

Board of Governors Meeting

via Teleconference/Webinar

February 9, 2021
1:00 PM – 3:15 PM

Welcome and Call to Order

Christine Goertz, DC, PhD
Chairperson, Board of Governors

Agenda



1:00-1:15	Welcome, Call to Order and Consider for Approval: January 12, 2021 Board Minutes
1:15-1:30	Consider for Acceptance: 2020 Financial Audit Report
1:30-2:15	Discussion of Expedited Approach to Developing Targeted PFAs
2:15-3:00	Principles for the Consideration of the Full Range of Outcomes
3:00-3:15	Strategic Planning Update
3:15	Wrap-up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the January 12, 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

FY2020 Independent Auditor's Report

Sharon Levine, MD
Chair, Governance Committee

Thomas J. Sneeringer, CPA
Partner, RSM US LLP



AUDITOR PRESENTATION

PCORI Board of Governors

February 9, 2021

FY2020 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	FY2020	FY2019
Revenue	\$455,047,029	\$615,205,771
Expenses	\$360,946,398	\$390,494,397
Realized and unrealized gain on investments	\$ 824,230	\$ 2,904,912
Change in Net Assets	\$94,924,861	\$227,616,286

Statement of Financial Position

Statement of Financial Position	FY2020	FY2019
Assets	\$1,460,831,185	\$1,376,285,798
Liabilities	\$76,505,557	\$86,885,031
Net Assets	\$1,384,325,628	\$1,289,400,767

Board Vote

Call for a Motion to:

- **Accept** the FY2020 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

Roll Call Vote:

- Vote to **Accept** the **FY2020 Audit Report**
- Ask for votes in favor, opposed, and abstentions

Developing Targeted PFAs in the Short-term while Strategic Planning is Underway

Nakela L. Cook, MD, MPH
Executive Director



The Big Picture for Research Agenda and Topics: Working on Three Tracks Simultaneously

Track One Strategic Planning

- National Priorities
- Research Agenda
- Commitment Plan

Track Two Revitalizing Topic Process

- Stakeholder-engaged, transparent, systematic process for developing topics aligned with National Priorities and Research Agenda to remain:
 - Evergreen
 - Responsive to emerging issues

Track Three Developing Targeted PFAs

- **Needed for next several cycles while Strategic Planning is underway**
- **Implementing an expedited approach with Board for developing Targeted PFAs**

Today's Discussion: ***Expedited approach for developing targeted PFAs*** in the short term

Rationale/Considerations for Expedited Approach in the Short-term



Development of new National Priorities and Research Agenda ongoing

- Completion late in 2021
- Targeted PFAs needed for several cycles in the meantime

Expedited Approach to development of these Targeted PFAs to be responsive, relevant, and meet commitment plan:

- Aims to substantially reduce time from idea to Targeted PFA
- Leverages work already underway and expands the full range of types of targeting to increase feasibility
- Calls for the Board to consider approving a set or several cycles' worth of topics

Aiming for convergence with ultimate National Priorities & Research Agenda

- New National Priorities and Research Agenda will drive PFA development beyond 2022
- Interim approach identifies a set of candidate topics with likely high resonance with ultimate National Priorities and Research Agenda
 - High burden conditions and issues
 - Expressed interest from Stakeholders and/or Board
 - Prior work/development
 - Emerging themes from Strategic Planning discussions
- From a large set of topics in various stages of development, we've identified a small subset of candidates for short-term focus based on criteria above
 - Subset is *in addition to* COVID-19, MMM, and IDD, which we continue to develop
 - Those not in subset *remain in the pipeline* for future development

Utilize Full Range of Approaches for Expedited Development of Targeted PFAs for the Next Several Cycles



Typical Targeted PFA

- **Questions identified and moderately to highly specified**
- Examples from portfolio:
 - Medication-Assisted Treatment (MAT) Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin
 - Treatment of Multiple Sclerosis
 - Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

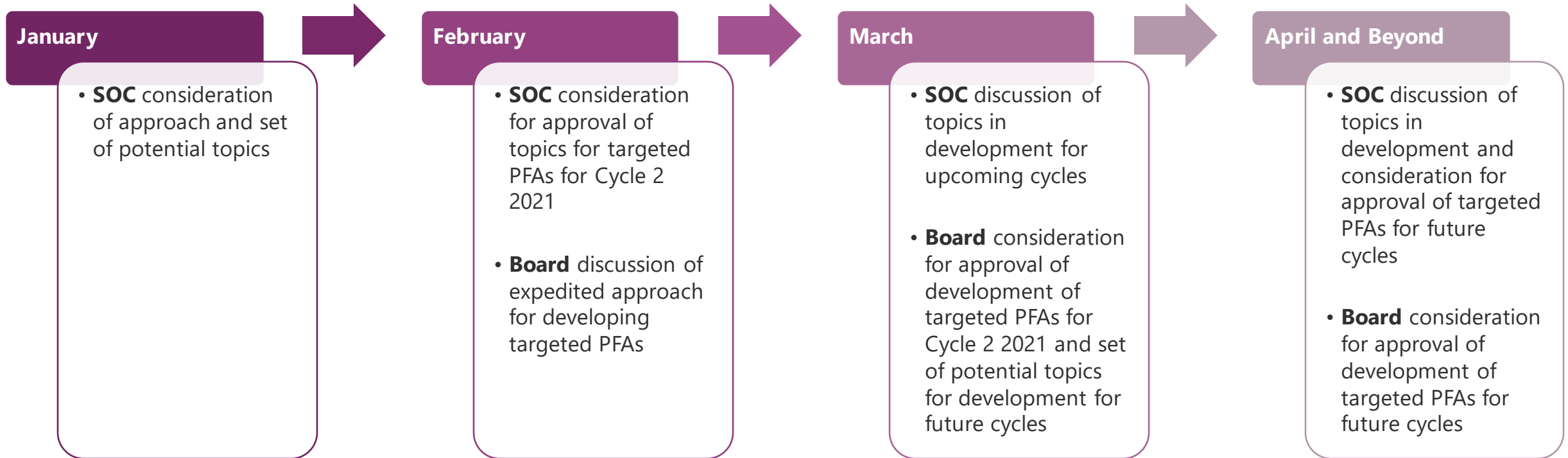
Expanded Targeted PFA

- **Issues/Conditions identified and moderately specified**
- More open for stakeholder-driven and investigator-initiated response within PCORI-focused topics
- Open for multiple cycles
- **Theme** with Related Subtopics
 - **Subtopics** with Example CER **Questions**

One or Two Large Studies

- **One highly-specified question**
- Typically collaborative
- Examples from portfolio:
 - Preventing Fall-Related Injuries in Older Adults, with NIA
 - Treatment Options in Uterine Fibroids: Developing a Prospective Multi-Center Practice-based Clinical Registry, with AHRQ
 - Testing Multi-Level Interventions to Improve Blood Pressure Control in Minority Racial/Ethnic, Low Socioeconomic Status, and/or Rural Population, with NHLBI and NINDS

Timeline for developing Targeted PFAs for the next several cycles while Strategic Planning is ongoing



Summary of Main Features of Expedited Approach to Targeted PFA Development in the Short-term



In summary, the main features of the expedited approach are:

- Substantial reduction of time from idea to Targeted PFA (by at least half)
 - Compressed timeline for staff work
 - Less time available for iterative discussions with SOC and Board
 - Exploring flexible and agile alternatives to maintain ample opportunities for input
- Consideration of a set or several cycles' worth of candidate topics (versus one at a time)
 - Allows for longer-range planning, both by PCORI and research and stakeholder community
 - Could result in more and better applications and enhance merit review
 - Facilitates more rapid development by concentrating focus on fewer topics
- Expansion and utilization of the full range of types of Targeted PFAs
 - From relatively broad on a topic/issue to very narrow on a single question
 - From moderately- to highly-specified

Questions and Discussion

- Do you have **any questions** about the expedited approach to developing Targeted PFAs in the short-term while Strategic Planning is underway?
- Do you have **additional considerations** for any aspect of this expedited approach?

At its March meeting, the Board will consider for approval targeted PFAs for development for Cycle 2 and a set of candidate topics to be developed for future cycles.

Summary of Feedback on PCORI's Proposed "Principles for the Consideration of the Full Range of Outcomes"

Andrew Hu, MPP

Director, Public Policy and Government
Relations

Joanna Siegel, ScD,

Program Director, Dissemination &
Implementation

Recap from December Meeting



- Overview of PCORI's Reauthorizing Law and authority
- PCORI's Implementation Plan
- Reminder of Proposed Principles
- Ongoing Activity and Next Steps
- **Goal for today: Present a synthesis of comments and potential considerations for PCORI**

Overview of PCORI's Cost Data Implementation Proposal



Pillar 1

- Providing guidance to Principal Investigators in future PFAs on how they should interpret this policy and incorporate it into their research proposals.
- **Timeline:** Final Principles and Initial Guidance for Applicants by **March 2021**

Pillar 2

- Establishing methodology standards to inform the how PCORI-funded studies should capture relevant data.
- **Timeline:** Approximately **12 months** from the initiation of this process

Pillar 3

- Convening discussions on how this information can/should be used.
- **Timeline:** Ongoing Discussion

Overview of Public Input



- PCORI obtained stakeholder feedback from a wide range of sources, including:
 - 60-Day Public Comment Period (Sept. 15-Nov. 13, 2020)
 - PCORI-hosted Webinar Series (Oct. 5-6, 2020)
 - Individual stakeholder discussions
- PCORI sought feedback from PCORI resources, including:
 - PCORI Advisory Panels (e.g., PEAP, CEDS, HDDR, RDAP)
 - PCORI Methodology Committee
- PCORI received comments from organizations and individuals representing the **full spectrum** of stakeholders – patients/patient groups, caregivers, clinicians, health systems, payers, purchasers, researchers, industry, and other multi-stakeholder groups.

Submitted Written Public Comments



Written submissions represent the **full spectrum** of stakeholders, with 1/3 representing patients and patient organizations



The 32 written submissions represent hundreds of individuals and stakeholder organizations



Verbal comments via the webinars and individual stakeholder discussions will be incorporated



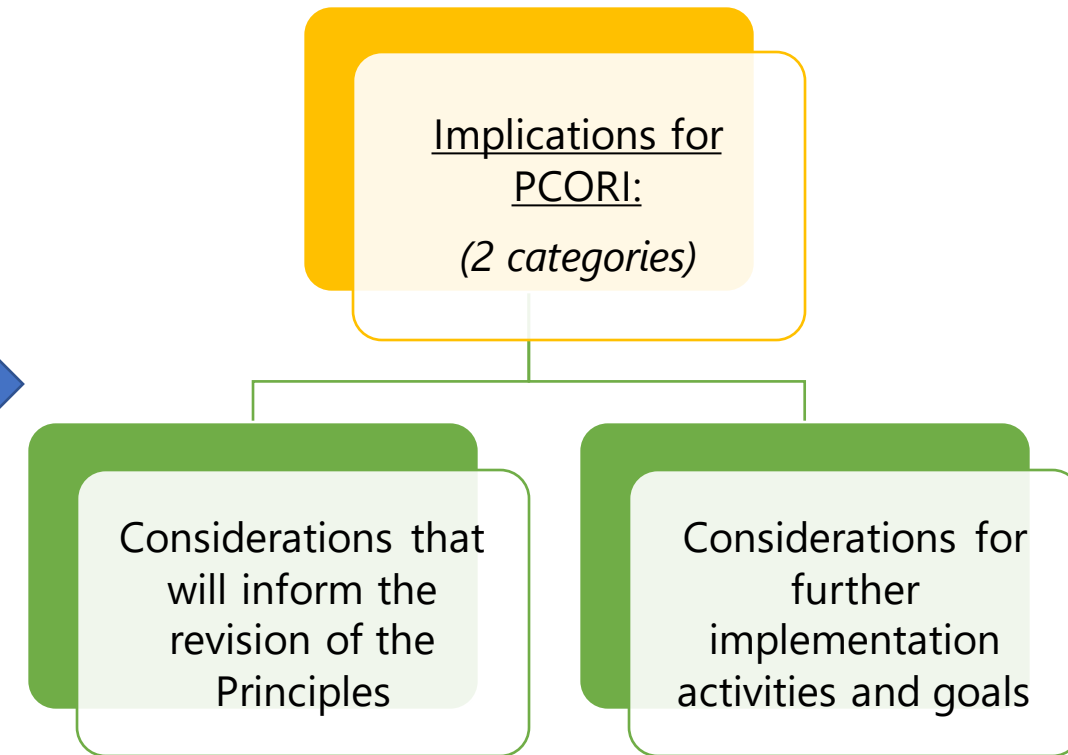
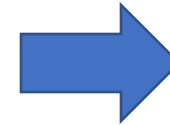
PCORI hosted two multi-stakeholder **advisory committee** meetings to further review summaries and analysis of comments

Stakeholder Group	Number of Submissions
Patients/Patient Advocates	11
Researchers	6
Clinicians and Hospitals/Health Systems	3
Caregivers	3
Purchasers	1
Multi-stakeholders	2
Payers	1
Anonymous	1
Industry	4
TOTAL	32

Overarching Themes and Potential Considerations for PCORI

What We Heard

- Ensure Patient-Centeredness in Implementation
- Conduct Ongoing Stakeholder Engagement
- Capture of Cost & Economic Impact Data Should Only be Done When Appropriate
- Provide Additional Guidance for Research Community
- Include Focus on Social Risk Factors
- Role of PCORI



Theme 1:

Ensure Patient-Centeredness in Implementation



Comments Reflected Support For:



- ☐ Principle 1 – identifying outcomes important to patients and caregivers
- ☐ PCORI's role in understanding and defining patient-centeredness
- ☐ Mitigate unintended consequences
- ☐ Maintain restrictions on PCORI funding of cost-effectiveness analysis

Potential Considerations:



- ☐ Retain Principle 1 as central to PCORI's implementation of the new authority
- ☐ Include patients and caregivers in providing input to PCORI in ongoing stakeholder engagement
- ☐ Develop or expand on trainings and tools that support patient-engagement in research
- ☐ Consider monitoring how data from PCORI-funded studies are used

"Including patients in the research is critical, it is imperative that researchers find creative ways to truly engage residents, having them participate is one thing, but they must have a voice at the table so their opinions must have a higher weight."

- Patient

Theme 2:

Conduct Ongoing Stakeholder Engagement

Comments Reflected Support For:



- ☐ Continuous engagement with diverse community of stakeholders
- ☐ Providing opportunities for engagement at the level of individual projects

Potential Considerations:



- ☐ Seek public and stakeholder input and at additional points in the implementation of PCORI's new authority (i.e., as PCORI develops additional guidance for researchers)
- ☐ Leverage existing committees and/or create a new cost data advisory committee for ongoing input
- ☐ Broaden existing stakeholder engagement in research studies to include input on research design and research questions addressing the full range of outcomes
- ☐ Consider conducting ongoing focus groups for continued evaluation of Principles

"We encourage PCORI to independently reach out to patient and caregiver advocacy organizations...to ascertain the adequacy of stakeholder engagement, and condition funding on applicant demonstration of a continuing engagement strategy throughout the research study."

- Patient

Theme 3:

Capture of Cost & Economic Impact Data Should Only be Done When Appropriate



Comments Noted:

Potential Considerations:



- ☐ Enthusiasm for the collection of cost and economic impact data, with the caveat that collection of these data is not always appropriate and relevant to the study
- ☐ Request for further clarification on when collection of data is appropriate or necessary

- ☐ Encourage the consideration of cost and economic impact data, but do not require it
- ☐ Describe circumstances in which PCORI would seek the consideration of cost and economic impact data
- ☐ Clarify criteria for cost data collection for applicants and for PCORI staff

"A main disadvantage is that a requirement such as this is that it make cost and economic impact the main driver to consider any research - and that would limit the importance of other factors that weigh in on the value equation that include a quality component."

- National Alliance of Healthcare Purchaser Coalitions

Theme 4:

Provide Additional Guidance for Research Community

Commenters Requested More Guidance:



- ☐ The types of cost analysis permitted
- ☐ Need for methodology standards and/or technical guidance
- ☐ Expanded lists of outcomes and standardization of these outcomes when feasible
- ☐ Need to comprehensively document data limitations

Potential Considerations:



- ☐ Develop detailed guidance on prioritized outcomes and allowable analysis
- ☐ Identify areas where data collection can be standardized; develop resources to facilitate the development of standards and methods, including to support Methodology Committee efforts.
- ☐ Consider developing guidance for reporting results
- ☐ Methodology Committee should regularly review to maintain guidance and methodology standards

*The need for additional guidance was described as providing **"guidepost[s]"** or demonstrating what is **"in and out of bounds."***

- Alliance for Aging Research

"There can and should be a role for PCORI's Methodology Committee in developing standards for PCORI researchers tasked with capturing these important data points."

- PIPC

Theme 5:

Consider Social Risk Factors When Considering Costs & Burdens



Commenters Strongly Supported:



- ☐ Consideration of social risk factors and social determinants of health in collecting data on cost and economic outcomes

Potential Considerations:



- ☐ When considering relevant cost and economic impacts, PCORI-funded research should consider the impacts of social risk factors and social determinants of health

*"The consideration of cost burden is key to PCORI's mission to eliminate health disparities. It's not enough just to address them. It's not enough just to know what they are. **You have to know them at a deep level, which is a patient centered level.** You also have to understand, particularly with health disparities, how the impact of cost is a barrier to access to quality, equitable, affordable health care...This is a place where I think PCORI can make a huge difference by identifying that data."*

- National Patient Advocate Foundation

Theme 6:

Role of PCORI



Comments Noted Opportunities for PCORI:



- ☐ Take a leadership role in defining relevant outcomes included in the "full range of outcomes" to be considered
- ☐ Advance methods for collecting data on relevant cost and other measures of burden

Potential Considerations:



- ☐ Make data collected publicly available
- ☐ Facilitate outreach and education activities between stakeholders and researchers
- ☐ Share examples of PCORI-funded research that successfully collected and analyzed these data
- ☐ Work with the Methodology Committee to identify areas of needed methods development; support development of methods to fill gaps

"PCORI will have an important role in guiding methodology that ensures prioritization and consistency in data collection and dissemination. Moreover, PCORI can elevate dialogue among various stakeholders about the priority cost components that cut across disease states and lay groundwork for standard taxonomy and data collection efforts that influence research practices and usage of such data beyond comparative effectiveness."

-Innovation and Value Initiative

Further Guidance and Methods for Researchers

Possible Pillar 2 Activities



Given the scope of comments related to the need for additional methods and guidance, this is an opportunity for PCORI and the Methodology Committee to play a proactive role.

- Commenters identified areas where additional methodology and guidance would be useful, such as:
 - Consideration of differential costs that are borne by patients and caregivers based on their insurance coverage, geography, etc.
 - Determining how best to recognize and accommodate differences in outcomes and their relative importance based on the patient population, disease area, and type of intervention.

Implementation Opportunities

Possible Pillar 3 Activities



Following strong interest among stakeholders and policymakers, PCORI can serve as a trusted resource to inform discussions on value and bridge the divide between patient groups and value assessors.

- Suggested opportunities include:
 - Series of convenings to connect stakeholders with researchers to identify relevant and impactful outcomes
 - Provide thought-leadership on what “patient-centered value assessment” may entail

PCORI is in the process of establishing a **“Resource Center”** to support PCORI and its Methodology Committee as they undertake activities in response to specific questions and priorities related to the implementation of PCORI’s authority to consider the full range of outcomes, including cost burdens and economic impact.

Next Steps

- PCORI will **Revise and Update** the proposed Principles based on public input
- Coordination with Methodology Committee in launch of **Pillar 2 activities**
- Establish a **Resource Center** to support broader implementation efforts
- At the **March 16, 2021** Board of Governors meeting:
 - Presentation of revised Principles to the Board for consideration for approval
 - Update on broader implementation and communications plans

Strategic Planning Update

Nakela L. Cook, MD, MPH

Sharon Levine, MD

Co-Chairs, Strategic Planning Committee

Full Scope of Strategic Planning Activities



Strategic Planning

- National Priorities
- Research Agenda
- PCORnet strategic vision for the next phase
- Methodology Committee focus for PCORI 2.0
- Commitment Planning and strategies to increase funding
- Scenario Planning based on the changes in landscape and environment
- Priorities from reauthorizing legislation
 - Maternal morbidity and mortality
 - Intellectual and developmental disabilities
 - Cost outcome data

Continued Input Collection Winter 2020 - 2021

We continue to garner input and have held multiple convenings and heard from a variety of stakeholders



Wrap Up and Adjournment



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