Advisory Panel on Patient Engagement: In-Person Meeting

October 5th, 2017

8:00 AM – 5:00 PM ET

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome, Introductions, and Review Agenda

Jean Slutsky, PA, MSPH

Chief Engagement and
Dissemination Officer

Kristin L. Carman, PhD

Director of Patient and Public
Engagement

Jane Perlmutter, PhD, MBA

Chair

David White, PhD

Co-chair

Agenda – Advisory Panel on Patient Engagement, October 5 2017

8:30 AM	Welcome from Jean and Kristin and Introductions
9:30 AM	Current State of Affairs
10:15 AM	BREAK
10:30 AM	PCORnet Update
11:00 AM	Science Program Updates
11:30 AM	Annual Meeting Overview
11:45 AM	PCORI Influence Webpage Preview
12:00 PM	Group Photo
12:15 PM	LUNCH
1:00 PM	Engagement Program Updates
2:00 PM	Engagement: Future Directions
2:15 PM	Planning for the Future of Public and Patient Engagement – Overview of Working Committees
3:00 PM	Wrap-Up and Next Steps
3:15 PM	Meeting Adjourned

Introductions

- Please quickly state the following:
  - Name
  - Position title and organization
  - Stakeholder group you represent

Introductions

Jane Perlmutter, PhD, MBA (*Chair)*

Long-Term Cancer Survivor and Volunteer Research Advocate

Representing: Patients, Caregivers, and Patient Advocates

Introductions

David White *(Co-Chair)*

Health Care Consultant

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Sonya Ballentine

Project Manager, College of Psychology, Illinois Institute of Technology

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Katherine Capperella

Global Patient Engagement Leader, Janssen Pharmaceuticals, Johnson & Johnson

Representing: Industry

Introductions

John Chernesky

Lead, Consumer Engagement, Rick Hansen Institute

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Emily Creek, MBA

Senior Director, Help & Support, Arthritis Foundation

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Libby Hoy

Founder/CEO, Patient & Family Centered Care Partners

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Gail Hunt

Board Member, PCORI Board of Governors

Member, Engagement, Dissemination and Implementation Committee

President and CEO, National Alliance for Caregiving

Introductions

Anjum Khurshid, PhD

Senior Health Systems Strategist, Louisiana Public Health Institute

Representing: Researchers

Introductions

Bennett Levitan, MD, PhD

Senior Director, Epidemiology, Janssen Pharmaceuticals, Johnson & Johnson

Representing: Industry

Introductions

Megan Lewis, PhD

Program Director, RTI International

Representing: Researchers

Introductions

Jimmy Lin, MD, PhD, MHS

President, Rare Genomics Institute

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Suzanne Madison, MPH, MPA, PhD

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Mark Mishra, MD

Assistant Professor, Radiation Oncology, University of Maryland

Representing: Clinicians

Introductions

Philip Posner, PhD

Science Advisor, ORISE/ORAU

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Ting Pun, PhD

Retired

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Brendaly Rodriguez, MA

Manager, Community Engagement and Cultural Diversity Program, Clinical and Translational Science Institute (CTSI) at University of Miami

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Beverly Rogers

CEO and Founder, Bev J Rogers Enterprises, LLC

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Thomas Scheid, MA

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Norah Schwartz, MPA, PhD

Professor and Researcher, El Colegio de la Frontera Norte

Representing: Researchers

Introductions

Ronnie Todaro, MPH

Vice President, National Programs, Parkinson's Disease Foundation

Representing: Patients, Caregivers, and Patient Advocates

Introductions

Jack Westfall, MD, MPH

Chief Medical Officer, Clinical Professor of Family Medicine, University of Colorado School of Medicine

Representing: Clinicians

Introductions

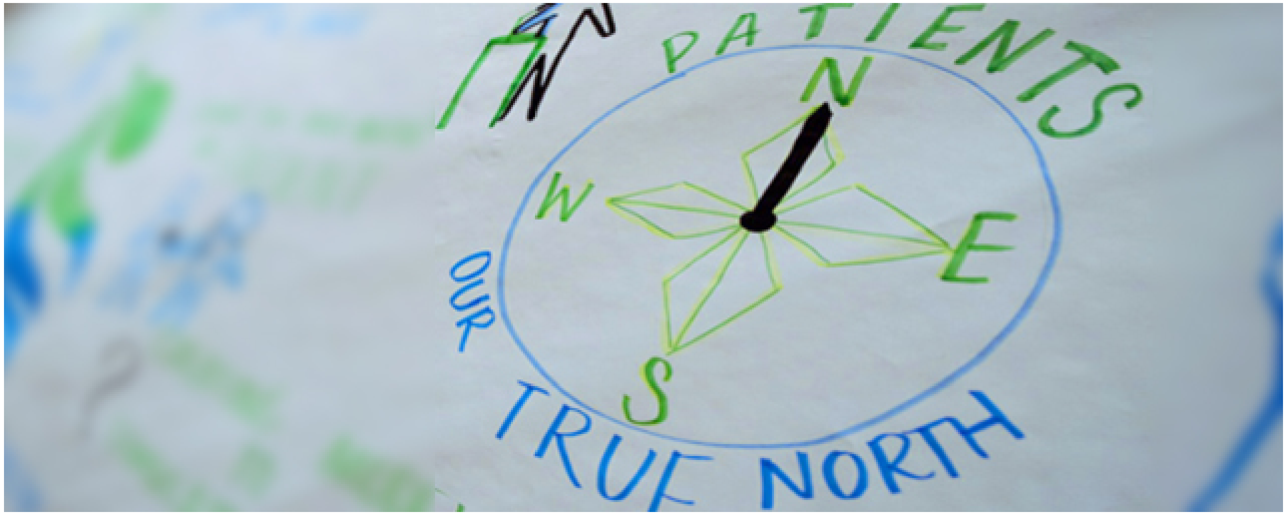
Freddie White-Johnson, MPA, MS

Program Director, University of Southern Mississippi

Representing: Patients, Caregivers, and Patient Advocates

PCORI is…

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns



We fund research that…

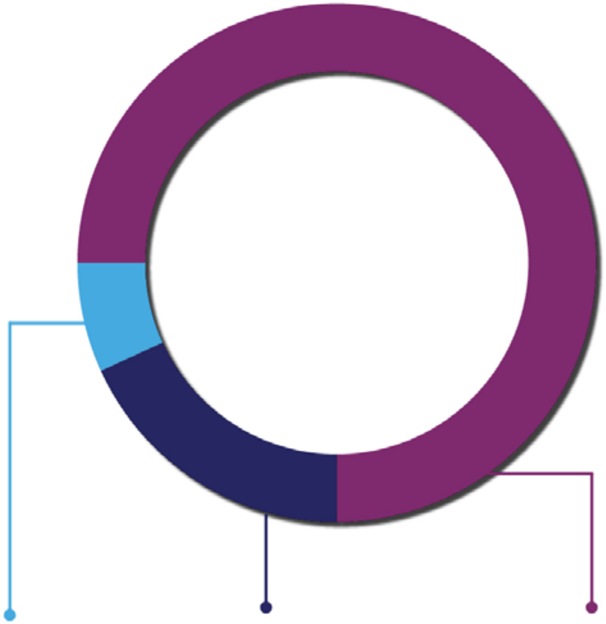
Meets these criteria:

1. **Potential for the study to fill critical gaps in evidence**
   Addresses a clinical uncertainty or decisional dilemma experienced by patients and other stakeholders
2. **Potential for the study findings to be adopted into clinical practice and improve delivery of care**
   Has the potential to lead to improvements in clinical practice and patient outcomes
3. **Scientific merit (Research design, analysis, and outcomes)**
   Has a research design of sufficient technical merit to ensure that the study goals will be met
4. **Investigator(s) and environment**
   The proposed project has a team with appropriate investigators (e.g. qualifications and experience), as well as an environment with sufficient capacity (e.g. resources, facilities, and equipment)
5. **Patient-centeredness**
   Focuses on improving patient-centered outcomes and employs a patient-centered research design
6. **Patient and stakeholder engagement**
   Includes patients and other stakeholders as partners throughout the entire research process

Funding research that matters

BY THE NUMBERS

Research Projects By Area

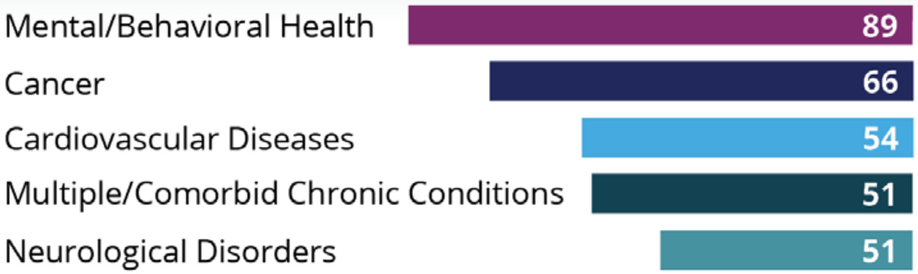


METHODOLOGY
$119 Million
(7.1%)

INFRASTRUCTURE (PCORnet)
$324 Million (19.2%)

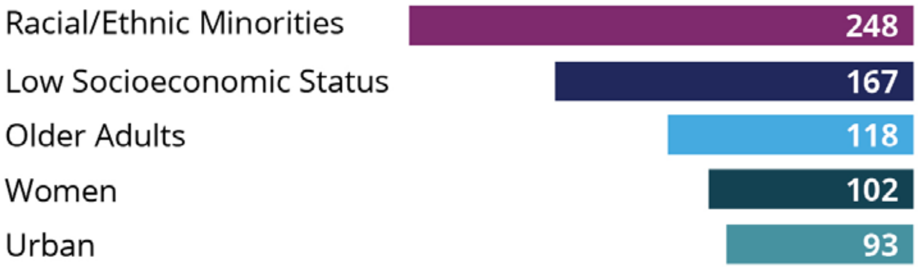
CER
$1.24 Billion
(73.7%)

Most Studied Conditions*



Mental/Behavioral Health	89
Cancer	66
Cardiovascular Diseases	54
Multiple/Comorbid Chronic Conditions	51
Neurological Disorders	51

Most Studied Populations of Interest*



Racial/Ethnic Minorities	248
Low Socioeconomic Status	167
Older Adults	118
Women	102
Urban	93

**Number of projects (out of a total of 365). A project may study more than one condition or population of interest.*

As of March 2017

What we mean by…

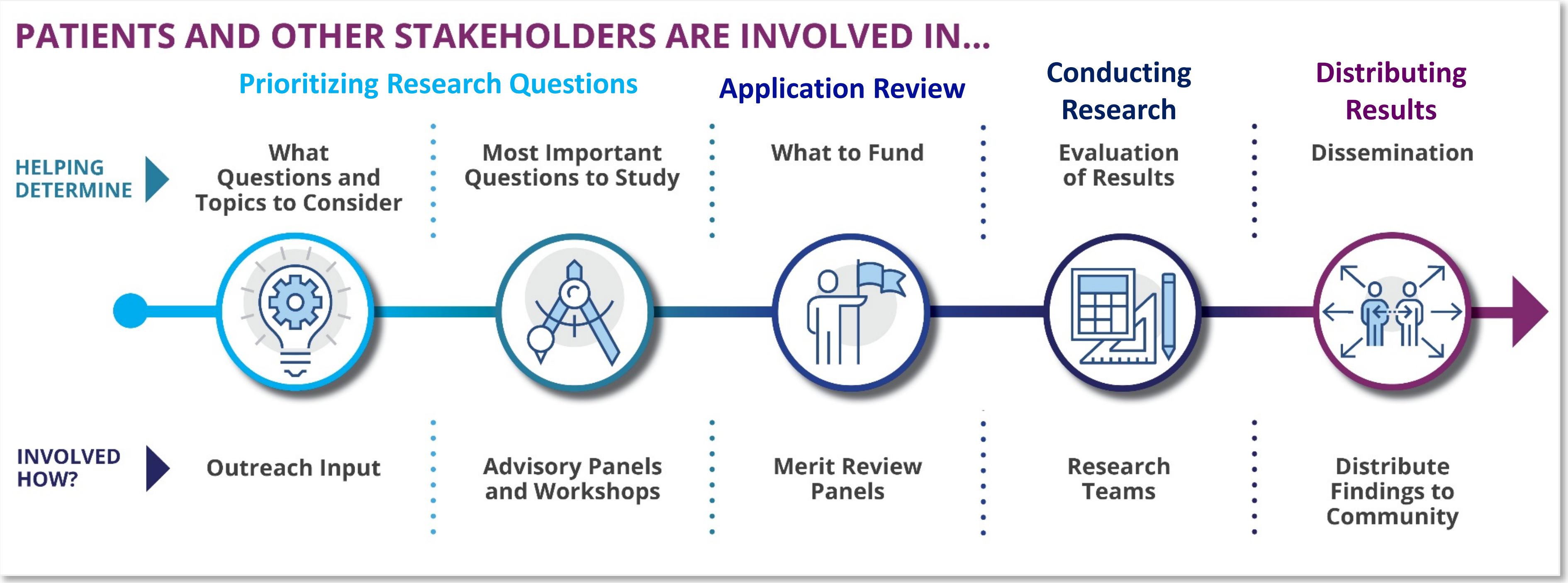
"Patient-centeredness"

- The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
- Research questions and outcomes should reflect what is important to patients and caregivers

"Patient and stakeholder engagement"

- Patients are partners in research, not just "subjects"
- Active and meaningful engagement between scientists, patients, and other stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought-out plan

Stakeholder driven



PATIENTS AND OTHER STAKEHOLDERS ARE INVOLVED IN…

	Prioritizing Research Questions		Application Review	Conducting Research	Distributing Results
HELPING DETERMINE	What Questions and Topics to Consider	Most Important Questions to Study	What to Fund	Evaluation of Results	Dissemination
INVOLVED HOW?	Outreach Input	Advisory Panels and Workshops	Merit Review Panels	Research Teams	Distribute Findings to Community

PCORI PEAP:
Public Policy Update

Andrew Hu, MPP
Director, Public Policy and Government Relations

Jean Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer

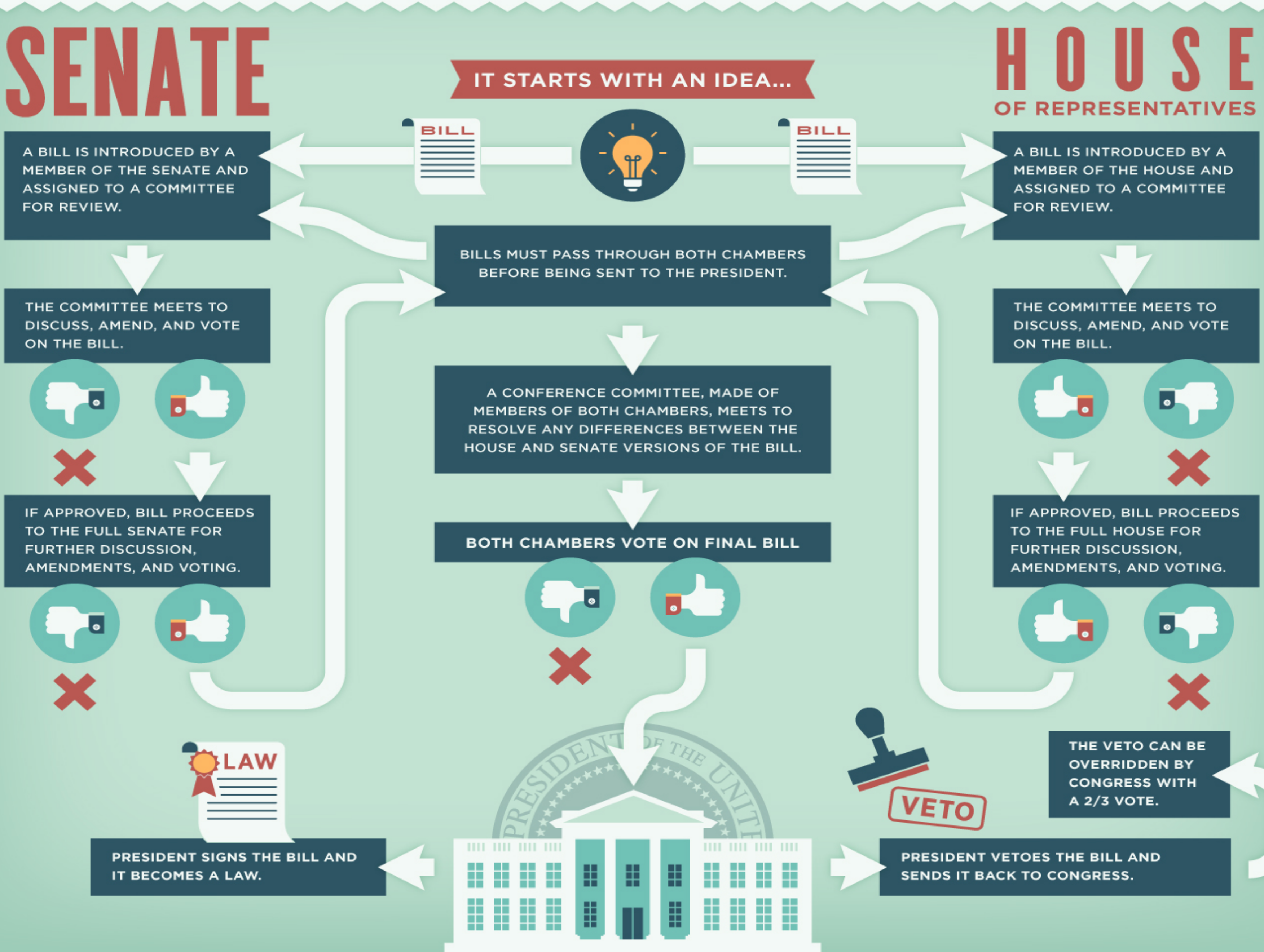
Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

worldvision.org/beyond5
@WVUSAdvocacy

THE US LEGISLATIVE PROCESS

World Vision



IT STARTS WITH AN IDEA...

SENATE

A BILL IS INTRODUCED BY A MEMBER OF THE SENATE AND ASSIGNED TO A COMMITTEE FOR REVIEW.

THE COMMITTEE MEETS TO DISCUSS, AMEND, AND VOTE ON THE BILL.

IF APPROVED, BILL PROCEEDS TO THE FULL SENATE FOR FURTHER DISCUSSION, AMENDMENTS, AND VOTING.

HOUSE OF REPRESENTATIVES

A BILL IS INTRODUCED BY A MEMBER OF THE HOUSE AND ASSIGNED TO A COMMITTEE FOR REVIEW.

THE COMMITTEE MEETS TO DISCUSS, AMEND, AND VOTE ON THE BILL.

IF APPROVED, BILL PROCEEDS TO THE FULL HOUSE FOR FURTHER DISCUSSION, AMENDMENTS, AND VOTING.

BILLS MUST PASS THROUGH BOTH CHAMBERS BEFORE BEING SENT TO THE PRESIDENT.

A CONFERENCE COMMITTEE, MADE OF MEMBERS OF BOTH CHAMBERS, MEETS TO RESOLVE ANY DIFFERENCES BETWEEN THE HOUSE AND SENATE VERSIONS OF THE BILL.

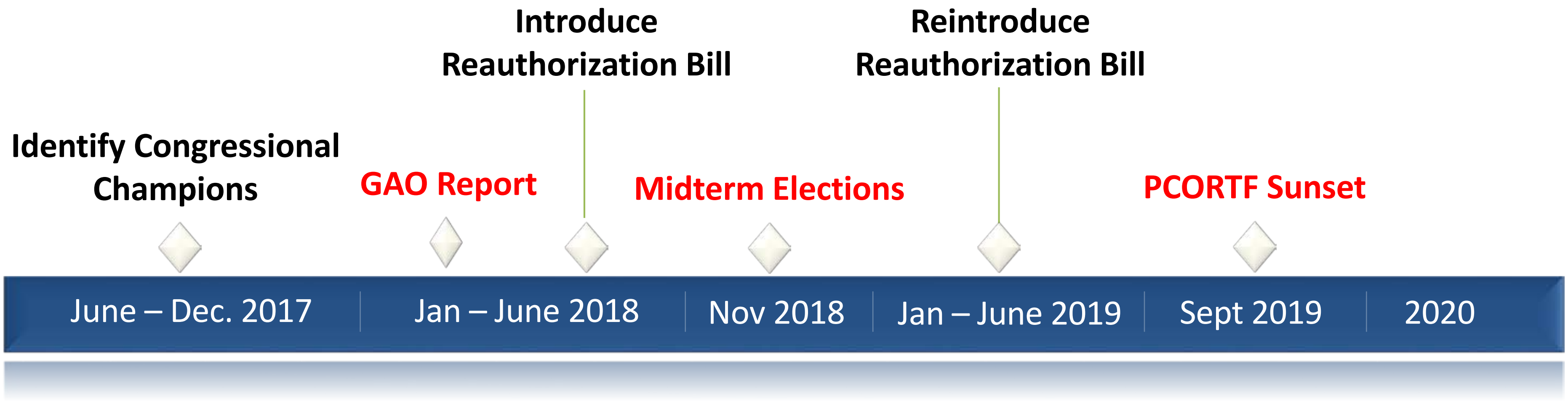
BOTH CHAMBERS VOTE ON FINAL BILL

PRESIDENT SIGNS THE BILL AND IT BECOMES A LAW.

PRESIDENT VETOES THE BILL AND SENDS IT BACK TO CONGRESS.

THE VETO CAN BE OVERRIDDEN BY CONGRESS WITH A 2/3 VOTE.

Timeline for Reauthorization



Introduce Reauthorization Bill

Reintroduce Reauthorization Bill

Identify Congressional Champions

GAO Report

Midterm Elections

PCORTF Sunset

June – Dec. 2017 | Jan – June 2018 | Nov 2018 | Jan – June 2019 | Sept 2019 | 2020

As we work to reauthorize PCORI's funding for the future, it is important to know that PCORI is committed to fulfilling our mandate from Congress and will continue to exist and support the generation of patient-centered research beyond 2019.

Current Priorities for Reauthorization

- Increase awareness of PCORI to policymaking community
- Showcase the value and impact of research
- Continued engagement with key stakeholders
- Frame the role of PCORI for the next 10 years
- Build upon third-party validation

What PCORI is Doing

Education and Increasing Awareness

- Direct engagement with Congressional staff and policymakers
- Congressional briefings
- Thought-leadership activities
- Increased media presence

Highlighting Results and Potential Impacts

- Promoting final results
- Developing economic impact analysis of study findings *(loss of work, decreased hospitalizations, etc.)*

Identifying Potential Policy Roles

- Early access to FDA data to support drug pricing/value debate
- Real-world evidence and early-market surveillance activities
- Coverage with evidence development
- Role in identifying key patient-reported outcomes

Building and Mobilizing Third-Party Support

- Identify and leverage third-party validators
- Activating PCORI validators and direct engagement with patient and stakeholder organizations
- Managing key stakeholder perspectives and opinions

Examples of Patient Org Engagement

- Targeting 40+ patient stakeholders for personal touches

Recent Meetings

- ✓ **American Diabetes Association**
- ✓ **American Heart Association**
- ✓ **American Lung Association**
- ✓ **Lung Cancer Alliance**
- ✓ **National Organization of Rare Disorders**

Key Requests

- More frequent updates throughout lifecycle of relevant projects
- Increase awareness of results timeline
- More accessible view of PCORI portfolio, e.g. where projects intersect with subtopics and populations of interest
- Interest in economic modeling

PCORI Follow-up

- ➢ Provided more detailed updates on specific studies of interest, per PCORI Program Officers.
- ➢ Created portfolio crosswalks based on subtopic, population, and types of outcomes.
- ➢ Arranged a PCORI speaker at NORD Annual Meeting.
- ➢ Opened door for ongoing dialogue.

Examples of Stakeholder Org Engagement

- Strategic targeting of medical specialty societies

Recent Meetings

- ✓ **American College of Surgeons**
- ✓ **American Medical Association**
- ✓ **Society of Thoracic Surgeons**
- ✓ **American Association of Neurological Surgeons**

Key Requests

- – Improve review process to make it easier for societies to apply for research
- – Fund studies that utilize physicians registries
- – Interested in further engagement regarding implementation and implementation strategies
- – More accessible understanding of our portfolio

PCORI Follow-up

- ➢ Planning a medical specialty society roundtable for Jan. 2018
- ➢ Working with individual societies to support research topic generation
- ➢ Engaging specialty societies around dissemination and implementation opportunities
- ➢ Leverage BoG relationships to increase PCORI engagement and presence at society meetings

Example of Congressional Briefing

Meeting

PCORI and **Anthem** cohosted a briefing on the need for evidence-based strategies to address America's opioid epidemic. Speakers included **Senator Shelly Moore Capito** (R- WV).

Stakeholders

Anthem (cohost), **PCORI-funded researcher** (Erin Krebs, MD, MPH), **Veterans Health Administration researcher** (Stephanie Tayler, PhD, MPH), **patient partner** (Christine Veasley)

Importance

PCORI will continue to use its **convening power** to demonstrate the crucial role **clinical comparative effectiveness research** will play in both solving the immediate opioid crisis, and building an **evidence base** for alternative chronic pain treatment options.

Examples of Third-Party Validation

The Value of Comparative Effectiveness Research

Dr. Phil Gingrey, The District Policy Group (link)

> ***"…I am impressed with the PCORI studies I reviewed and am encouraged by the manner in which the information is being disseminated and leveraged – to the benefit of patients, physicians and the health care system, and not in an autocratic way.***

The Future of Comparative Effectiveness Research

Hannah Martin, Bipartisan Policy Center (link)

> ***"…PCORI enjoys broad bipartisan support for its mission to provide providers with the best evidence-based information on treatments, while also giving them the flexibility to tailor treatments to each individual patient.***

PCORnet® Overview

Claudia Grossmann

Research Infrastructure

October 05 2017

pcornet® The National Patient-Centered Clinical Research Network

PCORnet®: the National Patient-Centered Clinical Research Network

An innovative initiative funded by the Patient-Centered Outcomes Research Institute (PCORI), PCORnet is **a large, highly representative, national patient-centered clinical research network**.

Our **vision** is to support a learning U.S. healthcare system and to enable **large-scale clinical research** conducted with **enhanced quality and efficiency**.

Our **mission** is to enable people to make informed healthcare decisions by efficiently conducting clinical research relevant to their needs.

With PCORnet®, we have developed a nationwide functional research network that…

- **Engages** people, clinicians, and health system leaders throughout
- **Creates** infrastructure, tools, and policies to support rapid, efficient clinical research
- **Utilizes** multiple data sources including electronic health records, insurance claims data, data reported directly by people, and other data sources
- **Enables** people and systems to work collaboratively

Patients, caregivers and others interested in clinical research provide leadership

- **Patients and caregivers** help identify knowledge gaps by sharing their experiences with the daily burden of disease conditions
- **Patient and stakeholder engagement**, is embodied within the PCORnet Governance Policy.
- **Patients and caregivers serve as principle investigators** for PCORnet studies and networks.

PCORnet® embodies a “network of networks” that harnesses the power of partnerships

20 Patient-Powered Research Networks (**PPRNs**) + 13 Clinical Data Research Networks (**CDRNs**) + 2 Health Plan Research Networks (**HPRNs**) + 1 Coordinating Center = A national infrastructure for people-centered clinical research

PPRNs

ABOUT Patient Powered Research Network (ABOUT Network)
University of South Florida

ARthritis patient Partnership with comparative Effectiveness Researchers (AR-PoWER PPRN)
Global Healthy Living Foundation

CCFA Partners Patient Powered Research Network
Crohn's and Colitis Foundation

Collaborative Patient-Centered Rare Epilepsy Network (REN)
Epilepsy Foundation

Community and Patient-Partnered Research Network
University of California Los Angeles

Community-Engaged Network for All (CENA)
Genetic Alliance, Inc.

COPD Patient Powered Research Network
COPD Foundation

DuchenneConnect Registry Network
Parent Project Muscular Dystrophy

Health eHeart Alliance
University of California, San Francisco (UCSF)

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

Interactive Autism Network
Kennedy Krieger Institute

Mood Patient-Powered Research Network
Massachusetts General Hospital

Multiple Sclerosis Patient-Powered Research Network
Accelerated Cure Project for Multiple Sclerosis

National Alzheimer's and Dementia Patient and Caregiver-Powered Research Network
Mayo Clinic

NephCure Kidney International
Arbor Research Collaborative for Health

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

Phelan-McDermid Syndrome Data Network
Phelan-McDermid Syndrome Foundation

PI Patient Research Connection: PI-CONNECT
Immune Deficiency Foundation

Population Research in Identity and Disparities for Equality Patient-Powered Research Network (PRIDEnet)
University of California San Francisco

Vasculitis Patient Powered Research Network
University of Pennsylvania

CDRNs

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

Chicago Area Patient Centered Outcomes Research Network (CAPriCORN)
The Chicago Community Trust

Greater Plains Collaborative (GPC)
University of Kansas Medical Center

Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) Network
Kaiser Foundation Research Institute

Research Action for Health Network (REACHnet)
Louisiana Public Health Institute (LPHI)

Mid-South CDRN
Vanderbilt University

National PEDSnet: A Pediatric Learning Health System
The Children's Hospital of Philadelphia

New York City Clinical Data Research Network (NYC-CDRN)
Weill Medical College of Cornell University

OneFlorida Clinical Data Research Network
University of Florida

Patient-Centered Network of Learning Health Systems (LHSNet)
Mayo Clinic

Patient-oriented SCAlable National Network for Effectiveness Research (pSCANNER)
University of California, San Diego (UCSD)

PaTH: Towards a Learning Health System
University of Pittsburgh

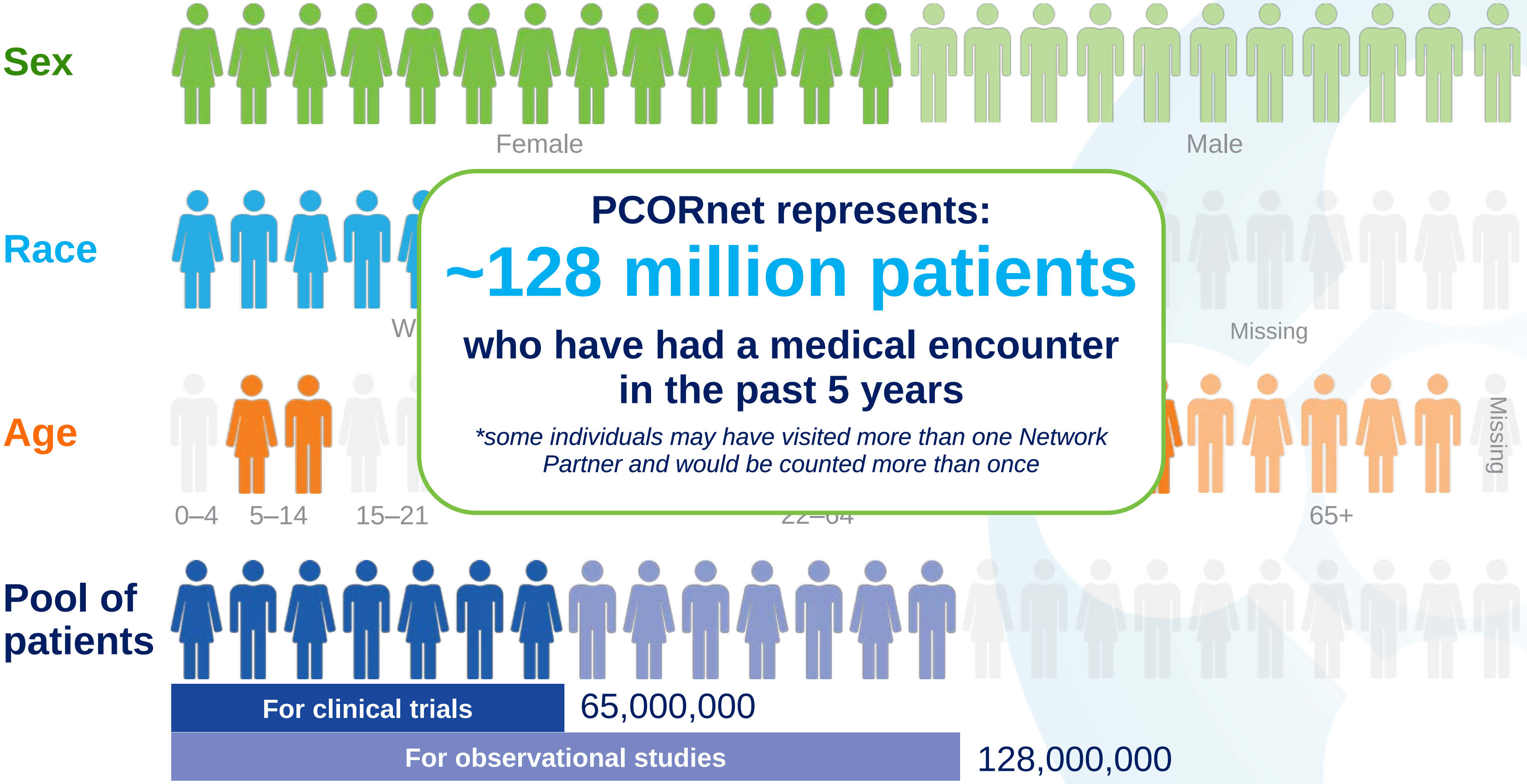
Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)
Harvard University

HPRNs

HealthCore (a subsidiary of Anthem)

Humana – Comprehensive Health Insights (CHI; a subsidiary of Humana Pharmacy Solutions)

Resulting in a national evidence system with unparalleled research readiness



PCORnet represents:

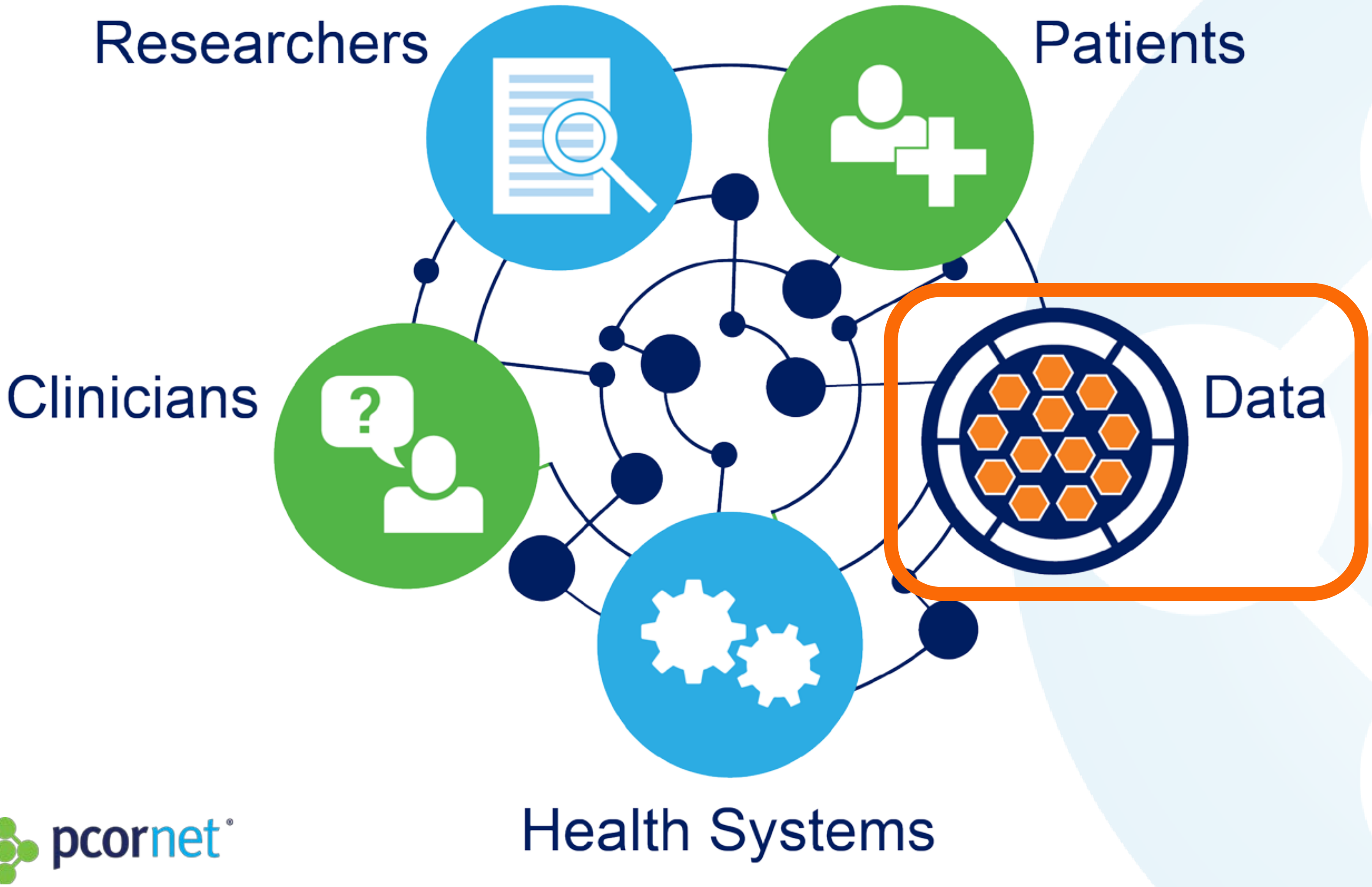
~128 million patients

who have had a medical encounter in the past 5 years

**some individuals may have visited more than one Network Partner and would be counted more than once*

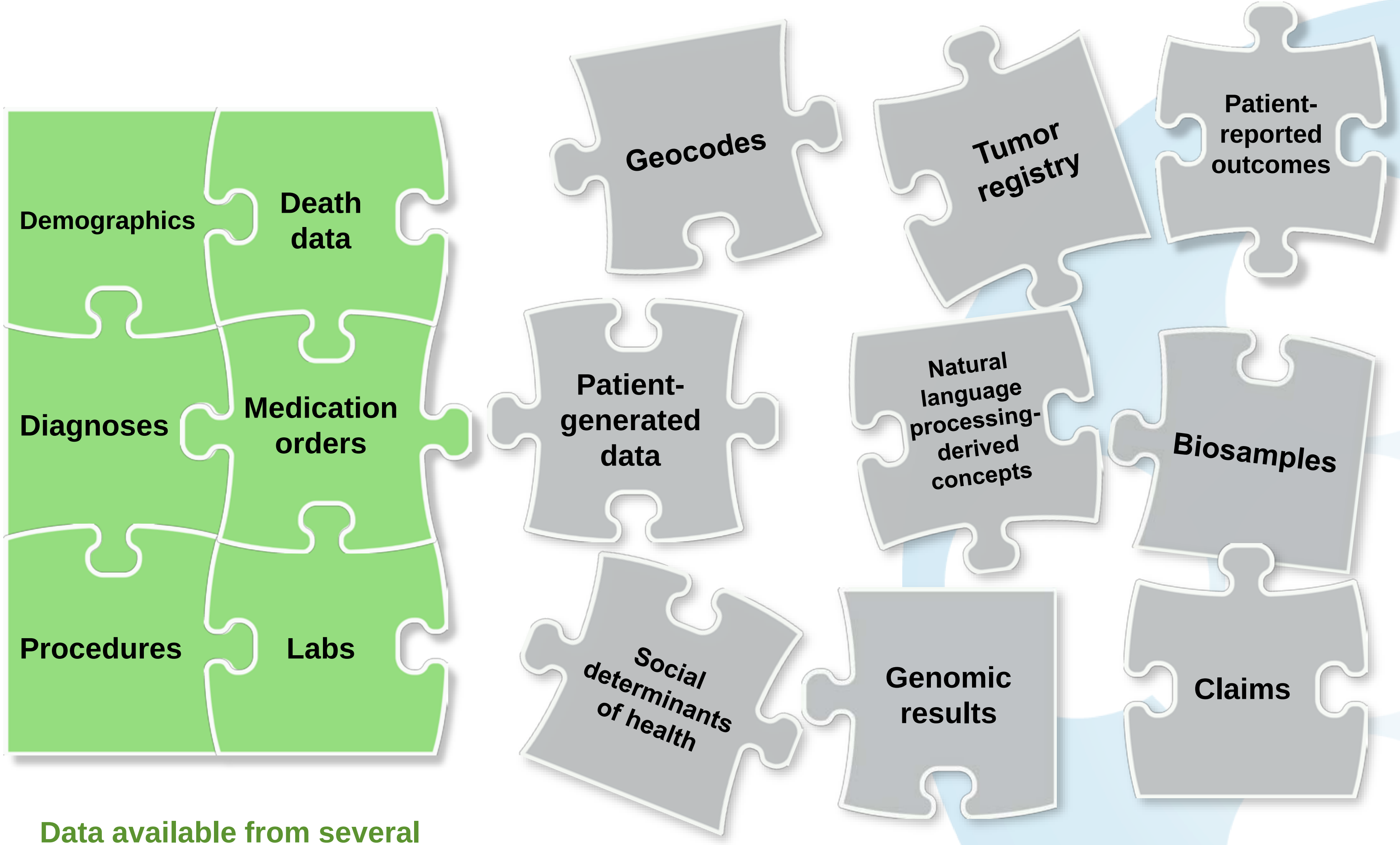
pcornet®

A community of research that unites data from patients, clinicians, and systems



pcornet

The PCORnet Common Data Model



Demographics

Death data

Diagnoses

Medication orders

Procedures

Labs

Geocodes

Tumor registry

Patient-reported outcomes

Patient-generated data

Natural language processing-derived concepts

Biosamples

Social determinants of health

Genomic results

Claims

Data available from several CDRN Network Partners, in the PCORnet CDM and ready for use in research.

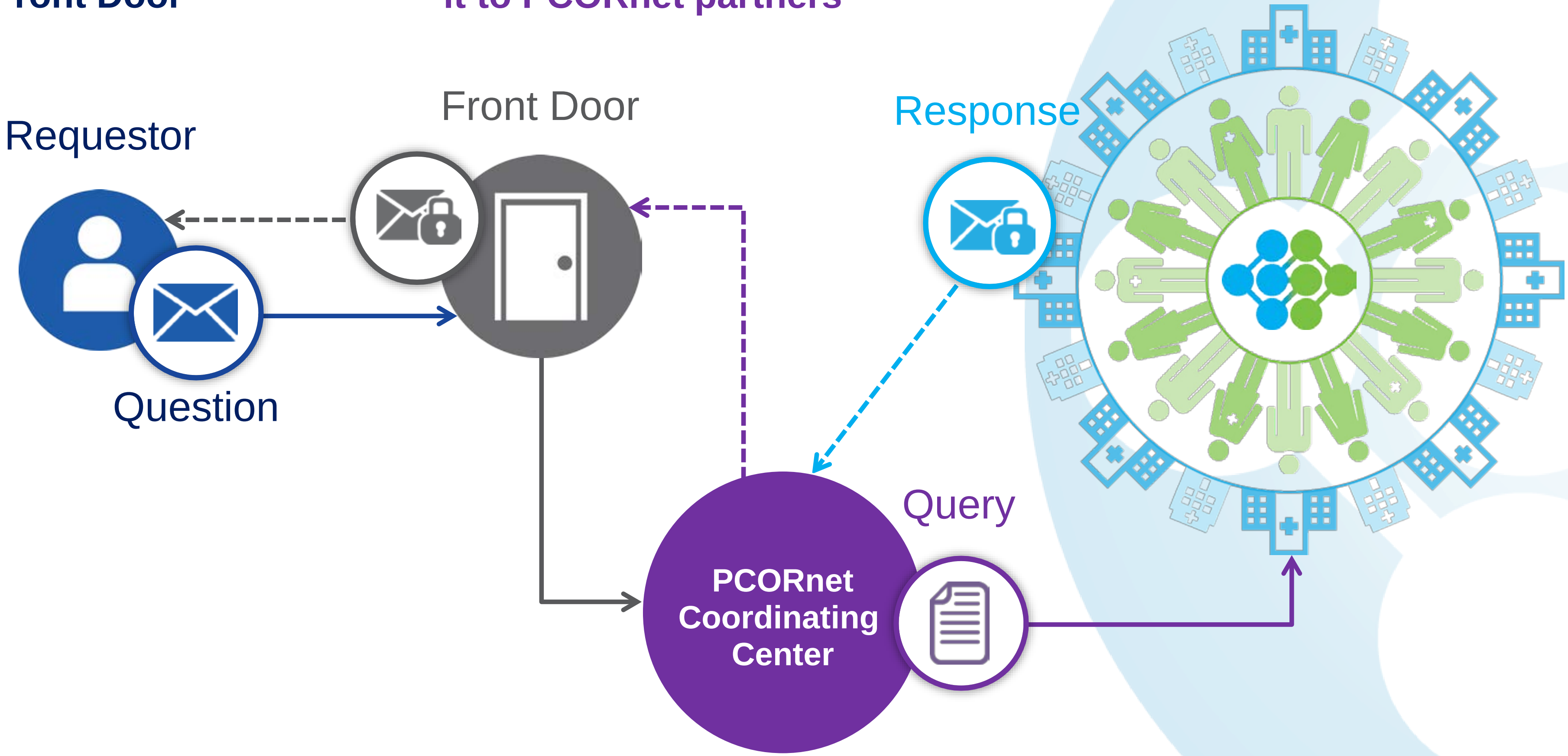
Data available at some CDRN Network Partners, may or may not be in the PCORnet CDM and requiring additional work for use in research.

Here's how the PCORnet® distributed research network works

The Requestor sends a question to the PCORnet Coordinating Center through the Front Door

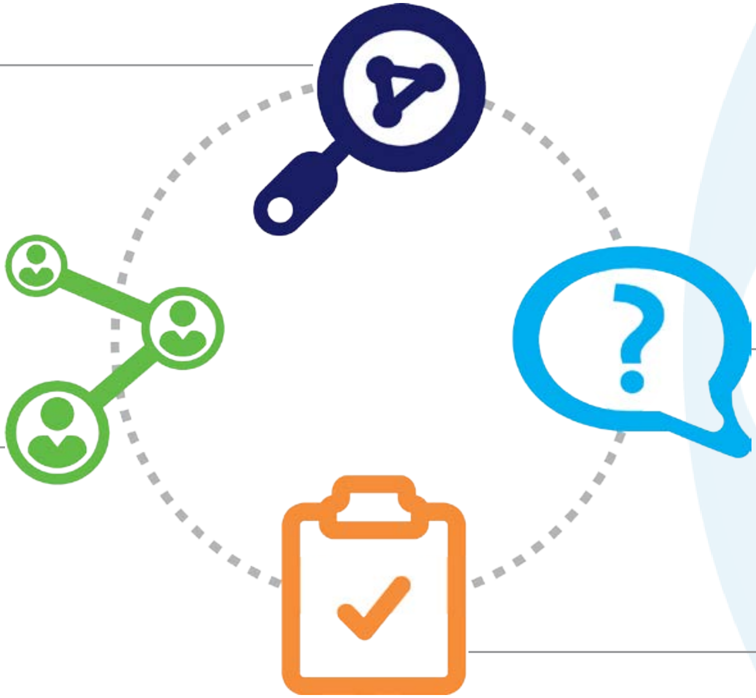
The Coordinating Center converts the question into a query with an underlying executable code, and sends it to PCORnet partners

PCORnet partners review the query and provide a response, which is sent back through the Front Door to the Requestor



Think of all the different ways you can leverage PCORnet®

PCORnet Front Door: Access point to PCORnet resources



Data
Network Request

Network
Collaborator Request

Study
Feasibility Review

PCORnet Study
Designation Request

You can use PCORnet® for many kinds of research

Pre-research

- Feasibility queries
- Engagement
- Match-making

Observational studies

- Cross-sectional
- Epidemiology
- Health services
- Comparative effectiveness or safety

Interventional studies

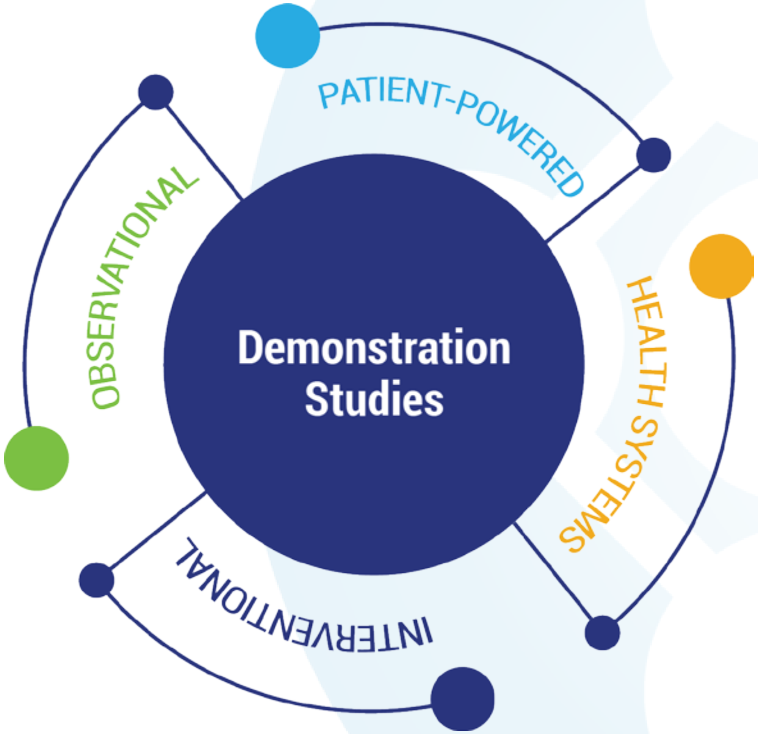
- Clinical trials
- Pragmatic randomized clinical trials
  - e-Identification
  - e-Consent
  - e-Randomization
  - e-Follow-up
- Cluster randomization

We've tested our system’s functionality in multiple research settings

14 PCORI-funded PCORnet demonstration studies are answering critical research questions while also testing the infrastructure and key functional aspects of PCORnet.

- Interventional studies
- Observational studies
- Patient-powered research network (PPRN) studies
- Health systems studies

Learn more about [PCORnet Demonstration Studies]



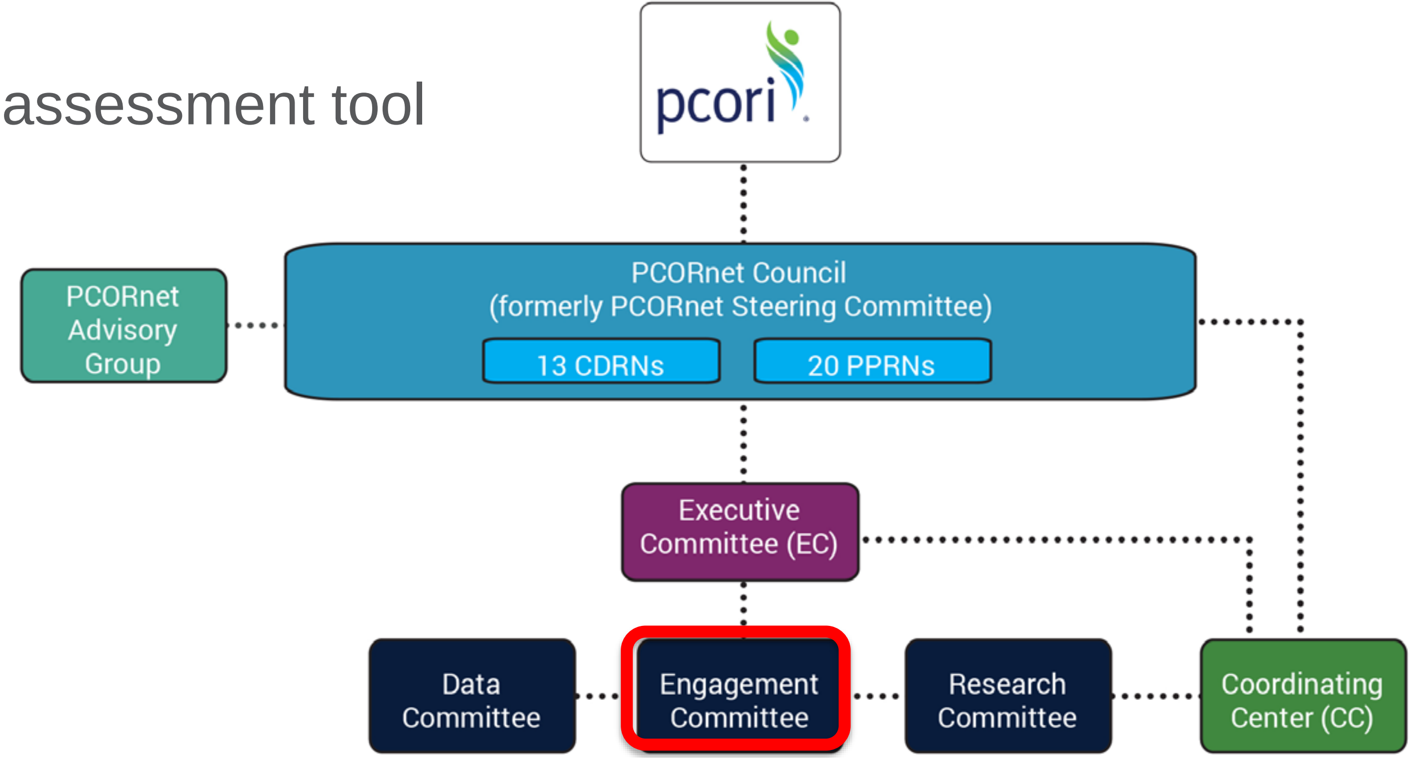
We've also amplified our research power with cross-network collaboration

Collaborative research groups: Catalyzing multi-network research

- Autoimmune and systemic inflammatory syndromes
- Behavioral health
- Cancer
- Cardiovascular health
- Diabetes and obesity
- Health disparities
- Health systems, health policy, and public health
- Hospital medicine
- Kidney health
- Pediatrics
- Pulmonary

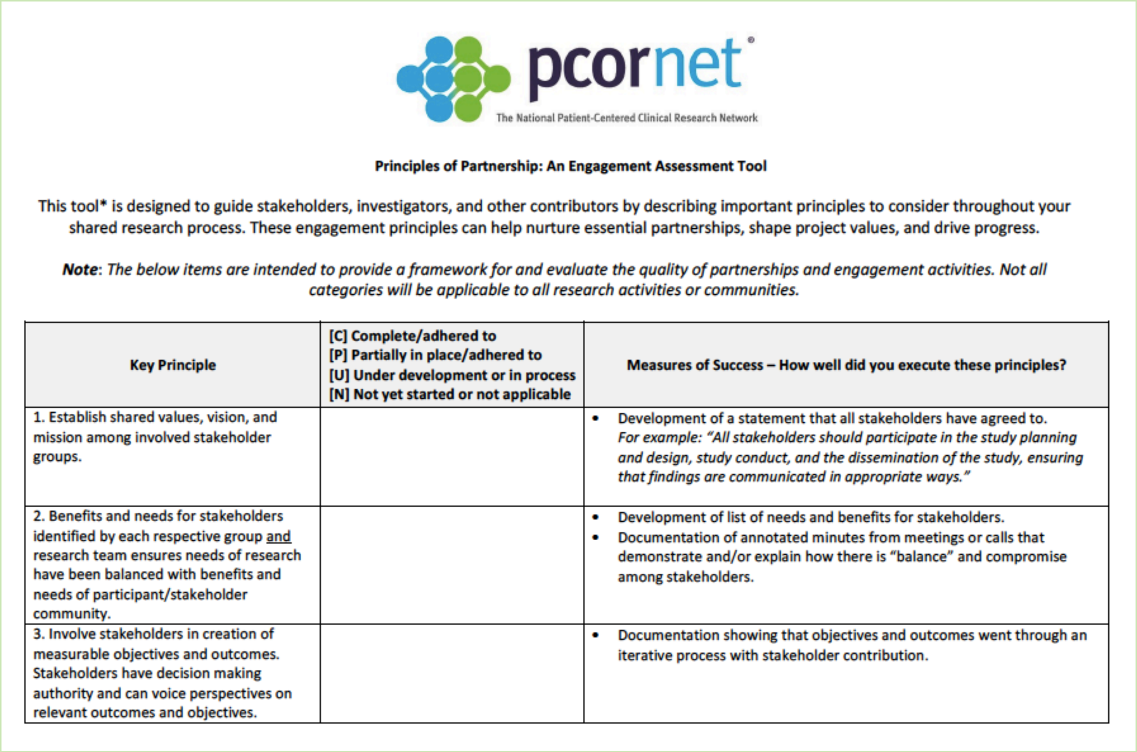
PCORnet Engagement Committee

- Report on overview of PCORnet engagement practices
- Engagement definitions
- Engagement assessment tool



PCORnet® engagement assessment tool

- The engagement assessment tool to ensure people remain central to our work.
- The tool is available to the public on the PCORnet Commons



pcornet®
The National Patient-Centered Clinical Research Network

Principles of Partnership: An Engagement Assessment Tool

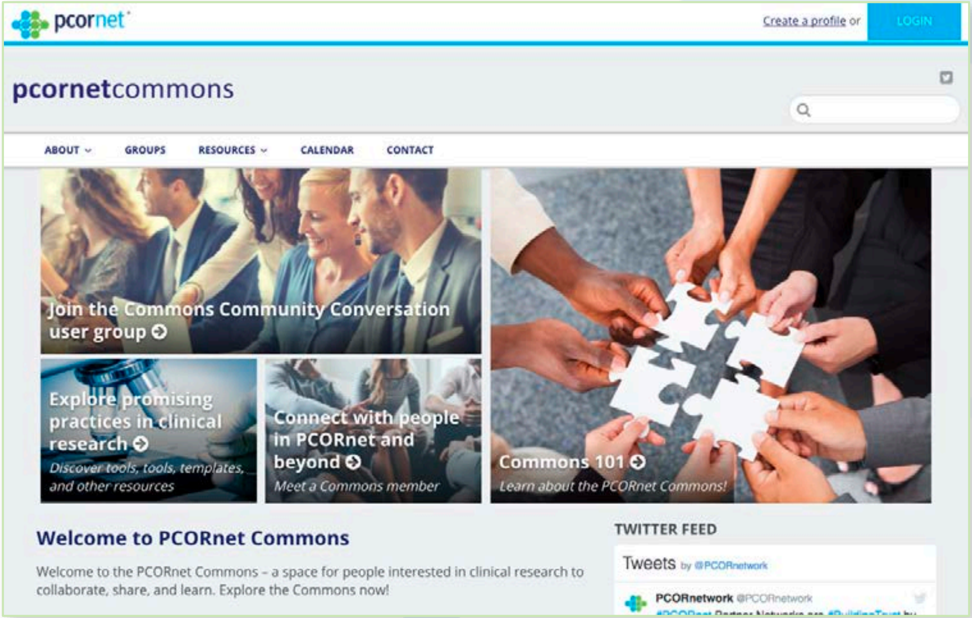
This tool* is designed to guide stakeholders, investigators, and other contributors by describing important principles to consider throughout your shared research process. These engagement principles can help nurture essential partnerships, shape project values, and drive progress.

***Note**: The below items are intended to provide a framework for and evaluate the quality of partnerships and engagement activities. Not all categories will be applicable to all research activities or communities.*

Key Principle	**[C] Complete/adhered to** **[P] Partially in place/adhered to** **[U] Under development or in process** **[N] Not yet started or not applicable**	**Measures of Success – How well did you execute these principles?**
1. Establish shared values, vision, and mission among involved stakeholder groups.		• Development of a statement that all stakeholders have agreed to. *For example: "All stakeholders should participate in the study planning and design, study conduct, and the dissemination of the study, ensuring that findings are communicated in appropriate ways."*
2. Benefits and needs for stakeholders identified by each respective group and research team ensures needs of research have been balanced with benefits and needs of participant/stakeholder community.		• Development of list of needs and benefits for stakeholders. • Documentation of annotated minutes from meetings or calls that demonstrate and/or explain how there is "balance" and compromise among stakeholders.
3. Involve stakeholders in creation of measurable objectives and outcomes. Stakeholders have decision making authority and can voice perspectives on relevant outcomes and objectives.		• Documentation showing that objectives and outcomes went through an iterative process with stakeholder contribution.

Use the PCORnet® Commons!

- The PCORnet Commons is a place for people striving to realize the vision of people-centered research.
- The goal of the PCORnet Commons is to provide opportunities to increase collaboration, efficiency, and people-centeredness in clinical research.



Join the Commons Community Conversation user group

Explore promising practices in clinical research

Discover tools, tools, templates, and other resources

Connect with people in PCORnet and beyond

Meet a Commons member

Commons 101

Learn about the PCORnet Commons!

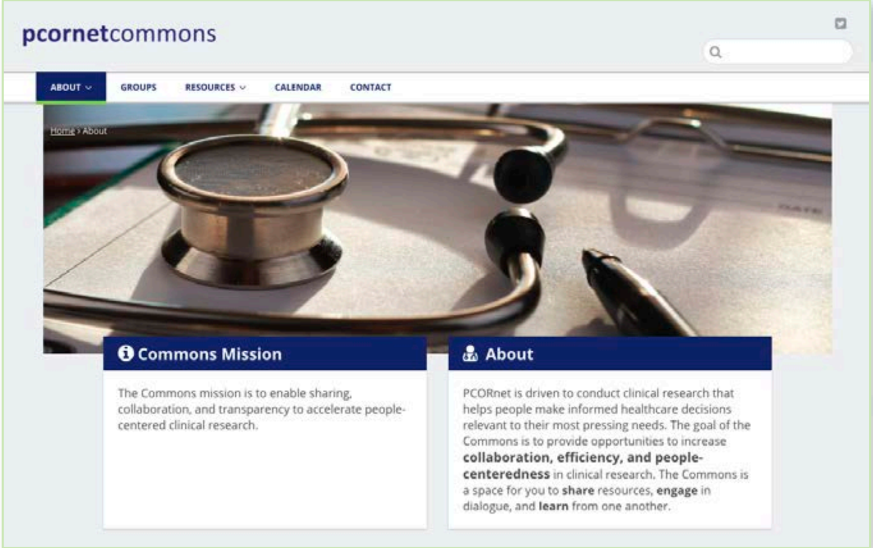
Welcome to PCORnet Commons

Welcome to the PCORnet Commons – a space for people interested in clinical research to collaborate, share, and learn. Explore the Commons now!

http://pcornetcommons.org/

The PCORnet® Commons allows you to:

- Connect with real people in PCORnet and beyond
- Discover tools, templates, and more
- Read about innovative case studies and experiences
- Start a group to discuss what's important to your community in real-time
- Explore today’s most promising practices in clinical research



Commons Mission

The Commons mission is to enable sharing, collaboration, and transparency to accelerate people-centered clinical research.

About

PCORnet is driven to conduct clinical research that helps people make informed healthcare decisions relevant to their most pressing needs. The goal of the Commons is to provide opportunities to increase **collaboration, efficiency, and people-centeredness** in clinical research. The Commons is a space for you to **share** resources, **engage** in dialogue, and **learn** from one another.

More information on PCORnet®

- Website: www.pcornet.org
- PCORnet Commons: http://pcornetcommons.org/
- Twitter: @PCORnetwork
- YouTube: PCORI YouTube Playlist
- Vimeo: PCORI Vimeo Playlist
- PCORnet communications contact: Jennifer.Cook@duke.edu

People-Centered Research Foundation (PCRF)

pcornet® The National Patient-Centered Clinical Research Network

People-Centered Research Foundation (PCRF) Progress is underway

- PCRF incorporated in DC as a **non-profit 501(c3)** corporation on March 16, 2017
  - Board Chair: **Dr. Robert Califf**
  - CEO: Dr. Kathy Hudson

- PCRF will continue **PCORnet's mission** to answer questions that matter to people and improve outcomes

- Its mission is "to engage patients, families, research participants, clinicians, scientists, and health system leaders in the design, conduct, dissemination, and implementation of research and analysis that leads to improvements in the health and well-being of individuals and populations and the performance of health care delivery systems"

- PCORI Board awarded $25.4M to PCRF in March 2017

- http://pcrfoundation.org/ is live and is being updated

People-Centered Research Foundation (PCRF) Progress is underway

- Board members include:
  - **Richard Bankowitz**, MD, MBA, FACP, Executive Vice President, Clinical Affairs, America's Health Insurance Plans (AHIP)
  - **Josephine P. Briggs**, MD, Director, National Center for Complementary and Integrative Health (NCCIH)
  - **Marc M. Boutin**, JD, Chief Executive Officer, National Health Council (NHC)
  - **Robert Califf**, MD, former FDA Commissioner and Professor of Cardiology at Duke
  - **Donna Cryer**, President and CEO of the Global Liver Institute
  - **Craig Lipset**, MPH, Head of Clinical Innovation, Global Product Development, Pfizer
  - **Reed Tuckson**, MD, FACP, Managing Director of Tuckson Health Connections
  - **Joanne Waldstreicher**, MD, Chief Medical Officer, Johnson & Johnson

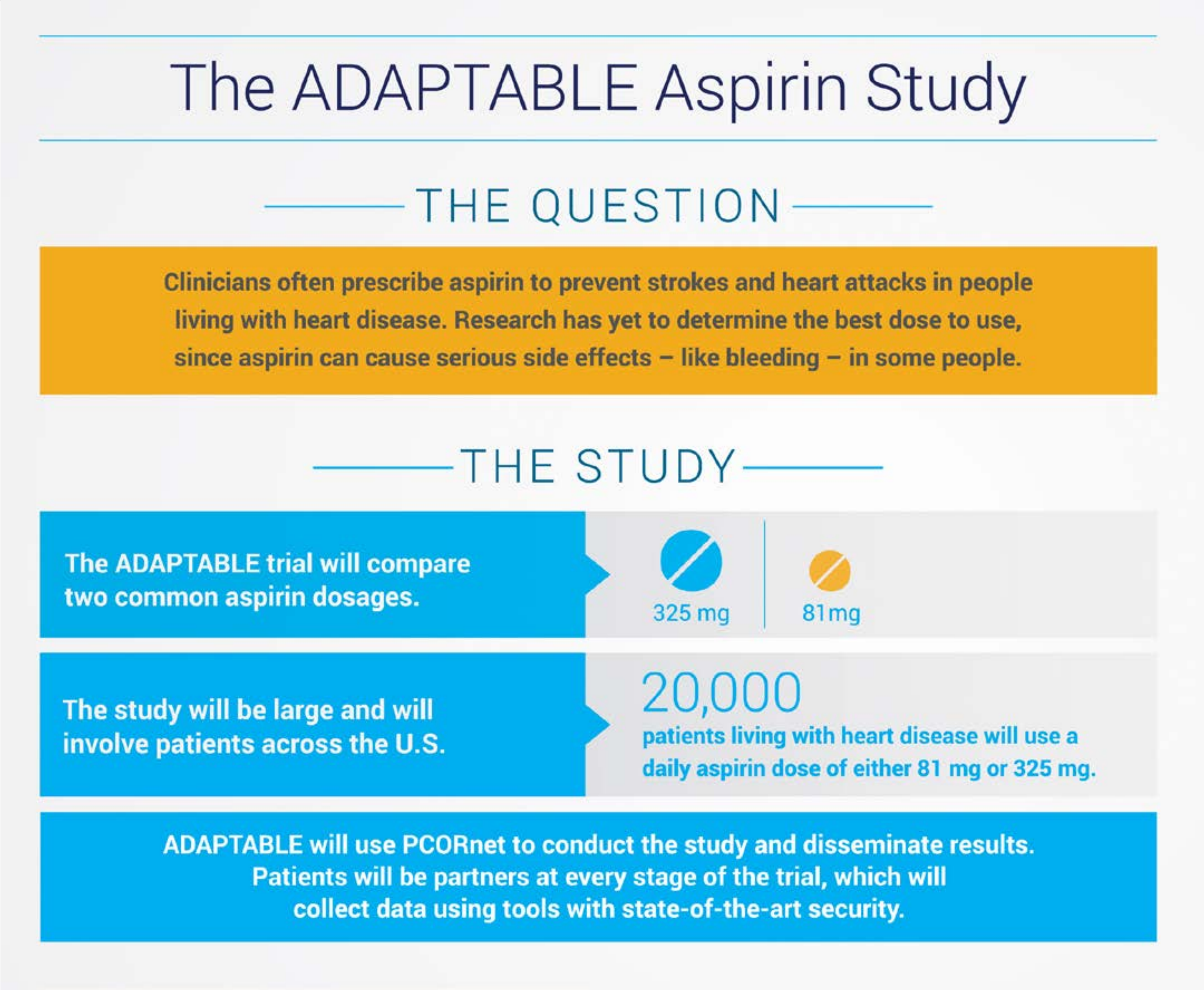
Questions?

pcornet® The National Patient-Centered Clinical Research Network

Appendix

pcornet® The National Patient-Centered Clinical Research Network

Let's take a look at what PCORnet® can do via a demonstration study



The ADAPTABLE Aspirin Study

THE QUESTION

Clinicians often prescribe aspirin to prevent strokes and heart attacks in people living with heart disease. Research has yet to determine the best dose to use, since aspirin can cause serious side effects – like bleeding – in some people.

THE STUDY

The ADAPTABLE trial will compare two common aspirin dosages.

The study will be large and will involve patients across the U.S.

20,000 patients living with heart disease will use a daily aspirin dose of either 81 mg or 325 mg.

ADAPTABLE will use PCORnet to conduct the study and disseminate results. Patients will be partners at every stage of the trial, which will collect data using tools with state-of-the-art security.

pcornet®

PCORnet® research

Types

- Comparative effectiveness
- Population health
- Health care delivery
- Patient-centered research

Data sources

- Electronic health records
- Patient-reported registries
- Patient-reported outcomes
- Clinical registries
- Health plan claims

Study designs

- Randomized controlled trials
- Cluster randomized trials
- Nonrandomized comparative trials
- Longitudinal studies
- Surveillance
- Cross-sectional

PCRF Updates

July	August	September	October	November
• Transition Workgroup report submitted to PCRF Board	• Executive Director hired	• First PCRF in-person Board meeting • PCRF response to Transition Workgroup report	• PCRF Board governance finalized	• Draft member type(s) and criteria • Draft outline committee structure and governance

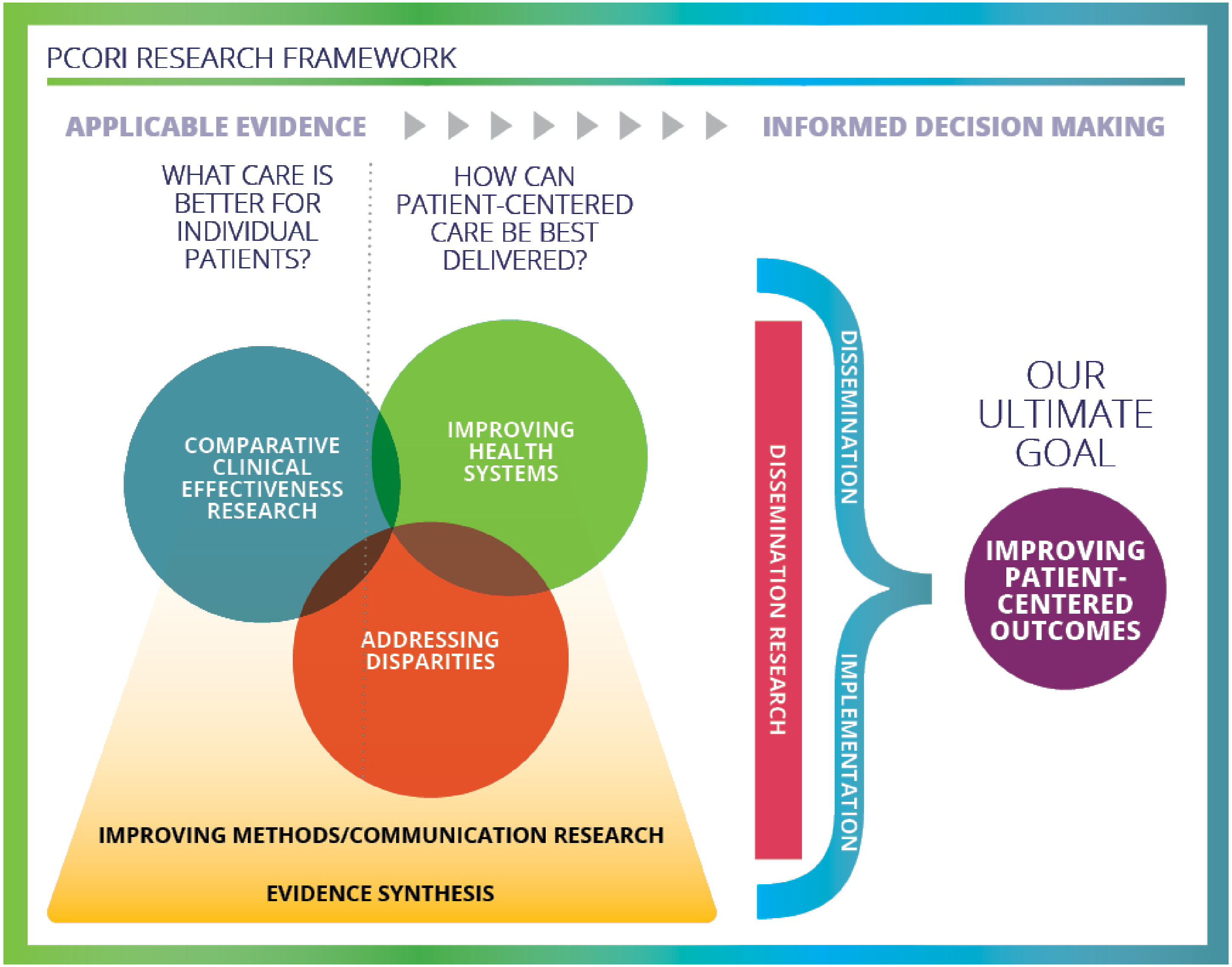
PCORI Science

Evelyn P. Whitlock, MD, MPH

Chief Science Officer

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Our Research Framework



PCORI RESEARCH FRAMEWORK

APPLICABLE EVIDENCE ▶ ▶ ▶ ▶ ▶ ▶ ▶ ▶ INFORMED DECISION MAKING

WHAT CARE IS BETTER FOR INDIVIDUAL PATIENTS?

HOW CAN PATIENT-CENTERED CARE BE BEST DELIVERED?

COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

IMPROVING HEALTH SYSTEMS

ADDRESSING DISPARITIES

IMPROVING METHODS/COMMUNICATION RESEARCH

EVIDENCE SYNTHESIS

DISSEMINATION RESEARCH

DISSEMINATION

IMPLEMENTATION

OUR ULTIMATE GOAL

IMPROVING PATIENT-CENTERED OUTCOMES

Research and Evidence Synthesis

PCORI and Evidence Synthesis

- PCORI's authorizing legislation states that **evidence synthesis** is a core function of PCORI:

> *"(C) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations…."*

Evidence Synthesis

- Methodologies for integrating evidence from variable sources to produce more comprehensive or best evidence
  - Provides knowledge beyond individual studies alone
  - Identifies areas of agreement and disagreement in quantitative and/or qualitative terms
  - Permits identification of research gaps
  - Examples: **Systematic reviews**, rapid reviews, decision models, analytic approaches (e.g., aggregate data meta-analysis (MA), individual patient-level data (IPD) MA, network MA, others)

From: *Evidence Synthesis in Healthcare: A Practical Handbook for Clinicians*.
T. Athanasiou, A. Darzi, editors.

Research Synthesis Overview

- “Research synthesis” is an umbrella term for tools and methods that synthesize information to create knowledge
- PCORI’s Research Synthesis Program covers a range of activities
  - Research data “re-use” to explore variation in treatment effect/more personalized medicine
  - Evidence synthesis (e.g., systematic review)
  - Portfolio Synthesis of PCORI’s research investments (e.g., portfolio “cluster” analyses, evidence mapping)

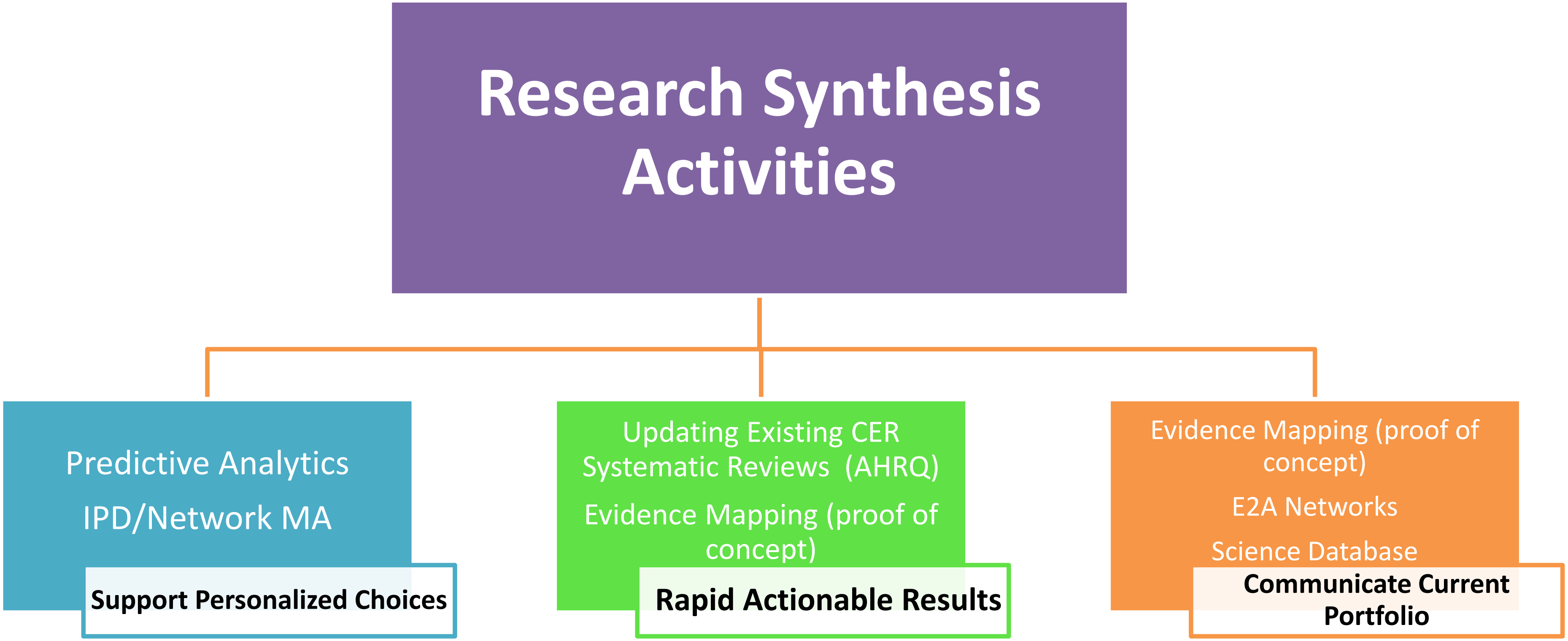
Research Synthesis *Cannot* be Separated from Strategic Topic Development

- Research synthesis methods and tools inform development of stakeholder-nominated topics by identifying evidence gaps
- Nominated research topics need to be placed into the context of our existing portfolio
- Understanding our portfolio allows identification of research ‘in-fill” opportunities as well as communication
- Research synthesis projects are the logical and right next step for some topics (e.g., IPD MA for progesterone and preterm birth) and a good option for others

PCORI’s Research Synthesis Program (2017)

- Three initial goals:
  1. Research to address heterogeneity of treatment effects, more personalized individual health care choices
  2. More rapid deployment of actionable CER evidence in context
  3. Communication of current portfolio (rationale, themes and lessons, context)

Overview of Research Synthesis Activities



Research Synthesis Activities

Predictive Analytics

IPD/Network MA

Support Personalized Choices

Updating Existing CER Systematic Reviews (AHRQ)

Evidence Mapping (proof of concept)

Rapid Actionable Results

Evidence Mapping (proof of concept)

E2A Networks

Science Database

Communicate Current Portfolio

Research Synthesis Program: Highlights

Initiative	Expected Date of Completion
Targeted Systematic Review Updates *Psychological and Pharmacological Treatments for Adults with PTSD* *Nonsurgical Treatments for Urinary Incontinence in Adult Women* *Drug Therapy for Rheumatoid Arthritis in Adults;* *Stroke Prevention in Atrial Fibrillation*	Dec 2017/Jan 2018
IPD Meta-Analysis project evaluating Progesterone in Preventing Pre-term Birth	March 2018
Research Data Re-use/ Predictive Analyses *Predicting Cardiotoxicity Among Patients Receiving Anthracycline Chemotherapy* *IRIS Study Analysis*	December 2017 April 2018
Portfolio Mapping & Communication *Transitions in Care Evidence-To-Action Network* *Evidence Maps* *Portfolio Mapping and Communication*	Ongoing

1st paper from PCORI-funded Insulin Resistance Intervention after Stroke (IRIS) Re-analysis

Published online
September 18, 2017

Mentions: IPD-MA Initiative Receives Attention

thebmj

FEATURE

The BMJ Awards 2017: UK Research Paper

Nigel Hawkes describes how the studies shortlisted for this year's award have the potential to change clinical practice in the UK and beyond

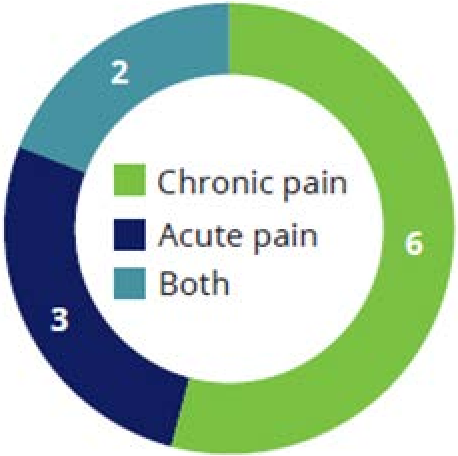
"There's been a huge amount of interest in the paper," Norman says. "The US Patient-Centered Outcomes Research Institute (PCORI) has launched an independent, patient level data meta-analysis of progesterone in preterm birth. We've agreed to share data with them, of course. We never really got into progesterone here but in the US there are a lot of entrenched opinions, so the PCORI study is really important for the specialty. We've been here before with things that have done harm—stilboestrol, thalidomide—so I think it's right that PCORI is having an independent group to look at it."

Hawkes Nigel. The BMJ Awards 2017: UK Research Paper BMJ 2017; 357 :j1822

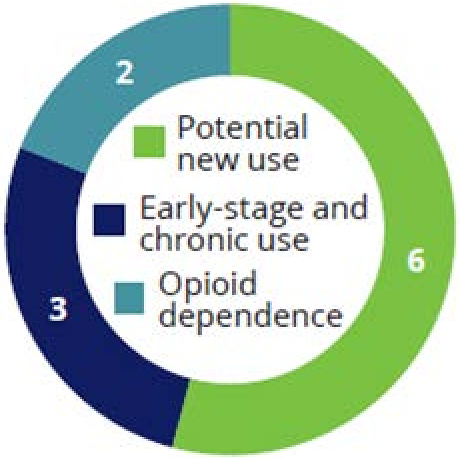
High Priority Topic: PCORI Responds to the Opioid Crisis

As of September 2017,
PCORI has awarded
$62 MILLION
TO FUND 11
CER studies related to opioid
use. These projects will
involve
≈11,000 STUDY
PARTICIPANTS.

Most Studied Pain Types



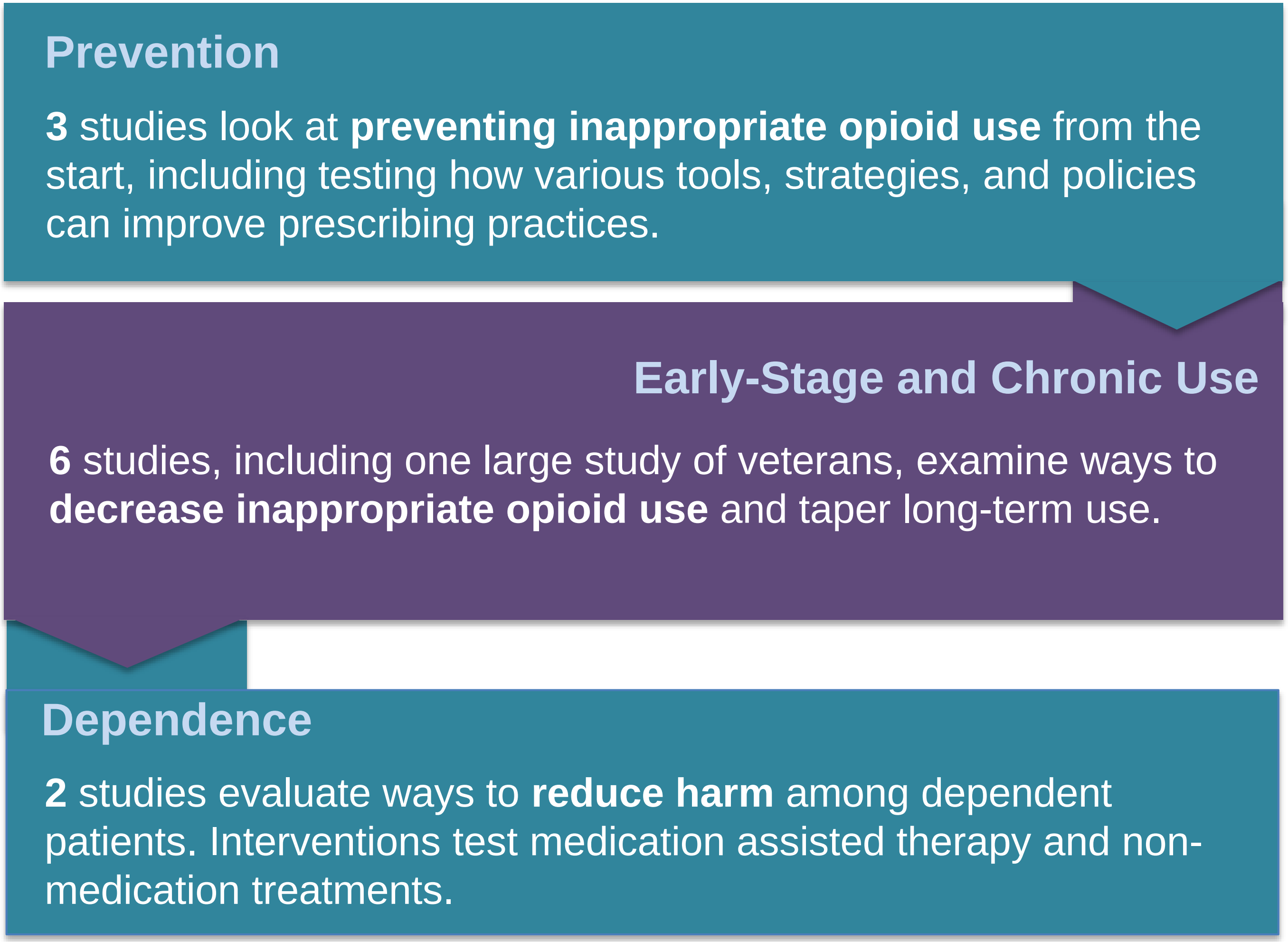
Most Studied Stages of Opioid Use



Research on opioid use and pain management is an ongoing priority for PCORI.

New funding opportunity on **medicated-assisted treatment delivery for pregnant women with substance use disorders** released in July 2017.

Opioid Studies Across the Care Continuum



Prevention

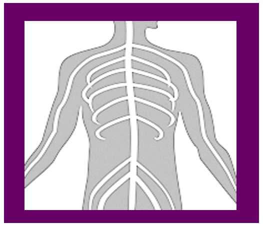
3 studies look at **preventing inappropriate opioid use** from the start, including testing how various tools, strategies, and policies can improve prescribing practices.

Early-Stage and Chronic Use

6 studies, including one large study of veterans, examine ways to **decrease inappropriate opioid use** and taper long-term use.

Dependence

2 studies evaluate ways to **reduce harm** among dependent patients. Interventions test medication assisted therapy and non-medication treatments.



New Investments: Palliative Care

- **$99 million** allocated to fund CER studies from **2 PFAs in 2016 and 2017**
- Aimed at advancing scientific knowledge on how to improve **patient and caregiver centered outcomes** by facilitating research on palliative care delivery models, advanced care planning, and symptom management.

7 Studies **$74M**	Comparing the clinical effectiveness of different community-based palliative care delivery models and approaches to facilitating advanced care planning for adult patients living with any advanced illness.
12 LOIs invited **$25M**	Comparing the effectiveness of different approaches to symptom management, including pharmacological interventions, for patients of any age living with any advanced illness.

Patient Engagement is Key to Evidence Synthesis As Well

- Involvement of patients, caregivers, and others in study identification and in design is relevant and important
- Use of Core Outcome sets can efficiently capture some patient perspectives
- Requirement of US patients and other stakeholders involvement, when research is awarded to a foreign institution
- Complementary Eugene Washington award investigating patient understanding and support of analytic methods that supports more personalized choices (alongside methods development)
- IPD MA in progesterone and preterm birth prevention:
  - Patient stakeholder on Secretariat guiding protocol and project
  - Patient, family, clinician stakeholders advising on outcomes of importance
  - Possible supplemental effort to develop consensus on robust, consistent patient engagement in these types of analyses

Hearing from the Experts: What are Your Experiences Engaging with Any Type of Research?

- The name of the research study and its focus
- How long you have been involved with the study and how did you become involved
- One brief statement about the contributions that patients and other stakeholders have made to the study
- What have you learned about what it takes to develop effective research partnerships
- Learnings or outcomes of the study from the patient engagement perspective

2017 PCORI Annual Meeting Update

Bill Silberg
Director, Communications

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

Overview

- October 31 - November 2
  - Crystal Gateway Marriott
- Theme: *Delivering Results, Informing Choices*
- 1,000+ stakeholders; 500-750 on webcasts
- Pre-session for Ambassadors, patients/caregivers, as well as health research trainees
- Four plenaries; eight breakouts; seven workshops, posters (pre-sessions and workshops, CME/CE)
- Registration opened in August

Join us for PCORI's Third Annual Meeting

Goals

- Report to the nation on selected results from our funded research and their usefulness to key stakeholder audiences.
- Showcase our broader work in enhancing public access to research results by highlighting our efforts in data sharing, peer review, and dissemination and implementation.
- Identify, demonstrate and explore opportunities for PCOR/CER evidence to be used by stakeholders in ways they find most useful.
- Continue to spotlight our leadership in engagement and other areas (e.g., improving value/reducing waste) as a path to more efficient, useful, and impactful research.
- Convene awardees/stakeholders to advance discussion of topics of interest, provide new partnership opportunities, inform future work.

Audiences

Three main audiences:

- Awardees (researchers and patient/other stakeholder partners)
- Prospective awardees/partners
- Broader stakeholder community interested in PCOR/results of our funded studies, especially DC-based policy/advocacy community.
    - This year, GAO representatives are expected to attend.

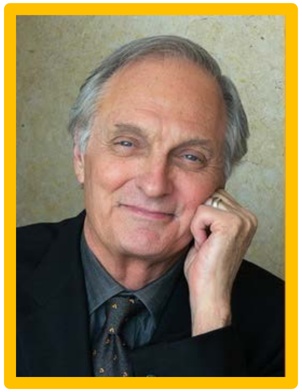
Registration to Date

- 575 (as of 10-3-17)
- Stakeholder breakdown
  - Researchers: 38%
  - Patients/caregivers/advocates/consumers: 36%
  - Hospital/health system, training institutions: 10%
  - Clinicians: 7%
  - Insurers/employers, industry: 2%
  - Policymakers: 1%
  - Unidentified/others: 6%
- Targeted outreach under way to boost attendance by payers, employers, clinicians, hospitals/health systems

Plenary Sessions

Oct. 31

- **Opening Session:** ***Access to Results that Matter***
    - Keynote: **Freddie White-Johnson**, Founder and President, Fannie Lou Hamer Cancer Foundation
    - Patient/Stakeholder panel (**Susannah Fox**, moderator)



Nov. 1

- **Morning Session:** ***Improving How We Talk to the Public About Science and Health***
    - Keynote: **Alan Alda**

Plenary Sessions – Continued

Nov. 1

- **Lunch Session:** ***Making Shared Decision Making Routine Practice in Health Care***
    - Keynote: **Harlan Krumholz, Yale School of Medicine**
    - Stakeholder panel (**Dominick Frosch**, moderator)

Nov. 2

- **Closing Session:** ***How CER/PCOR Can Support a Patient-Centered Healthcare System that Provides Value to All***
    - Keynote: **Trent Haywood, CMO, Blue Cross Blue Shield**
    - Stakeholder panel (**Marilyn Serafini**, moderator)

Strong Patient/Caregiver/Advocate Presence

- Patients Included designation (second year in a row)
- Patient/advocate representatives on Steering Committee
  - Stephanie Buxhoeveden; David White; Danny von Leeuwen; Paris Davis
- Opening speakers include several patient/caregiver/ community advocates
  - Keynoter: Freddie White-Johnson
  - Plenary panel: Sharon Terry, Bishop Simon Gordon + patient rep pending
- Patient/advocate representatives on other plenary panels
- Patient/advocate representatives among breakout session discussants
- Travel and other support available for all patient/caregiver attendees
- >100 scholarships/special pre-meeting programming for patients/Ambassadors

Patients™ Included

Patients Included is a Trademark of the REshape & Innovation Center

Breakout Sessions

- Developing PCORI's Policy on Data Sharing: Lessons from a Novel Pilot Project
- Helping People Understand Treatment Options in Cancer
- Improving Healthcare Efficiency
- Why Methods Matter: Putting Research to Work for Individual Patients
- Aligning Healthcare Delivery and Services to Enhance Function and Well-being in Patients with Chronic Conditions
- Patient-Centered Strategies to Improve Health and Health Outcomes in Vulnerable Populations
- Addressing the Opioid Epidemic by Improving Pain Management
- Rethinking Multiple Sclerosis Research -- A Patient-Centered Approach

Workshops

- D&I of PCORI Findings: Drawing from Implementation Studies
- New Methods Standards
- Getting to Know PCORI: from Application to Closeout
- PCORnet in Action: Utilizing PCORnet for Research
- PRECIS-ely: Questions and Challenges in Implementing Pragmatic Clinical Trials
- Research in Real-World Settings: Fundamentals of High-Quality CER
- What’s New in Engagement? A Conversation about PCORI’s Upcoming Engagement Initiatives

A Focus on Broader Stakeholder Involvement

- More speakers from payers, health systems, employers, and clinical communities, including:
  - Trent Haywood, CMO, Blue Cross Blue Shield Association
  - David Lansky, Pacific Business Group on Health
  - David Grossman, Kaiser Permanente/USPSTF
  - Laura Pennington, Washington State Health Care Authority
  - Carol Sakala, National Partnership for Women & Families
  - Juan Pablo Brito Campana, Mayo Clinic
  - Julie Wood, American Academy of Family Physicians
  - Rafael Alfonso, GSK
  - Elizabeth Fowler, Johnson & Johnson
  - William Shrank, UPMC
  - Shawn Leavitt, Comcast

Many thanks to many people

- The Science team, especially Evelyn, Dave, Steve, Yen-Pin and the POs organizing the breakouts and workshops
- The Engagement team, especially Jean, Greg, Kristin, Joanna, Andrew, Lia, Rachel and Vera
- The Meetings Management team, especially James
- The OCSO team, especially Joe, Michele, Nick, and Lori
- Capitol Consulting Corp., our event logistics vendor
- The Communications team, especially Roshan!

PCORI Annual Meeting Pre-Conference Sessions

Chinenye Anyanwu, PharmD, MPH
Engagement Officer
Patient & Public Engagement

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Annual Meeting Pre-Conference Sessions

Opportunity

- Engage patients, stakeholders, and graduate students
- Patients/Ambassadors and graduate students awarded scholarships to attend Annual Meeting
- Required to participate in a pre-conference workshop

Target Audience

- Patients
- Ambassadors
- Graduate-level trainees
  - in clinical or health services research, including those in medical residency and fellowship programs, on a trajectory toward an academic career conducting clinical effectiveness research.

Program Goals

PCORI Goals

- Build scientific capacity for CER while building PCOR community
- Provide opportunity for patients and stakeholders to connect with research community
- Provide opportunity for budding PCOR researchers to connect with POs and senior researchers

Patients/Ambassadors Session Goals:

- Develop an understanding of how to contribute to PCOR as research partners
- Obtain skills and resources to navigate and participate in the PCORI Annual Meeting
- Network with the PCOR community including patients, stakeholders, and researchers
- Learn about the various ways to be more involved with PCORI

Trainee (Graduate Student) Goals:

- Develop an understanding of high-quality clinical effectiveness research
- Engage with cohort of PCOR peer researchers
- Establish connections with patients and stakeholders currently involved and/or interested in partnering on research projects

Pre-Annual Meeting Curriculum for Trainees

- **Full day interactive workshop**
  - Hosted prior to Annual Meeting
  - 5 topics and 3 breakout sessions
  - Topics:
    - Increasing value and reducing waste in research
    - Fundamentals of high-quality CER
    - Engaging Partners in CER
    - Outcomes Research
    - Dissemination 101

Pre-Annual Meeting Curriculum for Patients/Ambassadors

- **Full day interactive workshop**
  - Hosted prior to Annual Meeting
  - 4 topics and 1 breakout
  - Topics:
    - Interpreting Scientific Results
    - Partnering on Dissemination
    - Engaging as Partners in Research (joint breakout session with Trainees)
    - Update on Ambassador Program

Questions?

PCORI Influence Webpage

Bill Silberg
Director, Communications

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Eugene Washington PCORI Engagement Award Program Update

Lia Hotchkiss, MPH

Director, Eugene Washington PCORI Engagement Awards Program

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Agenda

- Introductions
- Applications Received, Awards Made
- Lessons Learned
- Program Refinements
- Highlights from Awards

Introductions

Lia Hotchkiss, MPH
Director

Shivonne L. Laird, PhD, MPH
Program Officer

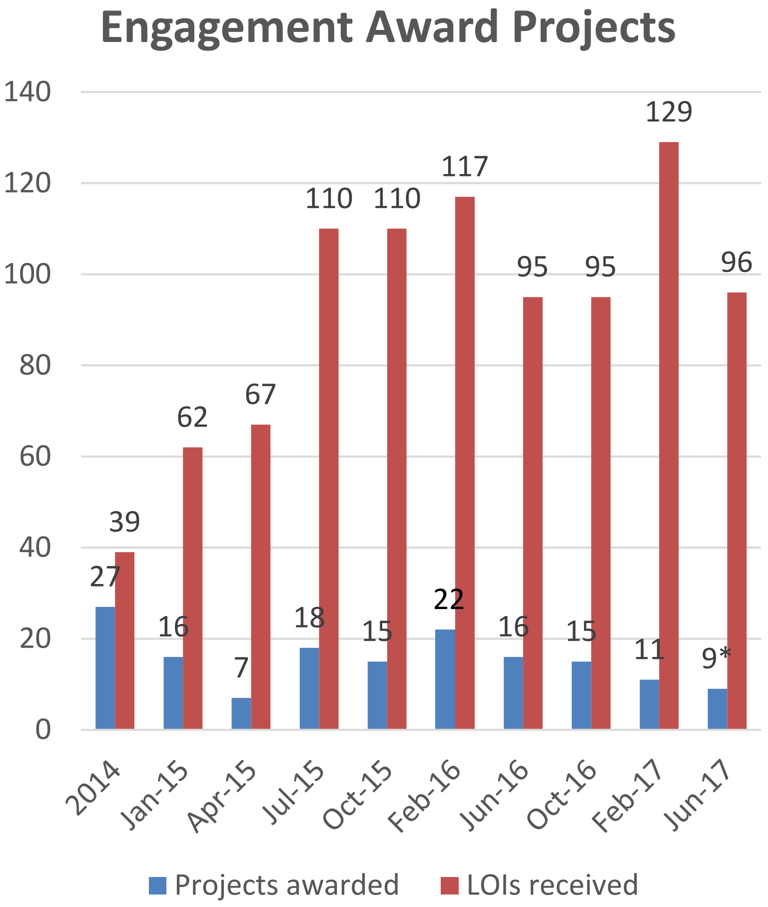
Yasmeen Long, MA
Program Officer

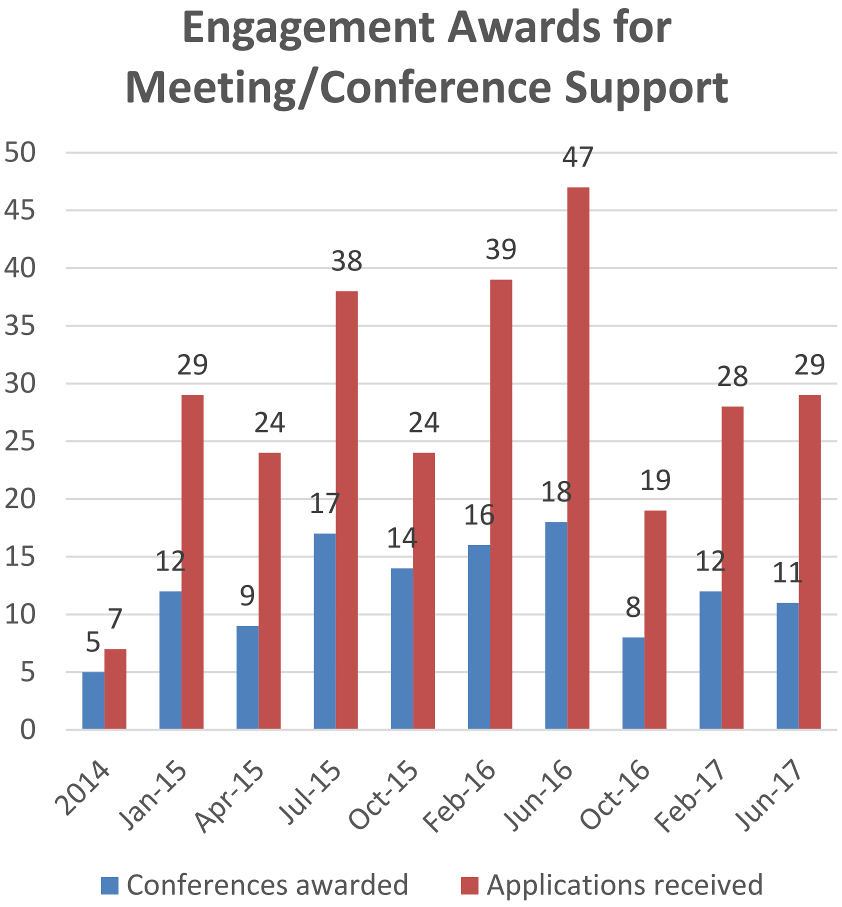
Rachel Mosbacher, MPA
Program Officer

Alicia Thomas, PhD, MHS
Program Officer

Ivey Wohlfeld
Program Associate

Applications Received & Awards Made

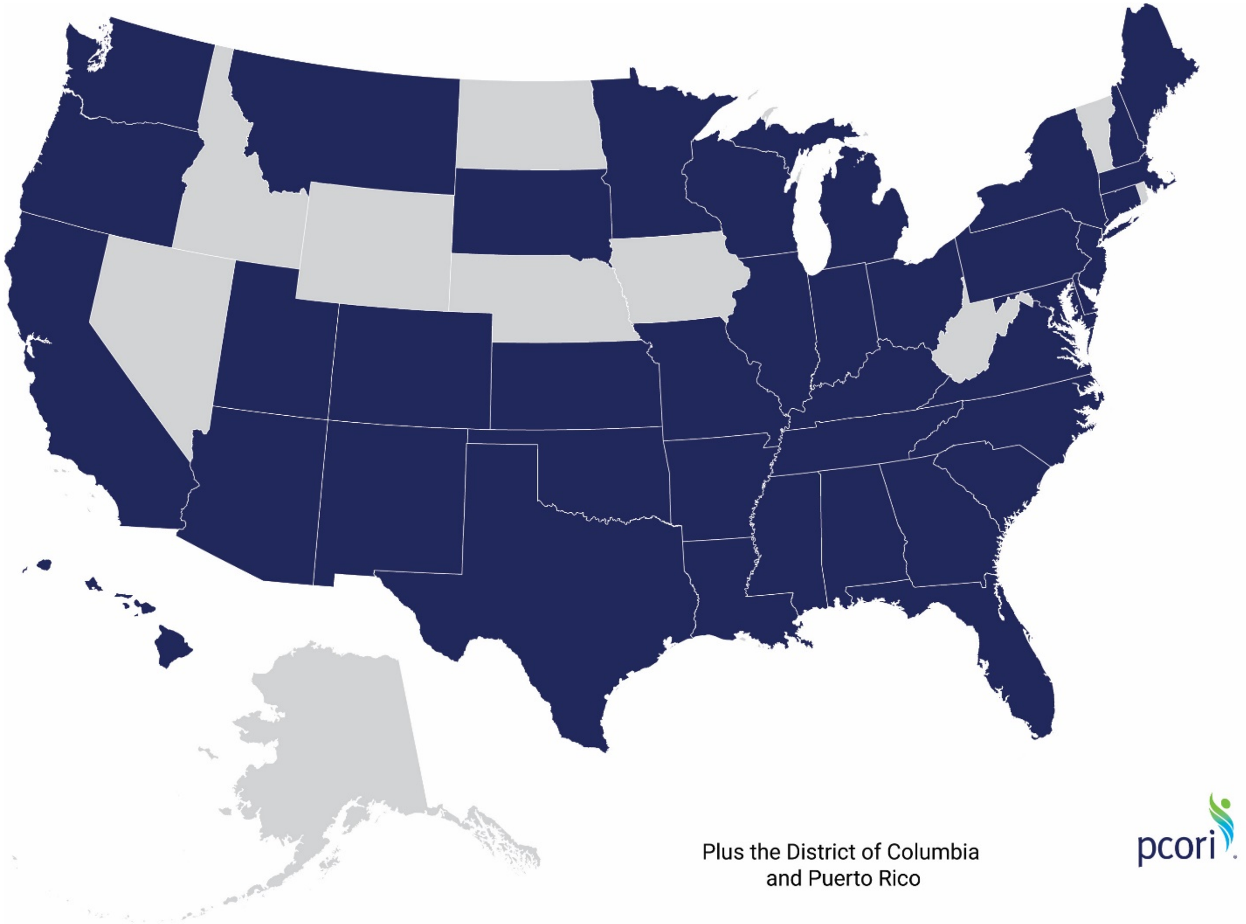




Since program launch in Feb 2014, we've selected 273 projects/conferences for Engagement Awards
***June 2017: Proposals still under review**

Building a National Network for PCOR

- ~$51.7 Million awarded



Plus the District of Columbia
and Puerto Rico

FY 2017 Engagement Award Recipients

- Henry Ford Health System
- Michigan Public Health Institute
- NYU
- University of Arkansas for Medical Sciences
- University of Pennsylvania
- University of Texas Health Science Center Houston
- Illinois Institute of Technology
- Cincinnati Children's Hospital Medical Center
- Henry Ford Health System
- South Dakota State University
- **Parkinson's Disease Foundation**
- **National Psoriasis Foundation**
- North American Primary Care Research Group
- University of Colorado Denver
- Children's Mercy Hospital
- Alliance of Community Health Plans Foundation
- Regents of the University of Michigan
- Milken Institute
- Louisiana Public Health Institute
- **Family Voices, Inc.**
- **National Alliance of Healthcare Purchaser Coalitions**
- Regents of the University of California, on behalf of its Riverside campus
- **Total Resource Community Development Organization**
- University of Kansas Center for Research, Inc.

FY 2017 Engagement Award Recipients, Cont.

- eRepublic/Governing
- University of Washington
- Boston Medical Center
- University of Colorado Denver
- **Hemophilia Federation of America**
- University of Rochester
- Billings Clinic
- University of Colorado
- Pacific Lutheran University
- **Alliance of Chicago Community Health Services**
- University of California, San Francisco
- **Bladder Cancer Advocacy Network**
- Cancer Research Advocacy Group
- American Institutes for Research
- Wayne State University
- **COPD Foundation**
- University of Arkansas Medical Sciences
- Yale University
- **Arthritis Foundation**
- **Community-Campus Partnerships for Health**
- Michigan Public Health Institute
- Johns Hopkins University
- Kokua Kalihi Valley Comprehensive Family Services
- Henry Ford Health System
- The Council for Jewish Elderly dba CJE SeniorLife
- Rural Health Innovation Collaborative
- Univ of Miami, Miller School of Medicine
- Center for Health Policy Development
- **Society to Improve Diagnosis in Medicine**

FY 2017 Engagement Award Conference Support Recipients

- **American Academy of Family Physicians**
- **Plastic Surgery Foundation**
- **A Twist of Fate-ATS**
- Mayo Clinic
- Tufts Medical Center
- **USAgainstAlzheimer's**
- Augusta University Research Institute, Inc.
- Bipartisan Policy Center
- The Cholangiocarcinoma Foundation
- **CP Now Foundation**
- **Coalition for Compassionate Care of California**
- East Tennessee State University College of Public Health
- **Institute for Patient and Family Centered Care**
- Arkansas Children's Hospital Research Institute
- **Society for Medical Decision Making**
- The University of Texas HSC at San Antonio
- Research Advocacy Network
- **The Angiogenesis Foundation**
- University of Washington
- University of Chicago
- **National Kidney Foundation**
- **Colorado Foundation for Public Health and the Environment**
- Boston University Medical Center
- Center for Health Policy Development
- **Metastasis Research Society**
- **HealthInsight**

FY 2017 Engagement Award Conference Support Recipients Cont.

- **American Statistical Association**
- **The Cholangiocarcinoma Foundation**
- **Association of Nurses in AIDS Care**
- Medical Technology and Practice Patterns Institute
- Boston University School of Public Health
- **Society for Academic Emergency Medicine**
- University of South Florida
- University of Michigan Health System
- **Children's Tumor Foundation**
- **Hereditary Neuropathy Foundation**

Lessons Learned

- Organizations have developed and implemented successful PCOR-focused trainings and programs, and there is a growing body of literature in this field.

- Successful methods and best practices for increasing patient and stakeholder engagement in research are not currently being disseminated at a pace consistent with the demands for patient-centered CER.

- It is vital that PCORI support organizations in laying the groundwork for active dissemination of PCORI-funded research findings to potential end-users.

- Disseminating and promoting the uptake of research findings is part of PCORI's legal mandate to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make better-informed health decisions.

Engagement Award Refinements

- Engagement Award Program is a funding opportunity to support PCORI’s Engagement Imperatives
- Revised Program Funding Guidelines and Webpages in June to align with priorities
  - Engagement Award categories de-emphasized; instead, focus on award objectives
  - Shifted away from “knowledge awards/identifying research gaps”
  - Refined objectives:
    - Equip patients and other stakeholders to engage as meaningful partners in PCOR/CER from topic selection to dissemination or implementation of results
    - Lay the groundwork for dissemination and implementation of research results or products derived from PCORI studies
  - Incorporated lessons learned from past three years
- Engagement Award Initiative Notice (EAIN) for meeting conference support now capped at $50,000 and one year duration

Engagement Award Overview Funding Opportunities

- Engagement Award (EA) **projects**
  - Equip patients and other stakeholders to engage as meaningful partners in PCOR/CER from topic selection to dissemination or implementation of results
  - Support organizations to lay groundwork for disseminating and implementing research results or products derived from PCORI

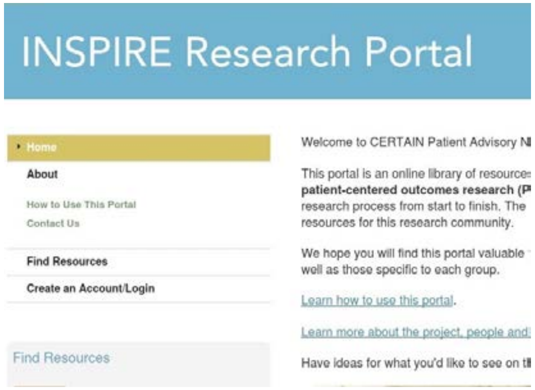
Awards of **up to $250,000** per project, up to **two years** in duration

- Funding through an Engagement Award Initiative Notice (EAIN) supports **meetings/conferences** that align with PCORI's mission and strategic plan, and facilitate expansion of PCOR/CER in areas such as:
  - research design and methodology
  - research development
  - dissemination and implementation

Awards of **up to $50,000** per conference, up to **one year** in duration

Highlights from Awards

- University of Washington launched CERTAIN Patient Advisory Network's INSPIRE Research Portal which provides easy access to existing tools and resources for PCOR
- University of Southern Mississippi project led to PCORI being recognized by a resolution of the State Senate and House of Representatives in Mississippi "…recognizing outstanding financial and resource support…for health care options to patients and providers in the Mississippi Delta"
- 6th Annual Alliance for Research in Chicagoland Communities (ARCC) Community-Engaged Research Partnership Award Recipient: Pastors4PCOR (P4P): Engaging faith-based communities in health research



Welcome to CERTAIN Patient Advisory N

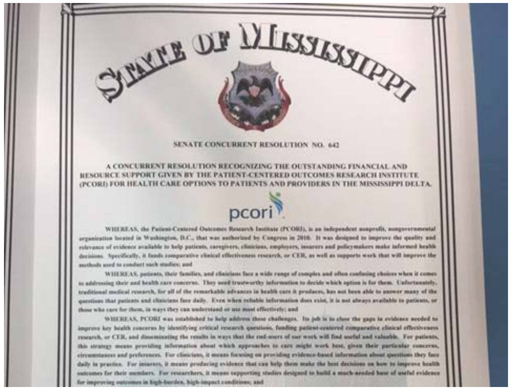
This portal is an online library of resource
patient-centered outcomes research (P
research process from start to finish. The
resources for this research community.

We hope you will find this portal valuable
well as those specific to each group.

Learn how to use this portal.

Learn more about the project, people and

Have ideas for what you'd like to see on t



STATE OF MISSISSIPPI

SENATE CONCURRENT RESOLUTION NO. 642

A CONCURRENT RESOLUTION RECOGNIZING THE OUTSTANDING FINANCIAL AND RESOURCE SUPPORT GIVEN BY THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI) FOR HEALTH CARE OPTIONS TO PATIENTS AND PROVIDERS IN THE MISSISSIPPI DELTA.

WHEREAS, the Patient-Centered Outcomes Research Institute (PCORI), is an independent nonprofit, nongovernmental organization located in Washington, D.C., that was authorized by Congress in 2010. It was designed to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers and policymakers make informed health decisions. Specifically, it funds comparative clinical effectiveness research, or CER, as well as supports work that will improve the methods used to conduct such studies; and

WHEREAS, patients, their families, and clinicians face a wide range of complex and often confusing choices when it comes to addressing their and health care concerns. They need trustworthy information to decide which option is for them. Unfortunately, traditional medical research, for all of the remarkable advances in health care it produces, has not been able to answer many of the questions that patients and clinicians face daily. Even when reliable information does exist, it is not always available to patients, or those who care for them, in ways they can understand or use most effectively; and

WHEREAS, PCORI was established to help address these challenges. Its job is to close the gaps in evidence needed to improve key health concerns by identifying critical research questions, funding patient-centered comparative clinical effectiveness research, or CER, and disseminating the results in ways that the end-users of our work will find useful and valuable. For patients, this strategy means providing information about which approaches to care might work best, given their particular concerns, circumstances and preferences. For clinicians, it means focusing on providing evidence-based information about questions they face daily in practice. For insurers, it means producing evidence that can help them make the best decisions on how to improve health outcomes for their members. For researchers, it means supporting studies designed to build a much-needed base of useful evidence for improving outcomes in high-burden, high-impact conditions; and

To help protect your privacy, PowerPoint has blocked automatic download of this picture.

Thank you!

Contact Information:

Eugene Washington PCORI Engagement Award Program
Patient-Centered Outcomes Research Institute (PCORI)
1828 L Street, NW 9th Floor
Washington, DC 20036

Telephone: 202-370-9312
Email: ea@pcori.org

Visit: http://www.pcori.org/funding-opportunities/programmatic-funding/eugene-washington-pcori-engagement-awards

Dissemination & Implementation Program Updates

Jane Chang, MPH

Program Officer, Dissemination & Implementation Program

Arielle Gorstein, MPH

Program Associate, Dissemination & Implementation Program

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

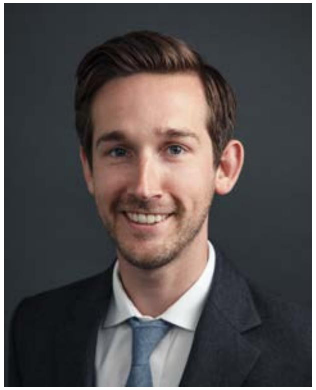
Introductions


Joanna E. Siegel, ScD
Program Director

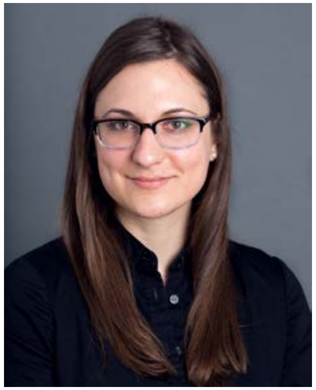

Jane Chang, MPH
Program Officer


Kristen DeCaires, MPH
Senior Program Associate


Kimberly Duong
Senior Administrative Assistant


Christopher Gayer, PhD
Senior Program Officer


Arielle Gorstein, MPH
Program Associate


Michelle Henton, MA
Senior Program Associate

PCORI Dissemination & Implementation Program

- The D&I Program is charged with heightening awareness of the results of PCORI-funded research, and with advancing efforts to put these findings into practice to improve healthcare delivery and health outcomes.

Meeting PCORI’s Public Reporting Mandate

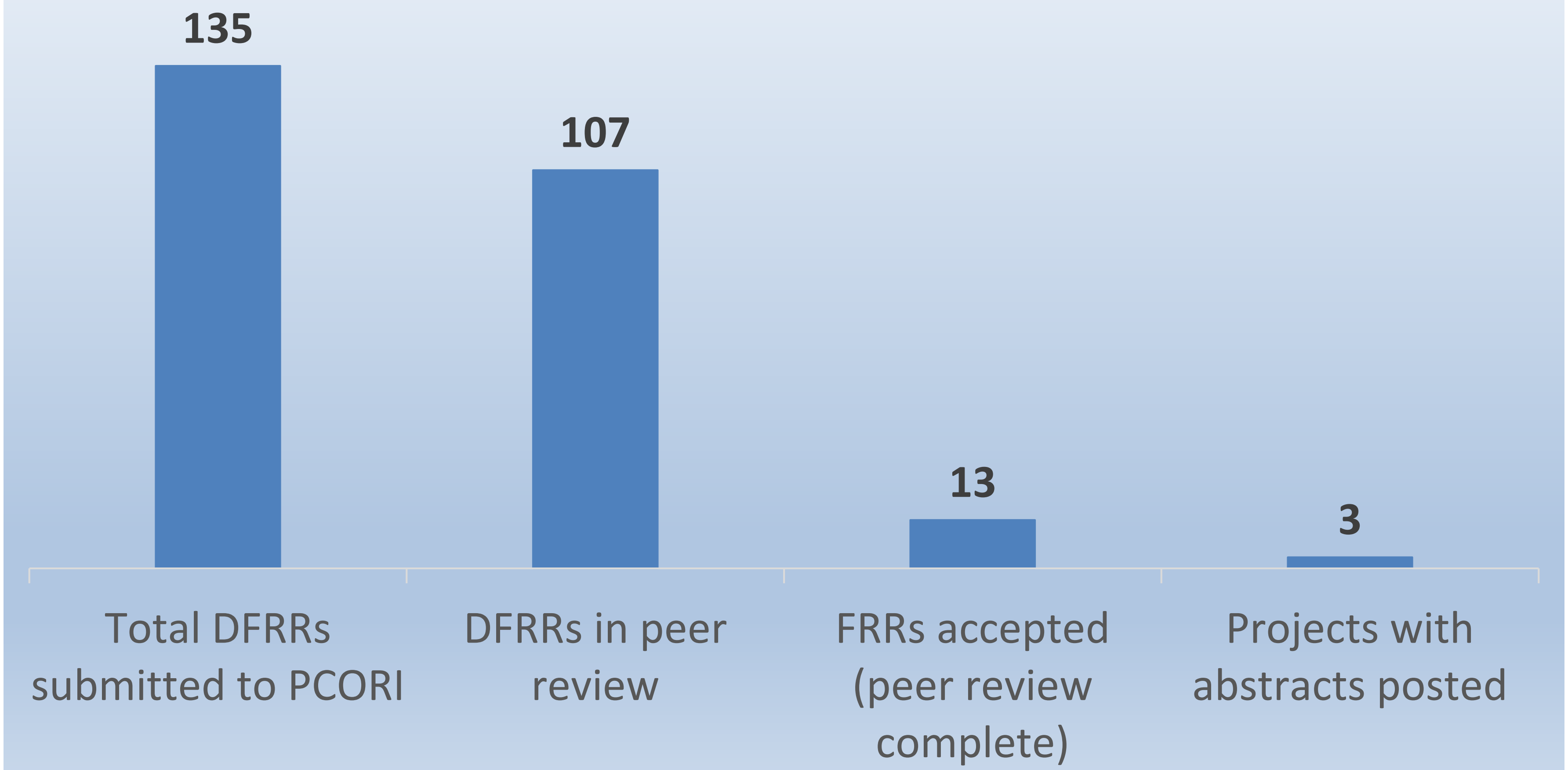
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Public Reporting of PCORI Research Findings following Peer Review

- PCORI's authorizing law and the processes adopted by the Board outline approach for releasing findings
- Post to pcori.org within 90 days of PCORI's acceptance of the draft final research report following peer review:
  - 500-word public abstract
  - 500-word professional abstract
  - Summary of peer review comments
- Post to pcori.org within 12 months of PCORI's acceptance of the DFRR:
  - Final Research Report
  - Detailed peer reviewer comments
- Assures accessibility and full transparency in reporting results from all PCORI studies

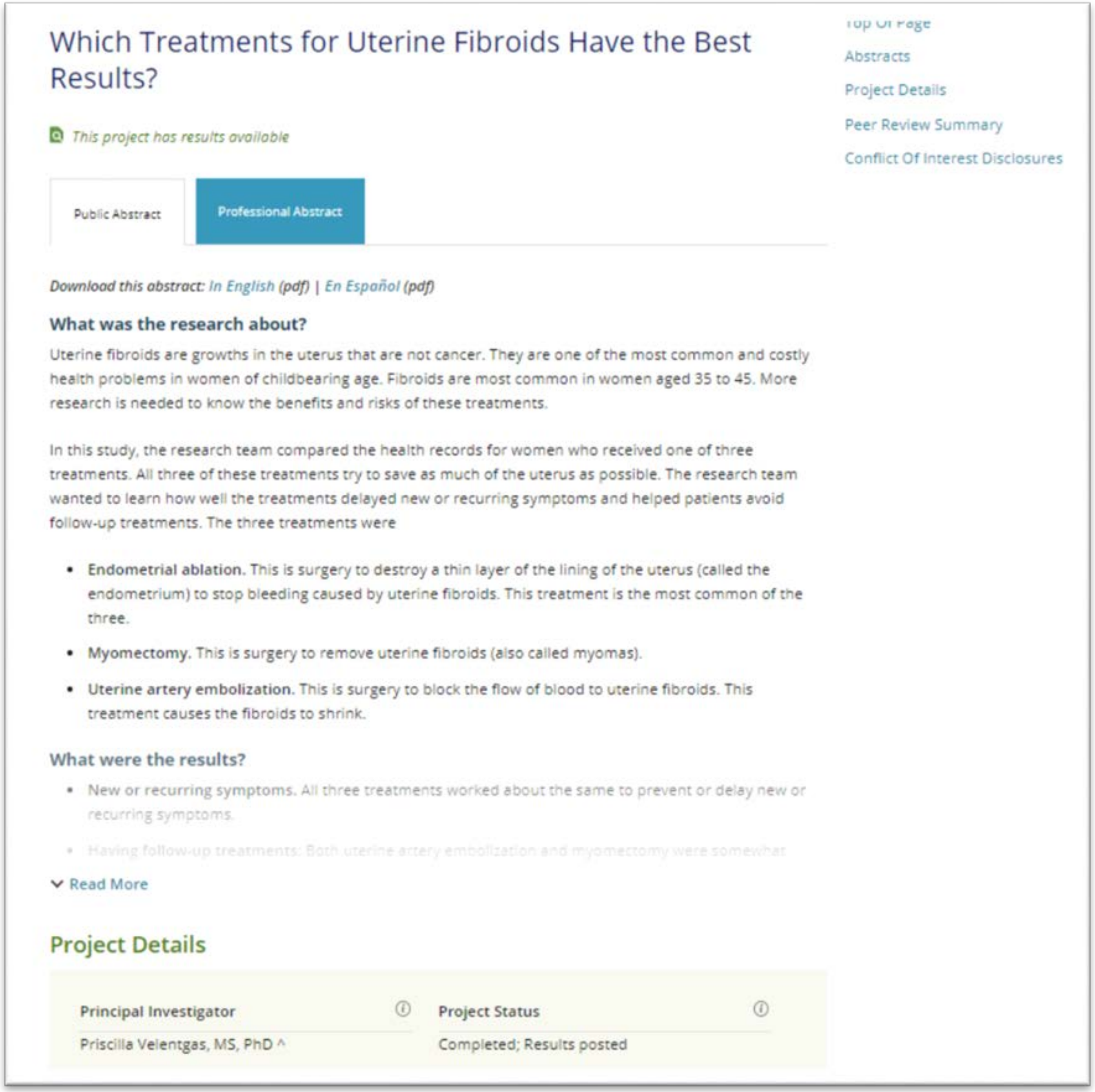
Public Release of PCORI Research Findings

Public and Professional Results Abstracts



As of October 2, 2017

Posting Primary Study Results to pcori.org



Which Treatments for Uterine Fibroids Have the Best Results?

This project has results available

Download this abstract: In English (pdf) | En Español (pdf)

What was the research about?

Uterine fibroids are growths in the uterus that are not cancer. They are one of the most common and costly health problems in women of childbearing age. Fibroids are most common in women aged 35 to 45. More research is needed to know the benefits and risks of these treatments.

In this study, the research team compared the health records for women who received one of three treatments. All three of these treatments try to save as much of the uterus as possible. The research team wanted to learn how well the treatments delayed new or recurring symptoms and helped patients avoid follow-up treatments. The three treatments were

- **Endometrial ablation.** This is surgery to destroy a thin layer of the lining of the uterus (called the endometrium) to stop bleeding caused by uterine fibroids. This treatment is the most common of the three.
- **Myomectomy.** This is surgery to remove uterine fibroids (also called myomas).
- **Uterine artery embolization.** This is surgery to block the flow of blood to uterine fibroids. This treatment causes the fibroids to shrink.

What were the results?

- New or recurring symptoms. All three treatments worked about the same to prevent or delay new or recurring symptoms.
- Having follow-up treatments: Both uterine artery embolization and myomectomy were somewhat

Project Details

Principal Investigator	Project Status
Priscilla Velentgas, MS, PhD ^	Completed; Results posted

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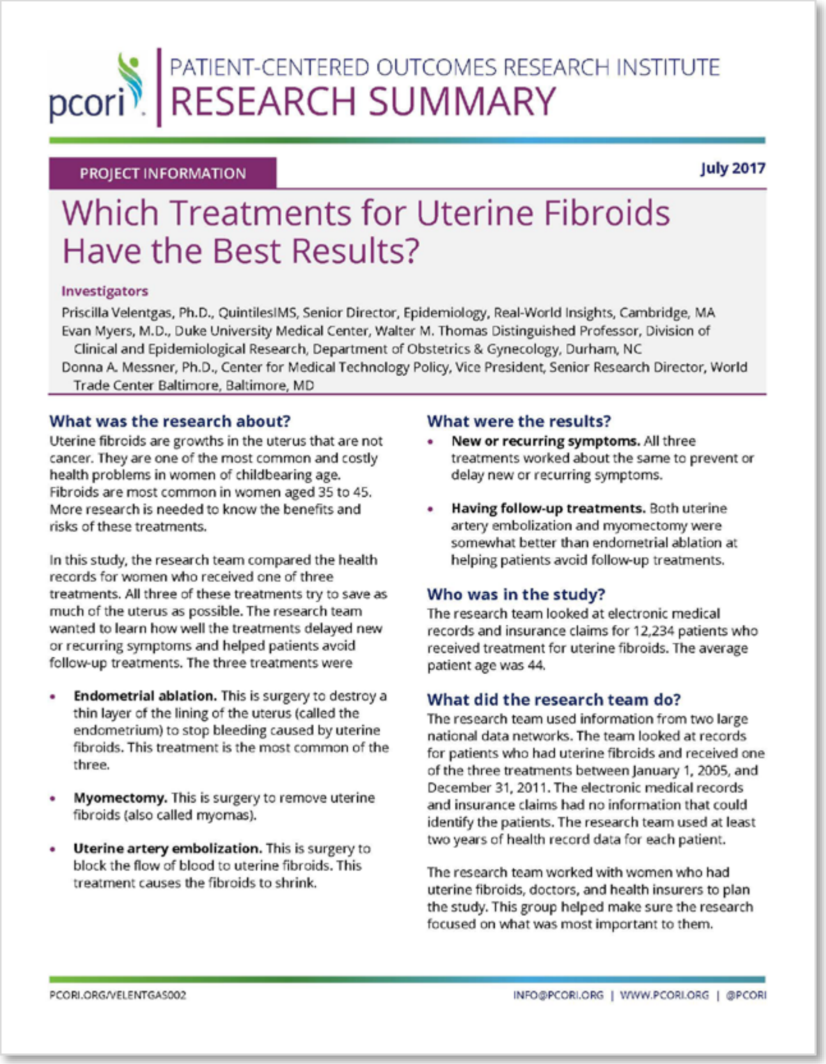
Primary Study Results – Downloadable English and Spanish Versions



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RESEARCH SUMMARY

PROJECT INFORMATION

July 2017

Which Treatments for Uterine Fibroids Have the Best Results?

Investigators

Priscilla Velentgas, Ph.D., QuintilesIMS, Senior Director, Epidemiology, Real-World Insights, Cambridge, MA
Evan Myers, M.D., Duke University Medical Center, Walter M. Thomas Distinguished Professor, Division of Clinical and Epidemiological Research, Department of Obstetrics & Gynecology, Durham, NC
Donna A. Messner, Ph.D., Center for Medical Technology Policy, Vice President, Senior Research Director, World Trade Center Baltimore, Baltimore, MD

What was the research about?

Uterine fibroids are growths in the uterus that are not cancer. They are one of the most common and costly health problems in women of childbearing age. Fibroids are most common in women aged 35 to 45. More research is needed to know the benefits and risks of these treatments.

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- **Myomectomy.** This is surgery to remove uterine fibroids (also called myomas).
- **Uterine artery embolization.** This is surgery to block the flow of blood to uterine fibroids. This treatment causes the fibroids to shrink.

What were the results?

- **New or recurring symptoms.** All three treatments worked about the same to prevent or delay new or recurring symptoms.
- **Having follow-up treatments.** Both uterine artery embolization and myomectomy were somewhat better than endometrial ablation at helping patients avoid follow-up treatments.

Who was in the study?

The research team looked at electronic medical records and insurance claims for 12,234 patients who received treatment for uterine fibroids. The average patient age was 44.

What did the research team do?

The research team used information from two large national data networks. The team looked at records for patients who had uterine fibroids and received one of the three treatments between January 1, 2005, and December 31, 2011. The electronic medical records and insurance claims had no information that could identify the patients. The research team used at least two years of health record data for each patient.

The research team worked with women who had uterine fibroids, doctors, and health insurers to plan the study. This group helped make sure the research focused on what was most important to them.

PCORI.ORG/VELENTGAS002

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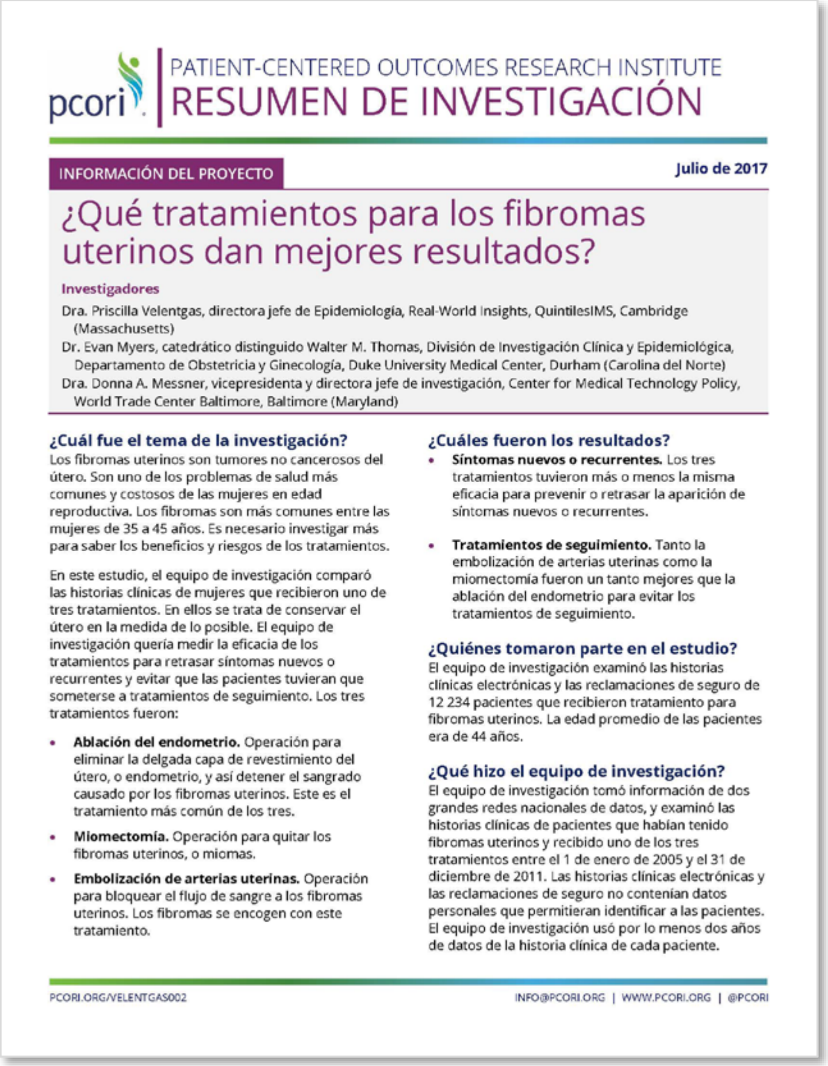

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RESUMEN DE INVESTIGACIÓN

INFORMACIÓN DEL PROYECTO

Julio de 2017

¿Qué tratamientos para los fibromas uterinos dan mejores resultados?

Investigadores

Dra. Priscilla Velentgas, directora jefe de Epidemiología, Real-World Insights, QuintilesIMS, Cambridge (Massachusetts)
Dr. Evan Myers, catedrático distinguido Walter M. Thomas, División de Investigación Clínica y Epidemiológica, Departamento de Obstetricia y Ginecología, Duke University Medical Center, Durham (Carolina del Norte)
Dra. Donna A. Messner, vicepresidenta y directora jefe de investigación, Center for Medical Technology Policy, World Trade Center Baltimore, Baltimore (Maryland)

¿Cuál fue el tema de la investigación?

Los fibromas uterinos son tumores no cancerosos del útero. Son uno de los problemas de salud más comunes y costosos de las mujeres en edad reproductiva. Los fibromas son más comunes entre las mujeres de 35 a 45 años. Es necesario investigar más para saber los beneficios y riesgos de los tratamientos.

En este estudio, el equipo de investigación comparó las historias clínicas de mujeres que recibieron uno de tres tratamientos. En ellos se trata de conservar el útero en la medida de lo posible. El equipo de investigación quería medir la eficacia de los tratamientos para retrasar síntomas nuevos o recurrentes y evitar que las pacientes tuvieran que someterse a tratamientos de seguimiento. Los tres tratamientos fueron:

- **Ablación del endometrio.** Operación para eliminar la delgada capa de revestimiento del útero, o endometrio, y así detener el sangrado causado por los fibromas uterinos. Este es el tratamiento más común de los tres.
- **Miomectomía.** Operación para quitar los fibromas uterinos, o miomas.
- **Embolización de arterias uterinas.** Operación para bloquear el flujo de sangre a los fibromas uterinos. Los fibromas se encogen con este tratamiento.

¿Cuáles fueron los resultados?

- **Síntomas nuevos o recurrentes.** Los tres tratamientos tuvieron más o menos la misma eficacia para prevenir o retrasar la aparición de síntomas nuevos o recurrentes.
- **Tratamientos de seguimiento.** Tanto la embolización de arterias uterinas como la miomectomía fueron un tanto mejores que la ablación del endometrio para evitar los tratamientos de seguimiento.

¿Quiénes tomaron parte en el estudio?

El equipo de investigación examinó las historias clínicas electrónicas y las reclamaciones de seguro de 12 234 pacientes que recibieron tratamiento para fibromas uterinos. La edad promedio de las pacientes era de 44 años.

¿Qué hizo el equipo de investigación?

El equipo de investigación tomó información de dos grandes redes nacionales de datos, y examinó las historias clínicas de pacientes que habían tenido fibromas uterinos y recibido uno de los tres tratamientos entre el 1 de enero de 2005 y el 31 de diciembre de 2011. Las historias clínicas electrónicas y las reclamaciones de seguro no contenían datos personales que permitieran identificar a las pacientes. El equipo de investigación usó por lo menos dos años de datos de la historia clínica de cada paciente.

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Web Analytics

The information PCORI is tracking includes

- Number of times the page has been viewed
- Number of unique visitors to the page
- How long visitors stay on the page
- What drove the visitors to the page (email, social media, search, direct traffic, etc.)
- Use of “social share” to print, email, or share the page on social media (Twitter, Facebook, LinkedIn, etc)
- Clicks on the Public and Professional Abstract tabs
- Number of Spanish and English PDF downloads and audio plays
- How far users scroll or click down the page
- How many users click on “Read more”/’Read less” link

Revising the Project Summaries

Improving consistency, comprehensibility, and accuracy of our summaries of **ongoing projects**

Project Summary

What is the research about?
Who can this research help?
What is the research doing?
Research methods at a glance

- 28 revised Project Summaries posted as of October 2

Targeted Dissemination Activities

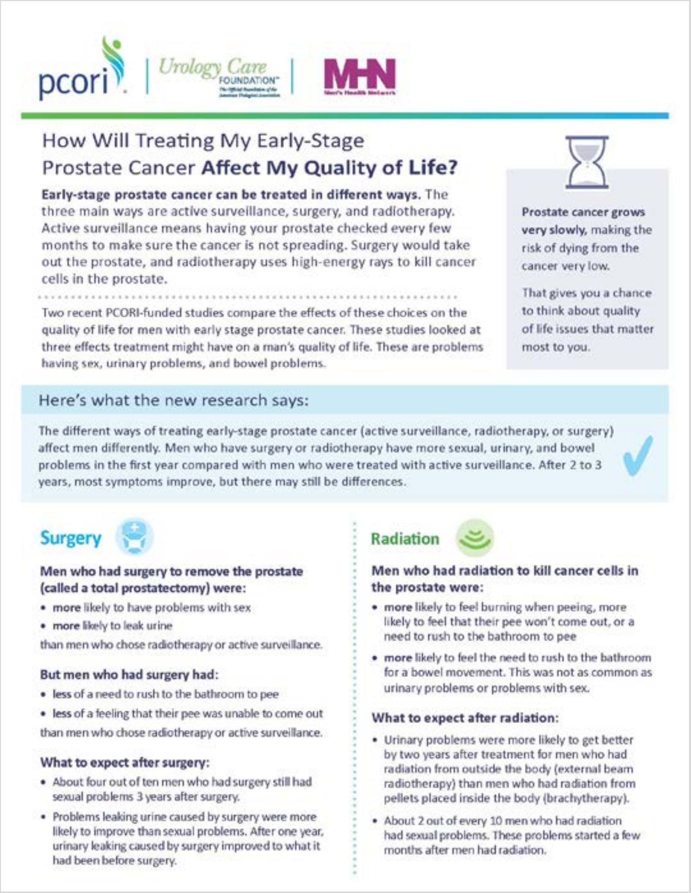
Disseminating New Evidence with High Impact Potential

- Collaborate with stakeholder partners to identify opportunities to reach targeted audiences

- Develop information updates and work with these partners to disseminate

Activities in Targeted Dissemination: Prostate Cancer

- Current Treatments for Localized Prostate Cancer and Symptom-Related Quality of Life (Penson, Chen)



pcori | Urology Care FOUNDATION | MHN Men's Health Network

How Will Treating My Early-Stage Prostate Cancer **Affect My Quality of Life?**

Early-stage prostate cancer can be treated in different ways. The three main ways are active surveillance, surgery, and radiotherapy. Active surveillance means having your prostate checked every few months to make sure the cancer is not spreading. Surgery would take out the prostate, and radiotherapy uses high-energy rays to kill cancer cells in the prostate.

Two recent PCORI-funded studies compare the effects of these choices on the quality of life for men with early stage prostate cancer. These studies looked at three effects treatment might have on a man's quality of life. These are problems having sex, urinary problems, and bowel problems.

Prostate cancer grows very slowly, making the risk of dying from the cancer very low.

That gives you a chance to think about quality of life issues that matter most to you.

Here's what the new research says:

The different ways of treating early-stage prostate cancer (active surveillance, radiotherapy, or surgery) affect men differently. Men who have surgery or radiotherapy have more sexual, urinary, and bowel problems in the first year compared with men who were treated with active surveillance. After 2 to 3 years, most symptoms improve, but there may still be differences. ✓

Surgery

Men who had surgery to remove the prostate (called a total prostatectomy) were:

- **more** likely to have problems with sex
- **more** likely to leak urine

than men who chose radiotherapy or active surveillance.

But men who had surgery had:

- **less** of a need to rush to the bathroom to pee
- **less** of a feeling that their pee was unable to come out

than men who chose radiotherapy or active surveillance.

What to expect after surgery:

- About four out of ten men who had surgery still had sexual problems 3 years after surgery.
- Problems leaking urine caused by surgery were more likely to improve than sexual problems. After one year, urinary leaking caused by surgery improved to what it had been before surgery.

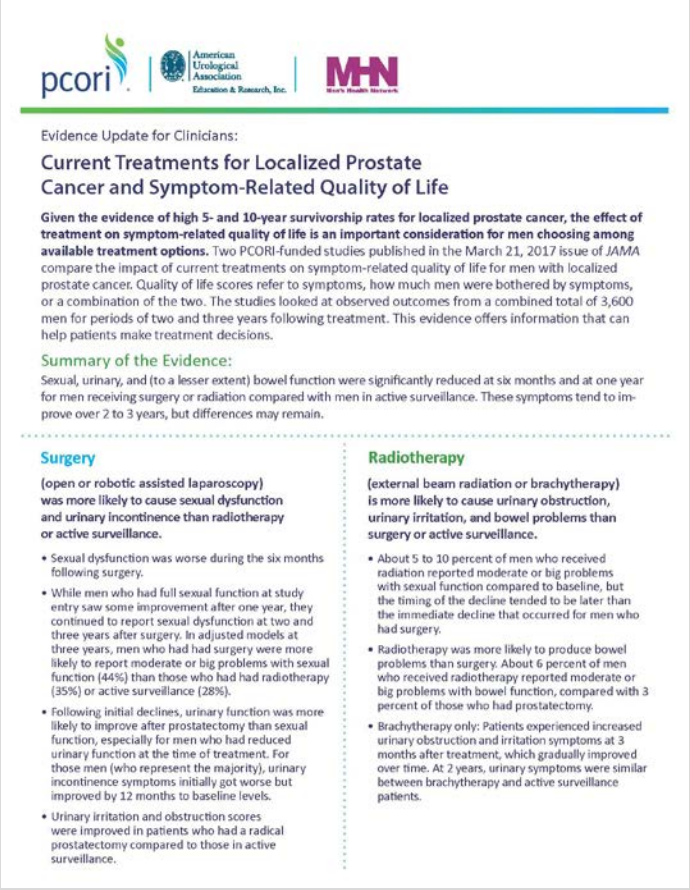
Radiation

Men who had radiation to kill cancer cells in the prostate were:

- **more** likely to feel burning when peeing, more likely to feel that their pee won't come out, or a need to rush to the bathroom to pee
- **more** likely to feel the need to rush to the bathroom for a bowel movement. This was not as common as urinary problems or problems with sex.

What to expect after radiation:

- Urinary problems were more likely to get better by two years after treatment for men who had radiation from outside the body (external beam radiotherapy) than men who had radiation from pellets placed inside the body (brachytherapy).
- About 2 out of every 10 men who had radiation had sexual problems. These problems started a few months after men had radiation.



pcori | American Urological Association Education & Research, Inc. | MHN Men's Health Network

Evidence Update for Clinicians:

Current Treatments for Localized Prostate Cancer and Symptom-Related Quality of Life

Given the evidence of high 5- and 10-year survivorship rates for localized prostate cancer, the effect of treatment on symptom-related quality of life is an important consideration for men choosing among available treatment options. Two PCORI-funded studies published in the March 21, 2017 issue of *JAMA* compare the impact of current treatments on symptom-related quality of life for men with localized prostate cancer. Quality of life scores refer to symptoms, how much men were bothered by symptoms, or a combination of the two. The studies looked at observed outcomes from a combined total of 3,600 men for periods of two and three years following treatment. This evidence offers information that can help patients make treatment decisions.

Summary of the Evidence:

Sexual, urinary, and (to a lesser extent) bowel function were significantly reduced at six months and at one year for men receiving surgery or radiation compared with men in active surveillance. These symptoms tend to improve over 2 to 3 years, but differences may remain.

Surgery

(open or robotic assisted laparoscopy) was more likely to cause sexual dysfunction and urinary incontinence than radiotherapy or active surveillance.

- Sexual dysfunction was worse during the six months following surgery.
- While men who had full sexual function at study entry saw some improvement after one year, they continued to report sexual dysfunction at two and three years after surgery. In adjusted models at three years, men who had had surgery were more likely to report moderate or big problems with sexual function (44%) than those who had had radiotherapy (35%) or active surveillance (28%).
- Following initial declines, urinary function was more likely to improve after prostatectomy than sexual function, especially for men who had reduced urinary function at the time of treatment. For those men (who represent the majority), urinary incontinence symptoms initially got worse but improved by 12 months to baseline levels.
- Urinary irritation and obstruction scores were improved in patients who had a radical prostatectomy compared to those in active surveillance.

Radiotherapy

(external beam radiation or brachytherapy) is more likely to cause urinary obstruction, urinary irritation, and bowel problems than surgery or active surveillance.

- About 5 to 10 percent of men who received radiation reported moderate or big problems with sexual function compared to baseline, but the timing of the decline tended to be later than the immediate decline that occurred for men who had surgery.
- Radiotherapy was more likely to produce bowel problems than surgery. About 6 percent of men who received radiotherapy reported moderate or big problems with bowel function, compared with 3 percent of those who had prostatectomy.
- Brachytherapy only: Patients experienced increased urinary obstruction and irritation symptoms at 3 months after treatment, which gradually improved over time. At 2 years, urinary symptoms were similar between brachytherapy and active surveillance patients.

Activities in Targeted Dissemination: Antipsychotics for Children & Youth

- Antipsychotics for Children & Youth (AHRQ systematic review)
  - Foster care system and children on Medicaid
  - Group and individual stakeholder discussions

Implementation of Effective Shared Decision Making Approaches in Practice Settings PFA

Background

- **SDM is effective[1]**:
  - Systematic Reviews have established the positive effect of shared decision making approaches on patient knowledge, understanding of risks and benefits, and increased confidence in decisions
- **Recognition of importance of SDM has grown in recent years[2, 3]:**
  - ACA language explicitly promotes SDM
  - Washington State legislation promotes SDM
  - National Quality Forum recently published certification standards based on international standards for patient decision aids/tools
  - CMS has started requiring SDM as a precondition for payment, for two treatment choices

[1] Stacey D et al., 2011

2 Elwyn G et al., 2013

3 Spatz E et al., 2017

Patient & Consumer Orgs are Interested in SDM

1. National Patient Safety Foundation held a webinar on June 21 titled, "Shared Decision Making and Patient Safety: Making the Connections"
   - "[SDM]…takes into account both clinical evidence as well as a patient's personal values and preferences. It has been called 'perfected informed consent.'"

2. The National Health Council (NHC) has submitted numerous statements and comments to regulatory bodies in support of SDM
   - Marc Boutin, NHC's CEO, "has been a leading voice for greater patient involvement at every stage of the continuum, starting with the development of new drugs, to regulatory oversight of health care delivery, to shared decision-making at the point of care."

Patient & Consumer Orgs are Interested in SDM

3. National Quality Forum (NQF) has formed The National Quality Partners (NQP) Shared Decision Making Action Team that is working to identify key barriers and solutions to advance SDM on a national sale
   - Co-chaired by Maureen Corry of the National Partnership for Women & Families
   - Includes representation from patient & consumer orgs such as the National Alliance for Caregiving, the National Coalition for Cancer Survivorship, the Patient & Family Centered Care Partners, Inc., and others

Background

However, uptake of SDM in clinical practice remains relatively low

- *"[D]espite these policy developments and the existence of over 100 randomized controlled trials that have demonstrated the efficacy of these interventions*[1]*, their* ***adoption into mainstream clinical practice has yet to be established, and their impact when used in routine workflows requires evaluation***[2]*."*

[1] Stacey D et al., 2011; [2] Elwyn G et al., 2013

The D&I program launched its second PFA to help bridge the gap between SDM evidence and SDM practice

Shared Decision Making Strategy Definition

For this PFA, PCORI defines an SDM strategy as…

> *an intervention or approach that draws on and presents available evidence to inform patients of available treatment options and their risks and benefits, and either engages patients in a decision-making process that reflects their values with their clinician, or promotes their ability to engage in such a process*

Patient and Stakeholder Engagement

We expect applicants to incorporate the perspectives and experiences of **patients and stakeholders** in their proposals. The following are a few of the questions that we ask them to address:

1. Does the application demonstrate that stakeholders central to the proposed project, including targeted end-users or their representatives, are engaged with the project planning and execution?
2. Does the application demonstrate that stakeholders central to the proposed project are engaged in planning for the sustainability of the proposed SDM approach?
3. Does the application demonstrate clear interest and support of personnel responsible for implementing SDM at target settings? In what ways is the application convincing that these personnel will participate as active partners in the project?

Implementation of SDM Approaches in Practice Settings Awards

Key Information (See PFA online for more info: https://www.pcori.org/funding-opportunities/announcement/pcori-funding-announcement-implementation-effective-shared)	
Cycle: Cycle 2 2017	
Full Announcement: Implementation of Effective Shared Decision Making Approaches in Practice Settings	**Deadlines:** Letters of Intent: October 2, 2017 Applications: January 10, 2018
Status: OPEN Online System Opens September 1, 2017	**Timeline:** Merit Review: March 2018 Awards Announced: August 2018
Applicant Town Hall Session: September 19, 2017	**Earliest Start Date:** October 2018
Letter of Intent (LOI): Competitive	**Funding Level:** $1,500,000 total direct costs.
Funds available up to: $6,500,000 per cycle	**Project Period:** 3 years maximum

Questions?

Education/Training Update

Erica Sarnes, MA

Senior Manager, Education & Training

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Introductions

Erica Sarnes, MA
Senior Manager,
Education & Training

Vera Kargbo, BS
Program Associate

William Stewart, MA
Program Associate

Education/Training Initiatives

Underway:

- Continuing Medical Education (CME)/Continuing Education (CE)

To begin shortly:

- Research fundamentals for non-scientists
- Team science for PCORI-funded research teams

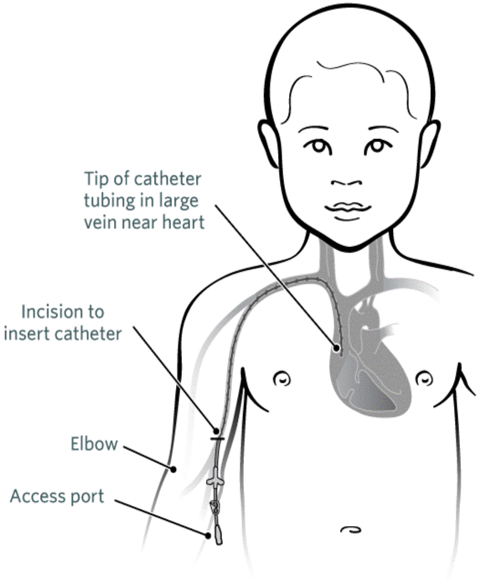
Overview of PCORI’s CME/CE Programs

Goal: To help clinicians become more familiar with how PCORI study results contribute to the existing body of evidence

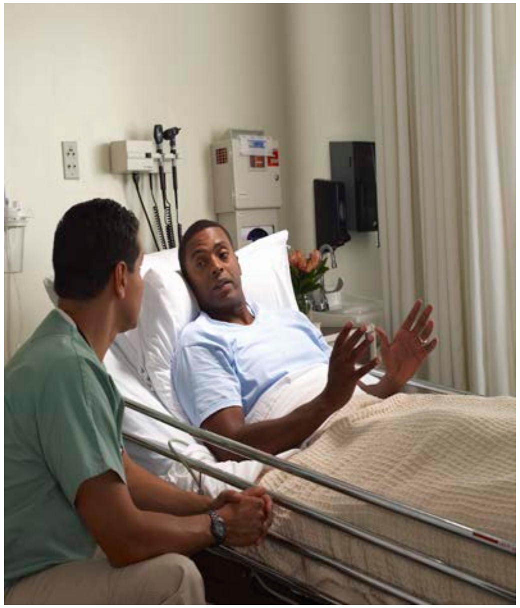
PCORI’s CME Providers are:

- Baylor College of Medicine (BCM)
- PRIME Education, Inc.

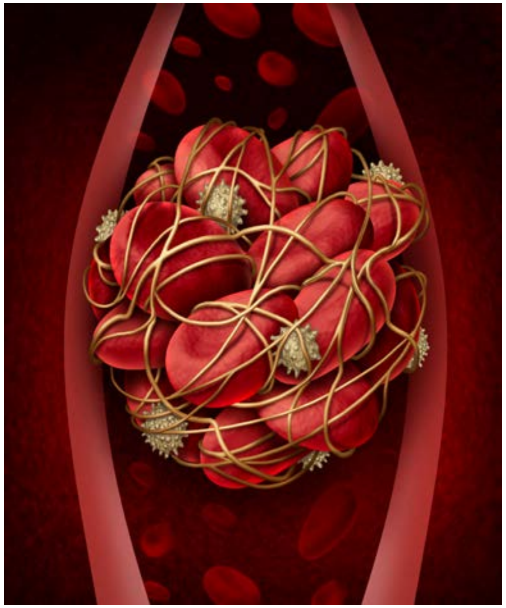
CME Programs to Support D&I



Osteomyelitis in Children
PI: Keren
CME Term: 5/15-6/17



Prostate Cancer
PIs: Penson, Chen
CME Term: 10/17-10/18



Stroke and AFib
PI: Hernandez
CME Term: 9/17-9/18

Patient Involvement in CME/CE Programs

- Patient partners are planners/faculty and presenters in all PCORI CME/CE programs
  - Aligns with ACCME’s new criteria (July 2016) for Accreditation with Commendation for accredited providers

Research Fundamentals

Goals:

- Help patients and public stakeholders understand PCOR, CER, basic research principles, and other content areas relevant to the conduct of stakeholder engaged research
- Help patients and public stakeholders be involved in PCOR

Time Frame (from date of contract award):

- Implementation: Months 15/16
- Evaluation: Ongoing from implementation through Month 30

Team Science

Goals:

- Enable teams of researchers, patients, and stakeholders to participate effectively in PCORI-funded research teams
- Enable research team members to understand their respective roles, contributions, and assets
- Enable diverse research team members to obtain the necessary skills and learn behaviors to work interdependently in a team environment comprising scientific and lay audiences

Time Frame (from date of contract award):

- Implementation: Months 19/20
- Evaluation: Ongoing from implementation through Month 30

Patient Involvement in Research Fundamentals and Team Science

In both projects, patients will:

- Serve as Stakeholder Advisory Group (SAG) members
- Pilot test materials

Areas for PEAP Members' Participation

PEAP members may be involved in the research fundamentals and/or team science project by:

- Serving as a SAG member
- Recommending tools to include in the environmental scan
- Pilot testing materials

Questions?

Thank You!

Where Engagement at PCORI is Heading: An Update and Look Ahead

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Kristin L. Carman, PhD

Director of Public and Patient Engagement

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Introductions

Kristin Carman, PhD, MA
Director of Public & Patient Engagement

Julia Anderson, MEM, MPH
Program Associate

Chinenye Anyanwu, PharmD, MPH
Engagement Officer

Meghan Berman,
Intern Engagement Assistant

Charmaine Boone
Senior Administrative Assistant

Jourdan Davis, MPP
Program Associate

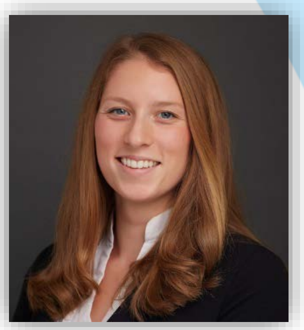
Julie Lesch, MPA
Engagement Officer

Athena McBride,
Senior Administrative Assistant

Whitney McInvale, MPH
Program Associate

Rachel Mosbacher, MPA
Program Officer

Lisa Stewart, MA
Engagement Officer



Krista Woodward, MPH, MSW
Senior Program Associate

April Meeting Recap

- The following areas were identified as focal points for the future of Public & Patient Engagement at PCORI:
  - **Integration of Public and Patient Engagement**
    - People and processes
  - **Outreach to Stakeholders**
    - Information sharing, gathering input and ideas, visioning PCORI 2.0
  - **Science of Engagement**
    - Promising practices and testing hypotheses

Key Priorities

1. Strengthen stakeholder relationships
2. Advance the science of engagement
3. Translate and share findings with the field
4. Promote dissemination and uptake

Theme of Key Priorities

A. Leverage existing knowledge and seek opportunities to take PCORI’s engagement work to the next level
B. Systematize processes that have been ad hoc in the past
C. Conceptualize efforts into new roles and formalize structures

***Note*: Updates on specific programs will be provided in “PEAP Working Committee Updates”**

Increase Capacity: Integration Update

- ☐ Restructure
- ☐ Reengineer and staff
- ☐ Refine structure and processes
- ☐ Support collaboration and innovation
- ☐ Strategize and prioritize

Priority #1:

Strengthen Stakeholder Relationships

Strengthen Stakeholder Relationships

- Conduct outreach/host meetings to frame up PCORI's portfolio in support of different stakeholder groups
- Target key stakeholder meetings to attend
- Scan PCORI's portfolio to highlight findings most important to groups; connect them to that evolving information
- Revise Ambassador Program, adapt approach to Speakers Bureau, and work towards broader, more innovative methods for public input

Priority #2:

Advance the Science of Engagement

Science of Engagement: The What & How

What is happening?

- Build on existing sources of data to describe engagement in PCORI projects more deeply, including how partnerships are initiated and fostered
- Further explore the influence and impact of engagement on research – what are we learning about it and what is happening *because of it*.

How is it happening & how is it influencing results?

- Explore how the influence is occurring, test associations between different types of engagement and specific impacts of engagement, better understand *how* people are making engagement happen.

Priority #3:

Translate & Share Findings with The Field

Translate & Share Findings with The Field

- Leverage accumulated knowledge & connect learnings across similar projects
- Innovate and evolve practice-based knowledge
- Interpret practice-based knowledge and speak to the field through webinars & tools like the Engagement Elements
- Translate patterns into recommendations and tools & guidance for individuals and groups
- Bring groups together to identify cross cutting resources
- Cultivate receptor sites in groups and organizations

Priority #4:

Promote Dissemination & Uptake

Promote Dissemination & Uptake

- Work with Dissemination & Implementation colleagues to support dissemination efforts and think about broader community-based participation and readiness for PCORI findings

- Leverage key stakeholders on projects to close the engagement lifecycle, transforming into receptor sites for PCOR/CER

Stay Tuned

Specific initiatives underway, or planned for launch in **FY2018:**

- ☐ Workshops to enhance topic refinement for potential funding announcements and one-on-one meetings with patient advocacy and physician organizations
- ☐ IDIQ projects to build on existing engagement data and resources to understand how engagement is happening, which tools and processes are working, and where potential receptor groups and sites exist
- ☐ Collaborative work towards developing an international set of standards for patient engagement in research
- ☐ Webinars and peer-to-peer learning to develop the practice-based evidence at the same time as we explore outcomes-based evidence
    - ☐ **PEAP subcommittee groups helping to support key initiatives to feed back into this process**

Questions and Discussion

Planning for the Future of Public and Patient Engagement –

Overview of Working Committees

- Ambassadors Program Redesign
- Enhancing the Merit Review Mentor Program
- Engagement Rubric 2.0

Advisory Panel on Patient Engagement
Fall 2017 Meeting
October 5, 2017

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Ambassador Redesign Working Committee

Sara van Geertruyden (Co-Chair)
Chinenye Anyanwu, PharmD, MPH (Co-Chair)

Committee Members:
Phil Posner
Ting Pun
Ronnie Todaro
Jack Westfall

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Purpose and Goals

- Issue:
  - When the PCORI Ambassador Program was launched, the primary focus of the initiative was to mobilize participants to share PCORI's vision, mission, and PCOR principles with their respective communities.
  - As PCORI moves into "PCORI 2.0", there is a growing need to shift the programmatic goals and re-evaluate the Ambassador program.

- Goals:
  - Re-design the PCORI Ambassador program to ensure better alignment with current PCORI priorities and Ambassadors' interests (PCORI staff)
    - Refocus the Ambassador program towards dissemination, translation, grassroots efforts, etc.
  - Inform the re-design of the PCORI Ambassador program by providing guidance as well as identifying necessary components of an efficient program (Working Committee members)

Goal, Deliverables and Key Activities

- Key Activities to date
  - First call August 23rd
  - Deployed Ambassador Program 2.0 Survey Oct 2nd

- Some specific deliverables
  - Ambassador program mission and vision statements
  - Revised program goals and objectives
  - Revised Ambassador training materials
  - Revised infrastructure (regional peer leadership boards/networks)
  - Communication mechanisms (e.g., newsletters, webinars, etc.)

- Term: 18 months (scheduled completion date, September 2018)
  - Using phase approach to implement tasks/activities

Enhancing the Merit Review Mentor Program

Whitney McInvale, MPH

Jane Perlmutter, PhD, MBA

Ronnie Todaro, MPH

Phil Posner, PhD

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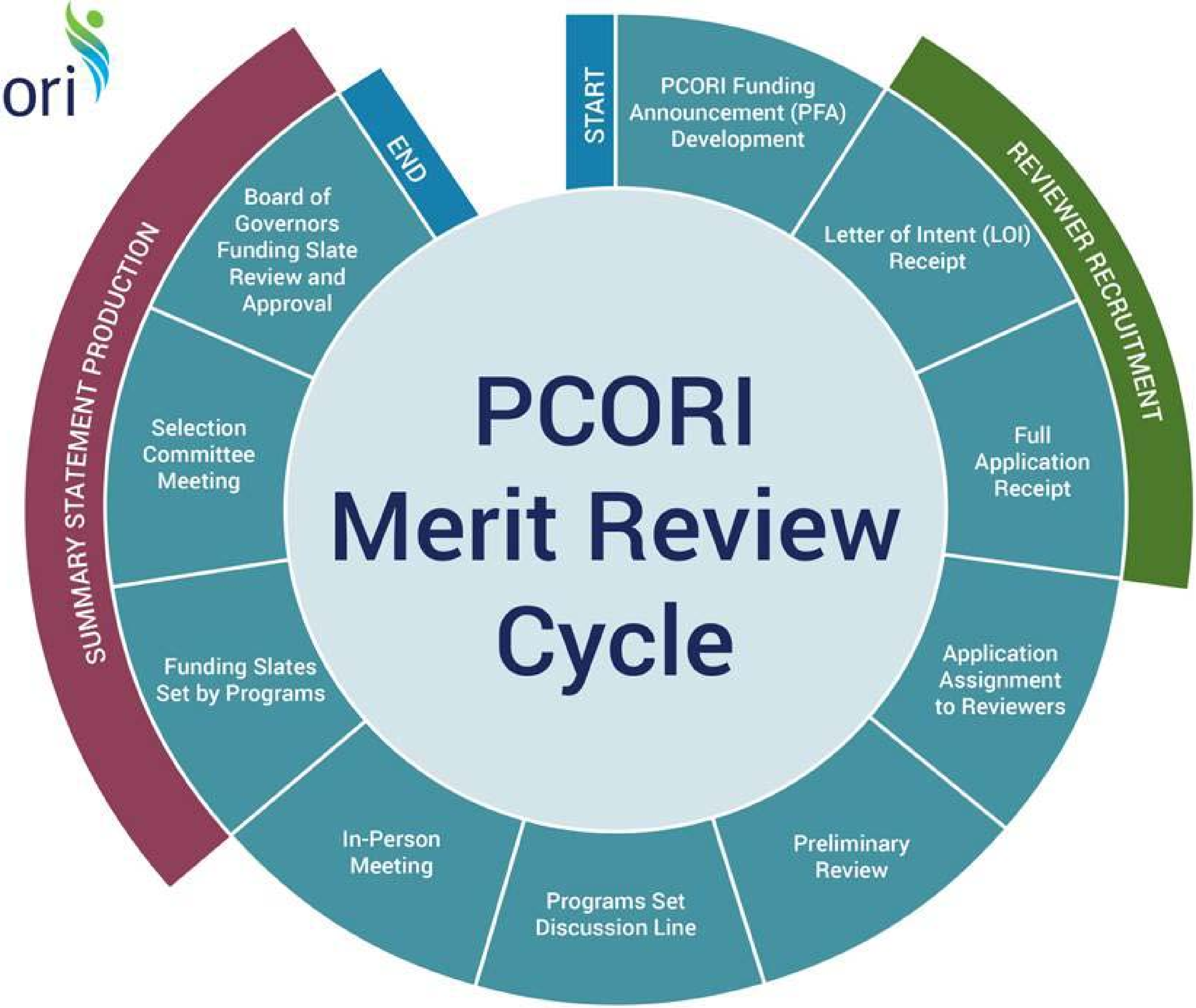

PCORI Merit Review Cycle

START

PCORI Funding Announcement (PFA) Development

Letter of Intent (LOI) Receipt

Full Application Receipt

Application Assignment to Reviewers

Preliminary Review

Programs Set Discussion Line

In-Person Meeting

Funding Slates Set by Programs

Selection Committee Meeting

Board of Governors Funding Slate Review and Approval

END

REVIEWER RECRUITMENT

SUMMARY STATEMENT PRODUCTION

Roles in the Merit Review Process

- Each panel involves preliminary review of full application by external patient, stakeholder, and scientist reviewers.
- Panel Composition consists of a PCORI Merit Review Officer, Panel Manager, Chair, reviewers, **Mentors**, and staff.
- Mentors are veteran reviewers who are charged with providing support and guidance to aid new reviewers in participating successfully throughout the cycle.

Purpose and Goals

- **Issue:**
  - The Merit Review Mentor Program has witnessed several changes in it's function to reviewers and is need of additional enhancements to ensure a sound and supported program.
- **Goals**
  - Help identify the necessary components of a successful Mentor Program
  - Provide guidance on a well-conceived program structure
  - Inform the development of Mentor training support
  - Identify effective evaluation methods of Mentor performance

Goal, Deliverables and Key Activities

- **Key Activities**
  - Bi-weekly meetings to ensure ideas and resources are shared
  - Collaboration with Merit Review to garner further context for program function and benefit to team members.
  - Informational session with current Mentors
- **Recommendations:**
  - Mentor Program Structure
  - Mentor training structure and support
  - Evaluation for Mentor Performance each Merit Review Cycle

Term: 5 Months – August 31, 2017 to January 1, 2018

Engagement Rubric 2.0 Working Committee

Co-chairs: Megan Lewis and Lisa Stewart

Members: Jack Chernesky, Mark Mishra, Jane Perlmutter, Ting Pun, Ronnie Todaro, Jack Westfall, Dave White

Term: September 2017 – March 2019

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Purpose and Goal

- Issue: PCORI’s Engagement Rubric was originally developed in 2013 with guidance provided by the Advisory Panel on Patient Engagement. Since its development the rubric has been an important reference for researchers and stakeholders, playing a role in the evolution of the field. With more engagement data now available, there is an opportunity and need to update the rubric so that it represents the most current practice-based knowledge available.

- Goal: To provide PCORI staff with recommendations that will inform Engagement Rubric 2.0, drawing from current data from PCORI’s portfolio and external sources.

PCORI's Engagement Rubric

Planning the study

POTENTIAL ACTIVITIES

- Developing research questions
- Selecting relevant outcomes
- Define study population characteristics

REAL-WORLD EXAMPLES

- Patient organization surveys members on treatment preferences
- Clinicians suggest a third arm to study based on variability in practice

Conducting the study

POTENTIAL ACTIVITIES

- Drafting or revising study materials
- Participating in study recruitment
- Participating in data analysis

REAL-WORLD EXAMPLES

- Patients develop informed consent to make it understandable to participants
- Patient representative serves on data safety monitoring board

Disseminating study results

POTENTIAL ACTIVITIES

- Identifying partners for dissemination
- Participating in dissemination efforts
- Presenting information about the study

REAL-WORLD EXAMPLES

- Research team holds stakeholder summit to speed implementation of findings
- Research team introduces study at a patient advocacy conference to inform community of the research

PCOR Principles

Reciprocal Relationships • Co-Learning • Partnerships • Transparency, Honesty, Trust

Reciprocal Relationships: Demonstrated when roles and decision-making authority of all research partners are defined collaboratively and clearly stated

Co-Learning: Researchers help patient partners better understand the research process, and researchers will learn about patient-centeredness and patient/stakeholder engagement

Partnerships: The time and contribution of patient and other stakeholder partnership is valued and demonstrated through compensation, cultural competency, and appropriate accomodations

Transparency, Honesty, Trust: Major decisions are made inclusively and information is shared readily among all research partners

Key Activities

- Prepare a summary document of the Engagement Rubric’s history, influence and critiques.
- Develop detailed project plan and timeline
- Early-stage identification and comparison of existing engagement frameworks (to be supplemented by Science of Engagement deliverables).
  - Review and assess existing frameworks
  - Compile citations list

Key Activities

- Review and assess literature and PCORI data
- Provide first-round recommendations, Engagement Rubric 2.0
- Gain input from stakeholder groups
  - Convene deliberations with internal and external stakeholders and incorporate feedback
- Submit final recommendations, including dissemination strategies

Resources

- Engagement Rubric

- Article: “The PCORI Engagement Rubric: Promising Practices for Partnering in Research,” Annals of Family Medicine, March/April 2017. (Susan Sheridan, Suzan Schrandt, Laura Forsythe, Advisory Panel on Patient Engagement, et al)

Questions?

Discussion & Wrap-up

Thank you
and
Safe Travels!

The Working Committees will meet from 3:30 – 5:00 PM