



Special Board of Governors Teleconference/Webinar

*December 17, 2013
12:00-1:30 p.m. ET*

Patient-Centered Outcomes Research Institute



Welcome and Introductions

Grayson Norquist, MD, MSPH

Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00 – 12:05 p.m.	Call to Order and Welcome
12:05 – 12:30 p.m.	Proposed Slate: Broad PCORI Funding Announcements (August 2013 Cycle) • Consideration of slate for approval
12:30 – 12:55 p.m.	Proposed Slate: Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs) (Phase One) • Consideration of slate for approval
12:55 – 1:20 p.m.	Proposed Slate: Treatment Options for African Americans and Hispanic/Latinos with Uncontrolled Asthma • Consideration of slate for approval
1:20 – 1:30 p.m.	Next Steps and Adjournment



PFA Slate Consideration: August 2013 Cycle

*Christine Goertz, DC, PhD, Chair, August 2013 Selection Committee,
Board of Governors*

Bryan Luce, PhD, MBA, Chief Science Officer

Patient-Centered Outcomes Research Institute

Selection Committee Members: August 2013

Board of Governors

- Grayson Norquist, MD, MSPH, Chair
- Debra Barksdale, PhD, RN
- Christine Goertz, DC, PhD (Selection Committee Chair)
- Gail Hunt
- Robert Zwolak, MD, PhD

Methodology Committee

- Robin Newhouse, PhD, RN, Chair
- Michael S. Lauer, MD

PCORI Staff

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



Slate Overview

What funding opportunities were open?

PCORI Funding Announcement (PFA)	Maximum Project Length in Years	Maximum Budget Per Year	Total Cycle Budget (\$76 M)
Assessment of Options (AO)	3	\$500,000	\$32 million
Improving Healthcare Systems (IHS)	3	\$500,000	\$16 million
Communication and Dissemination Research (CDR)	3	\$500,000	\$8 million
Addressing Disparities (AD)	3	\$500,000	\$8 million
Improving Methods for Conducting PCOR (Methods)	3	\$250,000	\$12 million

Slate Overview – August 2013 Cycle

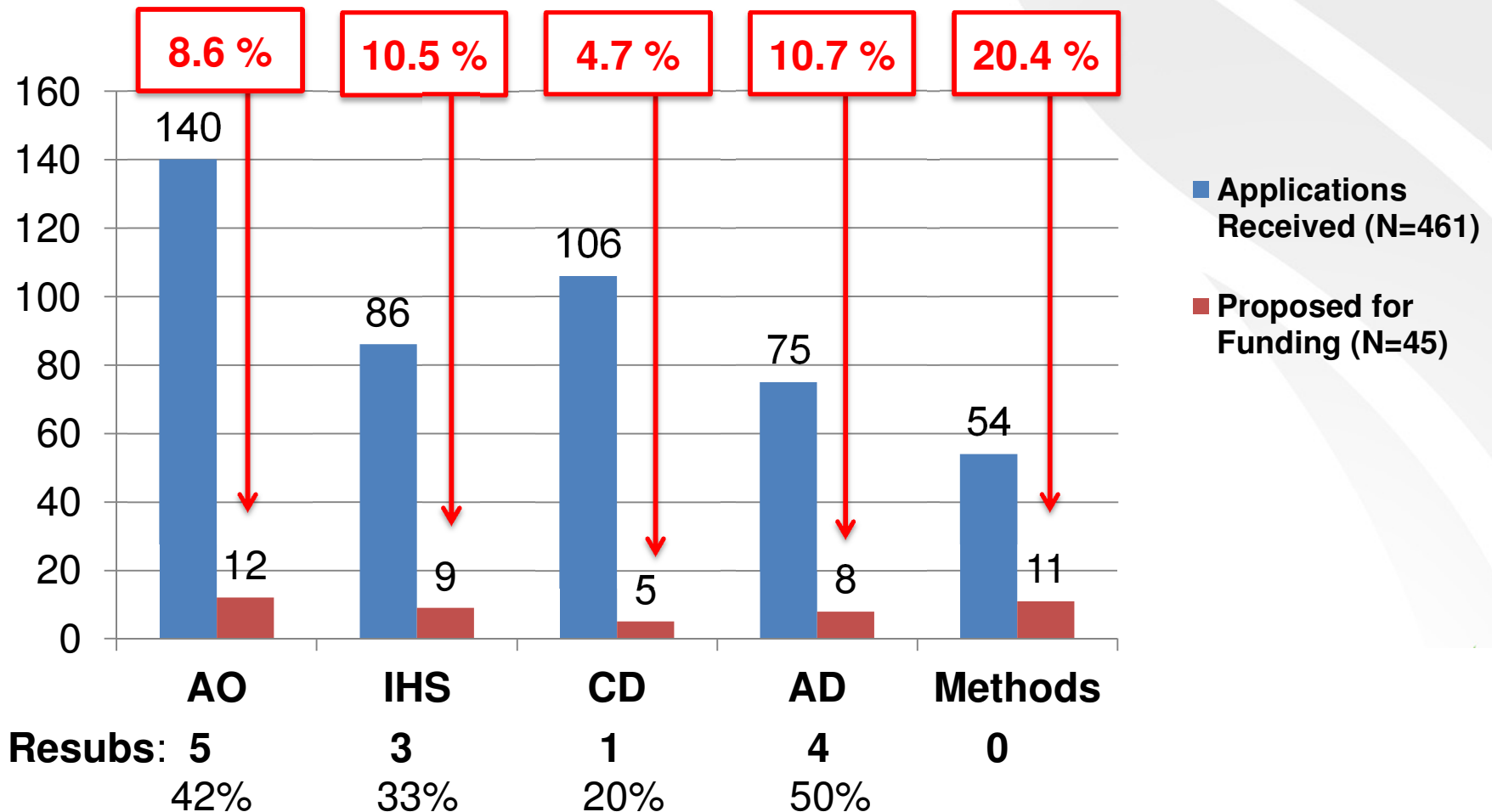
What is being recommended today?

PCORI staff proposes a slate with an ***average funding line at 11% of responsive applications***, which ranges between 4.7% and 20.4% of applications received for each PCORI Funding Announcement

Slate Overview – August 2013 Cycle

What percentage of applicants do we want to fund?

Average funding line at 11%...

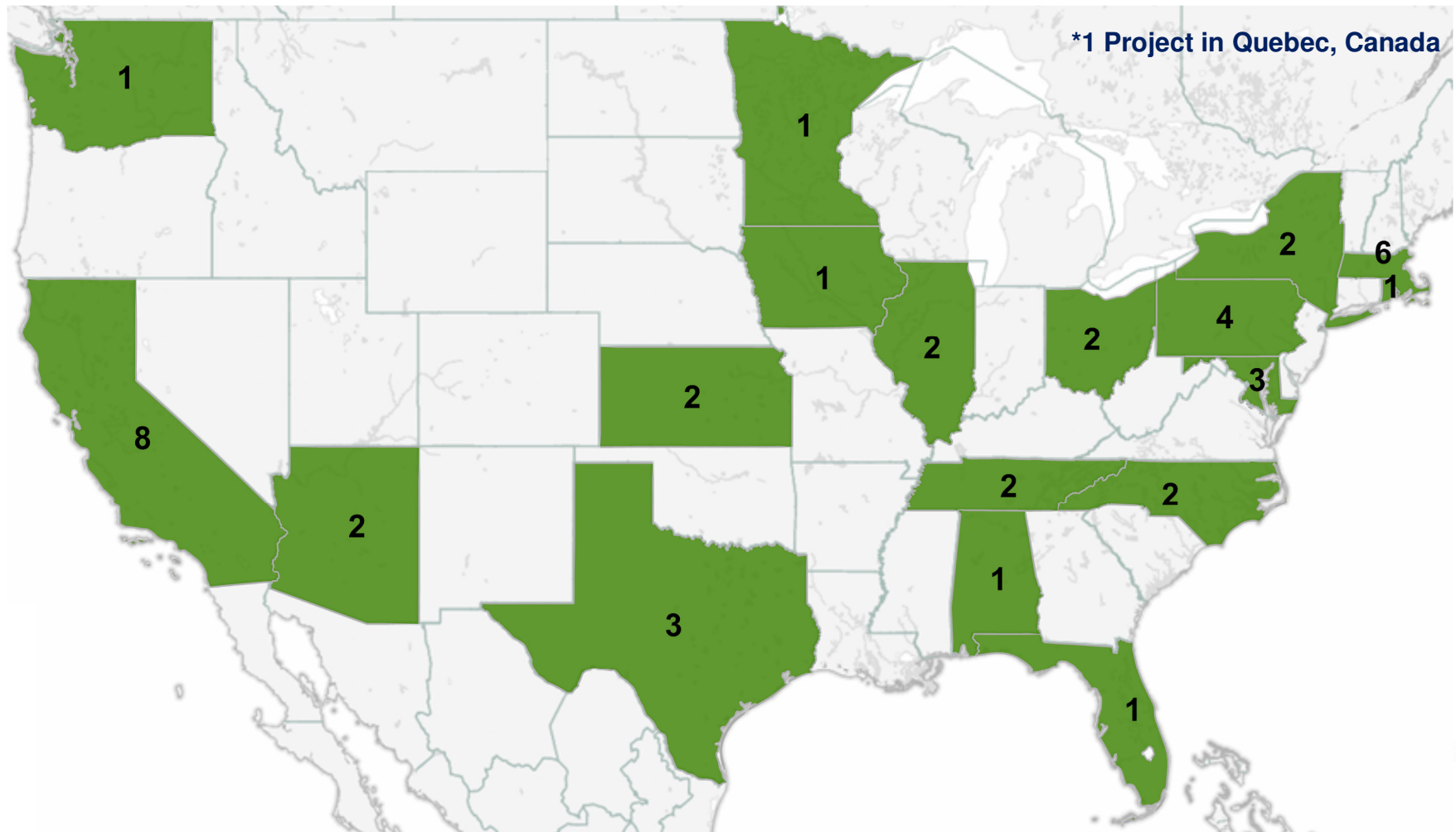


Slate Overview

What are we proposing to fund?

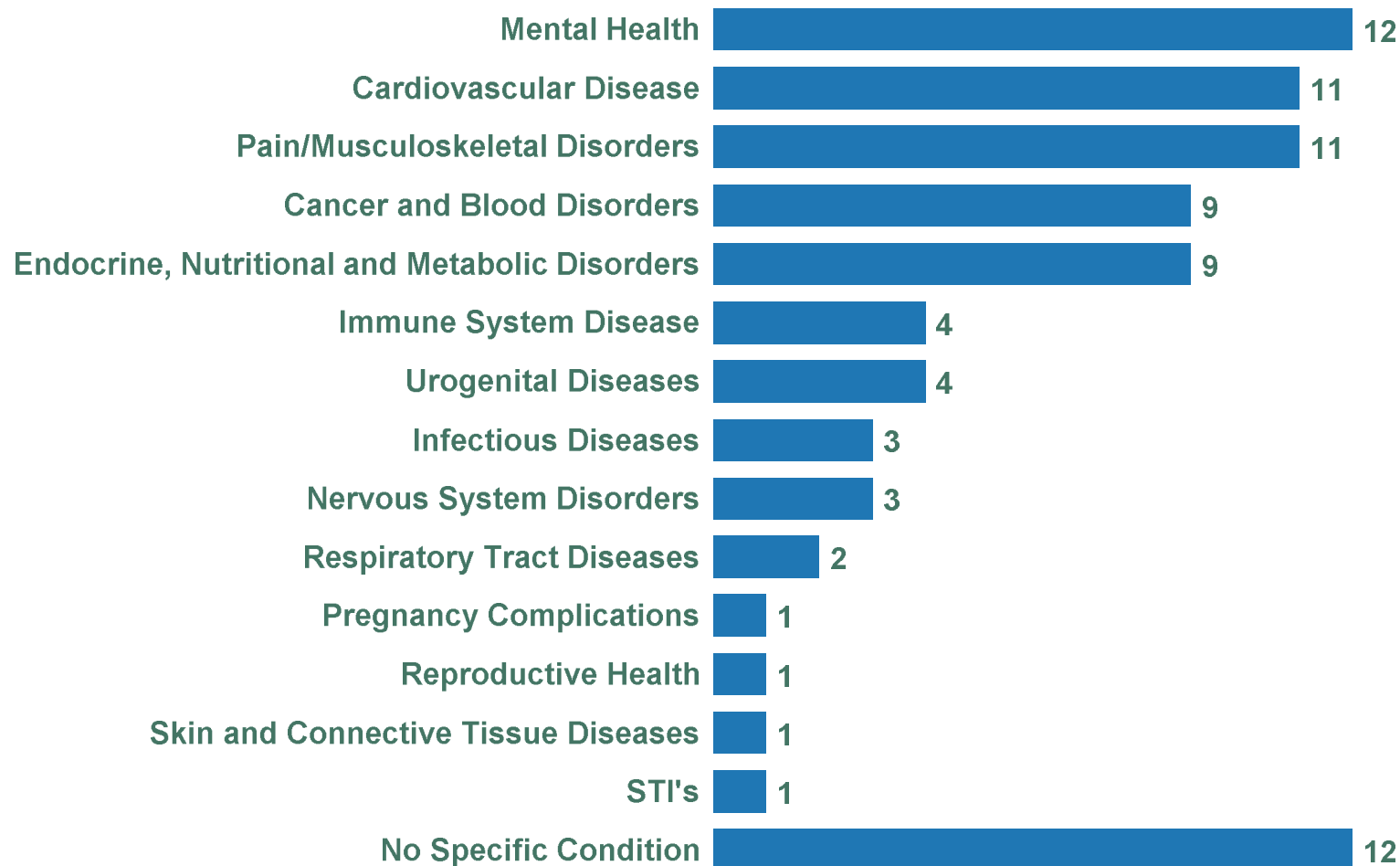
PCORI FUNDING ANNOUNCEMENT (PFA)	FUNDING DOLLARS	NUMBER OF PROJECTS
Assessment of Options	\$ 22,380,196	12
Improving Healthcare Systems	\$17,577,330	9
Communication and Dissemination Research	\$9,697,099	5
Addressing Disparities	\$14,614,257	8
Improving Methods for Conducting PCOR	\$10,079,711	11
TOTAL	\$74,348,593	45

Slate Overview - Map



Slate Overview

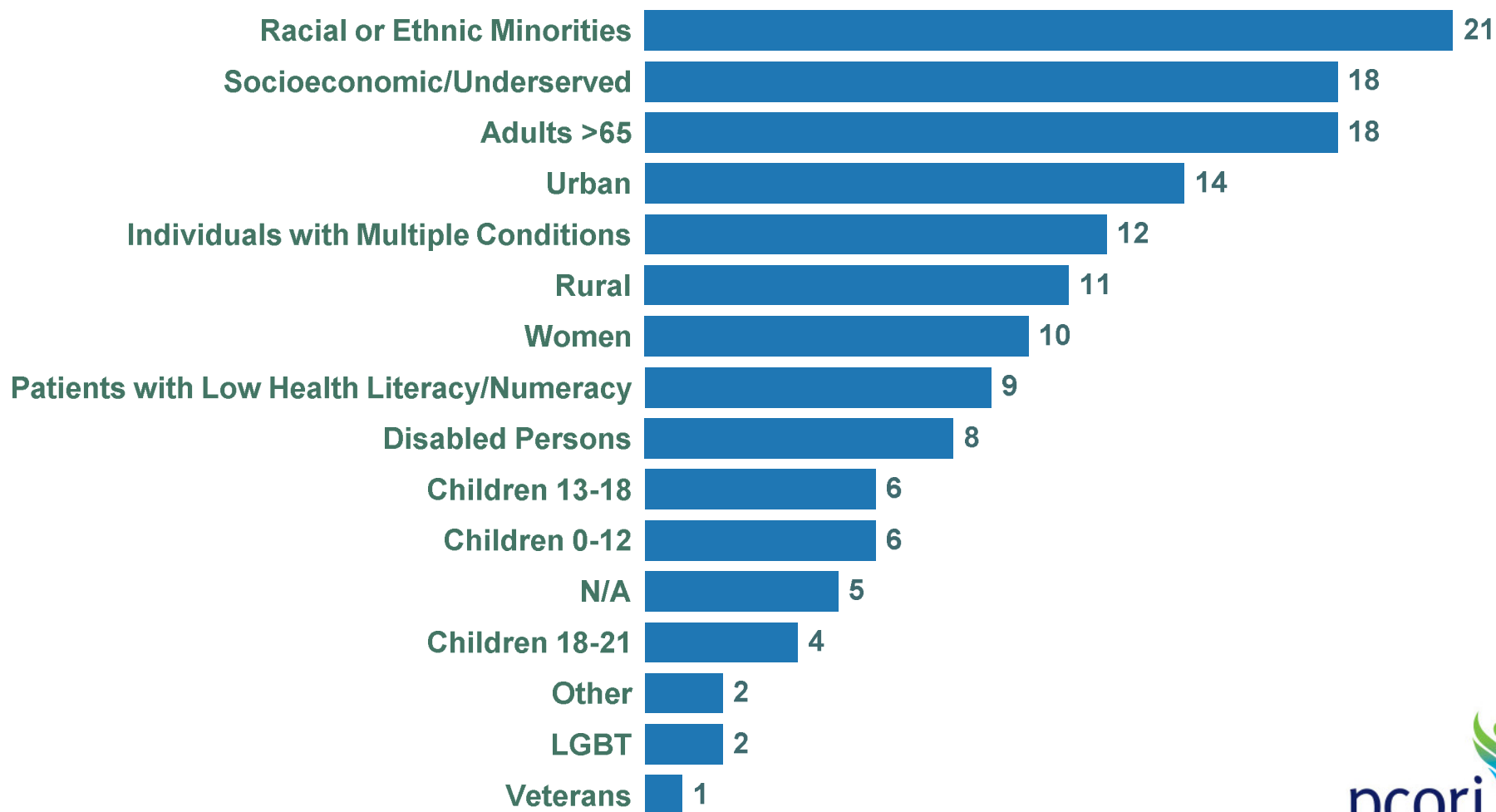
What conditions are studied?



*Some projects study multiple conditions.

Slate Overview

What populations are studied?



*Some projects study multiple populations.

Assessment of Options

Project Titles (Slide 1 of 2)

Evaluation of Parent-Based Interventions to Support Children after Traumatic Injury

Physical Therapy vs. Internet-Based Exercise Training for Patients with Knee Osteoarthritis

Comparative Effectiveness of Family Problem-Solving Therapy (F-PST) for Adolescent TBI

Heart Health 4 Moms: Engaging Women with a History of Preeclampsia to Reduce Their Risk for Cardiovascular Disease

Comparative Effectiveness of Behavioral Interventions to Prevent or Delay Dementia

Smoking Cessation Versus Long-Term Nicotine Replacement Among High-Risk Smokers

Improving the Effectiveness of Routine Surveillance Following Lung Cancer Resection

Assessment of Options

Project Titles (Slide 2 of 2)

Is MyPlate.gov Approach to Helping Overweight Patients Lose Weight More Patient-Centered?

Comparative Effectiveness of Postoperative Management for Degenerative Spinal Conditions

Promoting Informed Decisions about Lung Cancer Screening

Patient Assisted Intervention for Neuropathy: Comparison of Treatment in Real Life Situations

Optimizing Health Outcomes in Patients with Symptomatic Aortic Valve Disease

Improving Healthcare Systems

Project Titles

An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use

Optimizing Patient Engagement in a Novel Pain Management Initiative

Improving Post-Discharge Outcomes by Facilitating Family-Centered Transitions from Hospital to Home

Connecting Healthy Women

Persons with Disabilities Generating Quality Metrics to Inform Integrated Care

Peer-Driven Intervention as an Alternate Model of Care Delivery and Coordination for Sleep Apnea

Mobile Application for Improving Symptoms and Adherence to Oral Chemotherapy in Patients with Cancer

Evaluation of a Health Plan Initiative to Mitigate Chronic Opioid Therapy Risks

Specialized Community Disease Management to Reduce Substance Use and Hospital Readmissions

Communication and Dissemination Research

Project Titles

Bringing I-PASS to the Bedside: A Communication Bundle to Improve Patient Safety and Experience

Amplifying the Patient's Voice: Person-Centered Versus Measurement-Based Approaches in Mental Health

Preparing Spanish-Speaking Older Adults for Advance Care Planning and Medical Decision Making

Development and User Testing of a Decision Aid for Ventricular Assist Device Placement

Creating a Patient-Centered Tool to Help Medicare Beneficiaries Choose Prescription Drug Plans

Addressing Disparities

Project Titles

Addressing HIV Treatment Disparities Using a Self Management Program and Interactive Personal Health Record

Increasing CRC Screening among Hispanic Primary Care Patients

Patient-Centered Approaches to Collect Sexual Orientation/Gender Identity Information in the ED

Culturally Adapted Brief Motivational Intervention for Heavy Drinking Latinos

A Patient-Centered Strategy for Improving Diabetes Prevention in Urban American Indians

Integrated Care and Patient Navigators for Latinos with Serious Mental Illness

Health Coaching to Reduce Disparities for Patients with Chronic Obstructive Pulmonary Disease (COPD)

Improving Medication Adherence in the Alabama Black Belt

Improving Methods for Conducting PCOR

Project Titles (Slide 1 of 2)

Innovative Randomized Trial Designs to Generate Stronger Evidence about Subpopulation Benefits and Harms

Methods for Analysis and Interpretation of Data Subject to Informative Visit Times

Evaluating Observational Data Analyses: Confounding Control and Treatment Effect Heterogeneity

Development of Practical Outcome Measures to Account for Individual Differences and Temporal Changes in Quality of Life Appraisal

Improving Patient Engagement and Understanding Its Impact on Research through Community Review Boards

Computer-Administered Animation as a New Method for Measuring Young Children's Health Outcomes

Improving Methods for Conducting PCOR

Project Titles (Slide 2 of 2)

Modeling Strategies for Observational CER – What Works Best When?

Applying Methods of User-Centered Design to Achieve Patient-Centered Care

Semi-parametric Causal Inference Methods for Adaptive Statistical Learning in Trauma
Patient-Centered Outcomes Research

A Method for Patient-Centered Enrollment in Comparative Effectiveness Trials:
Mathematical Equipoise

Methods for Prioritizing Surrogate Desired Health Outcomes for Patients

Slate Overview

What's the bottom line?

- Continue to see high-quality and innovative applications
- Proposing to fund 45 projects out of 461 responsive applications
- 13 of 45 projects proposed for funding are resubmissions
- Proposed slate has a funding total of \$74.3 million
- Slate addresses a range of conditions and the needs of a variety of populations
- Funding rate at 11% in August 2013 Cycle compared to 12.7% in Cycle III, 12% in Cycle II, and 5% in Cycle I

Questions & Discussion

Board of Governors Vote

Call for motion to:

- **Approve the proposed slate** of 45 awards totaling \$74.3M for August 2013 Cycle

Call for motion to be seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:

- Roll Call Vote to **Approve** the **Final** Motion
 - Ask for votes in favor
 - Ask for votes opposed
 - Ask for abstentions



Cooperative Agreement Funding Announcements Slate Consideration: Clinical Data Research Networks and Patient-Powered Research Networks

*Michael S. Lauer, MD, Chair, Infrastructure Selection Committee,
Methodology Committee*

Rachael Fleurence, PhD, Director, CER Methods and Infrastructure

Patient-Centered Outcomes Research Institute

Selection Committee Members: Clinical Data Research Network/Patient-Powered Research Network

Board of Governors

- Francis S. Collins, MD, PhD
- Christine Goertz, DC, PhD
- Harlan Krumholz, MD

Methodology Committee

- Michael S. Lauer, MD (Selection Committee Chair)
- Jean Slutsky, PA, MSPH

PCORI CER Methods and Infrastructure Program Staff

- Rachael Fleurence, PhD
- Sarah Daugherty, PhD
- Sarah Greene, MPH
- Sarita Wahba, MSPH, MS
- Natalie Wegener



Slate Overview

What funding opportunities were open?

PCORI Funding Announcement (PFA)	Maximum Project Length in Years	Maximum Budget	Available Funds
Clinical Data Research Network (CDRN)	1.5	\$7 million	\$56 million
Patient-Powered Research Network (PPRN)	1.5	\$1 million	\$12 million

Slate Overview – CDRN

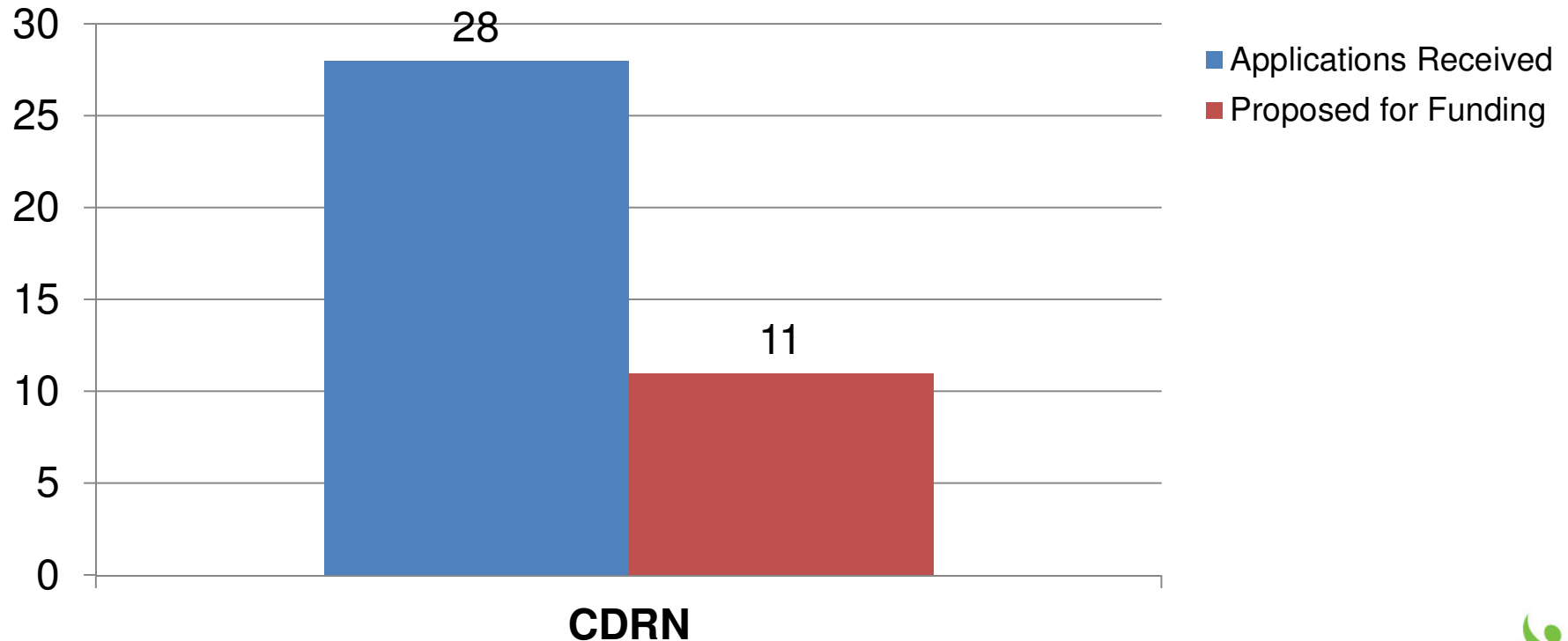
How was the slate identified?

- Review applications, Merit Review scores, and Merit Review critiques, taking into consideration:
 - Responsiveness to PFA
 - Geography
 - Size of population covered
 - Special population (e.g., pediatrics, safety net)
 - Type of health systems in the network or type of model proposed (e.g., academic health center, health information exchange, integrated health system, community trust)
 - Portfolio balance

Slate Overview – CDRN

What percentage of applicants do we want to fund?

Funding line at 39.3%...



Slate Overview – CDRN

What are characteristics?

Network Characteristics

- Academic Medical Centers, Integrated Health Delivery Systems, Community Trusts, Pediatric Networks, Safety Net Networks, Health Information Exchanges

States Covered

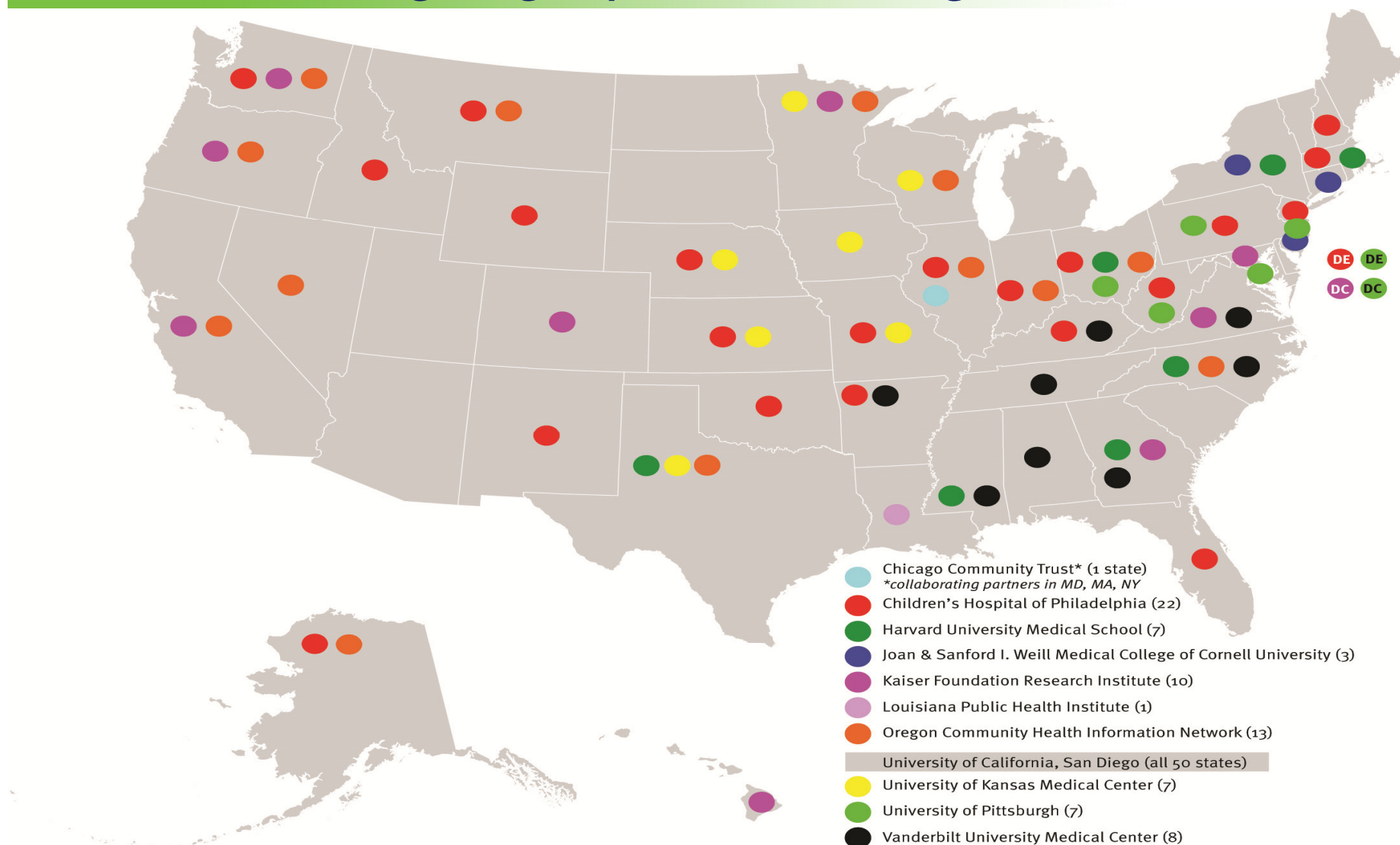
- All

Total Population Size

- Potential to include at least 11,000,000 patients across the United States

Slate Overview – CDRN

What is the geographic coverage?



Slate Overview–CDRN

What is the proposed budget?

Total budget	\$56 million*
Budget range across projects	\$6,987,163 to \$7,000,000
Average project budget	\$6,998,805

*Staff propose to increase budget from **\$56M** to **\$77M** to fund 11 instead of 8 projects.

CDRN

Project Titles (1 of 2)

Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)

Mid-South Clinical Data Research Network

Patient-oriented Scalable National Network for Effectiveness Research (pSCANNER)

The Greater Plains Collaborative

Kaiser Permanente and Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) Network

Louisiana Clinical Data Research Network

CDRN

Project Titles (2 of 2)

National Pediatric Learning Health System

New York City Clinical Data Research Network (NYC-CDRN)

Chicago Area Patient Centered Outcomes Research Network (CAPriCORN)

Accelerating Data Value Across a National Community Health Center Network (ADVANCE)

P2ath Towards a Learning Health System in the Mid-Atlantic Region

Questions & Discussion

Board Vote – CDRN Slate

Call for motion to:

- **Approve the proposed slate**
 - 11 CDRN awards totaling \$77M

Call for motion to be seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:

- Roll Call Vote to **Approve** the **Final** Motion
 - Ask for votes in favor
 - Ask for votes opposed
 - Ask for abstentions

Slate Overview–PPRN

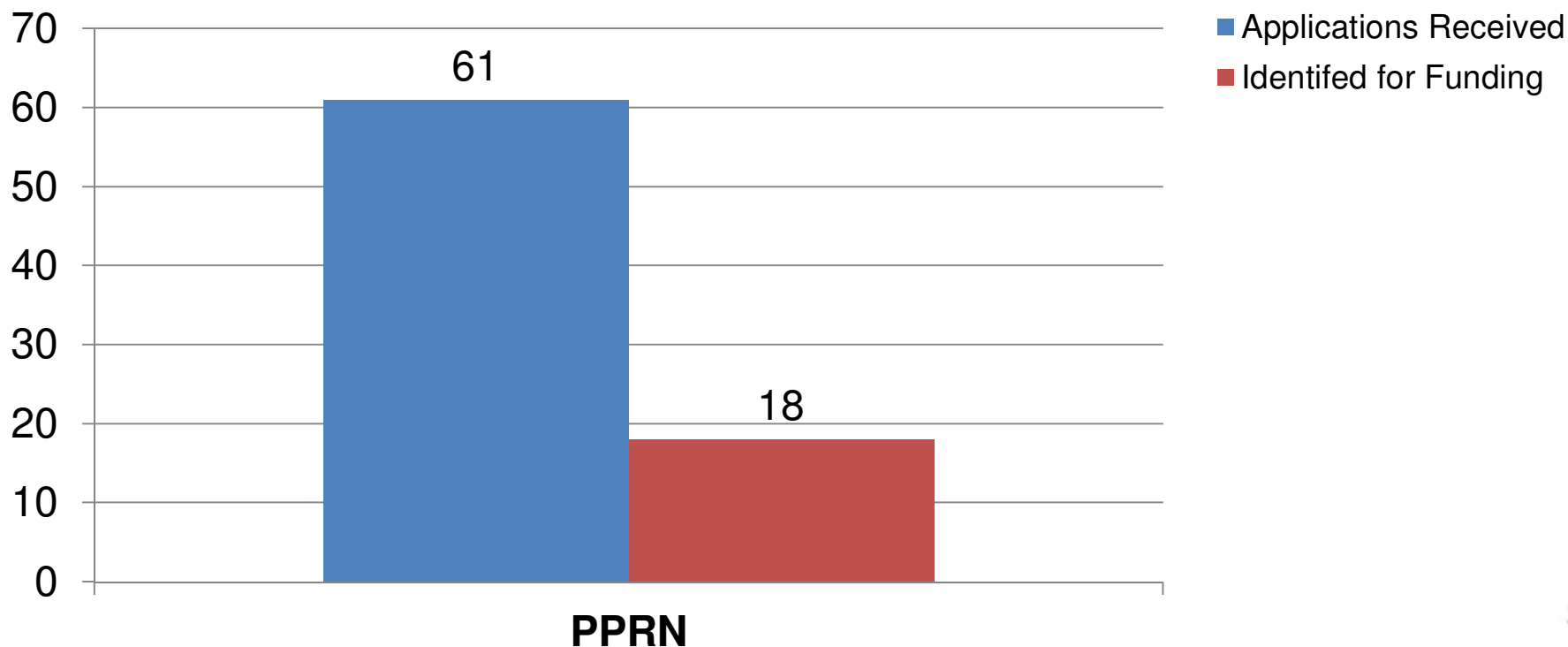
How was the slate identified?

- Review applications, Merit Review scores, and Merit Review critiques, taking into consideration:
 - Responsiveness to PFA
 - Quality of engagement model
 - Geography
 - Portfolio diversity of disease/condition populations
 - Portfolio balance

Slate Overview – PPRN

What percentage of applicants do we want to fund?

Funding line at 29.5%...



Slate Overview–PPRN

What are characteristics?

Network Characteristics

- Patient-Led Organizations, Academic Medical Centers, Diseases Advocacy Organizations, Pediatric Networks, Disease Consortia

Geographic reach covers all states

50% of proposed projects represent a rare disease

Slate Overview–PPRN

What is the proposed budget?

Total budget	\$12 million*
Budget range across projects	\$489,136 to \$1,000,000
Average project budget	\$936,669

* Staff propose to increase budget from **\$12M** to **\$16.8M** to provide additional funding for PPRNs that are proposing to accomplish particularly innovative work

PPRN (Non-Rare Conditions)

Project Titles

The Health eHeart Alliance

ImproveCareNow: A Learning Health System for Children with Crohn's Disease and Ulcerative Colitis

CCFA Partners Patient-Powered Research Network

Arthritis Patient Partnership with Comparative Effectiveness Researchers (AR-PoWER PPRN)

Sleep Apnea Patient-Centered Outcomes Network (SA-PCON)

The COPD Patient-Powered Research Network

Multiple Sclerosis Patient-Powered Research Network

American BRCA Outcomes and Utilization of Testing Patient-Powered Research Network (ABOUT Network)

Mood Patient-Powered Research Network

PPRN (Rare Conditions)

Project Titles

Patients, Advocates, and Rheumatology Teams Network for Research and Service (PARTNERS) Consortium

ALD Connect

Phelan-McDermid Syndrome Data Network

PI Patient Research Connection: PI-CONNECT

The Vasculitis Patient-Powered Research Network

The DuchenneConnect Patient-Report Registry Infrastructure Project

NephCure Kidney Network for Patients with Nephrotic Syndrome

Rare Epilepsy Network (REN)

Community-Engaged Network for All (CENA)

Questions & Discussion

Board Vote – PPRN Slate

Call for motion to:

- **Approve the proposed slate**
 - 18 PPRN awards totaling \$16.8M

Call for motion to be seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:

- Roll Call Vote to **Approve** the **Final** Motion
 - Ask for votes in favor
 - Ask for votes opposed
 - Ask for abstentions



PFA Slate Consideration: *Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma*

Arnold Epstein, MD, Chair, Asthma PFA Selection Committee

Romana Hasnain-Wynia, PhD, Director, Addressing Disparities

Patient-Centered Outcomes Research Institute

Selection Committee Members

Board of Governors

- Arnold Epstein, MD (Selection Committee Chair)
- Christine Goertz, DC, PhD
- Debra Barksdale, PhD, RN
- Freda Lewis-Hall, MD

Methodology Committee

- Jean Slutsky, PA, MSPH
- Clyde Yancy, MD, MSc

PCORI Addressing Disparities Program Staff

- Romana Hasnain-Wynia, PhD
- Ayodola Anise, MHS



Slate Overview

What funding opportunities were open?

PCORI Funding Announcement (PFA)	Maximum Project Length in Years	Maximum Budget	Available Funds
Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma	3	• Year 1: \$500,000 • Year 2: \$1.75 million • Year 3: \$1.75 million	\$24 million*

* Original funding amount of \$17 million was increased to \$24 million in response to the large number of meritorious applications.

Slate Overview

What did we seek to fund through this PFA?

Projects that:

- Focus on reducing adverse outcomes due to poorly controlled asthma in African American and/or Hispanic/Latino individuals, populations, and subgroups
- Compare interventions to improve clinician and patient adherence to guidelines by:
 - Enhancing provider and patient communication (e.g., use of mobile technology)
 - Improving systems of care (e.g., evaluate models that look at data integration)
 - Improving integration of care (e.g., team-based care)
 - Any combination of these that might have an impact on adherence to evidence-based guidelines
- Include patient-centered outcomes tailored to the needs of individuals and populations

Slate Overview

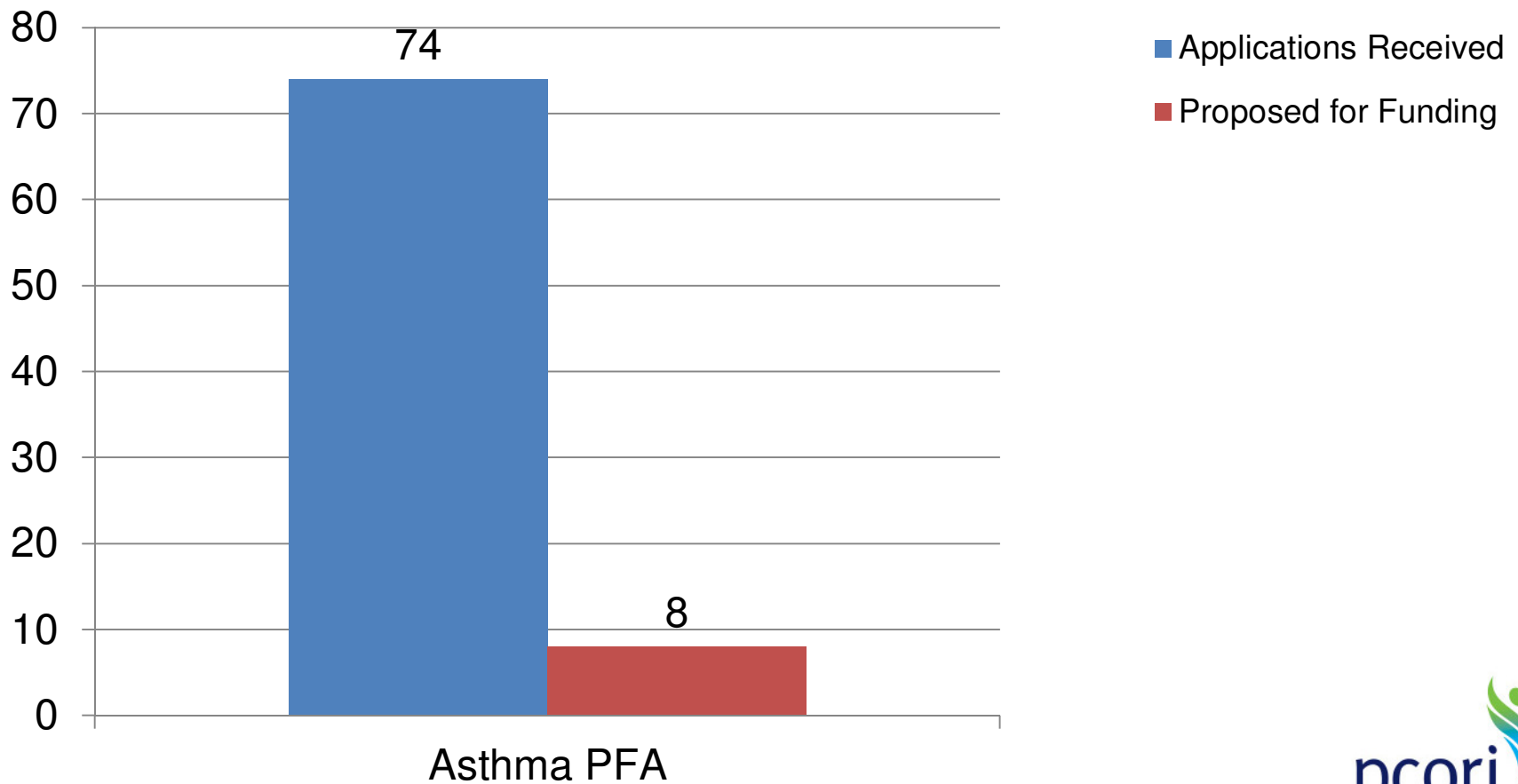
How was the slate identified?

- Review applications, Merit Review scores, and Merit Review critiques, taking into consideration:
 - Technical merit
 - Patient/stakeholder engagement
 - Patient-centered outcomes
 - Focus on patient and/or clinician adherence
 - Patient population
 - Focus of study
 - Potential impact on patients and clinicians
 - Geographic location of project

Slate Overview

What percentage of applicants do we want to fund?

Funding line at 10.8%...



Slate Overview

What are we proposing to fund?

- Projects address African American, Hispanic/Latino, and African American and Hispanic/Latino populations
- Projects address pediatric and adult populations
- Interventions are patient-centered and include strong patient and stakeholder partnerships and engagement

Slate Overview

What are common characteristics across interventions?

- Multi-component and multi-level;
- Use community health workers and community-level interventions;
- Include medication adherence, adjustment, and management;
- Include patient and provider education;
- Address systems of care through homes, schools, clinics, health plans, and use of EHRs; and/or
- Use technologies such as mobile health technology and telemedicine.

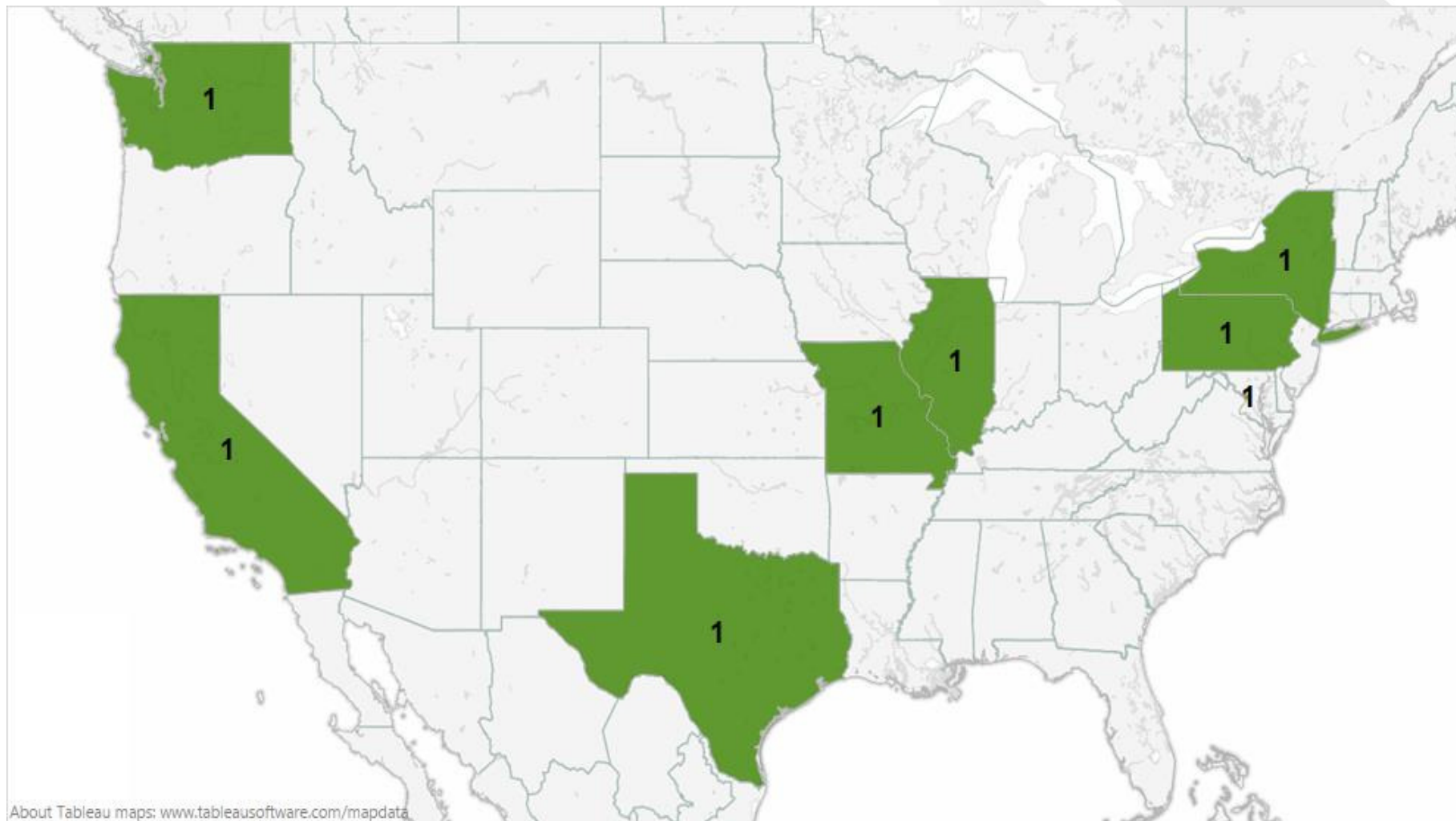
Slate Overview

What is the proposed budget?

Total budget	\$23,199,997
Budget range across projects	\$1,968,004 to \$4,000,000
Average project budget	\$2,899,999

Slate Overview – Asthma

Where are the projects located?



Asthma PFA

Project Titles

Imperial County Asthma CER Project

Preference and Effectiveness of Symptom-based Adjustment of Inhaled Corticosteroid Therapy in African-American Children

Using IT to Improve Access, Communication, and Asthma in African-American and Hispanic /Latino Adults

The Coordinated Healthcare Interventions for Childhood Asthma Gaps in Outcomes (CHICAGO) Trial

Guidelines to Practice (G2P): Reducing Asthma Health Disparities through Guideline Implementation

Parent-Centered Innovations to Improve Adherence in At-Risk Youth with Asthma

Clinic-based versus Home-based Support to Improve Care and Outcomes for Older Asthmatics

The Houston Home-based Integrated Intervention Targeting Better Asthma Control (HIIT-BAC) for African Americans

Questions & Discussion

Board of Governors Vote

Call for motion to:

- **Approve the proposed slate** of eight awards totaling \$23.2 M for the Asthma 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

Vote:

- Roll Call Vote to **Approve** the **Final** Motion
 - Ask for votes in favor
 - Ask for votes opposed
 - Ask for abstentions

Thank You and Congratulations!

All Applicants: Thank you for your interest in PCORI funding opportunities and for submitting an application. Our Spring 2014 Cycle opens on February 5, 2014, and Letters of Intent are due March 7, 2014.

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.

- 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 in coming weeks.
- PCORI will publicly announce the details of the approved projects later today.

Congratulations again on your successful application to PCORI research funding!



Where Our Funded Projects are Located





Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Patient-Centered Outcomes Research Institute