

Board of Governors Meeting

Via Teleconference/Webinar

December 11, 2018
12:00 PM – 1:30 PM ET

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

12:00 PM

Call to Order, Roll call, and Welcome

12:00 – 12:05

Consider for Approval: Minutes of the November 20, 2018 Board Meeting

12:05 – 12:30

Q4 Dashboard Review and End-of-Year Summary

12:30 – 1:00

Consider for Approval: Additional Applications from the Cycle 1 2018 Slates of Awards

1:00 PM

Wrap up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the November 20, 2018 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

Q4 Dashboard Review and End-of-Year Summary

Joe Selby, MD, MPH

Executive Director

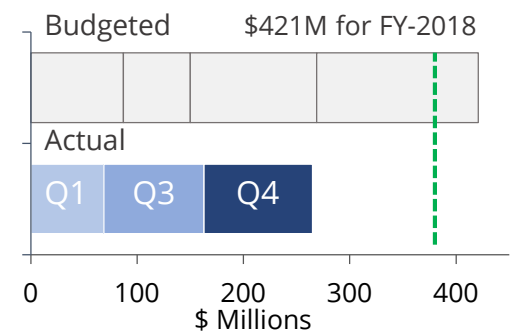
PCORI Board of Governors Dashboard

Fourth Quarter FY-2018 (As of 9/30/2018)

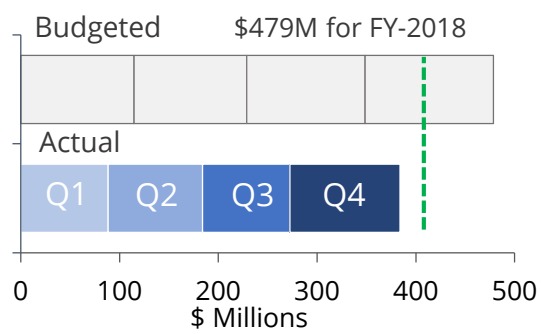
Dashboard Key

- Projected
- Q4 Target
- Meeting Target
- Off Target
- Needs Board Attention
- Target in Development
- Q1 2018
- Q2 2018
- Q3 2018
- Q4 2018

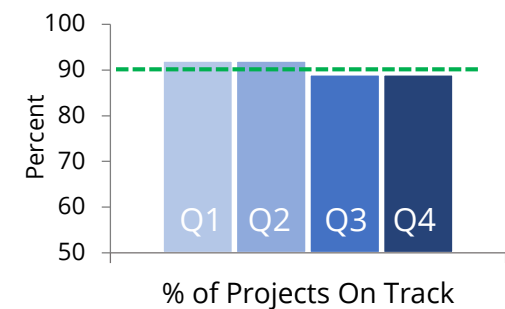
Funds Committed to Research



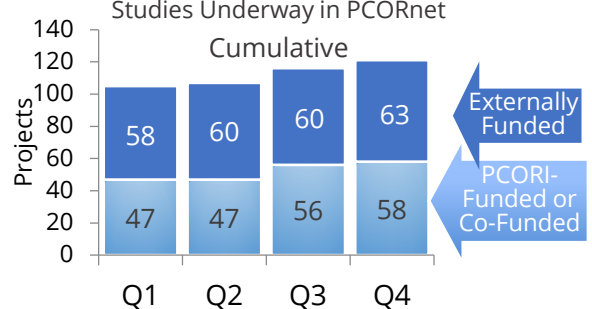
Expenses



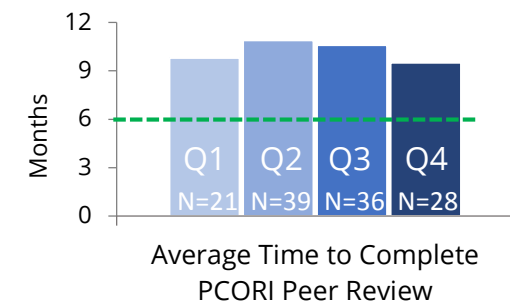
Project Performance



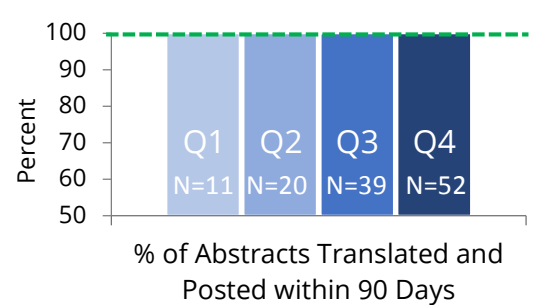
Research Using PCORnet



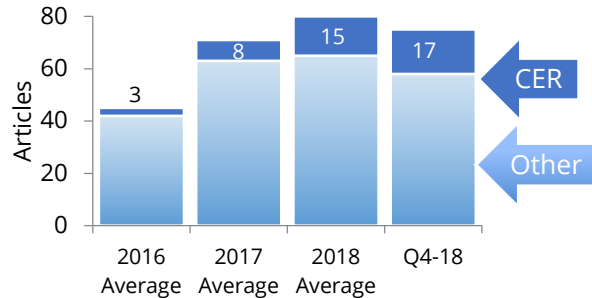
Speed of PCORI Peer Review



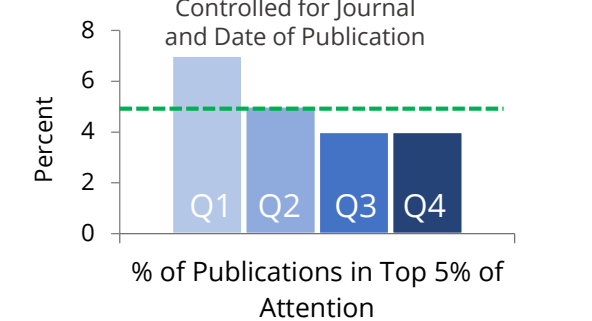
PCORI Abstracts Posted to Website



Results Published in Literature



Altmetric: Attention to PCORI Research



Featured Results on PCORI's Strategic Goals

Results on Goal 1: Increasing Information

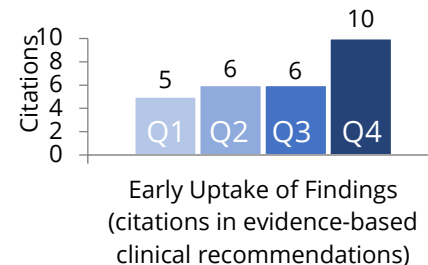
Results Highlight: A PCORI-funded study using PCORnet conducted a cohort study with over 65,000 adults to compare long-term effectiveness of three bariatric procedures. The study found that gastric bypass surgery yields greater weight loss than sleeve gastronomy or adjustable gastric banding.

Results Highlight: A PCORI-funded study compared usual care to a nurse-led program of transitional and self-management support for people hospitalized with COPD. 6 months after discharge, the nurse-led program resulted in fewer COPD-related hospitalizations, fewer ED visits, and better health-related quality of life.

Results on Goal 2: Speeding Uptake

As of Q4, results from PCORI studies have been cited 38 times in evidence-based clinical recommendations

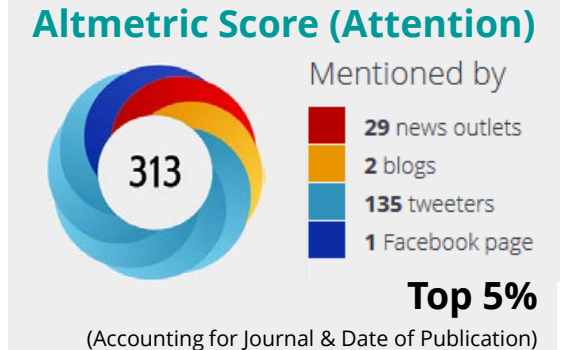
Uptake Highlight: In Q4, results from a PCORI-funded study of transgender people were cited in 4 UpToDate® topic pages. One topic page was updated only one day after results were published.



Goal 1: Results of PCORI-Funded Research

PCORnet Study Shows Gastric Bypass Surgery Yields Greater Weight Loss than Other Procedures

PCORI Study	Study Title: Comparing the Benefits and Harms of Three Types of Weight Loss Surgery -- The PCORnet Bariatric Study Principal Investigator: David Arterburn, MD, MPH, Kaiser Permanente Washington Health Research Institute
Results Publication	Arterburn D, Wellman R, Emiliano A, et al. Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss: A PCORnet Cohort Study. <i>Ann Intern Med.</i> Oct 2018.



Summary: There has been a dramatic shift in use of bariatric procedures, but little is known about their long-term comparative effectiveness.

Using PCORnet, this large retrospective observational **cohort study of more than 65,000 adult patients compared the effectiveness three procedures:** sleeve gastrectomy (SG), adjustable gastric banding (AGB), and Roux-en-Y gastric bypass (RYGB) on total weight loss after 1, 3, and 5 years, and compared 30-day rates of major adverse events.

The study found adults lost more weight with RYGB than with SG or AGB at 1, 3, and 5 years; however, RYGB had the highest 30-day rate of major adverse events. Small subgroup differences in weight loss outcomes were observed. This information can be incorporated into shared decision-making discussions for patients interested in bariatric surgery.

Patient engagement on this study helped shape the research questions. For example, the study included safety as an aim so patients could compare both benefits and risks:



The researchers involved us throughout the project... The researchers and clinicians made changes based on our recommendations. In my experience, research has only had one role for patients in a study: as subjects. In this study, patients were partners in the research process.

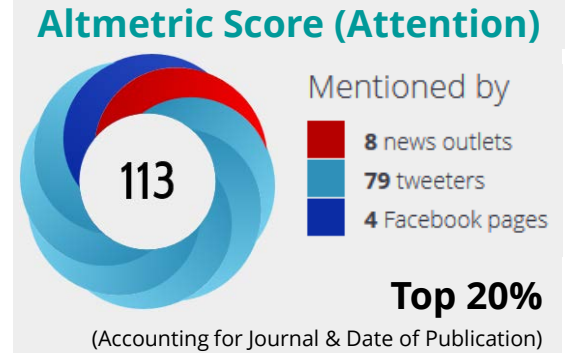
-Rev. Neely Williams, Mdiv
Patient-Principal Investigator
CEO of the Community Partners' Network

Goal 1: Results of PCORI-Funded Research

Self-Management Program for Patients with COPD Improves Quality of Life, Reduces Hospitalizations



PCORI Study	Study Title: An Integrative Multilevel Study for Improving Patient-Centered Care Delivery among Patients with Chronic Obstructive Pulmonary Disease Principal Investigator: Hanan J. Aboumatar, MD, MPH, Johns Hopkins University
Results Publication	Aboumatar H, Naqibuddin M, Chung S, et al. Effect of a Program Combining Transitional Care and Long-term Self-management Support on Outcomes of Hospitalized Patients With Chronic Obstructive Pulmonary Disease: A Randomized Clinical Trial. <i>JAMA</i> . Nov 2018.



Summary: Patients hospitalized for chronic obstructive pulmonary disease (COPD) exacerbations have high rehospitalization rates and reduced quality of life. Helping patients learn how to manage COPD at home may reduce this risk.

This single-site randomized clinical trial compared usual care to a program called BREATHE, a 3-month program that combines transition support and long-term self-management support for patients with COPD and family caregivers, led by COPD nurses.

Compared with usual care, **the program resulted in significantly fewer COPD-related hospitalizations and emergency department visits and better health-related quality of life at 6 months after discharge.**



When a person with COPD gets admitted to the hospital with difficulty breathing, the doctors and nurses focus on their immediate problem and not their chronic disease and overall health... [This program] is one way of reorganizing care in a way that reduces future hospitalization risk and expenses, while preserving patients' quality of life.

-Dr. Hanan Aboumatar, Principal Investigator
Johns Hopkins Medicine [News Release](#)

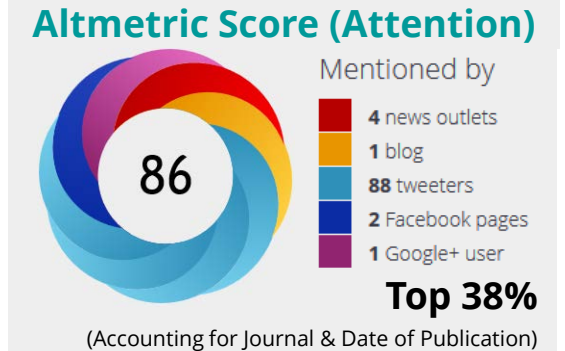
*BREATHE stands for Better Respiratory Education And Treatment Help Empower

Goal 1: Results of PCORI-Funded Research

User-Friendly Advance Care Planning Helps Older Adults in Diverse Populations Guide Future Medical Care



PCORI Study	Study Title: Preparing Spanish-speaking Older Adults for Advance Care Planning and Medical Decision Making Principal Investigator: Rebecca Sudore, MD, University of California San Francisco
Results Publication	Sudore RL, Schillinger D, Katen M, et al. Engaging Diverse English- and Spanish-Speaking Older Adults in Advance Care Planning: The PREPARE Randomized Clinical Trial. <i>JAMA Internal.</i> Oct 2018.



Summary: Advance care planning (ACP) helps align medical care with patients' values and improves patient satisfaction. ACP has recently been approved for reimbursement and recommended as a quality indicator in clinical guidelines.

A majority of older adults have not yet engaged in conversations about ACP, and participation is especially low among diverse patient populations. To mitigate literacy, culture, and language barriers to ACP, easy-to-read advance directives and a program called PREPARE For Your Care were created in English and Spanish.

This randomized trial compared PREPARE plus an easy-to-read directive (PREPARE arm) with an advance directive alone. Compared with the advance directive alone, in both English-speaking and Spanish-speaking populations, **PREPARE resulted in a higher rates of advance care planning documentation** (43% vs. 32%) and **higher patient-reported engagement scores** (98.1% vs 89.5%). Results were significant for both English and Spanish speakers.



Advance care planning is all about empowering patients to have a voice in their health care, to feel empowered to speak up about who they are as a person and what is most important in their life... These results suggest we can empower patients to plan for their future medical care in very scalable ways.

-Dr. Rebecca Sudore, Principal Investigator
UCSF [News Center Article](#)

Goal 2: Speed Uptake and Use of Information

Uptake into Evidence-Based Clinical Recommendations



In Q4-18 alone, results from PCORI-funded studies were cited at least 10 times in evidence-based clinical recommendations. Overall:

15
To date

Total Citations of PCORI-Results in UpToDate®

The 4 new citations in Q4 include topics of discussing goals of care, palliative care, surveillance after colorectal cancer resection, and evaluation and treatment for transgender women

12
To date

Total Citations of PCORI-Results in DynaMed Plus™

The 4 new citations in Q4 include topics of bariatric surgery, obesity in children and adolescents, mechanical circulatory support for heart failure, and posttraumatic stress disorder

11
To date

Total Citations of PCORI-Results in evidence-based clinical recommendations

The 2 new citations in Q4 include topics of diagnosis and management of adults with chronic heart failure, and transgender health

Goal 2: Speed Uptake and Use of Information

Uptake of Results from a PCORI-Funded Study in 4 UpToDate® Topic Pages

Recent results from a PCORI-funded cohort study of transgender people were cited in four UpToDate® topic pages, including one page that was updated **1 day after results were published**. The study examined the largest cohort of transgender people in research to date. The researchers reported in *Annals of Internal Medicine* that transgender women who receive estrogen treatments may face a higher risk for stroke and dangerous blood clots than previously thought

Topic pages titled:

1. Transgender women: Evaluation and management, updated Aug 22, 2018¹
2. What's new in primary care, updated Nov 27, 2018²
3. What's new in family medicine, updated Nov 27, 2018³
4. What's new in endocrinology and diabetes mellitus, updated Nov 27, 2018⁴

Study Title: Comparative Risks and Benefits of Gender Reassignment Therapies

Principal Investigator: Michael Goodman, MD, MPH, Emory University

Getahun D, Nash R, Flanders WD, et al. **Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study.** *Annals of Internal Medicine.* Aug 21, 2018.

¹Tangpricha V, Safer JD. Transgender women: Evaluation and management. In: UpToDate®, Martin KA (ed), UpToDate®, Waltham, MA, 2018

²Melin JA, Kunis L, Givens J, Sokol HN. What's new in primary care. In: UpToDate®, Waltham, MA, 2018

³Melin JA, Kunis L, Givens J, Sokol HN. What's new in family medicine. In: UpToDate®, Waltham, MA, 2018

⁴Martin KA, Mulder JE. What's new in endocrinology and diabetes mellitus. In: UpToDate®, Waltham, MA, 2018

Goal 3: Influence Research

Some Notable Examples of Institutions that Have Credited PCORI with Influencing them to be more Patient-Centered

We collect information via brief semi-structured interviews about how PCORI has influenced the way other researchers or organizations conduct, support, or promote patient-centered outcomes research (PCOR)



❖ Development of CER centers

- University of Pittsburgh Medical Center
- University of Arkansas for Medical Sciences

❖ Creation of PCOR awards programs

- University of Texas Health Science Center at San Antonio
- University of Wisconsin-Madison

❖ Creation of patient or community advisory groups

- Food and Drug Administration Center for Devices and Radiological Health
- Michigan Institute for Clinical Health Research
- American Heart Association

❖ Editorial guidance for people-centered language

- Editorial Board of the journal SLEEP

❖ Shaping graduate level courses

- University of Pittsburgh
- Tulane University
- Harvard University's T.H. Chan School of Public Health
- University of Florida's Clinical and Translational Science Institute

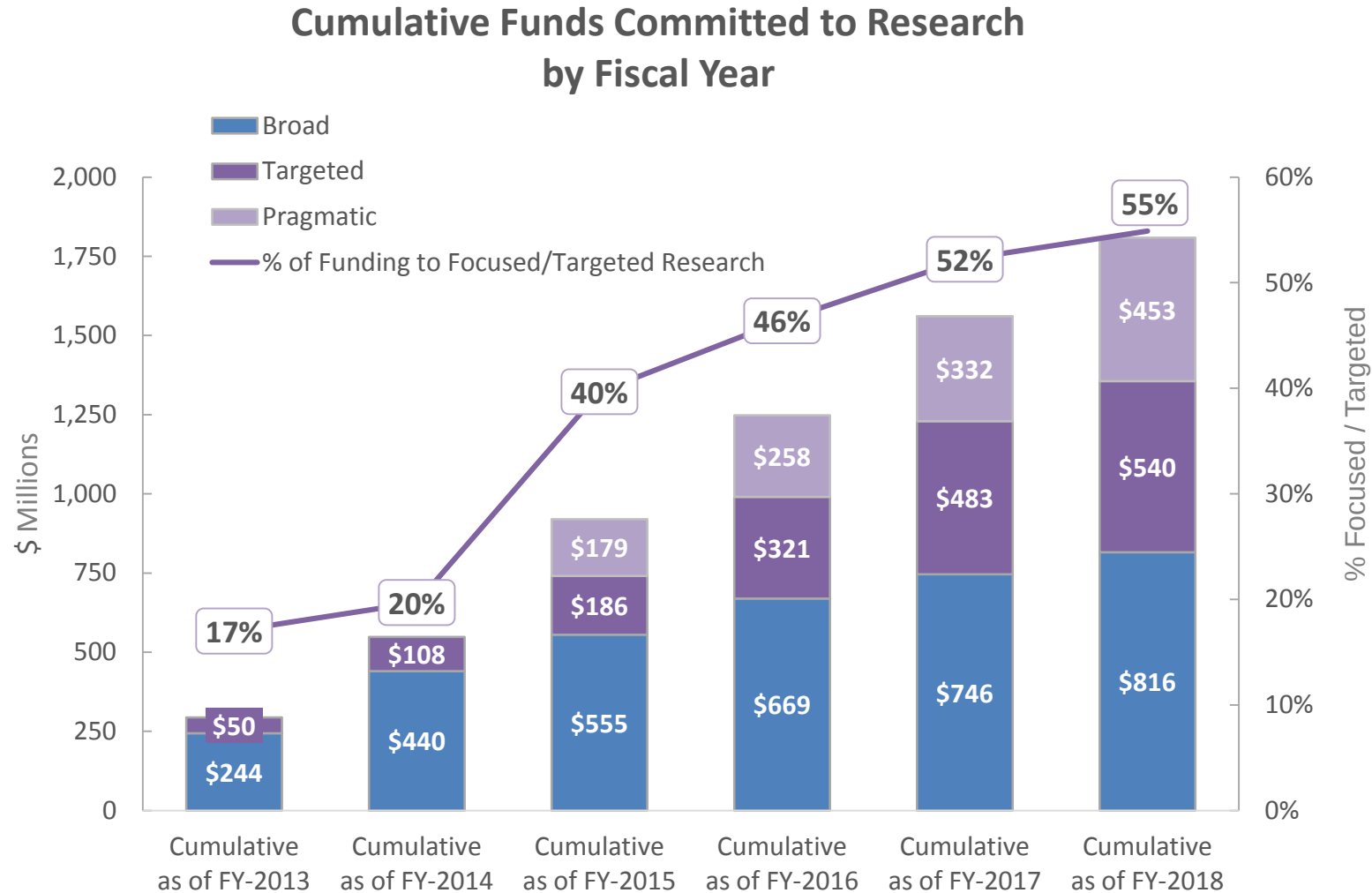
❖ Development of training programs for engagement

- Meharry-Vanderbilt Alliance
- University of Wisconsin-Madison
- University of Arkansas for Medical Science

❖ Development of a Citizen Scientist program

- University of Florida's Clinical and Translational Science Institute

We continue to make progress on our Strategic Priority to “Increase the proportion of research funding going to focused and targeted topics”



PCORI Priority Topics to Date: Active and Funded Topics

Active Topics

Active Targeted PFAs

- Age-Related Hearing Loss
- Anxiety in Children, Adolescents, & Young Adults
- Chronic Pain – Unsafe Opioid Prescribing
- MAT Delivery for Pregnant Women w/Opioid Use Disorders
- Office-Based Opioid Treatment for OUD
- Posttraumatic Stress Disorder in Adults
- Symptom Management for Patients with Advanced Illness

Active Priority Topics for PCS

- Adolescent Alcohol Abuse
- Anxiety in Children, Adolescents, & Young Adults
- Bladder Cancer Treatment
- Care Transitions – Neonatal ICU
- Community-Acquired Pneumonia
- Dental Caries
- Diabetes – Amputations
- Hip Fractures
- Insomnia
- Mental Health Integration – Primary Care Integration
- Osteoarthritis
- Pharmacist Integration in the Care of Patients with MCC
- Preterm Birth & Low Birth Weight
- Remote Delivery of Mental Healthcare
- Suicide Prevention
- Tobacco Cessation

Funded Topics

Funded via PCS

- Bipolar Disorder
- Breast DCIS – Informed Decision Making
- Breast DCIS – Treatment Options
- Crohn's Disease – Biologics
- Chronic Back Pain
- Dental Caries
- Hip Fractures
- Mental Health Integration – Scalable Models; PC Integration
- Migraine – Medication Overuse
- Opioid Use Disorder
- Particle Beam Therapy
- Pulmonary Nodules & CT Surveillance
- Tobacco Cessation
- Traumatic Brain Injury

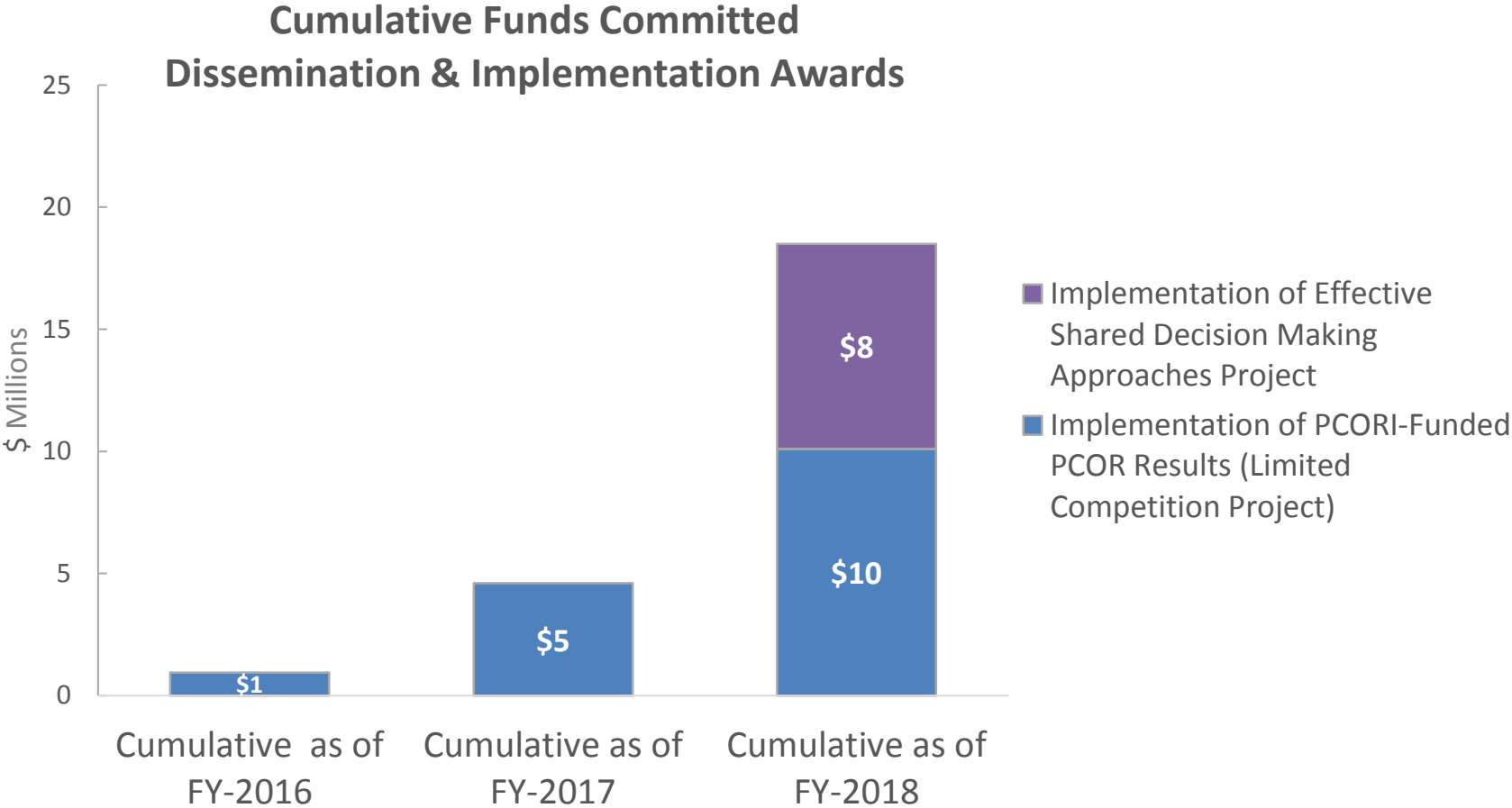
Funded via Limited, PCORnet PFAs

- PCORnet: Health Systems
- PCORnet: CAD – Aspirin Dose
- PCORnet: Diabetes – Natural Experiments
- PCORnet: Obesity

Funded via Targeted PFAs

- Care Transitions – Service Clusters
- Chronic Low Back Pain
- Chronic Pain/Long Term Opioid Therapy
- Chronic Pain – Unsafe Opioid Prescribing
- Falls in Elderly
- Hepatitis C – New Therapies; Hard-to-Treat Patients
- Hypertension
- MAT Delivery for Pregnant Women w/Opioid Use Disorders
- Multiple Sclerosis
- NOACs for Blood Clots
- Obesity
- Palliative Care
- Severe Asthma in African Americans & Hispanics
- Sickle Cell Disease
- Symptom Management for Patients with Advanced Illness
- Treatment-Resistant Depression
- Uterine Fibroids

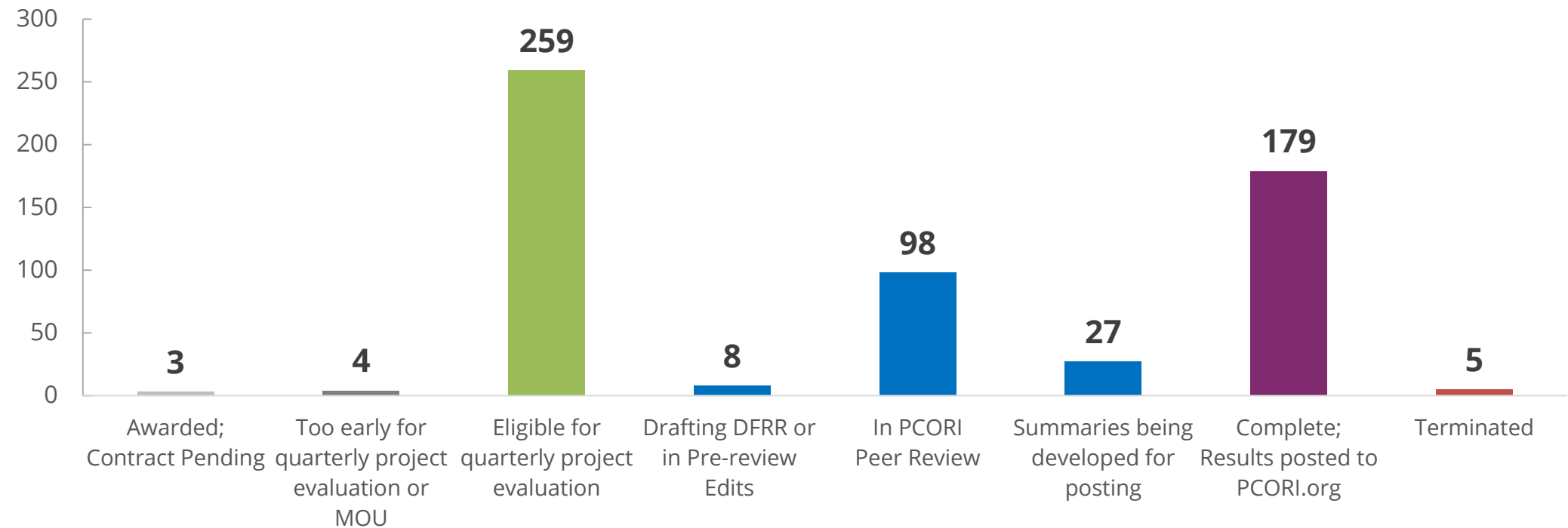
Our Dissemination and Implementation Awards Programs Are Ramping Up



Half of our funded research projects are entering PCORI Peer Review or have been completed, with their results posted to PCORI.org



Current Status of PCORI-Funded Research Projects
N=583, as of Q4-18



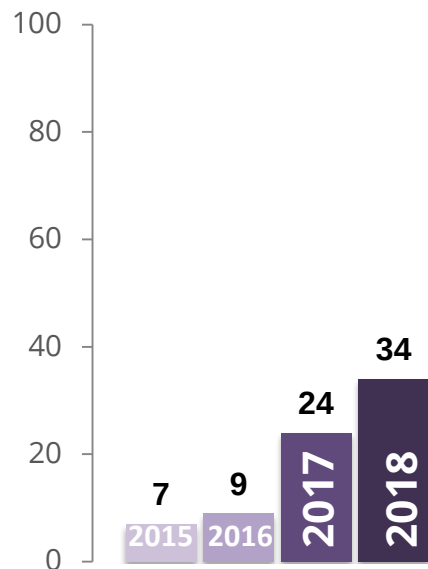
*Includes 50 Pilot Awards & 4 Systematic Reviews
*Does not include Infrastructure or D&I awards
*Does not include studies awarded in Q1-2019

Public Availability of Study Results By Year

Public Availability of Results

Publications of Primary CER Results by Year

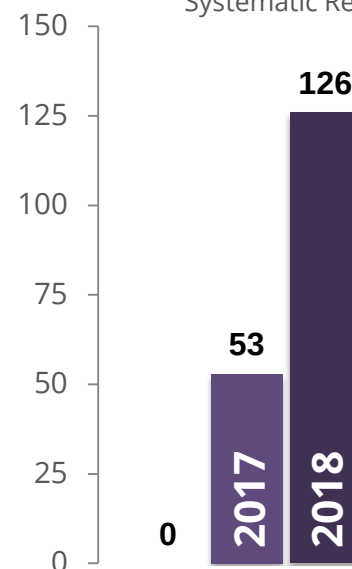
*Some studies publish multiple Primary results papers



Cumulative Primary CER Results Published: 74

PCORI Abstracts with Final Study Results posted to PCORI.org, by Year

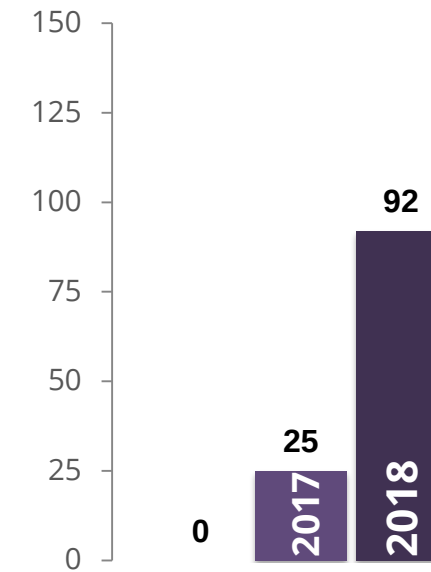
*Includes 50 Pilot Awards and 4 Systematic Reviews



Cumulative Results Posted: 179

Public Availability of CER Results

Studies with Primary CER Results in the Public Domain, either by publication or Abstracts posted to PCORI.org, by Year



Cumulative # of Studies with CER Results Posted: 117

PCORI Board of Governors Dashboard

Fourth Quarter FY-2018 (As of 9/30/2018)

Projected

Q4 Target

Meeting Target

Off Target

Needs Board Attention

Target in Development

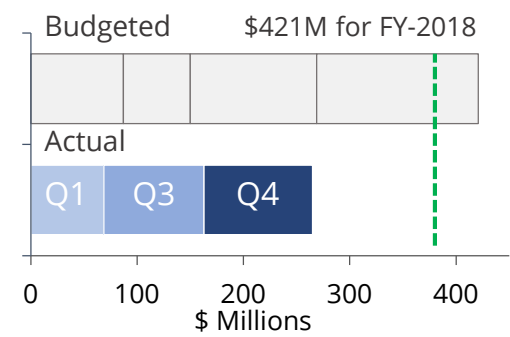
Q1 2018

Q2 2018

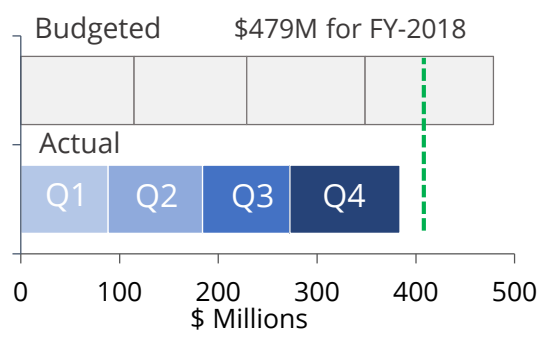
Q3 2018

Q4 2018

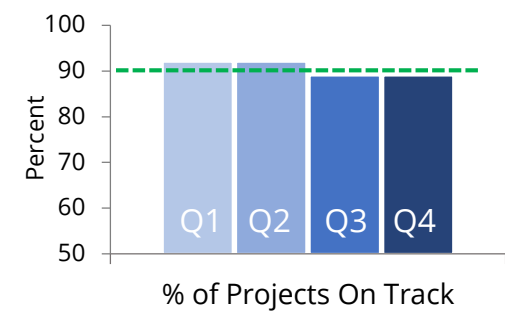
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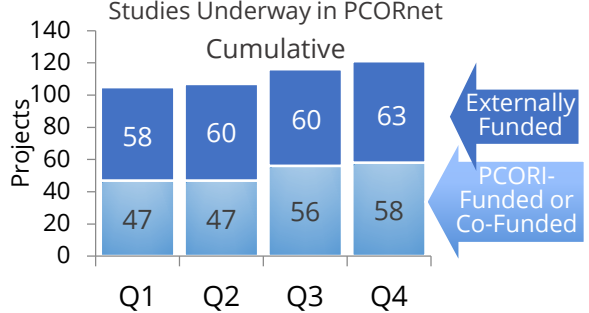
Expenses



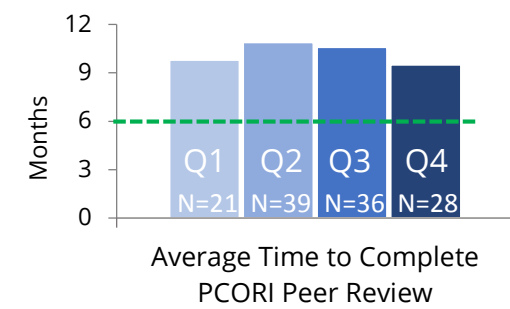
Project Performance



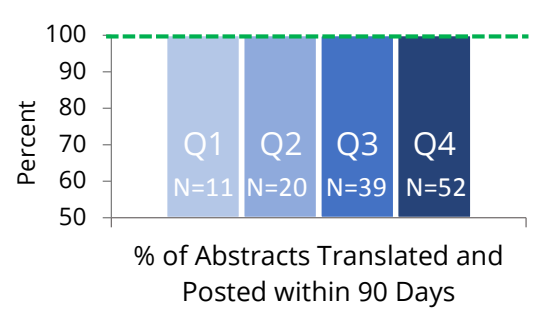
Research Using PCORnet



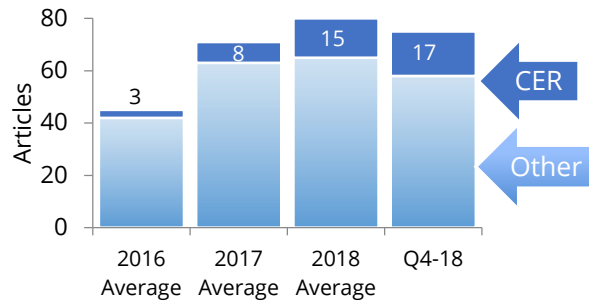
Speed of PCORI Peer Review



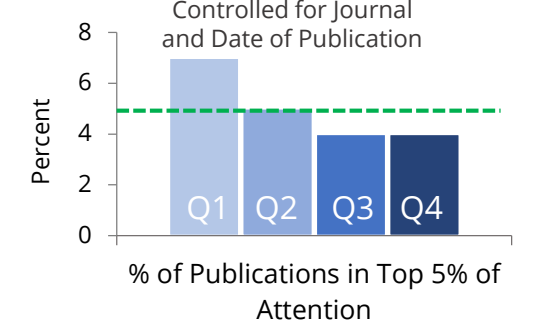
PCORI Abstracts Posted to Website



Results Published in Literature



Altmetric: Attention to PCORI Research



Featured Results on PCORI's Strategic Goals

Results on Goal 1: Increasing Information

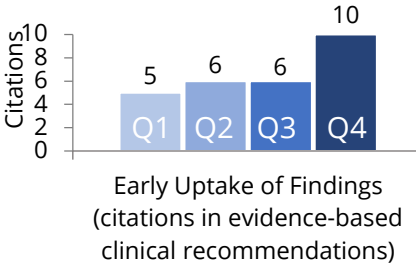
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Results on Goal 2: Speeding Uptake

As of Q4, results from PCORI studies have been cited 38 times in evidence-based clinical recommendations

Uptake Highlight: In Q4, results from a PCORI-funded study of transgender people were cited in 4 UpToDate® topic pages. One topic page was updated only one day after results were published.



Proposed Changes for 2019 Dashboard



Funding Commitments: Update Metric*

- We plan to modify this metric so that it includes all award commitments, including Engagement and Dissemination awards. It will have a small impact on the overall totals, but it will more accurately reflect our total award commitments.

Expenses: Update Metric*

- We plan to modify this metric to reflect only our operational budget expenses. By removing award payments from this metric (which we have relatively less control of and thus difficulty predicting), we will be able to focus on how well we are managing our operational budget.

Altmetric in Context: Update Metric

- We plan to focus on the Altmetric data for CER Results. In addition to controlling for journal and date of publication, by focusing on CER Results we will also control for publication type.

Uptake of Study Results: New Metric

- We have showed this on the Dashboard as a provisional metric, but we will now include it as a regular metric on the Dashboard, and will include all examples of uptake that we can identify. Targets for this metric will be provisional.

PCORI Abstracts Posted to Website: Replace with Uptake Metric

- We have been consistently meeting the target (100% posted within 90 days) since PCORI's Peer Review program started, so we no longer need to monitor it closely on the Dashboard.

Discussion Questions

- Do our FY-2018 Dashboard and associated background materials cover the topics that are most important for the Board to review?
- Does the in-depth focus this quarter on our cumulative results as of the end of the fiscal year and year-to-year trends tell you what you need to know about where we are now and how we got here?
- What changes would you like to see in our FY-2019 Dashboard?

Additional Proposed Study

Cycle 1 2018 Broad Award Slate

Barbara McNeil, MD, PhD

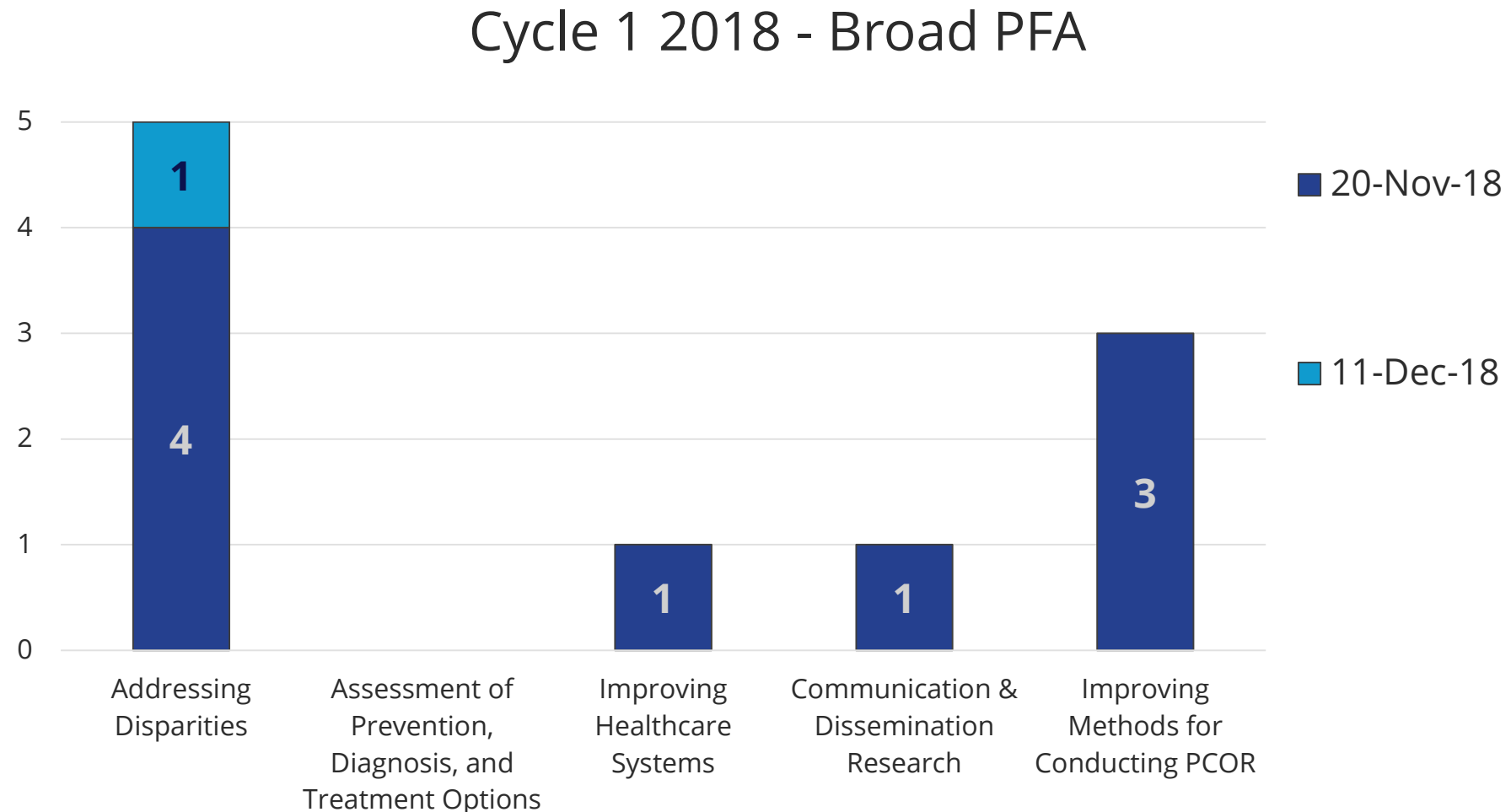
Chair, Selection Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Cycle 1 2018 – Broad PFA Overview

- November 20, 2018 – Board of Governors funded 9 applications out of 80 received applications
 - Funding rate: 11 percent
- Proposed additional study approved by the Selection Committee (SC) on November 13, 2018
 - **10** applications out of 80 received applications
 - Proposed funding rate: **12.5** percent



Cycle 1 – Broad PFA Overview



Broad PFA	Amount Posted	Total Awarded*	Proposed Award
Addressing Disparities	\$8M	\$14.9M	\$7.0M
Assessment of Prevention, Diagnosis, and Treatment Options	\$32M	--	--
Communication and Dissemination Research	\$8M	\$2.8M	--
Improving Healthcare Systems	\$16M	\$5.1M	--
Improving Methods for Conducting PCOR	\$12M	\$2.9M	--
TOTAL	\$76M	\$25.7M	\$32.7M

*Awards approved by the Board of Governors on November 20, 2018

Cycle 1 2018 – Addressing Disparities

1 Additional Recommended Project



Project Title
Reducing Oral Health Disparities of Older Adults: Comparative Effectiveness of 2 Treatments
Reducing Disparities in Behavioral Health Treatment for Children in Primary Care
Peer Online Motivational Interviewing for Sexual and Gender Minority Male Survivors
Leveraging mHealth and Peers to Engage African-Americans and Latinos in HIV Care (LEAN)
Greenlight Plus Study: A Randomized Study of Approaches to Early Childhood Obesity Prevention

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

Cycle 1 2018 – Broad PFA

*Slate Overview: 1 Additional Recommended Project**



Amount Budgeted	Previously Approved Award	Proposed Total Award
\$31M	\$25.7M	\$32.7M

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

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended additional award from the Cycle 1 2018 Broad 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

Additional Proposed Study

Cycle 1 2018 Pragmatic Clinical Studies Award Slate

Barbara McNeil, MD, PhD

Chair, Selection Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Cycle 1 2018 – Pragmatic Clinical Studies

1 Additional Recommended Project



Project Title
Comparing Smoking Cessation Interventions among Underserved Patients Referred for Lung Cancer Screening
Comparison of Surgery and Medicine on the Impact of Diverticulitis (COSMID) Trial
A Multi-Site Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings
Scaling up Psychological Treatments for Perinatal Depression and Anxiety Symptoms via Telemedicine

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

Project 1: Scaling Up Psychological Treatments for Perinatal Depression and Anxiety Symptoms via Telemedicine



- **Research Question:** What is the comparative effectiveness of telemedicine-delivered versus in-person psychological treatments, and of treatment delivered by a nurse versus a specialist for perinatal depressive and anxiety symptoms?
- **Population:** Pregnant and postpartum women ages 18+ in the United States and Canada
- **Comparator(s):**
 - Telemedicine versus in-person delivery of psychological treatments for perinatal depression delivered by EITHER specialists OR non-specialists (4 arms)
- **Outcomes of Interest:**
 - Primary: depressive symptoms
 - Secondary: maternal anxiety symptoms and behavioral satisfaction; child birthweight, length, and mental development; treatment quality and provider satisfaction
- **Potential Impact:** Potential to generate evidence regarding the most effective option(s) for delivering brief psychosocial treatments for perinatal depressive and anxiety symptoms
 - Could increase access to these treatments for underserved women (i.e. addressing the limited number of trained professionals and other physical/financial barriers to access)

Cycle 1 2018 – Pragmatic Clinical Studies PFA

*Slate Overview: 1 Additional Recommended Project**



Amount Budgeted	Previously Approved Award	Proposed Total Award
\$37M	\$28M	\$40.7M

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

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended additional award from the Cycle 1 2018 Pragmatic Clinical Studies 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

Wrap Up and Adjournment

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