Board of Governors Meeting

via Teleconference/Webinar

May 5, 2014

10:15 a.m. - 5:15 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 a.m.	Call to Order and Welcome
10:20 – 11:00 a.m.	Executive Director's Report
11:00 – 12:00 p.m.	Update on Science Processes
12:00 – 1:00 p.m.	Lunch
1:00 – 1:45 p.m.	Overview of Addressing Disparities Program
1:45 – 2:15 p.m.	Methodology Committee Update
2:15 – 2:30 p.m.	Engagement Update
2:30 – 3:00 p.m.	Evaluation Framework and Plan
3:00 – 3:15 p.m.	Break
3:15 – 4:00 p.m.	Mid-year Dashboard Review
4:00 – 4:30 p.m.	Consider for Approval: Resolution for a cash-secured letter of credit for additional office space lease. Financial Review as of 2/28/2014
4:30 – 5:00 p.m.	Public Comment
5:00 – 5:15 p.m.	Wrap Up and Adjourn Meeting

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Board Vote: Approval of April 22, 2014 Board Meeting Minutes

Call for a Motion to:	• **Approve** April 22, 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/ Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

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Executive Director's Report

Joe Selby, MD, MPH, Executive Director

PCORI Board of Governors Meeting

Alexandria, VA

May 2014

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PCORnet Structure and Milestones

- PCORnet Update
- Pragmatic Clinical Studies Update
- New Advisory Panels Report
- Welcome Jean Slutsky
- Review of Today's Agenda

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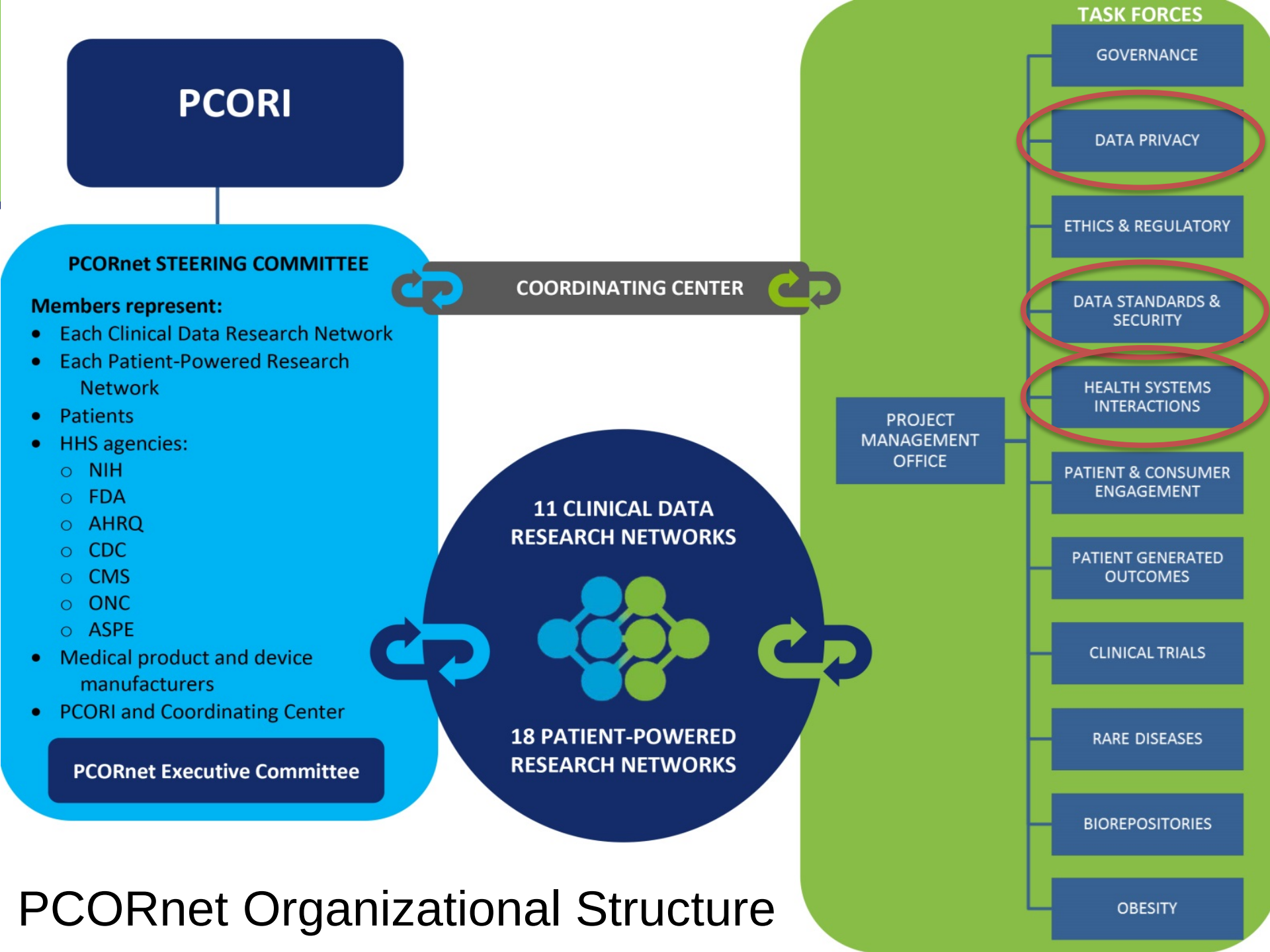


PCORnet Organizational Structure

PCORnet Timeline

Pragmatic Clinical Studies – Letters of Interest Invited:

Reducing Asthma Morbidity in Highly Impacted Populations

HCV Antiviral Treatments in a Diverse Population with Chronic Hepatitis C

Treatments to Improve Outcome for **Opioid Dependence**

Novel approaches to **reducing CVD risk in vulnerable populations**

Smoking Referral/Cessation Interventions in High Prevalence Populations

Personalized **pain management in Sickle Cell** disease

CE of population-based approaches for **preventing diabetes mellitus**

CE of approaches to use of **colony stimulating factor in cancer**

Inpatient vs. outpatient **workup of low risk chest pain**

Financial and social incentives to enhance **medication adherence**

CE of approaches to improving **functional outcomes after stroke**

Management of **chronic illness medications during cancer therapy**

Lithium vs other therapies for **bipolar disorder in adolescents** and young adults

Pragmatic Clinical Studies – Letters of Interest Invited:

School-based **caries prevention** to reduce disparities in children's oral health

Community-based **Depression/Anxiety interventions** to Reduce Disparities

Radiotherapy alternatives for common cancers

Monitoring strategies for **follow-up of lung nodules found at screening**

Endovascular repair vs.optimal medical **management of Type B aortic dissection**

Primary care approaches to **preventing progression of acute low back pain**

Prevention of C-section in low risk patients

Drugs Used in **treating a very rare disorder**

Personalized vs. annual mammography screening for breast cancer

Statins for primary prevention of coronary artery disease **after Age 75**

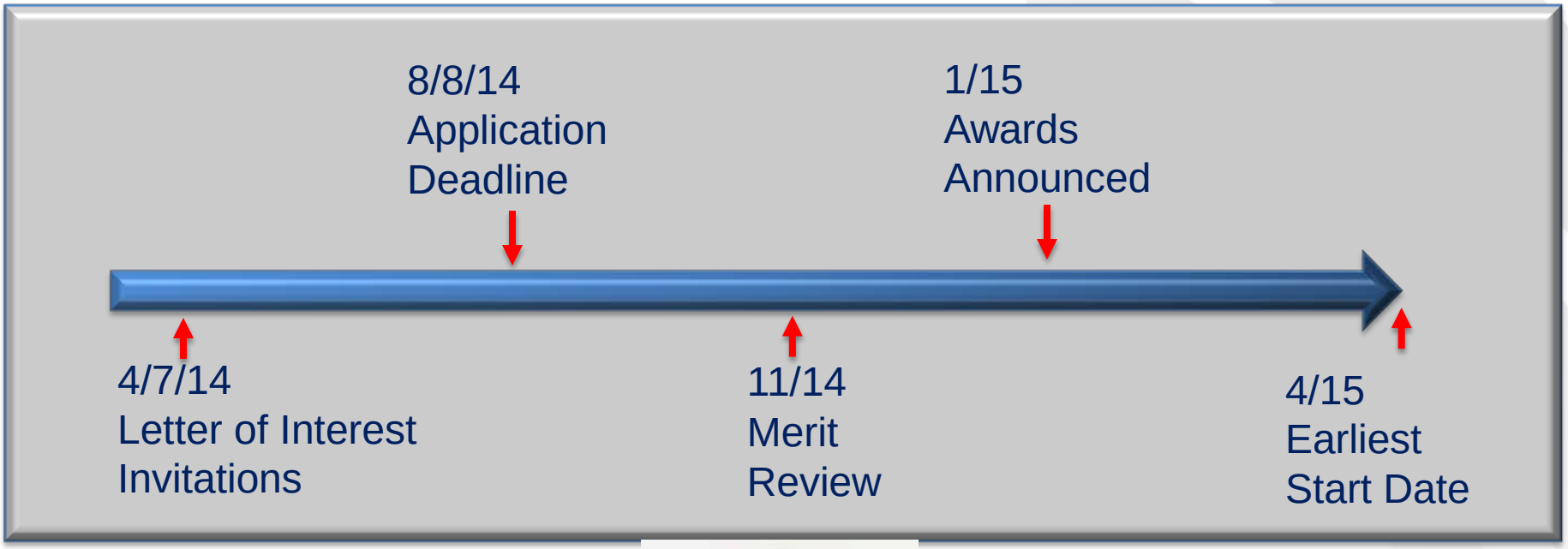
Management strategies for **ductal carcinoma in situ (DCIS)**

Gene expression testing vs. traditional risk stratification **in suspected CAD**

Managing **pain and maintaining physical function** in **osteoarthritis**

Pulmonary embolism prevention after hip and knee replacement

Pragmatic Clinical Studies Timeline



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Advisory Panel on Rare Diseases–April 30th Recap and Summary

- Initial Focus: Foundational Issues
  - Minimal datasets, data standards for rare diseases registries
  - Other issues of importance to registries, e.g., ownership of data, legacy issues, sustainability, access to data, Institutional Review Board issues
  - Landscape review on rare diseases research issues
  - Addressing Institutional Review Board issues related to rare disease research
  - Advise on appropriate CER methods and questions for rare diseases
- Coordinate with PCORI's research prioritization Advisory Panels on issues related to rare disease research
- Coordinate with PCORnet Task Force on Rare Diseases

Advisory Panel on Clinical Trials–May 1st Recap and Summary

- Review PCORI methodology standards related to clinical trials and advise on need for revisions and new standards
- Provide guidance for applicants on innovative methods (i.e. adaptive trials and/or Bayesian methods)
- In collaboration with the Methodology Committee, provide PCORI with methodologic consultation on the Letter of Interest and solicitation process for Targeted PFAs and Pragmatic Clinical Studies
- In collaboration with the Methodology Committee, provide methodological consultation to PCORI and to applicants to enhance the scientific rigor and pragmatic utility of proposed studies
- Advise PCORI on developing policies for Data and Safety Monitoring Board oversight and other human subjects issues for Clinical Trials (safety, efficacy, effectiveness)
- Discuss ethical assessment of low-risk pragmatic trials (with particular focus on PCORnet settings)

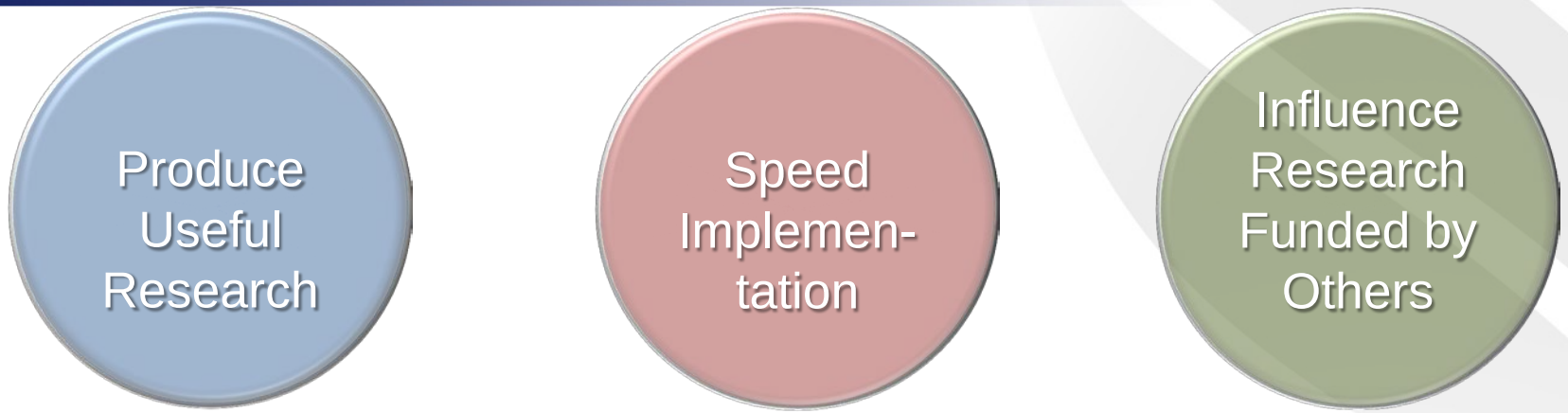
The First GAO 5-Year Review of PCORI Has Begun

- Notification letter from GAO in March
- It identifies 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?*
- Entrance Conference with the GAO Team in April
- GAO will return for a series of meetings with PCORI staff in May
- GAO's report to Congress is due in March of 2015

Jean Slutsky, PA, MPH

- Chief Engagement and Dissemination Officer
- Program Director, Communications and Dissemination Research

Preview of Today's Agenda



Monitor Performance:	2nd Quarter Dashboard Report on Addressing Disparities Portfolio 5-month Finance Review
Advise:	Ensuring Adherence to Methodology Standards Selecting Awards Selecting Priority Topics Methodology Update
Strategy:	PCORI Evaluation Plan Engagement Update

Science Process Update:

Implementing Methodology Standards
Award Selection
Topic Selection

Bryan Luce, PhD, Chief Science Officer

PCORI Board of Governors Meeting
Alexandria, VA
May 2014

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Meeting Agenda and Topics

What is being discussed today?

Report on implementing Methodology Standards	• Review timeline, progress, and plans
Award Selection	• Present final award selection process
Report on progress of topic selection	• Update on process improvement review

Implementing the PCORI Methodology Standards

Bryan Luce, PhD, Chief Science Officer

PCORI Board of Governors Meeting
Alexandria, VA
May 2014

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Session Topics and Objectives

What are we going to cover today?

Overview of Timeline	• Review the timeline for past and future activities related to implementing the Methodology Standards
Adherence to the Standards	• Review the process for monitoring adherence to the Methodology Standards
Training	• Discuss key training initiatives in place or underway

Timeline for Implementing Methodology Standards

- **Prior to July 2013:** Methodology Standards *recommended* for all projects (Cycles I-III)
  - Application Guidelines, Funding Announcements, Merit Reviewer Guidance
- **August 2013 Cycle :** Adherence *required* for all projects
  - Application Guidelines, Funding Announcements, Contract Language
- **December 2013:** Instituted process for pre/post-award adherence monitoring
- **April 2014:** Developed Pre-/Post-Award Adherence process for staff

Pre/Post Award Requirements

- **Pre-Award:** Adherence reviewed and required prior to contract activation
  - Checklist used by staff to track adherence
  - Research template modified to highlight standards through the application

- **Post-Award:** Adherence monitored through active portfolio management
  - Milestone schedule at six-month or year-one interim report and final report includes progress on methodologic adherence

Methodology Standards Checklist (excerpt)

Standard Category	Abbrev.	Standard	Monitor Adherence in Application?	Monitor Adherence During Study Implementation?	In Which Report Should Standard be Addressed?	Notes
Cross-Cutting Standards for PCOR						
Standards for Formulating Research Questions	RQ-1	Identify Gaps in Evidence	Yes			
	RQ-2	Develop a Formal Study Protocol	No (but plan to comply should have been provided in application)	Yes	Address in Milestones Interim Report	Could address the development of a protocol, but would not be complete at time of application.
	RQ-3	Identify Specific Populations and Health Decision(s) Affected by the Research	Yes			
	RQ-4	Identify and Assess Participant Subgroups	Yes			
	RQ-5	Select Appropriate Interventions and Comparators	Yes			

Research Strategy Template

A. Background

- *Describe the impact of the condition on the health of individuals and populations. (Criterion 1)*
- *Identify gaps in evidence. (RQ-1)*

B. Significance

- *Describe how the specific aims (see below) relate to the significance of the proposed research study.*
- *Describe the potential for the study to improve healthcare and outcomes. (Criterion 2)*
- *Describe the study's patient-centeredness. (Criterion 4)*

C. Study Design or Approach

- *Describe the research strategy or methodological approach.*
- *State the specific aims.*
- *Demonstrate the study's technical merit. (Criterion 3)*
    - *Within this section, describe adherence to methodology standards and:*
        1. *Describe the plan for developing a formal study protocol. (RQ-2)*
        2. *Describe how you will identify, select, recruit, and retain study participants representative of the spectrum of the population of interest and ensure that data are collected thoroughly and systematically from all study participants. (PC-2)*
        3. *Describe how you will or have selected appropriate interventions and comparators. (RQ-5)*
        4. *Describe the outcomes that people representing the population of interest notice and care about. (RQ-6)*
        5. *Describe your use of Patient-Reported Outcomes when patients or people at risk of a condition are the best source of information. (PC-3)*
        6. *Describe a priori specific plans for data analysis that correspond to major aims. (IR-3)*

Adherence to Methodology Standards

- August 2014 Cycle: all 53 projects (awarded in December 2013) were reviewed using this adherence review process
- All methodological issues requiring modification were shared with principal investigator, resolved, and added to milestone schedules

- Next Steps:
  - Staff developing a plan for reviewing projects funded in Cycles I-III
  - Training program being instituted

Methodology Standards Training

- Working with scientific expert on developing content and curriculum

- Schedule for Training Modules:
  - Patient/Stakeholder Reviewers (training: March 2014)
  - Staff (May 2014)
  - Technical Reviewers (July 2014)
  - Prospective applicants (September 2014)
  - Future in-person training conferences (planned)

Questions?

Award Selection Process

Bryan Luce, PhD, Chief Science Officer

PCORI Board of Governors Meeting

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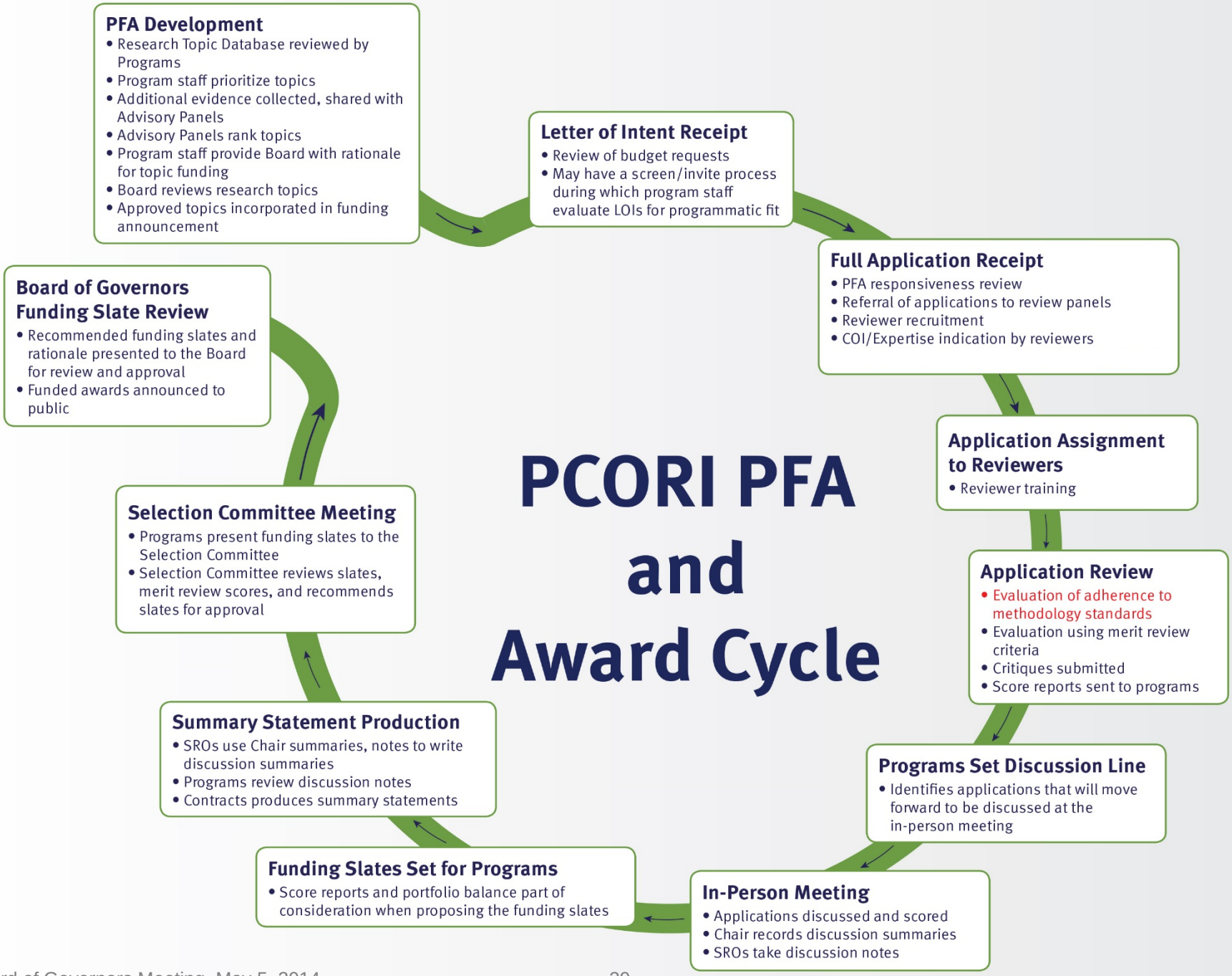
PCORI PFA and Award Cycle



Establishing Funding Slate

- Top scoring applications reviewed by Program Directors.
- Initial funding line set based on available program funding and application budgets
- Applications reviewed for possible budget adjustments
- Staff recommend slate based on merit scores and exception criteria
- Slate submitted to Selection Committee for review and approval
- Selection Committee brings slate to Board for final approval

Exceptions Criteria

- Fit with programmatic vision as outlined in each Program Strategic Framework
- Potential for synergy within the portfolio
- Avoiding duplication in project aims within the portfolio
- Possible adjustment to address between-panel scoring differences

Guidelines for Recommending Projects Using Other Considerations

- In addition to Merit Review Scores, projects are discussed based on exception criteria
- Selection Committee members will review abstracts and summary statements of all recommended projects based on considerations other than merit review scores alone and may request entire application
  - Selection Committee members include members of the Board and Methodology Committee

Note: Award selection process was reviewed by the Science Oversight Committee and all recommendations were incorporated

Questions?

Topic Selection Update

Bryan Luce, PhD, Chief Science Officer
PCORI Board of Governors Meeting
Alexandria, VA
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Brief Background and Status

- Board has indicated interest in reviewing the topic selection process and its role
- Science Oversight Committee (SOC): "engage a process improvement expert"
  - Completed in April
  - SOC has been briefed
  - Staff has vetted recommendations, revised processes
- Revised draft processes submitted to SOC
  - To be discussed at tomorrow's Committee meeting

Process Improvement Steps by Expert Consultant Group

- Reviewed all existing policies and procedures
- Interviewed Board members and Science staff
- Depicted detailed map of entire topic capture and prioritization process
- Special consideration of Board role in the process
- Recommended improvements

Eight Topic Capture and Research Prioritization Processes

1. Engaging stakeholders
2. Monitoring for new opportunities (i.e., gap analysis, discussion with other funders)
3. Developing individual Program strategic frameworks
4. Capturing topics and database management
5. Vetting and prioritization topics
6. Developing topic briefs/landscape reviews
7. Prioritizing topics by Program advisory panels
8. Refining research questions and developing funding announcements

Two Key Issues to Discuss with SOC

- Timing and nature of SOC/Board involvement
- Extent of information (e.g., topic brief, full landscape review, systematic evidence review) appropriate for SOC/Board review

Questions?

LUNCH

Join the conversation on Twitter via #PCORI

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Addressing Disparities Program Portfolio

Romana Hasnain-Wynia, PhD
PCORI Board of Governors Meeting
Alexandria, VA
May 2014

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Agenda

- **Addressing Disparities Program Background**
  - Program mission and goals
  - Program progress to date
- **Conceptual Framework and Driver Model**
  - Addressing Disparities program portfolio
  - Disparities projects across all PCORI programs
- **Next Steps**
- **Discussion**

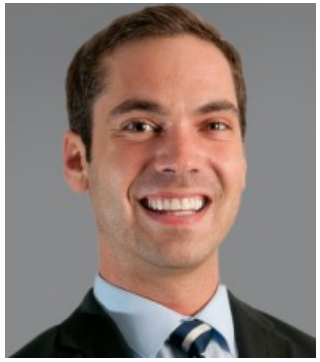
Addressing Disparities Program Staff

Romana Hasnain-Wynia, MS, PhD
Program Director

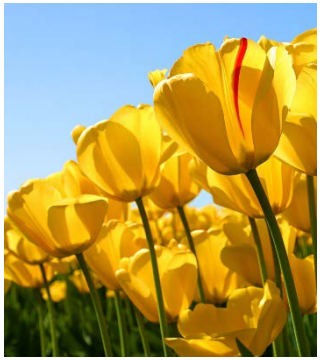
Cathy Gurgol, MS
Program Officer

Ayodola Anise, MHS
Program Officer

Katie Lewis, MPH
Program Associate



Mychal Weinert
Program Associate



Tomica Singleton
Senior Administrative Assistant

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PCORI Has a Broad and Complex Mandate

The purpose of the Institute is **to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions** by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed **through research and evidence synthesis** , …. **and the dissemination of research findings** with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services….."

-- from *Patient Protection and Affordable Care Act*

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Mandate includes a focus on Health Disparities

IDENTIFYING RESEARCH PRIORITIES.

The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care…

-- from *Patient Protection and Affordable Care Act*

Addressing Disparities Mission Statement

PCORI's
Vision, Mission, Strategic Plan

Program's Mission Statement

To **reduce disparities** in healthcare outcomes and **advance equity** in health and healthcare

Program's Guiding Principle

To support comparative effectiveness research that will identify best options for **eliminating disparities**

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Addressing Disparities: Program Goals

Identify Research Questions	• **Identify** high-priority **research questions** relevant to reducing and eliminating disparities in healthcare outcomes
Fund Research	• **Fund** comparative effectiveness **research** with the highest potential to reduce and eliminate healthcare disparities
Disseminate Promising/Best Practices	• **Disseminate** and facilitate the adoption of **promising/best practices** to reduce and eliminate healthcare disparities

Progress toward Goal (2012-2015)

Broad PFAs *4 cycles*	• **31** comparative effectiveness research projects totaling **$52.8M**
Targeted PFAs *1 cycle*	• Treatment Options for Uncontrolled Asthma: **8** comparative effectiveness research projects totaling **$23.2M**
Pipeline for Targeted PFAs	• Obesity treatment options in primary care, awards in August 2014 (Will fund up to **2** awards totaling **$20 M**) • Pragmatic clinical trials, awards in January 2015 • In Development Stage (Hypertension, Perinatal, Lower Limb Amputations)

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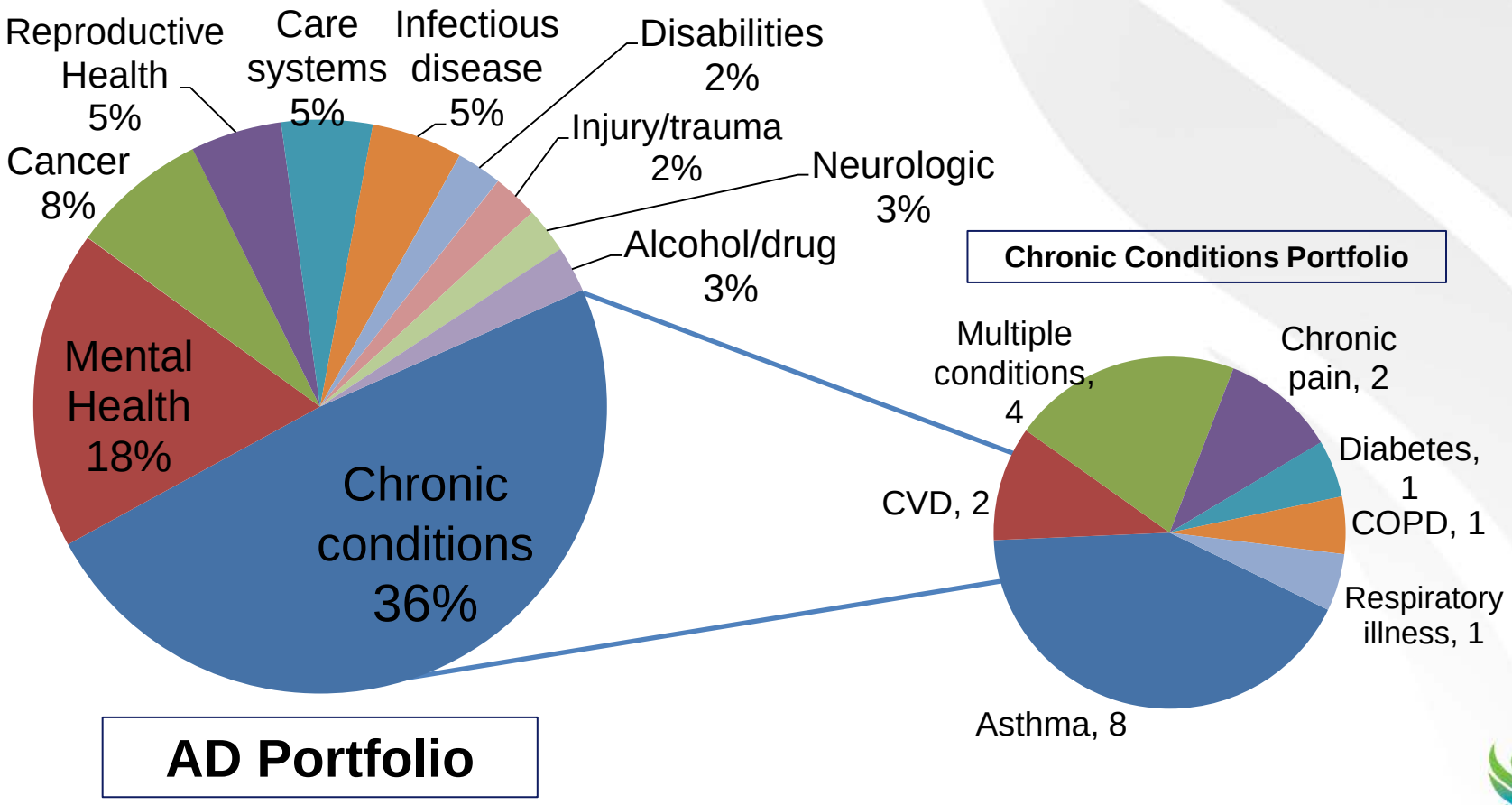
Addressing Disparities Comparative Effectiveness Research Portfolio Snapshot

Research Areas



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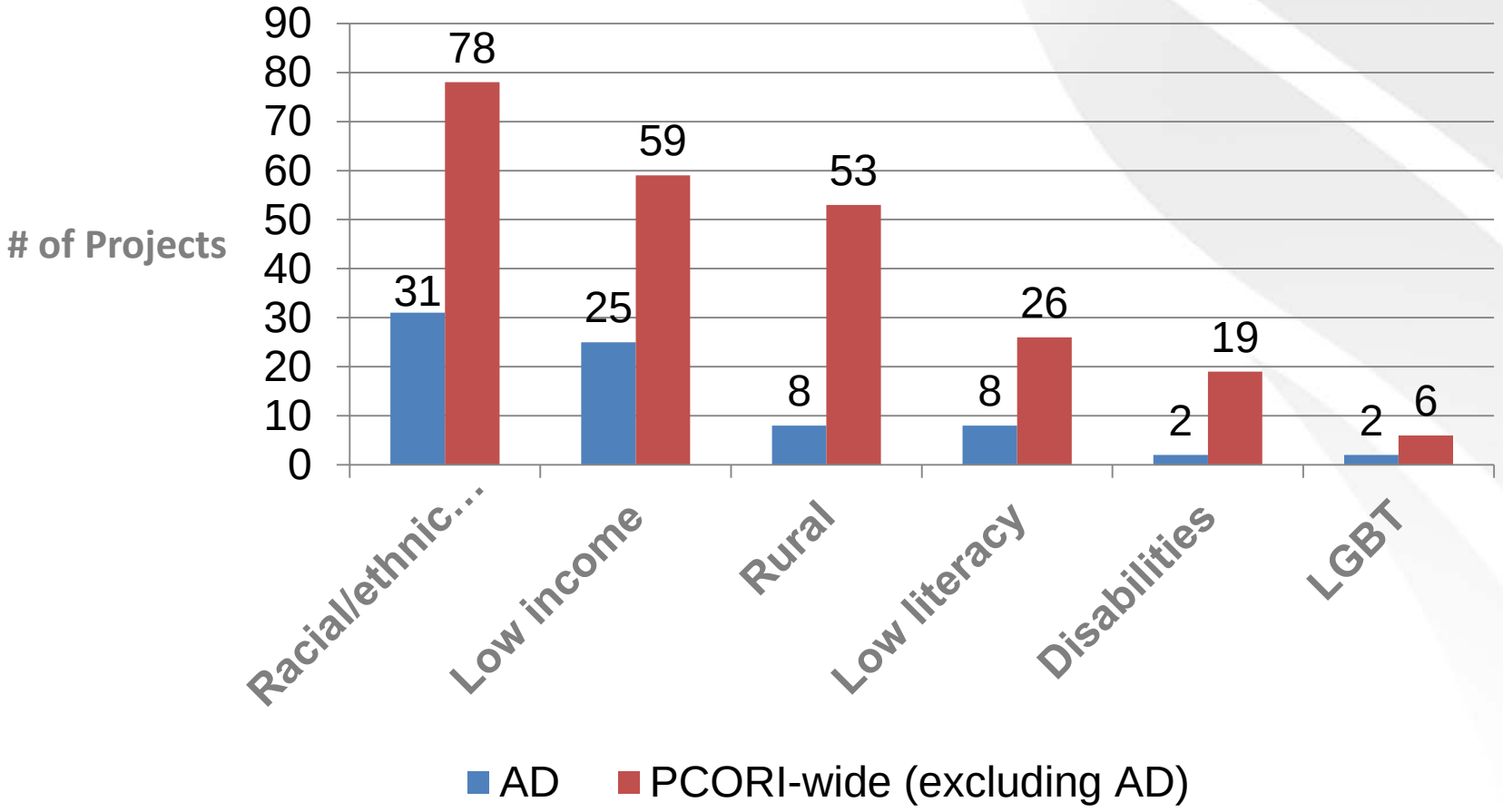
Addressing Disparities Comparative Effectiveness Research Portfolio Snapshot

Disparities Population (not mutually exclusive)



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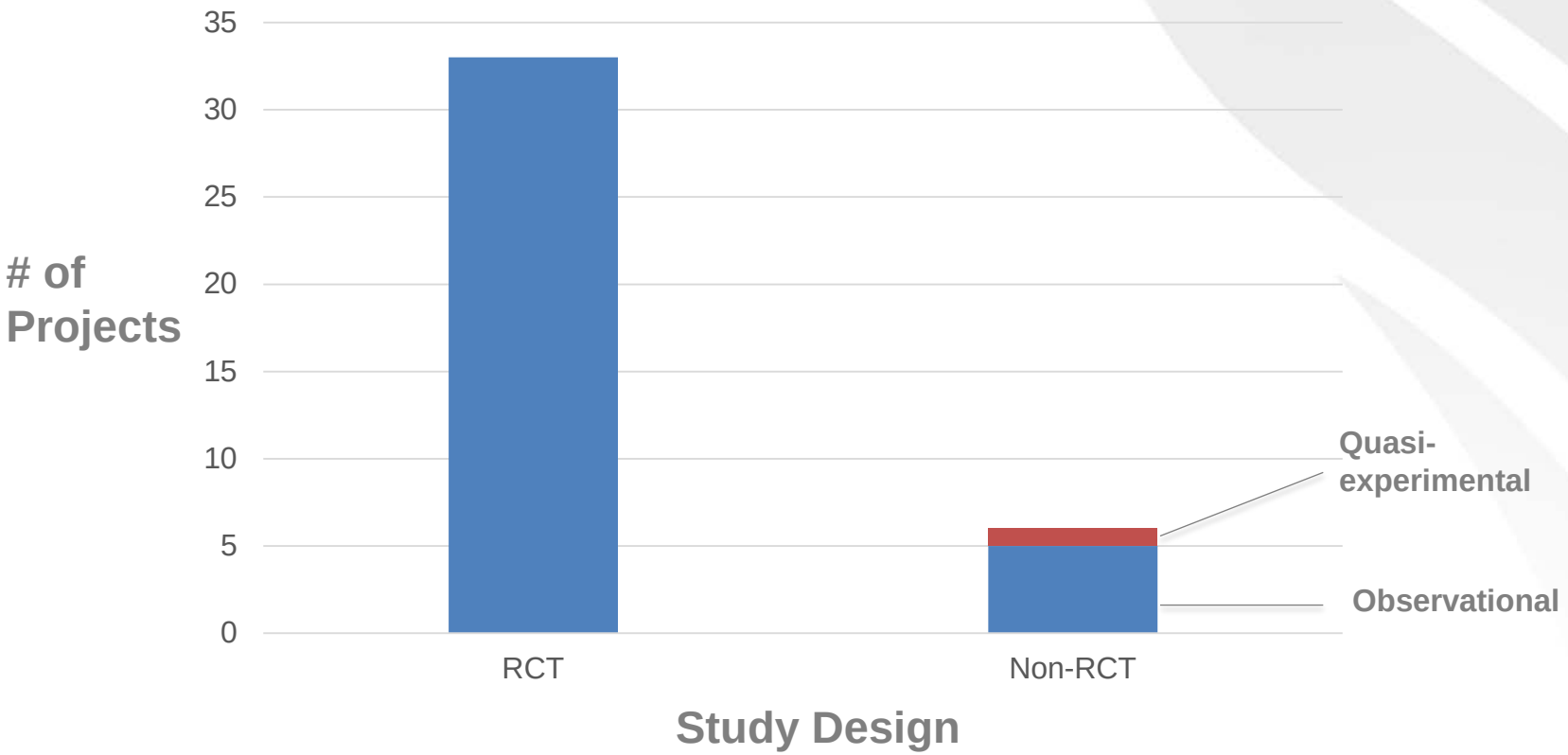
Addressing Disparities Comparative Effectiveness Research Portfolio Snapshot

Research Methods: Study Design



Long-Term Outcomes of Community Engagement to Address Depression Outcomes Disparities

Engagement

- Community agencies collaborate to tailor depression toolkits to the needs and strengths of community

Potential Impact

- Could change practice by providing information about how depressed patients prioritize outcomes and make decisions, and could affect practice by showing how clinicians respond to patients' preferences

Methods

- Mixed methods approach and a randomized controlled trial

Looks at long-term patient outcomes of community engagement intervention vs. a technical assistance model, identifies patient preferences and priorities for outcomes, and assesses community capacity to respond to these priorities.

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

Addressing Disparities Research Project, awarded December 2012

Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors

Engagement

- Patient focus groups will inform intervention design, and community members will recruit participants and educate patients

Potential Impact

- Could change practice by providing needed patient-centered cardiovascular disease (CVD) risk reduction to a major at-risk population living in an environment where CVD risk reduction is difficult

Methods

- Randomized controlled trial

Compares two approaches to reducing cardiovascular Disease risks among at-risk adults in Appalachian Kentucky. Study will look at referral to primary care physician) vs. HeartHealth, a patient-centered, self-care intervention.

Debra Kay Moser, DNSc, RN,
University of Kentucky
Lexington, KY

Addressing Disparities Research Project, awarded December 2012

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Rural Options at Discharge Model of Active Planning

Engagement

- Patient and provider surveys, interviews, and forums will inform design, evaluation, and dissemination of discharge tool, and Innovation Design Team, composed of all stakeholder groups, will guide study

Potential Impact

- Could change practice by reducing re-hospitalization by as much as 30%, and improving patient recovery and return to active life

Methods

- Quasi-experimental mixed methods

Designs rural options for a discharge model that improves patient outcomes and reduces disparities for rural patients. Rural Options at Discharge Model of Active Planning (ROADMAP) will be tested against the current standard discharge methods.

Tom Seekins, PhD,
University of Montana
Missoula, MT

Addressing Disparities Research Project, awarded May 2013

Mrs. A and Mr. B (People with Disabilities, Primary Care Provider Quality, and Disparities)

Engagement

- Patient participation informs the design and specific aims of the study, and qualitative data collection from families and clinicians examines access to care from additional perspectives

Potential Impact

- Could change practice by providing information to patients with disabilities on how they can best access care and stay healthier

Methods

- Secondary data analysis complemented by mixed methods

Investigates why it is more difficult for people with disabilities to get care, with the main goal of developing the Patient-Inspired Surveillance Tool to provide guidance on addressing disparities in care.

Margaret Stineman, MD,
University of Pennsylvania
Philadelphia, PA

Addressing Disparities Research Project, awarded May 2013

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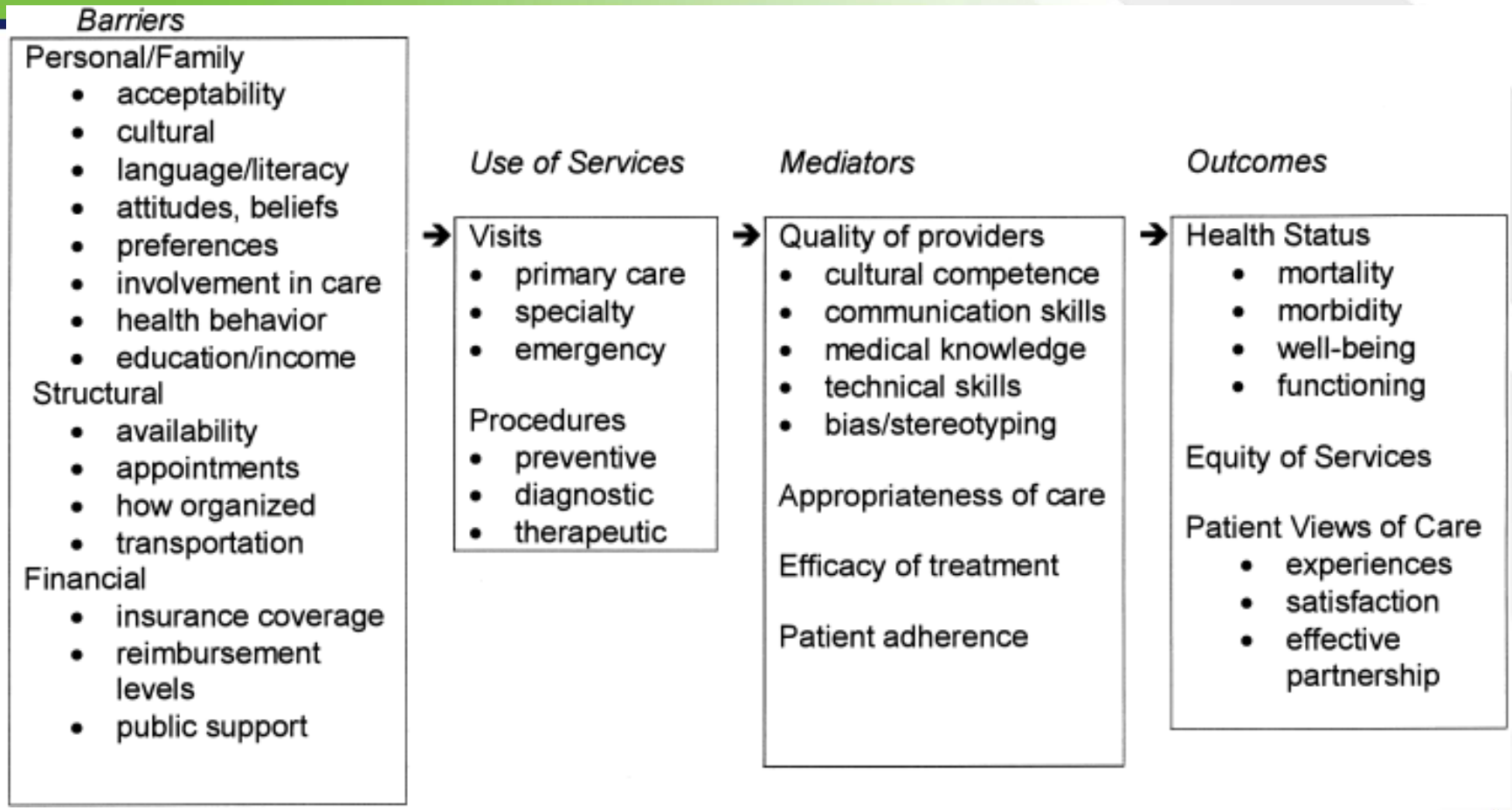
Conceptual Framework and Driver Model

Conceptual Framework: Designing and Evaluating Interventions to Eliminate Disparities in Health Care



Cooper, et al. Journal of General Internal Medicine
Volume 17, Issue 6, pages 477-486, 24 JUL 2002 DOI: 10.1046/j.1525-1497.2002.10633.x
http://onlinelibrary.wiley.com/doi/10.1046/j.1525-1497.2002.10633.x/full#f1

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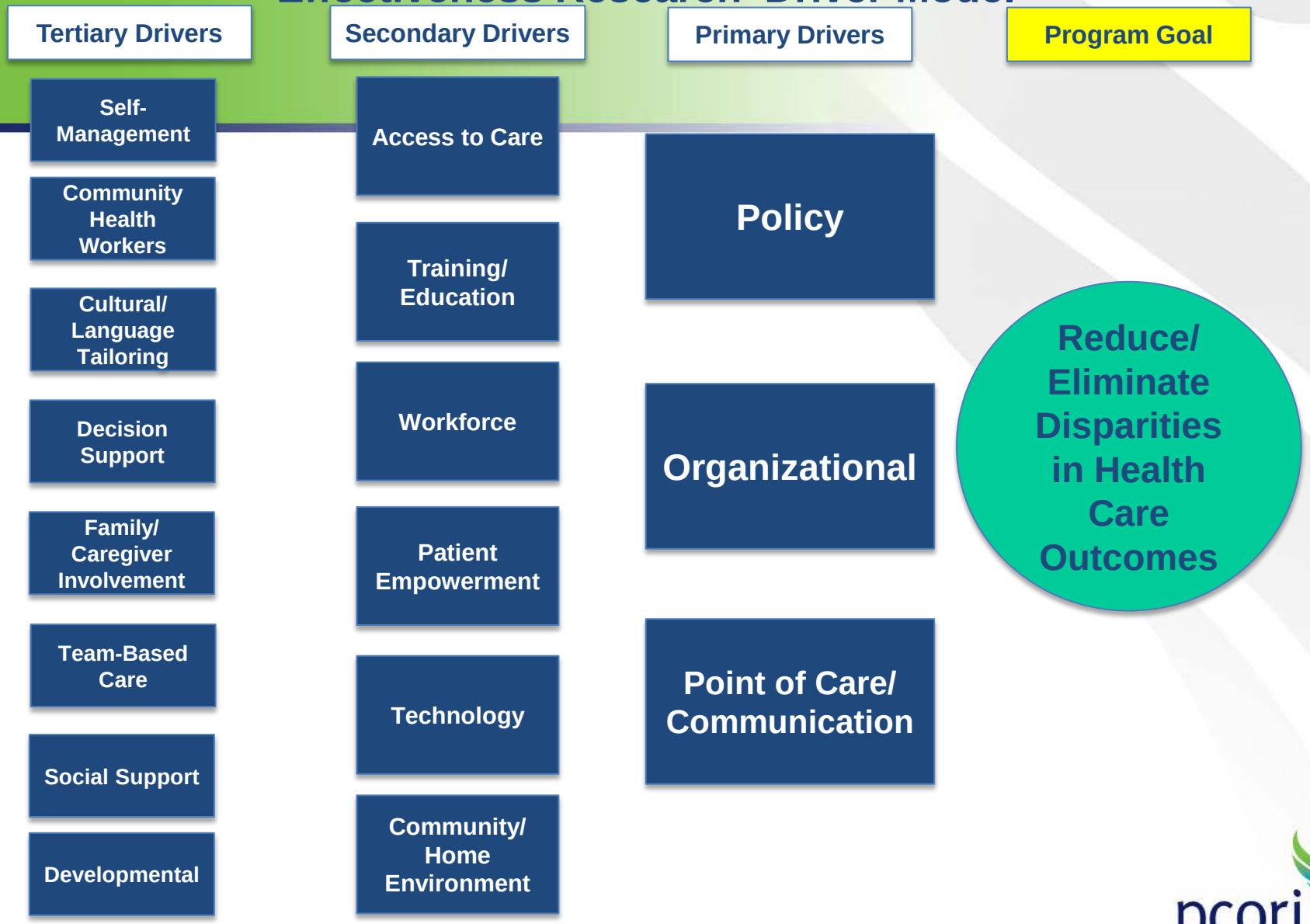
Addressing Disparities Program: Comparative Effectiveness Research Driver Model



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Addressing Disparities Driver Model

- The model is an *evolving* tool used to
  - Evaluate where we are
  - Identify where we need to go

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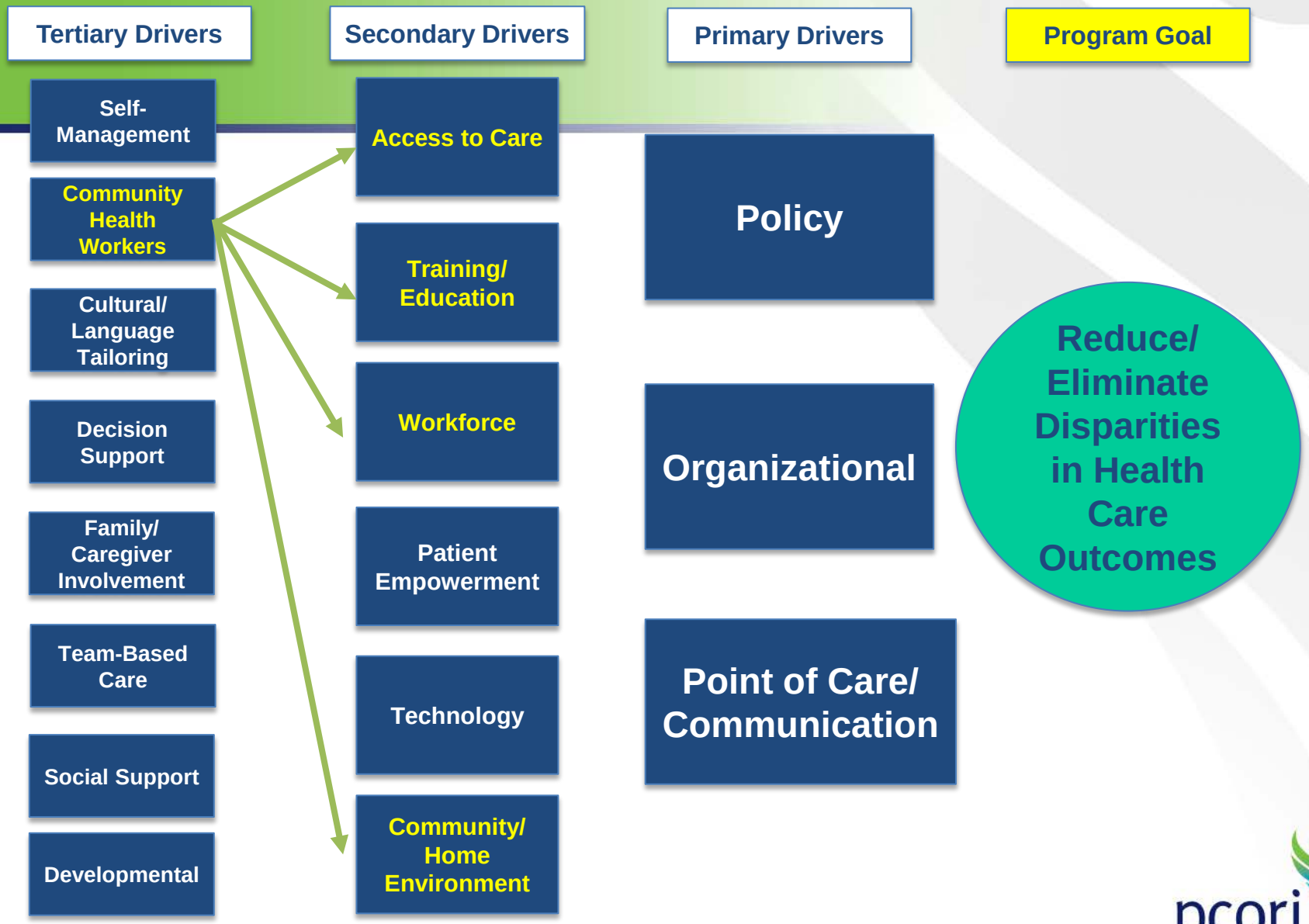
Targeted Funding Announcement: Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

- 8 Awards, $24 million
- Projects
  - Compare interventions to improve clinician and patient adherence to NHBLI guidelines by
    - Enhancing provider and patient communication (e.g., use of mobile technology)
    - Improving systems of care (e.g., evaluate models that look at data integration) and/or
    - Improving integration of care (e.g., team-based care)
  - Include patient-centered outcomes
  - Have strong stakeholder engagement

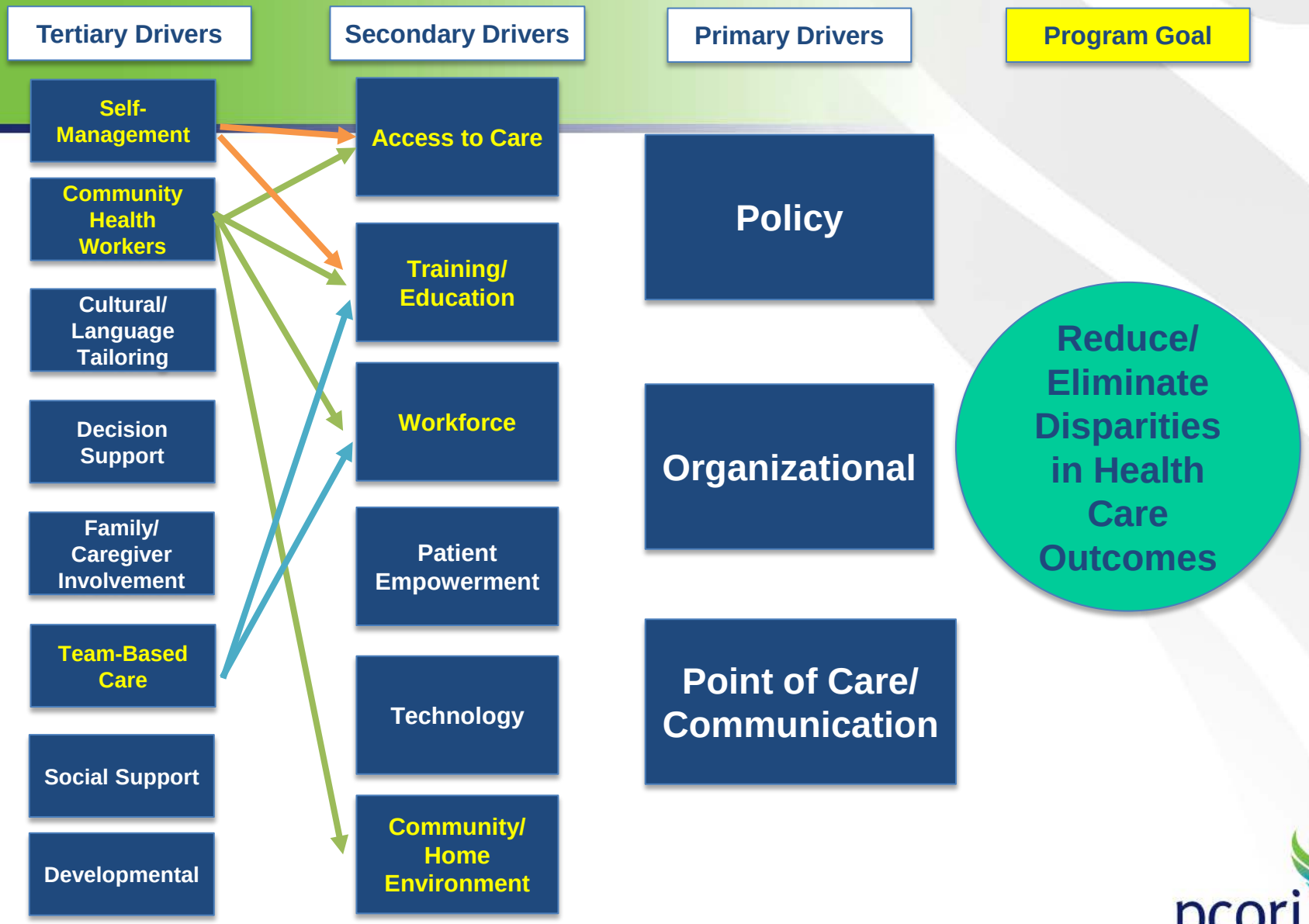
Addressing Disparities Project:
Mapping Example 1

Project Title	Guidelines to Practice: Reducing Asthma Health Disparities through Guideline Implementation
PI	James W. Krieger
Organization	Seattle-King County Public Health
State	Washington
Project Description	Compares the relative impact of multi-component, multi-systems interventions that aim to improve asthma outcomes among patients at community health centers in Seattle. Three-arm study includes: 1) health plan intervention plus provider education, 2) CHW home visits + self-management support, and 3) enhanced clinic care with decision support.

Addressing Disparities Driver Model: Mapping Example



Addressing Disparities Driver Model: Mapping Example



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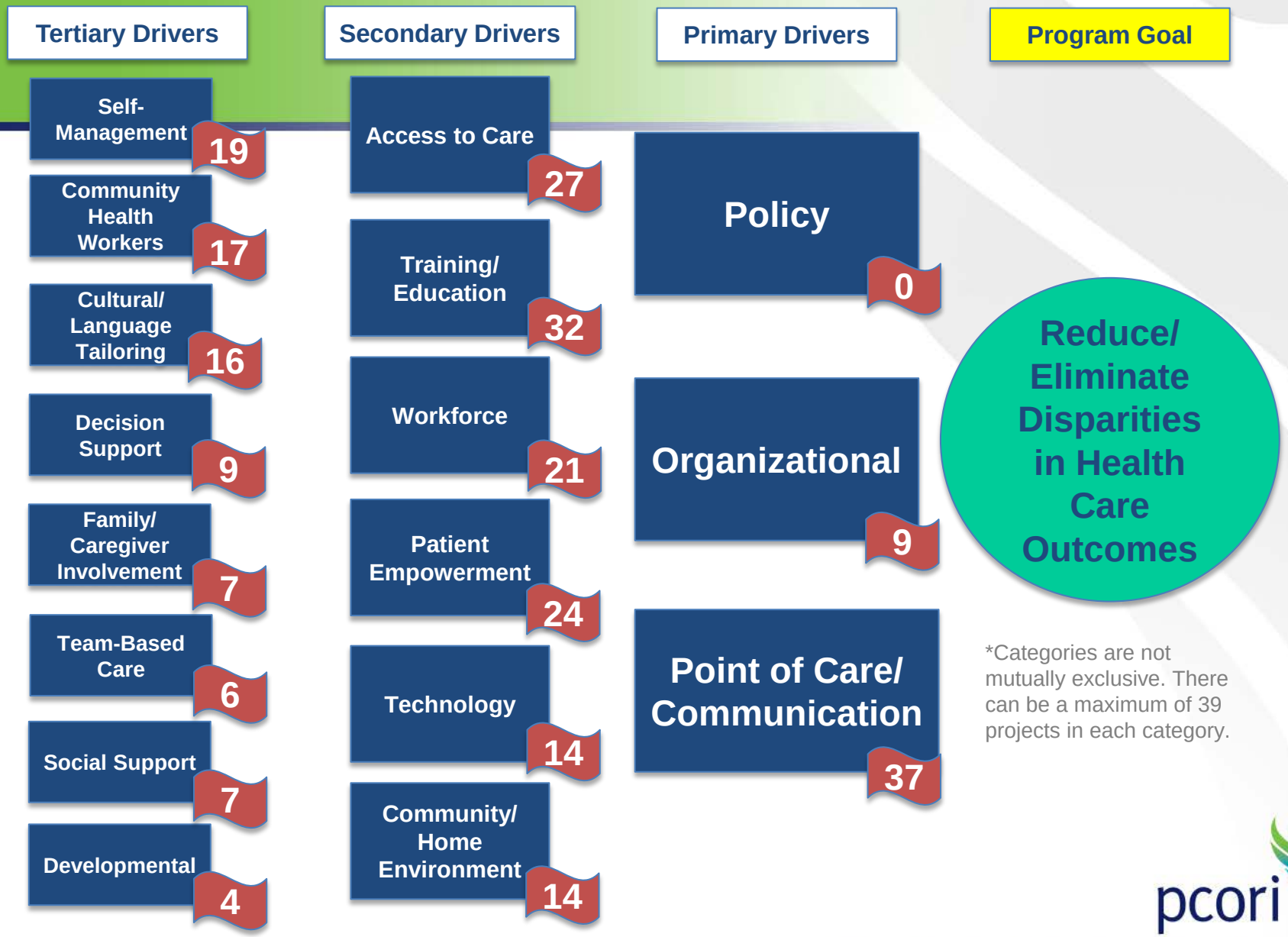
All Addressing Disparities Projects Mapped to Driver Model

Addressing Disparities Program: Comparative Effectiveness Research Driver Model (n=39*)



*Categories are not mutually exclusive. There can be a maximum of 39 projects in each category.

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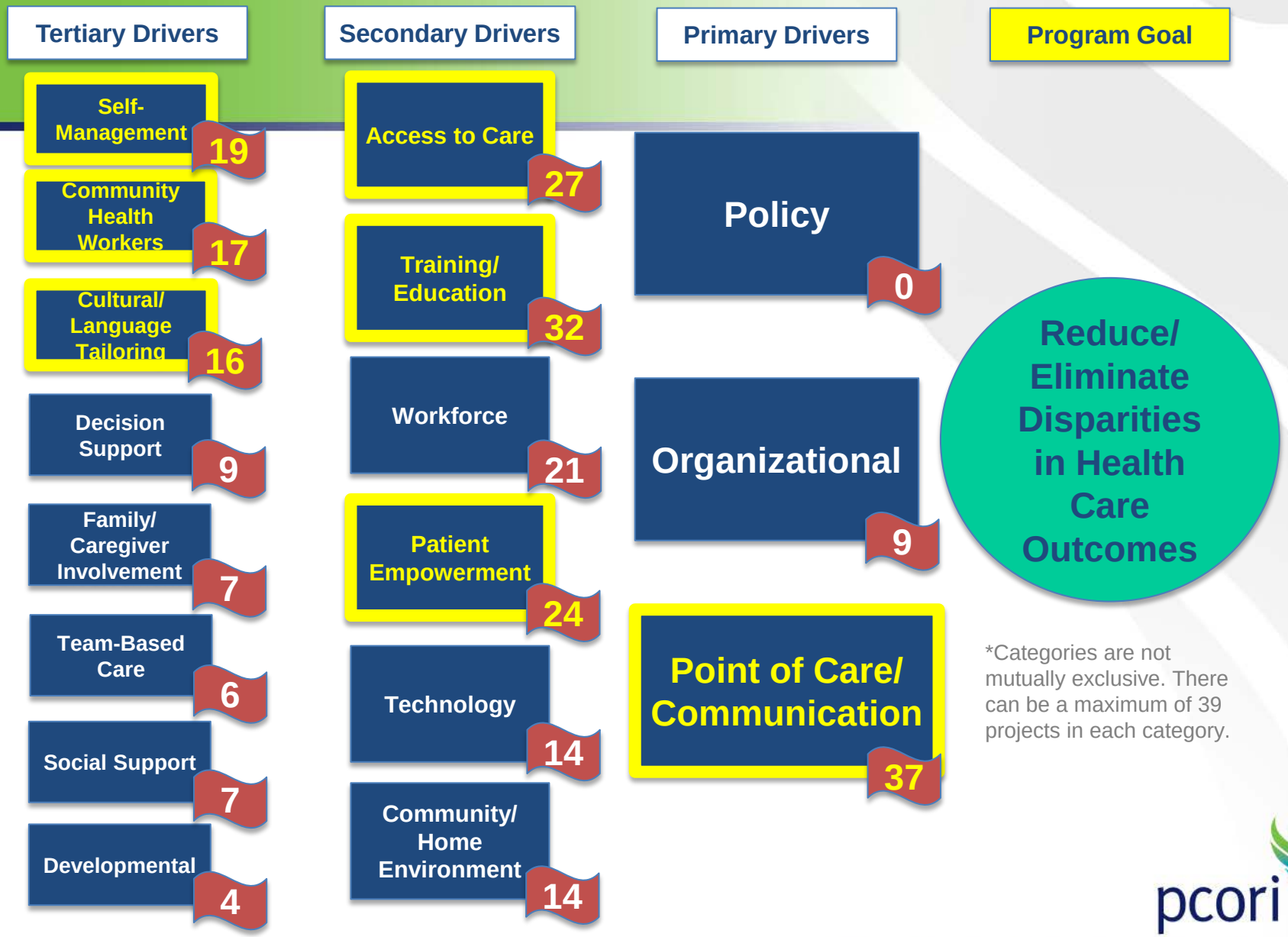
Addressing Disparities Program: Comparative Effectiveness Research Driver Model (n=39*)



*Categories are not mutually exclusive. There can be a maximum of 39 projects in each category.

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Number of Projects that Include Underserved Populations across PCORI Portfolio

Program	# of Disparities Projects	Total # of Projects in Program	% of Portfolio Looking at Disparities
Addressing Disparities	39	39	100%
Improving Healthcare Systems	31	41	76%
Assessment of Prevention, Diagnosis and Treatment Options	31	65	48%
Communication and Dissemination Research	12	25	48%
TOTAL	**113**	**170**	**66%**

Where Do We Go From Here?
Learning, Disseminating, and Implementing

- Engage patients and other end-users from start to finish (i.e., research topic generation → dissemination)

- Establish *learning communities* among PCORI-funded projects

  - Mechanism to foster cross-learning among project teams
  - Bring together the research community and end-users including patients, payers (e.g., AHIP), employers and purchasers (e.g., National Business Group on Health), clinicians, professional societies, policy makers, and training institutions

Where Do We Go From Here?
Learning, Disseminating, and Implementing

- Continue to develop a more sophisticated understanding of the practices that are effective in reducing/eliminating disparities in care

- Produce a strong evidence base of promising/best practices for disparities reduction strategies

- Disseminate promising/best practices in partnership with key stakeholders

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Addressing Disparities Program

Questions and Discussion

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Methodology Committee Update

Robin Newhouse, PhD, RN, NEA-BC, FAAN, Chair of the Methodology Committee
David Hickam, MD, MPH, Director of Clinical Effectiveness Research

PCORI Board of Governors Meeting
Alexandria, VA
May 2014

Patient-Centered Outcomes Research Institute

Session Topics and Objectives

What are we going to cover today?

Methodology Standards	• Update on new standards development • Public input process for new standards
PCORnet Methods Task Force	• New task force to consider methods questions for PCORnet
Open Science Work Group	• Update on development of an open science framework
Decision Sciences Initiative	• Update on planning for a workshop to discuss research opportunities in the field
Member Updates	• Update on GAO Solicitation for new members • Recognition of Al Berg and John Ioannidis

Methodology Standards

- The Methodology Committee is developing two sets of new standards in the areas of Research Designs Using Clusters and Complex Interventions
  - Draft standards will be made available for public comment for a period of 45-60 days, per the requirements of the legislation
- The Committee has also added a public solicitation feature to the website for recommendations for new standards
  - http://www.pcori.org/research-we-support/methodology/suggest-a-topic-area-for-new-methodology-standards/

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PCORnet Methods Task Force

- A task group has formed to address methods issues and gaps for PCORnet
- Membership includes Methodology Committee members, members of the PCORnet Coordinating Center, and PCORI staff
  - Methodology Committee member Sebastian Schneeweiss is the liaison

Open Science Work Group

- A work group, composed of Board and Methodology Committee members, has formed to develop a PCORI policy for open science and reproducible research
- The group will work under the oversight of the Research Transformation Committee and in collaboration with the Methodology Committee
- Steve Goodman, Methodology Committee vice-chair, and Harlan Krumholz are the leaders of the group

Decision Sciences Initiative

- Methodology Committee members and PCORI staff are working on several activities to explore research opportunities in the field of decision sciences
- The group has developed a framework that encompasses the domains to be considered
- Currently, the group is in the planning stages for a convening of experts to gather information

Member Updates

- The GAO opened a request for nominations to fill four seats on the Methodology Committee
  - The Methodology Committee submitted a formal response and recommendation for new members to the GAO
  - The request was live from March 14th – April 11th, 2014

- On behalf of the Methodology Committee, the Board, and PCORI staff, we recognize the work and contributions of Committee members
  - Al Berg
  - John Ioannidis

Update on Engagement

Jean Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer
PCORI Board of Governors Meeting
Alexandria, VA
May 2014

Patient-Centered Outcomes Research Institute

Quick Update on Engagement

- Jean named Chief Engagement and Dissemination Officer March 17, 2014
- Working in collaboration with PCORI's Chief Science Officer, planning and activities have started to integrate Science, Engagement, Communications, and Dissemination more closely
- The first Engagement Officer has been hired
- Offer made for the Director of the Eugene Washington PCORI Engagement Awards Program
- Initiated development of instructions for small to large conference award applications under the Engagement Awards Program
- Patient and Family Engagement Rubric has been completed and plans are underway to incorporate it into future funding announcements and provide training for Merit Reviewers and potential PCORI applicants

Evaluation at PCORI

Michele Orza, ScD, Senior Advisor to the Executive Director
PCORI Board of Governors Meeting
Alexandria, VA
May 2014

Patient-Centered Outcomes Research Institute

Objectives

The objectives of this presentation are to provide:

- An introduction to Evaluation at PCORI
- A progress report on some core activities
- A guide to where to find further information and opportunities to provide input

Our Current Tasks

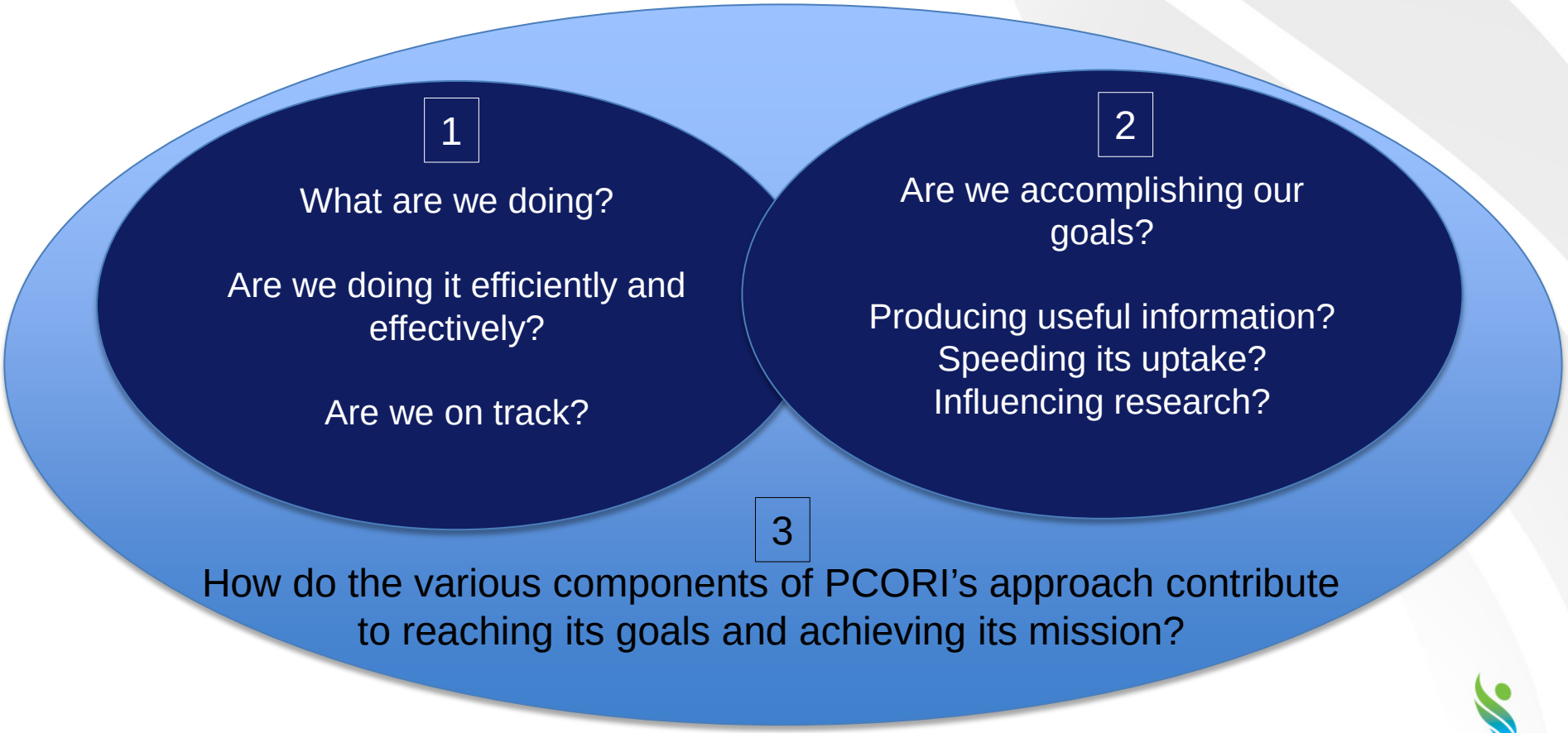
- Building our ***Evaluation Framework***, that is, delineating, organizing, and prioritizing the questions that staff and stakeholders have about PCORI's work and about PCOR in general
- Determining how we can measure some of the elements that we know already will be central to answering many of the questions, especially ***our three goals and Engagement in Research***
- Undertaking many evaluation activities that have clearly emerged as high priorities, such as surveys and ***assessing the impact of Engagement on the early phases of research***

What Is Our Evaluation Framework?

Our framework organizes our evaluation questions and describes how we will answer them

Evaluation Questions	Metrics/ Indicators	Methods	Sources
What do PCORI staff and stakeholders want/need to know about PCOR and PCORI?	For each evaluation question, what are we measuring and how will we measure it?	What approach will we take to answering each evaluation question?	From where will we get the data to answer each evaluation question?

Our Evaluation Framework Includes Three Kinds of Questions



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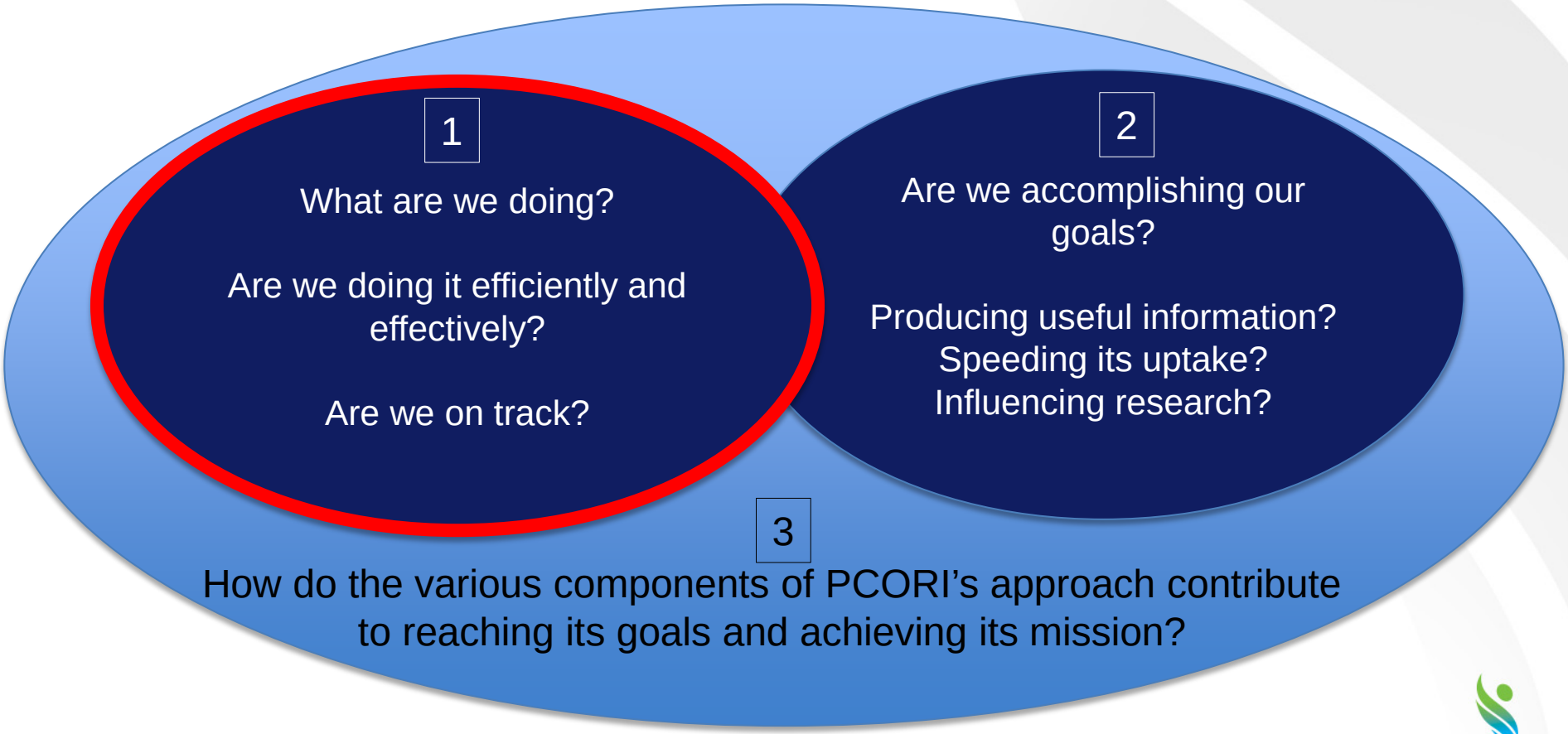
1: Questions about Our Day-to-Day Work



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Board of Governors FY2014 Dashboard (As of 3/31/2014)

Our Vision: ***Patients and the public have information they can use to make decisions that reflect their desired health outcomes.***

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

Legend

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- Off Track
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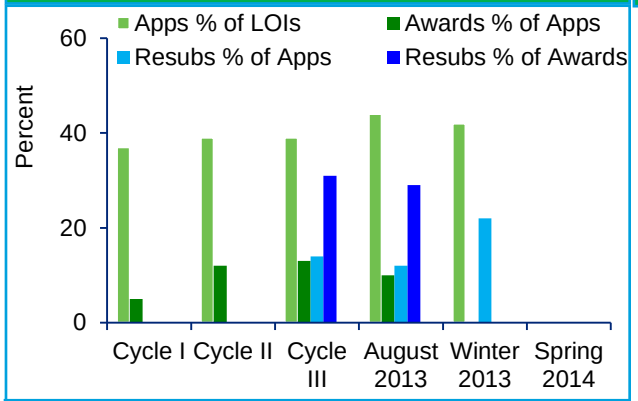
Broad Awards Summary



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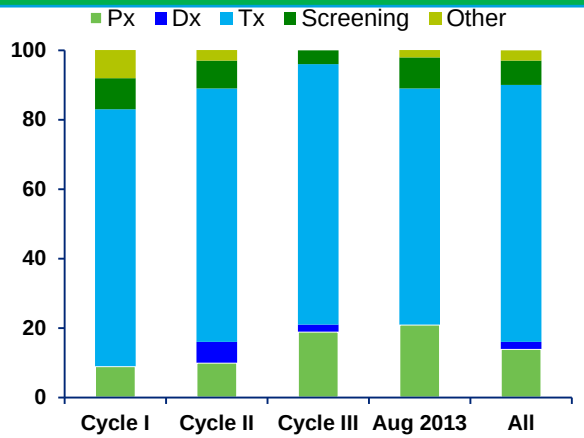

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Coming Q3

Priority Topics Pipeline – Funded by Q4 2014

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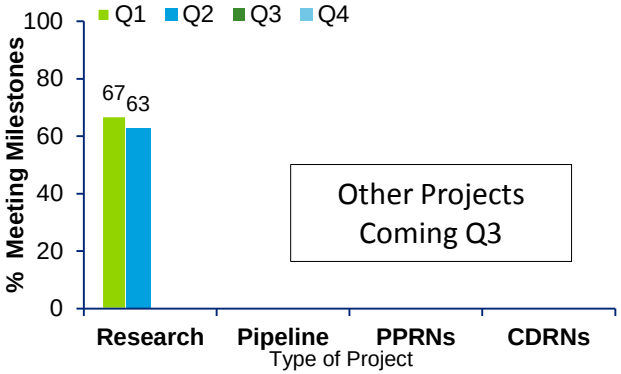
Usefulness: Coming by Q4

Engagement Impact: Coming by Q4

Progress of Projects



Pipeline to Proposal Awards

Engagement Event Survey Results

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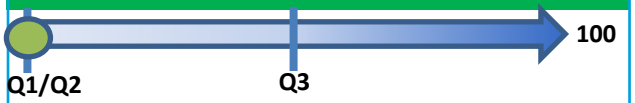
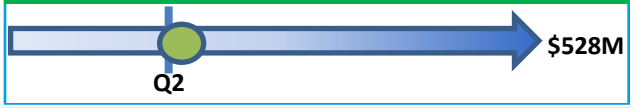


2014 Research Funding Commitment



Completion of Phase I of PCORnet

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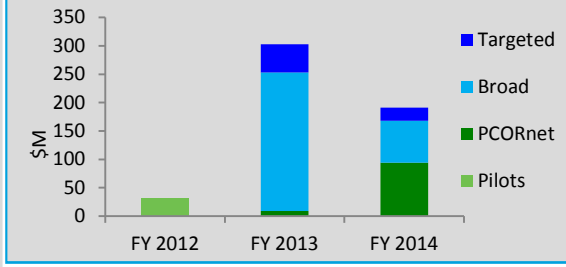

2014 Staffing Plan – Number of People

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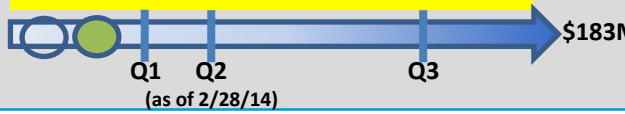
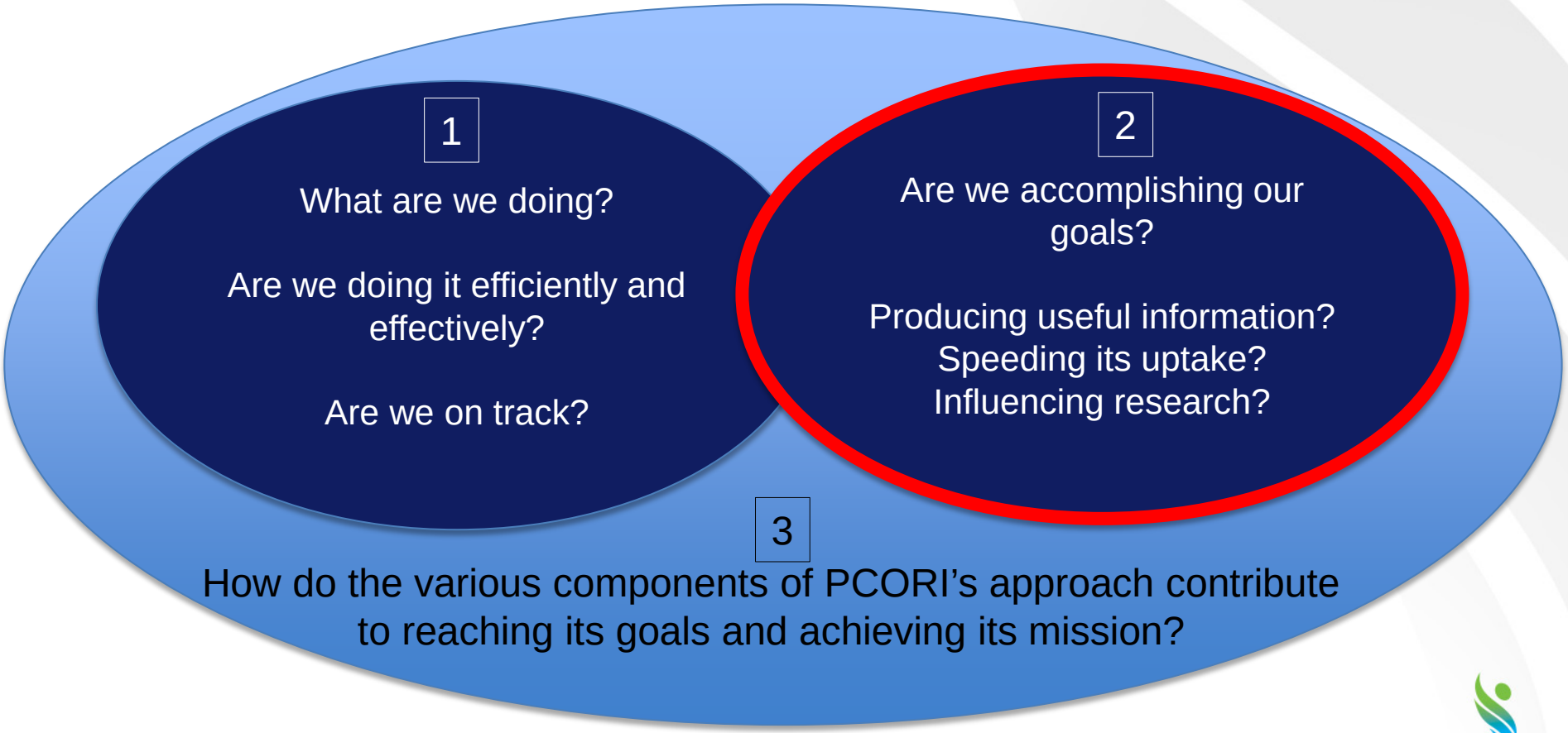


2: Questions about Our Goals



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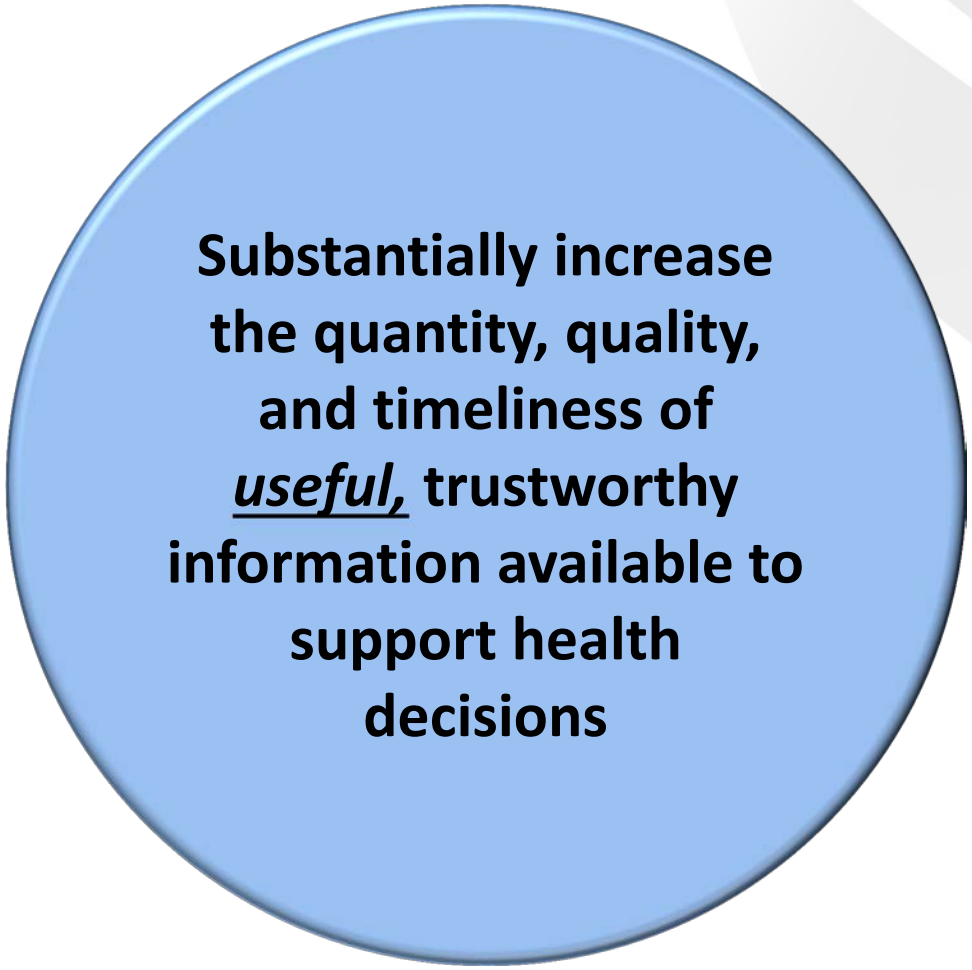
First Goal: Useful Information



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Draft Usefulness Criteria

We are developing criteria to assess the potential usefulness of the information we produce:

- Rationale/User-Driven
  - People who would use the information have been identified
  - Specific uses for the information have been identified
  - People who would use the information are asking the question
- Research Question/User-Focused
  - Study compares options that are relevant for the people who would use the information
  - Study assesses the outcome(s) that matter for the people who would use the information
- Real-world Use
  - Results could provide a clear answer to the question
  - Results could be tailored to individuals or subgroups
  - Results could be scaled/spread beyond the study setting

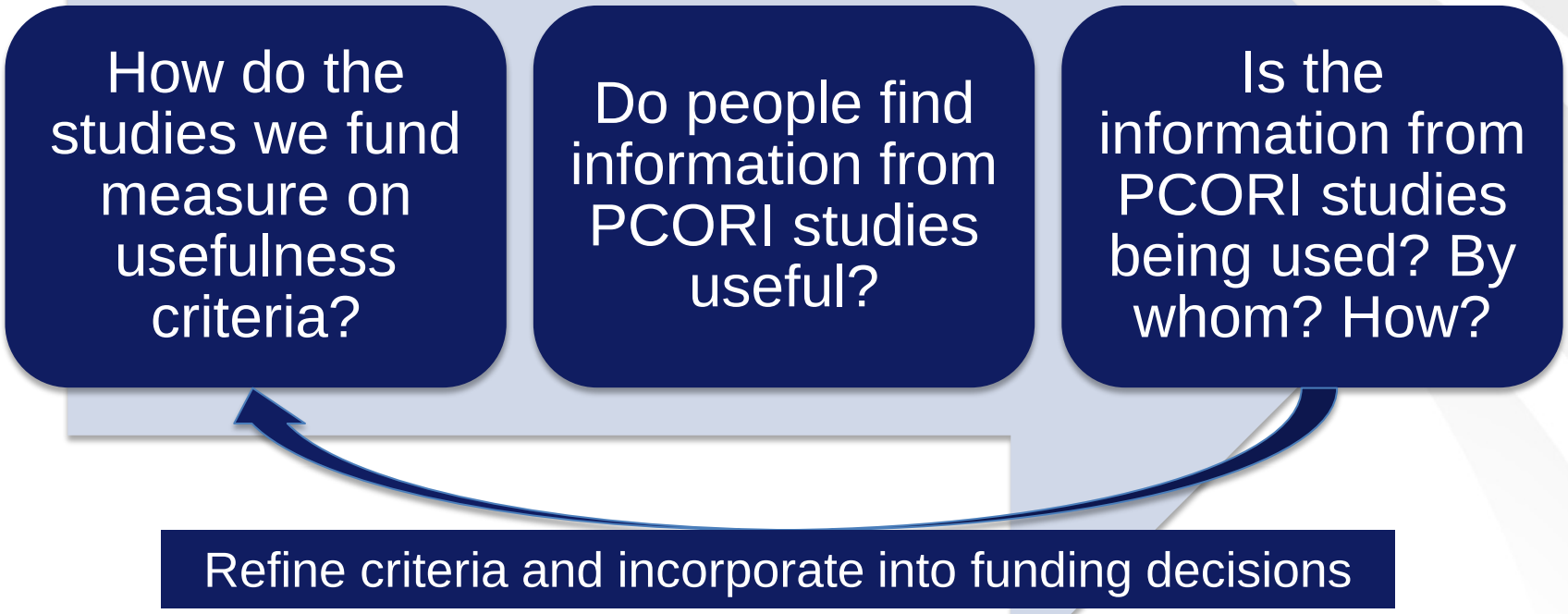
We are refining these criteria, cross-walking them with our other criteria (such as for Merit Review), and pilot testing them, and will soon apply them to our portfolio of funded studies.

Usefulness: What could we say about it in 2014?

- How our portfolio stacks up against our criteria for potential usefulness and
  - How applications we funded compare to those we didn't
  - How studies funded in earlier cycles compare to later ones
  - How studies funded under Broad PFAs compare to Targeted
  - How our portfolio compares to others on these criteria

- What patients and stakeholders think about the potential usefulness of our portfolio
  - For example, what concerned patients and relevant stakeholders think about the cluster of asthma, pediatric, or mental health studies we are funding

Assessing Potential and Actual Usefulness



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Second Goal: Use of PCORI Information

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Draft Measures of Use

Dissemination

(Measure for all PCORI funded studies)

- Results reported back to study participants
- Access to PCORI study report
- Presentations:
  - Scientific/professional audiences
  - Lay audiences
- Bibliometrics:
  - # of Publications
  - Time to publication
  - Impact factor
  - Citations
- Alternative metrics for key groups (patients, clinicians, payers, etc.):
  - # manuscript downloads
  - # manuscript bookmarks
  - Media coverage
  - Social media coverage

Uptake and Use

(Measure for a subset of PCORI funded studies)

- Adoption of study findings in the study setting
- Incorporation into:
  - Systematic reviews
  - Patient and consumer education materials
  - Graduate Medical Education (GME) or Continuing Medical Education (CME)
  - Practice guidelines
  - Decision making infrastructure (e.g. electronic decision aids, clinical reference tools)
  - Payer policies
  - Institutional, local, state, and national policy

Impact: Changes in Health Decisions or Care

(Measure for small set of exemplar studies)

- Change in health decisions or health care among key groups (patients, clinicians, payers, etc.)

Note: Most of these metrics are typically not measurable until after study completion, and in many cases, are typically not measureable until several years after study completion.

Third Goal: Influence Research

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Draft Measures of Influence

We are now or soon will be measuring:

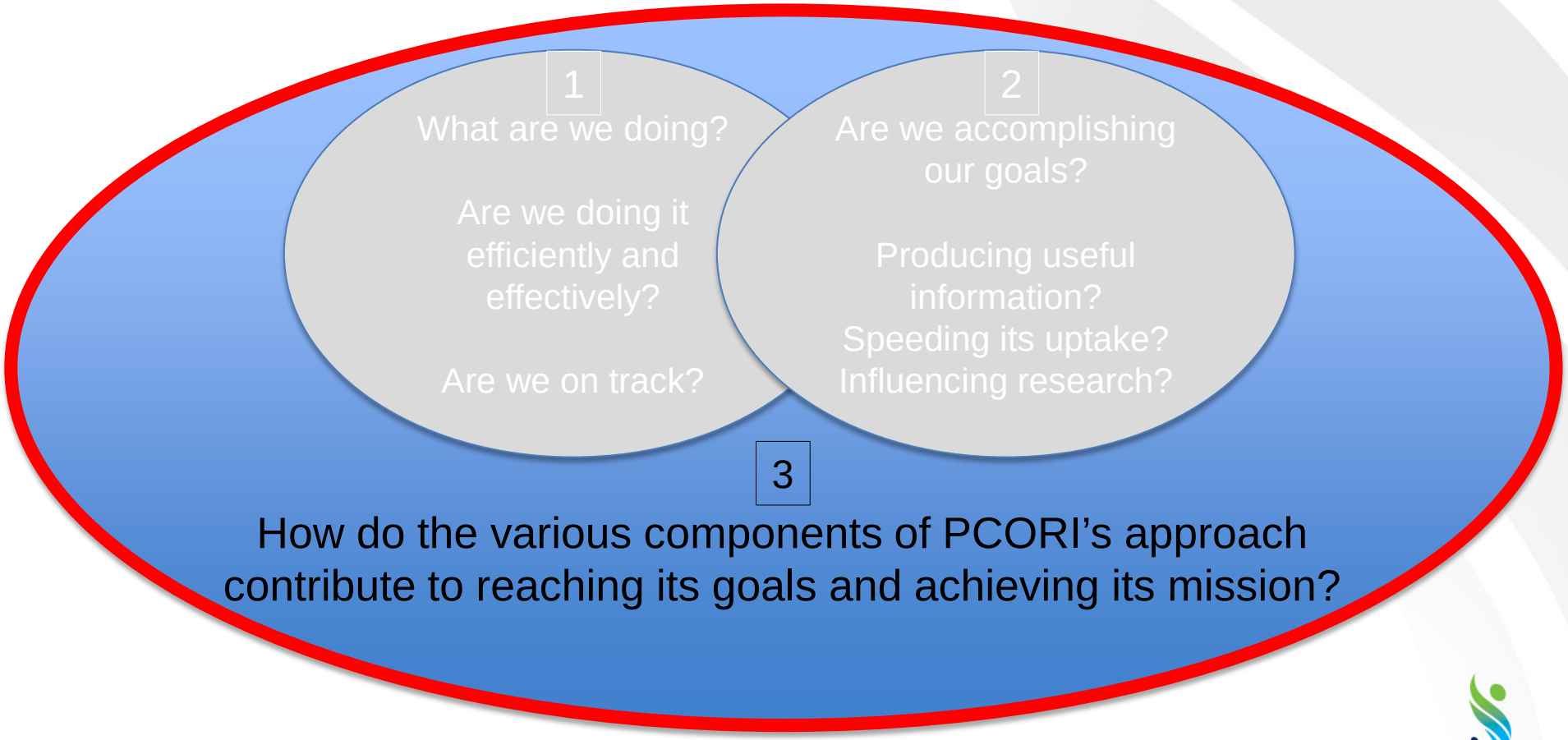
- Endorsement, Promotion, and Dissemination of PCORI work
- Use of PCORI Methodology Standards for Patient-Centeredness
- Use of PCORI approaches:
  - Topic Generation and Research Prioritization
  - Merit Review
  - Engagement
  - Communication and Dissemination
- Use of PCORI guidance re: Patient-Centered CER
- Use of PCORI-supported curricula or training
- Collaborations/Co-funding with other funders

We will have to wait a few more years to measure:

- Use of PCOR Methods evidence
- Use and support of PCORnet

3: Questions about Our Approach

What Difference Does "Research Done Differently" Make?



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Draft Evaluation Framework Document

Engagement in Research is the focus of an entire section, and every section also has questions about ***Engagement***, the main difference in PCORI's approach

Table of Contents

What Difference Does Engagement Make?

What are we looking at now? Some examples:

- Merit Review
  - What is the effect of the following on our portfolio of funded studies?
    - Stakeholder ***engagement*** in review
    - Our Merit review ***criteria***
    - Our review ***processes***
  - What is the ***experience of patients and stakeholders*** who participate?
- Engagement in Research
  - What is the effect of patient and stakeholder engagement:
    - On the functioning of the ***study team***?
    - On study ***design***?
    - On ***recruitment and retention***?

Impact of Engagement
ENgagement ACTivity Inventory (ENACT)

- We have developed a self report tool to measure and describe ***Engagement*** in our funded research studies

- We have developed versions for:
  - PCORI Pilot Projects
  - CER studies
  - PCORnet projects (to describe engagement of patients and other stakeholders in network development)

Impact of Engagement: Development of the ENgagement ACTivity (ENACT) Inventory

Spring 2013

- Initial engagement measurement tool developed by PCORI & Academy Health

July 2013

- Tool fielded with Pilot Project principal investigators

Fall 2013

- Patient and Family Engagement Rubric developed

Jan 2014

- Webinar with Pilot Project awardees re: initial findings

Fall 2013 to present

- Revisions to tool based on:
  - Engagement Rubric
  - Pilot project data collection and principal investigator input
  - PCORI Evaluation Group
  - Advisory Panel on Patient Engagement
  - PCORnet
  - Pipeline to Proposal program office

Impact of Engagement ENACT Captures:

- Who is engaged
- Partnership characteristics – how formed, length, frequency of engagement, etc.
- Level of engagement
- When in research process are they engaged
- Perceived level of influence of partners
- Perceived effects of engagement on research questions, study design, study implementation, and dissemination of results
- Challenges, facilitators
- Lessons learned for engagement
- PCOR principles – respect, co-learning, etc.

Impact of Engagement

- Using ENACT, we are assessing all studies that have reached their 12-month point
- For these studies, we expect to be able to describe the impact of ***Engagement*** on:
  - Formation of the Research Questions
  - Study Design
  - Functioning of the Study Team
  - Early Phase of Recruitment

An Example From Our Evaluation Framework

Evaluation Question	Metrics/ Indicators	Methods	Sources
What is the effect of patient and stakeholder engagement on the functioning of the study team and on study design?	Engagement Activity Inventory (ENACT): Elicits detailed descriptions of the nature of engagement and its effects	Qualitative and Quantitative Use of ENACT as well as structured interviews	ENACT Progress Reports Project and Engagement Officers

Welcome to Evaluation at PCORI!

- Follow our blog series – Evaluating the PCORI Way
  - http://www.pcori.org/blog/?blogcats=/evaluating-the-pcori-way/
  - These blogs link to materials from our PCORI Evaluation Group meetings and also ask for your input
- Review the questions in our Draft Evaluation Framework – let us know if yours is reflected
  - http://www.pcori.org/assets/2014/04/PCORI-Draft-Evaluation-Framework-042214.pdf
  - http://www.pcori.org/public-feedback-on-pcori-evaluation-framework/
- Comment on our draft Usefulness Criteria (others coming soon)
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- Comment on any or all of it!
  - info@pcori.org

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BREAK

Join the conversation on Twitter via #PCORI

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Dashboard Review
Midyear FY 2014

Joe Selby, MD, MPH, Executive Director
PCORI Board of Governors Meeting
Alexandria, VA
May 2014

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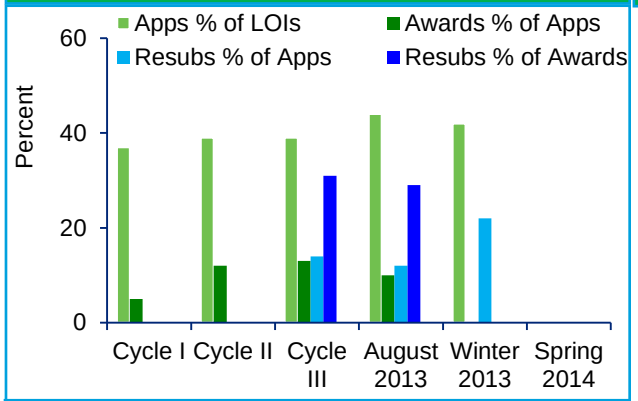

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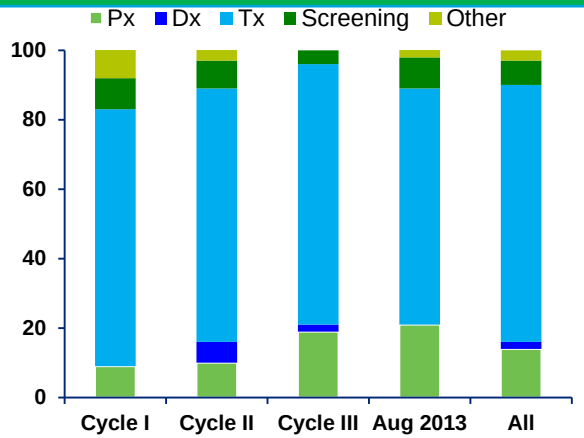

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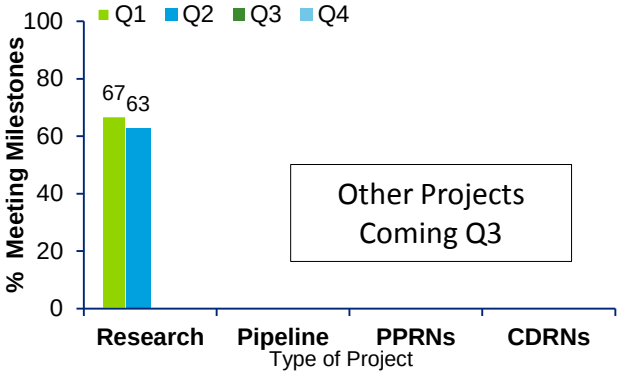

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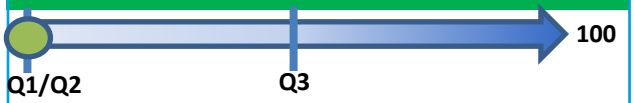

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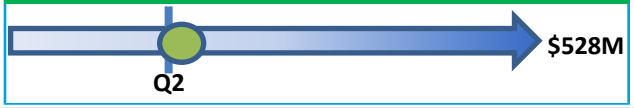

Completion of Phase I of PCORnet

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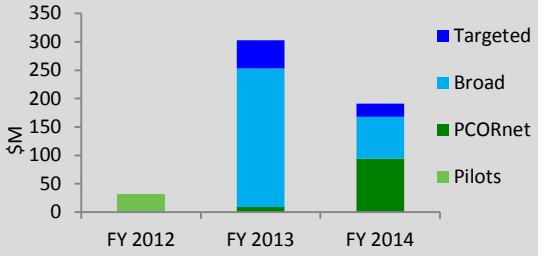

2014 Staffing Plan – Number of People

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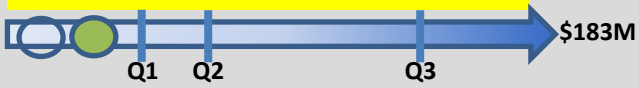
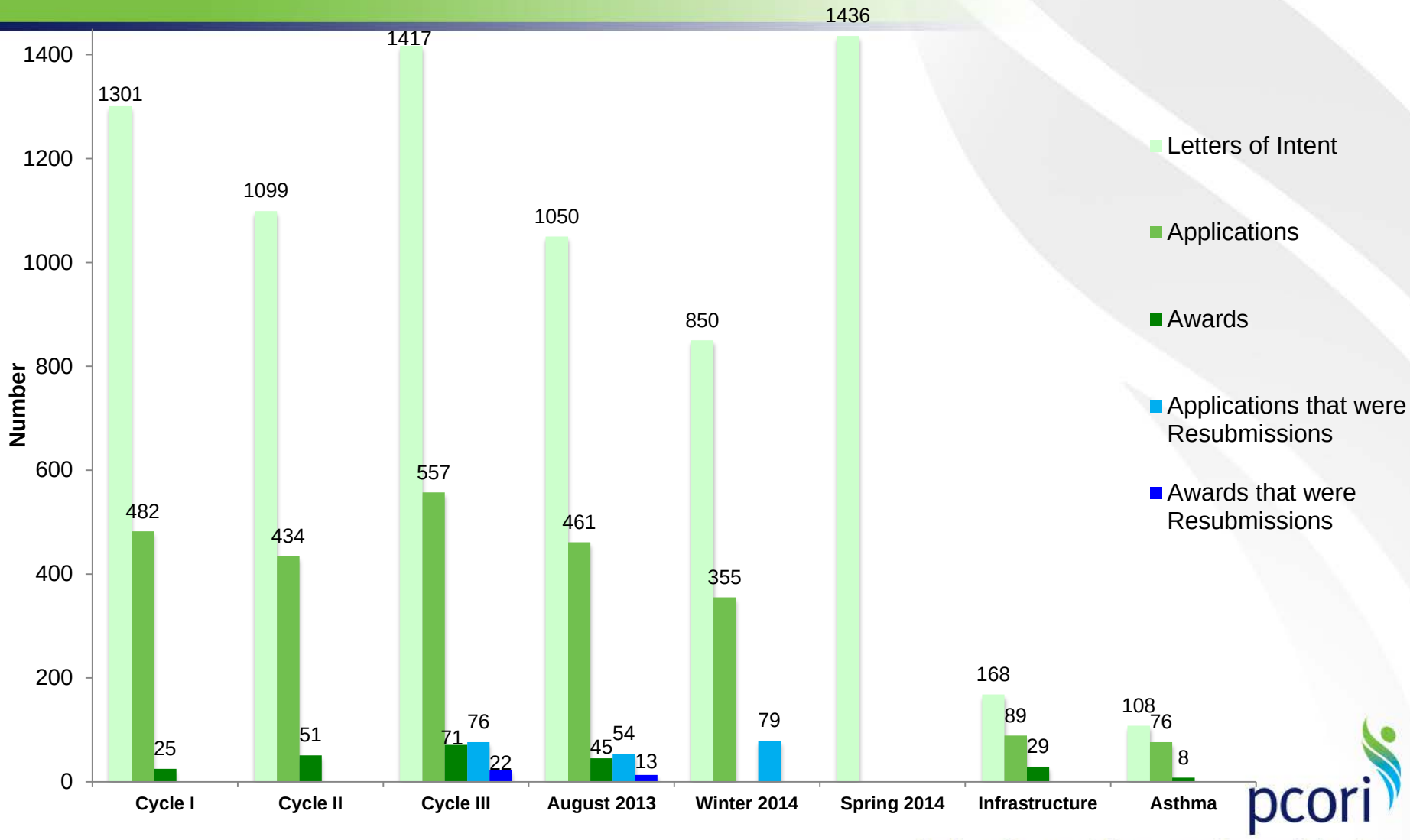


(as of 2/28/14)

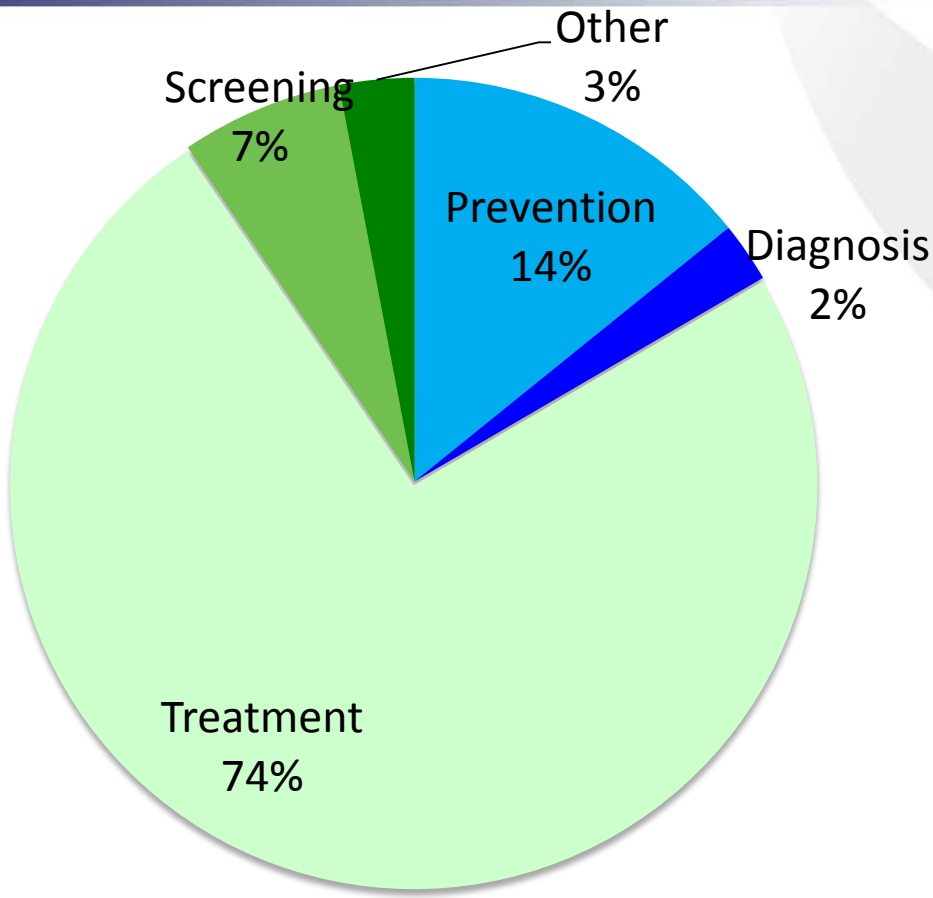
Increase Information

LOIs, Applications, and Awards



Increase Information

Composition of Current Portfolio



N = 169
(Cycles I-III and August 2013, not including Methods)

Projects included in "Other" overlap 2 or more categories

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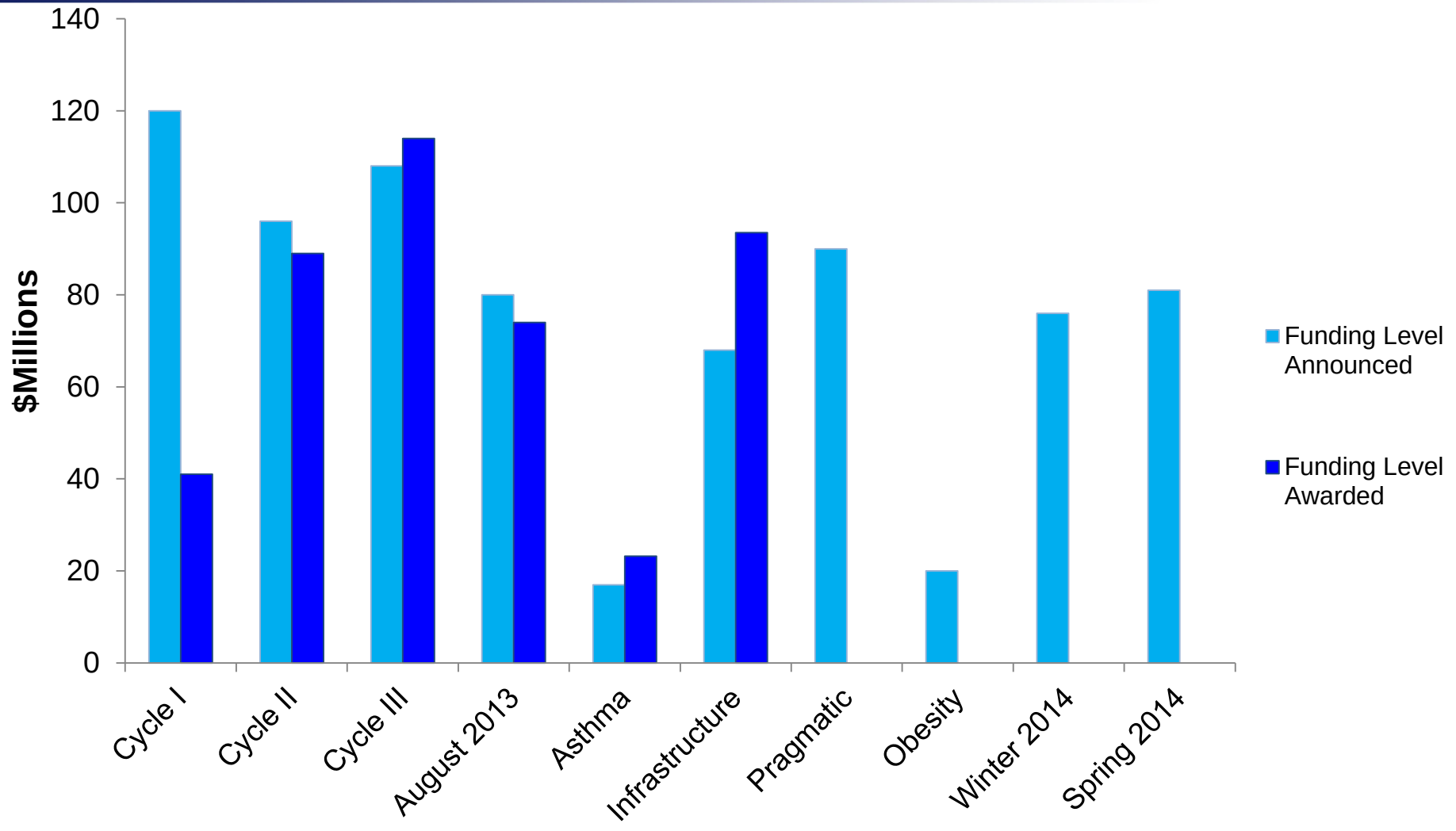
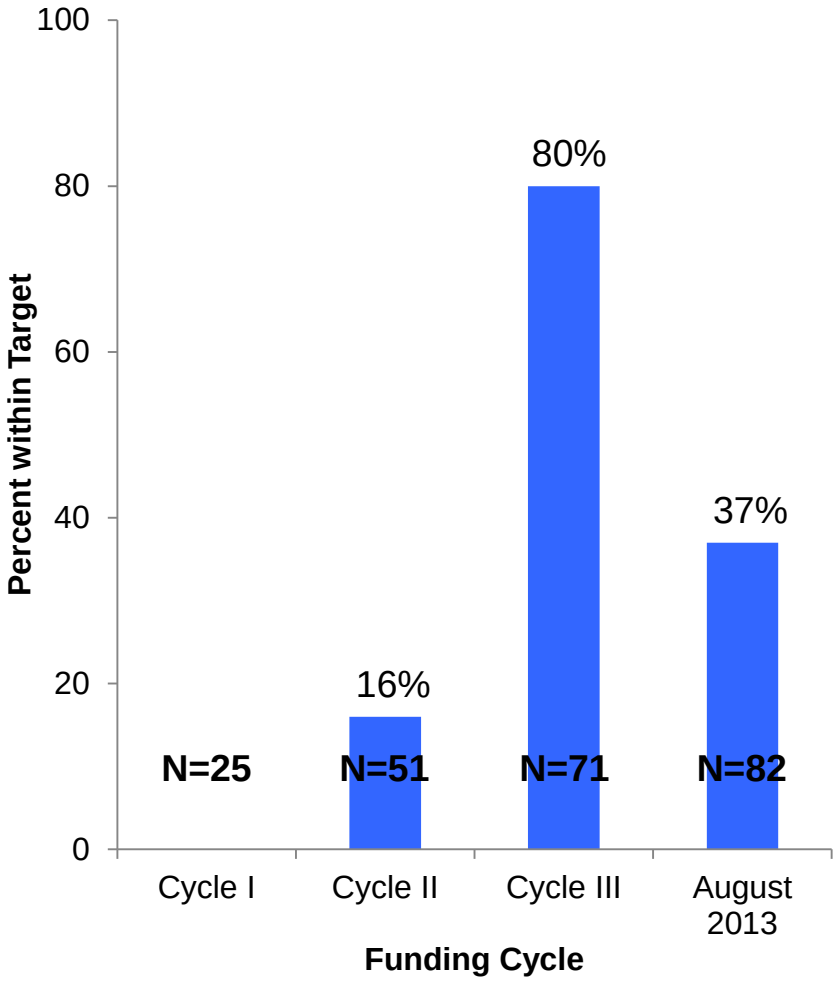
Increase Information

Comparison of Funding Level Announced with Funding Level Awarded



Operational Excellence

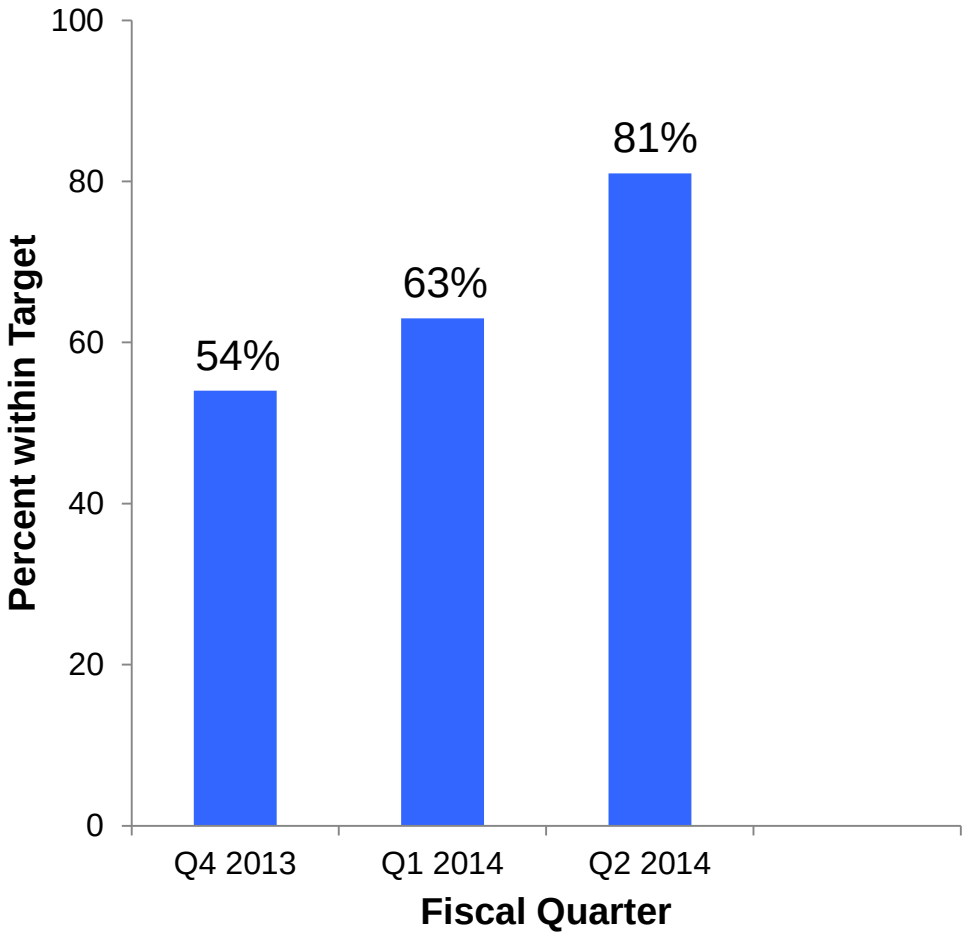
Time from Award to Contract Execution



- *Target = 90 Days*
- *Included in the 82 awards we made from the last cycle were 29 for new initiatives – the CDRNS and PPRNs.*
- *Despite the complexities in negotiating these novel contracts, we executed 41% of them within 90 days. To date, all but one which is pending signature have been executed.*
- *Once we started working on the other awards – 8 from the Targeted Asthma PFA and 45 from the Broad PFA – we executed 70% of them within 90 days.*

Operational Excellence

Science Response Time



Target: within 3 Business Days

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Influence Research

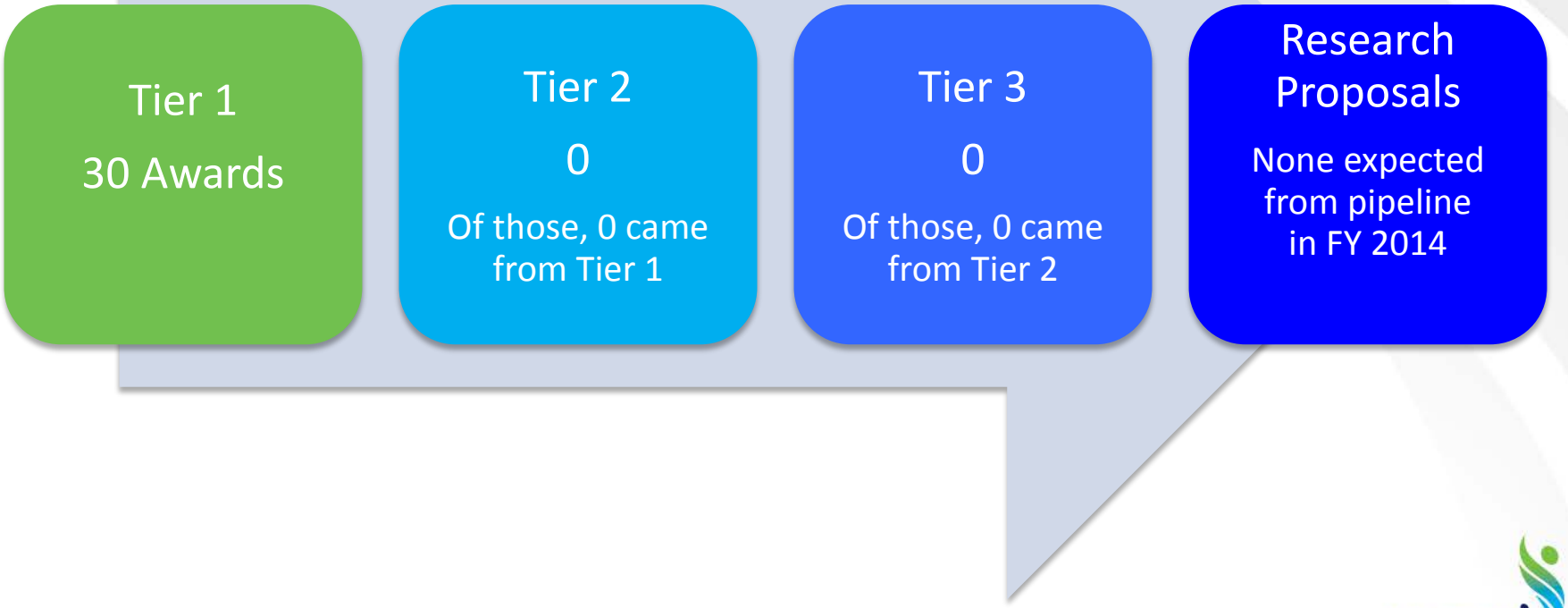
Adherence to PCORI Methodology Standards

- The August 2013 Cycle, awarded in December of 2013 **(N=53)**, was the first for which adherence to our Methodology Standards was required
- For four sets of standards, most or all of the standards were applicable to most or all of the studies at the time of application
- On average, these four sets of standards were adhered to by **74%** of the applications

Set of Standards	Average Percent of Applications Adhering to the Standards in the Set
Formulating Research Questions	**93%**
Patient-Centeredness	**91%**
Data Integrity and Rigorous Analyses	**72%**
Heterogeneity of Treatment Effect	**41%**

Influence Research

Pipeline to Proposal Awards – Q2 Snapshot



Influence Research

Engagement Event Survey Details

Since attending the PCORI Workshop, have you done anything **new** to **conduct, promote, or use patient-centered research**?

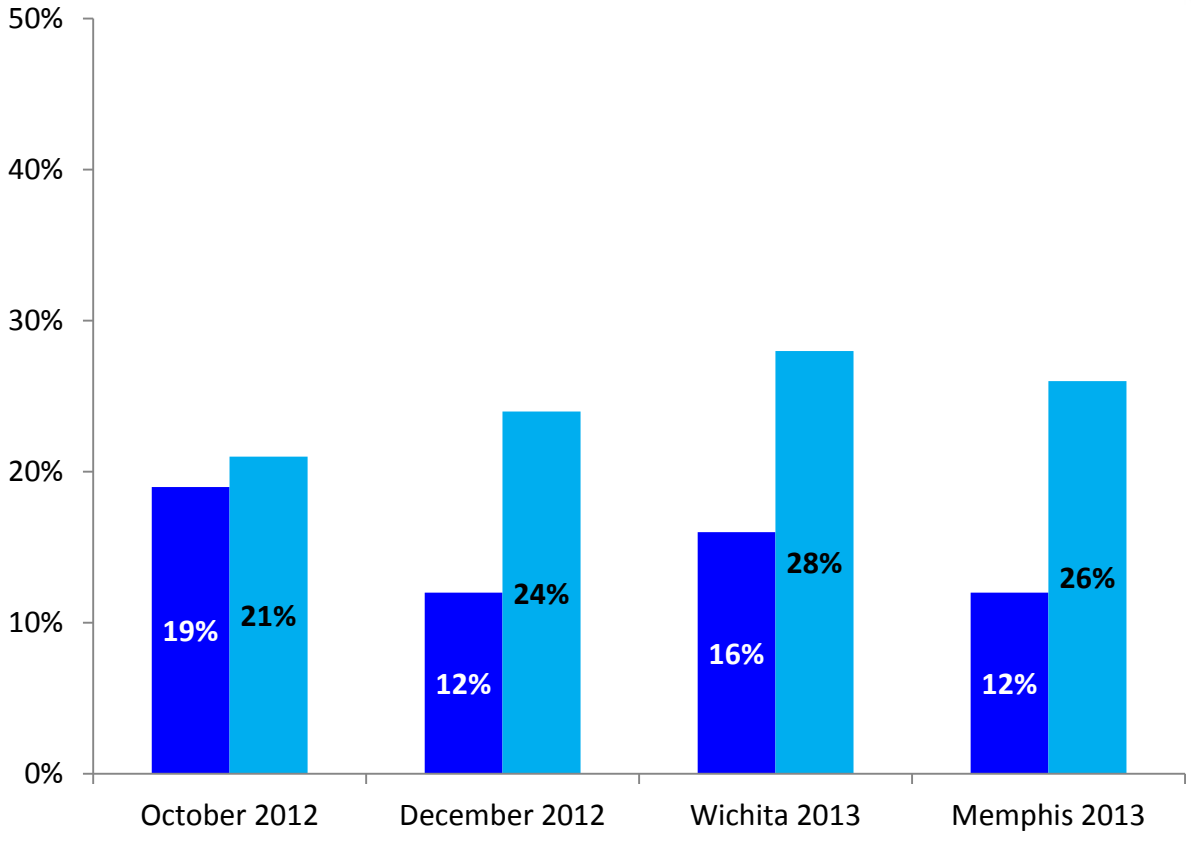
Among other things, this might include joining research teams that include researchers and patients, finding ways to incorporate patient input into your research, contacting local media outlets about patient-centered research, using patient-centered research to inform your clinical practice, or simply explaining to others what patient-centered research is and how it can benefit patients.

Event	Response Rate	Responded YES to Summary Question
October 2012 Engagement Workshop	49%	91%
December 2012 Engagement Workshop	39%	83%
Wichita Regional Workshop, 2013	39%	92%
Memphis Regional Workshop, 2013	40%	79%

*Surveys of workshop participants are conducted **six months following a workshop** to capture new activities in conducting, promoting, or using patient-centered research and new contributions to a proposal for PCORI research funding and are **live in the field for 3 weeks**.*

Influence Research
Engagement Event Survey Results

Since attending the PCORI Workshop, in which of the following ways have you ***contributed to a proposal for PCORI research funding****?*



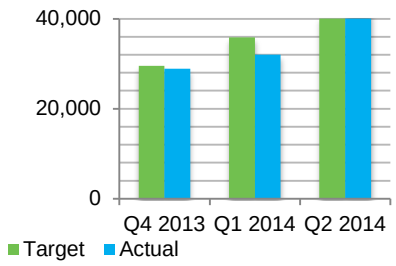
Influence Research
Communications

Communications

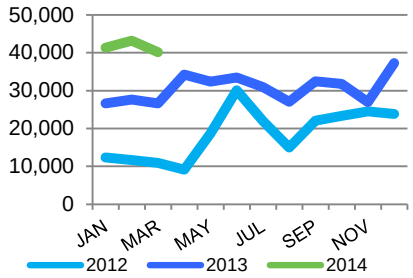
Website

Our Q2 website unique visitors has surpassed previous quarters and beat our target.

Website Unique Traffic



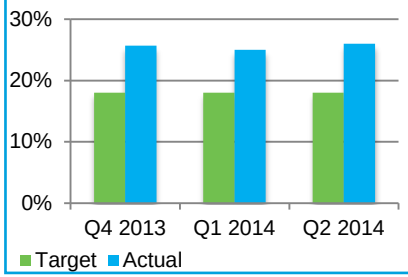
Monthly Unique Traffic



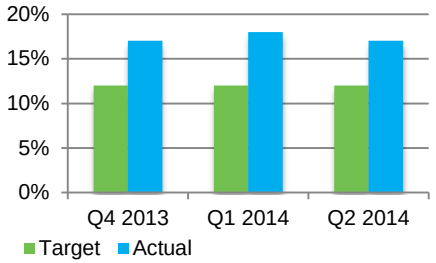
E-mail

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

Email Open Rate



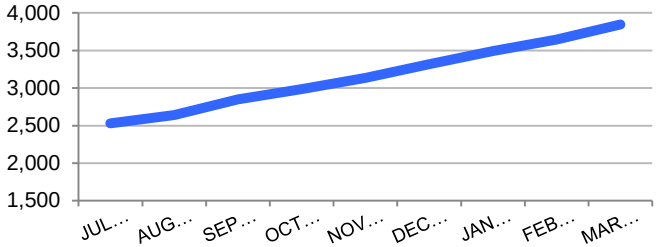
Email Click-Thru Rate



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 & Journal Articles

We continue to grow the number of mentions of our work in general/trade media and journal articles,

Media	2012	2013	2014
Q1	-	45	150
Q2	47	48	212
Q3	46	89	-
Q4	[illegible]	[illegible]	

Journal Articles	2013	2014
Q1	-	12
Q2	8	10
Q3	12	-
Q4	8	

Note: Media mentions and journal articles tallied here include pieces about PCORI's work by staff, Board and Methodology Committee members, or PCORI-funded PIs, as well as articles by others that mention our work prominently.

Resolution to Authorize a Letter of Credit

Regina Yan, Chief Operating Officer

Patient-Centered Outcomes Research Institute

Background

- Funds to lease additional office space are in the approved FY2014 budget
- The lease of 1919 M Street 2nd floor space requires a letter of credit of $150,000 as a form of security deposit
- The letter of credit requires authorization from the Board

Board Vote: Authorize a Letter of Credit

Call for a Motion to:	• **Approve** each resolution in "A Resolution of the Board of Governors of the Patient-Centered Outcomes Research Institute to Authorize a Letter of Credit"
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:	• Vote to **Accept** the **Final** Motion
	  • Ask for votes in favor
	  • Ask for votes opposed
	  • Ask for abstentions

FY2014 Financial Review
(As of 2/28/2014)

Regina Yan, MA
Chief Operating Officer

Board of Governors Meeting
Alexandria, VA
May 2014

Patient-Centered Outcomes Research Institute

Overview

1. Key Accomplishments
2. Summary
   - Revenue and Cash Balance
   - FY2014 Funding Commitments
   - Research Contract Obligations
3. Budget vs Actuals Review (as of 2/28/14)
   - Variance Analysis
   - Cost Savings
   - Delayed expenses
4. Next Steps
5. Strategic Question

Key Accomplishments (as of 2/28/2014)

- $191 million funding committed in December 2013 - PCORnet contracts executed
- Spring cycle PFAs, including Pragmatic Trials and 2 Targeted PFAs, issued
- Two new Advisory Panels established
- 30 Pipeline to Proposal Awards were selected for funding in the amount of $448,069
- Successful onboarding of 38 employees
- Performance review and staff training (management, compliance, etc.) rolled out

Summary: Revenue and Cash Balance
(as of 2/28/14)

Revenue from PCOR Trust Fund	**$206 million**
Federal Appropriation	*$120 million*
CMS Transfers	*$86 million*
Cash Balance	**$488 million**

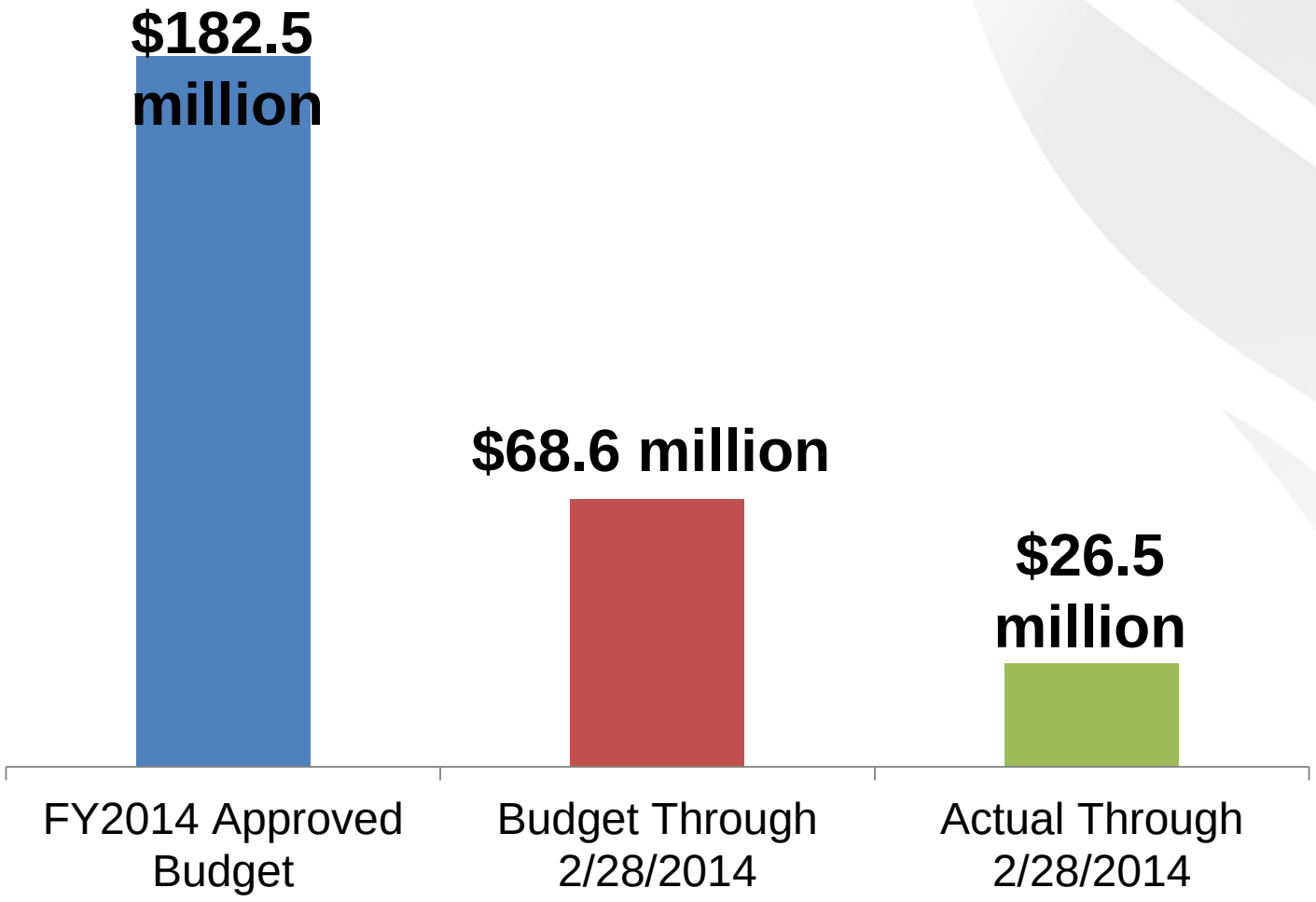
Summary: FY2014 Funding Commitments

FY2014 Funding Commitments already approved by Board as of 2/28/14	**$191 million**
Approved Total Funding Commitments for FY2014 (inclusive of $191M)	**$528 million**

Summary: Research Contract Obligations
(Includes all PCORnet awards)

Cumulative Obligation (Funding Commitment Made from inception to 2/28/2014)	**$525 million**
Outstanding Obligations (Pending Payments)	**$468 million**

FY2014 Budget vs Actuals (as of 2/28/2014)



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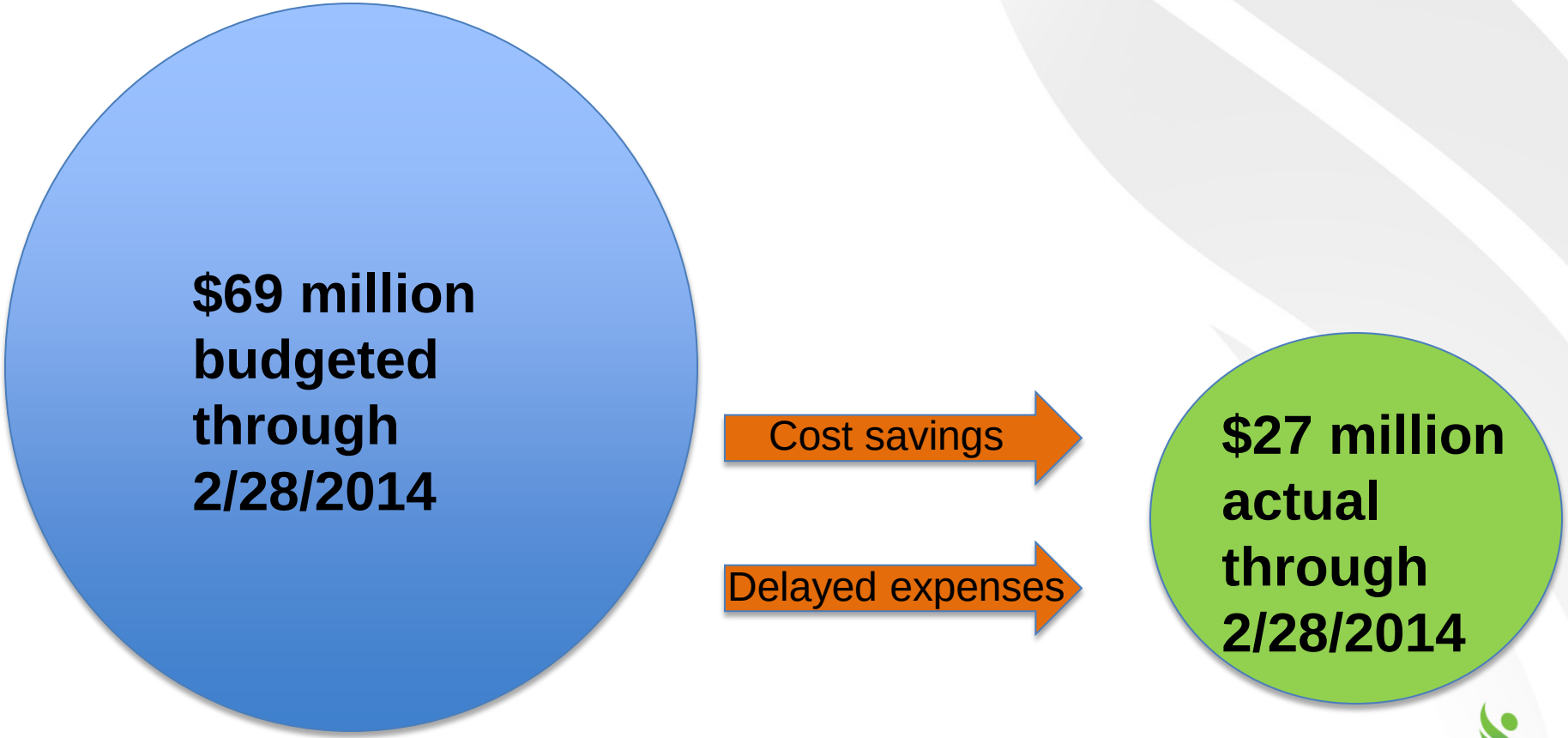
FY2014 Budget vs. Actuals by Broad Categories (as of 2/28/2014)

Department	2014 Budget	Budget thru 2/28/14	Actual thru 2/28/14	Variance thru 2/28/14 ($)	Variance thru 2/28/14 (%)
Program Expense					
Research and Engagement Awards	106,206,944	39,966,667	11,826,309	28,140,358	70%
Program Support					
Methodology Committee	2,745,000	643,750	550,496	93,254	14%
Science/Program Development & Evaluation	23,259,838	7,625,022	3,471,456	4,153,566	54%
Engagement	7,634,436	2,745,031	1,422,358	1,322,673	48%
Contracts Management	12,594,812	5,824,276	2,718,551	3,105,725	53%
Board of Governors	1,840,500	791,875	340,335	451,540	57%
Management and General	28,260,087	11,033,421	6,186,714	4,846,707	44%
	182,541,617	68,630,042	26,516,220	42,113,822	61%

Key Factors for the Variance



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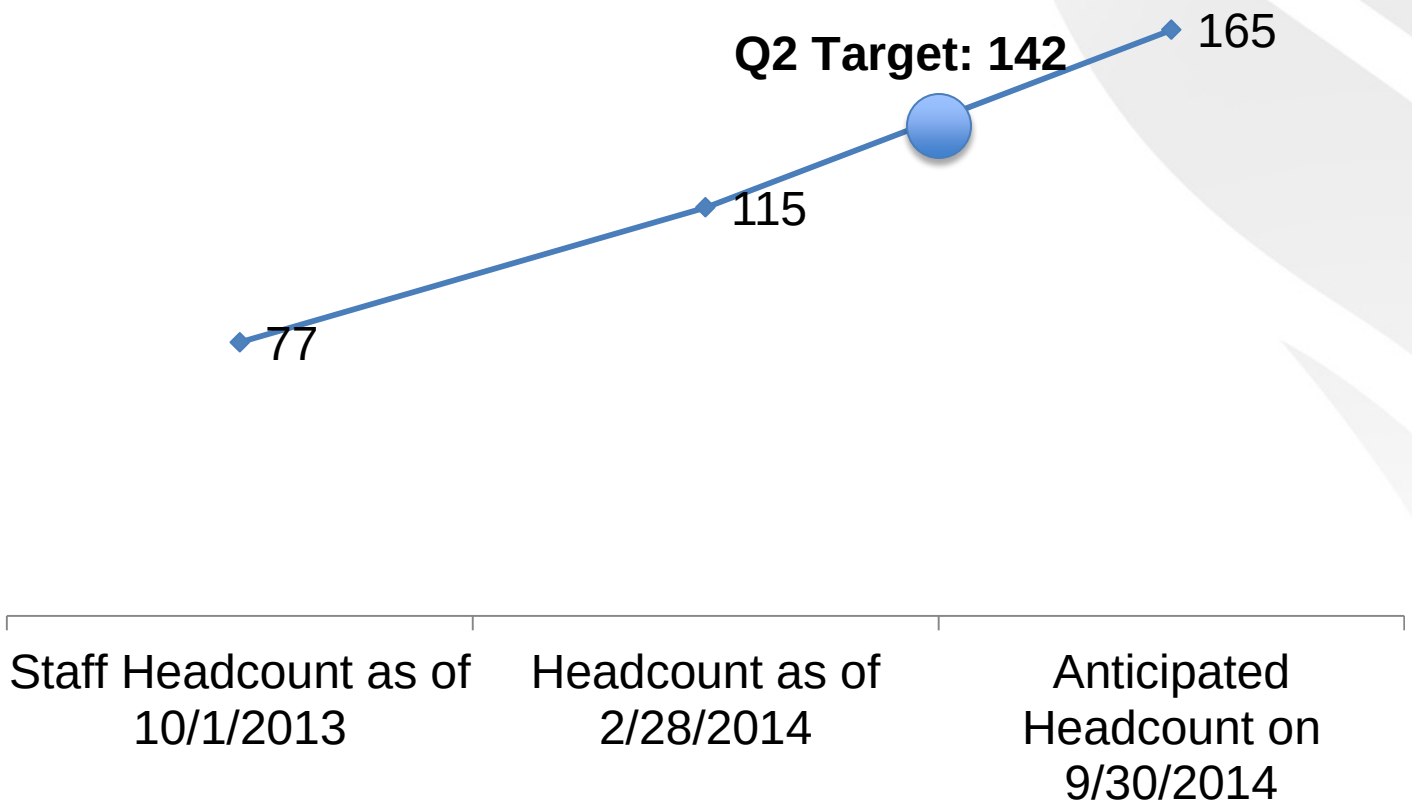
Underspending: Delayed Expenses

- Extramural Research Expense: $27.6 million
  - Majority of projects meet program milestones
  - Invoices and spending reports come in later than the estimated 90 days after contract execution
  - Analysis of financial reports and invoices under way to better forecast timing and pace of research spending
- Engagement: $1.3 million
  - Engagement awards timeline moved back
  - Economies realized in program activities

Underspending: Hiring Timeline



Underspending: Real Cost Savings

- Science: $2.0 million
  - The decision to fund pragmatic trials greatly reduces PFA development costs needed (e.g., workgroup meetings, landscape review, etc.)
  - More PFA development work was done in-house by staff rather than outsourced to consultants
- Contracts Management and Administration: $3.1 million
  - Reduced department support from external contractors
  - Reduced cost of merit review
  - Reduced negotiation costs, streamlined contract template and finalization

Next Steps and Revised Spending Forecast

- We are updating our spending forecast based on latest cost assumptions and activity timelines

- The revised FY2014 spending forecast will be presented to the Board in June for review and discussion

Strategic Question for Board Consideration

- In addition to outlining in our revised spending forecast any major activities that might be shifted into FY2015, what other issues do you want to ensure that we address?

PUBLIC COMMENT

Join the conversation on Twitter via #PCORI

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Patient-Centered Outcomes Research Institute

Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Patient-Centered Outcomes Research Institute