Board of Governors Meeting
via Teleconference/Webinar

July 21, 2015

12:00-1:30 p.m. ET

pcori®

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- 12:10	Call to Order, Roll Call, and Welcome Consent Agenda
12:10- 12:50	Consider for Approval: • Slate of PCORnet Phase II CDRN Awards • Slate of PCORnet Phase II PPRN Awards
12:50- 1:25	Evaluation Update: PCORI Application Process
1:25- 1:30	Annual Meeting Update
1:30	Wrap Up and Adjournment

Consent Agenda:
Minutes of the June 16, 2015 Board Meeting
CDR Advisory Panel Leadership

Advisory Panel on Communication and Dissemination Research Proposed Leadership

CHAIR: Lauren McCormack, PhD, MSPH – Researcher

Director, Center for Communication Science, RTI International

- Vast experience in communication and dissemination research that promotes patient-centered care, informed decision making, and behavior change
- Led a systematic review of the literature for AHRQ that focused on examining the comparative effectiveness of strategies to communicate and disseminate evidence-based information
- Adjunct Associate Professor at the University of North Carolina at Chapel Hill

CO-CHAIR: Danny van Leeuwen, MPH, RN, CPHQ – Patients, Caregivers, and Patient Advocates

Vice President, Quality Management, Advocates, Inc.

- Nationally recognized nurse leader and advocate for family caregivers
- Led the Patient Family Experience initiative for Boston Children's Hospital, serves on HIMSS Connected Patients Committee, member of the Society for Participatory Medicine
- Hosts a weekly blog with more than 2,000 registered users

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent Agenda, as reflected
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

PCORnet Phase II Clinical Data Research Networks (CDRN) and Patient-Powered Research Networks (PPRN)

Joe Selby, MD, MPH
Executive Director

Rachael Fleurence, PhD
Program Director, CER Methods and Infrastructure

PCORnet Phase II Goals

- Expand on the infrastructure built during Phase I of PCORnet by providing funding to CDRNs and PPRNs (existing and new)
- Complete construction of a large, highly representative national network for conducting clinical research
- Demonstrate more efficient conduct of multinetwork observational and interventional research studies using the PCORnet infrastructure resources
- Support a high volume of observational and interventional research

PPRN and CDRN PFA Goals

- Highly engaged patients, researchers, clinicians, and health systems participate in network governance and research topic generation
- Analysis-ready standardized data, use of the PCORnet Common Data Model, and preserving strong privacy and data-security protections
- An infrastructure for supporting clinical trials embedded within network delivery systems
- An oversight framework that fosters public trust in research
- A collaborative community that attracts a diverse set of researchers, funders, and other networks
- Sustainable research networks

PCORnet Phase II Merit Review

- PCORI received 42 applications (15 CDRNs; 27 PPRNs)
- A preliminary online review was conducted by:
  - External reviewers
  - Internal reviewers (program and other Science, CMA, Engagement staff)
- An in-person review was conducted by PCORI staff
- All reviewer feedback was utilized in the programmatic review of the applications

Merit Review Criteria

- **Successful achievement of each of the three major Phase I goals** by the start of Phase II (for Phase I networks) or at six months post-contract award (for new applicants)
- Ability and credible work plans to meet the various aspects of the **Phase II goals**
- Evidence of a solid and diverse staffing and management plan and budget

Consider for Approval: Slate of PCORnet Phase II Clinical Data Research Networks (CDRN) Awards

Joe Selby, MD, MPH
Executive Director

Rachael Fleurence, PhD
Program Director, CER Methods and Infrastructure

Summary of Proposed CDRN Slate

- Responsive applications received: 15
  - Currently funded CDRN Phase I Projects: 11
  - New CDRN applications: 4
- Recommended slate includes **13 networks** out of 15 responsive applications (86.7%)
  - Phase I applications: 11
  - New applications: 2

Phase II CDRN Slate Summary (1 of 2)

Network (Phase I Networks)
A PaTH Towards a Learning Health System (PaTH)
Accelerating Data Value Across a National Community Health Center Network (ADVANCE)
Chicago Area Patient Centered Outcomes Research Network (CAPriCORN)
The Greater Plains Collaborative
Kaiser Permanente & Strategic Partners Patient Outcomes Research to Advance Learning (PORTAL)
Louisiana Clinical Data Research Network
Mid-South Clinical Data Research Network
New York City Clinical Data Research Network
patient-centered SCAlable National Network for Effectiveness Research (pSCANNER)
PEDSnet: A Pediatric Learning Health System
Scalable Collaborative Infrastructure for a Learning Healthcare system (SCILHS)

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.

Phase II CDRN Slate Summary (2 of 2)

Network (New Phase II Network)
OneFlorida Clinical Research Network
The Patient-Centered Network of Learning Health Systems (LHSNet)

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.

Slate Overview: CDRN Phase II Networks

13
Projects

PCORnet Phase II PFA	Allotted	Proposed Total Budget*	*Difference*	Average Project Budget*
CDRN—Phase II	$113,750,000	$110,645,975	***-$3,104,025***	$8,511,228

*Total budget = direct + indirect costs

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 PCORnet Phase II CDRN 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

Consider for Approval: Slate of PCORnet Phase II Patient-Powered Research Networks (PPRN) Awards

Joe Selby, MD, MPH
Executive Director

Rachael Fleurence, PhD
Program Director, CER Methods and Infrastructure

Summary of Proposed PPRN Slate

- Responsive applications received: 27
  - Currently funded PPRN Phase I Projects: 18
  - New PPRN applications: 9
- Recommended slate includes **21 networks** out of 27 responsive applications (77.8%)
  - Phase I applications: 16
  - New applications: 5

Phase II PPRN Slate Summary (1 of 3)

Network (Phase I Networks)
ABOUT Network (American BRCA Outcomes and Utilization of Testing PPRN)
AR-PoWER (ARthritis Partnership with Comparative Effectiveness Researchers) PPRN
The CCFA Partners Patient Powered Research Network
Collaborative Patient-Centered Rare Epilepsy Network
Community Engaged Network for All
Continuation of the NephCure Kidney Network
The COPD Patient-Powered Research Network
DuchenneConnect Registry Network (DCN)

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.

Phase II PPRN Slate Summary (2 of 3)

Network (Phase I Networks)
The Health eHeart Alliance
ImproveCareNow Network
MoodNetwork
The Multiple Sclerosis Patient-Powered Research Network, iConquerMS™
Patients, Advocates, and Rheumatology Teams Network for Research and Service (PARTNERS)
Phelan-McDermid Syndrome Data Network (PMS_DN)
PI CONNECT
The Vasculitis Patient-Powered Research Network (V-PPRN)

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.

Phase II PPRN Slate Summary (3 of 3)

Network (New Phase II Networks)
Community and Patient-Partnered Centers of Excellence for Behavioral Health
The Fox Insight Network
Interactive Autism Network
The National Alzheimer's & Dementia Patient & Caregiver-Powered Research Network
Population Research in Identity and Disparities for Equality Patient-Powered Research Network (PRIDE-PPRN)

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.

Slate Overview: PPRN Phase II Networks

21
Projects

PCORnet Phase II PFA	Allotted	Proposed Total Budget*	*Difference*	Average Project Budget*
PPRN—Phase II	$36,960,000	$32,816,085	***-$4,143,915***	$1,562,670

*Total budget = direct + indirect costs

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 PCORnet Phase II PPRN 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

Evaluation Update

PCORI Application Process

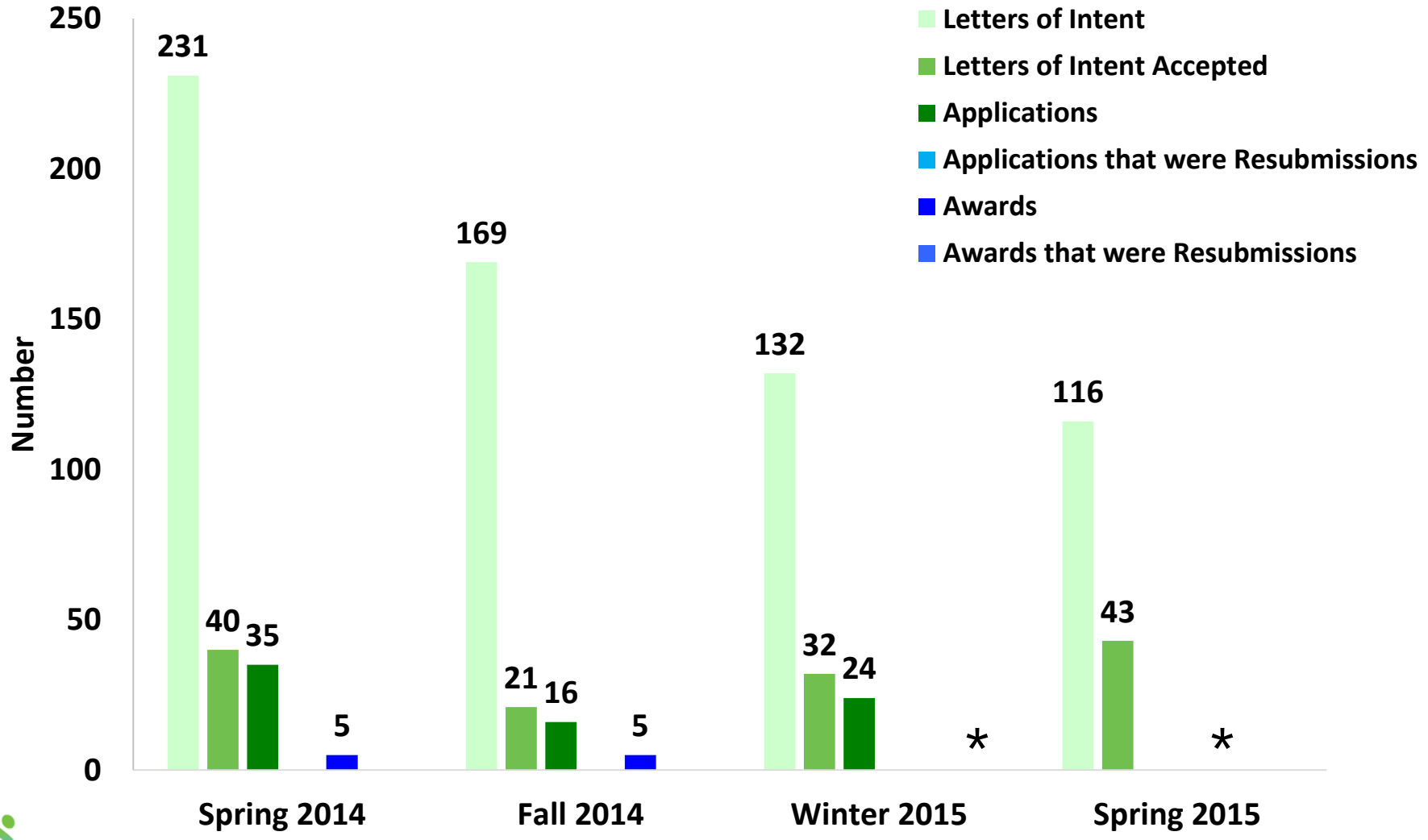
Diane Bild, MD, MPH
Senior Program Officer, Clinical Effectiveness Research

Laura Forsythe, PhD, MPH
Associate Director, Evaluation and Analysis

Presentation Overview

- Role of the Application Enhancement Workgroup
- Evaluation Plan
- Selected Findings to date
- Recommendations

LOIs, Applications, and Awards: First 4 Cycles of Pragmatic Clinical Studies



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*Awards to be announced

Application Enhancement Workgroup

- Convened by the Scientific Oversight Committee (SOC) to develop recommendations to improve the quantity of high-quality applications submitted to and funded by PCORI
- Will collaborate with staff evaluation efforts and ongoing process improvement initiatives

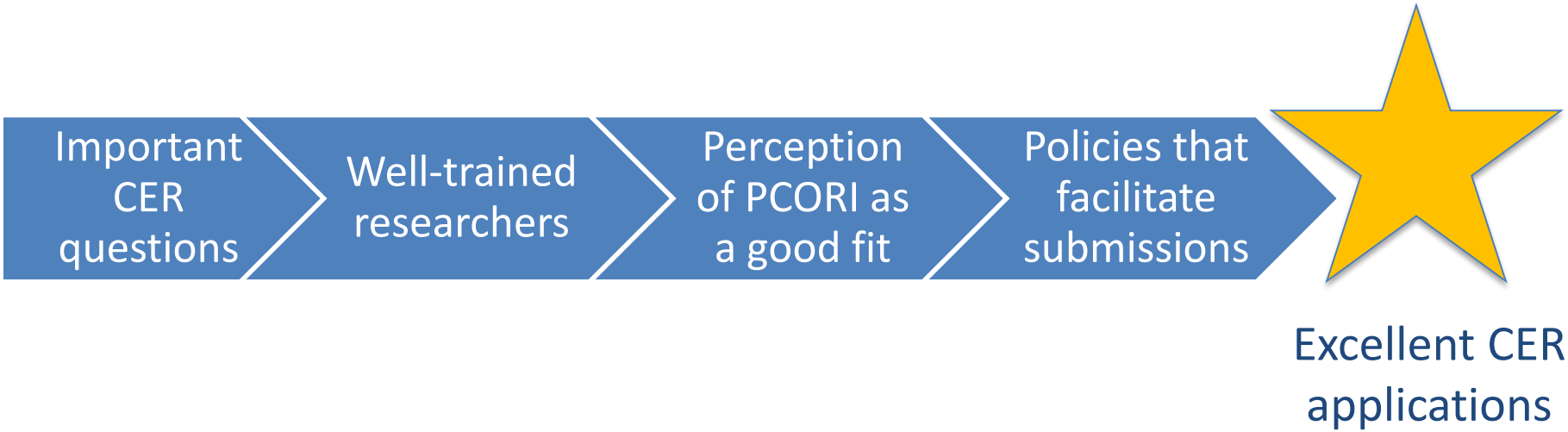
Application Enhancement Workgroup

- SOC members
  - Steve Lipstein, Rick Kuntz, Bob Zwolak
- PCORI staff members
  - Diane Bild, Lauren Fayish, Laura Forsythe, Hal Sox
- Frequent collaboration with
  - James Hulbert (Contracts Manager, Pre-Award), Tsahai Tafari (Associate Director, Merit Review) and other PCORI staff in Engagement, Operations, and Science

Evaluation Plan

Application Enhancement Workgroup Framework

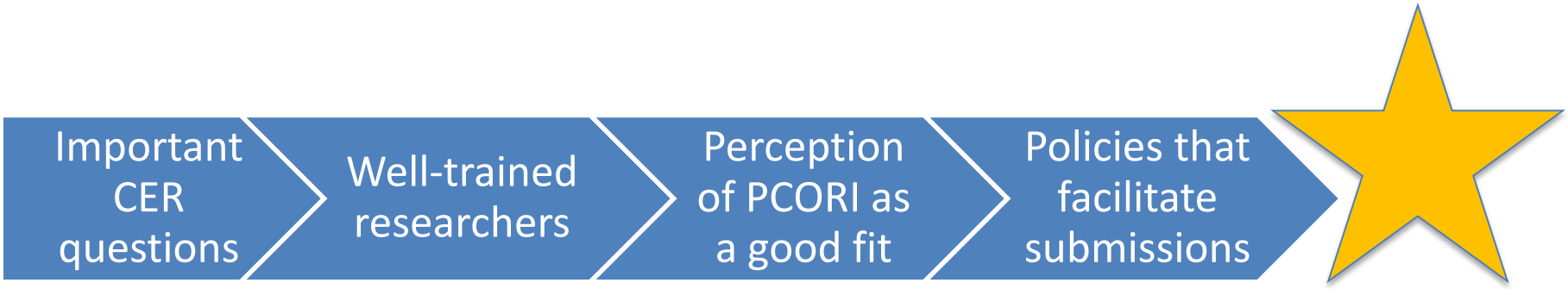
Theoretical Framework -- a series of conditions are necessary for high quality applications:



Application Enhancement Workgroup Framework

Workgroup Strategy:

Sample Hypotheses Investigated



- The requirement for engagement is challenging and not always well understood
- The effort to apply is high relative to the likelihood of award
- Timelines between announcement of award opportunities and LOI and application due dates are short

Selected Findings to Date

Information Collection

- Program staff review of LOIs and proposal critiques
- PCORI Stakeholder surveys (patients, caregivers, clinicians, researchers)
- Applicant survey
- Reviewer survey
- Reviewer focus groups
- Merit Review score analyses
- Data collection on engagement (awardees and partners)

PCORI Staff & Committees

For example,

- Application Enhancement Workgroup
- Merit Review Workgroup

Some Evidence: Applicants embrace engagement but find the requirements challenging

PCORI Researcher Survey (N=508):

- Most researchers are interested in engagement (63% *very* interested)
- Researchers who applied to PCORI (N = 272) rated PCORI's requirement for engagement as more difficult than adherence to Methodology Standards and meeting other requirements
- "What could be done to encourage researchers to involve patients and/or caregivers as partners?"
  - Increase funds available (75%)
  - Train researchers on engagement (71%)
  - Train stakeholders for engagement (67%)
  - Resources for matching with partners (66%)

Some Evidence: Applicants embrace engagement but find the requirements challenging

Qualitative themes from PCORI Applicant Survey:

- Engagement requires resources
- Meaningful and reciprocal partnerships take time
- Research partnership training needs
- Need for more clarity regarding definitions and roles, and guidance on building partnerships

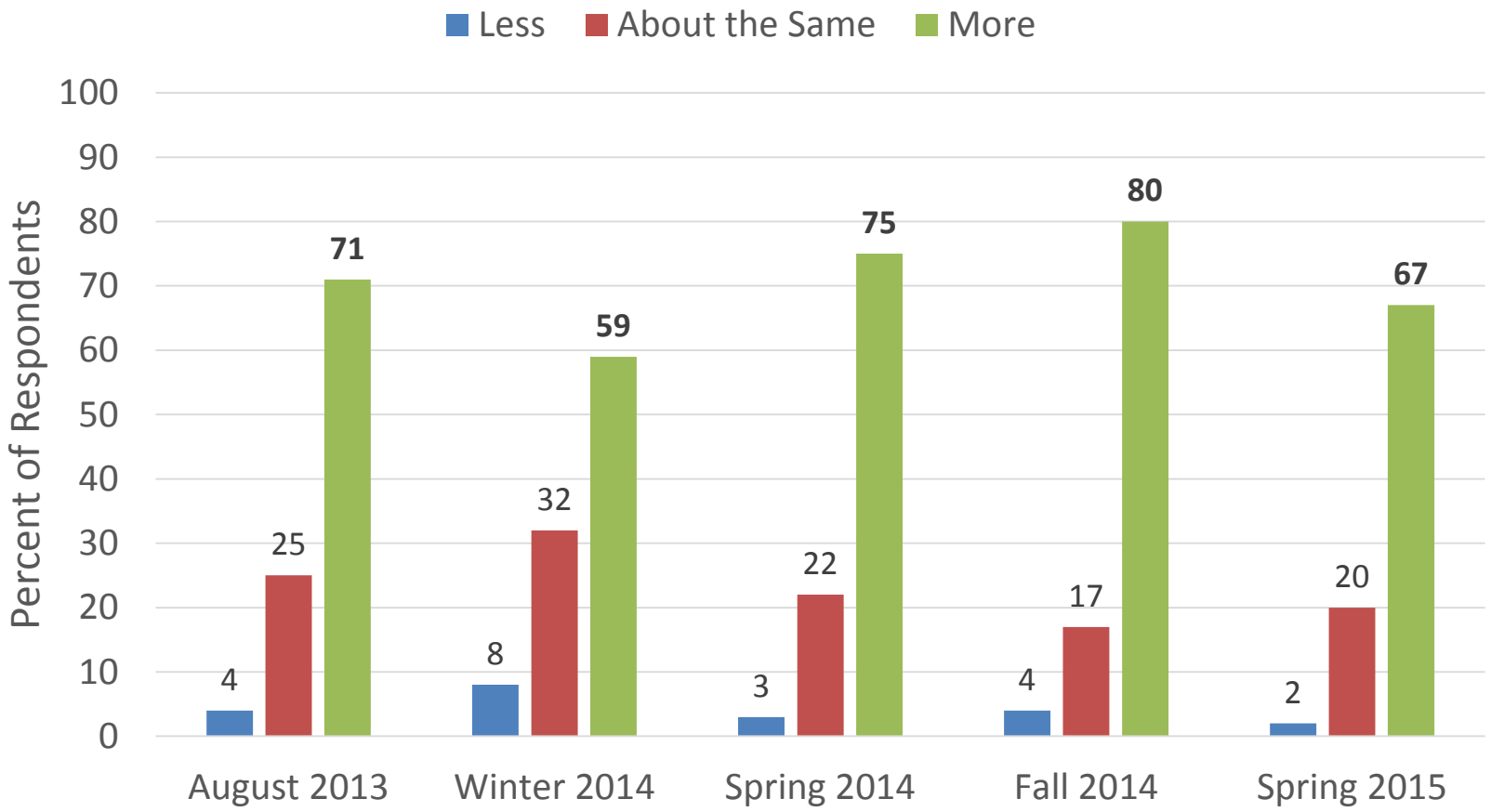
Illustrative quotes:

"Stakeholder engagement takes time and resources to do properly… Most investigators and stakeholders do not have these resources and just don't even try to apply because of this." [Fall 2014 Broad]

"It would be helpful to see more examples, as well as to have clearer expectations for what might be a 'minimum' level of stakeholder engagement... It honestly is the one piece for which I have no clue regarding the quality of my work." [Spring 2014 Broad]

Some Evidence: Applicants think the effort to apply is high relative to the likelihood of award

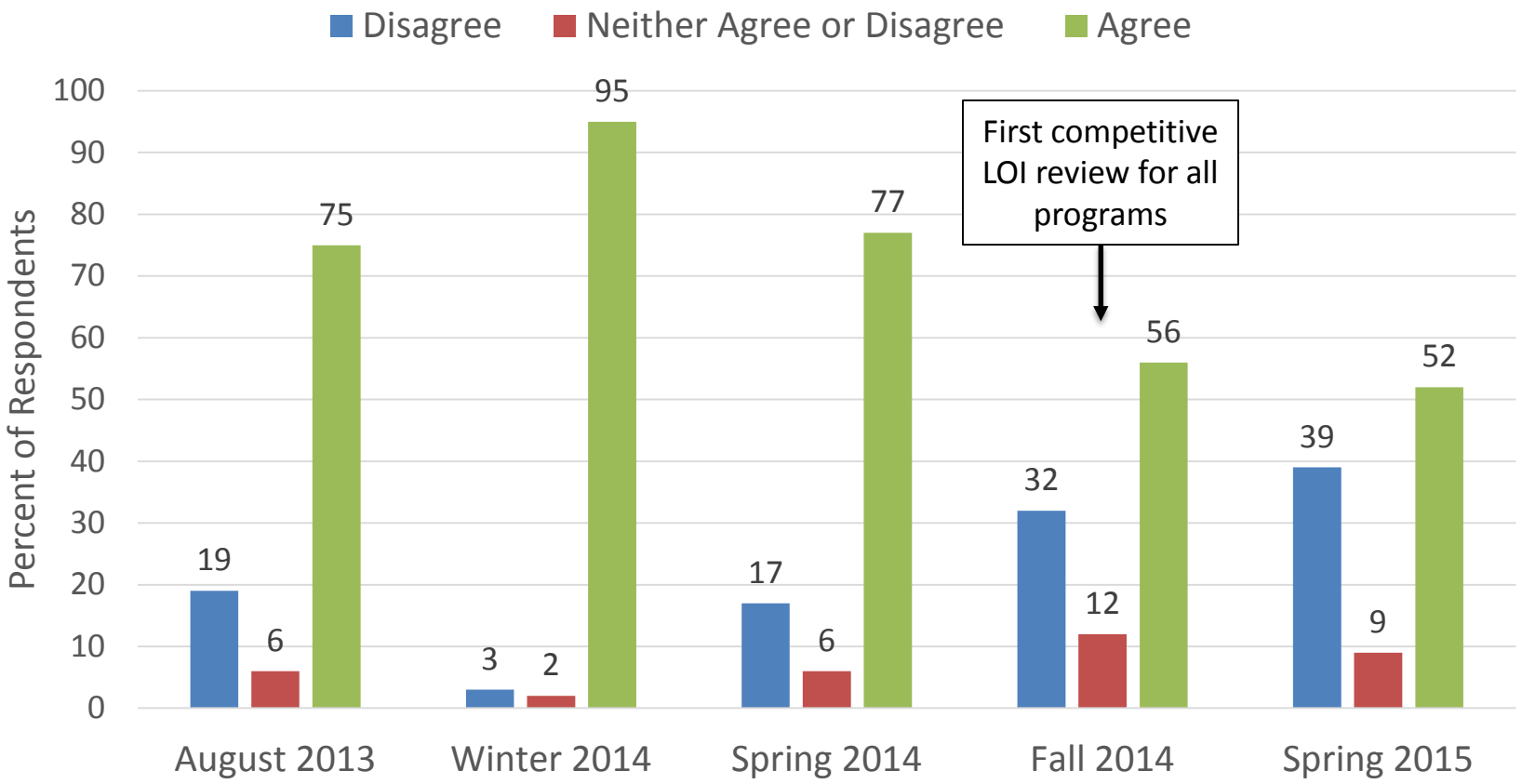
PCORI Applicant Survey: How difficult was it for you to meet the PCORI application requirements, relative to your experience with other funding organizations?



**Data from Broad funding cycles*

Some Evidence: Applicants think the timelines are compressed

PCORI Applicant Survey: "I had adequate time to prepare my application between the funding announcement and the deadline for proposal submission"



**Data from Broad funding cycles*

Additional Considerations

- The workgroup is discussing the potential effect of
  - Award size (direct costs)
  - PCORI's indirect rate cap

Next Steps

- Workgroup will recommend process improvements to be implemented by Board committees and appropriate staff
- Workgroup will perform additional evaluations to inform future recommendations, including:
  - Describe the landscape of CER researchers and reasons for not applying to PCORI
  - Determine reasons LOIs and applications are not selected
  - Identify challenges and opportunities for application process improvement

Summary

- Application Enhancement Workgroup
  - Identifying barriers to and facilitators of receiving high-quality applications
  - Serves as a point of coordination and strategy for facilitating high-quality applications
  - Developed a framework to identify issues to address
  - Will continue to explore hypotheses and recommend further actions

Discussion

2015 PCORI Annual Meeting:
Progress in building a Patient-Centered Outcomes Research Community

Bill Silberg
Director of Communications

Orlando Gonzales, MPA
Chief of Staff, Engagement

Session Structure

Plenaries:

Tuesday, Oct. 6 (afternoon)

- **Dissemination and Implementation of CER/PCOR**– Co-hosted with AHRQ

Wednesday, Oct. 7

- **Opening Plenary –State of CER/PCOR:** Keynote speaker and multi-stakeholder panel on the state of CER/PCOR and progress on building a patient-centered research community
- **Lunch Plenary – Patient Engagement in Research:** Moderated discussion with research teams and patient partners

Thursday, Oct. 8

- **Breakfast Plenary** – Open Science/Data Access and Sharing: In development

Breakouts:

- Results of our earlier funded projects; promising work in progress
- Organized by priority/program, cross-cutting themes from portfolio analysis

Joint Session on Dissemination and Implementation

Co-hosted by PCORI and AHRQ/AcademyHealth

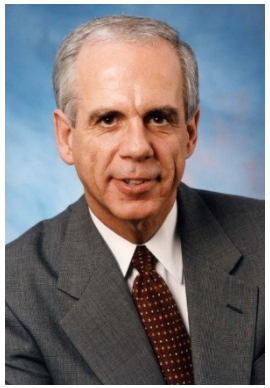
- **Opening and Welcome:** Joe Selby and Rick Kronick will review the roles of PCORI and AHRQ in CER/PCOR dissemination and implementation efforts
- **Two Multi-Stakeholder Panels:** Including scholarly journals, health systems, research leaders, clinicians, nurses, medical societies, patient/caregiver organizations, academia and funders, and payers
  - **Panel #1: Landscape of opportunities and challenges in D&I**
  - **Panel #2: Effecting change: lessons from the field**
- **Keynote presentation on decision-making and behavior change**

Opening Plenary: The State of CER/PCOR

KEYNOTE

Victor Montori, MD
Professor of Medicine,
Endocrinologist, Researcher
Mayo Clinic

Ms. Nancy Brown
Chief Executive Officer
American Heart Association

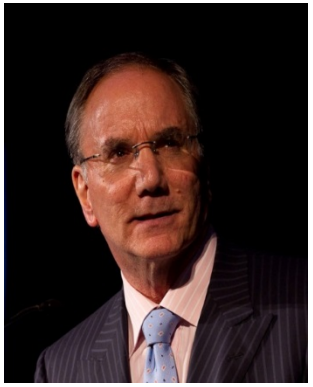


Tony Coelho
Chairman
Partnership to Improve
Patient Care (PIPC)

Helen Darling
Senior Advisor
National Business Group on
Health

Freda Lewis-Hall MD, DFAPA
Chief Medical Officer
Pfizer

Lew Sandy, MD, FACP
Senior Vice President, Clinical
Advancement
UnitedHealth Group



Ken Sharigian
Senior Vice President &
Chief Strategy Officer
American Medical
Association

Patricia Travis, PhD, RN, CCRP
Board Secretary
American Nurses Association

Cross-Cutting Themes (from portfolio analysis)

Up to 40 presentations expected featuring both researchers and partners

- Asthma
- Cancer Symptom and Side Effect Management
- Community Health Workers/Peer Health Workers/Patient Navigators
- Mental Health
- Palliative Care
- Pediatrics
- Rare Diseases
- Reproductive Health
- Shared Decision Making
- Telehealth/Mobile Health

Mini-Summits

- Ambassadors
- Contracts Management and Administration
- Eugene Washington PCORI Engagement Awards
- Evaluating Multi-Component, Multi-Level Interventions
- Methods
- PCORI Pilot Projects
- PCORnet
- Pragmatic Clinical Studies
- Transitional Care Evidence to Action Network

Questions and Discussion

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Directors