Board of Governors Meeting

September 15, 2014
10:15 a.m.-5:45 p.m. ET

Patient-Centered Outcomes Research Institute

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

Time	Agenda Item
10:15- 10:20	Welcome, Call to Order and Roll Call Consideration of August 26, 2014 Board Meeting Minutes for Approval
10:20- 11:15	Executive Director's Report and FY 2014 Q3 Dashboard Review
11:15- 12:00	Consider for Approval: FY 2015 Budget
12:00- 12:15	Consider for Approval: Posting for Public Comment of PCORI's Draft Proposal for Peer Review and Release of Research Findings
12:15- 12:30	Governance Committee Report
12:30- 1:15	Break
1:15- 2:15	Panel Discussion with PCORnet Clinical Data Research Network (CDRN) & Patient-Powered Research Network (PPRN) Principal Investigators (PI's)
2:15- 3:00	Review and Discuss Plans for Phase II of PCORnet
3:00- 3:30	Update on Methodology Committee Initiatives
3:30- 3:45	Break
3:45- 4:30	Improving Health Systems Program Overview
4:30- 5:15	Agency for Healthcare Research & Quality (AHRQ) PCOR Trust Fund Research Agenda
5:15- 5:45	Public Comment
5:45	Wrap Up and Adjournment

Board Vote: Approval of August 26, 2014 Board Meeting Minutes

Call for a Motion to:	• **Approve** the August 26, 2014 Board Meeting Minutes
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: PCORI at Four Years

Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute

Landmarks of Our First Four Years

2011

First Board Meeting – November 2010

Pilot Awards Funding Announcement Released – September

2012

National Priorities and Research Agenda Adopted – May
First Broad CER Announcements – May
Pilot Projects Awarded (50) – June
Draft Methodology Report Posted – July
First Methodology Standards Adopted – November
First CER Awards (25) – December

2013

First Targeted Award Announcement (Asthma) – June
Second Targeted Award Announcement – July

First Targeted Award (Asthma) – December

2014

First Pragmatic Studies Announcement – February

2015

First Pragmatic Clinical Studies to Be Awarded – February

Principles of PCOR

Patient-centered – comparisons and outcomes that matter to patients

Engaged – involvement of key stake-holders throughout the research process to enhance relevance and dissemination

Likely to Change Practice – research questions identified by decision-makers as representing true knowledge gaps

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Patient-Centered Themes Well Represented in Our Portfolio – Broad CER Announcements

Assessing Prevention, Diagnosis, and Treatment Options

- Self-care
- Caregiver Support
- Palliative Care

Improving Healthcare Systems

- Care transitions
- Telemedicine
- Patient Navigators
- Collaborative Care

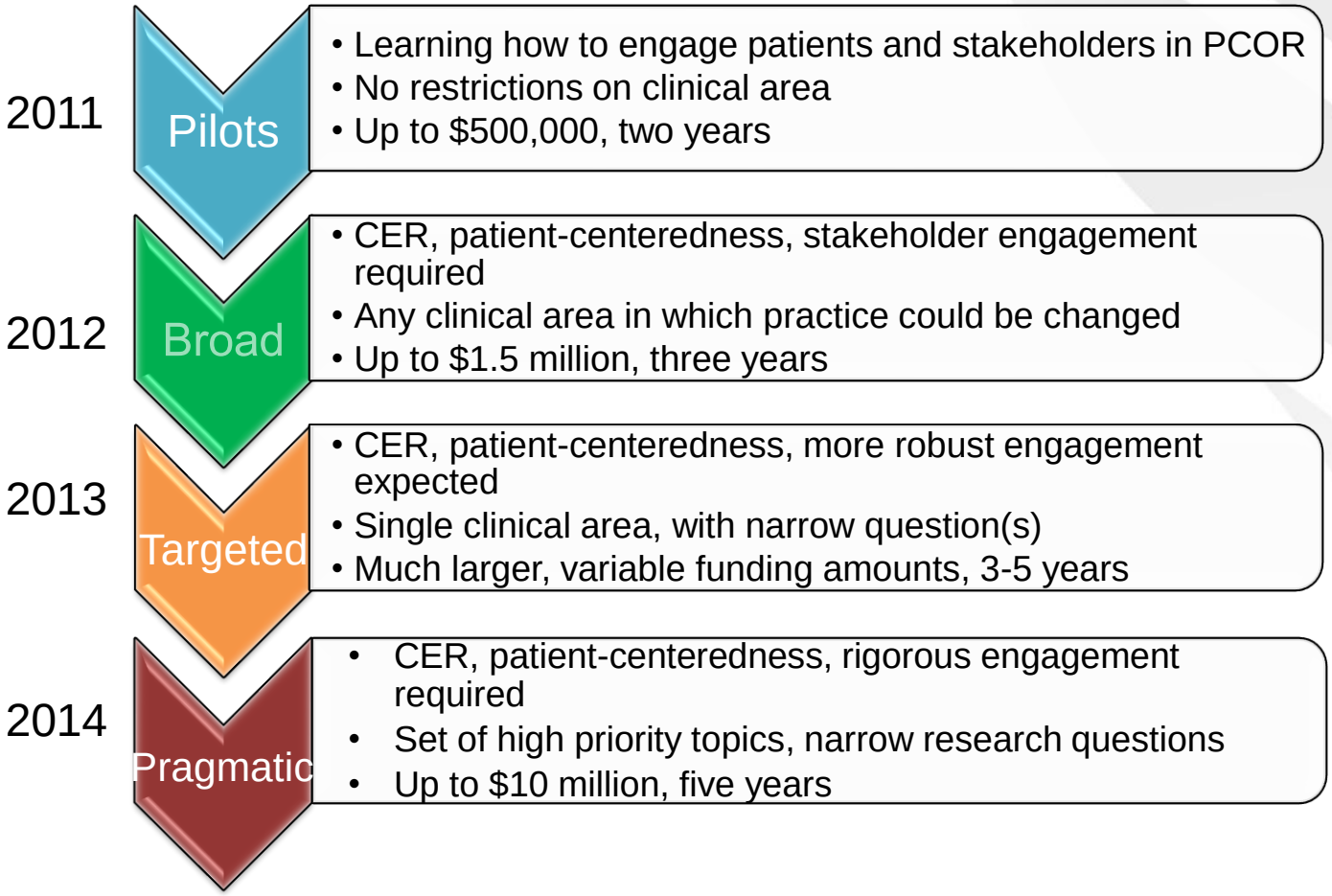
Addressing Disparities

- Cultural/Language Training
- Community Health Workers
- Self-management

Communication & Dissemination Research

- Shared Decision-making
- Parental Support in Pediatric Illness

Refining Our Research Agenda



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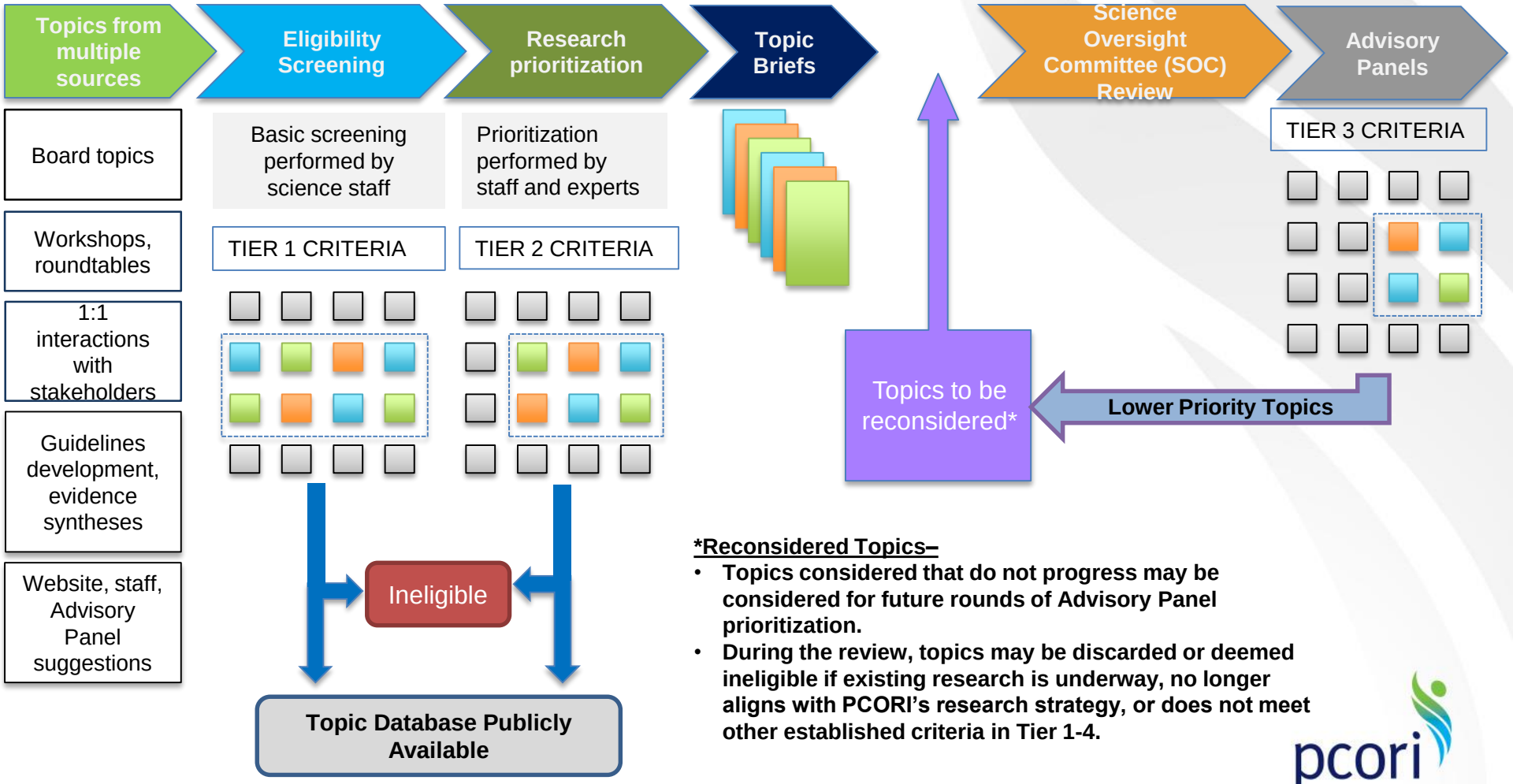
Approved Topics for Targeted PFAs

- Prevention of ***injurious falls*** in the elderly
- Treatment and management of ***severe asthma*** in minority populations
- Treatment options for ***uterine fibroids***
- ***Transitional care***
- Management of ***obesity*** in primary care
- Improving ***blood pressure*** control in vulnerable populations

PCORI Pathway for Topic Generation and Research Prioritization



***Reconsidered Topics–**

- **Topics considered that do not progress may be considered for future rounds of Advisory Panel prioritization.**
- **During the review, topics may be discarded or deemed ineligible if existing research is underway, no longer aligns with PCORI's research strategy, or does not meet other established criteria in Tier 1-4.**

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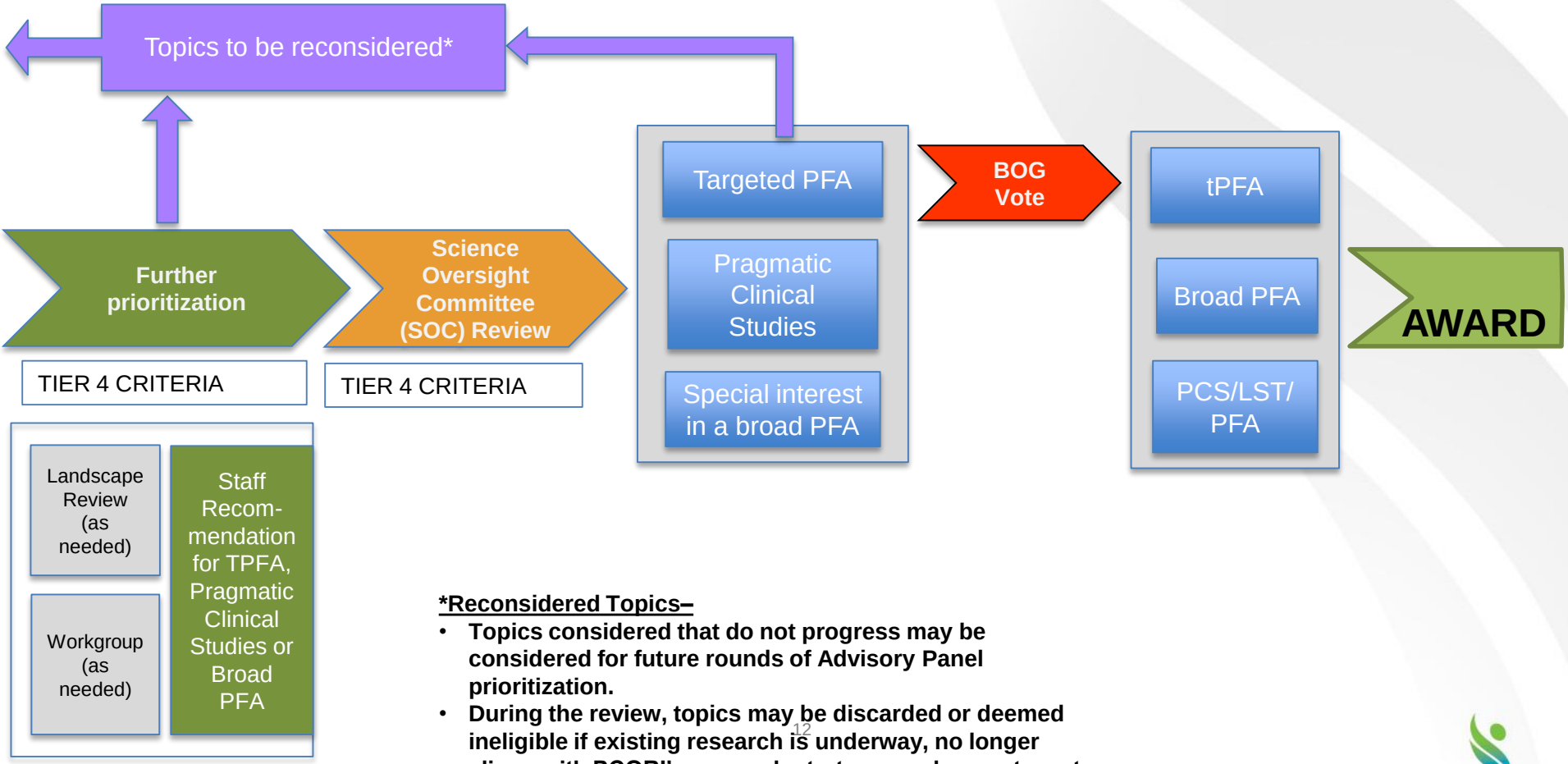
PCORI Pathway for Topic Generation and Research Prioritization



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12

Topics Invited (n=36) for First Round of Pragmatic Clinical Studies

TOPIC	PCORI PRIORITY	IOM CER 100	AHRQ FRN
Treatment alternatives for Bipolar disorder	√		
Breast ca/DCIS management (2)	√		
Breast cancer screening		Q1	√
Cancer (use of CSF)		Q3	
Cancer care med management	√	Q2	
Collaborative care in mental health	√	Q4	
CVD preventive care (5)	√	Q1	
Dental caries		Q1	
Diabetes prevention		Q1	
Alternatives for DVT prophylaxis		Q4	

Topics Invited (n=36) for First Round of Pragmatic Clinical Studies (continued)

TOPIC	PCORI PRIORITY	IOM CER 100	AHRQ FRN
Genetic testing for CAD		Q1	
New Hepatitis C therapies		Q4	√
Management of low back pain (3)	√	Q1	
Surveillance of lung nodules (2)	√		
Improving medication adherence	√	Q2	
Treatment of Migraine Headache	√	Q4	
OA management, decision-making	√	Q4	
Proton beam therapy in cancer	y	Q1	
Sickle cell Disease therapy		Q1	√
Smoking cessation (2)	√	Q4	
Stroke management		Q3	
Substance abuse treatment	√		
Aortic dissection repair (2)			
Chest pain ER management			
Fragile X syndrome			

Patient-Centered Versions of These Same Questions

My grandmother fractured her hip – what type of surgery will be best to get her walking again?

I've been diagnosed with multiple sclerosis, and I want to keep working as long as I can – which therapy will best keep my MS from progressing quickly?

My migraine headaches are unbearable – are drugs the best response, or are there other treatments that would keep my migraines from becoming more frequent?

Ten of my patients who were former smokers had a tiny lung nodule found by an imaging study – what sort of follow-up should I recommend to make sure they don't progress to cancer?

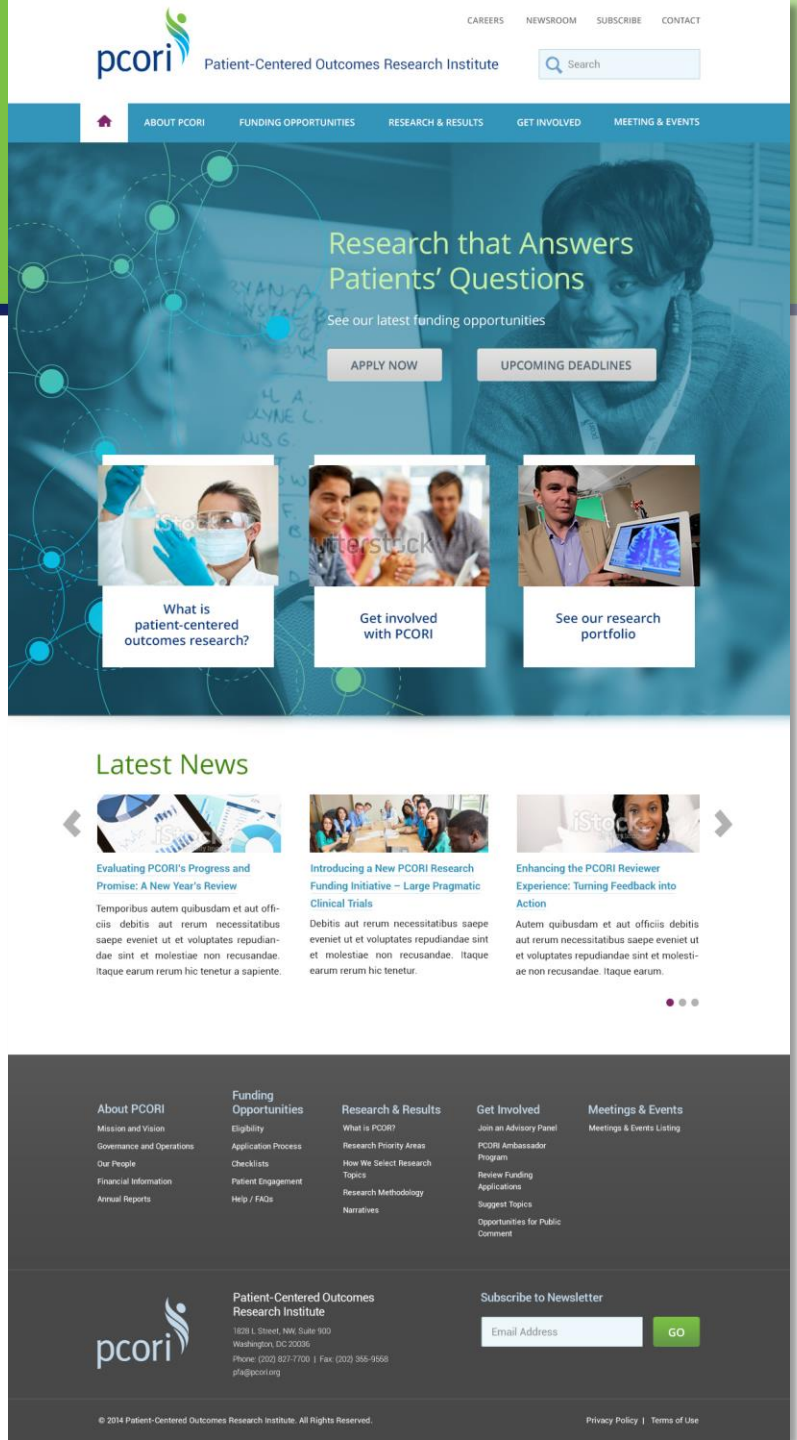
My doctor tells me that the pain bothering me comes from arthritis in my knee – will medications, injections, physical therapy, or other treatments keep it from getting worse and put off knee replacement surgery?

Onward to 2015…

- Build on PCORI's foundation of patient-centeredness, stakeholder engagement, and research likely to change practice
- Actively manage our present portfolio, synthesizing knowledge from the thematic areas we're funding, identifying opportunities for dissemination with AHRQ
- Work with our Science Oversight Committee, our Advisory Panels, and our stakeholder groups to continue moving toward more specific, focused, high-priority research questions
- Identify methods of moving high-priority topics more quickly through our topic generation and prioritization process

Update: First GAO 5-Year Review of PCORI

- We received our notification letter from GAO in March. It identified two primary objectives for the review, to determine:
  - To what extent has PCORI established research priorities and funded research in accordance with its legislative requirements?
  - To what extent has PCORI established plans and undertaken efforts to evaluate the effectiveness of its work?
- We had our Entrance Conference with the GAO Team in April
- We had a series of meetings with the GAO team in May, June, and July to discuss a wide range of topics, including Advisory Panels, Dissemination, Evaluation, Merit Review, PCORnet, and Research Funding
- Additional meetings are planned for late September/early October
- We anticipate our Exit Conference with the GAO team and opportunity to review and comment on the GAO's draft report during the winter
- GAO's report to Congress is due in March of 2015



The New PCORI.org

- New look and feel designed to reflect PCORI's mission and vision
- Designed to more clearly tell audiences who we are and what we do
- Improved user experience for applicants
- Flexible, expandable, open-source platform built to manage our future needs
- Weaves our focus on stakeholder engagement throughout all major content sections
- Automatically adjusts to work well on desktop, laptop, tablet, and smartphone
- More use of video to tell the stories of our work from stakeholder perspectives
- New interactive features

PCORI's Inaugural Annual Meeting

- Fall 2015 in Washington, DC area
- Opportunity to share updates on our work with research, patient, and other stakeholder communities
- Multi-day, multi-track
- Plenary and panel discussions, featuring invited research/patient partner presentations
- "How-to" workshops and "evidence-to-action network" sessions on key topics
- Program planning committee being formed

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Agenda for Today's Meeting

- Review Performance ***Dashboard***, 3rd Quarter 2014
- Consideration for Approval of PCORI ***2015 Budget***
- Consideration for Approval to Post for Public Comment PCORI's Draft Proposal for ***Peer Review and Release of Research Findings***
- Presentation from ***PCORnet*** Network PIs and Discussion of Plans for Phase II of PCORnet
- ***Methodology Committee*** Update
- Overview of PCORI's ***Improving Healthcare Systems Program***
- ***AHRQ's*** PCOR Trust Fund Portfolio

Dashboard Review
Third Quarter of FY 2014

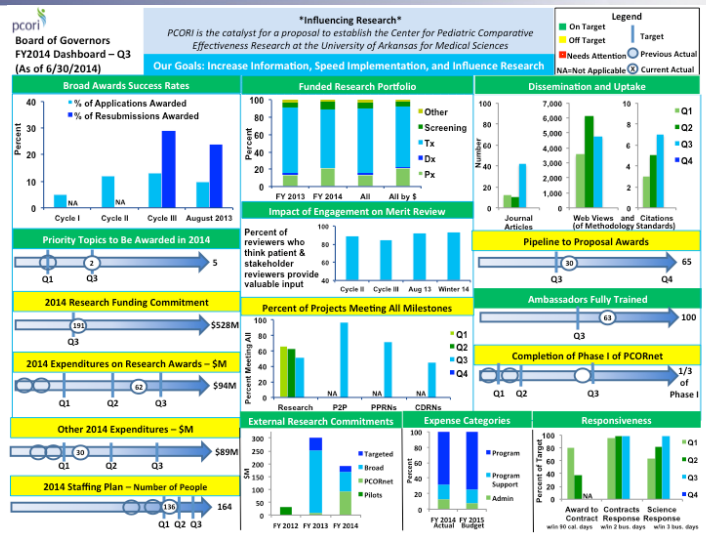
Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute

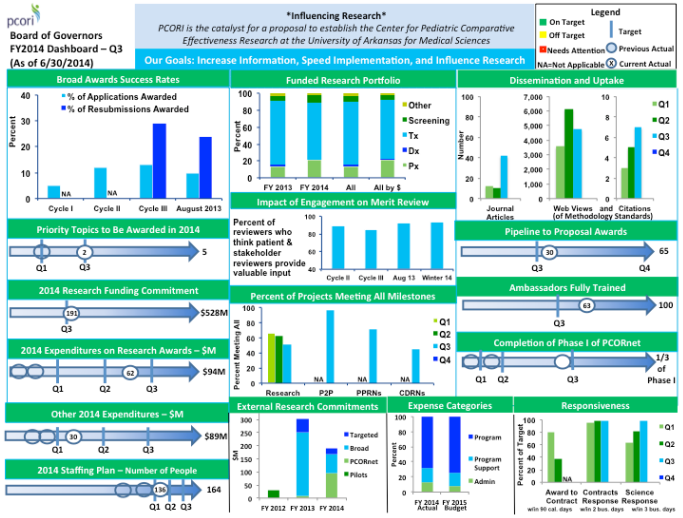
First Message from the Dashboard: Notice the Colors

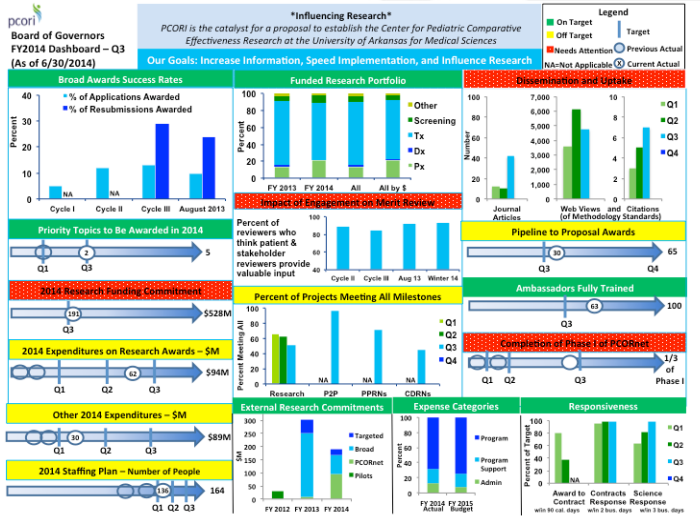
Legend

- On Target
- Off Target
- Needs Attention



For those of us who can't see red, the red boxes would show up in gray scale as dotted





Board of Governors FY2014 Dashboard – Q3 (As of 6/30/2014)

Influencing Research

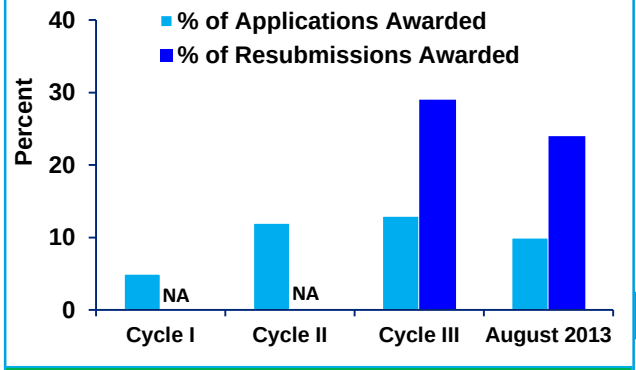
PCORI is the catalyst for a proposal to establish the Center for Pediatric Comparative Effectiveness Research at the University of Arkansas for Medical Sciences

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

Legend

On Target | Off Target | Needs Attention | NA=Not Applicable | Target | Previous Actual | Current Actual

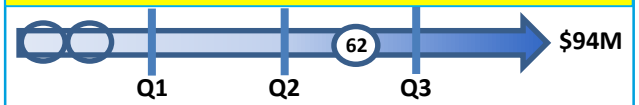
Broad Awards Success Rates



Priority Topics to Be Awarded in 2014

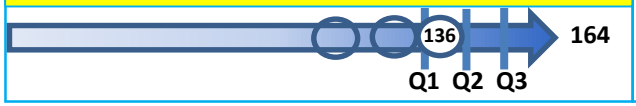
2014 Research Funding Commitment

2014 Expenditures on Research Awards – $M

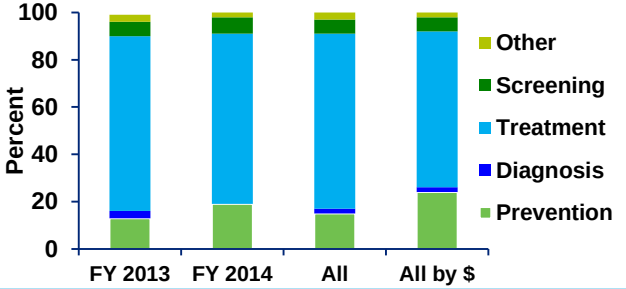


Other 2014 Expenditures – $M

2014 Staffing Plan – Number of People

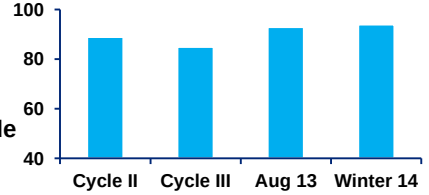


Funded Research Portfolio

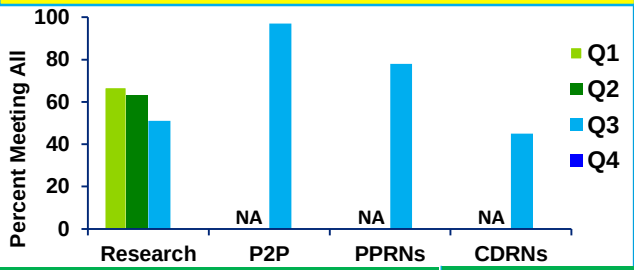


Impact of Engagement on Merit Review

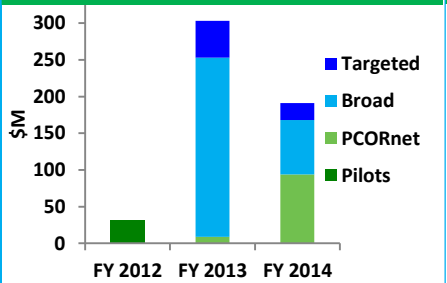
Percent of reviewers who think patient & stakeholder reviewers provide valuable input



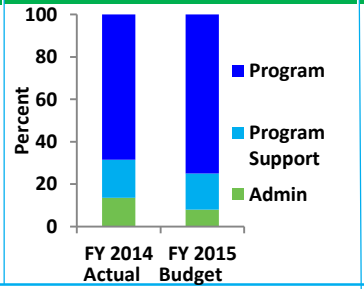
Percent of Projects Meeting All Milestones



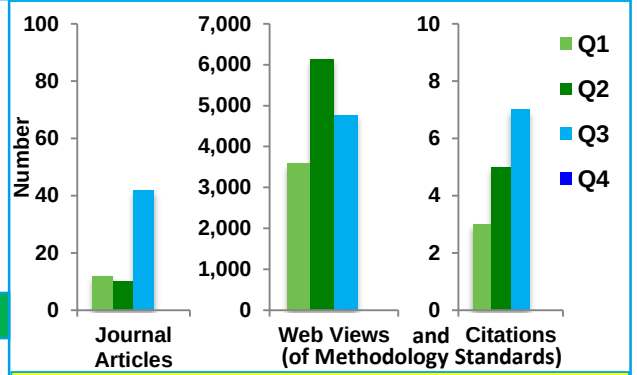
External Research Commitments



Expense Categories

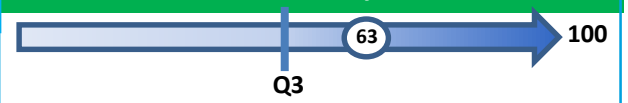


Dissemination and Uptake

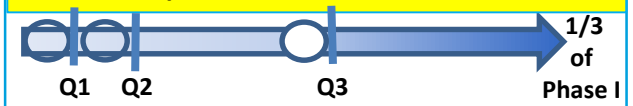


Pipeline to Proposal Awards

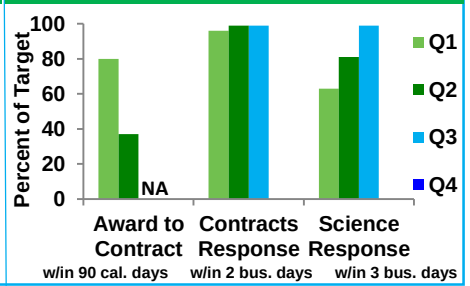
Ambassadors Fully Trained



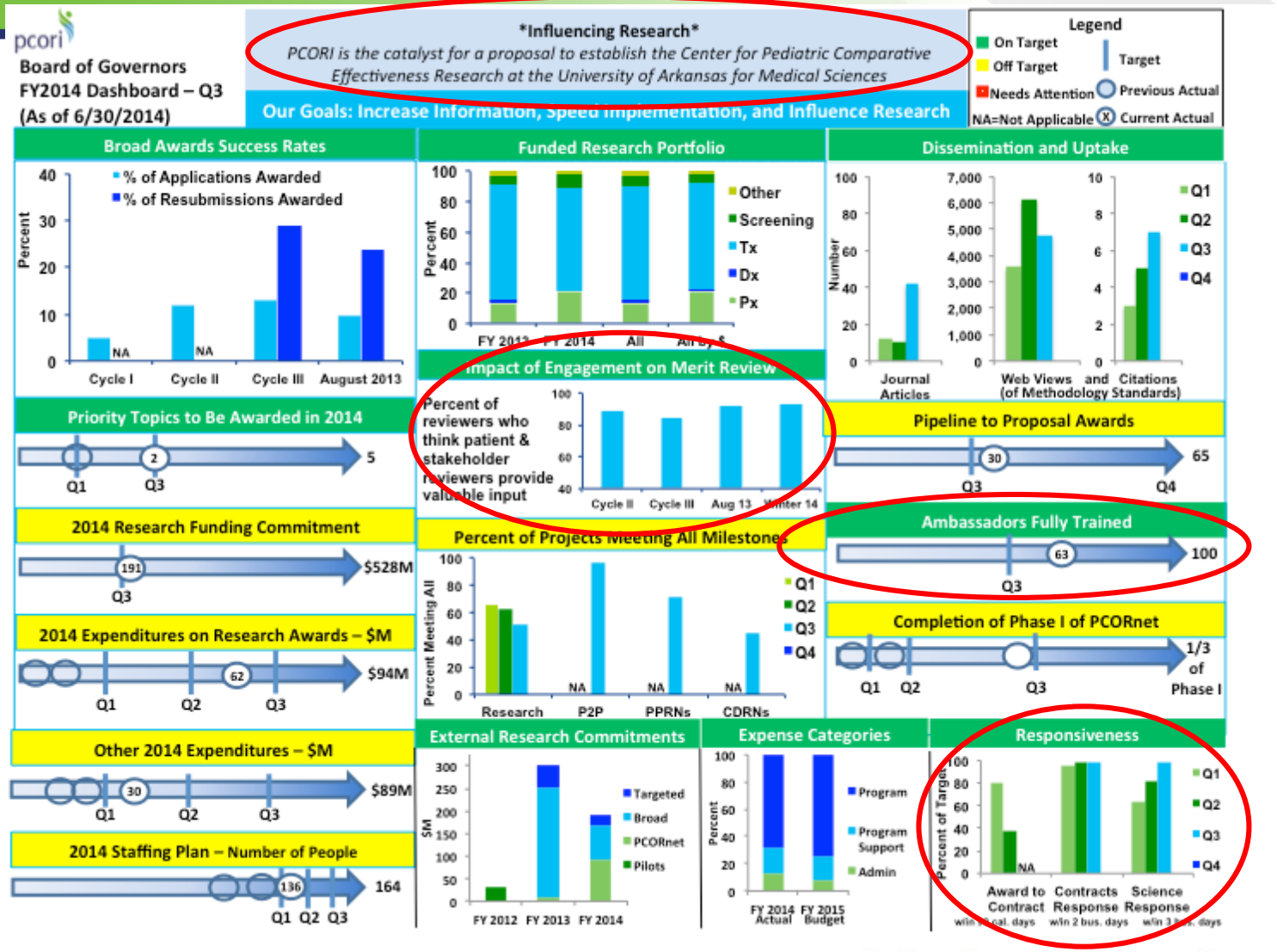
Completion of Phase I of PCORnet



Responsiveness



Noteworthy Items



Influence Research
Early Signs

Influencing Research
PCORI is the catalyst for a proposal to establish the Center for Pediatric Comparative Effectiveness Research at the University of Arkansas for Medical Sciences

- Dr. Debra Fiser was a critical care physician for 14 years, then Chair of the University of Arkansas for Medical Sciences (UAMS) Department of Pediatrics for 11 years, then served as Dean of the UAMS College of Medicine for 7 years. She said as a capstone for her career, she wanted to help others in her department achieve success by mentoring young clinicians and faculty. She particularly wanted to help physicians who have not been involved in research in the past to see the relevance of research in their work and to build capacity to engage in Comparative Effectiveness Research (CER).

- Dr. Fiser stepped down as Dean in May 2013 and attended the PCORI Engagement Workshop in Memphis, Tennessee, in August of 2013, which provided inspiration for her proposal to establish a ***Center for Pediatric Comparative Effectiveness Research*** at UAMS. She saw the work PCORI is doing to fund patient-centered CER as the catalyst UAMS needed to invest in training faculty in CER.

- The objective of the Center is to recruit, train, and mentor faculty in ***patient-centered CER methods***. It is up and running as of July 1, 2014, and currently has funding for five years to recruit five half-time faculty each with three years of support.

- The Center is focused on building capacity by preparing pediatric clinicians and faculty who are relatively new to research to ***conduct patient-centered CER***, with an end goal of successfully applying to PCORI for funding.

Increase Information

Merit Reviewer Survey Details

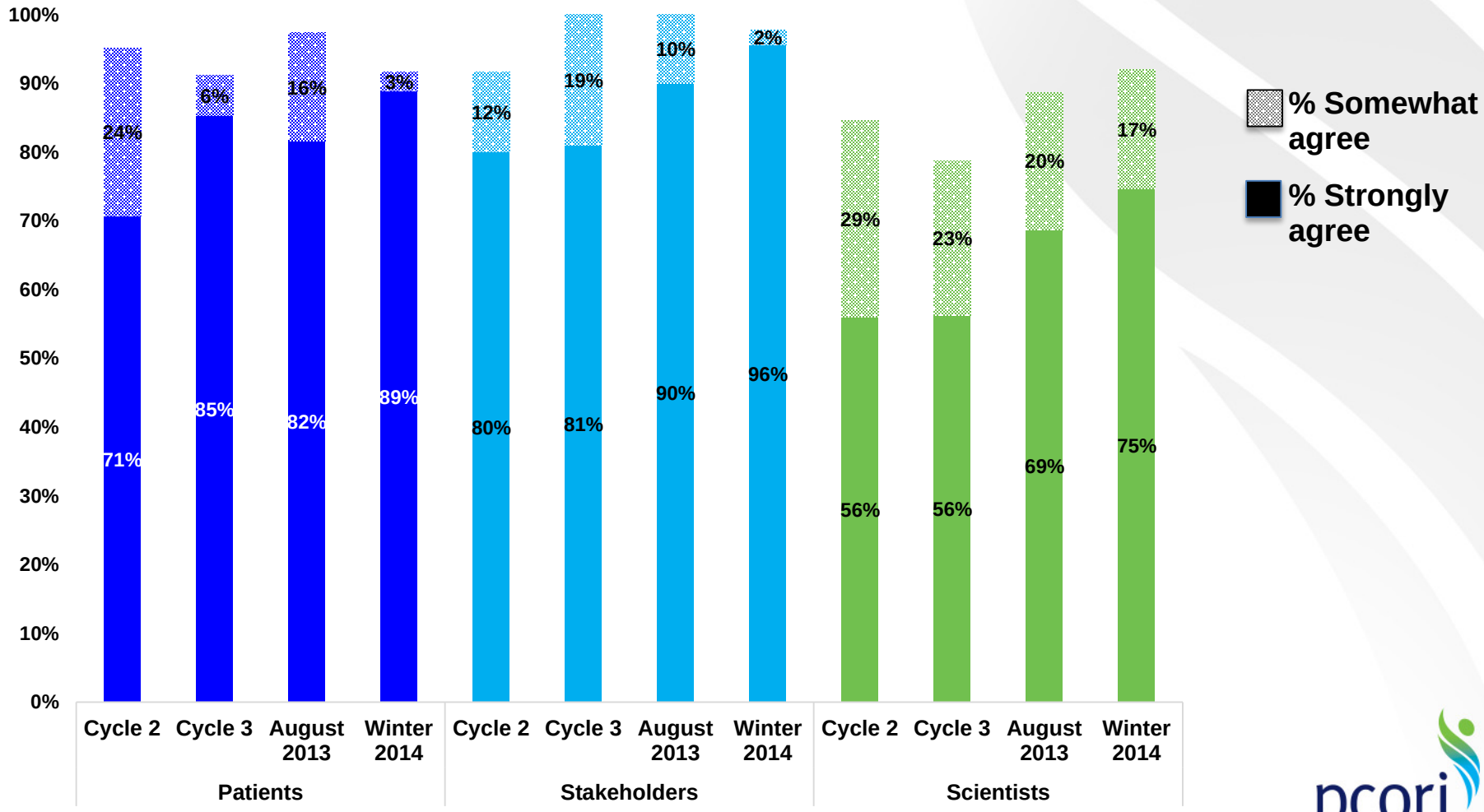
We asked merit reviewers to rate their agreement with the following statement:
The patient/stakeholder reviewers provided valuable input during the discussion

(Strongly Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, and Strongly Agree)

Survey	Sample Size	Survey Completion Rate	Percent Who Agree Somewhat or Strongly
Cycle II	205	94%	89%
Cycle III	167	97%	85%
August 2013	286	91%	93%
Winter 2014	209	83%	94%

*Surveys of merit reviewers are conducted **immediately following each in-person merit review** and are **live in the field for 2 weeks**.*

Percent of merit reviewers who agree with the statement: *"The patient/stakeholder reviewers provided valuable input during the discussion"*



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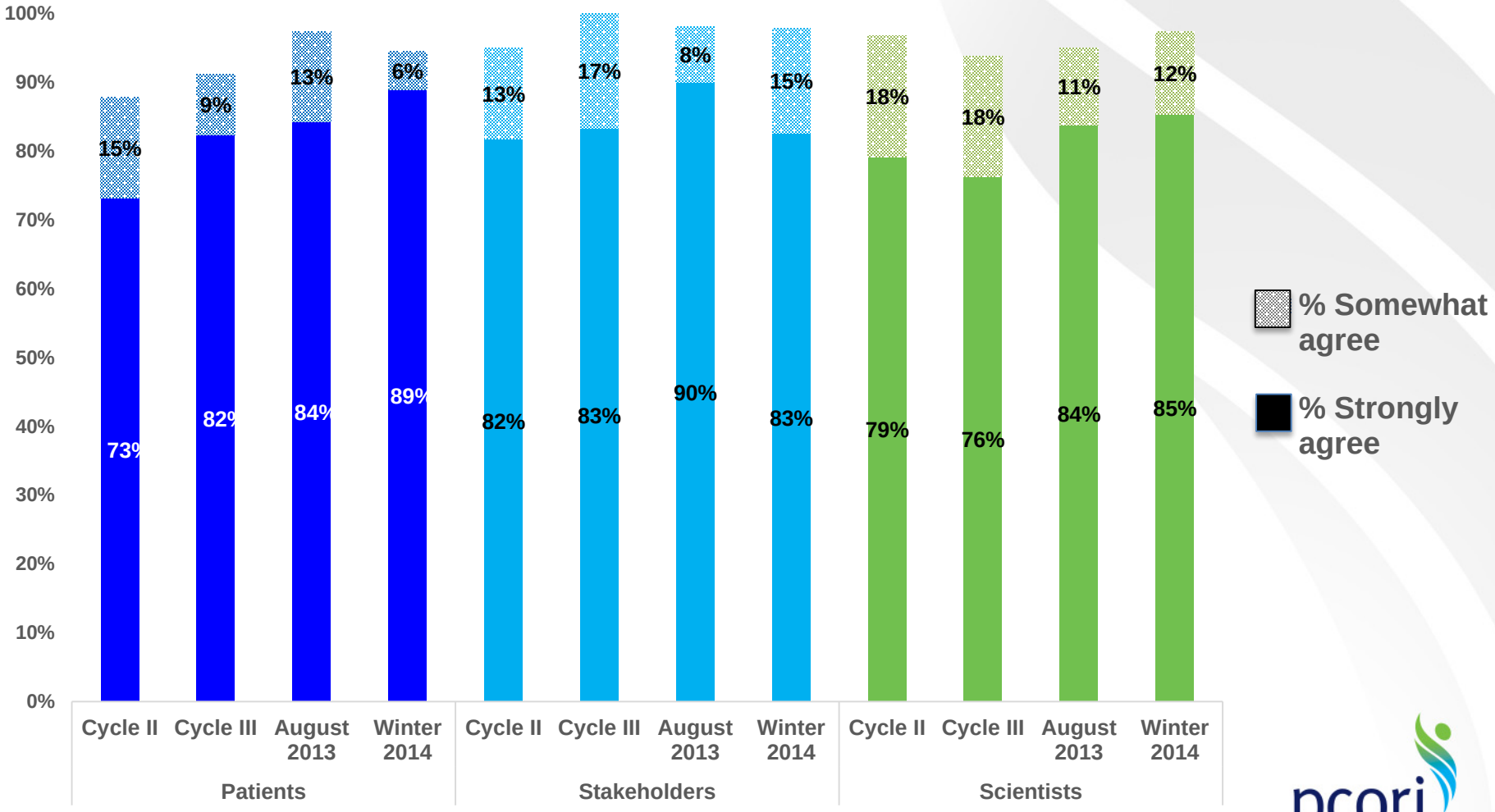
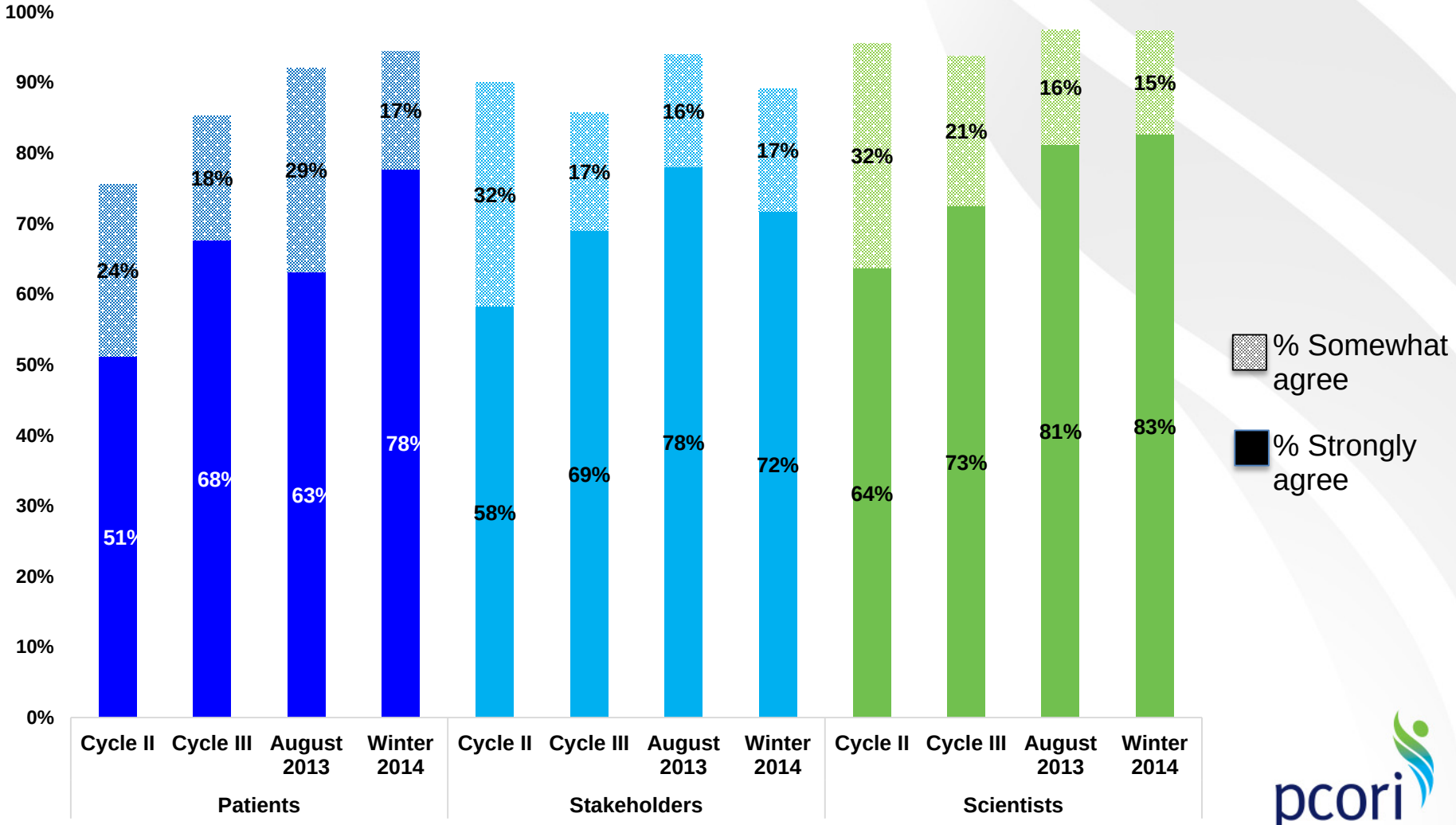
Percent of merit reviewers who agree with the statement: "*The scientific reviewers provided valuable input during the discussion*"



Percent of merit reviewers who agree with the statement: *"Overall, scientific reviewers were receptive to input from patient and stakeholder reviewers"*



Increase Information

Our first published study of Merit Review

RESEARCH AND REPORTING METHODS | Annals of Internal Medicine

Engaging Patients and Stakeholders in Research Proposal Review: The Patient-Centered Outcomes Research Institute

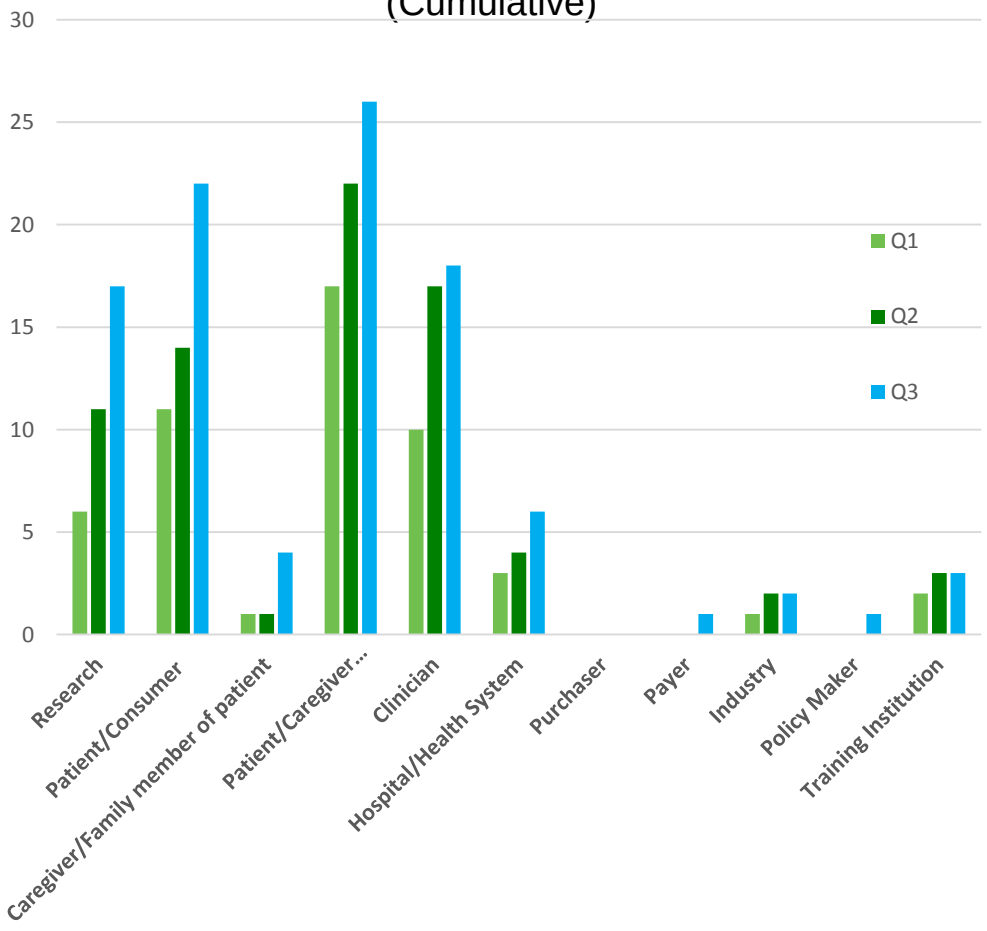
Rachael L. Fleurence, PhD; Laura P. Forsythe, PhD, MPH; Michael Lauer, MD; Jason Rotter, MHS; John P.A. Ioannidis, DSc, MD; Anne Beal, MD, MPH; Lori Frank, PhD; and Joseph V. Selby, MD, MPH

The inaugural round of merit review for the Patient-Centered Outcomes Research Institute (PCORI) in November 2012 included patients and other stakeholders, as well as scientists. This article examines relationships among scores of the 3 reviewer types, changes in scoring after in-person discussion, and the effect of inclusion of patient and stakeholder reviewers on the review process. In the first phase, 363 scientists scored 480 applications. In the second phase, 59 scientists, 21 patients, and 31 stakeholders provided a "prediscussion" score and a final "postdiscussion" score after an in-person meeting for applications. Bland–Altman plots were used to characterize levels of agreement among and within reviewer types before and after discussion. Before discussion, there was little agreement among average scores given by the 4 lead scientific reviewers and patient and stakeholder reviewers. After discussion, the 4 primary reviewers showed mild convergence in their scores, and the 21-member panel came to a much stronger agreement. Of the 25 awards with the best (and lowest) scores after phase 2, only 13 had ranked in the top 25 after the phase 1 review by scientists. Five percent of the 480 proposals submitted were funded. The authors conclude that patient and stakeholder reviewers brought different perspectives to the review process but that in-person discussion led to closer agreement among reviewer types. It is not yet known whether these conclusions are generalizable to future rounds of peer review. Future work would benefit from additional data collection for evaluation purposes and from long-term evaluation of the effect on the funded research.

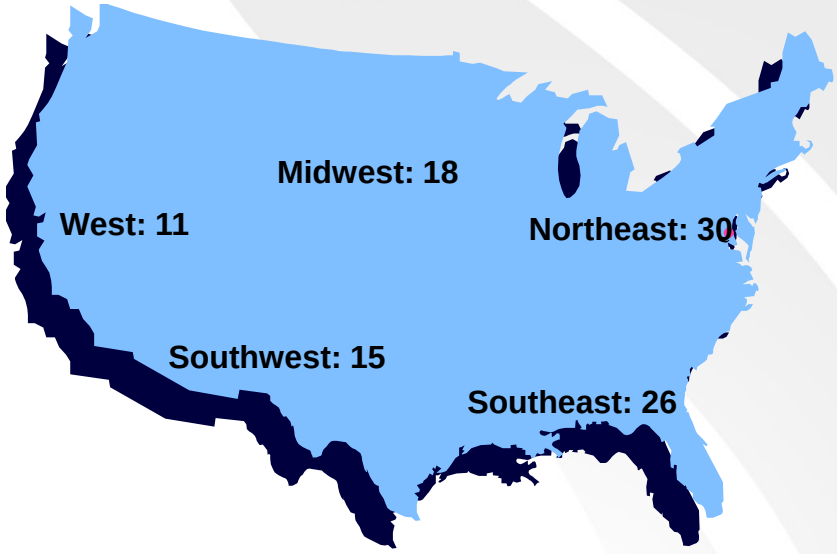
Ann Intern Med. 2014;161:122-130. doi:10.7326/M13-2412 www.annals.org
For author affiliations, see end of text.

Influence Research
PCORI Ambassadors Program

Ambassadors Enrolled by Stakeholder Group
(Cumulative)



Ambassadors Enrolled by Geographic Region



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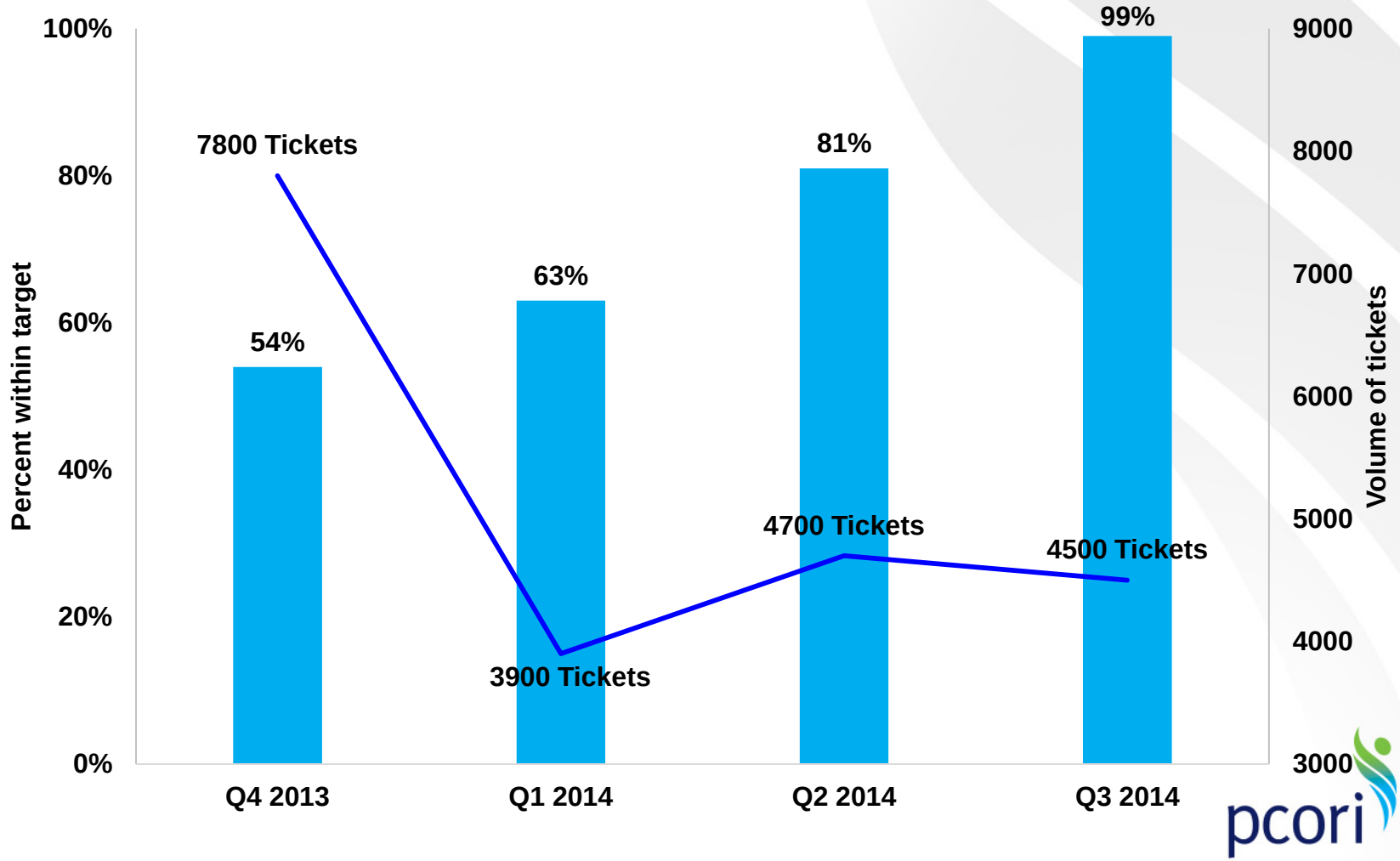
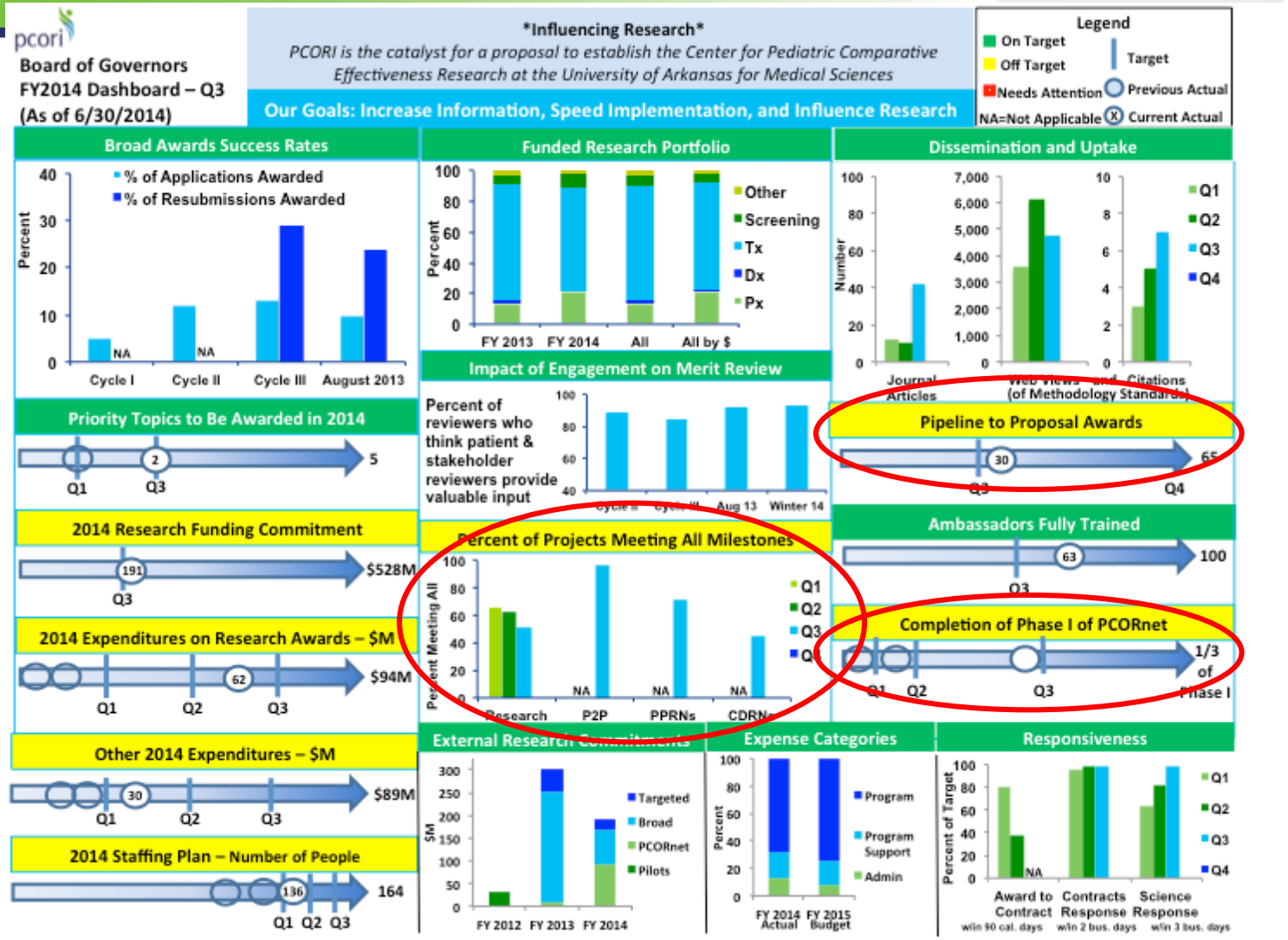
Operational Excellence

Q2 → Q3 **Science Response Time**

Target: 3 Business Days



Yellow-flagged Items – Off Target



Increase Information

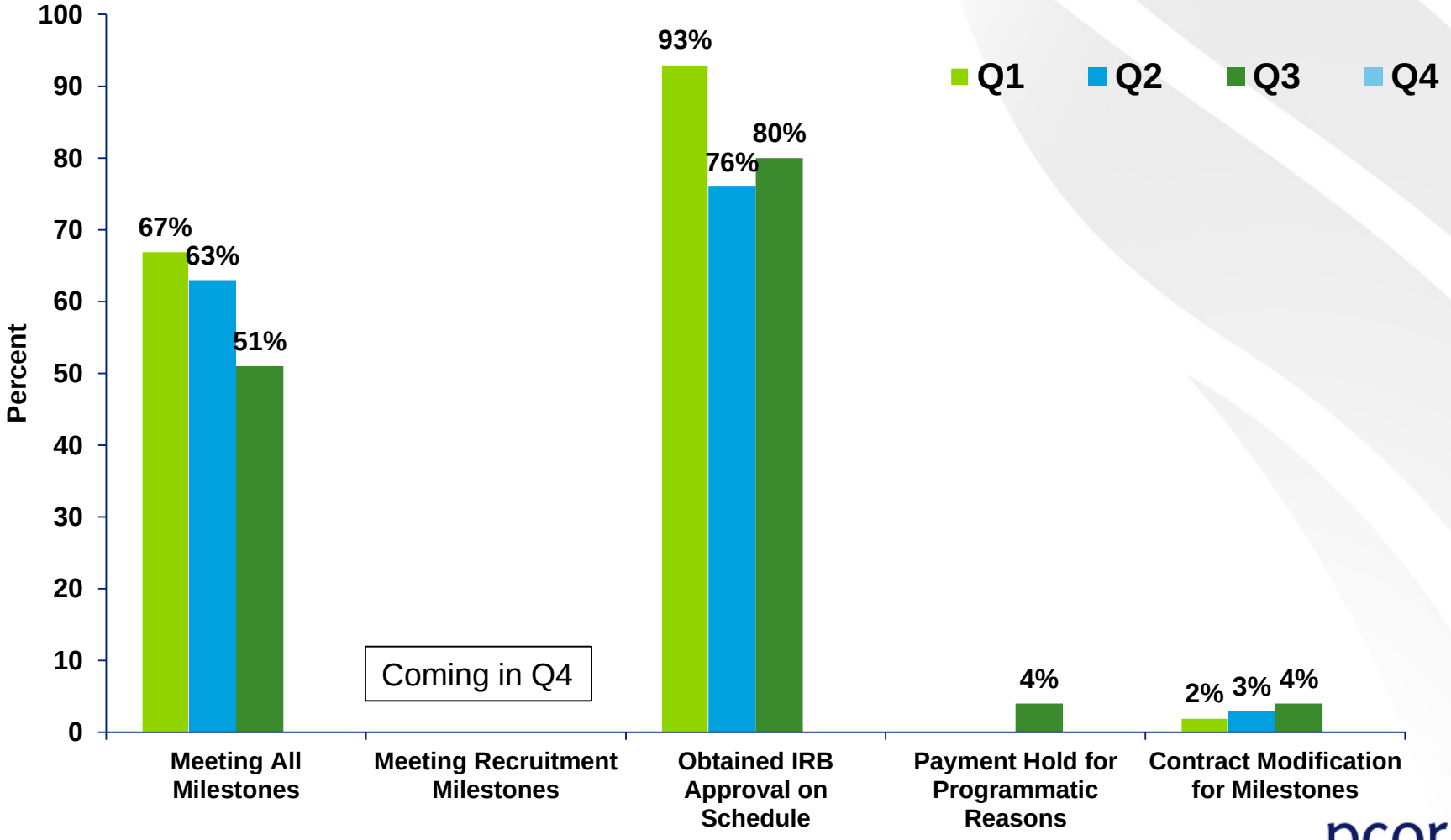
Progress of Research Projects

	Q1	Q2	Q3	Q4
Number of Projects with a Progress Report Due by Q3 2014 • Predominantly 6-month • A few 12-month • By next Q, a few 18-month	23	57	140	
Percent of Projects Meeting All Milestones Due	67%	63%	51%	
Average Percent of Milestones Due that Were Met	88%	87%	85%	

We are refining our approach to measuring and reporting on the progress of projects and will present additional analyses in Q4

Increase Information

Measures of Progress of Research Projects



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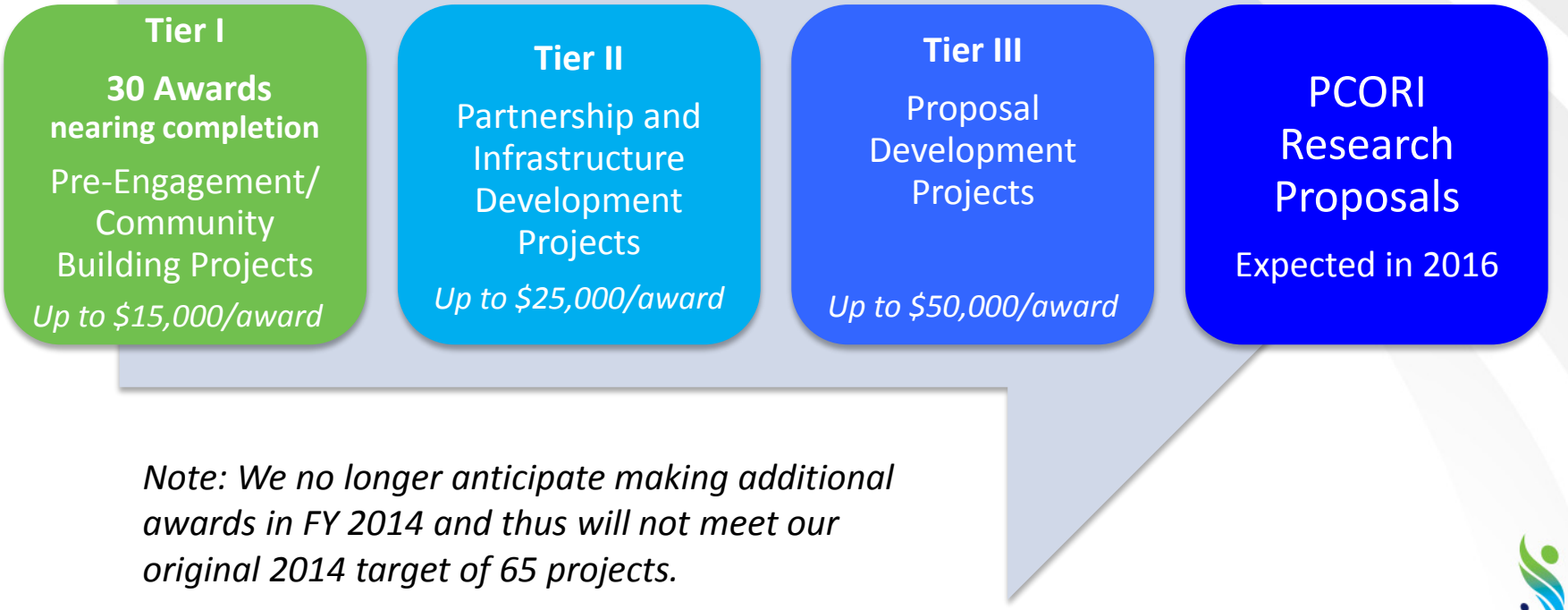
Influence Research

Pipeline to Proposal Awards – Q3 Snapshot



Note: We no longer anticipate making additional awards in FY 2014 and thus will not meet our original 2014 target of 65 projects.

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Influence Research
The Future of Pipeline to Proposal Awards

- Our initial 30 awardees and first Program Office are providing valuable data and feedback for refinement of our concept and plans for future funding rounds
  - ***29 out of 30 projects have met 100% of their milestones***

- Early in FY 2015, we plan to award:
  - 4 additional regional ***Program Offices***, for a total of 5
  - Up to 50 additional ***Tier I*** projects
  - Up to 30 ***Tier II*** projects that have advanced from Tier I
  - Up to 50 ***Tier III*** projects

Progress of PCORnet

Status of PCORnet Major Deliverables at Q3

- ✓ Common data model
  - *Version 1 completed*
- ❑ Governance policies
  - *2 of 8 policies in development are nearing completion*
- ✓ Clinical trial
  - *Topic determined*
- ✓ Steering Committee and Task Force
  - *Charters completed*
  - *Members selected and meetings occur regularly*
- ✓ Communications
  - *PCORnet.org launched*
  - *Collaborative workspace launched*

Board of Governors FY2014 Dashboard – Q3 (As of 6/30/2014)

Influencing Research

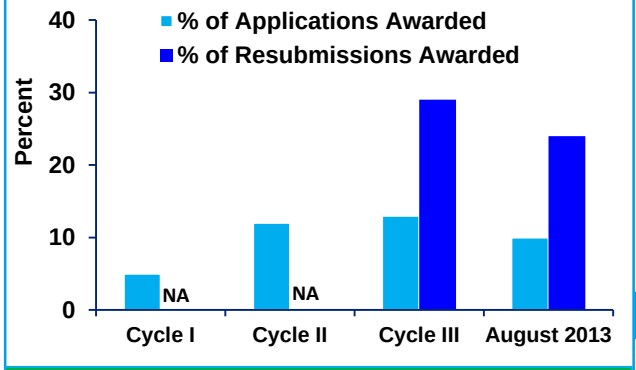
PCORI is the catalyst for a proposal to establish the Center for Pediatric Comparative Effectiveness Research at the University of Arkansas for Medical Sciences

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

Legend

On Target | Off Target | Needs Attention | NA=Not Applicable | Target | Previous Actual | Current Actual

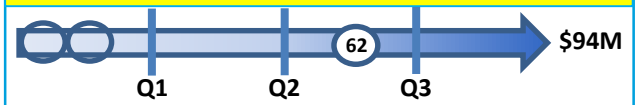
Broad Awards Success Rates



Priority Topics to Be Awarded in 2014

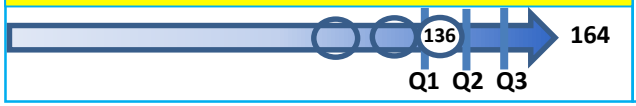
2014 Research Funding Commitment

2014 Expenditures on Research Awards – $M

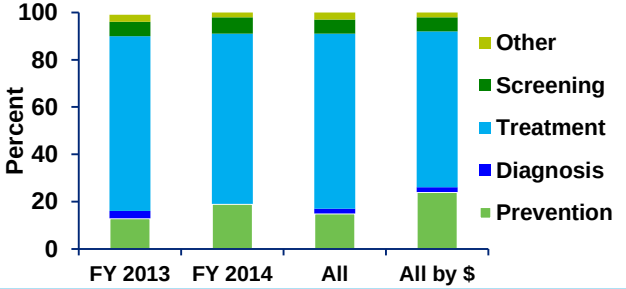


Other 2014 Expenditures – $M

2014 Staffing Plan – Number of People

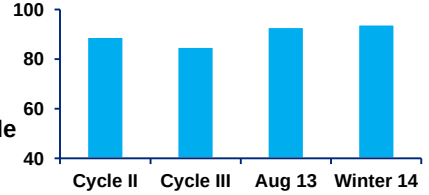


Funded Research Portfolio

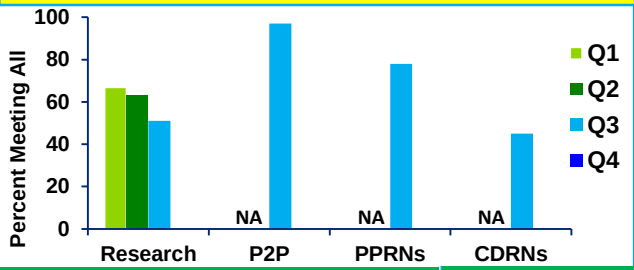


Impact of Engagement on Merit Review

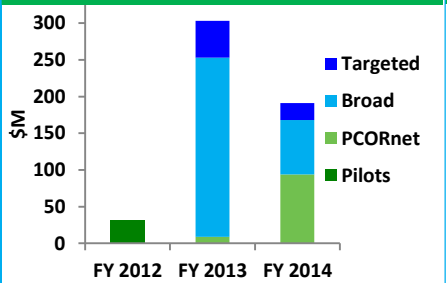
Percent of reviewers who think patient & stakeholder reviewers provide valuable input



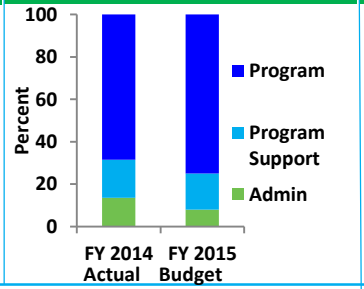
Percent of Projects Meeting All Milestones



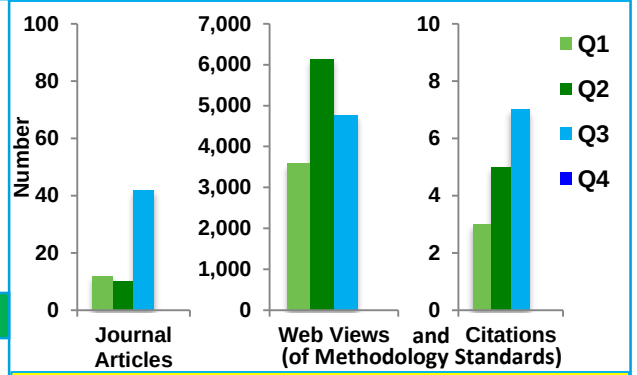
External Research Commitments



Expense Categories

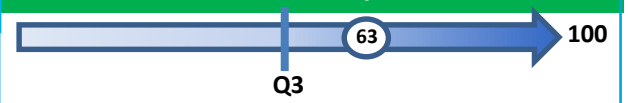


Dissemination and Uptake

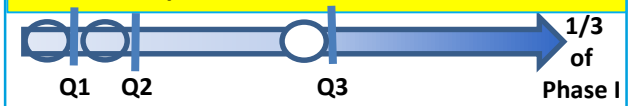


Pipeline to Proposal Awards

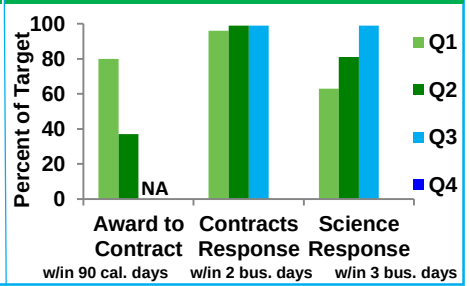
Ambassadors Fully Trained



Completion of Phase I of PCORnet



Responsiveness



Appendix

Additional Background Slides to Respond to Questions

Influence Research

Related Evaluation Activities

Our regular survey of Merit Reviewers is one example of our evaluation activities – other examples include:

- To evaluate ***Merit Review***, we also
  - Analyze scores (see recent publication by Fleurence, et al.)
  - Analyze written application critiques
  - Conduct small group discussions with merit reviewers
- We also evaluate the ***Impact of Engagement*** on
  - Topic prioritization
  - All phases of the research process
  - Dissemination
- To better understand our stakeholders, we also ***Survey*** and conduct focus groups with
  - LOI Submitters and Applicants
  - Patients and Caregivers
  - Clinicians and Researchers
  - Industry, Payer, and Purchaser Stakeholders

Influence Research

Progress of PCORnet: CDRNs at 3 months

Task

- ❑ Network ***Organizational Metadata*** complete – 3/11
- ❑ ***PopMedNet capability*** established (DataMartClient installation complete) – 2/11
- ❑ Performed ***test query*** run on fake dataset – 0/11
- ❑ Developed plans for ***streamlined Institutional Review Board*** – 5/11
- ✓ Patients currently engaged/finalizing ***engagement in governance*** – 11/11
- ❑ Developing ways to ***disseminate*** research results – 2/11
- ❑ Developing plans for conducting ***clinical trial*** without disrupting healthcare operations – 8/11

Meeting 100% of Milestones Due in Q3 – 5/11

Influence Research

Progress of PCORnet: PPRNs at 3 months

9 COMMON CONDITION PPRNs

- ❑ **Data domains**:
  - ✓ demographic 9/9
  - ❑ vital signs 5/9
  - ❑ enrollment, diagnosis data, and encounter data 4/9
- ❑ **Patient portals**:
  - ✓ Developing 9/9
  - ✓ Beta launch 6/9
  - ❑ Launched 1/9
- ❑ **IRB Approved:** 4/9
- ✓ **Patient Engagement**: 9/9 with patients in governance

Meeting 100% of Milestones Due Q3: 8/9

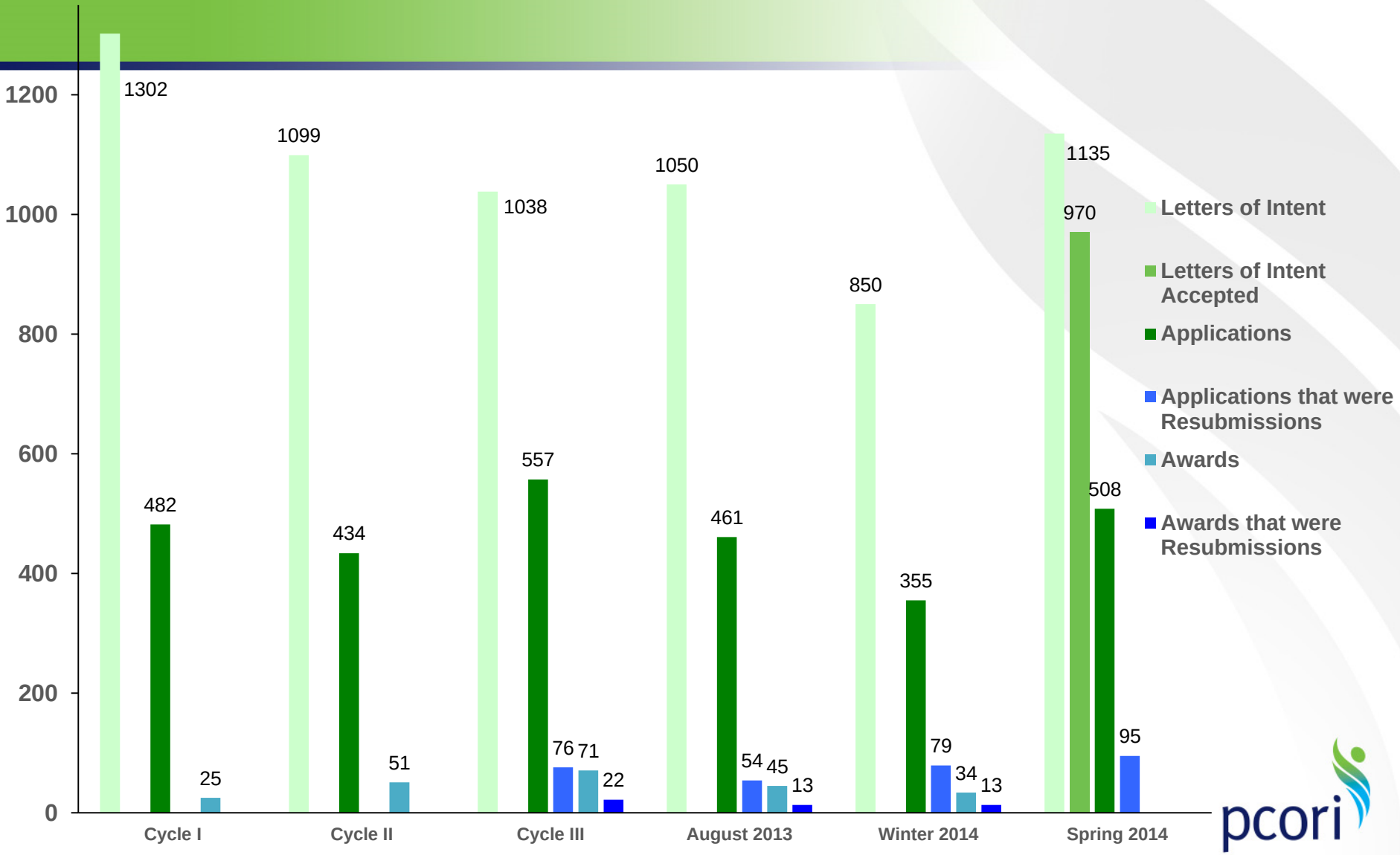
9 RARE CONDITION PPRNs + CENA

- ❑ **Data domains**:
  - ✓ demographic 9/9
  - ❑ vital signs 6/9 (1/9 undecided)
  - ❑ enrollment, diagnosis data, and encounter data: 8/9 ((1/9 undecided)
- ✓ **Patient portals**: 9/9
  - ❑ Launched and enrolling patients: 2/9
- ❑ **IRB Approval:**
  - ❑ Full: 3/9
  - ❑ Partial: 4/9
  - ❑ Under review: 1/9
  - ❑ Not submitted yet: 1/9
- ✓ **Governance Structures Developed:** 9/9
- ✓ **Patient Engagement**: 9/9 with patients in governance

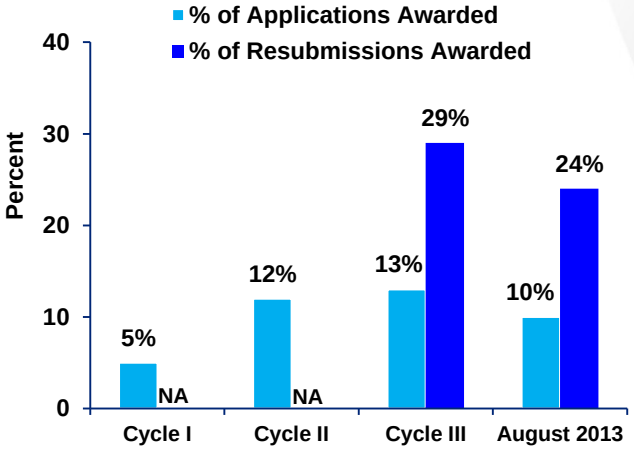
Meeting 100% of Milestones Due Q3 : 6/9

Increase Information

LOIs, Applications, and Awards: Broad PFAs



Increase Information
Point of Reference for Resubmissions



In Q4, we will have two additional PCORI funding cycles for this analysis

Data for 2013 from NIH "RePORT" – Success Rates/Research Project Grants/Spreadsheet #10

Fiscal Year	Type[1] and Submission Number[2]	RESEARCH PROJECT GRANTS[3]				R01-EQUIVALENT GRANTS[4]			
		Number of Applications Reviewed	Number of Applications Awarded	Success Rate[5]	Total Funding[6]	Number of Applications Reviewed	Number of Applications Awarded	Success Rate[5]	Total Funding[6]
2013	New - First Submission (A0)	33,740	3,144	9.3%	$1,375,817,409	16,999	1,440	8.5%	$624,473,802
2013	New with Resubmissions (A1)	10,620	3,345	31.5%	$1,221,237,108	6,263	1,892	30.2%	$808,914,272
2013	Continuations (A0)	3,030	873	28.8%	$497,759,255	2,755	719	26.1%	$310,767,843
2013	Continuations with Resubmissions (A1)	2,030	898	44.2%	$409,208,222	1,876	804	42.9%	$320,675,931
2013	Supplements	161	50	31.1%	$9,025,718	151	47	31.1%	$8,079,504

- Percent of NIH applications that were resubmissions in 2013 = 24% and 27% (for the 2 sets shown above)
- PCORI's last four cycles have averaged 17% resubmissions

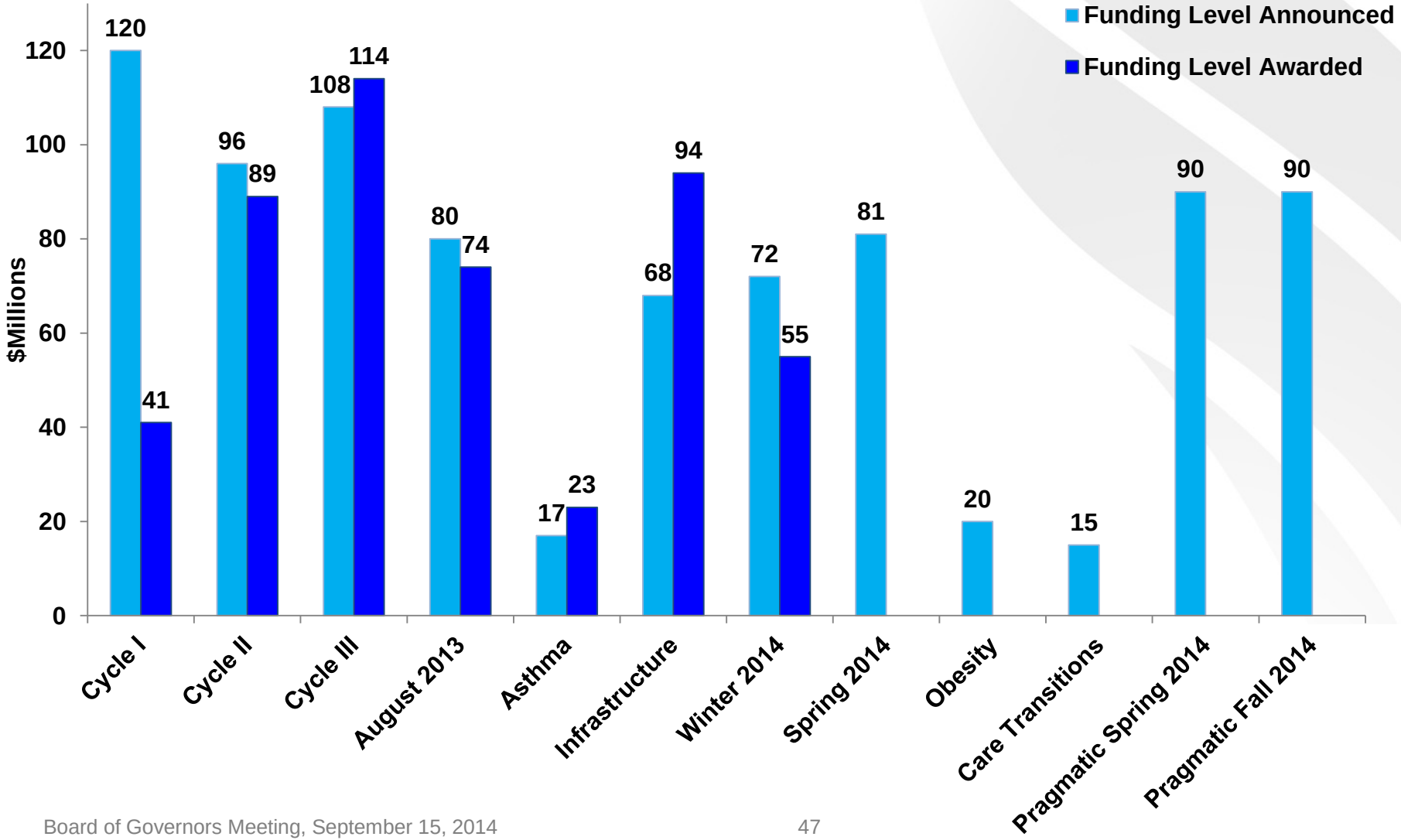
Increase Information

Status of Targeted Topics as of Q3

Topic Status	FY 2014	FY 2015
Awarded	✓ Asthma (Q1) – 8 Projects, $23M ✓ Falls (Q3) – 1 Project, $30M	
Year-to-Date Total	2 Topics, 9 Projects, $53M	
To Be Awarded	• Care Transitions – 1 Project, $15M • Fibroids – 1-2 Projects, $20M • Obesity – 2 Projects, $20M	• Hypertension – up to 2 Projects, $25M • 19 Pragmatic – up to 27 Projects, $270M
Posted	• 19 on Pragmatic Studies List	
Nearing SOC or Board Vote	• Perinatal • Hepatitis C	
Under Consideration	77 Topics	
Cumulative Total	2 Topics, 9 Projects, $53M	
Target for Year	5 Topics, ~24 Projects, $113M	To be established

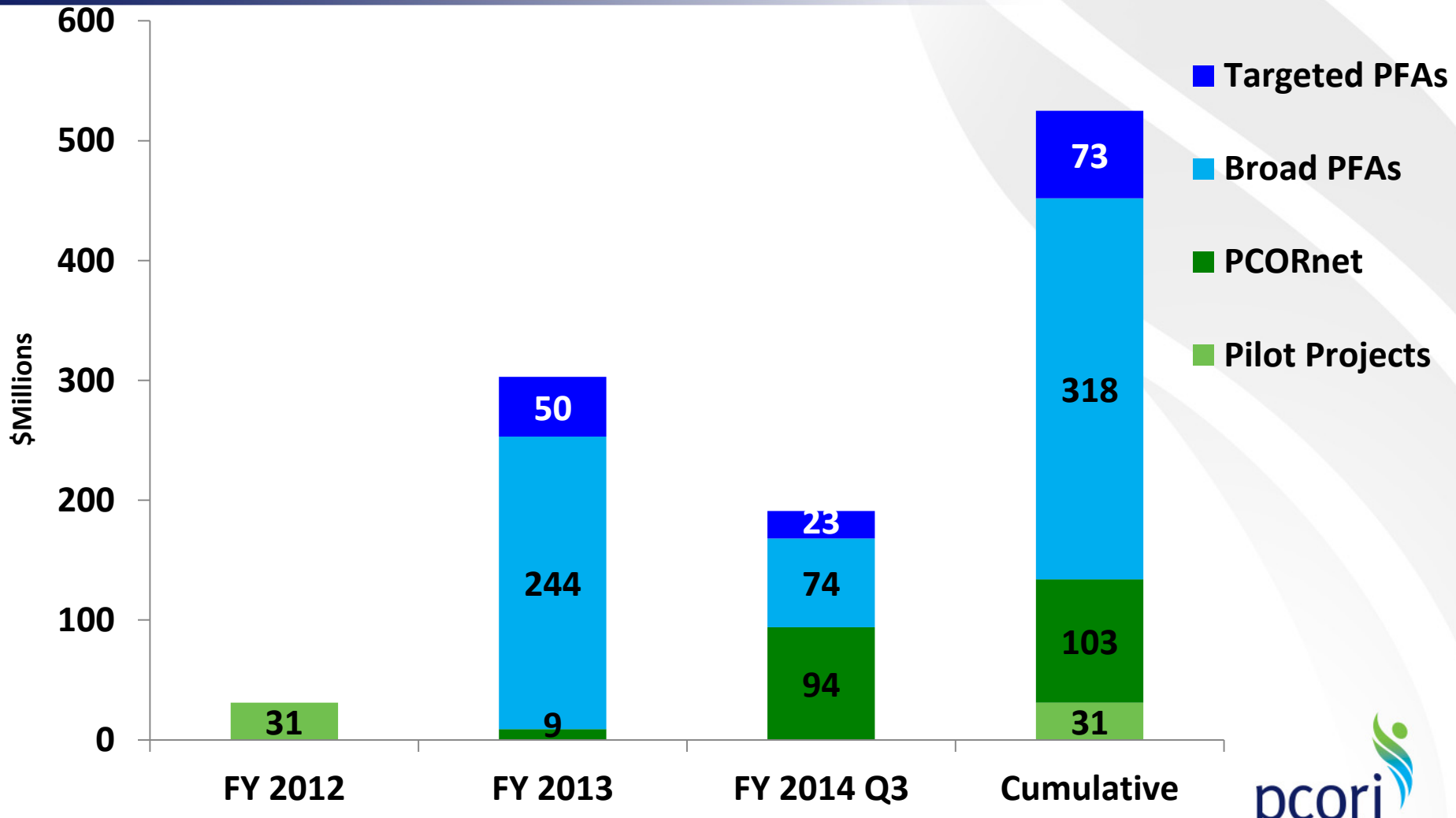
Increase Information

Funds Announced for Solicitations Compared with Funds Awarded



Increase Information

Funds Committed for External Research



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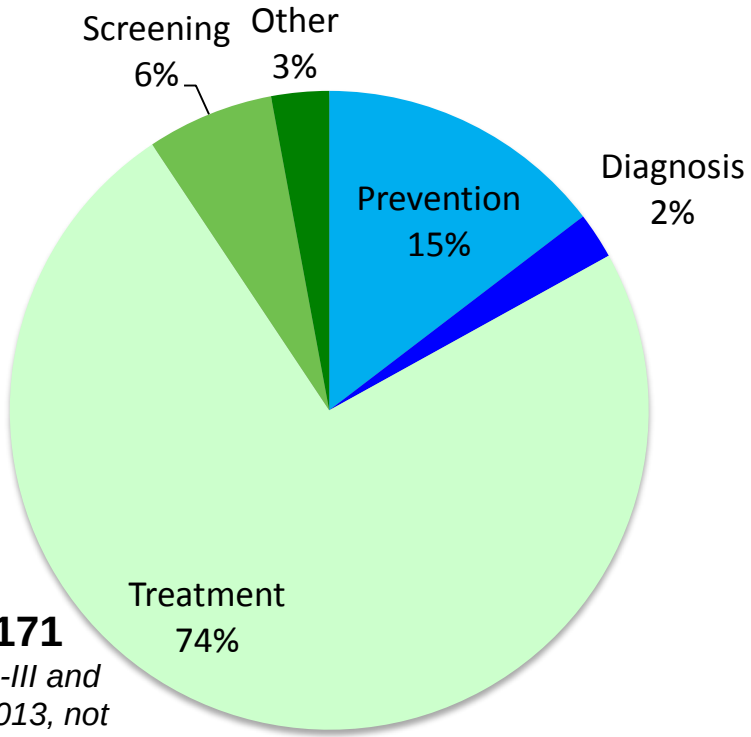
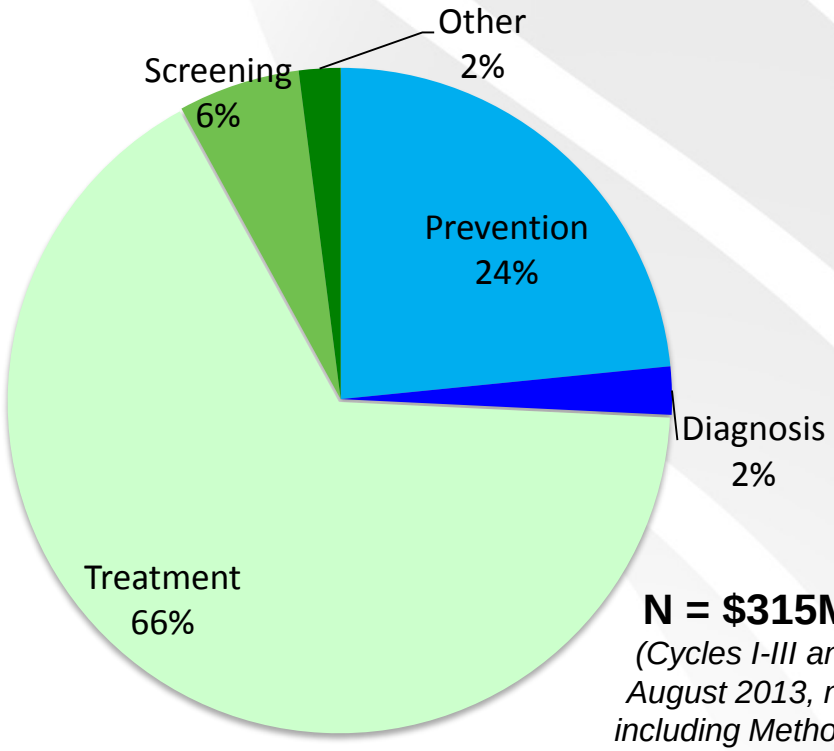
Increase Information

Composition of Current Total Portfolio (by projects and $)



N = 171
(Cycles I-III and August 2013, not including Methods, including Falls Study)



N = $315M
(Cycles I-III and August 2013, not including Methods, including Falls Study)

Prevention Diagnosis Treatment Screening Other

Projects included in "Other" overlap 2 or more categories

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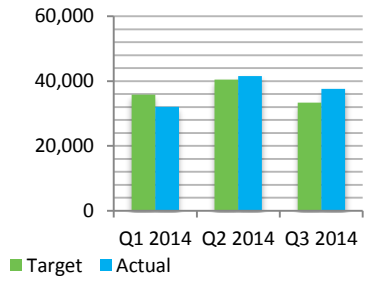
Influence Research
Communications

Communications

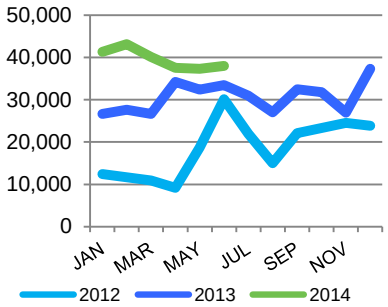
Website

Our Q3 unique website visitors numbers continue to beat our target.

Website Unique Traffic



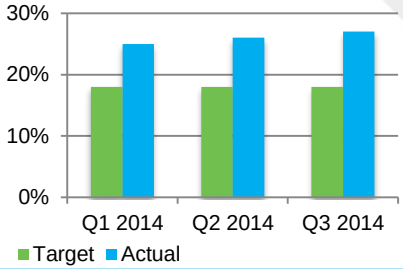
Monthly Unique Traffic



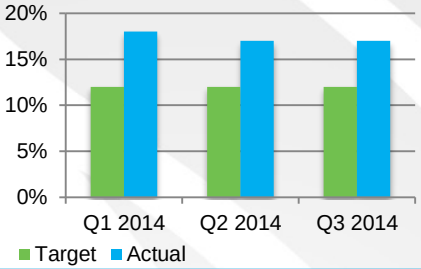
E-mail

We continue to exceed industry standards for open and click-through rates by a wide margin.

Email Open Rate



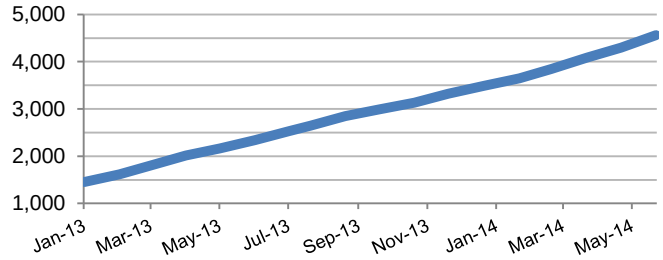
Email Click-Thru Rate



Social Media

Because our early Twitter stats were low, year-to-year comparisons against targets aren't useful. We're tracking follower growth and impressions and working on a more sophisticated reach analysis.

Monthly Twitter Follower Growth



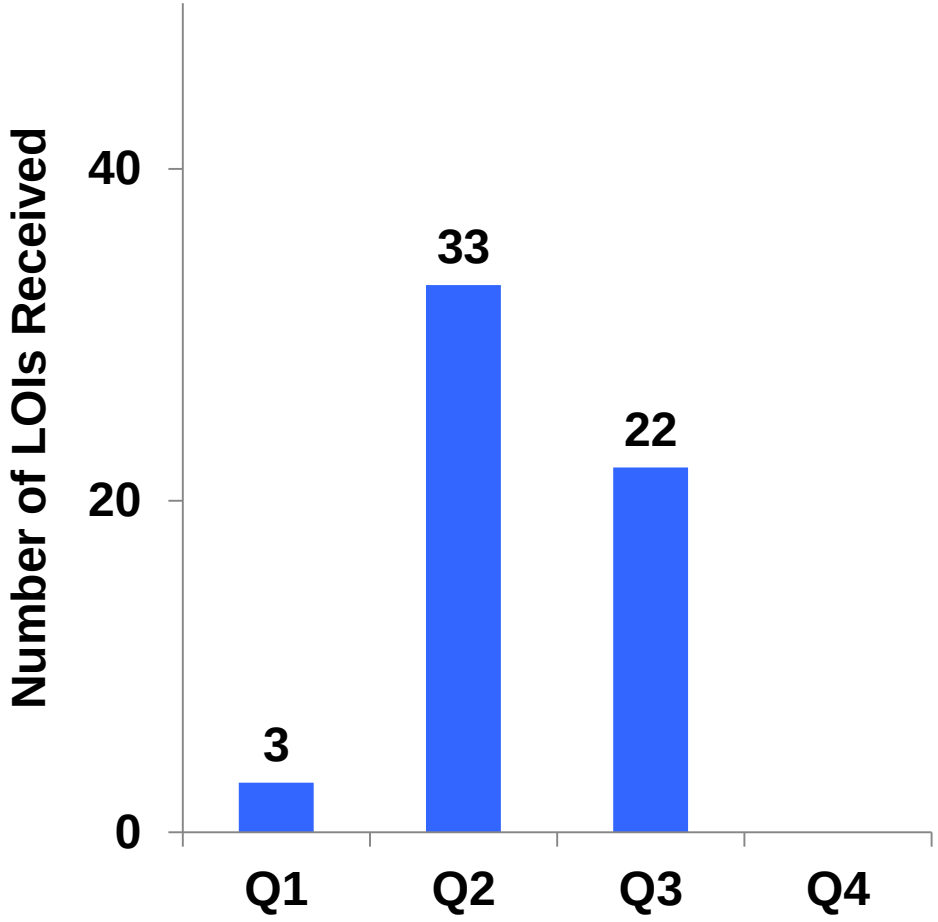
Media Coverage

We continue to grow the number of mentions of our work in general/trade media.

	2012	2013	2014
Q1	-	45	150
Q2	47	48	212
Q3	46	89	149
Q4	26	117	-

Influence Research

Eugene Washington Engagement Awards



- *Letters of Intent (LOI) and applications are currently received and reviewed on a rolling basis*
- *Beginning in October 2014, we will accept and review them on a quarterly cycle*

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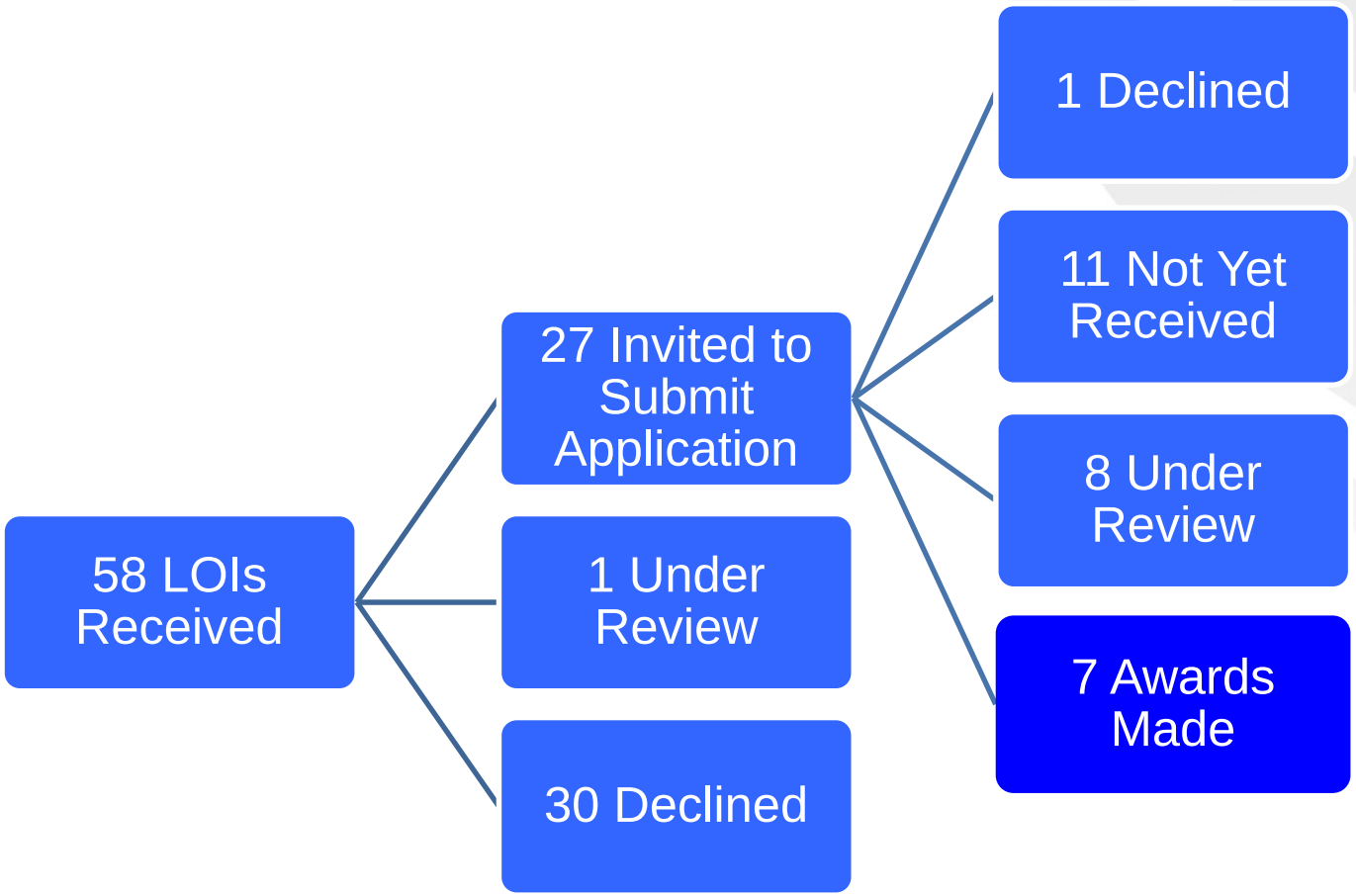
Influence Research

Eugene Washington Engagement Awards



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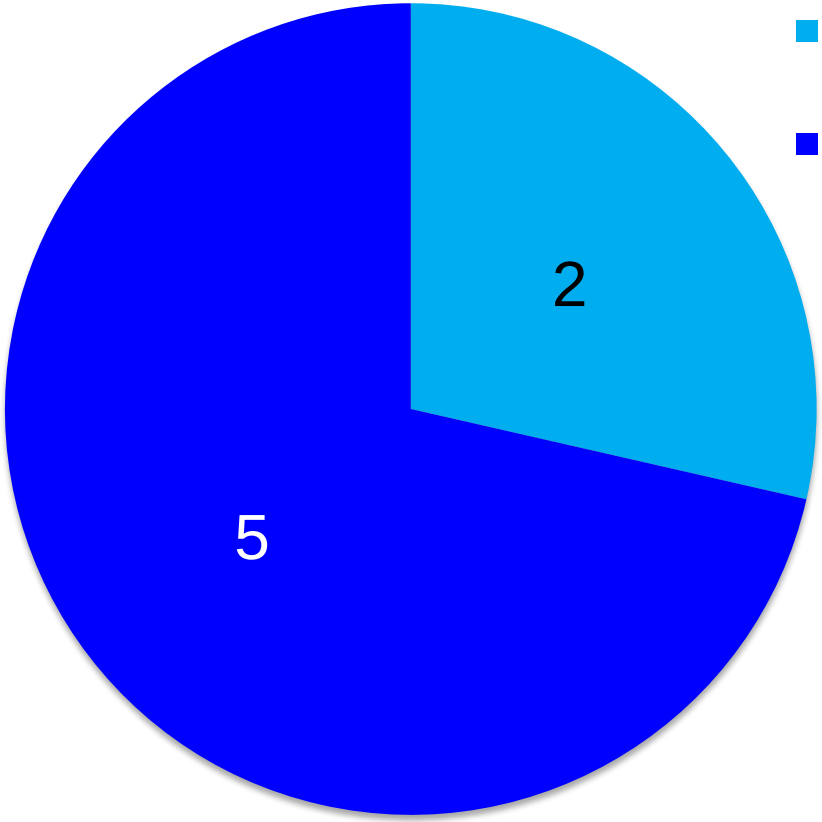
Influence Research

Eugene Washington Engagement Awards

N = 7 Awards in Total



Award Categories Not Yet Represented

- Dissemination
- Meeting/Conference Support
- PCORI Pilot Projects Learning Network Dissemination and Implementation Support

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Proposed FY 2015 Budget

(October 1, 2014 – September 30, 2015)

Regina Yan, MA
Chief Operating Officer

Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute

Overview

- Key Definitions
- FY 2015 Cash Flow
- Funding Commitment Plan
  - Cumulative
  - FY 2012 – 2019
- Research and Infrastructure Commitments and Spending
- Proposed FY 2015 Budget
  - Budget Summary
  - FY 2014 Forecast – FY 2015 Budget Comparison
- FY 2015 Staffing Plan
- Motion to Approve

Key Definitions

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.

Expenses – the amount PCORI will pay to research, infrastructure, and engagement awardees during FY 2015 in response to invoices received for costs incurred under awarded contracts.

Note: Commitments occur earlier than expenses and are higher in earlier years. Expenses lag commitments and are spread over multiple years.

FY 2015 Cash Flow

CASH FLOW ($ in Millions)	
Cash balance on October 1, 2014	**$667**
Cash receipts (FY 2015)	469
Cash disbursements (FY 2015)	(362)
Cash balance on[1] - September 30, 2015	**$774**

[1]Includes funds in the operating accounts and PCORTF.

Funding Commitment Plan:
Cumulative

COMMITMENTS ($ in Millions)	Prior	FY 2014 Forecast	FY 2015 Proposed	Cumulative as of September 30, 2015
Research awards	$331	$300	$475	$1,107
Infrastructure (PCORnet) awards		94	165	259
Engagement and Pipeline to Proposal awards		4	21	25
Total commitments	**$331**	**$398**	**$661**	**$1,391**

Funding Commitment Plan:
FY 2012 – FY 2019

COMMITMENT PERIOD ($ in Millions)				
FISCAL PERIOD	RESEARCH	INFRASTRUCTURE (PCORnet)	ENGAGEMENT	TOTAL
Prior	$331			$331
FY 2014	300	$94	$4	398
FY 2015	475	165	21	661
FY 2016	400		15	415
FY 2017	300		15	315
FY 2018	300		14	314
FY 2019	200		14	214
Total	**$2,306**	**$ 259**	**$83**	**$2,648**
	87%	10%	3%	100%

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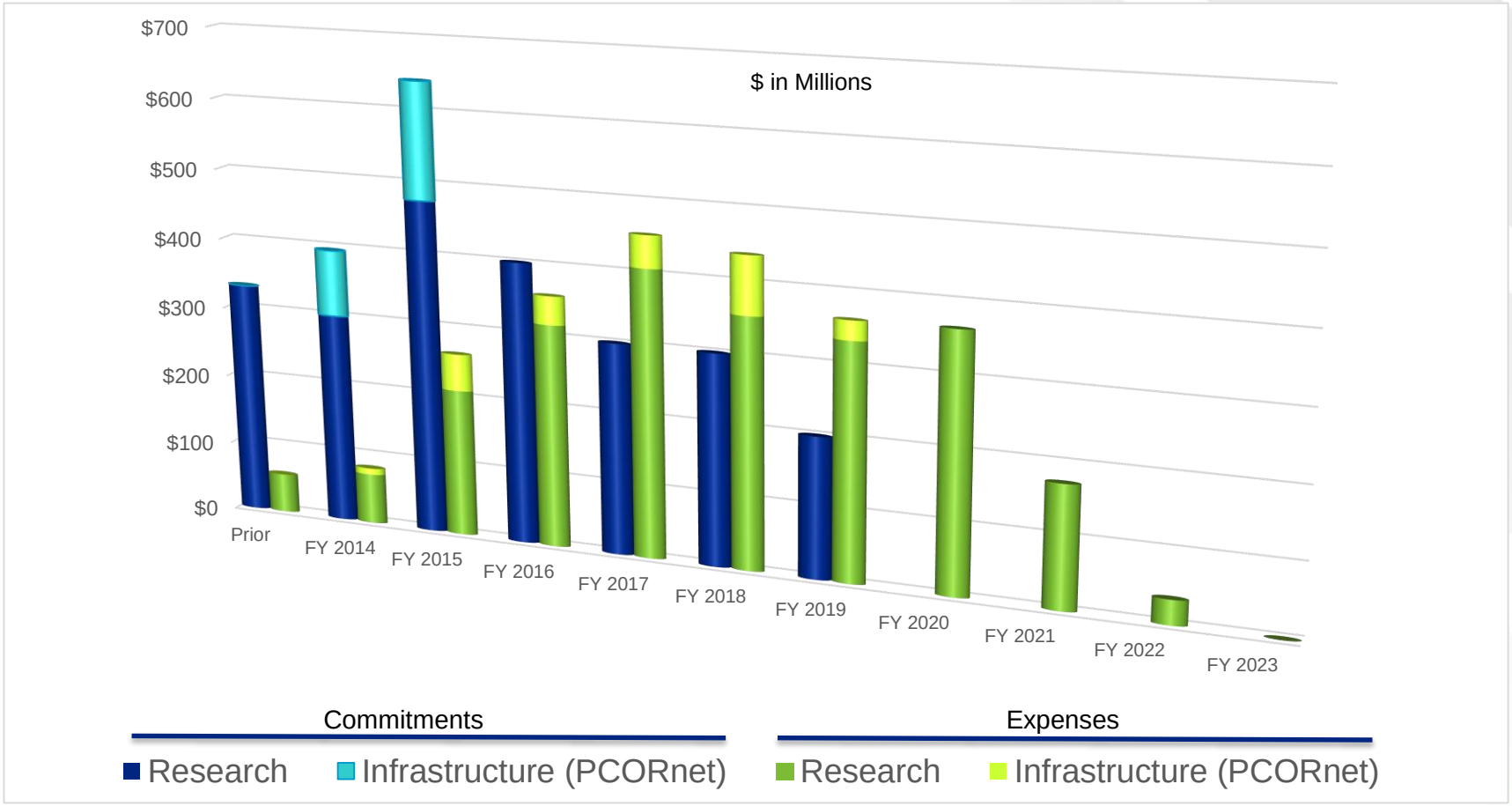
Research and Infrastructure Commitments and Expenses



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Proposed FY 2015 Budget:

Budget Summary (Program line items based on expense)

	FY 2014 Forecast		FY 2015 Proposed	
OPERATING REVENUE	**$ 424,573,600**		**$ 462,800,000**	
OPERATING EXPENSE				
Program Expense				
Research Expense	71,621,142		212,050,000	
Infrastructure (PCORnet) Expense	9,360,568		52,000,000	
Engagement Expense	334,639		7,856,381	
Total Program Expense	**81,316,349**	**64%**	**271,906,381**	**75%**
Program Support Expense				
Methodology Committee	1,053,000		2,275,000	
Science/Program Development and Evaluation	13,491,206		34,857,973	
Engagement	4,769,360		11,529,494	
Contracts Management/Merit Review	8,093,236		11,307,062	
Total Program Support Expense	**27,406,802**	**22%**	**59,969,529**	**17%**
Administrative Support Expense				
Board of Governors/Governance	1,040,000		1,250,000	
Management and General	16,716,402		28,416,598	
Total Administrative Support Expense	**17,756,402**	**14%**	**29,666,598**	**8%**
TOTAL OPERATING EXPENSE	**126,479,553**	**100%**	**361,542,508**	**100%**
Non-operating interest income	**226,988**		**325,000**	
NET INCOME	**$ 298,321,035**		**$ 101,582,492**	

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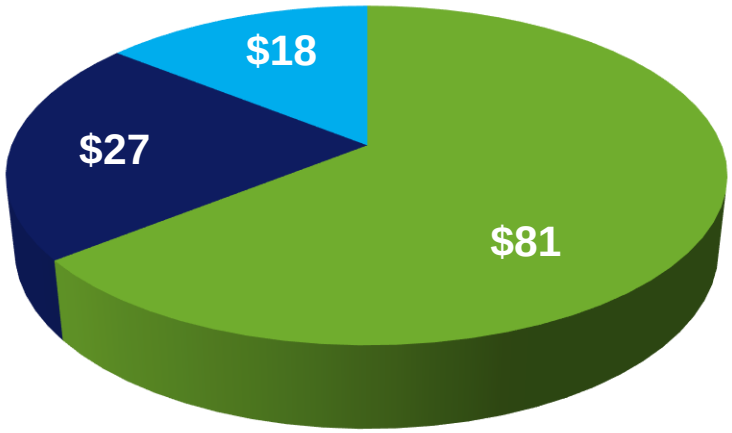
Proposed FY 2015 Budget:

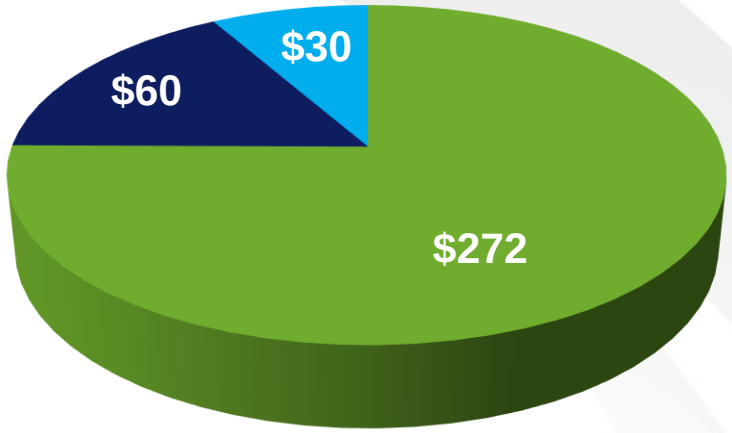
FY 2014 Forecast – FY 2015 Budget Comparison

FY 2014 Forecast – Expenses $126 Million



- Research, Infrastructure (PCORnet), and Engagement Expense (64%)
- Program Support (22%)
- Administrative (14%)

FY 2015 Proposed Budget – Expenses $361 Million



- Research, Infrastructure (PCORnet), and Engagement Expense (75%)
- Program Support (17%)
- Administrative (8%)

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FY 2015 Staffing Plan

PROGRAM/DEPARTMENT	FY 2014 Approved Staffing	FY 2015 Requested Positions	FY 2015 Proposed Staffing Level
Science/Program Development and Evaluation	70	29	99
Engagement	21	4	25
Contracts Management/Merit Review	16	5	21
Administrative	57	15	72
Total Employee FTE Count	164	53	217

Motion to Approve: Board Vote on the Proposed FY 2015 Budget

Call for a Motion to:	• **Approve** the FY 2015 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
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Getting the Word Out: PCORI's Proposal for Peer Review of Primary Research and Public Release of Research Findings

Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute

PCORI's Obligations Under its Authorizing Legislation

- **Conduct Peer Review of Primary Research**
  - Assess scientific integrity
  - Assess adherence to PCORI's Methodology Standards
- **Release of Research Findings**
  - No later than 90 days after "conduct or receipt"
  - Make available to clinicians, patients, and general public
  - Make comprehensible and useful to patients and providers for healthcare decisions
  - Include considerations specific to certain subpopulations, risk factors, and comorbidities
  - Describe process and methods, including conflicts of interest
  - Include limitations and further research needed

PCORI's Updated Proposal Following Board Discussion at Meeting on August 26, 2014

- **Board discussed proposal at its last meeting and asked for clarification of a few issues prior to final approval**
- **Updated proposal addresses these issues and is now submitted to Board for approval to be posted for public comment**

PCORI's Proposal

1. **Registration**. PCORI research projects must be registered at the site appropriate to study design: ClinicalTrials.gov, Registry of Patient Registries (RoPR), PROSPERO.

2. **Draft Final Report**. Awardee Institution submits draft final report to PCORI for peer review three months after completion of data analysis specified in the research protocol, which will be set in the milestones.

3. **PCORI Peer Review**. PCORI manages peer-review of final report using a combination of staff and contracted resources.

Components of Final Report

- **Description of Main Study Results**— Methods; Results; Sub-populations, risk factors, comorbidities; Limitations; Needed further research; Tables; Conclusions.

- **Abstract**— 500-word limit; for medical professionals.

- **Results Table**— Summarizes key findings; for submission to ClinicalTrials.gov (or other site) and PCORI.org.

- **Ancillary Information**— Identifies entity and investigators conducting research and discloses conflicts of interest.

Making Research Findings Publicly Available

1. **Information for Various Audiences.** After PCORI accepts final report, PCORI, with approval of Awardee Institution, will:
   - produce a summary of the abstract, results table, and ancillary information to *"convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions."*

2. **Public Posting on PCORI.org and Submission to ClinicalTrials.gov.** Within 90 days of PCORI's acceptance of final report:
   - PCORI will post information for patients and consumers to PCORI.org
   - Awardee Institution will ensure that results table is submitted to ClinicalTrials.gov (or other site) and ensure that links to abstracts posted on PCORI.org are provided.*

* For applicable clinical trials regulated under FDAAA, there may be instances when the results table is submitted to ClinicalTrials.gov before PCORI peer-review is completed.

NIH Concerns and PCORI Responses

1.	FDAAA-related concerns about assignment of responsibility for submitting results to ClinicalTrials.gov for FDAAA-regulated studies	Clarified language to reflect that: • The awardee institution must ensure that this happens, whether it or a third party is ultimately responsible under FDAAA • PCORI is not responsible
2.	Clarification of the date which triggers the beginning of the process	Changed trigger date from “end of contract” to “3 months after completion of data analysis specified in study protocol”
3.	Concerns about lack of detail for PROSPERO and RoPR repositories	More detail added and plan to gather more information from comments and directly from the repositories

Anticipated Timeline: Finalizing Proposed Process

Task	Date
Board Vote to Approve Posting Proposal for Public Comment	09/15/14
Public Comment Period (54 Days) Includes public event and webinar	09/15/14 – 11/7/14
Analyses and Synthesis Period	11/10/14 – 12/31/14
Analyses Report Due to PCORI	01/10/15
Strategy Committee Review Period	01/16/15 – 02/17/15
Board Vote on Revised Draft	02/24/15

Board Vote: Approve Posting for Public Comment of Proposed Process for Peer Review of Primary Research and Release of Research Findings

Call for a Motion to:	• **Approve** posting for public comment of proposed process for Peer Review of Primary Research and Release of Research Findings
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Governance Committee Report

Steven Lipstein, MHA
Chair, Governance Committee

Patient-Centered Outcomes Research Institute

Governance Committee Report

- Recommendation about establishing an Executive Committee
- Guidance on voting during Board meetings
- Status of topics for Board development and education

PCORI Executive Committee

Background

- Board has adopted and implemented multiple governance enhancement goals
- Board tasked the Governance Committee to make recommendation on whether an Executive Committee would facilitate governance and Board's ability to focus on strategic issues

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PCORI Executive Committee

An Executive Committee is a common governance avenue for non-profit Boards and can be useful for:

- Seeking needed Board approvals between Board meetings
- Providing final approval of matters that have already come to the Board
- Approving items that do not warrant time on the agenda for the full Board

PCORI Executive Committee

Governance Committee Considerations

- Implications of public meeting requirement for Board in PCORI's authorizing law
- Provisions in PCORI's authorizing law limiting delegation of certain matters
  - National research priorities, research project agenda, Methodological Standards, peer review process
- Provisions of DC Nonprofit law limiting authority of Executive Committees
  - Bylaws, naming Board committee members

PCORI Executive Committee

Governance Committee Considerations

- No significant matters have arisen in PCORI's history where an Executive Committee would have been utilized
- Avenues already exist that fulfill important needs
  - Executive Director has regular discussions with Board and Committee leadership
  - Board has authorized Chairperson and Vice Chairperson to approve certain expenditures that are part of Board-approved PCORI budget

PCORI Executive Committee

Governance Committee Recommendation

- The Governance Committee believes that PCORI's history does not reflect the need for an Executive Committee authorized to make decisions on the Board's behalf.

- The Governance Committee recommends that the Board of Governors not charter an Executive Committee at this time.

Guidance on Voting at Board Meetings

- Governance Committee is responsible for advising on Board effectiveness, function, and meetings.
- Governance Committee has outlined principles for planning and managing voting at Board meetings to ensure efficiency and transparency.
- Board Chairperson, working with Executive Director, plans meetings, taking guidance into account.

Guidance on Voting at Board Meetings

Voice votes will generally be used to take action on:

- Minutes
- Consent agenda items
  - All Board members retain the right to pull an item from the consent agenda for discussion and possible roll call vote

Guidance on Voting at Board Meetings

Roll call votes will primarily be used to take action on:

- Awards or slates of awards
- Budget
- Matters that require a heightened level of approval beyond a majority vote (e.g., Bylaws amendments)
- Adoption or amendment of PCORI's national priorities for research, research project agenda, methodological standards and peer review process

Status of Topic Presentations for Board Education

Overview of PCORI's research portfolio and impact

- ✓ Board has received an overview on the Addressing Disparities Program.
- ✓ Board has received an overview on the Clinical Effectiveness Research Program.
- ✓ Board will today receive an overview on the Improving Healthcare Systems Program.

Understanding AHRQ's focus and funding portfolio

- ✓ Richard Kronick, MD, Director of AHRQ, is scheduled to present today on AHRQ's PCOR Trust Fund portfolio.

Other Suggestions for Board Education

Other Governance Committee suggestions

- Overview of health care research world and PCORI's role in it
- Comparison of AHRQ, NIH, and PCORI funding
- Overview of healthcare infrastructure funding and research
- Report on international organizations that share PCORI's mission
- Review of effective board governance tools and resources

Governance Committee Members

Thanks to the members of the Governance Committee.

- Steve Lipstein, MHA, Chair
- Allen Douma, MD
- Sharon Levine, MD
- Robin Newhouse, PhD, RN (Methodology Committee Chair)
- Gray Norquist, MD, MSPH

Additional Topics for Board Education?

For Discussion

- What additional topics would you like to see presented to further Board education and development?

LUNCH

Join the conversation on Twitter via #PCORI

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Panel Discussion with Clinical Data Research Networks (CDRNs) & Patient-Powered Research Networks (PPRNs) Principal Investigators (PIs)

Patient-Centered Outcomes Research Institute

Overview/Background

- Presentations from four Principal Investigators
  - Thomas W. Carton, PhD – The Louisiana CDRN
  - Rachel Hess, MD, MS – PaTH CDRN
  - Holly Peay, MS – DuchenneConnect PPRN
  - Sharon Terry, MA – Community Engaged Network for All (CENA) PPRN

- Address the following themes:
  - Organization of the network, key partners, and how it came together
  - How you are creating cohesion across your partners?
  - What challenges and successes have you experienced in the first ~6 months?
  - What is it like to have patients involved in governance?
  - What new partnerships are emerging?
  - What does the totality of PCORnet represent for you—what is your vision for what it could do?

The Louisiana Clinical Data Research Network (LACDRN)

Thomas W. Carton, PhD

Louisiana Public Health Institute

Patient-Centered Outcomes Research Institute

Network Overview

GOAL

To facilitate the efficient conduct of **patient-centered comparative effectiveness research** by establishing a data network containing clinical records for **more than 1 million patients** in the **state of Louisiana**

PATIENT COHORTS	
Prevalent Health Conditions Diabetes Obesity/Weight Management	**Rare Disease** Sickle Cell Disease

Network Partners

Louisiana Public Health Institute

Pennington Biomedical Research Center

Tulane University

PATH — Partnership for Achieving Total Health: Using Innovation and Technology to Improve Health

LSU Health

Ochsner Health System

Cohesion Across Partners

Research

Institutional Review Board coordination

Cohort specific advisory groups that identify patient-centered research priorities

Engagement

Pragmatic trial App Suite: (1) Patient reported outcomes, (2) Recruitment, and (3) Management

"Health in our Hands" patient network

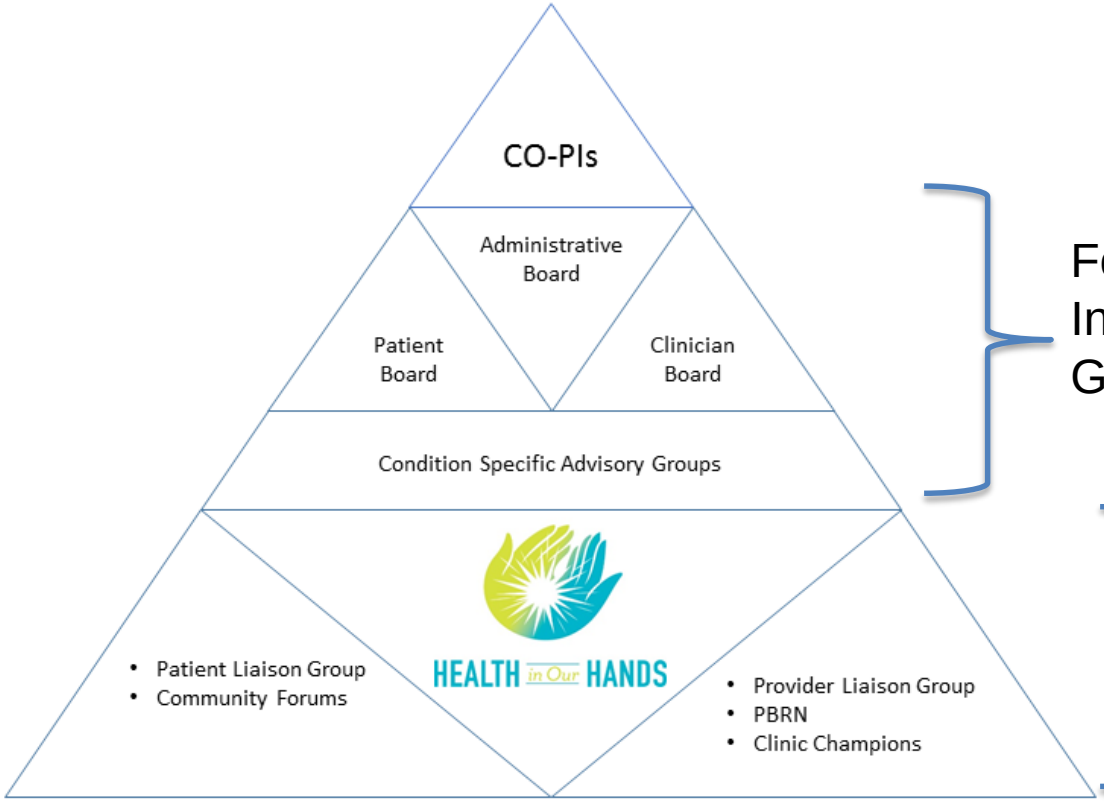
Data

Common Data Model

Global Patient ID

Informatics solution capable of linking clinical and patient generated data

Patient & Provider Representation in Decision Making



Patient and Provider Engagement Overview

Formal Patient Involvement in Governance

Methods of capturing patient & provider perspective to inform Network activities

Successes and Challenges

Successes

- Rapid design and procurement of integrated health informatics solution
- Partner co-development of the LACDRN App Suite and patient engagement strategy
- Engagement of patients and clinicians in network governance, decision-making, and priority-setting

Challenges

- Network partner decision-making (Co-Principal Investigators not final organizational decision makers)
- Achieving a balance between network standardization and nodal customization

New Partnerships

Partner Category	Individual Partners	Area of Engagement
CDRNs	CAPriCORN, NYC-CDRN, pSCANNER	Global Patient ID solution
	CAPriCORN, pSCANNER	VA engagement
	CAPriCORN, Mid-South	Sickle cell
	NYC-CDRN, ADVANCE	Diabetes
PPRNs	Health eHeart Alliance, PI CONNECT	Patient engagement, Queries
Potential network members	VA	Joining LACDRN
Health informatics	Louisiana Optical Network Initiative (LONI)	Leveraging big data
Additional Organizations	NCI Community Oncology Research Program (NCORP)	Operationalization of rare cancer cohort

Vision and Impact

Learning health network = Learning health state

- **Create capacity** to embed pragmatic comparative effectiveness research within health systems
- **Develop an innovative patient engagement approach** through App Suite and “Health in our Hands” patient network
- **Leverage resources through collaboration** with other statewide research projects and other CDRNs and PPRNs
- **Build and maintain a standardized and validated data infrastructure** linking clinical data to patient reported outcomes and capable of receiving various forms of patient generated data

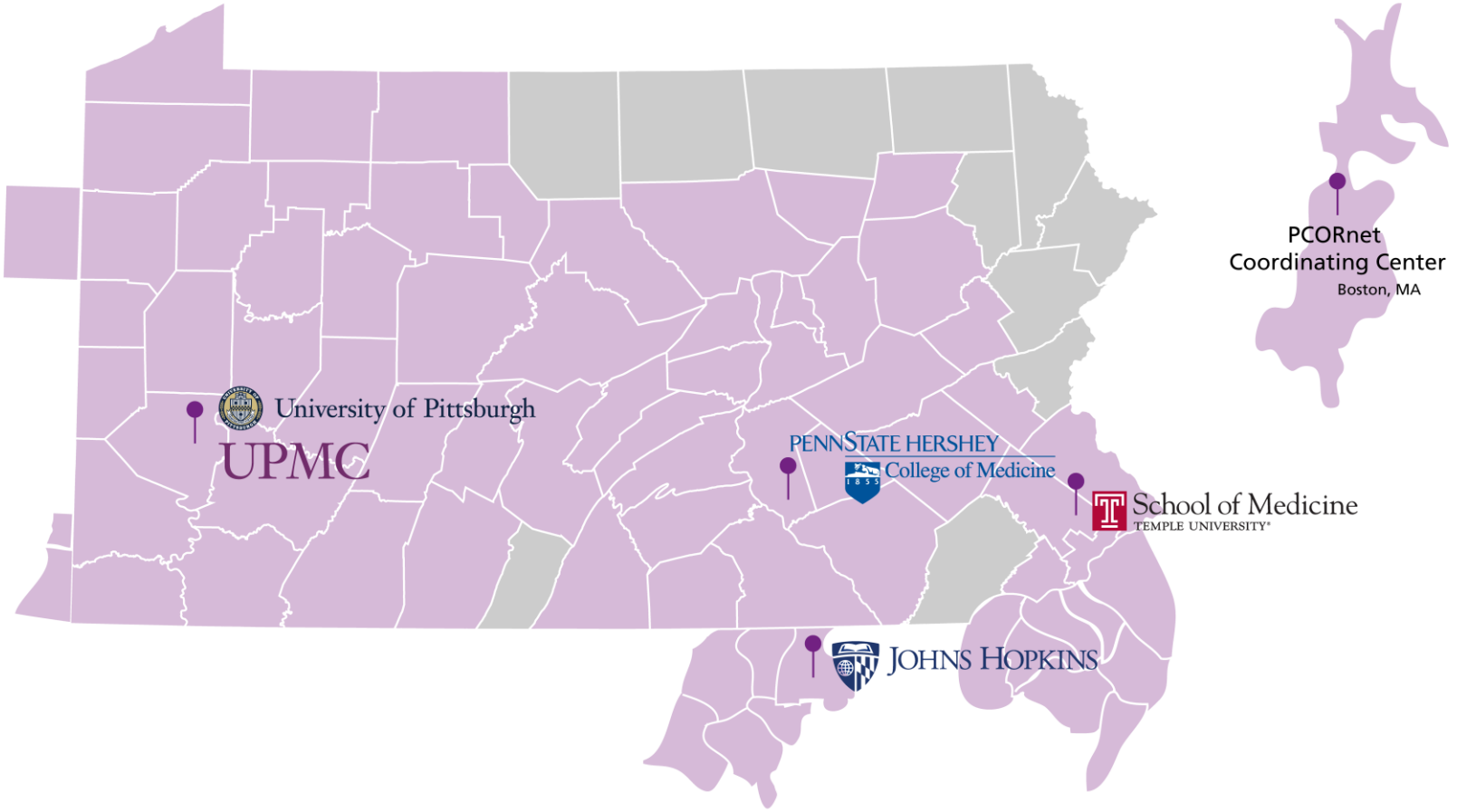
PaTH: a PCORnet CDRN

Rachel Hess, MD, MS

Principal Investigator, PaTH

Patient-Centered Outcomes Research Institute

Introduction to PaTH: Health Systems



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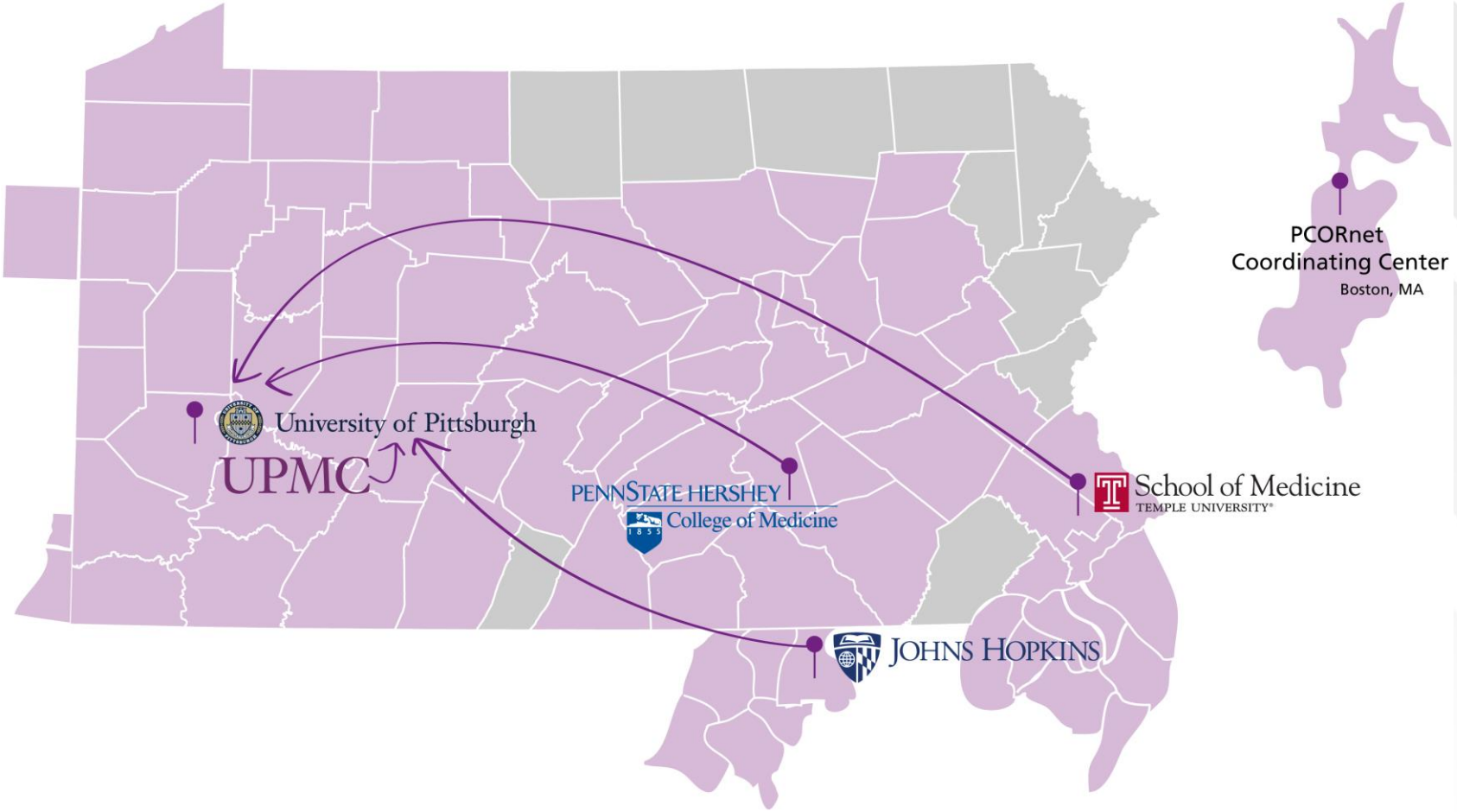
Introduction to PaTH: Health Systems



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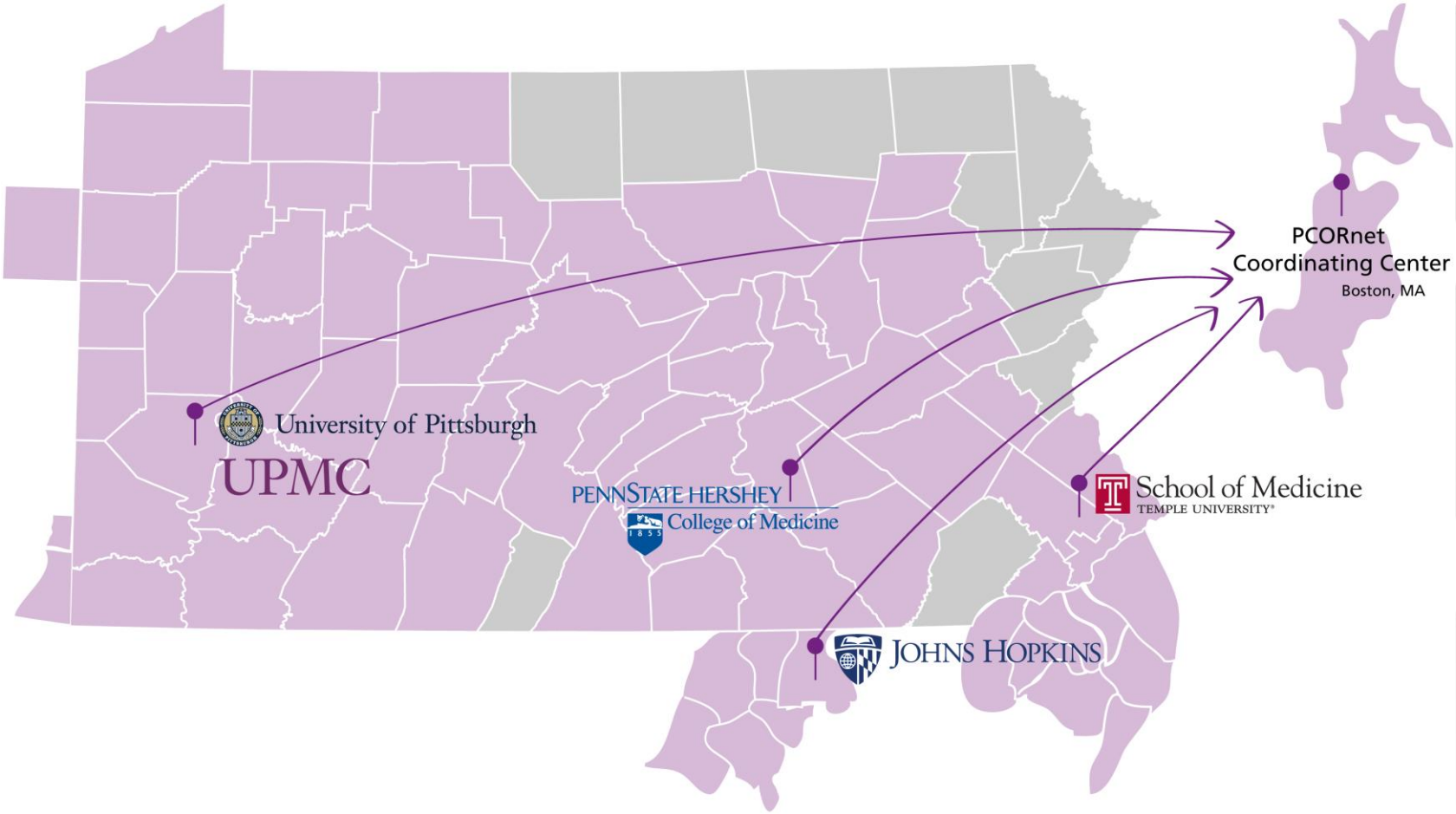
Introduction to PaTH: Health Systems



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Introduction to PaTH: Conditions

- Rare: Idiopathic Pulmonary Fibrosis
- Common: Atrial Fibrillation
- Obesity with a focus on long-term outcomes of bariatric surgery

PaTH Model Case Studies for Cohorts

Fred is a 67-year-old man who has been struggling with progressive shortness of breath and chest pain for the last 6 months. He was just diagnosed with ***idiopathic pulmonary fibrosis*** **(IPF)**. He met with his doctor to discuss next steps and is trying to understand the risks and benefits of the different options, including immunosuppressive medication, oxygen therapy, and lung transplantation, and what his prognosis means for his family.

Manuel is a 50-year-old man who was recently diagnosed with ***atrial fibrillation*** **(AF)**. His travel schedule for work makes it difficult for him to get his blood work checked at the right times to monitor his warfarin therapy, and the medicine that he is taking to control his heart rate leaves him feeling fatigued. He wants to do the right thing for his health but feels that his treatment is not a good fit for his lifestyle. He wants to know if there are other options.

Myrtle is a 60-year-old woman with ***obesity***. She has struggled with her weight her whole life; she exercises regularly and eats well but just cannot lose weight. At her last visit, her doctor told her that she was developing diabetes (both of her parents had diabetes). Between that and struggling to keep up with her young grandchildren due to worsening knee osteoarthritis, she is considering bariatric surgery "like Al Roker," but has some questions.

PaTH: Collaborative Decision Making

- Frequent Communication
- Shared Leadership
- Shared Decision Making
- In-person Sessions

PaTH: The First 6 Months

Success	Challenge
Data harmonization	Complete data
Regulatory oversight: Single Institutional Review Board (IRB)	Fully integrating patients into governance
Excitement to use PaTH	Sustainability cost structures
Collaboration with network partners	Timeline

PaTH: New Partnerships

- Local network
- Patient stakeholders
- Clinical stakeholders
- National network

The Right Care for Every Patient

- Data
- Adoption
- Implementation

PCORnet Moving Forward

"We're ready to begin the next phase of keeping things exactly the way they are."

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PaTH Retreat: November 2013

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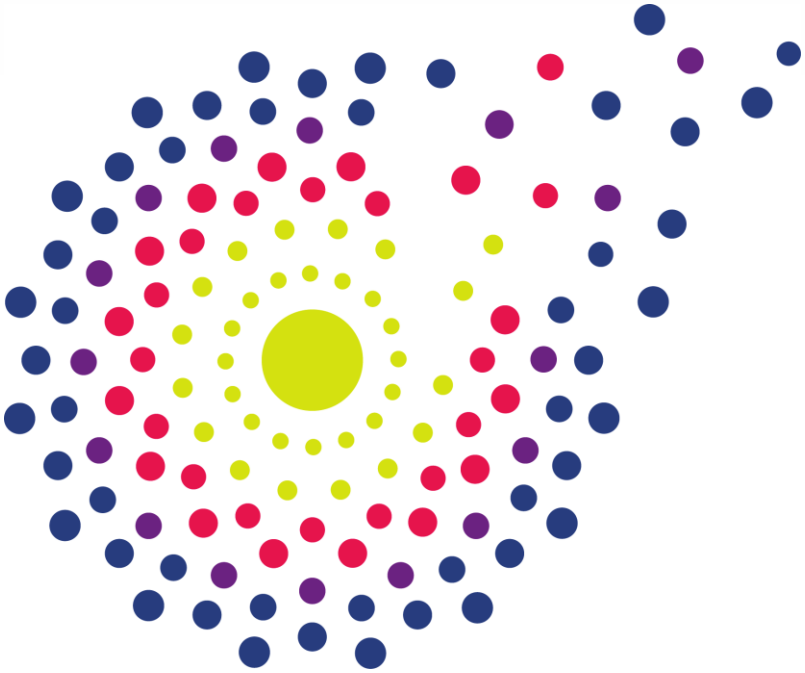


PaTH Network

patient empowered research

DuchenneConnect PPRN

Holly Peay, MS

Principal Investigator, DuchenneConnect PPRN

Patient-Centered Outcomes Research Institute

DuchenneConnect

Username ****** Login Forgot login?

Home | News | Register | Webinars | About DMD/BMD | Clinical Trials | Professionals

How Your Data is Being Used

Learn about recent uses of the DuchenneConnect data.

Quicklinks

Register | Research FAQ Sheets

Professionals | Webinars

Newsflash NEW

International Study on the Burden of DMD Published in Neurology

DuchenneConnect 2013 Annual Report

Decode Duchenne

A new genetic testing program that allows patients with Duchenne or Becker muscular dystrophy to have access to genetic testing. Decode Duchenne is administered by DuchenneConnect and Parent Project Muscular Dystrophy and is funded by Sarepta Therapeutics.

How Your Data Is Being Used

A program of Parent Project Muscular Dystrophy

pcori Patient-Centered Outcomes Research Institute

Background

- **Duchenne and Becker muscular dystrophy (DBMD)**
  - Most common neuromuscular disorder in childhood
  - Prevalence: ~13,000 (???) in the United States
  - Fatal disorder characterized by progressive muscle weakness

- **DuchenneConnect history**
  - Registry development funded by National Center Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC)
  - 7-year-old self-report registry for DBMD with over 3,000 registrants (more than 400 new registrants in 2013)
  - Clinical reports submitted by participants and curated by genetic counselor
  - Since inception: guided by Advisory Committee
  - Dataset utilized by industry, clinicians, and academic researchers
  - Registry platform has been extended to support registries for more than 250 disorders

PCORnet collaborative team

- ***DuchenneConnect***: Holly Peay (PI), Ann Martin (Project Director), Ann Lucas (Project Coordinator)
- ***Patient Crossroads:*** Kyle Brown, Jud Rhode
- ***UCLA:*** Stan Nelson, Nancy Halnon, Richard Wang
- ***Geisinger Health System***: Andy Faucett, Dan Davis
- ***Leadership Committee:*** People with DBMD and parents

How our team works together…

Neuro-QOL Item Bank v1.0 – Lower Extremity Function (Mobility)

Lower Extremity Function (Mobility)

Please respond to each question or statement by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
NQMOB37	Are you able to get on and off the toilet?...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB30	Are you able to step up and down curbs?...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB26	Are you able to get in and out of a car?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB32	Are you able to get out of bed into a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQMOB25	Are you able to push open a heavy door?	☐	☐	☐	☐	☐

Family-centered governance

- DuchenneConnect is a program of a parent-led advocacy group
- Historical engagement: DuchenneConnect Advisory board
  - Family members, researchers, and industry leaders
  - Informs traditional DuchenneConnect operations
- PCORnet engagement: Leadership committee
  - Informs PCORnet activities
  - Members identified through nomination process
- Leadership example: engaging the community to identify research priorities

PCORnet partnerships

- UC-REX: pSCANNER, Health eHeart, CENA, and DuchenneConnect
  - Collaborative identification and outreach effort through UC-REX
  - Joint Institutional Review Board proposal at UCSD
  - Possibility of data pull
- Greater Plains CDRN – building collaborative team to propose research questions

Challenges and Successes in the First 6 Months: Community Engagement

Challenges
Highly technical aspects of PCORnet
Less-tangible, short-term outcomes of PCORnet time investment
Successes
Engaged and committed leadership committee
Increasing two-way relationship with “giving back”: • Each new data collection coupled with educational material • Improved user experience
Community review and input: • Needs/preferences • Revised consent – community comment period
Developing ideas for further community engagement

Challenges and Successes in the First 6 Months: Rare Diseases

Challenges
Rare disease priorities can be lost in common disease priorities
Achieving diversity in registrants
Small numbers place increased burden on registrants to participate and adhere
Successes
Highly engaged and altruistic with fewer privacy concerns
Excellent model for attempting new approaches

Challenges and Successes in the First 6 Months

So many possibilities…. So little time

- Increased industry and academic interest as our network grows and expands
- CDRN partnerships emerging
- PCORnet-related opportunities are incredible but overwhelm a small Foundation staff

PCORnet/DuchenneConnect Vision

- Acting as good citizens of PCORnet
- Increasing awareness of research needs in DBMD
- Community empowerment
- Harnessing the power of PCORnet for answering natural history, comparative effectiveness questions/facilitate trials
  - Getting the most out of phase 1
  - Successful integration into phase 2 to reap the infrastructure-development rewards

PPRN: Community Engaged Network for All (CENA)

Sharon F. Terry, MA
CEO, Genetic Alliance

Patient-Centered Outcomes Research Institute

Overview/Background

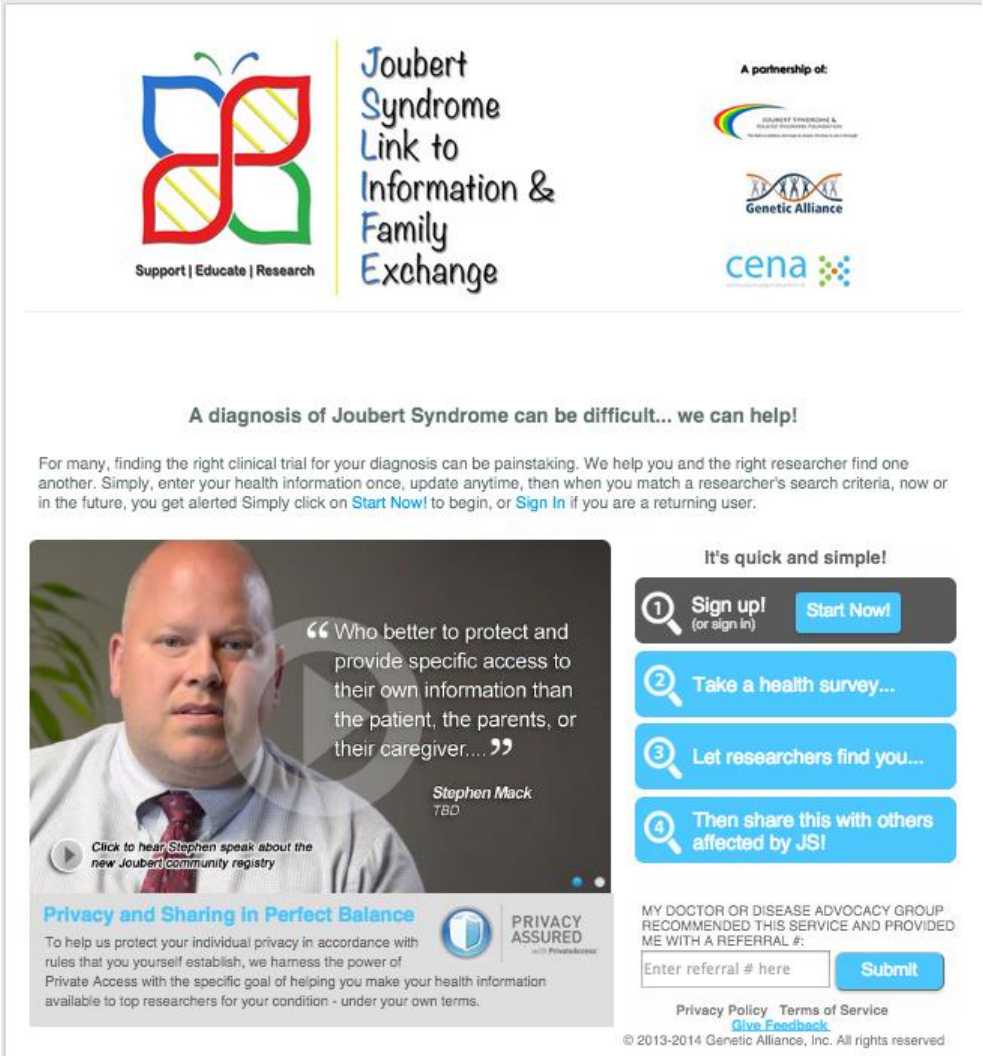
- Genetic Alliance (28-year-old advocacy umbrella) as lead
  - 9 Disease Advocacy Organizations (chosen from dozens of applicants)
    - Alström Syndrome International
    - AXYS (sex chromosome differences, Klinefelter's, Turners)
    - Dyskeratosis Congenita Outreach
    - Inflammatory Breast Cancer Research Foundation
    - Hepatitis Foundation International
    - Joubert Syndrome and Related Disorders Foundation
    - MLD Foundation (metachromatic leucodystrophy)
    - National Gaucher Foundation
    - PXE International (pseudoxanthoma elasticum)
  - 2 Universities
    - University of California, San Francisco
    - University of California, Davis
  - 1 Technology Partner
    - Private Access, Irvine, CA

cena
community engaged network for all

Cohesion – Common Goals in the Trenches

- Governance
  - Disease advocacy organizations' leadership and patient council
- Planning
  - Building standards and common data elements/instruments
  - Community consultations (x9)
  - Best practices for 'Guides', 'Navigators', and outreach
- Implementing and testing
  - Executive committee of Genetic Alliance, Private Access, UCSF and UCD
- Launches (9) and outreach (dozens of communities/partners)
- Computable phenotypes (UCSF/UCD and pSCANNER)
- Crowd-sourced research proposals (Open Proposal)
- Analysis (using Common Data Elements, including PROMIS29 for quality of life measures)

Platform for Engaging Everyone Responsibly (PEER)



General Information: *geneticalliance.org/programs/biotrust/cena*

Online demo (for JSRDF shown here): *jsrdf.org/JSLIFE-demo*

Multiple guides (one shown here) give an opportunity to use a variety of approaches, and selecting settings that are the most comfortable to each participant.

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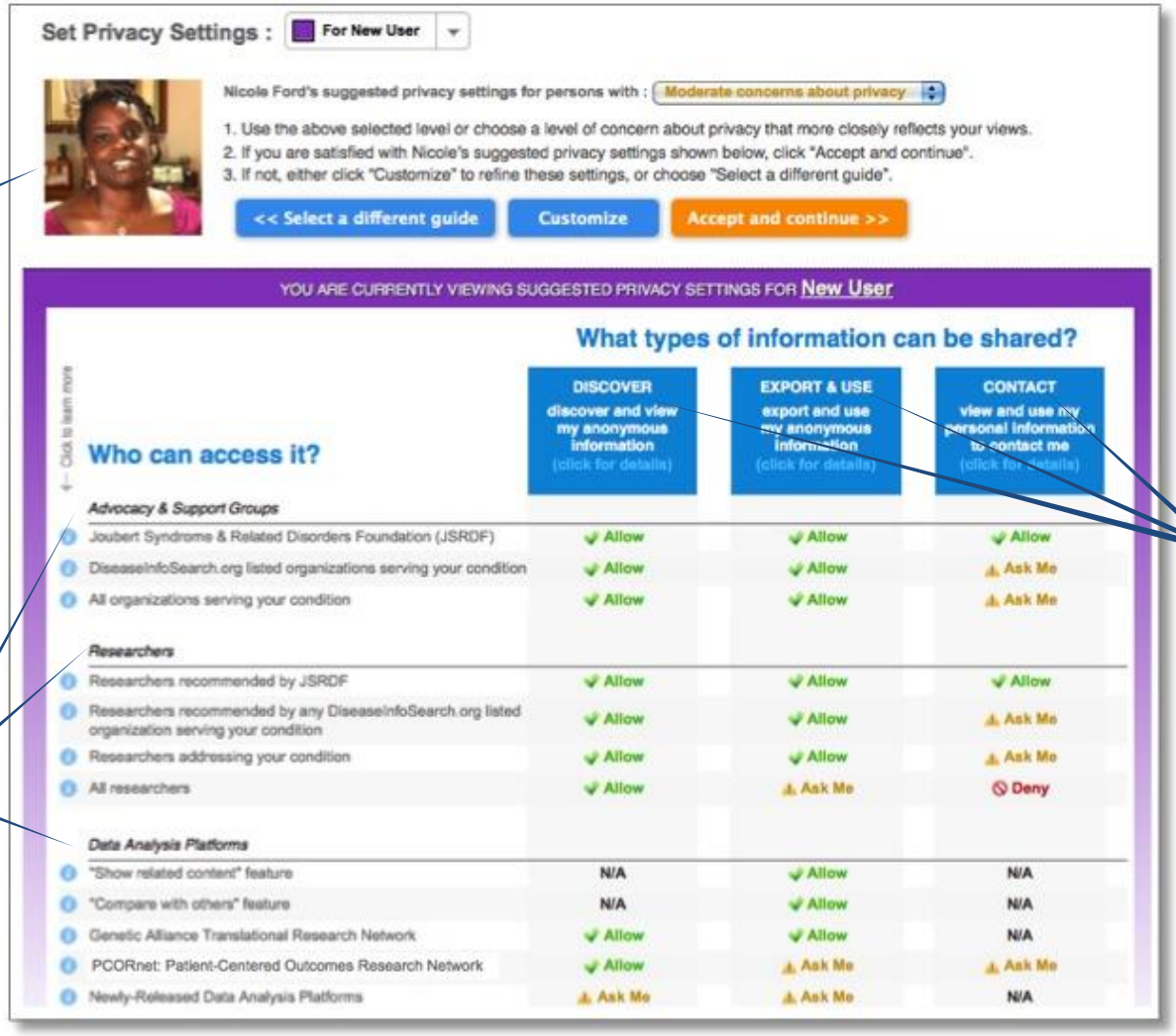
Platform for Engaging Everyone Responsibly (PEER)

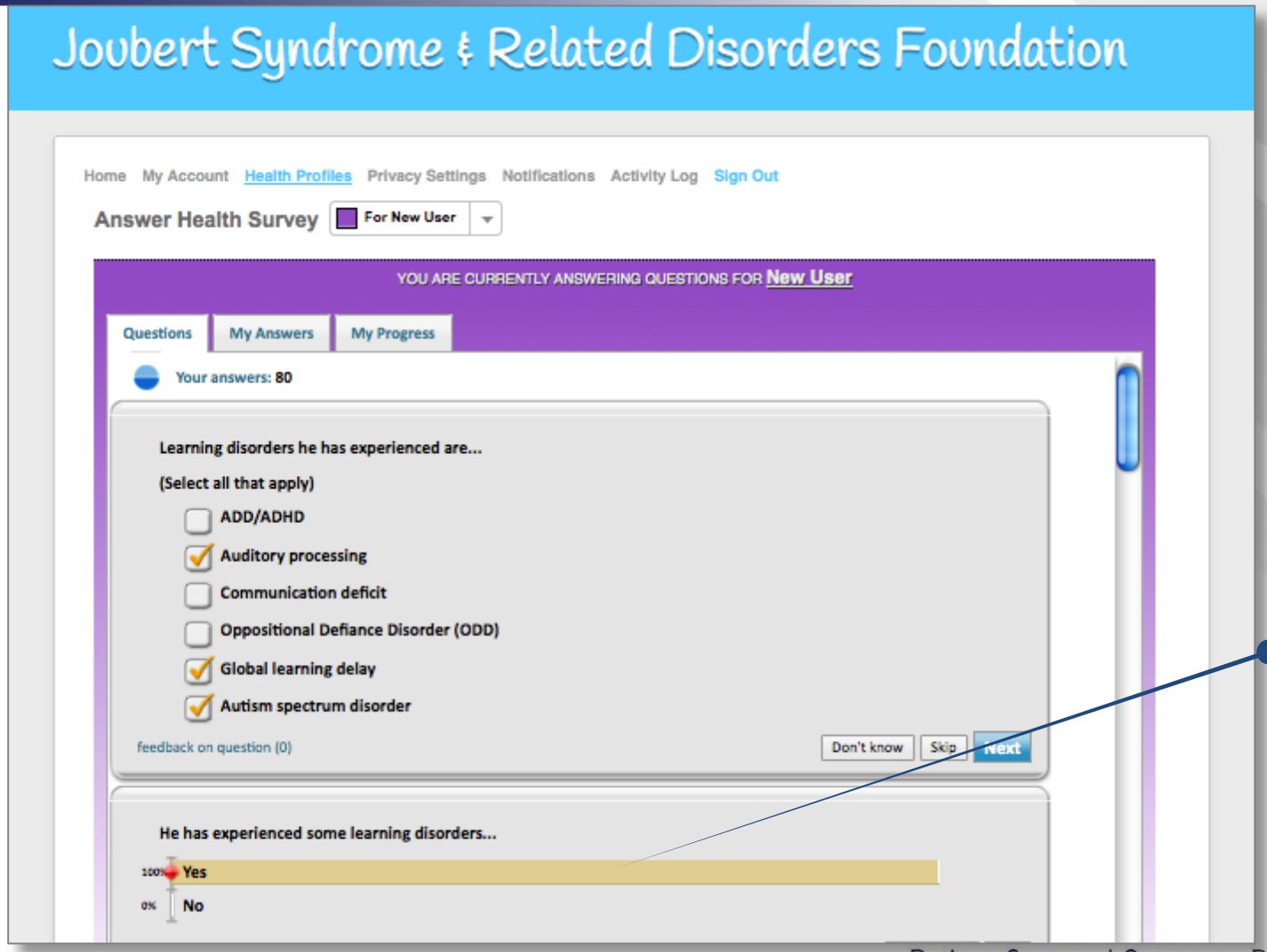
Each guide suggests his or her ideas as a possible starting point



For multiple categories of uses, and specified usage rights

Participants use privacy settings to specify who can, and cannot, access or use their de-identified and/or personal contact data, and for what purpose

Platform for Engaging Everyone Responsibly (PEER)



Participants see immediate feedback

Successes and Challenges

- Successes
  - All organizations engaged and meeting milestones
  - Incredible cross-condition consensus and collaboration
  - Robust connections to the clinical community (advisors)
  - Innovative engagement with University of California, San Francisco and University of California, Davis
  - Increased literacy (Common Data Elements, validated instruments, computable phenotype)
- Challenges
  - Scope creep
  - Diversity
  - Time

Participant (Patient) Engagement

Nothing about us without us

New Partnerships

- With other PPRN and CDRN
  - pSCANNER, DuchenneConnect, Health eHeart
  - Informally with others
- Outside PCORnet
  - Interest in process
  - Interest in policies
  - Interest in Platform for Engaging Everyone Responsibly

CENA Vision for PCORnet

- Research is radically altered because: People have discovered two secrets.
  1. My physician doesn't know everything, and
  2. I am essential to improving health: mine and others.
- The public is part of innovations in health.
- A learning healthcare system is powered by people.
- Health is accessible to all.

Discussion

- Principal Investigators
  - Thomas W. Carton, PhD – The Louisiana CDRN
  - Rachel Hess, MD, MS – PaTH CDRN
  - Holly Peay, MS – DuchenneConnect PPRN
  - Sharon Terry, MA – Community Engaged Network for All (CENA) PPRN

- Moderator:
  - Rachael Fleurence, PhD – Program Director

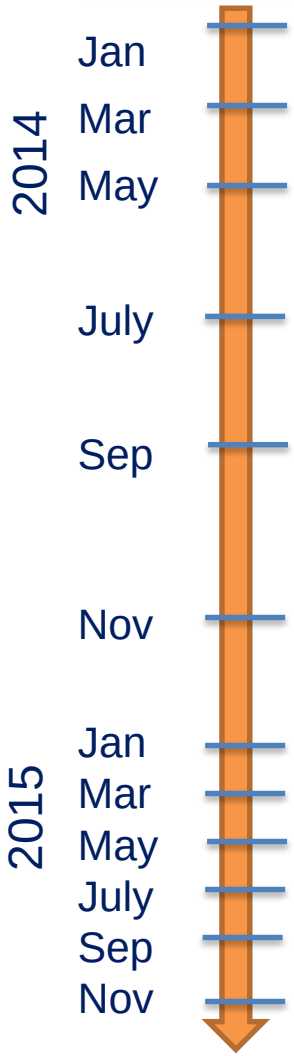
Review and Discuss Plans for Phase II of PCORnet

Rachael Fleurence, PhD
Program Director

Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute

PCORnet Phase I: 2014 – 2015



- Jan: ►Phase I Kick-Off, Washington DC
- May:
  - ►Common Data Model version 1.0 Released
  - ►PCORnet Patient Council Announced
  - ►Patient Data and Privacy Roundtable
- July:
  - ►Aspirin Clinical Trial Topic Approved by Board of Governors
  - ►1st Draft Governance Policies Under Review
- Sep:
  - ►Aspirin Clinical Trial Process Communicated to Networks
  - ►Test Queries Performed by the PCORnet Coordinating Center
  - ►Network 6-month Evaluations by PCORI Begin
  - ►Phase II Pre-announcement Released
- Nov:
  - ►Aspirin Clinical Trial Applications Due
  - ►Phase II RFP Released
- May (2015): ►Aspirin Clinical Trial Recruitment Begins
- Nov (2015): ► Phase II Begins

18-Month Aim

- PCORnet will bring together the expertise, populations, resources, and data of its participating organizations to create a national infrastructure that enables more efficient, patient-centered research. Hallmarks include:
  - Highly-engaged patients, clinicians, health systems, researchers and other partners
  - A collaborative community
  - Analysis-ready standardized data with strong privacy and data security protections
  - Oversight that protects patients, supports timely conduct of research, and builds trust in the research enterprise
  - Research integrated into care settings and with patient communities

4+ Year Aim (End of Phase II)

- PCORnet will serve as a national research infrastructure for conducting rapid, efficient, patient-centered observational and interventional research that improves healthcare delivery and health outcomes. Hallmarks include:
  - Highly-engaged patients, researchers, clinicians, health systems, and the public participate in network governance and topic generation
  - Greatly expanded analysis-ready standardized data, preserving strong privacy and data security protections
  - An oversight framework that fosters public trust in research
  - A collaborative community that attracts a diverse set of researchers, funders, and other networks
  - Research that is integrated into care settings and with patient communities, with research findings that inform care

Discussion: Funding Phase II of PCORnet

A Variety of Funding Sources will Support PCORnet in Phase II (start October 2015)

- Tapering infrastructure funding from PCORI
- Competitive funding from PCORI for specific research projects
- Research funding from other sources (NIH, other federal sources, industry)

Types of Support Required by CDRNs and PPRNs

- Organizational sustainability
- Data sustainability
- Research projects
- Pilot work

Types of Activities Anticipated for CDRNs in Phase II

- **Organizational maintenance**:
  - Develop and support CDRN governance
  - Continued engagement with key patient, health systems, clinician, and researcher stakeholders
  - Participate in PCORnet-wide activities
  - Streamline contracting and Institutional Review Board (IRB) processes
- **Data maintenance**:
  - Continue to build out Common Data Model and harmonize data to it
  - Maintain analysis-ready data sets, refresh regularly, do quality checks
  - Respond to prep-to-research queries
  - Link to multiple external sources to ensure data completeness and longitudinality, as well as privacy and security
  - Continue to develop disease-specific cohorts
  - Develop and maintain clinical trials infrastructure

Types of Activities Anticipated for PPRNs in Phase II

- **Organizational maintenance**:
  - PPRN governance activities and ensuring continued patient leadership
  - Engagement with key patient, clinical, and researcher stakeholders
  - Maintaining diversity of network membership
  - Participation in PCORnet-wide activities
  - Ensuring compliance with regulatory and legal requirements
- **Data maintenance**:
  - Harmonizing data to Common Data Model and building out capacity to include more data elements such as Patient Reported Outcomes
  - Refreshing data regularly, doing quality checks
  - Linkage to multiple external registries and other data sources (Patient Reported Outcomes, mHealth, claims, etc.)
  - Linking with other CDRNs and PPRNs

Important Information Anticipated for Phase II

- Request for Proposals will be issued with a clearly specified statement of work
- Funding will be available for up to 13 CDRNs and 22 PPRNs
- CDRNs must:
  - have a clinical researcher as a Principal Investigator or co-PI, with specific time commitments to PCORnet
  - describe areas of clinical expertise, ideally linked to current clinical cohorts, and progress toward funded clinical research
  - describe plans for linking with their CTSAs (if applicable)
  - show plans to link with major health plans to achieve data completeness
- CDRNs/PPRNs must:
  - provide a sustainability plan starting in 3rd year
  - show cross-linkage plans

Proposed Funding for CDRNs and PPRNs over 3-year Phase II*:

	Year 1	Year 2	Year 3	3-year Total
CDRN (direct)	$2,500,000	$2,500,000	$1,250,000	$6,250,000
PPRN (direct)	$480,000	$480,000	$240,000	$1,200,000

*This proposed level of funding was discussed and endorsed by PCORI's Research Transformation Committee on August 22nd

Discussion Questions

- Is this description of Phase II consistent with the Board's vision of a national patient-centered clinical data research network?

- How do we leverage the capacity of the CDRNs and PPRNs to do research?

Methodology Committee Update

Robin Newhouse, PhD, RN
Chair of the Methodology Committee

Patient-Centered Outcomes Research Institute

Session Topics and Objectives

What are we going to cover today?

Methodology Standards	• Dissemination and Implementation update • Update on development of new standards
Methods Monitoring in the Portfolio	• Discuss current activities and next steps
Translation Framework	• Discuss the future of the “Translation Table”
Network Research Methods Work Group	• Highlight Network Methods Work Group activities
Other Updates	• Value of Information RFI announcement • Decision Sciences Expert Meeting • GAO appointments – Awaiting announcement

Dissemination and Implementation of the Methodology Standards

- **Audiences:**
  - PCORI Staff, Merit Reviewers, and Applicants
  - Broader Research Community

- **Intended Outcomes:**
  - Increased researcher/stakeholder awareness of standards
  - Incorporation of the standards into key PCORI programs and activities
  - Increased use of the standards by researchers, publishers, and funders
  - Increased availability of tools and other resources to facilitate use of the standards

Dissemination and Implementation Activities Completed and/or Underway

Timeline	*Activities*	*Status*
Q1 2014 ***Ongoing***	Operationalize in PCORI merit review process: • Guidance in PFAs • Contract management	• Staff launched a Standards Work Group • Standards incorporated into PFAs, applications, and merit reviewer trainings • Using standards in contract management • Questions about standards in applicant and reviewer surveys • ***Developing adherence and interpretation guide, to be available this fall***
Q1 2014 ***Ongoing***	Dissemination activities: • Public audiences • Key partners	• 500 registrants for July webinar • ***Further partnerships are being cultivated*** • ***Scholarly article submission this winter*** • Staff are tracking journal and scholarly work

Dissemination and Implementation Activities Completed and/or Underway

Timeline	*Activities*	*Status*
Q2 2014 ***Ongoing***	Standards Training Activities: • Conduct needs assessment • Leverage existing training programs • Develop new training materials and/or tools	• Merit reviewer training • All scientific staff have completed a 3-part training session on use of the standards • ***Modify the existing training materials into several training modules for a wider audience***

Dissemination and Implementation Activities to be Completed

Timeline	*Activities*	*Status*
Q3 2014 ***Q4 2014***	Monitoring and Evaluation: • Develop performance metrics and data sources • Track progress and guide refinement of the plan	• The Standards Work Group will coordinate this activity • Input from Methodology Committee
Q4 2014 ***Q1 2015***	• Develop additional decision support tools for researchers and reviewers • Develop other tools for stakeholder groups	• Additional evaluation of the prior phases is needed

Development of New Methodology Standards

- Standards for ***Cluster Research Designs***
  - Objective: To develop and help refine a set of standards
  - Planning a Cluster Research Design meeting in Washington, DC, this fall

- Standards for ***Complex Interventions***
  - Objective: To develop and create a definition of complex interventions
  - Definitional work to be performed and plan for future standard development work in Q2 2015

Methods Monitoring in the Portfolio

- **Portfolio Analysis**
  - Types of projects in the PCORI Methods Research Portfolio
  - Methods used throughout PCORI's portfolio of funded projects
- **Clinical Trials Advisory Panel Subcommittees**
  - Consultation on clinical trials
- **Methodological Consultation**
  - Will be implemented for the first round of Pragmatic Clinical Studies applications in November 2014
  - Operational planning by staff – ongoing

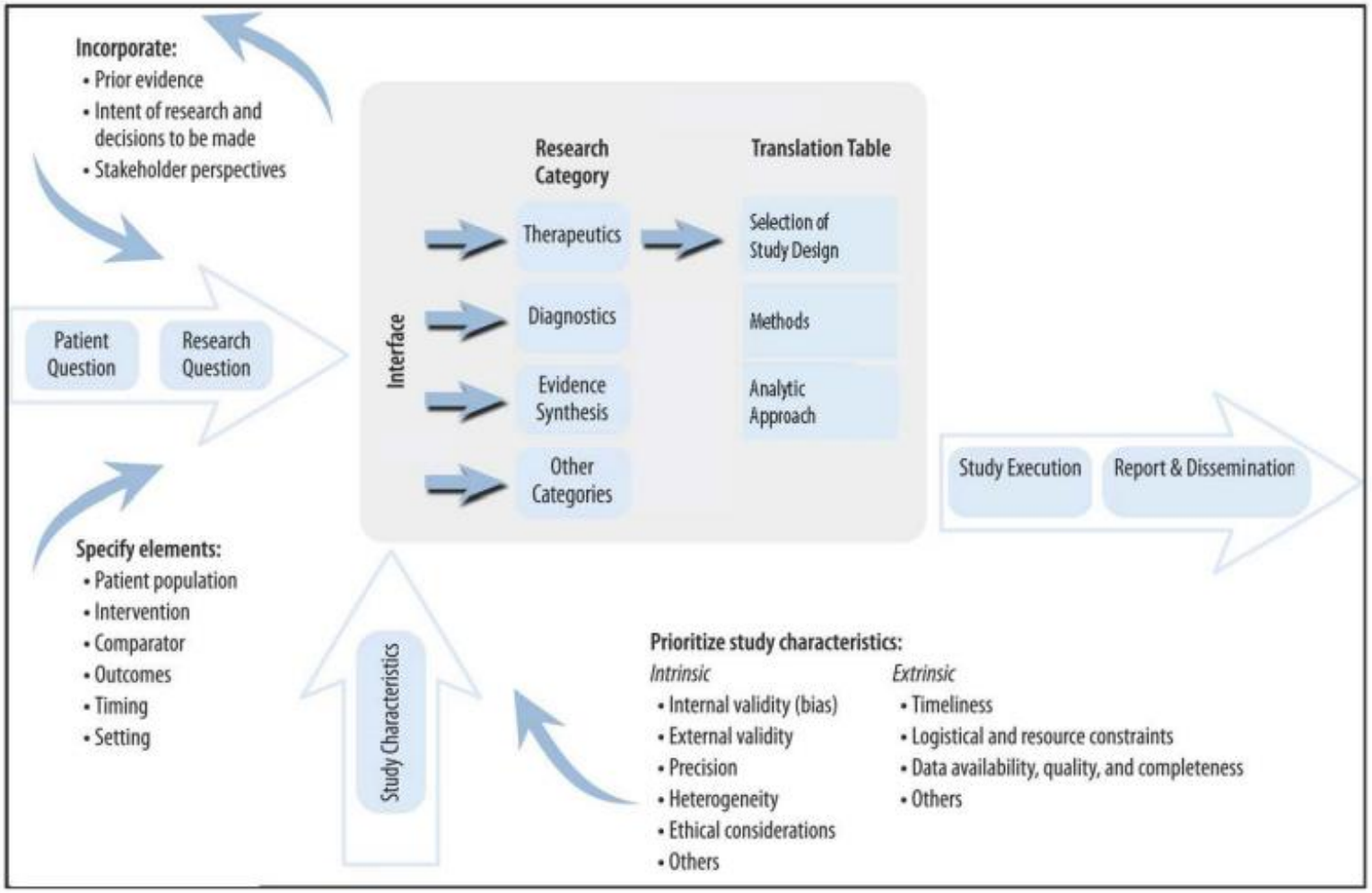
Translation Table

- **Legislative Mandate**
  - *A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question (6.C.2)*

- **Methodology Report** includes a Translation Framework that specifies the approach for developing translation tables for specific areas of clinical research (see next slide)

- Next Steps: Under discussion

Translation Framework in Methodology Report (2013)



Network Research Methods Work Group

- Promising Models and Future Research Needs on the Conduct of ***Distributed Analyses*** in Data Networks
  - Progress: Fall 2014 invitational workshop for representatives of data networks that currently conduct distributed analyses
    - Identified networks currently engaged in doing distributed data analyses and relevant individuals within those networks to invite to the workshop
    - Created a template from the structured abstracts for meeting invitees and starting a white paper
- MC Lead: Sebastian Schneeweiss

Network Methods Work Group

- Best Practices for ***Handling Missing and Inconsistent Data*** in Data Networks
  - Progress:
    - Expert committee to refine the scope of work related to both missing and/or inconsistent data
    - First focus will be on missing data
    - Currently surveying representatives of the CDRNs
- MC Lead: Sally Morton

Other Updates

- ***Decision Sciences*** Expert Meeting
  - Plan to convene a group of experts in November 2014

- ***Value of Information*** (VOI) RFI Announcement
  - RFI released on July 23, 2014, to collect input from stakeholders regarding priorities for research on processes for incorporating VOI into internal evaluation and research prioritization decisions
  - A public webinar was held on August 27, 2014, and final input was due September 5, 2014

- Awaiting announcement from the GAO regarding the appointment of new members

BREAK

Join the conversation on Twitter via #PCORI

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Improving Healthcare Systems Program Portfolio

Steven Clauser, PhD, MPA

Program Director, Improving Healthcare Systems

Patient-Centered Outcomes Research Institute

Presentation Overview

- Who we are
- What we do
- What we have learned
- Where we are going

The Improving Healthcare Systems (IHS) Program Team

Steven Clauser, PhD, MPA

Lynn D. Disney, PhD, JD, MPH

Alex Hartzman, MPH, MPA

Lauren Holuj, MHA

Hannah Kampmeyer

Penny Mohr, MA

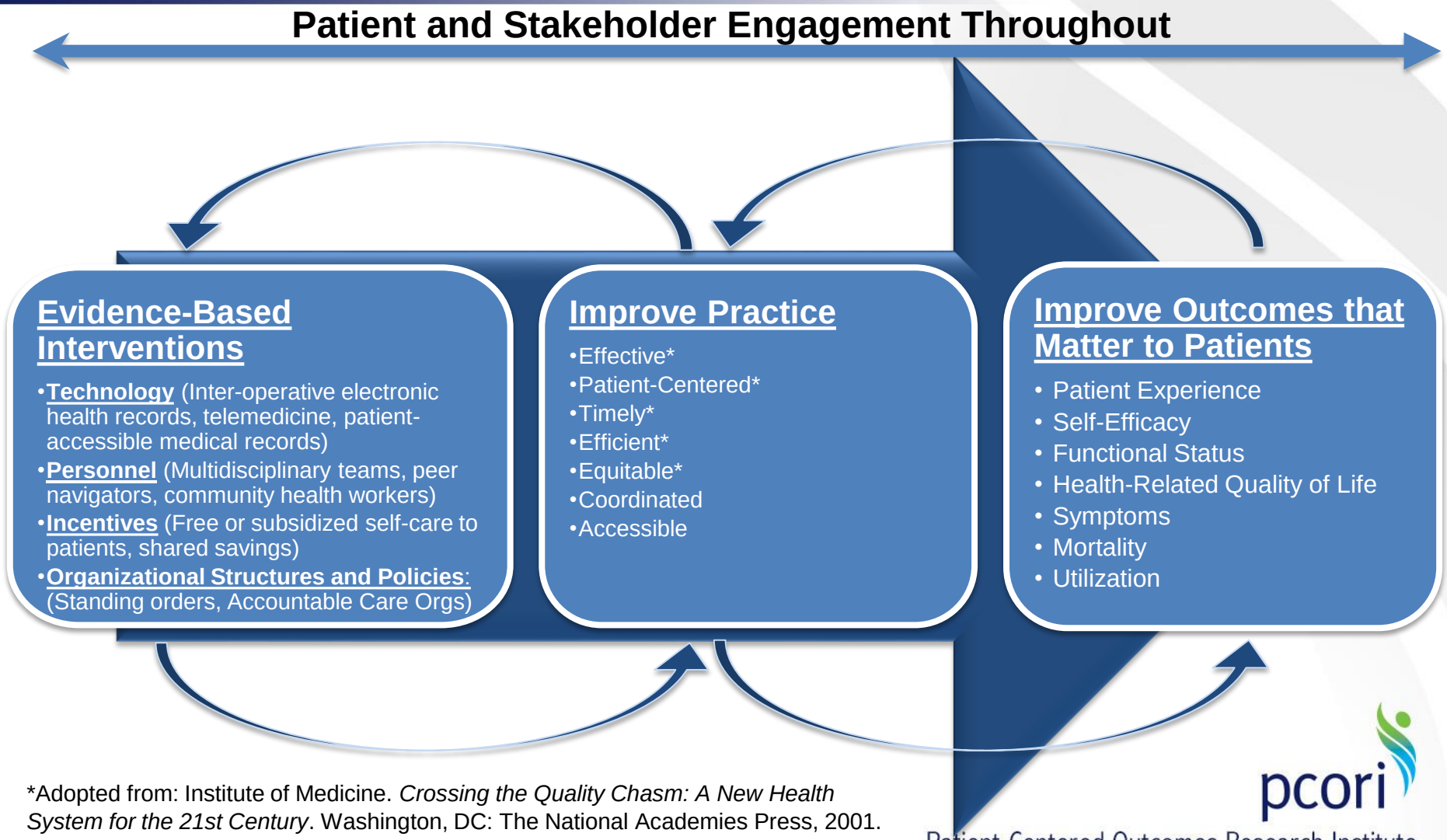
IHS Goal Statement

To support studies of the *comparative effectiveness of alternate features of healthcare systems* that will *provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders*, regarding which features of systems lead to better patient-centered outcomes.

Studies Comparing Interventions by System Level

System Level	# of Studies in the IHS Portfolio	Examples of Comparisons in the IHS Portfolio
Individual Patient	5	Compares the use of an electronic asthma medication tracker to standard primary care (no tracker) for children with asthma and their parents and caregivers
Family & Social Supports	6	Compares the use of advance planning tools for access to community-based and in-home services for the frail elderly and their caregivers to an electronic educational intervention of available services and programs
Provider/Team	14	Compares nursing home staff team-based training and palliative care delivery using an adapted National Quality Forum (NQF) protocol to a standard nursing home palliative care protocol
Organization and/or Practice Setting	17	Compares elements of patient-centered medical home (e.g., addition of a primary care physician in the context of regularly scheduled dialysis sessions and health promoters to help support patients and their caregivers) to traditional team-based specialty care for end stage renal disease patients
Local Community Environment	6	Compares an Emergency Department-to-home community health worker that links patients with community-based social support (e.g. home-delivered meals) and medical follow-up, to care transition programs using written & verbal discharge instructions alone

IHS Strategic Framework



*Adopted from: Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: The National Academies Press, 2001.

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Distinctive Components of IHS Studies

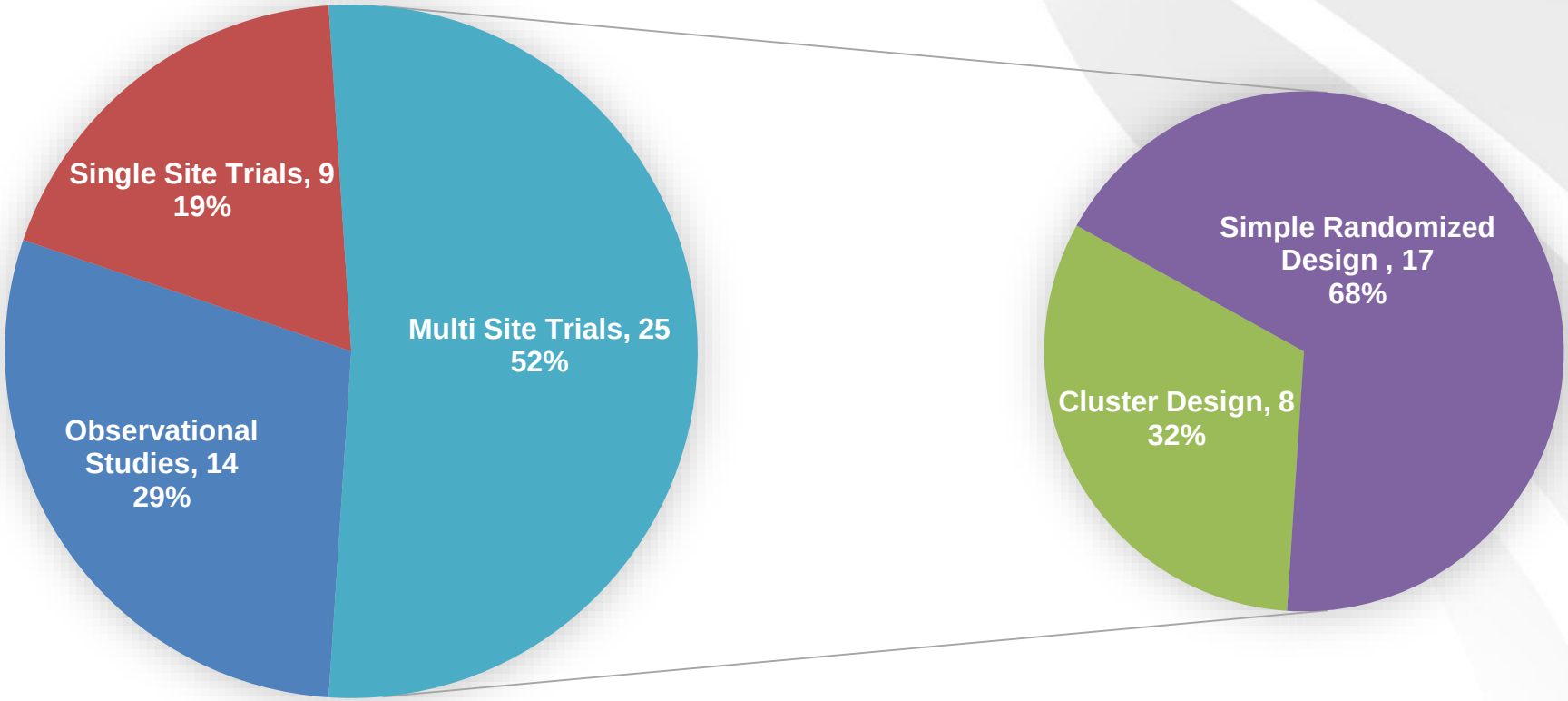
- Adapt PCOR model for CER beyond clinical treatment options to different levels of the healthcare system
- Require inclusion of well articulated and valid comparators, for both trials and studies using observational data
- Focus on outcomes relevant to patients
- Active involvement of patients and other stakeholders throughout the entire research process
- Conduct research in real-life settings

Current Foundation:
IHS Broad PCORI Funding Announcement (PFA)

Parameters of the IHS Broad PFA

- Comparative effectiveness of alternate features of healthcare systems
- Priorities reflect investigator interests, merit review assessment, and programmatic balance
- Five funding cycles to date
- Funding to Date (including Winter 2014 Cycle)
  - 48 investigator-initiated studies
  - Across 17 states and Washington, DC
  - $90.2 million awarded

Study Designs (n=48)



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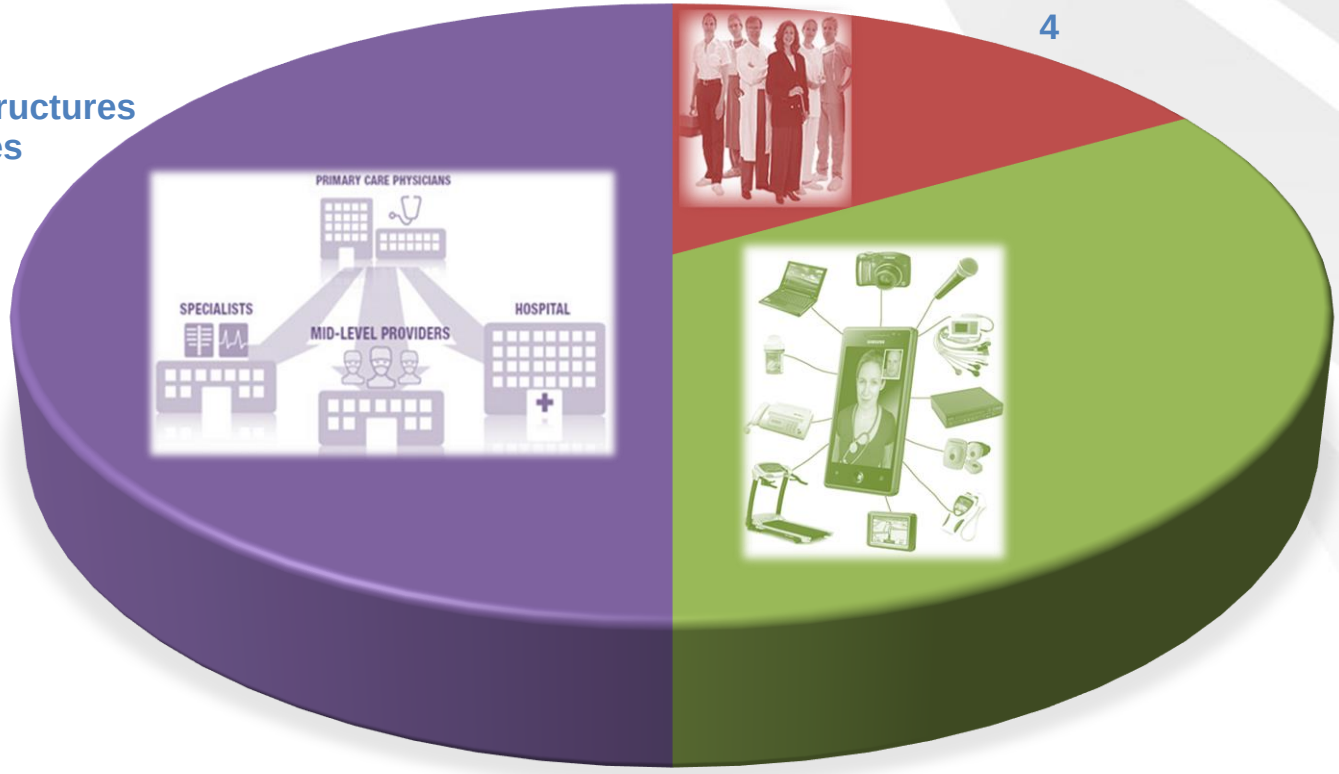
Projects With Single System Interventions (n = 22 out of 48)



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Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources *(Awarded September 2013)*

Study Design: RCT of 200, 8-16 year old diabetics across 2 pediatric diabetes centers, 2 arms).

Intervention: A resource identification program called Problem Recognition in Illness Self-Management (PRISM) that involves patients and caregivers in care planning and diabetes mgmt.

Comparator: Control clinics with family and caregiver barriers not formally assessed

Intervention Target: Organizational Structure and Policy

Engagement: Parents of children with diabetes and patients will engage in a collaborative design process with clinical staff and system leadership.

Taking a family-centered approach to diabetes management, in which resources are tailored to each family's unique challenges. Outcomes of interest include diabetes management, health-related quality of life, and improvement in blood sugar control. Builds on growing evidence that in order to better manage pediatric diabetes, parents and children must be formally involved in their care.

Elizabeth Cox, MD, PhD
University of Wisconsin Madison

Interactive Personal Health Records: Use of a Web Portal by Patients with Chronic Conditions *(Awarded May 2013)*

Study Design: Mixed methods: Large secondary data observational study and patient surveys

Intervention: Electronic health record-supported patient portal to enable patient direct access to medical information and care providers.

Comparator: Patients who do not use the portal and rely on traditional office visit/phone support for medical information and care.

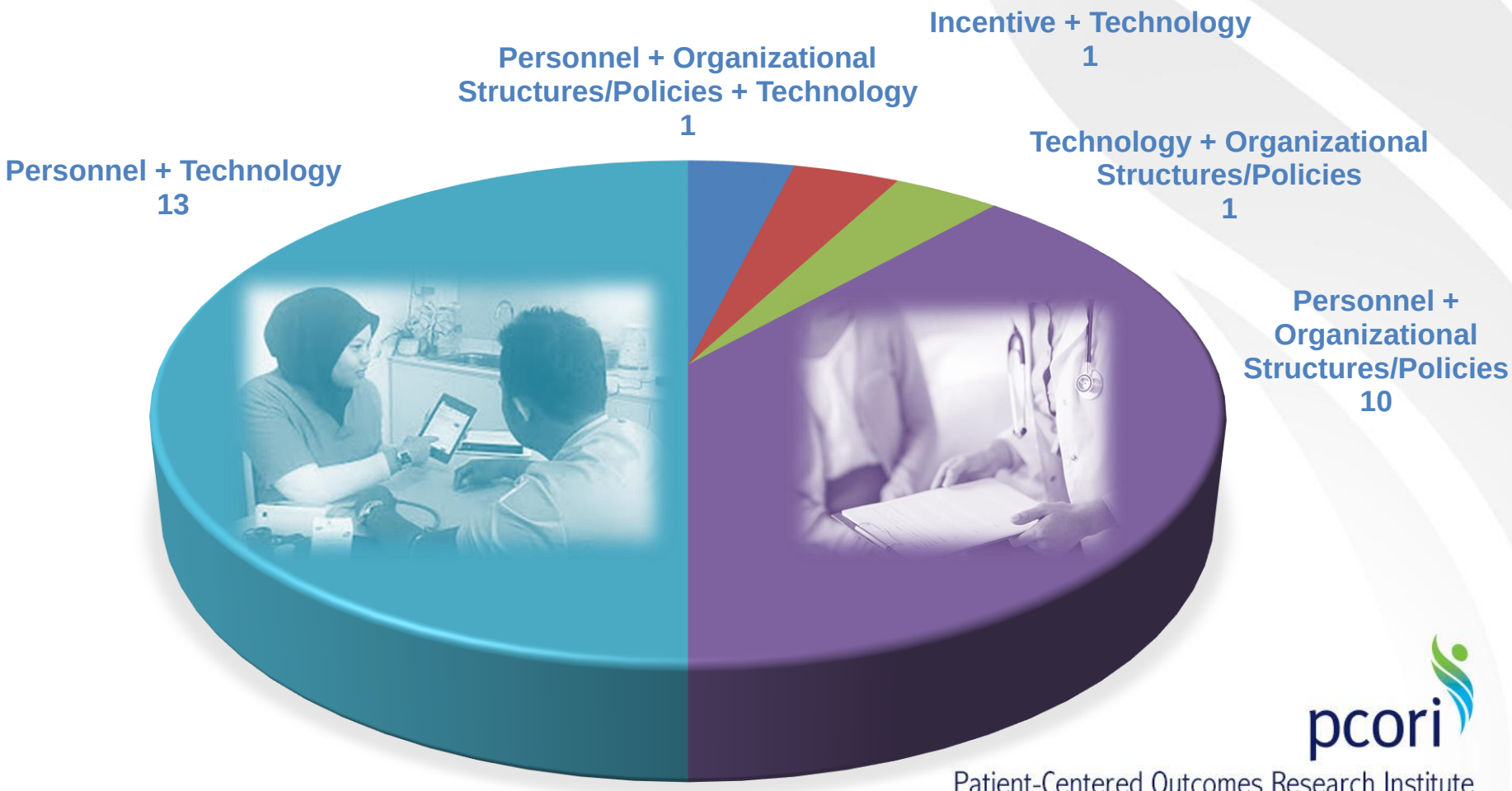
Intervention Target: Technology

Engagement: The study uses patient surveys to collect patient-reported preferences and experiences with using (or not using) patient portal tools.

Examines 800,000 patients with chronic conditions in a large delivery system to assess use of and preferences regarding personal health records and how these preferences affect utilization of health services and care outcomes. Could change practice by providing evidenced-based support for web-based portals as a path to improving the healthcare experience.

Mary Reed, DPH,
Kaiser Foundation Research Institute
Oakland, CA

Projects With Multi-Component Interventions (n = 26 out of 48)



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A Toolbox Approach to Obesity Treatment in Primary Care
(Awarded May 2013)

Study Design: Multisite RCT (350 obese and chronically ill patients across 4 primary care clinics; 2 arms).

Interventions: Level one is web-based self-monitoring tools for weight loss and selection of treatment options. Level 2 includes incentives to participate in comprehensive formal weight-loss program.

Comparator: Primary care with physician initiated assessment, counseling and referral to weight loss programs.

Intervention Targets: Technology and incentives

Engagement: Focus groups with patients in the first year and a patient advisory council that will advise investigators throughout the study.

Obese patients with diabetes, hypertension, or hyperlipidemia will be offered self-monitoring tools for weight management and an assessment to select from weight loss treatment options. Patients who complete this and record their food intake and physical activity for one week will be offered a "Level 2" treatment to help with weight loss. Level 2 treatments include: a voucher for a commercial weight-loss program; an intensive group behavioral weight-loss program; meal replacements; fitness center membership; or weight-loss medication. Primary outcome is weight loss (reduction in BMI).

Daniel Bessesen, MD
Denver Health and Hospital Authority

Improving Care Transitions for Acute Stroke Patients Through a Patient-centered Home Based Case Management Program *(Awarded July 2014)*

Study Design: Multisite RCT (480 acute stroke patients across 4 hospitals; 3 arms).

Interventions: Social Work Bridge Coordinator (SWBC) case management program plus a Virtual Stroke Support patient portal targeted to assist patients and caregivers with transition from hospital to home.

Comparators: (1) Social Work Bridge Coordinator (SWBC) case management program alone and (2) hospital care without case management or patient portal support.

Intervention Targets: Personnel and technology

Engagement: Two stakeholder panels: 1) stroke survivors and caregivers, and 2) stroke health care providers.

Testing two patient-centered interventions designed to improve transitions and outcomes for stroke patients who have returned home. Primary patient informed outcomes include stroke-specific quality of life, patient activation, self-efficacy, knowledge, and satisfaction. Caregiver informed outcomes include caregiver strain, preparedness for caregiving, knowledge, and satisfaction.

Matthew Reeves, DVM, PhD
Michigan State University

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IHS Targeted Funding Portfolio: Stakeholder-Initiated Priorities

STRIDE – STrategies to Reduce Injuries and Develop confidence in Elders

- PCORI-National Institute of Aging research partnership
  - $30 million / 5 year award made June 1, 2014
  - 3 Co-PIs:
    - Shalender Bhasin, MD, Harvard Medical School
    - David Reuben, MD, David Geffen School of Medicine at UCLA
    - Thomas Gill, MD, Yale School of Medicine
- Multi-site cluster randomized clinical trial
  - 6,000 participants
  - 10 sites / 80 local practices.
- Intervention - Falls Care Manager using evidence-based, multi- factorial individually-tailored services to reduce the risk of serious fall injuries among older persons (age 75+).
- Comparator - Primary care with falls risk assessment and patient educational materials

Upcoming Targeted Initiative

- Effectiveness of Transitional Care ($15 million)
  - Compare which transitional care service clusters (e.g., pre-discharge planning, medication reconciliation) are most effective in improving patient-centered outcomes
  - Intervention: Hospitals or communities who implemented defined clusters of transitional care components
  - Comparator: Hospitals or communities relying on traditional discharge and referral programs

This is the first topic prioritized by a PCORI Advisory Panel to complete the entire Targeted PFA process.

Pragmatic Clinical Studies PFA

- Improving Healthcare Systems Priority Topics
  - Integration of Mental Health and Primary Care
  - Innovative Strategies for Medication Adherence
  - Health Insurance Features
  - Involvement by Patients and Caregivers in Management of Chronic Mental Illness

- Other IHS-relevant research topics included in IOM's Top 100 Topics for CER or AHRQ's Future Research Needs

Conclusions and Future Directions

Lessons Learned from Cycle I and II Studies

Issues:

- Clinician and administrative leadership buy-in is essential for healthcare systems CER
  - Buy-in is especially important when interventions involve clinical system redesign
- Accrual of understudied populations is difficult

The Lesson:

- Close contract management and proactive communication with investigators is essential to minimize risks

Goals for the Next 12 Months

- Evaluate new initiatives to improve Broad PFA applications and programmatic fit
  - Competitive Screening of Letters of Intent
  - Allow larger project applications (up to $5 million/5 years)
  - Area of emphasis funding opportunities
- Work with the Methodology Committee and Clinical Trials Advisory Panel on health system CER challenges
- Develop new initiatives with other PCORI Programs
  - Communications and Dissemination – Choosing Wisely®
  - PCORnet – Rapid Cycle Research
- Engage AHRQ and other funders with IHS projects that may require additional implementation research, and collaborate on CER research

U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

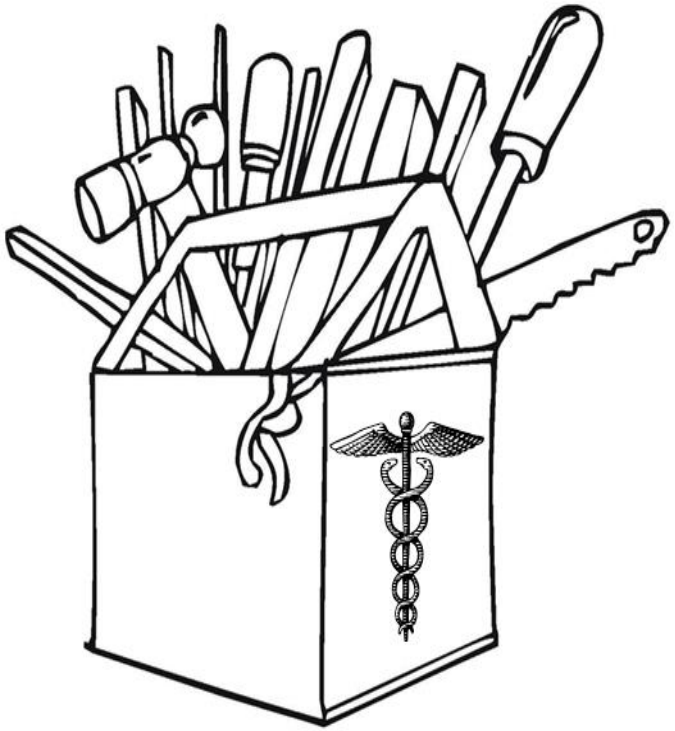
AHRQ Activities Funded By The Patient-Centered Outcomes Research Trust Fund

Richard Kronick, Ph.D.
Director
Agency for Healthcare Research and Quality

PCORI Board of Governors Meeting

Washington, DC – September 15, 2014

Agenda



- AHRQ Overview
- Past, Present and Future Work in Patient-Centered Outcomes Research
- Q & A

AHRQ's Mission

To produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used.

Priorities

Priority #1

Produce Evidence to Improve Health Care Quality

Priority #2

Produce Evidence to Make Health Care Safer

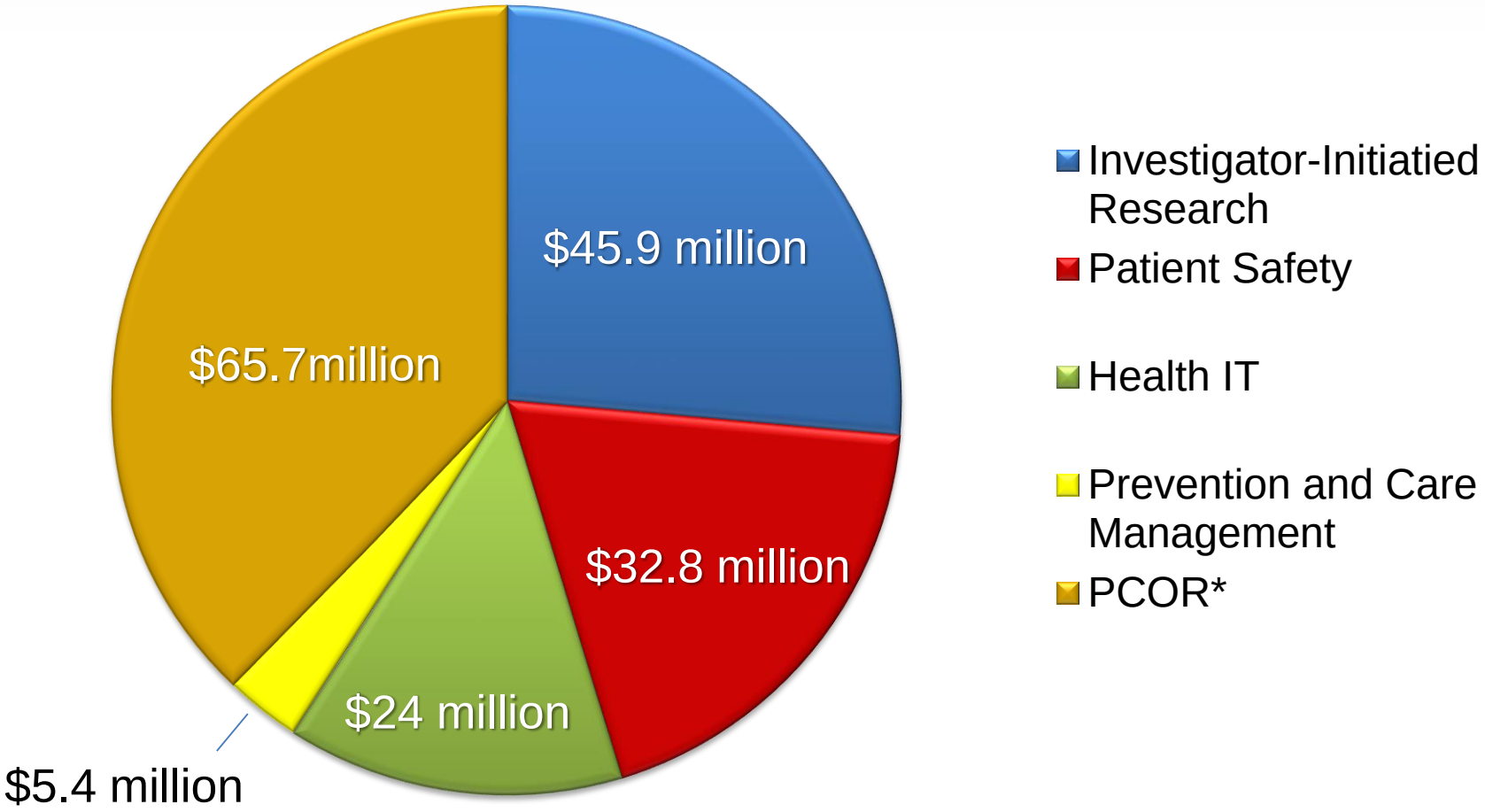
Priority #3

Produce Evidence to Increase Access to Health Care

Priority #4

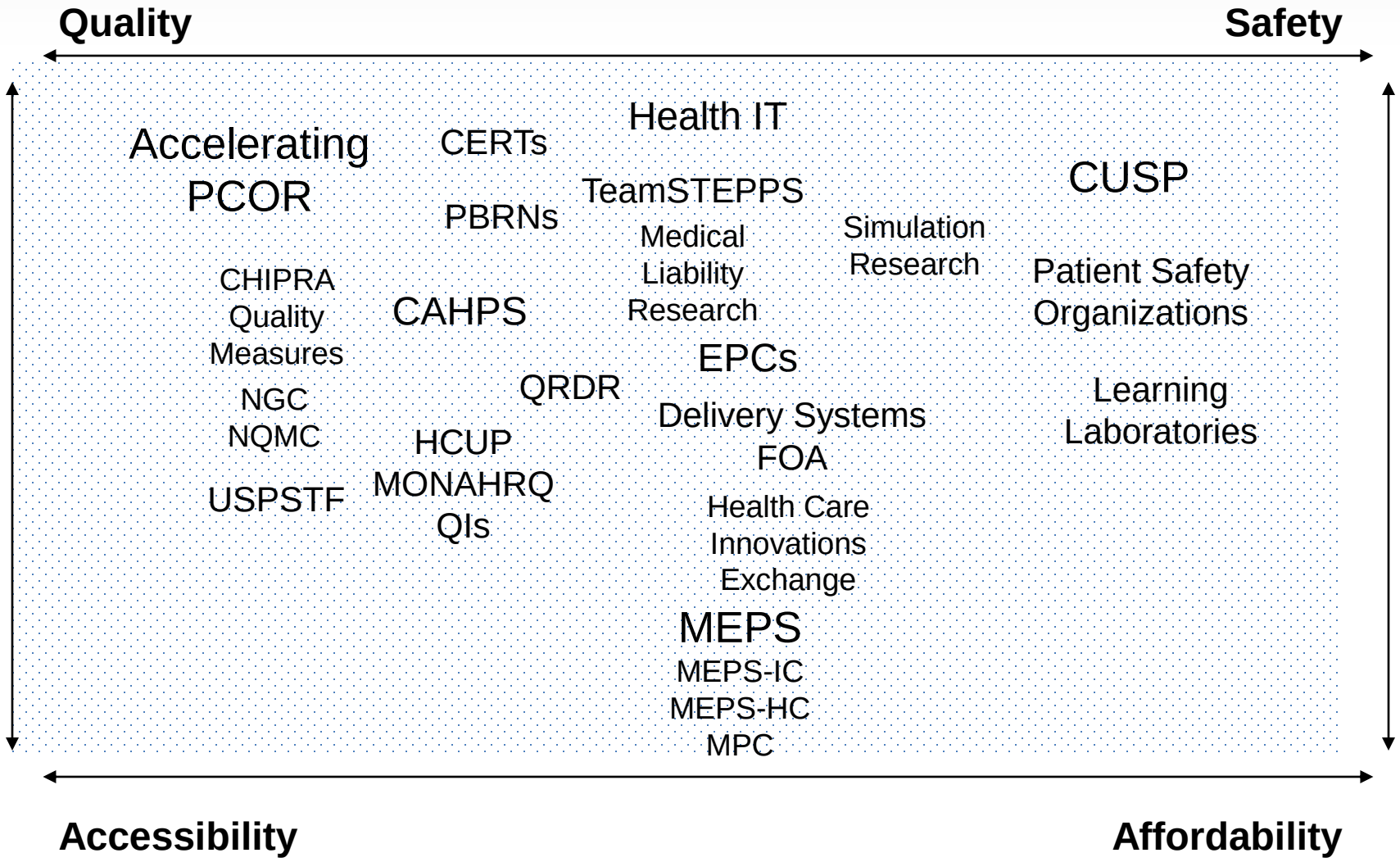
Produce Evidence to Improve Health Care Affordability, Efficiency and Cost Transparency

Approximately $170 Million in Total Grant Activity



*PCOR funding is an estimate for FY 2015. All other figures are for FY 2014.

Selected AHRQ Activities



AHRQ Effective Health Care (EHC) Program

- Funds patient-centered outcomes research for clinicians, consumers and policymakers
  - Reviews and synthesizes published and unpublished scientific evidence
  - Generates new scientific evidence and analytic tools
  - Translates research findings into useful formats for the various audiences

Created by the Medicare Modernization Act of 2003

http://effectivehealthcare.ahrq.gov

ARRA-Funded Work

EHC Initiatives

- Innovative Adaptation and Dissemination of AHRQ Comparative Effectiveness Research Products (iADAPT)
- Clinical and Health Outcomes in Comparative Effectiveness (CHOICE)
- PRospective Outcome Systems using Patient-specific Electronic data to Compare Tests and therapies (PROSPECT)
- Electronic Data Methods (EDM) Forum for Comparative Effectiveness Research

Dissemination and Training

- National Partnership Network
- Bundled Marketing of Clinician and Patient Summaries
- Academic Detailing
- Online CE/CME
- Individual PCOR Training Grants
- Institutional HSR Training Centers of Excellence
- Institutional Support and Infrastructure Development

Corticosteroid Does Not Reduce Pain For Patients With Lumbar Stenosis

- Addition of a corticosteroid to epidural injection of anesthetic did not enhance pain reduction in patients with lumbar spinal stenosis
- AHRQ-funded researchers studied 400 patients at 16 hospitals
  - First major clinical trial comparing epidural injections of anesthetic with and without corticosteroid for spinal stenosis
  - Published in July 3 issue of *New England Journal of Medicine*

www.nejm.org/doi/full/10.1056/NEJMoa1313265

AHRQ's Role In Patient-Centered Outcomes Research

AHRQ is charged with broadly disseminating research findings relevant to comparative clinical effectiveness research

- Production of systematic reviews and production and distribution of patient and clinician summary materials
- Direct work with providers to disseminate PCOR
- Understanding the factors that influence dissemination and use in health systems, and development of methods of measuring health system performance
- Training and physician support

Source: Affordable Care Act. Subtitle D—Patient-Centered Outcomes Research. PUBLIC LAW 111–148—MAR. 23, 2010.

PCORTF-Funded Dissemination/Translation Activities

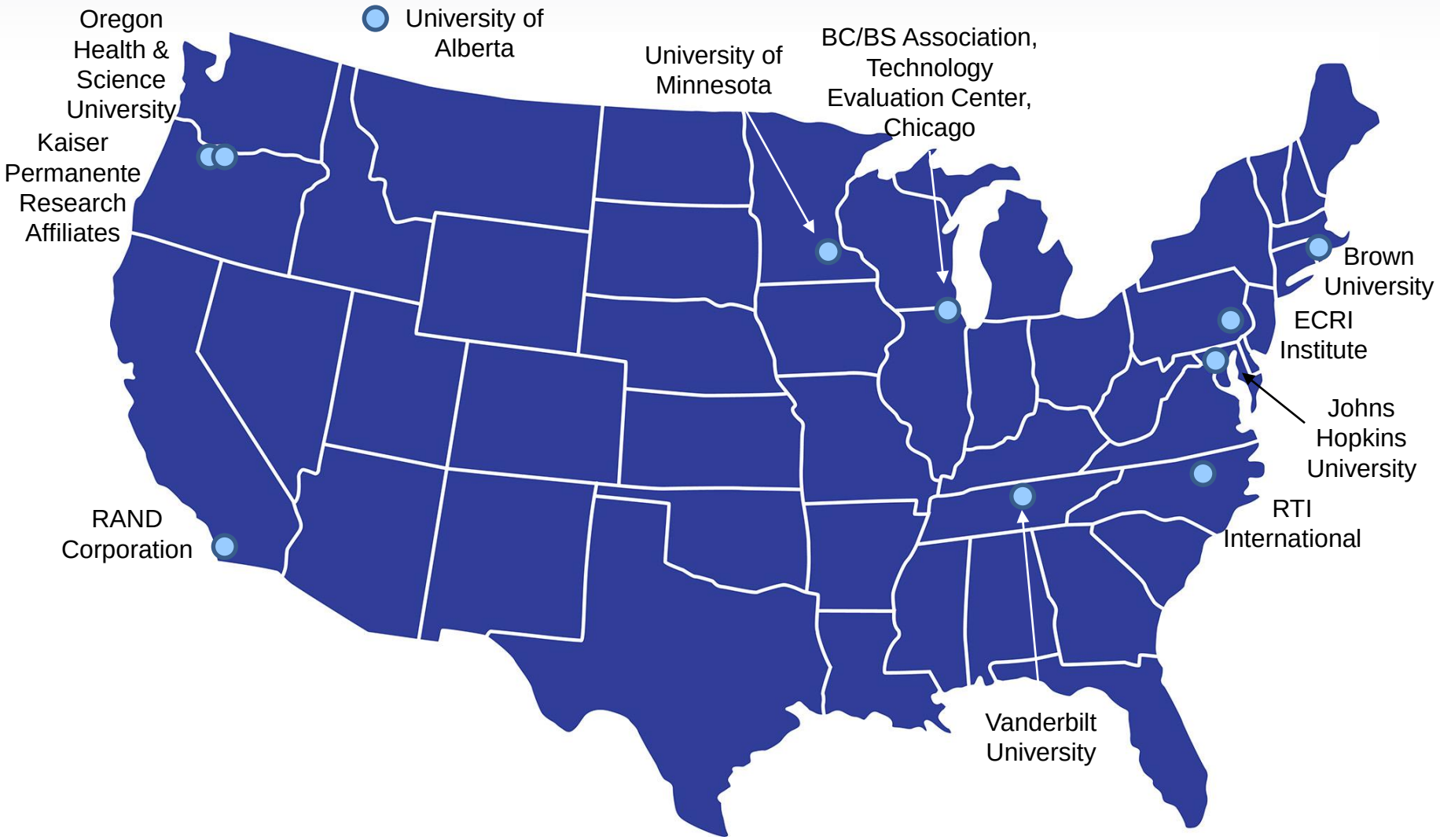
- Training
- Systematic Reviews and Updates
- Research Translation
- Large Broad-Based Implementation & Dissemination Activities

http://gold.ahrq.gov

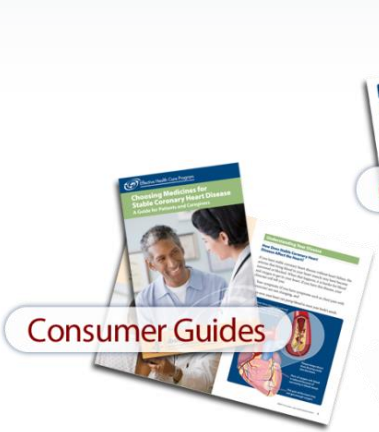
Training: PCORTF

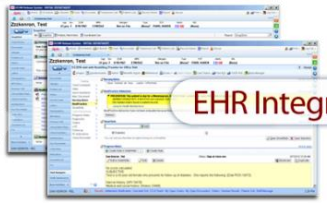
- As part of it's educational and career development program, the Agency offers training in the design, implementation and dissemination of patient-centered outcomes research. For example:
  - PATient-centered Involvement in Evaluating effectivNess of Treatment (PATIENTS)
    - Five-year project at the University of Maryland
    - Focus on comprehensive infrastructure expansion and development for use of PCOR in patient and clinician engagement

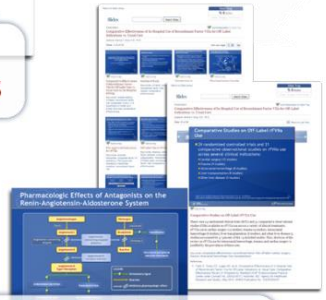
Systematic Reviews: Evidence-Based Practice Centers



Research Translation: Eisenberg Center



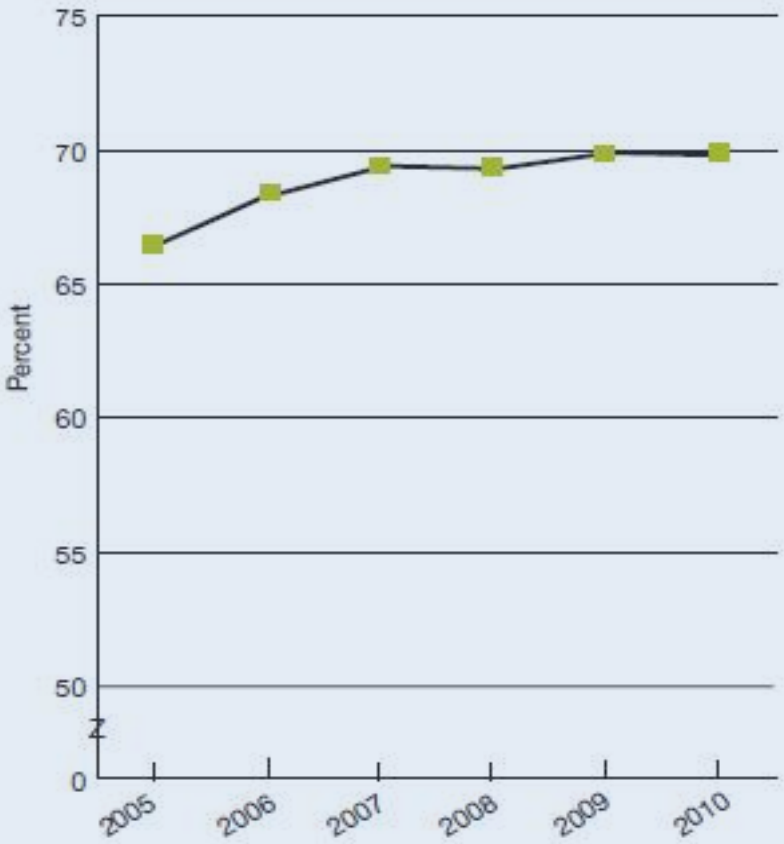




www.effectivehealthcare.ahrq.gov

Implementation and Use of PCOR Findings

Average proportion of recommended care received across a panel of quality of care measures, 2005-2010



AHRQ National Healthcare Quality Report

Selected Current Research and Dissemination Activities

- **Partnerships for Sustainable Research and Dissemination of Evidence-Based Medicine**
  - $2.3 million annually for up to three years for 7-10 awards
- **Patient-Centered Outcomes Research – Dissemination by Health Professional Associations**
  - $2.5 million annually for three years to fund 25-50 awards
- **Closing the Gap in Healthcare Disparities through Dissemination and Implementation of Patient-Centered Outcomes Research**
  - $3 million over three years to fund two awards

Accelerating Adoption of PCOR: Focusing on ABCS

- Accelerating Adoption of PCOR: Focusing on ABCS
  - Grants for dissemination of patient-centered outcomes research to small- and medium-size primary care practices
  - Focus: Million Hearts™ ABCS (**a**spirin use among people with heart disease, **b**lood pressure control, high blood **c**holesterol control and **s**moking cessation advice and support) campaign to prevent heart attacks and strokes

Comparative Health System Performance in Accelerating PCOR Dissemination

- Up to $10.5 million per year for 5 years to support up to three Centers of Excellence on Comparative Health System Performance in dissemination of PCOR
- Develop and implement methods of measuring health system performance on cost and quality domains, with an emphasis on performance in disseminating PCOR
- Work will seek to understand the characteristics of high performing systems.
- Published June 25; Applications due October 17

http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-14-011.html

Health IT and Patient-Centered Outcomes Research @ AHRQ

Facilitating incorporation of PCOR into clinical decision support tools

Moving Forward

- AHRQ's work in PCOR has pivoted to dissemination and training
- There is a great deal of excitement at the Agency about our new roles in PCOR
- Collaboration between AHRQ and PCORI is key to increasing the use of evidence-based research in decision making and translation into clinical practice

Thank You

http://www.ahrq.gov

Public Comment Period

Sue Sheridan, MBA, MIM
Director, Patient Engagement

Patient-Centered Outcomes Research Institute

Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Patient-Centered Outcomes Research Institute