

Board of Governors Meeting

via Teleconference/Webinar

December 8, 2020
11:30 AM – 3:15 PM

Welcome and Call to Order

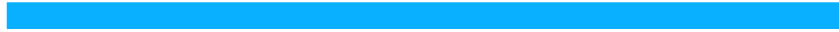
Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

11:30-11:45	Call to Order and Welcome
11:45-12:30	Commitment Planning Consider for Approval: Proposed 3-Year Commitment Plan
12:30-1:00	Update on Status of Cost Data Principles
1:30-2:45	Strategic Planning Committee Report and Discussion
2:45-3:15	Public Comment
3:15	Wrap-up and Adjournment

Commitment Planning



Nakela L. Cook, MD, MPH

Executive Director

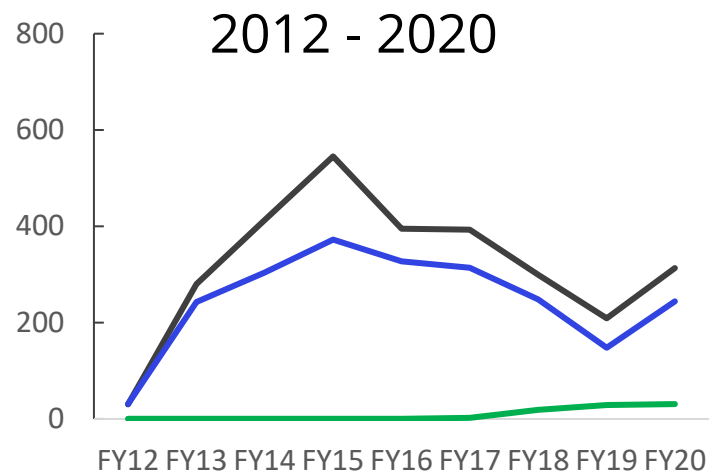


Commitment Plan Model

In September, the Board Discussed Options and Preferred a Hybrid Model "1.5"

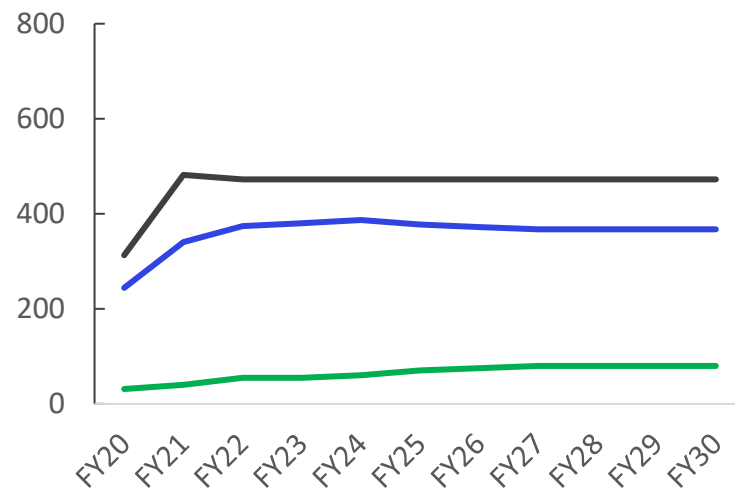
All figures in Millions (\$)

D&I and Research lines represent **subsets** of the overall commitments (black line)

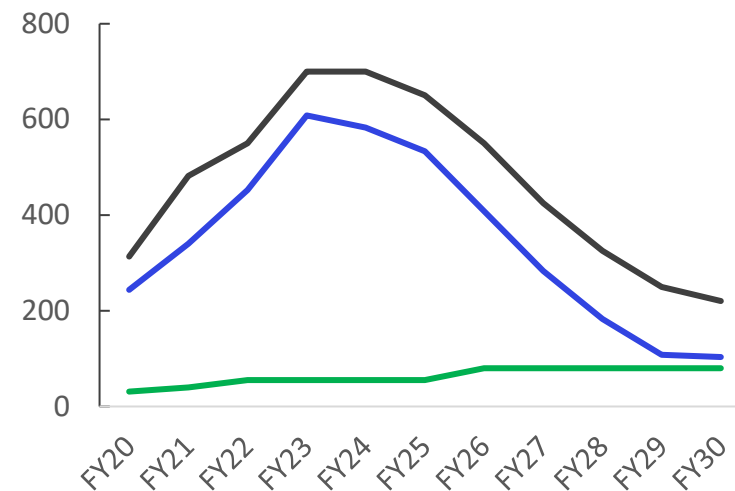


— All Commitments
— Research Commitments (subset)
— D&I Commitments (subset)

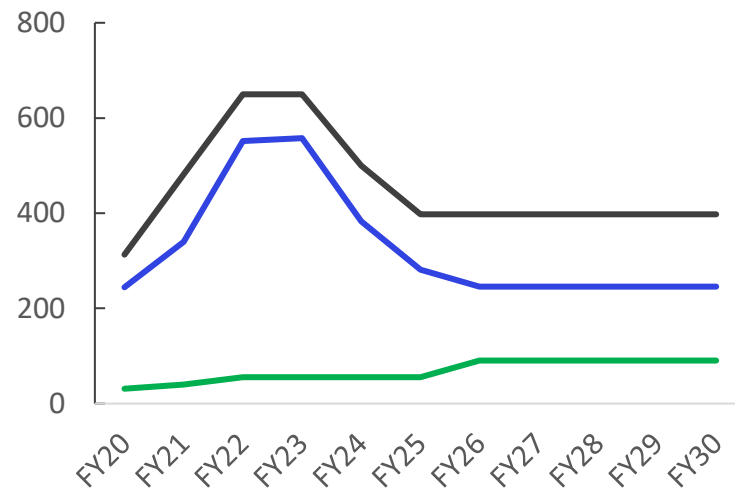
Steady State Model



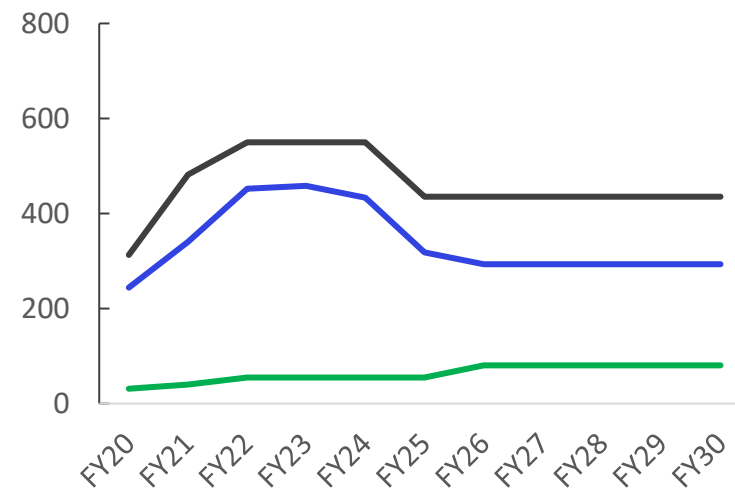
Ramp Up/Down Model



Hybrid Model #1



Hybrid Model #2



Context for Proposed 3-Year Commitment Plan

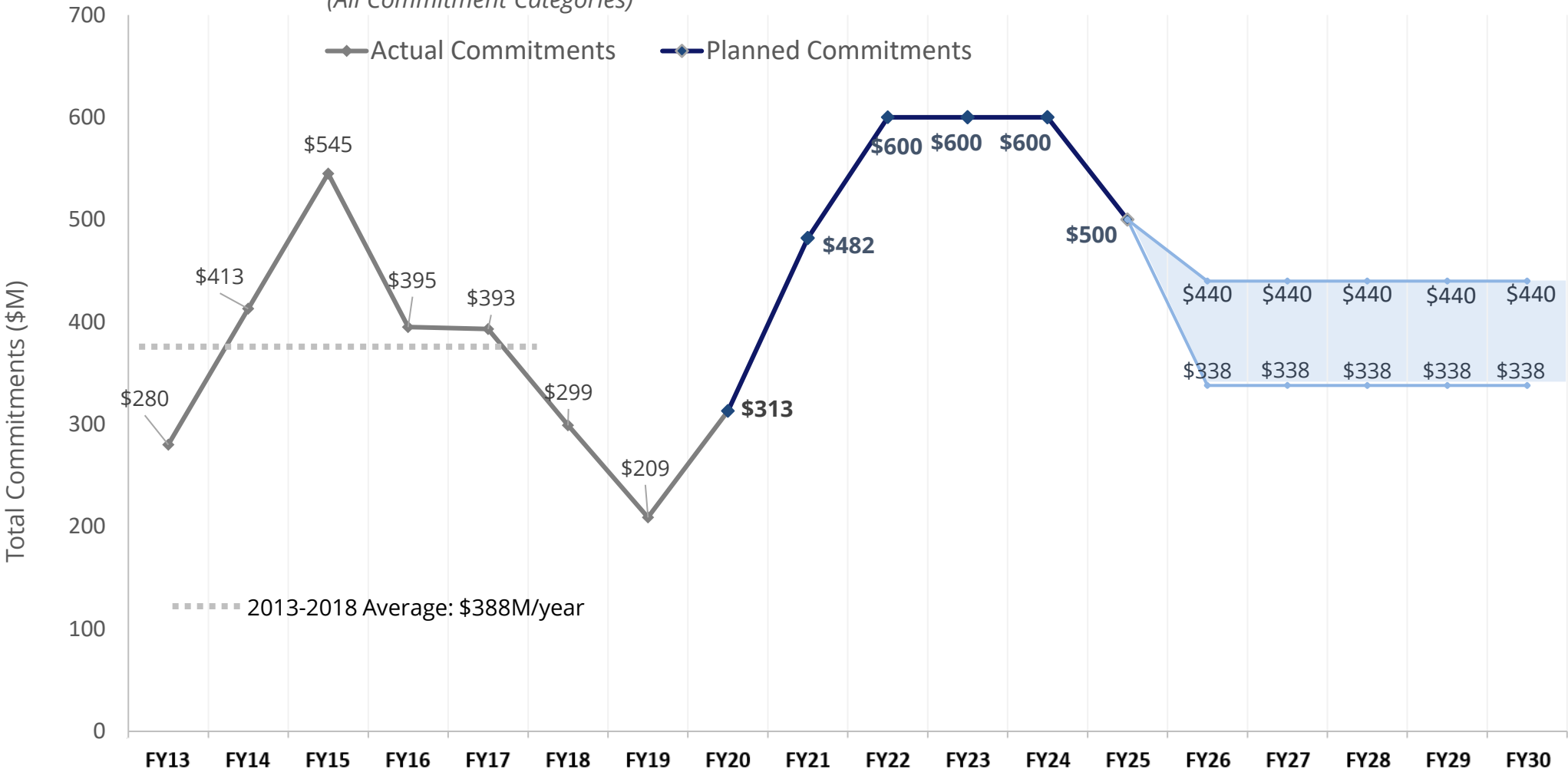


Yearly Commitments (\$M)

(All Commitment Categories)

Actual Commitments

Planned Commitments



Blue Range:
Average Commitment under
Two Different Assumptions
about PCOR Fee Level

Targets shown assume the
flexible funding described on
the next slide is committed
equally each year, but it may
vary from year to year

Proposed 3-Year Commitment Plan FY2021-2023



Funding Line (4 Larger Categories)	Projections for FY2021-2023			
	Average across FY2021-23: \$560M			
	FY2020 (\$M)	FY2021 (\$M)	FY2022 (\$M)	FY2023 (\$M)
Research	244	290	450	450
- Includes: - Half investigator-initiated, half PCORI priority via special areas of emphasis and targeted PFAs - PLACER - Full range of research spectrum - Short-term and long-term priorities				
Dissemination & Implementation Activities	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
- More than doubling of D&I commitments
- Infrastructure maintenance costs for PCORnet substantially less than building cost
- Average of \$50M per year flexibly available for new initiatives
- Estimated 10-15% increase in staffing
- Continual process improvement for efficiencies

Monitoring Progress on the Commitment Plan

Cycles are named for the fiscal year in which they are launched; awards generally result in the following year

Cycles Currently Under Review (Commitments in FY2021)

- Cycle 2 2020 Targeted PFA: Conducting Rare Disease Research Using PCORnet® (Limited Competition)
- Cycle 2 2020 Targeted PFA: Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes
- Cycle 2 2020 D&I PFAs: Limited Competition and Shared Decision Making

Expected to go to the Board for Funding Approval March 2021

Open Funding Opportunities (Commitments in FY2021)

- Cycle 3 2020 Targeted PFA on Suicide Prevention
- Cycle 3 2020 Broad PFAs with Special Emphasis Topics:
 - Maternal Mortality
 - Intellectual & Developmental Disabilities
- Cycle 3 2020 PLACER PFA (Phased Large Awards for Comparative Effectiveness Research)
- Cycle 3 2020 D&I PFAs: Limited Competition and Implementation of Findings from PCORI's Major Research Investments
- Engagement PFAs: Capacity Building, Dissemination Initiative, Stakeholder Convening Support

Upcoming FY2021 Cycles (Commitments in FY2022)

- Cycle 1 2021
 - Broad PFAs
 - D&I PFA: Limited Competition
 - Pragmatic Clinical Studies PFA
 - Targeted PFA(s) TBD
- Cycle 2 2021
 - Broad PFAs
 - D&I PFA: Limited Competition and Shared Decision Making
 - Pragmatic Clinical Studies PFA
 - Targeted PFA(s) TBD
- Cycle 3 2021
 - Broad PFAs
 - D&I PFA: Limited Competition
 - Pragmatic Clinical Studies PFA
 - Targeted PFA(s) TBD
 - PLACER TBD
- Engagement PFAs: Capacity Building, Dissemination Initiative, Stakeholder Convening Support
- PCORnet Infrastructure PFA TBD

Proposed Approach to Supporting Commitment Plan

Principles

- **Accountability and visibility** in progress toward commitment plan goals
- **Prospective planning** for a full fiscal year or even multi-year
- **Ramping up** to more solicitations and awards

Components

- **Longer-range topic planning** utilizing full spectrum (e.g., Special Areas of Emphasis, Targeted PFAs, other evidentiary products)
- **Board committees** deliberate on topic areas and alignment of slates with stated goals
- **Reporting** that provides context for proposed awards

Next Steps

- **Expedited approach** for topic planning
- **Framework for context** regarding funding plan and portfolio

Research Agenda and Topics: Three Parallel Tracks

Strategic Planning

- National Priorities
- Research Agenda
- Commitment Plan

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

Developing Targeted Topics

- Needed for next several cycles while Strategic Planning is underway
- Leverage ongoing work
- Pilot an expedited, prospective approach with Board for FY21

Funding Cycles in Context

Example: Cycle 1 2020 (Broad PFA slates approved at November Board meeting)



- LOIs, Applications, and Funding Rate were similar to historical averages
- Unusually high deferral rate this cycle due to COVID-19 pandemic

	Historical Average*		Actual Cycle 1 2020		Actual Cycle 2 2020		Actual Cycle 3 2020	
LOIs Submitted	190		170					
LOIs Invited	100	53%	88	52%				
Applications Submitted (% of LOIs invited)	75	75%	47	53%				
Applications Deferred** (% of LOIs invited)	N/A	N/A	19	22%				
Applications Proposed for Funding (% of Applications Submitted)	12	16%	7	15%				

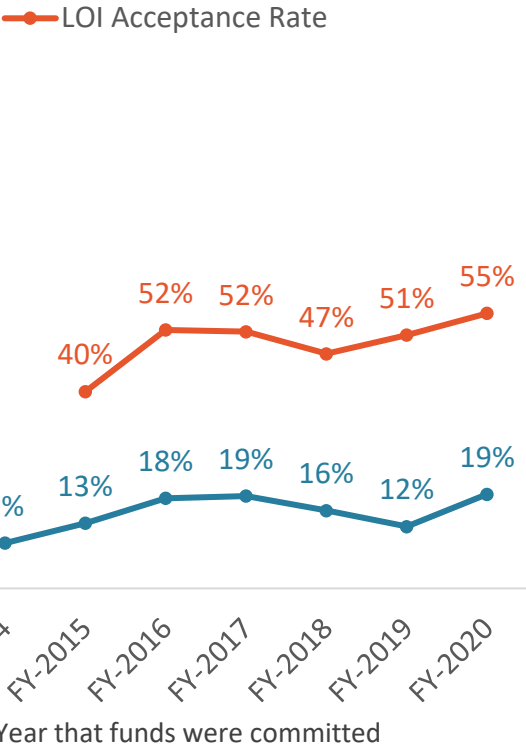
*Based on experience from 2017-2020

**Limited experience for establishing expectations

Context: Trends in Research LOI Acceptance and Application Success Rates

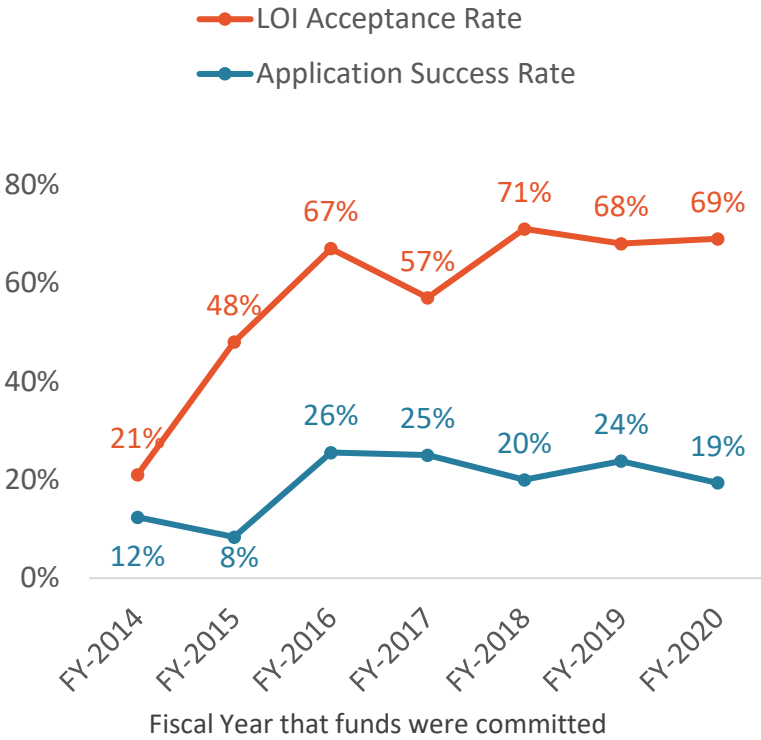


Broad PFAs



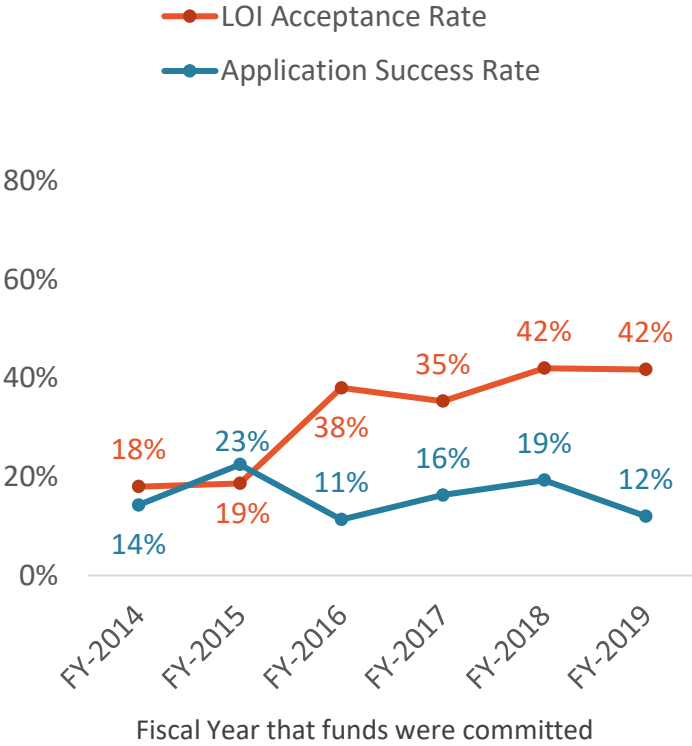
2016-2020 Broad PFAs
LOI Acceptance Rate: 52%
Application Success Rate: 17%

Targeted PFAs



2016-2020 Targeted PFAs
LOI Acceptance Rate: 66%
Application Success Rate: 23%

PCS PFAs



2016-2019 PCS PFAs
LOI Acceptance Rate: 39%
Application Success Rate: 15%

Example of a Generic Template for Setting Funding Cycles in Context

This is our XX funding cycle, the X of 3 launched in FY2020, and the X of 3 to be funded in FY2021

Parameter	Total Funded to Date		Funding this Cycle		Total w/ Cycle Added	
Alignment with National Priorities						
A	\$	%	\$	%	\$	%
B	\$	%	\$	%	\$	%
C	\$	%	\$	%	\$	%
Alignment to Research Agenda						
Investigator-initiated topics	\$	%	\$	%	\$	%
PCORI-priority topics	\$	%	\$	%	\$	%
Balance Across Funding Lines						
Research	\$	%	\$	%	\$	%
D&I	\$	%	\$	%	\$	%
Infrastructure	\$	%	\$	%	\$	%
Total	\$		\$		\$	

Example Generic Outline for Discussion of a Funding Cycle in Context

- **Funding Discussion**
 - Total budgeted for 3 cycles of Broad/PCS/Targeted/D&I awards
 - Anticipated funding, actuals/result (more/same/less), explanation
 - Amount remaining for future cycles
 - Expectation of whether amount will be sufficient/insufficient
 - If insufficient, request to revisit commitment plan
- **Priorities/Portfolio Discussion**
 - How cycle slates align with
 - National Priorities
 - Desired balance across investigator-initiated and PCORI priorities
 - Relationship of cycle slates to PCORI's existing portfolio and research agenda
 - If realignment is required, discussion of strategy for future cycles
- **What else would be informative for setting the cycle in context?**

Proposed 3-Year Commitment Plan FY2021-2023



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The proposal is to approve the 3-year Commitment Plan for FY2021-2023, subject to annual review and update by the Board

Board Vote

Call for a Motion to:

- **Approve** the Proposed 3-year Commitment Plan for FY2021-2023, 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

Roll Call Vote:

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

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

Andrew Hu

Director, Public Policy and Government Relations

Joanna Siegel, ScD

Program Director, Dissemination and Implementation

Overview of Reauthorization Legislation



PCORI's reauthorizing legislation directs PCORI to capture, as appropriate, the full range of outcomes data in the course of our research studies.

This includes economic and cost data related to the utilization of health care services, but also outcomes and measures of cost and burden important to patients.

PCORI is still prohibited from developing QALY measures and conducting cost-effectiveness analysis via our authorizing legislation.



H. R. 1865

One Hundred Sixteenth Congress
of the
United States of America
AT THE FIRST SESSION
Begun and held at the City of Washington on Thursday,
the third day of January, two thousand and nineteen

An Act
Making further consolidated appropriations for the fiscal year ending
30, 2020, and for other purposes.
Be it enacted by the Senate and House of Reps
the United States of America in Congress assembled,
SECTION 1. SHORT TITLE.
This Act may be cited as the "Further Consolid
2020".

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 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

Progress Report – Pillar 1

Proposed “Principles”

- PCORI Board of Governors approved the release of the proposed “Principles” for Public Comment on **September 14, 2020**

Seeking Public Input

- 60-Day Public Comment Period **closed November 13, 2020**
- Webinar Series
- Advisory Panels

Revising Principles & Guidance

- Revise “Principles” based on public input
- Guidance to applicants in PCORI funding announcements in Cycle 1 2021
- Final approval of “Principles” in March 2021

We are in this third phase

Proposed Principles

Identifying Outcomes Important to Patients

- **Principle #1:** PCORI-funded research may consider the full range of outcomes *important to patients and caregivers*, including burdens and economic impacts.

Identifying Outcomes Important to Stakeholders

- **Principle #2:** PCORI-funded research may consider the full range of outcomes *relevant to other stakeholders*, when these outcomes have a near-term or longer-term impact on patients.

Criteria Regarding the Collection of Data

- **Principle #3:** The collection of data on burdens and economic impacts of treatment options must be appropriate and relevant to the clinical aims of the study.

Consideration of Economic Analysis

- **Principle #4:** Beyond the collection of burden and economic impact data, PCORI may support the conduct of certain types of economic analyses as part of a funded research study, to enhance the relevance and value of this information to health care decision-makers.

Proposed Open Questions

Question #1:

- **Requirement to Capture Cost/Economic Data:** What are the advantages and disadvantages? Are there scenarios where the capture of this data does not contribute to the overall importance and value of the study findings?

Question #2:

- **Scope of Allowable Economic Analysis:** Working within the limits of PCORI's authorizing statute, what types of economic analyses will benefit stakeholders?

Collection and Analysis of Input

- PCORI will incorporate input and feedback from a wide range of sources, including:
 - Individual stakeholder discussions
 - PCORI Advisory Committees
 - PCORI-hosted Webinar Series
 - Public Comment Period
- PCORI received comments from organizations and individuals representing the **full spectrum** of stakeholders – patients, caregivers, clinicians, health systems, payers, purchasers, researchers and industry.

Emerging Themes of Input Received

- Broad **support** for the consideration of costs and economic impact data in PCORI research
- Focus on a **patient-centered and holistic** approach to the consideration of costs
- Consider the cost burdens and impacts from a **societal and community** level
- Helpful to capture **implementation or program costs**
- Having patient-centered cost/impact data can help in **value-based payment** models
- Consideration of relevant cost/economic data **not necessarily required** for all studies

Next Steps

- PCORI is in the process of **Collection, Analysis, and Disposition** of Public Comments *(ongoing)*
- Development of guidance and FAQs in advance of **Cycle 1 2021 PFA** *(ongoing)*
- Coordination with Methodology Committee in launch of **Pillar 2 activities** *(ongoing)*
- Consideration by the Board for approval at its **March 16, 2021** meeting

BREAK

We will return at 1:30 PM ET



Join the conversation on Twitter via
@PCORI

Welcome Back

Christine Goertz, DC, PhD

Chairperson, Board of Governors



Strategic Planning Committee

Report and Discussion

Sharon Levine, MD

Co-chair, Strategic Planning Committee

Nakela L. Cook, MD, MPH

Co-chair, Strategic Planning Committee



Strategic Planning Committee

Purpose and Today's Report Structure



Committee Purpose

The Strategic Planning Committee works on behalf of the PCORI Board of Governors, to develop and oversee the conduct of a strategic planning process and the development of a strategic plan for approval by the Board of Governors

Report Outline

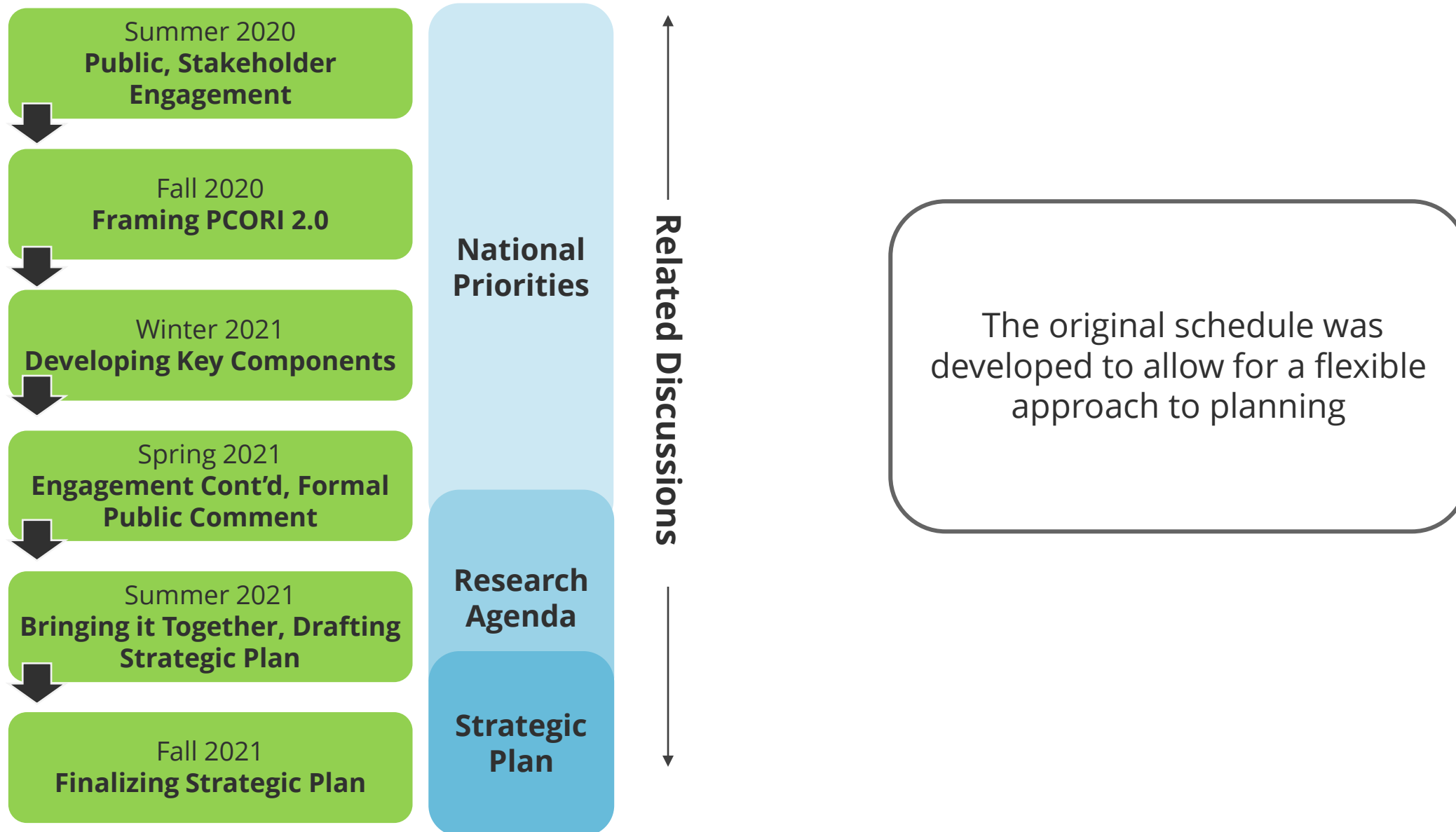
- Scope of and activities anticipated in strategic planning
- Updated schedule and timeline for upcoming Board decisions
- Summary of input received to date

Scope of Strategic Planning Activities

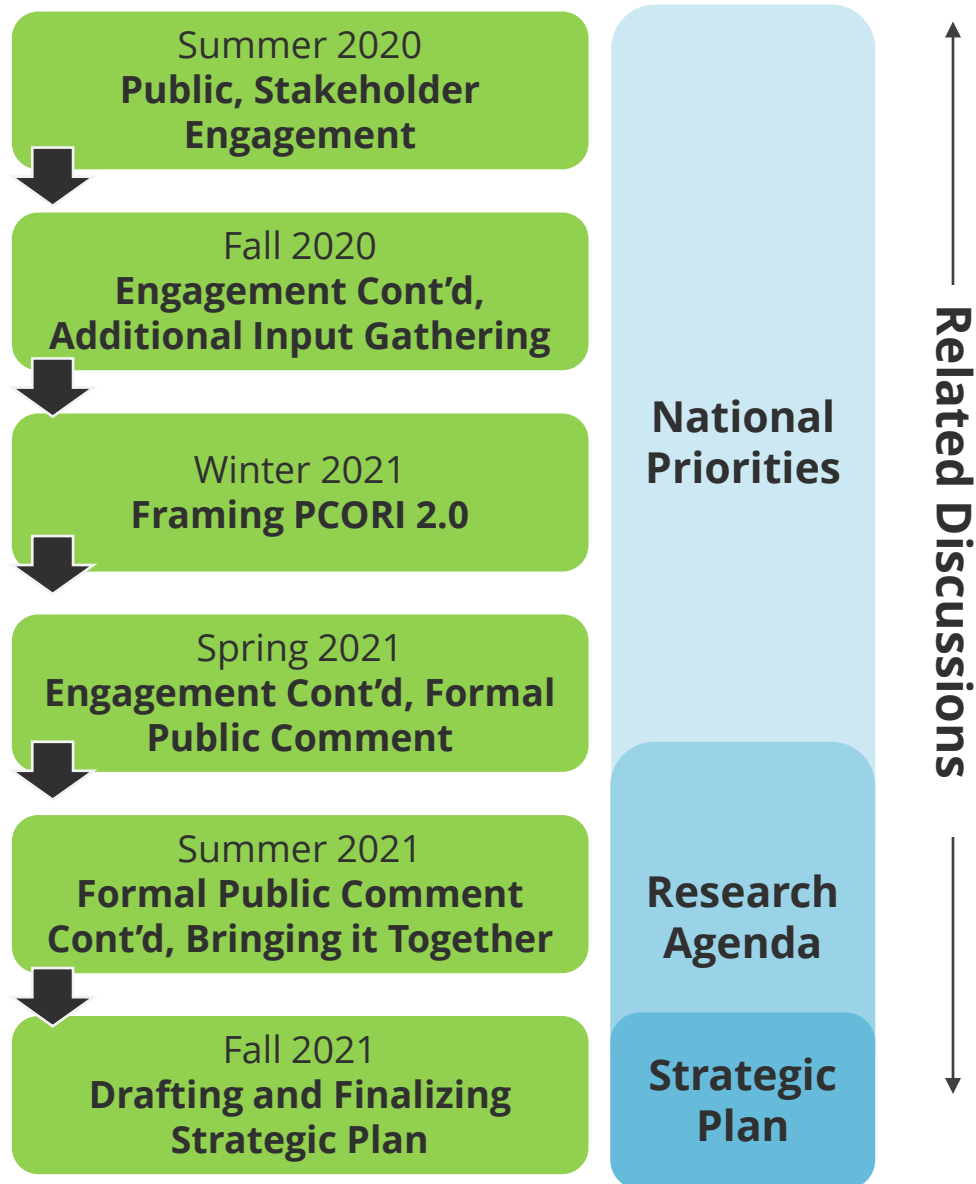
- National Priorities
- Research Agenda
- PCORnet strategic vision for the next phase
- Methodology Committee focus for PCORI 2.0
- Commitment Planning and strategies to increase funding
- Scenario Planning based on the changes in landscape and environment
- Priorities from reauthorizing legislation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



Strategic Planning: Original Timeline



Strategic Planning: Updated Timeline

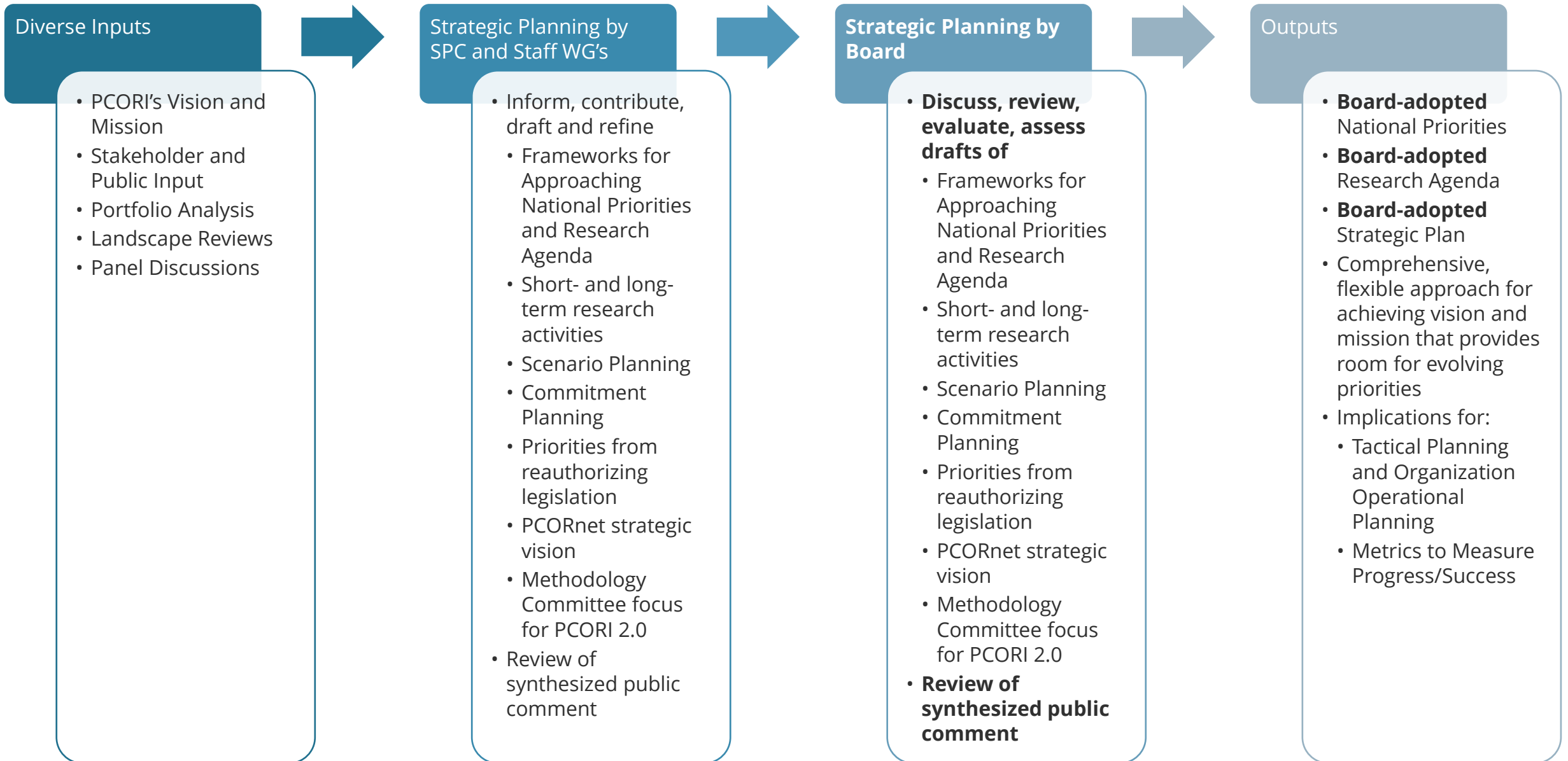


Updated schedule reflects incorporation of additional time to garner diverse inputs needed to inform identification of the National Priorities, which will serve as foundational pillars to the subsequent Research Agenda and Strategic Plan

Additional inputs added to process

- Health care landscape reviews to inform National Priorities

Overview of Strategic Planning Process: General Sequence



Timeline of Upcoming Decision Points for the Board

April, May

- Decide on draft National Priorities for public comment
- Review and confirm inputs (for Research Agenda)

June

- Confirm concepts for establishing a Research Agenda

October

- Consider final Research Agenda
- Confirm concepts to include in strategic plan

December

- Adopt final Strategic Plan

Winter 2021

Spring 2021

Summer 2021

Fall 2021

January, February

- Confirm PCORnet strategy for next phase
- Review and confirm inputs (for National Priorities)

March

- Confirm concepts for identifying National Priorities
- Consider cost data principles for adoption

July

- Consider final National Priorities for adoption

August

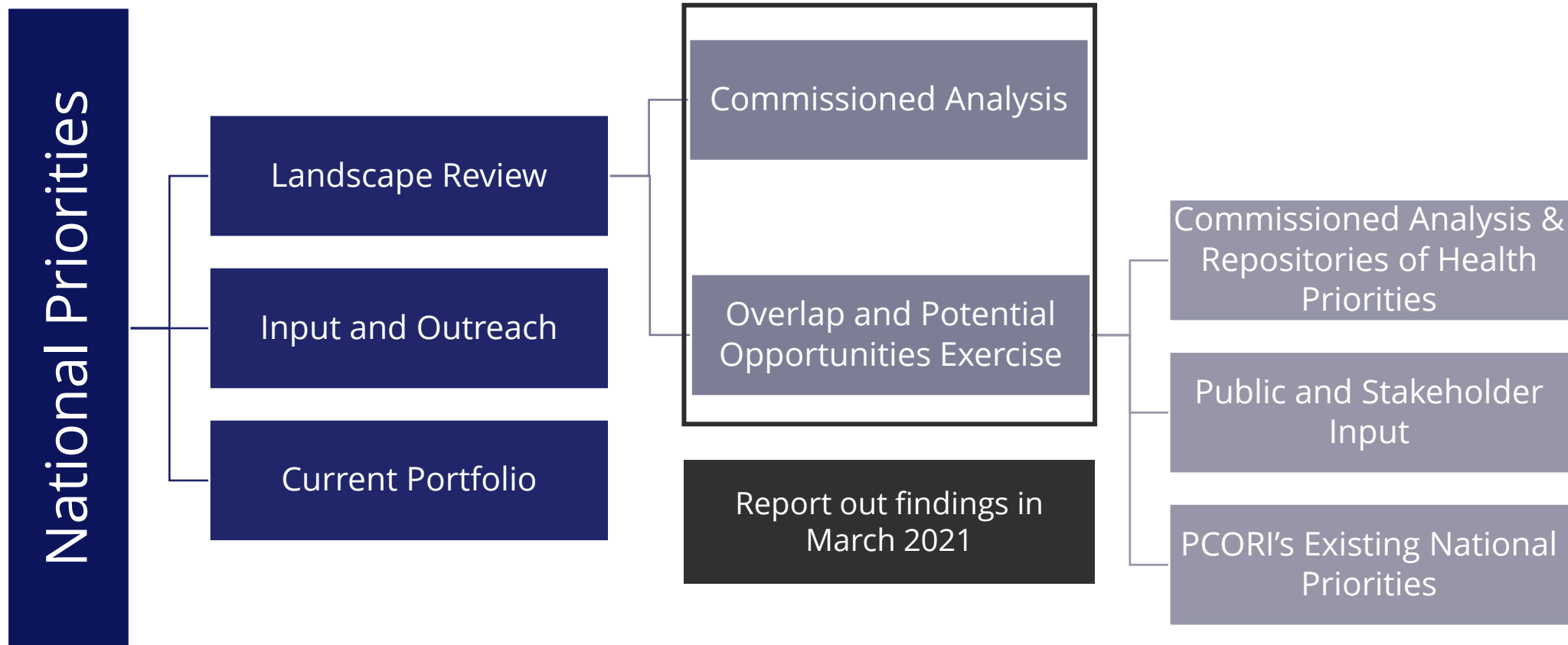
- Decide on draft Research Agenda

September

- Consider Commitment Plan for approval

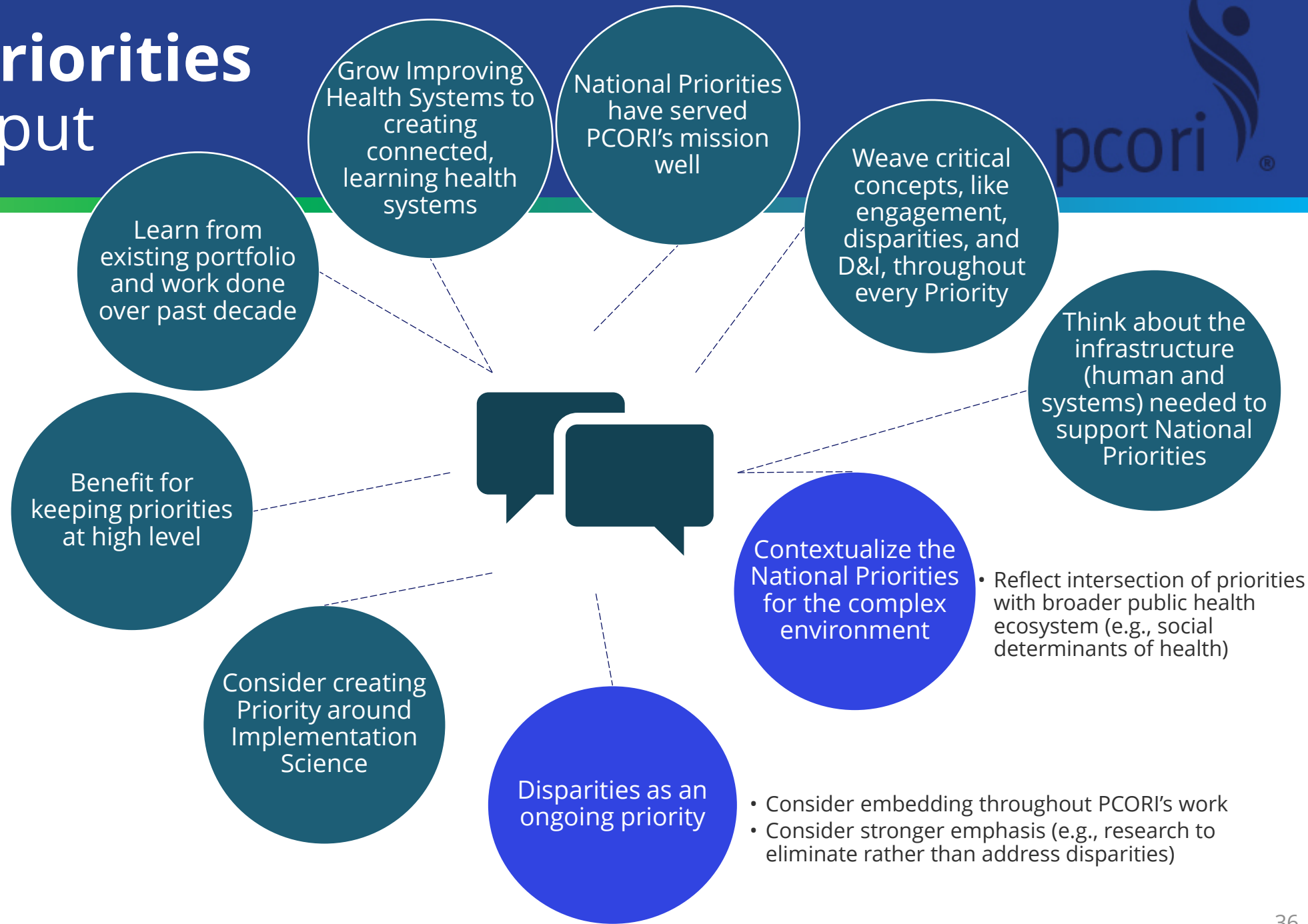
*Methodology Committee focus for PCORI 2.0, MMM, and IDD decision points to be added when dates become available

Structure for Identifying National Priorities



National Priorities Relevant Input

Input from Advisory Panels, Board discussions, and Annual Meeting



-  Input provided
-  Emerging theme from input provided

Emerging Themes from Input Received

- Potentially evolving Addressing Disparities to Eliminating Disparities or similar strengthening of work in this area
- Consider reflecting or embedding a public health and social ecosystem perspective within the National Priorities



Discussion

Public Comment Period

Kristin Carman, MA, PhD

Director, Public & Patient Engagement

Closing Remarks

Wrap Up and Adjournment

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 /PCORInstitute

 PCORI

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