

Board of Governors Meeting

via Teleconference/Webinar

July 27, 2021
1:00 – 2:30 PM

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

1:00	Welcome, Call to Order and Consider for Approval: Minutes of the June 15, 2021 Board Meeting
1:05-2:10	Consider for Approval: Cycle 3 2020 Research and Dissemination & Implementation (D&I) Award Slates • <i>Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA</i> • <i>Suicide Prevention: Brief Interventions for Youth Targeted PFA</i> • <i>Broad PFAs</i> • <i>Limited Competition Dissemination and Implementation PFA</i>
2:10-2:30	Strategic Planning Update
2:30	Wrap-up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the June 15, 2021 Board of Governors meetings

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

Overview of Award Slates to be Considered for Approval Today

Nakela L. Cook, MD, MPH

Executive Director

Overview

Four award slates are under consideration for approval today:

PFA Type	Amount	PFA
Research	\$135M	Cycle 3 2020 Phased Large Awards for Comparative Effectiveness Research (PLACER)
Research	\$37M	Cycle 3 2020 Targeted: Suicide Prevention: Brief Interventions for Youth
Research	\$82M	Cycle 3 2020 Broad
D&I	\$1.4M	Cycle 3 2020 Limited Competition D&I
Total	\$255M	

FY2021 Funding Cycles in Context

PLACER Award Slates



This is our first cycle of PLACER and thus we have no historical data for comparison

Targeted PFAs	Historical Average	Cycle 3 2020 PLACER (Phased Large Awards)		Cycle 3 2021 PLACER (Phased Large Awards)	
LOIs Submitted	N/A	109		TBD	
LOIs Invited (% of LOIs Submitted)	N/A	60	55%	-	-
Applications Submitted (% of LOIs Invited)	N/A	52	87%	-	-
Applications Proposed for Funding (% of Applications Submitted)	N/A	5	10%	-	-

FY2021 Funding Cycles in Context

Targeted PFA Award Slates



LOIs, Applications, and Funding Rates were generally higher than historical averages:

Targeted PFAs	Historical Average*	Cycle 3 2020 Suicide Prevention		Cycle 2 2021 Maternal Outcomes		Cycle 2 2021 Mental Health & IDD		Cycle 2 2021 Urinary Incontinence	
LOIs Submitted	15	29		26		9		14	
LOIs Invited (% of LOIs Submitted)	73%	16	55%	17	65%	2	22%	10	71%
Applications Submitted (% of LOIs Invited)	73%	13	81%	TBD	-	TBD	-	TBD	-
Applications Proposed for Funding (% of Applications Submitted)	21%	4	31%	-	-	-	-	-	-

*Historical Average based on experience from 2018-2020

FY2021 Funding Cycles in Context

Broad PFA Award Slates



LOIs, Applications, and Funding Rate were similar to historical averages:

Broad PFAs	Historical Average*	Cycle 3 2020 Broad PFAs		Cycle 1 2021 Broad PFAs		Cycle 2 2021 Broad PFAs	
LOIs Submitted	184	195		141		82	
LOIs Invited (% of LOIs Submitted)	51%	109	52%	87	62%	40	49%
Applications Submitted (% of LOIs invited)	75%	81	53%	56	64%	TBD	-
Applications Proposed for Funding (% of Applications Submitted)	15%	19	17%	TBD	-	-	-

* Historical Average based on experience from 2018-2020

FY2021 Funding Cycles in Context

D&I Award Slates



LOIs, Applications, and Funding Rate were similar to historical averages

Limited Competition (LC) D&I PFAs	Historical Average*	Cycle 3 2020 D&I LC PFA		Cycle 1 2021 D&I LC PFA		Cycle 2 2021 D&I LC PFA	
LOIs Submitted	13	6		6		8	
LOIs Invited (% of LOIs Submitted)	77%	4	67%	4	67%	4	50%
Applications Submitted (% of LOIs invited)	70%	3	75%	3	75%	TBD	
Applications Proposed for Funding (% of Applications Submitted)	29%	1	33%	TBD			

* Historical Average based on experience from 2018-2020

Today's Proposed Research and D&I Commitments in Context of FY2021 Commitment Plan



Research and D&I PFAs Funded in This Cycle	Commitment Target for Research and D&I in FY2021	Cumulative FY2021 Research and D&I Funding with today's slates
Research, Cycle 3 2020: • PLACER • Broad • Targeted: Suicide Prevention D&I, Cycle 3 2020: • Limited Competition	\$380M*	\$362M**

*Commitment Target for FY2021 includes \$340M for Research and \$40M for D&I

**Cumulative commitments include the \$11M for Cycle 2 2021 Expedited COVID-19 PFA award slate

Research Award Slates

Barbara McNeil, MD, PhD

Chair, Selection Committee

Phased Large Awards for Comparative Effectiveness Research (PLACER)

Cycle 3 2020 Award Slate

Anne Trontell, MD, MPH

Associate Director, Clinical Effectiveness and Decision Science

PLACER PFA

Overview



Objective of this PFA: Support large-scale, high-impact randomized trials in CER with attendant risks of achieving their research aims and thus merit an initial phase of testing and refinement to

- determine their feasibility and viability
- maximize the likelihood of full-scale trial success.

Total Direct Costs: Up to \$22M per award

- Up to \$2M (feasibility phase)
- Up to \$20M (full-scale study phase)

Project Duration: Up to 6.5 years per award

- Up to 1.5 years (feasibility phase)
- Up to 5 years (full-scale study phase)

Funds Allocated: \$150M

Cycle 3 2020 – Phased Large Awards for Comparative Effectiveness Research (PLACER)

Slate of 5 Recommended Projects



Project Title		
Achieving Blood Pressure Goals After Stroke		
Large pragmatic trial to prevent suicide attempts, deaths in moderate-to-high risk youth		
PRECIDENTD (PREvention of Cardiovascular and Diabetic kidney disease in Type 2 Diabetes)		
Specialty Compared to Oncology delivered Palliative Care for Patients with Acute Myeloid Leukemia (SCOPE-Leukemia)		
THRIVE: Trajectories of Recovery after Intravenous Propofol vs inhaled Volatile anesthesia		
Proposed Total Award*:		\$135M

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Project 1: Achieving Blood Pressure Goals After Stroke

- **Research Question:** What is the effectiveness of two evidence-based strategies to reduce blood pressure (BP) at home?
- **Population and Setting:** Stroke patients in the “Stroke Belt” of the US, ≥ 18 years of age, discharged home from the hospital or inpatient rehabilitation, with systolic BP (SBP) ≥ 130 mm Hg at baseline
- **Comparators:** *Intensive Tailored Telehealth Management (ITTM)*: digital home BP monitoring and transmission, tailored BP-focused care plan and health coaching, community service referrals, and clinician visits via telehealth vs. *Intensive Clinic Management (ICM)*: self-monitoring of BP, in-person clinic visits, standard care planning and health coaching
- **Outcomes of Interest:**
 - Primary:* SBP control (proportion of patients with SBP ≤ 130 mm Hg at 6 months follow-up)
 - Secondary:* 1-year incidence of major adverse cardiovascular events (MACE)

Project 2: Large pragmatic trial to prevent suicide attempts, deaths in moderate-to-high risk youth



- **Research Question:** Is a stepped-care suicide prevention program with dialectical behavioral therapy (DBT) superior to the Zero Suicide program in reducing suicide attempts among moderate-to-high risk youths?
- **Population & Setting:** Youth ages 13-17 at *moderate-to-high* risk for self-injury and suicide; four participating integrated healthcare systems
- **Comparators:** *Stepped care intervention:* three levels of service of increasing intensity determined by patient's risk level including monthly care management (CM), weekly CM plus safety planning (SP) and motivational interviewing (MI), and weekly CM, SP, MI plus DBT vs. *Zero Suicide (standard of care):* suicide/depression screening (PHQ-9), risk assessment (Columbia-Suicide Severity Rating Scale or C-SSRS), safety planning, and evidence-based treatment for depression (e.g., psychopharmacology, cognitive behavioral therapy)
- **Outcomes of Interest:**
 - Primary:* time to self-injury and/or suicide attempt
 - Secondary:* receipt of stepped care services, mental/behavioral health diagnoses, utilization of general and mental healthcare services, PHQ-9 score, GAD-7 score, C-SSRS score, completion of safety plan
 - Qualitative:* subgroup interviews using RE-AIM model (reach, effectiveness, adoption, implementation, maintenance)

Project 3: PRECIDENTD (PREvention of Cardiovascular and DiabEtic kidNey disease in Type 2 Diabetes)



- **Research Questions:** In patients with type 2 diabetes (T2DM) and Atherosclerotic Cardiovascular Disease (ASCVD) or at high ASCVD risk, with treatment with SGLT2 inhibitors (SGLT2i) or GLP-1 receptor agonists (GLP-1 RA) result in better cardiorenal or mortality outcomes? Further, does the combination of the two classes of medications, which have additive adverse effects and costs, offer any further cardiorenal benefit compared to one of these classes alone?
- **Population & Setting:** Adults aged 40-80 years with T2DM and ASCVD or at high ASCVD risk at 30-40 sites at healthcare systems across the United States, including 20+ sites at several PCORnet networks
- **Comparator(s):** SGLT2i monotherapy vs. GLP-1 RA monotherapy vs. SGLT2i and GLP-1 RA combination therapy
- **Outcomes:**
 - Primary.* Composite of the total (first and recurrent) number of episodes of MI, stroke, arterial revascularization; hospitalization for heart failure, end stage kidney disease or transplantation, and all-cause mortality
 - Secondary.* The total burden of adverse events (severe hypoglycemic episodes, diabetic ketoacidosis, genital fungal infections, amputation, fractures, worsening diabetic retinopathy, pancreatitis, and gall bladder disease) and patient-reported outcomes such as medication adherence, treatment satisfaction, and overall health

Project 4: Specialty Compared to Oncology delivered Palliative Care for Patients with Acute Myeloid Leukemia (SCOPE-Leukemia)



- **Research Question:** Is palliative care (PC) delivered by Oncology clinicians (“primary PC”) non-inferior to specialty PC for improving quality of life (QOL) among hospitalized patients diagnosed with acute myeloid leukemia (AML)?
- **Population & Setting:** Hospitalized adult patients diagnosed with acute myeloid leukemia (AML) receiving intensive chemotherapy and their caregivers
- **Comparators:** Primary PC (palliative care delivered by Oncology clinicians) vs. Specialty PC (care delivered by a Specialty Palliative Care Clinician)
- **Outcomes of Interest:**
 - Primary:* Patient self-reported QOL
 - Secondary:* Patients and Caregivers: Depression, anxiety, end-of-life communication, prognostic understanding, coping; Patients: PTSD, end-of-life care delivery, symptom burden, satisfaction with palliative care; Caregivers: QOL, caregiver burden

Project 5: THRIVE: Trajectories of Recovery after Intravenous Propofol vs inhaled Volatile anesthesia



- **Research Question:** In a comparison between intravenous propofol and inhaled volatile anesthetic, which technique yields a superior post-operative recovery and a non-inferior intraoperative experience of surgery?
- **Population & Setting:** Patients aged ≥ 18 undergoing elective non-cardiac surgery expected to last ≥ 60 min requiring general anesthesia, including a tracheal tube or laryngeal mask airway, at acute care hospitals, ambulatory surgery centers, and specialty surgery centers
- **Comparators:** Propofol Total Intravenous Anesthesia (TIVA) vs. Inhaled Volatile (isoflurane, sevoflurane, or desflurane)
- **Outcomes of Interest:**

Primary: Patient-reported Quality of Recovery-15 (measuring physical comfort, physical independence, psychological support, emotional state, and pain) and unintended intraoperative awareness with recall

Secondary: Delirium, functional status, kidney injury, pulmonary failure, and mortality

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 3 2020 –Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA

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

Suicide Prevention: Brief Interventions for Youth Cycle 3 2020 Award Slate

Els Houtsmuller, PhD

Associate Director, Healthcare Delivery & Disparities Research

Cycle 3 2020 – Suicide Prevention: Brief Interventions for Youth PFA Overview



- Objective of this PFA:
- To fund large, randomized controlled trials and/or observational studies that compare the effectiveness of brief suicide-prevention interventions for youth ages 15 to 24, with particular interest in culturally adapted approaches for specific populations at increased risk.
- Funds Allocated: \$30M
- Total Direct Costs per Project: Up to \$10M
- Maximum project period: 5 years

Cycle 3 2020 – Suicide Prevention: Brief Interventions for Youth

Slate of 4 Recommended Projects



Project Title	
A Comparison of Two Brief Suicide Prevention Interventions Tailored for Youth on the Autism Spectrum	
Comparative Effectiveness of Two Culturally Centered Suicide Intervention for Alaska Native Youth	
Preventing Suicide among Sexual and Gender Diverse Young Adults in Primary Care in Texas	
Youth Partners in Care for Suicide Prevention (YPIC-SP)	
Proposed Total Award*:	\$37M

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 3 2020 –Suicide Prevention: Brief Interventions for Youth PFA

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

Broad PFAs

Cycle 3 2020 Award Slate

Steve Clauser, PhD, MPA

Program Director, Healthcare Delivery and Disparities Research

Holly Ramsawh, PhD

Senior Program Officer, Clinical Effectiveness and Decision Science

Stanley Ip, MD

Interim Program Director, Clinical Effectiveness and Decision Science

Cycle 3 2020 – Addressing Disparities

Slate of 8 Recommended Projects



Project Title	
BEhavioral Health Stratified Treatment (BEST) to optimize transition to adulthood for youth with IDD	
Black midwives for Black women: Maternity care to improve trust and attenuate structural racism	
Clinically-integrated Breastfeeding Peer Counseling to Promote Breastfeeding Equity	
Culturally Adapted Online Couples Communication Program for Latina Breast Cancer Patients*	
Evaluation of telehealth services on mental health outcomes for people with IDD	
Reducing Racial Disparities in Maternal Care through Data-Based Accountability and Doula Support	
The Path to Optimal Black Maternal Heart Health: Comparing Two CVD Risk Reduction Interventions	
Vida Sana y Completa Trial: Treating obesity and food insecurity among Latina women*	
Proposed Total Award**:	\$52M

*Resubmission

** All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 3 2020 – Improving Healthcare Systems

Slate of 3 Recommended Projects



Project Title	
Comparative Effectiveness Trial of Two Supportive Cancer Care Delivery Models for Adults with Cancer*	
Comparing Two Ways to Manage Lymphedema in Head and Neck Cancer Survivors*	
Evaluating the Effectiveness of Mode of Meal Delivery on the Ability of Homebound Older Adults to Remain in the Community*	
Proposed Total Award**:	\$14M

*Resubmission

** All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 3 2020 – Assessment of Prevention, Diagnosis, and Treatment Options

Slate of 2 Recommended Projects



Project Title	
Music Therapy vs. Cognitive-Behavioral Therapy for Cancer-related Anxiety (MELODY)	
Treat-to-Target of Endoscopic Remission in Patients with IBD in Symptomatic Remission: Pragmatic RCT*	
Proposed Total Award**:	\$10M

*Resubmission

**All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 3 2020 – Improving Methods for Conducting PCOR

Slate of 6 Recommended Projects



Project Title	
Advanced Computation approaches for integrating data to assess effect heterogeneity	
Design and Methodological Development for a Patient Preference SMART*	
Mixed Data Meta Analysis: Integration of Individual Participant and Aggregate Data*	
New methods for planning cluster randomized trials to detect treatment effect heterogeneity	
Semantic Data Quality Standards for Multi-Center Clinical Research Studies and Networks*	
Studying Methods for Ethical and Human Subjects Protections Issues in Digital Health PCOR/CER	
Proposed Total Award*:	\$6M

*Resubmission

**All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 3 2020 Broad PFAs

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

Limited Competition: Dissemination and Implementation PFA

Implementation of PCORI-Funded Patient-
Centered Outcomes Research Results

Cycle 3 2020 Award Slate

Sharon Levine, MD

Vice Chair, Engagement, Dissemination, and
Implementation Committee

Joanna Siegel, SM, ScD

Director, Dissemination and Implementation Program



Project Title	
Implementing an Intervention to Address Concerns of Older Patients with Cancer Receiving Chemotherapy and Their Caregivers	
Proposed Total Award*:	\$1.4M

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended award slate from the Cycle 3 2020 Limited Competition Dissemination and Implementation PFA

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

Strategic Planning Update

Sharon Levine, MD

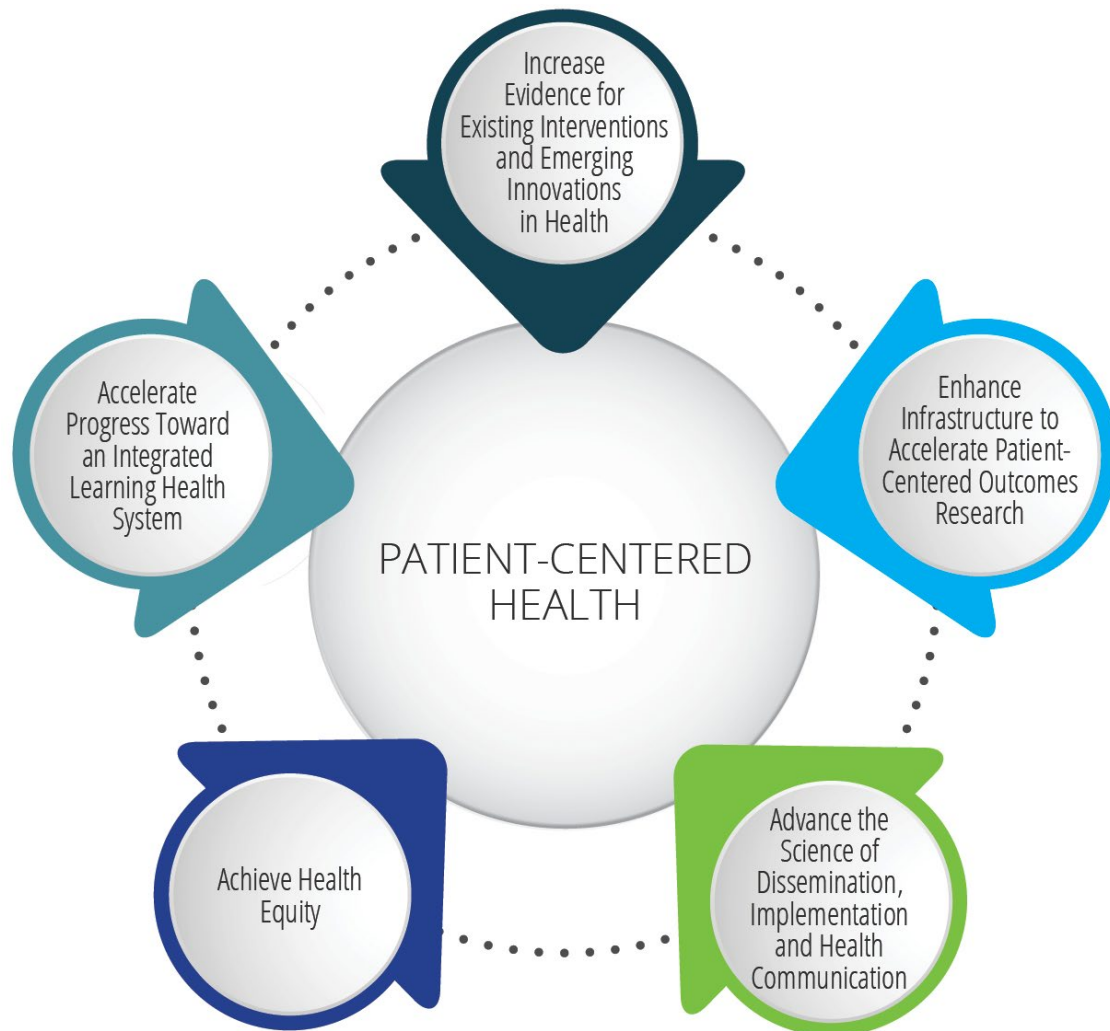
Co-Chair, Strategic Planning Committee

Nakela L. Cook, MD, MPH

Co-Chair, Strategic Planning Committee

National Priorities Public Comment Period

June 28– August 27



Help Shape PCORI's Proposed National Priorities

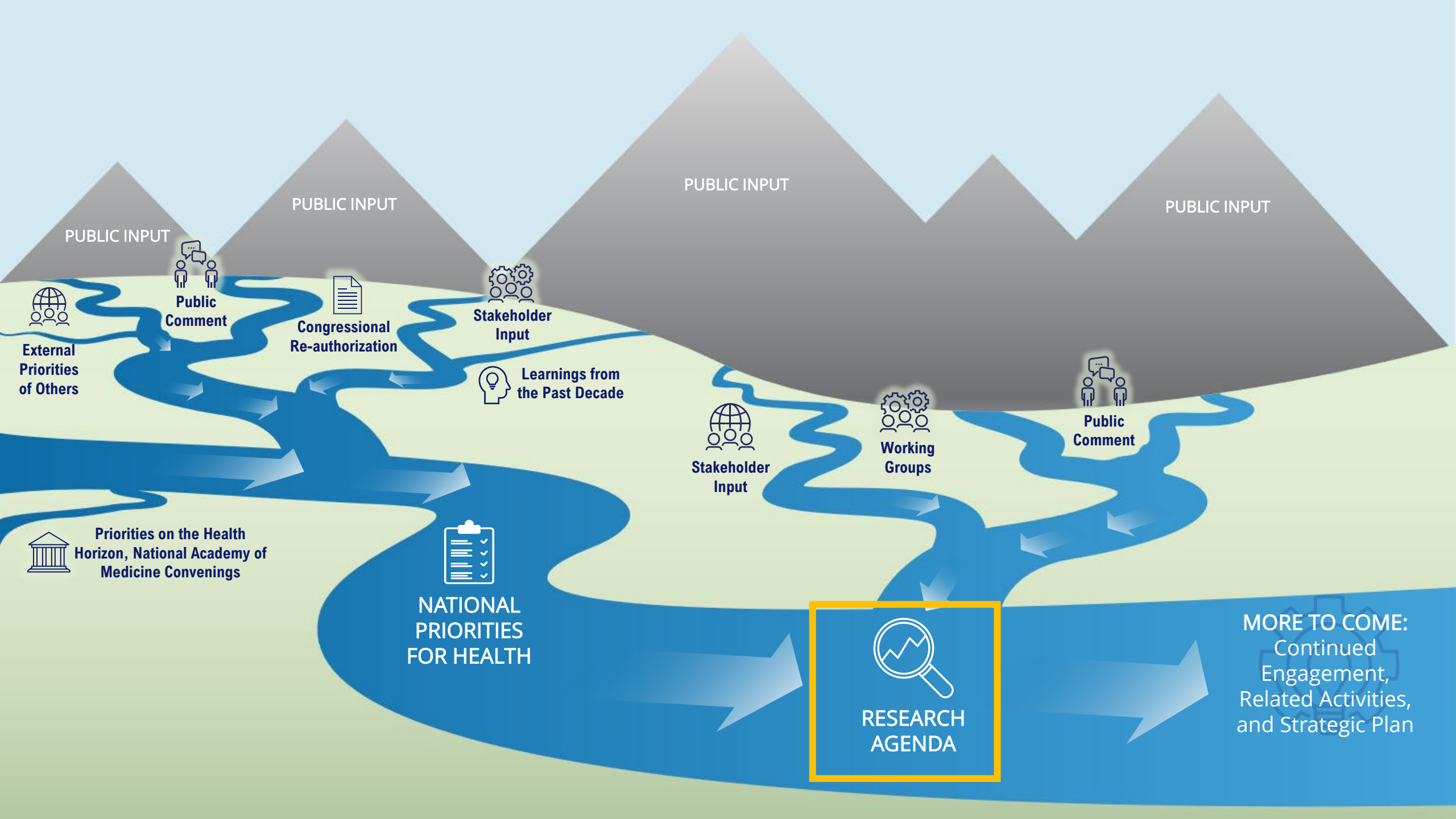
The proposed priorities will serve as a framework to guide PCORI's funding decisions and related initiatives. Let us know what you think — in English or in Spanish — during a 60-day comment period that ends on August 27.

[Share Your Comments](#)

Webinar About PCORI's Proposed National Priorities

Learn more about the proposed National Priorities for Health, PCORI and its mission, the various opportunities to provide input and shape the proposed priorities, and other elements of our strategic planning efforts.

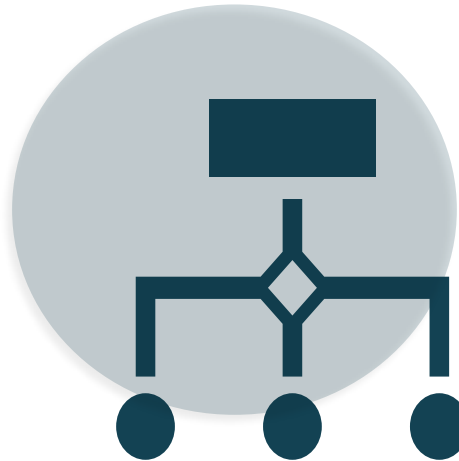
[Watch the Webinar](#)



Why is a Research Agenda Needed?



Establishes framework through which PCORI achieves progress on National Priorities

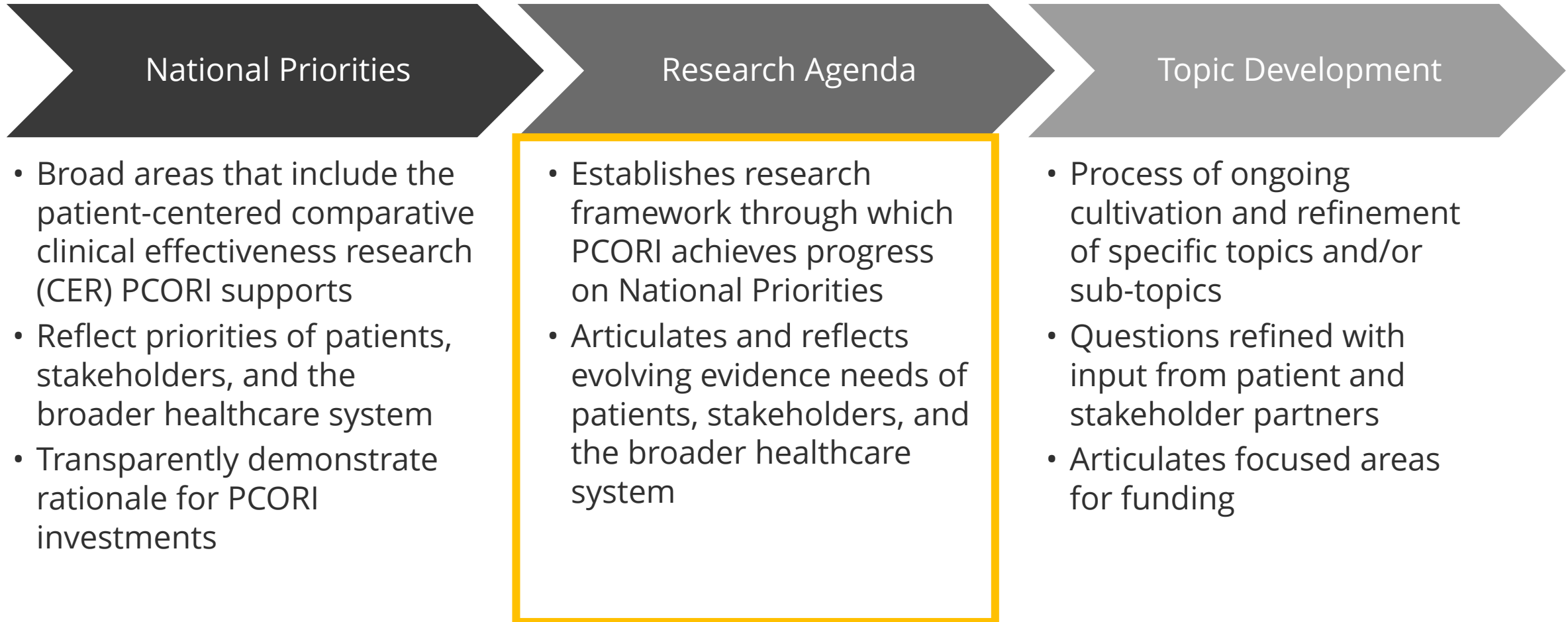


Supports ability to be responsive to evidence needs of stakeholders



Fulfills statutory requirement

Where the Research Agenda Fits



Examples of Input Already Received

In speaking with stakeholders about the National Priorities, we heard comments that ranged from specific conditions to research-related issues for each priority.*

Priority- specific

- Systemic and structural racism (health equity)
- Evidence gaps (emerging innovations)
- Telehealth (learning health system)
- Health literacy (health communication)
- Workforce training and capacity building (infrastructure)

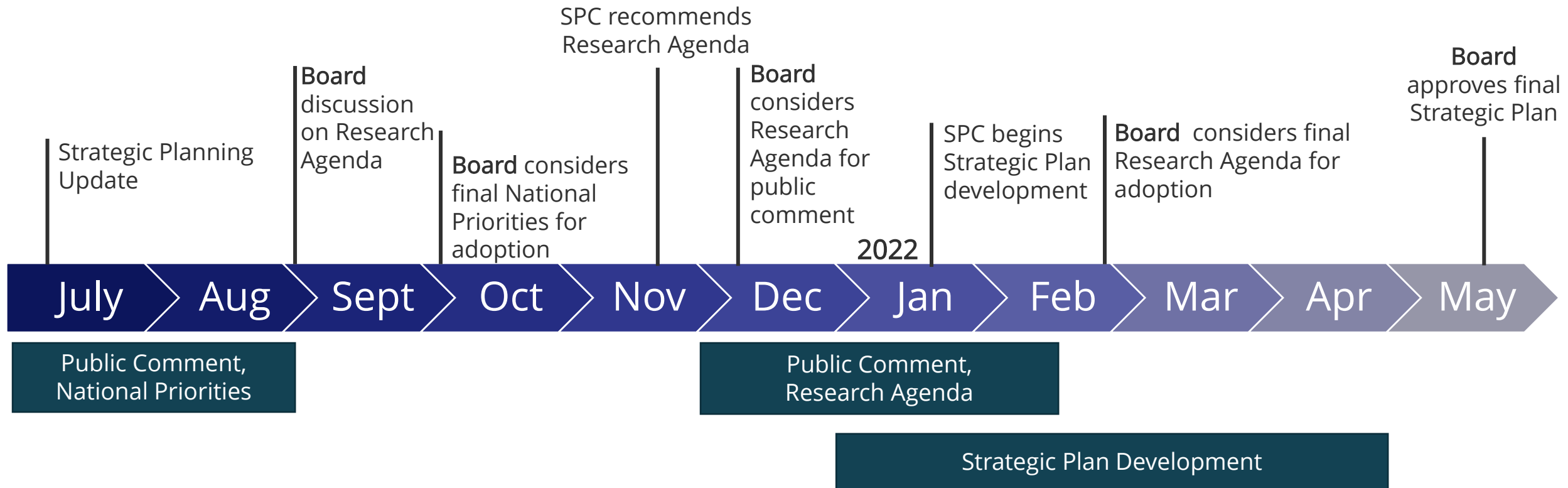
Cross- cutting

- PCORI's unique role
- Technological advances
- Research, community partnerships
- Health equity
- Data representativeness
- Evaluation and metric development

Conditions

- Long COVID-19
- Obesity/Diabetes
- Alzheimer's, dementia, and neurological issues
- Mental health, addiction, substance abuse, suicide prevention
- Palliative and hospice care

Anticipated Timeline



Note: Methodology Committee focus, MMM, and IDD decision points to be added when dates become available

Wrap Up and Adjournment

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