Board of Governors Meeting via Teleconference/Webinar

November 21, 2017

12:00 - 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

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:05	**Consider for Approval:** Minutes of the October 30, 2017 Board Meeting
12:05–12:25	**Consider for Approval:** Cycle 1 2017 Broad PFA Awards
12:25-12:45	**Consider for Approval:** Cycle 1 2017 Pragmatic Clinical Studies (PCS) Awards
12:45-1:00	Annual Meeting Debrief
1:00	Wrap up and adjournment

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the October 30, 2017 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

Cycle 1 2017
Broad PFA Slate

Leah Hole-Marshall, JD
Vice Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Broad Cycle 1 2017

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	**1. Study identifies critical methodological gap(s) in PCOR/CER**
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care	**2. Potential for the study to improve PCOR/CER methods**
3. Scientific merit (research design, analysis, and outcomes)	3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment	4. Investigator(s) and environment
5. Patient-centeredness	5. Patient-centeredness
6. Patient and stakeholder engagement	6. Patient and stakeholder engagement

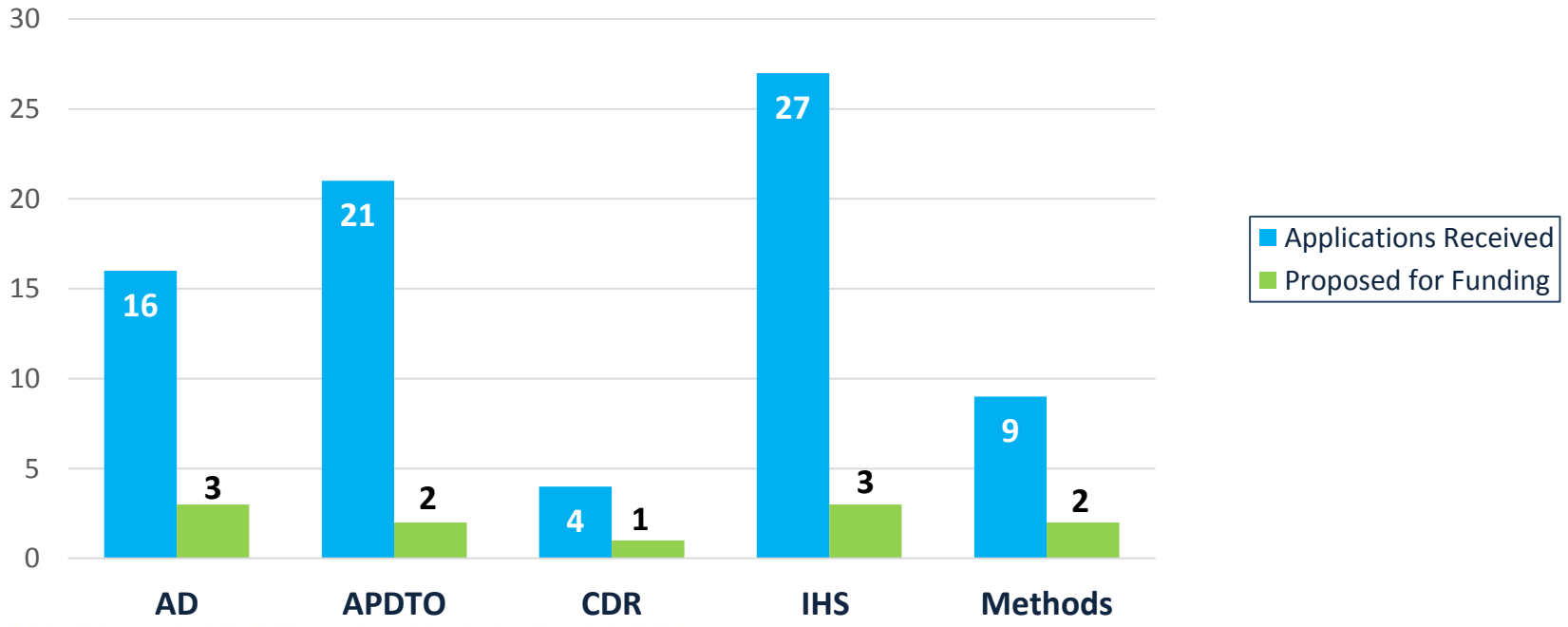
Slate Overview – Broad Cycle 1 2017

Process Overview

- 197 Letters of Intent (LOIs) submitted
- 99 LOIs invited to submit a full application (**50%**)
- 77 applications were received (**78% of invited LOIs**)

Overall funding rate is 14 percent

- We are proposing to fund 11 applications* out of 77 received applications



*Recommended by the Selection Committee

Slate Overview – Cycle 1 2017

Broad PFAs

11 Projects

Broad PFA	Proposed Total Award*
Addressing Disparities	$6.2M
Assessment of Prevention, Diagnosis, and Treatment Options	$4.5M
Communications and Dissemination Research	$2.1M
Improving Healthcare Systems	$10.3M
Improving Methods for Conducting PCOR	$2.1M
TOTAL:	$25.2M

* 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

Addressing Disparities

*3 Recommended Projects**

Project Title
Transgender Cohort Study of Gender Affirmation and HIV-Related Health
Reducing Health Disparities for Black Women in the Treatment of Insomnia
Comparative Effectiveness Research to Improve the Health of Sexual and Gender Minority (SGM) Patients through Cultural Competence and Skill Training of Community Health Center (CHC) Providers and Non-Clinical Staff

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

Assessment of Prevention, Diagnosis, and Treatment Options

*2 Recommended Projects**

Project Title
Randomized Controlled Trial of Laser Hair Depilation in Adolescents with Pilonidal Disease
Comparative Effectiveness of Mindfulness-Based Stress Reduction and Pharmacotherapy for Anxiety

* 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

Communication and Dissemination Research

*1 Recommended Project**

Project Title
Promoting Autonomy and Improving Shared Decision-Making for Older Adults with Advanced Kidney Disease

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

Improving Healthcare Systems

*3 Recommended Projects**

Project Title
Comparative Effectiveness of Clinical Decision-Making Processes Required by Public Health Systems
Comparison of Patient-Centered versus Provider-Centered Delivery of Cognitive Behavioral Treatment (CBT) for Pediatric Anxiety and Obsessive Compulsive Disorder (OCD)
A Comparative Effectiveness Trial of an Information Technology Enhanced Peer-Integrated Collaborative Care Intervention for US Trauma Care Systems

* 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

Improving Methods for Conducting PCOR

*2 Recommended Projects**

Project Title
Advancing Privacy Preserving Record Linkage Methods in the Context of Real-World Data Networks & Health Information Exchange
Unlocking Clinical Text in Electronic Medical Records by Query Refinement Using Both Knowledge Bases and Word Embedding

* 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

Broad Cycle 1 2017 Broad

Financial Overview

11
Projects

PFA	Amount Budgeted	Proposed Total Award
Cycle 1 2017 Broad	$46 M	$25.2 M

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Cycle 1 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

Pragmatic Clinical Studies

Cycle 1 2017 Award Slate

Leah Hole-Marshall, JD
Vice Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Pragmatic Clinical Studies – Cycle 1 2017

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

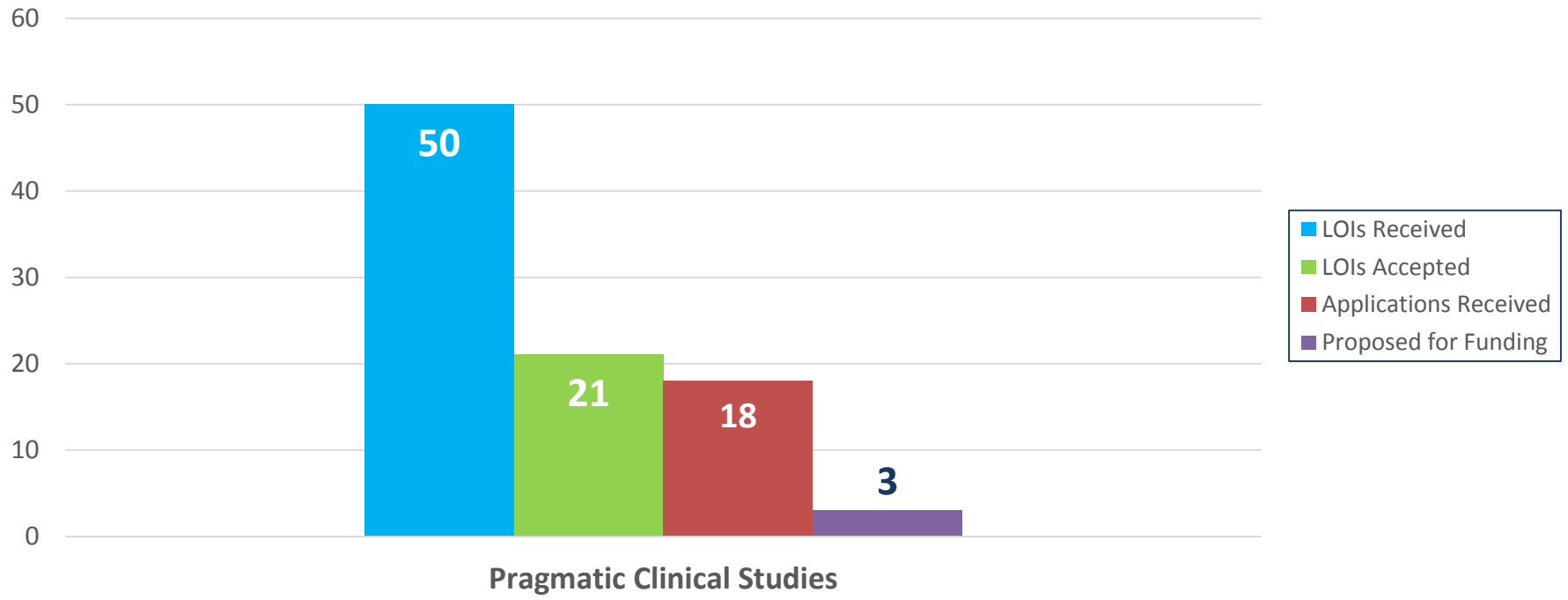
Pragmatic Clinical Studies – Cycle 1 2017

Process Overview

- 50 Letters of Intent (LOIs) submitted
- 21 LOIs invited to submit a full application (**42%**)
- 18 applications were received (**86% of invited LOIs**)

Funding rate is 17 percent

- We are proposing to fund 3 applications* out of 18 received applications



*Recommended by the Selection Committee

Pragmatic Clinical Studies – Cycle 1 2017

Slate Overview

Project
A Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Prostate Cancer ($11.9M)
Comparative Effectiveness of Health System-Based versus Community-Based Dementia Care ($13.6M)
Comparative Effectiveness of System Interventions to Increase HPV Vaccine Receipt in Federally Qualified Health Centers ($6.6M)

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: A Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Prostate Cancer

- **Research Question:** What is the comparative effectiveness of two modalities for delivering radiation therapy as treatment for prostate cancer?
- **Population:** Adult men, ages 30-80 years, with a diagnosis of localized prostate cancer and a life expectancy ≥ 10 years
- **Intervention:** Proton therapy (PT)
- **Comparator(s):** Intensity-modulated radiation therapy (IMRT)
- **Outcomes of Interest:**
  - *Primary:* Quality of life – measured across bowel, urinary, and sexual domains
  - *Secondary:* Physician and patient-reported treatment side effects, cancer recurrence
- **Study Design:** Prospective non-randomized parallel cohort comparison with a nested randomized trial
- **Sample Size**: 3,000 in observational cohort (PT: IMRT) and 900 in embedded RCT examining high intensity/shorter duration versus low intensity/longer duration (conventional) PT at all 24 US proton sites and 19 IMRT sites located nearby
- **Length of Follow-up:** 3 years
- **Duration of Active Intervention:** 4-8 weeks
- **Total Project Cost:** $11.9M

Project 1: A Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Prostate Cancer

- **Potential Impact:** Patients and providers will have data to make informed decisions regarding the benefits and risks of PT and IMRT for prostate cancer based on evidence about side effects, quality of life, and survival (at three years)
- **Patient-Centeredness:** The outcomes include measures that are known to be important in this patient population
- **Engagement:** Patients, caregivers, prostate cancer advocacy groups, insurers, and radiation equipment manufacturers will collaborate on the design and implementation of the study. There is a specific focus on minority participation
- **Implementation/Dissemination:** The team plans to collaborate with patient advocacy groups and medical specialties to disseminate findings

Project 2: Comparative Effectiveness of Health System-Based versus Community-Based Dementia Care

- **Research Question:** Is dementia care based within the health system superior to dementia care based in the community?
- **Population:** Patients diagnosed with dementia, not residing in nursing homes, have a caregiver that speaks English or Spanish, and have a primary care physician who is willing to partner with the program
- **Intervention:** Health System-based Dementia Care (HSDC)
- **Comparator(s):** Community-based Dementia Care (CBDC)
- **Outcomes of Interest:**
  - *Co-primary:* Neuropsychiatric Inventory Questionnaire (NPI-Q) severity (a measure of patient behavioral symptoms) and NPI-Q distress (a measure of caregiver distress due to patients' behavioral symptoms)
  - *Secondary:* Patient long-term nursing home placement and caregiver unmet needs and confidence, strain, and depressive symptoms
- **Study Design:** Two arm pragmatic randomized clinical trial
  - Sample Size: 1,534 patients (767 per arm), 1,534 caregivers
- **Length of Follow-up:** 18 months, including check-ins every 3-4 months during the intervention period
- **Duration of Active Intervention:** 18 months
- **Total Project Cost:** $13.6M

Project 2: Comparative Effectiveness of Health System-Based versus Community-Based Dementia Care

- **Potential Impact:** By determining whether a community-based or health system-based approach is more effective in enhancing dementia care, decision makers will better understand which types of approaches to implement where, potentially improving dementia care
- **Patient-Centeredness:** The outcomes of this study were identified by patients and other stakeholders. Going forward, a Study Advisory Committee will oversee the study
- **Engagement:** Local and national patient and stakeholder committees will be involved in every step of the research process, including recruitment/retention, educational material development/adaptation, identifying local resources, and dissemination. Additional foundation funding secured to support engagement and dissemination activities
- **Implementation/Dissemination:** A summary of findings will be published online and mailed to all participants and caregivers. The summary will be vetted by the National and Local Patient/Family Stakeholder committees, translated into Spanish and adapted to suit regional populations

Project 3: Comparative Effectiveness of System Interventions to Increase HPV Vaccine Receipt in FQHCs

- **Research Question:** Is a parent-focused, clinic-focused, or combined parent- and clinic-focused intervention more effective than usual care at increasing uptake of prophylactic HPV vaccine among underserved, ethnic minority adolescents receiving care through Federally Qualified Health Centers (FQHCs)?
- **Population:** Adolescents ages 12-17, the majority of whom are Latino
- **Intervention:** Combined intervention including parent reminders (text or mail) and a multi-level, multi-component clinic-based intervention consisting of provider education and establishment of policies and protocols to minimize missed opportunities for vaccinations
- **Comparator(s):**
  - Parent reminders
  - Multi-level, multi-component clinic-based intervention
  - Well-defined usual care
- **Outcomes of Interest:**
  - *Primary:* Completion of the HPV vaccine series as defined by the 2016 Advisory Committee on Immunization Practices age-specific guidelines
  - *Secondary:* Parent and adolescent care experiences and preference regarding intervention, provider burden, and satisfaction
- **Study Design:** Four arm stepped wedge cluster RCT
  - Sample Size: 17,000 adolescent patients, 352 parents (process outcomes only)
- **Length of Follow-up:** 6-12 months
- **Duration of Active Intervention:** 6-12 months
- **Total Project Cost:** $6.6M

Project 3: Comparative Effectiveness of System Interventions to Increase HPV Vaccine Receipt in FQHCs

- **Potential Impact:** This study could increase vaccine uptake in a population with elevated risk for HPV-related diseases. There is a potential for high replicability in a broad range of safety net health systems
- **Patient-Centeredness:** Prophylactic HPV vaccination is a breakthrough for cancer prevention. This study targets a population that has the potential to reap a significant benefit from HPV vaccine completion
- **Engagement:** The study will utilize a Patient Advisory Committee consisting of parents of adolescents receiving services at the FQHC. Vaccine-eligible adolescent patients will act as stakeholders. The study will also include a Project Advisory Committee composed of patients, providers, FQHC staff and leadership, research team members, and representatives from local and national stakeholder organizations
- **Implementation/Dissemination:** Study results will be disseminated using multiple channels including the development of intervention protocols and materials that can be widely distributed to other organizations interested in implementing the intervention. Dissemination will occur in collaboration with local, state, and national stakeholders

Pragmatic Clinical Studies Cycle 1 2017

Financial Overview

3
Projects

PFA	Amount Budgeted	Proposed Total Award
Cycle 1 2017 Pragmatic Clinical Studies	**$41 M**	**$32.1 M**

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Cycle 1 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 and Pragmatic Clinical Studies – Cycle 1 2017

SC Recommended Awards vs. Budget

PFA	Proposed Total Award* / Budget
Pragmatic Clinical Studies	**$32/41M (78%)**
Broad Clinical Studies	**$25/46M (55%)**
Total	**$57/87M (65%)**

* 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

- After referral from SC, SOC has begun examining LOI trends and recent application/award profiles across types of funding announcements
- SOC has recommended a communication outreach to remind research institutions that PCORI is still making awards and planning to oversee them through to completion (now underway)
- SOC is undertaking strategic conversations to guide productive approaches for awarding available research dollars

Annual Meeting Debrief

Bill Silberg
Director of Communications

Attendance

About 1,000 attendees from a variety of backgrounds:

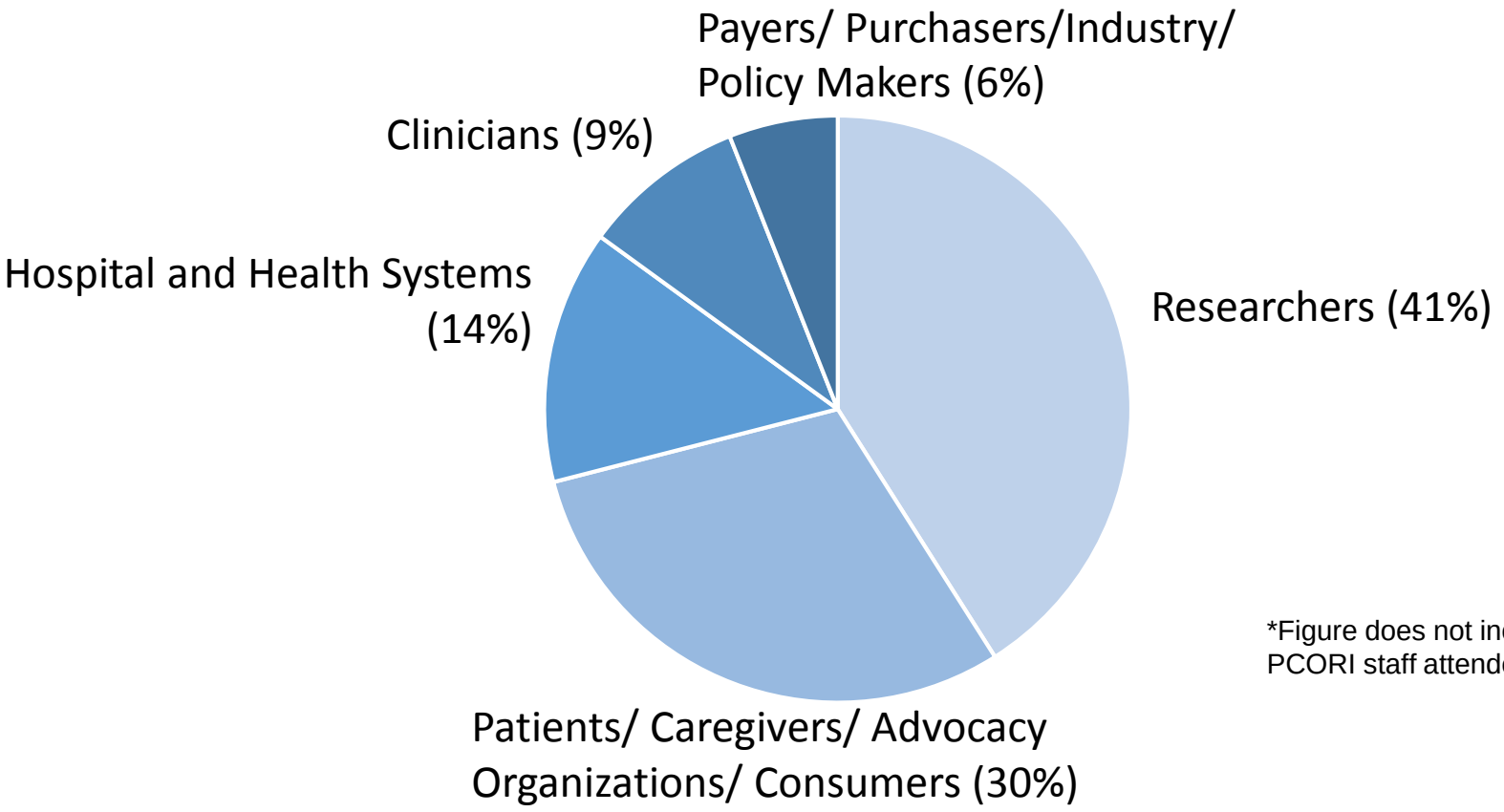
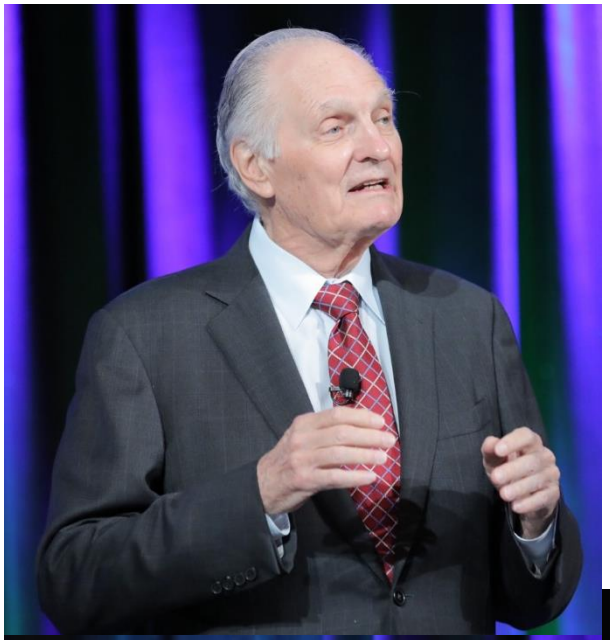


*Figure does not include PCORI staff attendees



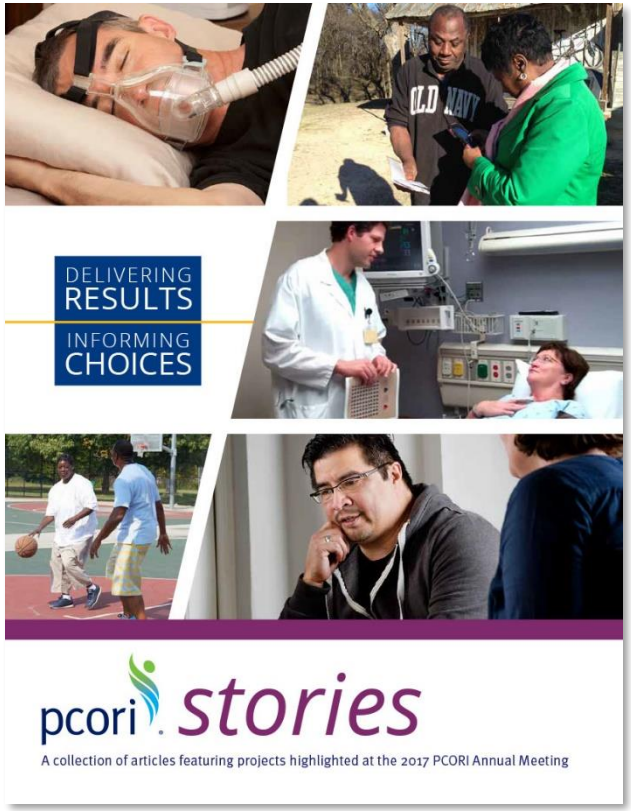
Plenary Webcasts

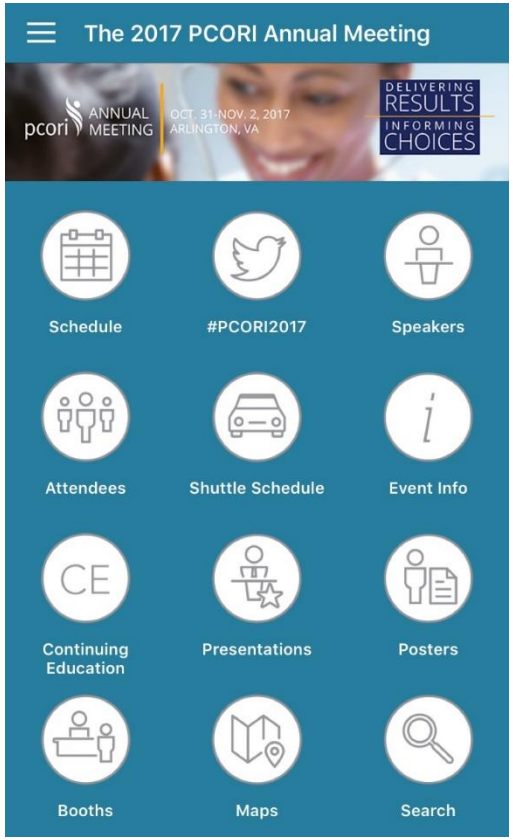
1,000 page views

400+ registrants for Alda talk

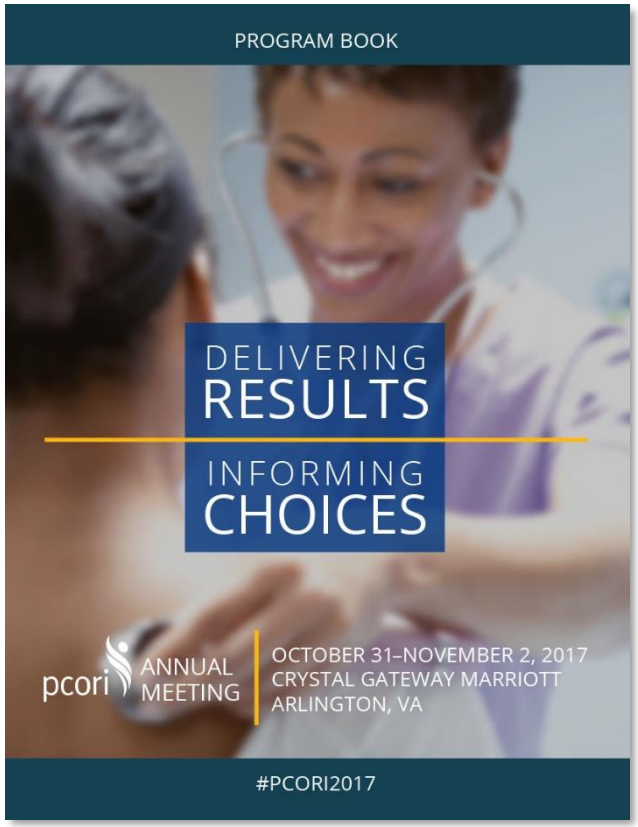
Promotional Material

"PCORI Stories"





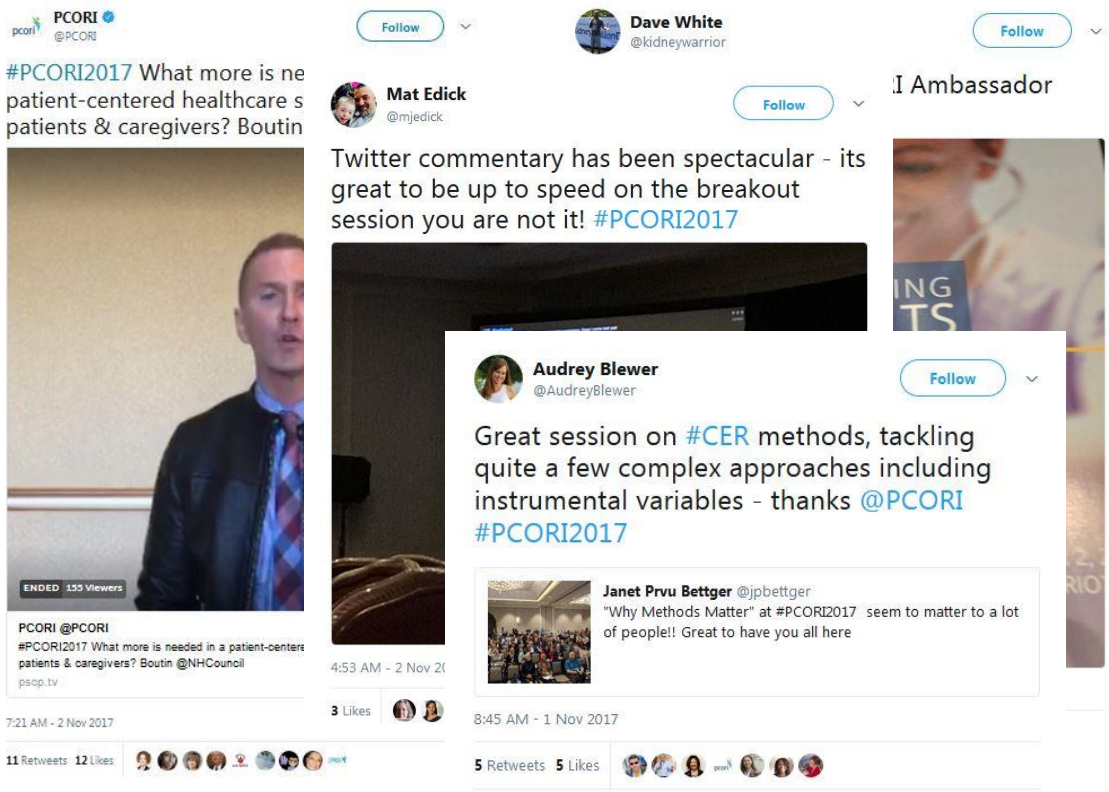
Annual Meeting app

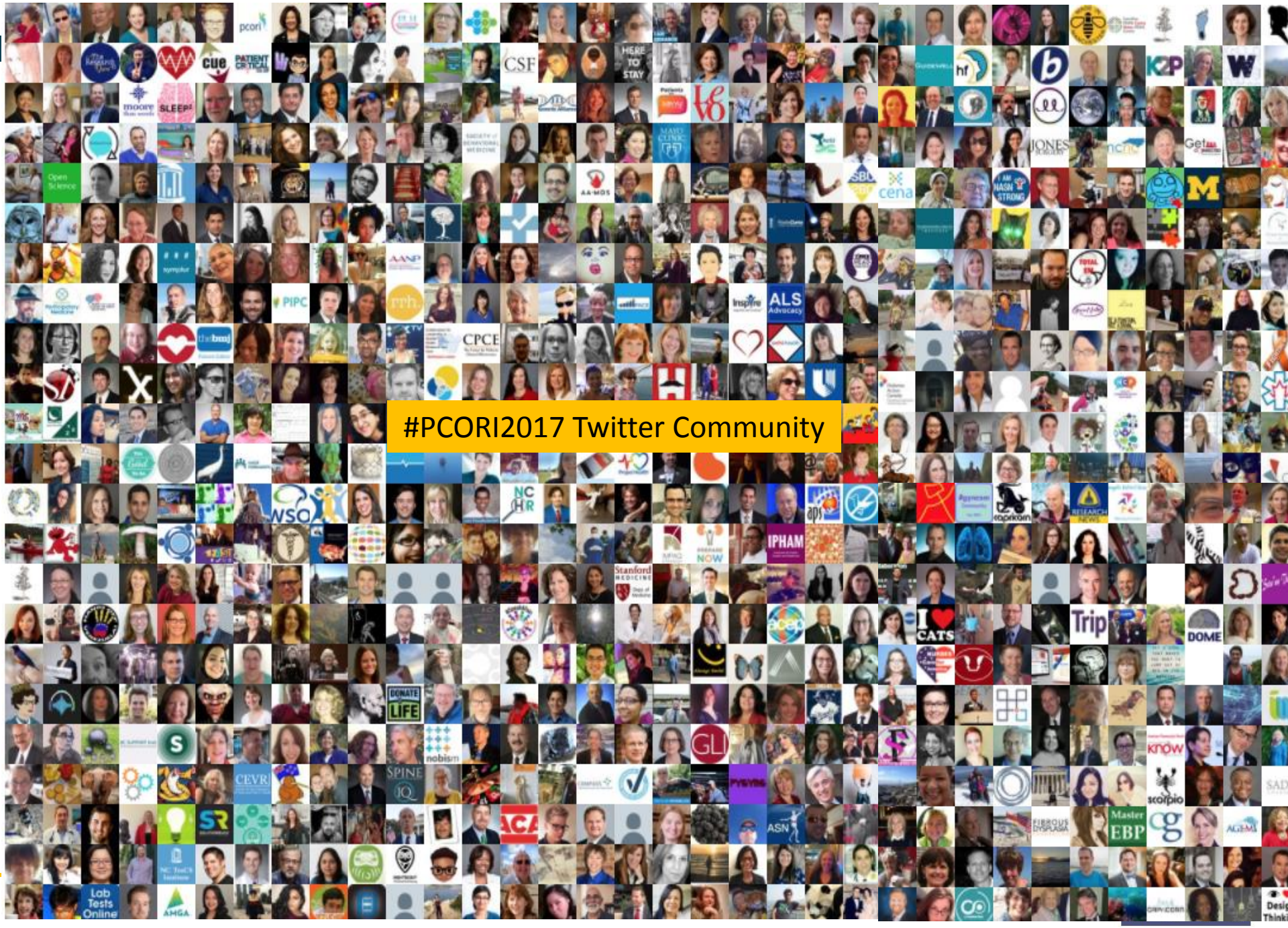


Program book

#PCORI2017 on Twitter

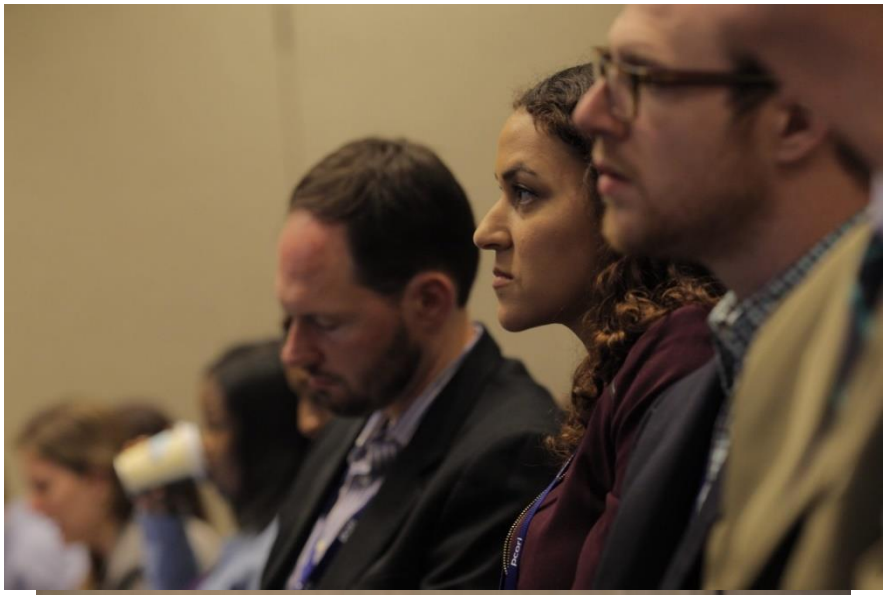
- Reach: 31 million users
- 8,500 Tweets using hashtag #PCORI2017




#PCORI2017 Twitter Community

"I learned about cutting edge research … and [gained] insights about research dissemination. I truly left feeling energized and committed to PCORI."

–Sharon Holder, Engagement Awardee



Thank You!

- **Steering Committee** and our **Board of Governors** and **Methodology Committee** for overall leadership and guidance.
- **PCORI staff** whose efforts helped put together a successful meeting- we couldn't have done it without you
- Our **attendees** and the **broader PCORI community**
- **We'll see you next year!**

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors