Board of Governors Meeting

In-Person and via Teleconference/Webinar

October 30, 2017

10:15 am - 5:30 pm ET

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the September 26, 2017 Board Meeting
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Agenda

Time	Agenda Item
10:15-10:30	Welcome, Call to Order and Roll Call **Consider for Approval:** Minutes of September 26, 2017 Board Meeting
10:30-11:15	Executive Director's Report and Q3 Dashboard Review
11:15-12:00	**Methodology Committee Update - Consider for Approval:** Release New Methodology Standards for Public Comment and Methodology Committee Efforts to Improve the Science and Methods of PCOR/CER
12:00-1:00	Break
1:00-1:30	The Honorable J. Phillip Gingrey, MD
1:30-1:45	**Consider for Approval:** Additional Application from the Cycle 3. 2016 Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain PFA
1:45-3:15	**PCORI at 7 Years:** Strategy Committee Reports
3:15-3:30	Break
3:30-5:00	**PCORI at 7 Years:** Moderated Board Discussion
5:00-5:30	Public Comment Period
5:30	Wrap-up and Adjourn Meeting of the Board

Executive Director's Update

Joe Selby, MD, MPH

Executive Director

Evolution of PCORI's Portfolio

$747 M

Broad – Established 2012

Investigator-initiated, **any topic** that could change practice
CER, **patient-centeredness** and engagement required
Up to $1.5 million, 3 years

$479 M

Targeted – Established 2013

Single, stakeholder-driven topic, narrow questions
CER, **patient-centeredness**, robust engagement expected
Much larger, variable funding amounts, 3-5 years

$332 M

Pragmatic – Established 2015

Stakeholder- or investigator-recommended topics
CER, **patient-centeredness**, robust engagement required
Up to $10 million direct costs, 5 years

$2 M

Dissemination & Implementation – Established 2016

Dissemination and Implementation Awards, Implementing **Shared Decision Making**

$2 M

Additional Research Initiatives– Established 2017

Evidence **Synthesis**, Individual Patient Data **Meta-analysis,** Predictive **Analytics**

*Dollars awarded as of October 1, 2017

PCORI in the Literature

This collection of papers, articles, and commentaries provides insights into PCORI-funded work to advance patient-centered comparative clinical effectiveness research.

PCORI Awardees' Peer-Reviewed Publication	Papers by PCORI Staff and Leadership	Other Papers on PCORI's Work
• 700 + Peer-reviewed publications • Selected open access full-text articles • Downloadable list of publications	• 100 + Papers • Chronological list of articles • Selected open access full-text articles	• 25 + Papers • Papers address PCORI's endeavors for patient-centered research • Array of facets related to PCORI's work

* All numbers as of October 1, 2017

PCORI in the Literature- Cont'd

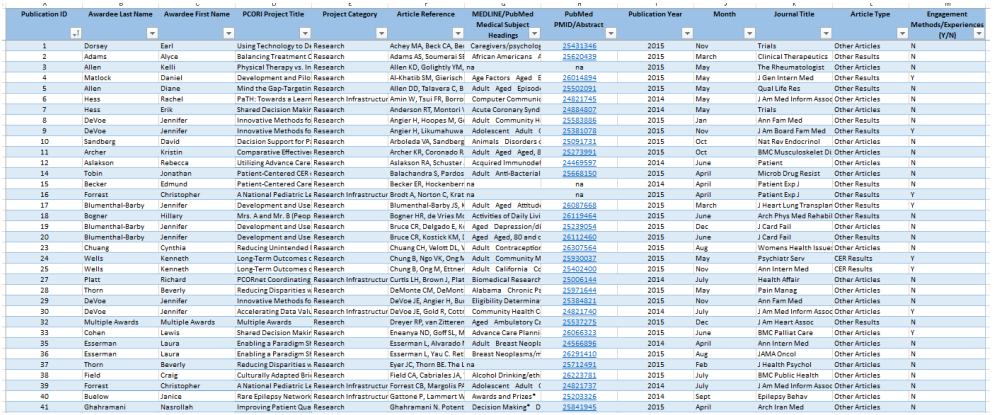
View All Literature

Papers from PCORI-Funded Studies	Papers by PCORI Staff and Leadership	Other Papers on PCORI's Work

PCORI Awardees' Peer-Reviewed Publications

View a list of peer-reviewed publications resulting from studies fully or partially funded by PCORI. These publications have been identified based on funding acknowledgements in the articles and/or reports from principal investigators.

View the List



Publication ID	Awardee Last Name	Awardee First Name	PCORI Project Title	Project Category	Article Reference	MEDLINE/PubMed Medical Subject Headings	PubMed PMID/Abstract	Publication Year	Month	Journal Title	Article Type	Engagement Methods/Experiences (Y/N)
1	Dorsey	Earl	Using Technology to De	Research	Achey MA, Beck CA, Ber	Caregivers/psycholog	25431346	2015	Nov	Trials	Other Articles	N
2	Adams	Alyce	Balancing Treatment C	Research	Adams AS, Soumerai SE	African Americans A	25620439	2015	March	Clinical Therapeutics	Other Results	N
3	Allen	Kelli	Physical Therapy vs. In	Research	Allen KD, Golightly YM,	na	na	2015	May	The Rheumatologist	Other Articles	N
4	Matlock	Daniel	Development and Pilo	Research	Al-Khatib SM, Gierisch	Age Factors Aged E	26014894	2015	May	J Gen Intern Med	Other Results	Y
5	Allen	Diane	Mind the Gap-Targetin	Research	Allen DD, Talavera C, B	Adult Aged Episodi	25502091	2015	May	Qual Life Res	Other Results	N
6	Hess	Rachel	PaTH: Towards a Learn	Research Infrastructur	Amin W, Tsui FR, Borro	Computer Communic	24821745	2014	May	J Am Med Inform Assoc	Other Articles	N
7	Hess	Erik	Shared Decision Makir	Research	Anderson RT, Montori V	Acute Coronary Syndr	24824907	2014	May	Trials	Other Articles	N
8	DeVoe	Jennifer	Innovative Methods fo	Research	Angier H, Hoopes M, Gi	Adult Community H	25583886	2015	Jan	Ann Fam Med	Other Results	N
9	DeVoe	Jennifer	Innovative Methods fo	Research	Angier H, Likumahuwa	Adolescent Adult (	25381078	2015	Nov	J Am Board Fam Med	Other Results	Y
10	Sandberg	David	Decision Support for Pi	Research	Arboleda VA, Sandberg	Animals Disorders (	25091731	2015	Oct	Nat Rev Endocrinol	Other Articles	N
11	Archer	Kristin	Comparative Effectiver	Research	Archer KR, Coronado R,	Adult Aged Aged, 8	25273891	2015	Oct	BMC Musculoskelet Di	Other Articles	N
12	Aslakson	Rebecca	Utilizing Advance Care	Research	Aslakson RA, Schuster	Acquired Immunodef	24469597	2014	June	Patient	Other Articles	N
14	Tobin	Jonathan	Patient-Centered CER	Research	Balachandra S, Pardos	Adult Anti-Bacterial	25668150	2015	April	Microb Drug Resist	Other Articles	N
15	Becker	Edmund	Patient-Centered Care	Research	Becker ER, Hockenberr	na	na	2014	April	Patient Exp J	Other Articles	N
16	Forrest	Christopher	A National Pediatric Le	Research Infrastructur	Brodt A, Norton C, Krat	na	na	2015	April	Patient Exp J	Other Results	Y
17	Blumenthal-Barby	Jennifer	Development and Use	Research	Blumenthal-Barby JS, K	Adult Aged Attitudi	26087468	2015	March	J Heart Lung Transplan	Other Results	Y
18	Bogner	Hillary	Mrs. A and Mr. B (Peop	Research	Bogner HR, de Vries Mc	Activities of Daily Livi	26119464	2015	June	Arch Phys Med Rehabil	Other Results	N
19	Blumenthal-Barby	Jennifer	Development and Use	Research	Bruce CR, Delgado E, Ki	Aged Depression/di	25239054	2015	Dec	J Card Fail	Other Articles	N
20	Blumenthal-Barby	Jennifer	Development and Use	Research	Bruce CR, Kostick KM, I	Aged Aged, 80 and c	26112460	2015	June	J Card Fail	Other Results	N
23	Chuang	Cynthia	Reducing Unintended I	Research	Chuang CH, Velott DL, V	Adult Contraceptior	26307564	2015	Aug	Womens Health Issue	Other Articles	N
24	Wells	Kenneth	Long-Term Outcomes c	Research	Chung B, Ngo VK, Ong N	Adult Community M	25930037	2015	May	Psychiatr Serv	CER Results	Y
25	Wells	Kenneth	Long-Term Outcomes c	Research	Chung B, Ong M, Ettner	Adult California Cc	25402400	2015	Nov	Ann Intern Med	CER Results	Y
27	Platt	Richard	PCORnet Coordinating	Research Infrastructur	Curtis LH, Brown J, Plat	Biomedical Research	25006144	2014	July	Health Affair	Other Articles	N
28	Thorn	Beverly	Reducing Disparities w	Research	DeMonte CM, DeMont	Alabama Chronic Pa	25971644	2015	May	Pain Manag	Other Articles	N
29	DeVoe	Jennifer	Innovative Methods fo	Research	DeVoe JE, Angier H, Bur	Eligibility Determina	25384821	2015	Nov	Ann Fam Med	Other Articles	N
30	DeVoe	Jennifer	Accelerating Data Valu	Research Infrastructur	DeVoe JE, Gold R, Cottr	Community Health C	24821740	2014	July	J Am Med Inform Assoc	Other Articles	Y
32	Multiple Awards	Multiple Awards	Multiple Awards	Research	Dreyer RP, van Zitteren	Aged Ambulatory Ca	25537275	2015	Dec	J Am Heart Assoc	Other Results	N
33	Cohan	Lewis	Shared Decision Makir	Research	Eneanya ND, Goff SL, M	Advance Care Planni	26066323	2015	June	BMC Palliat Care	Other Articles	Y
35	Esserman	Laura	Enabling a Paradigm Sh	Research	Esserman L, Alvarado F	Adult Breast Neopla	24566896	2014	April	Ann Intern Med	Other Articles	N
36	Esserman	Laura	Enabling a Paradigm Sh	Research	Esserman L, Yau C, Ret	Breast Neoplasms/m	26291410	2015	Aug	JAMA Oncol	Other Articles	N
37	Thorn	Beverly	Reducing Disparities w	Research	Eyer JC, Thorn BE, The L	na	25712491	2015	Feb	J Health Psychol	Other Articles	N
38	Field	Craig	Culturally Adapted Bri	Research	Field CA, Cabriales JA,	Alcohol Drinking/eth	26223781	2015	July	BMC Public Health	Other Articles	N
39	Forrest	Christopher	A National Pediatric Le	Research Infrastructur	Forrest CB, Margolis PA	Adolescent Adult (	24821737	2014	July	J Am Med Inform Assoc	Other Articles	N
40	Buelow	Janice	Rare Epilepsy Network	Research Infrastructur	Gattone P, Lammert M,	Awards and Prizes*	25203326	2014	Sept	Epilepsy Behav	Other Articles	N
41	Ghahramani	Nasrollah	Improving Patient Qua	Research	Ghahramani N. Potent	Decision Making* D	25841945	2015	April	Arch Iran Med	Other Articles	N

Searching the PCORI Project Portfolio

Explore Our Portfolio

(If you would like more detailed information about research projects PCORI has funded, please contact info@pcori.org)

Enter keyword(s) SEARCH PROJECTS

Displaying 1 - 10 of 543: Research Project Reset All Filters

Download these results | View a list of projects with results

RESEARCH PROJECT

A Pragmatic Trial of Home versus Office-Based Narrowband Ultraviolet B Phototherapy for the Treatment of Psoriasis

Joel Mitchell Gelfand, MD, MS | University of Pennsylvania

Refine Your Results

Project Type

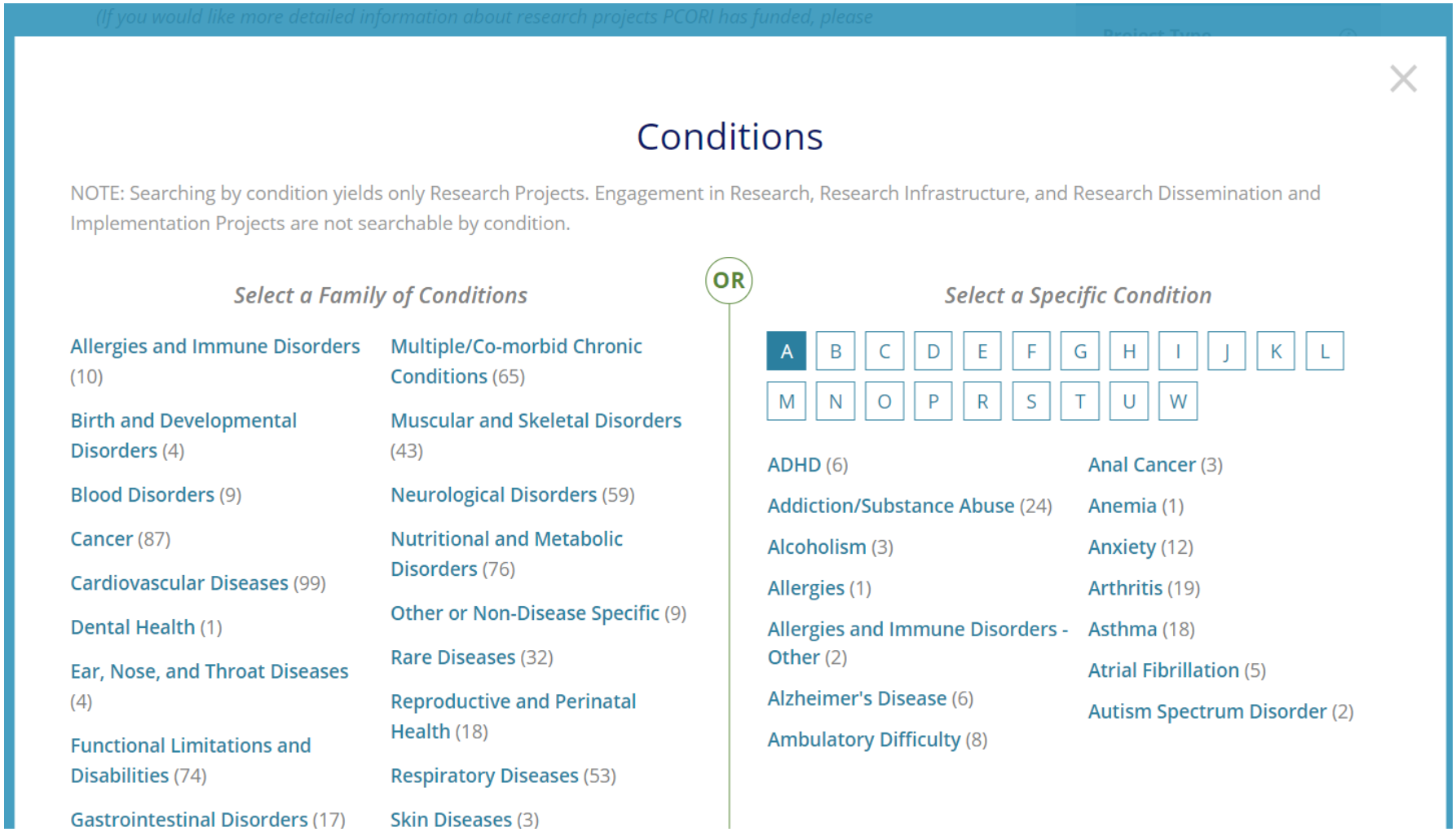
- All project types (1206)
- Engagement in Research Project (589)
- Research Project
- Research Infrastructure Project (66)
- Research Dissemination and Implementation Project (7)

Project Status

Conditions

PCORI Research Priority Area

Example of Available Filters



2017 Annual Meeting

Delivering Results, Informing Choices

Details

October 31 – November 2
Crystal Gateway Marriott
Arlington, VA

Agenda

Four **plenary** and eight **breakout sessions** featuring research results, **workshops**, **poster session**, and **networking** opportunities.

Special Sessions

Two sessions focusing on our portfolios of work include *Addressing the **Opioid** Crisis by Improving Pain Management* and *Rethinking **Multiple Sclerosis** Research- A Patient-Centered Approach*

Plenaries

Range of **patient-centered topics** such as producing more-relevant **evidence** for patients, promoting **shared decision making**, patient-centeredness in the **healthcare system**, and improving science **communication**.

Attendees

Approximately 1,000 members of the PCORI Community including researchers, patients, caregivers, clinicians, employers, insurers, life sciences professionals, staff & others.

Dashboard Review
Third Quarter of FY-2017

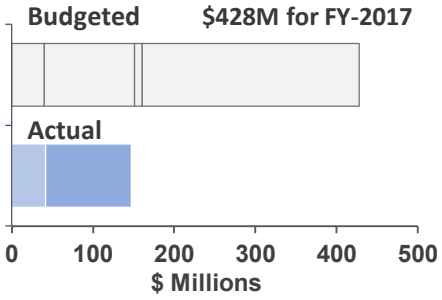
Joe Selby, MD, MPH
Executive Director

Board of Governors Dashboard
Third Quarter FY-2017 (As of 6/30/2017)

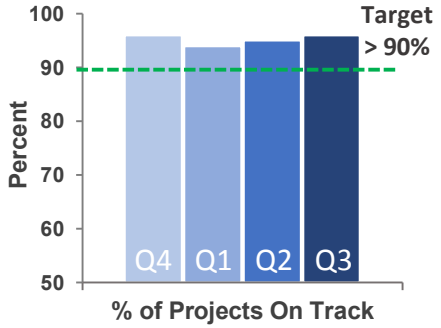
On Target
Off Target
Needs Board Attention
Too Early to Evaluate / No Target
Projected/Target
Q4 2016
Q1 2017
Q2 2017
Q3 2017

Funds Committed to Research

Includes funds committed to PCORnet

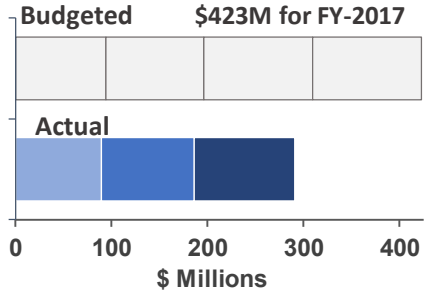


Project Performance

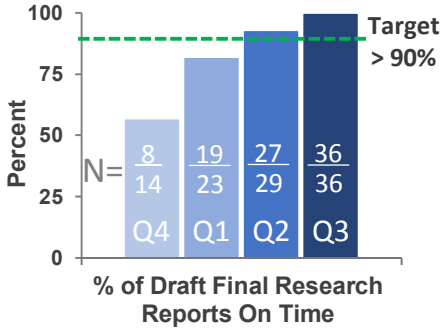


Budget

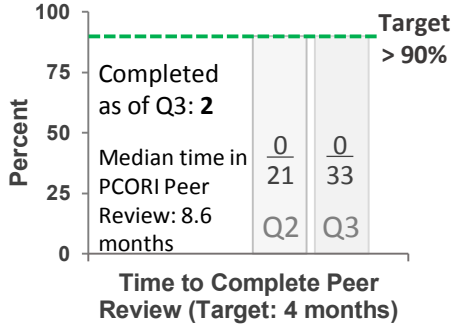
Operating Budget and Research Awards



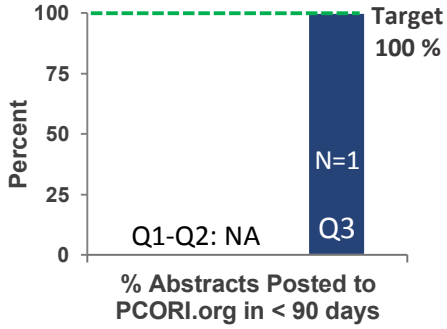
Draft Final Research Reports



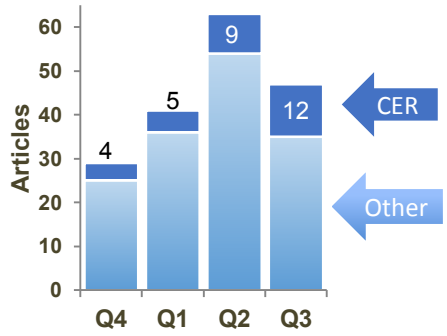
PCORI Peer Review



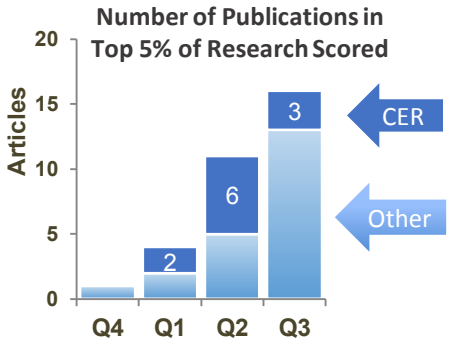
Public Reporting of Research Findings



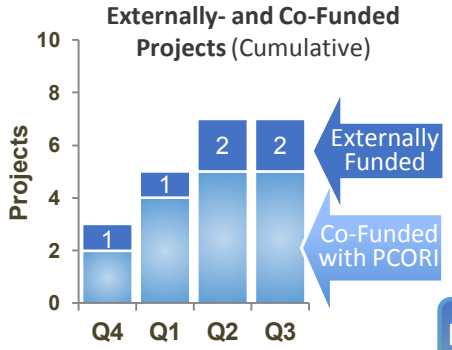
Results Published in Literature



Altmetrics



External Funding in PCORnet



Inputs
Process
Outputs
Uptake
Use
Impact

Narrative Examples

Goal 1: Increasing Information

A PCORI-funded study of people with non-insulin-dependent Type 2 diabetes found that daily blood glucose self-monitoring had no differences in disease control, hospitalization rates, need to start using insulin, or quality of life- results that augment findings of previous research.

Goal 2: Speeding Uptake

Three PCORI-funded results have been taken up into practice via UpToDate®, a point-of-care, evidence-based medical resource software used by clinicians globally, and nearly 90% of major academic medical centers in the US.

Goal 3: Influencing Research

PCORI is credited with inspiring the establishment of a Patient and Family Advisory Council for the Cancer Outcomes Research Program at Massachusetts General Hospital, in order to increase stakeholder involvement in cancer research efforts.

# PCORI Peer Review Process and Public Release of Findings
N=111 as of Q3-17

Studies in PCORI Peer Review Process or Completed PCORI Peer Review
N=111, as of Q3-17

As of today, **20** studies have completed PCORI Peer Review

We expect **62** studies to be completed by end of Q1-18 (Dec 31st)

*Does not include Pilots, Infrastructure, or D&I awards

Results of PCORI-Funded Research:

For many with Type 2 diabetes, daily finger stick offers little value

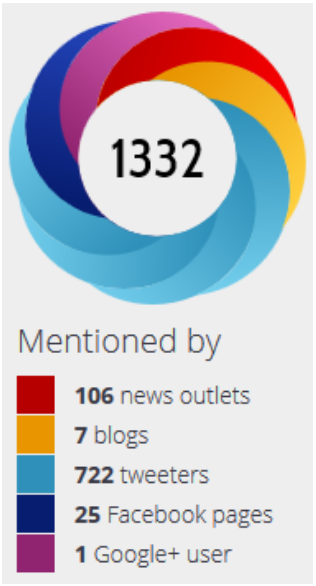
Young LA, Buse JB, Weaver MA, et al. **Glucose Self-monitoring in Non–Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings: A Randomized Trial.** *Jama Internal.* July 2017.

Study title: Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-Insulin Treated Diabetes

There has been debate about how much self-monitoring of blood glucose (SMBG) enhances the health of people with non-insulin-dependent Type 2 diabetes and whether the benefits exceed the inconvenience and discomfort of daily finger pricking, anxiety it can induce, and financial burdens related to out-of-pocket costs for the testing equipment.

This study compared 3 approaches of SMBG for effects on hemoglobin A1c levels and health-related quality of life at 1 year of follow-up. They found that ***self-monitoring achieves no significant differences in disease control, hospitalization rates, need to start using insulin, or quality of life***— results that augment findings of previous research.

- Principal Investigator: Katrina Donahue, MD, MPH, University of North Carolina Chapel Hill



> Our study results have the potential to transform current clinical practice for patients and their providers by placing a spotlight on the perennial question, 'to test or not to test?'
>
> *-Dr. Katrina Donahue, Study Investigator*

[Med.unc.edu Article]

Results of PCORI-Funded Research:
Substantial Media Attention

- Results from this study ***have appeared in at least 120 news stories*** from 106 news outlets, demonstrating broad interest

U.S.News & World Report Health

Can Folks With Type 2 Diabetes Forgo the Finger Stick?

June 12, 2017, at 7:00 a.m.

HealthDay

By Steven Reinberg
HealthDay Reporter

SATURDAY, June 10, 2017 (HealthDay News) -- People with type 2 diabetes who aren't taking insulin don't necessarily need to check their blood sugar levels, a new study contends.

Many of these patients use "finger prick" blood sugar monitors, but "testing blood sugar didn't have any impact on their blood sugar," said study author Dr. Laura Young, an assistant professor of medicine at the University of North Carolina.

(HEALTHDAY)

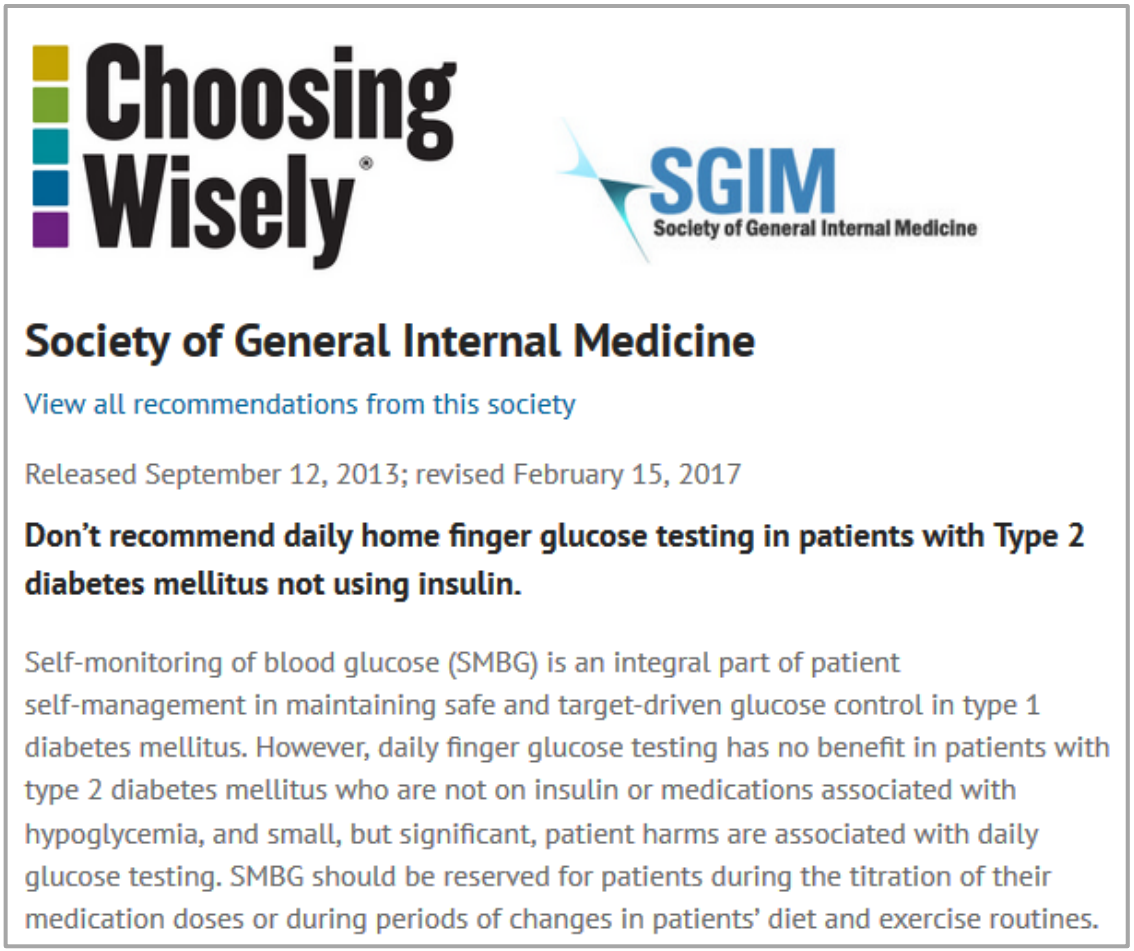
https://health.usnews.com/health-care/articles/2017-06-10/can-folks-with-type-2-diabetes-forgo-the-finger-stick

Results of PCORI-Funded Research:
Context of Results

The results of this study support the recommendations of *Choosing Wisely*: SGIM's top five tests and procedures that physicians and their patients should question.

Choosing Wisely is an initiative of the ABIM Foundation in partnership with Consumer Reports that seeks to advance a national dialogue ***on avoiding wasteful or unnecessary medical tests, treatments and procedures.***

http://www.choosingwisely.org/societies/society-of-general-internal-medicine/



Goal 2: Speed Uptake and Use of Information

Uptake of 3 Results from PCORI-Funded Studies in UpToDate®

3 results publications from PCORI-funded studies have been taken up in UpToDate®, a point-of-care, evidence-based medical resource software used by more than 1.3 million clinicians in 187 countries, including nearly 90% of major academic medical centers in the United States[1].

- Topic page titled: **Initial Approach to Low- and Very Low-Risk Clinically Localized Prostate Cancer**, updated Mar 29, 2017[2]
  - Barocas DA, et al. Association Between Radiation Therapy, Surgery, or Observation for Localized Prostate Cancer and Patient-Reported Outcomes After 3 Years. *JAMA*. March 2017.
    - **PI: David Penson, MD MPH, Vanderbilt University Medical Center**
  - Chen RC, et al. Association Between Choice of Radical Prostatectomy, External Beam Radiotherapy, Brachytherapy, or Active Surveillance and Patient-Reported Quality of Life Among Men With Localized ***Prostate Cancer.*** *JAMA*. March 2017
    - **PI: Ronald Chen, MD MPH, University of North Carolina Chapel Hill**
- Topic page titled: **Hematogenous Osteomyelitis in Children: Management**, updated Sep 20, 2017[3]
  - Keren R, et al. Comparative effectiveness of intravenous vs oral antibiotics for postdischarge treatment of ***acute osteomyelitis*** in children. JAMA Pediatr. February 2015.
    - **PI: Ron Keren, MD MPH, The Children's Hospital of Philadelphia**

[1]UpToDate. About Us. UpToDate®, Inc. 2017. https://www.uptodate.com/home/about-us
[2]Krogstad, P. Hematogenous osteomyelitis in children: Management. In: UpToDate®, Torchia, MM (ed), UpToDate®, Waltham, MA, 2017
[3]Klein EA, Ciezki, JP. Initial approach to low- and very low-risk clinically localized prostate cancer. In: UpToDate®, Ross, ME (ed), UpToDate®, Waltham, MA, 2017

Goal 2: Speed Uptake and Use of Information

New PCORI CME/CE Activities

PCORI launched two new Continuing Medical Education (CME/CE) programs in Sept and Oct 2017, and will show data on these programs beginning in the Q1-18 Dashboard

- **Contemporary Treatment Options for Prostate Cancer,** based on two PCORI funded studies with results
  - PI: David Penson, MD MPH, Vanderbilt University Medical Center
  - PI: Ronald Chen, MD MPH, University of North Carolina Chapel Hill)
- **Applying Evidence from the PCORI PROSPER Studies in Stroke Prevention and Care,** based on a PCORI-funded study with results
  - PI: Adrian Hernandez, MD MHS, Duke University
- Link to PCORI CME/CE Activities

Goal 3: Influencing Research Example:

Use of PCORI Stakeholder-Engaged Approach to Research

A PCORI-funded project (PI: Joseph Greer) influenced the establishment of a Patient and Family Advisory Council (PFAC) for the Cancer Outcomes Research Program at **Massachusetts General Hospital**.

PFAC Mission: To help advance the mission of cancer care anchored in patient perspective in a clinically meaningful way.

Goal: To heighten the community's understanding and appreciation of cancer research and increase stakeholder involvement in supportive care research efforts.

- Developed as a result of the patient/stakeholder engagement in the PCORI project
- Born out of the desire to have long-standing relationships with research partners beyond a given study
- Consists of 8 individuals representing the trajectory of cancer care which includes oncology, psychiatry, psychology, nursing and palliative care
- Geared toward local and national research relationship-building

> We were not historically always engaging stakeholders in such a direct way in all our previous clinical research experience until the PCORI award. Focus groups were standard, but the idea of **partnering with stakeholders as collaborators is a different way of working with stakeholders and PCORI forced us to get out of that old mode**…The PFAC members are adept at providing feedback on how to make the studies more patient-centered and effective.

– Joseph Greer, PhD

Program Director, Center for Psychiatric Oncology & Behavioral Sciences,
Associate Director,
Cancer Outcomes Research Program,
Massachusetts General Hospital Cancer Center

High Altmetric Scores

Publications from PCORI-Funded Studies, Q3-17

16 publications from Q3-17 have high Altmetric scores, and 7 of these publications (listed below) have very high Altmetric scores (>100). The score indicates attention in news articles (red), on social media (blues), and in blogs (gold).

Altmetric	Publication
	Young LA, et al. **Glucose Self-monitoring in Non-Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings: A Randomized Trial**. *JAMA Intern Med*. June 2017. **CER Results**
	Haider AH, et al. **Emergency Department Query for Patient-Centered Approaches to Sexual Orientation and Gender Identity : The EQUALITY Study**. *JAMA Intern Med.* April 2017. **Other Results**
	Blewer AL, et al. **Cardiopulmonary Resuscitation Training Disparities in the United States.** *J Am Heart Assoc.* May 2017. **Other Results**
	Tully KP, et al. **The fourth trimester: a critical transition period with unmet maternal health needs**. *Am J Obstet Gynecol.* April 2017. **Meeting Abstract**
	Taveras EM, et al. **Comparative Effectiveness of Clinical-Community Childhood Obesity Interventions: A Randomized Clinical Trial.** *JAMA Pediatr*. June 2017. **CER Results**
	Mayo-Wilson E, et al. **Multiple outcomes and analyses in clinical trials create challenges for interpretation and research synthesis.** *J Clin Epidemiol.* May 2017. **Other Results**
	Fisher D, et al. **Mental illness in bariatric surgery: A cohort study from the PORTAL network.** *Obesity (Silver Spring).* May 2017. **Other Results**

Q3-17 Focus on Study Recruitment

Two key questions about Recruitment:

1. What proportion and number of studies have successfully completed enrollment?
2. To what extent do studies need to modify project plans/milestones in order to complete recruitment?

Recruitment Benchmarks

Through literature searches and working with other funders, we identified ***points of reference for research projects:***

pcori

Results to date

Around 10% of research projects are **not successfully completed**

Less than **5%**

47% of studies meet agreed upon recruitment timeline[1,2,3]

69% (Some modified timelines)

Study timelines are typically **extended to nearly double** their original duration to meet desired recruitment levels[3]

Average Extension: 6.3 months

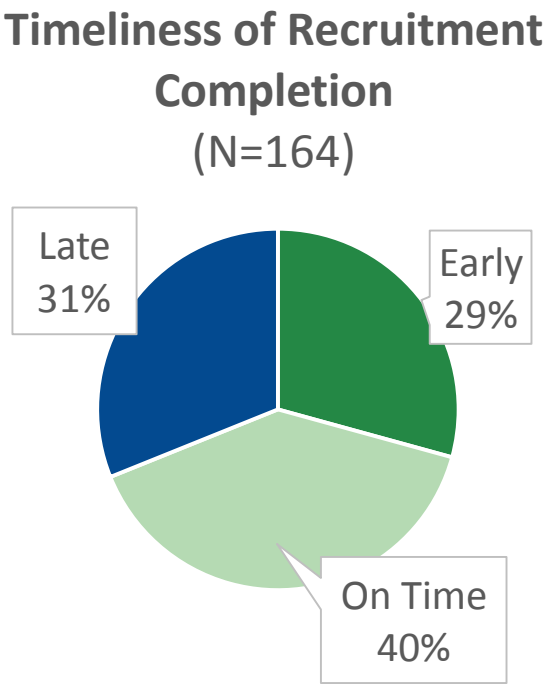
1. Mary Jo Lamberti et al. **Evaluating the Impact of Patient Recruitment and Retention Practices.** *Clinical Trials, 2012*
2. Kenneth Getz. **Enrollment Performance- Weighing the "Facts."** *Applied Clinical Trials,* 2012
3. Tufts Center for the Study of Drug Development. **89% of Trials Meet Enrollment, but Timelines Slip, Half of Sites Under-enroll.** *Tufts CSFDD Impact Reports.* January/February 2013, Vol. 15 No. 1.

Recruitment Status of PCORI Projects as of Q3-17

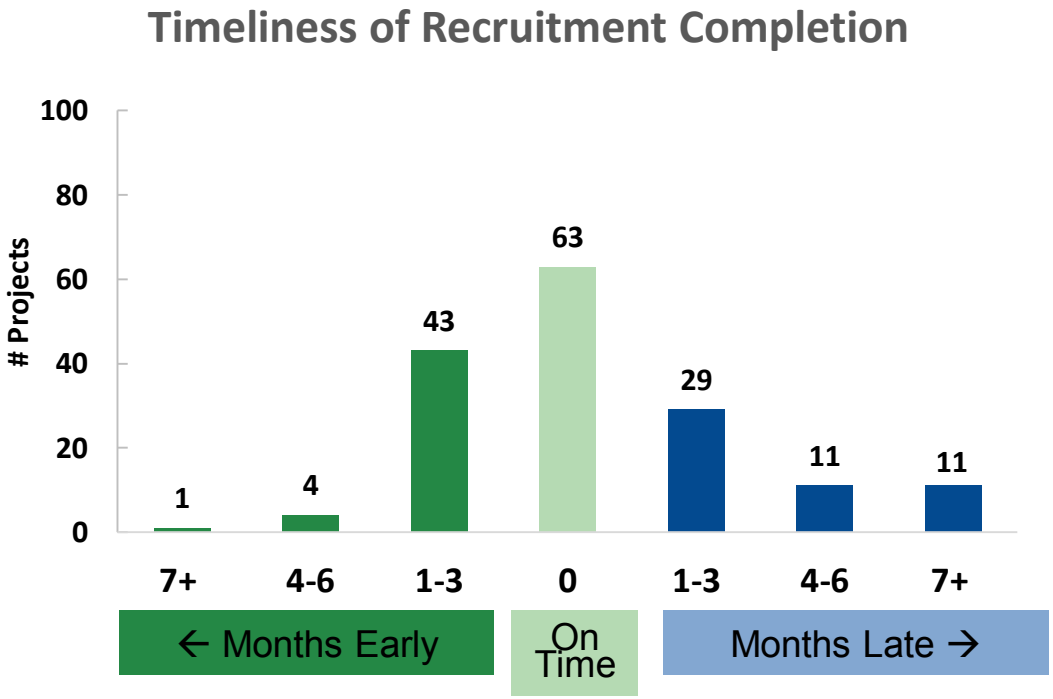
309 Projects: 85% Broad, 6% PCS, 9% Targeted

Did Projects Complete Recruitment on Time?

For projects that have completed recruitment (N=164)



69% Completed on time or early



Contract Modifications: Recruitment Timeline

To what extent do studies need to modify recruitment timeline to complete recruitment?

62/164 (38%) of studies that have completed recruitment have extended planned recruitment time by >1 month

- Median recruitment extension: 5.3 months (Average 6.3 m)
- 61% completed recruitment on time with new deadline
- 39% completed recruitment late, even with new deadline

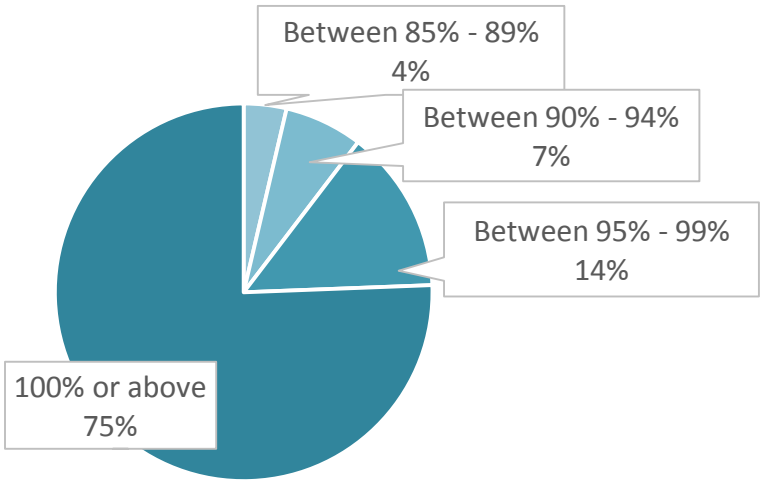
The average time to complete recruitment was 130% of the original planned recruitment timeline (median 109%)

Enrollment Targets

Among studies that have completed recruitment (N=164)

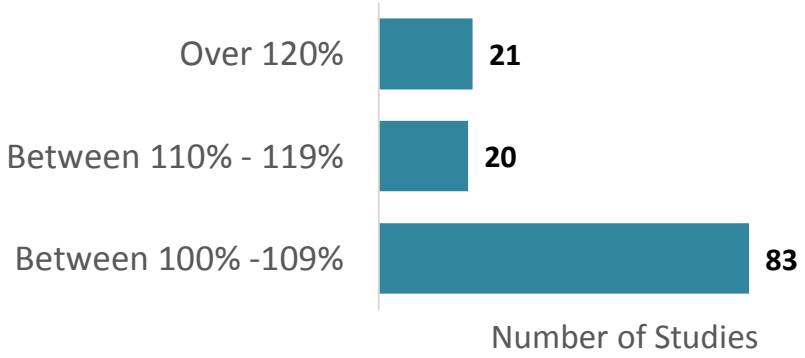
Proportion of Enrollment Target Achieved

N=164



Details on Enrollment of 100% of Target or Higher

Percent of Target Enrollment, N=124



96% achieved >90% of enrollment target

13% of PCORI studies that have completed recruitment achieved >120% of enrollment target

Modifications to Enrollment Target

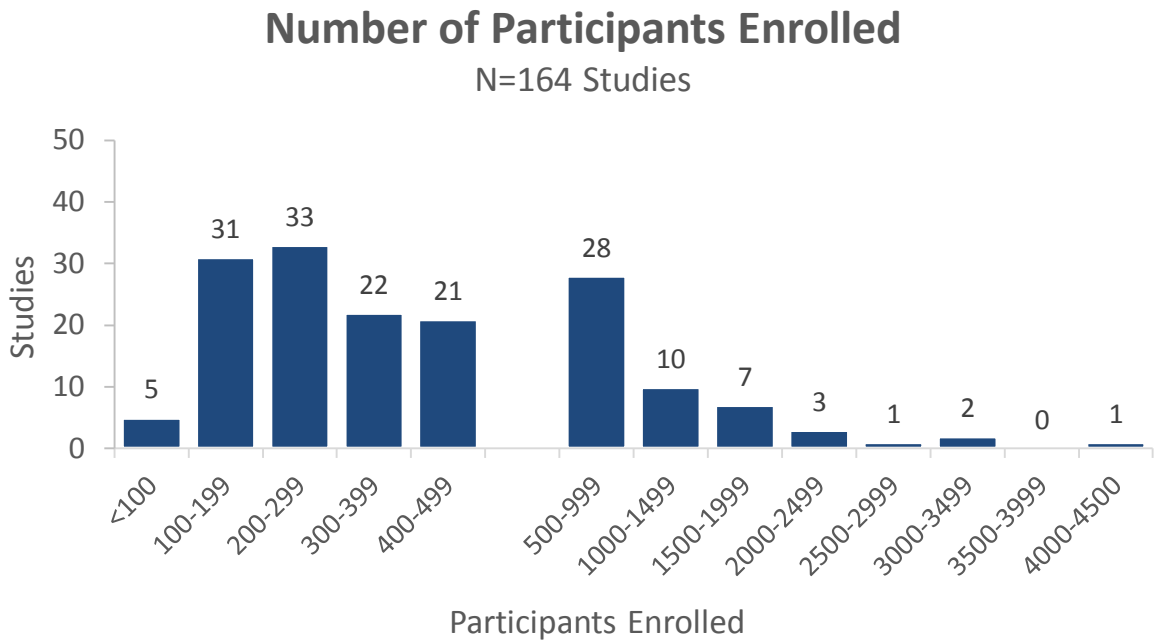
To what extent do studies need to modify enrollment targets to complete recruitment?

17/164 (10%) of studies that completed recruitment needed to decrease enrollment targets

- Median: 76% of original enrollment target (range 58%-90%)
- 15 of these studies (88%) achieved modified enrollment target, while 2 (12%) achieved <100% of new enrollment target, even with modification

Total Participants Enrolled

Among studies that have completed recruitment (N=164)



Median: 353 participants per study
Average: 577 participants per study

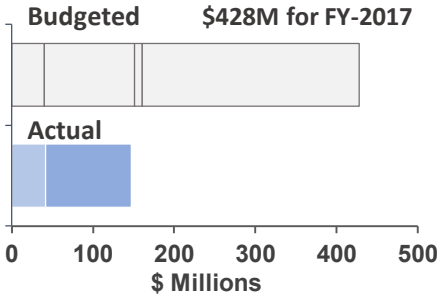
- 32% Enrolled more than 500 participants
- 15% Enrolled more than 1000 participants

Board of Governors Dashboard
Third Quarter FY-2017 (As of 6/30/2017)

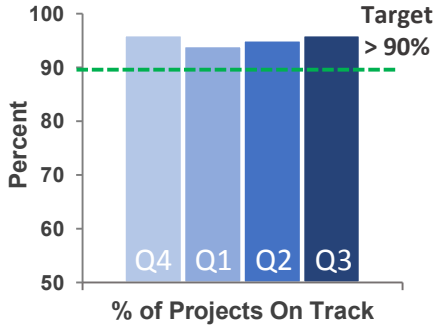
On Target
Off Target
Needs Board Attention
Too Early to Evaluate / No Target
Projected/Target
Q4 2016
Q1 2017
Q2 2017
Q3 2017

Funds Committed to Research

Includes funds committed to PCORnet

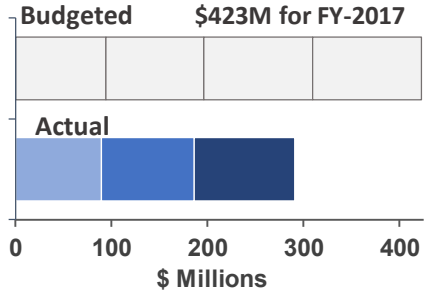


Project Performance

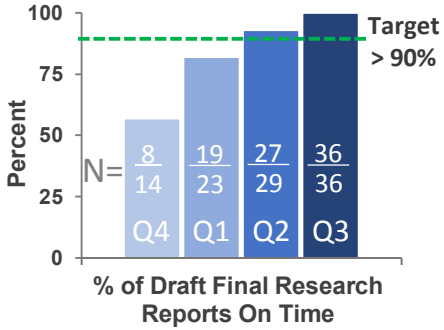


Budget

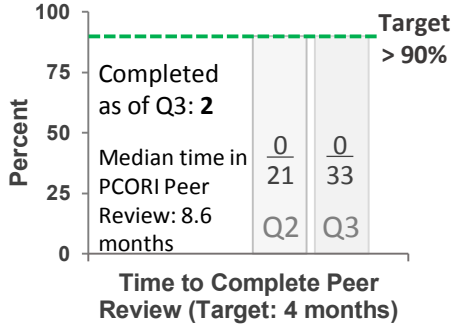
Operating Budget and Research Awards



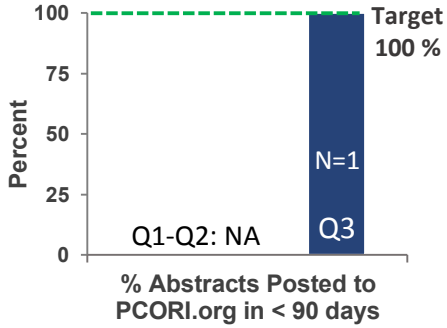
Draft Final Research Reports



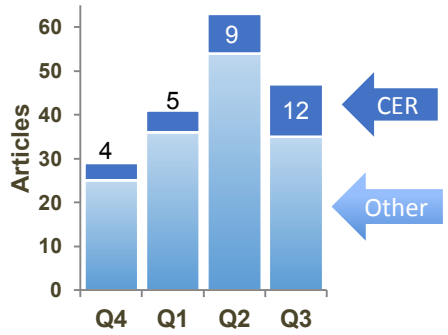
PCORI Peer Review



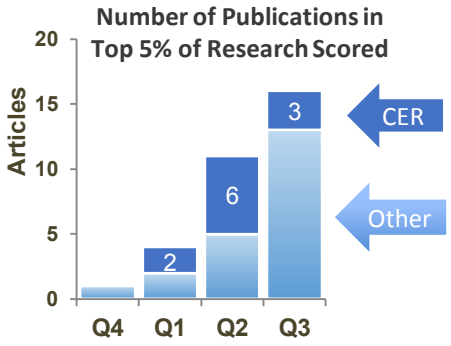
Public Reporting of Research Findings



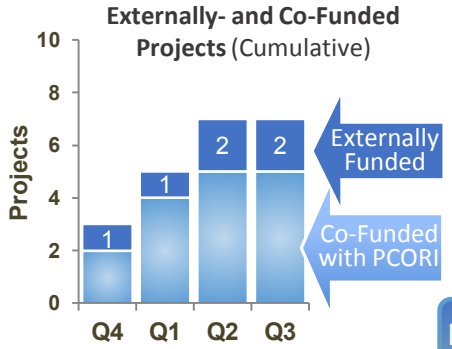
Results Published in Literature



Altmetrics



External Funding in PCORnet



Inputs
Process
Outputs
Uptake
Use
Impact

Narrative Examples

Goal 1: Increasing Information

A PCORI-funded study of people with non-insulin-dependent Type 2 diabetes found that daily blood glucose self-monitoring had no differences in disease control, hospitalization rates, need to start using insulin, or quality of life- results that augment findings of previous research.

Goal 2: Speeding Uptake

Three PCORI-funded results have been taken up into practice via UpToDate®, a point-of-care, evidence-based medical resource software used by clinicians globally, and nearly 90% of major academic medical centers in the US.

Goal 3: Influencing Research

PCORI is credited with inspiring the establishment of a Patient and Family Advisory Council for the Cancer Outcomes Research Program at Massachusetts General Hospital, in order to increase stakeholder involvement in cancer research efforts.

Methodology Committee Update: Proposed New Standards

Robin Newhouse, PhD, RN
Chair, PCORI Methodology Committee

Steve Goodman, MD, MHS, PhD
Vice Chair, PCORI Methodology Committee

PCORI Methodology Committee

Consistent with PCORI's authorizing law, the Methodology Committee works to develop and improve the science and methods of comparative clinical effectiveness research.

Methodology Committee Members:

- Robin Newhouse, Chair
- Steven Goodman, Vice Chair
- Naomi Aronson
- Ethan Basch
- Stephanie Chang
- David Flum
- Cindy Girman
- Mark Helfand
- Michael Lauer
- David Meltzer
- Brian Mittman
- Sally Morton
- Neil Powe
- Adam Wilcox
- Susan Zickmund (Advisor)

PCORI's Methodology Standards

- Required by PCORI's authorizing law
- Developed by the Methodology Committee and proposed to the Board for adoption after opportunity for public comment
- Represent minimal standards for design, conduct, and reporting of comparative effectiveness research (CER) and patient-centered outcomes research (PCOR)
- Provide guidance to researchers and those who use research results
- Reflect generally accepted best practices
- Used to assess the scientific rigor of funding applications and monitor conduct of research awards

Methodology Committee: Proposing Five New Standards

The Methodology Committee is proposing five new standards to be posted for public comment:

- Standards for Studies of Complex Interventions (new category, 4 standards)
- Standards for Data Integrity and Rigorous Analyses (1 additional standard)

The Methodology Committee takes a systematic approach to developing proposed new standards:

1. Workgroups (PCORI staff & Methodology Committee members) develop an early draft of standards, based on the scientific literature in this area
2. Proposed standards and revisions are shared with the Methodology Committee at biweekly meetings
3. External experts are asked to provide feedback on proposed standards, as needed
4. The Methodology Committee makes further revisions to the proposed standards before voting to propose them to the Board for approval for release for public comment

Proposed New Standards: Studies of Complex Interventions

Rationale:

- Additional guidance is needed to ensure the appropriate design, conduct, analysis, and reporting of studies of complex interventions, which are being studied with increased frequency in health services research

Titles of proposed new standards:

- **SCI-1:** Fully describe the intervention and comparator and define their core functions
- **SCI-2:** Specify the hypothesized causal pathways and their theoretical basis
- **SCI-3:** Specify how adaptations to the form of the intervention and comparator will be allowed and recorded
- **SCI-4:** Describe planned data collection and analysis

Proposed New Standard: Data Integrity & Rigorous Analyses

Rationale:

- Data management plans (DMPs) are critical to ensuring the scientific integrity of clinical research and facilitating data-sharing efforts

Titles of new standard:

- **IR-7:** In the study protocol, specify a data management plan that addresses, at a minimum, the following elements: collecting data, organizing data, managing data, describing data, preserving data, and sharing data

Next Steps

- Seek Board approval to release the 5 proposed new Methodology Standards for public comment
- If the Board approves, make proposed new Methodology Standards available on PCORI's website for public comment
- Read, process, and categorize public comments
- If indicated, revise the proposed new Methodology Standards based on public comments
- Methodology Committee develops revised Methodology Report based on proposed revisions and additions to the Methodology Standards
- Seek Board approval to adopt the revised proposed new Methodology Standards and accept the accompanying Methodology Report
- Expected timeline: November 2017 through May 2018

Board Vote

Call for a Motion to:	• **Approve** release for public comment of the proposed new Methodology Standards
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Methodology Committee Update: Efforts to Improve the Science and Methods of PCOR/CER

Robin Newhouse, PhD, RN
Chair, PCORI Methodology Committee

Steve Goodman, MD, MHS, PhD
Vice-Chair, PCORI Methodology Committee

PCORI's Methodology Committee

- Established by Congress in 2010 to develop and improve the science and methods of comparative clinical effectiveness research

- Provides guidance and recommendations to the Board of Governors and PCORI regarding methods for patient-centered outcomes research (PCOR), including:
  - Appropriate use of methods in PCOR
  - Methodological standards
  - Identifying and addressing gaps in research methods or their application

Highlighting the Methodology Committee's Work

- **Contributions to PCORI and the broader research community**
  - Formative work in defining PCOR and research priorities
  - Methodology Report & Methodology Standards

- **Current Activities**
  - Continued updating and development of guidance to the research community
    - Developing standards for data quality, individual participant data meta-analysis (IPD-MA), and qualitative and mixed methods

- **Future Initiatives**
  - Examining PCORI's portfolio to identify and leverage opportunities (and address challenges) for improving the quality of evidence generated by clinical research

Break

We will return at 1:00 pm ET

Join the conversation on Twitter via @PCORI

Guest Speaker

The Honorable J. Phillip Gingrey, MD

Senior Advisor, District Policy Group
DrinkerBiddle

US Representative (GA-11, 2003-2015)

Additional Proposed Study

Cycle 3 2016 Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain Award Slate

Christine Goertz, DC, PhD
Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain

Cycle 3 2016 Funding Slate – 1 Additional Project

Project
Comparative Effectiveness of Pain-Cognitive Behavioral Therapy and Chronic Pain Self-Management within the Context of Opioid Reduction
Integrated Health Services to Reduce Opioid Use while Managing Chronic Pain

Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain

Slate Overview

Approved
1
Project

Proposed
1 + 1 = 2
Projects

Cycle 3 2016 Posted Amount	Previously Approved Award	Proposed Total Award*
$19 M	$8.8 M	$17.8 M

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Additional Project: Integrated Health Services to Reduce Opioid Use while Managing Chronic Pain

- **Research Question:** In clinics where providers receive a 4 hour training on the revised CDC guidelines, what is the comparative effectiveness of Shared Decision Making (SDM) versus Cognitive Behavioral Therapy for chronic pain (CBT) and Motivational Interviewing (MI) for patients on chronic opioid therapy?
- **Population:** Patients aged 18 or older using opioids to treat chronic pain (≥50 mg daily MED for 90 or more days) using ≥6 prescriptions in a 12-month period
- **Comparators:**
  - CBT-MI + 4 hour training on the CDC guidelines
  - SDM + 4 hour training on the CDC guidelines

  Outcomes of Interest:
  - *Primary:* opioid dose reduction
  - *Secondary:* physical functioning, pain interference, self-reported pain status, generalized anxiety disorder, depression, self-efficacy to manage pain, satisfaction with pain care
- **Study Design:** Randomized Controlled Trial
  - Sample Size: 1060
- **Length of Follow-up:** 12 months
- **Duration of Active Intervention:** Intervention: 2 sessions of MI, and 8 sessions of CBT-CP for Comparator Arm: up to 12 sessions of SDM
- **Total Project Cost:** $9M

Additional Project: Integrated Health Services to Reduce Opioid Use while Managing Chronic Pain

- **Potential Impact:** Study has the capacity to facilitate opioid reduction in patients who are not receiving benefits from the opioids and/or who are interested in dose reduction. Additionally, the study may provide valuable insight regarding implementing the CDC guidelines in real world settings
- **Patient-Centeredness:** Reviewers noted that the intervention and outcomes are patient-centered
- **Engagement:** Study Advisory Committee includes patients, advocacy organizations, experts in the field of pain management, state health departments, and insurers. To date, key stakeholders have contributed to decisions about the study design, intervention and outcomes
- **Implementation/Dissemination or Evaluation Plan:** Study results will be disseminated through peer-reviewed publications, conference presentations, training materials at participating institutions, and fact sheets

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended additional award from the Cycle 3 2016 Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Goal 1: Increasing Information Science Oversight Committee Report to the Board

Robert Zwolak, MD, PhD
Chair, Science Oversight Committee

Alicia Fernandez, MD
Vice Chair, Science Oversight Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer

Science Oversight Committee Members

- Robert Zwolak (Chair)
- Alicia Fernandez (Vice Chair)
- Leah Hole-Marshall
- Russell Howerton
- Gail Hunt
- Richard E. Kuntz
- Barbara McNeil
- Ellen Sigal
- Michael S. Lauer

PCORI's Strategic Imperatives: Research Priorities

1

Develop and fund a research agenda with a high potential for impact

2

Manage research portfolio carefully to maximize success

3

Partner with other funders to foster patient-centeredness in research

1

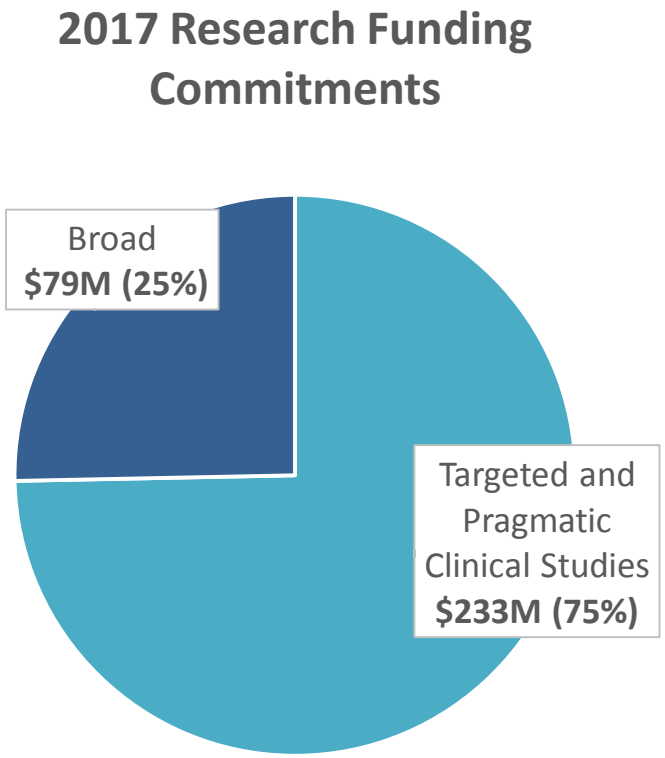
Develop and fund a research agenda with a high potential for impact

Overview – State of our Research Enterprise in 2017

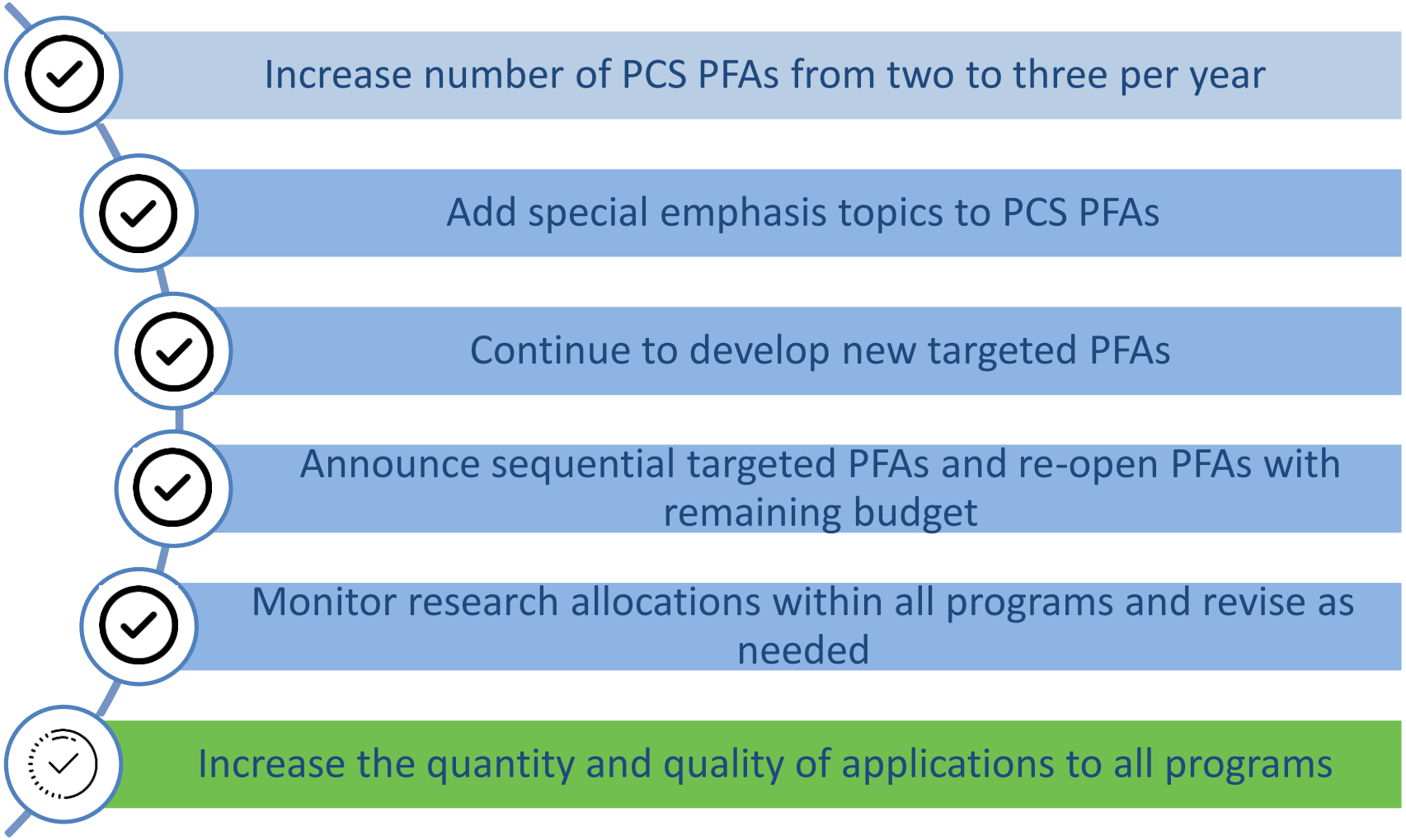
- PCORI maintains broad and targeted work to address its 5 national priorities
- Focused funding opportunities are a growing investment for critical clinical topics
- Research synthesis activities are aimed at supporting personalized decisions, producing rapid, actionable results, and communicating our current portfolio
- PCORI continues to develop its portfolio by seeking out new research areas from stakeholders and working internally to identify evidence gaps within topics of interest to patients
- We are critiquing and contextualizing results from early awards, including targeted PFAs, as these become available
- PCORI continues to refine and improve its pre-award and post-award processes through close and constructive collaboration between the SOC and Science Staff

Cumulative Process: PCORI's Research Funding Programs

- Progress made in eliciting and awarding **focused funding opportunities**
  - In 2014, **23%** of funding was targeted/pragmatic clinical studies
  - By 2016, **65%** of funding was targeted/pragmatic clinical studies
  - → In 2017: **75%** of funding was targeted/pragmatic clinical studies
  - Continuing quest for high priority topics and versatile focused funding opportunities



Multi-Pronged Approach to Improving PCORI's Research Productivity - 2017



Areas of Portfolio Focus

Our website highlights PCORI Research Areas

www.pcori.org/research-results/research-topics

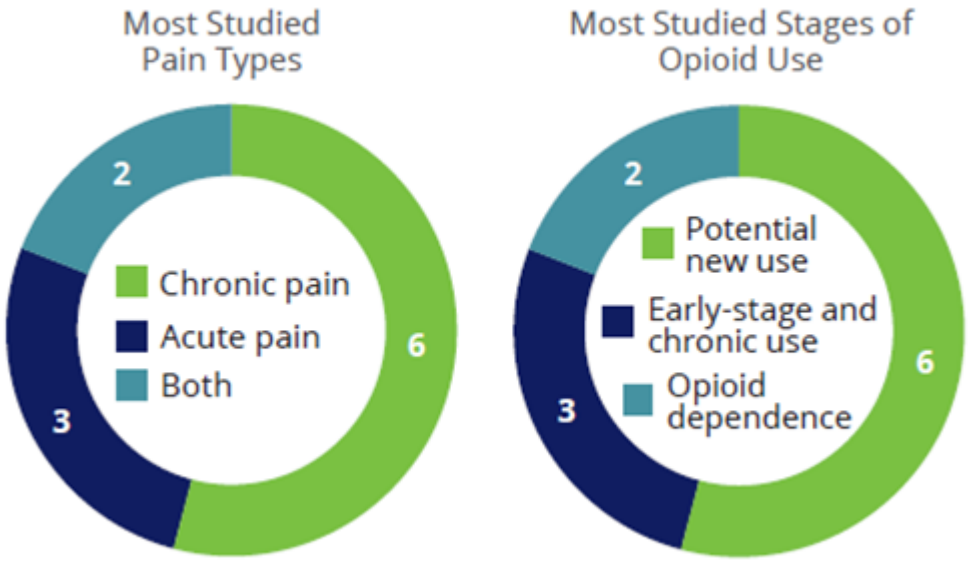
High Priority Topic: PCORI Responds to the Opioid Crisis

As of September 2017, PCORI has awarded

$62 MILLION TO FUND 11

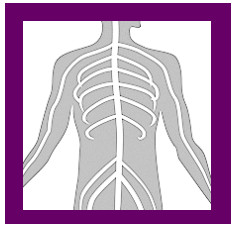
CER studies related to opioid use. These projects will involve

≈11,000 STUDY PARTICIPANTS.



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

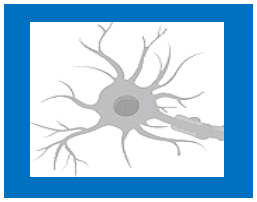
New funding opportunity on **medication-assisted treatment delivery for pregnant women with substance use disorders** released in July 2017.



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 Invited to Apply $25M	Comparing the effectiveness of different approaches to symptom management, including pharmacological interventions, for patients of any age living with any advanced illness.

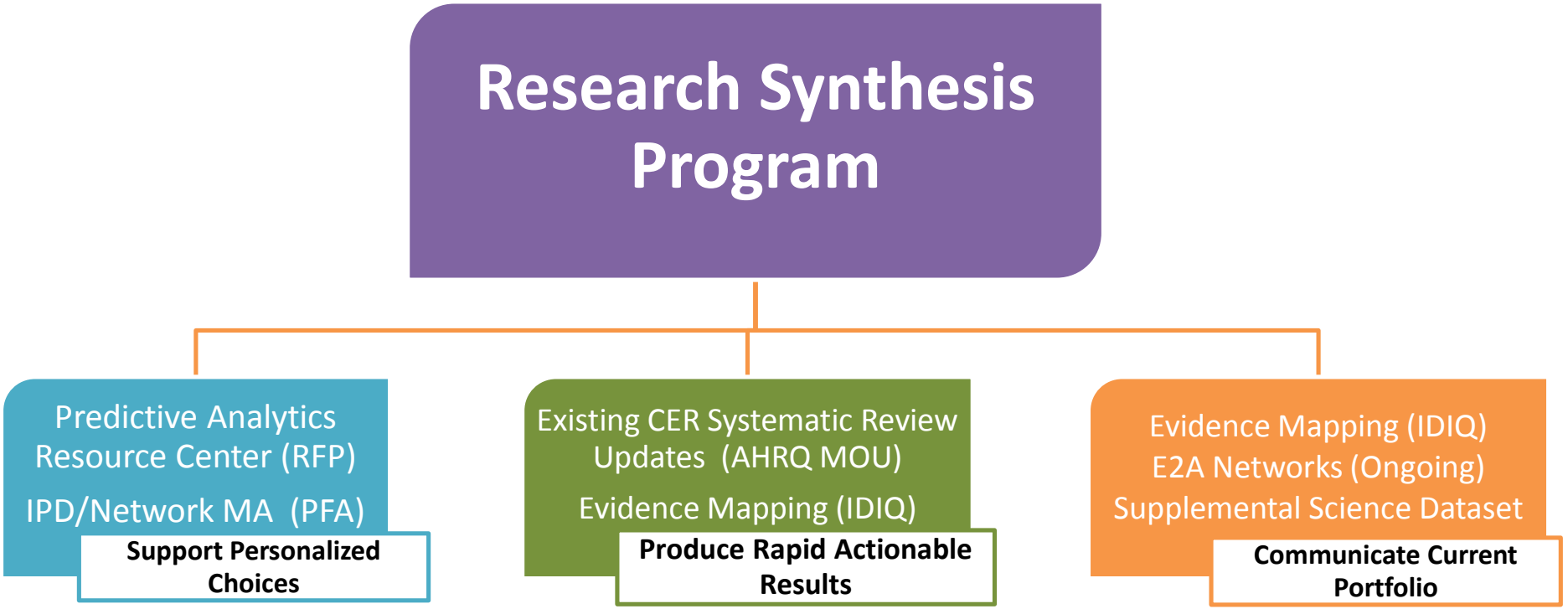


Cumulative Investments: Multiple Sclerosis

- **$ 65.5 million** to fund **12 studies**, including 9 studies funded by Targeted PFAs in 2015 and 2016
- The investigators will work to harmonize studies to increase comparability and impact of results
- The studies will address the questions identified by stakeholders, including the following:

5 Studies $39.1 M	Comparing the effectiveness of various disease modifying therapies or therapeutic strategies, including discontinuation of therapy.
3 Studies $17.7 M	Comparing the effectiveness of telerehabilitation vs. conventional direct care interventions for improving outcomes such as functional status and quality of life.
4 Studies $ 8.6 M	Comparing the effectiveness of interventions to reduce symptoms of MS, such as fatigue, a very prominent symptom among patients with MS.

Research Synthesis Program Launch: 2016-2017



Research Synthesis Outputs

Initiative	Expected Date of Completion
4 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 Funded Award: *Evaluating Progesterone in Preventing Pre-term Birth*	March 2018
Predictive Analytics (2 funded projects) *Predicting Cardiotoxicity Among Patients Receiving Anthracycline Chemotherapy* *Preventing Stroke Recurrence (IRIS)*	December 2017 Sept 2017, April 2018
Portfolio Mapping & Communication *Transitional Care & Asthma Evidence-To-Action Networks* *Evidence Maps (Ductal carcinoma in situ, Fatigue in Multiple Sclerosis, and Relapsing-remitting Multiple Sclerosis)* *Portfolio Visualizations (e.g. Opioids)*	Ongoing

PCORI's IPD-MA Initiative

Stewart L, Llewellyn A, Simmonds M, et al. **Evaluating Progestogens for the Prevention of Preterm Birth International Collaborative (EPPPIC) – Individual Participant Data (IPD) Meta-Analysis.** PROSPERO 2017.

Review
Evaluat
treatm

Evaluat
(co-trea

Title: **The BMJ Awards 2017: UK Research Paper**

"Nigel Hawkes describ
shortlisted for this yea
potential to change cli
and beyond."

Hawkes Nigel. The BMJ A
Paper. *BMJ* 2017. 357 :j18

"There's been a huge amount of interest in the paper. The US Patient-Centered Outcomes Research Institute (PCORI) has launched an independent, patient level

PLOS | MEDICINE

PERSPECTIVE

Preterm birth prevention—Time to PROGRESS beyond progesterone

Jane E. Norman[1]*, Phillip Bennett[2]

1 MRC Centre for Reproductive Health, University of Edinburgh, Edinburgh, United Kingdom, 2 Institute for Reproductive and Developmental Biology, Imperial College London, London, United Kingdom

* jane.norman@ed.ac.uk

Check for updates

OPEN ACCESS

Citation: Norman JE, Bennett P (2017) Preterm birth prevention—Time to PROGRESS beyond progesterone. PLoS Med 14(9): e1002391. https://doi.org/10.1371/journal.pmed.1002391

Published: September 26, 2017

In this week's *PLOS Medicine*, Crowther and colleagues publish the results of the PROGRESS Study, which examined the effect of maternal vaginal progesterone on the risk of respiratory distress syndrome in the baby [1]. Women at high risk of preterm birth because of a previous spontaneous preterm birth were recruited to this study, which involved self-administering 100 mg progesterone or a placebo vaginally from 20 to 34 weeks of pregnancy. No differences were found in the rate of the primary outcome (incidence of respiratory distress syndrome and severity of respiratory disease) between the progesterone and the placebo groups (incidence of respiratory distress syndrome in 42/402 [10.5%] and 41/388 [10.6%], respectively [RR 0.98, 95% CI 0.64–1.49]), nor were there differences in any of the other secondary outcomes. The study, a double-masked randomised placebo-controlled trial, was well conducted. About 40% of women who were approached agreed to participate. The primary outcome was available for all participating women, and around 65% of women were still taking study treatment by 34 weeks gestation. Rates of preterm birth were 36% and 17% before 37 and 34 weeks, respectively; hence, the recruitment strategy effectively identified a group at high risk. Although the study was terminated earlier than planned (after recruitment of 787 women rather than the

1st Paper from PCORI-Funded Insulin Resistance Intervention after Stroke (IRIS) Re-Analysis

Kernan WN, Viscoli CM, Dearborn JL, et al. **Targeting Pioglitazone Hydrochloride Therapy After Stroke or Transient Ischemic Attack According to Pretreatment Risk for Stroke or Myocardial Infarction.** *JAMA Neurology.* September 2017.

Importance: There is growing recognition that patients may respond differently to therapy and that the average treatment effect from a clinical trial may not apply equally to all candidates for a therapy.

Objective: To determine whether, among patients with an ischemic stroke or transient ischemic attack and insulin resistance, those at higher risk for future stroke or myocardial infarction (MI) derive more benefit from the insulin-sensitizing drug pioglitazone hydrochloride compared with patients at lower risk.

Conclusion: After an ischemic stroke or transient ischemic attack, patients at higher risk for stroke or MI derive a greater absolute benefit from pioglitazone compared with patients at lower risk. However, the risk for fracture is also higher.

Areas of Continued Focused Topic Development: 2017-2019

- Anxiety in Youth
- Improving Birth Outcomes
- Atrial Fibrillation
- Type 2 Diabetes Treatments
- Updates to the PCS Priority Topic List, including Special Areas of Emphasis
- Program/Advisory Panel Priorities
- Just-in-time opportunities (FDA, NHLBI, others)
- In-fill opportunities based on portfolio assessments
- Targeted PFA Re-postings, including Opioids

2

Manage research portfolio carefully to maximize success

Supporting Success: Process Improvements & Monitoring

- **Applications**
  - Integrated, shortened templates for letters of intent (LOIs) and research plan applications
  - Evaluating impact on researchers
- **Merit Review**
  - Revised merit review criteria and expanded merit review panels
  - Incorporated sufficient advanced communication with potential applicants into process
- **Project Monitoring**
  - Increased attention to recruitment and retention, known challenges for clinical research
  - Consistent and timely earlier attention given to troubled projects
  - Enhanced support for project monitoring
  - Portfolio Management

Actively Monitoring Projects: Supporting Success & Classifying Progress

GREEN	YELLOW	ORANGE	RED
The Project is meeting >85% of milestones on time **-AND-** **Recruitment occurring on schedule, at expected rate** ***-AND-*** PO judges that the project has a high probability of meeting its objectives as planned. PO judgment is based on close review of study progress, including recruitment status.	**Project does not meet all criteria for "Green"** ***-AND-*** **Project is meeting ≥65% of milestones on time.** ***-OR-*** **Recruitment is ≤75% and >50% of target accrual** ***-OR-*** PO has concerns that without remediation efforts the project will not be able to meet objectives within project period.	**Project does not meet all criteria for "Yellow"** ***-AND-*** **Project is meeting ≥50% of milestones on time.** ***-OR-*** **Recruitment is ≤50% of target accrual** ***-OR-*** PO has concerns that the project will not meet objectives within the approved project period. Modifications to the Milestone Schedule and/or project plan are likely required.	**Project does not meet all criteria for "Orange"** ***-AND-*** **Project is meeting <50% of milestones on time.** ***-OR-*** **Recruitment is persistently and significantly ≤50% of target** ***-OR-*** PO has significant concerns that the project cannot meet its original objectives. Major modifications to Milestone Schedule are required for the project to be completed.
Next Steps			
Continue monitoring project through active portfolio management and per SOPs.	**Increased communication** with the PI to monitor and assist with getting the project back on track	**Placed Under Review** at PCORI to determine if it is able to meet its original project plan. **Pursue modifications** to project plan or milestone schedule as appropriate.	**Project Remediation Plan** (PRP) memo sent to PI with a 30-day completion date deadline. **Inform Leadership of Status**

Peer Review is Up and Rolling

- To date, over **140** draft final research reports (DFRRs) have been submitted
- Adjustments have been made to the Peer Review process to: **maintain high quality reports** but reduce the number of revisions to the DFRR a PI must complete, as well as the overall length of time in Peer Review
- Work in Peer Review is **integrated with Scientific close-out**, including qualification of results for communication, and with initiatives for Dissemination and Implementation (D&I)

A Snapshot of DFRRs and Final Reports Currently in the Pipeline

DFRR in Pre-review	DFRR in Peer Review	DFRR Completed Peer Review	Final Report Approved	Report Summaries Posted	Final Research Report Posted
17	91	17	14	4	0

3

Partner with other funders to foster patient-centeredness in research

Developing Innovative Practices in Research

Collaborative work in patient preferences

(FDA)

Determining areas of important focus for potential predictive analytics work

(FDA)

International consortium to reduce research waste and ensure value

(Funders' Forum)

Co-sponsoring stakeholder meetings to address the role of core outcome measures in health care delivery, research, and regulatory affairs

(ICHOM, Pacific Business Group on Health)

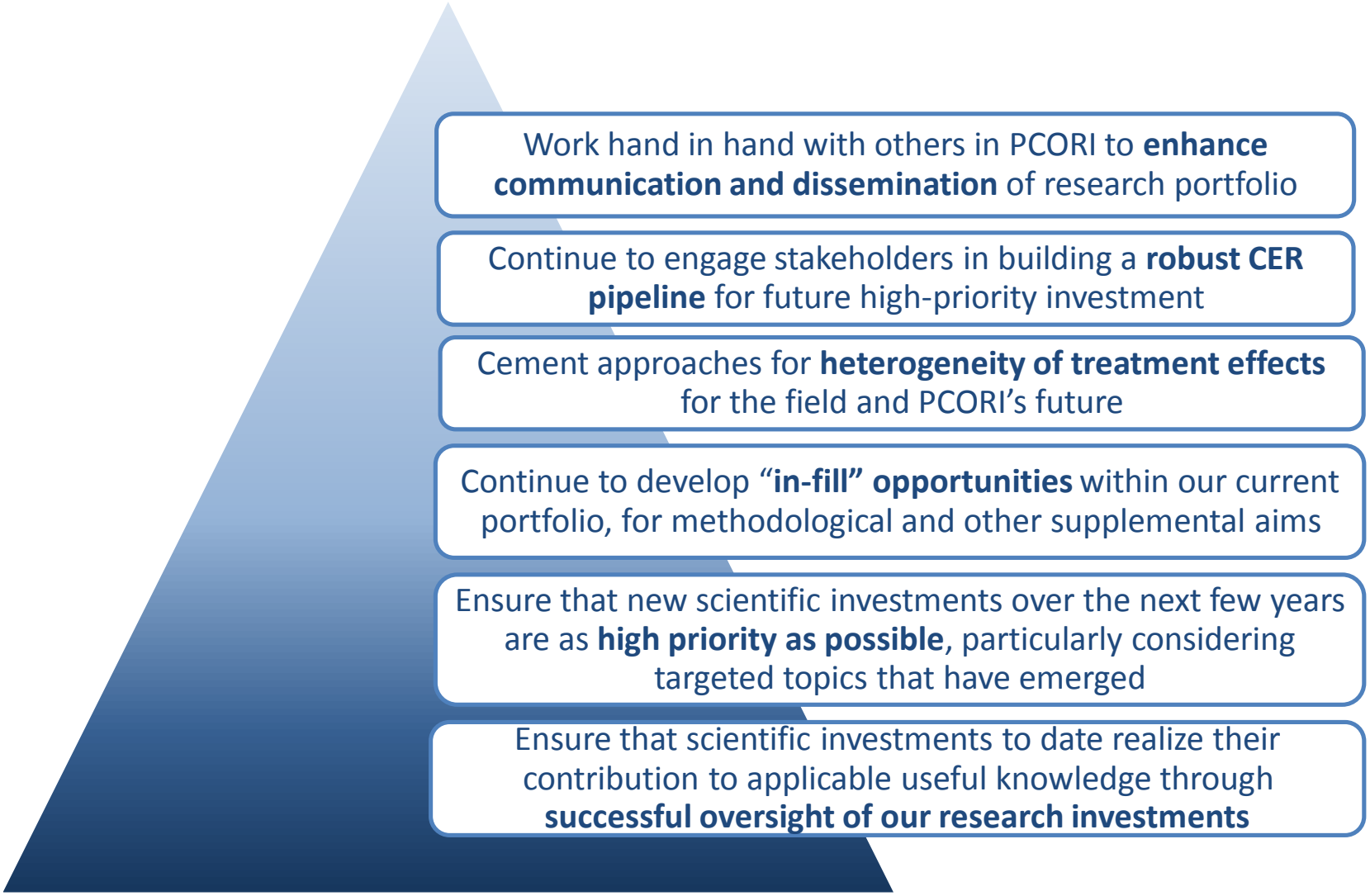
Working group on potential large collaborative CVOT trial

(NHLBI-NIDDK)

IPD MA: Preventing Preterm Birth Using Progesterone

(March of Dimes)

Looking Ahead



Board of Governors: Member Discussion

Research Funding & Awards

What is the best approach to take when faced with an influx of meritorious research applications in response to a funding announcement? In light of the fact that our MS Re-post and our Palliative Care calls were highly successful ***–how do we determine when we have maximized our impact and investment?***

Goal 2: Speeding Uptake
Engagement, Dissemination and Implementation Committee Report to the Board

Debra Barksdale, PhD, RN

Chair, Engagement, Dissemination and Implementation Committee

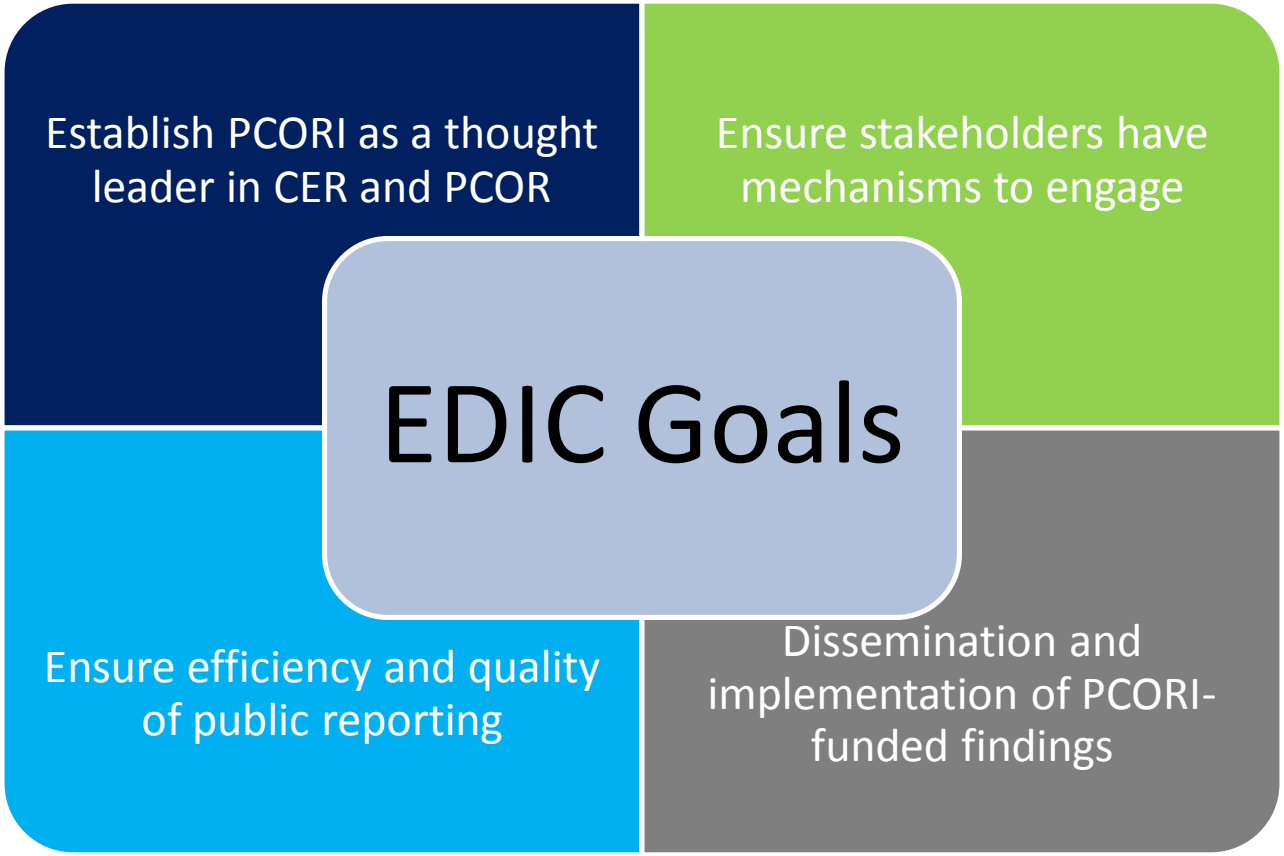
Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer

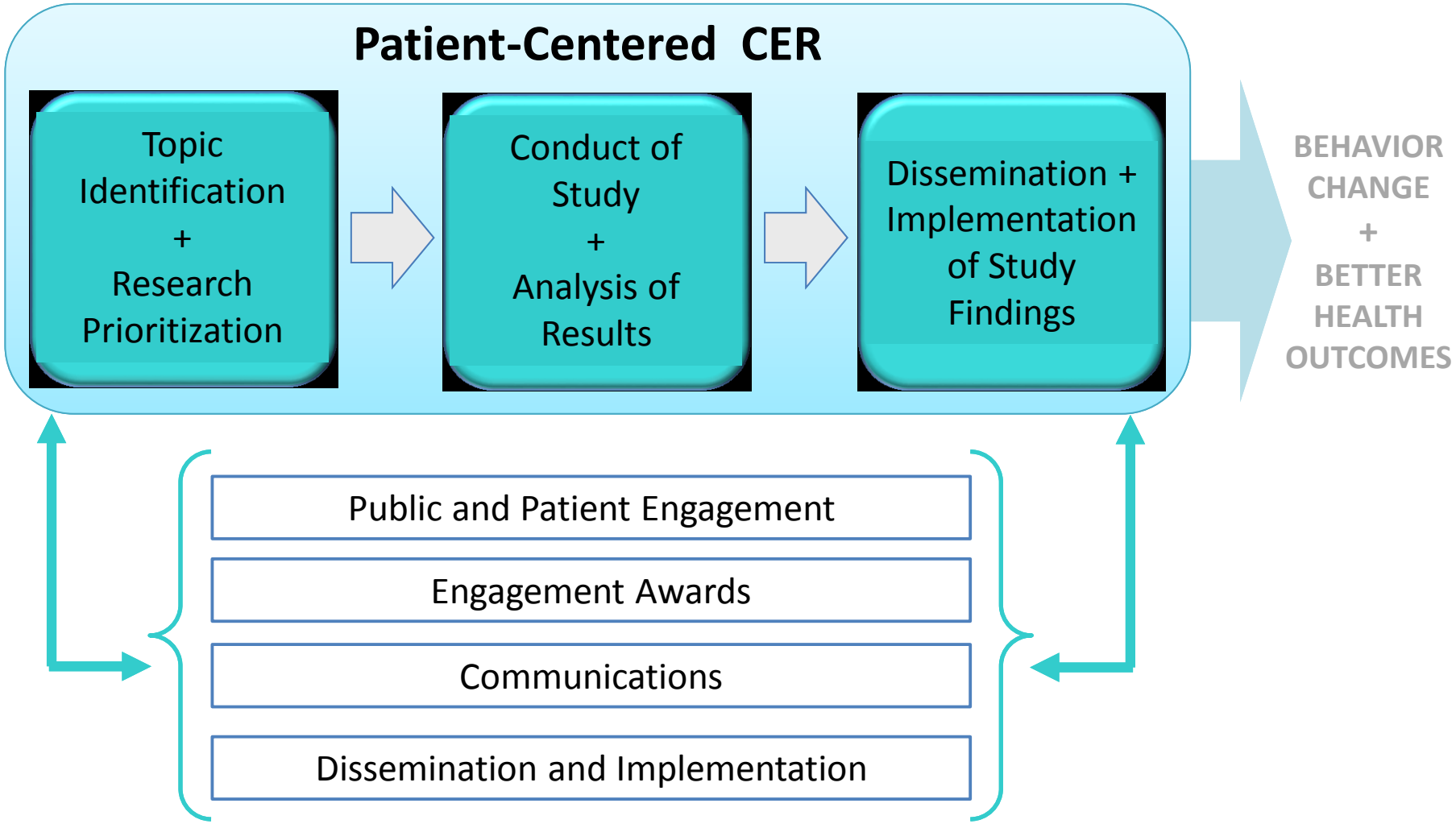
PCORI's Strategic Goals

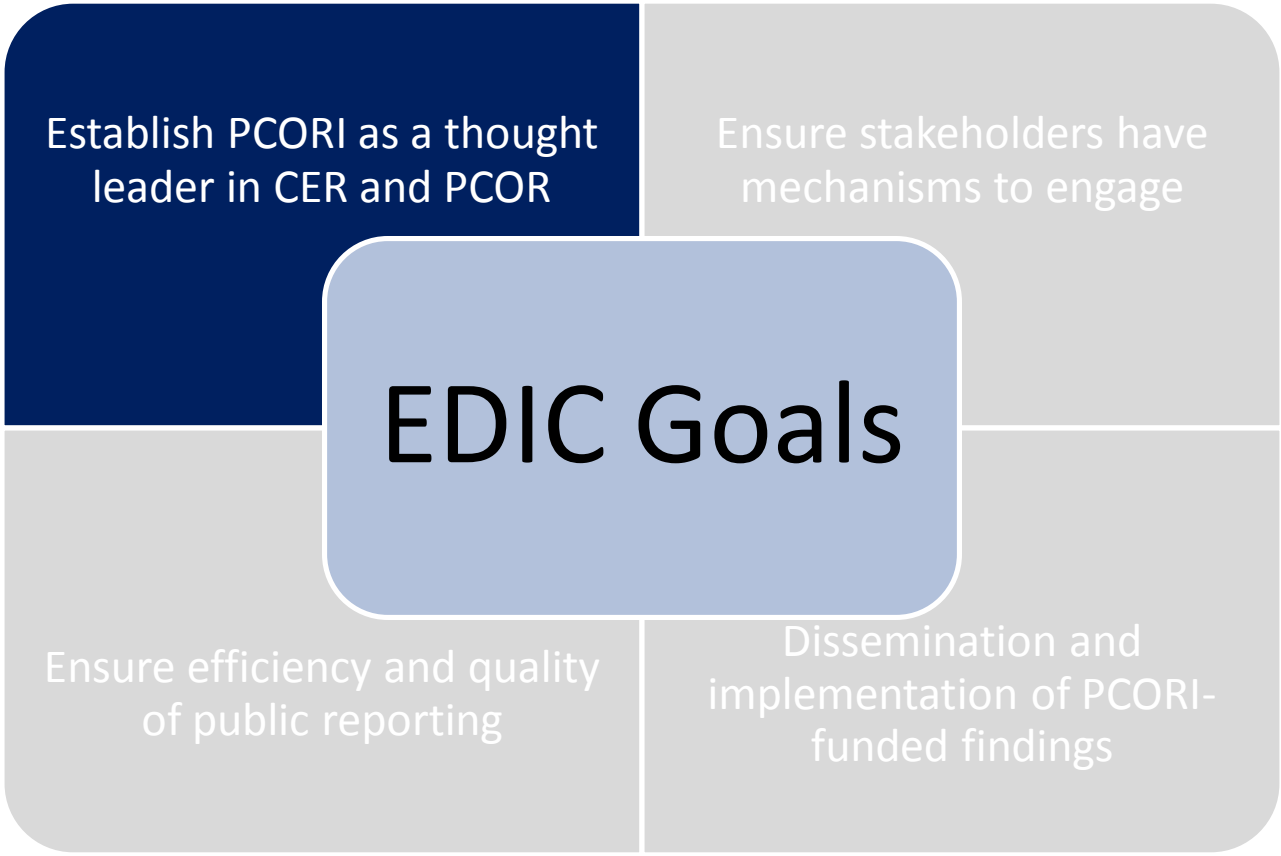
Engagement, Dissemination and Implementation Committee Members

- Debra Barksdale (Chair)
- Larry Becker
- Allen Douma
- Gail Hunt
- Gopal Khanna
- Sharon Levine
- Brian Mittman
- *Robert Jesse*


Establish PCORI as a thought leader in CER and PCOR
Ensure stakeholders have mechanisms to engage
EDIC Goals
Ensure efficiency and quality of public reporting
Dissemination and implementation of PCORI-funded findings

Support for PCOR and Achievement of Improved Health Outcomes

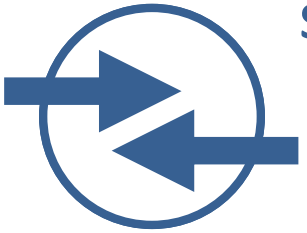



Establish PCORI as a thought leader in CER and PCOR
Ensure stakeholders have mechanisms to engage
EDIC Goals
Ensure efficiency and quality of public reporting
Dissemination and implementation of PCORI-funded findings

Establishing PCORI As a Trustworthy Leader

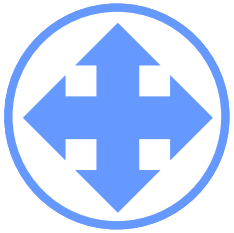
Supporting PCORI's Internal Work

- Engagement Officers
- Tools & Resources
- Merit Review Training



Supporting Internal and External Communities

- Stakeholder Meetings and Workshops
- Communications
- Engagement Awards
- Science of Engagement
- Advisory Panels

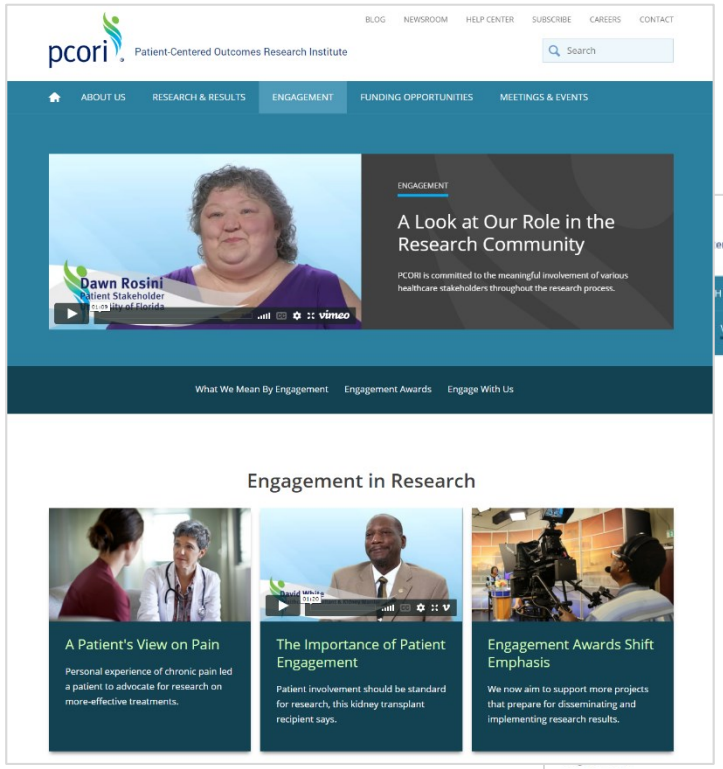


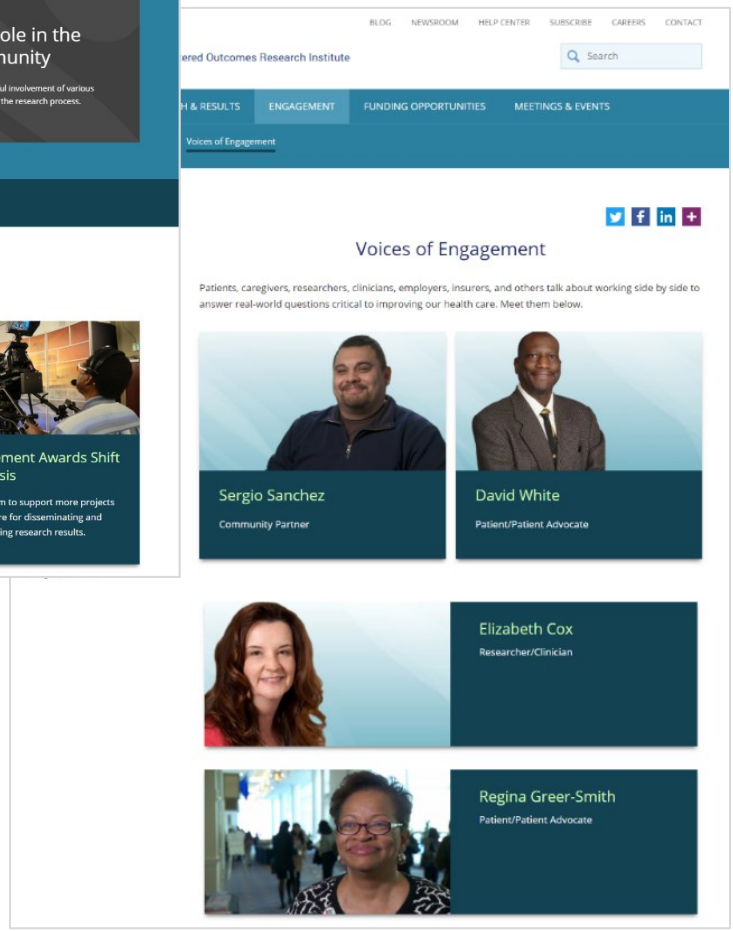
External Activities

- Public Reporting
- Web site and social media
- Dissemination and Implementation Awards

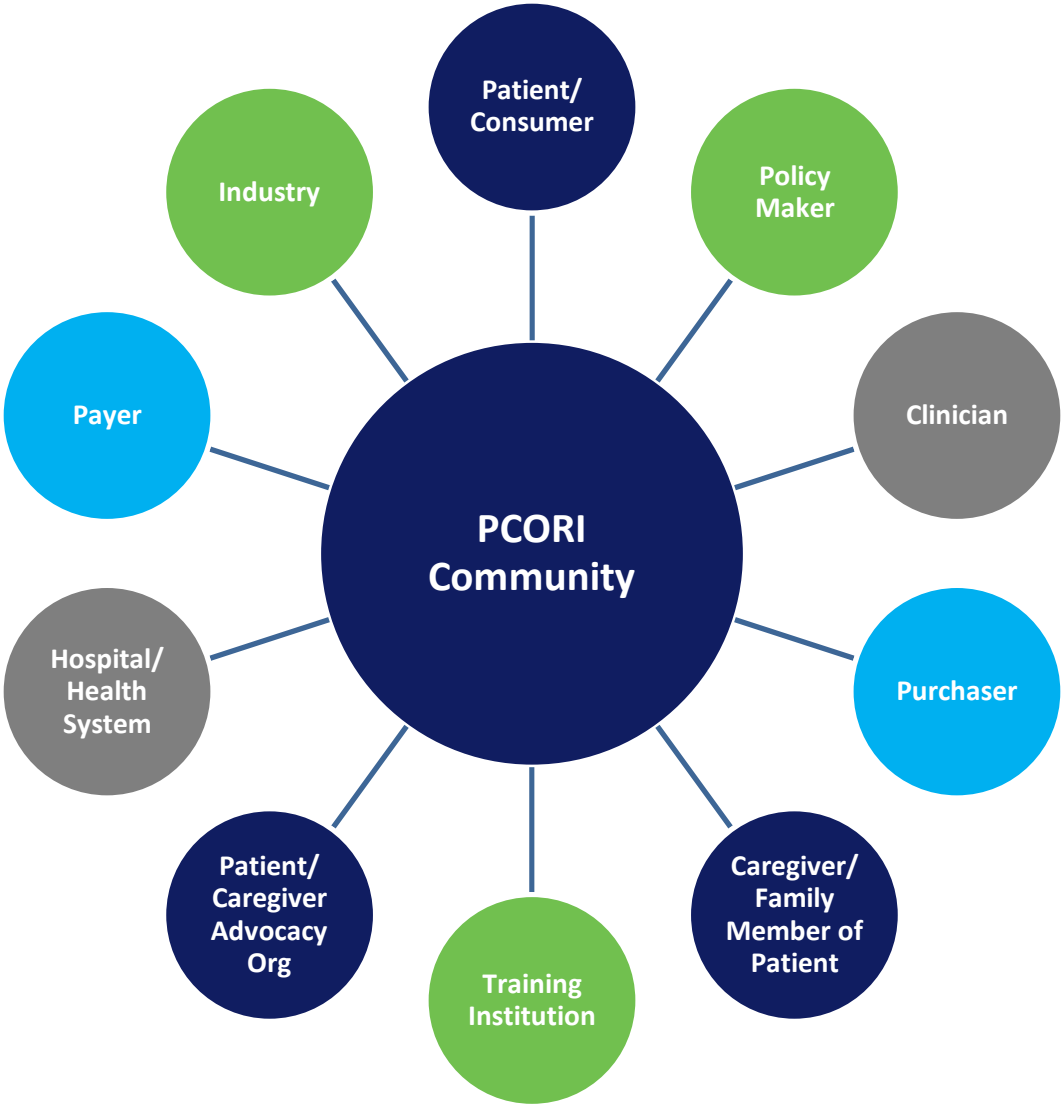
Highlighting the Value of Engagement

- Using **real-world examples** to make the impact of engagement real
- Providing a platform for the **voices and stories** of patients, caregivers, other partners.
- Working with **stakeholder communities** to explain how our work is valuable to them
- Enhancing relationships that can **support dissemination** of study results to those who need them





Who Are Our Stakeholders?



740

61

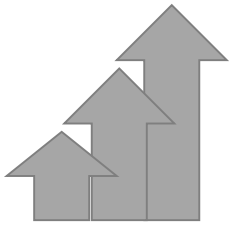
Engagement Case Study: Patients

National Multiple Sclerosis Society

1:1 Engagement

Invited to submit CER topics and questions. PCORI selected topic.

Research Prioritization



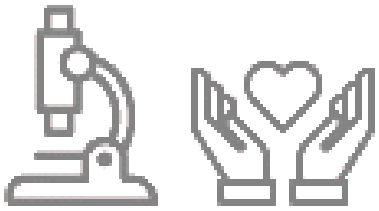
Small multi-stakeholder refinement workgroup. Joined small, payer and industry community-focused workgroups. Large multi-stakeholder workshop.

Targeted PFA

Two targeted PFAs; 12 awards totaling $65 million.

NMSS Engaged in Projects

Discontinuation of Disease Modifying Therapies: NMSS financially supporting study sites



All activities lead to better science and better health outcomes

Engagement Case Study: Payers

Medicaid Medical Directors Network (MMDN)

1:1 Engagement

Proactive outreach to MMDN

Engagement Awards

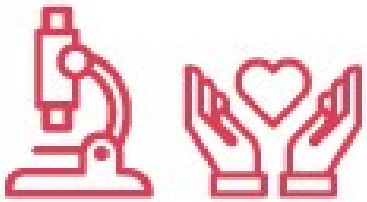
PCORI awarded funding to support the MMDN to support topic nomination reports, dissemination report, annual MMDN meetings, “open mic” calls to discuss high priority topics

Research Prioritization

Solicited MMDN application to advisory panels. MMDN participation in 11 multi-stakeholder workshops.

Dissemination and Implementation

Active engagement led to high interest among MMDs in disseminating and implementing PCORI findings



All activities lead to better science and better health outcomes

Establishing PCORI As a Thought Leader on Engagement in Research

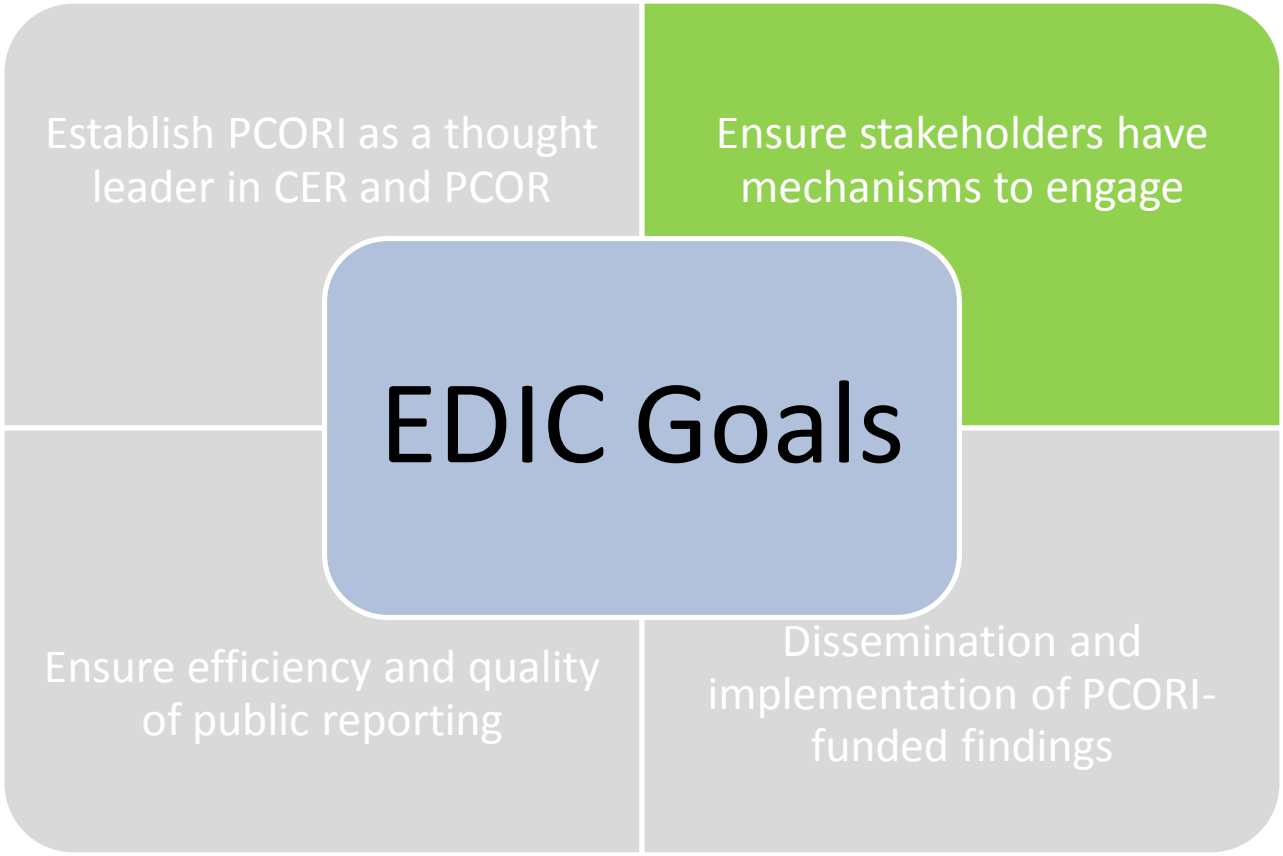
Science of Engagement

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.

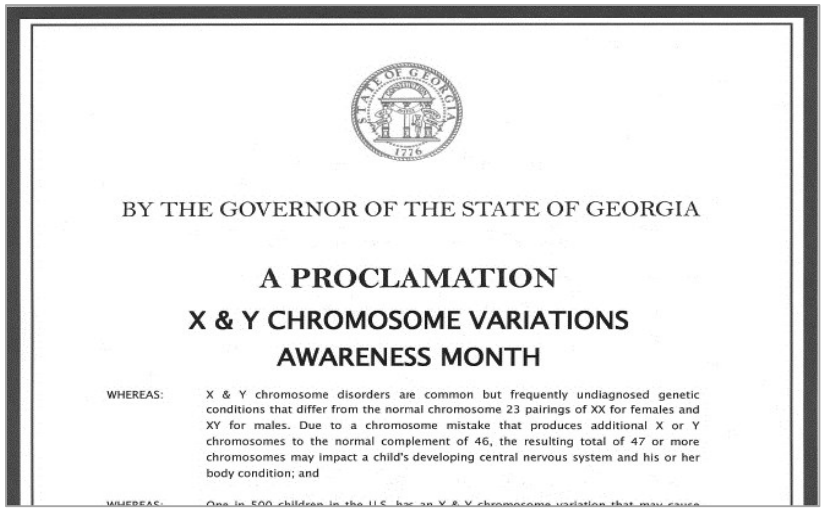

Establish PCORI as a thought leader in CER and PCOR
Ensure stakeholders have mechanisms to engage
EDIC Goals
Ensure efficiency and quality of public reporting
Dissemination and implementation of PCORI-funded findings

Ensuring Stakeholders Have Mechanisms to Engage

Engagement Awards: Providing Opportunities for Engagement

- **277 projects awarded** since February 2014 to build patient and stakeholder capacity to:
  - Partner in research,
  - Identify research priorities, and,
  - Serve as channels for dissemination and implementation of PCORI-funded research findings

Highlights from Engagement Awards

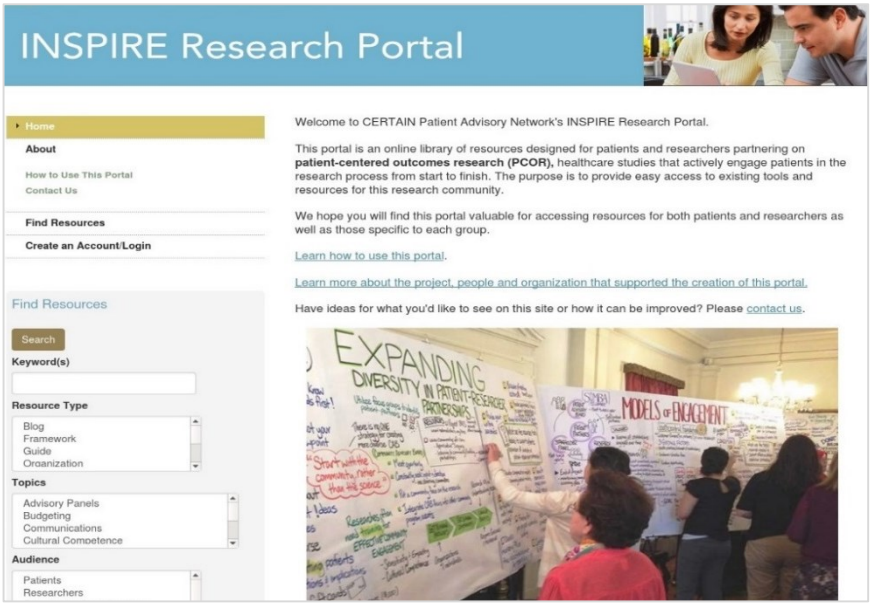


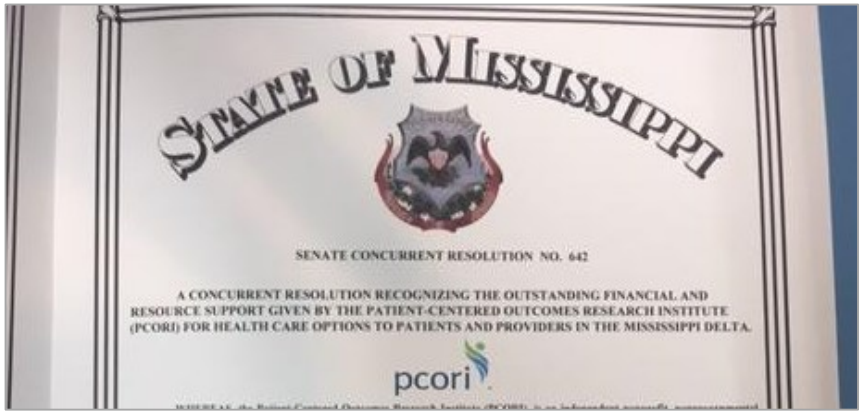
BY THE GOVERNOR OF THE STATE OF GEORGIA

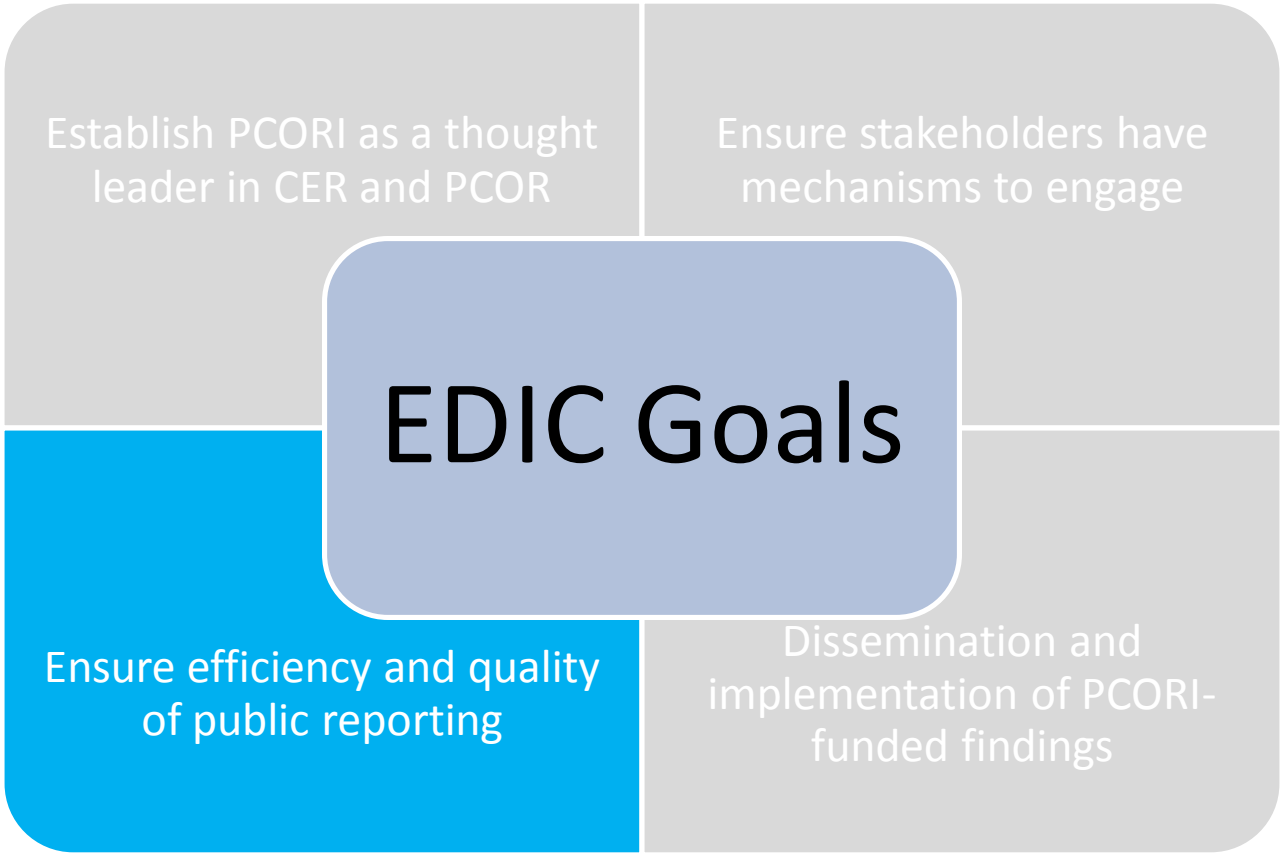
A PROCLAMATION

X & Y CHROMOSOME VARIATIONS AWARENESS MONTH

WHEREAS: X & Y chromosome disorders are common but frequently undiagnosed genetic conditions that differ from the normal chromosome 23 pairings of XX for females and XY for males. Due to a chromosome mistake that produces additional X or Y chromosomes to the normal complement of 46, the resulting total of 47 or more chromosomes may impact a child's developing central nervous system and his or her body condition; and






Establish PCORI as a thought leader in CER and PCOR
Ensure stakeholders have mechanisms to engage
EDIC Goals
Ensure efficiency and quality of public reporting
Dissemination and implementation of PCORI-funded findings

Project Explorer

Explore Our Portfolio

(If you would like more detailed information about research projects PCORI has funded, please contact info@pcori.org)

Enter keyword(s) SEARCH PROJECTS

Displaying 1 - 10 of 543: Research Project Reset All Filters

Download these results | View a list of projects with results

RESEARCH PROJECT
A Pragmatic Trial of Home versus Office-Based Narrowband Ultraviolet B Phototherapy for the Treatment of Psoriasis
Joel Mitchell Gelfand, MD, MS | University of Pennsylvania

RESEARCH PROJECT
Comparative Effectiveness of Pain Cognitive Behavioral Therapy and Chronic Pain Self-Management within the Context of Opioid Reduction
Beth Darnall, PhD | Stanford University School of Medicine

RESEARCH PROJECT
Comparing the Effectiveness of Fatigue Management Programs for People with MS
Matthew A. Plow, PhD | Case Western Reserve University

Refine Your Results

Project Type
- All project types (1206)
- Engagement in Research Project (589)
- Research Project
- Research Infrastructure Project (66)
- Research Dissemination and Implementation Project (7)

Project Status

Conditions

PCORI Research Priority Area

Funding Announcement

State

Year Awarded

Project Explorer

Explore Our Portfolio

(If you would like more detailed information about research projects PCORI has funded, please contact info@pcori.org)

Enter keyword(s) SEARCH PROJECTS

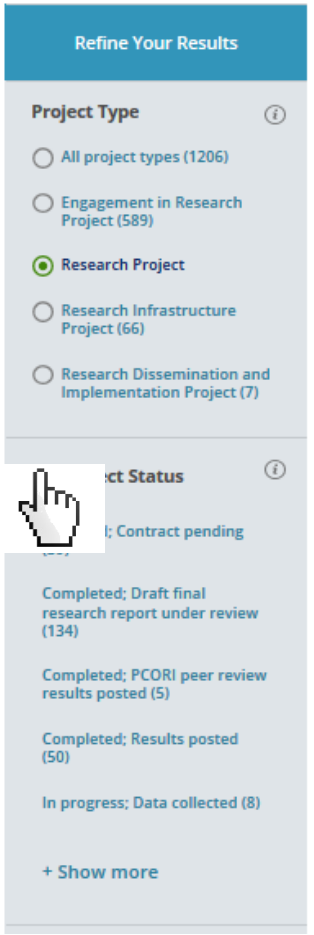
Displaying 1 - 10 of 543: Research Project Reset All Filters

Download these results | View a list of projects with results

RESEARCH PROJECT
A Pragmatic Trial of Home versus Office-Based Narrowband Ultraviolet B Phototherapy for the Treatment of Psoriasis
Joel Mitchell Gelfand, MD, MS | University of Pennsylvania

RESEARCH PROJECT
Comparative Effectiveness of Pain Cognitive Behavioral Therapy and Chronic Pain Self-Management within the Context of Opioid Reduction
Beth Darnall, PhD | Stanford University School of Medicine

RESEARCH PROJECT
Comparing the Effectiveness of Fatigue Management Programs for People with MS
Matthew A. Plow, PhD | Case Western Reserve University



Project Explorer

Explore Our Portfolio

(If you would like more detailed information about research projects PCORI has funded, please contact info@pcori.org)

Enter keyword(s) SEARCH PROJECTS

Displaying 1 - 10 of 50: Research Project Completed; Results posted Reset All Filters

Download these results | View a list of projects with results

RESEARCH PROJECT
Pilot Project: Measuring Care in Psychiatric Hospitals from Patient and Staff Points of View
Kathleen R. Delaney, PhD, PMH-NP | Rush University Medical Center/Rush College of Nursing

RESEARCH PROJECT
Pilot Project: Using Video Games to Help People with Arm Weakness Recover
Lynne V. Gauthier, PhD | The Ohio State University

RESEARCH PROJECT
Pilot Project: Creating an App That Helps Stroke Survivors and Their Caregivers
Sharon Januchowski, RN ^ | National Stroke Association

Refine Your Results

Project Type
- All project types (50)
- Research Project

Project Status
- Completed; Results posted

Funding Announcement

State

Year Awarded

MAP OF ALL PROJECTS >>

Content and Resources Arranged by Topic

TOPIC SPOTLIGHT

Cardiovascular Disease

No. 1 cause of death | **800,000** deaths each year | **$320 BILLIO** in healthcare costs and lost productivity annually

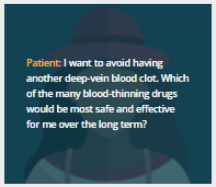
Source: Centers for Disease Control and Prevention

To address this problem, PCORI has funded **61 comparative clinical effectiveness research studies** and related projects to help patients and those who care for them make **better-informed decisions** about their options for **preventing, diagnosing,** and **treating cardiovascular disease.**

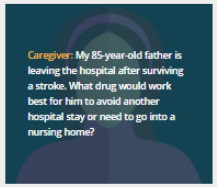
As of September 2017

PCORI Answers Critical Questions

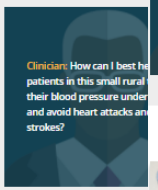
Evidence gaps can make it difficult to know which cardiovascular disease treatment will work best given patient's needs. PCORI funds studies that seek to help patients, clinicians and others answer various ques they might have about treatment options, such as:



Patient: I want to avoid having another deep-vein blood clot. Which of the many blood-thinning drugs would be most safe and effective for me over the long term?



Caregiver: My 85-year-old father is leaving the hospital after surviving a stroke. What drug would work best for him to avoid another hospital stay or need to go into a nursing home?

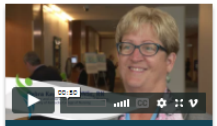


Clinician: How can I best he patients in this small rural their blood pressure under and avoid heart attacks an strokes?

Cardiovascular Disease Study Spotlights

Applying Evidence from Stroke Prevention Research

View a Continuing Medical Education activity to help patients with atrial fibrillation and stroke risk decide on treatments.



Addressing Disparities in Heart Disease

People in Appalachian Kentucky get heart disease more than other Americans. This study is trying to help people there make healthier choices.

Testing Drugs to Pr Recurrent Blood Cl

People who have had a blood high risk of having another. Th assesses the benefits and risks of long-term use of three blood-thinning drugs.

TOPIC SPOTLIGHT

Cancer

1.69 MILLION people in the United States diagnosed with cancer in 2016

No. 2 cause of death in the United States

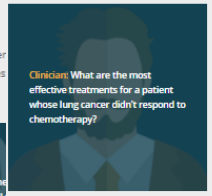
Source: Centers for Disease Control and Prevention

To address this problem, PCORI has funded **77 comparative clinical effectiveness research studies** and related projects to help patients and those who care for them make **better-informed decisions** about their options for **preventing, diagnosing,** and **treating cancer.**

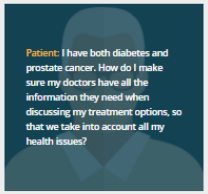
As of September 2017

PCORI Answers Critical Questions

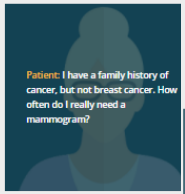
Evidence gaps can make it difficult to know which approach to cancer care will work best given a particular patient's needs. PCORI funds studies that seek to help patients, clinicians and others answer a range of questions they might have about cancer care, such as:



Clinician: What are the most effective treatments for a patient whose lung cancer didn't respond to chemotherapy?



Patient: I have both diabetes and prostate cancer. How do I make sure my doctors have all the information they need when discussing my treatment options, so that we take into account all my health issues?



Patient: I have a family history of cancer, but not breast cancer. How often do I really need a mammogram?

Cancer Study Spotlights

Breast Cancer Screening: Annual versus Personalized

National guidelines call for middle-aged women to get annual mammograms, even though they have different risks for developing breast cancer. This study compares annual screening versus screening tailored to individual risk levels.

Results Highlights for Patients and Clinicians

Early-stage prostate cancer can be treated in different ways. Two recent PCORI-funded research studies provide new information on the effects of treatments and can help patients navigate their treatment decisions.

Informed Decisions abou Lung Cancer Screening

Annual lung cancer screening for smokers could save 12,000 lives, although the test itself carries some risks. This study compares the impact on screening rates and patient outcomes of an informational video versus standard patient educational materials.

TOPIC SPOTLIGHT

Pain Care and Opioids

Chronic pain costs an estimated **$600 billion** in lost productivity and wages, medical expenses, and disability payments in the US.

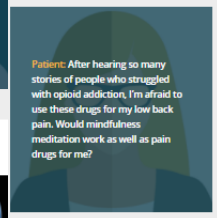
Source: Centers for Disease Control and Prevention

To address this problem, PCORI has funded **55 comparative clinical effectiveness research studies** and related projects to help patients and those who care for them make **better-informed decisions** about their options for **preventing, diagnosing,** and **treating chronic pain** while reducing inappropriate use or overuse of opioids.

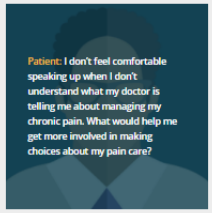
As of September 2017

PCORI Answers Critical Questions

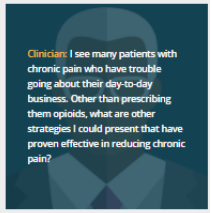
Evidence gaps can make it difficult to know which pain treatments work best while reducing the risk associated with long-term opioid use, given a patient's needs. PCORI funds studies that seek to help patients, clinicians and others answer questions they might have about treatment options, such as:



Patient: After hearing so many stories of people who struggled with opioid addiction, I'm afraid to use these drugs for my low back pain. Would mindfulness meditation work as well as pain drugs for me?



Patient: I don't feel comfortable speaking up when I don't understand what my doctor is telling me about managing my chronic pain. What would help me get more involved in making choices about my pain care?



Clinician: I see many patients with chronic pain who have trouble going about their day-to-day business. Other than prescribing them opioids, what are other strategies I could present that have proven effective in reducing chronic pain?

Pain Care and Opioids Study Spotlights

Tackling Chronic Pain While Reducing Opioid Use

This study found that a clinical plan to encourage safe opioid prescribing for pain succeeded in lowering patients' doses.

Chronic Pain Treatment without Opioids

Hear about how this PCORI-funded project explores how to provide nonpharmacological alternatives for managing pain to help patients in low-income areas.

Non-Opioid Therapies for Chronic Low Back Pain

This study compares how well cognitive behavioral therapy and mindfulness meditation work in mitigating pain and enabling people to reduce or discontinue opioid use.

Fact Sheets Highlight Activities and Portfolios


pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
1828 L STREET NW, SUITE 900
WASHINGTON, DC 20036
202.827.7700
RESEARCH SPOTLIGHT ON
Cancer
There are more than 100 kinds of cancer, each with a distinct pathology and a unique
environmental triggers. People facing a cancer diagnosis often face decisions over se
little consensus on what will work best given their individual circumstances and prefe
physical, emotional, and financial burdens on patients and their families.
1.69 MILLION
people in the United States were diagnosed with cancer in 2016
Source: Centers for Disease Control and Prevention
Research Addressing Questions That Matter
PCORI funds comparative clinical effectiveness research (CER) to determine which healthcare options work best for which patients, based on their needs and preferences. CER produces evidence that helps people make better-informed healthcare choices.
PATIENT
My lung cancer didn't respond to chemotherapy and I'm wondering which of the next-line treatment options available might work best for a 70-year-old former smoker like me?
STUDY SPOTLIGHT
Patient-Centered Information for Decision Making in Localized Prostate Cancer
This study analyzed quality of life changes over three years among prostate cancer patients who received either radical prostatectomy (surgery), external beam radiotherapy (radiation), or those who pursued active surveillance. It found that those who had either surgery or radiation reported more adverse effects. However, quality of life levels evened out among all patients after three years. More information may be found at www.pcori.org/Penson007.
PCORI.ORG


pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
RESEARCH SPOTLIGHT ON
Cardiovascular Disease
Heart disease remains one of the leading causes of death in the nation, even with many efforts to prev
treat cardiovascular conditions. When heart disease and stroke are not fatal, they can result in serious
and decreased quality of life. Heart disease and stroke cost the nation $320 billion in healthcare costs
productivity in 2011, according to the US Department of Health and Human Services.
Heart disease is the #1 cause of death in the United States, killing 614,348 p
Source: Centers for Diseas
Research Addressing Questions That Matter
PCORI funds comparative clinical effectiveness research (CER) to determine which healthcare options work best for which patients, based on their needs and preferences. CER produces evidence that helps people make better-informed healthcare choices.
PATIENT
My doctor is concerned that I'm at risk of having a heart attack or stroke if I can't get my high blood pressure under control. I've heard about a telehealth program that works with patients like me, but how can I know if it will work as well as going into my doctor's office?
STUDY SPOTLIGHT
Older vs. Newer Drugs for Preventing Recurring Blood Clots
Patients who have a blood clot typically receive a blood thinning drug for three to six months. This study will compare two newer drugs, rivaroxaban and apixaban, to one another and to the older drug warfarin to evaluate each drug's safety and effectiveness in preventing further clots in people who are at high risk for another. More information may be found at www.pcori.org/Ortel005.
Keeping Stroke Survivors Independently Longer
Using the blood thinning drug warfarin
survivors—even those over age 80—to
their homes longer—on average 46 mor
to those who didn't take the drug, this st
the study also measured rates of major
health problems, staying in their homes
institutionalized in a healthcare facility is the outcome that mattered most to patients advising the researchers. Further details are at www.pcori.org/Hernandez006.
PCORI.ORG | INFO@PCORI.ORG | FOLLOW US @PCORI

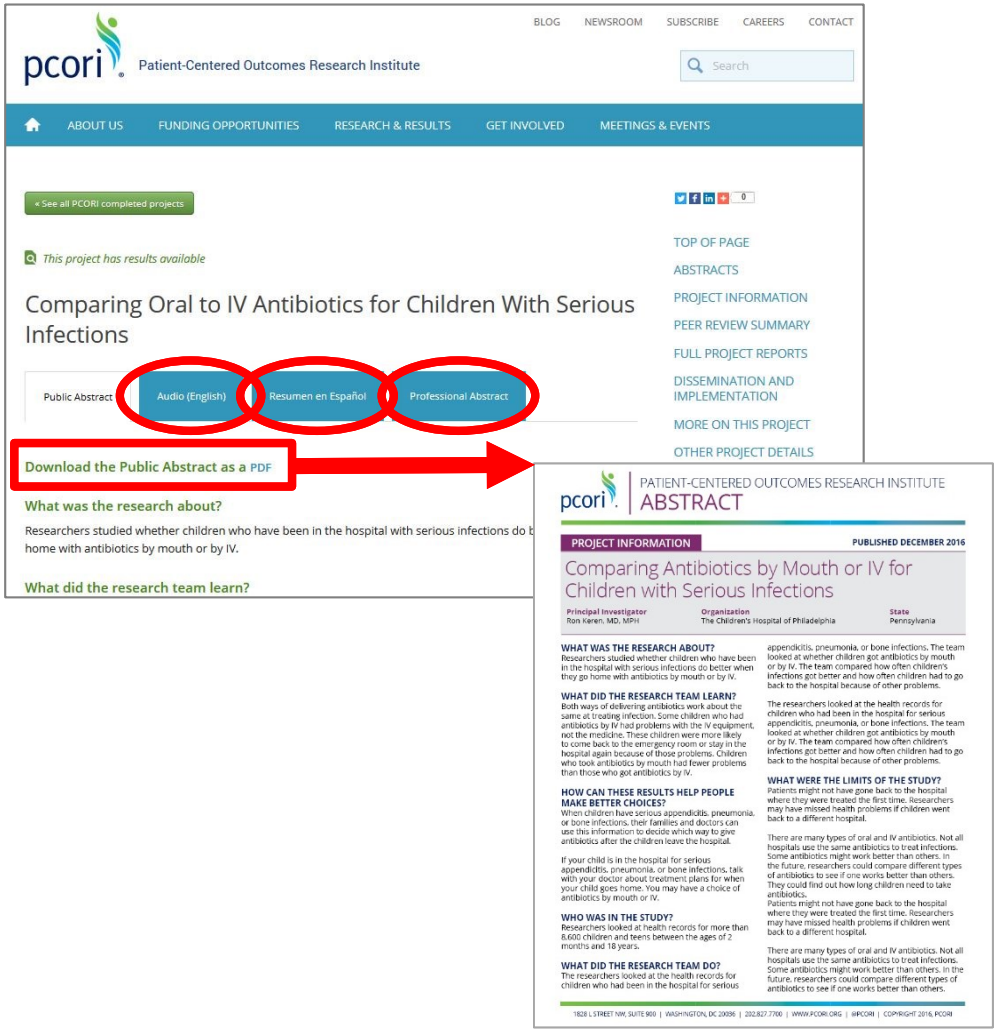

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
1828 L STREET NW, SUITE 900
WASHINGTON, DC 20036
202.827.7700
RESEARCH SPOTLIGHT ON
Pain Care and Opioids
Determining how to best treat pain is challenging for patients and clinicians. The alarming increase in opioid use and potentially fatal misuse has focused national attention on how to use these drugs appropriately and safely and treat opioid use disorders while also ensuring that people dealing with pain have a range of safe and effective treatment options available to them.
100 MILLION
adults in the United States are affected by chronic pain
Source: National Academy of Medicine
33,000
Americans died from opioid overdoses in 2015
Source: Centers for Disease Control and Prevention
$600 BILLION
Estimated total annual costs related to pain
Source: National Institutes of Health
Addressing the Roots of the Opioid Crisis and Inadequate Pain Management
PCORI funds comparative clinical effectiveness research (CER), which studies which healthcare options work best for which patients, based on their needs and preferences. PCORI-funded CER is filling the full continuum of evidence gaps in regards to both pain not related to cancer and opioid use disorders. The goal is not only to improve treatment for noncancer-related pain and to prevent and treat opioid addiction but also to address the factors that cause these problems.
PCORI-FUNDED CER STUDIES ARE DETERMINING WHAT'S MOST EFFECTIVE IN:
Managing acute and chronic pain
Preventing unsafe prescribing of opioids
Reducing reliance on opioids among people already using them
Preventing opioid use disorders
Treating opioid use disorders
STUDY SPOTLIGHT
Alternative Therapies for Opioid-Treated Chronic Low Back Pain
Many people with chronic low back pain as well as those who care for them are interested in alternatives to opioids, given the risks of addiction. This study is comparing how well two such alternative therapies—cognitive behavioral therapy and mindfulness meditation—work in easing pain and helping people reduce or discontinue opioid use. More details are at www.pcori.org/Zgierska010.
PCORI.ORG | INFO@PCORI.ORG | FOLLOW US @PCORI

Promoting Open Access to Journal Publications Presenting Findings from PCORI-Funded Research

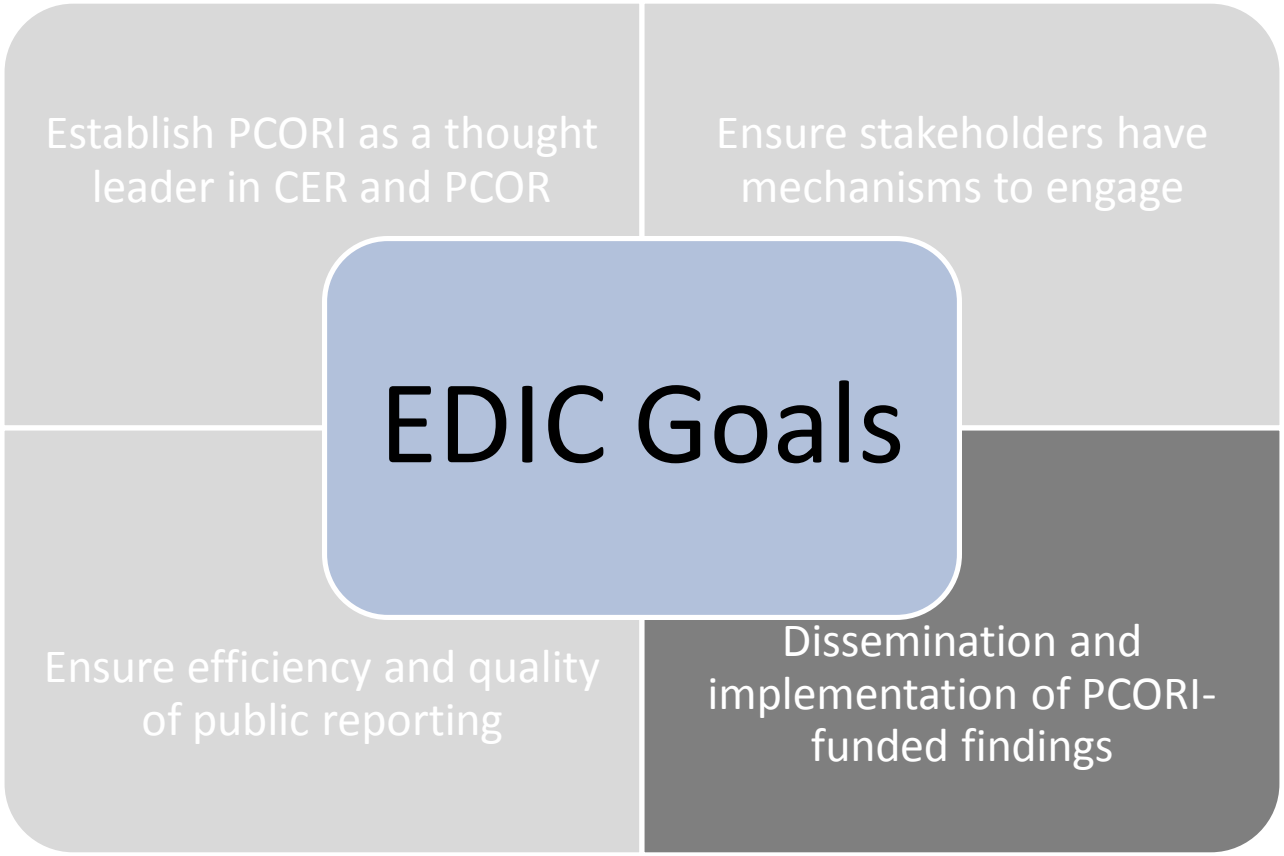
- PCORI investigators may request PCORI coverage of open access fees when a manuscript presenting results has been accepted.
- So far:
  - 26 open access requests from PCORI investigators
  - PCORI accepted **22** of these requests based on our policy requirements
- PCORI is working with PubMed Central to facilitate the deposit of all published manuscripts to enable full public access within 12 months of publication.

Public Reporting of Study Results

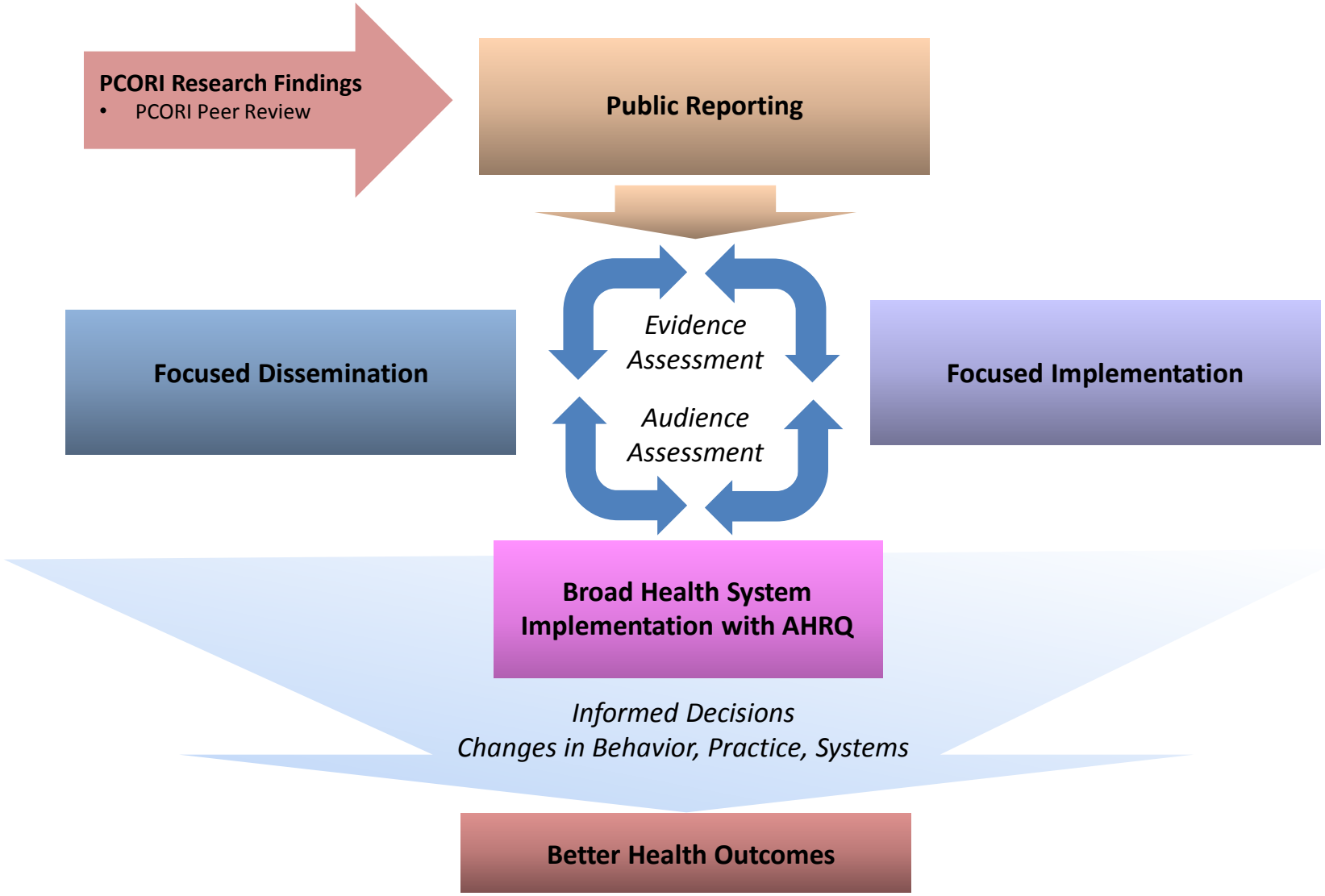
- PCORI release of findings
- Peer-reviewed publications that present results of PCORI-funded studies
- Initiatives to promote public access to peer-reviewed literature
- Reporting of results back to study participants



PCORI Public Release of Findings

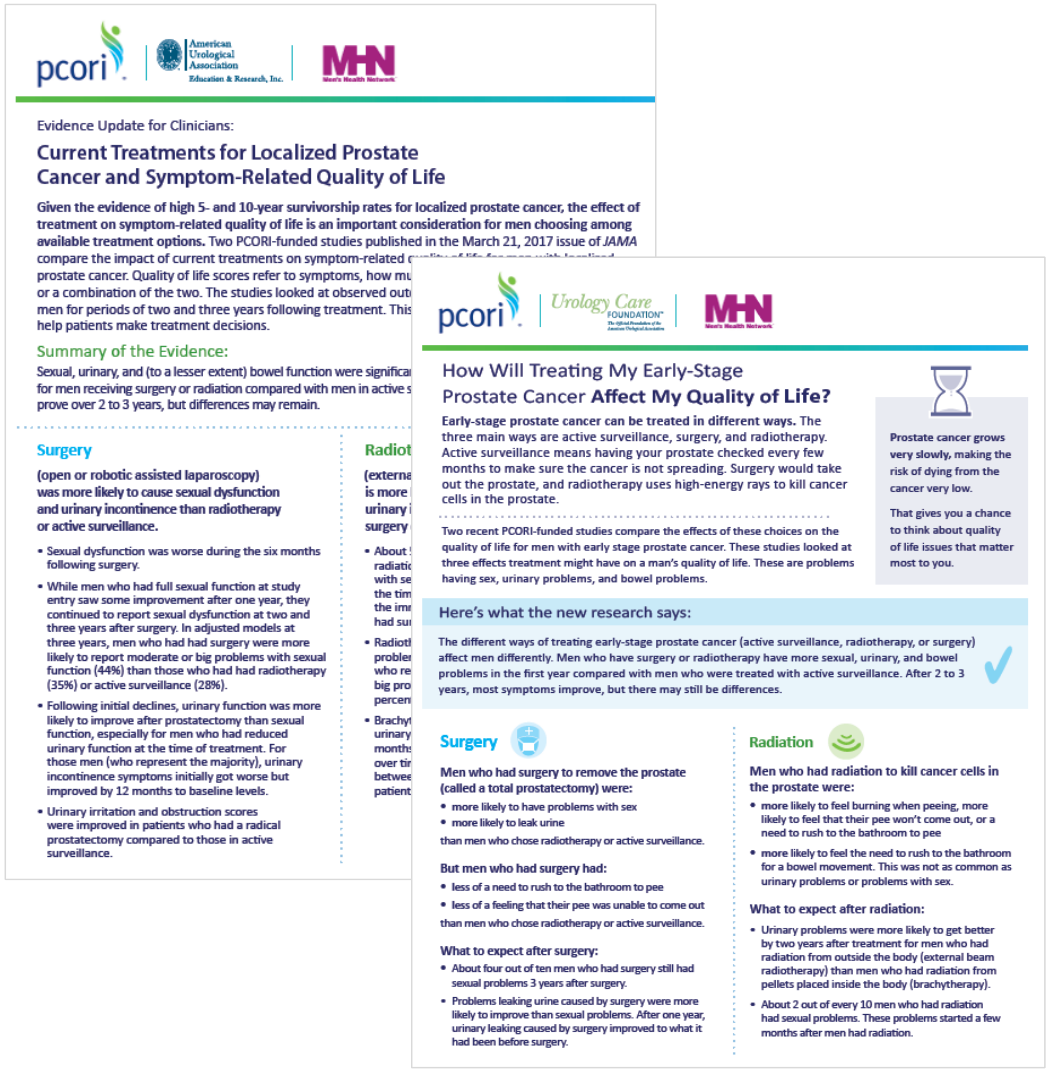

Establish PCORI as a thought leader in CER and PCOR
Ensure stakeholders have mechanisms to engage
EDIC Goals
Ensure efficiency and quality of public reporting
Dissemination and implementation of PCORI-funded findings

PCORI Dissemination & Implementation of Research Results



Focused Dissemination

- Activities to disseminate results from PCORI-funded research on Current Treatments for Localized Prostate Cancer and Symptom-Related Quality of Life include:
  - Evidence Updates for Clinicians and Patients
  - Continuing Medical Education/Continuing Education



pcori | American Urological Association Education & Research, Inc. | MHN

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 mu... or a combination of the two. The studies looked at observed outc... men for periods of two and three years following treatment. This... help patients make treatment decisions.

Summary of the Evidence:

Sexual, urinary, and (to a lesser extent) bowel function were significa... for men receiving surgery or radiation compared with men in active s... prove 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.

Radiot...

(externa... is more ... urinary ... surgery

- About ... radiatio... with se... the tim... the im... had su...
- Radiotl... proble... who re... big pro... percen...
- Brachyt... urinary ... months ... over tir... betwee... patient...

pcori | Urology Care FOUNDATION | MHN

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:

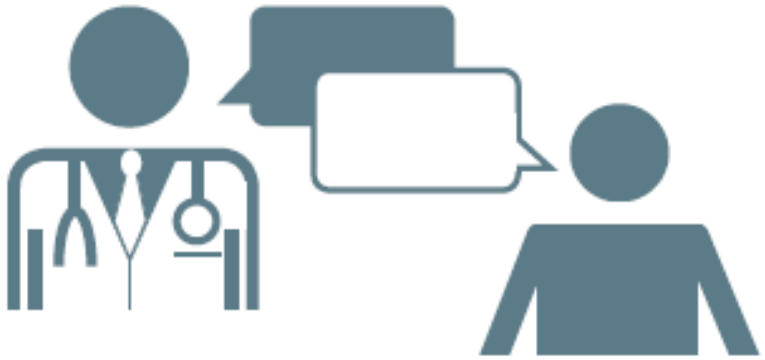
- more likely to feel burning when peeing, more likely to feel that their pee won't come out, or a need to rush to the bathroom to pee
- more likely to feel the need to rush to the bathroom for a bowel movement. This was not as common as urinary problems or problems with sex.

What to expect after radiation:

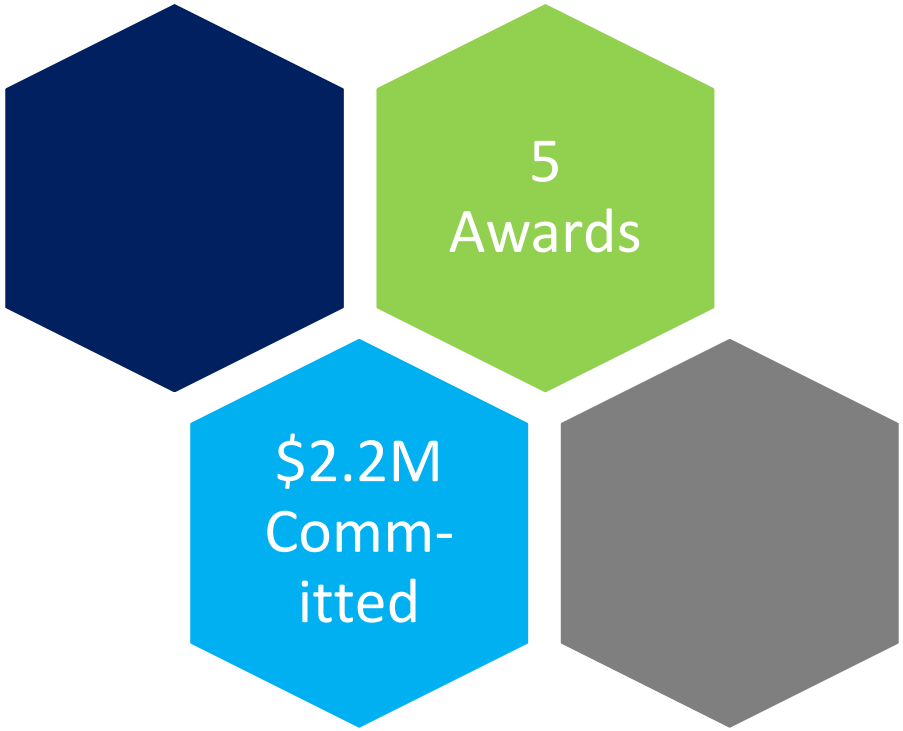
- Urinary problems were more likely to get better by two years after treatment for men who had radiation from outside the body (external beam radiotherapy) than men who had radiation from pellets placed inside the body (brachytherapy).
- About 2 out of every 10 men who had radiation had sexual problems.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

Focused Implementation

- **Implementation of Effective Shared Decision Making Approaches in Practice Settings**
  - Promotes the targeted implementation and systematic uptake of shared decision making (SDM) in healthcare settings
  - In line with PCORI's mission of supporting patients in making informed decisions about their care.



Dissemination and Implementation Awards



- Including awards disseminating and implementing PCORI-funded research results on:
  - Improving **Diabetes Prevention** with **Benefit-Based Tailored Treatment**
  - **Virtual Care Visits for Parkinson's Disease**
  - Preventing **Venous Thromboembolism (VTE)**

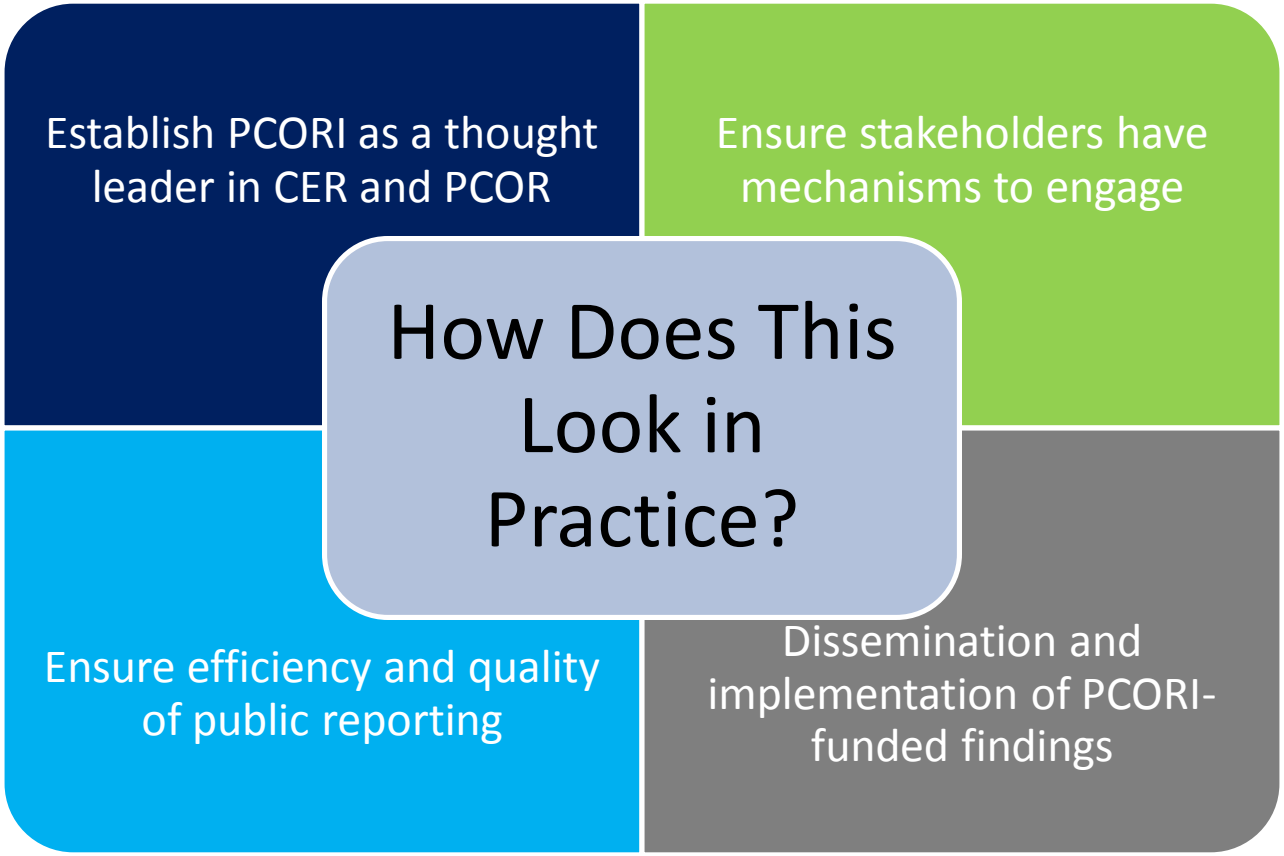
Broad Health System Implementation with AHRQ

AHRQ is also charged with dissemination and implementation of PCOR findings.

AHRQ considering several broad initiatives including:

- Anticoagulants to Prevent Stroke for Patients with Atrial Fibrillation
  - Based on PCORI submission of study results to AHRQ
- Cardiac Rehabilitation
  - Highly relevant PCORI study in progress

In addition, PCORI and AHRQ are collaborating on systematic reviews and PCORI will disseminate findings from these projects as they are completed.


Establish PCORI as a thought leader in CER and PCOR
Ensure stakeholders have mechanisms to engage
How Does This Look in Practice?
Ensure efficiency and quality of public reporting
Dissemination and implementation of PCORI-funded findings

Shared Commitment with Stakeholders

"Unfortunately, the health needs of working Americans have not been as effectively addressed by research and analysis as they could be …

PCORI plays a critical role in convening people who would approach research or clinical care in isolation of each other.

I have been fortunate to have a seat at the table in PCORI-convened meetings to represent the voices of employers and those helping employers to improve employee health and wellbeing."

Kimberly Jinnett
Executive Vice President
Integrated Benefits Institute

Questions for the Board of Governors

Thoughts on the balance of dissemination vs targeted implementation?

Are there initiatives that should be added or enhanced?

Goal 3: Influencing Research
Research Transformation Committee Report to the Board

Freda Lewis-Hall, MD

Chair, Research Transformation Committee

Allen Douma, MD

Vice Chair, Research Transformation Committee

Joe Selby, MD, MPH

Executive Director

Research Transformation Committee Members

- Naomi Aronson
- Francis Collins
- Allen Douma (Vice Chair)
- Christine Goertz
- Steve Goodman
- Harlan Krumholz
- Freda Lewis-Hall (Chair)
- Kathleen Troeger

Responsibilities of the RTC

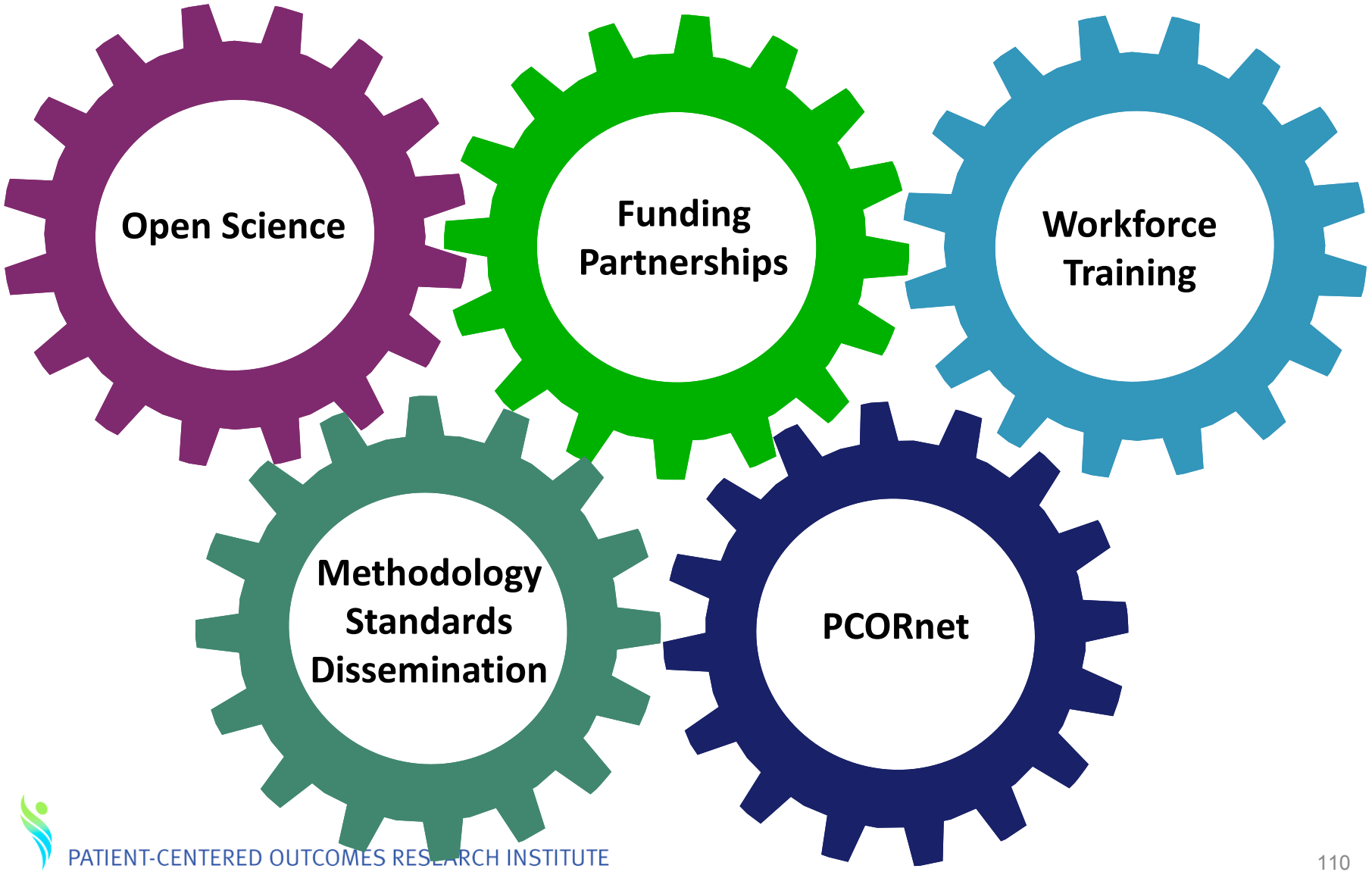
Influence clinical and health care research funded by others to be more patient-centered

- PCORI Strategic Plan, November 2013

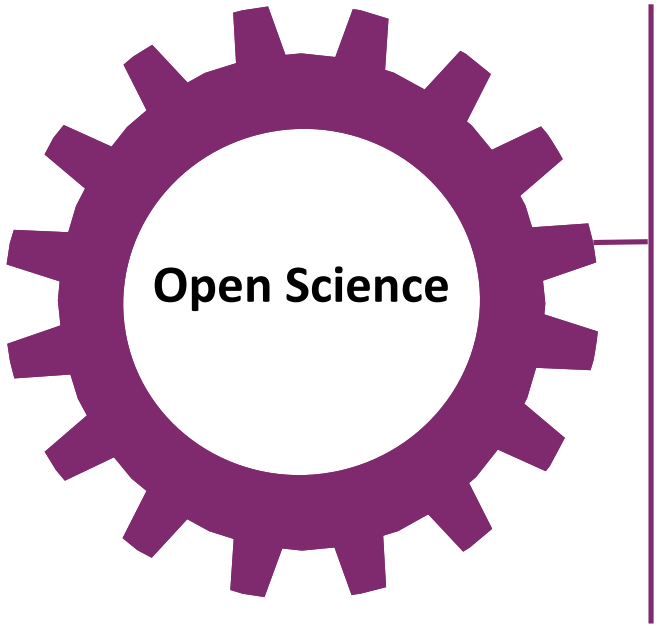
"…advise and assist the Board of Governors and PCORI on encouraging **clinical and health care research**, including **research funded by others**, to be **more patient-centric** by promoting **open science**, the development of **transformative research platforms**, and the conduct of more patient-centric and **methodologically rigorous research**..."

- Research Transformation Committee Charter, April 2017

RTC Initiatives to Influence Research (Outlined in RTC's 2015 Priorities)



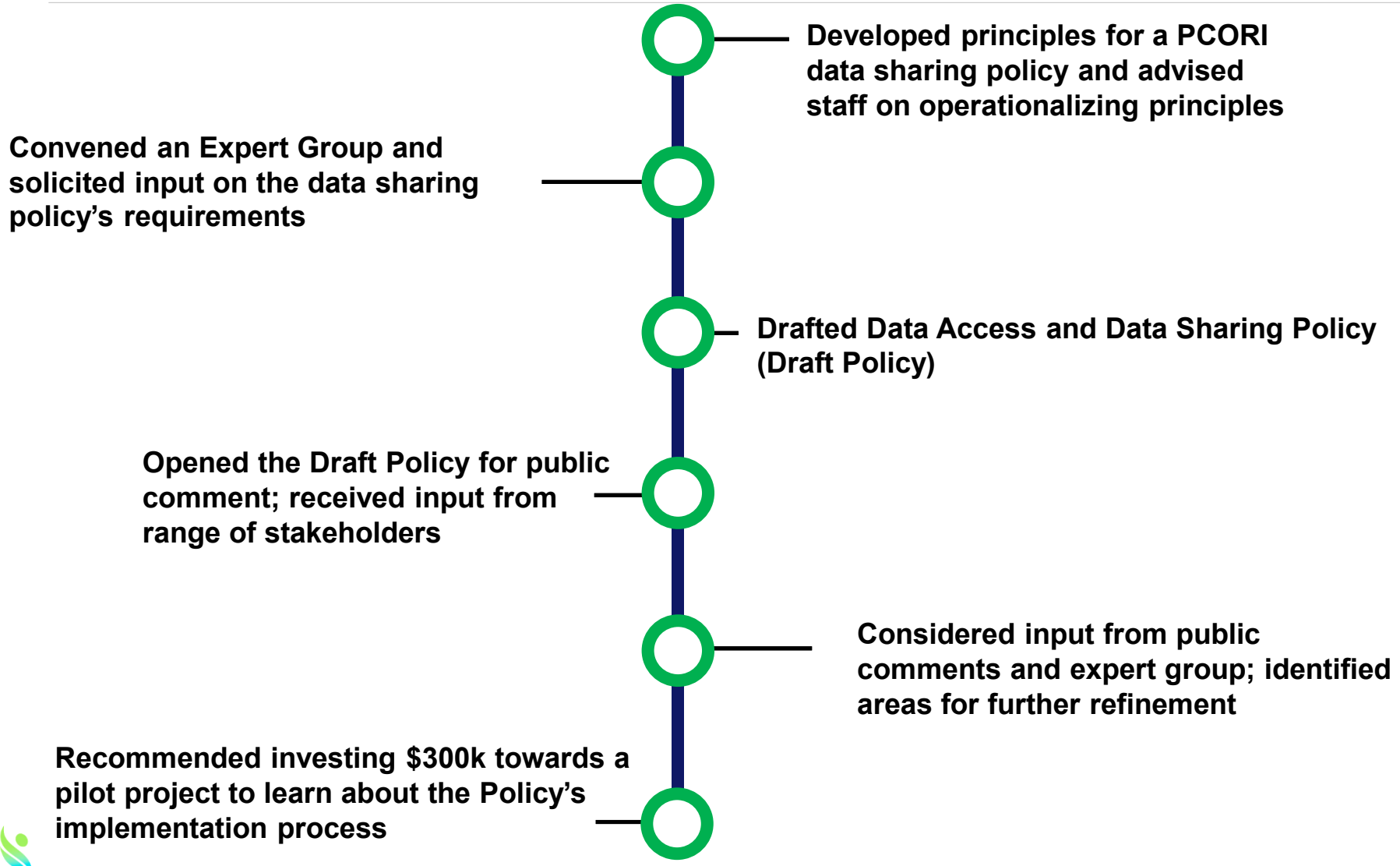
RTC Oversight of Open Science Initiative



The RTC serves as the central advisor to staff and the Board of Governors for developing and implementing PCORI's Policy for Data Access and Data Sharing (the Policy).

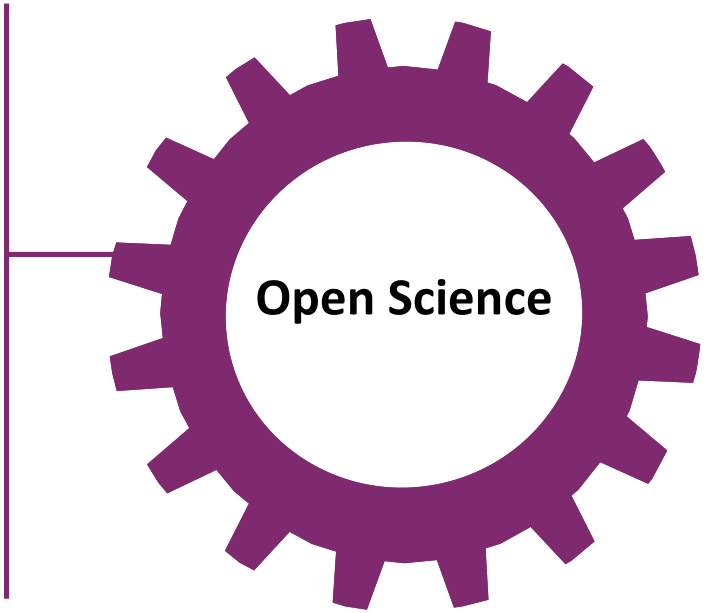
- Provides guidance to staff in assessing options and trade-offs for implementing the Policy
- Ensures alignment of the Policy with ongoing work in the research community

Open Science Initiative Activities- Policy for Data Access and Data Sharing

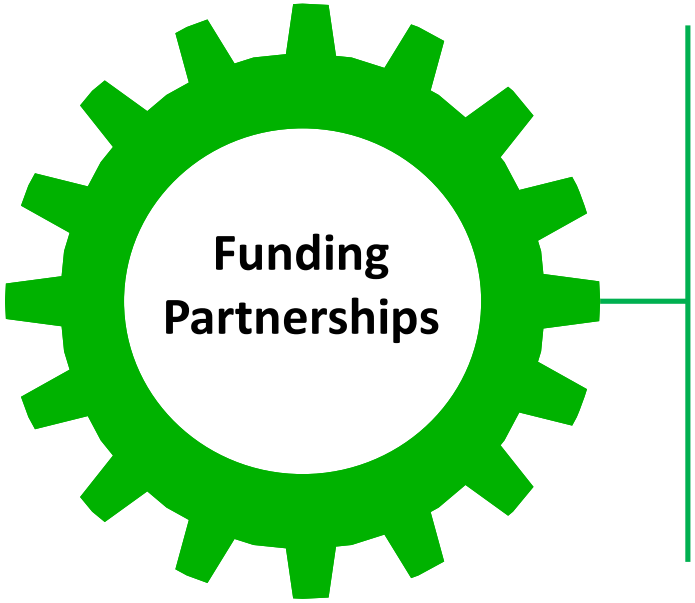


RTC Future Work on Open Science

- Evaluate and learn from the pilot project (March 2018)
- Recommend a final Policy for Data Access and Data Sharing for consideration by the Board (May 2018)
- Monitor the implementation and progress on data-sharing and advise staff on possible modifications
- Monitor other emerging areas in open science



RTC Oversight of Funding Partnerships Initiative



The RTC encourages the use of PCORI's Collaboration Principles and monitors funding collaborations.

- Reviews existing collaborations to ensure they continue to be aligned with PCORI's Collaboration Principles
- Considers additional active partnerships PCORI could seek to pursue high priority projects best achieved through collaboration (with a special focus on PCORnet)

Examples of Funding Partnership Initiative Activities

National Institutes of Health

- National Institute on Aging - Randomized Trial of a Multifactorial Fall Injury Prevention Strategy
- National Heart, Lung, and Blood Institute & National Institute of Neurological Disorders and Stroke
  - Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities
  - Collaboration to Improve Blood Pressure in the US Black Belt-Addressing the Triple Threat

Agency for Healthcare Research and Quality

Comparing Options for Management: Patient-Centered Results for Uterine Fibroids

American Heart Association

Jointly funded crowdsourced project has led to current co-funded announcement on Decision-making and Choices to Inform Dialogue and Empower Atrial Fibrillation Patients

Partnerships in PCORnet

- Current funding announcement: Partnerships to Conduct Research (PaCR) – requires partnerships with industry, institutions, and foundations
- Natural Experiments for Translation in Diabetes Second Phase (NEXT-D) with the Center for Disease Control and Prevention – involves 6 Clinical Data Research Networks in studying systems and policy approaches to improving the prevention and treatment of diabetes mellitus
- FDA Partnerships – 3 pilot projects (2 on drugs and 1 on devices) using PCORnet and SENTINEL data

RTC Future Work on Funding Partnerships

- Monitor success of PCORnet PaCR awards for impact of co-funding
- Actively seek out opportunities to partner with other organizations
- Endeavor to have at least two to five new co-funded projects* in the next two years

*Including PaCR awards

RTC Oversight of Workforce Training Initiative

The RTC ensures that sufficient attention is paid to training a new workforce of PCOR researchers.

- Conduct a field scan to understand the current landscape of workforce training.
- Create a plan for how PCORI can contribute to and increase the availability of training resources.

Workforce Training Initiative Activities

PCORI committed $30 M for a Learning Health Systems Mentored Career Development Program (K12)

Origin

Builds on the work of a **Technical Expert Panel**, convened by the Agency for Healthcare Research and Quality (AHRQ) in 2016 and including PCORI representation to develop a framework and competencies for Learning Health Systems Researchers.

Purpose

To train **clinical and research scientists** to conduct PCOR within learning health systems focused on generation, adoption and application of evidence to improve the quality of care and patient outcomes

Including PCORI Values

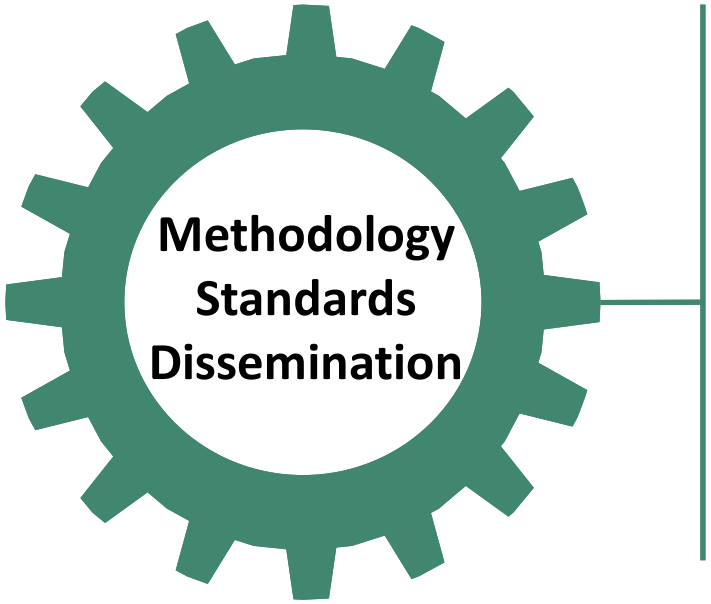
The Program incorporates the **PCORI Methodology Standards** and requires applicants/awardees to address how **patient centeredness**, **patient engagement**, health disparities, and health equity will be incorporated in the training plans.

Applications due by January 2018

RTC Future Work on Workforce Training

- Monitor impact of current PCORI- AHRQ learning health system program
- Consider other opportunities to support workforce training

RTC Oversight of Methodology Standards Dissemination Initiative



The RTC collaborates with the EDIC and MC to provide strategic direction on dissemination activities for the Methodology Standards.

- Ensures appropriate integration of the Methodology Standards in PCORnet

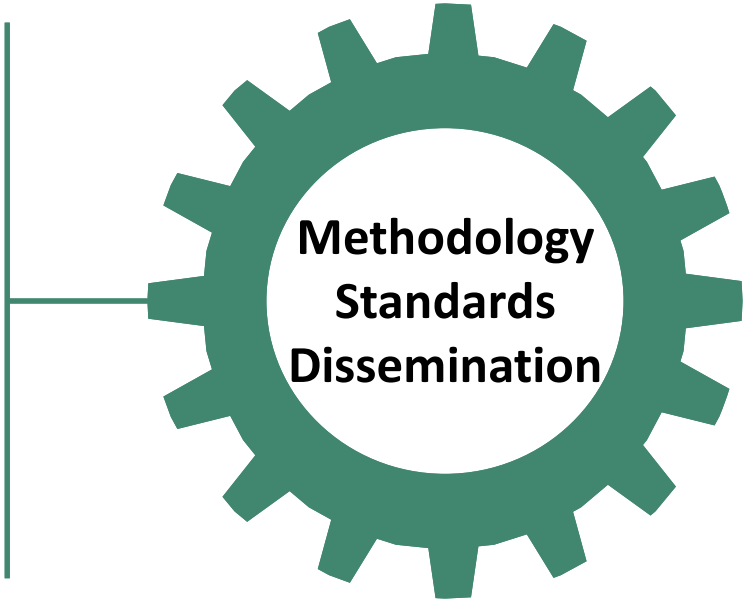
Methodology Standards Dissemination Initiative Activities

(Led predominantly by the MC and EDIC)

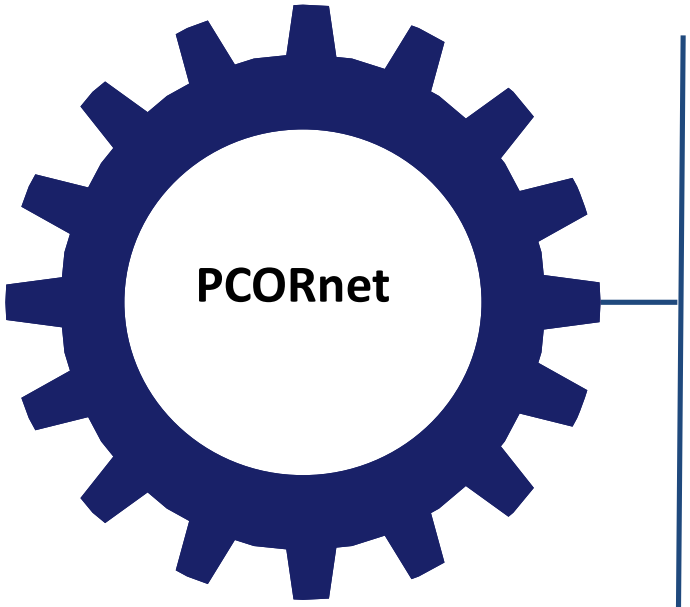
- Supporting integration of the Methodology Standards into continuing education and workforce training initiatives
- Supporting identification of specific standards that may need more targeted dissemination efforts

RTC Future Work on Methodology Standards Dissemination

- Develop enhanced strategies to support dissemination of the Methodology Standards, with a focus on the newly approved Standards
- Encourage the development of processes that assess implementation of Methodology Standards overtime in research funded by PCORI and by others in the research community



RTC Oversight of PCORnet Initiative



The RTC guides strategy for infrastructure development in PCORnet.

- Ensures PCORnet's commitment to patients, clinicians, health systems, and plans
- Monitors governance policies and practices
- Supports the development of and evaluates PCORnet business plan for sustainability
- Pursues external co-funding opportunities to ensure sustainability
- Monitors PCORI-funded demonstration research projects

PCORnet Initiative Activities

Research Examples

- 14 demonstration studies
- 2 major clinical trials
- 8 externally funded or co-funded research projects (as of October 1, 2017)

New Funding Mechanisms

- Rapid Cycle Research – 4 funded projects (diabetes, cancer, hepatitis C, PCSK9 inhibitor)
- Partnerships to Conduct Research (PaCR)

Sustainability Plan

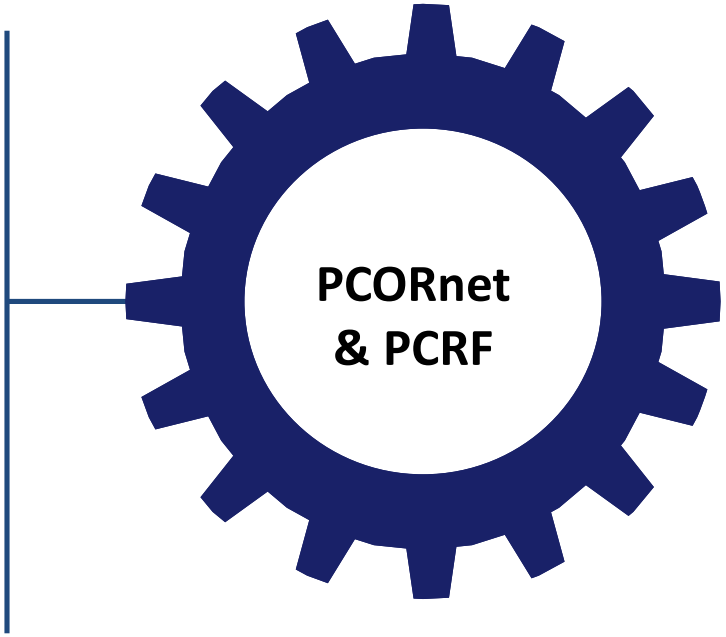
An independent non-profit organization, the People-Centered Research Foundation (PCRF), emerged as the solution for sustainability in serving as a patient-centered national evidence generation platform

Summary of PCORI's Values for PCORnet & PCRF

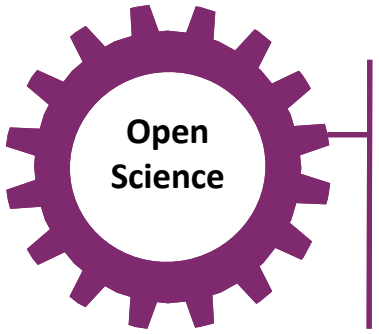
- Provide governance and operational mechanisms for the meaningful **engagement of patients and other stakeholders**, including community members, families, caregivers, clinicians, delivery systems, payors and researchers, in all phases of the research process
- Conduct services through a distributed research network model that is **committed to building a national resource** that is accessible via a central gateway to researchers within and outside of the network
- Conduct services through a network model that **encourages and facilitates the sharing of resources and tools**, including through an on-line "commons" that is available to the networks and public
- Conduct services using a **common data model** that standardizes the definition, format, and content of data across participating data networks so that standardized applications, tools, and methods can be applied to **advance data quality and consistency**
- Provide services using **streamlined and standardized mechanisms**, including centralized IRB models (e.g., SMART IRB) and standardized data use agreements, for the efficient and rapid conduct of research in the network
- Conduct services through a network model that **advances the quality and availability of complete and comprehensive data sets**, including through linkages of disparate sources of complementary data
- Conduct services in **compliance with applicable laws, regulations, and legal requirements**, including but not limited to those governing privacy, security, data, research, and human subjects

RTC Future Work on PCORnet & PCRF

- Monitor the transition of PCORnet to sustainability through the People-Centered Research Foundation (PCRF)
- Evaluate PCRF's business planning and report to the Board
- Consider and make recommendations to the Board on future infrastructure funding to PCRF



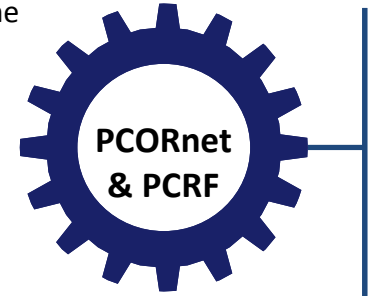
Summary of the RTC Future Work Initiatives



- Evaluate and learn from the pilot
- Recommend a final Policy for Data Access and Data Sharing
- Monitor implementation of Policy
- Monitor other emerging areas

- Develop strategies for dissemination of Methodology Standards
- Encourage development of processes that assess implementation

- Monitor success of PCORnet PaCR awards
- Seek out opportunities to partner with other organizations
- Two to five new co-funded projects* in the next two years



- Monitor transition of PCORnet to sustainability through PCRF
- Evaluate PCRF's business planning and report to the Board
- Make recommendations to the Board on future infrastructure funding to PCRF

- Monitor impact of current PCORI- AHRQ learning health system program
- Consider other opportunities to support workforce training

*Including PaCR projects

Questions for the Board of Governors

How should the RTC prioritize the five initiatives in the coming years?

Are there initiatives that should be added or removed?

Break

We will return at 3:30 pm ET

Join the conversation on Twitter via @PCORI

Discussion Questions

SOC

- What is the best approach to take when faced with an influx of meritorious research applications in response to a funding announcement?
- In light of the fact that our MS Re-post and our Palliative Care calls were highly successful, how do we determine when we have maximized our impact and investment?

EDIC

- Thoughts on the balance of dissemination vs targeted implementation?
- Are there initiatives that should be added or enhanced?

RTC

- How should the RTC prioritize the five initiatives in the coming years? (*Initiatives include Open Science, Funding Partnerships, Workforce Training, Methodology Standards Dissemination, PCORnet*)
- Are there initiatives that should be added or removed?

Public Comment Period

Kristin Carman, MA, PhD

Director, Public and Patient Engagement

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chairperson, Board of Directors