

Board of Governors Meeting

via Teleconference/Webinar

July 21, 2020
1:00 – 2:00 PM

Welcome and Introductions

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

1:00 pm

Call to Order, Roll Call, and Welcome

1:00 – 1:05

Consider for Approval:

- Minutes of the June 23, 2020 Board meeting
- Proposed Amendments to Bylaws

1:05-1:10

Update on Funding COVID-19 Enhancements

1:10 – 2:00

Strategic Planning: Focus on National Priorities

2:00 pm

Wrap up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the June 23, 2020 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

Proposed Amendments to PCORI Bylaws to Fulfill Legal Requirements for Officers

Sharon Levine, MD

Chair, Governance Committee

Mary Hennessey, Esq.

General Counsel



Proposed Bylaws Amendments



- Under the current Bylaws:
 - The Board appoints key corporate officers of PCORI
 - President – the Executive Director, ex-officio; Treasurer – the Board appointed the Chief Operating Officer, ex-officio; Secretary – the Board appointed the General Counsel, ex-officio
 - The Board can appoint other officers or assistant officers to perform duties
 - However, there is no Bylaws provision enabling the appointment of assistant officers that empowers them to exercise powers if the lead officer is absent
- The proposed amendments to PCORI Bylaws:
 - Allows for the appointment of assistant officers by the Chairperson if the lead officer is absent, unwilling, or unable to perform their officer duties for any reason
 - Provides that the Board retains the power to remove any assistant officer so appointed
 - Enables PCORI to fulfill its legal requirements and aligns with D.C. Nonprofit Law

Board Vote

Call for a Motion to:

- **Approve** the Proposed Amendments to the PCORI Bylaws

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 Funding of COVID-19 Enhancements

Nakela Cook, MD, MPH

Executive Director



PCORI's Response to the COVID-19 Health Crisis



Many approaches to supporting critical work in these areas and more:

Awards

- Enhancements of existing awards
- Solicitation of new awards
- Healthcare worker registry/trial

Information Sharing

- Webinars
- Collaboration with other funders

Adapting for Awardees and Applicants

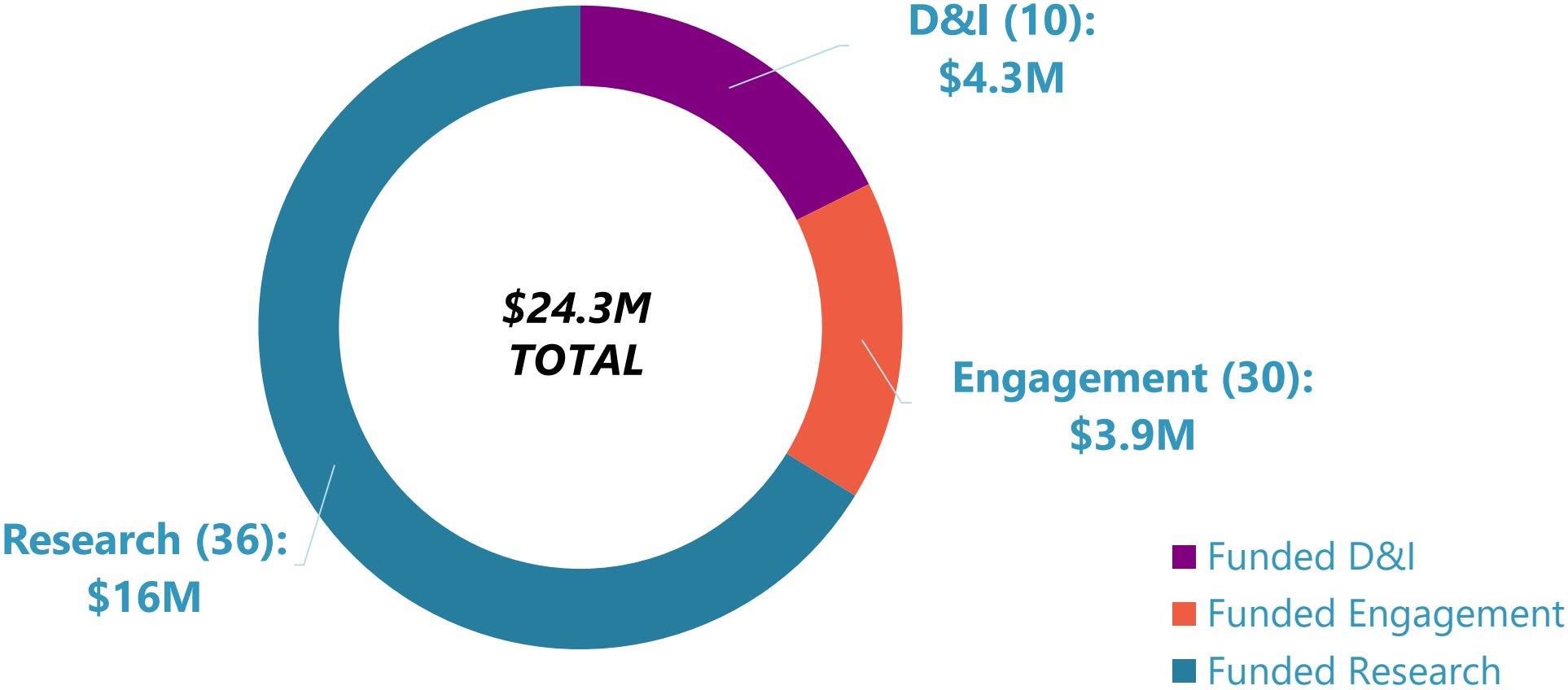
- Adaptations to existing projects
- Extending application timelines

COVID-19 Enhancements – Current PCORI Funding



Funded Enhancements Data

Last updated: July 15, 2020



COVID-19 Enhancements – Current PCORI Funding

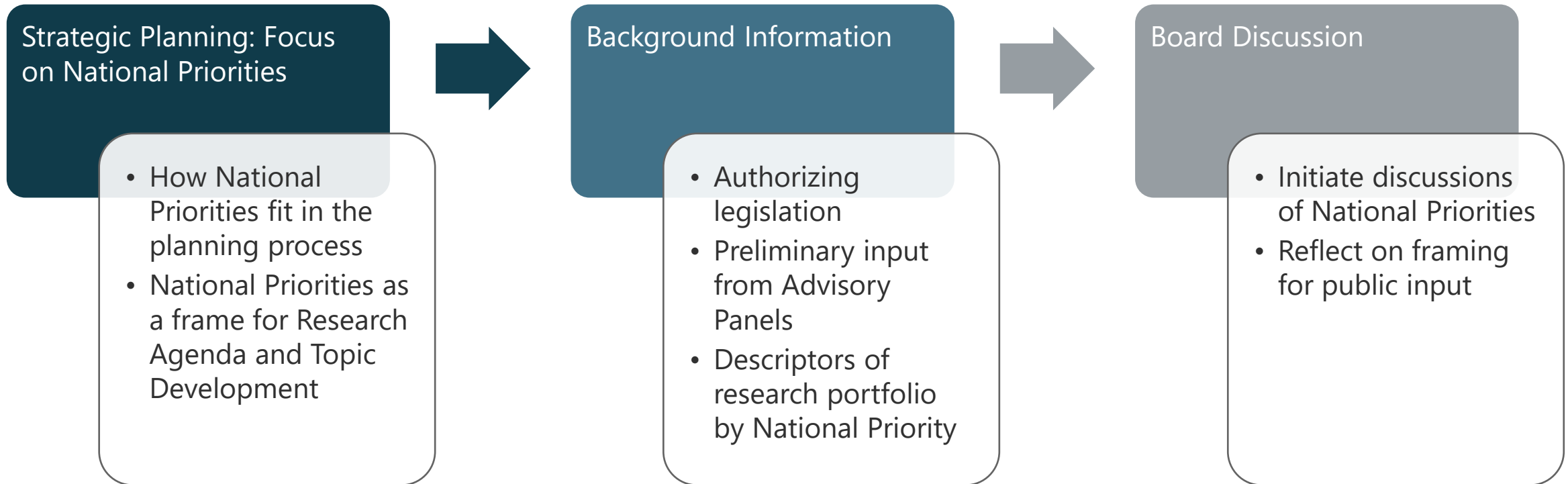
Health Condition	Research Awards & Intervention Strategy										Dissemination & Implementation Awards	Engagement Awards
	Drug	Other Clinical	Health Services	Tele-medicine	Training & Education	Screening	Technology	Policy	Behavioral	N/A		
Cancer												
Cardiovascular Diseases												
Gastrointestinal Disorders												
Genetic Disorders												
Infectious Diseases												
Mental/Behavioral Health												
Multiple/Comorbid Chronic Conditions												
Muscular & Skeletal Disorders												
Neurological Disorders												
Nutritional & Metabolic Disorders												
Rare Disease												
Reproductive & Perinatal Health												
Respiratory Diseases												
Other or Non-Disease Specific												
Kidney Diseases												
Blood Disorders												

Strategic Planning: Focus on National Priorities

Nakela Cook, MD, MPH
Executive Director



Outline for Today's Presentation



Questions for Consideration

- What key principles should guide the identification of National Priorities?
- What are your reflections on the National Priorities that will help achieve the vision for PCORI going forward?
- What learnings from the current National Priorities can inform these discussions?
- What considerations for identifying National Priorities will enable PCORI to be nimble and responsive to evolving health and healthcare needs?
- What other information would be helpful as the Board considers identifying National Priorities?

Strategic Planning: Encompassing Complex Components



Components that Guide PCORI's Work

National Priorities

- Broad areas that encompass the patient-centered comparative effectiveness research (CER) PCORI supports
- Reflect priorities of patients, stakeholders, and the broader healthcare system
- Transparently demonstrate rationale for PCORI investments
- Articulate and reflect values of PCORI and Congressional mandate

Research Agenda

- More specific topic areas that address research priorities
- Establishes framework through which PCORI makes CER investments
- Articulates and reflects evolving evidence needs of patients, stakeholders, and the broader healthcare system

Topic Development

- Process of ongoing cultivation and refinement of specific topics and/or sub-questions
- Questions refined with input from patient and stakeholder partners
- Articulates focused areas for funding

Fitting It Together

A Matrixed Approach

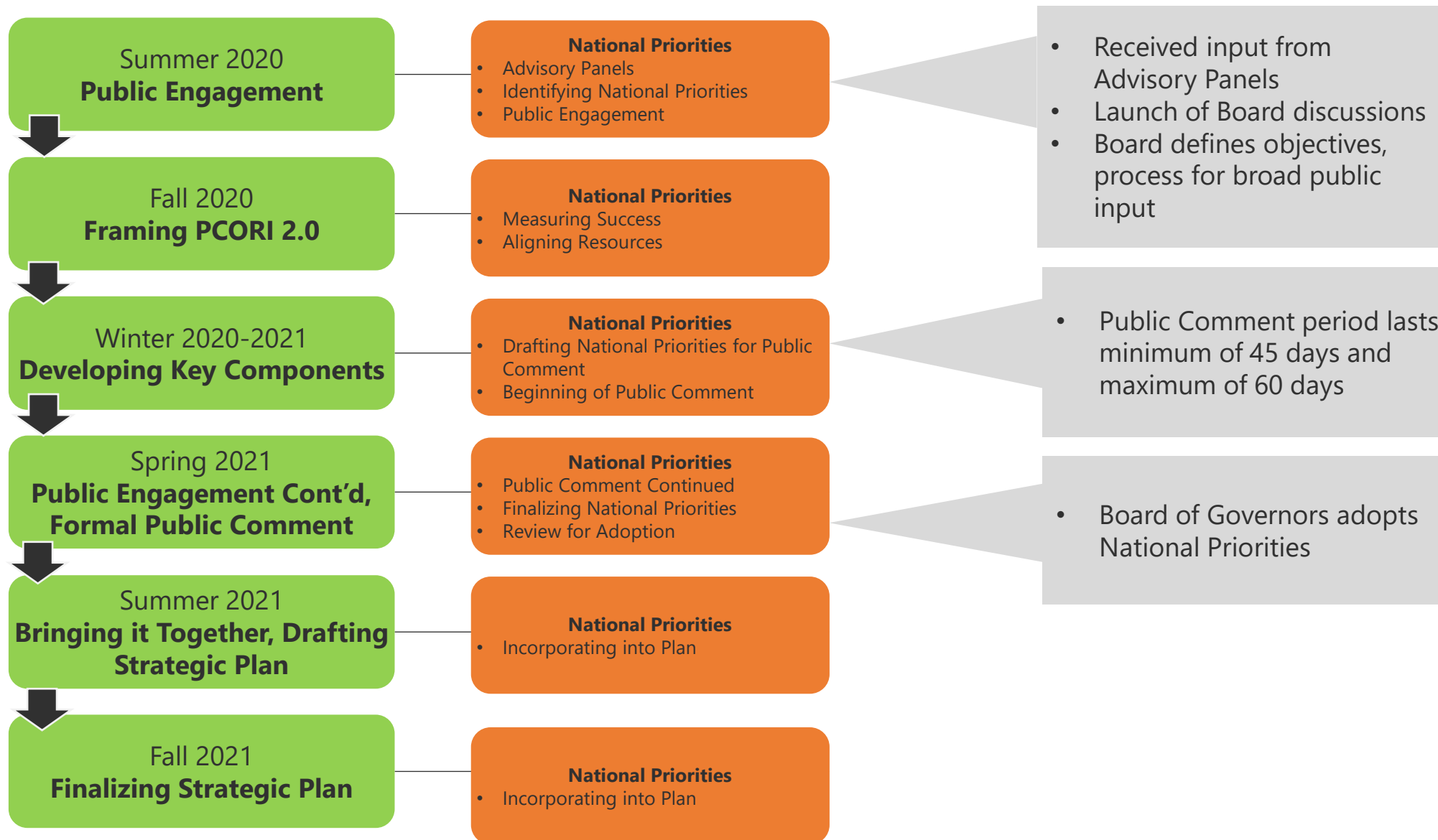
	National Priority A	National Priority B	National Priority C
Research Topic 1	A1	B1	C1
Research Topic 2	A2	B2	C2
Research Topic 3	A3	B3	C3

Research topic areas cut across National Priorities and National Priorities are represented in a variety of research topics.

Planning Schedule: Highlights



Planning Schedule: Focus on National Priorities



National Priorities: Core Responsibilities

"The Institute shall identify national priorities for research, taking into account **factors of disease** incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), **gaps in evidence** in terms of clinical outcomes, **practice variations** and **health disparities** in terms of delivery and outcomes of care, the **potential for new evidence** to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions..."

Subtitle D—Patient-Centered Outcomes Research

SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"SEC. 1181 [42 U.S.C. 1320e]. (a) DEFINITIONS.—In this section:

"(1) BOARD.—The term 'Board' means the Board of Governors established under subsection (f).

"(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

"(A) IN GENERAL.—The terms 'comparative clinical effectiveness research' and 'research' mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

"(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

2019 Amending Legislation Added to Identifying Research Priorities



“Such national priorities shall include research with respect to **intellectual and developmental disabilities and maternal mortality**. Such priorities should reflect a balance between **long-term priorities and short-term priorities**, and be **responsive to changes** in medical evidence and in health care treatments.”

Intellectual and developmental disabilities and maternal mortality identified in amending legislation as priority topics for our *Research Agenda*

Activities are underway

Legislatively-Mandated Priority Topics Cut Across Our National Priorities



	National Priority A	National Priority B	National Priority C
Intellectual and Developmental Disabilities	A1	B1	C1
Maternal Mortality	A2	B2	C2

Intellectual and developmental disabilities and maternal mortality:
Priority topics for the next 10 years

Current National Priorities (Adopted in 2012)

Addressing Disparities (AD)

Identifying potential differences in prevention, diagnosis, or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

Assessment of Prevention, Diagnosis, and Treatment Options (APDTO)

Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

Communication and Dissemination Research (CDR)

Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision making between patients and their providers.

Improving Healthcare Systems (IHS)

Comparing health system-level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

Accelerating PCOR and Methodological Research (Methods)

Improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients, and other stakeholders to participate in this research.

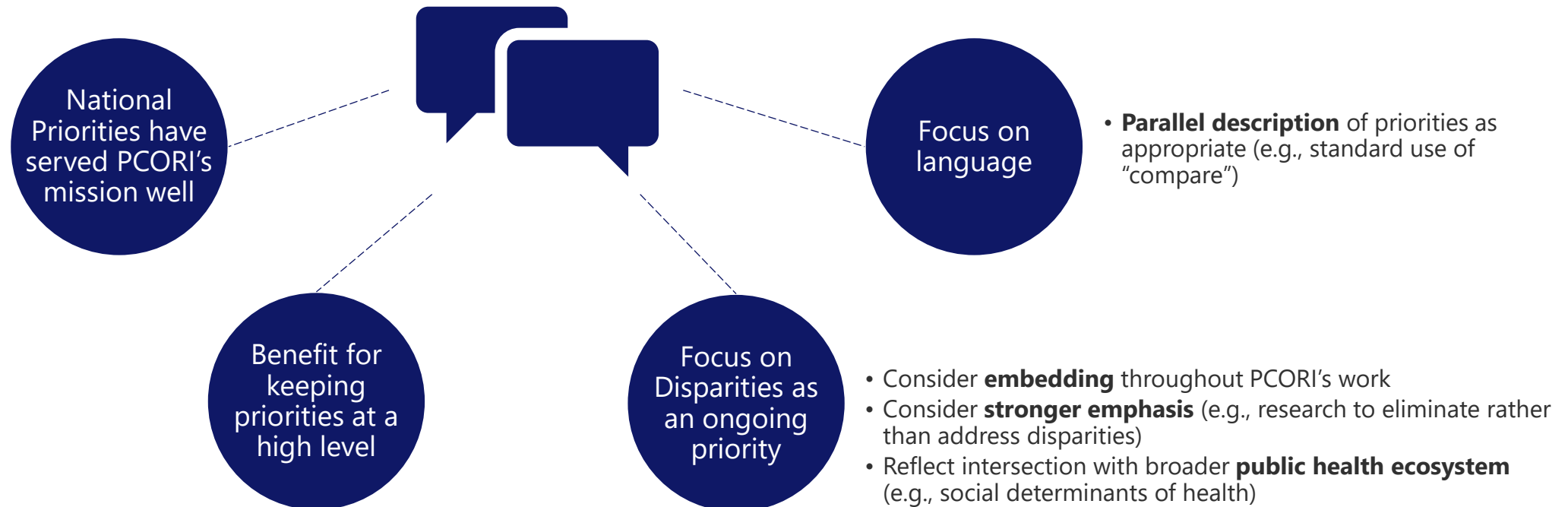
Advisory Panel Input on National Priorities: Common Themes

Advisory Panel on
Clinical Effectiveness
and Decision Science

Advisory Panel on
Healthcare Delivery and
Disparities Research

Advisory Panel on
Patient Engagement

Advisory Panel on Rare
Disease

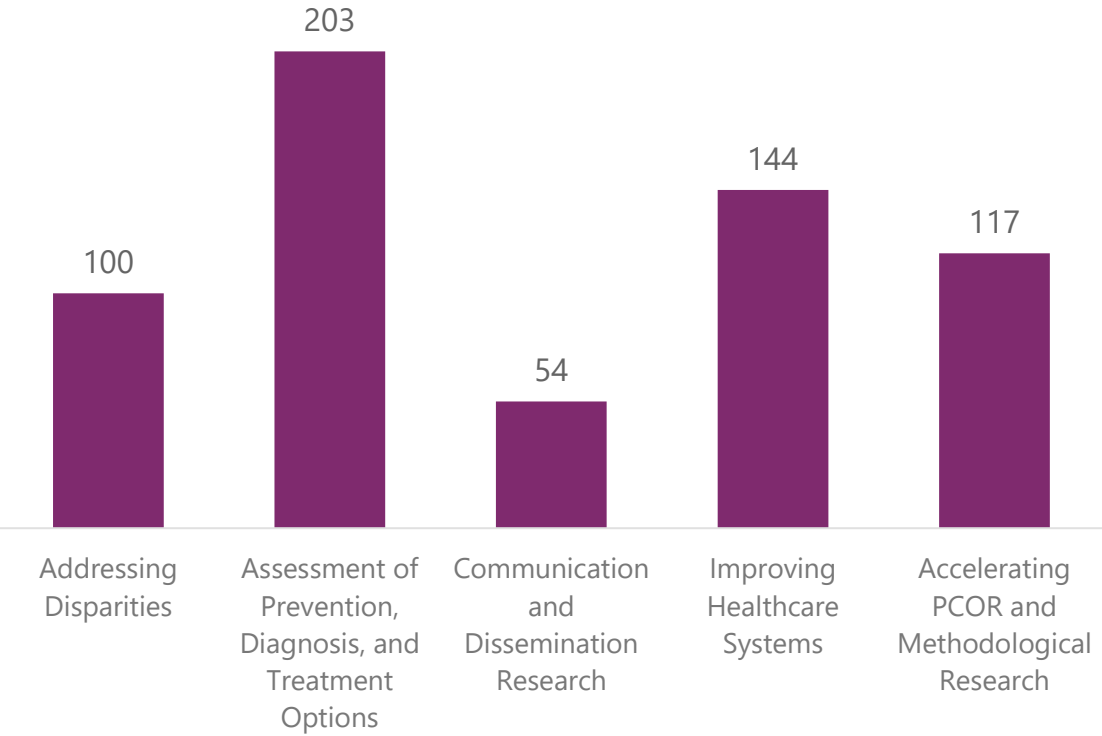


Overall Portfolio by National Priorities

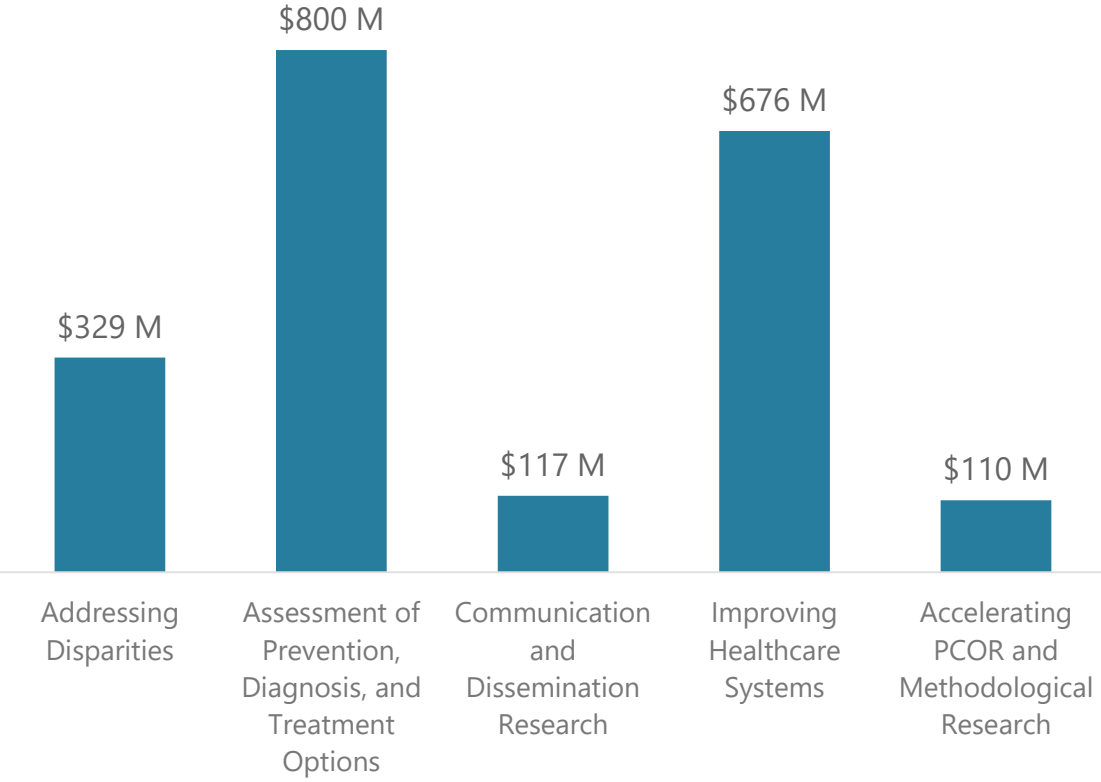
Funding and Number of Studies



Number of Funded Studies
(Through 2019, Cycle 3)



Funding Amount
(Through 2019, Cycle 3)

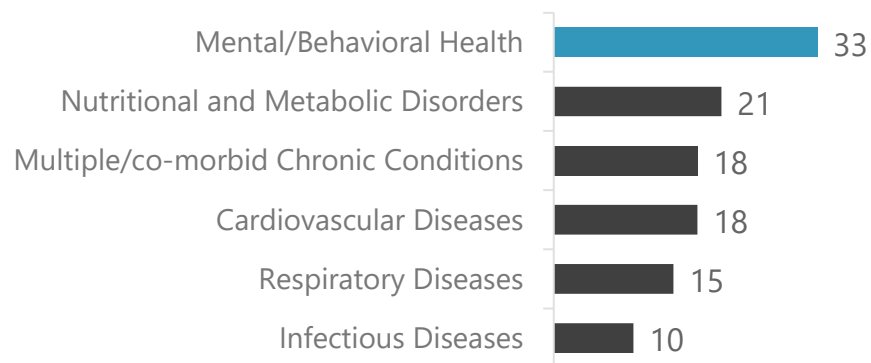


Health Conditions Cut Across National Priorities

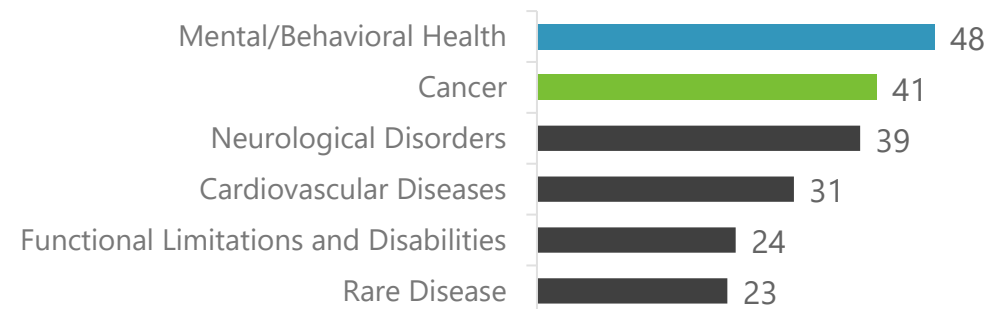
Research Portfolio



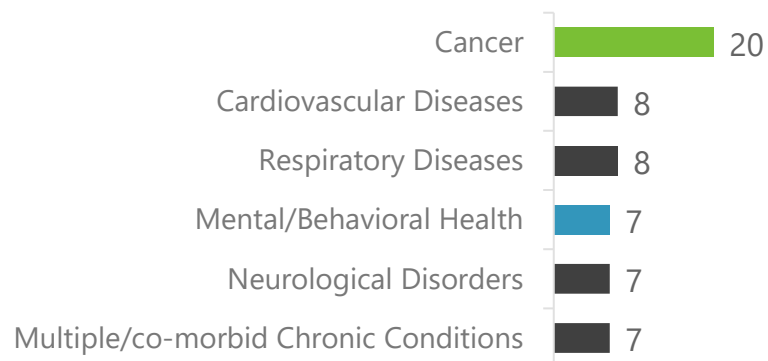
Addressing Disparities



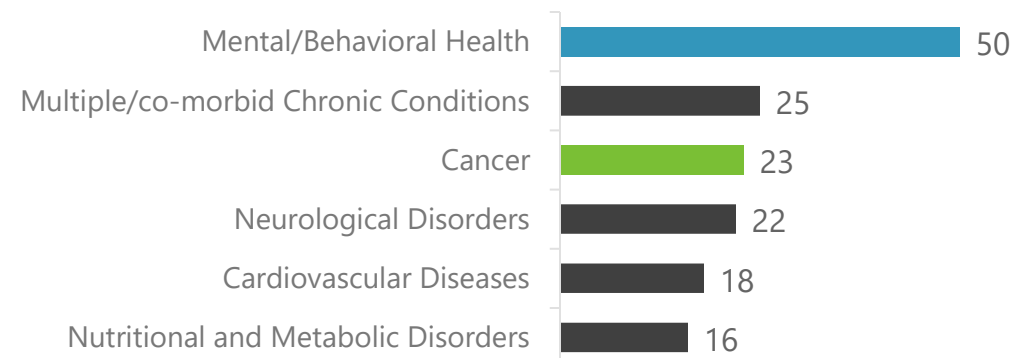
Assessment of Prevention, Diagnosis, and Treatment Options



Communication and Dissemination Research



Improving Health Systems

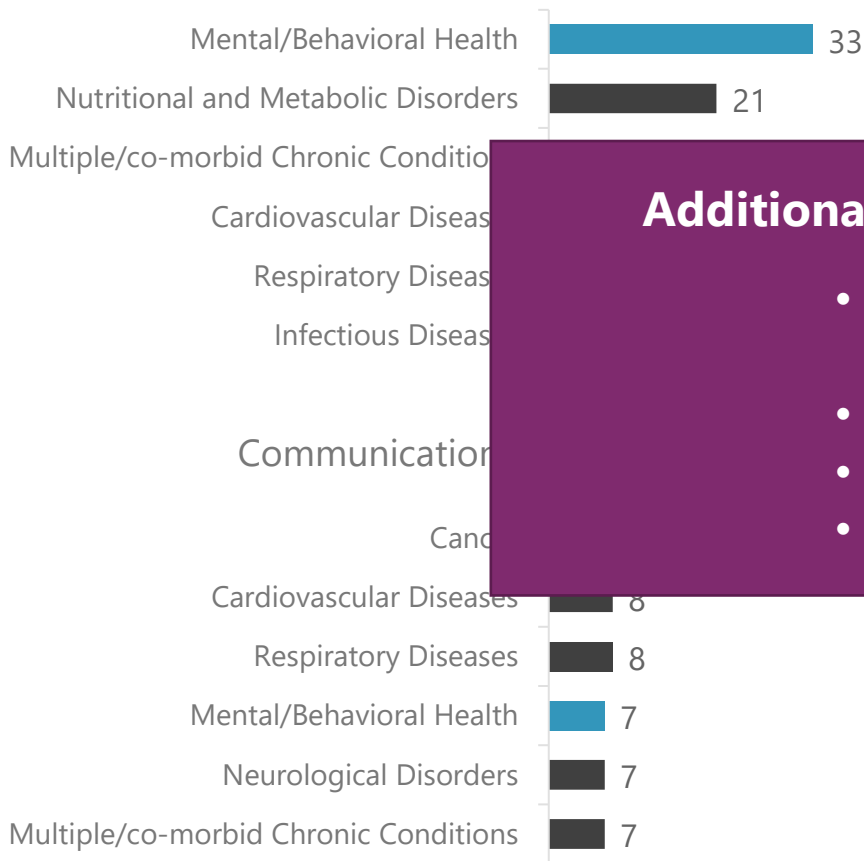


Health Conditions Cut Across National Priorities

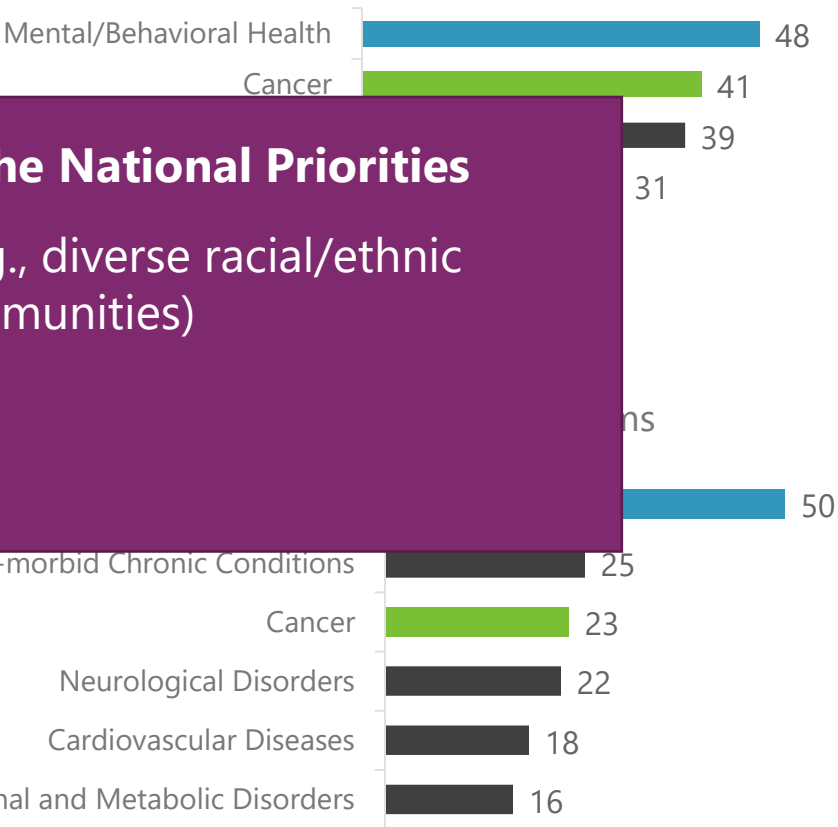
Research Portfolio



Addressing Disparities



Assessment of Prevention, Diagnosis, and Treatment Options



Additional Elements Cut Across the National Priorities

- Priority Populations (e.g., diverse racial/ethnic backgrounds; rural communities)
- Study Settings
- Intervention Types
- Outcomes

Recap

Strategic Planning: Focus on National Priorities

- National Priorities, Research Agenda, and Topic Development are **mutually reinforcing components** that guide funding patient-centered comparative effectiveness research



Background Information

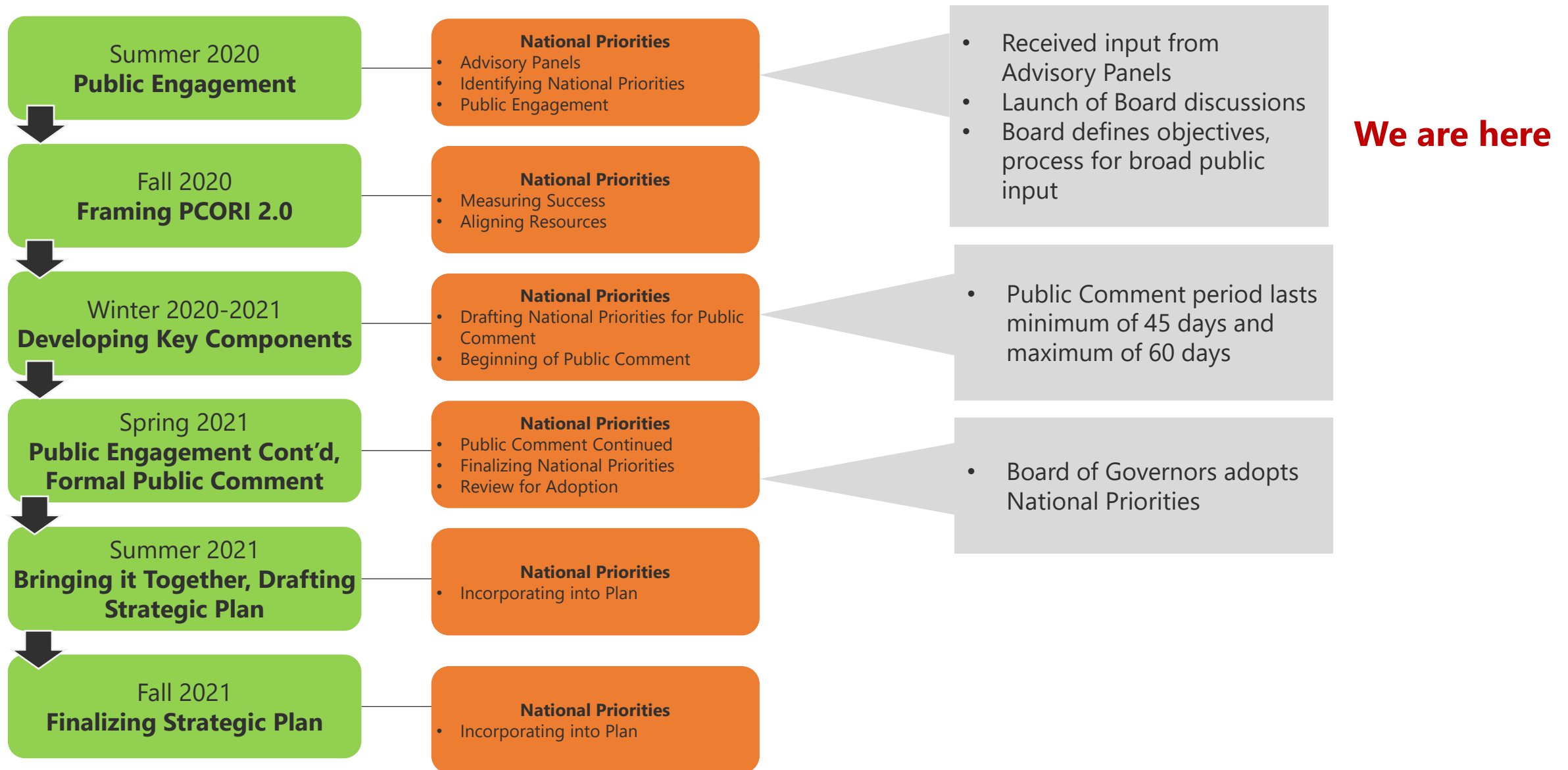
- Articulating National Priorities is a **core responsibility** under authorizing law
- Advisory Panels noted benefit in **high-level** priorities, incorporating influence of public health ecosystem, and strengthening of disparities priority
- National Priorities **reflect crosscutting issues** in research portfolio such as in health conditions and priority populations



Board Discussion- **Next Steps**

- First of several Board discussions
- Consider **how to frame National Priorities** for public input
- Comments to be provided to **Strategic Planning Committee** for refinement and **future discussion**

Next Steps: Focus on National Priorities



- What key principles should guide the identification of National Priorities?
- What are your reflections on the National Priorities that will help achieve the vision for PCORI going forward?
- What learnings from the current National Priorities can inform these discussions?
- What considerations for identifying National Priorities will enable PCORI to be nimble and responsive to evolving health and healthcare needs?
- What other information would be helpful as the Board considers identifying National Priorities?

Wrap Up and Adjournment



202.827.7700



info@pcori.org



www.pcori.org



@pcori



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