Board of Governors Meeting via Teleconference/Webinar

December 12, 2017

12:00 - 1:30 pm ET

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:05	**Consider for Approval:** Minutes of the November 21, 2017 Board Meeting
12:05–12:25	**Consider for Approval:** Cycle 1 2017 Large Dissemination & Implementation (D&I) PFA Awards
12:25-12:50	**Consider for Approval:** Targeted PFA Development
12:50-1:05	**Consider for Approval:** Advisory Panels Integration, Implementation Plan, and Charters
1:05-1:30	Q4-2017 Dashboard Review
1:30	Wrap up and adjournment

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the November 21, 2017 Board Meeting
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

Proposed Funding Slate of Large Awards from the Limited PCORI Funding Announcement (Cycle 1 2017):

Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research Results

(D&I Limited Competition)

Debra Barksdale, PhD, RN

Chair, Engagement, Dissemination, and Implementation Committee (EDIC)

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer

Background

- On September 26, 2017 Board approved
  - Program Plan and Approval Process for Large ($500k and over) Dissemination & Implementation Awards

- Overview of this Process:
  - Staff presents full slate of recommended projects to the Chief Engagement and Dissemination Officer (CEDO)
  - CEDO approves awards under $500k
  - Projects $500k and over are presented to Engagement Dissemination and Implementation Committee (EDIC)
  - EDIC-endorsed slate is presented to the Board of Governors for approval - **Today's Presentation**

Dissemination & Implementation Limited Competition PFA Overview

- Purpose is to give PCORI awardee teams an opportunity to:
  - propose investigator-initiated strategies for **disseminating and implementing** findings from their PCORI funded studies in the context of existing evidence
  - undertake the **next step(s)** for making their research results more useful, actionable, and accessible to targeted end users

- Standard award:
  - $350k direct costs, 2 year project period
  - Applicants may propose Large Projects that require additional budget and/or time during the Letter of Intent (LOI) stage

D&I Limited Competition Cycle 1 2017

Merit Review Criteria

D&I Limited Competition Merit Review Criteria
1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for dissemination
3. Technical merit (project design, evaluation, and outcomes)
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

D&I Limited Competition Cycle 1 2017 - Overview

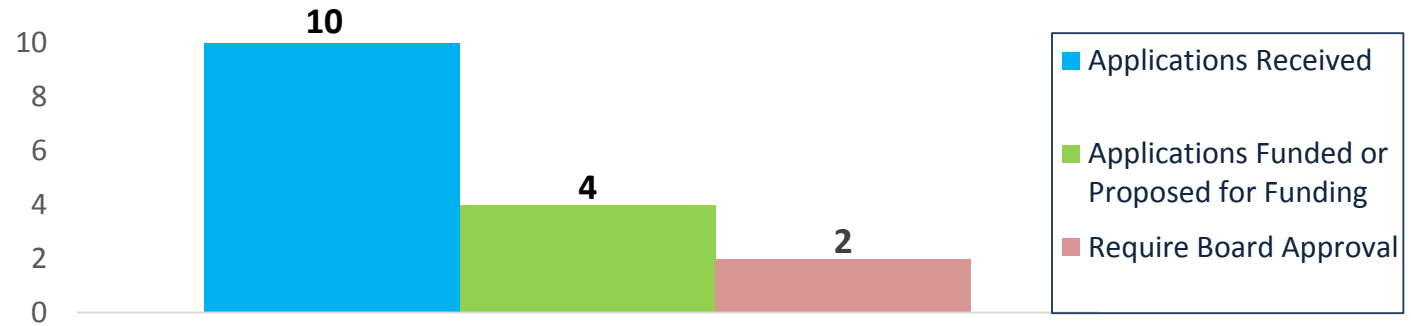
Application overview:

- 24 Letters of Intent (LOIs) submitted
- 15 LOIs invited to submit a full application - 63% of submitted LOIs
- 10 applications (5 requesting funds over $500k) were received - 67% of invited LOIs

The CEDO has approved 2 projects under $500k for funding:

- Implementation of Childbirth-Specific Patient-Reported Outcomes Measures in the Hospital Setting
- Utilizing a Learning Collaborative Approach to Support Behavioral Health Home Dissemination

EDIC is recommending a slate of 2 large projects ($500k or over) for Board approval



D&I Limited Competition Cycle 1 2017

*2 Recommended Large Projects**

Project
Implementation of a Shared Decision Making Intervention in Practice: The Chest Pain Choice Pathway
Disseminating Child Abuse Clinical Decision Support to Improve Detection, Evaluation and Reporting

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

Project 1: Implementation of a Shared Decision Making Intervention in Practice – The Chest Pain Choice Pathway

This D&I project will:

- Implement a **chest pain decision aid** in routine emergency care in 5 Emergency Departments in 3 large health systems
- Original study found that compared to usual care, patients in decision aid arm
  - had greater knowledge of their risk for acute coronary syndrome and options for care, were more involved in the decision
  - less frequently decided with their clinician to be admitted for cardiac testing, and had decreased healthcare utilization (lower rates of imaging during the ED visit, lower rates of 45-day testing)
  - There were no major adverse cardiac events associated with the intervention

Anticipated Reach: Approx. 36,000 patients presenting in the ED with chest pain at low risk for acute coronary syndrome; diversity in geographic region, type of health system, and population demographics

Total Project Cost: $740,383

Project 2: Disseminating Child Abuse Clinical Decision Support to Improve Detection, Evaluation and Reporting

This D&I project will:

- Adapt child abuse clinical decision support for use in two additional electronic health record platforms and implement in 5 emergency departments, within two additional health systems

Original study found:

- The alert system is sensitive (96.8%) and specific (98.5%) for identifying children under age 2 with possible, probable, or definite child abuse
- **No differences in the odds of being screened** based on child demographics or hospital type, suggesting that use of system removed previously reported disparities
- **No difference between study groups on compliance with American Academy of Pediatrics guidelines** around screening for child abuse -- compliance was high in both groups. (Providers in both study arms used the order set with the same frequency although providers in the control arm had to manually search for the order set.)
- **Rate of reports to child protective services** was significantly higher in children who were screened vs. those who were not

Anticipated Reach: Screening for 58,000 – 67,000 children, diverse population

Total Project Cost: $709,000

D&I Limited Competition Cycle 1 2017

Financial Overview of Large Projects

Large Projects ($500k and over) recommended for Board Approval:

PFA	Proposed Total Award
D&I Limited Competition Cycle 1 2017 (Large Projects)	**$1.45 Million**

Board Vote

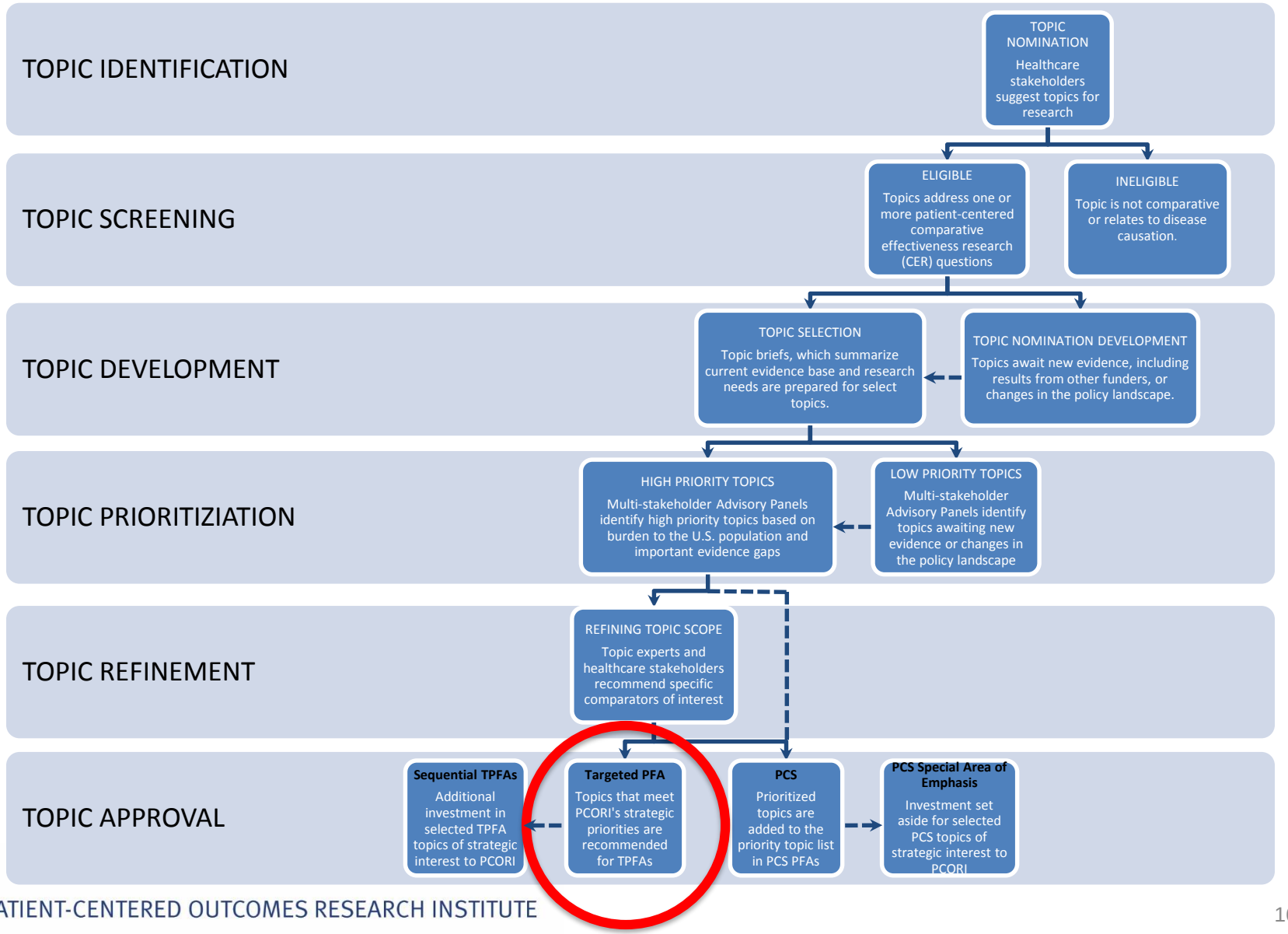
Call for a Motion to:	• **Approve** funding for the recommended slate of large awards from the Cycle 1 2017 D&I Limited Competition PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Targeted PFA: The Pharmacological Treatment of Anxiety Disorders in Children, Adolescents, and/or Young Adults

Robert Zwolak, MD, PhD
Chair, Science Oversight Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

PCORI Topic Prioritization Pathway



Media Coverage Highlights Burden and Need for Pediatric Anxiety Research

- Denizet-Lewis, B. (2017, October 11) **Why are more American teenagers than ever suffering from severe anxiety?** *The New York Times.* Retrieved from https://www.nytimes.com
- Doyne, S. (2017, June 12) **Do You Think Anxiety Is A Serious Problem Among Young People?** *The New York Times.* Retrieved from https://www.nytimes.com
- Klass, P. (2017, December 11) **Treating Anxiety in Children.** *The New York Times.* Retrieved from https://www.nytimes.com
- Leahy, M. (2017, May 30) **My son's anxiety is making him miss out on some of life's best moments.** *The Washington Post.* Retrieved from https://www.washingtonpost.com
- Stephens-Davidowitz (2016, August 7) **Fifty States of Anxiety**. *The New York Times.* Retrieved from https://www.nytimes.com
- Strauss, V. (2016, February 2) **Facing down debilitating anxiety- a college freshman's story.** *The Washington Post.* Retrieved from https://www.washingtonpost.com
- Williams, A. (2017, June 10) **Prozac Nation is Now the United States of Xanax.** *The New York Times*. Retrieved from https://www.nytimes.com

Findings from the 2017 Anxiety in Children AHRQ Systematic Review

- According to the review, the **main treatment options for pediatric anxiety disorders** include:
  - **Psychological interventions**
    - Cognitive Behavioral Therapy (CBT) has low to moderate strength of evidence compared to wait-list controls
  - **Pharmacotherapy**
    - Selective-serotonin reuptake inhibitors (SSRIs) and selective-norepinephrine reuptake inhibitors (SNRIs) have moderate to high strength of evidence compared to placebo
  - **Psychological + pharmacotherapy combination approaches**
    - Combination CBT + drug approaches have moderate strength of evidence for improving primary anxiety symptoms, function, and clinical response more than either CBT or drug alone

Research Needs Identified by the 2017 AHRQ Review

- More research is needed to assess:
  - **The most beneficial components of CBT,** and how this may vary by age
  - The impact of **comorbidities, family demographics, and stressors** as treatment effect modifiers
  - **Head-to-head comparisons of medications, comparisons of CBT to medications, and combination therapy versus monotherapy**
- **Larger trials with follow-up of at least 2-3 years** are needed to address the longer-term safety of medications and advance patient care

Recent Predictive Analysis Emphasizes Need for Combination Therapy

- A more specific predictive analysis of the Child/Adolescent Anxiety Multimodal Study (CAMS) published in September 2017 demonstrates the **importance of combination drug/psychological therapy for** children and adolescents with **severe anxiety**

- CAMS reanalysis showed that:
  - Children with mild- to moderate-anxiety at baseline remitted with any active intervention (CBT, sertraline, or combination therapy)
  - Children with severe anxiety required combination therapy to achieve a statistically significant improvement in likelihood of remission

Monotherapy Insufficient in Severe Anxiety? Predictors and Moderators in the Child/Adolescent Anxiety Multimodal Study. Taylor JH, Lebowitz ER, Jakubovski E, Coughlin CG, Silverman WK, Bloch MH. J Clin Child Adolesc Psychol. 2017 Sep 28:1-16

Research Needs Identified at Stakeholder Workshop

- **Topic refinement workshop held on July 26, 2017:**
  - 29 stakeholders representing clinicians, researchers, payers, and patients participated in the meeting
- **Stakeholders expressed need for additional research on:**
  - Comparisons of **various models of CBT** (e.g., delivery mechanism, intensity, type of support) (PCS Priority Topic, Special Area of Emphasis)
  - **Community-based approaches** for early intervention (e.g., school-based mindfulness programs) (current lack of efficacy)
  - Models evaluating **care coordination and integration** across primary and special care (language to be integrated into announcements)
  - **Head-to-head comparisons of pharmacotherapy** (particularly SSRIs and SNRIs) in combination with CBT (not yet addressed; **proposed Targeted PFA**)
  - Comparisons of approaches to **treatment initiation, sequencing, and maintenance strategies** for relapse prevention (PCS Priority Topic)

Key Challenge Faced by Clinicians: Selecting Medications for the Treatment of Pediatric Anxiety

Stakeholder Need: Significant interest from stakeholders, including psychiatrists, pediatricians, and other primary care providers in head-to-head comparisons of medications

- Studies that directly assess the **risks and benefits associated with various drugs** in diverse populations of patients
- Key question faced by primary care providers when pediatric patients present with moderate- to severe-anxiety, particularly when CBT is not accessible: **Which medication to prescribe?**

FDA Approval: Commonly Used Anxiety Drugs

- **SSRIs**
  - **Fluoxetine –** Approved for obsessive compulsive disorder (OCD) in children 7 and older; major depressive disorder in children 8 and older
  - **Sertraline –** Approved for OCD in children 6 and older
- **SNRIs**
  - **Duloxetine –** Approved for generalized anxiety disorder in children 7 and older

Conversations with FDA and NIMH

- Guidance from both FDA and National Institute of Mental Health (NIMH) was consistent and encouraging
- Investigational new drug applications (INDs) will be needed, but no concerns raised about feasibility of obtaining INDs for such studies
- Awardee will need to have specific and adequate human subject protection measures in place (e.g., the inclusion of a data safety monitoring board, a risk monitoring plan, and the discussion of potential risk and how it will be monitored in the consent process)

PICOTS for PFA Question

- **Population:** Children, adolescents, and/or young adults with moderate- to severe-anxiety (investigators to provide rationale for study inclusion criteria within range of 7-25 years)
  - Special populations of interest: Underserved populations including racial and ethnic minority youth, low-income youth, and youth living in rural areas
- **Intervention/Comparisons of Interest:** Head-to-head comparisons of SSRIs and/or SNRIs delivered in conjunction with CBT or other evidence-based psychological intervention (investigators to select and justify appropriate pharmacological comparators for specific age/severity of study population)
- **Outcomes:** Symptom improvement + outcomes that are important to children and adolescents with anxiety and their families (e.g., school attendance/engagement in social activities; family burden; acceptance of treatment, etc.)
- **Timing:** Minimum of one year of follow-up, two years preferred
- **Setting:** Pediatric primary care/combined primary & specialty care; models evaluating coordination and integration encouraged

Requested Research Commitment

- The **total commitment** requested for this PFA is up to **$40 million** in total costs
  - Estimated number of studies: 2
  - Total direct costs/study: $15 million
  - Maximum project period: 5 years

Timeline

Action	Date
SOC Approval	December 1, 2017
Board of Governors Vote	**December 12, 2017**
Preannouncement Released	December 13, 2017
Targeted PFA Released	January 16, 2018
Letter of Intent Due	February 13, 2018
Application Deadline	May 16, 2018
Merit Review	August 6-7, 2018
Board Approval/Awards Announced	November 20, 2018

Board Vote

Call for a Motion to:	• **Approve** the development of and release of The Pharmacological Treatment of Anxiety Disorders in Children, Adolescents, and/or Young Adults PFA
Call for the Motion to Be Seconded:	• **Second** If further discussion, may propose **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

National Priority Advisory Panels Integration, Implementation Plan, and Charters

Evelyn P. Whitlock, MD, MPH

Chief Science Officer

Advisory Panels: Background & Rationale

- PCORI's authorizing law allows for the appointment of expert advisory panels to assist PCORI in identifying research priorities and to establish its research project agenda and for other purposes.

- To help advise PCORI in these focused priority areas, the Board created expert Advisory Panels on:
  - Assessment of Prevention, Diagnosis, and Treatment Options (April 2013)
  - Communication and Dissemination Research (January 2015)
  - Improving Healthcare Systems (April 2013), and
  - Addressing Disparities (April 2013)

- Since the formation of these panels, the Advisory Panel members have greatly helped to:
  - Model robust patient and stakeholder engagement efforts;
  - Refine and prioritize specific research questions; and,
  - Provide scientific and technical expertise.

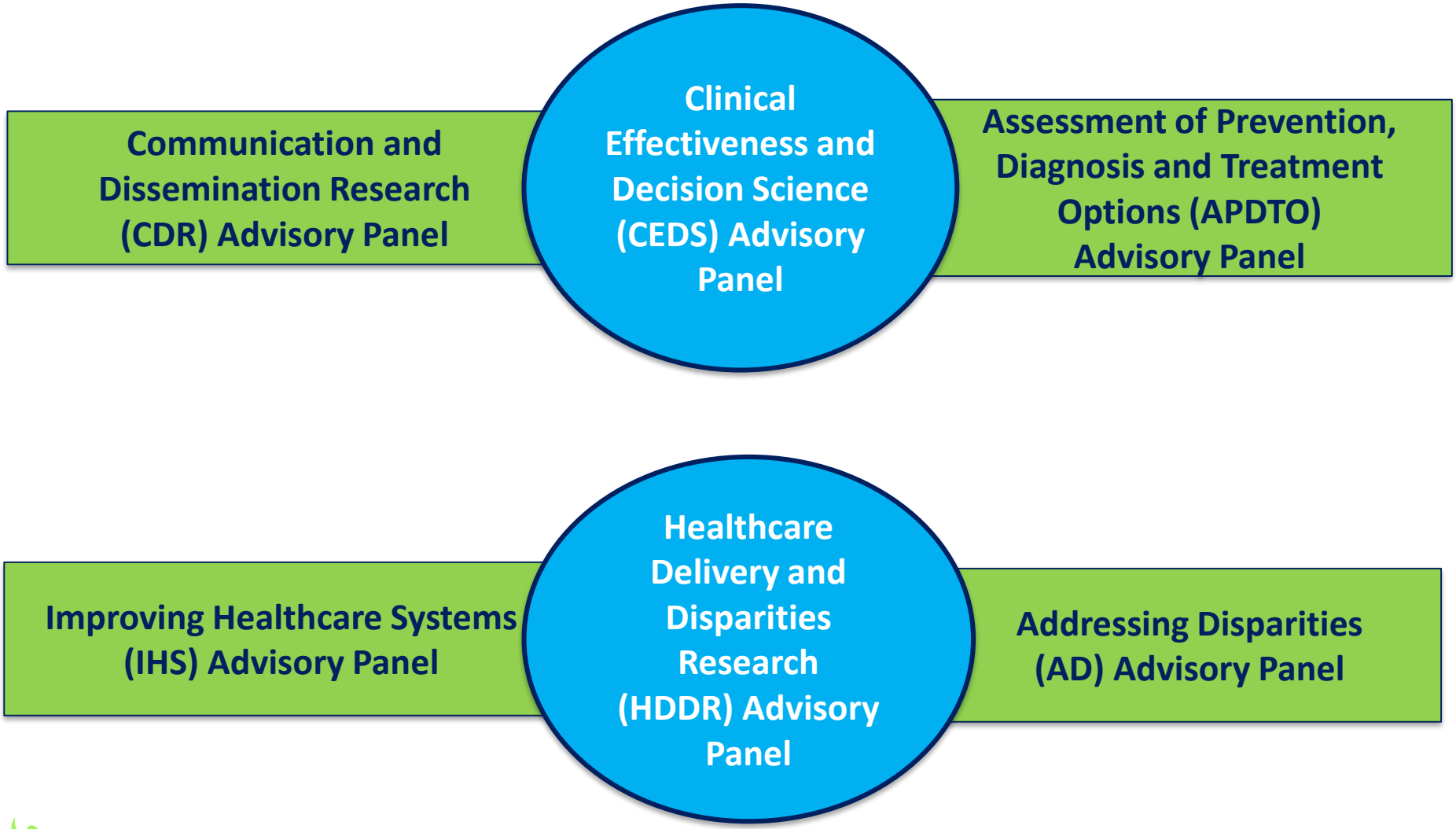
Advisory Panels: Transition to the Future, Realignment Plan

- As PCORI grows and matures, it has recognized that by merging the talent, expertise, and scope of work of our Advisory Panels, a synergy can be created to more readily advance PCORI's National Research Priorities.

- Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options and Advisory Panel on Communication and Dissemination Research
  - Have synergy that would facilitate the translation of clinical effectiveness research from research into practice

- Advisory Panel on Improving Healthcare Systems and Advisory Panel on Addressing Disparities
  - Have synergy that would allow for a collaborative focus on both improving healthcare delivery and reducing disparities in care

Proposed Integration of Advisory Panels



Focus of New Advisory Panels*: Alignment with National Research Priorities

- **Clinical Effectiveness and Decision Science (CEDS) Advisory Panel**
  - This panel integration will advise on research in clinical areas having important evidence gaps, with a particular focus on:
    - Bringing new clinical evidence to practice
    - Examining outcomes important to patients and variation in those outcomes across patient subgroups; and
    - Improving the uptake of evidence by decision makers

- **Healthcare Delivery and Disparities Research (HDDR) Advisory Panel**
  - This panel will advise on research comparing the clinical effectiveness of alternative features of healthcare systems, with a focus on:
    - Optimizing the quality, outcomes and efficiency of care for patients; and
    - Informing the choice of strategies to eliminate disparities in health and healthcare outcomes

*All existing Advisory Panel members will transfer onto new panels.

New Advisory Panel Charter Development and Implementation Plan

- The implementation plan and the proposed new Advisory Panel charters were presented to and endorsed by the Science Oversight Committee (SOC). They were also presented to the Engagement, Dissemination and Implementation Committee (EDIC)

- The intention to revise and refocus the panels was presented to the members of all four existing Advisory Panels for discussion

- All current panel members from the four existing panels will transfer onto the two new panels and will complete their current appointed terms

Implementation Steps: Advisory Panel Charters

- Sunset existing charters for:
  1. Assessment of Prevention, Diagnosis and Treatment Options Advisory Panel
  2. Communication and Dissemination Research Advisory Panel
  3. Improving Healthcare Systems Advisory Panel
  4. Addressing Disparities Advisory Panel

- Approve proposed new charters for:
  1. Clinical Effectiveness and Decision Science Advisory Panel
  2. Healthcare Delivery and Disparities Research Advisory Panel

Implementation Steps: Recommended membership, positions and terms for Advisory Panel on Clinical Effectiveness and Decision Science:

Panel Member	Representation	Original Panel	Term Ends	Term length (in years)
Jonathan Klein*	Researchers	APDTO	2018	1
Leslie Levine*	Patients, Caregivers, and Patient Advocates	APDTO	2018	1
Michael Herndon*	Payers	APDTO	2018	1
Robert Bonomo*	Clinicians	APDTO	2018	1
Roy Poses*	Researchers	APDTO	2018	1
Clifford Ko*	Clinicians	CDR	2018	1
Giovanna Devercelli*	Industry	CDR	2018	1
Janice Buelow*	Patients, Caregivers and Patient Advocates	CDR	2018	1
LaRita B. Jacobs*	Patients, Caregivers and Patient Advocates	CDR	2018	1
Lauren McCormack , Chair*	Researchers	CDR Chair	2018	1
Michael Pignone*	Researchers	CDR	2018	1
Robert Volk*	Researchers	CDR	2018	1
Janice Radak	Patients, Caregivers and Patient Advocates	CDR	2019	1
Felix Fernandez	Clinicians	APDTO	2019	2
Jeff Hersh	Industry	APDTO	2019	2
Michael Schneider	Researchers	APDTO	2019	2
Nancy White	Clinicians	APDTO	2019	2
Rafael Alfonso Cristancho	Industry	APDTO	2019	2
Susan Lin	Patients, Caregivers and Patient Advocates	APDTO	2019	2
Zeeshan Butt	Researchers	APDTO	2019	2
Ashish Atreja	Researchers	CDR	2019	2
Danny van Leeuwen , Co-Chair	Patients, Caregivers, and Patient Advocates	CDR Co-Chair	2019	2
Emilie Johnson	Clinicians	CDR	2019	2
Frank Rider	Patients, Caregivers and Patient Advocates	CDR	2019	2
Kristin Voorhees	Patients, Caregivers, and Patient Advocates	CDR	2019	2
Nancy Perrin	Researchers	CDR	2019	2
Andrew Rosenberg	Patients, Caregivers, and Patient Advocates	CDR	2020	3
Cornell Wright	Policy Makers	CDR	2020	3
Helen Osborne	Patients, Caregivers, and Patient Advocates	CDR	2020	3
Lawrence Goldberg	Clinicians	APDTO	2020	3
Melissa Hicks	Patient, Caregivers, and Patient Advocates	APDTO	2020	3
Nancy Blake	Clinicians	CDR	2020	3
Neela Goswami	Researchers	CDR	2020	3
Robin Karlin	Patients, Caregivers, and Patient Advocates	APDTO	2020	3
Ruth M. Parker	Patients, Caregivers and Patient Advocates	CDR	2020	3
Sandi Smith	Researchers	CDR	2020	3

*As these members rotate off the Advisory Panel in 2018, we thank them for their service to PCORI and to healthcare.

Implementation Steps: Recommended membership, positions and terms for Advisory Panel on Healthcare Delivery and Disparities Research:

Panel Member	Representation	Original Panel	Term Expires	Term length (years)
Barbara Kornblau*	Patient, Caregiver, Patient Advocate	AD	2018	1
Bonnie Clipper*	Clinician	IHS	2018	1
Carolyn Petersen*	Patient, Caregiver, Patient Advocate	IHS	2018	1
Cheryl Pegus*, Co-Chair	Patient, Caregiver, Patient Advocate	AD Chair	2018	1
Danielle Pere*	Clinician	AD	2018	1
Elinor Schoenfeld*	Researcher	AD	2018	1
Jim Bellows*	Health Systems	IHS	2018	1
Kenneth Mayer*	Researcher	AD	2018	1
Lisa Freeman*	Patient, Caregiver, Patient Advocate	IHS	2018	1
Ravi Govila*	Payer	IHS	2018	1
Ronald Copeland*	Health Systems	AD	2018	1
Sinsi Hernandez-Cancio*	Patient, Caregiver, Patient Advocate	AD	2018	1
Terrie Black*	Clinician	AD	2018	1
Timothy Daaleman*, Co-Chair	Researcher	IHS Chair	2018	1
Alexis Snyder	Patient, Caregiver, Patient Advocate	IHS	2019	2
Ana Maria Lopez	Clinician	AD	2019	2
Christine Joseph	Researcher	AD	2019	2
Craig Umscheid	Health Systems	IHS	2019	2
Deidra Crews	Clinician	AD	2019	2
Donald Klepser	Researcher	AD	2019	2
Ignatius Bau	Patient, Caregiver, Patient Advocate	IHS	2019	2
James Perrin	Researcher	IHS	2019	2
Leah Backhus	Clinician	IHS	2019	2
Mitzi Wasik	Payer	IHS	2019	2
Nancy Yedlin	Researcher	IHS	2019	2
Rebecca Aslakson	Researcher	IHS	2019	2
Tung Nguyen	Researcher	AD	2019	2
Umbereen Nehal	Payer	AD	2019	2
Cheryl Holly	Researcher	AD	2020	3
Danielle Brooks	Industry	IHS	2020	3
James Wharam	Researcher	IHS	2020	3
Mary Grace Pagaduan	Patient, Caregiver, Patient Advocate	AD	2020	3
Nadine Barrett	Health Systems	AD	2020	3
Rachel Raia	Payer	IHS	2020	3

*As these members rotate off the Advisory Panel in 2018, we thank them for their service to PCORI and to healthcare.

Board Vote

Call for a Motion to:	**(a) Sunset the four existing Advisory Panel charters, as recommended;** **(b) Approve the two proposed new Advisory Panel charters, as recommended; and,** **(c) Approve the recommended members, positions and terms of the two new Advisory Panels, as recommended**
Call for the Motion to Be Seconded:	• **Second the Motion** • **If further discussion, may propose Amendment to the Motion or an Alternative Motion**
Voice Vote:	• **Vote to Approve the Final Motion** • **Ask for votes in favor, opposed, and abstentions**

Dashboard Review
Fourth Quarter of FY-2017

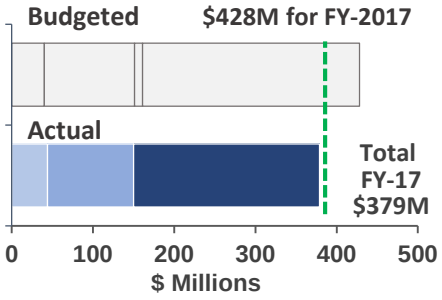
Joe Selby, MD, MPH
Executive Director

Board of Governors Dashboard
Fourth Quarter FY-2017 (As of 9/30/2017)

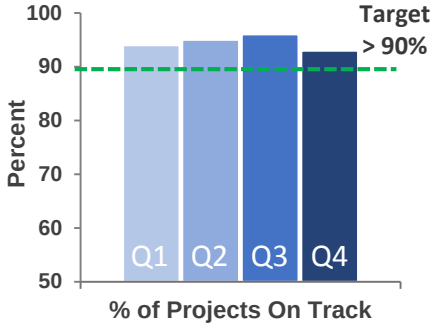
On Target
Off Target
Needs Board Attention
Too Early to Evaluate / No Target
Projected/Target
Q1 2017
Q2 2017
Q3 2017
Q4 2017

Funds Committed to Research

Includes funds committed to PCORnet

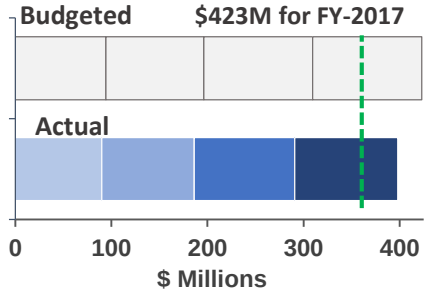


Project Performance

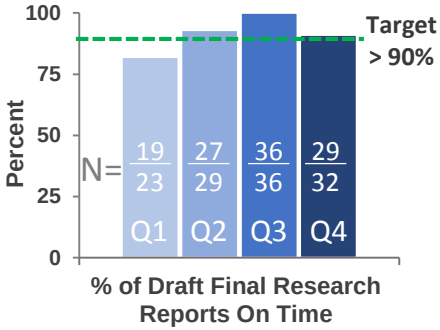


Budget

Operating Budget and Research Awards

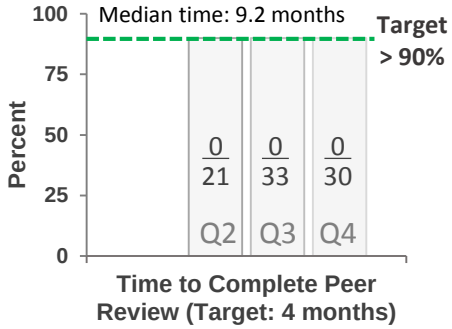


Draft Final Research Reports

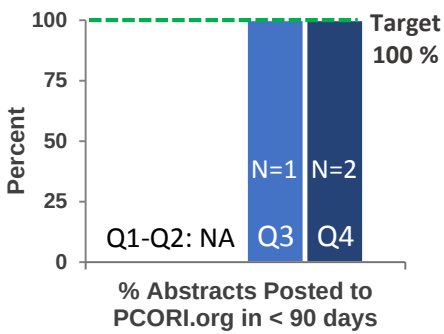


PCORI Peer Review

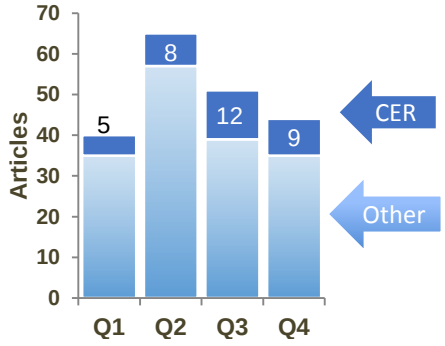
Completed as of Q4: 12
Median time: 9.2 months



Public Reporting of Research Findings

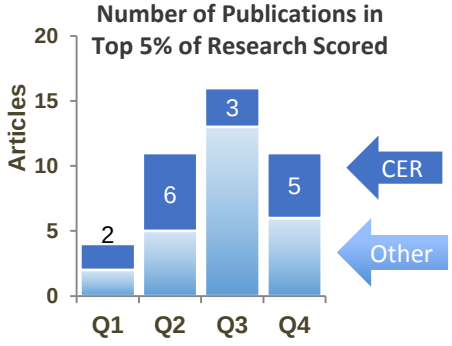


Results Published in Literature



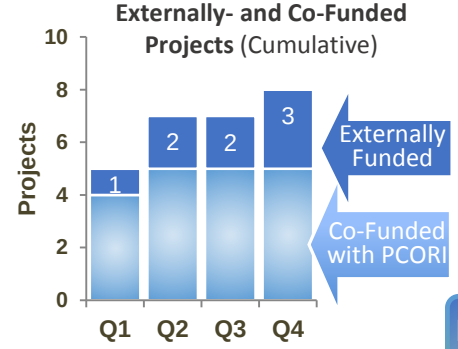
Altmetrics

Number of Publications in Top 5% of Research Scored



External Funding in PCORnet

Externally- and Co-Funded Projects (Cumulative)



Inputs
Process
Outputs
Uptake
Use
Impact

Narrative Examples

Goal 1: Increasing Information

A PCORI-funded study comparing two programs to prevent falls among older adults found that a group-based standing-exercise program called On The Move is more effective than commonly used seated exercises

Goal 2: Speeding Uptake

PCORI-funded results on self-monitoring of blood glucose have been taken up into practice via UpToDate®, a point-of-care, evidence-based medical resource software used by clinicians globally, and nearly 90% of major academic medical centers in the US.

Goal 3: Influencing Research

PCORI is credited with inspiring policy changes and capacity building efforts at the University of Arkansas for Medical Science (UAMS), including an IRB Dissemination policy on returning results to the community and participants

Goal 1: Results of PCORI-Funded Research

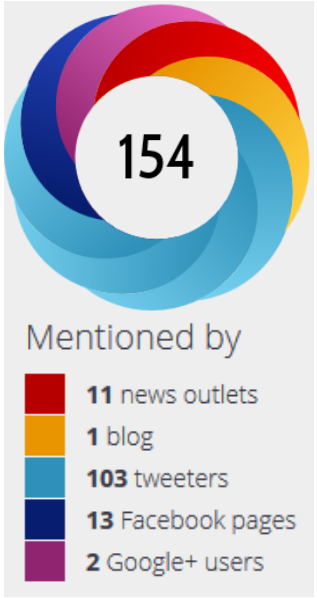
Standing-exercise is more effective than seated exercise in improving mobility in older adults

Brach JS, Perera S, Gilmore S, et al. **Effectiveness of a Timing and Coordination Group Exercise Program to Improve Mobility in Community-Dwelling Older Adults: A Randomized Clinical Trial.** *Jama Internal.* Aug 2017.

Study title: On the Move: Optimizing Participation in Group Exercise to Prevent Walking Difficulty in At-Risk Older Adults

Exercise is beneficial to physical and mental health and may prevent walking difficulty and promote independence for community-dwelling older adults. Exercise programs offered to older adults are typically a seated range-of-motion exercises that do not involve walking.

This study compared the effectiveness of an exercise program (On the Move) that focuses on the timing and coordination of movement with usual care (a seated strength, endurance, and flexibility program). **The study found that the On the Move program was more effective than the seated exercise program at improving function, disability, and walking ability of older adults.**



- Principal Investigator: Jennifer S. Brach, PhD, University of Pittsburgh at Pittsburgh

> Older adults who are interested in improving their mobility should consider participating in a group-based exercise program… Timing and coordination exercises are designed to be more challenging for participants, but they are important for walking and can improve mobility.
>
> *-Dr. Jennifer Brach, Study Investigator*
>
> *Consumer.HealthDay.com article*

Goal 2: Speed Uptake and Use of Information

Uptake of 3 Results from PCORI-Funded Studies in UpToDate®

Recent results from a PCORI-funded study on self-monitoring of blood glucose (SMBG) have been taken up in UpToDate®, a point-of-care, evidence-based medical resource software used by more than 1.3 million clinicians in 187 countries, including nearly 90% of major academic medical centers in the United States[1].

- Topic page titled: **Self-monitoring of blood glucose in management of adults with diabetes mellitus**, updated Oct 31, 2017[2]
  - Young LA, et al. Glucose Self-monitoring in Non–Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings: A Randomized Trial. *JAMA Internal*. June 2017.
    - **PI: Katrina Donahue, MD, MPH, University of North Carolina at Chapel Hill**

At least 4 CER results publications from PCORI-funded studies have now been taken up in UpToDate®

[1]UpToDate. About Us. UpToDate®, Inc. 2017. https://www.uptodate.com/home/about-us
[2]McCulloch, DK. Self-monitoring of blood glucose in management of adults with diabetes mellitus. In: UpToDate®, Hirsch, IB (ed), UpToDate®, Waltham, MA, 2017

Goal 3: Influencing Research Example:
Establishment of Policies and Programs to Promote PCOR

A PCORI-funded project (PI: Peter Kohler, MD, University of Arkansas for Medical Sciences) has inspired ***policy changes and capacity building efforts*** at the University of Arkansas for Medical Science (UAMS)

Policy changes:

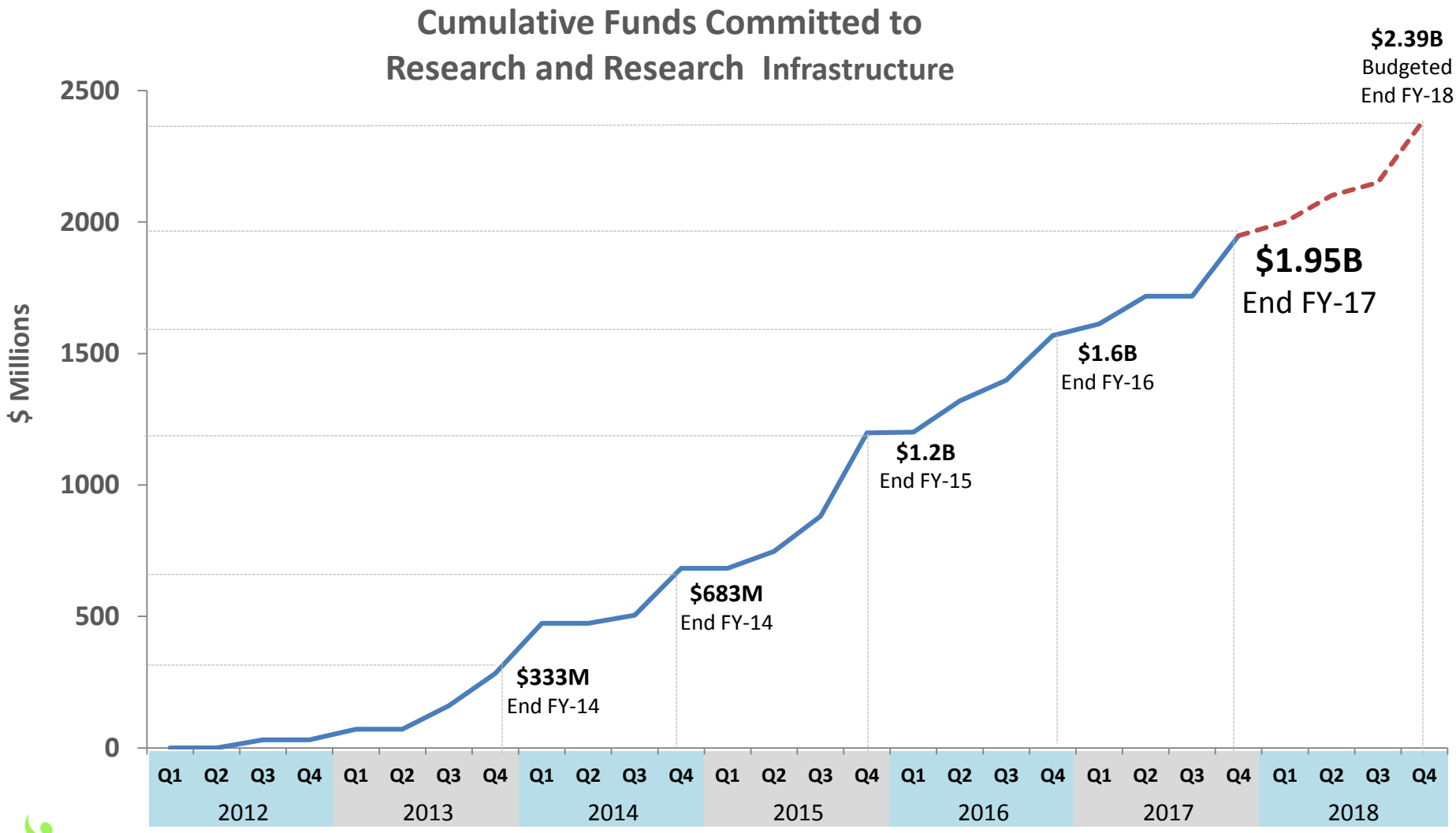
- **Hiring policy:** Redefining the classification and necessary qualifications for research coordinators, interpreters, and community health workers representing the communities of research focus
- **IRB Dissemination policy** on returning results to the community and study participants (implementation in progress)

Capacity building:

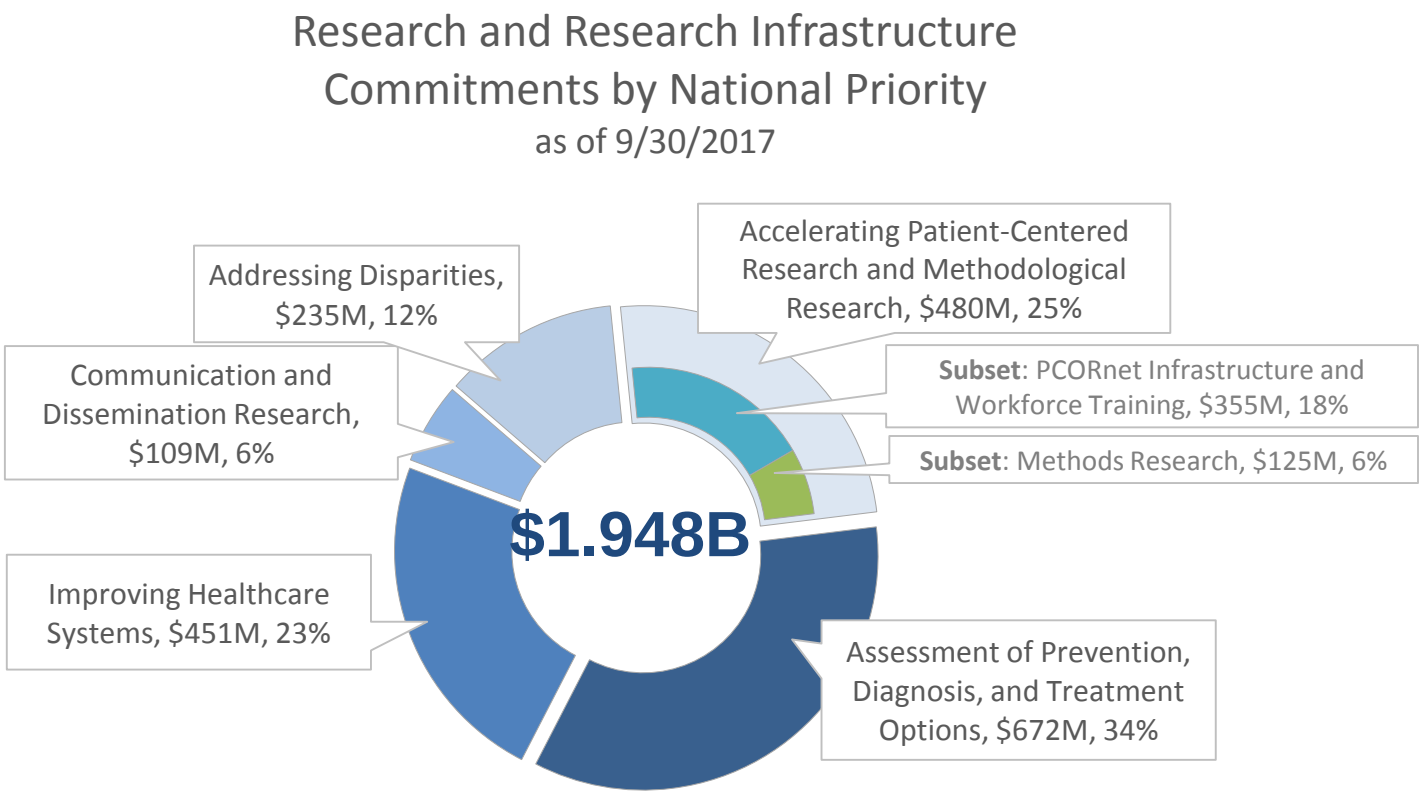
- Implementation of a **training on the responsible conduct of research** for **non-academic research partners**
- Bolstered services offered through **Community Engagement** component of the UAMS Translational Research Institute to mentor ~25 UAMS researchers

[Peter Kohler, MD & Pearl McElfish, Ph.D; July 2017]

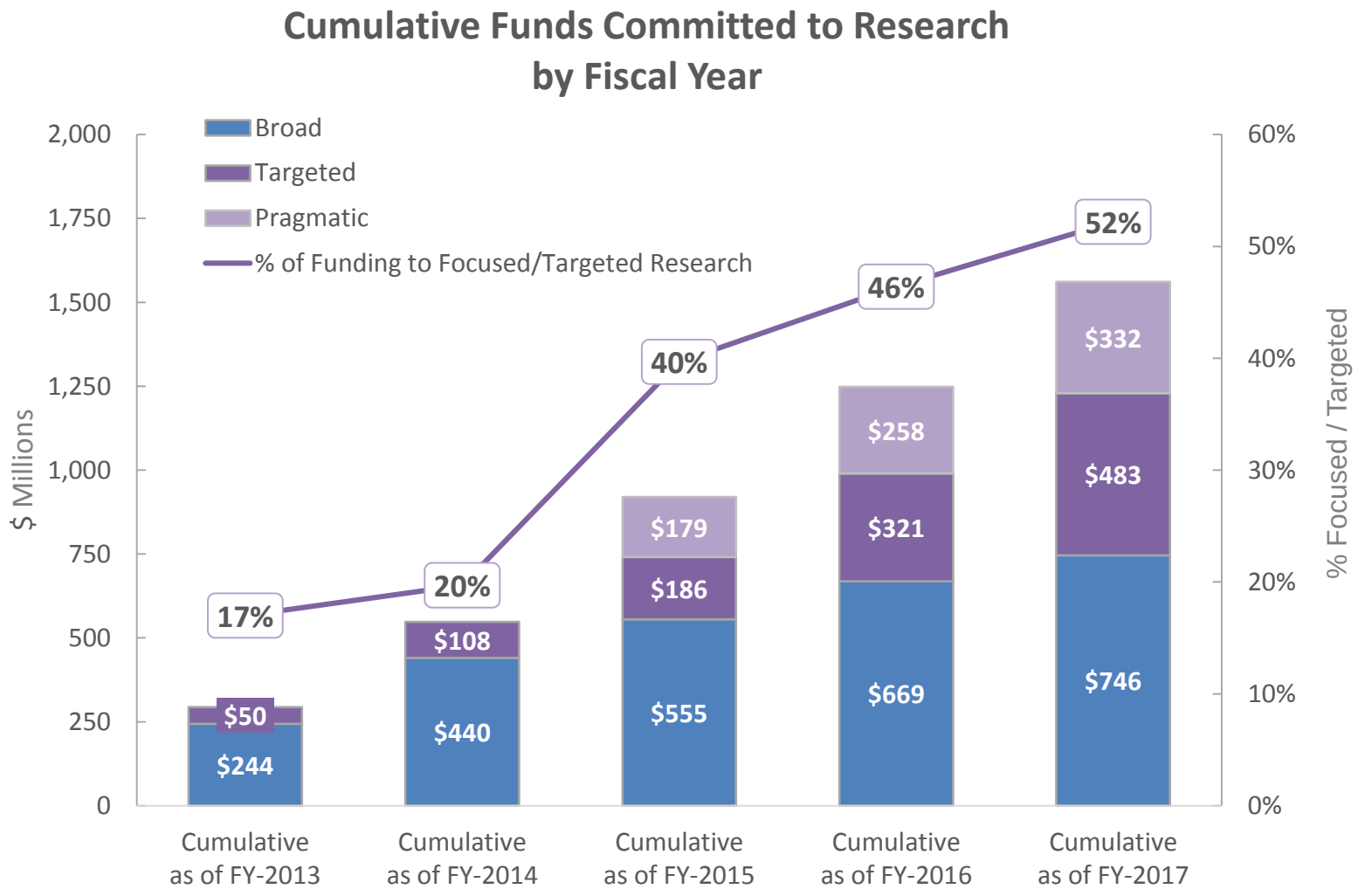
$1.95B Committed to Research through FY-2017



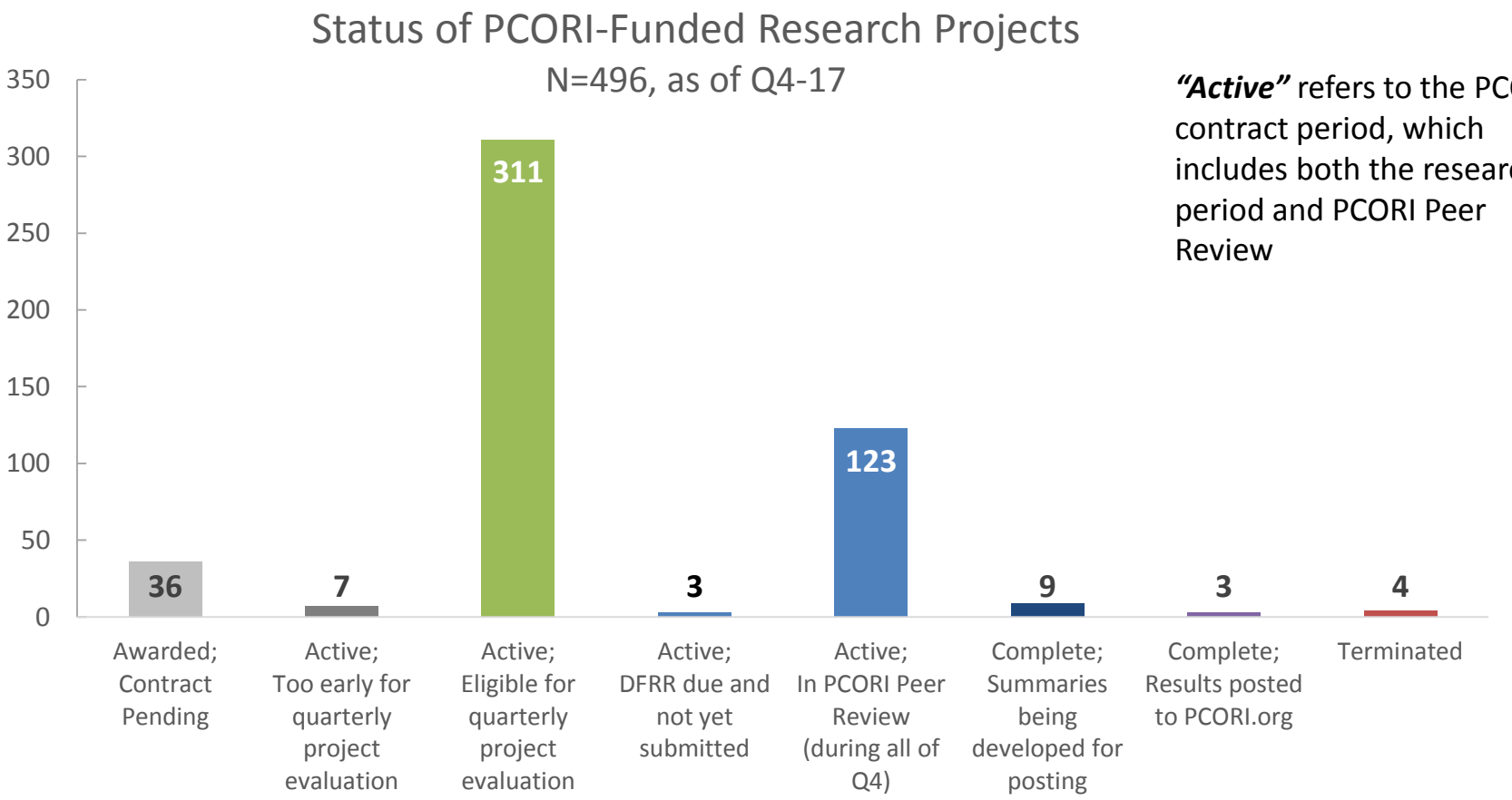
Cumulative Research & Research Infrastructure Funding Commitments by National Priority for Research as of FY-2017



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



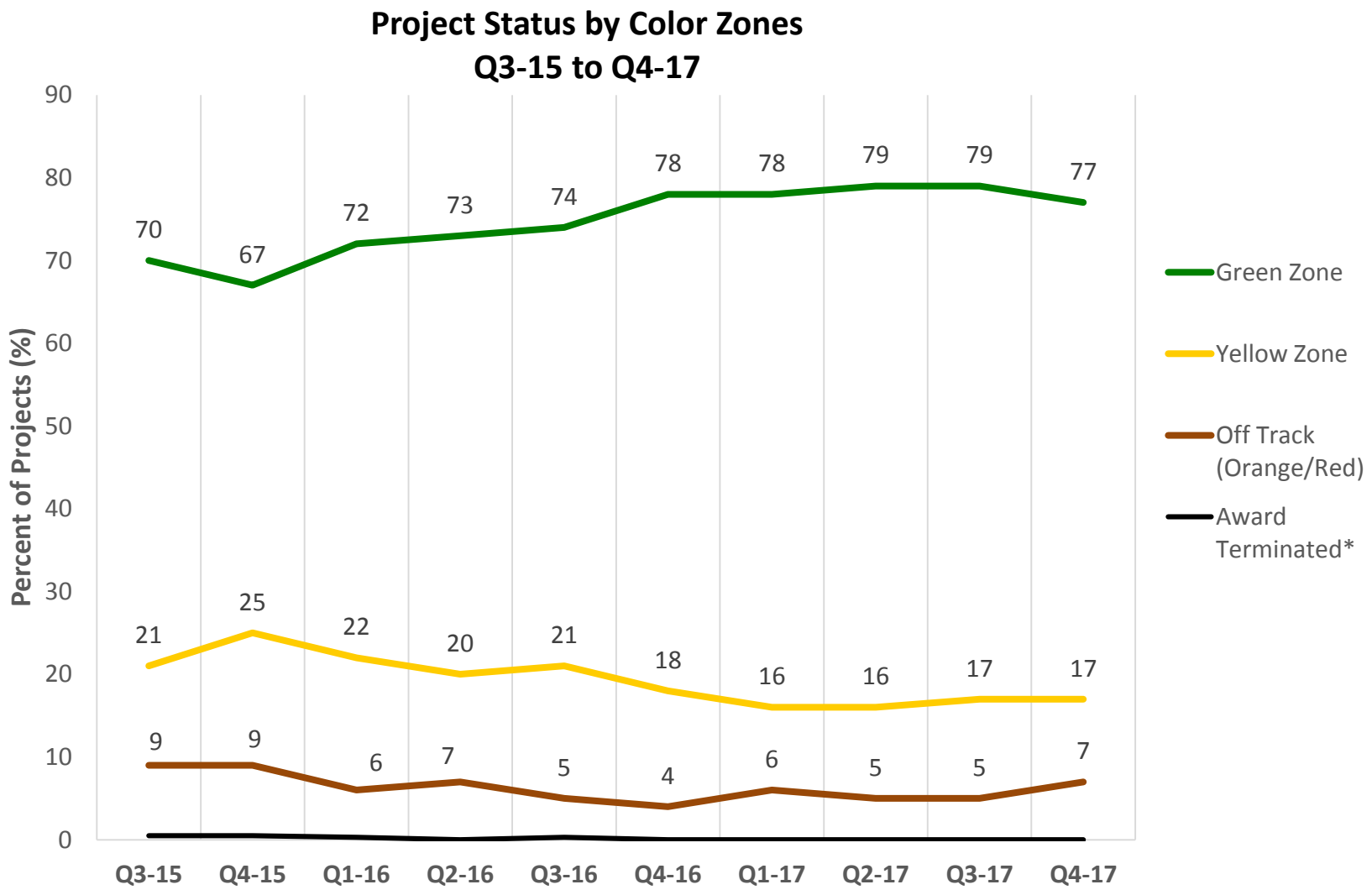
Status of PCORI-Funded Research Projects



"Active" refers to the PCORI contract period, which includes both the research period and PCORI Peer Review

*Does not include Pilots, Infrastructure, or D&I awards
*Does not include studies awarded in Q1-2018
*This slide includes a correction identified during the original presentation

We are monitoring trends and shifts in project status

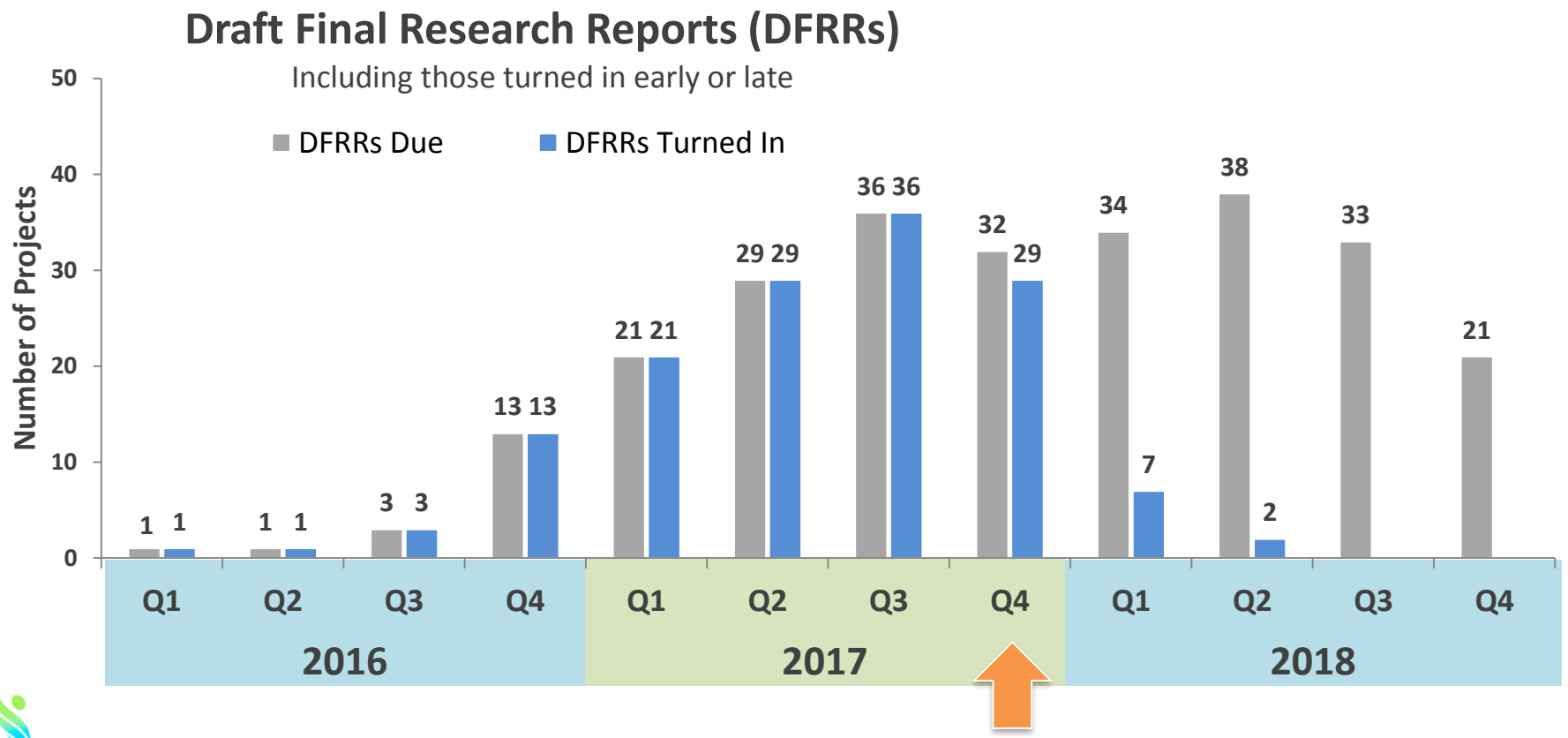


*Notice of Termination Issued, <1% in each quarter

Draft Final Research Reports Submitted

Trends Over Time

This figure shows that many DFRRs due in early 2018 have already been turned in



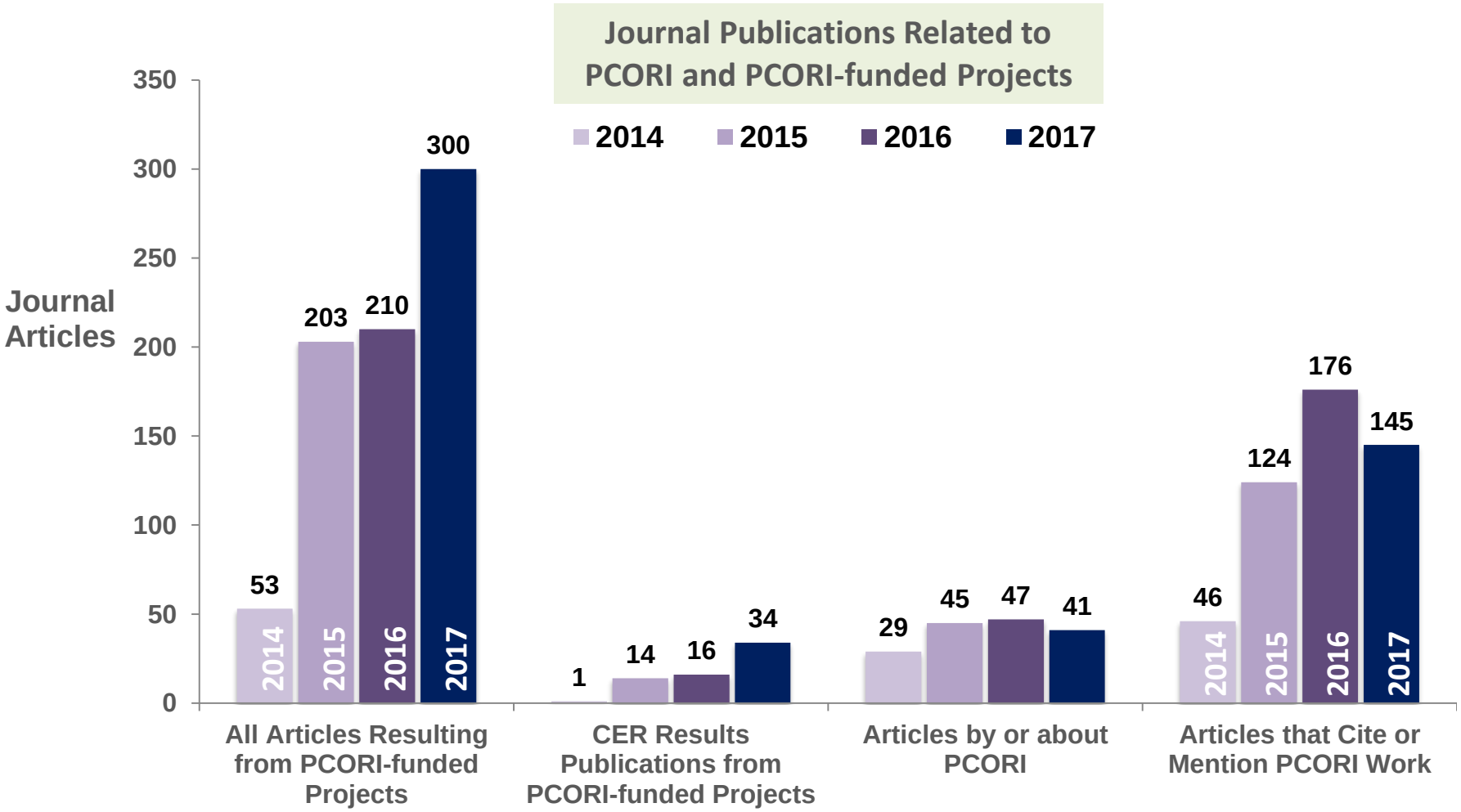
PCORI Peer Review Process and Public Release of Findings

Studies in PCORI Peer Review Process or Completed PCORI Peer Review
N=135, as of Q4-17

We expect **40-50** studies to be completed by end of Q1-18 (Dec 31st)

*Does not include Pilots, Infrastructure, or D&I awards

Journal Publications by Year

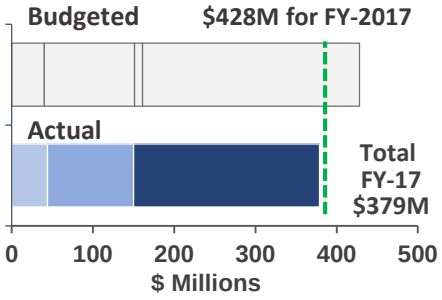


Board of Governors Dashboard
Fourth Quarter FY-2017 (As of 9/30/2017)

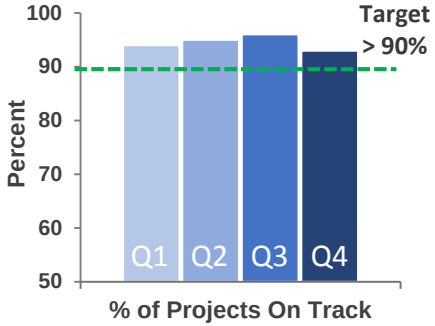
On Target
Off Target
Needs Board Attention
Too Early to Evaluate / No Target
Projected/Target
Q1 2017
Q2 2017
Q3 2017
Q4 2017

Funds Committed to Research

Includes funds committed to PCORnet

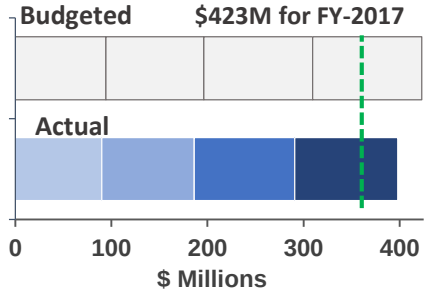


Project Performance

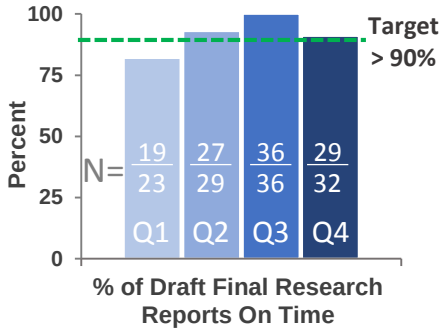


Budget

Operating Budget and Research Awards

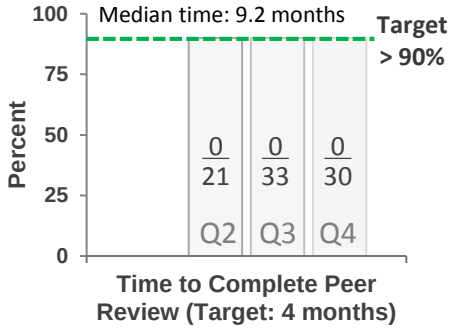


Draft Final Research Reports

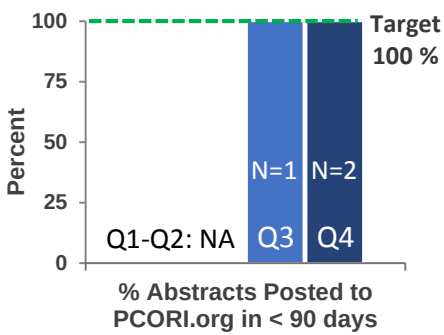


PCORI Peer Review

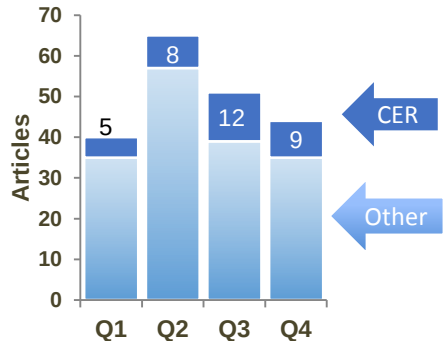
Completed as of Q4: 12
Median time: 9.2 months



Public Reporting of Research Findings

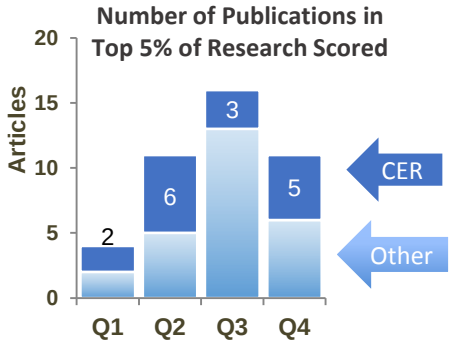


Results Published in Literature



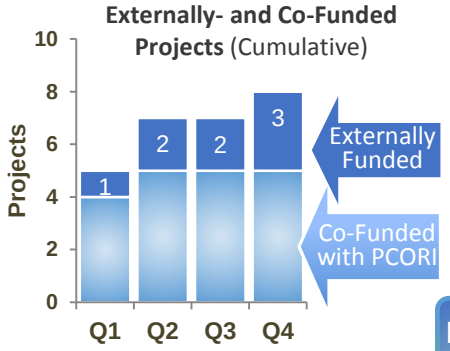
Altmetrics

Number of Publications in Top 5% of Research Scored



External Funding in PCORnet

Externally- and Co-Funded Projects (Cumulative)



Inputs
Process
Outputs
Uptake
Use
Impact

Narrative Examples

Goal 1: Increasing Information

A PCORI-funded study comparing two programs to prevent falls among older adults found that a group-based standing-exercise program called On The Move is more effective than commonly used seated exercises

Goal 2: Speeding Uptake

PCORI-funded results on self-monitoring of blood glucose have been taken up into practice via UpToDate®, a point-of-care, evidence-based medical resource software used by clinicians globally, and nearly 90% of major academic medical centers in the US.

Goal 3: Influencing Research

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Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors