

Board of Governors Meeting

via Teleconference/Webinar

December 2, 2021
11:30 – 4:30 PM

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

11:30	Welcome, Call to Order, and Consent Agenda for Approval: October 26, 2021, Board Minutes and Nomination of Advisory Panel on Clinical Trials Member
11:40-12:30	Executive Director's Report
12:30-1:00	Consider for Approval: FY2022 to FY2024 Commitment Plan
1:00-1:30	Consider for Approval: Proposed Research Agenda for Posting for Public Comment
2:00-2:45	Consider for Approval: Award Slates
2:45-3:15	Consider for Approval: Cycle 1 2022 Targeted PFAs
3:15-4:00	Consider for Approval: Health Systems Implementation Initiative (HSII)
4:00-4:30	Public Comment
4:30	Wrap-up and Adjourn

Consent Agenda Items

Christine Goertz, DC, PhD

Chairperson, Board of Governors



Board Vote



- That the Board approve:
 - Minutes from the October 26, 2021, Board meeting
 - Nomination of Cristina Murray-Krezan as a member of the Advisory Panel on Clinical Trials to serve through August 2024, or until a successor is appointed
 - Recommended for Board approval by the Methodology Committee
 - Stakeholder Group: Researcher (Statistician)
 - Institution: University of Pittsburgh

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

Thank you and Best Wishes!



Andrew Hu, MPP

Director, Public Policy & Government Relations

Executive Director's Report

Nakela L. Cook, MD, MPH
Executive Director

FY-2021 Dashboard End-of-Year Review

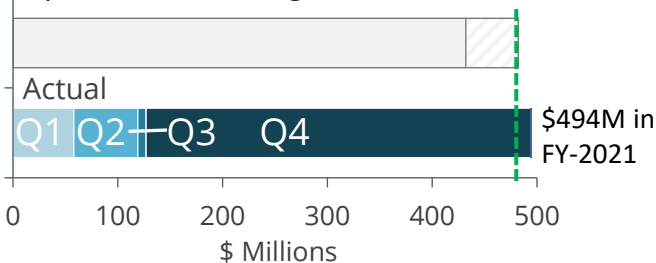
PCORI Board of Governors Dashboard

FY-2021 End-of-Year Review (As of 9/30/21)

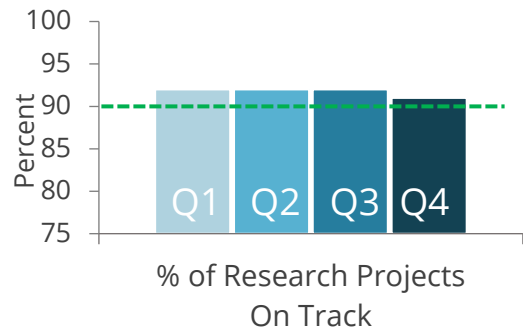


Funds Committed

Commitment Plan 2021 Target:
(up to \$482 including New Initiatives)



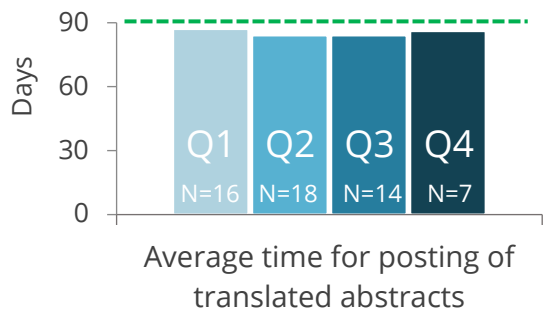
Research Project Performance



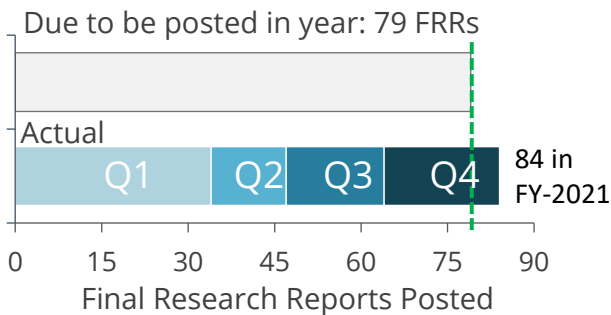
Dashboard Key

Q1 2021	Meeting Target
Q2 2021	Not Meeting Target
Q3 2021	Needs Board Attention
Q4 2021	Target Not Applicable
Projected for 2021	
End-of-Year (Q4) Target	

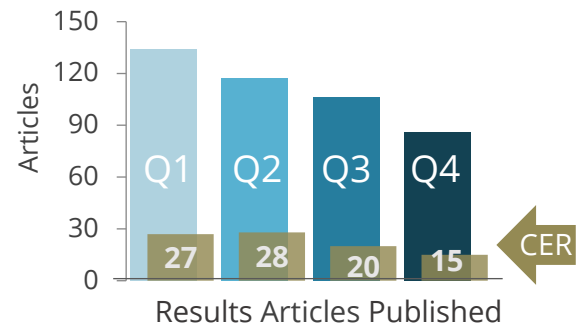
Time to Release of Research Findings



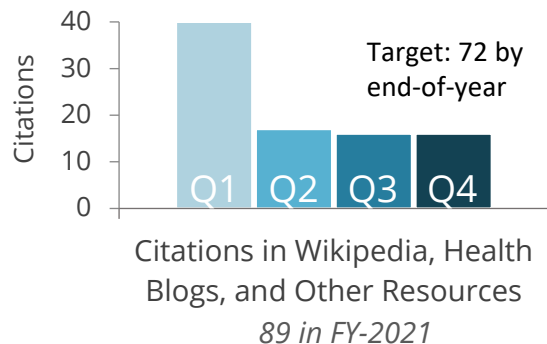
Final Research Reports Posted to PCORI.org



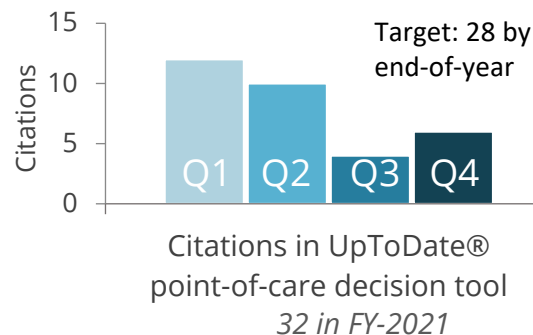
Results Published in the Literature



Uptake into Public/Patient Resources



Uptake of Results into UpToDate®



Other Examples of Uptake

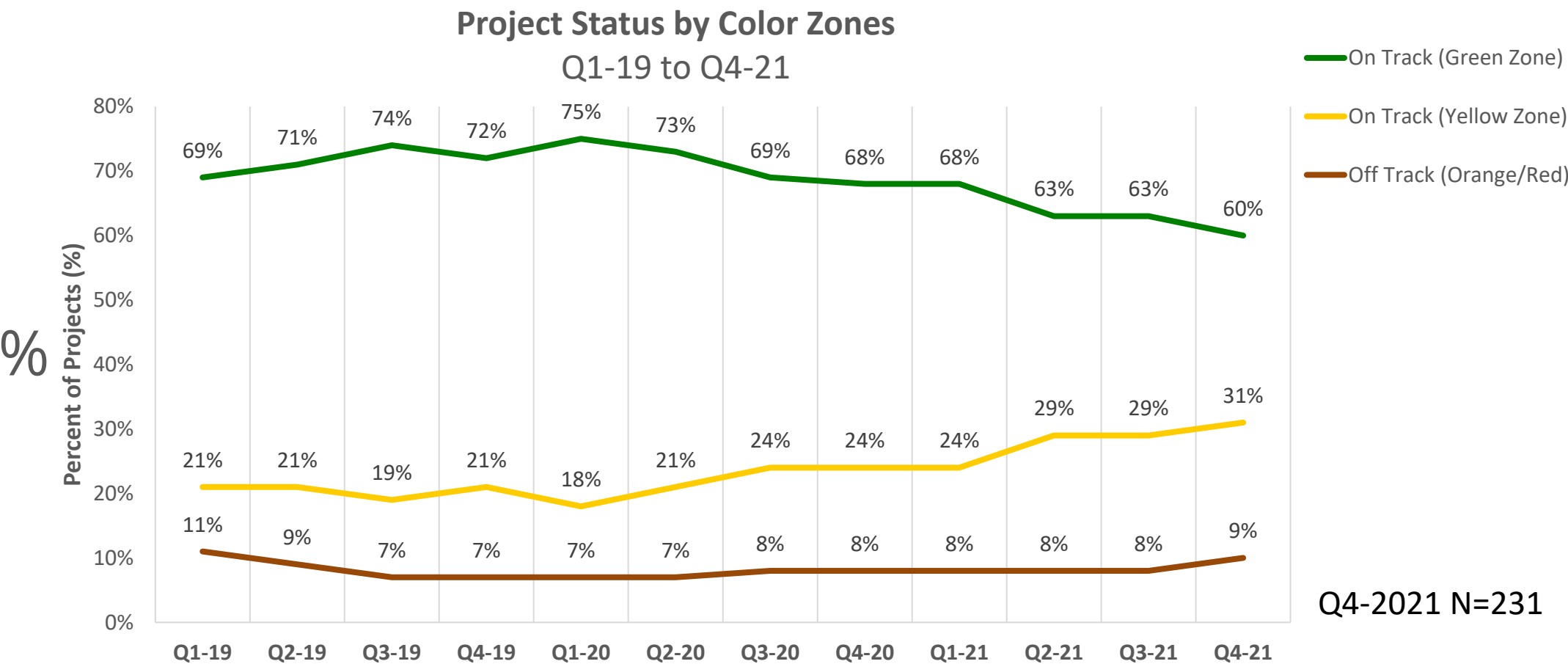


Status of PCORI-Funded Research Projects:

Percent of Yellow-status projects higher due to COVID-19 delays



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

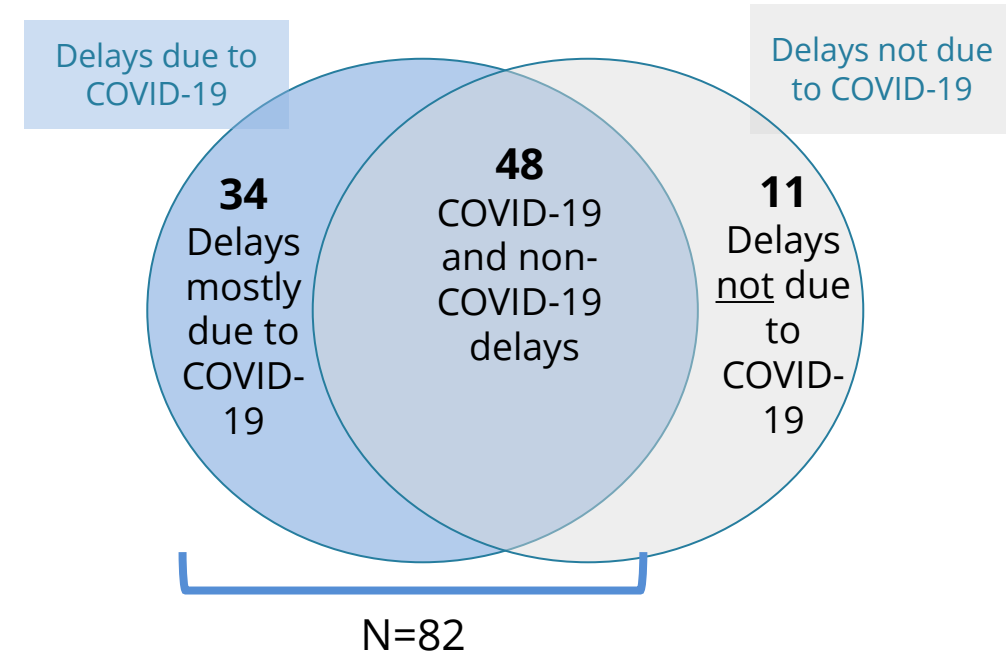


COVID-19 Disruptions/Delays in PCORI-Funded Research

Of 231 PCORI-funded studies eligible for status evaluation:

- 138 (60%) projects are Green
- 93 (40%) projects are Yellow, Orange, or Red
 - 82 (88%) of these projects have COVID-19-related delays
 - Delays for 34 (41%) of these primarily due to COVID-19
 - Delays for the other 48 (59%) partly due to COVID-19

Yellow-, Orange-, Red-Status Projects (N=93)



The PCORnet® Dashboard



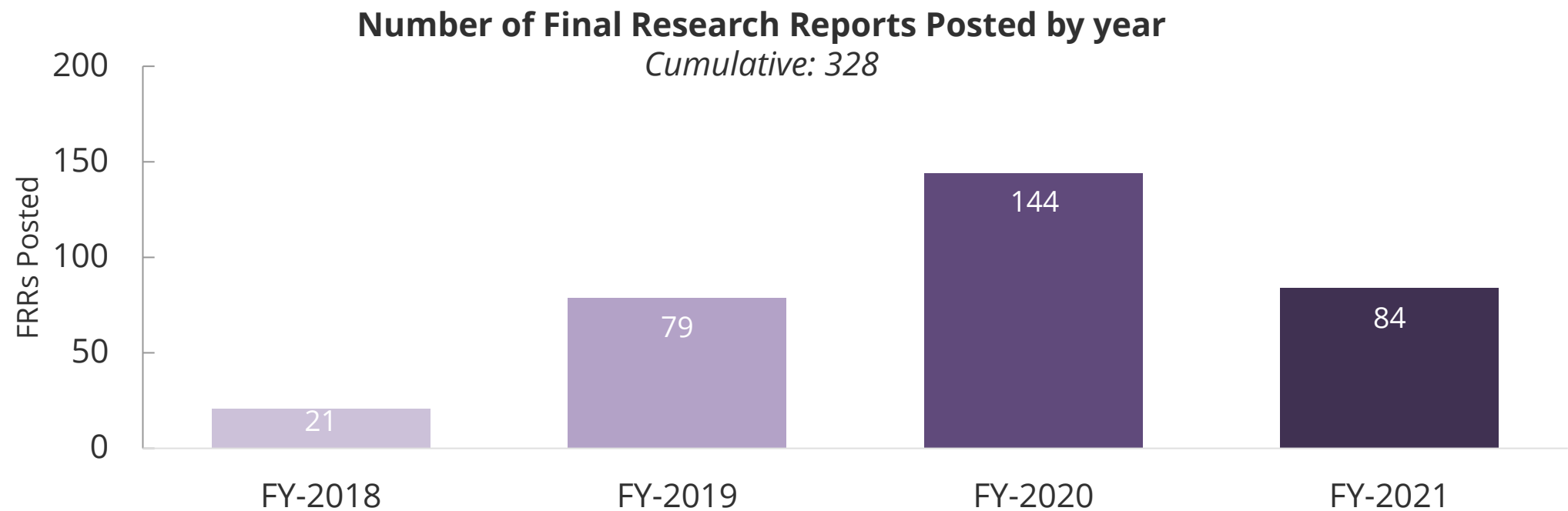
- Available on PCORI's website and the PCORnet website
- Includes 13 metrics monitoring Front Door requests, COVID-19 projects, Data Quality, Publications, Resource Utilization, and Funded Studies
- PCORI staff and the Research Transformation Committee provide oversight
- Closely monitoring progress toward the Prioritizing Principles for Infrastructure Funding Relating to PCORnet



Posting of Final Research Reports from PCORI-Funded Studies to PCORI.org



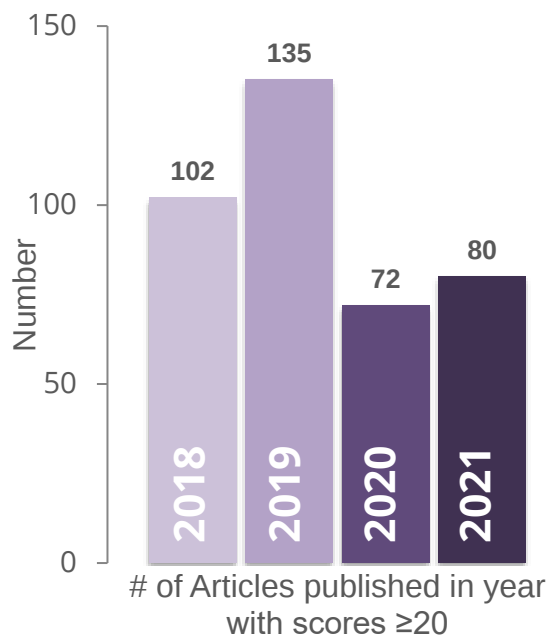
The Final Research Report (FRR) is a comprehensive, PCORI peer-reviewed, report on the PCORI-funded study, typically equivalent to the length and content of 3-5 journal articles.



Attention to Journal Publications from PCORI-Funded Studies

Number of Publications with High Altmetric Scores

Includes all types of publications (results, editorials, etc.)

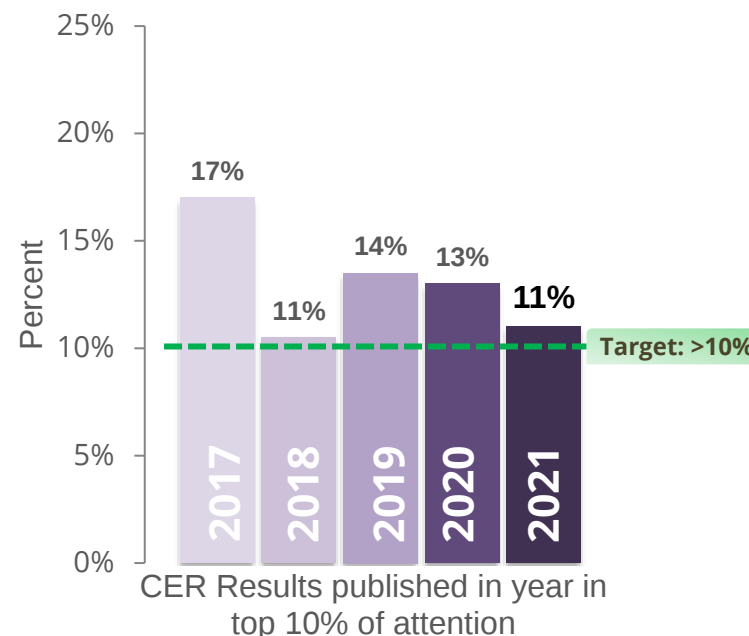


Cumulative: 568

(18% of articles indexed in Altmetric)

Altmetric Scores for CER Results in Context

CER results only, Controlled for Journal and Date of Publication



Average: 13% each year

Attention to Journal Publications with CER Results from PCORI-Funded Studies

CER Results publications from PCORI-funded studies with Altmetric scores ≥ 100 , considered a very high score

Altmetric	CER Results Publications Highlights	Score in Context*
	CODA Collaborative, Flum DR, et al. <u>A Randomized Trial Comparing Antibiotics with Appendectomy for Appendicitis.</u> <i>New England Journal of Medicine</i> . Nov 2020. [Primary CER Results]	Top 11% of attention
	Schuyler Jones W, et al. <u>Comparative Effectiveness of Aspirin Dosing in Cardiovascular Disease.</u> <i>New England Journal of Medicine</i> . May 2021. [Primary CER Results]	Top 18% of attention
	Almazan AN, et al. <u>Association Between Gender-Affirming Surgeries and Mental Health Outcomes.</u> <i>JAMA Surgery</i> . July 2021. [Secondary CER Results]	Top 3% of attention
	Bramante CT, et al. <u>Metformin and risk of mortality in patients hospitalised with COVID-19: a retrospective cohort analysis.</u> <i>Lancet Healthy Longev</i> . Jan 2021. [Secondary CER Results]	Top 5% of attention
	Stevens JM, et al. <u>Risk Factors Associated With Transition From Acute to Chronic Low Back Pain in US Patients Seeking Primary Care.</u> <i>JAMA Network Open</i> . Feb 2021. [Secondary CER Results]	Top 13% of attention
	Fortney JC, et al. <u>Comparison of Teleintegrated Care and Telereferral Care for Treating Complex Psychiatric Disorders in Primary Care.</u> <i>JAMA Psychiatry</i> . August 2021. [Primary CER Results]	Top 28% of attention

* Controlled for journal and date of publication

Goal: Increase Information for Health Decision-Making

Results from PCORI-Funded Study: Spinal anesthesia and general anesthesia are equally safe for hip fracture surgery



PCORI-Funded Study

Study Title: A Practical Intervention to Improve Patient-Centered Outcomes after Hip Fractures Among Older Adults (Regain Trial)

Principal Investigator: Mark Neuman, MD, MS, The Trustees of the University of Pennsylvania

Results Publication

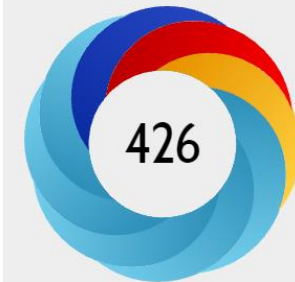
Neuman MD, et al. **Spinal Anesthesia or General Anesthesia for Hip Surgery in Older Adults.** N Engl J Med. 2021 Oct 9. doi: 10.1056/NEJMoa2113514. [Link to Publication.](#)

Summary: Each year, 300,000+ adults in the U.S. break a hip; 90% occur in people aged 50 or older. Nearly all people with a hip fracture need surgery with anesthesia. Patients receive either general anesthesia, which often requires a temporary breathing tube, or spinal anesthesia, which does not. This PCORI-funded study compared how these two types of anesthesia affect patients' recovery and long-term health.

- 45 university and community hospitals in the U.S. and Canada
- 1,600 patients aged 50 and older scheduled to have surgery for a hip fracture
- Assessed patients' ability to walk, overall health, other outcomes, 2 months after surgery

The study found that spinal anesthesia for hip-fracture surgery in older adults was not superior to general anesthesia with respect to survival and ability to walk two months post-surgery; both forms of anesthesia were equally safe. These results could help decision making about which anesthesia option best fits a patient's preferences.

Altmetric Score (Attention)



Mentioned by

- 11 news outlets
- 2 blogs
- 508 tweeters
- 5 Facebook pages

Top 5% of Attention given the journal



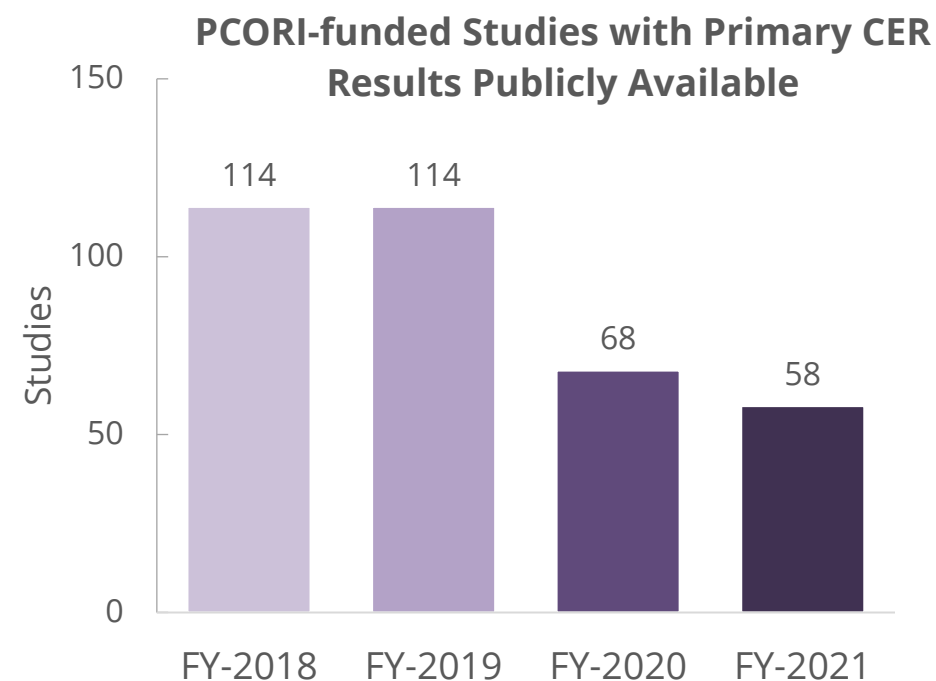
"Our study argues that, in many cases, either form of anesthesia appears to be safe. This is important because it suggests that choices can be guided by patient preference rather than anticipated differences in outcomes in many cases."

- Dr. Mark Neuman, from PennToday Press Release, 10/14/21

Public Availability of Primary CER Results from PCORI-Funded Studies

As of Q4-21, **388 PCORI-funded studies have primary CER results peer-reviewed and publicly available**, and this number is steadily increasing.

- **Primary results** are from a comparison of clinical approaches using the pre-specified primary outcome(s). Also commonly referred to as primary publications, or Public Disclosure of Results (PDOR).
- 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

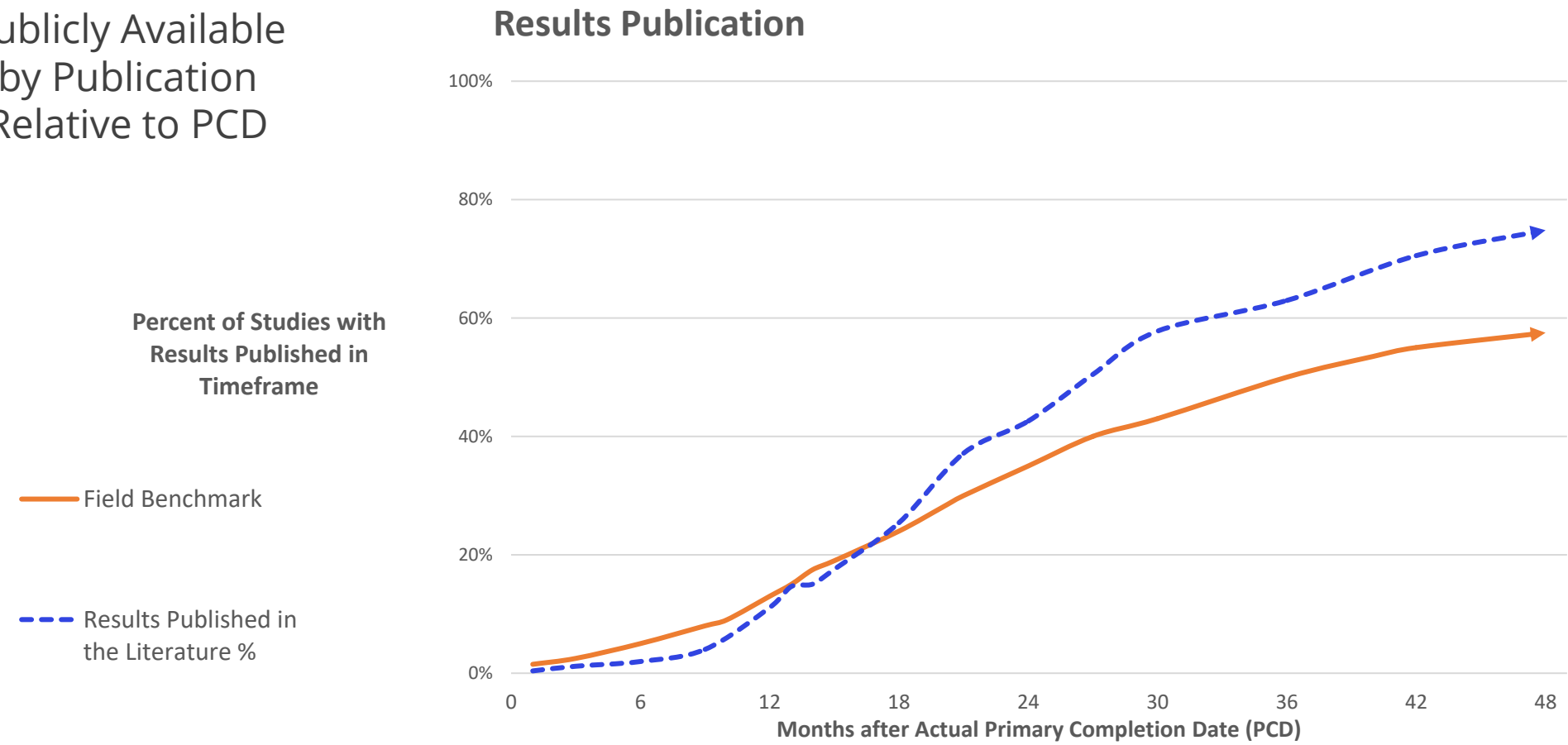


Cumulative: 388 PCORI-funded studies
with publicly available CER results

Research Results from PCORI-Funded Trials Published in Peer-reviewed Literature at Rate Similar to or Greater than Benchmark



% CER Results Publicly Available by Publication Relative to PCD



Results Publications from PCORI-funded Trials

Benchmark
Max: 60% at 60 months

Benchmarks Based on:

- C Riveros, A Dechartres, et al. Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals. Plos One, Dec 2013.
- R Chen, N Desai, H Krumholz, et al. Publication and Reporting of Clinical Trial Results: Cross Sectional Analysis Across Academic Medical Centers. BMJ, Jan 2016.

PCORI's Progress Toward Target to Speed Public Availability of Research Results from PCORI-Funded Trials

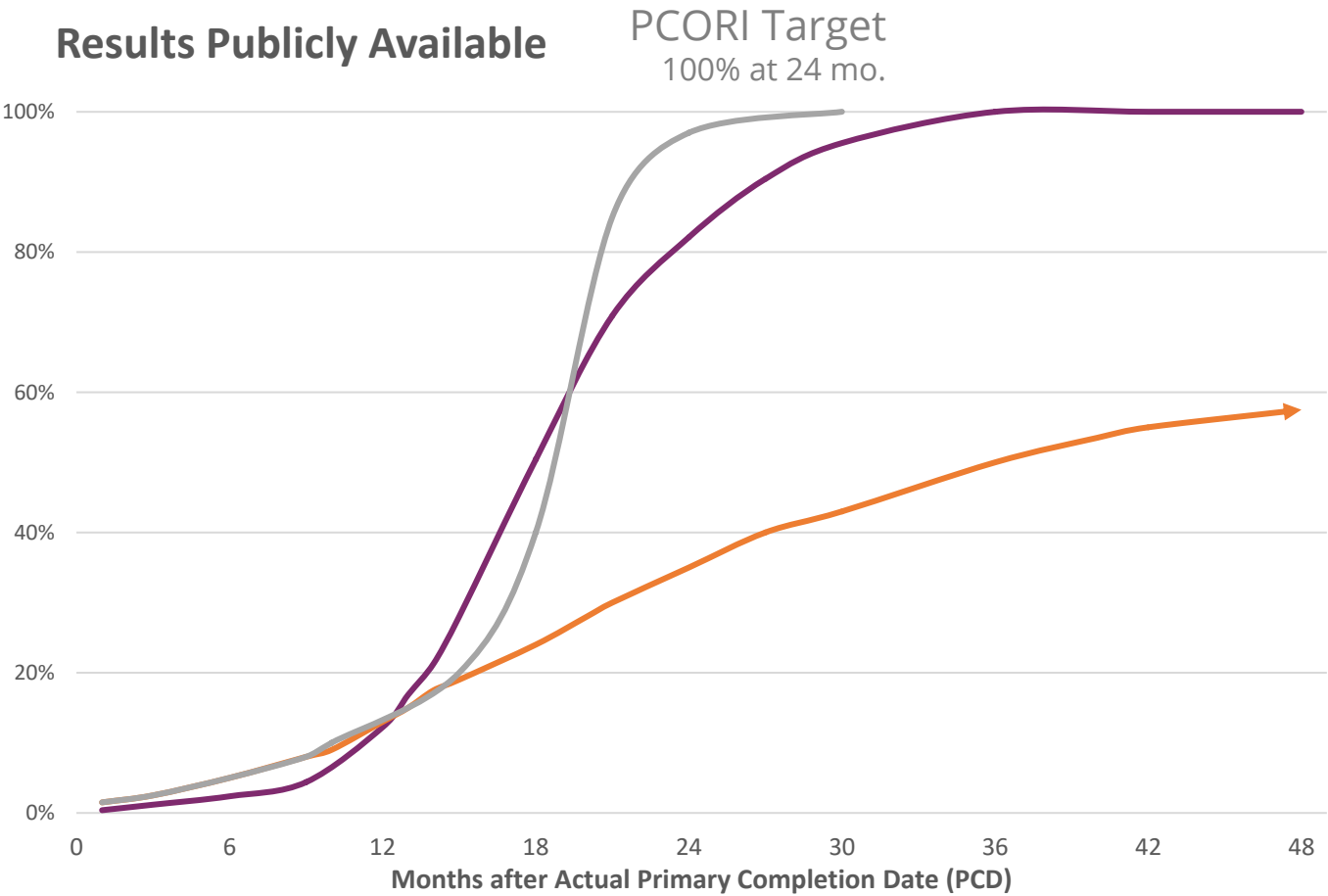


% CER Results Publicly Available (Publication or Posted Abstract) Relative to PCD

Studies with Results Publicly Available in Timeframe %

- First Publically Available Results Frequency %
- Field Benchmark

PCORI Target



PCORI's Process Provides Complete and Earlier Availability to the Public of Research Results from PCORI-Funded Trials



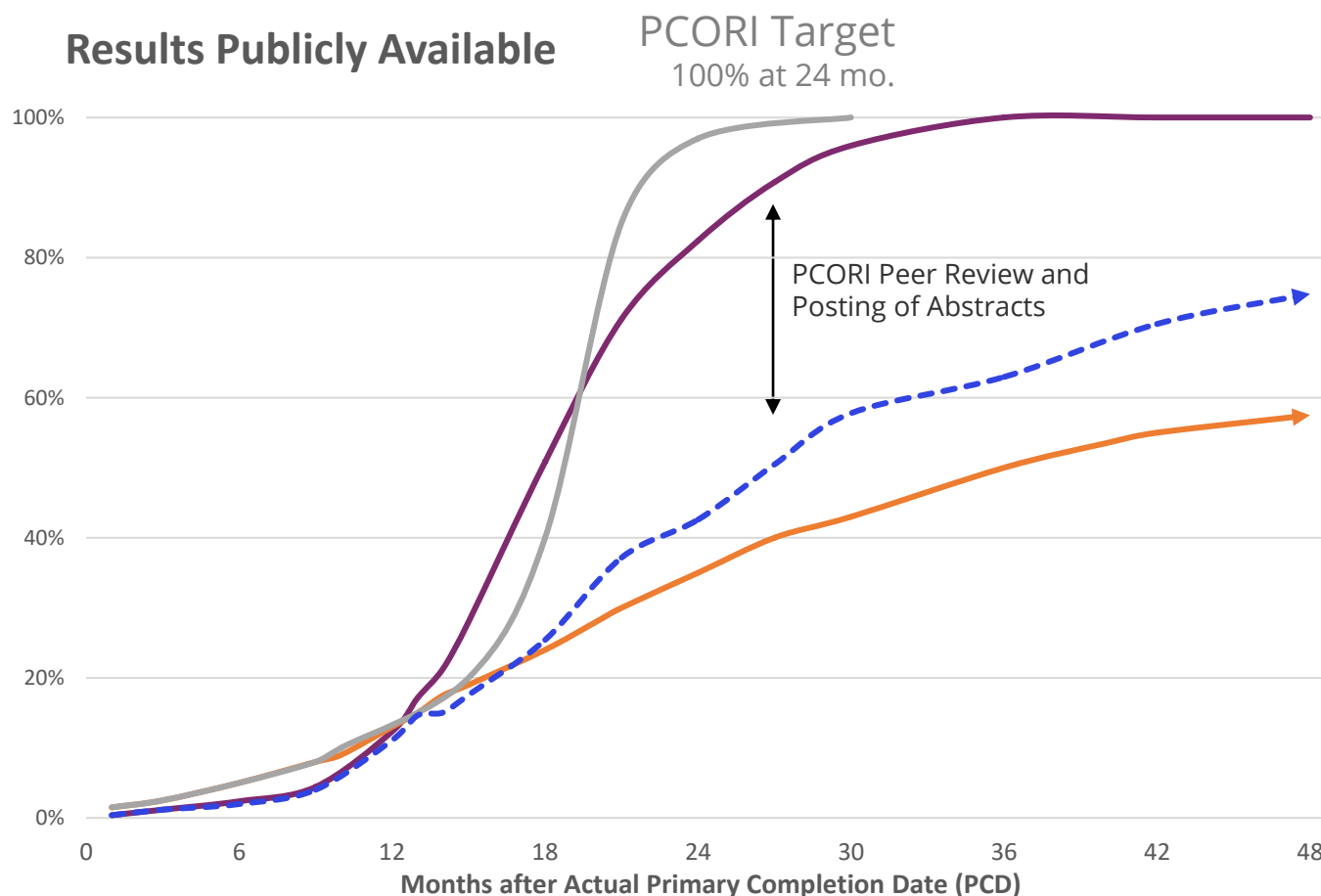
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Studies with Results Publicly Available in Timeframe %

— First Publically Available Results
— Frequency %
— Field Benchmark

— PCORI Target

- - - Results Published in the Literature %



Public Availability of Results from PCORI-funded Trials

51% after 18 months
82% after 24 months
100% after 36 months

PCORI Results Publications

Benchmark
Max: 60% at 60 mo.

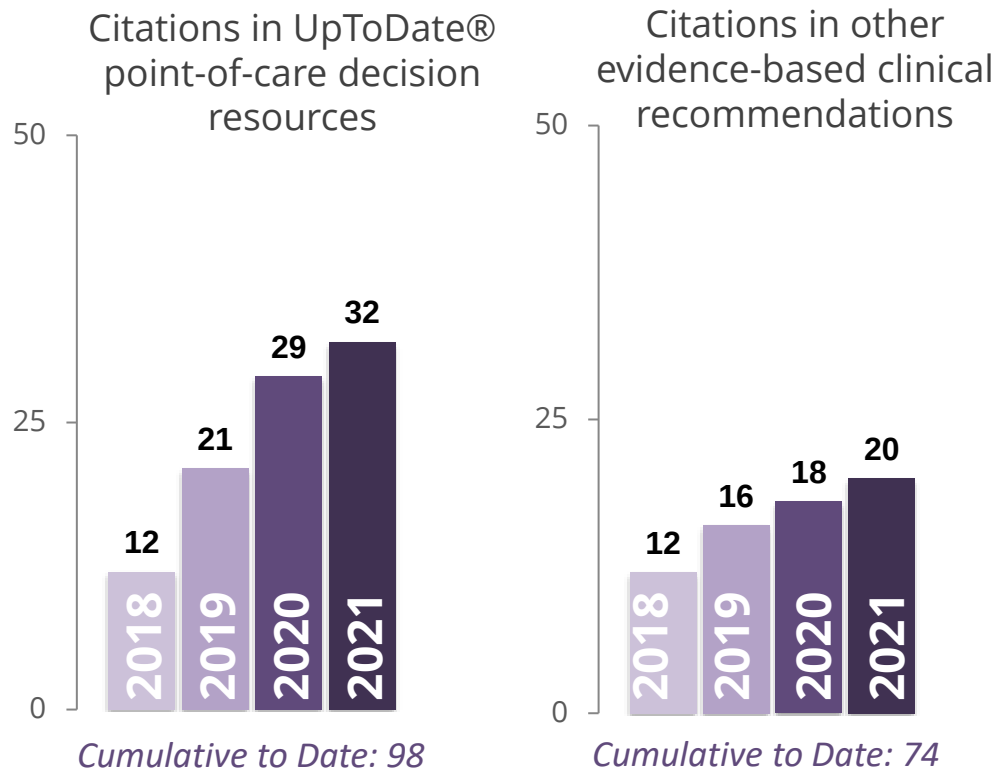
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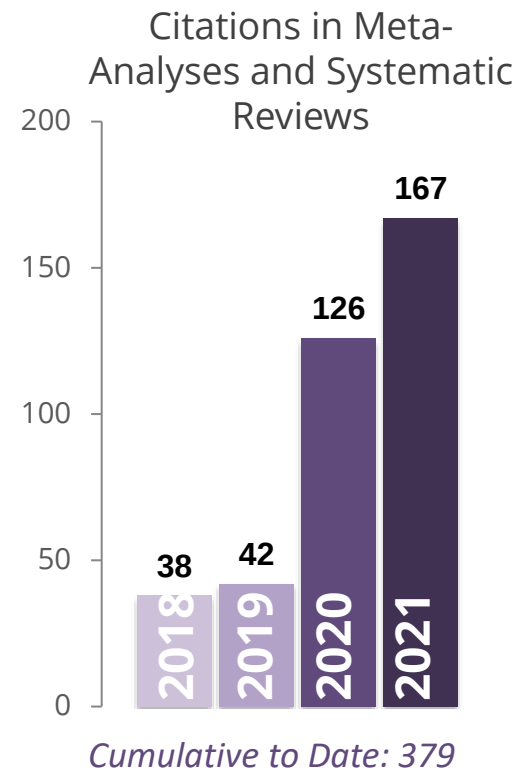
Uptake of Results from PCORI-Funded Studies



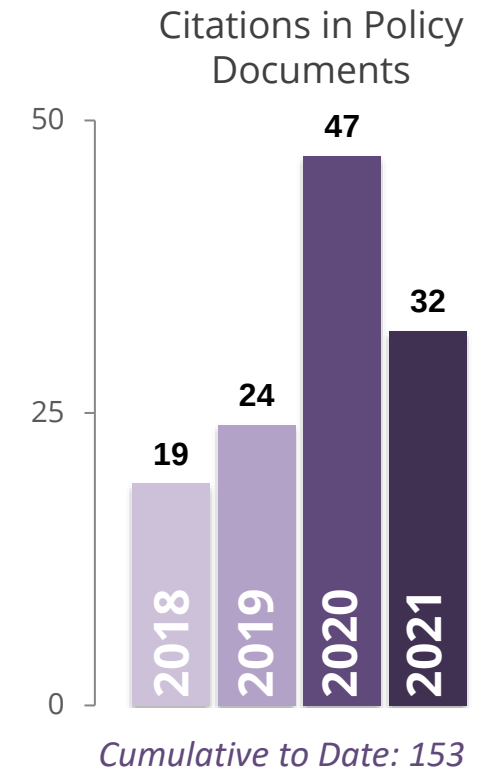
Uptake into Evidence-Based Clinical Recommendations



Uptake into Systematic Reviews Publications



Uptake into Policy Documents



Goal: Speed Uptake and Use of Information

Results from PCORI-Funded Study Incorporated into UpToDate Pages



Results from a PCORI-funded Patient-Powered Research Network (PPRN) Research Demonstration Project were **taken up into two UpToDate clinical topic pages**:

- “Data on the [Specific Carbohydrate Diet] SCD in adults with Crohn disease are limited [29,30]. In a trial including 194 patients with mild to moderate Crohn disease, there was no significant difference in rates of symptomatic remission after six weeks of adhering to the SCD compared with a Mediterranean diet (47 versus 44 percent).” – *Nutrition and Dietary Management for Adults with Inflammatory Bowel Disease*
- “Although epidemiologic and biologic research suggests a possible role for dietary factors in the pathogenesis of inflammatory bowel disease (IBD), there is no good evidence for specific dietary regimens other than to eat a healthy, diverse diet. A study in adults with CD compared the specific carbohydrate diet to the Mediterranean diet and found comparable remission rates.” – *Overview of the Management of Crohn's Disease in Children and Adolescents*



[image source: Getty Images Plus, used with permission, accessed 4/29/21]

Full Citation:

Lewis JD, et al. **A Randomized Trial Comparing the Specific Carbohydrate Diet to a Mediterranean Diet in Adults With Crohn's Disease.** *Gastroenterology*. Sept 2021. doi: 10.1053/j.gastro.2021.05.047.

Study Title: Comparative Effectiveness of Specific Carbohydrate and Mediterranean Diets to Induce Remission in Patients With Crohn's

PI: James Lewis, MD, MSCE

Organization: Crohn's and Colitis Foundation of America

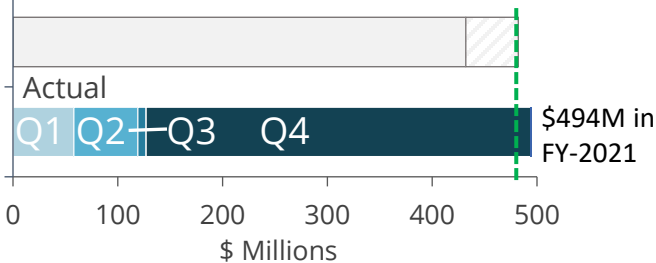
PCORI Board of Governors Dashboard

FY-2021 End-of-Year Review (As of 9/30/21)

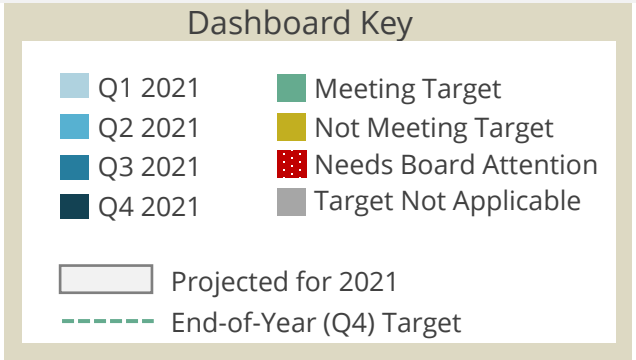
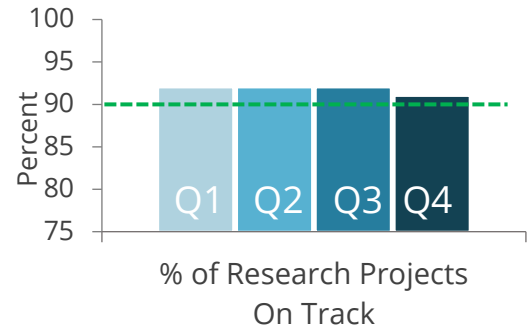


Funds Committed

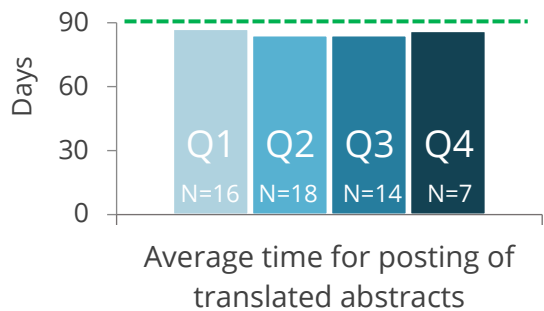
Commitment Plan 2021 Target:
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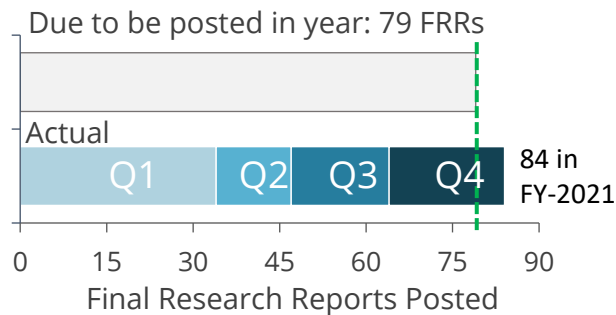
Research Project Performance



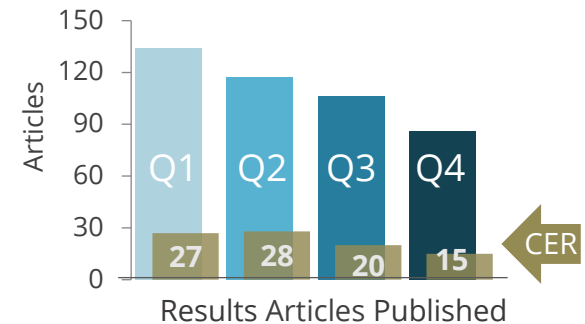
Time to Release of Research Findings



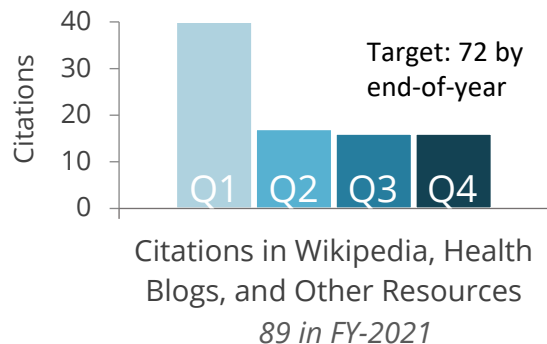
Final Research Reports Posted to PCORI.org



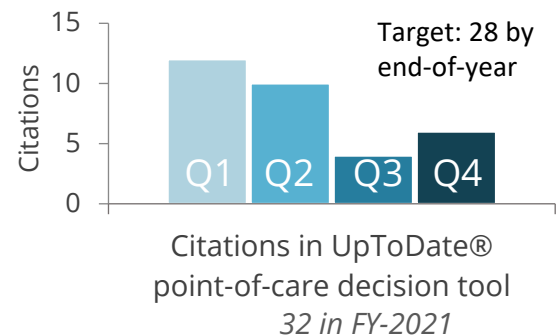
Results Published in the Literature



Uptake into Public/Patient Resources



Uptake of Results into UpToDate®



Other Examples of Uptake



Discussion Questions

- Do our FY-2021 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?
- As we develop our Strategic Plan, what role and content do you envision for the Dashboard in monitoring progress and measuring success?

Year in Review



New Members of PCORI Leadership Welcome!



Sri Mishra, MBA
Chief Information
Officer



Yolanda Hutchins, MA
Chief People Officer



Carolyn Best, PhD
Program Operations Chief

New PCORI Website



Find It Fast

Help Center

Careers

Contact Us



About ▼

Research ▼

Impact ▼

Topics ▼

Engagement ▼

Funding Opportunities ▼

Events



Webpage

Leadership Perspective: Why Are PCORI's Stakeholders So Critical to Our Work?

Award-Winning Annual Report



MarCom Gold Award
PCORI 2020 Annual Report



3rd year in a row!

PCORI's Second Virtual Annual Meeting



Opening Plenary:
Coming Together to Achieve Health Equity
Sindy Benavides, Daniel Dawes, Garth Graham, Adam Myers, Darshali Vyas

**Understanding Emerging Innovations
in the Current Healthcare Context**
Scott Berns, Karen DeSalvo, Liz Fowler, Trent Haywood



What We Do and How We Work

What We Do



Fulfilling the
Mission

How We Work



Collaboration &
Teamwork



Diversity, Equity,
& Inclusion



Fulfilling the Mission

Strategic Planning



- Develop overarching plan*
- Respond to changes in external landscape
- Outreach, listen, engage
- Advance trust for patient & community engagement in research,
- Implementation of cost provision, and reach of stakeholders engaged

Funding Approaches

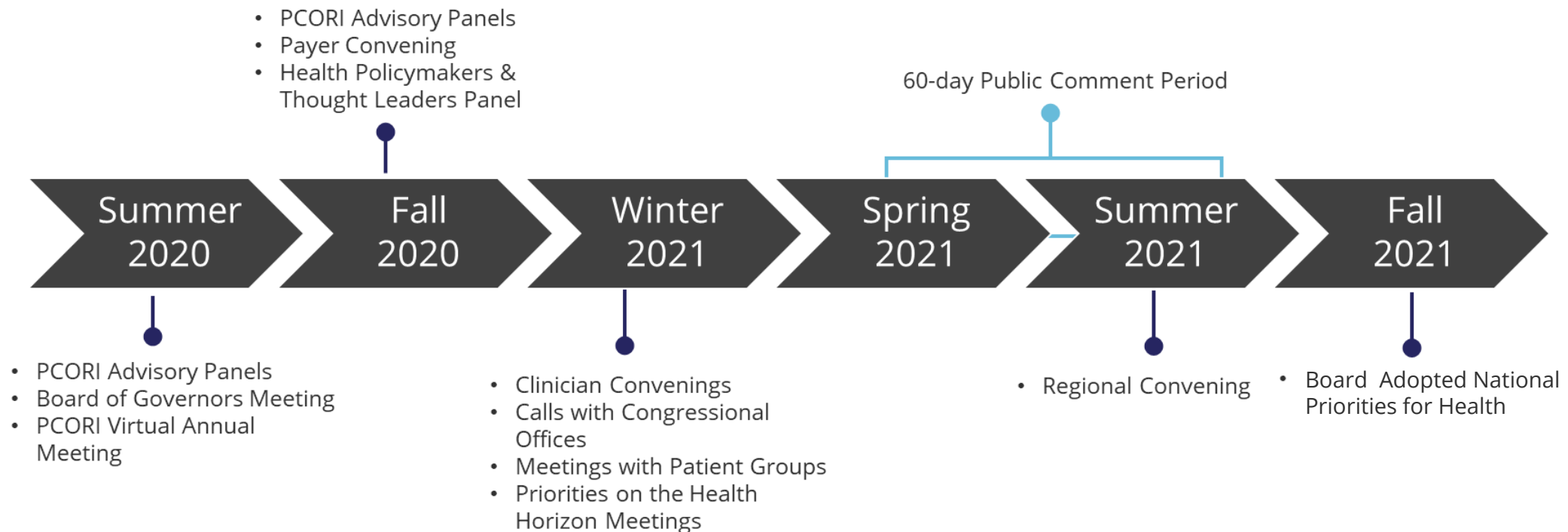


- Build and implement COVID-19 response
- Execute PFA Programming in alignment with commitment plan
- Implement rapid funding approaches

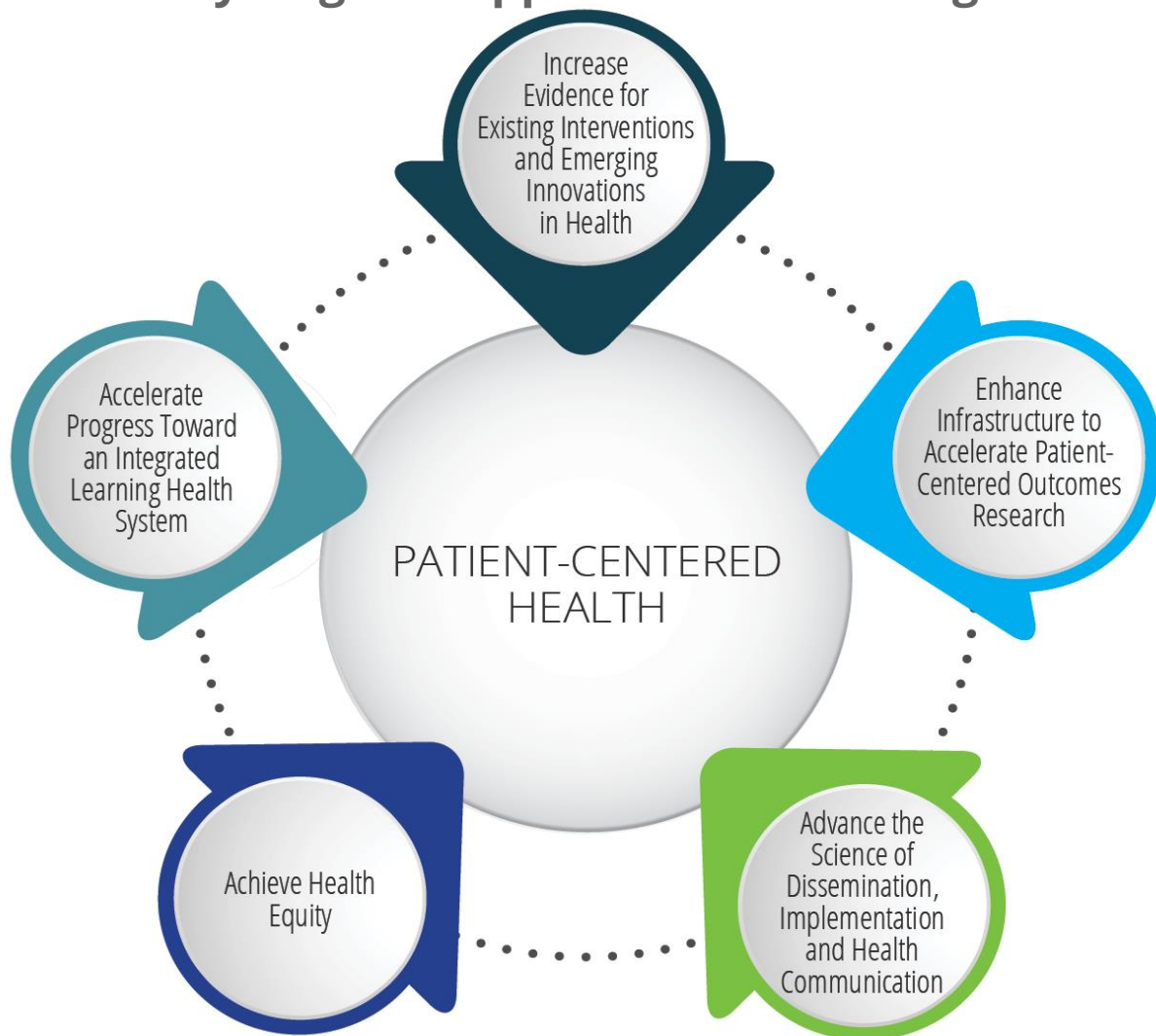
** Includes: Governance, National Priorities, Research Agenda, Priorities from Reauthorization, Priorities for PCORnet, Scenario and Commitment Planning, Methodology Committee Activities*

Strategic Planning Activities

- National Priorities for Health
- Research Agenda
- Commitment Plan
- Strategic Principles for PCORnet® phase 3
- Methodology Committee next phase
- Priorities from reauthorizing law



National Priorities for Health: Synergistic Opportunities for Progress



Proposed Research Agenda: A Framework for Achieving Progress on the National Priorities

Fund research that fills patient- and stakeholder-prioritized evidence gaps and is representative of diverse patient populations and settings

Fund research that aims to achieve health equity and eliminate health and healthcare disparities

Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships

Fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders

Fund research that focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play

Fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings

Priority Research Areas in Reauthorizing Legislation



Stakeholder Engagement

- Active
- Long-term
- Existing, new, diverse groups & lived experience

Funding Opportunity Development

Framing of Other Evidence Products (e.g., systematic reviews)

Implementation Plans for Data Collection



About ▼ Research ▼ Impact ▼ Topics ▼ Engagement ▼ Funding Opportunities ▼ Events

Funding Opportunities

Special Areas of Emphasis

- Increasing Access to and Continuity of Patient-Centered Maternal Care
- Improving Care for Individuals with Intellectual and/or Developmental Disabilities Growing into Adulthood

Targeted PFAs:

- Comparative Effectiveness of Interventions targeting Mental Health Conditions in individuals with Intellectual and Developmental Disabilities
- Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities

Overview of PCORI's Implementation Activities Relevant to the Full Range of Outcomes Data



Principles

- Providing guidance to PIs on how to interpret PCORIs authority and incorporate it into research proposals.
- Principles → Guidance for Applicants

Healthcare Cost and Value Workgroup

- Define PCORI's strategy/position and integrate into strategic plan
- Identify opportunities for PCORI to contribute to solutions that address rising healthcare costs & to serve as a resource on patient-centered value

Communications

- Morning Consult: *"The Key to Addressing Rising Health Care Costs Is Patient-Centered Evidence"*
- Health Affairs blog: *"Pursuing Health Care Value Post-COVID-19: Keep The Focus On Patients"*

PCORI's Response to the COVID-19 Pandemic



Award Funding

(158 Awards; ~\$80M)

- Enhancements & Adaptations
- Targeted Solicitations
- PCORnet HERO Program

Information Sharing

- COVID-19 Horizon Scanning
- Webinar Series

COVID-19 Related Efforts

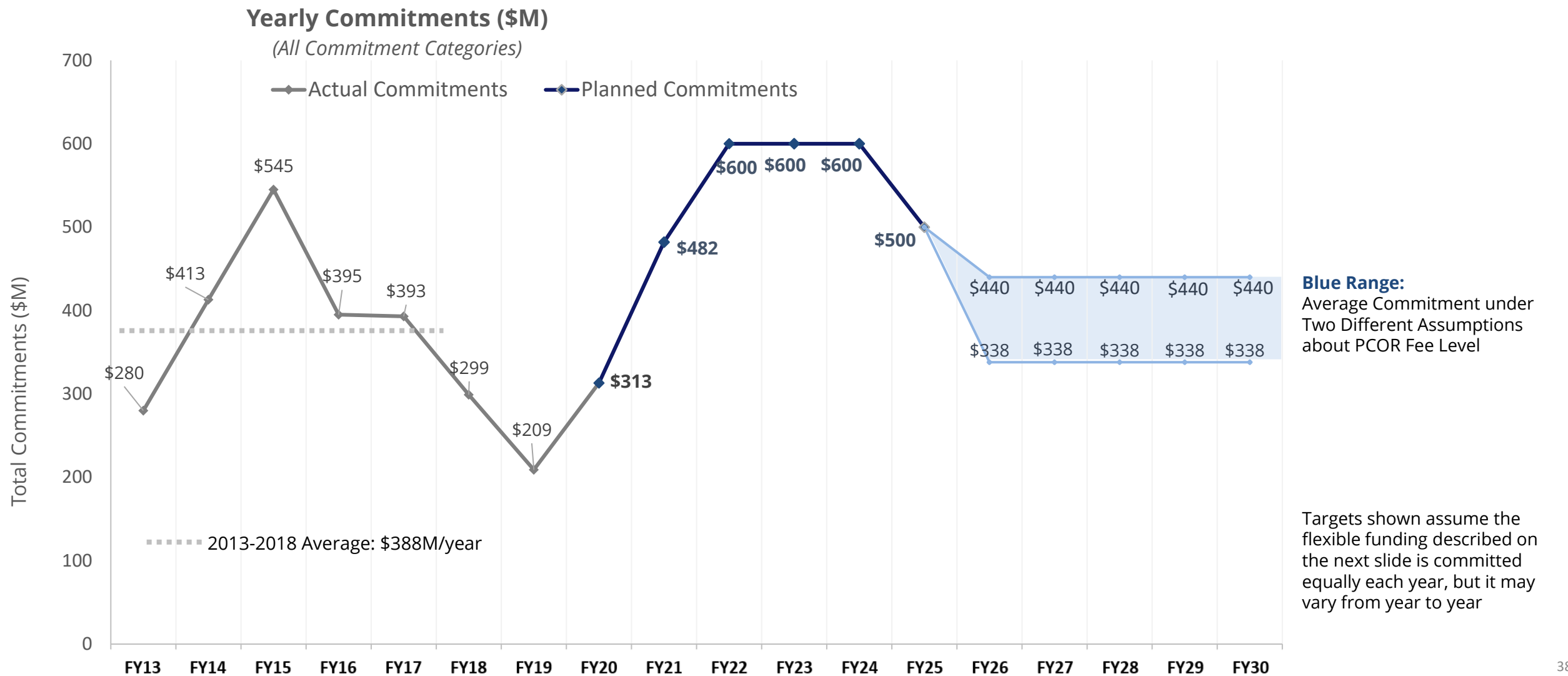
Collaborating

- PCORnet CDC Partnership
- FDA Evidence Accelerator
- ACTIV-6

Embedding

- Broad PFA COVID-19 Special Areas of Emphasis

Approved Model for Commitment Planning



Progress on Board-Approved Candidate Topics

Funding Mechanism	Cycles 2&3 2021	Cycle 1 2022	Cycle 2 2022	Cycle 3 2022
Targeted PFA or Special Area of Emphasis	☒ Nonsurgical interventions for women with urinary incontinence ☒ Healthy Aging: Optimizing physical and mental function across the aging continuum ☒ Multimodal interventions to prevent osteoporotic fractures ☒ Treatments for migraine prevention ☒ Addressing racism, discrimination, and bias throughout the care continuum* ☒ Leveraging telehealth for chronic disease management among vulnerable populations with complex needs*	Substance Abuse in Youth Delirium	<i>Visual Impairment</i> <i>Hypertension control</i> <i>Advancing health equity*</i>	<i>Telehealth*</i> <i>Suicide prevention</i> <i>Cancer immunotherapy</i>
Large Single Study	<i>Abdominal aortic aneurysm screening in women</i>			

Notes: Set of topics is *in addition to* COVID-19, MMM, IDD which are underway and continue; Timing is tentative

*Example of leading with a Special Area of Emphasis

Balancing Long- and Short-term Activities



- Horizon scanning reports & database
- Emerging technology reports
- Evidence maps & Rapid reviews



- Systematic reviews
- Focused observational research



- Phased trials (up to \$22M)
- Large pragmatic studies (up to \$10M)
- Broad research studies (up to \$5M)

Time to
Complete

Up to 1 year

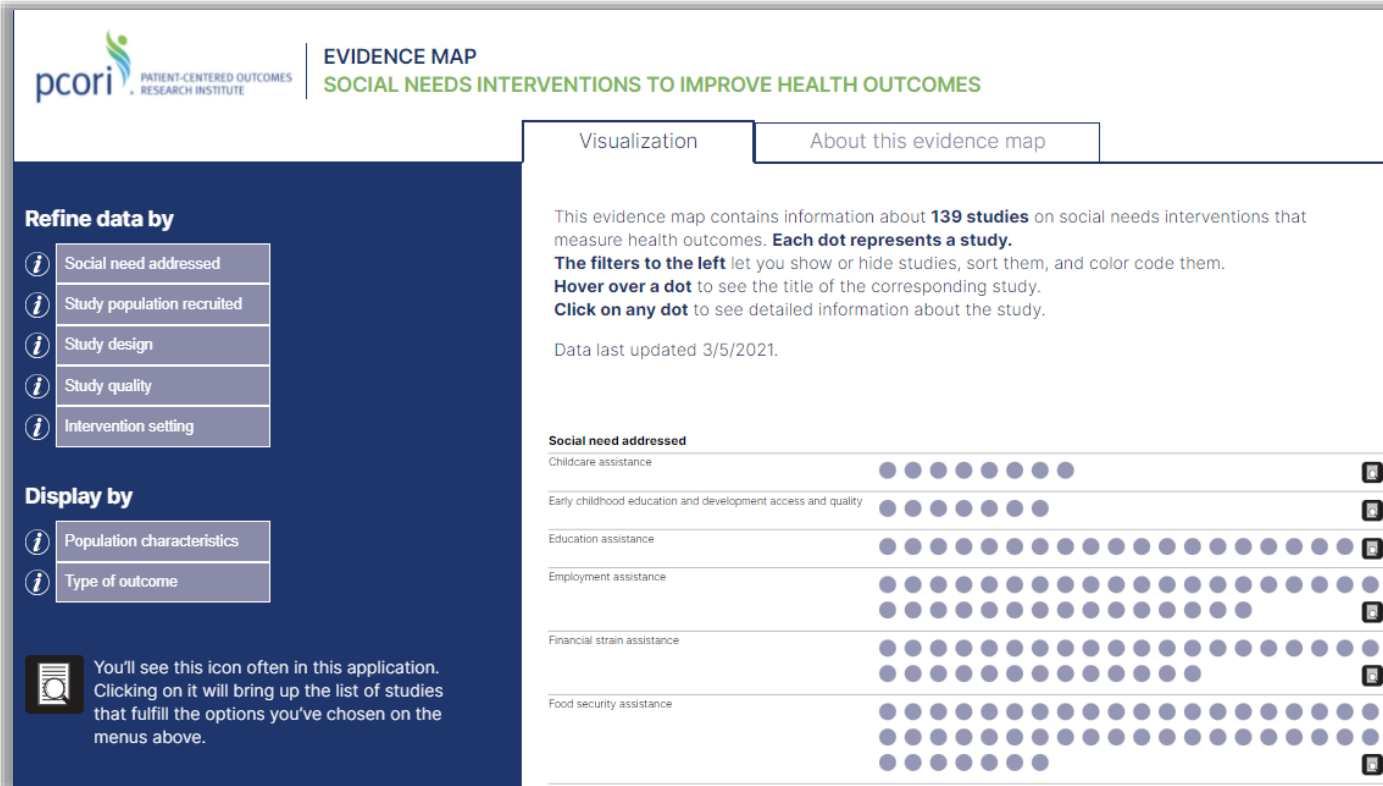
1-2 years

3-7 years

D&I activities occur throughout timeline

Stakeholders provide input for report and research topics

Examples of Short-Term Evidence Products: Evidence Maps and Rapid Reviews



A Rapid Review of Telehealth Strategies for the Delivery of Maternal Healthcare



Project Summary

This project is ongoing and does not have results.

PCORI is commissioning a rapid review to assess evidence on the effectiveness of telehealth strategies for the delivery of maternal healthcare. Because telemedicine has experienced a swift and widespread adoption in the United States, PCORI seeks to understand the evidence base on a compressed timeline in order to inform our future research investments.

A Rapid Review of Video-Teleconferencing for Disease Prevention, Diagnosis, and Treatment

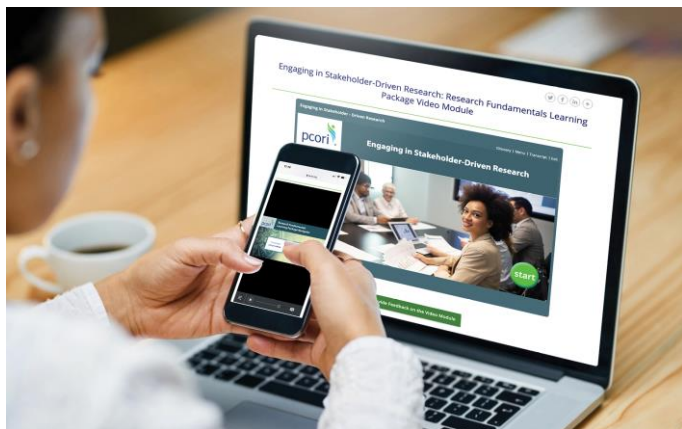


Project Summary

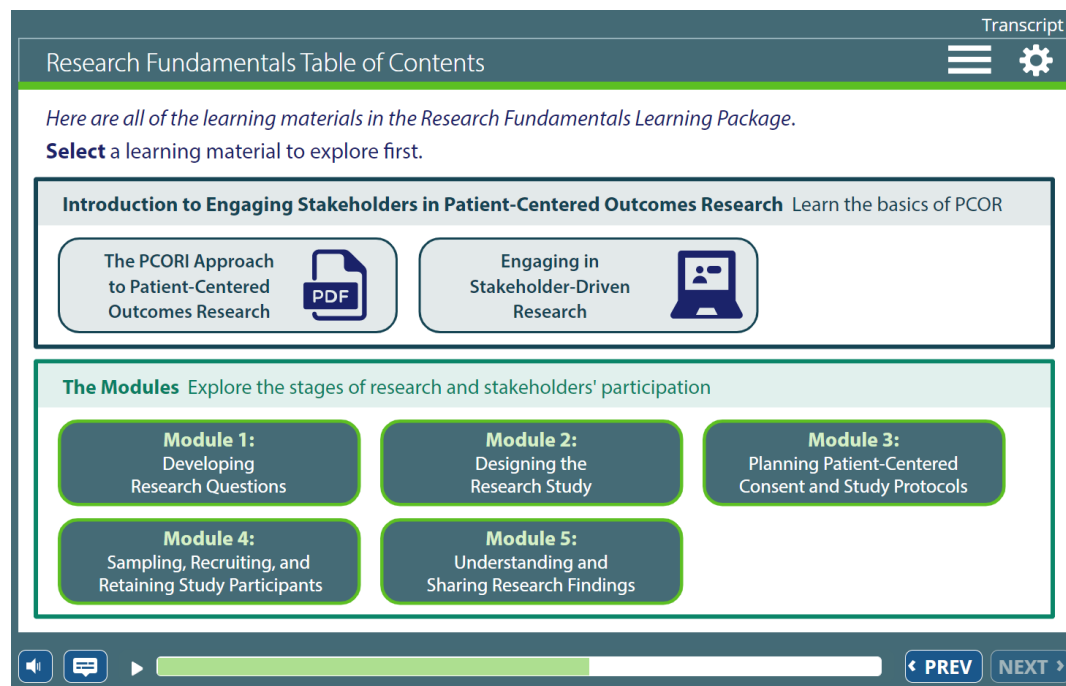
This project is ongoing and does not have results.

PCORI is commissioning a rapid review to assess evidence on the effectiveness of synchronous video-teleconferencing (VTC) visits for disease prevention, diagnosis, and treatment. Because telemedicine visits have experienced swift and widespread adoption in the United States, PCORI seeks to understand the evidence base on a compressed timeline in order to inform our future research investments on video-delivered care.

Resources for Effective Engagement in Research



Research Fundamentals: Preparing to Successfully Contribute to Research



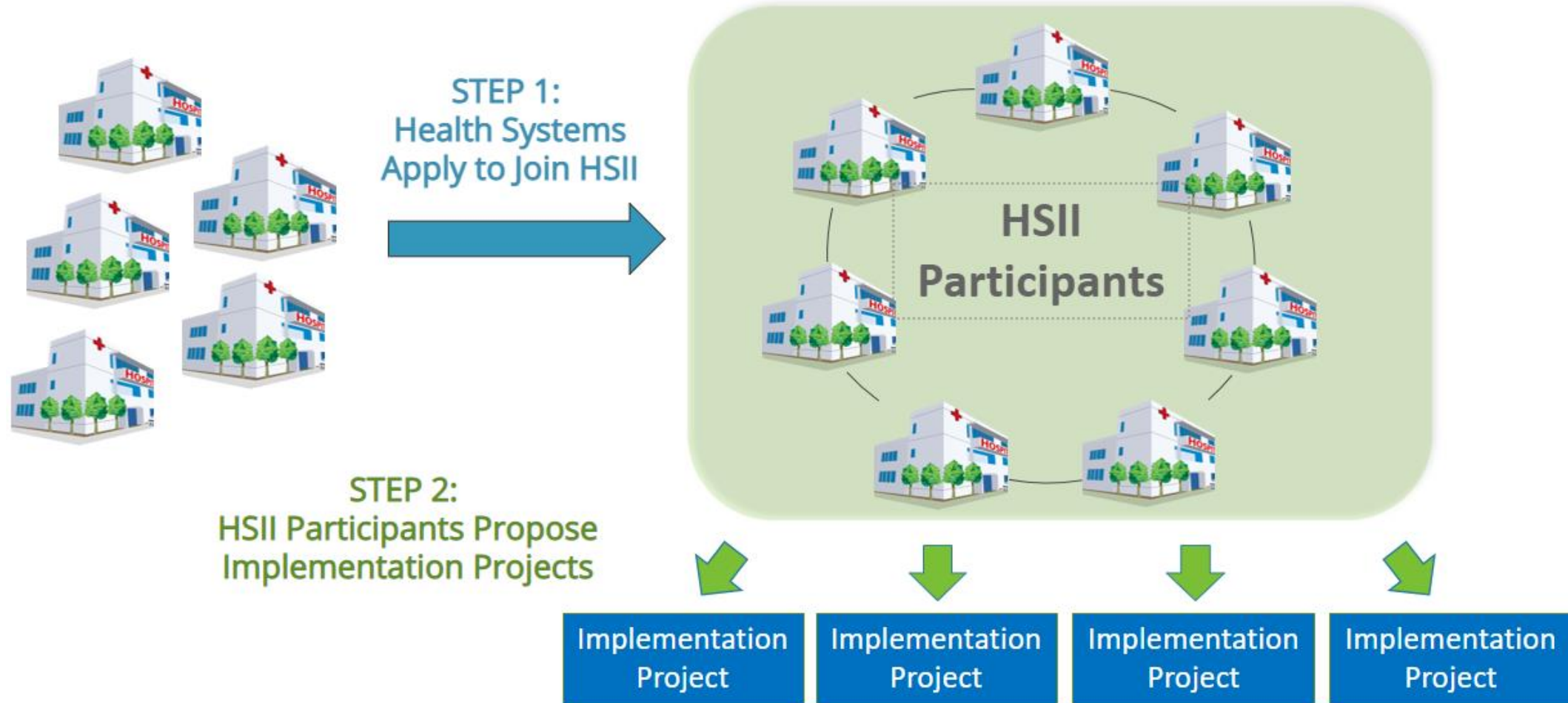
The screenshot shows a web interface titled "Research Fundamentals Table of Contents". It includes a "Transcript" button and a settings icon. The main content area states: "Here are all of the learning materials in the Research Fundamentals Learning Package. Select a learning material to explore first." Below this, there is a section for "Introduction to Engaging Stakeholders in Patient-Centered Outcomes Research" with two options: "The PCORI Approach to Patient-Centered Outcomes Research" (with a PDF icon) and "Engaging in Stakeholder-Driven Research" (with a person icon). A "The Modules" section follows, describing the stages of research and stakeholder participation, with five modules: Module 1: Developing Research Questions, Module 2: Designing the Research Study, Module 3: Planning Patient-Centered Consent and Study Protocols, Module 4: Sampling, Recruiting, and Retaining Study Participants, and Module 5: Understanding and Sharing Research Findings. At the bottom, there are navigation controls including a play button, a progress bar, and "PREV" and "NEXT" buttons.

Building Effective Multi-Stakeholder Research Teams

<https://www.pcori.org/engagement/research-fundamentals>

https://research-teams.pcori.org/?utm_campaign=Building+Effective+Multi-Stakeholder+Research+Teams&utm_medium=bitly&utm_source=website

Health Systems as Partners to Accelerate Evidence to Implementation



Collaboration & Teamwork

PCORI Culture



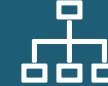
- Create a unified cultural vision; optimize virtual environment
- Develop cohesive and collaborative leadership team and cross-departmental staff teams

Workforce and Workplace



- Build & Implement Staffing Plan for PCORI Next
- Secure sustainable space plan
- Implement COVID-19 response

Organization Transformation



- Execute organizational assessment and future state model
- Implement recruitment & onboarding strategies
- Optimize processes for effectiveness and efficiency

PCORI *Next* Vision



PCORI *Next* is our organizational transformation effort to invest in our Operational, Cultural and Professional Excellence. Our ultimate goal is to strengthen and optimize the delivery of our mission - focusing on Patient-Centered Outcomes Research that enables better-informed healthcare decisions.

PCORI's New Offices

1333 New
Hampshire
Avenue NW
Washington, DC



How We Work

Diversity, Equity, and Inclusion

Diversity, Equity and Inclusion



- Develop and execute PCORI-wide DEI initiative with external and internal components

PCORI's commitment to diversity, equity, and inclusion is critical to achievement of its mission.

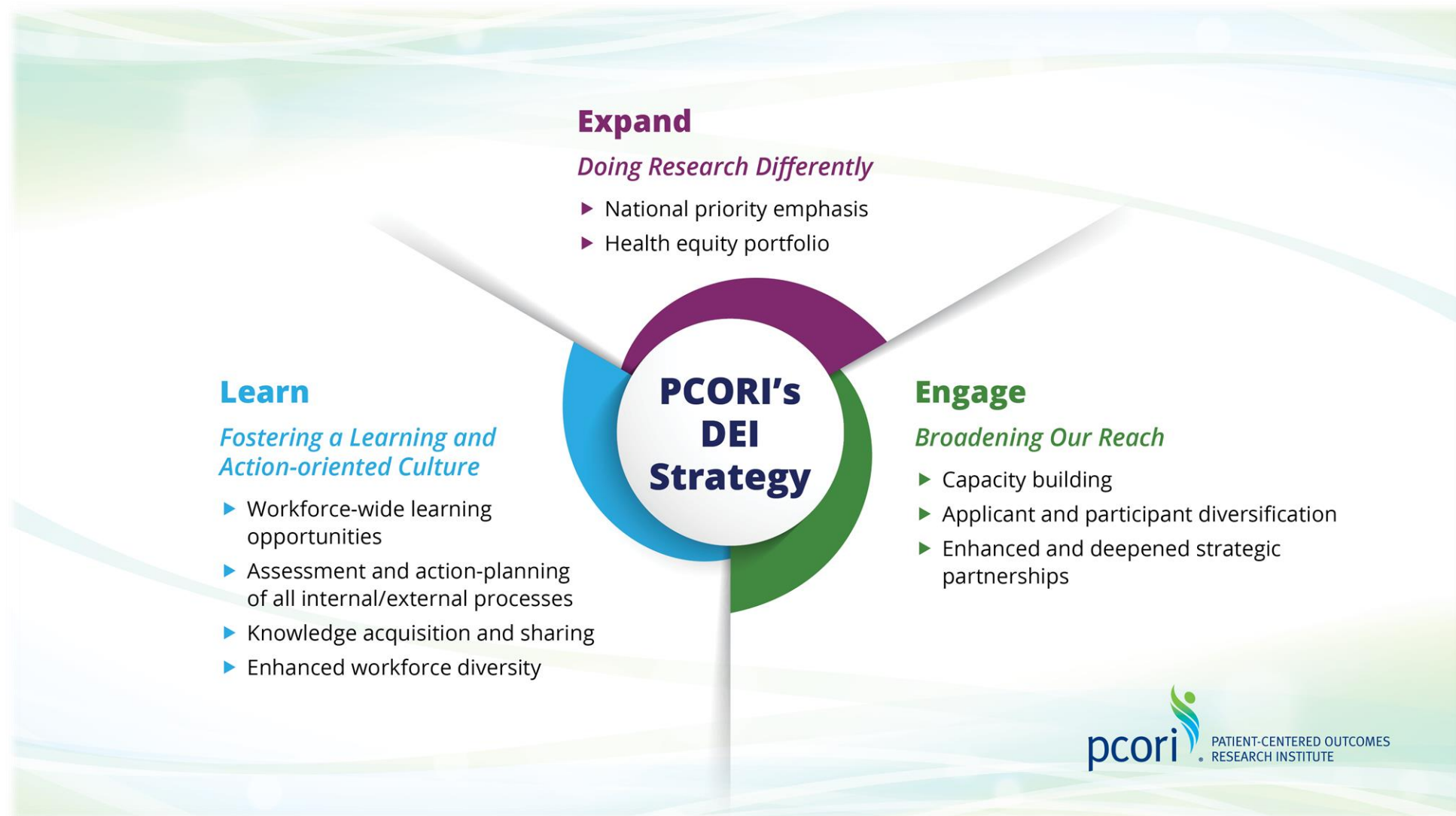
Internally Facing

Committed to cultivating a diverse workplace and a culture that values equity and derives strength from diverse backgrounds, perspectives, talents, and experiences and promotes all staff feeling included, connected, and engaged to bring their unique skills toward fulfillment of the mission

Externally Facing

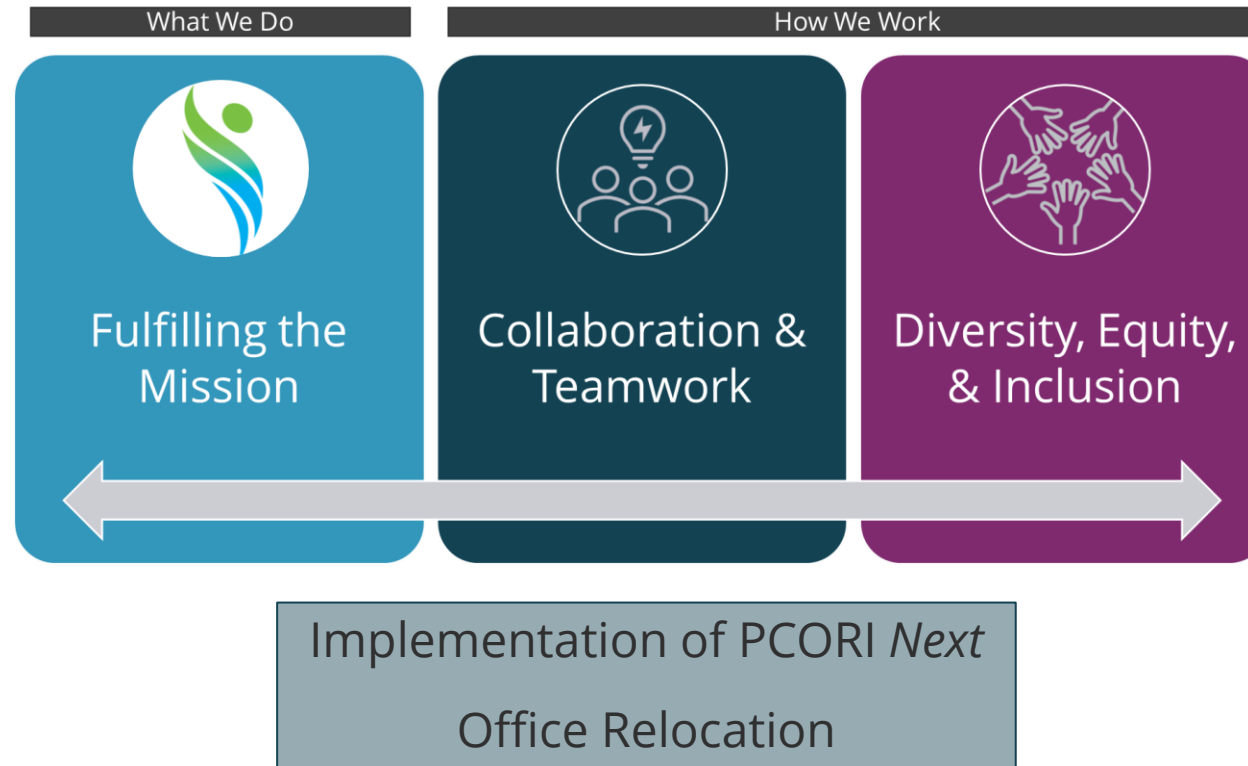
Committed to being equitable in engaging diverse stakeholders, promoting diverse and inclusive convenings, as well as a diverse pool of applicants, awardees, and participation in research

Three Main Goals of Our Strategy: Learn, Expand, Engage



Looking Forward...

- Strategic Plan Summer 2022
- Commitment Plan Peak
- Prospective Planning for Topic Development
- COVID-19 and Reauthorization Priorities



- Ongoing Assessment and Strategies
- Health Equity Funding

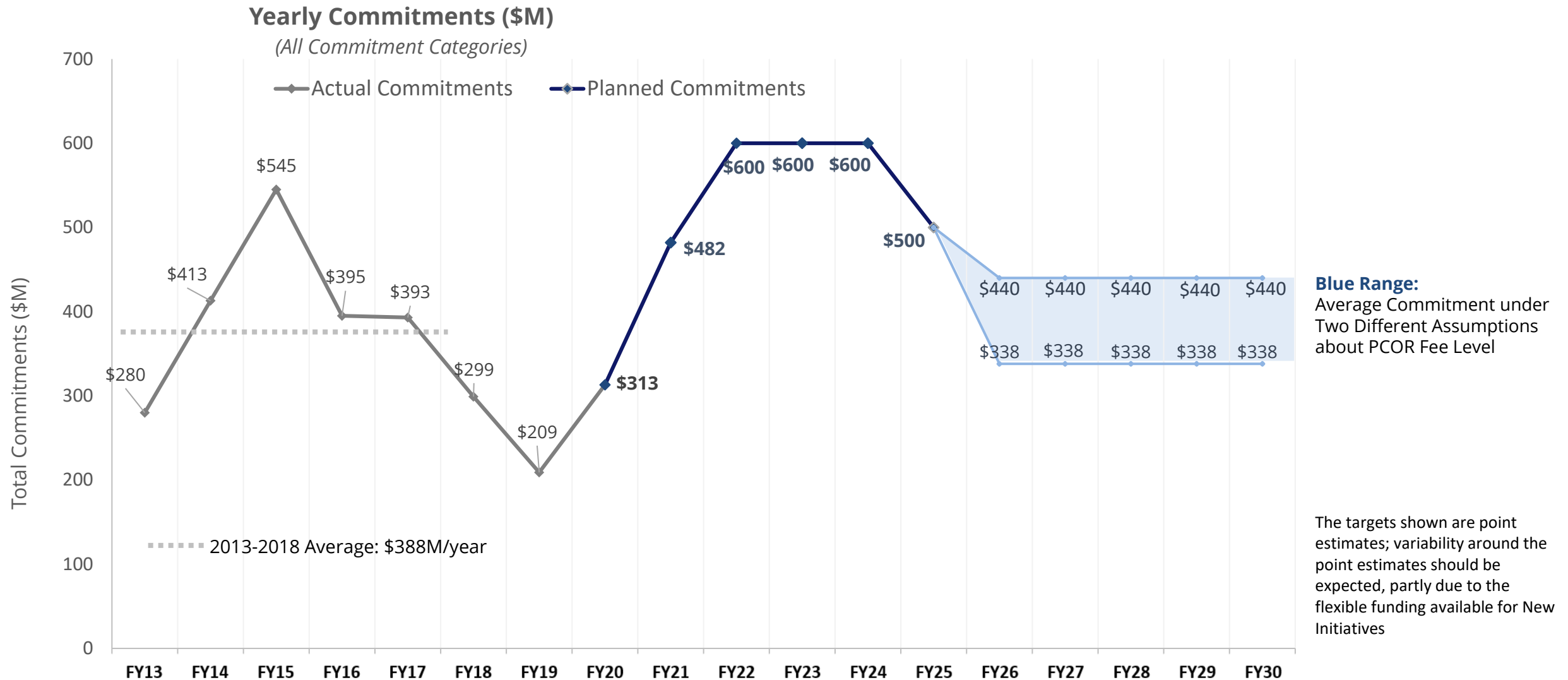
Commitment Planning: Annual Update and Consideration of FY2022 to FY2024 Plan

Nakela L. Cook, MD, MPH

Executive Director



Recap: Approved Model for Commitment Planning



Recap: Approved 3-Year Commitment Plan

FY2021-2023, subject to annual review and update by the Board



Funding Line (4 Larger Categories)	Projections for FY2020-2023			
	Average across FY2021-23: \$560M			
	FY2020 (\$M)	FY2021 (\$M)	FY2022 (\$M)	FY2023 (\$M)
Research	244	290	450	450
- Includes: - Half investigator-initiated, half PCORI-prioritized via special areas of emphasis and targeted PFAs - PLACER - Full range of research spectrum - Short-term and long-term priorities				
Dissemination & Implementation	31	40	57	63
- Includes: - Several lines of D&I Awards - Full range from Translation Center to large scale implementation projects - Other D&I Activities				
Infrastructure/Accelerating PCOR	38	102	43	37
- Includes: - Engagement Awards - Community Building - Workforce Awards - PCORnet® Infrastructure Awards				
New Initiatives/Emerging Issues		50	50	50
New initiatives for research, D&I, and infrastructure				
Total Commitments	313	482	600	600

Requires:

- Full complement of PFAs in all 3 cycles
- ~50% Increase in research commitments
- Doubling of D&I commitments
- ~15% increase in staffing
- Continual process improvement for efficiencies

Update: FY2021 Commitment Target Met!



Funding Line (4 Larger Categories)	FY2021 Target (\$M)	FY2021 Actual (\$M)	FY2022 Target (\$M)	FY2023 Target (\$M)	FY2024 Target (\$M)
Research	290	389	500	500	500
- Includes: - Half investigator-initiated, half PCORI-prioritized via targeted, special emphasis, and priority topics - PLACER - Full range of research spectrum - Short-term and long-term priorities					
Dissemination & Implementation	40	16	40	60	60
- Includes: - Several lines of D&I Awards - Full range from Translation Center to large scale implementation projects - Other D&I Activities					
Infrastructure/Accelerating PCOR	102	89	60	40	40
- Includes: - Engagement Awards - Community Building - Workforce Awards - PCORnet® Infrastructure Awards					
New Initiatives	50	--	50	50	50
New initiatives for research, D&I, and infrastructure					
Total Commitments	482	494	600 <i>(Up to 650)</i>	600 <i>(Up to 650)</i>	600 <i>(Up to 650)</i>

- **D&I** under due to COVID 19-related delay in launch of HSII
- **Infrastructure** under largely due to shift of timing of PCORnet® Coordinating Center awards to 2022
- Under-commitments and **New Initiative** Funds used to fund larger-than-anticipated first slate of PLACER awards and other robust **Research** award slates

Proposed 3-Year Commitment Plan

FY2022-2024



Funding Line (4 Larger Categories)	FY2021 Target (\$M)	FY2021 Actual (\$M)	FY2022 Target (\$M)	FY2023 Target (\$M)	FY2024 Target (\$M)
Research	290	389	500	500	500
- Includes: - Half investigator-initiated, half PCORI-prioritized via targeted, special emphasis, and priority topics - PLACER - Full range of research spectrum - Short-term and long-term priorities					
Dissemination & Implementation	40	16	40	60	60
- Includes: - Several lines of D&I Awards - Full range from Translation Center to large scale implementation projects - Other D&I Activities					
Infrastructure/Accelerating PCOR	102	89	60	40	40
- Includes: - Engagement Awards - Community Building - Workforce Awards - PCORnet® Infrastructure Awards					
New Initiatives	50	--	50	50	50
New initiatives for research, D&I, and infrastructure					
Total Commitments	482	494	600 <i>(Up to 650)</i>	600 <i>(Up to 650)</i>	600 <i>(Up to 650)</i>

Board Vote

Call for a Motion to:

- **Approve** the Proposed 3-year Commitment Plan for FY2022-2024, subject to annual review and update by the Board

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

Consider for Approval:

Proposed Research Agenda for Posting for Public Comment

Sharon Levine, MD

Co-Chair, Strategic Planning Committee

Nakela L. Cook, MD, MPH

Executive Director



Purpose and Structure of Today's Discussions

Purpose

- Review proposed Research Agenda
- **Consider for approval** the proposed Research Agenda for posting for public comment

Structure

- Review revisions to Research Agenda based on Board discussions from October meeting
- Overview of anticipated next steps
- **Board vote**

Scope of Strategic Planning Activities



Strategic Planning

- National Priorities for Health
- **Research Agenda**
- Strategic principles for PCORnet® phase 3
- Methodology Committee focus for PCORI's next phase
- Commitment Planning and strategies to increase funding
- Scenario Planning based on the changes in landscape and environment
- Priorities from reauthorizing law
 - Maternal morbidity and mortality
 - Intellectual and developmental disabilities
 - Full range of outcomes data
- Monitoring progress and measuring success

Components of Our Strategic Plan



- The **strategic plan** centers on achieving the National Priorities for Health, and the Research Agenda is one major component of the plan. The strategic plan aims to describe all the various components and present a cohesive vision for PCORI's future activities.
- The **Research Agenda** provides a framework for achieving progress on the National Priorities for Health specifically through the strategy of funding comparative clinical effectiveness research (CER). The Research Agenda helps guide the development of continuously relevant **Research Project Agenda** via an on-going, stakeholder-engaged process.
- PCORI utilizes other strategies in addition to funding CER (for example, Dissemination & Implementation) to achieve the National Priorities for Health, and these will be described in other components of the strategic plan.

Creation of the Research Agenda



Research Agenda Parameters

Based on PCORI's authorizing law, preliminary stakeholder input, and desire to allow for adaptability, the following parameters serve to help shape the Research Agenda.

Accommodate a Full Range of

- Outcomes important to patients & stakeholders
- Short- and long-term priorities
- Short- and long-term decision needs
- Potential individual and societal burdens and economic impacts
- Issues/topics across the lifespan
- Issues/topics across the care continuum
- Interventions
- Settings that influence health/healthcare
- People/professionals involved in health

Also Be

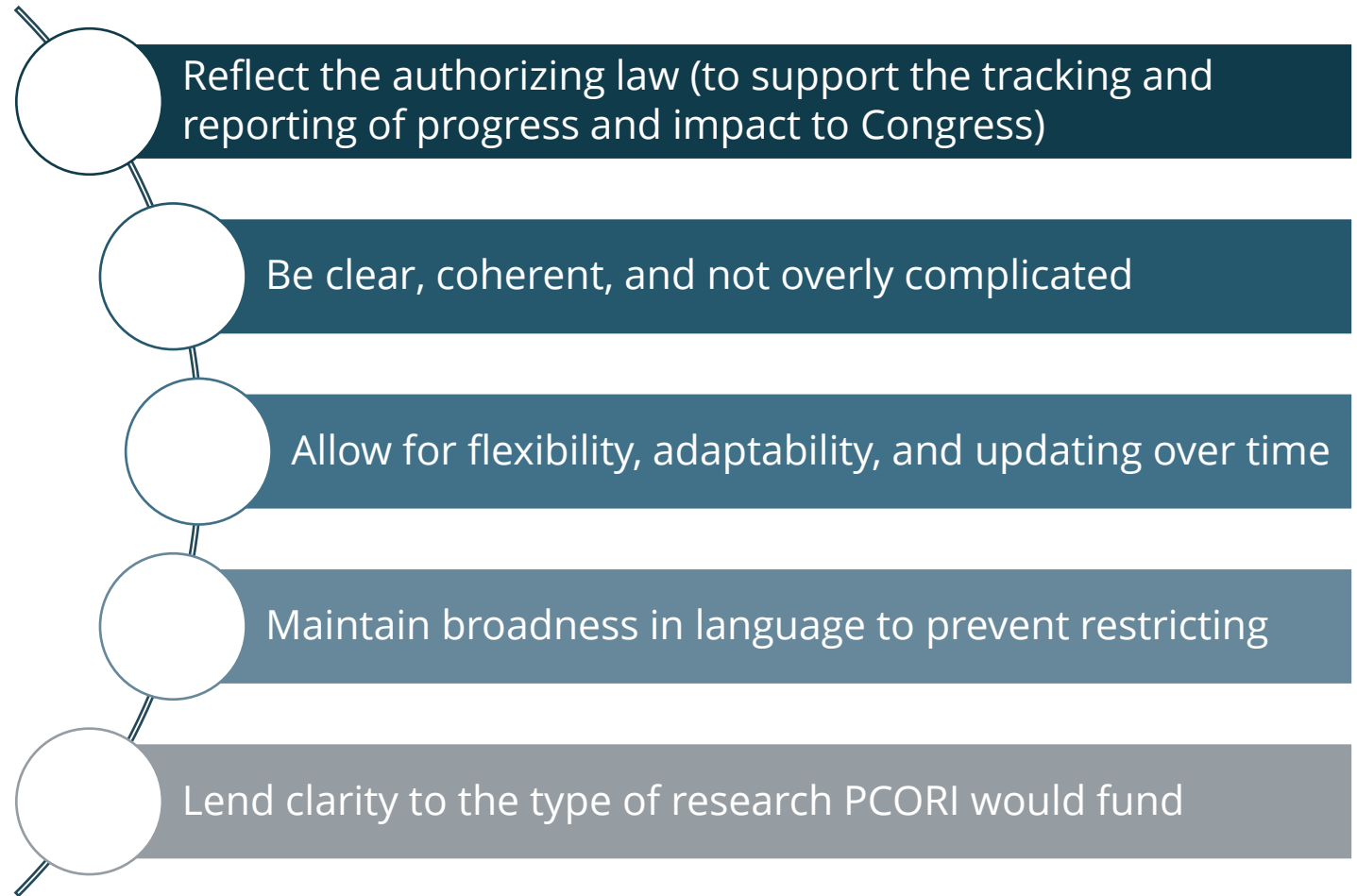
- In support of the National Priorities for Health
- Inclusive of issues affecting all groups/populations, with a focus disparities/inequities
- Responsive to emerging issues and new evidence
- Responsive to innovations

Take Into Account

- PCORI's unique role within the research ecosystem
- PCORnet® as a unique resource
- Social determinants of health
- Advances and innovations in methods
- State-of-the-art methods in D&I, engagement, and health communication
- Disease incidence, prevalence, & burden
- Differences in effectiveness of interventions
- Gaps in evidence
- Potential for new evidence to improve health, well-being, quality of care
- Effect on national expenditures assoc. with a treatment, strategy, or condition

Board and Strategic Planning Committee Input Inform Draft Research Agenda

Board and SPC members agreed
that the Research Agenda should:



Fund Research That...

1. Focuses on the preservation of health, promotion of well-being, or addresses health drivers that occur where people live, work, and play
2. Aims to prevent and eliminate health and health care disparities
3. Aims to achieve health equity
4. Builds the evidence base for innovative and emerging interventions
5. Examines the diverse burdens and clinical and economic impacts important to patients
6. Optimizes and links the full range of data resources to gain a more holistic view of patient health and healthcare
7. Uses data representative of diverse patient populations and settings to generate more inclusive evidence
8. Examines approaches for communicating evidence such that patients, clinicians, and the broader health community can access, understand, and act on research findings
9. Integrates implementation science to promote the uptake of findings
10. Fills patient- and stakeholder-prioritized evidence gaps

Overall Feedback from October Board Discussion



- Language in Research Agenda should continue to be action- and solution-oriented
- Terminology and word choices should be precise, consistent, and explicit (rather than overly conceptual)
- Be specific to get the appropriate point across and minimize misinterpretation but not overly prescriptive
- Research Agenda will help shape the Research Project Agenda
- **There was broad support of the Research Agenda, but additional refinement was needed:**
 - Determine if the Research Agenda should consist of the Statements and Characteristics or just the Statements
 - Possibly include some Characteristics as illustrative examples
 - Possibly combine complementary Statements (e.g., eliminating health disparities and achieving health equity; approaches for communicating evidence and implementation science)
 - Simplify the content of the Research Agenda while remaining precise

Strategic Planning Committee Response to Board Discussion

Informed by Board Feedback

- Refined Research Agenda to consist of six statements
- Included characteristics as illustrative examples for additional descriptive information

Restructured
Agenda



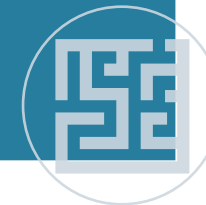
- Combined statements with complementary or related concepts

Combined
Statements



- Focused statements
- Revised language to be more explicit
- Consolidated illustrative examples

Simplified
Content



Proposed Research Agenda



- Fund research that fills patient- and stakeholder-prioritized evidence gaps and is representative of diverse patient populations and settings
- Fund research that aims to achieve health equity and eliminate health and healthcare disparities
- Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships
- Fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders
- Fund research that focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play
- Fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings

Proposed Research Agenda and Examples for Supporting Context

Research Agenda Statement:

Fund research that fills patient- and stakeholder-prioritized evidence gaps and is representative of diverse patient populations and settings

Illustrative Examples

- Research on topics and outcomes of high relevance and value to patient and stakeholder communities that generates timely evidence to inform decisions
- Research that recruits study participants that are representative of communities most affected by conditions being studied and are representative of the diversity of the nation in order to understand potential differences in treatment effects and outcomes across populations
- Research that involves investigators that reflect the population or community where the research is conducted and for whom the research is intended

Research Agenda Statement:

Fund research that aims to achieve health equity and eliminate health and healthcare disparities

Illustrative Examples

- Research across conditions, populations, and subpopulations on topics where disparities in health outcomes occur
- Research on innovations for health systems that drive practice change to promote equitable care and eliminate discriminatory health care practices
- Research that supports and develops the talent of diverse, early career investigators and the health care workforce

Proposed Research Agenda and Examples for Supporting Context- Continued

Research Agenda Statement:

Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships

Illustrative Examples

- Research that leverages evidence synthesis and stakeholder engagement to meet the evidentiary needs of federal, state, and local policymakers and stakeholders
- Research on innovations identified through relationships with federal partners including the FDA, CMS, NIH, VA, CDC, and AHRQ
- Research using optimized methods of data capture that are inclusive of diverse sources of real-world information (including patient-provided data)

Research Agenda Statement:

Fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders

Illustrative Examples

- Research that engages patients, caregivers, and other key stakeholders in identifying important outcomes, unintended consequences, burden, and economic impacts
- Research that assesses the full range of factors that influence health outcomes, such as patient preferences, economic issues, practice variation, and disparities in the delivery of care

Proposed Research Agenda and Examples for Supporting Context- Continued

Research Agenda Statement:

Fund research that focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play

Illustrative Examples

- Research in cross-sector collaboration with organizations with expertise in social determinants of health (e.g., economic stability; education access and quality; health care access and quality; neighborhood and built environment; social and community context)
- Research on upstream topics such as social determinants of health, public health, and policies or programs that influence population-level health
- Research that examines the use of and investment in health-promoting resources in the community

Research Agenda Statement:

Fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings

Illustrative Examples

- Research that studies the effectiveness of ways to get information to the right people, at the right time, in the right way that addresses cultural and other tailoring, modes of communication, and appropriate messengers for specific populations
- Research on approaches for rapid dissemination of evidence to inform the immediate decisional needs of patients, clinicians, health systems, and other stakeholders
- Research on the effectiveness of implementation strategies that have potential for accelerating the uptake of evidence into practice
- Research that assesses methods for explaining uncertainty, applicability, and communicating risk, including approaches for tailoring these methods for diverse populations

Overview Potential Timeline

Consideration for Approval for Posting for Public Comment

December 2, 2021

Public Comment Period

- Early December 2021 to Late January 2022

Presentation of Revised Research Agenda for Consideration for Adoption

March 2022

Discussion

Do you concur with the revisions to the
Proposed Research Agenda?

Board Vote

Call for a Motion to:

- **Approve** the Proposed Research Agenda for Posting for Public Comment

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

BREAK

We will return at 2:00 PM ET



Join the conversation on Twitter via
@PCORI

Overview of Award Slates to be Considered for Approval Today

Nakela L. Cook, MD, MPH

Executive Director

Overview of Award Slates to be Considered for Approval Today



The Selection Committee recommends funding three award slates:

PFA Type	Amount	PFA
Research Cycle 1 2021	\$23.5M	Pragmatic Clinical Studies
	\$26M	Broad
Infrastructure Cycle 2 2021	\$18M	Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research Network Slate
Total	\$67.5M	

FY2022 Funding Cycles in Context

Pragmatic Clinical Studies (PCS) Award Slates



Numbers and rates of LOIs, Applications, and Funding vary from historical averages:

Pragmatic Clinical Studies PFAs	Historical Average*	Cycle 1 2021		Cycle 2 2021	
LOIs Submitted	56	36		23	
LOIs Invited (% of LOIs Submitted)	43%	19	53%	9	39%
Applications Submitted (% of LOIs Invited)	75%	16	84%	7	78%
Applications Proposed for Funding (% of Applications Submitted)	22%	3	19%	TBD	TBD

* Historical Average based on experience from 2017-2018, prior to a pause in PCS PFAs; this is the first PCS PFA since Cycle 1 of 2018

FY2022 Funding Cycles in Context

Broad PFA Award Slates



Broad PFAs	Cycle 3 2020*		Cycle 1 2021		Cycle 2 2021		Cycle 3 2021	
LOIs Submitted	201		146		83		157	
LOIs Invited (% of LOIs Submitted)	112	56%	89	61%	40	48%	91	58%
Applications Submitted (% of LOIs invited)	84	75%	58	65%	35	88%	TBD	TBD
Applications Proposed for Funding (% of Applications Submitted)	19	23%	6	10%	TBD	TBD	TBD	TBD

*Broad PFAs were not offered in Cycle 2 2020

FY2022 Funding Cycles in Context

Phase 3 Coordinating Center Functions for PCORnet® Award Slate



Coordinating Center for PCORnet® PFAs	Phase 1 Design 2014		Phase 2 Capacity Building* 2016		Phase 3 Optimization** 2022	
LOIs Submitted	N/A		N/A		9	
Applications Submitted (% of LOIs Submitted)	8		1		9	
Applications Proposed for Funding (% of Applications Submitted)	1	12.5%	1	100%	5	56%
Total Funding	\$14M		\$39M		\$18M	

*Invited application

**Limited Competition PFA

Today's Proposed Commitments in Context of FY2022 Commitment Plan



Slates Proposed for Funding	Commitment Targets in FY2022	Cumulative FY2022 Funding with today's slates
Research, Cycle 1 2021: • PCS • Broad	\$450M For all Research PFAs	\$49.5M
Infrastructure, Cycle 2 2021: • Phase 3 Coordinating Center Functions for PCORnet®	\$60M For Engagement, PCORnet, and Workforce Awards	\$18M

Sufficient funds remain for future cycles of research and infrastructure funding; we are not proposing modifications to the Commitment Plan at this time

Research Award Slates

Jennifer DeVoe, MD, DPhil

Vice Chair, Selection Committee

Pragmatic Clinical Studies (PCS) Cycle 1 2021

Carly Khan, PhD, MPH, RN

Associate Director, Healthcare Delivery & Disparities
Research (HDDR)

Cycle 1 2021 –Pragmatic Clinical Studies (PCS)

Slate of 3 Recommended Projects



Project Title	
Expanding first-line Options for Depression & Matching Treatments: Hatha Yoga vs Behavioral Therapy	
Comparative Effectiveness of Online Cognitive Behavioral Therapy vs. an Online Single-Session Pain Relief Skills Class for Chronic Pain	
Comparative Effectiveness of Mobile Health Smoking Cessation Approaches among Underserved Patients	
Total Funds Requested*:	\$23.5M

* 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 1 2021 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

Voice Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Broad PFA

Cycle 1 2021 Award Slate

Steve Clauser, PhD, MPA

Program Director, Healthcare Delivery and Disparities
Research

Holly Ramsawh, PhD

Senior Program Officer, Clinical Effectiveness and Decision
Science

Cycle 1 2021

Addressing Disparities and Improving Health Systems Slates

Total of 4 Recommended Projects



Addressing Disparities Slate: Project Titles

Equity-Enhancements to Reduce Disproportionate Unmet Mental Health Need of African American Children

Comparative Effectiveness of Treating Genital Herpes Infection to Reduce Racial Disparities in the Risk of Severe Maternal Morbidity (SMM)

Improving the health of adolescents and transition-age youth with IDD

Total Funds Requested*:	\$13.8M
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Improving Health Systems Slate: Project Title

The Follow-up Automatically vs As-Needed Comparison (FAAN-C) Trial

Total Funds Requested*:	\$7M
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* 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 2021 – Assessment of Prevention, Diagnosis, and Treatment Options and Improving Methods for Conducting PCOR

Total of 2 Recommended Projects



Assessment of Prevention, Diagnosis and Treatment Options Slate: Project Title

The CARES Trial: Comparing Analgesic Regimen Effectiveness and Safety after surgery

Total Funds Requested*:

\$4M

Improving Methods for Conducting PCOR Slate: Project Title

Improved Statistical Methods for Instrumental Variable Designs in CER

Total Funds Requested*:

\$1M

* 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 slates of awards from the Cycle 1 2021 Broad PFAs

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

Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research Network Cycle 2 2021

Laura Lyman Rodriguez, PhD

Interim Chief Program Support Officer

Senior Advisor to the Executive Director

Recap: PCORI Priorities for PCORnet®



- PCORnet Priorities Working Group established to propose set of **Prioritizing Principles for PCORnet** to guide PCORI Board and staff in decision-making about funding for PCORnet's next stages and to align with PCORI's overall strategic planning
- Prioritizing Principles for PCORnet focused on: patient-centeredness, utilizing Network for studies with national scope, promoting collaboration, partnerships & optimizing governance systems
- Board approved Prioritizing Principles for PCORnet and development of funding opportunities for PCORnet Phase 3 on January 12, 2021

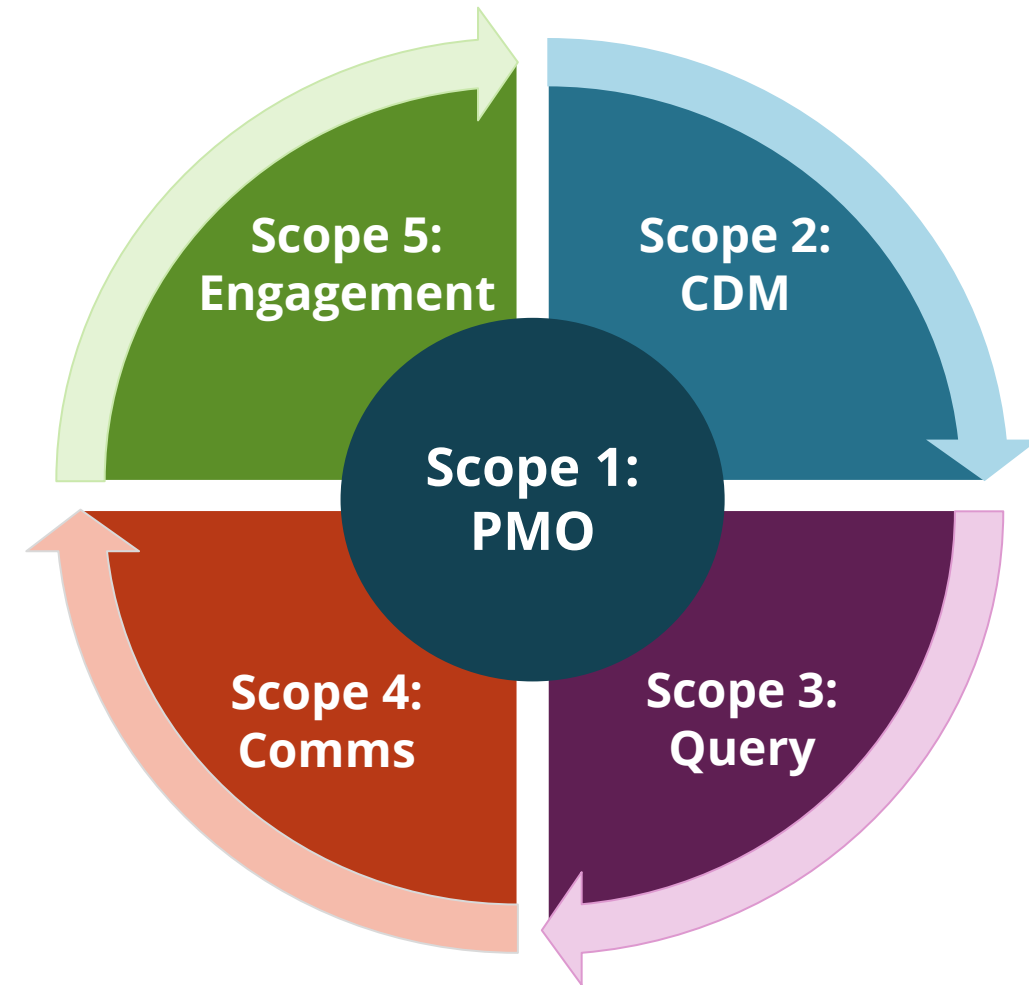
PCORnet Phase 3 Funding	Per Year	Total (3 years)	Slate Status
Clinical Research Networks	\$20 million	\$60 million	Board Approved 9/28/21
Coordinating Center	\$6 million	\$18 million	Board Considers Today
Total	\$26 million	\$78 million	

- Working Group will continue its work in 2022 as part of PCORI's on-going Strategic Planning process

Cycle 2 2021 – Coordinating Center Functions to Advance Phase 3 of PCORnet®

Scopes of Work

Coordinating Center Functional Scopes of Work	
Scope 1: PMO	Program Management Office (PMO) to facilitate PCORnet governance, collaboration, and operations to enable multi-network PCORnet research of definitive studies of national scope
Scope 2: CDM	Maintenance and Development of the PCORnet Common Data Model (CDM), Data Characterization, and Privacy Preserving Record Linkage
Scope 3: Query	PCORnet Designated Study Consultation and Query and Analytic Tool Development to Enable Multi-network PCORnet Research
Scope 4: Comms	PCORnet Communications
Scope 5: Engagement	Highly Engaged Patients, Researchers, Clinicians, Health Systems, and Health Plans



Cycle 2 2021 –Coordinating Center Functions to Advance Phase 3 of PCORnet®

Slate of 5 Recommended Projects



Coordinating Center Functional Scope	Project Title
Scope 1: PMO	PCORnet Coordinating Center: Program Management, Collaboration and Coordination
Scope 2: CDM	PCORnet Coordinating Center: Common Data Model Maintenance, Expansion and Linkage
Scope 3: Query	PCORnet Designated Study Consultation and Query and Analytic Tool Development to Enable Multi-network PCORnet Research
Scope 4: Comms	Strengthening Communications to Support the PCORnet Research Community
Scope 5: Engagement	PCORnet Engagement Coordinating Center
Total Funds Requested*: \$18M	

* 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 2021 – Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research Network 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

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions

Overview of Targeted PFA Development to be Considered for Approval Today

Nakela L. Cook, MD, MPH

Executive Director

Progress on Targeted PFAs



Under our *expedited and enhanced process*, we have launched 6 targeted PFAs to date

Cycle 2 & 3 2021 Targeted PFAs	Funding
Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities	Up to \$50M
Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with Intellectual and Developmental Disabilities	Up to \$40M
Nonsurgical Interventions for Women with Urinary Incontinence	Up to \$40M
Comparative Effectiveness of Novel Pharmacologic and Evidence-based Nonpharmacologic Treatments for Migraine Prevention	Up to \$40M
Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum	Up to \$50M
Multimodal Interventions to Prevent Osteoporotic Fractures	Up to \$40M
Total	Up to \$260M

Progress on Board-Approved Candidate Topics

Funding Mechanism	Cycles 2&3 2021	Cycle 1 2022	Cycle 2 2022	Cycle 3 2022
Targeted PFA or Special Area of Emphasis	☒ Nonsurgical interventions for women with urinary incontinence ☒ Healthy Aging: Optimizing physical and mental function across the aging continuum ☒ Multimodal interventions to prevent osteoporotic fractures ☒ Treatments for migraine prevention ☒ Addressing racism, discrimination, and bias throughout the care continuum* ☒ Leveraging telehealth for chronic disease management among vulnerable populations with complex needs*	Substance Abuse in Youth Delirium	<i>Visual Impairment</i> <i>Hypertension control</i> <i>Advancing health equity*</i>	<i>Telehealth*</i> <i>Suicide prevention</i> <i>Cancer immunotherapy</i>
Large Single Study	<i>Abdominal aortic aneurysm in women</i>			

Notes: Set of topics is *in addition to* COVID-19, MMM, IDD which are underway and continue; Timing is tentative

*Example of leading with a Special Area of Emphasis

Targeted PFA Development Under Consideration Today



The Science Oversight Committee recommends that the Board approve the development of the following Targeted PFAs:

Targeted PFAs for Development for Cycle 1 2022	Funding
Brief Interventions for Adolescent Alcohol Use	Up to \$30M
Prevention, Early Identification, and Treatment of Delirium	Up to \$30M
Total	Up to \$60M

Development and Funding of Targeted PFA: Brief Interventions for Adolescent Alcohol Use

Alicia Fernandez, MD

Chair, Science Oversight Committee

Els Houtsmuller, PhD

Associate Director, HDDR

Recommendation for Targeted PFA

Question of interest:

What is the comparative effectiveness of brief behavioral interventions, adapted for adolescents ages 12-17, to address alcohol use?

Recommendation for Targeted PFA

Population	Adolescents ages 12-17
Intervention/ Comparators	Brief interventions for alcohol use (may include motivational interviewing, brief advice, education, personalized feedback, goal setting, booster sessions, other), adapted for adolescents (e.g., family involvement, digital delivery, peer delivery, tailoring for specific adolescent populations, other)
Example Outcomes	Alcohol use; consequences of alcohol use; other substance use; consequences of other substance use; healthcare utilization; patient engagement; patient satisfaction with care; school performance; substance use diagnoses, other mental health diagnoses
Timing	12-month follow-up

- Total requested for this PFA is \$30M in total costs
- Estimated number of cycles: Up to 3
- Estimated number of studies: 3-5
- Maximum project duration: Up to 5 years

Board Vote

Call for a Motion to:

- **Approve** the development of “Brief Interventions for Adolescent Alcohol Use” Targeted PFA with funding up to \$30M in total costs

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

Development and Funding of Targeted PFA: Prevention, Early Identification & Treatment of Delirium

Alicia Fernandez, MD

Chair, Science Oversight Committee

Yewande Akinbami, MD, MPH

Program Officer

Recommendation for Targeted PFA

Question of interest:

What is the comparative effectiveness of evidence-based single and/or multicomponent interventions to improve prevention, early identification, or treatment of delirium in older adults?

Recommendation for Targeted PFA

Population	Older adults (65+) at risk of developing or diagnosed with delirium, including underrepresented minority population
Intervention/Comparators	Single and multi-component interventions (i.e., nonpharmacologic, pharmacologic, training guidelines, telehealth, etc.), implementation strategies
Example Outcomes	Delirium occurrence, severity, time to resolution, cognition, Health-Related Quality of Life (HRQOL), patient discharge disposition, caregiver burden or distress, hospital stays, re-admission
Timing	Varies but <5 years

- Total requested for this PFA is \$30M in total costs
- Estimated number of cycles: Up to 3
- Estimated number of studies: 3-5
- Maximum project duration: 5 years

Board Vote

Call for a Motion to:

- **Approve** the development of “Prevention, Early Identification & Treatment of Delirium” Targeted PFA with funding up to \$30M in total costs

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

Health Systems Implementation Initiative (HSII)

Michael Herndon, DO

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

Joanna Siegel, SM, ScD

Director, Dissemination and Implementation Program

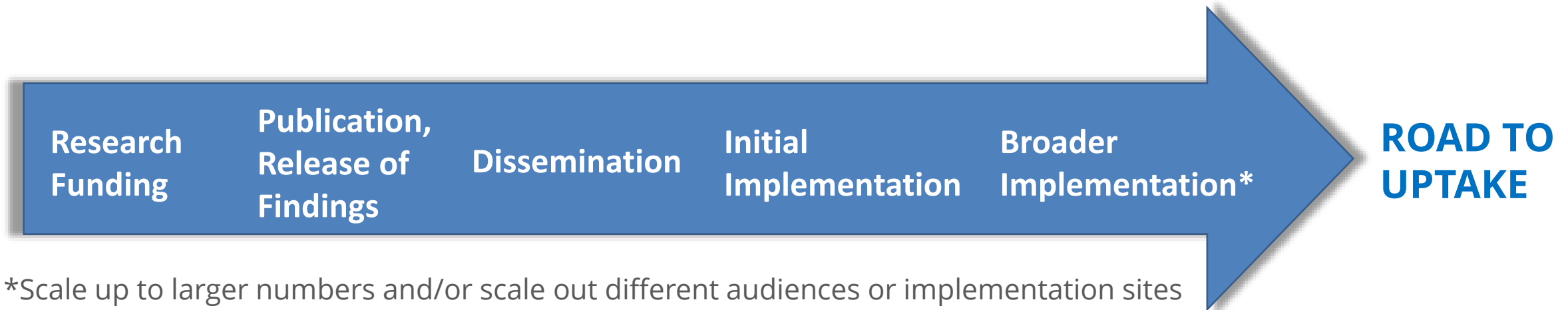
Dissemination & Implementation at PCORI



PUBLICATION

Traditionally, research funders have focused on publication as the end-goal of research.

PCORI is committed to extending the pathway from funded research through dissemination and implementation – to assure that findings from research **are used to improve health care and health.**



*Scale up to larger numbers and/or scale out different audiences or implementation sites

What is the Health Systems Implementation Initiative (HSII)?



New Dissemination & Implementation initiative will provide funding **to healthcare delivery systems and provider-affiliated health plans directly**, to undertake implementation projects that promote the uptake of specific PCORI-funded evidence within their care delivery settings.

Advantages HSII offers:

- Engage the experience and expertise that reside in healthcare delivery systems.
- Leverage health systems' reach.
- Leverage health systems' commitment and enthusiasm.
- Deep integration into health system operations will facilitate efforts to change practice and provide a ready path to sustainability.
- Clear potential for scaling within all relevant units of each participating healthcare system.
- Lay groundwork for future scale-up by adapting and demonstrating pathways to uptake and by documenting impact through program evaluation.
- Facilitate the transfer of learnings across health systems

Initiative Status and Today's Request



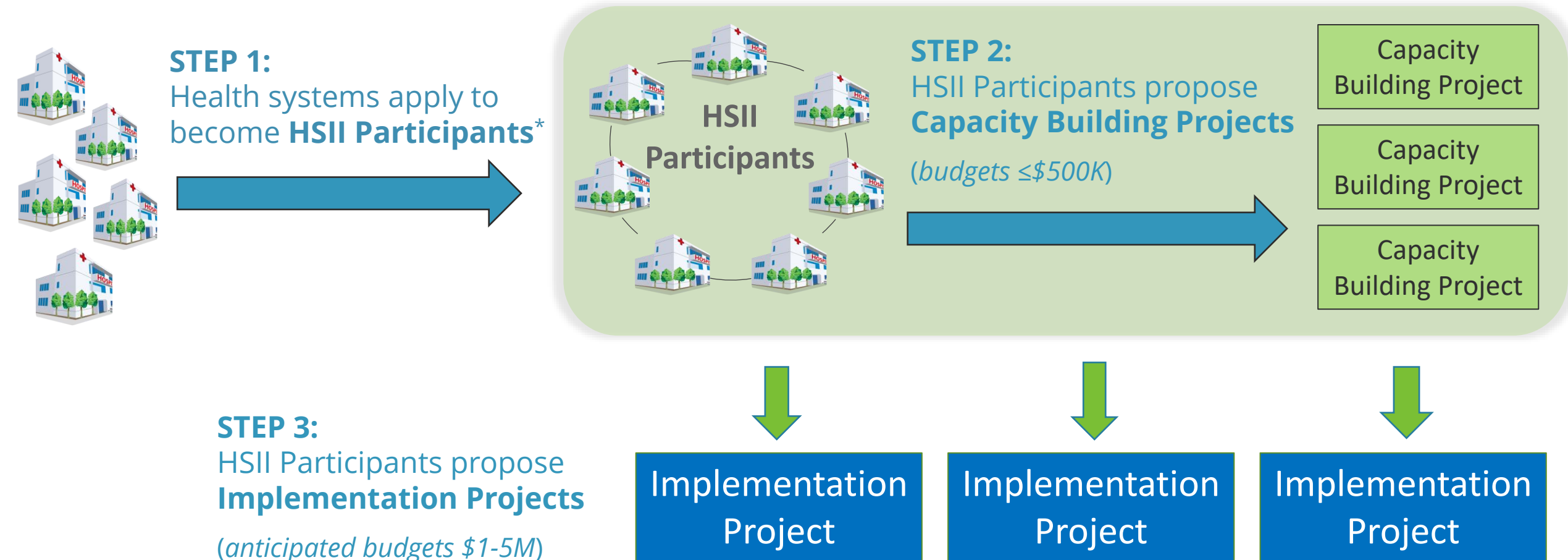
Progress to Date:

- PCORI issued a **Request for Information** (open May - July 2021) and received a robust response from the potential applicant community; informed initiative development.
- PCORI staff presented to the EDIC about the HSII Award Program in June and October.
- The EDIC voted to recommend the Board approve the proposed approval framework for HSII Implementation Projects and commitment of funds for HSII (Nov. 9, 2021)

Next Steps:

- **Today:** Present the HSII Award Program and request Board approval of the proposed Approval Framework for HSII Implementation Projects and funding commitment for HSII
- Release invitation for applicant organizations to apply to join HSII accompanied by broad outreach effort (*target: Winter 2022*)

HSII's Three-Step Process



Initiative Goals

To support the uptake of findings from PCORI-funded research:

- **Demonstrate feasible and scalable approaches** for integrating evidence from specific PCORI-funded research into practice.
- **Accomplish meaningful uptake** in diverse healthcare delivery settings through HSII Implementation Projects.
- **Initiate the scaling** of successful implementation approaches in partnership with AHRQ and interested stakeholders.

Reaching Diverse Organizations



PCORI will seek HSII Participants that have:

- Diverse patient reach, including racial, ethnic and socioeconomic diversity.
- Experience serving underserved and vulnerable patient populations.
- Close relationships with community partners and key stakeholders, as well as the ability to ensure meaningful patient engagement.

Further, PCORI will seek to include as HSII Participants:

- Different types of healthcare delivery systems, including less-resourced systems.
- Healthcare systems across different geographic areas and serving different types of communities.
- Healthcare systems not heavily engaged in research, as well as those that have ongoing research programs.

- Projects' evaluation will document successes and challenges in specific implementation efforts, including impacts on healthcare and health outcomes.
- Longer term evaluation will assess the sustainment of uptake in HSII Participant systems, as well as capturing uptake in organizations beyond those participating in HSII.
- Upon project completion, HSII Participants will
 - Report on achievements and impact, and
 - Make tools and materials developed during the project publicly available to support broader uptake.

HSII Learning Network



- HSII Participants will participate in a **Learning Network** to support their success in implementation efforts.
- The Learning Network will provide a venue for HSII Participants to:
 - Share experiences and learn from colleagues,
 - Consult with experts and each other on specific implementation strategies, data collection for evaluation, and other implementation project components,
 - Provide input to PCORI on potential implementation opportunities.
- Learning Network attendees will be leaders familiar with operations throughout their healthcare delivery system and who have experience in previous initiatives involving practice change.
- The Learning Network will facilitate the transfer of learnings and expertise across health systems.

HSII Approval Framework

HSII Review and Approval: Guiding Principles



- **Speed and efficiency** – A paramount goal for all parties.

RFI respondent: “Rapid timelines from project idea, to contract, to implementation are critical because the priorities of healthcare systems change quickly. Lengthy delays between idea approval and contract funding will diminish the ability for healthcare systems to participate most effectively.”

- **Transparency and fairness** – Through use of existing PCORI review and approval structures, developed to ensure community responsiveness.
- **Rigor** – Ensuring we gain input from external reviewers with subject matter expertise and maintaining input from EDIC in the approval process for HSII Implementation Projects.
- **Appropriate levels of authority** – Approval processes within PCORI should emulate previously used, Board-approved processes.

Step 1: Selecting HSII Participants

Establishing a pool of vetted healthcare delivery organizations

- Applicant organizations—healthcare delivery systems and provider-affiliated health plans—will respond to an initial Call for Proposals to become HSII Participants.
- Proposals will include information on applicant organizational composition and structure, commitment and capability to implement practice change, ability to achieve significant and diverse reach.

Review and Approval Process:



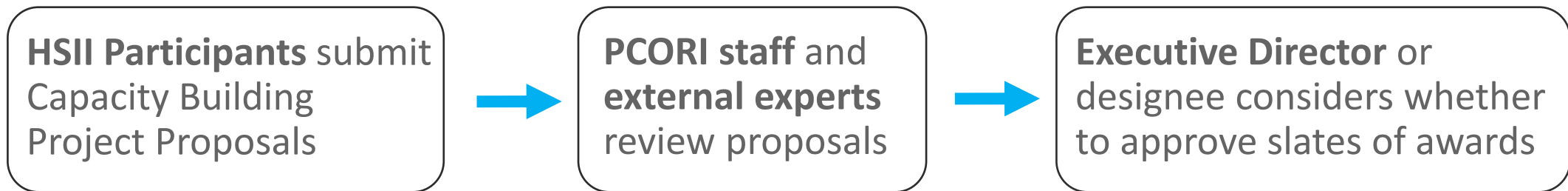
Note: No PCORI funds will be associated with being approved as an HSII Participant.

Step 2: HSII Capacity Building Projects

Strengthening HSII Participant's capacity to support practice change

- Immediately after their selection, HSII Participants will respond to a PCORI Call for **HSII Capacity Building Project** Proposals and propose projects to bolster their ability to conduct successful implementation projects under HSII.
- HSII Capacity Building Projects will have budgets <\$500K.

Review and Approval Process:

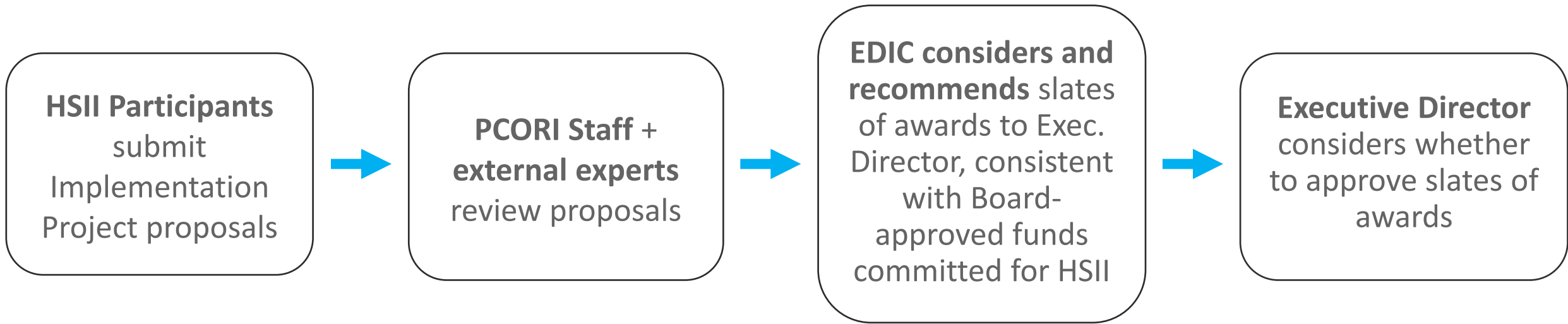


Step 3: HSII Implementation Projects

Supporting implementation efforts in HSII Participant healthcare delivery systems.

- With HSII Participant input, PCORI will identify the evidence focus for HSII Implementation Projects and issue topic-specific Calls for Implementation Project Proposals.
 - HSII Participants can respond to as many topics as they wish.
 - Implementation Projects will have budgets of \$1-5M and be mostly 2-4 years in length.
- HSII Participants will propose Implementation Projects outlining
 - Implementation strategies and plans that are consistent with implementation science and appropriate for their delivery settings.
 - Evaluation plans to assess implementation and impacts on healthcare and health outcomes.
 - Commitment and specific plans for sustaining the practice change beyond the project.

Proposed Approval Framework for HSII Implementation Projects



EDIC = Engagement, Dissemination & Implementation Committee

Note: The proposed approval process, with the ED approval of slates of awards at a similar funding level, has precedent in a process previously approved by the Board, authorizing the ED to approve slates of COVID-19 tPFA awards recommended by the Selection Committee.

Board Vote



Call for a Motion to:

- **Approve**
 - The Proposed Approval Framework for HSII Implementation Projects, including PCORI staff review of proposals, EDIC consideration of projects and recommendation of slates of awards, and Executive Director consideration and approval of slates of awards
 - The commitment of funding of up to \$15 million per fiscal year beginning in FY 2022 to fund projects awarded under the Health Systems Implementation Initiative, not to exceed a total of \$50 million for 5 fiscal years.

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

Public Comment Period

Kristin L. Carman, MA, PhD

Director, Public & Patient Engagement

Closing Remarks

Wrap Up and Adjournment



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