Board of Governors Meeting

via Teleconference/Webinar

December 7, 2020
1:30 PM – 4:45 PM

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

1:30 PM	**Call to Order and Welcome** • Minutes of November 17, 2020 Board Meeting
1:45-2:45	**Executive Director's Report**
3:00-4:30	**Panel Discussion**
4:30-4:45	**Wrap up and Adjournment**

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the November 17, 2020 Board of Governors 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

Executive Director's Report

Nakela L. Cook, MD, MPH

Executive Director

Executive Director's Report Overview

- PCORI Updates
- GAO Report
- End-of-Year Dashboard Review
- COVID-19 Update

PCORI Updates

Jean Slutsky

Regina Yan

Larry Becker

GAO issued its
3rd mandated review of PCORI
on November 18, 2020

COMPARATIVE EFFECTIVENESS RESEARCH: Patient-Centered Outcomes Research Institute and HHS Continue Activities and Plan New Efforts

GAO Highlights

Highlights of GAO-21-61, a report to congressional committees

November 2020

COMPARATIVE EFFECTIVENESS RESEARCH

Patient-Centered Outcomes Research Institute and HHS Continue Activities and Plan New Efforts

Why GAO Did This Study

The 2010 Patient Protection and Affordable Care Act (PPACA) authorized establishment of PCORI to conduct CER and improve its quality and relevance. PPACA also established new requirements for HHS to, among other things, disseminate findings from federally funded CER and coordinate federal programs to build data capacity for this research. To fund CER activities, PPACA established the Trust Fund, which provided a total of about $3.6 billion to PCORI and HHS for CER activities during fiscal years 2010 through 2019. The Further Consolidated Appropriations Act, 2020, added new CER requirements and extended funding at similar levels through fiscal year 2029.

PPACA and the Appropriations Act 2020 included provisions that GAO review PCORI and HHS's CER activities. This report describes (1) the CER activities PCORI and HHS carried out to meet legislative requirements, (2) how PCORI and HHS allocated funding to those CER activities, and (3) PCORI and HHS efforts to evaluate the effectiveness of their CER dissemination and implementation activities, such as changes in medical practice.

GAO reviewed legislative requirements and PCORI and HHS documentation and data for fiscal years 2010-2019. GAO also interviewed PCORI and HHS officials and obtained information from nine selected stakeholder groups that were familiar with PCORI's or HHS's CER activities. These groups included payer, provider, and patient organizations. GAO incorporated technical comments from PCORI and HHS as appropriate.

View GAO-21-61. For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

GAO found that the Patient-Centered Outcomes Research Institute (PCORI)—a federally funded, nonprofit corporation—and the Department of Health and Human Services (HHS) have continued to perform comparative clinical effectiveness research (CER) activities required by law since our prior report issued in 2015. CER evaluates and compares health outcomes, risks, and benefits of medical treatments, services, or items. The requirements direct PCORI and HHS to, among other things, fund CER and disseminate and facilitate the implementation of CER findings.

GAO's analysis of PCORI and HHS documents show that they allocated a total of about $3.6 billion for CER activities and program support during fiscal years 2010 through 2019 from the Patient Centered Outcomes Research Trust Fund (Trust Fund). Specifically, PCORI allocated about $2 billion for research awards and another $542 million for other awards, to be paid over multiple years. HHS allocated about $598 million for activities such as the dissemination and implementation of CER findings. PCORI and HHS also allocated about $470 million for program support.

PCORI and HHS Allocations for Comparative Clinical Effectiveness Research (CER) Activities, Fiscal Years 2010 through 2019

Source: GAO analysis of Patient-Centered Outcomes Research Institute (PCORI) and Department of Health and Human Services (HHS) data. | GAO-21-61

[a]Totals may not add up due to rounding.
[b]PCORI and HHS allocated $457 million and $13 million for program support, respectively.

PCORI assessed the effectiveness of its activities using performance measures and targets. Since fiscal year 2017, when early CER projects were completed, PCORI officials reported that the institute met its performance targets, such as an increased number of research citations of its CER findings in news and online sources. HHS described accomplishments or assessed the effectiveness of its dissemination and implementation activities. PCORI and HHS officials told GAO they are planning comprehensive evaluations of their CER dissemination and implementation activities as part of their strategic plans for the next 10 years.

United States Government Accountability Office

Dashboard Review

End-of-Year (FY2020)

PCORI Board of Governors Dashboard

Fourth Quarter FY2020 (As of 9/30/2020)

Inputs

Process

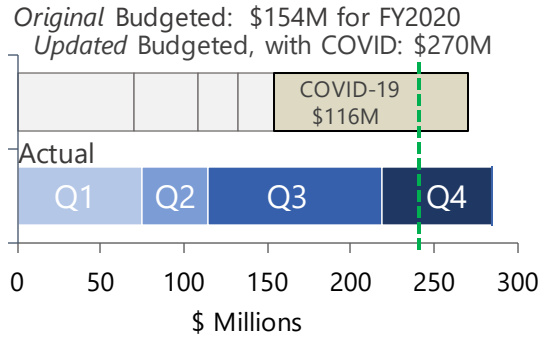
Outputs

Uptake

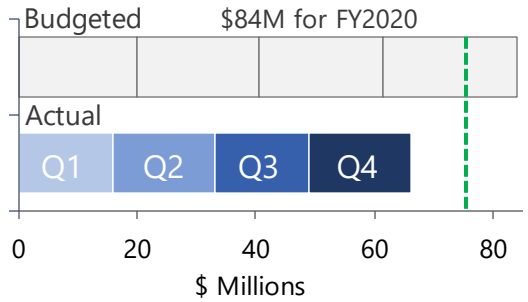
Use

Impact

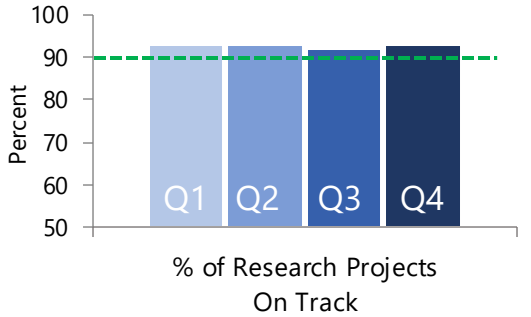
Funds Committed



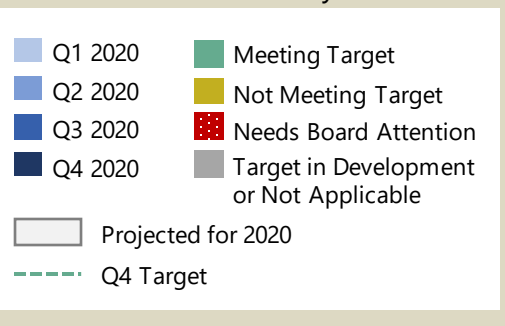
Operational Expenses



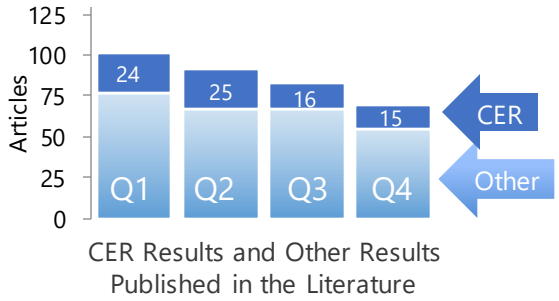
Research Project Performance



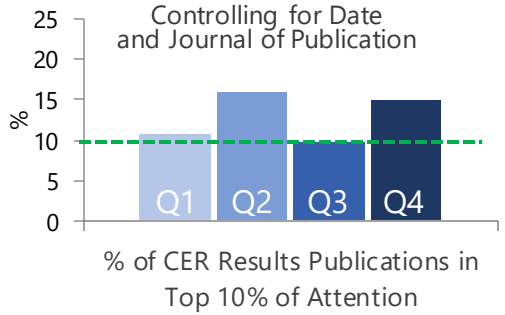
Dashboard Key



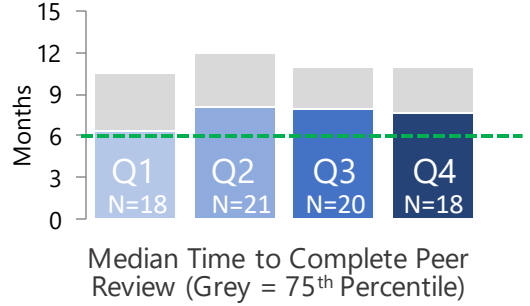
Results Published in Literature



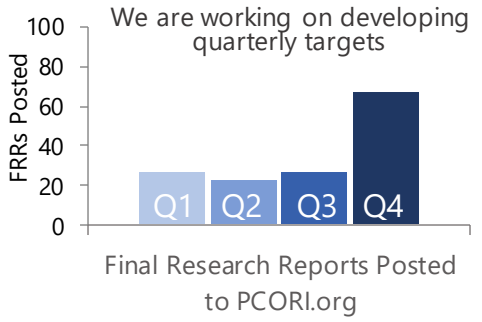
Altmetric: Attention to PCORI Results



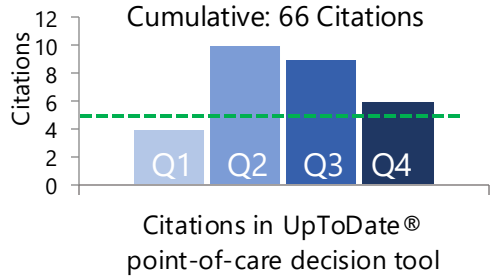
Speed of PCORI Peer Review



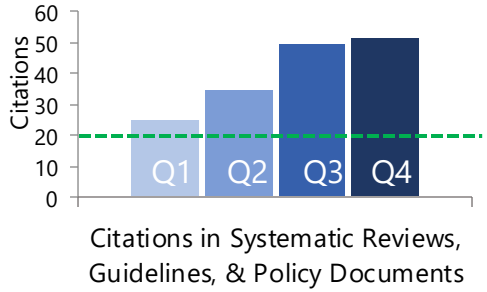
Final Research Reports Posted to PCORI.org



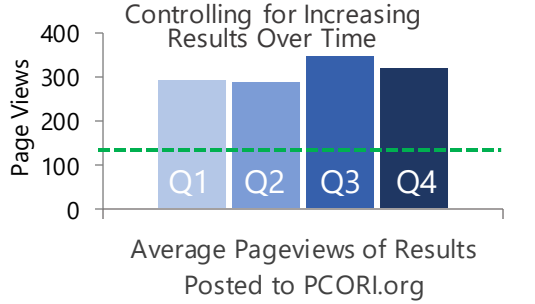
Uptake of Results into UpToDate®



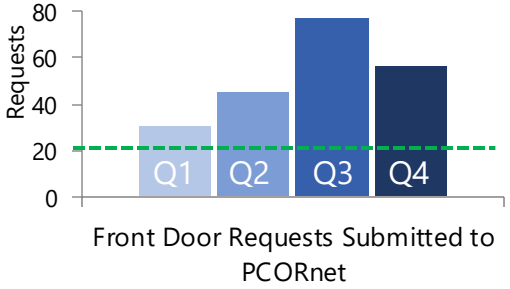
Other Examples of Uptake



Results Viewed on PCORI.org



Front Door Requests to PCORnet



Goals 1 and 2: A Completed PCORI-Funded Study, on the Path from Results to Impact

Can Nurse and Patient Education Reduce Missed Doses of Medications to Prevent Blood Clots in Hospitals?

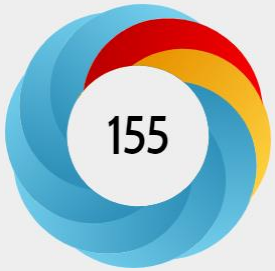
Principal Investigator: Elliott R. Haut, MD, PhD, Johns Hopkins University

Study Title: Preventing Venous Thromboembolism (VTE): Empowering Patients and Enabling Patient-Centered Care via Health Information Technology

- **Results**: Published in *JAMA Network Open* and *PLOS One;* Results summaries posted to PCORI.org; Final Research Report posted to PCORI.org
- **Funding for Implementation:** PCORI-funded Implementation Projects to scale up and to further expand delivery of the intervention
- **Dissemination by External Groups:** Johns Hopkins University and a CMS-funded Hospital Improvement Innovation Network

PCORI-Funded Study Results:

Educating nurses and patients about the importance of VTE blood clot prevention medications reduces missed doses in hospitalized patients

PCORI-Funded Study	**Study Title:** Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology **Principal Investigator:** Elliott R. Haut, MD, PhD, Johns Hopkins University	**Altmetric Score (Attention)**
Results Publication Highlight #1	Haut EP, et al. **Effect of Real-time Patient-Centered Education Bundle on Administration of Venous Thromboembolism Prevention in Hospitalized Patients.** *JAMA Network Open*. Nov 2018. jamanetwork.com/journals/jamanetworkopen/fullarticle/2714505 • "Timely, targeted education significantly reduces nonadministration of VTE prophylaxis in hospitalized patients and improves health care quality by leveraging real-time data to target interventions for at-risk patients."	 **Top 25%** of attention, given the journal
Results Publication Highlight #2	Lau BD, et al. **Effectiveness of two distinct web-based education tools for bedside nurses on medication administration practice for venous thromboembolism prevention: A randomized clinical trial.** *PLOS One*. Aug 2017. journals.plos.org/plosone/article?id=10.1371/journal.pone.0181664 • "Education for nurses significantly improves medication administration practice. Dynamic learner-centered education is more effective at engaging nurses. These findings suggest that education should be tailored to the learner."	 **Top 2%** of attention, given the journal

PCORI-Funded Study Results ⇨ Implementation Project #1

- **Title:** Preventing Venous Thromboembolism (VTE): Engaging Patients to Reduce Preventable Harm from Missed/Refused Doses of VTE Prophylaxis
- **Principal Investigator:** Elliott R. Haut, MD, PhD, Johns Hopkins University
- This project scaled up implementation of a patient-centered VTE prevention education intervention in 2 hospitals (17,000 patients total).
  - **Academic Hospital:** Expanded to all floors. This academic hospital served as the original study site (4 floors only). The implementation project adapted the programs to ensure integration with hospital workflows and extended the programs to the remaining 16 floors throughout this hospital.
  - **County Hospital:** All floors of a medium-sized community, suburban, non-teaching hospital.

This implementation project has:

- **Improved the scalability** of the tested VTE prophylaxis program by integrating into regular nursing care, developing feedback mechanisms, and building in flexibility for implementation across hospitals and hospital units
- **Improved VTE prophylaxis administration**. All improvements were significant ($p<0.001$):
  - Increase in number of VTE prophylaxis doses administered during hospitalization
  - Decrease in overall number of missed VTE prophylaxis doses
  - Decrease in number of missed VTE prophylaxis doses due to patient opt-out

PCORI-Funded Study Results ⇨ Implementation Project #2

- **Title:** Implementing Best-Practice, Patient-Centered Venous Thromboembolism (VTE) Prevention in Trauma Centers
- **Principal Investigator:** Elliott R. Haut, MD, PhD, Johns Hopkins University
- Following the initial implementation effort, this project will expand delivery of intervention to 10 trauma centers across the US, including a mix of different hospital sizes, types, and locations.
    - Involving all nurses across 61 floors
    - Reaching 32,000 trauma patients (~40% non-white)
    - Continue to assess missed doses of VTE prophylaxis and VTE events; intervention delivery

If successful, the American College of Surgeons Committee on Trauma (ASC-COT) has agreed to support scaling this intervention to 800 hospitals across all 50 states

Potential to reach 1M+ patients admitted to trauma centers each year

PCORI Funded Study Results → Dissemination by External Groups

Video, Handouts, and Nurse Education Module

The Johns Hopkins Venous Thromboembolism Collaborative has developed a video and an educational handout to better engage patients and families as partners in preventing blood clots.

- The educational video is available on Youtube and has gained over 200,000 views
- The nurse education modules are now available on the Armstrong Institute's learning management system, available to the public
- The handout is now available in 13 languages, and in large-print English

CMS-Funded Quality Improvement Initiative

CMS funded several Hospital Improvement Innovation Networks (HIINs) to make progress on core patient safety efforts, with a focus on preventable harm including VTE prevention. One of those HIINs collaborated with Dr. Elliott Haut on a **6-month quality improvement initiative for VTE**.

- 22 hospitals and health systems in 14 states were a part of this initiative
- The initiative included disseminating the nurse education module and covered the cost of over 1,000 licenses to the module, given out to approximately 20 institutions to use for staff training

Goal 3: Influence the Way Research is Done

Development of Resources to Promote/Support PCOR

PCORI's approach inspired the Children and Youth with Special Health Care Needs National Research Network's (CYSHCNet) compensation guides for researchers and research partners

PCORI's Engagement Rubric, Budgeting for Engagement Activities, and Compensation Framework inspired CYSHCNet's creation of more tailored compensation guides meeting their needs for:

- Youth and family research partners
- Researchers

CYSHCNet compensation guides now shared with other institutions:

- Lucille Packard Foundation, American Academy of Pediatrics, including the Pediatric Research in Office Settings program, American Board of Pediatrics, and others

Involving youth and families as partners in research studies is a concept that has been promoted by family and community organizations…like the Patient-Centered Outcomes Research Institute…Organizations such as these have determined that involving youth and families in research studies as partners makes the research more meaningful to all stakeholders and improves the quality of the end product.

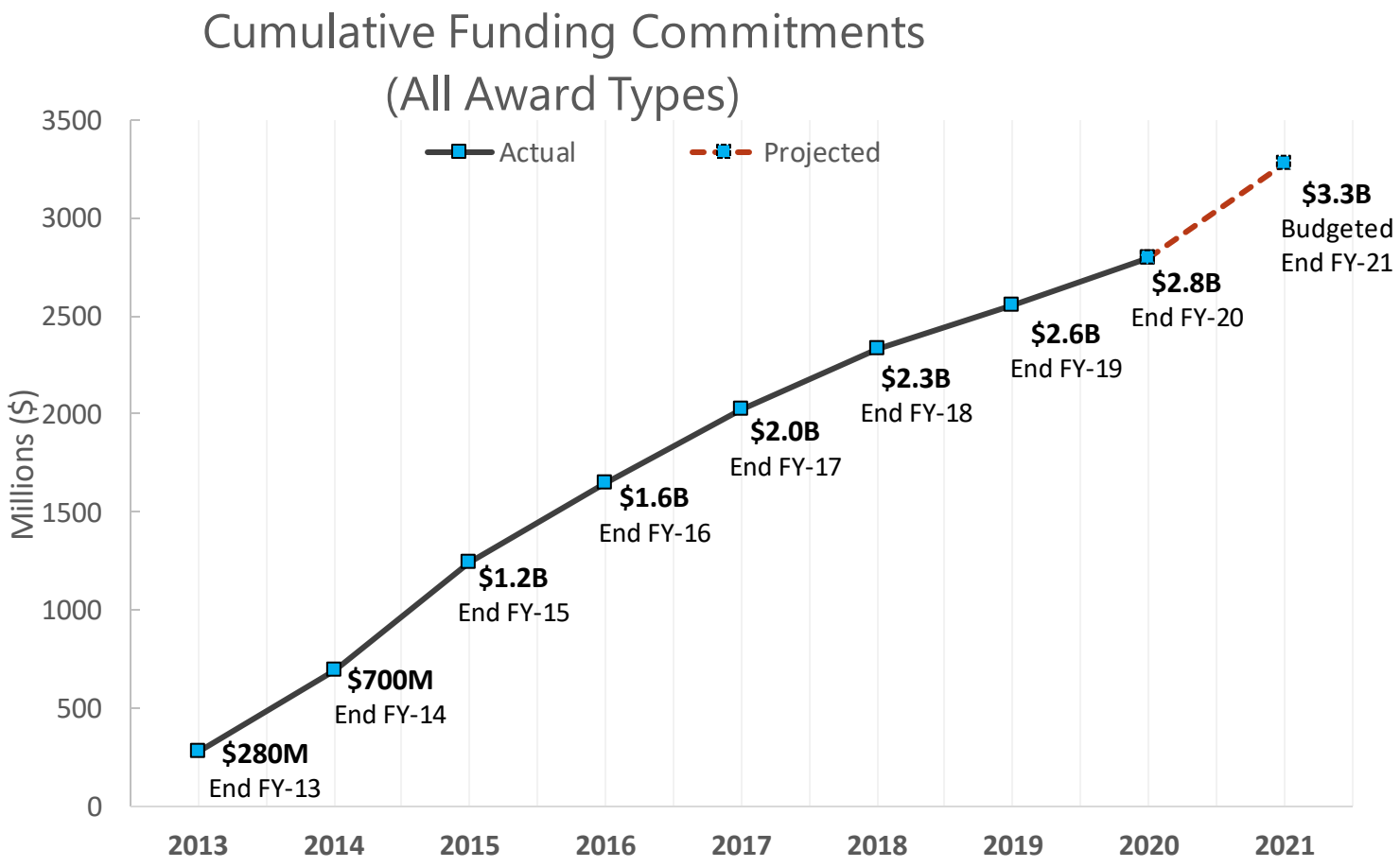
– from CYSHCNet's Partnering with Youth & Families in Research: A Standard of Compensation

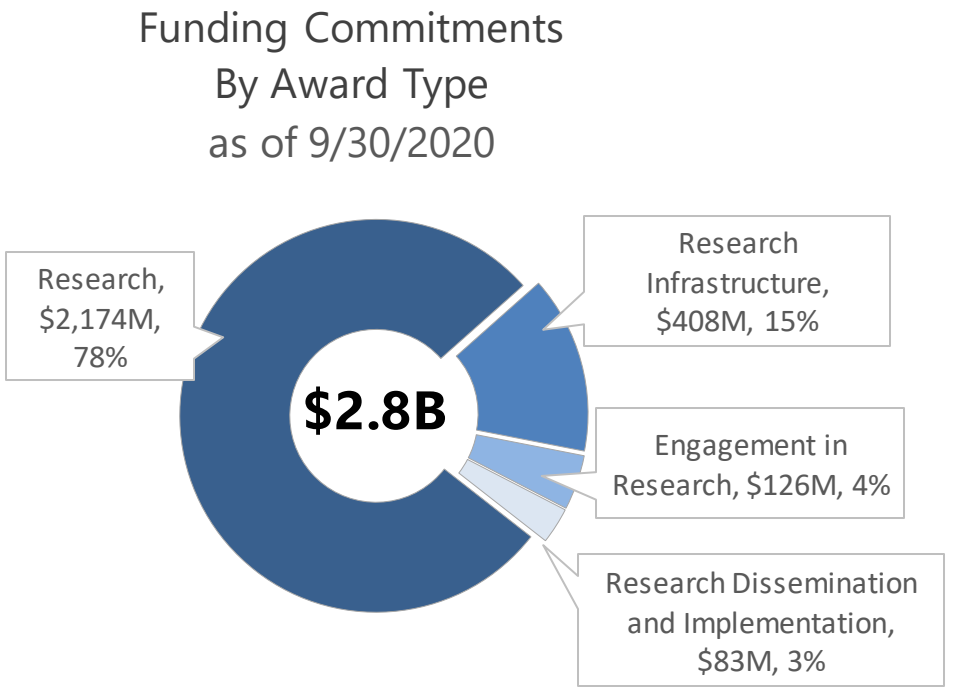
A Standard of Compensation for Youth and Family Partners

https://cyshcnet.org/compensation-guide-for-youth-family-partners/

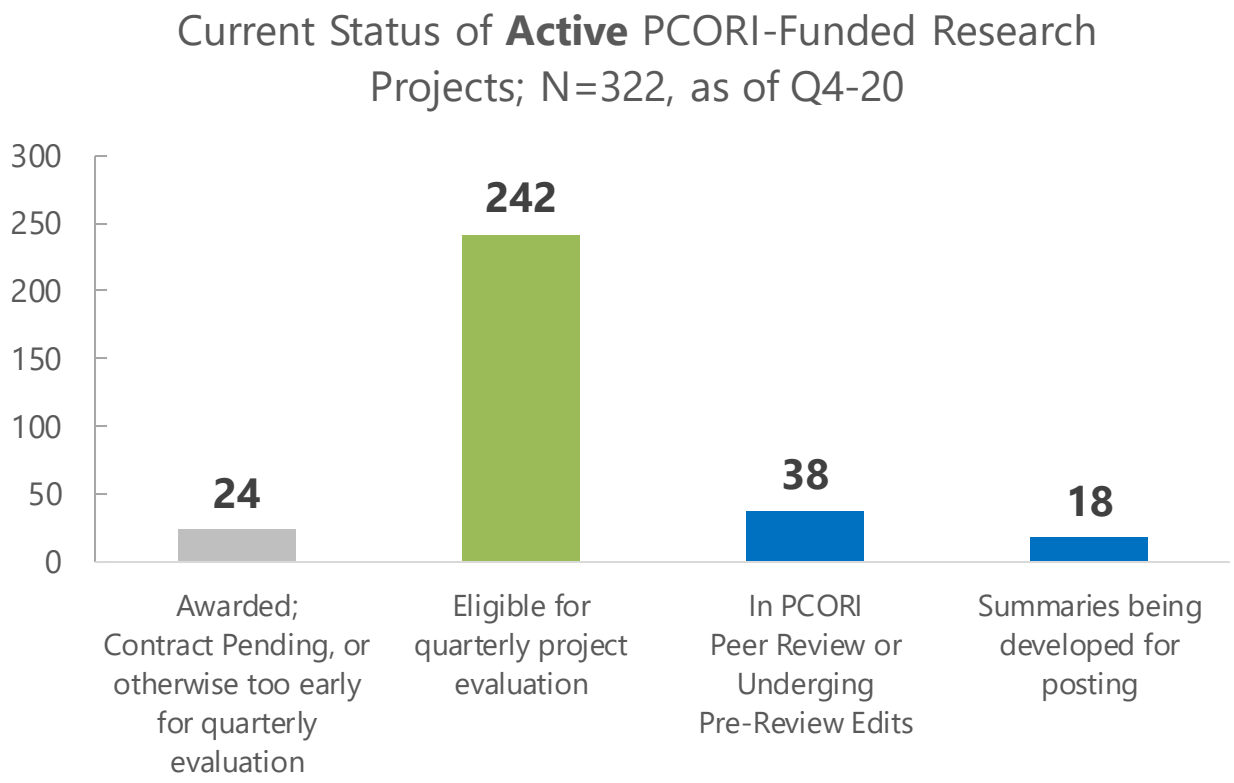
Charlene Shelton, RN, MA, MPA, PhD; CYSHCNet [October 2019]

$2.8B in Cumulative Funding Commitments as of FY2020





Status of PCORI-Funded Research Projects



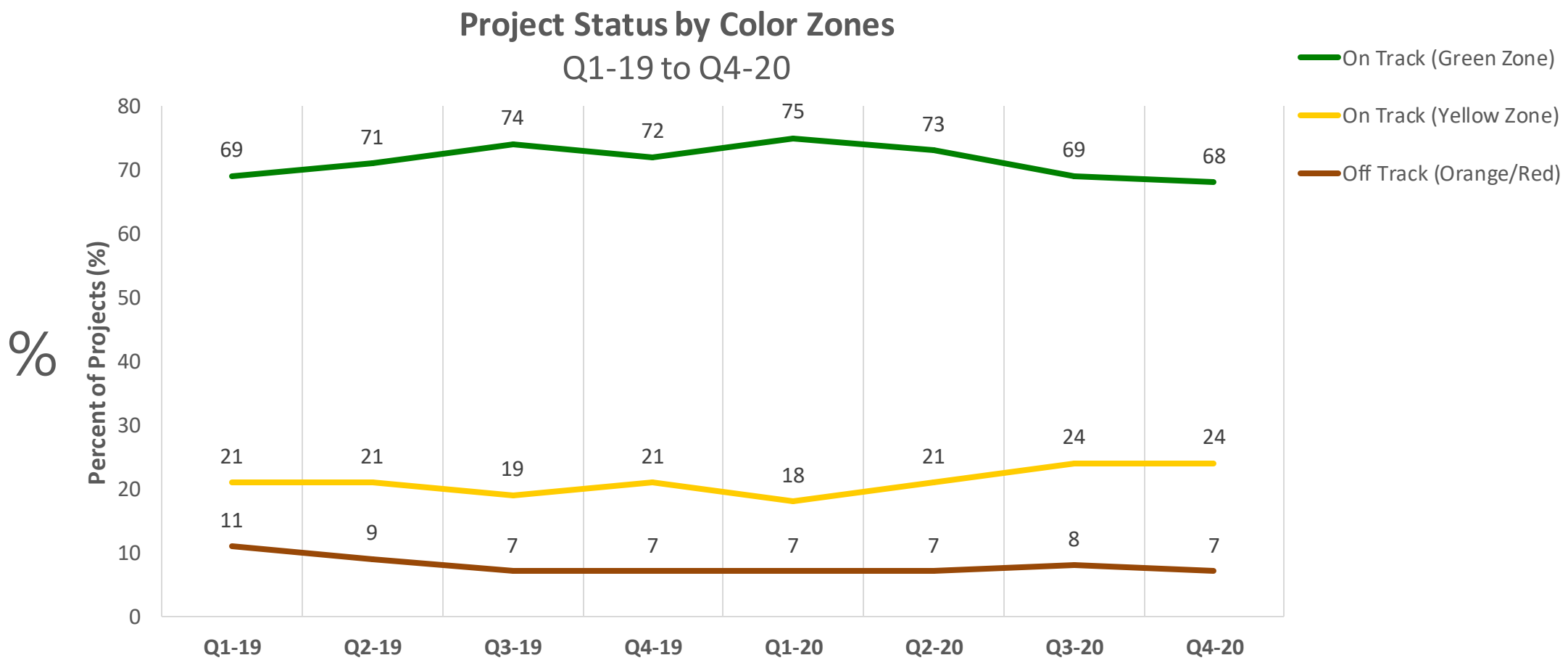
Count of **Completed** Research Projects as of Q4-20

368

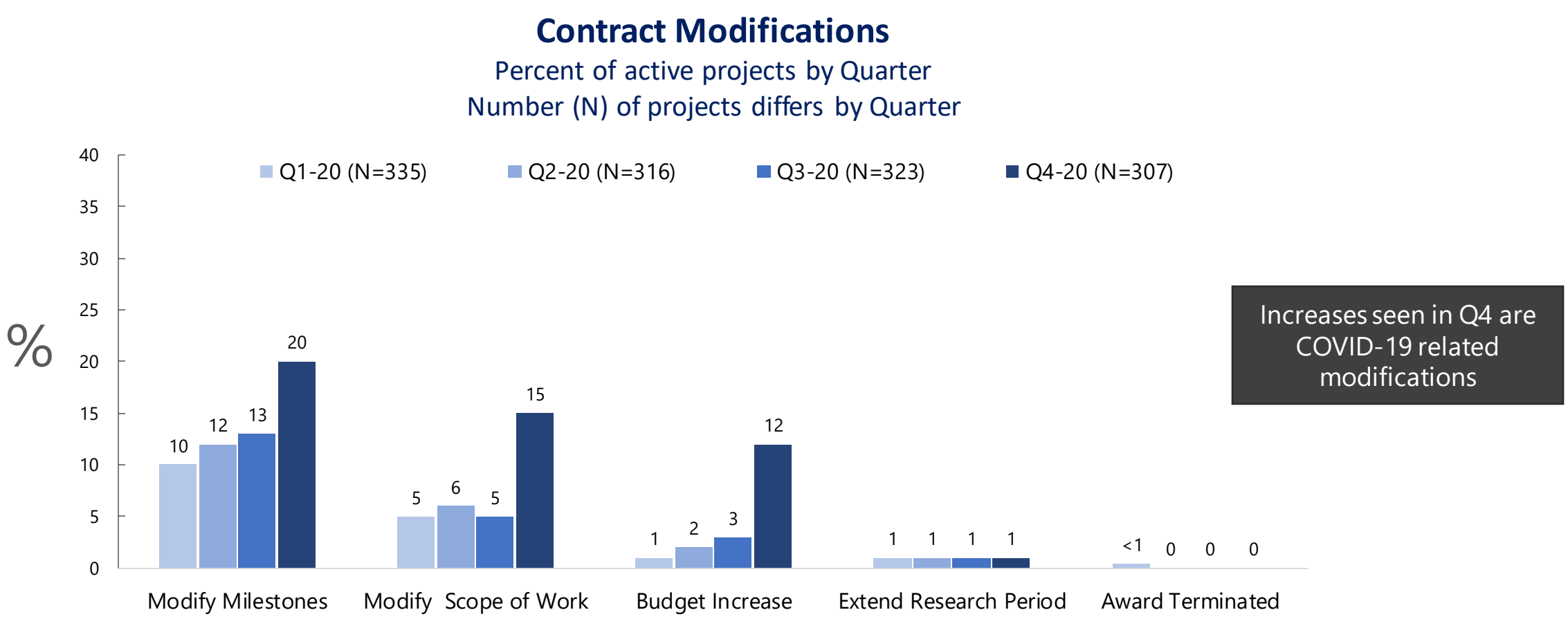
Status of PCORI-Funded Research Projects:

% of projects in Yellow is higher than usual due to COVID delays

We are monitoring trends and shifts in project status (most recent 8 quarters shown)



Contract Modifications
Q4-20 Update



Results from early cycles indicate that PCORI-funded studies are doing better on recruitment than available points of reference

Through literature searches and working with other funders, we identified ***points of reference for research projects:***

55% of studies meet original **enrollment target**[1]

Around 10% of research projects are **not successfully completed**[2]

To meet desired recruitment levels, average enrollment timelines are **194% of planned duration (nearly double)**[2]

pcori®
Results to date

64%
Meet original enrollment target

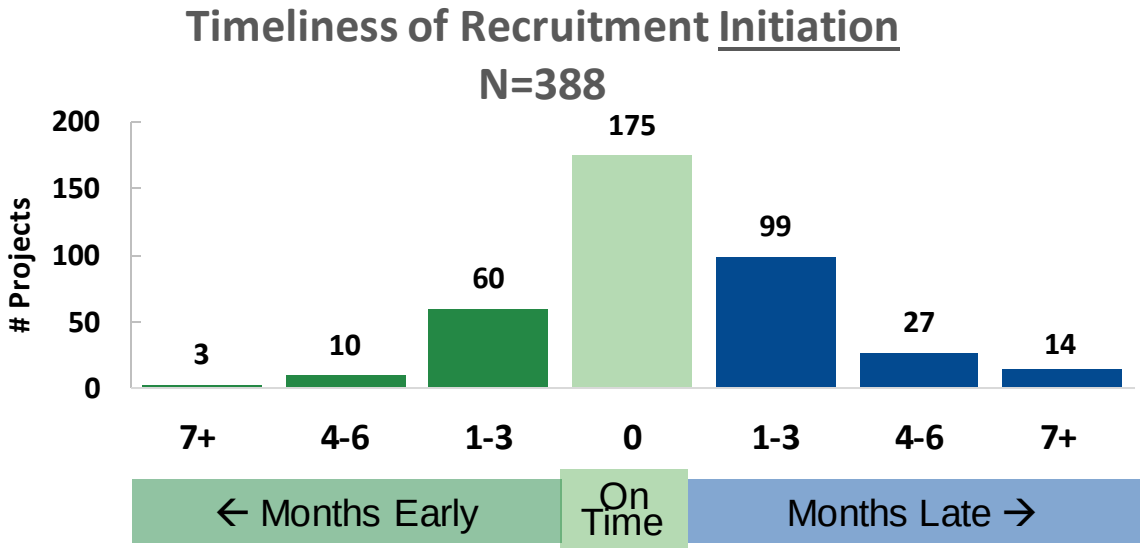
6%
Not successfully completed

135%
Of original timelines

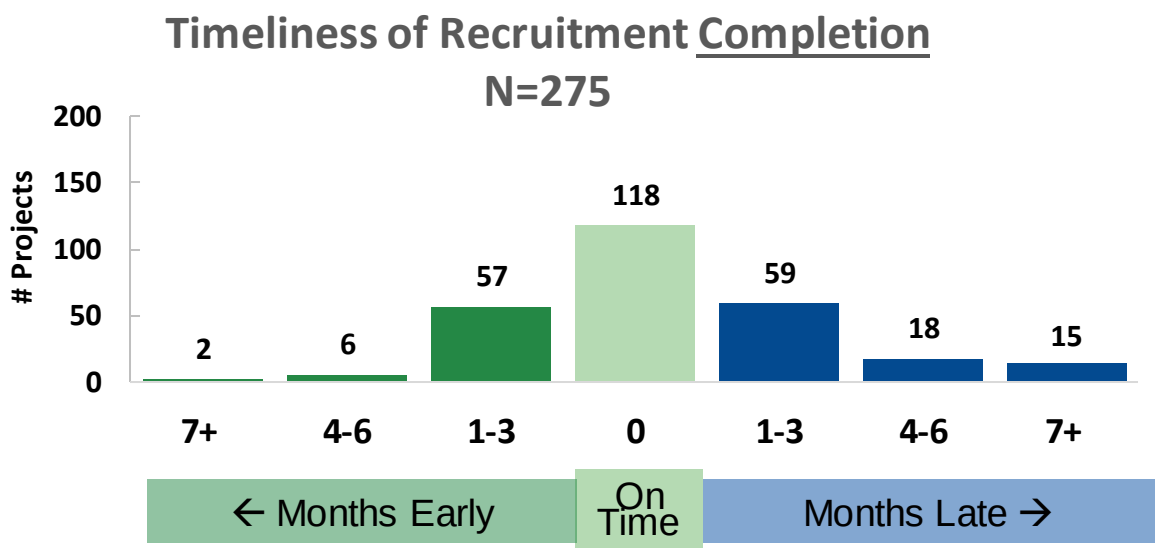
Points of Reference:

1. O'Sullly, BG, Julious SA, Nicholl J. **A Reinvestigation of Recruitment to Randomised, Controlled, Multicenter Trials: A Review of Trials Funded by Two UK funding Agencies**. *Trials*. Jun 2013.
2. Tufts Center for the Study of Drug Development. **89% of Trials Meet Enrollment, but Timelines Slip, Half of Sites Under-enroll.** *Tufts CSFDD Impact Reports.* January/February 2013, Vol. 15 No. 1.

Recruitment Initiation & Completion Timing



62% Started on time or early



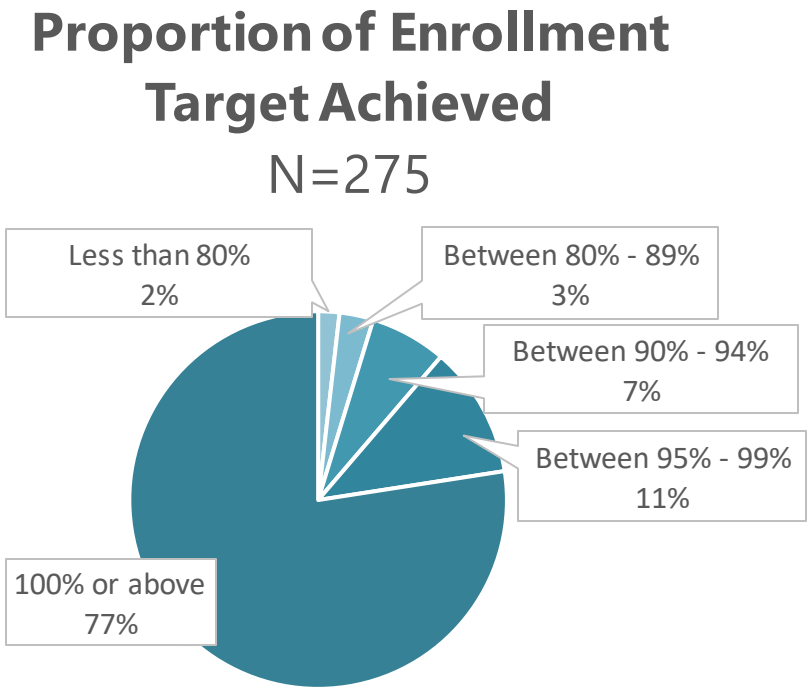
67% Completed on time or early

The majority of those that initiated or completed recruitment late were less than 3 months behind

Timelines in this slide refer to current contractual milestones, not to originally-intended timelines (explored separately)

Enrollment Targets

Among studies that have completed recruitment (N=275)



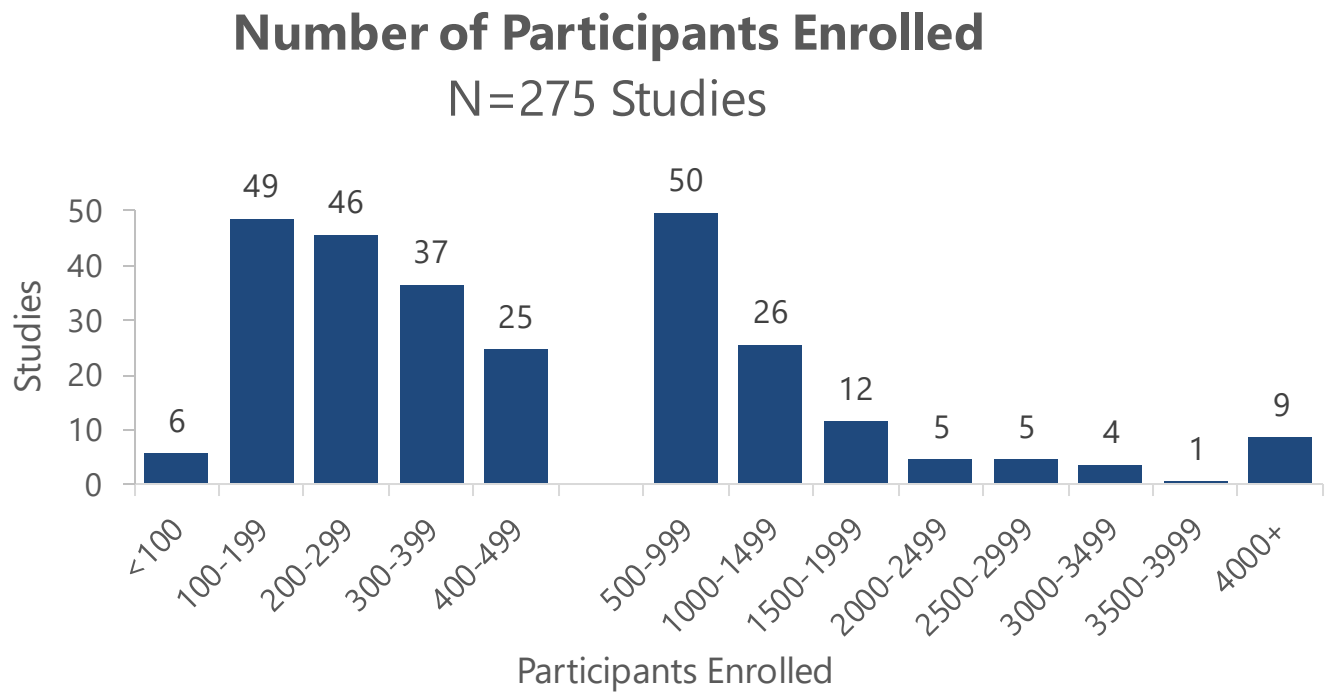
95% achieved >90% of enrollment target

Some Modified Targets: 8% of studies had decreases in enrollment target that were associated with a decrease in statistical power

PCORI: 77% met or exceeded enrollment target (64% met or exceeded *original* enrollment target) vs. Point of Reference: 52-55% (Tufts 2013, *Trials* 2013)

Total Participants Enrolled

Among studies that have completed recruitment (N=275)



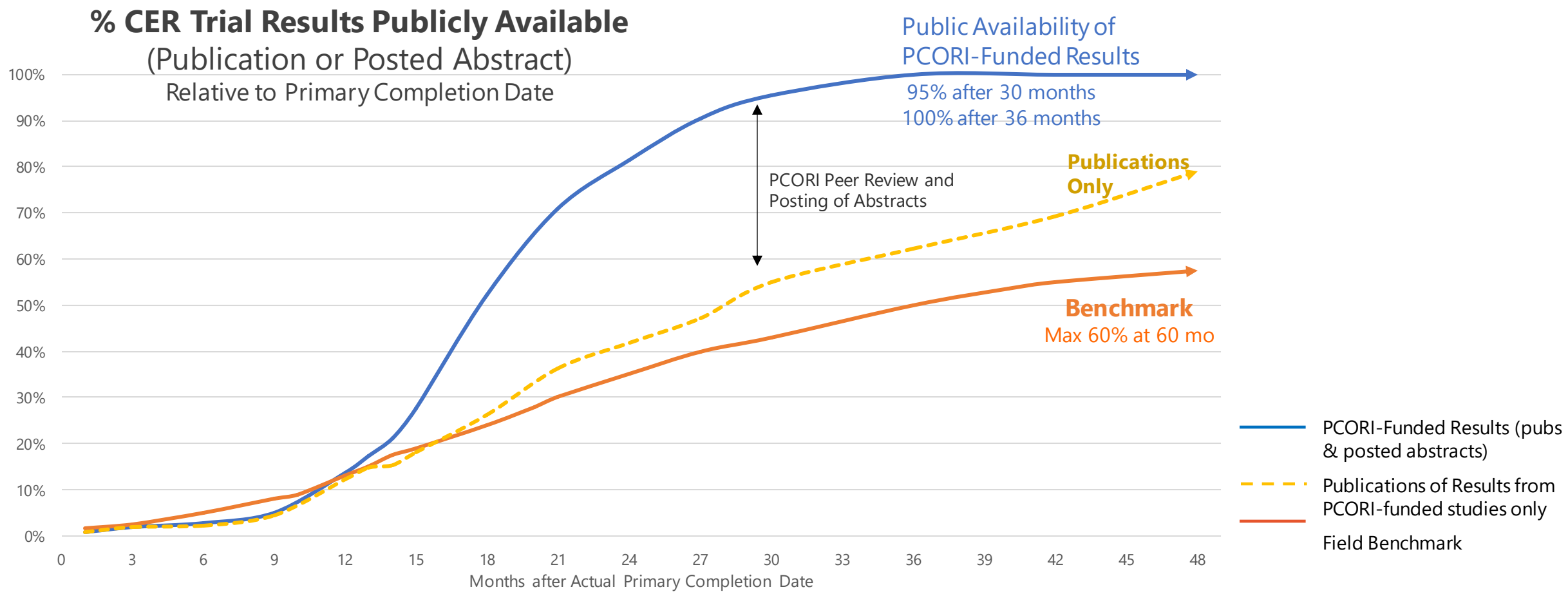
The break in the X axis represents a change in size of the groupings

Median: 398 participants per study
Average: 997 participants per study

- 23% Enrolled more than 1000 participants

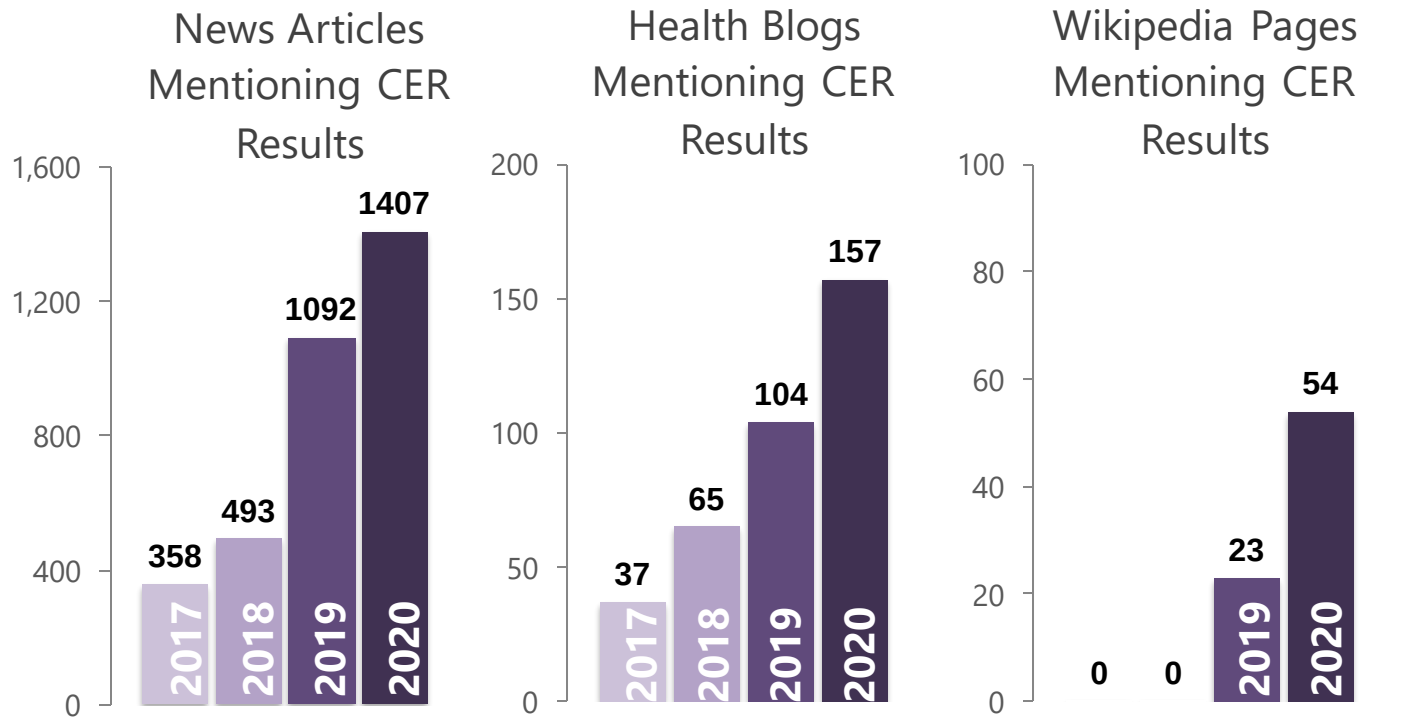
PCORI Average: 997 Enrolled vs. Point of Reference: Average 622 Enrolled (Tufts 2013)

PCORI's Process Provides Complete and Earlier Availability of Results in the Public Domain



Attention to CER Results from PCORI-Funded Studies
Cumulative Totals by End of Year

News, Blogs, and Wikipedia

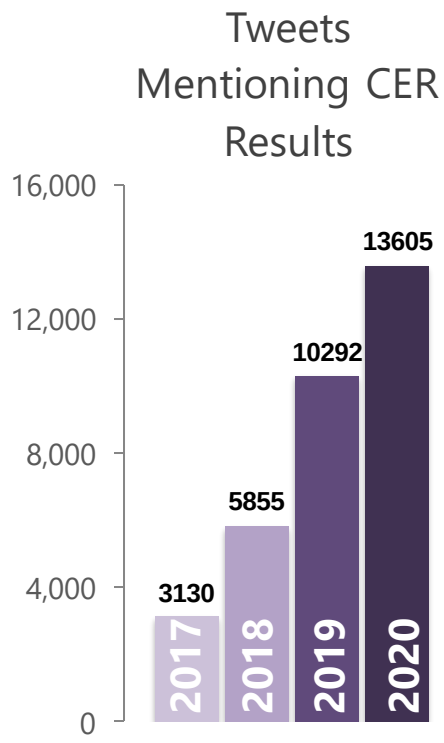


Cumulative News Articles: 1407

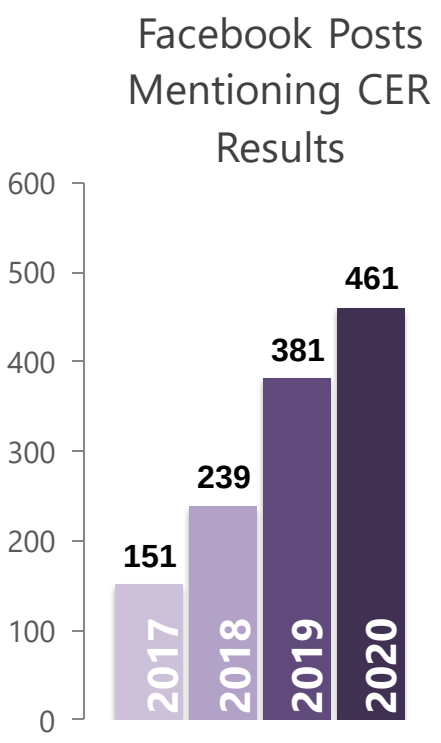
Cumulative Health Blogs: 157

Cumulative Wikipedia Citations: 54

Social Media (public posts only)



Cumulative Tweets: 13605

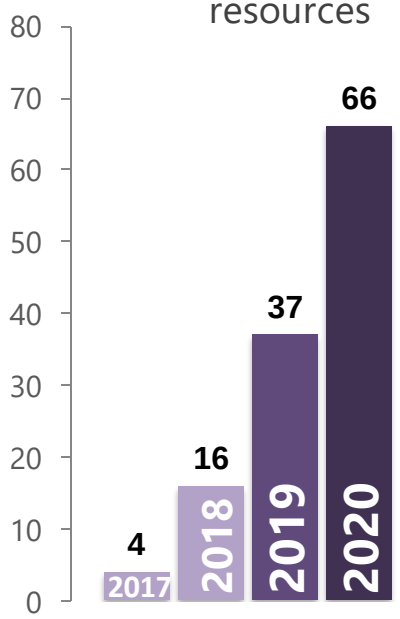


Cumulative Facebook Posts: 461

Uptake and Use of Results from PCORI-Funded Studies
Cumulative Totals by End of Year

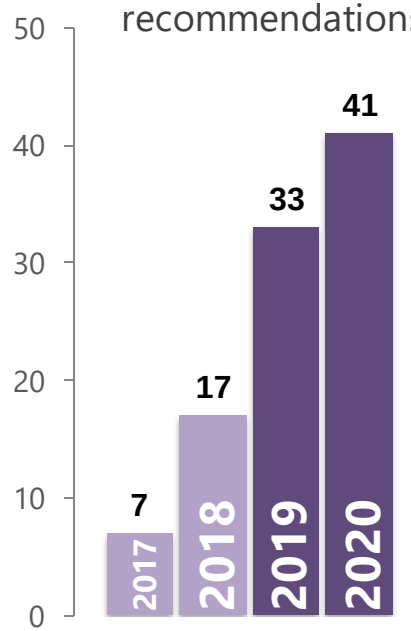
Uptake into Evidence-Based Clinical Recommendations

Citations in UpToDate® point-of-care decision resources



Cumulative Citations in UpToDate®: 66

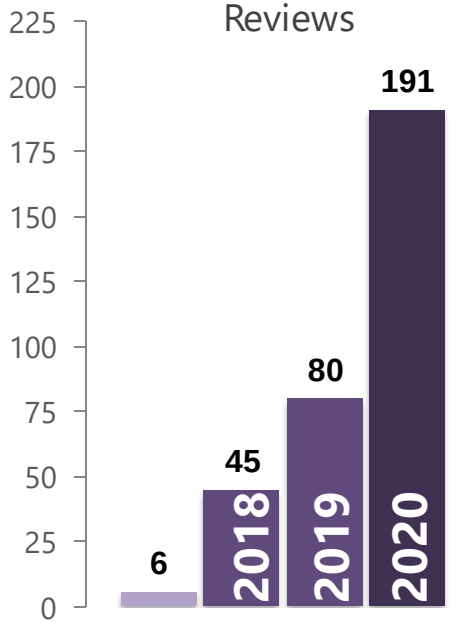
Citations in other evidence-based clinical recommendations



Cumulative Other Citations: 41

Uptake into Systematic Reviews Publications

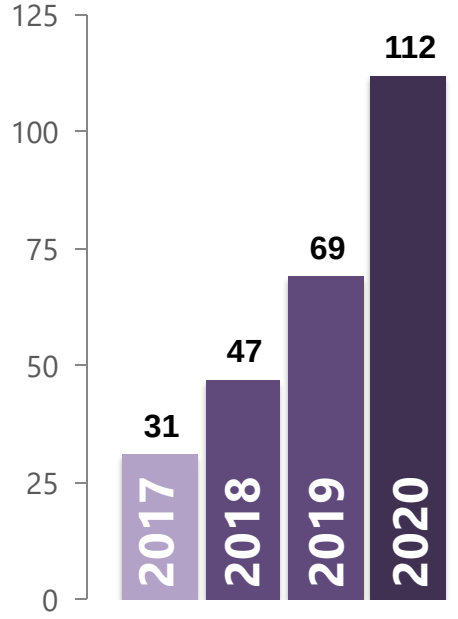
Citations in Meta-Analyses and Systematic Reviews



Cumulative Citations in Systematic Reviews: 191

Uptake into Policy Documents

Citations in Policy Documents



Cumulative Citations in Policy Documents: 112

The Future of the Dashboard

- Link to Strategic Planning Process
  - Major revisions to content may flow from that
- Frequency of review
  - Propose mid-year and end-of-year versus quarterly
    - With interim review and discussion of any issues as necessary

- **Discussion:**
  - Do the Q4 features shared today (Recruitment Update, End of Year Summary) tell you what you need to know about our progress?
  - What changes would you like to see in our FY2021 Dashboard?

COVID-19 Update

Example Ongoing and Emerging Priorities

- Comparative Effectiveness Research and Data Infrastructure for Prevention and Treatment Options
- Disparities in outcomes (including health of essential workers)
- Long-term health implications
- Prevention from deterioration to serious illness
- Emerging conditions (e.g., MIS-C, coagulopathy)
- Complications related to comorbidities or pre-existing health status (e.g., chronic disease, pregnancy)
- Social isolation and implications on mental health
- Health of front-line healthcare workers
- Strategies and scenarios (e.g., care adaptations, testing, health implications of policy interventions, approaches to NPIs)

PCORI's Response to the COVID-19 Health Crisis

Many approaches to supporting critical work in these areas and more:

Awards

- Enhancements of existing awards
- Solicitation of new awards
- Healthcare worker registrytrial

Information Sharing

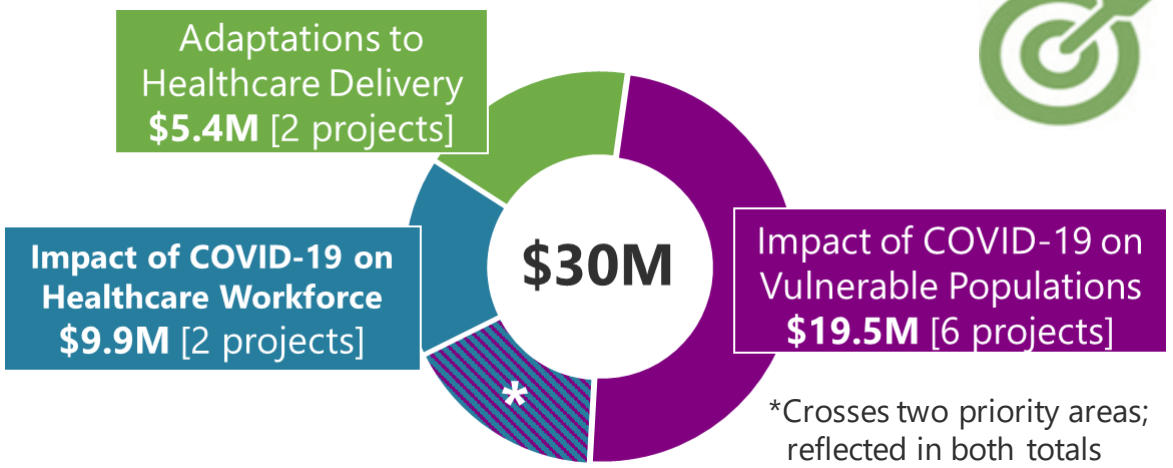
- COVID-19 Horizon Scanning
- PCORI Annual Meeting
- Webinars
- Collaboration with other funders

Adapting for Awardees and Applicants

- Adaptations to existing projects
- Extending application timelines

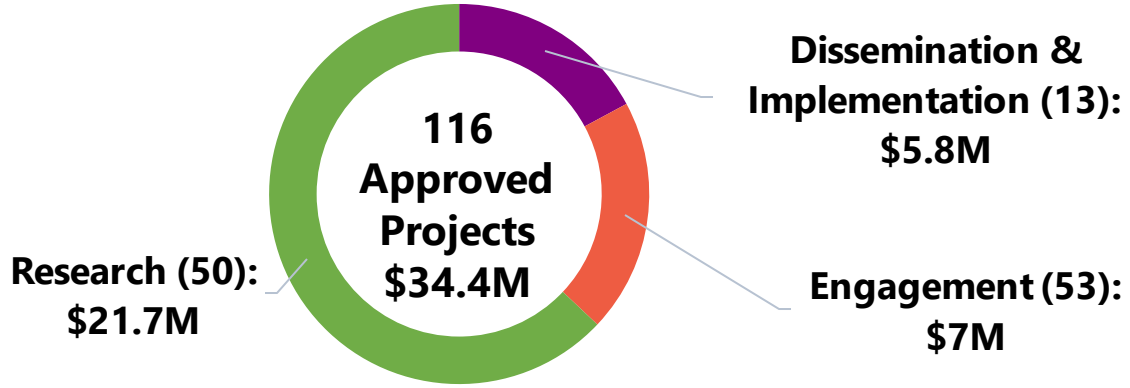
PCORI COVID-19 Funding to Date

COVID-19 Targeted Funding



*Crosses two priority areas; reflected in both totals

COVID-19 Enhancement Projects



Specific conditions and populations

www.heroesresearch.org

PIs: Adrian Hernandez, MD, MHS; Emily O'Brien, PhD; Suzanna Naggie, MD

Institution: Duke University

- Healthcare Worker Registry
- HCQ Trial
- COVID-19 CDM
  - CDC Partnership/Surveillance
  - Coagulopathy and MIS-C
  - Long-term Complications

Example Ongoing and Emerging Priorities: PCORI Funding to Date and Future Opportunities

Ongoing and Emerging Priorities	PCORI Approach
Comparative effectiveness research and data infrastructure for prevention and treatment options	PCORnet dialogue; leverage HERO • Future Board discussion
Long-term health implications	PCORnet COVID-19 Common Data Model efforts
Emerging conditions (e.g., MIS-C, coagulopathy)	PCORnet COVID-19 Common Data Model efforts
Health of front-line healthcare workers	HERO Program and Targeted PFA
Disparities in outcomes (including health of essential workers)	Targeted PFA • Future Board discussion
Complications related to comorbidities or pre-existing health status (e.g., chronic disease, pregnancy)	Enhancement Program
Social isolation and implications on mental health	Future Opportunity
Prevention from deterioration to serious illness	Future Opportunity
Strategies and Scenarios (e.g., care adaptations, testing, health implications of policy interventions, approaches to non-pharmaceutical interventions)	Targeted PFA & Future Opportunity

BREAK

We will return at 3:00 PM ET

Join the conversation on Twitter via @PCORI

Panel Discussion:
Strategic Planning for PCORI 2:0: Health Policymakers and Thought-Leaders

- **Sheila Burke**, MPA, RN, Strategic Advisor, Baker Donelson
- **Lisa Fitzpatrick**, MD, Founder and CEO, Grapevine Health
- **Liz Fowler**, JD, PhD, Executive VP for Programs, The Commonwealth Fund
- **Chris Jennings**, Founder and President, Jennings Policy Strategics Inc.
- **Rodney Whitlock**, PhD, VP, MCDermott+Consulting

Celebrating Jean Slutsky

Thank you, Jean, for over a decade of service to PCORI

Your leadership and dedication helped to create PCORI as we know it and to advance the science and practice of engagement, patient-centered research, and dissemination and implementation of relevant findings

Wrap Up and Adjournment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