

Board of Governors Meeting via Teleconference/Webinar

March 21, 2017

12:00 - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Gray 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 February 28, 2017 Board Meeting
12:05-12:25	Consider for Approval: • Cycle 2 2016 PCS Slate • Additional Cycle 3 2015 Methods Award
12:25-12:45	Consider for Approval: Funding for PCORnet Sustainability
12:45-1:15	Q1 Dashboard Review
1:15	Wrap Up and Adjournment



Board Vote

Call for a Motion to:

- **Approve** the minutes of the February 28, 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



Cycle 2 2016

Pragmatic Clinical Studies Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH

Chief Science Officer



Pragmatic Clinical Studies Cycle 2 2016

Merit Review Criteria

1. Potential for the study to fill critical gaps and generate actionable evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Patient-centeredness
5. Patient and stakeholder engagement



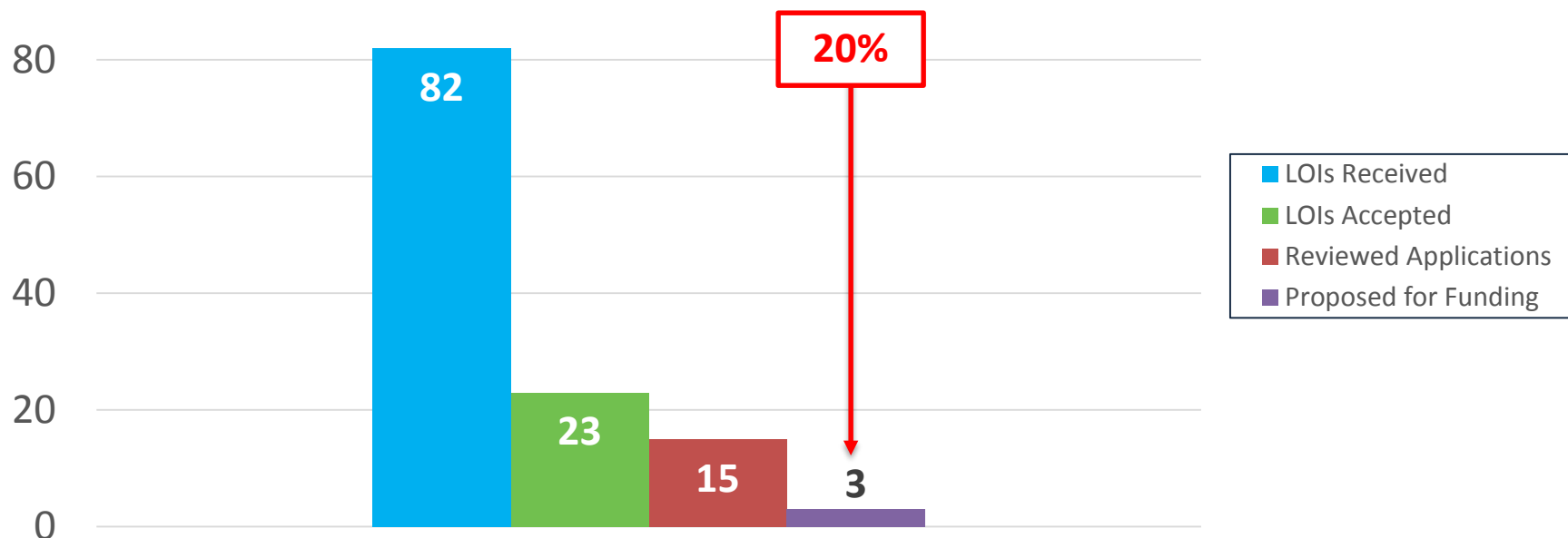
Slate Overview - Pragmatic Clinical Studies Cycle 2 2016

Process Overview

- 82 Letters of Intent (LOIs) submitted
- 23 LOIs invited to submit a full application (28%)
- 15 applications were received (65% of invited LOIs)

Overall funding rate is 20 percent

- We are proposing to fund 3 applications* out of 15 reviewed applications
 - 67% (2) of applications recommended for funding are resubmissions



Pragmatic Clinical Studies – Cycle 2 2016

*Proposed Project Titles**

Project Titles
A Simple Large Trial of Patient-Centered Care for Opioid Use Disorders in Federally Qualified Healthcare Centers and Specialty Care Settings
Operative Versus Non-Operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial
Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury**

*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.

** This project is in alignment with the PCS priority topic on Traumatic Brain Injury.



Project 1: A Simple Large Trial of Patient-Centered Care for Opioid Use Disorders in Federally Qualified Healthcare Centers and Specialty Care Settings

- **Research Question:** What is the **most effective option** for treating vulnerable **patients with opioid use disorder (OUD)** receiving care in Federally Qualified Health Centers (FQHCs)?
- **Population:** Primarily **low-income patients** with **moderate to severe OUD**
- **Intervention:** Personalized Addiction Treatment to Health **(PATH) model within FQHCs**, including Medication-Assisted Treatment and Contingency Management
- **Comparator(s):** **Standard care with referral** to community treatment programs
- **Outcomes of Interest:**
 - Primary: Reduction in opioid use, treatment retention
 - Secondary: Healthcare utilization, employment/educational attainment, social engagement/quality of life outcomes, HIV risk reduction
- **Study Design:** Randomized clinical trial at 4 participating east coast sites
 - Sample Size: 800 patients, primarily from low-income populations
- **Length of Follow-up:** 18 months (6 months post treatment)
- **Duration of Active Intervention:** 12 months from randomization
- **Total Project Cost:** \$13M



Project 1: A Simple Large Trial of Patient-Centered Care for Opioid Use Disorders in Federally Qualified Healthcare Centers and Specialty Care Settings

- **Potential Impact:** Improved access to care, by integrating OUD care at low-income patients' usual source of care (FQHCs), could overcome barriers associated with travel needs and perceived stigma of substance use disorder
- **Patient-Centeredness:** Provides personalized, comprehensive treatment plan within a patient's routine primary care setting as an alternative to standard care provided via referral to a community-based program
- **Engagement:** Patient community advisory board and steering committee with:
 - Advocacy Groups
 - Recovery Prevention Groups
 - Payers
 - Government
- **Implementation/Dissemination or Evaluation Plan:** Dissemination and implementation through committees described above, with reach to over 50 million
 - Spanish translation will facilitate broader dissemination
 - CMS and insurer involvement facilitates broader uptake and payer dissemination



Project 2: Operative Versus Non-Operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial

- **Research Question:** Among patients with an **atraumatic rotator cuff tear**, what is the comparative effectiveness of **operative versus non-operative** treatment?
- **Population:** Patients aged ≥ 50 years with a **symptomatic, atraumatic rotator cuff tear**
- **Intervention:** Arthroscopic surgery
- **Comparator(s):** Physical therapy-directed exercise program
- **Outcomes of Interest:**
 - Primary: Shoulder pain and disability
- **Study Design:** Randomized clinical trial
 - Sample Size: 700 patients from 11 sites
- **Length of Follow-up:** 12 months
- **Duration of Active Intervention:** 3-5 months
- **Total Project Cost:** \$7.5M



Project 2: Operative Versus Non-Operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial (cont.)

- **Potential Impact:** The findings will provide better evidence for guiding more individualized decisions about shoulder surgery
- **Patient-Centeredness:** Because neither surgical nor non-surgical treatment has optimal response rates, this study will address patients' desires for more targeted treatment recommendations
- **Engagement:** Diverse patient and stakeholder board, including patients, clinicians, industry, insurance companies
- **Implementation/Dissemination or Evaluation Plan:** Alliances with national surgical and non-surgical organizations



Project 3: Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury

- **Research Question:** What is the comparative effectiveness of **standardized discharge versus optimized transition care** in improving patient-centered outcomes for patients with Traumatic Brain Injury (TBI)?
- **Population:** Patients with **moderate-to-severe TBI** discharged to community from inpatient rehabilitation facilities
- **Intervention:** Standardized Discharge Care (SDC) **plus** optimized transition care via a TBI care manager
- **Comparator(s):** Standardized Discharge Care (SDC)
- **Outcomes of Interest:**
 - Primary: Participation in usual roles and activities, health-related quality of life
 - Secondary: Healthcare utilization, caregiver burden, process variables
- **Study Design:** Randomized clinical trial
 - Sample Size: 900 patients; 675 caregivers (6 geographically dispersed TBI model system sites)
- **Length of Follow-up:** 12 months post-discharge from inpatient care
- **Duration of Active Intervention:** 6 months
- **Total Project Cost:** \$12.7M



Project 3: Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury (cont.)

- **Potential Impact:** Closes effectiveness gap in patient-centered approaches to overcoming barriers to appropriate provision and coordination of transitional care for TBI patients in order to improve patient quality of life and function
- **Patient-centeredness:** Current practice inadequately supports individuals with TBI and their caregivers leading to poor quality of life following inpatient rehab discharge. TBI care coordinator will provide ongoing social and vocational assistance
- **Engagement:** Strong involvement from patients and caregivers who helped develop the research project. National patient/clinical advocacy groups involved in the steering committee
- **Implementation/Dissemination:** Through health systems, advocacy groups, and payers, as well as the TBI research community. Local and national stakeholders expressed strong support in disseminating and implementing findings



Slate Overview – Cycle 2 2016

Pragmatic Clinical Studies

3
Projects

PFA	Proposed Total Award*
Pragmatic Clinical Studies	\$33.3 Million

* The total award amount in Cycle 2 2016 is within the Board-approved budgeted amount.

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

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 2 2016 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



Additional Proposed Study

Cycle 3 2015 Methods Award Slate

Christine Goertz, DC, PhD
Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer



Improving Methods for Conducting PCOR

*Cycle 3 2015 Funding Slate - 1 Additional Recommended Project**

Project Title

Expansion of Methods for Two-Stage Trial Designs for Testing Treatment, Self-Selection and Treatment Preference Effects

Developing and Validating Quantitative Measures to Assess Community Engagement in Research: Addressing the Measurement Challenge

Linking Randomized Clinical Trials and Claims Data for Enhancing Randomized and Non-randomized Patient-centered Outcomes Evidence Generation

Leveraging Visual Analytics for the Identification of Patient Subgroups: Application to Improving the Prediction of Hospital Readmission in the Elderly

Statistical Methods for Phenotype Estimation and Analysis Using Electronic Health Records

Improving Causal Inference Methods via Statistical Learning with High-dimensional Data

Linking Unique Device Identifiers to Insurance Claims: A Pilot Demonstration

Realization of a Standard of Care for Rare Diseases Using Patient-Engaged Phenotyping

*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.



Slate Overview – Cycle 3 2015

Broad PFAs

Approved
23
Projects

Proposed
23 + 1 = 24
Projects

Previously Approved Awards	Proposed Total Awards*
\$54.4M	\$55M

* The total award amount in Cycle 3 2015 is within the Board approved budgeted amount. No additional funding amount is requested.

*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 3 2015 Improving Methods for Conducting PCOR 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



Request for Approval: Planning for Implementation of the FY17 Funding Commitment Plan to Support PCORnet Sustainability

Joe Selby, MD, MPH

Executive Director

Rachael Fleurence, PhD

Program Director, Research Infrastructure



FY2017 Budget Activities

Budget Line	Total FY17 Approved	Committed	Request	Remaining
Research	up to \$37.0 M	\$7.0 M	\$0.0 M	\$30.0 M
Infrastructure (capacity building)	up to \$34.2 M	\$8.8 M	\$25.4 M	\$0.0 M

- PCORI's goal is to provide infrastructure resources to develop a sustainable PCORnet by the end of Phase II
- A workgroup within PCORnet developed the proposal to move PCORnet to sustainability by forming an independent, non-profit entity
 - New entity incorporated under the name, the People-Centered Research Foundation (The Foundation) on March 16, 2017



Progress since the February PCORI Board Meeting

- The People-Centered Research Foundation was incorporated in the District of Columbia as a nonprofit with tax exempt status. *(IRS review is pending, but expectation is that the Foundation will be a 501(c)(3))*
 - The Foundation's goal is to advance and support PCORnet's legacy of Patient/People-Centered research
 - Patient-centeredness and engagement are instantiated in its Articles of Incorporation, Bylaws, and People-Centricity Policy
- Initial Board Members will meet for first time in March/April to ratify the Bylaws and other initial policies (i.e., Conflict of Interest, People-Centricity)



Implementing the FY2017 Funding Commitment Plan

- The goal will be to accelerate business development and performance of expanded research through PCORnet and to support sustainability
- Funds will be used to support PCORI's goal for a sustainable PCORnet through infrastructure funding to the Foundation to:
 - Support activities at the Foundation's Program Office
 - Expand the data and clinical trial capabilities of PCORnet
- Funding would be awarded for a two-year term via a cost-reimbursement infrastructure contract

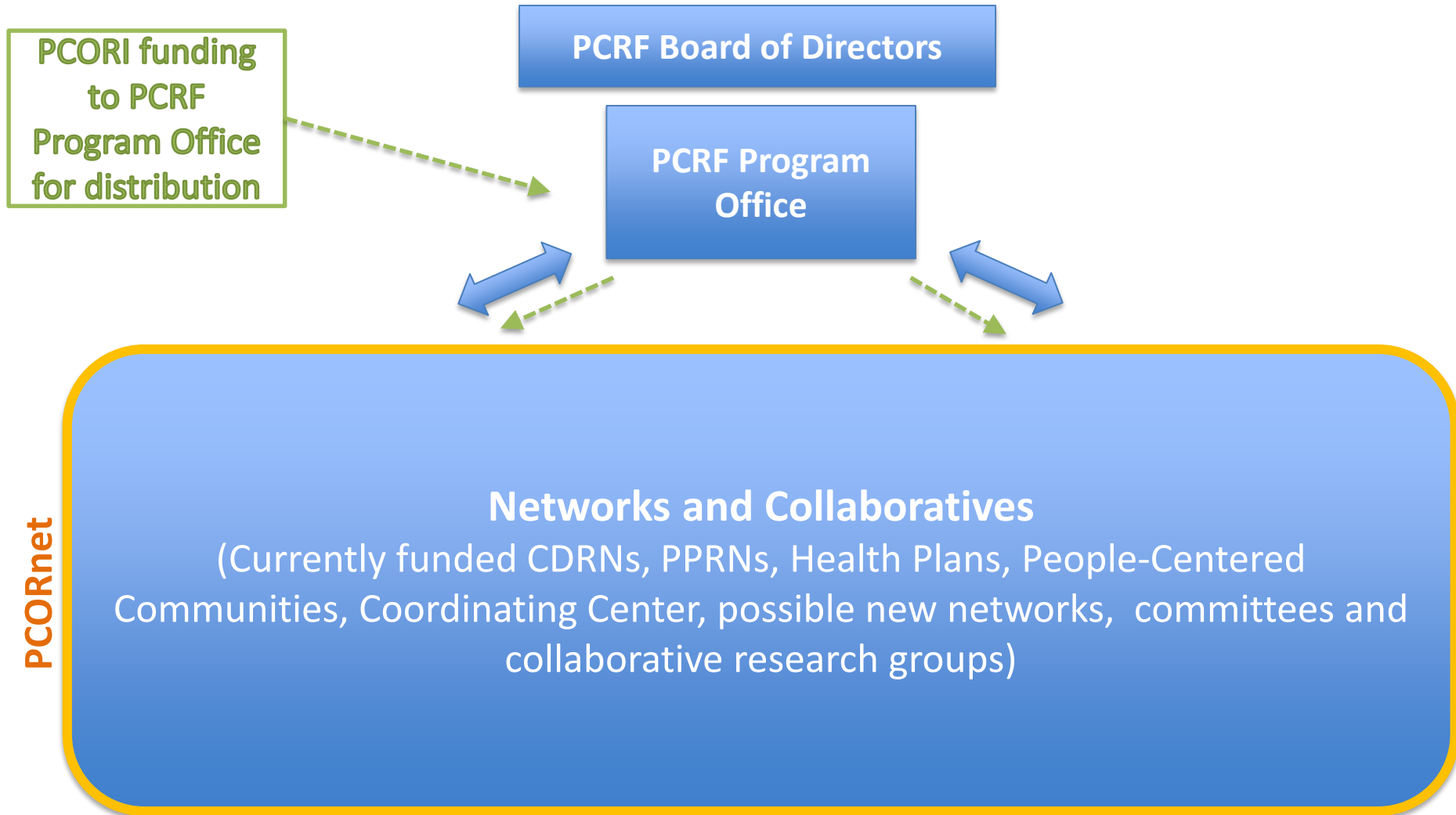
Request is within the approved FY2017 funding commitment plan for PCORnet research and infrastructure.

This specific request was initially endorsed by the Research Transformation Committee (RTC) on December 19, 2016.



Funds Flow Through the Program Office to PCORnet Partner Networks

The People-Centered Research Foundation (PCRF)

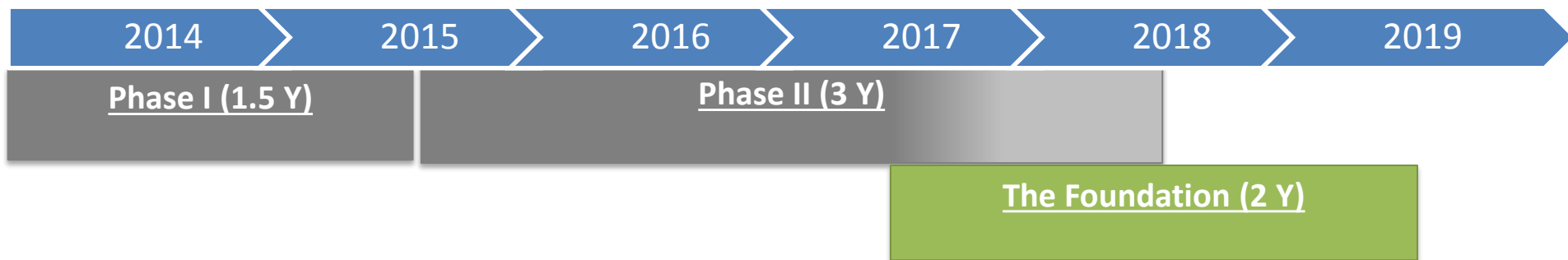


Funding will be Awarded through a Cost-reimbursable Master Contract

- Master Contract with discrete statements of work allows staged implementation and flexibility as the Foundation develops
- Payments are tied to defined milestones and deliverables within the contract
- Evaluations throughout the course of the award to monitor progress
- Budget proposed is a maximum budget – PCORI staff will negotiate each budget item and discuss the timing of each statement of work
- PCORI's RTC will continue to oversee and will be consulted and informed throughout the contract



Funding to the Foundation will Expand Upon the Current Infrastructure Investment



Infrastructure Funding Directed to the Foundation

<u>Activity</u>	<u>Cost (M)</u> <u>(2017 – 2019)</u>
Program Office (initial statements of work) - Implement governance for a working relationship between the Foundation and PCORnet partner networks - Implement business development strategies for ongoing sustainability	\$2.0
Data and Network Nodes (subsequent statements of work) - Expand the volume of standardized data in the PCORnet Common Data Model - Add additional sources of data (i.e. registries and claims) - Support data linkages between people-centered communities and health systems - Support addition of new networks	\$23.4
Budget Request	\$25.4

PCORI's FY2017 Budget has \$25.4M remaining to commit to PCORnet infrastructure. Additional infrastructure funding is available in FY2018, pending Board approval.



Initial Statements of Work: Program Office

- **Governance**

- Implement governance structure and policies to ensure smooth functioning within the foundation and between the Foundation and PCORnet partner networks
- Form and implement Foundation Committees
- Develop criteria for the partnerships between the Foundation and PCORnet partner networks

- **Operations**

- Develop contracting mechanisms between the Foundation and PCORnet partner networks
- Develop research contracting mechanisms and pricing models for the Foundation
- Implement processes and procedures for operational and financial management for the Foundation
- Implement the strategic communications plan to support the business model
 - Implement a branding strategy



Initial Statements of Work: Program Office

- **Research Portfolio**
 - Implement a strategic business development plan that secures a diverse and balanced portfolio of research funded by government, industry, foundations, and other sources to enable participating PCORnet network partners to both lead and participate in mission-aligned, people-centered research
- **Engagement**
 - Implement policies to meaningfully engage people, including both patients and clinicians, in all aspects of research and organizational governance
- **Data Network**
 - Establish the role of the Foundation in oversight and strategic development of the Data Network in close collaboration with the PCORnet Coordinating Center and PCORnet partner networks



Board Vote

Call for a Motion to:

- **Approve** up to \$25.4 million to support the Foundation program office and infrastructure expansion over the next two-years, subject to negotiation of final terms and conditions.

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



Dashboard Review

First Quarter of FY-2017

Joe Selby, MD, MPH

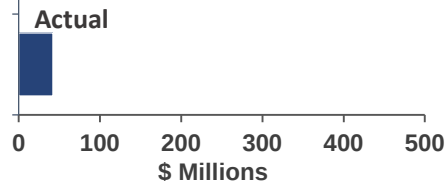
Executive Director



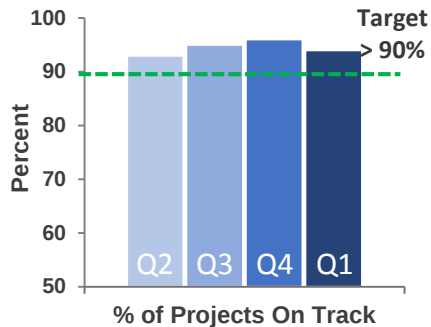
Funds Committed to Research

Includes funds committed to PCORnet

Budgeted \$428M for FY-2017



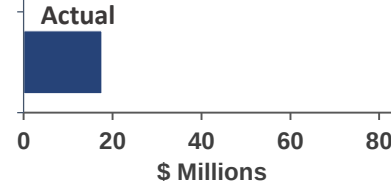
Project Performance



Operating Budget

Does not include Research Awards

Budgeted \$81M for FY-2017



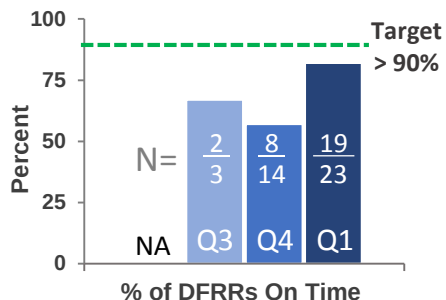
Narrative Examples

Goal One

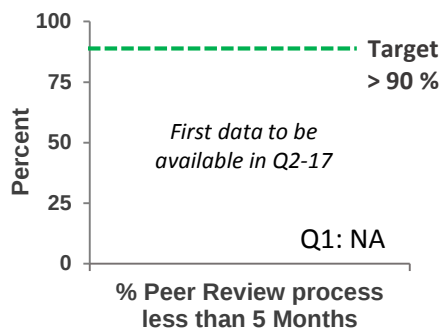
Increasing Information

Use of a decision aid in patients with low risk **chest pain** increased understanding of risk and safely decreased the rate of admission to an observation unit for cardiac testing

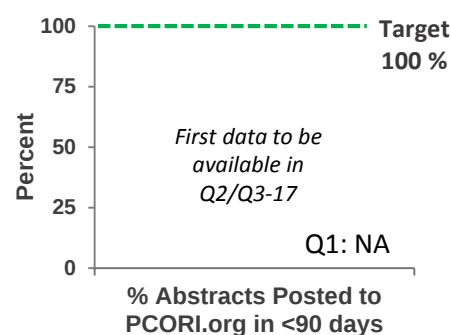
Draft Final Research Reports



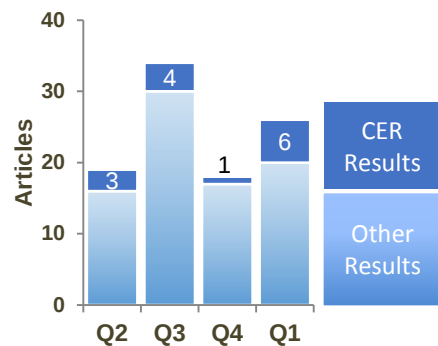
PCORI Peer Review



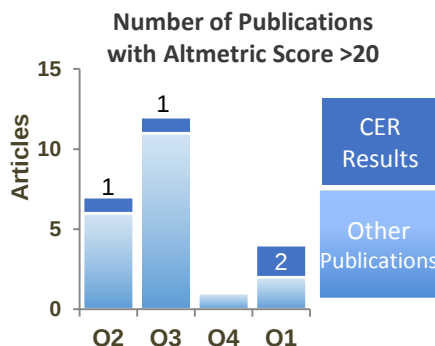
Public Reporting of Research Findings



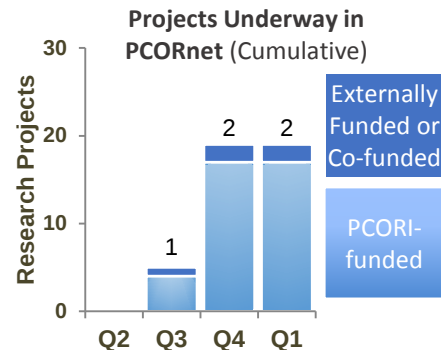
Results Published in Literature



Altmetrics



Research in PCORnet



Inputs
Process
Outputs
Uptake
Use
Impact

Goal Three

Influencing Research

PCORI is credited as a model for Henry Ford Health System's **Patient Engagement Research Center** (PERC), which brings together researchers and patient advisory groups to improve patient care

Results of PCORI Research:

Shared Decision Making in ED for Evaluation of Low Risk Chest Pain Safely Decreases Hospital Admissions

Chest pain is the second most common reason patients visit emergency departments across the United States. To avoid missing a heart attack diagnosis, doctors frequently admit patients to the hospital even when they are at very low risk. These low-risk admissions result in unnecessary testing, patient anxiety, and disruption in patients' lives, as well as increased healthcare costs.

This study compared the effectiveness of shared decision making vs. usual care in choice of admission for observation and further cardiac testing or for referral for outpatient evaluation in patients with low risk chest pain. ***Use of the decision aid increased patient knowledge about their risk, increased engagement, and safely decreased the rate of admission to an observation unit for cardiac testing.***

Hess EP, Hollander JE, Schaffer JT, et al. **Shared Decision Making in Patients with Low Risk Chest Pain: Prospective Randomized Pragmatic Trial.** *BMJ*. December 2016. 355:i6165

Results (Abstract): Compared with usual care, patients using the decision aid had greater knowledge of their risk for acute coronary syndrome and options for care (questions correct: decision aid, 4.2 v usual care, 3.6; mean difference 0.66, 95% CI 0.46 to 0.86), were more involved in the decision (observing patient involvement scores: decision aid, 18.3 v usual care, 7.9; 10.3, 9.1 to 11.5), and less frequently decided with their clinician to be admitted for cardiac testing (decision aid, 37% v usual care, 52%; absolute difference 15%; $P < 0.001$). There were no major adverse cardiac events due to the intervention.



- Awarded 2012, Assessment of Prevention, Diagnosis, and Treatment Options project
- Principal Investigator: Erik Paul Hess, MD, MS, Mayo Clinic



Patients can be effectively educated and engaged in the emergency care setting in decisions about testing and follow-up... it is feasible to do so in the flow of clinical care.



Dissemination of Results:

D&I Project for Preventing Venous Thromboembolism (VTE)

AHRQ has called VTE prevention in patients the number one strategy to improve patient safety in hospitals. A PCORI-funded study found that patients want to be educated on VTE, and that educating bedside nurses and implementing a patient-centered education intervention led to significant reduction in non-administration of VTE prophylaxis.

PCORI Dissemination Project:

This project aims to scale up the implementation of a patient-centered VTE prevention education intervention in 2 settings:

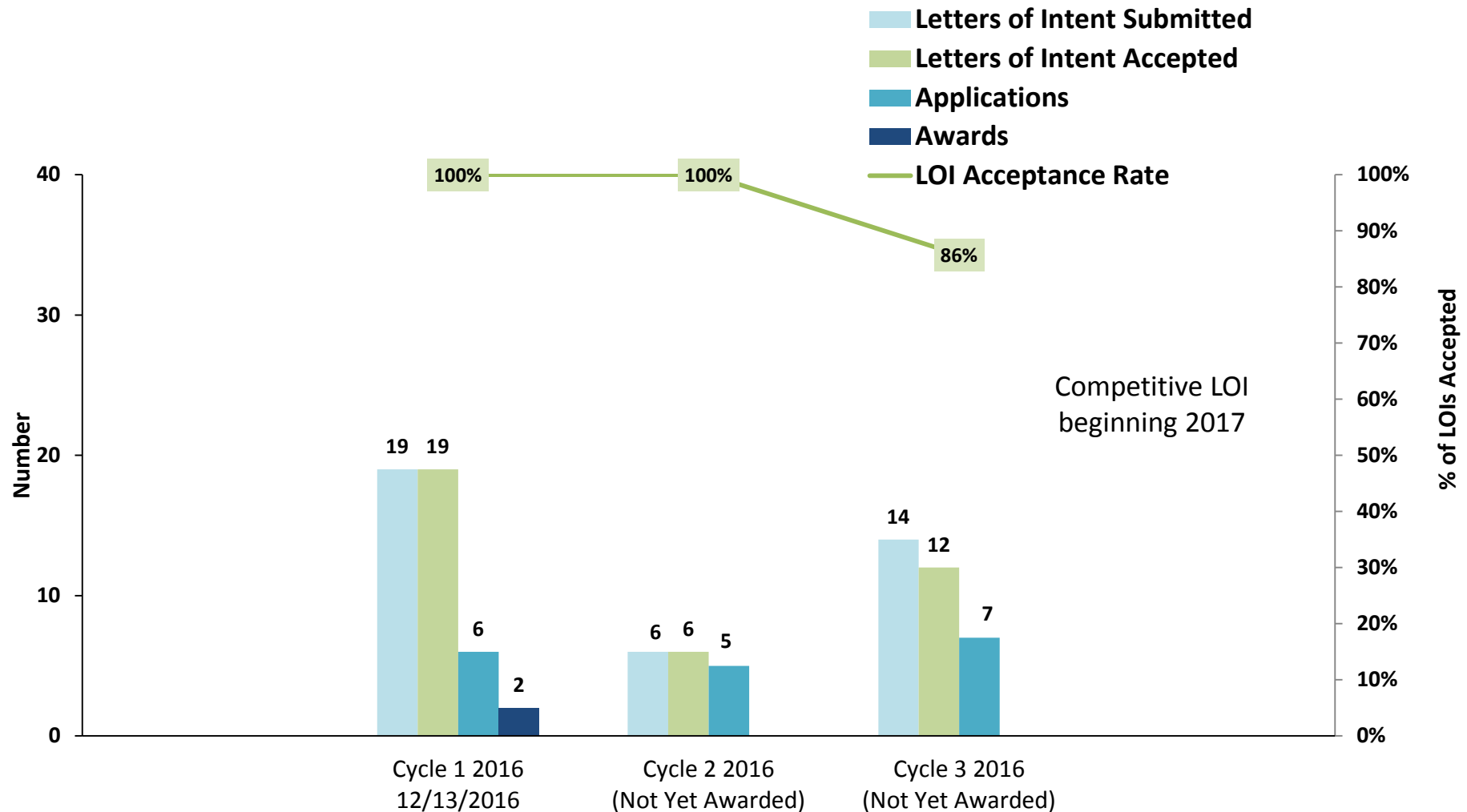
1. To all floors of the large, academic teaching hospital where the intervention was originally tested (Johns Hopkins)
2. To all floors of a medium-sized community, suburban, non-teaching hospital

The goal is to decrease refused doses of VTE prophylaxis among inpatients within these two hospitals. If successful, this D&I project will result in improved quality of patient-nurse communication and more informed patient decisions regarding the choice to take VTE pharmacologic prophylaxis.



D&I PFA - Limited Competition

LOIs, Applications, and Awards (All Cycles)



Influence Example:

PCORI Credited with Serving as a Model for Patient Engagement in Research at Henry Ford Health System

PCORI is credited with serving as a *model for patient engagement* at **Henry Ford Health System Patient Engagement Research Center (PERC)**, which was created to develop the [infrastructure](#) for patient-centered outcomes research at Henry Ford Health System and improve the way Henry Ford delivers patient care and treatment of diseases. An [AHRQ grant](#) was awarded in 2013.

Goal: Henry Ford's flexible engagement model facilitates meaningful dialog between patients, caregivers, physicians and researchers to address topics that matter to all.

Results of the PERC include:

- Educating and engaging stakeholders through:
 - Creation of a diverse Patient Advisor group (~300 currently enrolled)
 - Building Patient Advisors skills to collaborate as full members of research teams.
 - Implemented an education module to prepare researchers for effective engagement
- Expanding dedicated resources for 4 research function cores:
 - Patient Engagement
 - Study Design, Analysis and Measurement
 - Patient Data Network
 - Dissemination and Implementation



PCORI's support, resources and guidance have been key to PERC's success, particularly PCORI website resources, and monthly guidance from the Pipeline to Proposal team— Karen Kippen

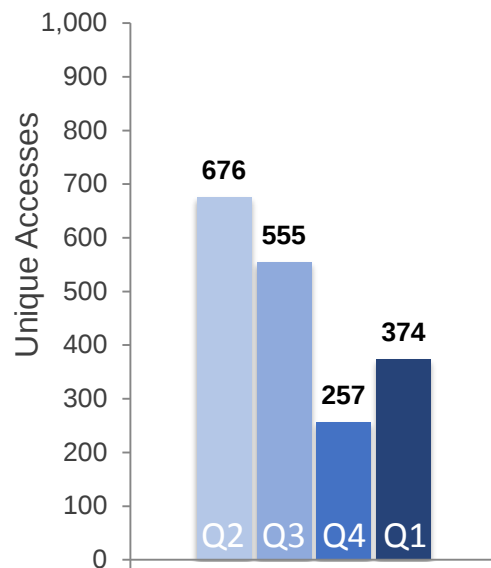


Influence on Research: Uptake of the PCORI Engagement Rubric

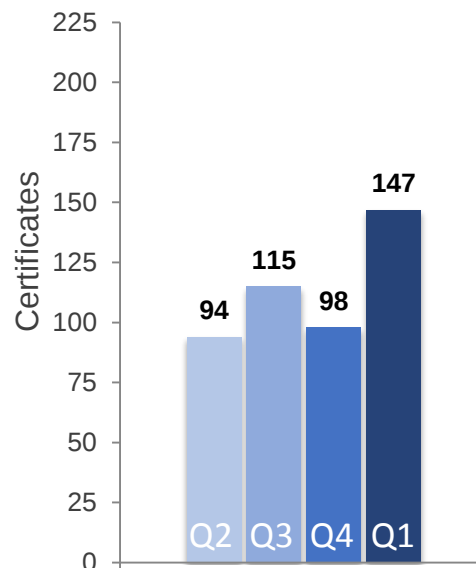
PCORI Engagement Rubric

CME/CE Activity released Jan 2016

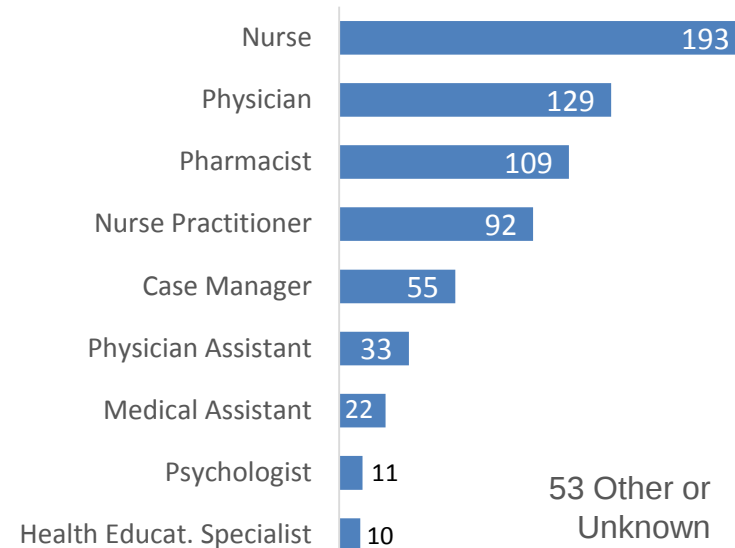
Unique Accesses
By Quarter (N=1862)



CME/CE Certificates*
By Quarter (N=454)



Cumulative CME/CE Learners
By Profession (N=707)

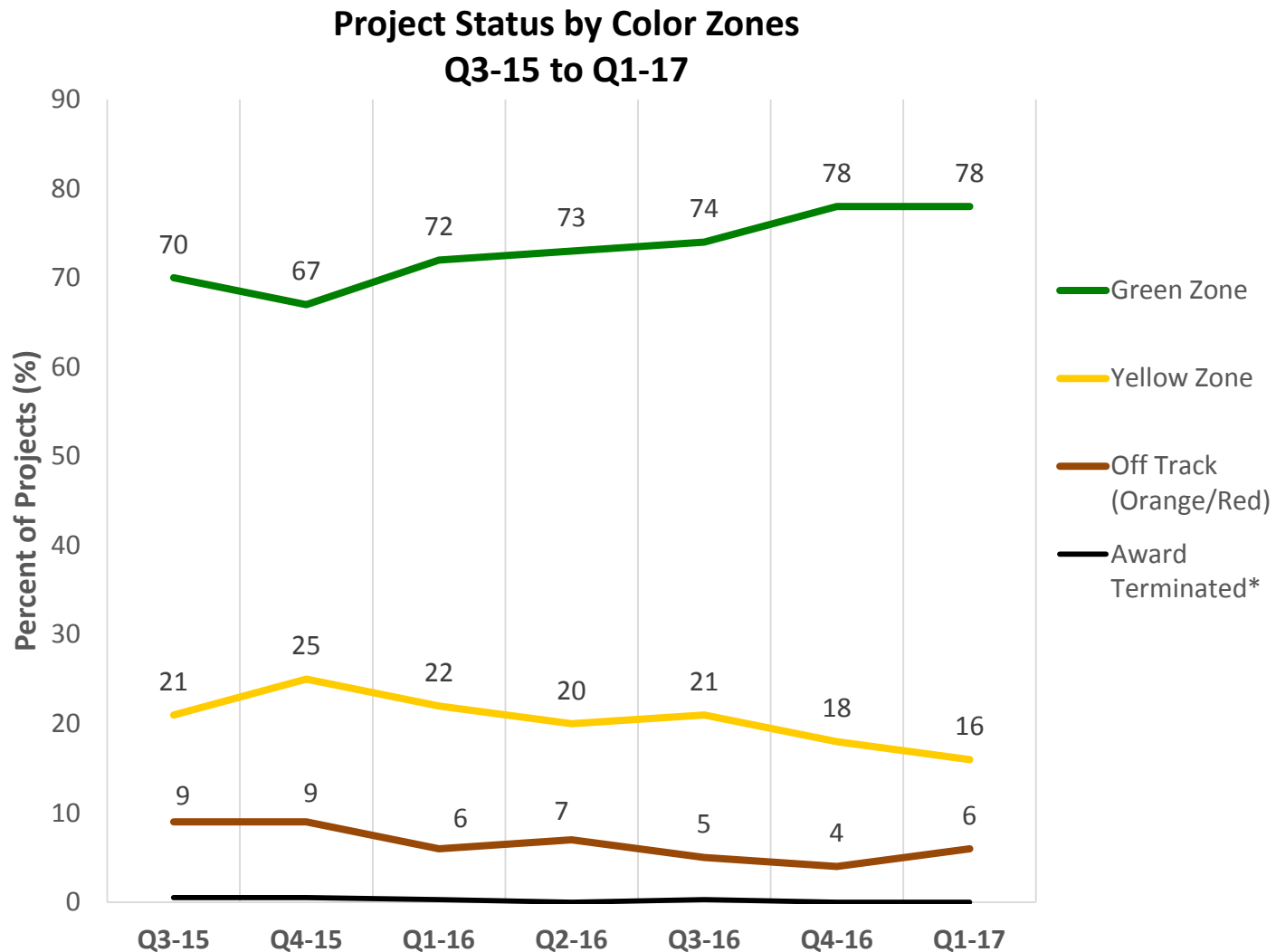


We actively monitor our projects, support them to be successful,
and classify their progress as shown below

GREEN	YELLOW	ORANGE	RED
The Project is meeting >85% of milestones on time -AND- Recruitment occurring on schedule, at expected rate -AND- PO judges that the project has a high probability of meeting its objectives as planned. PO judgment is based on close review of study progress, including recruitment status.	Project does not meet all criteria for "Green" -AND- Project is meeting $\geq 65\%$ of milestones on time. -OR- Recruitment is $\leq 75\%$ and $> 50\%$ of target accrual -OR- PO has concerns that without remediation efforts the project will not be able to meet objectives within project period.	Project does not meet all criteria for "Yellow" -AND- Project is meeting $\geq 50\%$ of milestones on time. -OR- Recruitment is $\leq 50\%$ of target accrual -OR- PO has concerns that the project will not meet objectives within the approved project period. Modifications to the Milestone Schedule and/or project plan are likely required.	Project does not meet all criteria for "Orange" -AND- Project is meeting $< 50\%$ of milestones on time. -OR- Recruitment is persistently and significantly $\leq 50\%$ of target -OR- PO has significant concerns that the project cannot meet its original objectives. Major modifications to Milestone Schedule are required for the project to be completed.
Next Steps			
Continue monitoring project through active portfolio management and per SOPs.	Increased communication with the PI to monitor and assist with getting the project back on track	Placed Under Review at PCORI to determine if it is able to meet its original project plan. Pursue modifications to project plan or milestone schedule as appropriate.	Project Remediation Plan (PRP) memo sent to PI with a 30-day completion date deadline. Inform Leadership of Status

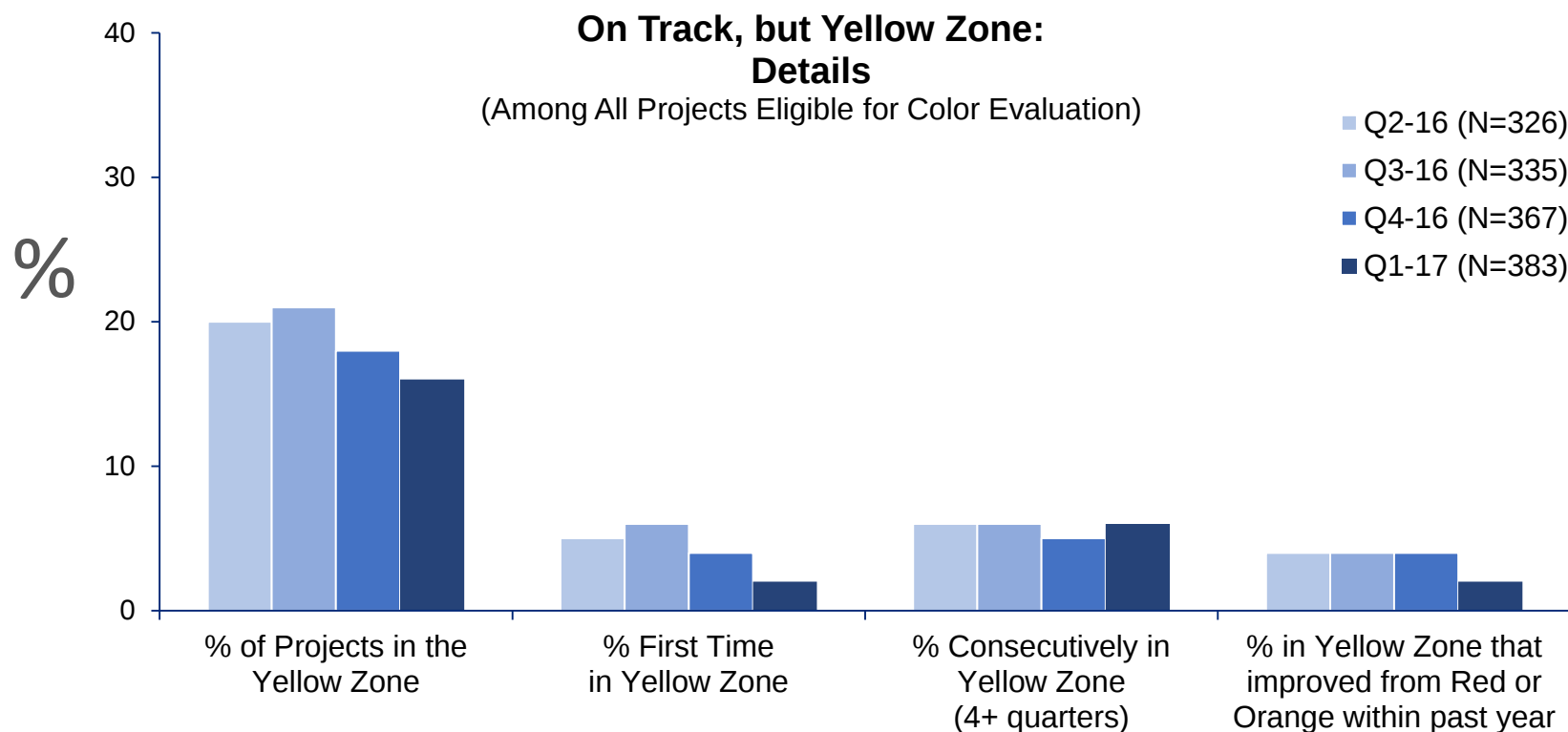


We are monitoring trends and shifts in project status



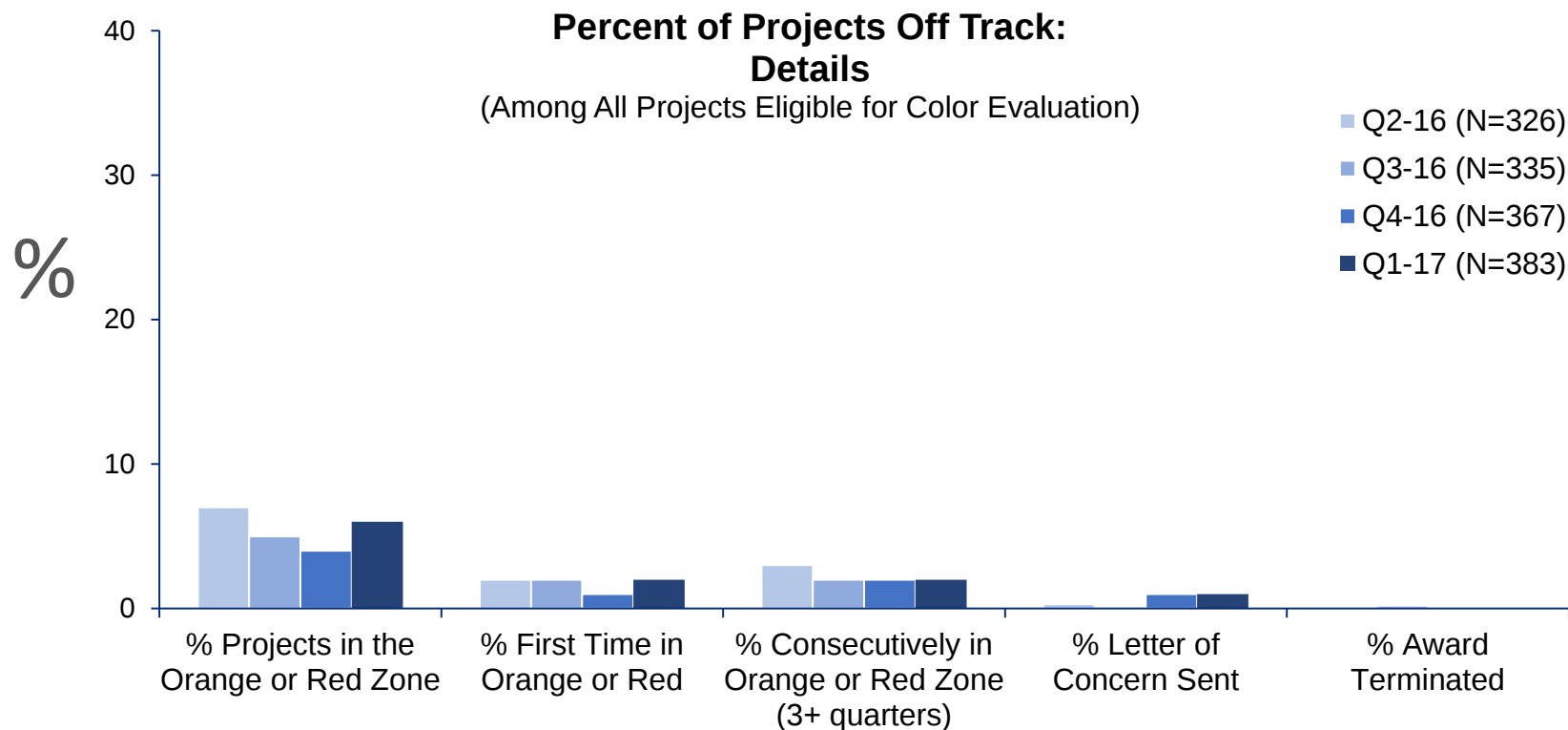
Projects On Track

Subset of Projects in the Yellow Zone



Projects Off Track

Subset of Projects in the Orange or Red Zone



DFRR Submission

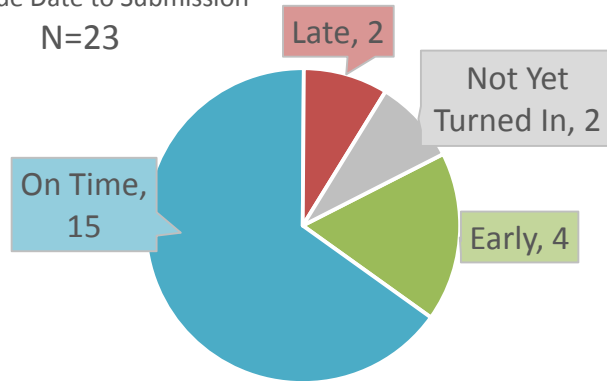
Based on DFRR Due Date in Contract

- On Target
- Off Target
- Needs Board Attention
- Too Early to Evaluate

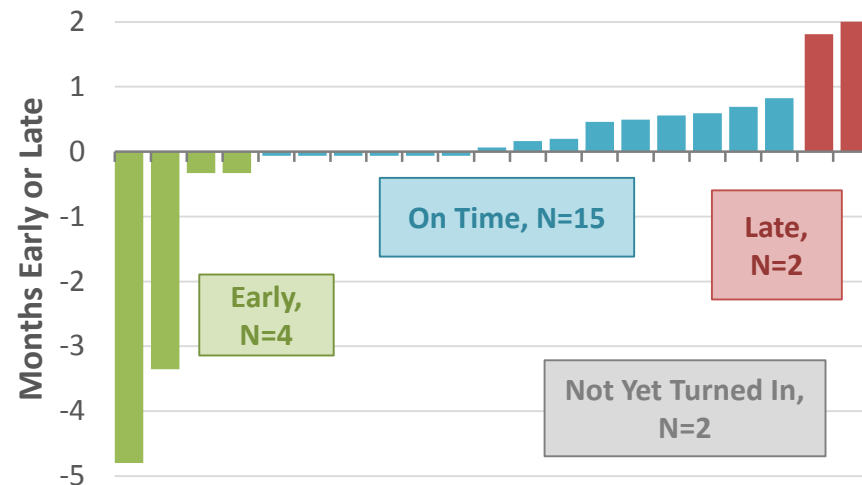
Timeliness of Q1-17 DFRR Submission

From Due Date to Submission
N=23

Target: 90% in on time
Q1-17: 82% in on time



How early or late were the Q1-17 DFRRs?

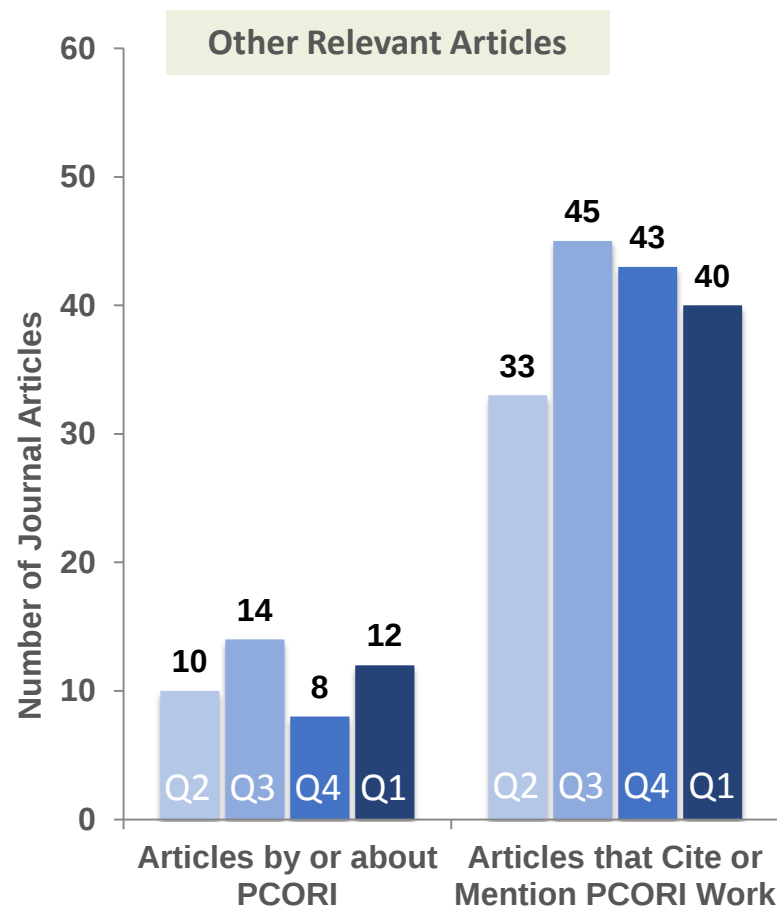
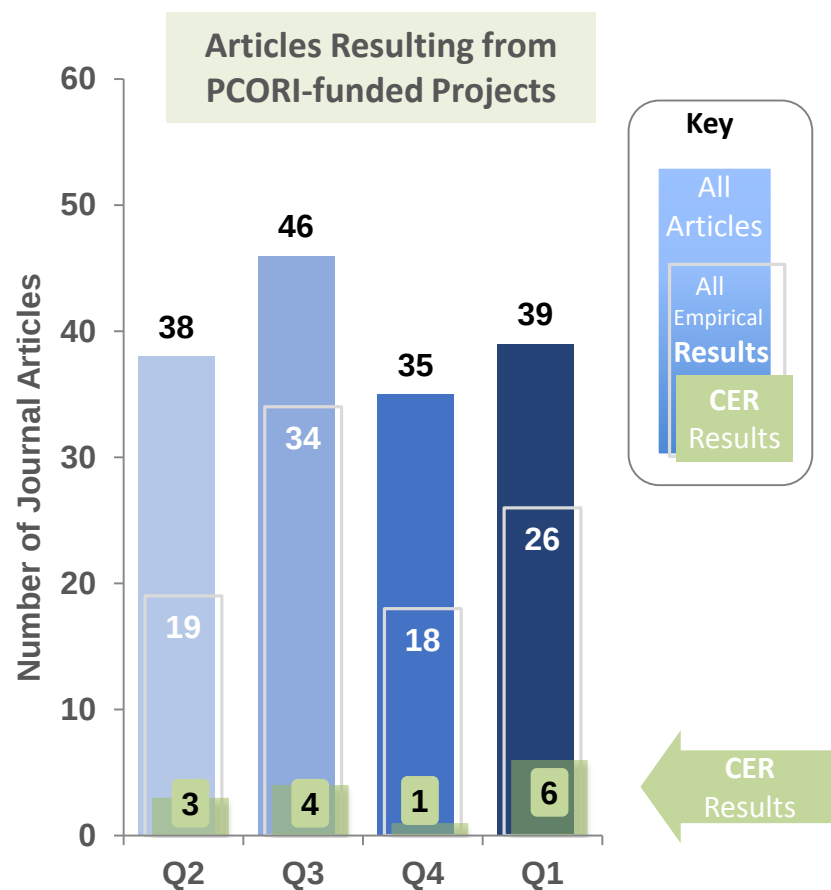


Journal Publications

Q1-17 Update

■ Q2 2016
■ Q3 2016
■ Q4 2016
■ Q1 2017

Out of the 39 articles resulting from PCORI-funded projects in Q1-17, 26 were empirical results, and 6 of those were CER results.



High Altmetric Scores

PCORI Funded Publications from Q1-17

These 4 publications from Q1-17 have high Altmetric scores, indicating attention in news articles (red), on social media (blues), and in blogs (gold).

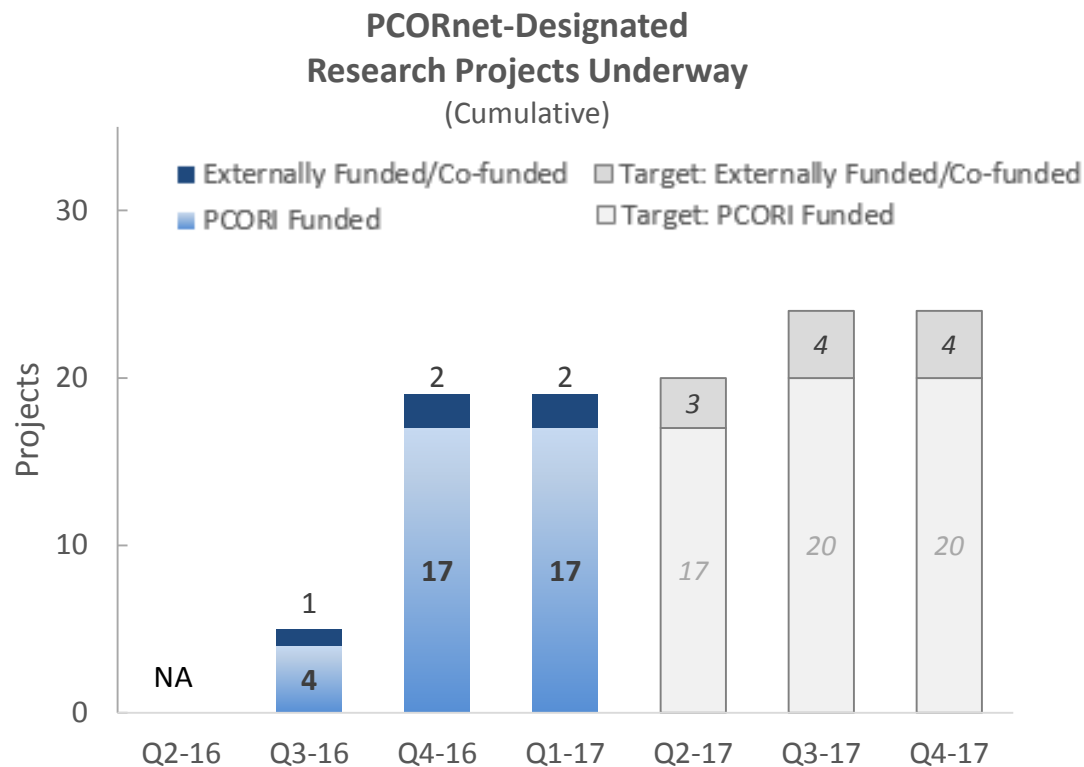
Altmetric	Publication	Summary
	Bryant-Stephens T, et al. Home Visits are Needed to Address Asthma Health Disparities in Adults. <i>J Allergy Clin Immunol.</i> 2016 Oct 21. pii: S0091-6749(16)31218-0. (link)	Perspective: Explores barriers to reducing asthma morbidity and mortality in low-income and minority patients. Researchers conclude that in-home visits are necessary for understanding SES barriers to decrease mortality and morbidity of asthma.
	Shah SS, Srivastava R, Keren R, Wu S, et al. Intravenous Versus Oral Antibiotics for Postdischarge Treatment of Complicated Pneumonia. <i>Pediatrics.</i> 2016; December 138(6):e20161692 (link)	CER Results: Compares the effectiveness of oral and intravenous (PICC) antibiotic treatment for complicated pneumonia in children. The study found no increased efficacy of PICC compared to oral antibiotics, but higher levels of complications and adverse reactions with PICC.
	Hess EP, et al. Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial. <i>BMJ.</i> 2016 Dec 5;355:i6165. (link)	CER Results: Compares usual care to decision aid (patient actively engages in decision-making process) and found that, using the decision aid, patients at low risk for coronary syndrome safely decreased the rate of admission to an observation unit for testing.
	Martin MA, et al. Care transition interventions for children with asthma in the emergency department. <i>J Allergy Clin Immunol.</i> 2016 Dec;138(6):1518-1525. (link)	Review: Investigates ED care transition interventions for children. Evidence to date suggests that ED care transition interventions should consider expanding beyond the ED to bridge the multiple sectors children with asthma navigate, including health care settings, homes, schools, and community spaces.



PCORnet

Designated Research Projects

As of Q1-2017, there are 19 PCORnet Designated research projects underway. The target for 2017 is 24 Designated studies underway, including 4 externally-funded or co-funded studies.



2017 Target:
24 Studies Underway,
4 Externally Funded or Co-funded

*PCORI-Funded: includes designated PCORnet Demonstration projects and PCORI projects that use PCORnet

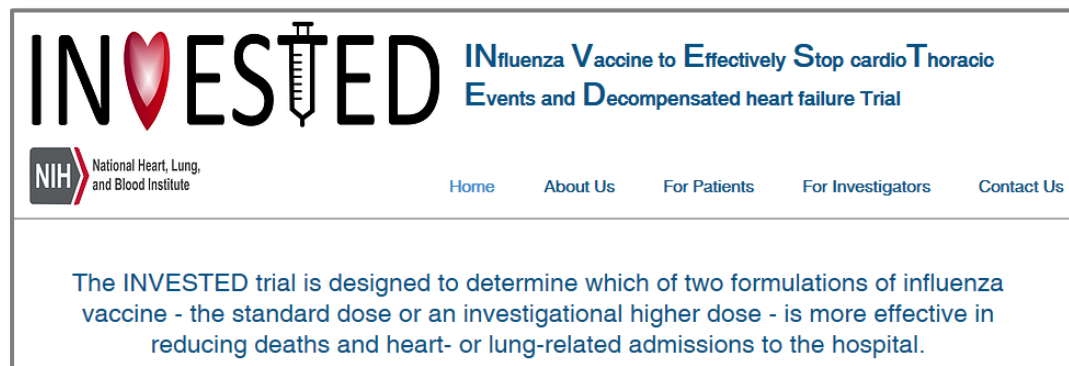


PCORnet

Designated Research Projects

First Externally-Funded PCORnet-Designated Study – **the INVESTED Trial**

A comparative effectiveness study of doses of ***influenza vaccine among patients with a history of myocardial infarction or heart failure***. Funded by the NIH, this study seeks to enroll and randomize 9,300 patients, and will leverage 7 Clinical Data Research Networks (CDRNs). ([NCT02787044](https://clinicaltrials.gov/ct2/show/study/NCT02787044))



The screenshot shows the top section of the INVESTED trial website. The header features the word "INVESTED" in large black letters, with a red heart replacing the 'V' and a syringe icon for the 'I'. To the right, the full name of the trial is written in blue: "INfluenza Vaccine to Effectively Stop cardioThoracic Events and Decompensated heart failure Trial". Below this is the NIH logo and the text "National Heart, Lung, and Blood Institute". A navigation bar contains links for "Home", "About Us", "For Patients", "For Investigators", and "Contact Us". The main content area begins with the text: "The INVESTED trial is designed to determine which of two formulations of influenza vaccine - the standard dose or an investigational higher dose - is more effective in reducing deaths and heart- or lung-related admissions to the hospital."

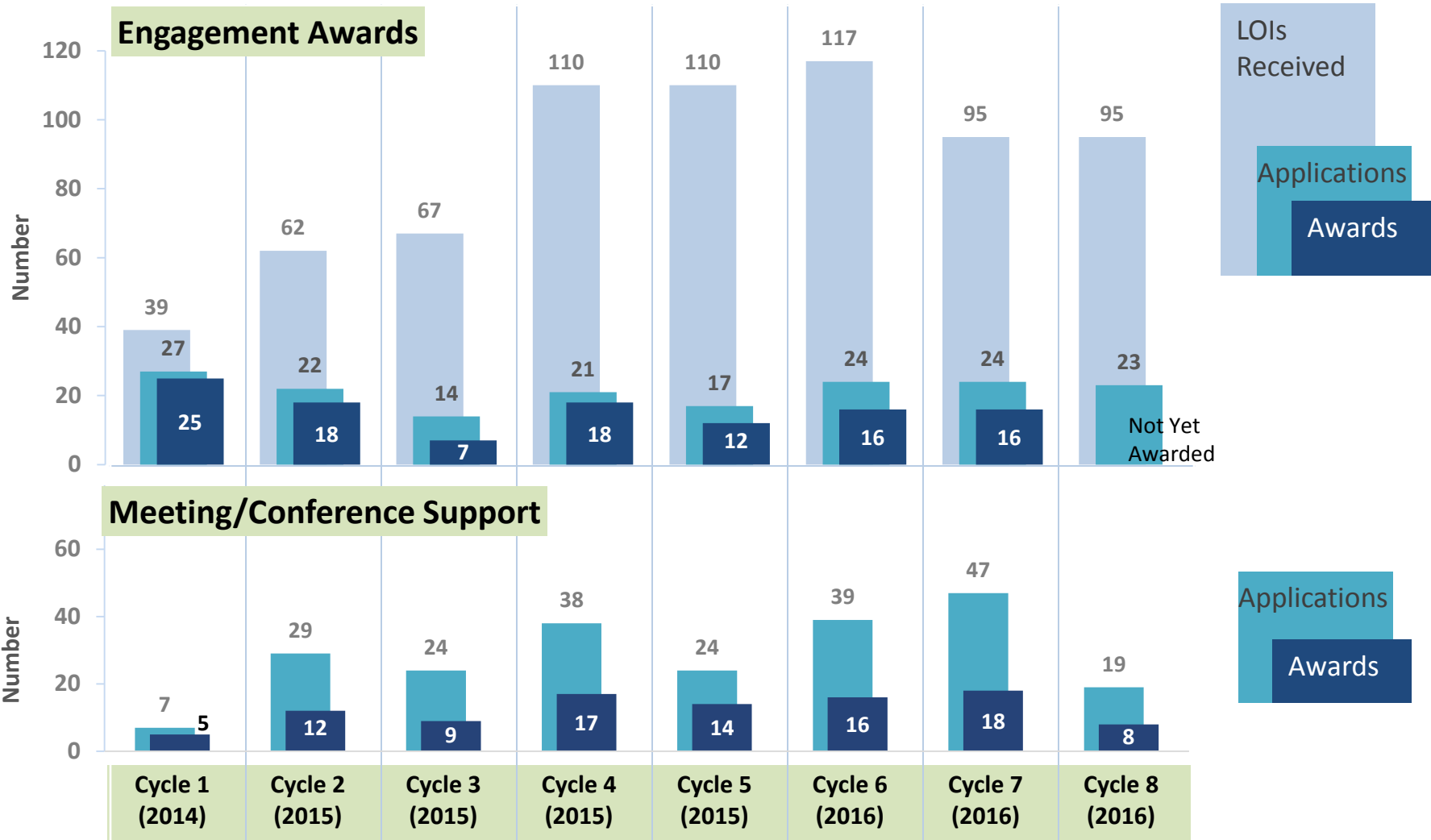
“Early results from the INVESTED pilot study showing that the SMART IRB approach yielded an efficiency boost during startup foreshadows the improvements we anticipate as we implement the SMART IRB platform across all of our PCORnet studies. We hope to be able to share more positive results as we continue to analyze and collect more data from INVESTED.”

Amy Franklin
PCORnet SMART IRB Coordinator



Engagement Awards

Q1-17 Update



Wrap Up and Adjournment

Gray Norquist, MD, MSPH

Chairperson, Board of Directors

