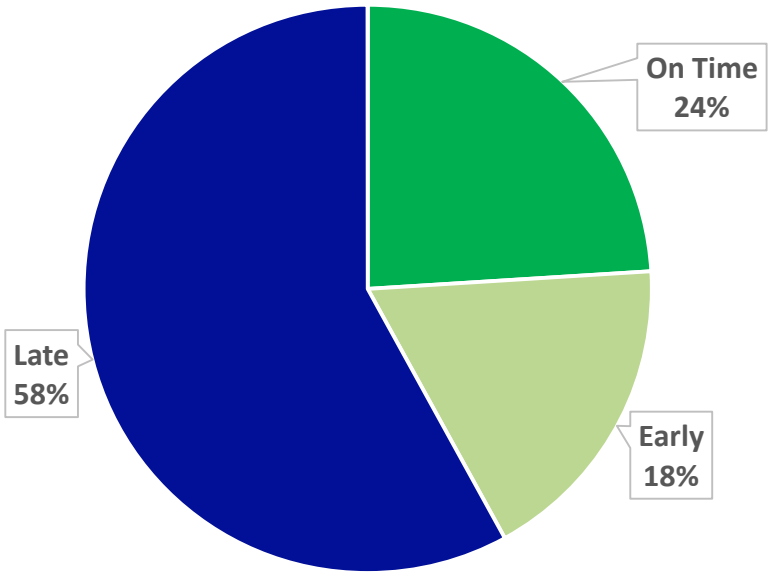


Because it is especially critical to the success of projects, we are focusing on recruitment

- Analysis of 190 projects that involve recruitment
- As of Q3:
  - 31 have not yet started recruiting
  - 136 are currently recruiting
  - 23 have finished recruiting

Did projects initiate recruitment on time?

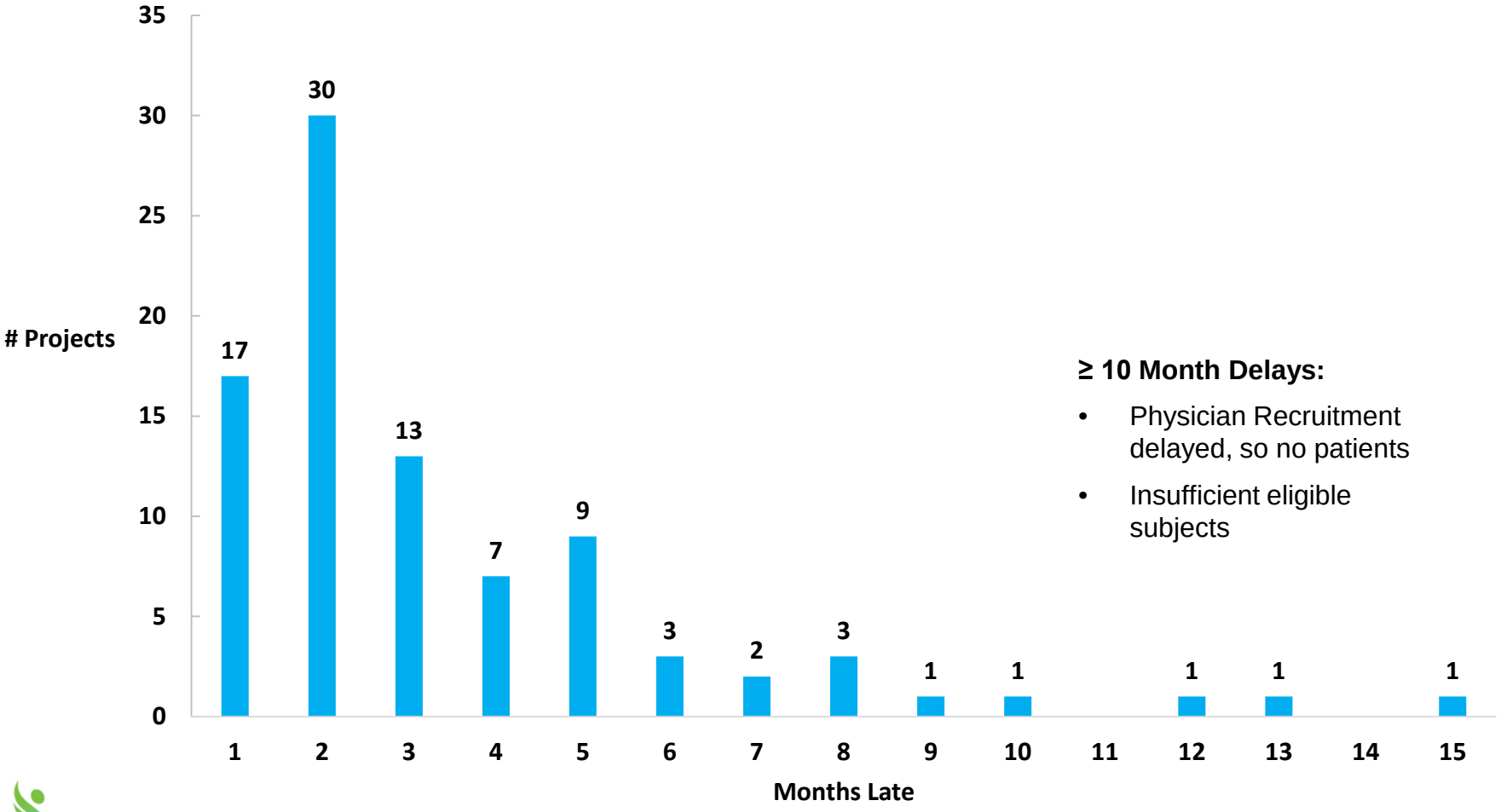
Timeliness of Recruitment Initiation



Reasons for Delayed Initiation

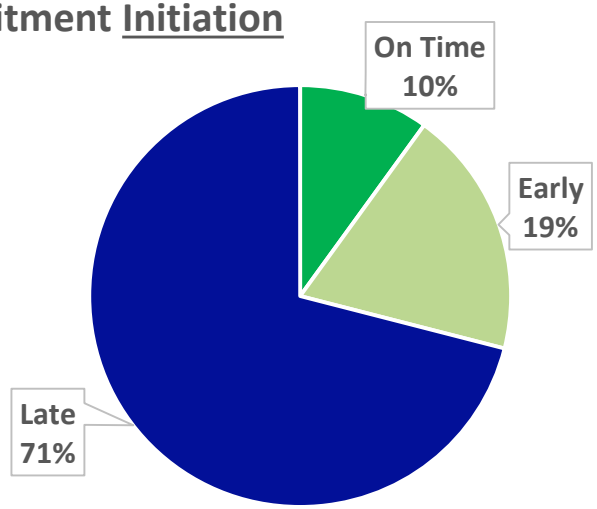
- Delay finalizing intervention
- IRB delays
- Sites withdrawing after randomization
- PI or staff changes, relocations
- Rescheduled or missed appointments
- Restrictive enrollment criteria
- Seasonal issues (asthma symptoms, record snowfall)

By how long were studies delayed in initiating recruitment?

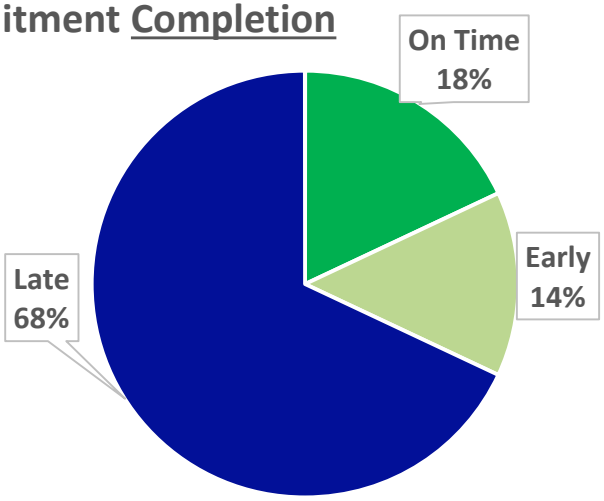


Patterns among studies that have completed recruitment

Timeliness of Recruitment Initiation



Timeliness of Recruitment Completion



Recruitment Initiation \ Recruitment Completion	Early or On Time	Late
Early or On Time	9%	19%
Late	24%	48%

Time

- 57% Stay in same timeliness category
- 24% Start late but “Catch up”
- 19% Start on time but end late

Discussion Questions

- Does this set of metrics and analyses tell you what you want to know about the progress of our projects?
- What other questions do you have?

Board of Governors FY2015 Dashboard – Q3 (As of 6/30/2015)

Increasing Useful Information

Results from 3 PCORI-funded studies: improving stroke outcomes important to patients, individualizing diabetes treatment, and less-invasive care for children with serious infections.

Our Goals: Increase Information, Speed Implementation, and Influence Research

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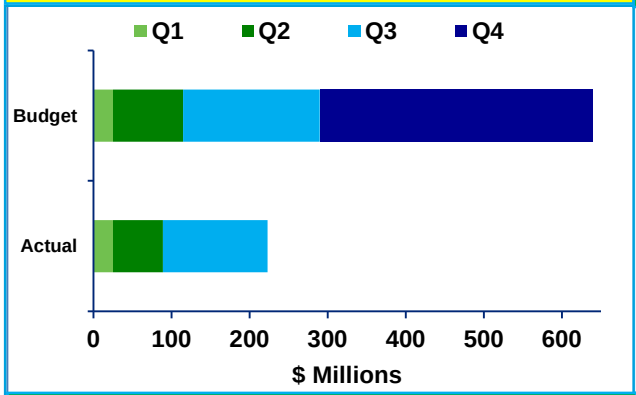
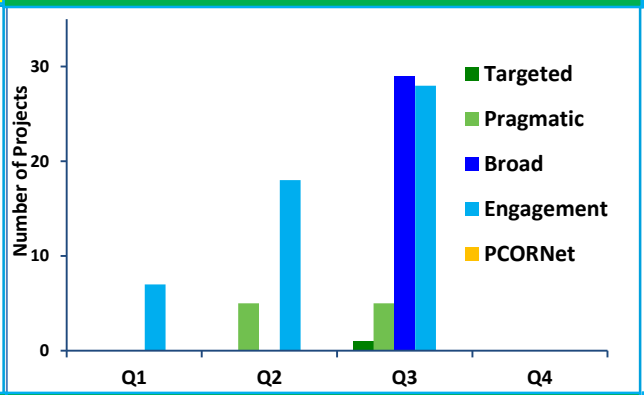
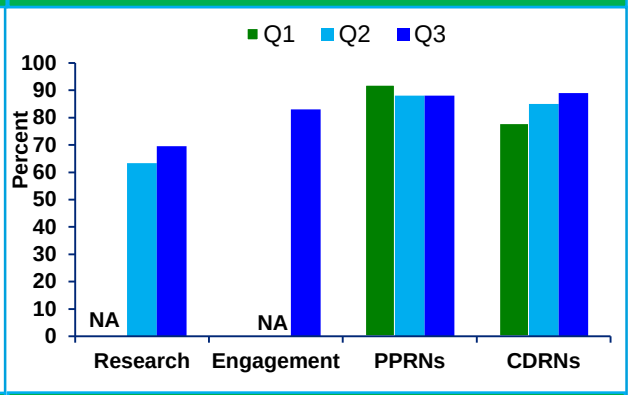
Funds Committed to Research – up to $640M



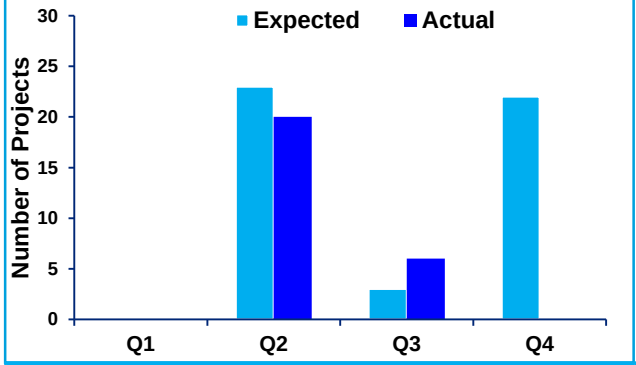
Projects Awarded



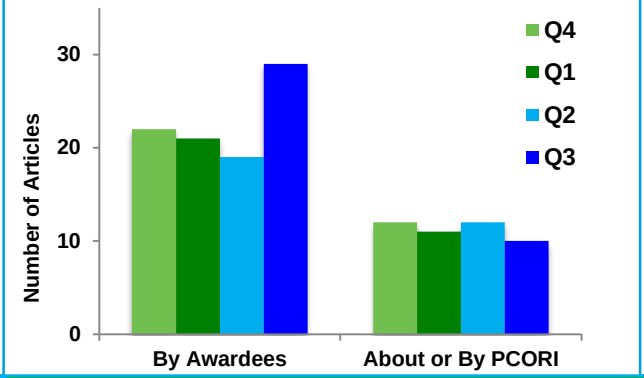
Percent of Projects on Track



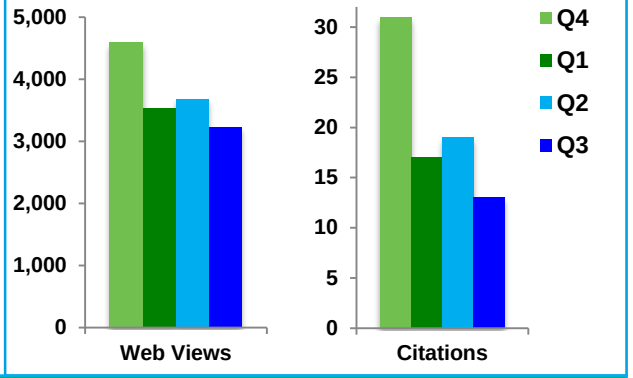
Projects Completed as Expected



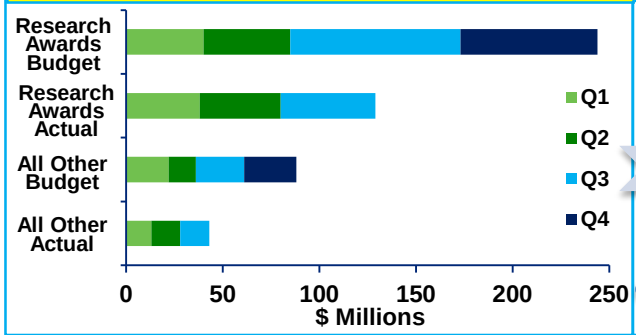
Journal Articles Published



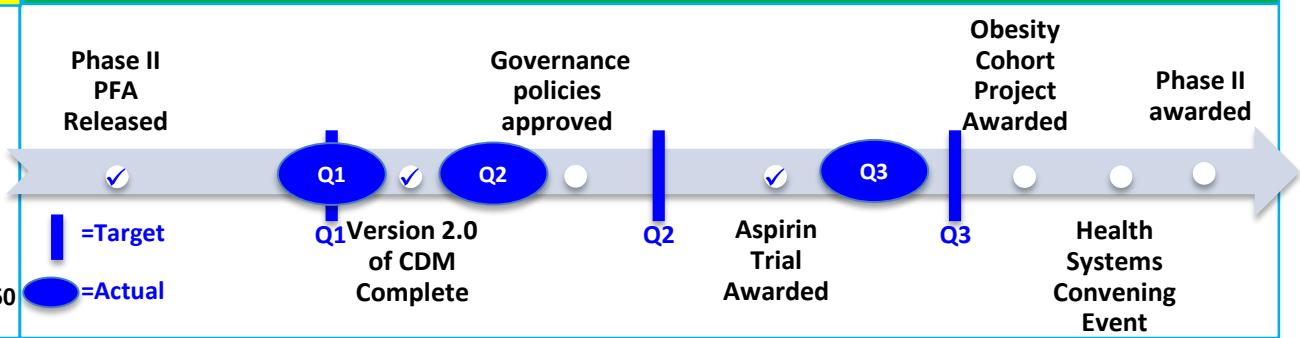
Uptake of Methodology Standards



Expenditures – Total Budget, up to $362M



Progress of PCORnet – Completion of Phase I



Proposed FY2016 Budget
(October 1, 2015-September 30, 2016)

Larry Becker
Chair, Finance and Administration Committee
Regina Yan
Chief Operating Officer

Agenda

- Key Definitions
- Budget Development Process
- FY2016 Budget
  - Proposed FY2016 Budget
  - FY2015 Approved Budget v. FY2016 Proposed Budget
  - FY2015 Projection v. FY2016 Proposed Budget
- Award Commitments
  - Revenue v. Expense
  - Funding Commitment Plan
  - FY2016 Research and Infrastructure Award Commitments by Funding Category
  - Award Commitments v. Award Expenses
- Cash Balances
  - Projected FY2015
  - Projected FY2016
- Staffing Plan
  - FY2016 Proposed Staffing Plan
- Motion to approve

Key Definitions

Award Commitments – the amount of funding PCORI intends to award or has awarded, most in the form of multi-year contracts for research, infrastructure, and engagement awards.

Award Expenses – the amount PCORI pays to research, infrastructure, and engagement/dissemination awardees in response to invoices received for costs incurred under awarded contracts.

- Note: Award commitments occur earlier than award expenses and are higher in earlier years. Award expenses lag award commitments and are spread over multiple years.

Program Support – all operating costs associated with Science, Engagement/Dissemination, and Contract Management departments

Budget Development Process

PCORI's budget is developed through a comprehensive process grounded in its strategic plan

Board Approves Strategic Plan and 2013-2015 Priority Activities ***(November 2013)***

Board Reviews Strategic Plan and 2016-2018 Priority Activities ***(February 2015)***

PCORI Staff Drafts and Refines Operating Plans and Budgets based on Priority Activities ***(Spring/Summer 2015)***

Committee-Level Review of Key Activities, Proposed Budget and Staffing Requests ***(Summer 2015)***

Proposed FY2016 Budget Brought to Board for Approval ***(September 28, 2015)***

Proposed FY2016 Budget

Revenue	$	491,200,000	
Award Expense			
Research Awards		246,807,550	
Infrastructure (PCORnet)		73,000,000	
Engagement Awards		11,718,750	
		331,526,300	78%
Program Support			
Methodology Committee		1,636,000	
Science/Program Development & Evaluation		32,592,650	
Engagement & Dissemination		12,148,203	
Contracts Management		6,674,025	
		53,050,878	13%
Administrative Support			
Board of Governors/Governance		1,085,000	
Management and General		37,819,122	
		38,904,122	9%
Total Expenses		423,481,300	100%
Net Income *	$	67,968,700	

* Net Income includes $250,000 of interest earned in PCOR Trust Fund

Budget: FY2015 Approved v. FY2016 Proposed

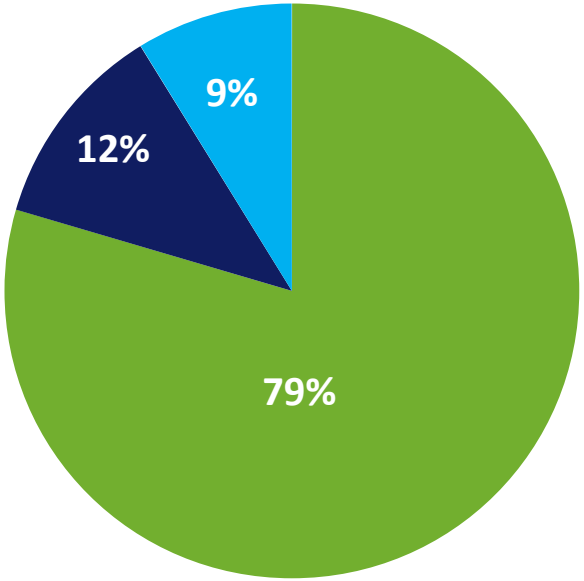
	2015 Budget		2016 Budget		FY15 Bud. v FY16 Bud. $ Var	% Var
Revenue	$ 462,800,000		$ 491,200,000		$ 28,400,000	6%
Award Expense						
Research Awards	212,050,000		246,807,550		34,757,550	16.39%
Infrastructure (PCORnet)	52,000,000		73,000,000		21,000,000	40.38%
Engagement Awards	7,856,381		11,718,750		3,862,369	49.16%
	271,906,381	75%	331,526,300	78%	59,619,919	21.93%
Program Support						
Methodology Committee	2,275,000		1,636,000		(639,000)	-28.09%
Science/Program Development & Evaluation	34,857,973		32,592,650		(2,265,323)	-6.50%
Engagement & Dissemination	11,529,494		12,148,203		618,709	5.37%
Contracts Management	11,307,062		6,674,025		(4,633,037)	-40.97%
	59,969,529	17%	53,050,878	13%	(6,918,650)	-11.54%
Administrative Support						
Board of Governors/Governance	1,250,000		1,085,000		(165,000)	-13.20%
Management and General	28,388,398		37,819,122		9,430,724	33.22%
	29,638,398	8%	38,904,122	9%	9,265,724	31.26%
Total Expenses	361,514,308	100%	423,481,300	100%	61,966,993	17.14%
Net Income *	**$ 101,610,692**		**$ 67,968,700**		**$ (33,641,993)**	-33.11%

* **Net Income includes, for FY2015 $325,000 and for FY2016 $250,000 of interest earned in PCOR Trust Fund.**

Budget: FY2015 Projection v. FY2016 Proposed

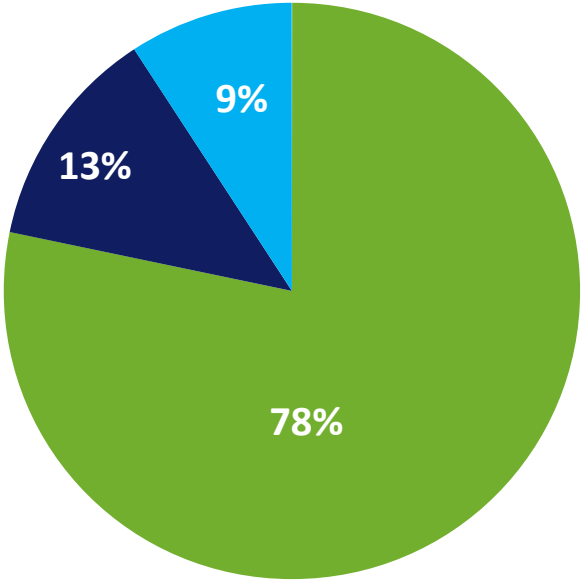
While the budget grows, the proportion of costs remains about the same

FY2015 Projection – Expenses $312 Million



- Research, Infrastructure (PCORnet) and Engagement Expense ($248M)
- Program Support ($36M)
- Administrative ($28M)

FY2016 Proposed Budget – Expenses $423 Million



- Research, Infrastructure (PCORnet) and Engagement Expense ($331M)
- Program Support ($53M)
- Administrative ($39M)

Budget: FY2015 Projection v. FY2016 Proposed

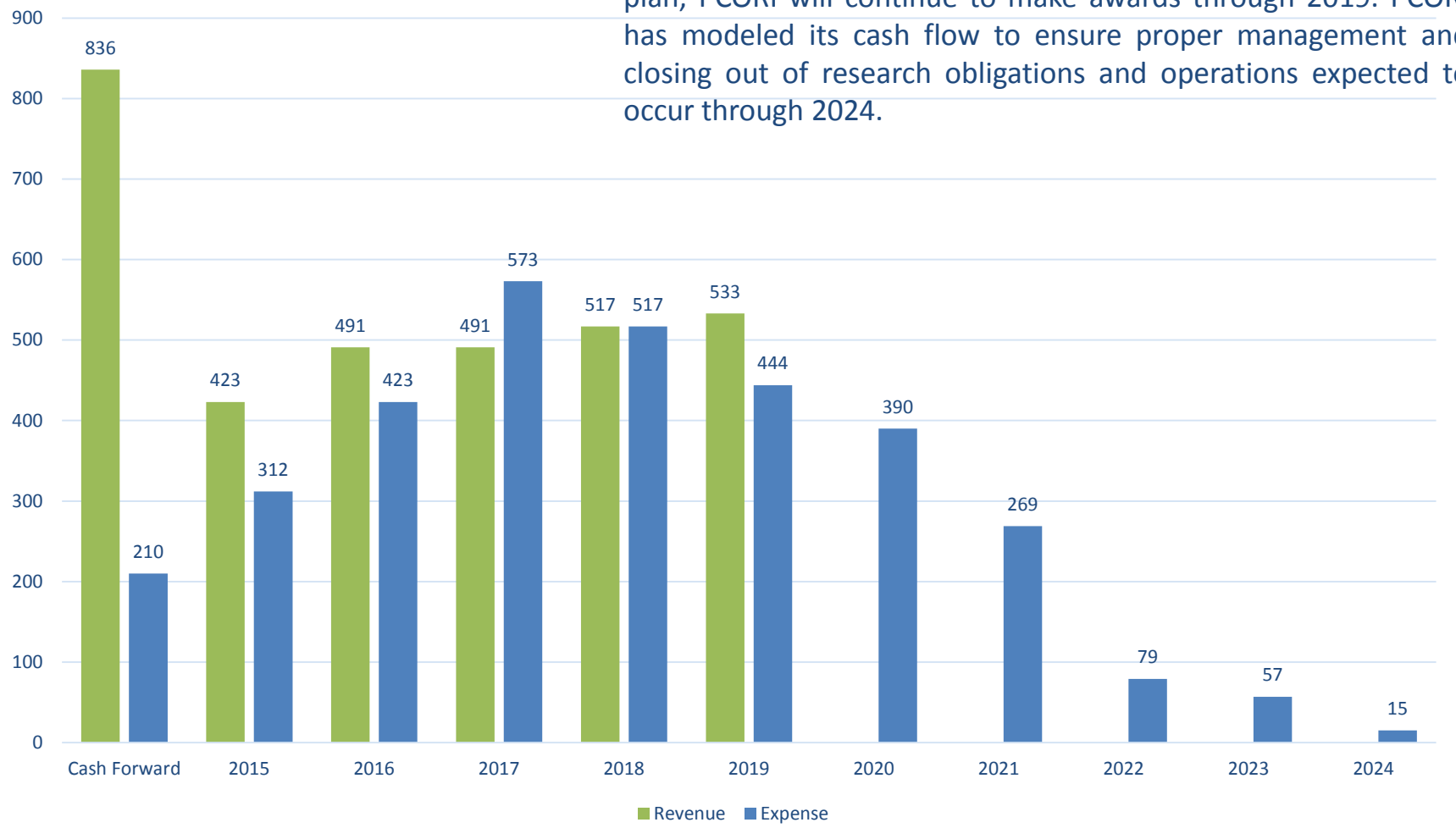
Patient-Centered Outcomes Research Institute
FY2015 Projections v FY2016 Proposed Budget

	2015 Projection		2016 Budget		FY15 Proj. v FY16 Bud. $ Var	% Var
Revenue	$ 422,893,090		$ 491,200,000		$ 68,306,910	16.2%
Award Expense						
Research Awards	201,150,000		246,807,550		45,657,550	22.7%
Infrastructure (PCORnet)	46,000,000		73,000,000		27,000,000	58.7%
Engagement Awards	1,250,000		11,718,750		10,468,750	837.5%
	248,400,000	80%	331,526,300	78%	83,126,300	33.5%
Program Support						
Methodology Committee	463,000		1,636,000		1,173,000	253.3%
Science/Program Development & Evaluation	21,001,000		32,592,650		11,591,650	55.2%
Engagement & Dissemination	8,492,890		12,148,203		3,655,313	43.0%
Contracts Management	6,296,500		6,674,025		377,525	6.0%
	36,253,390	12%	53,050,878	13%	16,797,488	46.3%
Administrative Support						
Board of Governors/Governance	1,149,350		1,085,000		(64,350)	-5.6%
Management and General	26,365,847		37,819,122		11,453,275	43.4%
	27,515,197	9%	38,904,122	9%	11,388,925	41.4%
Total Expenses	312,168,587	100%	423,481,300	100%	111,312,713	35.7%
Net Income *	**$ 110,924,503**		**$ 67,968,700**		**$ (42,955,804)**	-38.7%

*** Net Income includes in FY2015 $200,000 and in FY2016 $250,000 interest earned in PCOR Trust Fund**

Revenue v. Expense

Per the Board's adoption in 2013 of the funding commitment plan, PCORI will continue to make awards through 2019. PCORI has modeled its cash flow to ensure proper management and closing out of research obligations and operations expected to occur through 2024.



Funding Commitment Plan:
FY2012-FY2019

COMMITMENT PERIOD ($ in Millions)				
FISCAL PERIOD	RESEARCH	INFRASTRUCTURE (PCORnet)	ENGAGEMENT/ DISSEMINATION	TOTAL
Prior	$324			324
FY 2014	254	$ 94*	$4	352
FY 2015	385	142	21	548
FY 2016	515	39	25	579
FY 2017	356		25	381
FY 2018	235		25	260
FY 2019	85		25	110
	$2,154	$275	$125	$2,554
	84%	11%	5%	100%

*FY2014 Infrastructure does not include $11 million service agreement awarded for the PCORnet Coordinating Center: Phase 1.

Funding Commitment Plan

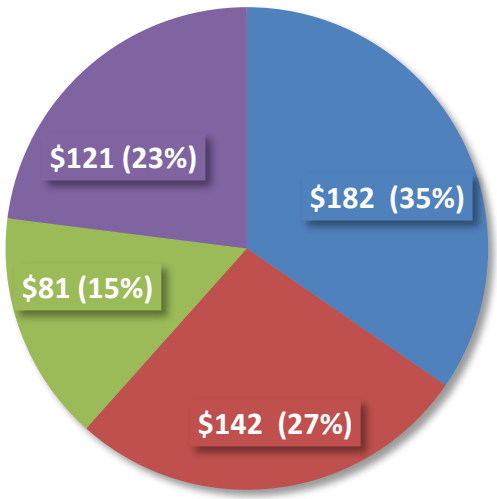
At the end of FY2016, PCORI plans to have committed 71% of its total award commitments funds of $2.554 B

COMMITMENTS ($ in Millions)	Prior	FY2015 Projection	FY2016 Proposed	Cumulative as of Sept 30, 2016
Research awards	$578	$385	$515	$1,478
Infrastructure (PCORnet) awards	94	142	39	275
Engagement and Pipeline to Proposal awards	4	21	25	50
Total commitments	**$676**	**$548**	**$579**	**$1,803**

FY2016 Research and Infrastructure Award Commitments by Funding Category

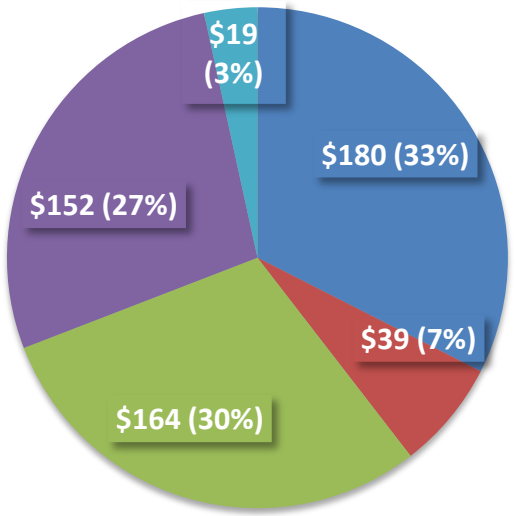
Funding for pragmatic studies and targeted awards increased from 50% in FY2015 to 63% in FY2016

FY2015 Projected
$527 Million



Pragmatic Studies
Infrastructure(PCORnet)
Targeted Funding
Broad Funding

FY2016 Proposed Budget
$554 Million

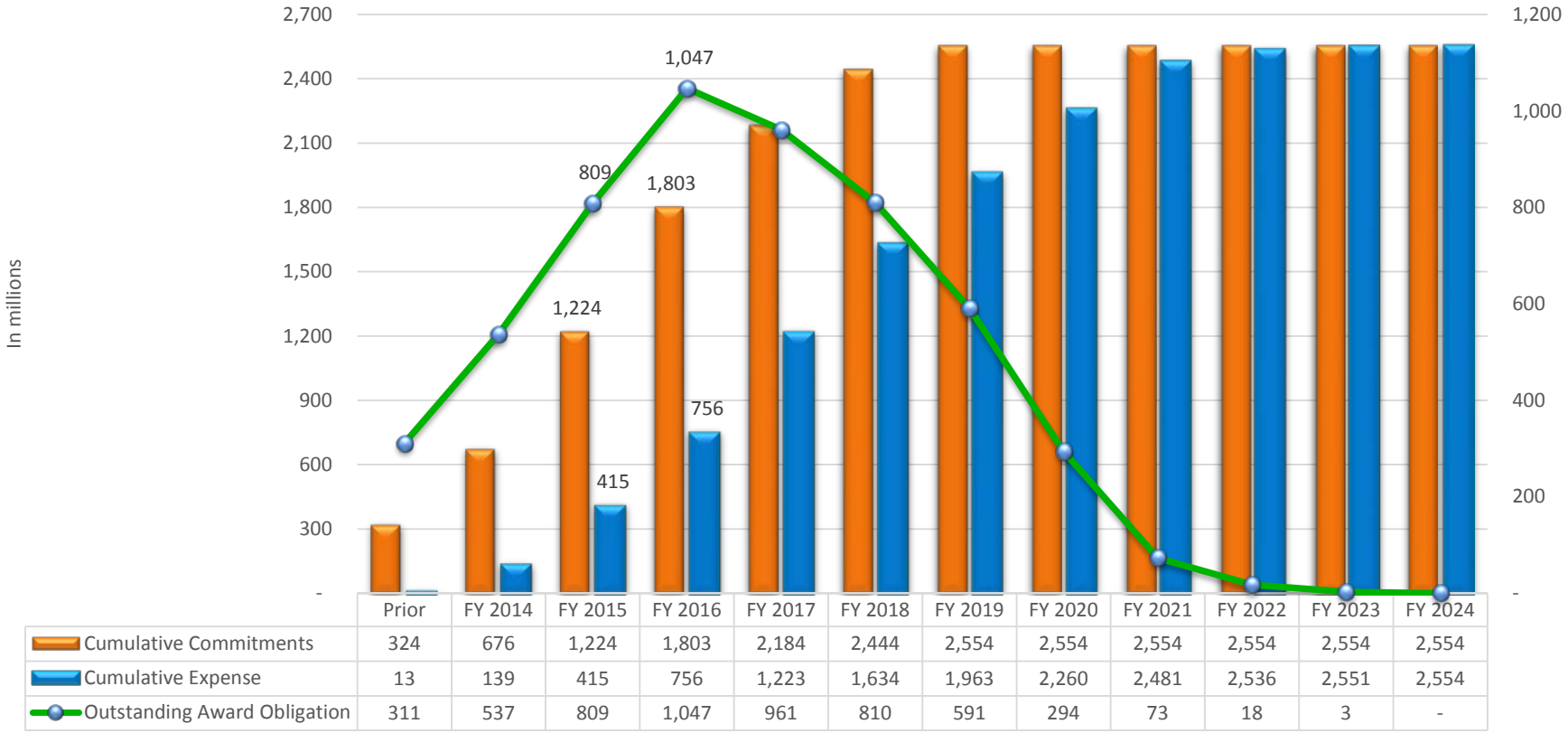


Pragmatic Studies
Infrastructure
Targeted Funding
Broad Funding
Other

This slide is intended to show the breakdown of Research and Infrastructure awards only. Accordingly, Engagement Awards are not included.

Cumulative Award Commitments v. Award Expenses

$2.5 billion will be committed by 2019. Expenses will continue through 2024 until all projects are completed



	Prior	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Cumulative Commitments	324	676	1,224	1,803	2,184	2,444	2,554	2,554	2,554	2,554	2,554	2,554
Cumulative Expense	13	139	415	756	1,223	1,634	1,963	2,260	2,481	2,536	2,551	2,554
Outstanding Award Obligation	311	537	809	1,047	961	810	591	294	73	18	3	-

Projected FY2015 Cash Balances

CASH FLOW ($ in Millions)	
Cash balance on October 1, 2014	**$626**
Cash receipts (FY2015)	423
Cash disbursements (FY2015)	(312)
Cash balance on[1] September 30, 2015	**$737**
Outstanding Award Obligation – September 30, 2015	**$809**

[1]Includes funds in the operating accounts and PCORTF

Projected FY2016 Cash Balances

CASH FLOW ($ in Millions)	
Cash balance on October 1, 2015	**$737**
Cash receipts (FY2016)	491
Cash disbursements (FY2016)	(423)
Cash balance on[1] September 30, 2016	**$805**
Outstanding Award Obligation – September 30,2016	**$1,047**

[1]Includes funds in the operating accounts and PCORTF

FY2016 Proposed Staffing Plan

Additional positions for new activities

PROGRAM/DEPARTMENT	FY2015 Approved Staffing	FY2016 Proposed Positions	Total Positions
PROGRAM SUPPORT			
Science	101	16	117
Engagement and Dissemination	27	6	33
Contracts Management and Administration	21	3	24
Management and General			
Administrative	75	8	83
Total employee FTE count	224*	33	257

*This includes 7 additional positions approved by the Executive Director during FY2015 based on an emerging need of work to be addressed. Cost for these positions was within the approved FY2015 budget.

Board Vote

Call for a Motion to:	• **Approve** the proposed FY 2016 budget
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Slate of Spring 2015 Broad Awards

Christine Goertz, DC, PhD
Chair, Selection Committee

Bryan Luce, PhD, MBA
Chief Science Officer

Broad Spring 2015 Cycle

Merit Review Criteria

Broad PFAs (except Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
1. ***Impact of the condition on the health of individuals and populations**** 2. ***Potential for the study to improve healthcare and outcomes**** 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement	1. ***Impact on the field of PCOR methods**** 2. ***Potential for the study to improve PCOR methods**** 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement

Slate Overview—Broad Spring 2015 Cycle

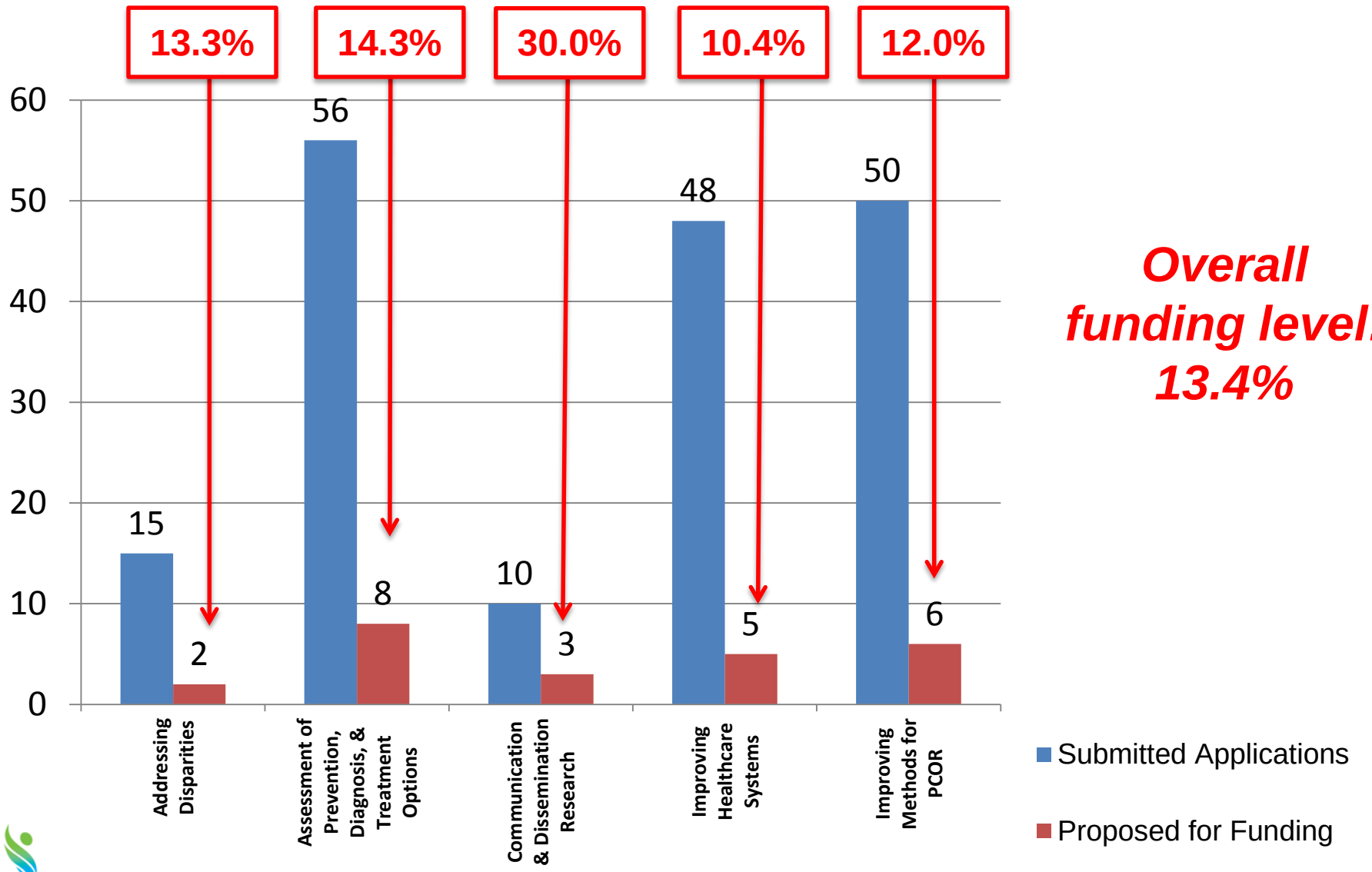
Process Overview

- 483 Letters of Intent (LOIs) submitted
- 227 LOIs invited to submit a full application (47% of all LOIs)
- We are proposing to fund 24 applications* out of 179 responsive applications (13.4%)

*Recommended by the Selection Committee

Broad Spring 2015 Cycle

What Percentage of Applicants are We Proposing to Fund?



Overall funding level: 13.4%

Slate Overview – Broad Spring 2015 Cycle

Resubmissions and funding rates

- 23.2% (112) of submitted Letters of Intent (LOIs) were resubmissions
  - 22.5% (51) of LOIs invited to submit an application were resubmissions
- 21.2% (38) of applications submitted were resubmissions
- 37.5% (9) of applications recommended for funding were resubmissions

Conditions

Broad Spring 2015 Cycle

16 of 24 proposed projects address one of the following Disease/Conditions

Disease/Condition	Number of Projects (mutually exclusive)
Rare Diseases	3
Cancer	3
Mental/Behavioral Health	3
Nutritional and Metabolic Disorders	1
Allergies and Immune Disorders	1
Cardiovascular Health	1
Kidney Disease	1
Muscular and Skeletal Disorders	1
Neurological Disorders	1
Reproductive and Perinatal Health	1

PCORI Populations of Interest

Broad Spring 2015 Cycle

21 of the 24 proposed projects address at least 1 *PCORI Population of Interest*

PCORI Population of Interest	Number of Projects (not mutually exclusive)
Older Adults	8
Racial and Ethnic Minorities	7
People with Low Incomes	7
Women	6
People with Multiple Chronic Conditions	5
People with Rare Disease	3
Children	3
People with Low Health Literacy	2
People with Disabilities	2
People Living in Rural Areas	1
People Living in Urban Areas	1

Open Funding Opportunities

Broad Spring 2015 Cycle

Broad PFA	Maximum Project Length	Maximum Direct Costs Allowed	Total Budget
Addressing Disparities	3 years	$1.5 Million	$8 Million*
Assessment of Prevention, Diagnosis and Treatment Options	3 years	$2 Million	$32 Million*
Communications and Dissemination Research	3 years	$1.5 Million	$8 Million*
Improving Healthcare Systems	3 years	$1.5 Million (small)	$16 Million*
	5 years	$5 Million (large)	
Improving Methods for Conducting Patient-Centered Outcomes Research	3 years	$750,000	$12 Million

*Additional funds available for rare disease-focused projects: $12 Million

Addressing Disparities

*2 Recommended Projects**

Project Title
Addressing Racial Disparities in Implantable Cardioverter Defibrillator Therapy Via Innovative Designs (VIVID)
Reducing Health Disparities in Unintended Pregnancies Among Hispanic Adolescents Using a Patient-Centered Computer-Based Clinic Intervention

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.
Resubmissions in bold

Assessment of Prevention, Diagnosis, and Treatment Options

*8 Recommended Projects**

Project Title
Comparative Effectiveness of Metabolic and Bariatric Surgery Using Patient-Reported Outcome Measures (PROMs)
Optimizing the Effectiveness of Routine Post-treatment Surveillance in Prostate Cancer Survivors
Comparative Effectiveness of Therapy in Rare Diseases: Liver Transplantation vs. Conservative Management of Urea Cycle Disorders**
Posterior Fossa Decompression with or without Duraplasty for Chiari Type I Malformation with Syringomyelia**
Comparative Effectiveness and Safety of Inhaled Corticosteroids and Antimicrobial Compounds for Non-Cystic Fibrosis Bronchiectasis**
Comparing the Effectiveness of Guideline-Concordant Care to Active Surveillance for Ductal Carcinoma in Situ (DCIS): an Observational Study
Rivaroxaban vs. Low-Molecular Weight Heparin or Coumadin for Treatment of Venous Thromboembolism (VTEs) in Cancer Patients
Discontinuation of Disease Modifying Therapies (DMTs) in Multiple Sclerosis (MS)

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

**Rare Disease Application

Resubmissions in bold

Communication and Dissemination Research

*3 Recommended Projects**

Project Title
Navigating High-Risk Surgery: Empowering Older Adults to Ask Questions that Inform Decisions about Surgical Treatment
Enhancing Patient Ability to Understand and Utilize Complex Information Concerning Medication Self-management
Comparative Effectiveness of Decision Support Strategies for Joint Replacement Surgery

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Improving Healthcare Systems

*5 Recommended Projects**

Project Title
3D Team Care for Cognitively Vulnerable Older Adults
Acute Community Care to Avoid Unnecessary Emergency Department Visits
Using a Teachable Moment Communication Process to Improve Outcomes of Quitline Referrals
Enhancing the Cardiovascular Safety of Hemodialysis Care: A Cluster-randomized, Comparative Effectiveness Trial of Multimodal Provider Education and Patient Activation Interventions
Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Resubmissions in bold

Improving Methods for Conducting PCOR

*6 Recommended Projects**

Project Title
Advancing Patient Centered Outcomes Research in Survival Data with Unmeasured Confounding to Improve Patient Risk Communication
Causal Inference Guidelines for Pragmatic Clinical Trials
Concept Mapping as a Scalable Method for Identifying Patient-Important Outcomes
Patient-Centered Research for Standards of Outcomes in Diagnostic Tests (PROD)
A Model for Improving Patient Engagement and Data Integration with PCORnet Patient Powered Research Networks and Payer Stakeholders
Making Better Use of Randomized Trials: Assessing Applicability & Transporting Causal Effects

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Resubmissions in bold

Slate Overview – Spring 2015 Cycle

Broad PFAs

24 Projects

Broads PFA	Allotted	Proposed Total Budget*	Average Project Budget*
Addressing Disparities	$8,000,000	$3,893,258	$1,946,629
Assessment of Prevention, Diagnosis, and Treatment Options	$32,000,000	$12,154,991	$2,430,998
Communications and Dissemination	$8,000,000	$5,888,601	$1,962,867
Improving Healthcare Systems	$16,000,000	$18,655,105	$3,731,021
Improving Methods for Conducting PCOR	$12,000,000	$6,063,103	$1,010,517
Rare Disease	$12,000,000	$7,386,291	$2,462,097
TOTALS:	$88,000,000	$54,041,349	$2,251,723

*Total budget = direct + indirect costs

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Spring 2015 Broad Cycle PFAs
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Break

We will return at 1:15 pm ET

Join the conversation on Twitter via #PCORI

Stakeholder Perspectives: Health Plans

Moderator: Kerry Barnett, JD, Board Member

Lewis Sandy, MD

Senior Vice President, Clinical Advancement – UnitedHealth Group

Sam Nussbaum, MD

Executive Vice President, Clinical Health Policy – Anthem, Inc.

Slate of Clinical Management of Hepatitis C Infection Awards

Christine Goertz, DC, PhD
Chair, Selection Committee

Bryan Luce, PhD, MBA
Chief Science Officer

Clinical Management of Hepatitis C Infection
Goals of Targeted PFA

- Address critical clinical and healthcare delivery choices faced by hepatitis C (HVC) patients, their caregivers, clinicians, and/or delivery systems
- Research questions:
  - **Screening:** Which hepatitis C screening methods, confirmatory testing strategies, and clinical settings lead to the best rates of detection and linkage to treatment?
  - **Care management:** What is the comparative effectiveness of interventions to support the care of hard-to-treat patients with chronic hepatitis C infection (e.g., substance abuse, complex medical regimens, mental illness), as measured by receipt of treatment, medication adherence, patient quality of life, and sustained viral response?
  - **Head-to-head:** How do new regimens of oral antiviral medications for the treatment of hepatitis C infection compare in long-term virologic response and adverse effects?
  - **Delayed Treatment:** What are the comparative benefits and harms of treating patients with hepatitis C infection at the time of diagnosis versus waiting to treat only those patients who show early signs of progression of liver disease or other manifestations of hepatitis C infection?

Care Management

Patient-Centered Models of Hepatitis C Care for People Who Inject Drugs

- Research Question
  - Which hepatitis C treatment delivery model for people who inject drugs (PWIDs) is more effective for enhancing hepatitis C treatment uptake, adherence, completion and virological outcomes, and reinfection?
- Study Design/Sample Size/Population
  - 2-arm RCT; N = 1,000; hepatitis C-infected individuals who have used drugs within the past 3 months will be recruited from 16 health centers in 8 states, all with on-site hepatitis C care (8 methadone clinics and 8 community health centers)
- Outcomes
  - Primary: Sustained virological response (SVR), adherence, treatment completion, reinfection
  - Secondary: Quality of life, relapse, cirrhosis complications
- Total Budget: $14M

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Care Management (cont.)

Patient-Centered Models of Hepatitis C Care for People Who Inject Drugs

- Engagement
  - Each research site will have a multi-stakeholder advisory board consisting of patients, local representatives from participating clinics and community health centers, and hepatitis C care providers
  - National stakeholder advisory board
- Potential Impact
  - Results from this study will have the potential to guide programs serving the high-risk people who inject drugs population

Head-to-Head

THE PRIORITIZE STUDY: A Pragmatic, Randomized Study of Oral Regimens for Hepatitis C: Transforming Decision-Making for Patients, Providers, and Stakeholders

- Research Question
  - What are the comparative benefits and harms of three direct-acting antivirals in adults infected with HCV in the US?
- Study Design/Sample Size/Population
  - Open-label 3 arm RCT; N = 3,750; Adults in the US diagnosed with hepatitis C genotype 1 recruited from 45 clinical sites
- Outcomes
  - Primary: SVR12, patient-reported and clinically-documented side effects
  - Secondary: Treatment adherence, treatment persistence, out-of-pocket costs, amelioration of hepatitis C symptoms, post-treatment progression or regression of liver disease, persistence of viral cure at 3 years post-treatment, and functional status during and after treatment
- Total Budget: $15M

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Head-to-Head (cont.)

THE PRIORITIZE STUDY: A Pragmatic, Randomized Study of Oral Regimens for Hepatitis C: Transforming Decision-Making for Patients, Providers, and Stakeholders

- Engagement
  - Hepatitis C patient advisory group
  - Patient organization partnership committee includes representatives from 8 patient advocacy organizations
- Potential Impact
  - Provide decision-makers with evidence about the comparative effectiveness and safety of new direct acting antiviral drugs for hepatitis C

Slate Overview – Spring 2015 Targeted PFA

Clinical Management of Hepatitis C Infection

2 Projects

Hepatitis C PFA	Allotted	Proposed Total Budget*
Clinical Management of Hepatitis C Infection	**$50,000,000**	**$29M**

*Total budget = direct + indirect costs

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Clinical Management of Hepatitis C Infection PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Targeted PCORI Funding Announcements Development

Christine Goertz, DC, PhD
Science Oversight Committee Chair

Bryan Luce, PhD, MBA
Chief Science Officer

Pathway to a Funding Announcement

Staff use Tier 1 and Tier 2 review criteria to determine topic eligibility, producing List 1

↓

Science Oversight Committee (SOC) reviews and endorses topics for topic briefs, producing List 2

↓

SOC reviews topic briefs and approves them for Advisory Panel review, producing List 3

↓

Advisory Panel (AP) reviews topic briefs using Tier 3 review criteria, producing List 4

↓

SOC reviews AP results and staff recommendations; endorses topics for further refinement, producing List 5

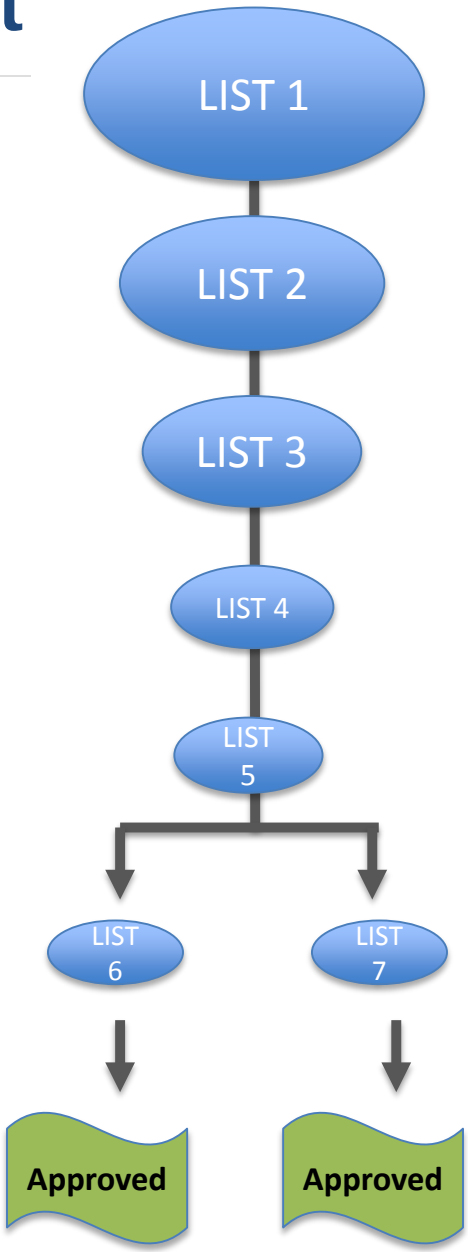
↓

Staff and SOC use Tier 4 review criteria to assess questions; SOC assigns questions to targeted or Pragmatic Clinical Studies PFA, producing Lists 6 and 7

↓

Board reviews and approves questions for targeted PFA

SOC reviews and approves questions for Pragmatic Clinical Studies PFA



Approved Targeted PFAs (List 6)

- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma
- Treatment Options in Uterine Fibroids (Administered by AHRQ)
- The Effectiveness of Transitional Care
- Clinical Trial of a Multifactorial Fall Injury Prevention Strategy in Older Persons (Administered by NIA)
- Obesity Treatment Options Set in Primary Care for Underserved Populations
- Optimal Maintenance Aspirin Dose for Patients with Coronary Artery Disease
- Testing Multi-Level Interventions to Improve Blood Pressure Control in High-risk Populations (Administered by NHBLI)
- Clinical Management of Hepatitis C Infection
- Treatment-Resistant Depression
- New Oral Anticoagulants

Targeted PFA Pipeline

- For Board Vote Today
  - Long-Term Opioid Treatment for Chronic Pain
  - Treatment of Multiple Sclerosis
- Currently on List 5 – Approved for further Development and Refinement
  - Chronic Low-Back Pain
  - Integration of Mental Health into Primary Care
  - Diabetes

Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain

Overview

- Chronic pain, defined as pain lasting longer than 3 months, is extremely common, debilitating, and costly
  - Affects more than 100 million Americans
- Opioids are widely used for chronic pain
  - Opioid prescriptions have increased 3-fold over the last 20 years
  - Between 5 million and 8 million Americans use opioids for chronic pain management
- Although there is little evidence regarding the effectiveness opioid therapy for chronic pain, mounting evidence suggests that it may be associated with important harms
  - In 2013, there were over 16,000 deaths due to prescription opioids
  - Harms include: overdose, abuse, addiction, sedation, impaired cognitive function, depression, constipation, and nausea
    - Prolonged use of high-dose opioids has been associated with tolerance, abuse, addiction, hormonal effects, and immunosuppression

Evidence Gaps

A recent AHRQ systematic review identified a number of key evidence gaps including:

- Long-term effectiveness of dosing strategies and treatment options:
  - Little available evidence on the effectiveness of decreasing opioid dose, tapering protocols, short-/long-acting opioids, and opioid rotation for outcomes >1 year
  - No comparative effectiveness studies of opioid plus non-opioid (pharmacological or non-pharmacological) vs. opioid or non-opioid therapy alone for outcomes >1 year
- Harms and adverse events:
  - No long-term studies examining how harms vary depending on cause of pain and patient comorbidities
- Risk mitigation strategies:
  - No long-term studies evaluating the effectiveness of risk mitigation strategies for improving outcomes related to overdose, addiction, or misuse

Summary from the June 9th Multi-stakeholder Workgroup

- The workgroup included 47 participants
- Of the 78 research questions that were submitted by the invited stakeholders, staff identified two categories for the workgroup to consider:
  - Panel 1: Pharmacologic Treatment Options and Dosing Strategies
  - Panel 2: Multimodal Treatment Options, Risk Mitigation Strategies, and Opioid Dependency

Focus of the Two Proposed Questions:

- Research Question 1:
  - Comparative effectiveness of strategies to reduce/eliminate opioid use while managing pain
- Research Question 2:
  - Comparative effectiveness of strategies to prevent dose escalation

Proposed Research Question 1

Among patients with chronic non-cancer pain on moderate- to high-dose, long-term opioid therapy, what is the comparative effectiveness of strategies for reducing/eliminating opioid use while managing pain? (Strategies may include: dose reduction protocols, adjunct use of non-opioid interventions: pharmacological and non-pharmacological, e.g. cognitive behavioral therapy)

- **Population:** Patients with chronic non-cancer pain on high-dose, long-term opioid therapy
- **Comparators may include:** Structured opioid dose reduction versus opioid dose reduction combined with non-opioid interventions (pharmacological or non-pharmacological)
- **Outcomes:** Pain control at 6 and 12 months, opioid dose reduction/elimination at 6 and 12 months, functional status, health-related quality of life, opioid misuse, safety, mortality, medical side effects of treatment, depression score, hospitalizations, and health services use
- **Follow-up:** >1 year
- **Study Design:** Randomized controlled trial
- **Project Period:** 3-5 years
- **Subgroup Analyses:** How does effectiveness vary based on:
  - Patient comorbidities: mental health disorders, past or current substance use disorders
  - Type or cause of pain

Proposed Research Question 2

Among patients on moderate/low-dose, long-term opioid therapy, what are the comparative effectiveness and harms of strategies used to limit dose escalation?

- **Population:** Patients with chronic non-cancer pain on moderate/low-dose long-term opioid therapy
- **Comparators:** Protocols to limit dose escalation vs. standard risk mitigation strategies: comparisons may include combinations of: non-opioid interventions, opioid rotation, dosing strategies, or risk mitigation strategies
- **Outcomes:** Pain control at 6 and 12 months, opioid dose at 6 and 12 months, tolerance, functional status, health-related quality of life, opioid misuse, safety, mortality, medical side effects of treatment, depression score, hospitalizations, and health services use
- **Follow-up:** >1 year
- **Study Design:** Randomized controlled trial
- **Project Period:** 3-5 years
- **Subgroup Analyses:** How does effectiveness vary depending on:
  - Patient comorbidities: mental health disorders, past or current substance use disorders
  - Type or cause of pain

- **Research Commitment for Questions 1 and 2:**
  - Up to 4 studies, $40M (total costs)

Board Vote

Call for a Motion to:	• **Approve** $40M for Long-Term Opioid Treatment for Chronic Pain targeted PFA development
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Treatment of Multiple Sclerosis

Overview

- Multiple sclerosis (MS) is a chronic degenerative condition of the central nervous system characterized by damage to the myelin sheaths of nerves, resulting in fatigue, numbness, visual disturbances, bladder problems, mobility difficulties, and other symptoms
- Approximately 400,000 Americans have MS. Most patients are diagnosed between 20 and 40 years of age; ~70% are female
- The clinical course is highly variable, generally unfolding over decades, and symptoms range from mild to the development of severe disability
- There are three approaches to MS treatment:
  - Disease-modifying therapy (DMT) to slow progression
    - There are now at least 12 FDA-approved DMTs to treat MS, including three oral therapies introduced since 2010
  - Steroids for relapses
  - Symptomatic treatments for specific symptoms (non-DMT) of the disease and side effects of treatment regimens

Patient-Centeredness

- Over a long clinical course, MS causes symptoms that affect quality of life and are lifelong
  - Newly-diagnosed patients cite disease progression as their top concern
  - Common symptoms include fatigue, numbness and tingling, spasticity, bladder problems, pain, cognitive changes, and depression
- DMTs are used in patients with relapses or inflammatory activity (until evidence of suboptimal response or intolerable side effects); however, there is little evidence to support specific DMT choices or strategies
- There are many symptom-specific medications that have not been well evaluated or compared

Summary from the April 2nd Multi-stakeholder Workgroup

- The workgroup included 43 participants
- Of the 60 research questions submitted by workshop invitees, the workgroup discussed the following topics:
  - Comparison of DMTs, including differential effects in subgroups
  - Care strategies
  - Non-DMT and non-pharmacologic therapy for specific symptoms and overall health
  - Timing of therapy and study design

Need for Better Evidence

- Canadian Agency for Drugs and Technologies in Health (CADTH 2013) note limited number of RCTs directly comparing DMTs for relapsing remitting MS
- 17 systematic reviews indicate insufficient evidence of treatment of MS symptoms
- Recent systematic review (of 9 RCTs) on tele-rehabilitation for patients with MS concluded there is a need for more robust trials

Proposed Research Question 1

What are the comparative benefits and harms of different DMTs or therapeutic strategies in patients with relapsing-remitting MS on symptoms, functioning, quality of life, disease activity, and disease progression? (Strategies may include: comparisons of initial DMT treatment, or comparisons of follow-on treatments in patients for whom initial DMT treatment has failed)

- **Population:** Patients with relapsing-remitting MS
- **Comparators:** Different DMTs, including strategies for sequencing or combining agents, changing to a different DMT, or escalating DMT dose
- **Outcomes:** Symptoms, functioning, quality of life, disease activity, disease progression
- **Setting:** Outpatient
- **Study Design:** Randomized controlled trial
- **Project Period:** 5 years
- **Research Commitment:** Up to 2 studies, $30M (total costs)

Proposed Research Question 2

What are the comparative benefits and harms of different approaches, other than DMTs, for ameliorating important symptoms in people with MS? Symptoms of interest include fatigue, difficulty walking, memory or attention problems (cognition), bladder problems, numbness or tingling, and pain.

- **Population:** Patients with MS, including progressive MS
- **Comparators:** Non-DMT symptomatic therapies
- **Outcomes:** Symptom relief, quality of life
- **Setting:** Outpatient
- **Study Design:** Randomized controlled trial
- **Project Period:** 3 years
- **Research Commitment:** Up to 4 studies, $10M (total costs)

Proposed Research Question 3

In people with MS, what is the comparative effectiveness of tele-rehabilitation vs. conventional direct care interventions for improving outcomes in people with MS, such as functional status, fatigue, and quality of life?

- **Population:** Patients with MS, including with progressive MS
- **Comparators:** Conventional direct care vs. tele-rehabilitation
- **Outcomes:** Functional improvement, fatigue, patient experience, health-related quality of life
- **Study Design:** Randomized controlled trial
- **Project Period:** 4 years
- **Research Commitment:** Up to 2 studies, $10M (total costs)

Board Vote

Call for a Motion to:	• **Approve** $50M for Treatment of Multiple Sclerosis targeted PFA development
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Break

We will return at 3:30 pm ET

Join the conversation on Twitter via #PCORI

Methodology Committee Update

Robin Newhouse, PhD, RN
Chair of the Methodology Committee
Steve Goodman, MD, MHS, PhD
Vice-Chair, PCORI Methodology Committee

Session Topics and Objectives
What are we going to cover today?

Decision Sciences	• Update on June 4th expert meeting • Next steps
New Methodology Standards	• Designs Using Clusters • Complex Interventions
Methodology Standards Review	• Status of standards revisions • Process for approval of revisions
Methodology Standards Dissemination Activities	• Baylor CME/CE Initiative update • Academic Curriculum update

Decision Sciences

- **Current Status**
  - June 4th meeting included experts, MC members and PCORI staff
  - Research Triangle Institute (RTI) is drafting a meeting report that will be reviewed by staff
- **Next Steps**
  - RTI report to be completed early Fall 2015
  - PCORI staff and MC members are evaluating the possibility of developing a research agenda
- **MC Leads:** David Flum, Mark Helfand, and David Meltzer
- **Projected Timeframe** December 2015

New Methodology Standards: Designs Using Clusters

- **Current Status**
  - Staff presented draft standards to the Advisory Panel on Clinical Trials in May and to the MC in July
  - Revisions completed and final draft standards ready for review
- **Next Steps**
  - The MC will vote to accept a final version of these standards on October 29th
  - If approved, the MC will request the Board to authorize dissemination for public comment
- **MC Members:** Naomi Aronson, Cindy Girman, Bob Kaplan, Sally Morton, Robin Newhouse, and Sebastian Schneeweiss
- **Projected Timeframe:** Fall 2015

New Methodology Standards: Complex Interventions

- **Current Status**
  - Multi-Component, Multi-Interventions Summit is planned for October 8th at the Annual Meeting
  - The summit will include about 35 participants including experts, MC members and staff
  - An initial literature search is underway
- **Next Step**
  - Standards will be drafted based on feedback from the October 8th meeting
  - A December meeting on the same topic is being planned by AcademyHealth; the PCORI workgroup and a group from AcademyHealth will continue to work together to minimize duplication
- **MC Lead:** Brian Mittman
- **MC Members:** Naomi Aronson, David Flum, Robin Newhouse, and Mary Tinetti
- **Projected Timeframe:** February – December 2015

Methodology Standards Review

- **Current Status:**
  - All eleven categories of standards have been reviewed or are currently under review
- **Next Steps**
  - Ten reviewed and revised Standards categories will be presented to the MC for final approval at the October 29th meeting
  - The eleventh category will be approved at or shortly after the October 29th meeting
- **MC Lead:** Each standards category has one or two MC leads
- **Projected Timeframe:** November 2014 – Fall 2015

Methodology Standards Dissemination: Baylor College of Medicine CME/CE Initiative

- **Current Status**
  - MC members involved in developing Standards modules
  - Modules have been or are under review by MC members and selected staff
- **Next Step**
  - MC to help determine organizations for promotion of CME/CE activities
- **MC Lead:** Mark Helfand
- **Projected Timeframe:** Fall 2015

Methodology Standards Dissemination: Academic Curriculum Development

- **Current Status**
  - Methodology Standards Curriculum module development in progress by the Johns Hopkins University
  - Each of the 13 modules are being reviewed by two MC members as they are completed
- **Next Steps**
  - MC members will continue to review modules as they are completed
  - Based on Johns Hopkins' dissemination recommendations, PCORI will implement the final dissemination plan
- **MC Leads:** Sally Morton and Neil Powe
- **Projected Timeframe:** Fall 2015

Other MC Activities

"Usual Care" Definitions & Components	• Plan in place for literature review by MC members • Plan being developed for writing a position paper for the *Annals of Internal Medicine*
Clinical Trial Design and Design Simulation Initiative	• Purpose: Identify types of innovative approaches to study design that PCORI would like to simulate or consider • First meeting occurred August 18, discussed possible approach to generate studies with innovative designs
PCORI Network Research Methods Group Activities	• Purpose: Identify and prioritize methods development opportunities for PCORnet • Agenda drafted for a meeting in December: Data Quality and Missing Data in Patient-Centered Outcomes Research using EMR/Claims Data
Patient-Centered Measurement Activities	• Patient-reported outcomes (PROs) in electronic health records (EHRs) is a key focus • Contract with a Johns Hopkins University group to help plan a "PROs in EHRs follow up workshop" to the November 2013 workshop

Methodology Committee Members

- Robin Newhouse, PhD, NR, Chair
- Steven Goodman, MD, MHS, PhD, Vice Chair
- Naomi Aronson, PhD
- Ethan Basch, MD, MSc
- David Flum, MD, MPH
- Cindy Girman, DrPH
- Mark Helfand, MD, MS, MPH
- Bob Kaplan, PhD
- Michael Lauer, MD
- David Meltzer, MD, PhD
- Brian Mittman, PhD
- Sally Morton, PhD
- Neil Powe, MD, MPH, MBA
- Sebastian Schneeweiss, MD, ScD
- Mary Tinetti, MD
- Adam Wilcox, PhD
- Clyde Yancy, MD, MSc

Evaluation Update

PCORI Applicants

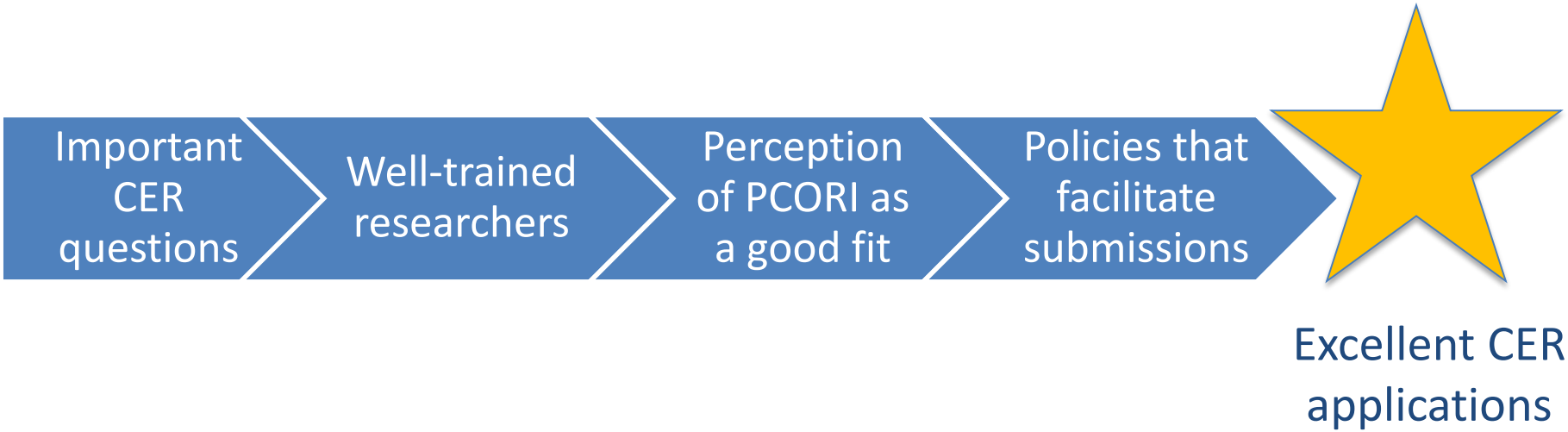
Lori Frank, PhD,
Program Director, Evaluation and Analysis

Laura Forsythe, PhD, MPH,
Associate Director, Evaluation and Analysis

Application Enhancement Workgroup Framework

Theoretical Framework

A series of conditions are necessary for high quality applications:



Application Enhancement Workgroup

Workgroup Strategy:

Application Enhancement Activities

- Presented evidence for three hypotheses
  - Applicants think the effort to apply is high relative to the likelihood of award
  - Applicants think the timelines are compressed
  - Researchers embrace engagement but find the requirements challenging
- Reviewed evidence and recommendations for process improvements

Outcomes from Application Examination To Date

- Reviewing PCORI application process to identify opportunities to reduce applicant burden, increase clarity about PCORI requirements
- Extended applicant preparation time through pre-announcements, other changes being reviewed
- Shifting responsibility to PCORI for some aspects of engagement before application
- Enhancing Engagement Rubric and other resources

Agenda

1. Describe the PCORI applicant pool. Do funded applicants differ from unfunded applicants in terms of training, research experience, and history of interaction with PCORI?

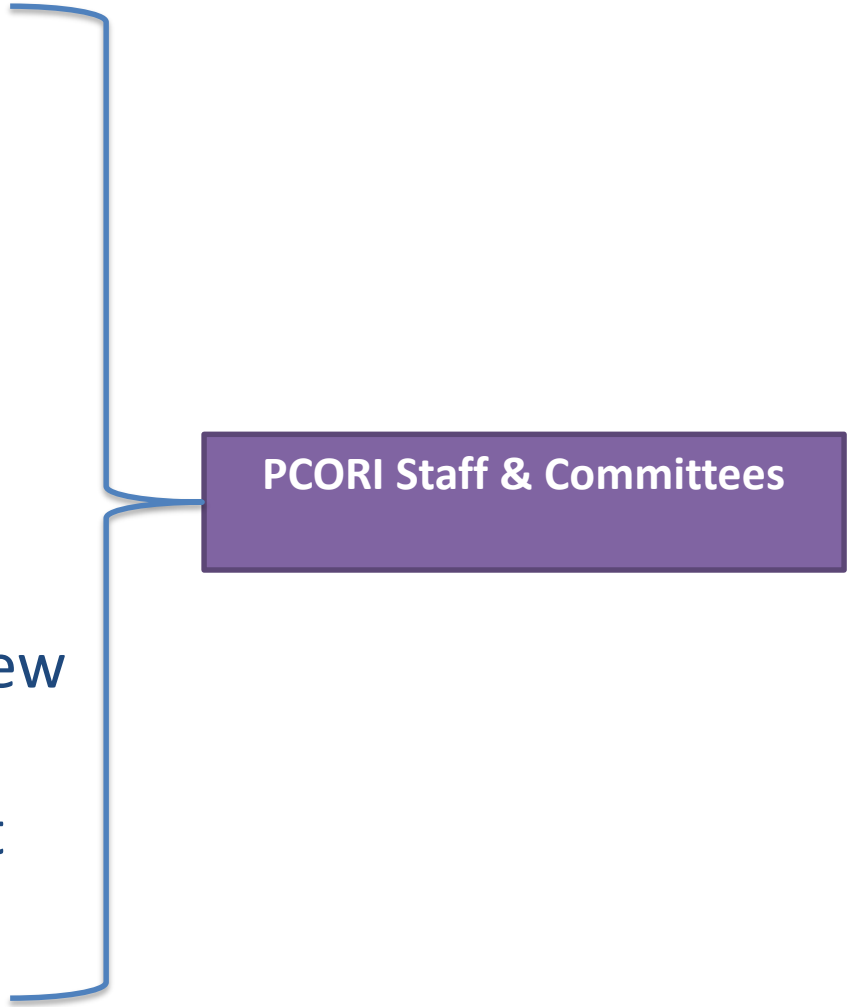
2. Is there a pool of well-qualified CER researchers who are not applying to PCORI?

- If so, are they not aware of PCORI? Are they aware but prefer other funding sources?

3. What proportion of health services and outcomes researchers have experience with CER and/or pragmatic studies? What proportion could be PCORI applicants and what should be done to increase that?

Information Sources

- **Analysis of applicant characteristics**
- **CER literature search**
- **PCORI Stakeholder surveys**
  Applicant survey
- Reviewer survey
- Reviewer focus groups
- LOIs and proposal critique review
- Merit Review score analyses
- Data collection on engagement



Findings

Agenda

1. Describe the PCORI applicant pool. Do funded applicants differ from unfunded applicants in terms of training, research experience, and history of interaction with PCORI?

2. Is there a pool of well-qualified CER researchers who are not applying to PCORI?

- If so, are they not aware of PCORI? Are they aware but prefer other funding sources?

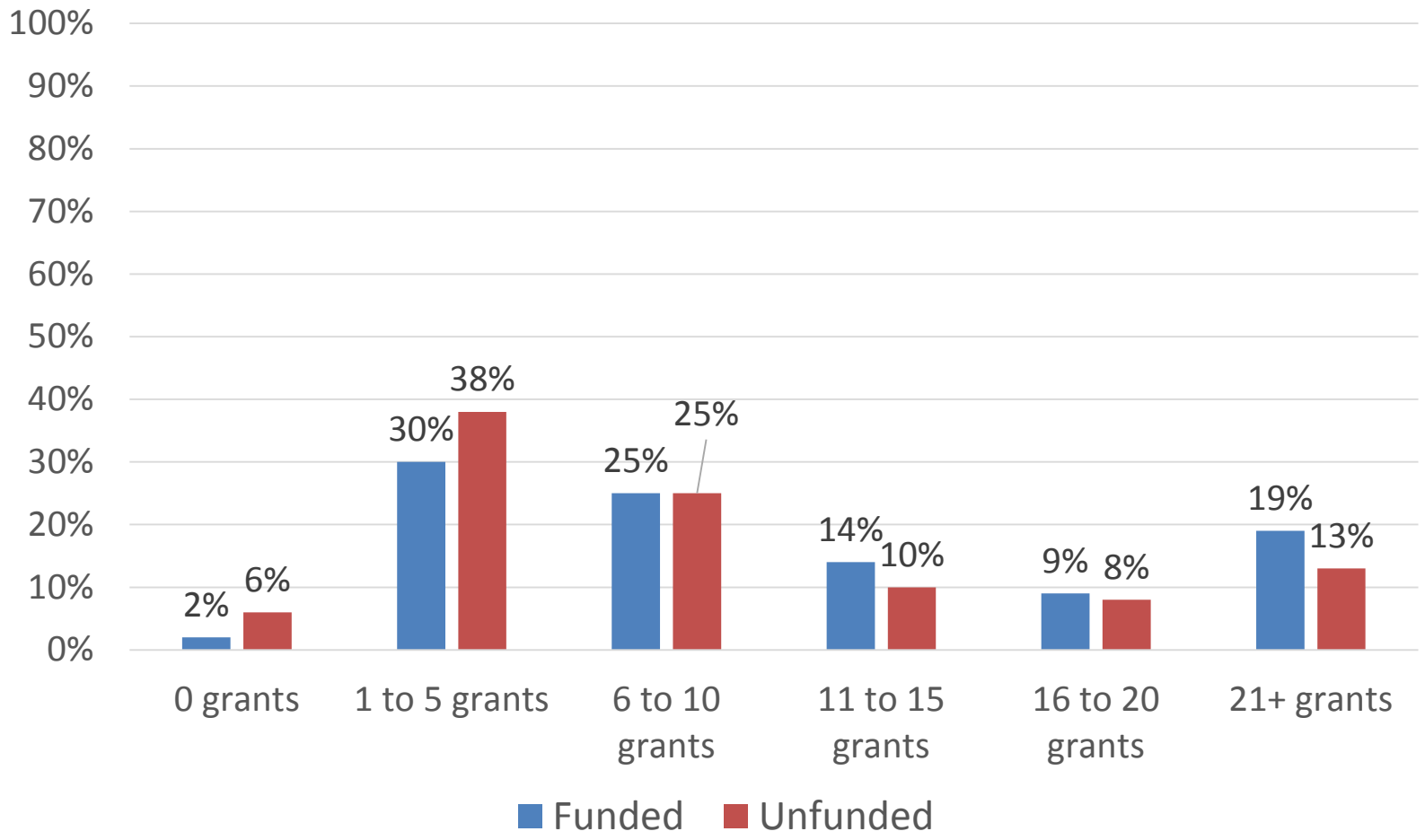
3. What proportion of health services and outcomes researchers have experience with CER and/or pragmatic studies? What proportion could be PCORI applicants and what should be done to increase that?

Applicant Characteristics: Training and Funding

	Awardees	Unfunded Applicants
Doctoral degree	99%	97%
Clinical degree	53%	55%
Prior NIH funding	83%	66%
Prior AHRQ funding	30%	18%
Prior PCORI funding	7%	2%

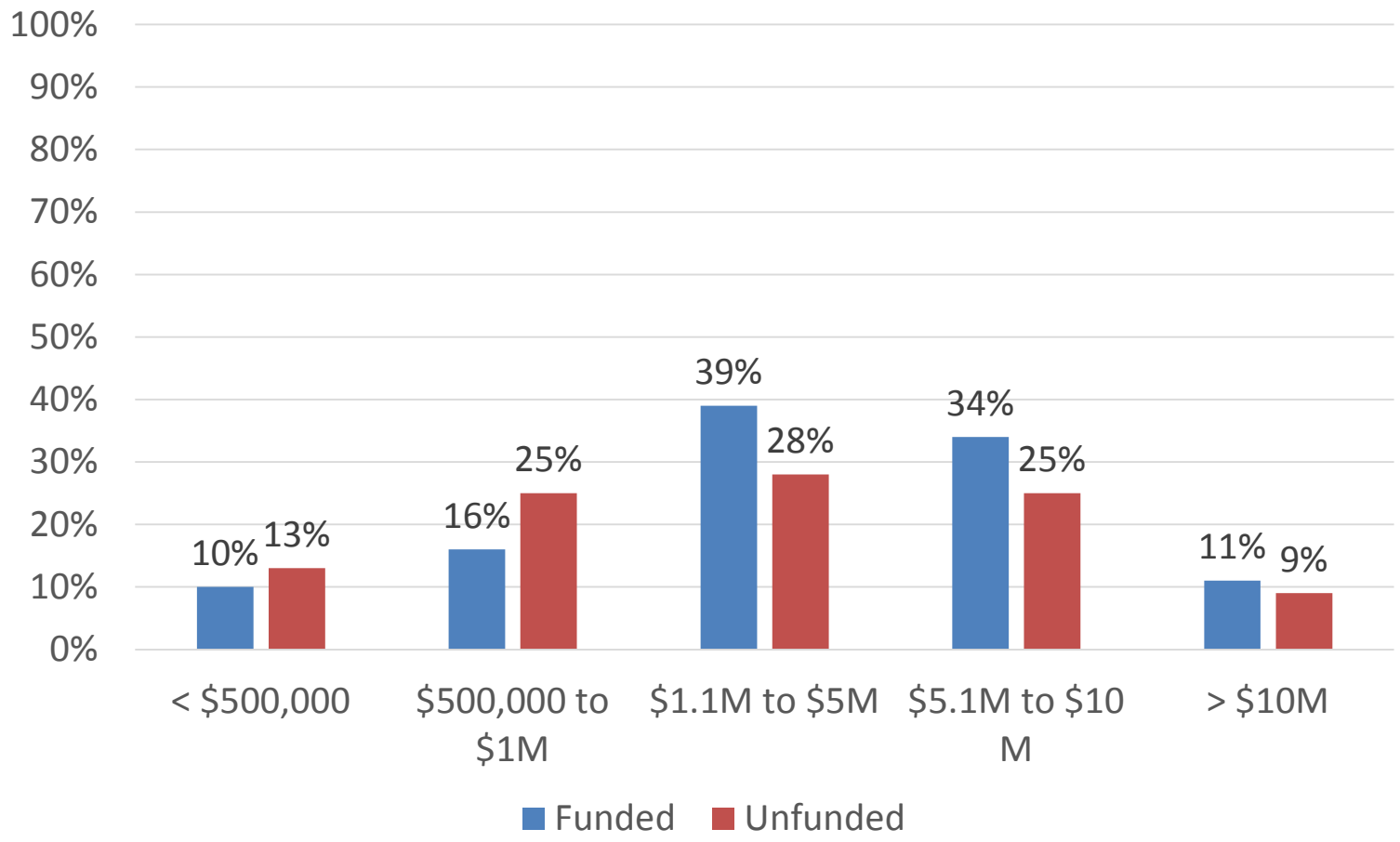
Based on submissions for Broad proposals from August 2013 through Fall 2014 (N = 161 funded, N = 1375 unfunded)

Applicant Characteristics: Prior grants



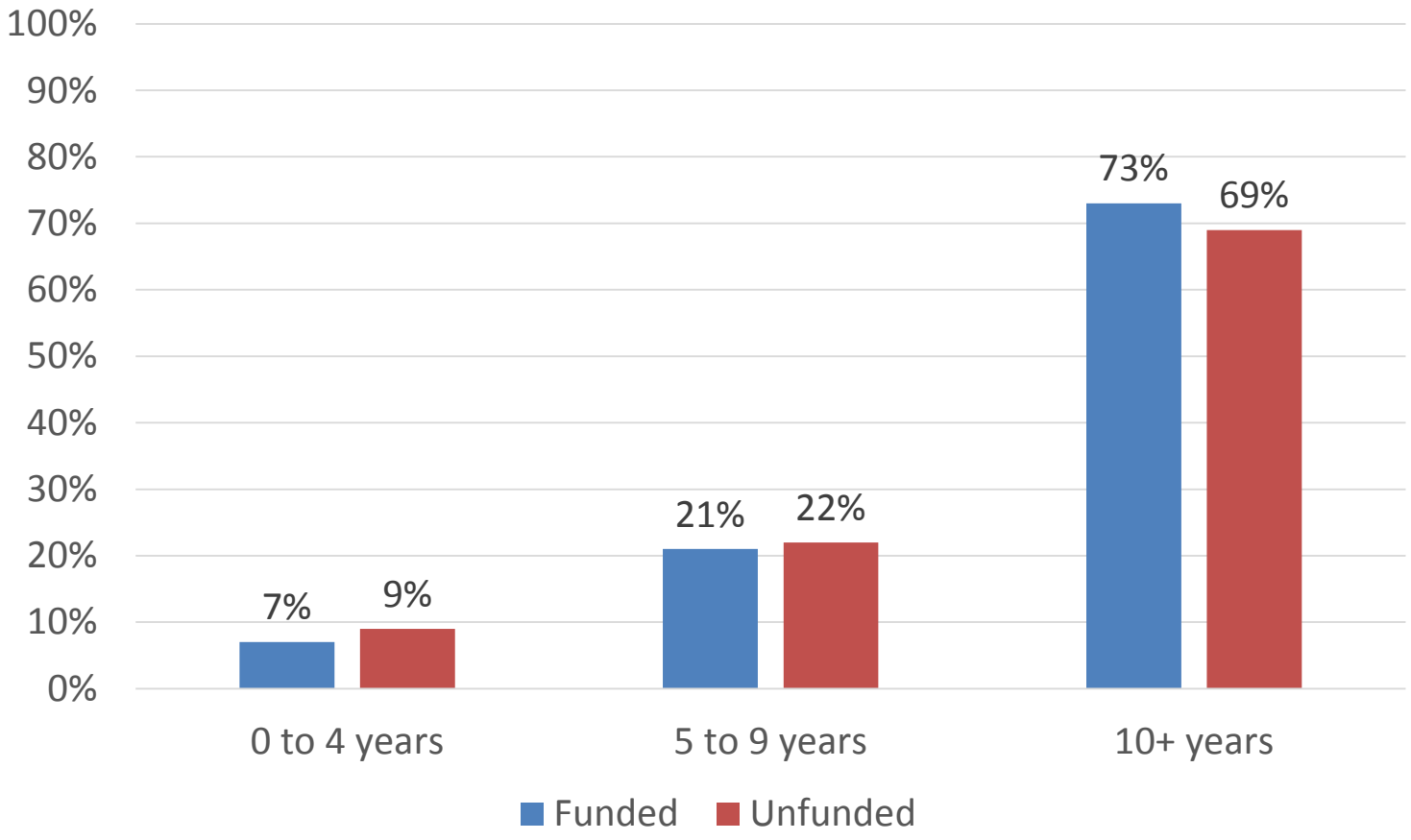
Based on submissions for Broad proposals from August 2013 through Fall 2014 (N = 161 funded, N = 1375 unfunded)

Applicant Characteristics: Largest prior grant



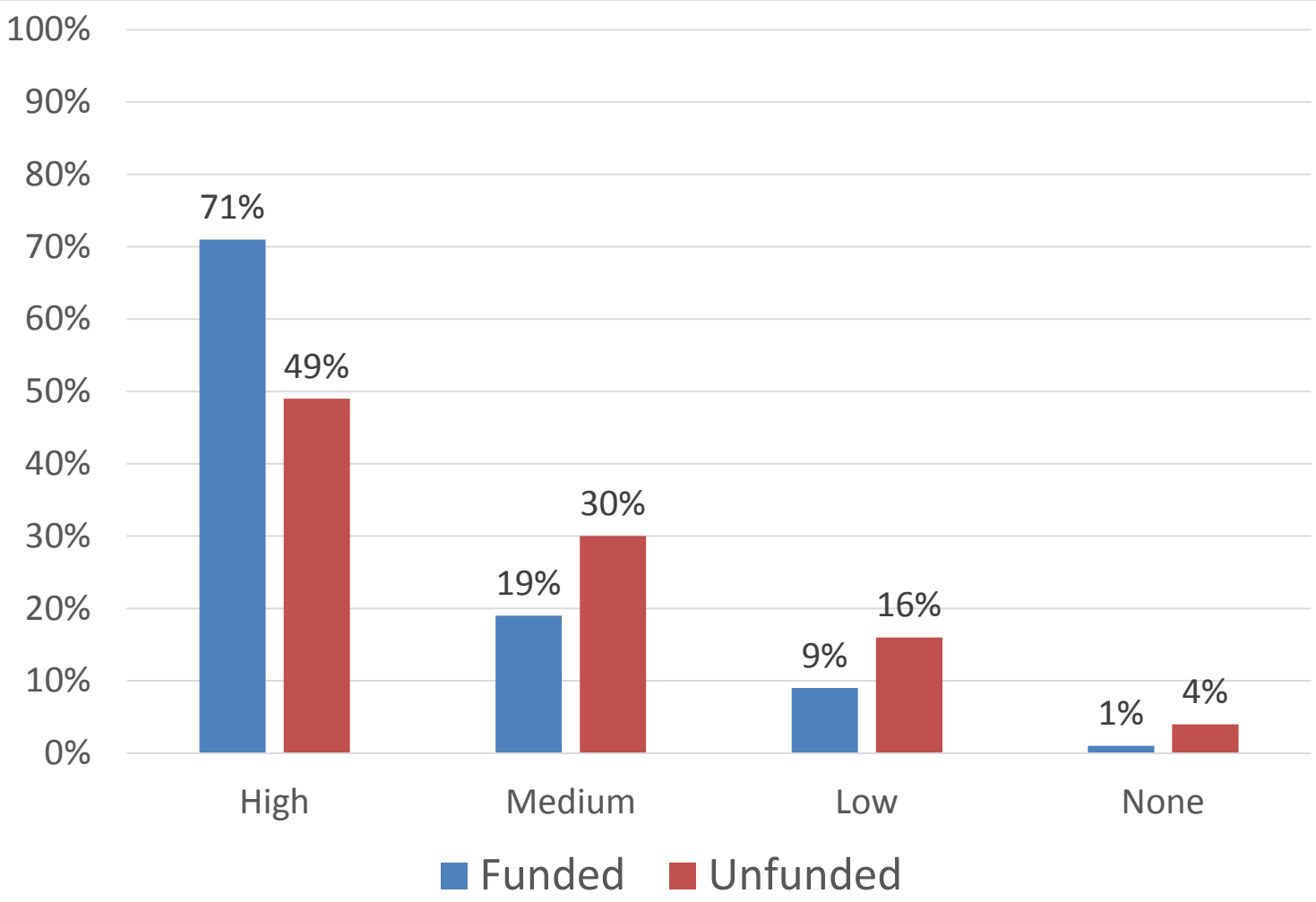
Based on submissions for Broad proposals from August 2013 through Fall 2014 (N = 161 funded, N = 1375 unfunded)

Applicant Characteristics: Years of Research Experience



Based on submissions for Broad proposals from August 2013 through Fall 2014 (N = 161 funded, N = 1375 unfunded)

Applicant Characteristics: Experience with PCORI



Based on submissions for Broad proposals from August 2013 through Fall 2014 (N = 161 funded, N = 1375 unfunded)

PCORI Applicants: Conclusions

- PCORI applicants are experienced researchers and successful with other funders.
- There are few differences between funded and unfunded applicants in terms of years of training and number and size of prior grants.
- More funded than unfunded applicants have had prior NIH and ARHQ funding.
- More funded than unfunded applicants have been actively involved with PCORI prior to application (e.g., applied for funding, served as merit reviewer, attended PCORI workshop)

Agenda

1. Describe the PCORI applicant pool. Do funded applicants differ from unfunded applicants in terms of training, research experience, and history of interaction with PCORI?

2. Is there a pool of well-qualified CER researchers who are not applying to PCORI?

- If so, are they not aware of PCORI? Are they aware but prefer other funding sources?

3. What proportion of health services and outcomes researchers have experience with CER and/or pragmatic studies? What proportion could be PCORI applicants and what should be done to increase that?

Is there a pool of well-qualified CER researchers who are not applying to PCORI?

Literature Search #1, for CER ***as identified by authors or NLM indexers***

April 2014 to April 2015

Search terms included one of the following:

- Comparative Effectiveness Research (MeSH term)
- comparative effectiveness (text word)
- CER (text word)
- comparative efficacy (text word)

- AND another term for study design, such as clinical trial, observational study, or meta-analysis
- English language

CER studies in the published literature
April 2014 – April 2015

- The search yielded 216 CER trials or observational studies
  - 80 (37%) were conducted entirely outside the US

- Of the remaining 136 studies:
  - 75 (55%) are connected to PCORI, most as applicants or awardees

Is there a pool of well-qualified CER researchers who are not applying to PCORI?

Literature Search #2, focus on CER Trials

October 2014-April 2015, in 5 journals:

- Annals of Internal Medicine
- The British Medical Journal
- Journal of the American Medical Association
- The Lancet
- The New England Journal of Medicine

CER studies published in five journals
October 2014 – April 2015

- The search yielded 141 CER RCTs
  - 92 (65%) were conducted entirely outside the US

- Of the remaining 49 studies:
  - 33 (67%) are connected to PCORI, most as applicants or awardees

  We are collecting feedback from a subset of those not connected to PCORI in any way.

Feedback from CER Researchers Not Currently Connected With PCORI

"PCORI is new and not many people know much about it. [Researchers] tend to rely on our usual sources of funding, even if they aren't working that well for us anymore."

"I have not yet applied for PCORI funding because I am still developing the preliminary data that I believe would justify the CER proposal I am envisioning submitting to PCORI."

"It's been unclear to us how we could involve patients in observational studies."

"Earlier today my colleagues and I were discussing the potential for PCORI funding for a research idea…all of us felt it was highly unlikely that PCORI would be interested in secondary data analyses."

Conclusions: Is there a pool of well-qualified CER researchers who are not applying to PCORI?

- PCORI is reaching a high proportion of recently published CER researchers
- Continued outreach about PCORI funding could yield additional applicants who have not yet considered PCORI funding

Agenda

1. Describe the PCORI applicant pool. Do funded applicants differ from unfunded applicants in terms of training, research experience, and history of interaction with PCORI?

2. Is there a pool of well-qualified CER researchers who are not applying to PCORI?

- If so, are they not aware of PCORI? Are they aware but prefer other funding sources?

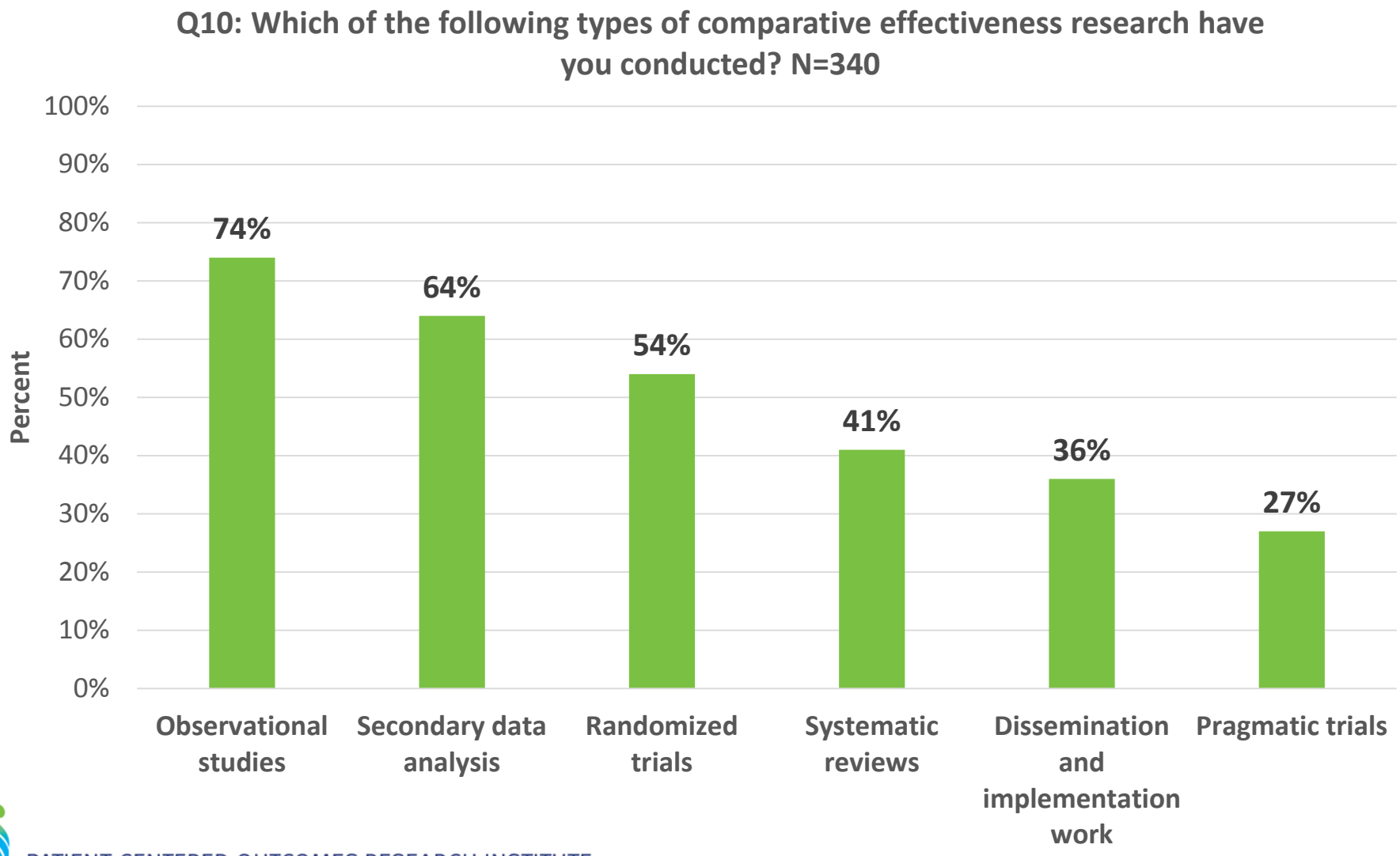
3. What proportion of health services and outcomes researchers have experience with CER and/or pragmatic studies? What proportion could be PCORI applicants and what should be done to increase that?

Do health services and outcomes researchers have experience with CER and/or pragmatic studies?

PCORI Researcher Survey, 2014

- Clinical, health services and health outcomes researchers invited via 23 professional organizations and the PCORI mailing list (N=508)
- High familiarity with PCORI (52% very familiar, 38% somewhat familiar)
- 59% applied to PCORI, 43% of those received funding

PCORI Researcher Survey: CER Experience



Conclusions: Do health services and outcomes researchers have experience with CER and/or pragmatic studies?

- The majority of these CER researchers had experience with observational CER studies and secondary analyses.
- Among these CER researchers, approximately half report experience running randomized trials and one quarter report experience with pragmatic trials.

Summary

- While the pool of health researchers successful with other funders is large, there is a more limited set of US researchers who conduct randomized and/or large pragmatic studies
- More funded than unfunded applicants have had prior interaction with PCORI and have a history of funding from NIH and AHRQ
- PCORI has reached many with CER experience, but there are opportunities to improve awareness of and interest in PCORI funding

Next Steps

APPLICATION PROCESS

- Use input from prior applicants to improve process
- Analyze resubmissions to aid with process improvements

ACTIVE CER RESEARCHERS

- Track proportion applying to PCORI to monitor outreach
- Query those who have not applied to understand reasons

MERIT REVIEW CRITIQUES

- Identify opportunities for improving communication to applicants

Discussion

PCORnet Phase II

Rachael Fleurence, PhD
Program Director, CER Methods and Infrastructure
Joe Selby, MD, MPH
Executive Director, CER Methods and Infrastructure

Agenda

- Overview of New Phase II Networks
- PCORnet Demonstration Projects and Initiatives
- PCORnet Common Data Model
- PCORnet Governance
  - Phase I Work Groups
  - Phase II Structure
- PCORnet Business Plan Development
- Discussion

Phase II networks

- Board of Governors approved Phase II networks on July 21st
- Total of 33 CDRNs and PPRNs in Phase II
- PCORI is pursuing contract negotiations with six new networks
  - 4 new PPRNs
  - 2 new CDRNs

Patient-Centered Network of Learning Health Systems (LHSNet)

Veronique Roger, MD, MPH; Mayo Clinic

- Learning Health System focused on Learn, Translate, Disseminate
- 10 million patients
  - 3 million linked patients
- Geographic distribution across 10 states
- Active patient engagement, established collaborative relationships, community partnerships, and public health engagement
- Ethnic and socio-economic diversity
- Established clinical trial and informatics experience
- Disease Focuses
  - Obesity
  - Heart Failure
  - Osteogenesis Imperfecta

OneFlorida Clinical Data Research Network

Elizabeth Shenkman, PhD; University of Florida

- Research consortium in the begun in 2009
- 10 million patients across all of Florida's 67 counties
  - 1,240 practices
  - 4,000 physician providers
  - 22 hospitals
- Disease cohorts
  - Hypertension (1.3M)
  - Obesity (1.8M adults, 681K children)
  - Duchenne Muscular Dystrophy (311)
- Nearly two decades working with claims data
- Active, well-integrated citizen scientist program

Interactive Autism Network

Jessica Law, MD, MPH; Johns Hopkins University School of Medicine

- Founded in 2006 at the Kennedy Krieger Institute in Baltimore, MD
- Goal: Engage families and adults with ASD in research
- Key Accomplishments
  - Family-centered research community with 50,000+ participants
  - Network-led studies
  - Families have volunteered to participate in over 500 studies
- PPRN goals
  - Expand network enrollment and engagement
  - Integrate patient-provided data and clinical data
  - Collaborate and explore overlapping concerns and priorities (epilepsy, genetic disorders, mood disorders)
  - Expand clinical trial infrastructure

Population Research in Identity and Disparities for Equality Patient-Powered Research Network (PRIDEnet)

Mitchell R. Lunn, MD; University of California, San Francisco

- Population-based, disease agnostic
- Devoted to sexual and gender minorities (SGMs)
- Diverse, heterogeneous communities (SO/GI, race, region)
- SGMs are underserved, understudied, and vulnerable to poor health
- SGMs experience significant bias and discrimination in medical and investigational communities
- 40+ partner organizations from across country (community centers, health clinics, service/advocacy orgs)

National Alzheimer's & Dementia Patient & Caregiver-Powered Research Network

Ron Peterson, MD-PhD; Mayo Clinic

- Collaboration between Mayo Clinic, the University of Florida, and UsAgainstAlzheimer's (UsA2) Networks
- Network Governance: patients, caregivers, leaders of patient groups, directors of existing patient registries, CDRN/PPRN collaborators, and clinical studies representatives
- Amplifying the patient and caregiver voice to accelerate development of effective treatments for Alzheimer's disease (AD) and related dementias
- Alzheimer's PPRN Aims:
  - Enroll an increasingly large number of subjects into this patient-centered network with a minority recruitment focus
  - Obtain self-reported information and measures of cognition at baseline and longitudinally
  - Screen & refer subjects for clinical trials
  - Test a computable patient phenotype

Community and Patient-Partnered Participatory Research Network (CPPRN)

Kenneth Wells, MD, MPH; University of California, Los Angeles

- Focus on behavioral health in under-resourced communities
- Emphasizes co-leadership and equal authority in all research phases by community, patient, academic, and other stakeholders
- Leverages a decade of partnered behavioral health research and services collaboration with under-resourced communities
- Goal: To establish a patient, community, and researcher network to develop a co-led, partnered participatory comparative effectiveness research approach and data infrastructure, centered on behavioral health and social risk factors, while ensuring alignment with community, patient, and caregiver priorities
- Built around principles of trust, respect, transparency, strength-based, power and knowledge sharing, co-leadership, two-way capacity development, and co-ownership of all products including data

PCORnet Demonstration Projects

- Interventional Trial: Optimal Maintenance Aspirin Dose for Patients with Coronary Artery Disease (ADAPTABLE)
  - PCORnet's first pragmatic clinical trial
  - A Clinical Trails Advisory Panel (CTAP) sub-committee has advised on the protocol and contract negotiations are in progress
  - Recruitment is scheduled to begin in January 2016
- Observational Research
  - Two obesity demonstration projects were approved by the Board of Governors in August
    - Comparative effectiveness of bariatric surgery interventions
    - Comparative effectiveness of alternative antibiotics on weight outcomes in pediatric populations
  - A CTAP sub-committee is providing recommendations to finalize the protocols

PPRN Demonstration Projects

- PPRN Research Demonstration Projects
  - LOIs were due in August and applicants were invited to submit full applications
  - Full applications are due September 30th
- Cross-PPRN Demonstration Project
  - PFA is in development and is anticipated to be released in fall 2015

Natural Experiments Network

- Collaborative initiative with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH)/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- PCORI is funding up to three projects to expand the number of research projects within the CDC and NIH/NIDDK Natural Experiments Network
  - CDC and NIH/NIDDK funded five research projects toward the co-funded Natural Experiments Network. Two of the five projects involved PCORnet CDRNs
- Projects will investigate the "impact of population-targeted health policies and large-scale interventions on risk and complications of diabetes, and reducing disparities in these risks and complications" with particular attention to patient-centeredness and patient and stakeholder engagement
- Applications were due to PCORI on September 16th and are currently in the merit review process

Health Systems Demonstration Projects

- CDRNs were provided supplemental funding to engage health systems leaders during fall 2015
- In January, the National Academy of Medicine will host a meeting to engage the health systems' leaders across the CDRNs
  - Goal is to identify and prioritize a set of data-driven research activities of high interest to systems and/or clinicians within the systems to be included in a limited PFA
- PCORI will award up to five one-year studies through a limited PFA
- Limited PFA is scheduled to be posted in spring 2016

Initiative on Health Plan/System Data Partnerships

- Critical element for many anticipated uses of PCORnet is the availability of complete, longitudinal data on populations receiving health care with the CDRNs and PPRNs
- PCORI is seeking to fund up to two major US health plans that cover significant numbers of patients in one or more of the PCORnet CDRNs and/or PPRNs to engage in data linkage activities
- PFA is scheduled to be released in fall 2015

Advances in the PCORnet Common Data Model

PCORnet CDM Domains, v3.0

CONDITION v2.0
A condition represents a patient's diagnosed and self-reported health conditions and diseases. The patient's medical history and current state may both be represented.

DEATH v3.0
Reported mortality information for patients.

DEATH_CAUSE v3.0
The individual causes associated with a reported death.

DEMOGRAPHIC v1.0
Demographics record the direct attributes of individual patients.

DIAGNOSIS v1.0
Diagnosis codes indicate the results of diagnostic processes and medical coding within healthcare delivery.

DISPENSING v2.0
Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer. Outpatient dispensing is not commonly captured within healthcare systems.

ENROLLMENT v1.0
Enrollment is a concept that defines a period of time during which all medically-attended events are expected to be observed. This concept is often insurance-based, but other methods of defining enrollment are possible.

ENCOUNTER v1.0
Encounters are interactions between patients and providers within the context of healthcare delivery.

HARVEST v3.0
Attributes associated with the specific PCORnet datamart implementation

LAB_RESULT_CM v2.0
Laboratory result Common Measures (CM) use specific types of quantitative and qualitative measurements from blood and other body specimens. These standardized measures are defined in the same way across all PCORnet networks.

PCORNET_TRIAL v3.0
Patients who are enrolled in PCORnet clinical trials.

PRESCRIBING v3.0
Provider orders for medication dispensing and/or administration.

PRO_CM v2.0
Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined in the same way across all PCORnet networks. Each measure is recorded at the individual item level: an individual question/statement, paired with its standardized response options.

PROCEDURES v1.0
Procedure codes indicate the discreet medical interventions and diagnostic testing, such as surgical procedures, administered within healthcare delivery.

VITAL v1.0
Vital signs (such as height, weight, and blood pressure) directly measure an individual's current state of attributes.

PCORnet Phase I Executive Committee Work Groups

Workgroup	Goal
Dashboard	Developing a PCORnet dashboard and metrics
Front Door	Developing a front door policy that is currently in progress
IRB	Developing a strategy for streamlined IRB
Contracts	Developing two master contracts
Engagement	Developing an outlined engagement plan that will evolve into a plan for PCORnet
Industry	Aiming to host a follow-up in-person meeting in fall 2015 and have pilot projects in development early in 2016

Structure of PCORnet Phase II

PCORnet policies were approved on August 31st by the PCORnet Steering Committee and established the following structure:

- Networks (CDRNs & PPRNs)
- **PCORnet Council (PC)**
  - Nominating Committee
  - PCORnet Council & Committee Chairs
- PCORnet Advisory Group
- **Executive Committee**
- Engagement Committee
- Data Committee
- Research Committee
- Coordinating Center (CC)

Voting Members:
- 1 from each CDRN
- 1 from each PPRN
- 1 CC Rep
- 1 PCORI Rep

Voting Members:
- PC Chair
- PC Vice Chair
- 1 CC Rep
- 2 PPRN Investigators
- 2 CDRN Investigators

PCORnet Business Plan Development

- PCORI has contracted with PricewaterhouseCoopers (PwC) to develop a business plan for PCORnet
- Beginning in May, PwC has been engaged with PCORnet stakeholders including PPRN and CDRN PIs, members of the Board of Governors, and PCORI
- Activities have included interviews with key PCORnet stakeholders and a landscape analysis
- In August, PwC conducted a one-day Facilitated Design Session with PCORnet stakeholders to further develop the concepts within the initial framework of a business plan
- A final business plan will be presented to the PCORnet Executive Committee in October and shared with the Board of Governors
- The plan will recommend a contractual consortium model

Public Comment Period

Susan Hildebrandt, MA

Director, Stakeholder Engagement

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Directors