

Board of Governors Meeting

In-person and via
Teleconference/Webinar

September 20, 2022
9:00 AM – 1:00 PM

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

Time	Agenda Item
9:00am	Welcome, Call to Order, and Consider for Approval: July 26, 2022, Board Meeting Minutes and Committee Nominations Relating to Board Transitions
9:15-9:55	Executive Director's Report
9:55-10:25	Consider for Approval: Proposed FY 2023 Budget
10:25-10:55	Consider for Approval: Proposed Governance Framework
10:55-11:10	BREAK
11:10-11:55	Consider for Approval: Proposed <i>Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance</i>
11:55-12:25	Fond Farewell for Outgoing Board Members
12:25-12:55	Public Comment
12:55-1:00pm	Wrap-up and Adjourn

Board Vote

Call for a Motion to:

- **Approve** Minutes of the July 26, 2022, 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

Committee Nominations Relating to Board Transitions

Sharon Levine, MD

Chair, Governance Committee

Proposed Motion #1 Relating to Committee Appointments



Motion #1

- The Board appoints the following Board members to serve on the specified committees in the specified roles:
 - Finance and Administration Committee:
 - James Huffman, Vice Chair
 - Kate Berry, Member
 - James Schuster, Member
 - Engagement, Dissemination, and Implementation Committee
 - Connie Hwang, Vice Chair

Proposed Motion #2 Relating to Committee Chair Succession



Motion #2

- The Board resolves that:
 - If the Chair of a Board-related Committee resigns or is no longer able or available to fulfill the responsibilities of the Chair position, the Vice Chair of that Committee is appointed to the position of Chair of the Committee, unless otherwise appointed by the Board.

Board Vote

Call for a Motion to:

- **Approve** Motion #1 relating to Committee Appointments and Motion #2 relating to Committee Chair Succession

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

Welcome Mieke Martinez, MBA

Chief Financial Officer



Mieke Martinez is joining us from Howard University, where she served as the Vice President and Interim Chief Financial Officer as well as Assistant Vice President and Deputy Chief Financial Officer since 2018. She oversaw a staff inclusive of the Controller, Assistant Treasurer, Procurement, Finance, Insurance and Risk Management, Special Projects, and Data Analysis. Previously, Mieke held various strategic, operational and financial roles at the director and chief level within Georgetown University. She has had oversight of operating budgets as large as \$1B funded by tuitions and fees, endowments and gifts, sponsored activity, and auxiliary enterprises.

Ms. Martinez is a seasoned executive with over 38 years of experience in strategic financial management and operational leadership and has delivered over 20 years of materially balanced operating results. She has developed numerous intermediate and long-range financial plans and other financial models and tools to support resource allocation, capital planning, deferred maintenance, and strategic and operational goals, and implemented numerous initiatives to streamline operations effectiveness and efficiencies, including service centers, matrix reporting structures, procurement processes, and implementation of ERP systems for Finance, Human Resources, Research Awards, and Budget.

Ms. Martinez received both her Master of Business Administration (Beta Gamma Sigma) and her Bachelor of Science in Business Administration in Finance and International Management from the McDonough School of Business at Georgetown University.

PCORI Updates: Ad Hoc Committee and Work Group Activities Relating to the Board

Strategic Planning Committee

PCORnet® Priorities Workgroup

WG to Optimize Effective Governance and Board Engagement

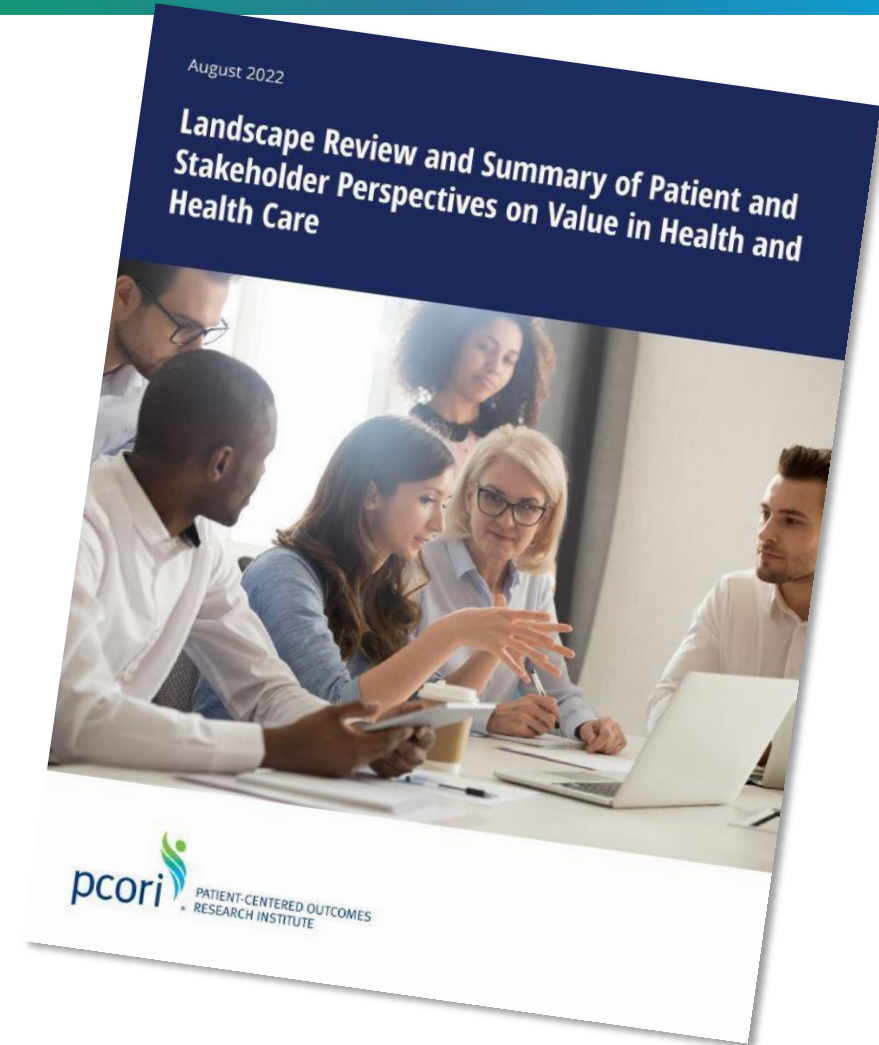
Healthcare Cost and Value Workgroup

Charge	Work on behalf of the Board to develop and oversee the conduct of a strategic planning process and the development of a strategic plan for approval by the Board	Build upon the Prioritizing Principles and propose strategies to inform the evaluation framework; guide Board considerations including future investments; advance the strategic plan	Develop options for an evolved approach for the Board's strategic oversight of PCORI's work	Develop framework for activities to support PCORI's approach to collecting the full range of outcomes, informing the value conversation and supporting policy priorities
Composition	  		 	  
Timeline	Aug 2020- July 2022	Stage 1: Nov 2020 - Jan 2021 Stage 2: Feb-Aug/Sept 2022	March 2022 – Sept 2022	Oct 2021-Dec 2022
Outcomes to Date	- National Priorities for Health - Research Agenda - Strategic Plan	- Prioritizing Principles for Funding - Charge for Stage 2 - Considerations for measuring success - Priorities for Data/ Population Expansion - Strategic opportunities	Proposed governance framework with new strategy committee	- Framework for Activities - Landscape Review - Stakeholder Listening Sessions

Health Care Cost and Value Workgroup

Informing the Value Conversation

- Landscape review summarizing patient and stakeholder perspectives on value published on PCORI web site September 2
- Multistakeholder workshop hosted on September 7
 - Learnings from workshop and additional engagement activity will be synthesized in forthcoming draft report



Year in Review



New Members of the Leadership Team



Brian Trent, MPA
Deputy Executive
Director for Operations



Harv Feldman, MD
Deputy Executive
Director for Patient
Centered Research
Programs



**Yolanda
Hutchins, MA**
Chief People Officer



Sri Mishra, MBA
Chief Information
Officer



Carolyn Best, PhD
Chief, Program
Operations



Erin Holve, PhD
Chief, Research
Infrastructure



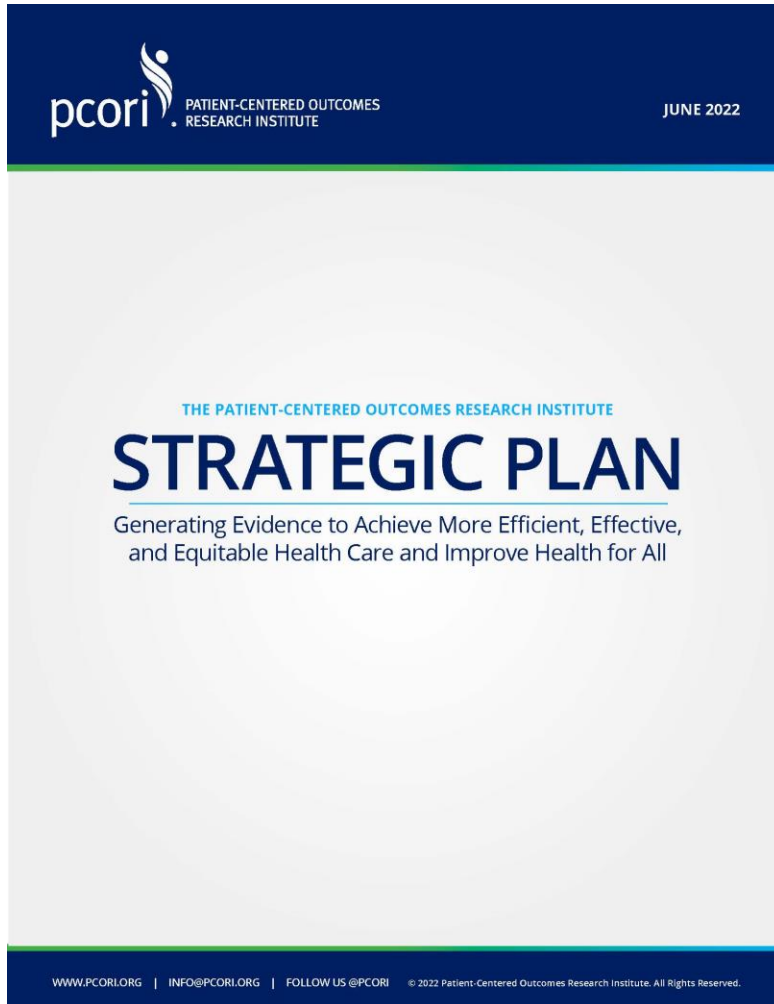
Mieke Martinez, MBA
Chief Financial Officer

PCORI's New Offices

1333 New
Hampshire
Avenue NW
Washington, DC



PCORI Strategic Plan



PCORI's Strategic Plan

- A bold vision and an aspirational roadmap for how PCORI will continue to pursue its mission
- Centered on five long-term, reinforcing goals — the National Priorities for Health — which will guide all our work
- Expanded focus on health equity
- Responsive to the overall health landscape

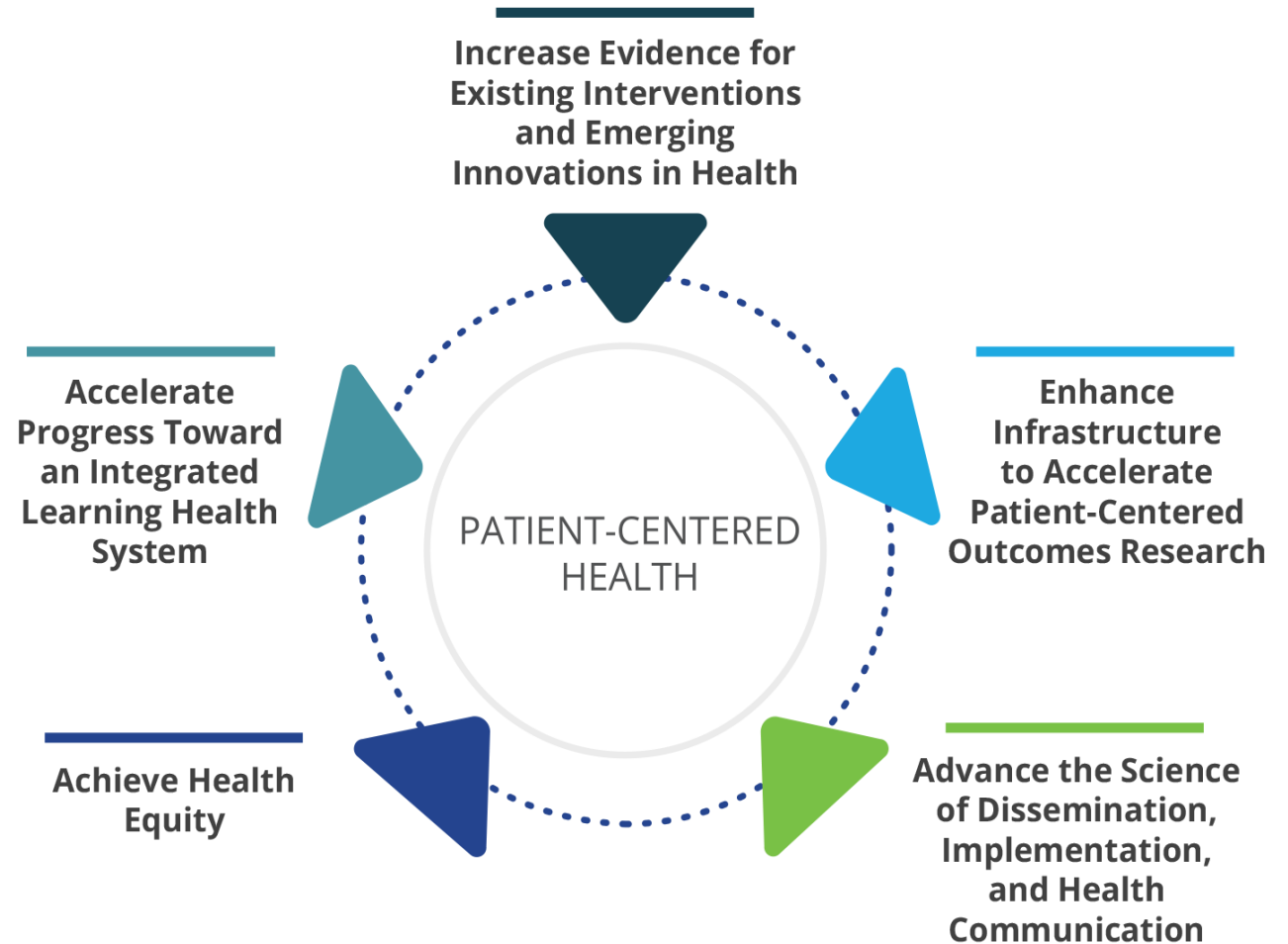
Visit: <https://www.pcori.org/pcori-strategic-plan>

PCORI Strategic Plan



National Priorities for Health

- Five ambitious long-term goals
- Interconnected and mutually reinforcing
- Focus:
 - Anchor PCORI's research funding and other initiatives
 - Make a positive and significant impact on health and healthcare outcomes



Holistic Approach

- Reflects a holistic approach to generating and promoting the use of evidence designed to enable a more patient-centered system of health
 - CER Funding
 - Engagement
 - Dissemination & Implementation
 - Infrastructure
- Working in concert with one another, these components drive and facilitate our mission and enable us to be responsive



Methodology Committee Framework and Nomination of New Members



PCORI Board Seeks Nominations to Fill Seats on its Methodology Committee

The Patient-Centered Outcomes Research Institute Board of Governors, or PCORI Board, issues a call for nominations to fill seats on its PCORI Methodology Committee.

- Approved Amended Methodology Committee Charter
- Approved Conflict of Interest Policy Relating to PCORI Funding for Members of Board of Governors, Members of Methodology Committee, and Employees
- Approved Framework for Nomination and Appointment of New Methodology Committee Members

Award-Winning Annual Report



MarCom Gold Award
PCORI 2020 Annual Report
3rd year in a row!

PCORI's Second Virtual Annual Meeting

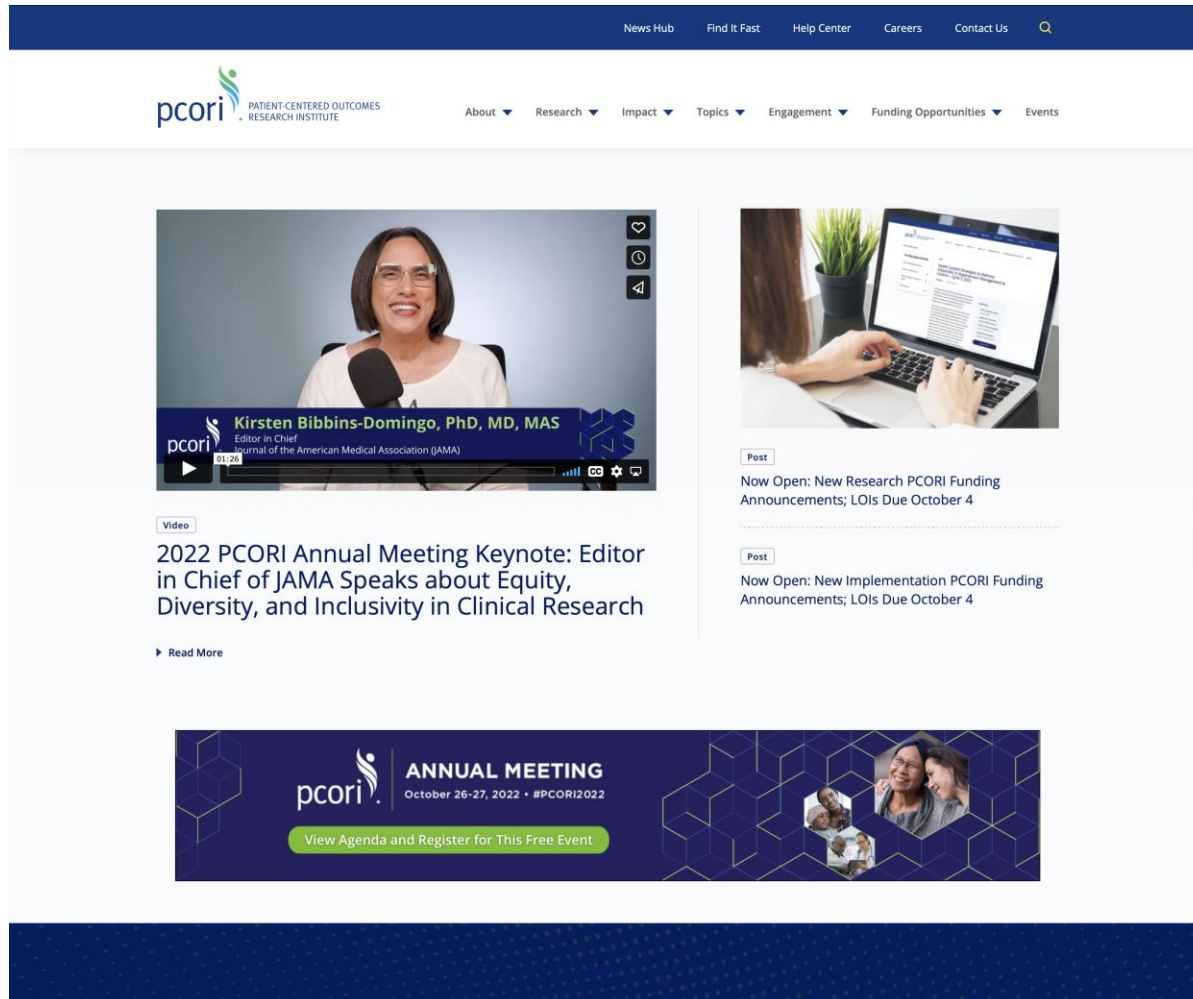


Opening Plenary:
Coming Together to Achieve Health Equity
Sindy Benavides, Daniel Dawes, Garth Graham, Adam Myers, Darshali Vyas

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



PCORI's New Website



- Showcase PCORI as a leading source of actionable information for the healthcare community
- Demonstrate the impact of PCORI-funded work
- Engage diverse stakeholders with the latest priorities and progress in patient-centered research
- Develop a modern vehicle to highlight our work and improve the user experience for our visitors

Innovative Initiatives



Health Systems Implementation Initiative



Health Equity Initiative



Science of Engagement



Learning Health Systems



Topic Themes



11 Targeted PFAs

FY 2022 Commitments Relative to Target

Funding Line	FY 2022 Target	FY 2022 Estimated
Research	\$500M	\$398 – 428M
Dissemination & Implementation	\$40M	\$15 – 20M
Infrastructure	\$60M	\$38M
<i>New Initiatives</i>	<i>\$50M*</i>	<i>\$25M**</i>
Total	\$600M	\$476– 511M

**Funds available for New Initiatives are not included in the total target*

***This commitment is for a Workforce initiative and thus will be counted toward the Infrastructure funding total*

FY 2022 Commitments in Context

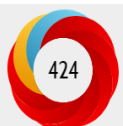
Total Award Commitments				
Average 2013 to 2019	2020	2021	2022	2023 Target
\$388M	\$313M	\$494M	\$476 – 511M	\$600M

Results Coming to Fruition

CER Results publications from PCORI-funded studies with Altmetric scores ≥ 300 , considered a very high score.

All publications are in the top 5% of all research outputs scored by Altmetric

* Controlled for Journal and date of publication

Altmetric	CER Results Publications Highlights	Score in Context*
	Neuman MD, et al. Spinal Anesthesia or General Anesthesia for Hip Surgery in Older Adults . <i>New England Journal of Medicine</i> . Nov 2021. [Primary CER Results]	Top 15% of attention
	Israel, E, et al. Reliever-triggered Inhaled Glucocorticoid in Black and LatinX Adults with Asthma . <i>New England Journal of Medicine</i> . Feb 2022. [Primary CER Results]	Top 18% of attention
	Delgado, MK, et al. Comparative Effectiveness of an Automated Text Messaging Service for Monitoring COVID-19 at Home . <i>Annals of Internal Medicine</i> . Nov 2021. [Primary CER Results]	Top 7% of attention
	Green BB, et al. Clinic, Home, and Kiosk Blood Pressure Measurements for Diagnosing Hypertension: A Randomized Diagnostic Study . <i>Journal of General Internal Medicine</i> . Mar 2022. [Primary CER Results]	Top 1% of attention
	Schwarz EB, et al. Comparative Effectiveness and Safety of Intrauterine Contraception and Tubal Ligation . <i>Journal of General Internal Medicine</i> . Feb 2022. [Primary CER Results]	Top 1% of attention
	Albritton, J, et al. Video Teleconferencing for Disease Prevention, Diagnosis, and Treatment: A Rapid Review . <i>Annals of Internal Medicine</i> . Dec 2021. [Primary CER Results]	Top 5% of attention



Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19

MMWR Morb Mortal Wkly Rep (2022)

Study conducted using PCORnet®. Externally funded.

Data from 40 health care systems from January 2021–January 2022 found that the risk for cardiac complications was significantly higher after SARS-CoV-2 infection than after mRNA COVID-19 vaccination for both males and females in all age groups.

BP-CHECK Study

JGIM (2022)

A 3-arm randomized trial of 510 adults with elevated BP, compared BP monitoring in clinic, home, and kiosk vs. APBM for effectiveness in diagnosing hypertension. Monitoring BP at home had better diagnostic performance, adherence and acceptability than at the clinic or kiosk.

Clinical Features and Burden of Postacute Sequelae of SARS-CoV-2 Infection in Children and Adolescents

JAMA Pediatrics (2022)

Study conducted using PCORnet®. Externally funded.

This retrospective cohort study using data from 9 children's hospitals of 659,286 children tested between March 1, 2020, and October 31, 2021 for SARS-CoV-2, found low burden of pediatric PASC presented to health systems; myocarditis as the most commonly diagnosed PASC-associated condition; and acute illness severity, young age, and comorbid chronic disease increased risk of PASC.

Celebrating Their Service

Founding PCORI Board Members 2010–2022



Christine Goertz, DC, PhD



Sharon Levine, MD



Ellen Sigal, PhD



Robert Zwolak, MD, PhD

Proposed FY 2023 PCORI Budget

(October 1, 2022 – September 30, 2023)

Russell Howerton, MD

Chair, Finance and Administration Committee

Brian Trent, MPA

PCORI Deputy Executive Director, Operations

Projected FY 2023 Fund Balance

PROJECTED FUND BALANCE *		
Accrual Basis		
(\$ in millions)		
Projected Fund Balance at 9/30/2022	\$	1,663
Revenue (FY 2023)		607
Expenses (FY 2023)		(451)
Projected Fund Balance at 9/30/2023		1,819
Projected Outstanding Award Obligations at 9/30/2023 **		(1,625)
Net Funds Available at 9/30/2023 ***	\$	194

* Includes PCOR Trust Fund and bank accounts

** Outstanding award obligations include assumptions about the planned commitment amounts in FY 2023 and are subject to change

*** These funds are available for new award commitments and operating costs

Proposed FY 2023 PCORI Budget

By Major Budget Component and Funding Area

\$ in millions



EXPENSES	FY 2023 Proposed Budget			FY 2022 Year-End Projection			Increase/ (Decrease)		
PROGRAM SERVICES									
Award Payments									
Research*	\$	263.6	59%	\$	225.0	59%	\$	38.6	17%
Dissemination & Implementation		27.7	6%		20.9	5%		6.8	32%
Infrastructure		59.4	13%		49.2	13%		10.2	21%
Total Award Payments		350.7	78%		295.1	77%		55.6	19%
Total Programs & Program Support		63.2	14%		54.5	14%		8.7	16%
TOTAL PROGRAM SERVICES		413.9	92%		349.6	91%		64.3	18%
Total Administrative Support		37.1	8%		35.7	9%		1.4	4%
TOTAL EXPENSES	\$	451.0	100%	\$	385.3	100%	\$	65.7	17%

* Includes \$1 million in Rapid Response payments

Board Vote

Call for a Motion to:

- **Approve** the Proposed FY 2023 PCORI Budget

Call for the Motion to be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

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

Proposed Governance Framework

Kathleen Troeger, MPH

Chair, Work Group to Optimize Effective
Governance and Board Engagement

Christine Goertz, DC, PhD

Vice Chair, Work Group to Optimize Effective
Governance and Board Engagement

Nakela L. Cook, MD, MPH

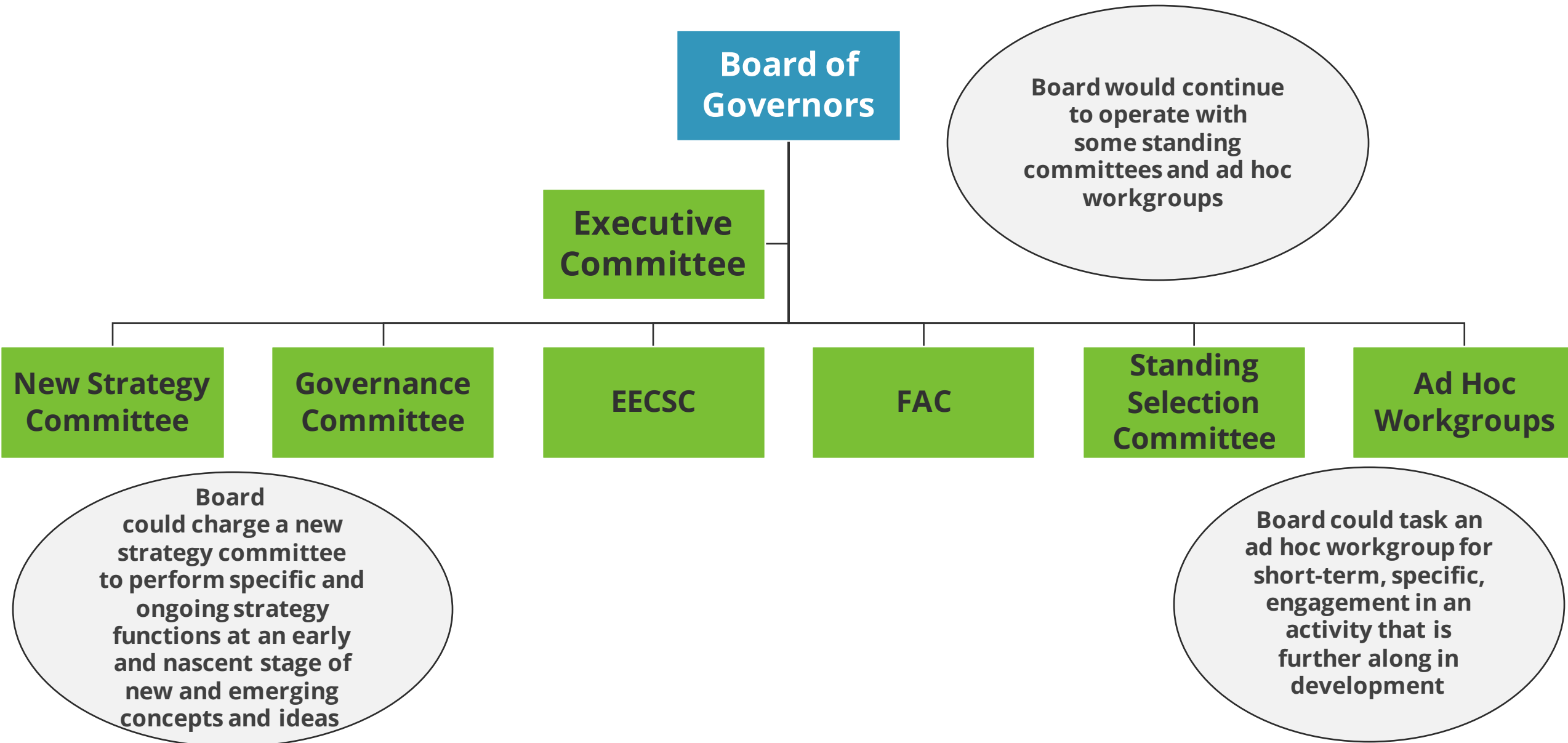
Executive Director

Members of the Work Group to Optimize Effective Governance and Board Engagement



- Nakela Cook, MD, MPH
- Harv Feldman, MD
- Alicia Fernandez, MD
- Christine Goertz, DC, PhD, *Vice Chair*
- Mary Hennessey, Esq.
- Russell Howerton, MD, FACS
- Sharon Levine, MD
- Michele Orza, ScD
- James Schuster, MD, MBA
- Maureen Thompson, MA
- Kathleen Troeger, MPH, *Chair*
- Danny van Leeuwen, MPH, RN

Elements of the Proposed Governance Framework



Proposed Governance Framework



- **Retain the following standing committees:** Governance Committee, Finance and Administration Committee (FAC), Executive Evaluation and Compensation Subcommittee (EECSC), and Executive Committee
- **Create a new standing Strategy Committee**
- **Pause the convenings of the three current standing Strategy Committees** (Engagement, Dissemination, and Implementation Committee; Research Transformation Committee; Science Oversight Committee)
- **Expand the standing Selection Committee** to include consideration of additional award types
- **Formally incorporate ad hoc work groups** into the governance framework
- **Assess the new governance framework** to determine if it is achieving the desired outcomes

Discussion

Board Vote

Call for a Motion to:

- **Approve** the Proposed Governance Framework

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 11:10 AM ET



Join the conversation on Twitter via
@PCORI

Proposed Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance

Robert Zwolak, MD, PhD

Chair, PCORnet Priorities Workgroup

Kara Ayers, PhD

Vice Chair, PCORnet Priorities Workgroup

Erin Holve, PhD, MPH, MPP

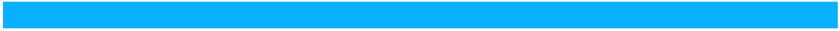
Chief Research Infrastructure Officer

Members of the PCORnet® Priorities Workgroup (Stage 2)



- Robert Zwolak, MD, PhD, Chair
- Kara Ayers, PhD, Vice Chair
- Kate Berry
- Alicia Fernandez, MD
- Christopher Friese, PhD, RN, AOCN, FAAN
- Russell Howerton, MD
- Michael Lauer, MD
- Barbara J. McNeil, MD, PhD
- Danny van Leeuwen, MPH, RN

Background



Board-Approved PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet® (Work Group Stage 1)

Patient-Centered

- I. Strengthen the central role of patient and caregiver engagement to produce true partnership in the full research process
- II. Attend to and strengthen the diversity of the patient populations served and the inclusion of care sites that serve underserved populations

National Scope

- III. Recognize and strengthen the unique ability of PCORnet to generate definitive evidence through studies of national scope; prioritize investments that strengthen that capability particularly for studies focused on PCORI *Strategic Research Priorities*
- IV. Build on the unique capabilities of the PCORnet data structures, prioritizing investments that will align with the PCORI *Strategic Research Priorities*

Governance and Partnerships

- V. Continue to develop the shared governance model which builds trust among participating networks and is coupled with close milestone-based monitoring of PCORI's infrastructure funds. As appropriate, encourage the development of mechanisms for cost recovery for infrastructure use related to projects supported by other funders
- VI. Recognize the importance of optimum distribution of core coordinating functions, with the dual goals of optimizing effective network function and capitalizing on the distributed expertise and capabilities of this complex network
- VII. Recognize, enable and promote the value of PCORnet to contribute to a learning health care system through effective partnerships with all stakeholders. Strengthen the educational resources needed to achieve this goal
- VIII. Recognize, enable and optimize the value of PCORnet for building partnerships with Federal Health Agencies

PCORnet® Priorities Workgroup (Stage 2)

Goals



- Building upon the *Prioritizing Principles for Infrastructure Funding Relating to PCORnet*, propose strategies to inform PCORI's evaluation framework for PCORnet and guide future Board consideration of:
 - PCORnet accomplishments attributable to PCORI infrastructure funding
 - Decisions about future PCORI investments in PCORnet to support baseline network functions and opportunities for the infrastructure to expand and evolve
- Propose crosscutting strategies to integrate and leverage PCORnet assets to advance PCORI's National Priorities for Health and Research Agenda
- Provide information, reports, and recommendations to inform deliberations of Strategy Committees, the Board Strategic Planning Committee, and the Board

***Proposed Strategies to Leverage PCORnet® to
Advance PCORI's National Priorities for Health
and Evaluate PCORnet Performance***

Summary of Strategies Recommended by the PCORnet® Priorities Workgroup (Stage 2)



Crosscutting Strategies to Leverage PCORnet

- Funding research
- Investing in PCORnet infrastructure to continuously learn & improve
- Expanding the use of PCORnet
- Increasing use of PCORnet for PCORI's operational and strategic priorities

Evaluation Strategies for PCORnet

- Continuous monitoring
- Evaluate performance
- Align evaluation with infrastructure maturity

Crosscutting Strategies to Leverage PCORnet®



- **Fund research that:**

- Uses the PCORnet infrastructure to conduct definitive studies that advance PCORI's National Priorities for Health. In addition to other patient-centered CER priorities, special attention should be given to intellectual and/or developmental disabilities, maternal morbidity and mortality, health equity, and rare disease research.

Crosscutting Strategies to Leverage PCORnet®

(Continued)



- **Invest in PCORnet infrastructure to continuously learn and improve by:**
 - Maintaining baseline network functions and enhancing data quality and network research capacity to ensure efficient and effective study execution
 - Accelerating participation of diverse, underrepresented, and underserved populations including in network governance and among investigators using PCORnet
 - Supporting PCORnet coverage that is comparable to the general United States population
 - Innovating to advance PCORI's National Priorities for Health, including enhancing data capacity (e.g., non-clinical data) and open science to accelerate progress toward an integrated learning health system
 - Enhancing engagement infrastructure to support meaningful patient and stakeholder partnership in network governance and all stages of the research process and contribute to advancing the science of engagement

Crosscutting Strategies to Leverage PCORnet®

(Continued)



- **Expand use of PCORnet by enhancing:**
 - Visibility and stakeholder understanding of the unique capabilities of PCORnet as a disease-agnostic network capable of supporting the full trajectory of research and a range of study designs (e.g., platform trials, pragmatic trials, high-quality observational studies) that facilitate the development and execution of patient-centered CER studies
 - Access and use by researchers, patients, caregivers, communities, health systems, and other health stakeholders
 - Partnerships with other organizations to support conduct of research aligned with PCORI's strategic priorities
- **Increase use of PCORnet for PCORI's operational and strategic priorities**

Evaluation Strategies for PCORnet®



- **Use continuous monitoring and evaluation to:**
 - Contribute to PCORnet Network Partners' capacity to continuously learn and improve
 - Inform Board's strategic planning and decision-making about 1) baseline network functions and maintenance and 2) innovation and expansion of network functions
 - Assess performance of the Network as a whole and all participating Network Partners—CRNs and Coordinating Center—and sites

Evaluation Strategies for PCORnet®

(Continued)



- **When evaluating PCORnet performance:**
 - In considering the network research capacity to ensure efficient and effective study execution, prioritize better and faster over cheaper
 - Consider the evaluation needs and perspectives of the different stakeholders in the PCORnet ecosystem (e.g., PCORI, PCORnet governance, CRN leaders and staff, patients, clinicians, health systems, PCORnet users and potential users), as well as stakeholders' roles and how they contribute to PCORnet success
 - Benchmark PCORnet performance against appropriate comparators whenever possible

Evaluation Strategies for PCORnet®

(Continued)



- **Align evaluation of PCORnet with:**
 - PCORI's Strategic Plan, National Priorities for Health, Research Agenda, and organization-wide strategy for monitoring progress and measuring success
 - Maturity of PCORnet, by developing and leveraging a maturity model that defines expectations for PCORnet performance at multiple levels of maturity (e.g., emerging, intermediate, advanced) for a set of key domains (e.g., research, data and technology, engagement)

Board Vote

Call for a Motion to:

Approve the *Strategies to Leverage PCORnet® to Advance PCORI's National Priorities for Health and Evaluate PCORnet Performance*

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

Fond Farewell for Outgoing Board Members

Nakela L. Cook, MD, MPH

Executive Director

Celebrating 12 Years of Service to PCORI

Founding PCORI Board Members 2010–2022



Christine Goertz, DC, PhD



Sharon Levine, MD

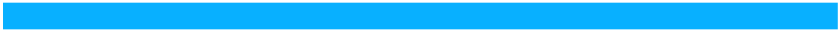


Ellen Sigal, PhD



Robert Zwolak, MD, PhD

Public Comment Period



Kristin L. Carman, MA, PhD

Director, Public & Patient Engagement

Wrap up and Adjourn

Christine Goertz, DC, PhD
Chairperson, Board of Governors

Wrap Up and Adjournment

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