Board of Governors Meeting
via Teleconference/Webinar

January 26, 2016

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

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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 p.m.	Call to Order, Roll Call, and Welcome
12:00 – 12:10	**Consent Agenda:** Minutes of the Dec. 7, 2015 Board Meeting & Committee Assignments
12:10 – 12:30	**Consider for Approval:** ADAPTABLE: Supplemental Funding Request
12:30– 12:50	**Consider for Approval:** Awards for The Natural Experiments Network (NEN): A Collaborative Initiative
12:50 – 1:15	**Consider for Approval:** Cycle 1 2015 Large Pragmatic Studies
1:15 – 1:25	**Consider for Approval:** Addition to the Spring 2015 Cycle Broad Slate
1:25 – 1:30	Annual Meeting Update
1:30 p.m.	Wrap up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Motion for Consent Agenda Items

Approve minutes from December 7, 2015 Board meeting

Approve nominations by the Governance Committee for

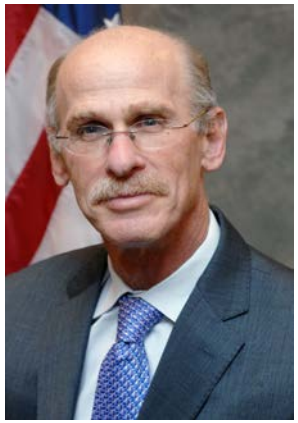
- Board Member Robert Zwolak to serve out the remaining term as Chair for Christine Goertz on the Science Oversight Committee (SOC) to 9/30/2016;
- Board Member Alicia Fernandez to serve out the remaining term as Vice Chair for Bob Zwolak on the Science Oversight Committee (SOC) to 9/30/2016;
- Board Member Richard Kronick to serve as a member of the Science Oversight Committee;
- Removal of Methodology Member Robert Kaplan from the Science Oversight Committee due to his resignation; and
- Board Member Christine Goertz to replace Alicia Fernandez as a member on the Finance and Administration Committee (FAC).

We thank these members for their previous Committee service, and look forward to their future contributions.

Christine Goertz, DC, PhD

Robert Zwolak, MD, PhD

Alicia Fernandez, MD



Richard Kronick, PhD

Robert Kaplan, PhD

Board Vote

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

Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE)

Supplemental Funding Request

Rachael Fleurence, PhD
Program Director, CER Infrastructure

Joe Selby, MD, MPH
Executive Director

Context for the ADAPTABLE Supplement Request

- ADAPTABLE is PCORnet's first pragmatic clinical trial
- Its success is critical to PCORnet and to the future sustainability of the network to attract future funders
- ADAPTABLE was approved by the PCORI Board of Governors in May 2015 for $14M total costs which was the cap set by the Board in 2014 when the PFA was approved
- The Clinical Trials Advisory Panel requested a number of additional activities that PCORI Staff and the ADAPTABLE investigators agreed were important to support the scientific and operational conduct of the trial
- **The budget supplement request is for $3.81M in total costs**
- **PCORI RTC approved this request on Friday, January 15, 2016**
- **PCORI SOC approved this request on Tuesday, January 19, 2016**

Overview of the ADAPTABLE Trial

- **Population:** High-risk patients with a history of heart attack or heart disease. Primary safety endpoint is major bleeding complications
- **Comparators may include:** Compare effectiveness of two daily doses of Aspirin (81mg vs 325mg) in reducing composite of all-cause death and hospitalization for nonfatal heart attack, or nonfatal stroke
- **Study Design:** Individual Randomized Controlled Trial
- **Sample Size/Priority Population:** 20,000 high-risk patients with heart disease
- **Outcomes:**
  - Composite endpoint of all-cause mortality and hospitalization for nonfatal heart attack or nonfatal stroke
  - Major bleeding complications
  - Patient-Reported Outcomes
  - Develop and refine PCORnet infrastructure for conducting faster, cheaper clinical trials
- **Maximum Follow-up Time:** 36 months
- **Total Budget:** $14.7M total costs

ADAPTABLE Strengths

- Answers important **patient-centered question as a real CER study**
- **Builds Infrastructure/breaks new ground – a "demonstration project"**
- Integrates the trial within **routine clinical care and health care delivery**
- Includes **5 of 13** CDRNS (and will include 7/13 with the supplement)
- Uses **eligibility criteria** that create a sizable population of patients and provides more generalizable results
- Leverages available medical data from **electronic health record (EHR) data** to identify **eligible** patients and inform **baseline data** collection
- Ascertains **endpoints** as part of routine healthcare delivery and administrative claims;
- Assures complete **follow-up** data collection through systematic approaches using direct patient contact (patient-reported outcomes) and linkage with multiple data sources
- Novel online **informed consent** and telephone contact for patients without internet access
- Tests **streamlined IRB** and **streamlined contracting** processes for PCORnet

Justification for Additional Budget Items

- Inclusion of Patients with no Internet Access
  - Includes resources for contacting and recruiting patients without internet access
- Recruitment and Retention of Patients and Addition of 2 CDRNs
  - This budget item reflects (1) the effort to launch the sites, support IRB approval, and develop consistent and robust approaches to screening, identifying and recruiting patients using novel approaches and (2) the inclusion of 2 additional CDRNs to meet recruitment targets
- Out of Network Event Ascertainment
  - This activity ensures complete ascertainment for events occurring outside of the CDRN networks
  - The costs support the request, collection, management, analysis of this data including fees to CMS, private health plans and the National Death Index
- Endpoint Validation Plan
  - This sub-study evaluates whether events classified as primary endpoints using the ADAPTABLE coding algorithms are comparable to clinical endpoints confirmed using adjudication methods from traditional trials

Supplemental Budget Request

Project Title	Funds Requested (Direct Costs)	Funds Requested (Total Costs)
Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)	$2.72M	$3.81M

Board Vote

Call for a Motion to:	• **Approve** $3.81M total funds in additional funding for critical activities for ADAPTABLE.
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

Awards for the Natural Experiments Network (NEN): A Collaborative Initiative

Christine Goertz, DC, PhD

Chair, Selection Committee

Evelyn Whitlock, MD, MPH

Chief Science Officer

Natural Experiments
Overview & Slate Recommendation

Natural Experiments Network Limited PFA
Background

- Natural Experiments Network (NEN), is a Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)/ National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded 5-year multi-center study based in five health systems
  - The second 5-year cycle was re-competed and the CDC/NIH funded 5 sites at $450K/year and a coordinating center at $250K/year in 2015
- PCORI is joining the CDC and NIH in co-funding the second 5-year cycle of this initiative
- The NEN is a multi-center network intended to:
  1. Test the comparative health impact of naturally occurring interventions
  2. Improve the methods and research infrastructure for natural experiments for clinical comparative effectiveness in public health
- This partnership allows PCORI to leverage successful continuation of CDC's natural experiments project and its robust scientific network to examine population-based health systems interventions to improve diabetes care

Natural Experiments Network Limited PFA

PFA Goals

- PCORI funding for this one-time announcement was limited to PCORnet Clinical Data Research Networks (CDRNs) that applied to the CDC Funding Opportunity Announcement (FOA) RFA-DP-15-001
- Three CDRNs secured funding as two of the five CDC awards under this FOA
  - CAPriCORN and Greater Plains Collaborative
  - ADVANCE
- The Board authorized funding for up to three additional NEN projects; three PCORnet CDRNs applied:
  - PCORI CDRNs are unique in NEN because they were required to incorporate patient centeredness and patient engagement into their applications
- PCORI accepted the CDC technical score and convened a Merit Review Panel solely to assess the two additional criteria of patient-centeredness and patient/stakeholder engagement

Natural Experiments Network Limited PFA

Project Titles
The Impact of Medicaid Health Homes on Patients with Diabetes
A Patient-Centered Path to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities
Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and Its Complications

PCORI Merit Review only covered the **Patient-centeredness and **Patient and Stakeholder Engagement** criteria. The technical components on research design, data analysis, etc., were reviewed by CDC reviewers when these applicants were being considered for funding by the CDC/NIH FOA.*

Project #1

The Impact of Medicaid Health Homes on Patients with Diabetes

- Research Question: What is the comparative effectiveness of the Medicaid Health Homes program to treatment as usual in reducing unnecessary hospitalizations and other health disparities for Medicaid patients with diabetes?
- Population: Adult Medicaid enrollees with type 2 diabetes and at least one other chronic condition in a northeastern city
- Intervention: Medicaid Health Homes
- Comparators: Treatment as usual
- Outcomes: Diabetes preventable hospitalizations, HbA1c, blood pressure control, LDL-C control (NCQA); diabetes short- and long-term complications and rate of lower extremity amputation among patients with diabetes; medical attention for nephropathy
- Study Design: Population-based observational study, using longitudinal data (2007-2017) from EHRs linked with Medicaid claims data from 7 health systems
  - Sample Size: N=13,000; 6,500 in 14 Health Homes and 6,500 propensity score matched patients with diabetes

Project #1 (cont.)
The Impact of Medicaid Health Homes on Patients with Diabetes

- Engagement: State health agencies, Medicaid, Patient and Clinician Advisory Board of CDRN, diabetic patients, director of a large Health Home, health coaches, and clinical partnerships
  - Initial retreat with Patient and Clinician Advisory Board to more broadly engage stakeholders; listening sessions with broad range of stakeholders in designing research questions, study approach and outcomes; quarterly meetings with stakeholder workgroups
- Potential Impact: Inform state policymakers on whether they should institute Health Homes for the Medicaid population with diabetes. For those states which already offer Health Homes, clinicians and patients can learn whether patients with diabetes and other chronic conditions can benefit from enrollment

Project #2
A Patient-Centered Path to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities

- Research Question: What is the comparative effectiveness of obesity education and counseling versus treatment as usual in improving weight loss for adults either with or at high risk of type 2 diabetes?
- Population: Patients with or at high risk of type 2 diabetes who live in three different states
- Intervention: Obesity education and counseling services
- Comparators: Privately-ensured and Medicare-eligible people who do not receive the services
- Outcomes: Healthy People 2020 objectives for diabetes, including access to services, weight loss, visits for counseling, HbA1C, blood pressure control receipt of an annual eye exam and annual urinary microalbumin test
- Study Design: Population-based prospective observational study in 3 states, with a focus on rural versus urban patients, 6 large health systems, using both retrospective and prospective data from the electronic health record, integrated with linked data from local insurers and Medicare
  - Sample Size: 320,000 patients with diabetes and 2,000,000 at risk of diabetes

Project #2 (cont.)
A Patient-Centered Path to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities

- Engagement: Four patient co-investigators; stakeholder advisory board consists of patients, clinicians, state agencies, and national patient advocacy and professional organizations that meets quarterly
- Potential Impact: Study findings could inform how to address obesity in rural diabetic populations, who have higher prevalence rates and lower concordance rates with guideline based diabetes care. Diabetes is the second highest priority for Rural Healthy People 2020

Project #3
Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and Its Complications

- Research Question: What is the comparative effectiveness of remotely delivered care coordination services versus treatment as usual on diabetes outcomes for adults with type 2 diabetes and at least one other chronic condition?
- Population: Medicare-eligible (65-74) and non-Medicare eligible (55-64) with type 2 diabetes and at least one other chronic condition residing in a southern state
- Intervention: Remotely delivered chronic care management services (CCM)
- Comparators: Medicare- and non-Medicare eligible people who do not receive CCM
- Outcomes: HbA1c, blood pressure control, LDL control, documented smoking cessation counseling if applicable, prescribed aspirin for existing vascular disease, diabetes complications; utilization such as hospitalizations and ER visits; PROs such as health-related quality of life and satisfaction
- Study Design: Population-based prospective observational study
  - Sample Size: 21,000 Medicare eligible and 26,000 non-Medicare eligible patients across 22 diverse clinics in 4 separate health systems

Project #3 (cont.)
Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and Its Complications

- Engagement: Two diabetes advisory groups in southern cities; practicing physicians, an insurer, and a large Medicare health plan, patients, and stakeholders
- Potential Impact: Medicare coverage of CCM services is a new innovation of chronic disease management; study findings could enhance delivery and may influence physician uptake of services and assist underserved, complex diabetes patients to choose which service approaches improve self-management and health outcomes

Slate Overview

Natural Experiments Network Limited PFA

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Projects

PFA	Funds Available	Proposed Total Budget*
The Natural Experiments Network: A Collaborative Initiative	$6.75M	$6.75M

*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 Motion to:	• **Approve** the recommended slate of awards from the Natural Experiments Network Limited 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

Large Pragmatic Studies to Evaluate Patient-Centered Outcomes Cycle 1 2015 Award Slate

Christine Goertz, DC, PhD
Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Cycle 1 2015 Pragmatic Studies PFA

- Goal of PFA:
  - Fund large pragmatic clinical trials, large simple trials, or large-scale comparative observational studies that involve representative patient populations. Studies should:
    - Take place within typical clinical care and community settings
    - Compare the relative effectiveness of two or more alternatives for improving patient-centered outcomes
    - Have a sample large enough to make statistically valid estimates of differences in effect sizes in the entire study population and in patient subgroups
- Up to $10M in direct costs and up to 5 years duration
- Funds available up to $90M total costs

Cycle 1 2015 Pragmatic Studies

Merit Review Criteria

1. Impact of the condition on the health of individuals and populations
2. Potential for the study to improve health care and outcomes
3. Technical merit
4. Patient-centeredness
5. Patient and stakeholder engagement

Slate Overview – Cycle 1 2015 Pragmatic Studies

Process Overview

- 116 Letters of Intent (LOIs) were submitted and reviewed
  - 43 LOIs invited to submit full application (37% of all LOIs)
  - 36 applications submitted, 34 responsive applications reviewed at Merit Review
- Convened post-Merit Review methodology consultation panel with the assistance of our Methodology Committee and Advisory Panel on Clinical Trials
- Reviewed proposed slate with Selection Committee
- ***The Selection Committee recommends funding 5 projects*** (15% of responsive applications)

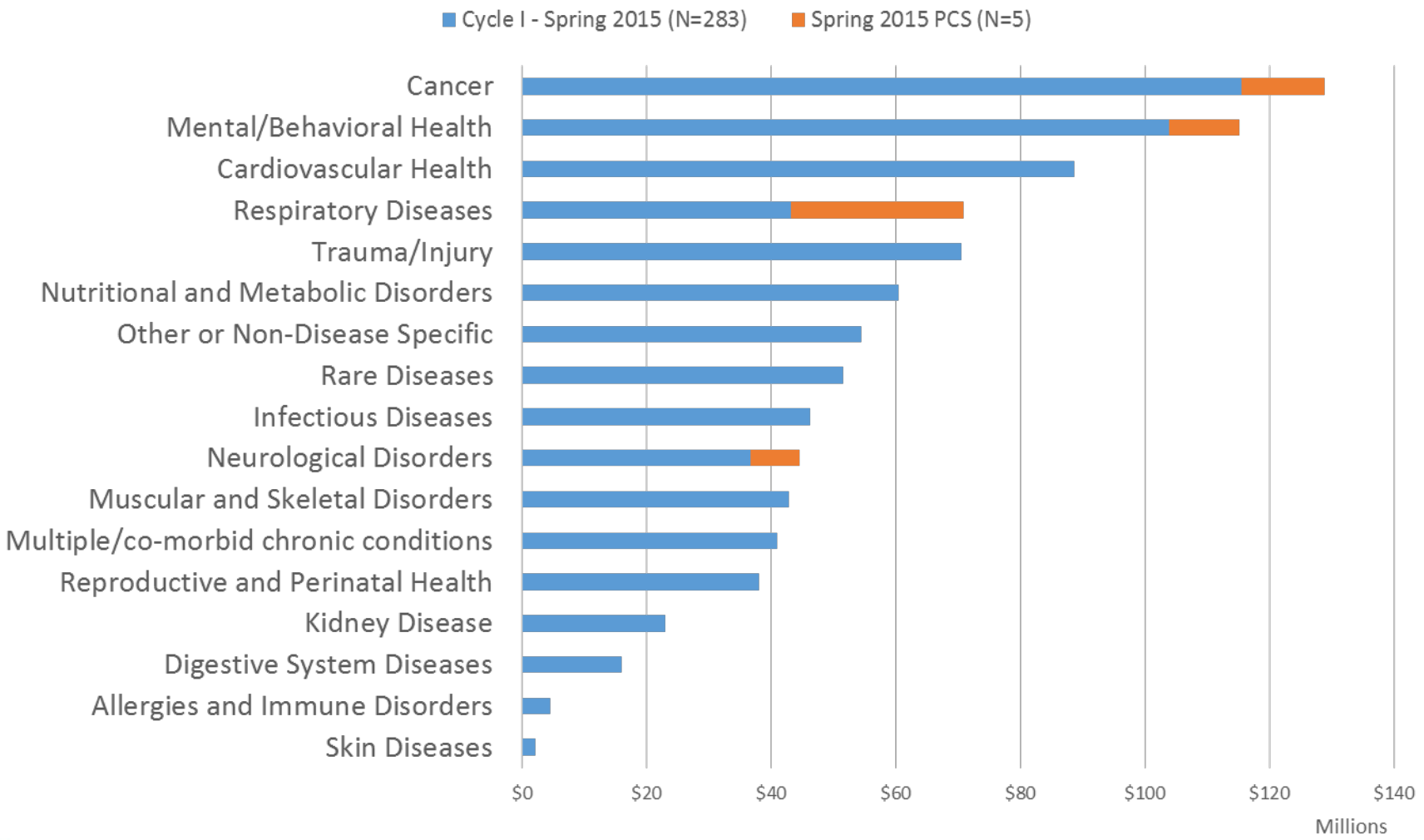
Cycle 1 2015 Pragmatic Studies Funding Slate

*5 Recommended Projects**

Project Title
Determining the Optimal Treatment Strategy for Patients who have Chronic Migraine with Medication Overuse
RofLumilast or Azithromycin to preveNt Chronic Obstructive Pulmonary Disease (COPD) Exacerbations (RELIANCE)
Dissemination of Effective Smoking Cessation Treatment to Smokers with Serious Mental Illness
Patient-Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations
Comparison of Operative versus Medical Endocrine Therapy for Low Risk Ductal Carcinoma in Situ (DCIS): The COMET Trial

**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.*

Approval of this recommended slate would increase our investment in Cancer, Mental and Behavioral Health, Neurological Disorders, and Respiratory Diseases



Does not include Methods Projects
Categories are mutually exclusive

Contribution to PCORI-Directed Large Study Investments

- Proposed slate addresses three more of our priority topics:
  - Ductal Carcinoma in Situ
  - Migraine
  - Substance Abuse-Tobacco Cessation

- Approval of this recommended slate will bring our portfolio of pragmatic studies to a total of ***19 projects and $237M*** since inception (Spring 2014)

Project #1

Determining the Optimal Treatment Strategy for Patients Who Have Chronic Migraine with Medication Overuse

- Research Question: Should overused migraine medications be stopped?
- Population: Adults ages 21-64 who have chronic migraines and very frequently use medications to treat acute headaches
- Intervention: Early discontinuation of the overused medication, switching to other medications, and modification of migraine prophylactic therapy
- Comparator: Migraine prophylactic therapy without early discontinuation of the overused medication
- Outcomes: Frequency of moderate to severe headache days, functional impairment, medication use, treatment adherence, relapse rates
- Study Design: Randomized controlled trial
  - Sample Size: 1,280 participants
- Total Budget: $7.03 million

Project #1 (cont.)

Determining the Optimal Treatment Strategy for Patients Who Have Chronic Migraine with Medication Overuse

- Engagement: Patients and stakeholders have roles as co-investigators and steering committee members of this study; involvement from 4 national clinical specialty groups
- Potential Impact: Despite the high prevalence of medication overuse in the migraine population and the importance of treating medication overuse, the best treatment strategy for these types of patients who have chronic migraine is unknown; new evidence could improve patient function through greater patient and clinician certainty about management approaches.

Project #2

RofLumilast or Azithromycin to preveNt COPD Exacerbations (RELIANCE)

- Research Question: What is the comparative effectiveness of medications for reducing clinical exacerbations of chronic obstructive pulmonary disease (COPD)?
- Population: High-risk adult patients with COPD, including current and former smokers
- Intervention: Azithromycin (an antibiotic with anti-inflammatory properties)
- Comparator: Roflumilast (a phosphodiesterase-4 inhibitor)
- Outcomes: Hospitalization or death; physical, mental, social health; adverse events over 3 years
- Study Design: Head-to-head randomized controlled trial, Bayesian adaptive trial
  - Sample Size: 3,200 participants
- Total Budget: $13.77 million

Project #2 (cont.)

RofLumilast or Azithromycin to preveNt COPD Exacerbations (RELIANCE)

- Engagement: Input from patients, clinicians, and stakeholders; leverages existing partnerships with a PCORnet PPRN and CDRN, and practicing clinicians; multiple bodies will support engagement in all phases of the study, including a steering committee and stakeholder advisory group
- Potential Impact: Evidence-based guidelines in 2015 called for additional trials of effective treatments to reduce exacerbations, particularly of long-term azithromycin vs. roflumilast, and with sufficient power to determine treatment differences among current versus past smokers. Patients and clinicians will also learn about tolerability and harms of both medications. Findings could also help support efforts to promote antibiotic stewardship

Project #3

Dissemination of Effective Smoking Cessation Treatment to Smokers with Serious Mental Illness

- Research Question: What is the most effective strategy for increasing smoking cessation rates in smokers with serious mental illness (SMI)?
- Population: Smokers aged 19 years and older with SMI
- Intervention: Tailored education and tools with community health worker support
- Comparators (2): Tailored education and tools; treatment as usual
- Outcomes: Smoking abstinence (biochemically validated and patient-reported outcomes), health-related quality of life patient-reported outcomes
- Study Design: 3-arm cluster RCT (clinic-level) with nested RCT (patient-level)
  - Sample Size: 1,300 smokers with SMI across 40 clinical sites
- Total Budget: $11.36 million

Project #3 (cont.)

Dissemination of Effective Smoking Cessation Treatment to Smokers with Serious Mental Illness

- Engagement: State agencies on public and mental health, a state medical society, Medicaid, providers including dual eligible patients' interest, people with SMI, family members of those with SMI, nationwide grassroots advocacy group, peer specialists, practicing physicians, leadership and employees of psychiatric rehab organizations
- Potential Impact: More than 50% of people with SMI smoke and they also experience a very large (~28.5 year) reduction in expected lifespan, compared with the general population. Effective strategies to reduce CVD risk through smoking cessation could improve health and longevity in those with SMI and support effective practice of clinicians who care for them.

Project #4

Patient-Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations

- Research Question: Does symptom-based use of inhaled corticosteroids (ICS) reduce asthma exacerbations compared to daily use of ICS?
- Population: African American and Hispanic/Latino patients between the ages of 18-75 with asthma who use ICS or had an exacerbation in the past year
- Intervention: Patient-Activated Reliever-Triggered ICS (PARTICS) approach plus provider-educated standard of care
  - Use of ICS + short-acting beta-agonist (SABA) reliever only when asthma symptoms are present
- Comparator: Daily use of ICS + long-acting beta-agonist (LABA) plus provider-educated standard of care (regardless of presence of asthma symptoms)
- Outcomes: Asthma exacerbations, asthma control, quality of life, days lost from work or school
- Study Design: Randomized controlled trial
  - Sample Size: 1,200 participants
- Total Budget: $13.86 million

Project #4 (cont.)

Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations

- Engagement
  - Patients, patient advocacy groups, providers (including pharmacists), professional societies, health care policy experts, and content experts engaged in formulating the research question, selecting the intervention, outcomes, and analysis; patients and other stakeholder groups are part of study governance structure.
  - Stakeholder support from national clinical specialty groups and pharmaceutical companies
- Potential Impact: Results cited as needed, thus likely to influence national guideline groups. Intervention reflects patient preferences and could reduce asthma burden in an underserved population. Pragmatic study features increase potential for scalable and sustainable real-world results. Strong partnerships for dissemination and implementation in policy and practice

Project #5

Comparison of Operative versus Medical Endocrine Therapy for Low Risk DCIS: The COMET Trial

- Research Question: How does active surveillance compare to guideline-based care for women diagnosed with low risk ductal carcinoma in situ (DCIS)?
- Population: Women diagnosed with low risk DCIS
- Intervention: Active surveillance with hormonal manipulation
- Comparator: Conventional care (surgery, radiation, chemotherapy)
- Outcomes: 2 year invasive breast cancer rate in the same breast, health related quality of life
- Study Design: Randomized controlled trial, non-inferiority design
  - Sample Size: 892 participants
- Engagement: Study team includes a patient leadership team comprised of cancer survivors
- Total Budget: $13.40 million

Project #5 (cont.)

Comparison of Operative versus Medical Endocrine Therapy For Low Risk DCIS: The COMET Trial

- Potential Impact: Results will inform treatment decision-making and potentially help to mitigate overtreatment and treatment-related morbidity of DCIS, a common screen-detected condition in women. Education and decision-support tools developed, refined and disseminated for this project will provide clear, objective, evidence-based information for patients, health care providers and other stakeholders.

Slate Overview – Cycle 1 2015
Large Pragmatic Studies PFA

5
New Projects

Pragmatic Studies PFA	Funds Available	Proposed Total Budget for Awards*
Large Pragmatic Studies to Evaluate Patient-Centered Outcomes	$90M	$59M

*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** the recommended slate of awards from the Cycle 1 2015 Large Pragmatic 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

Addition to the Spring 2015 Slate

Christine Goertz, DC, PhD
Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Brief History of Addition to the Spring 2015 Slate

- The Board approved the Spring 2015 Slate of Broad Awards on September 28, 2015, including 5 projects in our Improving Health Systems Program
- The Selection Committee had considered an additional Improving Health Systems project from this PFA that scored well in merit review and requested further discussion of that application among the PI and PCORI staff
- After those discussions were completed, the Selection Committee considered this project again in January

- ***The Selection Committee recommends funding this additional project from the Spring 2015 Slate:***

Project Title: Improving Self-Care Decisions of Medically Underserved African Americans with Uncontrolled Diabetes: Effectiveness of Patient-Driven Text Messaging versus Health Coaching

Improving Self-Care Decisions of Medically Underserved African Americans with Uncontrolled Diabetes: Effectiveness of Patient-Driven Text Messaging versus Health Coaching

- Research Question: What is the relative effectiveness of interventions for improving self-care in medically-underserved African Americans with uncontrolled diabetes and multiple chronic conditions?
- Population: African Americans aged 35-75 with uncontrolled diabetes and multiple chronic conditions in a medically underserved area in a southeastern state (i.e., one safety net hospital and its associated clinics).
- Interventions: Customized text messages from the doctor's office versus community-based diabetes wellness coaches
- Comparator: Enhanced usual care
- Outcomes: Summary of Diabetes Self Care Activities survey (3 of 6 subscales), diabetes specific quality of life, primary care engagement, and average HBA1c
- Study Design: 3-arm randomized controlled trial
  - Sample Size: 1,000 participants

Improving Self-Care Decisions of Medically Underserved African Americans with Uncontrolled Diabetes: Effectiveness of Patient-Driven Text Messaging versus Health Coaching (cont.)

- Engagement: Patient advisory council of 12 people with diabetes, a community advisory council with local and national representatives, and a provider leadership counsel from participating practices
- Potential Impact: Provide evidence-based strategies to support better self-management of diabetes in medically underserved populations with consideration of differences based on literacy, age, technology use, and disease complexity; ability to consider tailoring of strategies in rural vs non-rural settings.

Slate Budget Overview
Spring 2015 Cycle – *Broad PFAs*

Approved 24 Projects

Proposed 24 + 1 = 25 Projects

Broad PFA	Funds Available	Previously Approved Total Award Budget*	Proposed Total Award Budget with Addition of One IHS Study*
Addressing Disparities	$8.0M	$3.9M	$3.9M
Assessment of Prevention, Diagnosis, and Treatment Options	$32.0M	$12.2M	$12.2M
Communications and Dissemination	$8.0M	$5.9M	$5.9M
Improving Healthcare Systems	$16.0M	$18.7M	$23.9M
Improving Methods for Conducting PCOR	$12.0M	$6.1M	$6.1M
Rare Disease	$12.0M	$7.4M	$7.4M
TOTALS:	$88.0M	$54.2M	$59.4M

*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** the recommended addition to the Spring 2015 Broad Cycle awards
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

Annual Meeting Update

Joe Selby, MD, MPH

Executive Director

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chairperson, Board of Directors