

Board of Governors Meeting via Teleconference/Webinar

May 22, 2018

12:00 - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Larry Becker

Chair, Finance & Administration Committee

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:10	Consider for Approval: Consent Agenda Minutes of the April 30, 2018 Board Meeting and Nomination of Co-Chair for the Advisory Panel on Rare Disease (RDAP)
12:10–12:25	Consider for Approval: Revisions to the Delegation of Authority and Expenditure Approval Policy
12:25-12:45	Review of Q2 FY-2018 Dashboard
12:45-1:15	People-Centered Research Foundation (PCRF) Update
1:15	Wrap up and adjournment

Consent Agenda Items

Larry Becker

Chair, Finance and Administration Committee



Motion for Consent Agenda Items

That the Board approve:

- Minutes from April 30, 2018 Board of Governors meeting
- Nomination of Co-Chair for Advisory Panel on Rare Disease to serve until August 31, 2020 or until a successor is named
 - Co-Chair Nominee: Cindy Luxhoj, MUP
 - Represents Patients, Caregivers and Patient Advocates
 - Executive Director and Founder of Alagille Syndrome Alliance (ALGSA), focused on Alagille Syndrome, a rare genetic disease affecting fewer than one in 70,000 individuals worldwide
 - Former PCORI Merit Reviewer for Communication and Dissemination Research proposals
 - Co-chair of the Patient Advocacy Committee of the Childhood Liver Disease Research Network (ChiLDReN)



Board Vote

Call for a Motion to:

- **Approve** each of the Motions on the Consent Agenda

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 Revisions to the *Delegation of Authority and Expenditure Approval Policy*

Regina Yan, MA

Chief Operating Officer



Overview

- PCORI periodically reviews its policies to ensure:
 - They remain accurate and applicable
 - Are in conformance with current legal standards and requirements
 - Are not duplicative or outdated
 - Can be implemented within a reasonable framework
- On March 20, 2018, the Finance and Administration Committee (FAC) reviewed the *Delegation of Authority and Expenditure Approval Policy* approved by the Board on September 27, 2016
 - Policy addresses the circumstances under which an officer, director, employee, or other representative of PCORI may legally bind PCORI, authorize payments, and/or commit to expenditures on behalf of PCORI
 - FAC recommends several changes to reflect evolving PCORI organizational structure and practice



Summary of Recommended Changes

- Added language in section A to specify authority of the Chief Program Support Officer in executing, modifying, and terminating agreements or otherwise legally binding PCORI
 - Authority previously approved for Executive Director, Chief Operating Officer, Chief Science Officer, Chief Engagement & Dissemination Officer, and General Counsel
 - Since policy was approved in 2016, PCORI expanded its Executive-level staff to include a Chief Program Support Officer who oversees contracts management for all programs, which includes responsibility for signing award contracts



Summary of Recommended Changes

- Added language in section B to specify the authority of the Chief Program Support Officer in authorizing payment execution, signing checks and other instruments of withdrawal, or directing transfers in the name of or on behalf of PCORI
- Removed authorities for the Chief Science Officer and Chief Engagement and Dissemination Officer related to authorizing payment execution, signing checks and other instruments of withdrawal, or directing transfers in the name of or on behalf of PCORI
 - Maintains strict internal controls over such activities by restricting the number of authorized personnel to the following five individuals:
 - Executive Director
 - Chief Operating Officer
 - General Counsel
 - Chief Program Support Officer
 - Director of Finance



Recommended Board Action

- The FAC recommends the following Board action:
 - Amend the *Delegation of Authority and Expenditure Approval Policy* approved on September 27, 2016, to include the proposed revisions



Board Vote

Call for a Motion to:

- **Approve** proposed revisions to the *Delegation of Authority and Expenditure Approval Policy* approved on September 27, 2016

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



Dashboard Review

Second Quarter of FY-2018

Joe Selby, MD, MPH

Executive Director

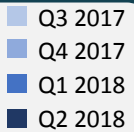
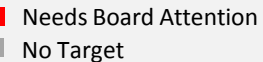
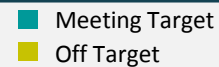
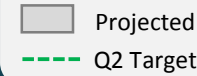


PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

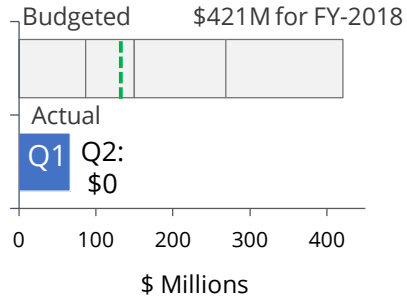
PCORI Board of Governors Dashboard

Second Quarter FY-2018 (As of 3/31/2018)

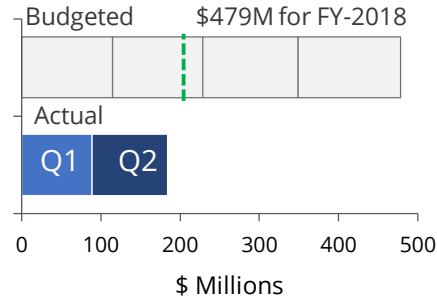
Dashboard Key



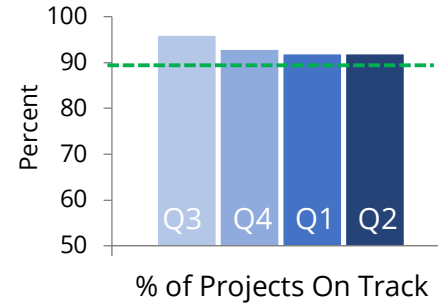
Funds Committed to Research



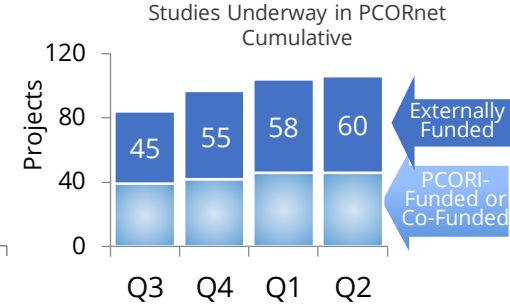
Expenses



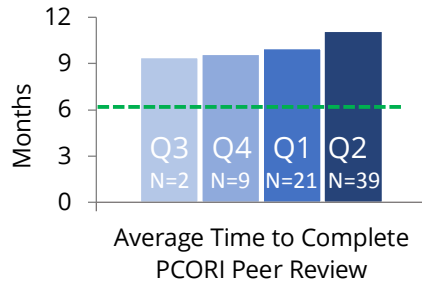
Project Performance



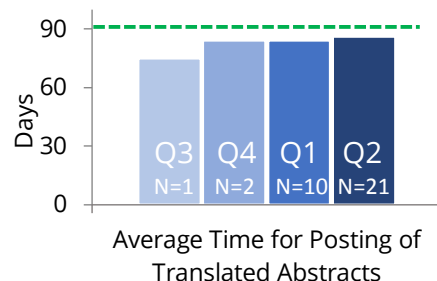
Research Using PCORnet



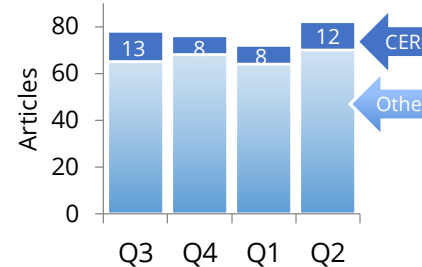
Speed of PCORI Peer Review



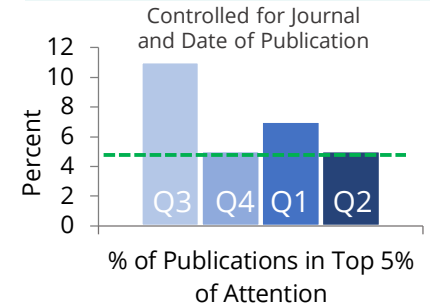
PCORI Abstracts Posted to Website



Results Published in Literature



Altmetric: Attention to PCORI Research



Featured Results on PCORI's Strategic Goals

Results on Goal 1

Increasing Information

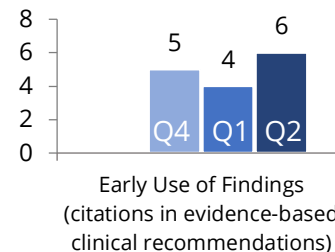
Highlight: A PCORI-funded study found that in patients with PAD, a home-based exercise intervention consisting of a wearable activity monitor and telephone coaching, compared with usual care, did not improve walking performance.

Results on Goal 2

Speeding Uptake

As of Q2, results from PCORI studies have been cited 19 times in evidence-based clinical recommendations.

Uptake Highlight: In Q2, results from PCORI studies were cited in point-of-care decision resources at least 6 times; topics include hepatitis C, pneumonia in children, and others.



Results on Goal 3

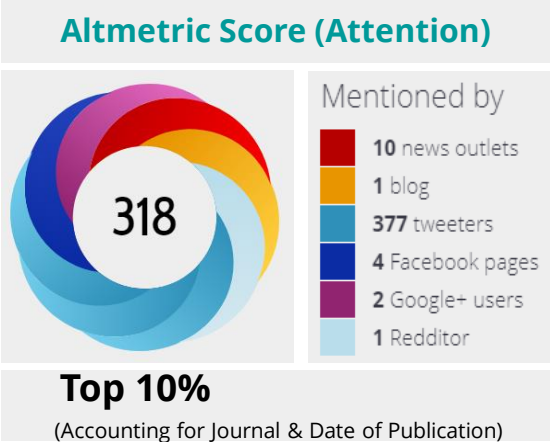
Influencing Research

Highlight: PCORI is credited with inspiring the revision of courses to support patient-centered multidisciplinary research, and the creation of a Citizen Scientist program at the University of Florida's Clinical and Translational Science Institute.

Goal 1: Results of PCORI-Funded Research

For PAD, Home-Based Exercise With Phone Coaching & Activity Monitor Does Not Improve Walking

PCORI Study	Study Title: Patient-Centered Home Exercise Program for Peripheral Artery Disease (PAD) Principal Investigator: Mary McDermott, MD, Northwestern University
Results Publication	McDermott MM, Spring B, Berger JS, et al. Effect of a Home-Based Exercise Intervention of Wearable Technology and Telephone Coaching on Walking Performance in Peripheral Artery Disease: The HONOR Randomized Clinical Trial. JAMA. 2018 April 4.



Summary: Lower extremity peripheral artery disease (PAD) affects eight million people in the US, causing physical limitations and loss of mobility. Supervised treadmill exercise programs are shown to improve walking ability, however, regular travel to an exercise center can be burdensome to patients and hinder participation.

In this study, 200 participants with PAD were randomized to a home-based walking exercise program (consisting of a wearable activity monitor and telephone coaching) or usual care, and followed for 9 months to measure improvements in walking performance.

The study found that in patients with PAD, the **home-based exercise intervention with a wearable activity monitor and telephone coaching did not improve walking performance compared with usual care.**

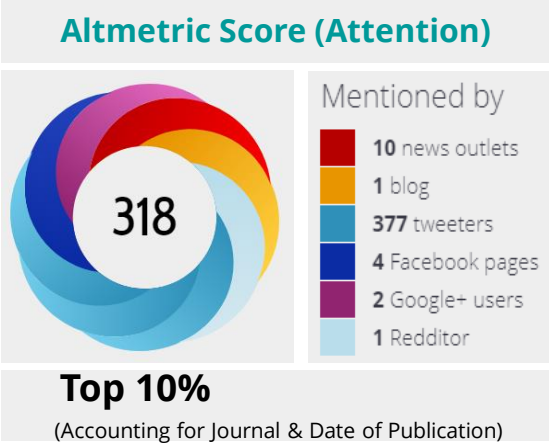
” There is a lot of enthusiasm about the potential for wearable devices to improve medical outcomes, but in this study they just weren't sufficient, even combined with telephone calls, to improve walking outcomes

-Mary McDermott, MD,
Study Investigator
[MedPage Today® Article](#)

Goal 1: Results of PCORI-Funded Research

For PAD, Home-Based Exercise With Phone Coaching & Activity Monitor Does Not Improve Walking

PCORI Study	Study Title: Patient-Centered Home Exercise Program for Peripheral Artery Disease (PAD) Principal Investigator: Mary McDermott, MD, Northwestern University
Results Publication	McDermott MM, Spring B, Berger JS, et al. Effect of a Home-Based Exercise Intervention of Wearable Technology and Telephone Coaching on Walking Performance in Peripheral Artery Disease: The HONOR Randomized Clinical Trial. <i>JAMA</i> . 2018 April 4.
Summary	The study found that among patients with PAD, a home-based exercise intervention consisting of a wearable activity monitor and telephone coaching, compared with usual care, did not improve walking performance at 9-month follow-up.



What are patients and physicians saying about this finding on Twitter?

- 

This is exactly why there needs to be more PUBLISHED research of negative studies so that we have REAL-WORLD translation for treatment & devices. [#Wearables](#) are helpful but maybe not for all AND need to be reliable data <https://t.co/ZhV8FUTeNY>
- 

I love that this was published as it helps all of us learn. The big question is HOW do we get people to move? Behaviour change is hard... It most likely needs a cultural shift to have a chance. <https://t.co/fFzR5KlCTp>
- 

I find this study to be interesting and innovative. Kudos to [@JAMA_current](#) for publishing it albeit negative. <https://t.co/Pgm9QWSy7a>

Goal 2: Speed Uptake and Use of Information Uptake into Evidence-Based Clinical Recommendations



Citations of PCORI-Results in UpToDate®

Topics of results cited include prostate cancer survivors, parapneumonic effusion and empyema in children, prescription drug misuse, and antiviral therapy for chronic hepatitis C virus infection



Citations of PCORI-Results in DynaMed Plus™

Topics of results cited include treatment of localized prostate cancer, lupus nephritis, and chest pain



Citations of PCORI-Results in evidence-based clinical recommendations

Topics of results cited include prescribing opioids for chronic pain, lipid guidelines for high risk patients, bone and joint infections in children, management of type 2 diabetes, and clinically localized prostate cancer

Goal 3: Influence Research Courses and Citizen Science Program to support PCOR

PCORI is credited with inspiring the revision of courses and the creation of a Citizen Scientist program at the University of Florida's Clinical and Translational Science Institute in collaboration with OneFlorida Clinical Data Research Network.

Courses

- Originally offered courses to doctoral students, fellows and faculty on overall implementation science and community engagement from the researcher perspective
- **Now, courses provide learners with skills required to develop a career in more patient-centered multidisciplinary clinical and translational research** by embracing:
 - Team-science approach (citizen scientists and practicing clinicians)
 - Didactic experience paired with team science “on the ground” learning in health systems

Citizen Scientist Program

- Learned from PCORI reviewer feedback to **create a program that bridges the gap between researchers and community members by engaging citizen scientists** (see [Citizen Science Curriculum](#)) from research topic prioritization to dissemination with the aim of:
 - Improving the quality, applicability, and relevance of research
 - Translating the findings into a broad range of health care delivery settings
 - Ultimately improving health outcomes relevant to patients and their families



Public Availability of Primary CER Results

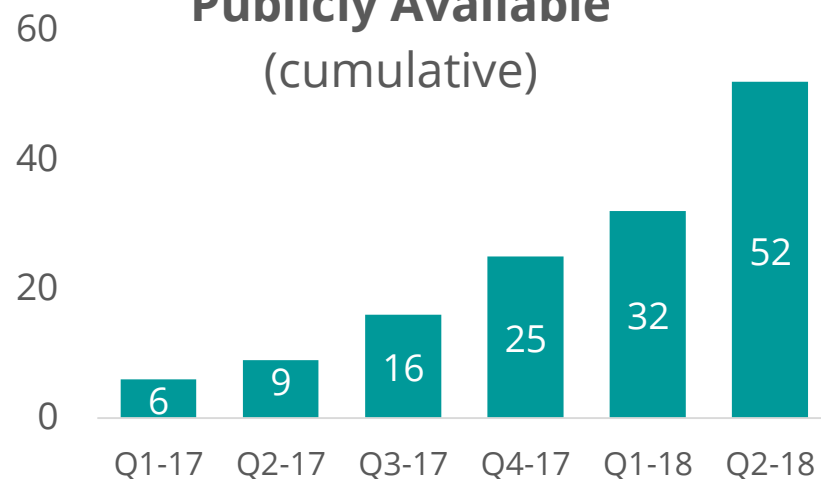
As of Q2-18, **52 CER Studies** have their primary results peer-reviewed and publicly available, and this number is steadily increasing

- **Primary results** are results that report on a comparison of clinical approaches using the pre-specified primary outcome(s). Also commonly referred to as primary publications, or public disclosure of results
- Primary results can be **made publicly available** by being published in a peer-reviewed journal, and/or by completing the PCORI Peer Review Process and having abstracts posted to PCORI.org

Of the 52 CER studies with primary results:

- 36 (69%) were first made available via publications
- 16 (31%) were first made available via PCORI.org

**Primary CER Results
Publicly Available**
(cumulative)



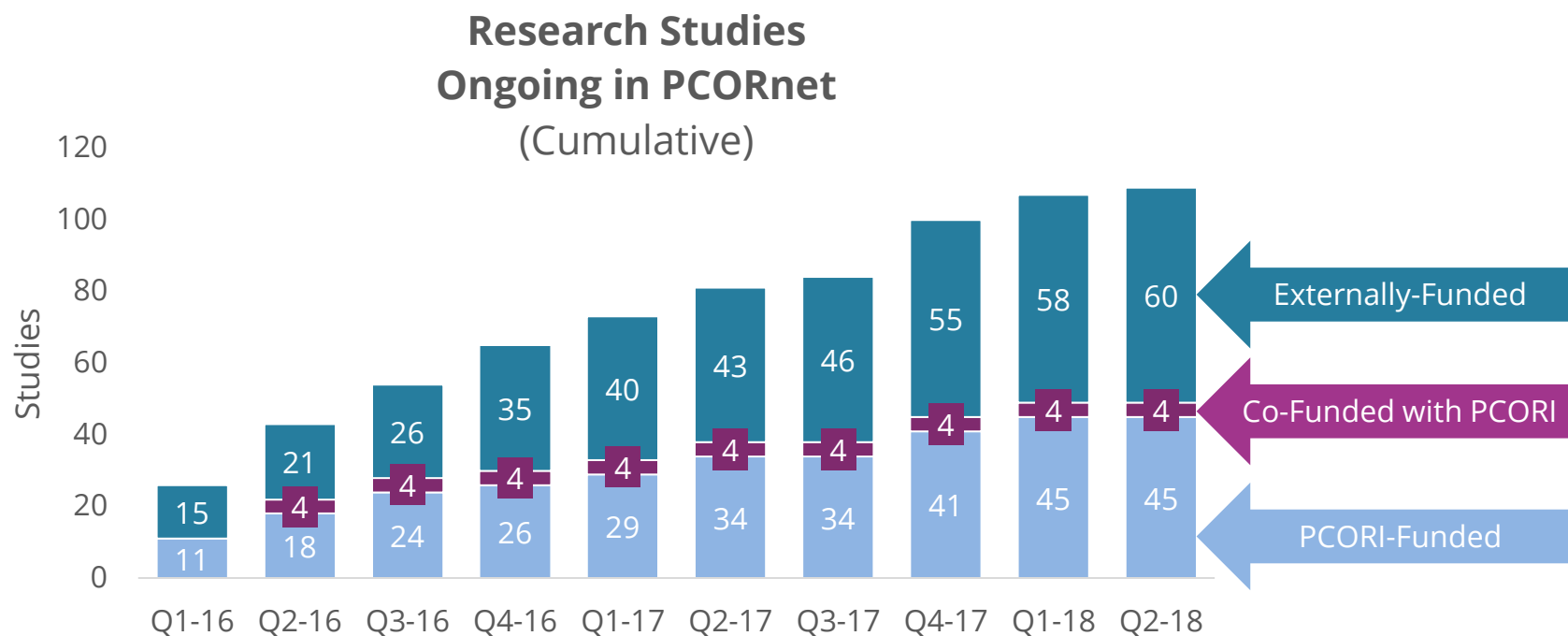
Update:

As of 5/15/18, **74 CER studies** have publicly available primary results

PCORnet

Research Studies Underway

Many of the research studies underway in PCORnet are externally funded or co-funded. As of Q2-18, **there are 64 externally- or co-funded studies underway in PCORnet.**



- During its March meeting, the PCORI Board suggested that regular Network-specific dashboard reports are needed
- Additional potential metrics were discussed at the April Board meeting, and are now being considered for prioritization
- The PCORnet Coordinating Center will develop dashboards that will help inform the Board, the Network, and the public about key PCORnet accomplishments
- PCORnet dashboards are also being created to provide a longitudinal record of progress on measures important to the health of the Network
- Dashboards will provide both static updates, as well as graphs to depict change over time

- **Patient Metrics**

- Number of patients in the Network, demographics, etc.

- **Front Door Activity**

- Front door requests, responses to requests, etc.
- Number of funded research projects, and funding sources

- **Research Metrics**

- For clinical trials, prospective cohort studies
- Timeliness of key study milestones, enrollment progress, etc.

- **Manuscript Metrics**

- Number of manuscripts, overall and within studies
- Altmetrics, bibliometrics, etc.

- **Query Metrics**

- Queries executed to date, query turnaround time, etc.

- **Administrative Simplicity Metrics**

- Percent signed on to data sharing agreement (DSA), percent signed on to single (SMART) IRB, etc.

The PCORnet Dashboard(s) are being developed by the PCORnet Coordinating Center

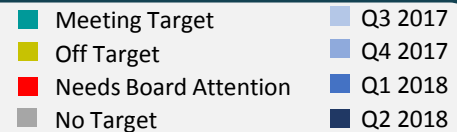
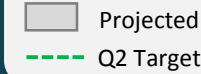
Discussion Questions

- Do our FY-2018 Dashboard and associated background materials cover the topics that are most important for the Board to review?
- Do you have concerns about our progress or performance on any of our Dashboard indicators?
- Do you have questions regarding the development of the PCORnet Dashboard?
- What questions do you have for our Q3-18 in-depth focus on Recruitment, Modifications, Progress of Projects?

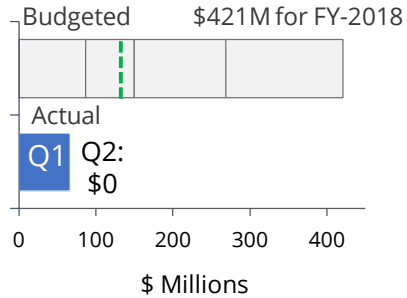
PCORI Board of Governors Dashboard

Second Quarter FY-2018 (As of 3/31/2018)

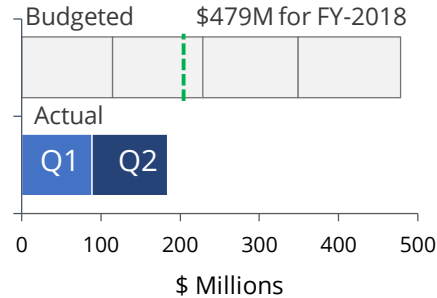
Dashboard Key



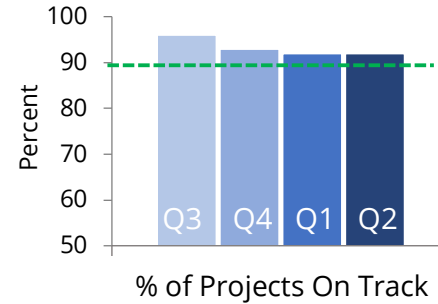
Funds Committed to Research



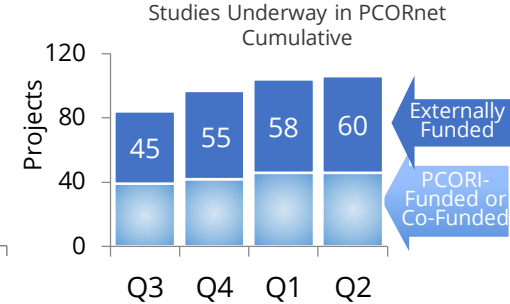
Expenses



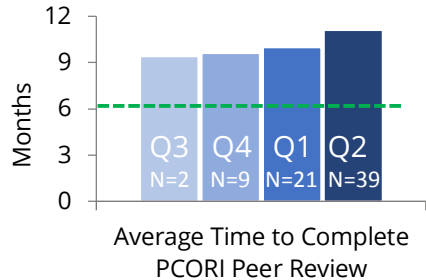
Project Performance



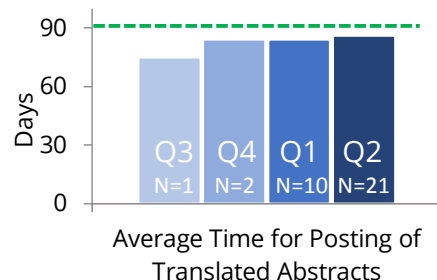
Research Using PCORnet



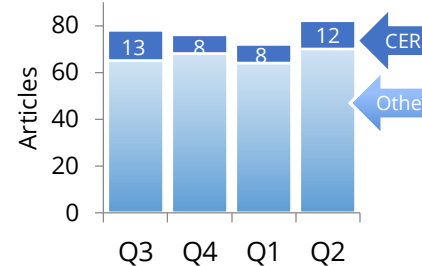
Speed of PCORI Peer Review



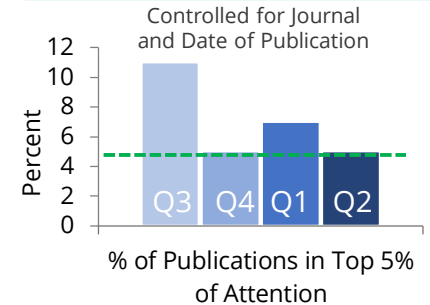
PCORI Abstracts Posted to Website



Results Published in Literature



Altmetric: Attention to PCORI Research



Featured Results on PCORI's Strategic Goals

Results on Goal 1

Increasing Information

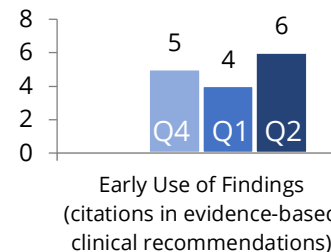
Highlight: A PCORI-funded study found that in patients with PAD, a home-based exercise intervention consisting of a wearable activity monitor and telephone coaching, compared with usual care, did not improve walking performance.

Results on Goal 2

Speeding Uptake

As of Q2, results from PCORI studies have been cited 19 times in evidence-based clinical recommendations.

Uptake Highlight: In Q2, results from PCORI studies were cited in point-of-care decision resources at least 6 times; topics include hepatitis C, pneumonia in children, and others.



Results on Goal 3

Influencing Research

Highlight: PCORI is credited with inspiring the revision of courses to support patient-centered multidisciplinary research, and the creation of a Citizen Scientist program at the University of Florida's Clinical and Translational Science Institute.

People-Centered Research Foundation (PCRF) Update

Kathy Hudson, PH.D.
Chief Executive Officer
PCRF



PCORI, PCORnet, and PCRF Relationships

- PCORnet is a large national clinical research network that is independent from but was developed with initial funding from the Patient-Centered Outcomes Research Institute (PCORI) with unique data, clinical trial, and engagement capabilities
- PCORnet aims to deliver answers to questions that matter most to patients, clinicians and health systems faster and more affordably
- PCRF is a nonprofit charitable organization created by leaders of networks participating in PCORnet that ensures coordination and long term sustainability
- PCORI currently has awarded funding to networks participating in PCORnet and to PCRF

PCORI, PCORnet, and PCRF Relationships

- PCORnet is going through an evolution to ensure that all parts of the network are committed and able to conduct highly efficient, networked, and patient-centered studies, supported by a range of public and private research funders
- Two initial areas of major focus for PCORnet are research related to “heart and mind” conditions; however, PCORnet is intended to be a resource for conducting critical research in other areas and is receptive to proposals across the clinical spectrum

Wrap Up and Adjournment

Larry Becker

Chair, Finance & Administration Committee

