Board of Governors Meeting

Via Teleconference/Webinar

August 21, 2018
12:00 PM – 1:30 PM ET

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

12:00 PM	**Call to Order,** Roll Call, and Welcome
12:00 – 12:05	**Consider for Approval:** Minutes of the July 24, 2018 Board Meeting
12:05 – 12:20	**Consider for Approval:** Proposed Advisory Panel Members
12:20 – 1:00	**Consider for Approval:** Proposed Slates, Cycle 2 2017 and Cycle 3 2017
1:00 – 1:15	**Consider for Approval:** Planning for Implementation of the FY18 Funding Commitment Plan for PCORnet Network Support
1:15	Wrap up and Adjournment

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the July 24, 2018 Board 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

Approval of Advisory Panel Members

Sharon Levine, MD
Incoming Chair, Engagement, Dissemination,
and Implementation Committee

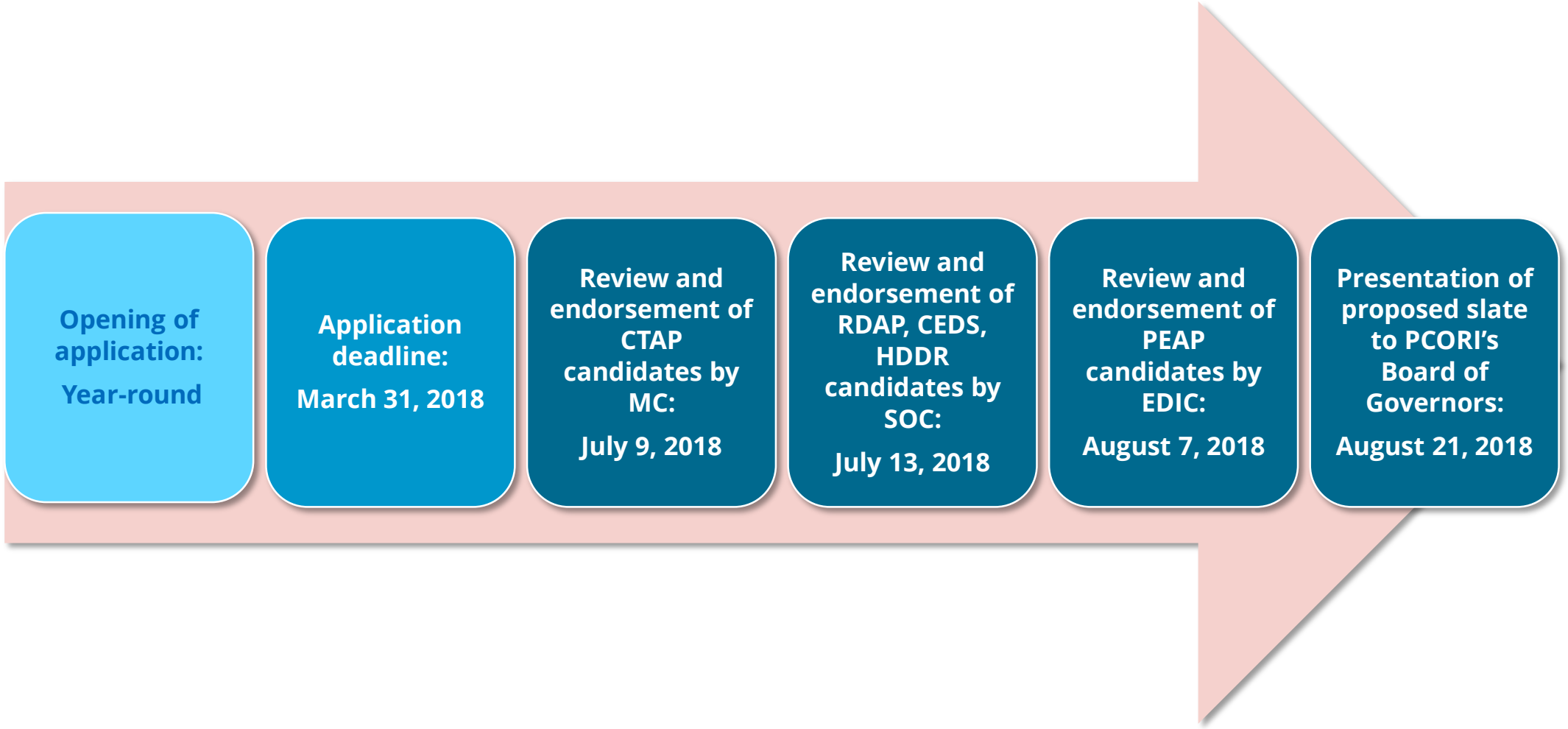
Robert Zwolak, MD, PhD
Chair, Science Oversight Committee

Robin Newhouse, PhD, RN
Chair, Methodology Committee

Jean Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer

Diane E. Bild, MD, MPH
Acting Chief Science Officer

Advisory Panel Selection Timeline



Total Applications Received

Advisory Panel	Applications Received
Rare Disease	57
Clinical Trials	80
Clinical Effectiveness and Decision Science	89
Healthcare Delivery and Disparities Research	131
Patient Engagement	204
Total	**561**

Proposed Panelists

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Reappointed Panelists	Proposed Number of Chairs/Co-Chairs	Total Number of Panelists*
Rare Disease	7	0	0	14
Clinical Trials	5	0	0	15
Clinical Effectiveness and Decision Science	2	0	0	32
Healthcare Delivery and Disparities Research	3	0	0	25
Patient Engagement	11	5	2	23
Total	**28**	**5**	**2**	**109**

***total number of panelists - includes proposed, reappointed, and current panelists**

Panelists Proposed by the EDIC

Sharon Levine, MD

Incoming Chair, Engagement, Dissemination, and Implementation Committee

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer

Advisory Panel on Patient Engagement: Proposed Panelists

- Eleven new panelists are being nominated to serve on the PEAP
- Five current panelists, having served a 2-year term, are being recommended for an additional 1-year term, to complete a 3-year term and balance the number of staggered terms
- A new Chair, David White, and Co-Chair, Thomas Scheid, are also being nominated to these positions

Advisory Panel on Patient Engagement: Proposed Panelists

Name	Stakeholder Group	Primary Affiliation	Term (in Years)
Jennifer Canvasser	Patients, Caregivers, and Patient Advocates	Necrotizing Enterocolitis Society	3
Gwen Darien	Patients, Caregivers, and Patient Advocates	National Patient Advocate Foundation	3
Marilyn Geller*	Patients, Caregivers, and Patient Advocates	Celiac Disease Foundation	3
Jill Harrison	Patients, Caregivers, and Patient Advocates	Planetree International	3
Anita Roach	Patients, Caregivers, and Patient Advocates	National Sleep Foundation	3
Sandy Sufian	Patients, Caregivers, and Patient Advocates	University of Illinois at Chicago	3
James Harrison	Researcher	University of California, San Francisco	3
Matthew Hudson	Researcher	Greenville Health System	3
Maureen Fagan	Clinician	University of Miami Health System	3
Sarah Donelson	Life Sciences Industry	BioMarin Pharmaceuticals	3
Umair Shah	Policy Maker	Harris County Public Health	3

***Proposed panelists that were nominated by a third party organization have been marked with an asterisk**

Advisory Panel on Patient Engagement: Term Extensions - One Year

Name	Stakeholder Group	Primary Affiliation	Term (in years)
Emily Creek	Patients, Caregivers, and Patient Advocates	Arthritis Foundation	1
Ting Pun	Patients, Caregivers, and Patient Advocates	Retired	1
David White	Patients, Caregivers, and Patient Advocates	Independent Healthcare Consultant	1
Megan Lewis	Researcher	RTI International	1
Jack Westfall	Clinician	Santa Clara Valley Medical Center	1

Advisory Panel on Patient Engagement: Proposed Chair and Co-Chair

Name	Proposed New Role	Stakeholder Group	Primary Affiliation	Remaining Year(s)
David White	Chair	Patients, Caregivers, and Patient Advocates	Independent Healthcare Consultant	1
Thomas Scheid	Co-Chair	Patients, Caregivers, and Patient Advocates	Retired	2

Panelists Proposed by the SOC and MC

Robert Zwolak, MD, PhD
Chair, Science Oversight Committee

Robin Newhouse, PhD, RN
Chair, Methodology Committee

Diane E. Bild, MD, MPH
Acting Chief Science Officer

Advisory Panel on Rare Disease: Proposed Panelists

Name	Stakeholder Group	Primary Affiliation	Term (in years)
Roxanna Bendixen	Researcher	University of Pittsburgh	3
Scott Berns	Clinician	National Institute for Children's Health Quality	3
Sherene Shalhub	Clinician	University of Washington Department of Surgery	3
Kathleen Babich*	Patients, Caregivers, and Patient Advocates	Middlesex County College	3
Vanessa Boulanger	Patients, Caregivers, and Patient Advocates	National Organization for Rare Disorders	3
Julie Gortze	Patients, Caregivers, and Patient Advocates	Rare New England	3
Tilicia Mayo-Gamble	Patients, Caregivers, and Patient Advocates	Georgia Southern University	3

***Proposed panelists that were nominated by a third party organization have been marked with an asterisk**

Advisory Panel on Clinical Trials: Proposed Panelists

Name	Stakeholder Group	Primary Affiliation	Term (in years)
Catherine Crespi	Researcher	UCLA Fielding School of Public Health	3
Nancy Dreyer	Researcher	IQVIA (Formerly Quintiles and IMS Health)	3
Elisa A. Hurley	Researcher (Ethicist)	PRIM&R	3
Henry Sacks	Researcher	Thomas C Chalmers Clinical Trials Unit, Icahn School of Medicine	3
Jane Perlmutter	Patients, Caregivers, and Patient Advocates	Gemini Group	3

Advisory Panel on Clinical Effectiveness and Decision Science: Proposed Panelists

Name	Stakeholder Group	Primary Affiliation	Term (in years)
Evelyn White	Payer	Blue Cross Blue Shield Minnesota	3
Kate Houghton	Patients, Caregivers, and Patient Advocates	Critical Mass: The Young Adult Cancer Alliance	3

Advisory Panel on Healthcare Delivery and Disparities Research: Proposed Panelists

Name	Stakeholder Group	Primary Affiliation	Term (in years)
Carmen Pace	Patients, Caregivers, and Patient Advocates	Facing Our Risk of Cancer Empowered	3
Kathy Phipps	Patients, Caregivers, and Patient Advocates	Memorial Hermann Health System	3
Barbara Warren	Patients, Caregivers, and Patient Advocates	Mount Sinai Health System	3

Board Vote

Call for a Motion to:	• **Approve** the proposed slates of members, positions, and terms for the following Advisory Panels: PEAP, RDAP, CTA, CEDS, HDDR
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

Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Noncancer Pain

Cycle 2 2017 Award Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Cycle 2 2017 – Strategies to Prevent Unsafe Opioid Prescribing
Objective of the PFA

- PCORI seeks to fund studies that compare two or more alternatives to prevent unsafe opioid prescribing in primary care among patients with acute or chronic non-cancer pain, while ensuring adequate or improved pain management

Priority Research Questions:

- What is the comparative effectiveness of different **payer or health-system strategies** that aim to prevent unsafe opioid prescribing while ensuring access to non-opioid methods for pain management with the goal of reducing pain and improving patient function and quality-of-life outcomes, while reducing patient harm?
- What is the comparative effectiveness of different **patient- and provider-facing interventions** that facilitate improved knowledge, communication, and shared decision making about the relative harms and benefits of opioids and alternative treatments on prevention unsafe prescribing and improved patient outcomes?

Cycle 2 2017 – Strategies to Prevent Unsafe Opioid Prescribing
Merit Review Criteria

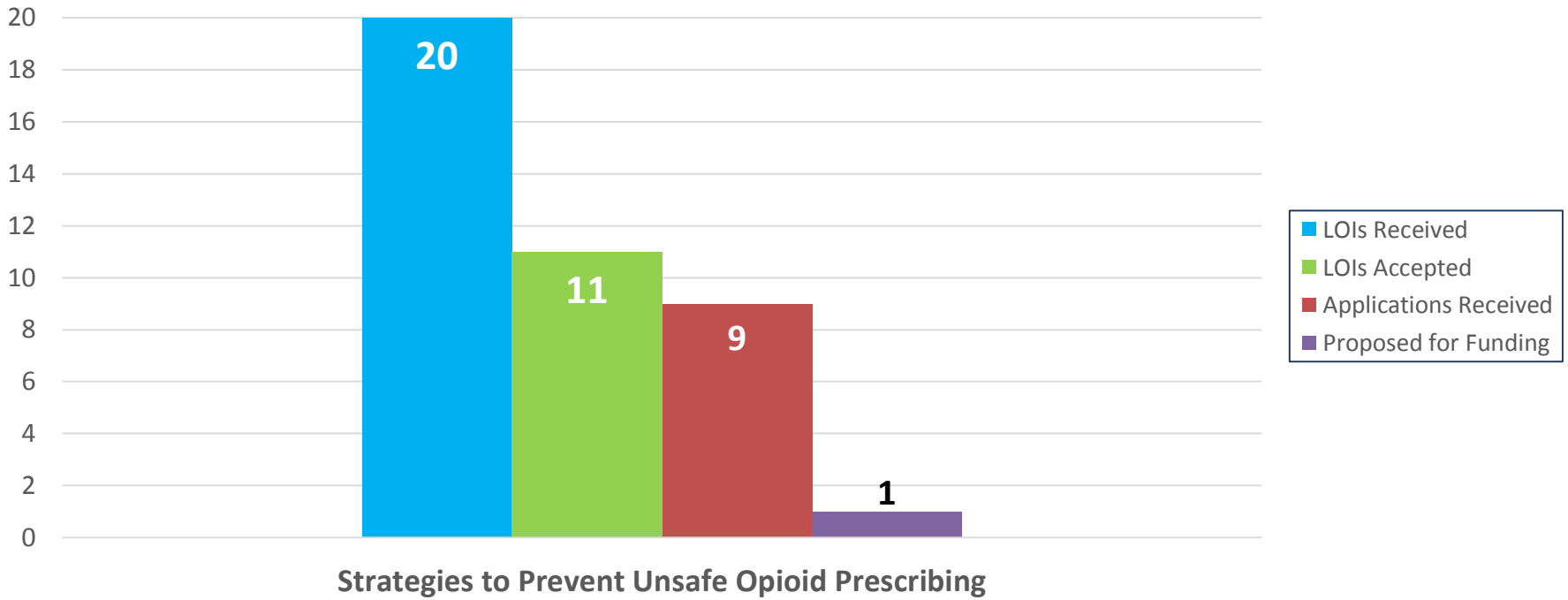
1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

Cycle 2 2017 – Strategies to Prevent Unsafe Opioid Prescribing
Process Overview

- 20 Letters of Intent (LOIs) submitted
- 11 LOIs invited to submit a full application **(55%)**
- 9 applications were received **(82% of invited LOIs)**

Funding rate is 11 percent

- We are proposing to fund 1 application* out of 9 received applications



*Recommended by the Selection Committee

Cycle 2 2017 – Strategies to Prevent Unsafe Opioid Prescribing
1 Recommended Project*

Project
Comparative Effectiveness of Two State Payer Strategies to Prevent Unsafe Opioid Prescribing ($5M)

* 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: Comparative Effectiveness of Two State Payer Strategies to Prevent Unsafe Opioid Prescribing

- **Research Question:** What is the comparative effectiveness of different **payer or health system** strategies that aim to prevent unsafe opioid prescribing?
- **Population:** Injured workers (age 18-64) with work-related musculoskeletal conditions who have been prescribed at least one opioid in the first six weeks since injury
- **Study Design:** A nested, mixed methods study comparing prospective cohorts in two state workers' compensation programs that use different approaches to prior authorization (PA)
  - A sub-study where about half of all injured workers receive coordinated, stepped care aimed at preventing chronic disabling pain and half do not
  - Qualitative component to assess barriers and facilitators
- **Comparator(s):** Prospective PA with hard stops vs. retrospective review with prescriber notification
  - In sub-study, injured workers receiving PA alone (usual care) vs. those subject to PA within the collaborative, stepped care model
- **Outcomes of Interest:**
  - Primary: Unsafe prescribing measures (chronic use > 60 days), concurrent sedatives and hypnotics, high dose ≥50 morphine milligram equivalents (MME) for chronic phase
  - Secondary: Prescribing measures: scripts > 7 days for subacute phase; Patient-reported outcomes on pain, pain interference (powered for both of these), function, QOL, return to work, opioid-related items
- **Length of Follow-up:** 12 months after injury
- **Total Project Cost:** $5M (project duration: 3 years)

Project 1: Comparative Effectiveness of Two State Payer Strategies to Prevent Unsafe Opioid Prescribing

- **Potential Impact:** Could inform mechanisms to prevent unsafe prescribing of opioids throughout the United States. The collaborative, stepped care model could prove to be an important program for improving patient QOL, reducing pain, and improving functioning
- **Patient-Centeredness:** Patient involvement in:
  - Developing the application
  - Prioritizing outcome measures such as pain, pain interference with activities, quality of life, and return to work
  - Designing patient survey on injured worker experiences with the opioid review process and potential impacts on workers' lives
- **Engagement:** Study Advisory Committee to include:
  - Injured workers
  - Pharmacy managers
  - National and state leaders from workers' compensation insurers
  - Primary care clinicians
  - National pain advocacy and support groups

Cycle 2 2017 – Strategies to Prevent Unsafe Opioid Prescribing
1 Recommended Project*

PFA	Amount Budgeted	Proposed Total Award
Cycle 2 2017 Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Noncancer Pain	**$20M**	**$5M**

* 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 from the Cycle 2 2017 Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Noncancer Pain 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
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Pragmatic Clinical Studies
Cycle 3 2017 Award Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Cycle 3 2017 – Pragmatic Clinical Studies
Merit Review Criteria

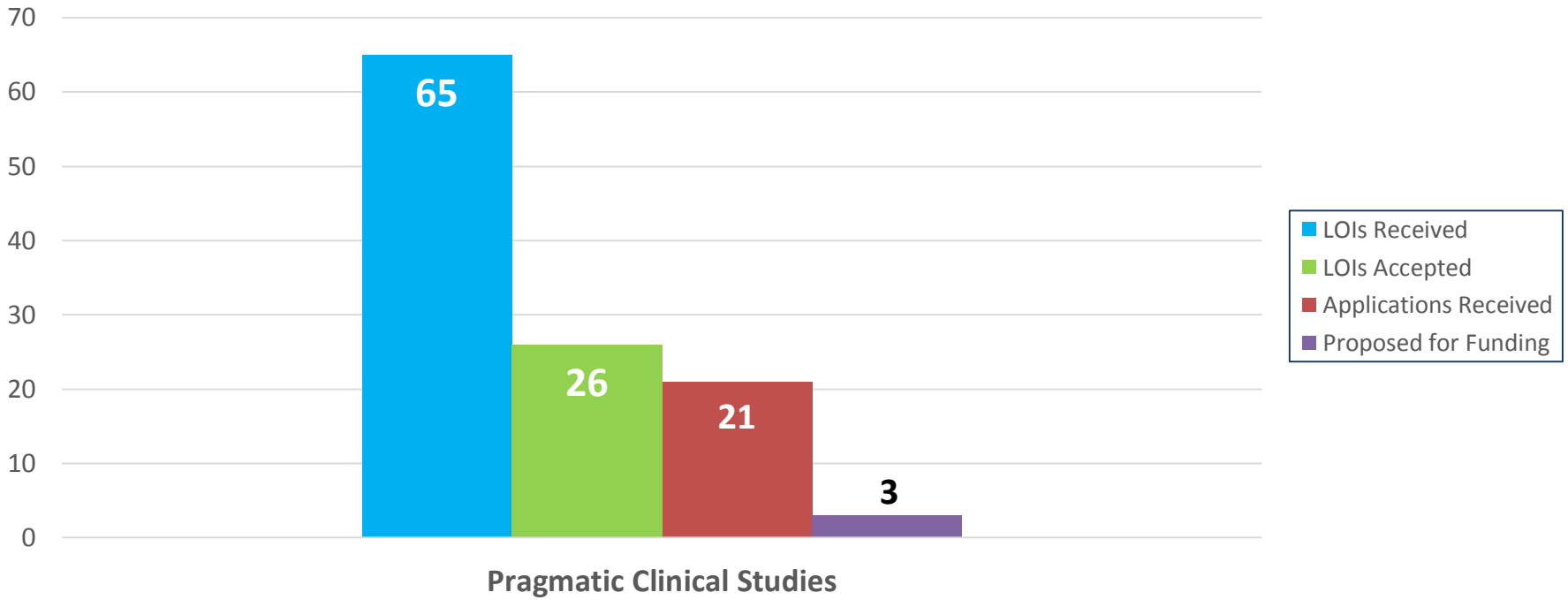
1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

Cycle 3 2017 – Pragmatic Clinical Studies
Process Overview

- 65 Letters of Intent (LOIs) submitted
- 26 LOIs invited to submit a full application **(40%)**
- 21 applications were received **(81% of invited LOIs)**

Funding rate is 14 percent

- We are proposing to fund 3 applications* out of 21 received applications



*Recommended by the Selection Committee

Cycle 3 2017 – Pragmatic Clinical Studies
3 Recommended Projects*

Project
Comparative Effectiveness Randomized Trial to Improve Stroke Care Delivery: C3FIT: Coordinated, Collaborative, Comprehensive, Family-Based, Integrated, and Technology-Enabled Care ($15.7M)
CISTO: Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer ($8.5M)
Remote Cognitive Behavior Therapy for Major Depression (RTD) in Primary Care ($13.3M)

Resubmissions in Bold

* 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: Comparative Effectiveness Randomized Trial to Improve Stroke Care Delivery: C3FIT: Coordinated, Collaborative, Comprehensive, Family-Based, Integrated, and Technology-Enabled Care

- **Research Question:** Is the patient-centered Integrated Stroke Practice Unit superior to the current model of stroke care, the Comprehensive/Primary Stroke Center?
- **Population:** Patients age 18+ years with a confirmed stroke diagnosis
- **Intervention:** Integrated Stroke Practice Unit (ISPU)
- **Comparator(s):** Joint Commission-certified Comprehensive/Primary Stroke Centers (CSC/PSC)
- **Outcomes of Interest:**
  - Primary: Patient function and QOL
  - Secondary: Short-term function and QOL; control/management of stroke risk factors; recurrent stroke rates; hospital readmission rates; and durability of CSC/PSC vs ISPU treatment differences
- **Study Design:** Cluster Randomized Controlled Trial (18 stroke centers)
  - Sample Size: 1,800 patients diagnosed with stroke
- **Duration of Active Intervention:** 12 months
- **Length of Follow-up:** 24 months
- **Total Project Cost:** $15.7M

Project 1: Comparative Effectiveness Randomized Trial to Improve Stroke Care Delivery: C3FIT: Coordinated, Collaborative, Comprehensive, Family-Based, Integrated, and Technology-Enabled Care

- **Potential Impact:** This study will provide trial evidence to determine if the ISPU stroke care model is superior to the current model of stroke care and results may inform professional organizations regarding stroke care and accreditation standards
- **Patient-Centeredness:** Fragmented stroke care negatively impacts outcomes for stroke patients. This study will assess the superiority of a coordinated and patient-centered stroke care model on outcomes that are endorsed by patients and their caregivers
- **Engagement:**
  - Patient and other stakeholder partners (i.e., caregivers, systems, CMS, professional organizations) from the CMS-funded pilot project will continue to participate in the proposed study steering and engagement committees
  - Research team has developed partnerships with national professional and accrediting organizations

Project 2: CISTO: Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer

- **Research Question:** What is the comparative effectiveness of intravesical versus surgical therapy for patients with non-muscle-invasive bladder cancer (NMIBC) that recurs after initial non-surgical treatment?
- **Population:** patients with NMIBC ≥18 years who received BCG first-line therapy and experienced either recurrent disease or intolerance to treatment
- **Comparators:** Intravesical therapy (repeat BCG induction, chemotherapy, or new treatments) vs. radical cystectomy
- **Outcomes of Interest:**
  - Primary: Cancer-related quality of life
  - Secondary: Self-reported urinary and sexual function; attitudes about treatment; healthcare utilization; return to work/normal activities; and cancer control outcomes
- **Study Design:** Prospective observational cohort study
  - Sample Size: 900 patients (300 cystectomy and 600 intravesical therapy)
- **Length of Follow-up:** 12 months
- **Total Project Cost:** $8.5M

Project 2: CISTO: Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer

- **Potential Impact:** Findings will provide information to help patients and clinicians choose between two treatments that differ in their associated morbidities
- **Patient-Centeredness:** Patients with NIMBC and their caregivers identified the outcome metrics that matter most to them
- **Engagement:**
  - Prior PCORI Engagement Award provided research training to patients and caregivers, facilitating meaningful engagement throughout the proposed study
  - Advocate Advisory Board and Clinician Advisory Board will work with research team to oversee study conduct and dissemination
  - Engaged patient organizations and professional medical associations to disseminate study findings

Project 3: Remote Cognitive Behavior Therapy for Major Depression (RTD) in Primary Care

- **Research Question:** What is the comparative effectiveness of provider access to guided vs. unguided internet-based Cognitive Behavior Therapy (eCBT) for patients with Major Depressive Disorder (MDD)?
- **Population:** Adults in rural areas aged 18+ seeking MDD treatment in FQHC/primary care practice for the first time in the past six months
- **Interventions:** Provider access to unguided eCBT or to guided eCBT with remote case management
- **Comparator:** Usual care (typically antidepressants; providers do not have access to eCBT)
- **Outcomes of Interest:**
  - Primary: Remission at 16 weeks post-baseline; remission maintenance at 26 weeks
  - Secondary: depressive and non-depressive symptoms (e.g., anxiety), substance use symptoms; antidepressant medication (ADM) treatment adherence, treatment engagement, shared decision-making
- **Study Design:** Cluster RCT (234 Primary Care Providers)
  - Sample Size: 8,000
- **Duration of Active Intervention:** 16 weeks
- **Length of Follow-up:** 26 weeks
- **Total Project Cost:** $13.3M

Project 3: Remote Cognitive Behavior Therapy for Major Depression (RTD) in Primary Care

- **Potential Impact:** Study results may inform the level of intensity (beyond usual care) that different MDD patients prefer and require with eCBT to improve functioning. This study has the potential to expand rural primary care options for providing eCBT for the treatment of MDD

- **Patient-Centeredness:** MDD causes serious illness burden for patients without access to appropriate therapy. The study results may increase the options for patient-centered treatment for MDD for patients in rural areas. Patients have been and will be involved in the planning, conduct, and dissemination phases of the study. Patients endorsed proposed study outcomes

- **Engagement:** Several national organizations representing patients, purchasers, and policymakers are represented on the Study Advisory Committee. The study will be conducted in collaboration with the regional patient advocacy and research organizations

Cycle 3 2017 – Pragmatic Clinical Studies
3 Recommended Projects*

PFA	Amount Budgeted	Proposed Total Award
Cycle 3 2017 Pragmatic Clinical Studies	**$41M**	**$37.6M**

* 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 2017 Pragmatic Clinical Studies 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
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Broad PFAs
Cycle 3 2017 Award Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Cycle 3 2017 – Broad PFAs
Merit Review Criteria

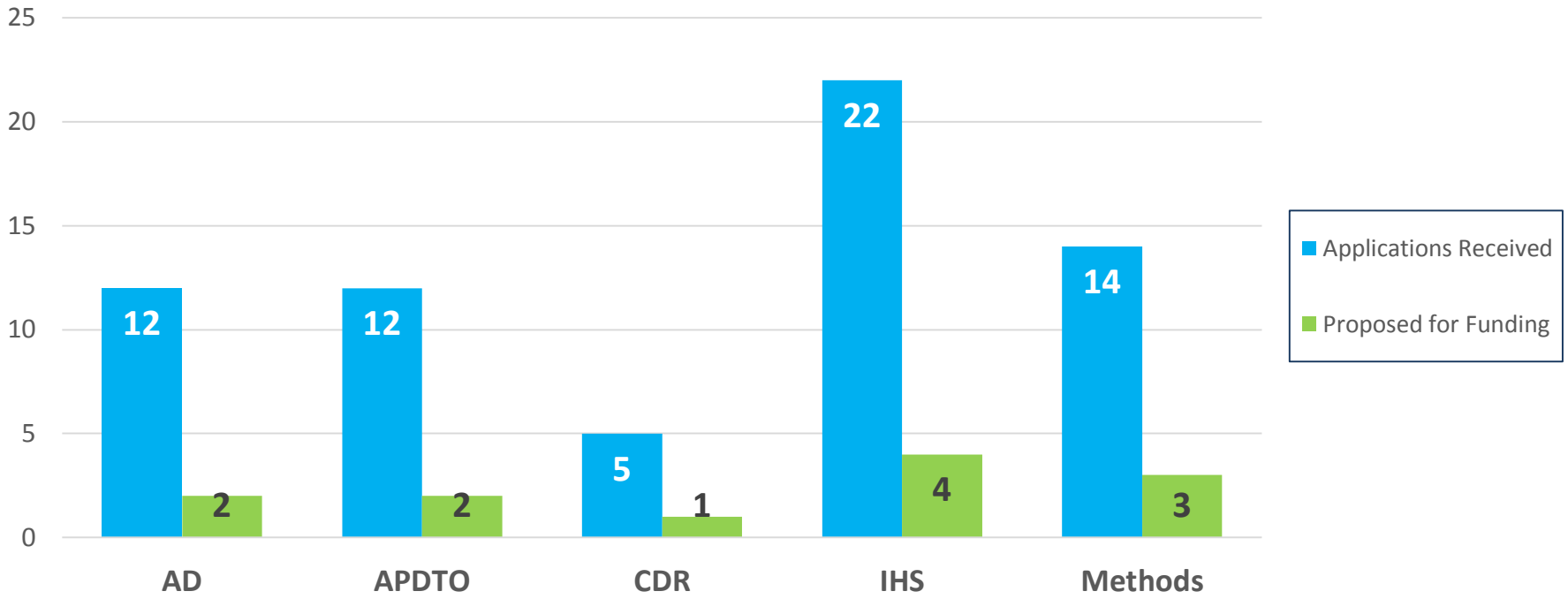
Broad PFAs (excluding Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and Environment 5. Patient-centeredness 6. Patient and stakeholder engagement	**1. Study identifies critical methodological gap(s) in PCOR/CER** **2. Potential for the study to improve PCOR/CER methods** 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and Environment 5. Patient-centeredness 6. Patient and stakeholder engagement

Cycle 3 2017 – Broad PFAs
Process Overview

- 208 Letters of Intent (LOIs) submitted
- 92 LOIs invited to submit a full application **(44%)**
- 65 applications were received **(71% of invited LOIs)**

Funding rate is 18 percent

- We are proposing to fund 12 applications* out of 65 received applications



*Recommended by the Selection Committee

Cycle 3 2017 – Broad PFAs
Slate Overview

Broad PFA	Posted Amount	Proposed Total Award
Addressing Disparities	$8M	$5M
Assessment of Prevention, Diagnosis, and Treatment Options	$32M	$5.6M
Communication and Dissemination Research	$8M	$2.5M
Improving Healthcare Systems	$16M	$27.9M
Improving Methods for Conducting PCOR	$12M	$2.2M
TOTAL:	$76M	$43.2M

* 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 2017 – Broad PFAs
12 Recommended Projects*

PFA	Amount Budgeted	Proposed Total Award
Cycle 3 2017 Broad	$44M	$43.2M

* 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 2017 – Addressing Disparities
2 Recommended Projects*

Project
Patient and Caregiver-Centered Diabetes Telemanagement Program for Hispanic/Latino Patients ($3M)
Effectiveness of Universal vs. Targeted School Screening for Adolescent Major Depressive Disorder ($2M)

Resubmissions in Bold

* 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 2017 – Assessment of Prevention, Diagnosis, and Treatment Options

2 Recommended Projects*

Project
Comparative Effectiveness of Metformin for Type 2 Diabetes with Chronic Kidney Disease ($2.8M)
Transseptal versus Retrograde Aortic Approach to Left Ventricular Catheter Ablation ($2.8M)

* 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 2017 – Communication and Dissemination Research
1 Recommended Project*

Project
A Randomized Trial to Promote Informed Decisions about Cancer Screening in Older Adults (PRIMED Study) ($2.5M)

Resubmissions in Bold
* 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 2017 – Improving Healthcare Systems
4 Recommended Projects*

Project
Preventing Tipping Points in High Comorbidity Patients: A Lifeline from Health Coaches ($7.6M)
Specialty Medical Homes to Improve Outcomes for Patients with Inflammatory Bowel Disease (IBD) and Behavioral Health Conditions ($6.3M)
Primary Care and Community-Based Prevention of Mental Disorders in Adolescents ($7M)
System-Level Capture of Family History Data to Assess Risk of Cancer and Provide Longitudinal Care Coordination ($7M)

Resubmissions in Bold

* 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 2017 – Improving Methods for Conducting PCOR
3 Recommended Projects*

Project
Bayesian Additive Regression Trees for Causal Inference with Multiple Treatments and a Binary Outcome ($438K)
Enhancing Hybrid Study Designs for Comparative Effectiveness Research ($732K)
Improving CER/PCOR Methods for Analyzing Linked Data Sources in the Absence of Unique Identifiers ($982K)

* 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 2017 – Broad PFAs
12 Recommended Projects*

PFA	Amount Budgeted	Proposed Total Award
Cycle 3 2017 Broad	$44M	$43.2M

* 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 2017 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
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Planning for Implementation of the FY18 Funding Commitment Plan for PCORnet Network Support

Freda Lewis-Hall, MD

Chair, Research Transformation Committee

Joe Selby, MD, MPH

Executive Director

This specific commitment request refers to funds set aside for this purpose in our FY18 Approved Funding Commitment Plan

Budget Line	Total FY18 Approved	Committed	This Request
Research	$29.3M	$23.5M	---
Infrastructure (capacity building)	$31.8M	$1.5M	$16.0M

- March 2017: PCORI Board approved initial funding of $25.4M in FY2017 for the People-Centered Research Foundation (PCRF) to support the sustainability of PCORnet, with specific funding for the PCRF program office, various administrative and coordination activities, and $16M for some infrastructure development and support funds for the PCORnet networks
- This request is to commit an additional $16M from the FY2018 funding commitment plan, which was approved last fall, and which contained an additional $16M – the remainder of the funds intended to support network infrastructure in PCORnet 2.0 for FY 2019-2020

This specific request is within the Board-approved FY2018 funding commitment plan and was initially endorsed by the RTC on September 19, 2017.

FY2018 Funding Commitment Plan

Activity	Amount
Infrastructure (Capacity Building)	**$31.8 M**
Network Support	$16.0 M
Data Linkage (Health Plans or other)	$10.0 M
Collaborative Research Group (CRG) Projects Cycle III	$1.2 M
Supplemental Funding, other discretionary.	$4.6 M
PCORnet Research	**$29.3 M**
Partnership to Conduct Research within PCORnet (PaCR)*	$21.0 M
Health Systems Demo Cycle II	$3.0 M
Phased approaches of current initiatives (RCR or Data Linkage)	$4.0 M
Supplemental Funding, other discretionary.	$1.3 M
Total Funding Commitment Plan	**$61.1 M**

*Carry over funds from FY17 approved funding commitment plan

PCRF Progress – 5 Project Statements (funded from FY2017 Funds)

- **PS1- Administration, Governance, and Membership ($3.9M)**
  - Development and release of network membership application
  - Merit review process including external reviewers and site visits
  - 9 CDRNs have been selected for funding during PCORnet 2.0
  - Currently working with networks to develop scope of work and milestones
- **PS2 – Business Development ($1.02M)**
  - Contracted with a business development consultant
  - Consultant has begun to meet with network representatives
- **PS3 – External PCORnet Communications ($1.6M)**
  - Contracted with a communications firm
  - Developing communication goals and strategic plan
- **PS4 – Network Infrastructure Support – *for discussion today***
- **PS5 - PCORnet Policy Development and Implementation ($600K)**
  - Formed policy workgroup to develop policies to support PCORnet network development, governance, sustainability and expansion
  - Relationship between PCORI and PCRF

Project Statement #4: Implementing the Network Infrastructure Support Commitment

- Funds requested here will largely be directed by PCRF to the CDRNs under terms of a negotiated Project Statement and a cost-reimbursement mechanism

- Funded activities over two years will include but not be limited to:
  - Maintaining and improving data quality
  - Query fulfillment to support study feasibility assessment, business development, and data quality standards
  - Patient and stakeholder engagement activities
  - Participation in network governance
  - Participation in business plan development
  - Participation in communications activities
  - Expand clinical trial capacity
  - Data linkage for complete data
  - Participation in PCORnet 2.0 Committees
  - Possible addition of new sites and/or networks

PCRF Project Statement 4	Budget
PCRF Staff and Operations	$2.25 M
Network Support FY 2017 FY 2018	 $16M $16M
TOTAL PS 4 Costs	$34.25M*

**final amount still subject to negotiation*

Board Vote

Call for a Motion to:	• **Approve** up to an additional $16 million for PCORnet network support over the next two years, subject to negotiation of final terms and conditions
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

Wrap Up and Adjournment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