

Board of Governors Meeting

via Teleconference/Webinar

February 15, 2022
1:00 – 2:30 PM

Welcome and Call to Order

Sharon Levine, MD

Vice Chairperson, Board of Governors

Agenda



1:00-1:10	Welcome, Call to Order, and Consider for Approval: December 2, 2021, Board Minutes
1:10-1:25	Consider for Acceptance: 2021 Financial Audit Report
1:25-1:55	Strategic Planning Committee Report
1:55-2:25	Healthcare Cost and Value Workgroup Report
2:25-2:30	Closing Remarks
2:30	Wrap-up and Adjourn

Board Vote

Call for a Motion to:

- **Approve** Minutes of the December 2, 2021 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

FY2021 Independent Auditor's Report

Sharon Levine, MD

Chair, Governance Committee

Thomas J. Sneeringer, CPA

Partner, RSM US LLP



AUDITOR PRESENTATION

to the PCORI Board of Governors



Thomas J. Sneeringer, CPA

Partner, RSM US LLP

February 15, 2022

FY2021 Independent Auditor's Report

PCORI received an unmodified opinion; the financial statements presented fairly, in all material respects, the financial position, the changes in its net assets, and its cash flows.

- There are no findings related to deficiencies in internal control over financial reporting.
- There are no findings related to compliance or other matters.

Statement of Activities

Statement of Activities	FY2021	FY2020
Revenue	\$493,491,514	\$455,047,029
Expenses	\$356,313,400	\$360,946,398
Realized and unrealized (loss) gain on investments	(\$3,091,772)	\$ 824,230
Change in Net Assets	\$134,086,342	\$94,924,861

Statement of Financial Position

Statement of Financial Position	FY2021	FY2020
Assets	\$1,589,395,711	\$1,460,831,185
Liabilities	\$70,983,741	\$76,505,557
Net Assets	\$1,518,411,970	\$1,384,325,628

Board Vote

Call for a Motion to:

- **Accept** the FY2021 Audit Report

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 **Accept** the **FY2021 Audit Report**
- Ask for votes in favor, opposed, and abstentions

Strategic Planning Committee Report

Nakela L. Cook, MD, MPH

Executive Director

Sharon Levine, MD

Co-Chair, Strategic Planning Committee



Public Comment Period

- December 10, 2021- January 31, 2022
- Strategic Planning Committee (SPC) to review key takeaways from public feedback on proposed Research Agenda, including any recommended revisions at February meeting
- Board anticipated to consider for adoption in March 2022

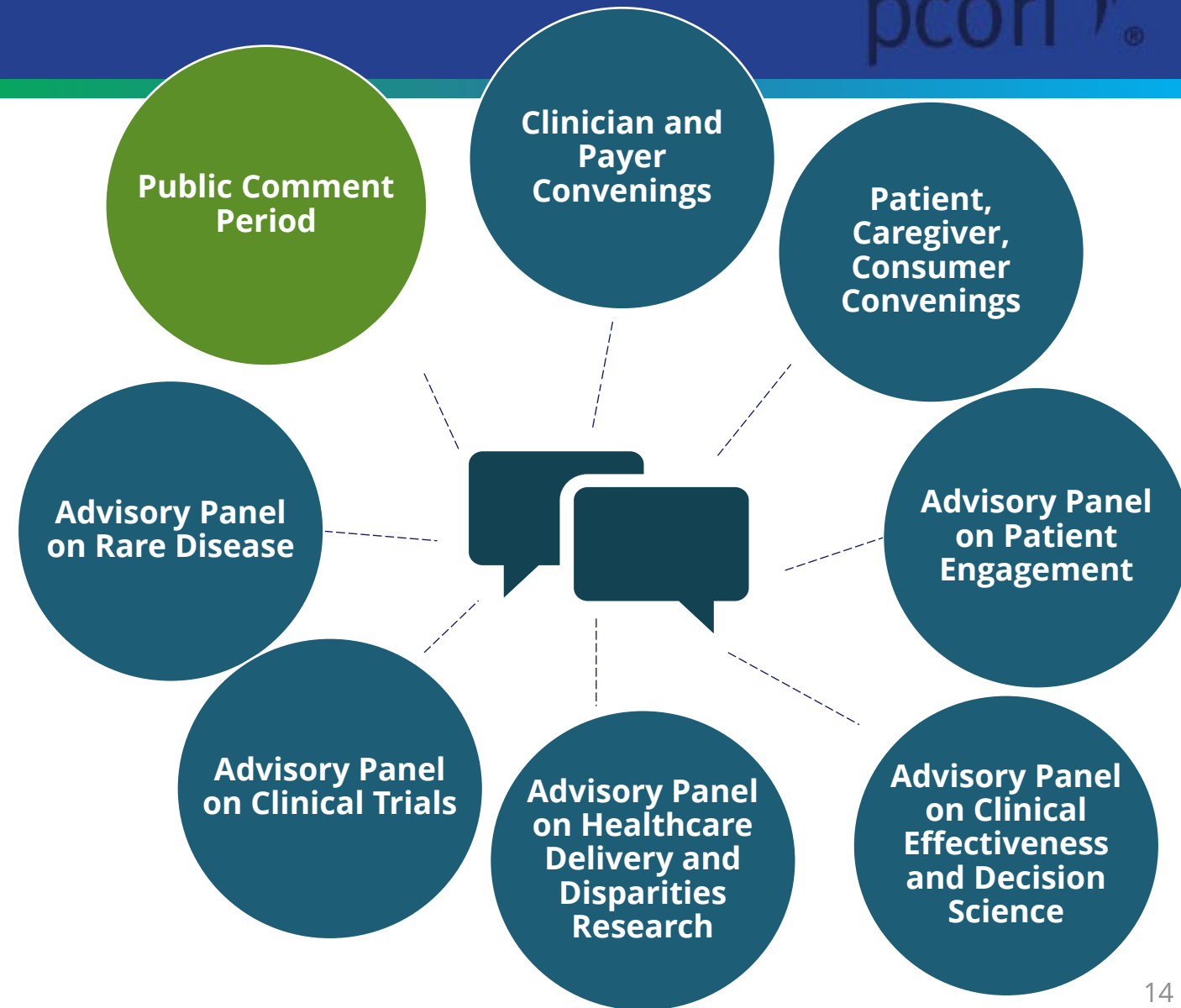


Proposed Research Agenda

-  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

Gathering Input

Since December 2021, when the Board approved the proposed Research Agenda for posting for public comment, stakeholders have provided input via multiple avenues such as meetings and surveys. This approach helped PCORI continue to hear from multiple stakeholders, including patients, caregivers, purchasers, payers, researchers, and clinicians.



Sample of Emerging Themes: What We are Hearing from Stakeholders



Engagement

- Promote awareness, understanding, and opportunities for engagement with communities and cross-sector partners
- Support diversity in awardees and equity in access to funding
- Emphasize dissemination, implementation, and health communication research
- Reinforce diverse representation within study teams and study participants

Cross-Sector Collaboration

- Convene, connect and promote research partnerships among diverse stakeholder communities, disciplines, and researchers
- Promote different disciplines and sectors to partner on research design, execution, and dissemination
- Reinforce engagement with communities

Responsive to Change

- Respond to emerging challenges in health care
- Incorporate advanced technologies in research designs
- Consider innovative and/or alternative study designs to meet the range of stakeholder evidentiary needs
- Study, utilize, and promote evidence-based practices for dissemination, implementation and health communication

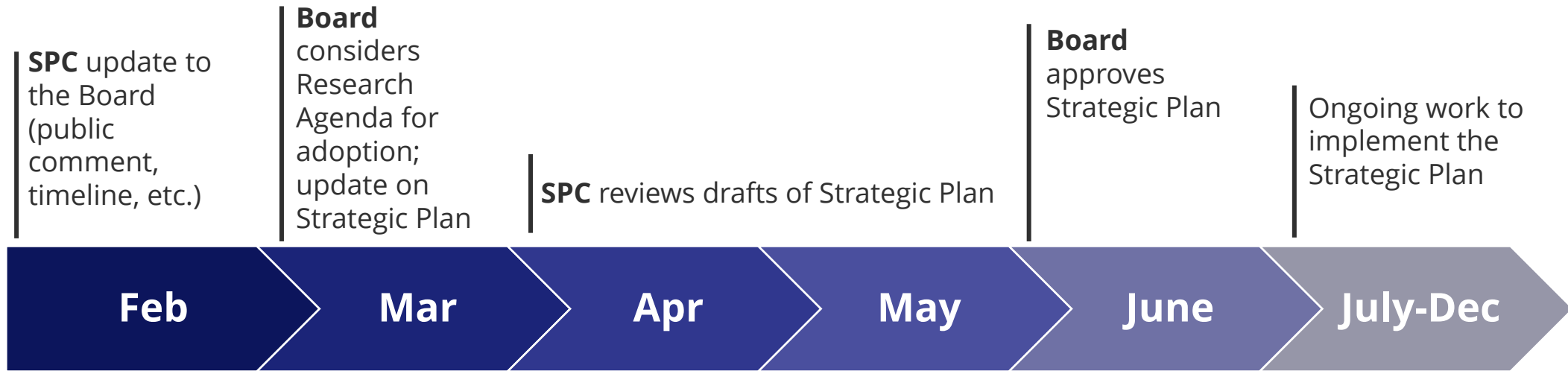
Data Infrastructure

- Enhance access to and standardization of data across sectors and systems
- Consider data needs to address root causes of health inequities
- Increase awareness of data gathered by other research teams in similar studies and encourage collaboration

Health Equity

- Examine measures of diversity, equity and inclusion (DEI)
- Diversify and expand researchers' capabilities from historically underrepresented groups to help research be representative and reflect unique needs
- Support infrastructure and learning that promote leadership and participation in research from historically underrepresented groups

Anticipated Timeline and Snapshot of Discussions



Expected Discussion Sequence

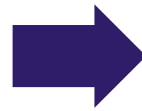
February SPC

- Additional discussion on developing the Strategic Plan
- Review of key Research Agenda takeaways from public feedback
- Review recommended changes to Research Agenda (if needed)



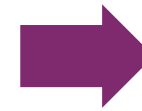
March Board

- Review of key takeaways from public feedback on Research Agenda
- **Board considers Research Agenda for adoption**
- Update on Strategic Plan



April and May SPC

- Informed by the Board, SPC continues to draft and refine Strategic Plan



June Board and SPC

- **Board considers the Strategic Plan for approval**
- SPC identifies next steps for staff and other workgroups on implementation of plan and tracking progress

Developing the Strategic Plan

- Demonstrate how PCORI achieves its mission
- Provide opportunity for stakeholders to see themselves in PCORI's vision
- Serve as a communication tool
- Serve as the basis for operational plans

Purpose



- Patients and caregivers
- Researchers and clinicians
- Congress and GAO
- Healthcare purchasers, payers, industry, hospitals, and other health systems
- Broader health community

Audience



- Digital format (e.g., clickable, interactive webpages)
- Printable "at-a-glance" handouts (e.g., two-page PDFs)

Accessibility



Scope of Strategic Planning Activities

- National Priorities for Health
- Research Agenda
- Strategic priorities 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



Outline for Strategic Plan “Document”

Letter from Board Chairperson and Executive Director

Executive Summary

Introduction and Overall Structure of Strategic Plan

Holistic Approach to Patient-Centered CER: PCORI's National Priorities for Health

Describes comprehensive set of activities – all in support of achieving the National Priorities for Health – that drive patient-centered CER and facilitate the generation of evidence to improve clinical decision making; Includes the National Priorities, Research Agenda, and an overview of the Research Project Agenda process

Measuring Success and Monitoring Progress

Describes general approach for tracking and evaluating progress towards National Priorities

Conclusion

Holistic Approach to Patient-Centered CER: PCORI's National Priorities for Health

Describes comprehensive set of activities – all in support of achieving the National Priorities for Health – that drive patient-centered CER and facilitate the generation of evidence to improve clinical decision making; Includes the National Priorities, Research Agenda and an overview of the Research Project Agenda process

Section would include the following strategies: engagement, research funding, methods, infrastructure, and dissemination and implementation

Section would seek to

- Describe PCORI's unique, comprehensive approach to generating and promoting uptake of rigorous patient-centered CER results
- Articulate the multi-faceted strategies needed to advance the National Priorities for Health (e.g., engaging stakeholders; supporting infrastructure, like PCORnet®; and defining methodological standards)
- Outline the Research Agenda and provide an overview of the Research Project Agenda process as central elements of achieving the National Priorities for Health

Outline for Strategic Plan, Continued



Measuring Success and Monitoring Progress

Describes general approach for tracking and evaluating progress towards the National Priorities for Health

- Section would include a general overview of plans for measuring and tracking progress on the National Priorities for Health
- Once the Strategic Plan is approved, metrics and targets to be further developed and a revised dashboard to be completed

Scope of Strategic Planning Activities



Component	To Be Reflected In Strategic Plan
National Priorities for Health	Section describing the holistic approach to support patient-centered CER. Individual components to be incorporated under respective strategy (e.g., priorities for PCORnet described as supporting PCORI's infrastructure strategy)
Research Agenda	
Strategic priorities for PCORnet® phase 3	
Methodology Committee focus for PCORI's next phase	
Priorities from reauthorizing law • Maternal morbidity and mortality • Intellectual and developmental disabilities • Full range of outcomes data	
Commitment Planning and strategies to increase funding	Section describing the holistic approach to support patient-centered CER, particularly related to the Research Agenda Project process and forthcoming implementation plans
Scenario Planning based on the changes in landscape and environment	Section that introduces and frames PCORI's work in the larger context of health and healthcare research
Monitoring progress and measuring success	Section describing general approach to evaluating work in the future

Additional Formats To Meet Needs of Stakeholders



Digital Plan

- Describes what PCORI anticipates doing, links to process pieces involved
- Includes clickable components so individuals can read about key aspects in more detail
- More general descriptions of strategies on main pages with links to detailed information as that is made available



"At-a-Glance" Handout(s)

- Describes what PCORI anticipates doing, less on the processes involved
- Includes concise information on key aspects (e.g., National Priorities for Health) to quickly share information
- More general descriptions that share main points about PCORI's work

Questions for the Board

- Do you concur on the purpose and general structure of the Strategic Plan?
- Will the envisioned Strategic Plan and additional formats meet the needs of the stakeholder community?
- What additional considerations should be kept in mind as the Strategic Plan is developed?

Healthcare Cost and Value Workgroup Report

Greg Martin

Acting Chief Engagement and
Dissemination Officer



Workgroup Membership

- Neeraj Arora
- Kristin Carman
- Nakela Cook
- Claudia Grossman
- Mike Herndon
- James Huffman
- Connie Hwang
- Bill Lawrence
- Greg Martin
- Caitlin McCormick
- Neil Powe
- Eboni Price-Haywood
- Joanna Siegel
- Ellen Sigal

PCORI Approach to Healthcare Cost and Value: Framework for Activities

Collection of the Full Range of Outcomes

PCORI can ensure the appropriate and relevant data are identified and collected in PCORI awards

Support broadening of PCORI guidance to awardees through literature reviews, patient & stakeholder focus groups to clarify types of potential burdens, costs, and economic impacts to be included in PCORI-funded research, and data sources

Develop guidance for capture of specific types of potential burdens or costs consistent with a patient-centered perspective, as a basis for PCORI guidance to awardees and the field

Informing the Value Conversation

PCORI can help advance patient-centered approaches to the value conversation by supporting understanding of stakeholder perspectives on what constitutes “patient-centered value”

Conduct a landscape review of current stakeholder statements, perspectives, and frameworks around value

Convene patient and stakeholder groups to identify the components or attributes necessary in “patient-centered value”

Supporting Policy Priorities

PCORI can consider undertaking specific activities that contribute to priority policy goals (i.e., generating evidence to inform healthcare value discussions)

Consider placing an emphasis on research focused on emerging technologies/therapies

Consider building upon evidence synthesis capabilities to provide more timely information

Collection of the Full Range of Outcomes

- Clarify current guidance for awardees and identify gaps.
- Undertake background reviews to assess current practices and recommendations relevant to collection of cost and economic data, to support additional guidance.
- Convene stakeholders as needed to provide input on background review findings.

Informing the Value Conversation

- Advance the discussion on “patient-centered value” based on listening to and learning from stakeholders.
- Conduct landscape review of stakeholder statements, perspectives, and frameworks on value.
- Conduct key informant interviews and convenings with stakeholders to identify the necessary attributes or components to stakeholders of “patient-centered value”.

Supporting Policy Priorities

- Determine scope of activities around emerging technologies and therapeutics.
- Draw on patient and stakeholder views of “patient-centered value” in efforts to disseminate evidence from PCORI portfolio.

Informing the Value Conversation

Landscape Review: Review of current stakeholder statements, perspectives, and frameworks around value.

1. What organizations have been involved in offering, or offered, recommendations or guidance for conceptualizing and measuring value in health and healthcare?
2. What are the various ways different stakeholder communities conceptualize value in health and healthcare? What elements, attributes, or components do different stakeholders consider to be part of value measurement?
3. Which aspects of value do different stakeholders believe can and should be measured and monitored over time, at what level, and how? What are different stakeholders' perspectives on the appropriateness and validity of different ways of understanding or assessing value?
4. What concerns and challenges have been discussed relating to value measurement, including for defining and assessing patient-centered value?
5. How are different stakeholder communities defining "patient-centered value"? Where are the similarities and where are the differences?

Identifying the Components of Patient-Centered Value: Convene patient and stakeholder representatives to identify the components or attributes necessary in “patient-centered value.”

1. What does patient-centered value mean to different communities? What elements, attributes, or components do different stakeholders consider to be part of value measurement?
2. Which aspects of patient-centered value do different stakeholders believe can and should be measured and monitored over time, at what level, and how? What are different stakeholders' perspectives on the appropriateness and validity of different ways of understanding or assessing value?
3. What components might be included in a comprehensive assessment of patient-centered value?
4. What are recommended approaches for collecting data on and assessing components or overall assessments of patient-centered value?
5. What additional methods need to be developed to support PCORI researchers in operationalizing a uniform approach to measuring patient-centered value?
6. What additional work may facilitate the conversation on patient-centered value in health and healthcare?

Questions for the Board

- Do the direction, activities, and goals resonate with you?
- Will the activities meet the informational needs of the stakeholder community and our applicants?
- What additional considerations should be kept in mind as we proceed?

Closing Remarks

Nakela L. Cook, MD, MPH
Executive Director

Wrap Up and Adjournment



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