

Board of Governors Meeting

Via Teleconference/Webinar

November 20, 2018
12:00 PM – 1:30 PM ET

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 October 29, 2018 Board Meeting

12:05 – 12:10

Debrief of Annual Meeting

12:10 – 12:15

Consider for Approval: Nominations of New Committee Members and Leadership

12:15 – 12:30

Consider for Approval: Cycle1 2018 D&I Limited Competition PFA Awards

12:30 – 1:00

Consider for Approval: Proposed Cycle 1 2018 Slates of Awards

- Broad PFA
- Pragmatic Clinical Studies PFA

1:00 – 1:30

Consider for Approval: Targeted PFAs

- Treatment for Posttraumatic Stress Disorder (PTSD) in Adults
- Treatment Options for Age-Related Hearing Loss

1:30 PM

Wrap up and Adjournment

Call for a Motion to:

- **Approve** the Minutes of the October 29, 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

2018 Annual Meeting Debrief



Attendance

Over 950 attendees joined us this year

Variety of stakeholder groups were represented*

- 42% researchers
- 34% patients, caregivers, consumers, advocates
- 15% clinicians, hospitals/health systems, training institutions
- 9% industry, payers, policy makers, purchasers

Webcasts

More than 1,000 unique webcast viewers

Archived video is available

Watch the presentations of our two keynote speakers, as well as all the plenary and breakout sessions at pcori.org/live

Follow Up Survey

Sent out to attendees to learn about their experiences at the Annual meeting

Survey had a 40% response rate (285 respondents)

Questions covered various aspects of the meeting such as the impact of study results and quality of discussions

Will present survey findings at upcoming Board meeting

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 for making this one of the best so far!

Nominations for Committee Members and Leadership

Christine Goertz, DC, PhD

Chair, Governance Committee
Vice Chairperson, Board of Governors

Strategy Committee Membership Proposed by the Governance Committee



Engagement, Dissemination, and Implementation Committee

Continuing Members

- Sharon Levine, Chair
- Lawrence Becker, Vice Chair
- Gail Hunt
- Gopal Khanna

Nominations

- Trent Haywood
- Michael Herndon
- Naomi Aronson (MC Member)

Research Transformation Committee

Continuing Members

- Kathleen Troeger, Chair
- Freda Lewis-Hall, Vice Chair
- Francis Collins
- Steven Goodman (MC Member)
- *[Resigning: Christine Goertz, Naomi Aronson, MC member]*

Nominations

- Kara Ayers
- Michelle McMurry-Heath
- Janet Woodcock

Science Oversight Committee

Continuing Members

- Robert Zwolak, Chair
- Alicia Fernandez, Vice Chair
- Gail Hunt
- Barbara McNeil
- Ellen Sigal
- Michael Lauer (MC Member)
- *[Resigning : Russell Howerton]*

Nominations

- Jennifer DeVoe
- Christopher Friese

Other Committee Membership Proposed by the Governance Committee

Finance and Administration Committee

Continuing Members

- Lawrence Becker, Chair
- Robert Zwolak
- *[Resigning: Christine Goertz, Vice Chair]*

Nominations

- Russell Howerton *(Nominated for membership and Vice Chair position)*
- Trent Haywood
- Michael Herndon

Governance Committee

Continuing Members

- Christine Goertz, Chair and Board Vice Chairperson
- Sharon Levine, Vice Chair
- Grayson Norquist, Board Chairperson
- Robin Newhouse (MC Member)

Nominations

- Michelle McMurry-Heath

Call for a Motion to:

- **Appoint** the nominated members and leadership of the following Committees:
 - EDIC
 - FAC
 - RTC
 - Governance
 - SOC

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

Selection Committee Membership by Appointment by Board Chairperson

Selection Committee

Continuing Members

- Barbara McNeil, Chair
- Gail Hunt, Vice Chair
- Alicia Fernandez
- Michael Lauer (MC Member)

Appointed by Board Chairperson

- Kara Ayers
- Jennifer DeVoe
- Janet Woodcock

Proposed Funding Slate from the Limited Competition PCORI Funding Announcement (Cycle 1 2018):

Implementation of PCORI-Funded Patient-
Centered Outcomes Research Results

Sharon Levine, MD

Chair, Engagement, Dissemination,
and Implementation Committee

Joanna Siegel, ScD

Director, Dissemination and Implementation Program



Cycle 1 2018 – Limited D&I PFA

Purpose of this funding initiative

- To give PCORI awardee teams an opportunity to
 - Propose **investigator-initiated** strategies for disseminating and implementing findings from their PCORI funded studies in the context of existing evidence
 - Undertake the **next step(s)** for making their research results more useful, actionable, accessible and available to targeted end users

Cycle 1 2018 – Limited D&I PFA

Merit Review Criteria

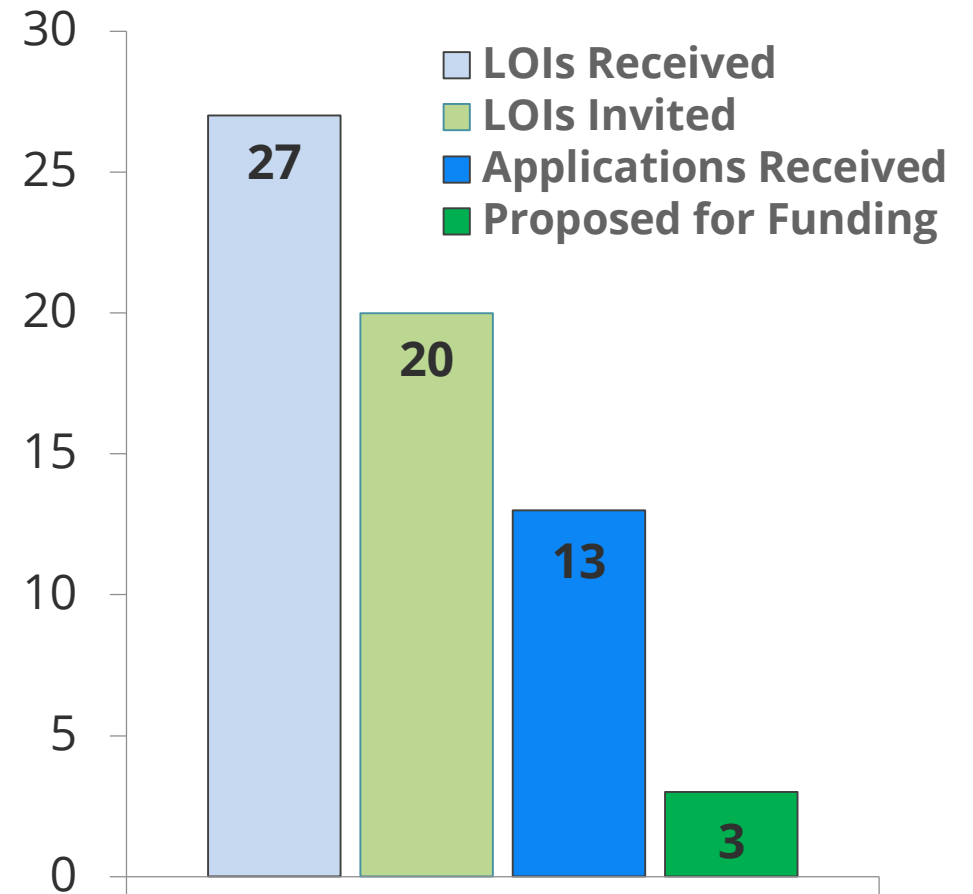
1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for dissemination
3. Technical merit (project design, evaluation, and outcomes)
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

Cycle 1 2018 – Limited D&I PFA

Process Overview



- **Application overview**
 - 27 Letters of Intent (LOIs) submitted
 - 20 LOIs invited to submit a full application (74% of submitted LOIs)
 - 13 applications received (65% of invited LOIs)
- **Overall funding rate is 23 percent**
 - EDIC proposes to fund a slate of 3 applications* out of 13 received applications
- **Proposed funding slate recommended by the Engagement, Dissemination, and Implementation Committee (EDIC)* on October 30, 2018**



* Convened with appointed EDIC members whose Board service continued beyond September 23, 2018

Cycle 1 2018 – Limited D&I PFA

Slate of 3 Recommended Projects



Project Title

SAFE CT: Software, Actionable Feedback, and Education for CT: To Help Institutions Optimize Their Radiation Doses

Disseminating Community Health Worker Training

Rethink the Strip: De-adoption of Glucose Monitoring for Non-Insulin Treated Type 2 Diabetes in Primary Care

- Average requested budget per project is \$1.3M
- All proposed projects, including requested budgets and project periods, if approved by the Board, will be subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 1 2018 – Limited D&I PFA

Slate of 3 Recommended Projects



PFA	Amount Budgeted per Year	Proposed Total Award*
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results	\$9M	\$3.9M

*Note: Budgeted amount is for up to 3 cycles per year. This is the first cycle for FY 2019

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 1 2018 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results 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 1 2018 Award Slate

Barbara McNeil, MD, PhD
Chair, Selection Committee

Diane Bild, MD, MPH
Acting Chief Science Officer

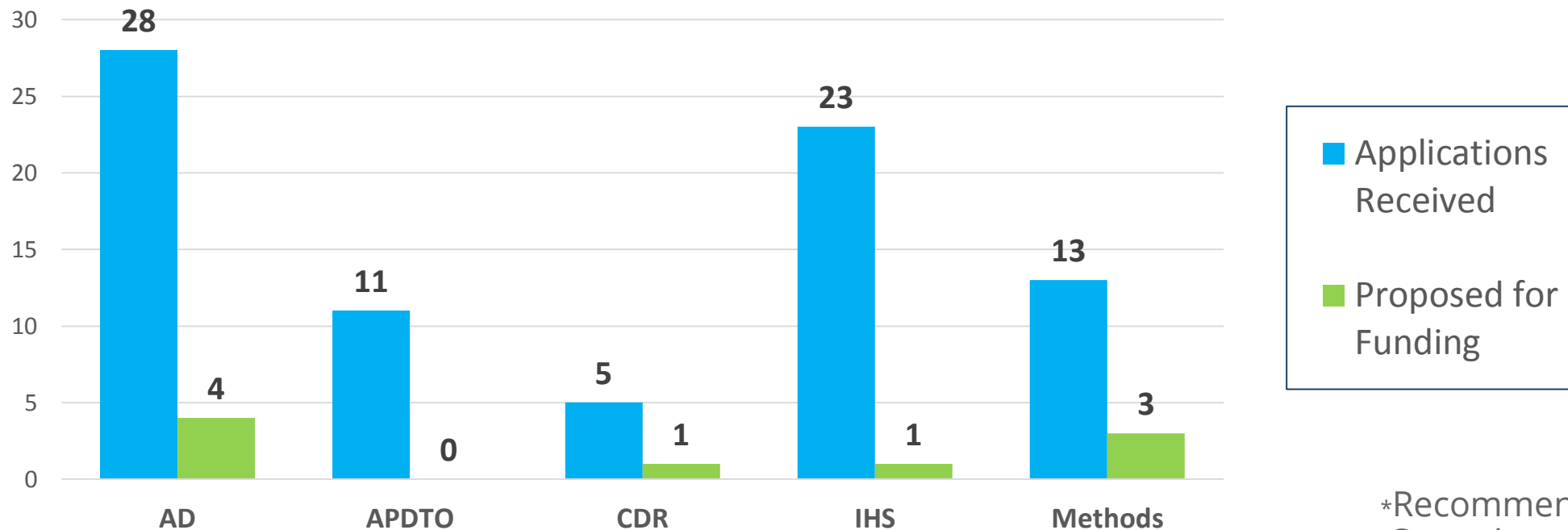
Broad PFAs (excluding Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
<ol style="list-style-type: none">1. Potential for the study to fill critical gaps in evidence2. Potential for the study findings to be adopted into clinical practice and improve delivery of care3. Scientific merit (research design, analysis, and outcomes)4. Investigator(s) and Environment5. Patient-centeredness6. Patient and stakeholder engagement	<ol style="list-style-type: none">1. Study identifies critical methodological gap(s) in PCOR/CER2. Potential for the study to improve PCOR/CER methods3. Scientific merit (research design, analysis, and outcomes)4. Investigator(s) and Environment5. Patient-centeredness6. Patient and stakeholder engagement

Cycle 1 2018 – Broad PFAs

Process Overview



- 224 Letters of Intent (LOIs) received
- 107 LOIs invited to submit a full application
- 80 applications were received
- SC proposes to fund a slate of 9 applications* out of 80 received applications
- **Funding rate is 11 percent**



*Recommended by the Selection Committee on October 15, 2018 20

Cycle 1 2018 – Broad PFAs

Slate Overview



Broad PFA	Amount Posted	Proposed Total Award
Addressing Disparities	\$8M	\$14.9M
Assessment of Prevention, Diagnosis, and Treatment Options	\$32M	--
Communication and Dissemination Research	\$8M	\$2.8M
Improving Healthcare Systems	\$16M	\$5.1M
Improving Methods for Conducting PCOR	\$12M	\$2.9M
TOTAL	\$76M	\$25.7M

* 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 1 2018 – Addressing Disparities

Slate of 4 Recommended Projects



Project Title
Reducing Oral Health Disparities of Older Adults: Comparative Effectiveness of 2 Treatments
Reducing Disparities in Behavioral Health Treatment for Children in Primary Care
Peer Online Motivational Interviewing for Sexual and Gender Minority Male Survivors
Leveraging mHealth and Peers to Engage African-Americans and Latinos in HIV Care (LEAN)

Resubmissions in Bold

Note: 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 1 2018 – Communication and Dissemination Research

Slate of 1 Recommended Project



Project Title
Comparing Strategies for Implementing Primary HPV Testing for Routine Cervical Cancer Screening

Comparing Strategies for Implementing Primary HPV Testing for Routine Cervical Cancer Screening

Cycle 1 2018 – Improving Healthcare Systems

Slate of 1 Recommended Project



Project Title
Patient-Centered Enhancements in School Behavioral Health: A Randomized Trial

Resubmissions in Bold

Note: 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 1 2018 – Improving Methods for Conducting PCOR

Slate of 3 Recommended Projects



Project Title

Evaluation of Complex Interventions on Drug (Re)fill Behavior Using Electronic Healthcare Data

Incremental Privacy-Preserving Record Linkage (iPPRL) to Improve Data Quality

Natural Language Processing for Medication Adherence: Complex Semantics and Negation

Cycle 1 2018 – Broad PFAs

Slate of 9 Recommended Projects*



PFA	Amount Budgeted	Proposed Total Award
Cycle 1 2018 Broad	\$31M	\$25.7M

* 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

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 1 2018 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 2018 Award Slate

Barbara McNeil, MD, PhD

Chair, Selection Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Cycle 1 2018 – Pragmatic Clinical Studies

Merit Review Criteria

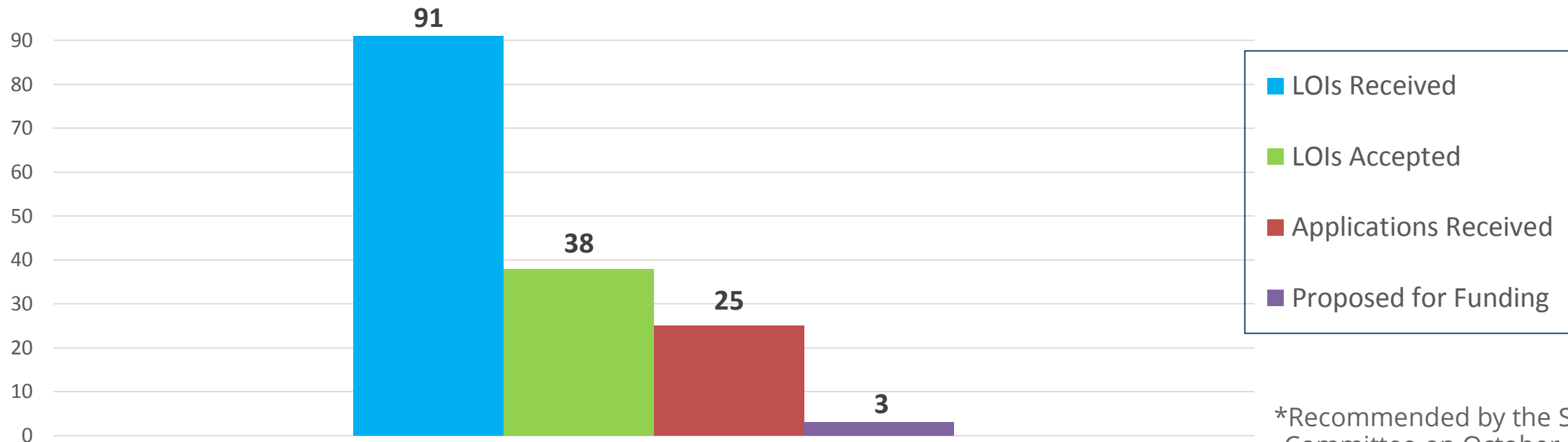


1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder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

Cycle 1 2018 – Pragmatic Clinical Studies Process Overview



- 91 Letters of Intent (LOIs) received
- 38 LOIs invited to submit a full application
- 25 applications were received
- SC proposes to fund slate of 3 applications* out of 25 received applications
- **Funding rate is 12 percent**



*Recommended by the Selection Committee on October 15, 2018

Cycle 1 2018 – Pragmatic Clinical Studies

Slate of 3 Recommended Projects



Project Title

Comparing Smoking Cessation Interventions among Underserved Patients Referred for Lung Cancer Screening

Comparison of Surgery and Medicine on the Impact of Diverticulitis (COSMID) Trial

A Multi-Site Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings

Note: 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: Comparing Smoking Cessation Interventions among Underserved Patients Referred for Lung Cancer Screening



- **Research Question:** What health system strategies are best for helping high-risk people who currently smoke referred for lung cancer screening quit smoking?
- **Population:** People who currently smoke referred for lung cancer screening and who are black, Hispanic, low socioeconomic status, or who have rural residence
- **Comparator(s):**
 - Ask-Advise-Refer (AAR) approach
 - AAR plus free access to nicotine replacement therapy and other pharmacotherapies
 - AAR plus pharmacotherapy plus mobile health application to promote episodic future thinking
 - AAR plus pharmacotherapy plus mobile health app plus financial incentives to quit smoking
- **Outcomes of Interest:**
 - Primary: sustained smoking abstinence for six months
 - Secondary: motivation to quit, quality of life, self-efficacy, anxiety and other patient-reported outcomes
- **Potential Impact:** Addresses an important evidence gap regarding which smoking cessation interventions are most effective for low-income, racial/ethnic minorities and rural patients undergoing lung cancer screening

Project 2: Comparison of Surgery and Medicine on the Impact of Diverticulitis (COSMID) Trial



- **Research Question:** For patients with quality of life (QoL)-limiting diverticulitis, is elective colectomy more effective than ongoing best medical management?
- **Population:** Adults ≥ 18 years with a history of recurrent diverticulitis OR persisting abdominal complaints for ≥ 3 months after an episode of diverticulitis AND at least one episode confirmed by CT scan
- **Comparators:**
 - Elective Colectomy
 - Best Medical Management (stepped treatments adapted from professional association guidelines)
- **Outcomes of Interest:**
 - Primary: GI Quality of Life Index measured at 6 months post randomization
 - Secondary: PROMIS and other measures to capture decisional regret, work productivity, urinary symptoms, sexual function, serious complications, and health care utilization
- **Potential Impact:** This study will assist individuals in deciding whether to manage their diverticulitis medically or surgically. This treatment question was the highest ranked research priority of the leadership of surgical professional societies.

Project 3: A Multi-Site Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings



- **Research Question:** What is the comparative effectiveness of outpatient and inpatient psychiatry treatment for adolescent patients at risk for suicide?
- **Population:** Adolescents aged 12 to 18 brought to the emergency department with suicidal thoughts or behaviors, who require treatment for suicidality but are not at imminent risk of suicide
- **Comparators:**
 - Outpatient crisis intervention clinic (OCIC)
 - Inpatient psychiatry treatment
- **Outcomes of Interest:**
 - Primary: Time to and number of suicidal events (i.e., suicide attempt, interrupted attempt, hospitalization due to suicidal risk, emergency room/urgent evaluation due to suicidal risk, death by suicide)
 - Secondary: Satisfaction with life, treatment satisfaction
- **Potential Impact:** This study has the potential to provide evidence to help patients and clinicians make informed decisions about which treatment setting works best for improving suicidal event outcomes for adolescents referred for treatment

Cycle 1 2018 – Pragmatic Clinical Studies

Slate of 3 Recommended Projects*



PFA	Amount Budgeted	Proposed Total Award
Cycle 1 2018 Pragmatic Clinical Studies	\$37M	\$28M

* 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

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 1 2018 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

Targeted PFA: Treatment for Posttraumatic Stress Disorder (PTSD) in Adults

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Treatments for Posttraumatic Stress Disorder (PTSD) in Adults

- Multiple clinical societies have identified the need for more research into effective treatment for PTSD. Current guidelines from U.S. Department of Veterans Affairs/ Department of Defense (2017) and the American Psychological Association (2017) highlight the need for the following:
 - Head-to-head comparisons of **evidence-based psychological, pharmacological, and/or combination treatments**
 - Studies that assess the **heterogeneity of treatment effect** (i.e., what works best for whom) for evidence-based interventions in subgroups of interest (e.g., military or civilian, men or women, type of trauma)
 - Studies that include patients with comorbid conditions
 - Studies that evaluate patient-centered outcomes

Treatments for Posttraumatic Stress Disorder (PTSD) in Adults



- **PCORI funded a systematic review update** that was co-published with **AHRQ** in 2018 that found insufficient evidence regarding:
 - The efficacy of some psychological and many pharmacological treatments;
 - The comparative effectiveness various treatments and combination treatments; and
 - Whether any treatment approaches are more effective for patients with specific characteristics
- Review of ongoing research in ClinicalTrials.gov revealed persistent gaps:
 - Many comparators not evidence-based
 - Small sample sizes
 - Lack of studies in subpopulations of interest

Treatments for Posttraumatic Stress Disorder (PTSD) in Adults

Question of interest: Which psychological and/or pharmacological treatments are most effective, and for whom?

Population	Adults with diagnosed PTSD, allowing a broad patient population, including those with comorbidities
Intervention/ Comparators	Psychotherapies and/or pharmacotherapies for which there is demonstrated evidence of efficacy
Outcomes	PTSD symptoms; loss of PTSD diagnosis; functional outcomes
Timing	At least 6 months of follow-up

Requested Research Commitment

- Total requested for this PFA is \$15M in total costs
- Estimated number of studies: 2
- Maximum project duration: 3.5 years

Call for a Motion to:

- **Approve** the development and release of Treatment for Posttraumatic Stress Disorder (PTSD) in Adults Targeted 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

Targeted PFA: Treatment Options for Age-Related Hearing Loss

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Diane Bild, MD, MPH

Acting Chief Science Officer

Treatment Options for Age-Related Hearing Loss



Stakeholder Interest in Hearing Loss Research

- America's Health Insurance Plans (AHIP), James Lind Priority Setting Partnerships, and World Health Organization have stated hearing loss is a research and public health priority, including the need to compare the effectiveness of the different treatments

Policy: Improving Hearing Health Care Accessibility and Affordability

- President's Council of Advisors on Science and Technology (2015) and National Academy of Sciences, Engineering, and Medicine (2016) recommended provision of over-the-counter (OTC) hearing aids and support service models for these devices to improve patient access to hearing health care
- OTC Hearing Aid Act (2017): FDA will create a new class of OTC devices and publish regulations in 2020
- FDA approved one self-fitting hearing aid in October

Treatment Options for Age-Related Hearing Loss

Evidence gaps identified in systematic reviews and by experts:

- Limited evidence for the effectiveness of current digital hearing aids
- Limited information on the comparative effectiveness of different hearing devices (e.g., direct-to-consumer devices, different types of hearing aids) and the support services for these devices

Limitations of Ongoing Studies

- Few large studies registered in ClinicalTrials.gov
- Lack of important patient-centered outcomes to inform decision making

Treatment Options for Age-Related Hearing Loss

Question of Interest: Which hearing device and/or support service(s) offered for the device are most effective for the treatment of age-related hearing loss?

Population	Adults \geq 50 years with mild-to-moderate age-related hearing loss
Intervention/ Comparator	Hearing devices and/or support services offered with devices <ul style="list-style-type: none">• Devices include personal sound amplification products and hearing aids• Support services include self-fitting, audiologist or other certified hearing specialist fitting; and education or counseling
Outcomes	Hearing-specific HRQoL; psychosocial outcomes; hearing aid benefit and satisfaction
Timing	Up to 6 months of follow up

Requested Research Commitment

- Total requested for this PFA in Cycles 1 and 2 2019 is \$12M in total costs
- Estimated number of studies: 4-5
- Maximum project duration: 3 years

Call for a Motion to:

- **Approve** the development and release of Age-Related Hearing Loss Targeted 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

Wrap Up and Adjournment

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 @pcori

 /PCORInstitute

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