



Special Board of Governors Teleconference/Webinar

***September 10, 2013
12:00 p.m. – 1:00 p.m. ET***

Patient-Centered Outcomes Research Institute



Welcome and Introductions

Eugene Washington, MD, MSc
Chair, Board of Governors

Joe Selby, MD, MPH
Executive Director

Patient-Centered Outcomes Research Institute



PFA Cycle III Applications

Proposed Slate

Christine Goertz, DC, PhD

Board Member and Chair, Program Development Committee

Bryan Luce, PhD, MBA

Chief Science Officer

Patient-Centered Outcomes Research Institute

Cycle III Selection Committee Membership

Board of Governors

- Christine Goertz, DC, PhD
- Debra Barksdale, PhD, RN
- Ellen Sigal, PhD
- Gail Hunt
- Grayson Norquist, MD, MSPH

Methodology Committee

- Michael Lauer, MD

PCORI Staff

- Joe Selby, MD, MPH
- Bryan Luce, PhD, MBA
- Kara Walker, MD, MPH, MSHS
- Chad Boult, MD, MPH, MBA
- Romana Hasnain-Wynia, PhD
- David Hickam, MD, MPH

Slate Overview – Cycle III

What funding opportunities were open?

PCORI Funding Announcement (PFA)	Maximum Project Length (Yrs.)	Maximum Budget (Per Yr.)	Total Cycle Budget (\$96 M)
<i>Addressing Disparities</i>	3	\$500,000	\$12 million
<i>Assessment of Prevention, Diagnosis and Treatment Options</i>	3	\$500,000	\$48 million
<i>Communication and Dissemination Research</i>	3	\$500,000	\$12 million
<i>Improving Healthcare Systems</i>	3	\$500,000	\$24 million

Slate Overview – Cycle III

What is being recommended today?

The Selection Committee recommends a slate with an average funding line at 12.7 percent of responsive applications across the 4 Cycle III PFAs, depending on panel scores and review of established criteria by PCORI's scientific staff

Slate Overview – Cycle III

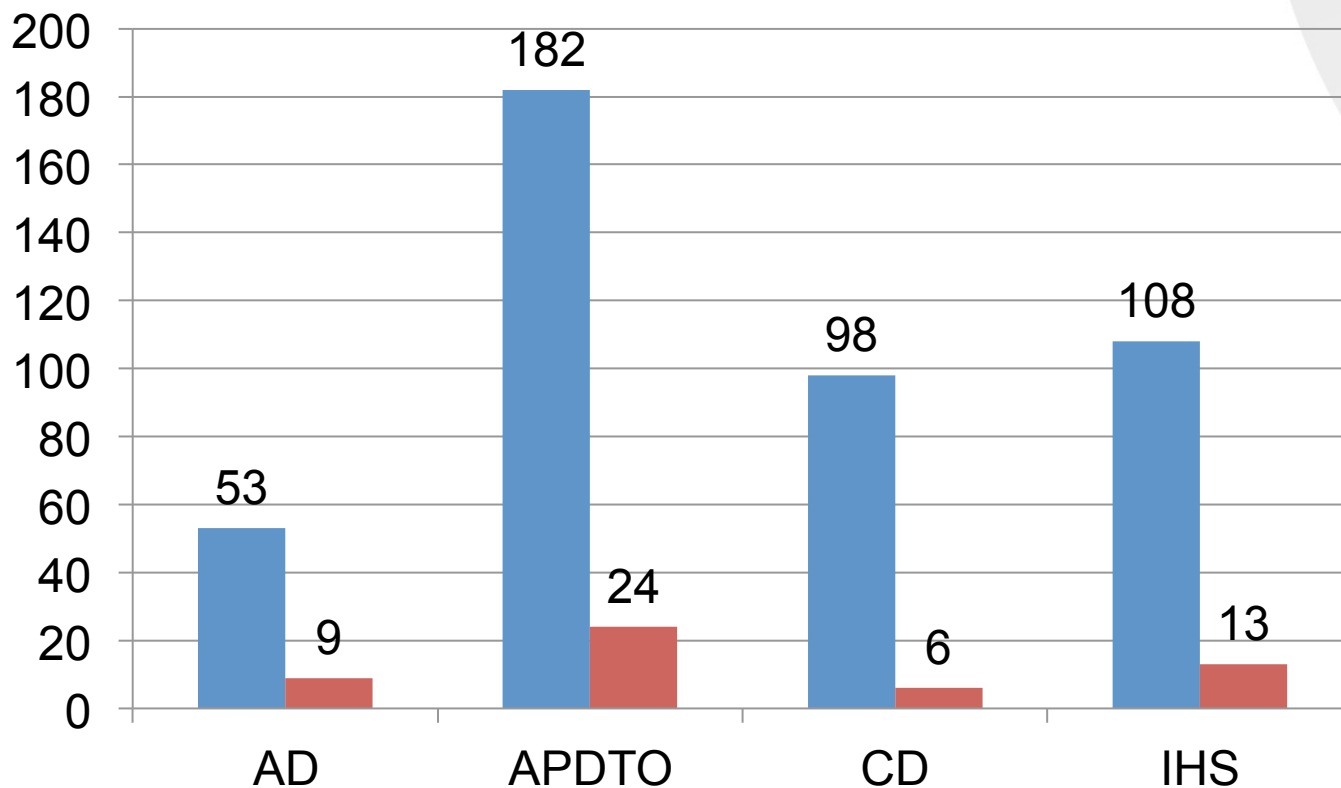
What are we proposing?

PCORI FUNDING ANNOUNCEMENT (PFA)	FUNDING DOLLARS	NUMBER OF PROJECTS
<i>Addressing Disparities</i>	\$15,048,300	9
<i>Assessment of Prevention, Diagnosis and Treatment Options</i>	\$ 45,679,145	24
<i>Communication and Dissemination Research</i>	\$10,938,633	6
<i>Improving Healthcare Systems</i>	\$24,523,025	13
TOTALS:	\$96,189,103	52

Slate Overview – Cycle III

What is the success rate for applications?

Average funding line at 12.7 percent of responsive applications...

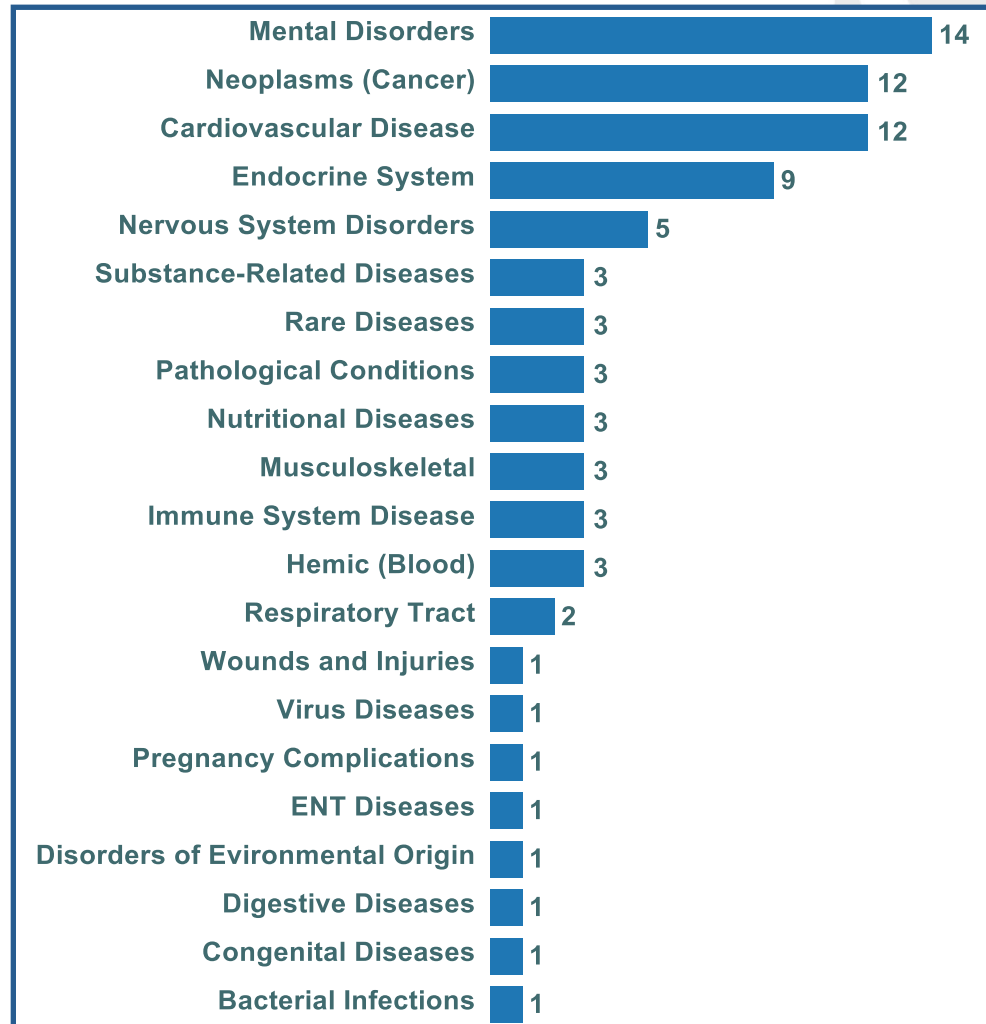


441
Applications

■ Applications Received
■ Identified for Funding

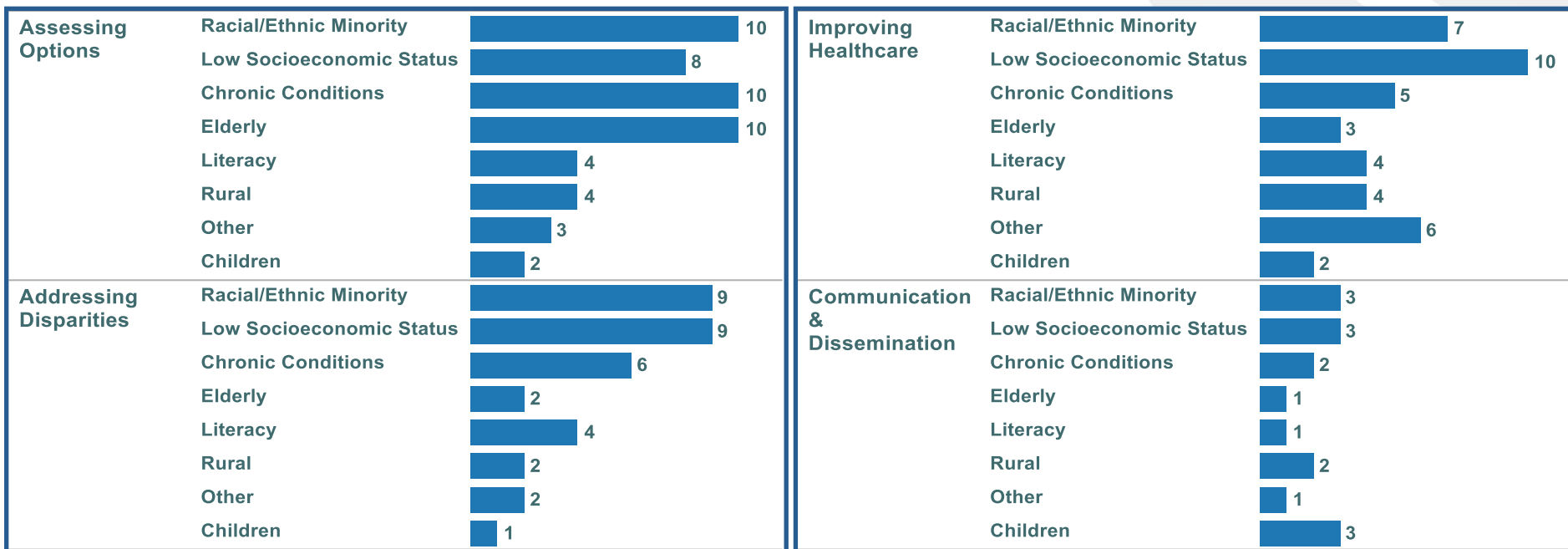
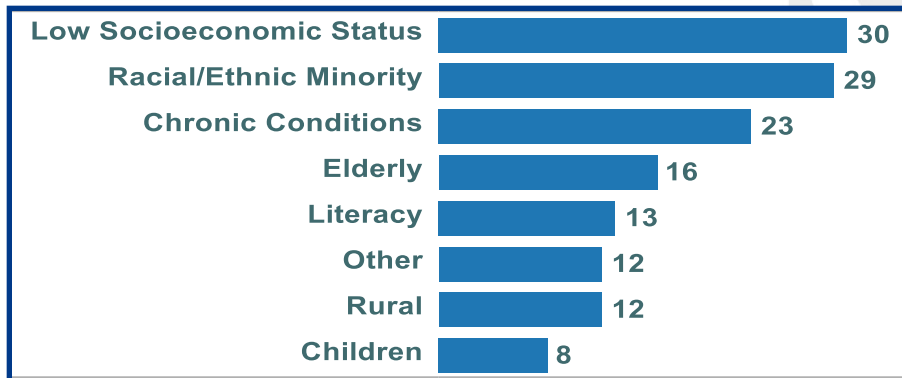
Conditions

What's in the slate?



Populations

What's in the slate?



Addressing Disparities

Project Titles

Addressing Disparities PFA – Project Titles
A Community-Based Executive Function Intervention for Low Income Children with ADHD and ASD
Eliminating Patient Identified Socio-legal Barriers to Cancer Care
Evaluating the Navajo Community Outreach & Patient Empowerment (COPE) Program
A Helping Hand to Activate Patient-Centered Depression Care among Low-Income Patients
Impact of patient navigators on health education and quality of life in formerly incarcerated patients
Improving Health Outcomes among Native Americans with Diabetes and Cardiovascular Disease
Integrative Medicine Group Visits: A Patient-Centered Approach to Reducing Chronic Pain and Depression in a Disparate Urban Population
Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill
Telehealth Self-management Program in Older Adults Living with Heart Failure in Health Disparity Community

Assessment of Prevention, Diagnosis and Treatment Options

Project Titles

Assessment of Prevention, Diagnosis and Treatment Options PFA – Project Titles
Balancing Treatment Outcomes and Medication Burden among Patients with Symptomatic Diabetic Peripheral Neuropathy
Benchmarking the Comparative Effectiveness of Diabetes Treatments Using Patient-Reported Outcomes and Socio-Demographic Factors
Cervical Spondylotic Myelopathy Surgical Trial (CSM-S Trial)
Collaborative Assessment of Pediatric Transverse Myelitis: Understand, Reveal, Educate (CAPTURE) Study
Comparative Effectiveness of Broad vs. Narrow Spectrum Antibiotics for Acute Respiratory Tract Infections in Children
Comparative effectiveness of PEer-Led supplemental O2 Infoline for patients and Caregivers (PELICAN)
Comparative effectiveness of surveillance imaging modalities in breast cancer survivors
Comparing Effectiveness of Treating Depression With and Without Comorbidity to Improve Fetal Health
Comparison of Peer Facilitated Support Group and Cognitive Behavioral Therapy for Hoarding Disorder

Assessment of Prevention, Diagnosis and Treatment Options

Project Titles (cont'd)

Assessment of Prevention, Diagnosis and Treatment Options PFA – Project Titles
Contralateral Prophylactic Mastectomy and Breast Cancer: Clinical and Psychosocial Outcomes
Developing and testing a Personalized, Evidence-based, Shared Decision-Making Tool for Stent Selection in PCI
Improving Informed Consent for Palliative Chemotherapy: Development of a Regimen-Specific Multi-Media Informed Consent Library To Promote Patient-Centered Decision-Making about Treatment of Advanced Gastrointestinal Cancers
Improving Patient Decisions About Bariatric Surgery
Individualized Patient Decision Making for Treatment Choices among Minorities with Lupus
Northern-Manhattan Hispanic Caregiver intervention Effectiveness study (NHICE)
On the Move: Optimizing Participation in Group Exercise to Prevent Walking Difficulty in At-risk Older Adults
Patient Centered Comprehensive Medication Adherence Management System to Improve Effectiveness of Disease Modifying Therapy with Hydroxyurea in Patients with Sickle Cell Disease

Assessment of Prevention, Diagnosis and Treatment Options

Project Titles (cont'd)

Assessment of Prevention, Diagnosis and Treatment Options PFA – Project Titles
Patient-centered Outcomes Recovery from Treating peripheral Arterial disease: Investigating Trajectories (PORTRAIT)- Phase II
Patient-centered Research into Outcomes Stroke patients Prefer and Effectiveness Research (PROSPER)
Patient Centered, Risk Stratified Surveillance After Curative Resection of Colorectal Cancer
Patient-Centered Support for Contraceptive Decision Making
Post-Treatment Surveillance in Breast Cancer: Bringing CER to the Alliance
Quality of life in allogeneic hematopoietic stem cell transplant patients is improved when their caregiver's distress is reduced
Tools and Information to Guide Choice of Therapies in Older & Medically Infirm Patients with AML

Communication and Dissemination

Project Titles

Communication and Dissemination Research PFA – Project Titles

CT Radiation Dose Registry to Ensure a Patient Centered Approach for Imaging

Enhancing Genomic Laboratory Reports to Enhance Communication and Empower Patients

Improving Communication in the Pediatric Intensive Care Unit for Patients Facing Life-Changing Decisions

Randomized Trial to Increase Adherence to Cervical Cancer Screening Guidelines for Young Women

Reducing Unintended Pregnancies Through Reproductive Life Planning and Contraceptive Action Planning

Shared Decision Making and Renal Supportive Care

Improving Healthcare Systems

Project Titles

Improving Healthcare Systems PFA – Project Titles
Building a Multidisciplinary Bridge Across the Quality Chasm in Thoracic Oncology
CASA: Care and Support Access Study for Implementation of a Palliative Approach with HIV Treatment
Changing the Healthcare Delivery Model: A Community Health Worker/Mobile Chronic Care Team Strategy
A Comparative Effectiveness Trial of Optimal Patient-Centered Care for US Trauma Care Systems
Computerized PAINRelieveIt Protocol for Cancer Pain Control in Hospice
Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources
The Impact of Burnout on Patient-Centered Care: A Comparative Effectiveness Trial in Mental Health
Improving Childhood Obesity Outcomes: Testing Best Practices of Positive Outliers
Improving Delivery of Patient-Centered Cardiac Rehabilitation

Improving Healthcare Systems

Project Titles (cont'd)

Improving Healthcare Systems PFA – Project Titles
Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis
Improving Transitional Care Experience for Individuals with Serious Mental Illness
Increasing Health Care Choices and Improving Health Outcomes Among Persons with Serious Mental Illness
An Integrative Multilevel Study for Improving Patient-centered Care Delivery Among Patients with Chronic Obstructive Pulmonary Disease

Key Information to Consider

What's the bottom line for Cycle III?

- Continue to see high-quality and innovative applications
- Proposing to fund 52 projects based on the 409 responsive applications that were received
- Recommending funding total of \$96.19 million in Cycle III
- 22 of the 52 projects recommended for funding are resubmissions
- Slate addresses a range of conditions and the needs of a variety of populations
- PCORI is proposing funding projects in three new states:
 - Connecticut
 - Texas
 - Wisconsin
- The funding rate in Cycle III would be 12.7 percent
 - Increase from 12 percent in Cycle II and 5 percent in Cycle I

Questions & Discussion

- Questions and discussion on the PFA Cycle III proposed slate

Board of Governors Vote

Call for Motion to:

- **Approve the proposed slate** of 52 awards totaling \$96.19M for PFA Cycle III.

Once the Motion Is Seconded:

- **Discussion** of the motion, including consideration of any amendments to the motion.

Vote:

- Roll call **vote to approve the slate.**



Improving Methods Applications Inaugural Proposed Slate

Robin Newhouse, PhD, RN
Chair, Methodology Committee

Rachael Fleurence, PhD
*Program Director, Comparative Effectiveness Research Methods
and Infrastructure*

Patient-Centered Outcomes Research Institute

Selection Committee and Program Staff

Selection Committee

- Robin Newhouse, Chair**
- Debra Barksdale*
- Arnold Epstein*
- Sherine Gabriel**
- Michael Lauer**
- Jean Slutsky**

CER Methods Program Staff

- Rachael Fleurence
- Jason Gerson
- Kelly Dunham

* PCORI Board Members

** PCORI Methodology Committee Members

Overview of Selection Process

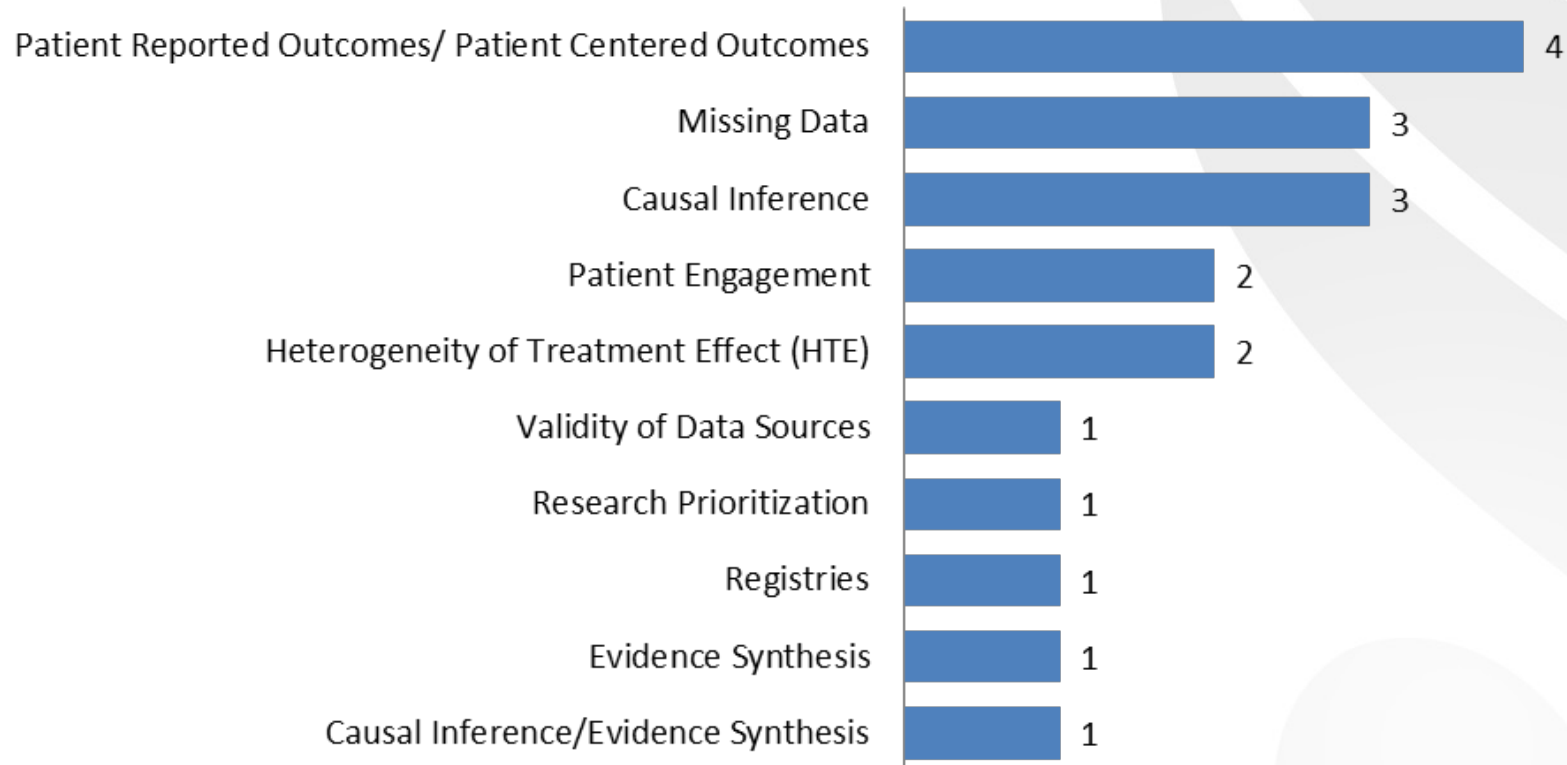
138 applications received by deadline	March 19, 2013
52 applications reviewed by Methods Merit Review Panels	June 13-14, 2013
Top applications were reviewed by PCORI staff for programmatic fit and balance	By July 30, 2013
19 applications recommended for funding	July 31, 2013

Overview of Proposed Slate

Average Budget	\$949,789
Total Budget Amount	\$18,045,991*
Lowest Request	\$535,375
Highest Request	\$1,765,540
Number of Organizations	13

* PCORI established an initial pay line of 10% for the Inaugural Methods cycle. The pay line was expanded to 13.8%.

Proposed Slate by Methods Area



Proposed Slate- Slide 1 of 2

Causal Inference for Effectiveness Research in Using Secondary Data

Methods for Comparative Effectiveness and Safety Analyses in a High-dimensional Covariate Space with Few Events

Development of a Causal Inference Toolkit for Patient-Centered Outcomes Research

Integrating Causal Inference, Evidence Synthesis, and Research Prioritization Methods

Integrating Multiple Data Sources for Meta-analysis to Improve Patient-centered Outcomes Research

Filling Two Major Gaps in the Analysis of Heterogeneity of Treatment Effects for Patient-Centered Outcomes Research

Understanding Treatment Effect Estimates When Treatment Effects Are Heterogeneous For More Than One Outcome

Sensitivity Analysis Tools for Clinical Trials with Missing Data

The Handling of Missing Data Induced by Time-Varying Covariates in Comparative Effectiveness Research Involving HIV Patients

Statistical Methods for Missing Data in Large Observational Studies

Proposed Slate- Slide 2 of 2

Evaluating Methods to Engage Minority Patients and Caregivers as Stakeholders

Creating Locally Relevant Health Solutions with the Appreciative Inquiry and Boot Camp Translation Method

Advancing Stated-preference Methods for Measuring the Preferences of Patients with Type 2 Diabetes

Developing Patient-Centered Outcomes for Dementia: Goal Setting and Attainment

Measuring Patient-Centered Communication for Colorectal Cancer Care and Research

Facilitating Patient Reported Outcome Measurement for Key Conditions

Improving the Use of Patient Registries for Comparative Effectiveness

A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information

Building PCOR Value and Integrity with Data Quality and Transparency Standards

Questions & Discussion

- Questions and discussion on the Inaugural Improving PCOR Methods Cycle proposed slate

Board of Governors Vote

Call for Motion to:

- **Approve the proposed slate** of 19 awards totaling \$18M for the Inaugural Improving PCOR Methods Cycle.

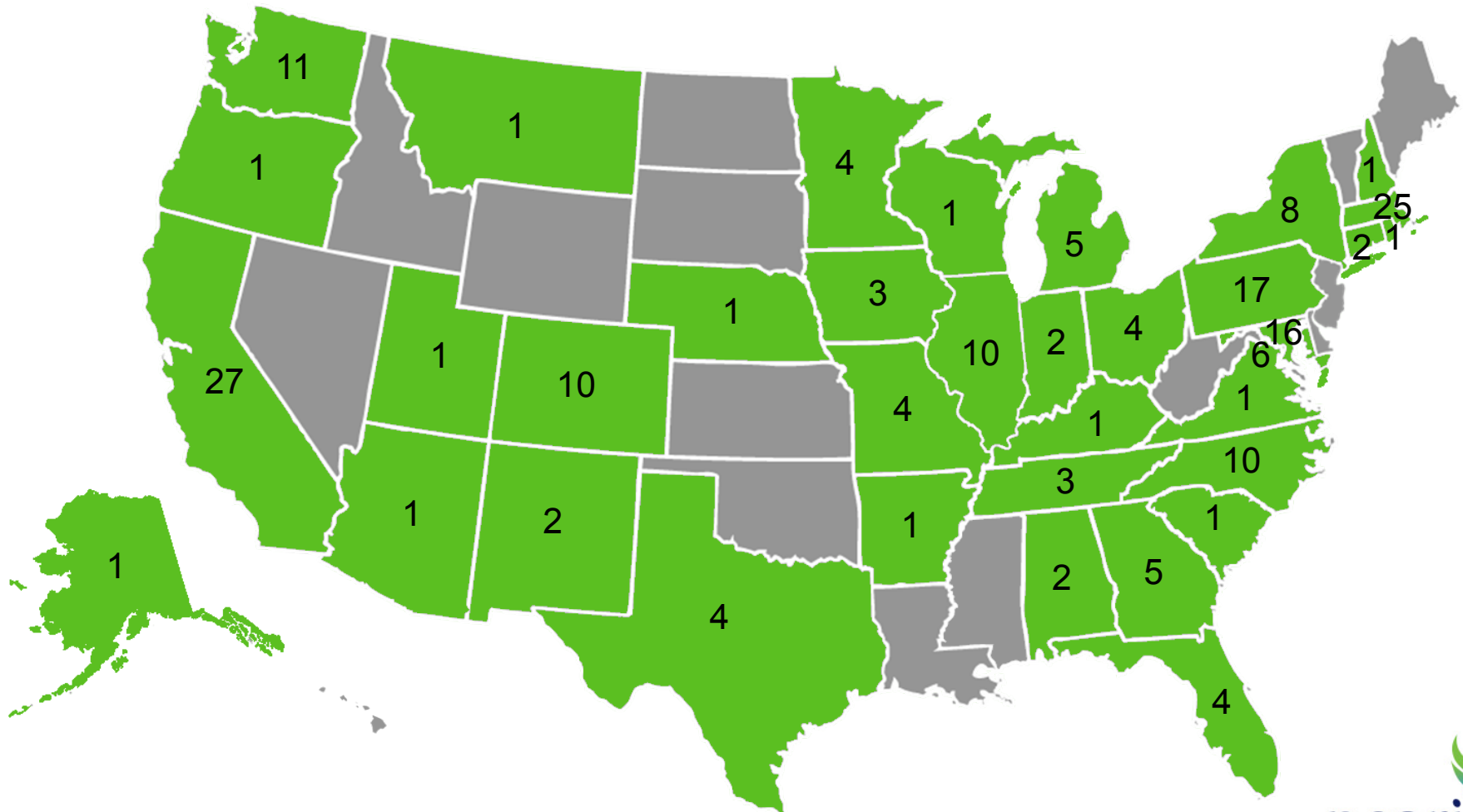
Once the Motion Is Seconded:

- **Discussion** of the motion, including consideration of any amendments to the motion.

Vote:

- Roll call **vote to approve the slate.**

Pilot Project, Cycle I-III PFA, and Inaugural Methods Awards Locations



Thank You and Congratulations!

All applicants: Thank you for your interest in PCORI funding opportunities and for your applications. Please look out for our next funding announcement.

Awardees: Congratulations and welcome to the PCORI family of funded researchers. We look forward to working with you to advance PCORI's mission in the weeks, months, and years ahead.

For awardees:

- You will receive notification from PCORI shortly after this meeting.
- We will send your contract, along with activation instructions and a request for information form to you by September 25, 2013.
- PCORI will publicly announce the details of the approved projects at 2 p.m. ET today, September 10, 2013.

Congratulations again on your successful application to PCORI research funding!



National Patient-Centered Clinical Research Network Coordinating Center Proposed Award

Christine Goertz, DC, PhD

Board Member and Chair, Program Development Committee

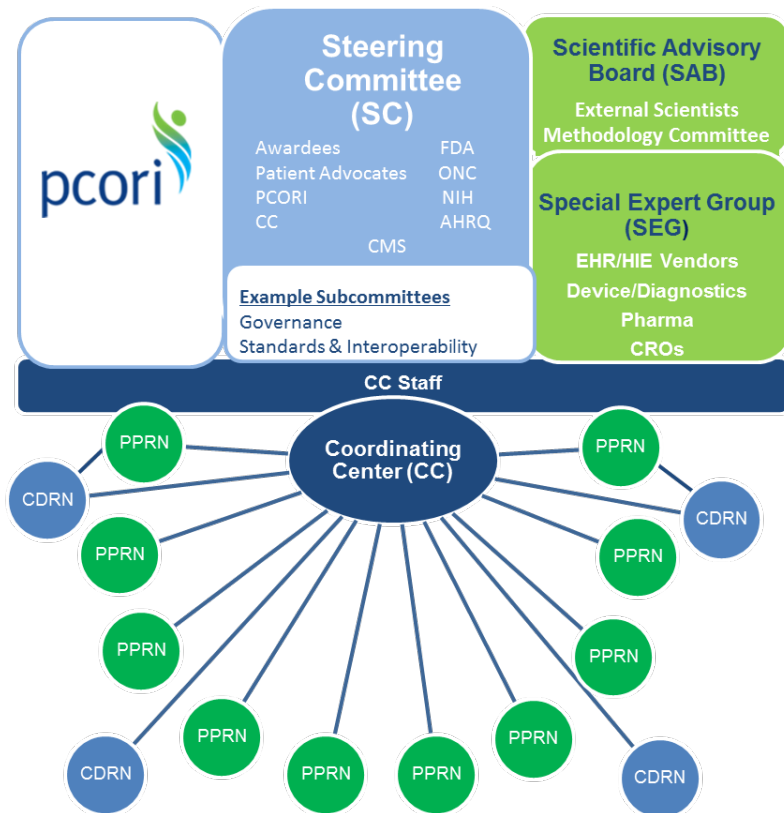
Rachael Fleurence, PhD

*Program Director, Comparative Effectiveness Research Methods and
Infrastructure*

Patient-Centered Outcomes Research Institute

National Patient-Centered Clinical Research Network (NCCRN) Coordinating Center (CC)

Roles and Responsibilities



The CC will support:

- Up to 8 **Clinical Data Research Networks (CDRNs)**
- Up to 18 **Patient-Powered Research Networks (PPRNs)**
- The execution of recommendations and policies of the **SC** and the **SAB**.

The CC will also provide:

- Program management
- Technical assistance
- Logistical support
- Cross-awardee communications and coordination
- Program evaluation

PCORI RFP Procurement Process

- 3-part procurement process
 - RFP publicly posted
 - Individual evaluation of technical proposals
 - 11 reviewers from PCORI science and executive staff
 - Review team deliberation of technical proposals
 - Cost proposal analysis
 - PCORI deputy director of finance plus 2 external CPAs

PCORI Staff and Board Program Development Committee (PDC) Recommendation

- Endorse **Harvard Pilgrim Health Care** as choice for the NCRN Coordinating Center
 - PI: **Richard Platt, MD, MSc** (Harvard Pilgrim, Harvard Medical School)
 - Co-PI: **Robert Califf, MD** (Duke Clinical Research Institute, Duke University)
 - **Other participating organizations:** AcademyHealth, America's Health Insurance Plans (AHIP), Brookings Institution, Center for Democracy & Technology, Center for Medical Technology Policy, Group Health Research Institute, The Johns Hopkins University, RAND
- Endorse budget amount not to exceed **\$9 million for 24 months**

Board of Governors Vote

Call for Motion to:

- **Approve** Harvard Pilgrim Health Care to receive the NCRN Coordinating Center Award for up to \$9M for 24 months.

Once the Motion Is Seconded:

- **Discussion** of the motion, including consideration of any amendments to the motion.

Vote:

- Roll call **vote to approve the award.**



Change of Fiscal Year-End to September 30

Kerry Barnett

*Board Member and Chair, Finance, Audit and Administration
Committee*

Regina Yan

Chief Operating Officer

Patient-Centered Outcomes Research Institute

Agenda

- Challenges with Current Fiscal Year
- Proposed Solution
- Proposed Bylaws Amendment

Challenges with Current Fiscal Year

- Current fiscal year ends December 31
- Authorizing bill requires annual report on PCORI to be sent to Congress on April 1
- PCORI has 5 weeks between fiscal year end to complete its annual audit and to have it approved by the board to meet February 10 submission deadline to GAO
- Current timeline does not provide sufficient time for thorough completion and review of PCORI's annual financial audit

Proposed Solution

- Change PCORI fiscal year to end September 30
- PCORI fiscal year 2013 will end September 30, 2013. An annual financial audit will be performed for a short fiscal year 2013 (9 months)
- PCORI fiscal year 2014 will start October 1, 2013. From here on, PCORI fiscal year will be October 1 – September 30

Proposed Bylaws Amendment

- Under Article X. 10.1. Fiscal year. The Corporation's fiscal year shall be calendar year
- Amend it to: The Corporation's fiscal year shall be October 1 – September 30
- PCORI bylaws requires a vote of two-thirds (2/3) of members present at a meeting of the Board at which a quorum is present to effect any bylaws amendment

Board of Governors Vote

Call for Motion to:

- **Amend bylaws language** to change PCORI fiscal year to October 1 – September 30

Once the Motion Is Seconded:

- **Discussion** of the motion, including consideration of any amendments to the motion.

Vote:

- Roll call **vote to approve the bylaws amendment.**



Wrap-up and Adjournment

Eugene Washington, MD, MSc
Chair, Board of Governors

Patient-Centered Outcomes Research Institute