Our Vision
Patients and the public have the information they need to make decisions that reflect their desired health outcomes.

Our Mission
The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

“I’m seeing researchers engaging with patients and changing how they do their research. They’re realizing that they should have been doing this in the first place.”

PETER W. THOMAS, JD
Attorney, Advocate for People with Disabilities, Patient Partner for a PCORI-Funded Study
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Patients, caregivers, and others across the healthcare community are having a more meaningful say than ever before in what traditionally has been the province of scientists. These diverse voices are helping decide which health research questions to study, which outcomes to measure, and how to use research findings to improve health.

As we look back on PCORI's record of achievement in FY 2016, it's clear we have been a leader in creating and advancing this trend—something of which we're very proud.

Incorporating the perspectives of patients and other healthcare decision makers throughout the research process has been PCORI's central commitment since we were established. Our core belief has always been that this approach will yield results far more relevant for everyday care than research designed solely by scientists. For example, scientists may want to measure morbidity and mortality rates, but patients are likely to want to know whether treatments differ in their impact on overall quality of life as well.

As you'll see in this 2016 Annual Report, we are now starting to see the fruits of the groundwork PCORI put in place to accomplish its critical mission—funding comparative clinical effectiveness research (CER) focused on topics and outcomes that patients and other healthcare stakeholders tell us are most important to them.

In the past year, all our Pilot Projects, designed to see how patient-centered CER can best be done, have been completed. The first of our funded CER studies also came to a close. In addition, we put in place the last of the procedures for meeting the unique requirements of our authorizing law: a process for peer-reviewing the studies and providing summaries of those findings that are understandable to a wide audience of stakeholders.

We also point to achievements in improving research methodology, another facet of our mandate, and the exciting growth of PCORnet, the data infrastructure initiative we have funded to enhance the nation's ability to conduct patient-centered health research faster, with more robust findings, and at a lower cost.

All of this work, and the results, influence, and impact we are starting to see it yield, is especially important in today's rapidly changing healthcare environment. From the parents of children going home after hospitalization for serious infections, to patients with chest pain, to men considering initial treatment for localized prostate cancer, to clinicians who want to prevent diabetes, our early research has provided important information people can use to better make decisions.

Our healthcare system is evolving to be more patient centered, efficient, and better able to deliver maximum value to all. The bond between patients and those who care for them is more vital than ever, as patients take on greater responsibility to decide with their clinicians which healthcare options are best for them and their families. They can do that well only if they have reliable, useful information that answers the questions that matter most to them. That is what PCORI is here to provide.

As we look back on our accomplishments in FY 2016, we also focus on meeting our mandate in the years ahead. We do so with ongoing gratitude to the patients, family caregivers, researchers, clinicians, and others across the healthcare community whose generous partnership and support make it possible.

Grayson Norquist, MD, MSPH
Chairperson, PCORI Board of Governors; Vice-Chair, Emory University Department of Psychiatry and Behavioral Sciences; Chief, Psychiatry Service, Grady Health System

Kerry Barnett, JD
Vice-Chairperson, PCORI Board of Governors; President and CEO, SAIF Corporation
CORI's leadership team is pleased to report significant progress in the past year in meeting the challenge that Congress set for us in 2010: to fund comparative clinical effectiveness research (CER) that will help patients and those who care for them make better-informed healthcare decisions.

Our Board of Governors approved $371 million in research and related awards in FY 2016, bringing our total portfolio by year's end to nearly $1.6 billion in funding for CER and related projects—551 in all—since we began funding studies in 2012. About three-quarters of these studies compare different care approaches to determine which work best, for whom, under which circumstances. The rest of the projects either develop improved methods for conducting patient-centered CER or build and enhance infrastructure needed to carry it out.

Over the past year, we continued our stakeholder-guided shift to funding larger targeted studies of conditions that impose a substantial burden on patients, their families, and the healthcare system—with a focus on specific comparative questions. We were especially pleased to see our Board of Governors approve major awards designed to improve care for multiple sclerosis, compare the effectiveness of new oral anticoagulants, and reduce long-term opioid use for chronic pain.

We were pleased to see several of the early CER studies that we funded complete their work in FY 2016 and start moving through the independent peer-review process required by our authorizing law. Those summaries will start appearing on our website by mid-2017. We also continued to see a steady stream of articles resulting from our projects published in major medical journals, a body of work that should grow rapidly in the coming year.

We're particularly pleased at the impressive progress made in the past year by PCORnet, our initiative to harness the power of data and patient partnerships to support more efficient research. Several demonstration studies were under way using PCORnet's resources, and we look forward to the opening of PCORnet to the research community nationwide in 2017.

Our open science initiative also made progress in FY 2016. We released for public comment a draft policy designed to ensure that the data resulting from our funded studies are available for other research. We expect to finalize our policy in 2017.

In addition, we began to implement a major expansion of our Evidence Synthesis program, which will thoroughly review sets of completed studies, funded by PCORI and others, and summarize the evidence. Such reviews can quickly provide useful information to inform practice.

These achievements would be impossible without the guidance of patients and others from across the healthcare community. Their generous support of our commitment to “research done differently” has led to the growing number of examples of our work making health research more patient-centered.

We invite you to learn more about our achievements and plans in the pages that follow.

Joe V. Selby, MD, MPH
Executive Director
Evelyn P. Whitlock, MD, PhD
Chief Science Officer
Jean R. Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer
Regina L. Yan, MA
Chief Operating Officer
Mary C. Hennessey, Esq.
General Counsel
The Path toward Delivering Results That Matter to Patients

PCORI is pleased to point to a clear record of achievement and growing influence this past fiscal year as the nation’s leading funder of patient-centered, stakeholder-driven comparative clinical effectiveness research (CER).

Guided by our National Priorities for Research and Research Agenda, our Board of Governors approved funding this past year for a range of projects comparing drugs, procedures, and other approaches to preventing, diagnosing, and managing diseases and conditions that impose a substantial burden on patients, their families, and the healthcare system. In the process, we continued to focus attention and funding this past year on larger, targeted studies of critical patient-centered research questions that our stakeholder communities told us were important to them.

To complement the research we have funded, we began to undertake a substantial expansion of our Evidence Synthesis program to review available study results on topics of critical concern to patients and other stakeholders. The goal of this activity is to expediently provide stronger evidence than the findings of a single study.

A major achievement of this past year is the implementation of our

FY 2016 MILESTONES

- PCORI partners with American Heart Association on challenge to identify critical research needs
- Board approves $70 million for nine new CER projects, including five more pragmatic clinical studies
- Board approves $12.5 million for five new PCORnet demonstration projects
- PCORI joins CDC and NIH to launch the Natural Experiments Network focused on diabetes
- Engagement Awards program surpasses $20 million in project support
- Board approves funding for five PCORnet demonstration projects focusing on Crohn’s disease diets, depression in the LGBT community, safe use of biological therapies, physical activity among people with mood disorders and heart disease risk, and sleep apnea in people with COPD
FY 2016 ANNUAL REPORT

A process for peer-reviewing results from our research projects and releasing summaries so patients, clinicians, and the public can use them to make better-informed healthcare decisions. Peer review is part of our legal mandate, and we fully embrace it as a natural expression of how seriously we take our name and mission. Our peer reviewers include not just scientists, statisticians, and methodology experts but also patients and other healthcare stakeholders. The goal is to assess not only the scientific integrity of the projects but also their patient-centeredness, stakeholder engagement, and usefulness to patients and others in the real world. The first summaries of results, from our earliest-funded CER studies, will appear on our website by mid-2017.

In January 2016, we initiated a new type of award to further the use of results from the projects we fund. These Dissemination and Implementation Awards enable PCORI-funded investigators to...
undertake activities to disseminate and implement promising research findings.

We moved ahead this past year on three other fronts that seek to make research results more widely available. First, we began requiring our awardees to deposit study-related manuscripts accepted for publication by journals in the federal PubMed Central database, where those papers become freely accessible, typically within 12 months. Second, we agreed to cover the fees that many journals charge for free real-time public access to selected published papers. Third, we drafted a policy on access to, and sharing of, data from our funded studies.

PCORnet, the National Patient-Centered Clinical Research Network continued to make progress in harnessing large-scale health data and stakeholder partnerships to boost the pace and power of health research at lower cost than was previously possible. By the end of FY 2016, the 33 partner networks were engaged in projects to develop and test their capacity to conduct large-scale research. In more than 20 clinical trials and observational studies, researchers started running queries against health records and other data from as many as 145 million individuals. PCORnet also began planning how to enable outside teams to take advantage of the data.

By continuing to fully engage patients and other healthcare stakeholders in all of our work, and also requiring such engagement from our awardees, we moved toward our goal of “research done differently.” We expanded our programs that fund stakeholder-researcher partnerships as they become capable of conducting patient-centered CER. We also created new resources to help research project awardees meaningfully involve patients and other stakeholders in their projects. Finally, we continued to evaluate the impact of engagement on the way our awardees conduct their studies.

We have more examples than ever before of how PCORI’s commitment to engaging patients and other stakeholders in research is influencing others to take a similar approach. In fact, we selected “Changing the Conversation about Health Research” as the theme of PCORI’s second Annual Meeting, to be held at the start of FY 2017. We see that meeting as a platform for people across the healthcare community to come together to hear from national thought leaders, researchers, patients, family caregivers, clinicians, and others about key trends in patient-centered research and improving dissemination and uptake of important research results.

Congress set a substantial challenge for us when it authorized PCORI in 2010—to use patient-centeredness and stakeholder engagement as guiding principles to ensure that CER findings become widely used in clinical decision making. As we enter our seventh year, we’re optimistic that we’re well on the way to making that a reality.

This past year, as more of our earliest-funded studies were completed, we ramped up our process for reviewing the results of those projects and making them available to the public. In anticipation of this forthcoming wave of results, we established a comprehensive program to disseminate important findings to the broader healthcare community through means designed to promote their use.

It is hard to imagine ever doing another study where I don’t start out with patients and families first. It absolutely changes the way we look at a project and the way we do business.

ELIZABETH D. COX, MD, PHD, Associate Director, Department of Pediatrics, University of Wisconsin-Madison
This past year, we saw a number of our earliest-funded patient-centered comparative clinical effectiveness research (CER) studies conclude. Their results started making their way through the peer review process we established to vet the findings prior to their being made publicly available. We also saw a growing stream of papers reporting results from our early studies appearing in the scientific literature and presented at major professional conferences.

At the same time, we continued building our research portfolio, strategically targeting critical research questions with large studies that patients and others across the healthcare community identified as important. To lead this effort going forward, we were pleased to welcome a new Chief Science Officer, Evelyn P. Whitlock, MD, MPH, a nationally recognized expert on evidence-based medicine and research synthesis who came to PCORI from Kaiser Permanente Northwest.

Supporting Crucial Projects
Our Board of Governors approved $371 million in funding in FY 2016 for CER and related projects, bringing our total portfolio to 551 projects and nearly $1.6 billion in investment since we began funding research in 2012. The majority of these studies compare different treatments or care-delivery approaches in an effort to help patients and those who care for them make better-informed clinical and policy decisions. The rest of our funded projects support efforts to improve the methods for conducting patient-centered CER and enhance the infrastructure needed to carry out this research.

As planned from our initial rounds of funding, we continued to focus more attention—and funding—this past year on larger targeted studies of critical patient-centered research questions comparing drugs, medical procedures, and other approaches to disease prevention, diagnosis, and treatment. Two-thirds of the funding our Board approved in FY 2016 went to such projects, bringing our cumulative investment in targeted studies to almost 50 percent of our total research funding to date.
We also continued to support projects on investigator-initiated topics approved under our “broad” funding announcements, which seek the research community’s best ideas for patient-centered CER projects. Our Board approved 44 such awards on topics including postpartum depression, misuse of antibiotics, post-traumatic stress disorder among veterans, and joint replacement.

Preparing to Review the Results of Our Funded Studies
As noted earlier, one of our major accomplishments in FY 2016 was to finalize and begin implementing our authorizing law’s mandate that we peer review our funded research and make the results broadly available to the public within a specific time frame. We have embraced this challenge as an opportunity to substantially increase access by the healthcare community and general public to the results of publicly funded research—regardless of the nature of the findings. Our Board approved a process in 2015 for carrying out this mandate, which is unique among publicly funded US research organizations.

Under our process, clinical researchers, statisticians, and methodology experts review the draft final research reports submitted by our awardees to assess each study’s scientific integrity and adherence to the PCORI Methodology Standards. In addition, although not required by our authorizing law, we engage patients and other healthcare stakeholders to assess each project’s relevance to real-world clinical situations and decision making. To oversee the peer review process, we established a new team within the Office of the Chief Science Officer. The peer review team works with our contractor, Oregon Health & Science University, to recruit peer reviewers and conduct the reviews.

Once we accept each final research report following peer review, our PCOR Translation Center, run by the American Institutes for Research under contract to PCORI, works with the investigators to create summaries of the results for both health professionals and the general public. These must be posted on our website within 90 days of the end of the peer review process. More detail on this process can be found on page 17.
By the end of the year, 14 of our primary research projects had been completed and provided us with their draft final research reports for peer review. The first studies we funded, our 50 Pilot Projects, had closed earlier and provided us with results summaries for staff review prior to posting on our website. The Pilot Projects, designed to explore evidence-based methods and strategies to advance patient-centered outcomes research, spanned a wide range of therapeutic areas and methodological approaches.

**Progress in Building a Platform for Advancing Patient-Centered CER**

This past year was one of major accomplishments for PCORnet, the National Patient-Centered Clinical Research Network initiative that PCORI launched in 2013. It entered its second phase of development in Fall 2015. We envision PCORnet as a way to harness the power of health data and unique partnerships to help the nation conduct patient-centered health research faster, more efficiently, and less expensively than was previously possible.

The main focus of PCORnet’s work this past year was to begin to demonstrate the network’s readiness to serve as an efficient research platform, enhance its underlying technical capacity, and implement its governance structure. PCORnet networks initiated a variety of demonstration research projects aimed at answering important patient-centered research questions.

**EMERGING RESULTS AND GROWING INFLUENCE**

In FY 2016, results from a number of our earliest-funded studies were presented at major specialty meetings and published in top-tier journals. We also saw more examples of how our work is influencing others to make research more patient-centered. Here is a sampling:

**Results**

- A study from the Group Health Research Institute in Washington State found physicians in practices that had implemented an initiative to reduce high-dose chronic opioid therapy showed greater reductions in the prescribing of these drugs than physicians in practices not offered the initiative.
- Researchers at the Children’s Hospital of Philadelphia found that for post-discharge treatment of complicated appendicitis in children, oral antibiotics were associated with lower rates of treatment failure and hospital revisits compared with intravenous antibiotics.
- Mayo Clinic researchers found that among patients who came to an emergency department with chest pain but were at low risk for heart attack, a one-page decision aid safely decreased the rate of hospital admission for further cardiac testing.

**Influence**

- In designing its new commission on patient- and family-centered care, the American College of Radiology looked to PCORI for a successful model of patient engagement.
- The Meharry-Vanderbilt Alliance, citing PCORI’s work, developed pre- and postdoctoral programs in community-engaged research and began including healthcare stakeholders in their grant review process.
- The Center for Medicare and Medicaid Services Quality Measure Development Plan recognized PCORI’s patient/caregiver engagement framework as a best practice.

Among PCORnet’s operational advances was the implementation of a Data-Sharing Agreement (DSA) designed to guide researchers in sharing information gathered from
the various institutions and clinical systems participating in the Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs) of PCORnet. Developed by those PCORnet partner networks, the DSA reduces the administrative burden for individual studies by outlining standard terms and conditions for information sharing between partner networks. Through its Common Data Model (CDM), updated in FY 2016, PCORnet has taken a distributed approach in which individual-level data stay with the CDRNs and PPRNs that collected them, protecting patient privacy.

At the start of the year, PCORnet reported the first view of the data within the CDM, stratified by sex, race, and age, and a detailed look at the data for nine conditions, also stratified by age, race, and sex. By year’s end, PCORnet’s 13 health system-based CDRNs reported the ability—under privacy and security protocols—to access information from about 110 million patient encounters within the past five years and had expanded the list of preliminary conditions to 10 (diabetes, pulmonary disease, malignancy, myocardial infarction, stroke, arthritis, ulcerative colitis, hypertension, renal disease, and influenza/pneumonia).

**Pursuing Research While Building Capacity**

Efforts also continued through the year to demonstrate PCORnet’s capacity to conduct both interventional and observational research studies faster and more efficiently, while ensuring patient privacy and data security. The 14 PCORI-funded demonstration research studies, which address a range of conditions in pediatric and adult populations, include pragmatic clinical trials, interventional and observational studies, and health systems studies.

PCORnet’s first demonstration project, known as ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness), is a large pragmatic clinical trial that compares the benefits and harms of low- and regular-strength daily aspirin doses in preventing recurrence of heart attacks or strokes in people living with heart disease. This trial launched its recruitment efforts in May 2016, using a novel online platform to enroll study participants.

In addition, the study will be conducted in a variety of clinical settings. This also makes ADAPTABLE different from many traditional clinical trials, which often take place in specialized clinical centers.

Meanwhile, work progressed on two large observational studies focused on obesity, one comparing the benefits and risks of the three main methods of bariatric surgery, the other on the possible impact of antibiotics given to infants and young children on their weight in later childhood.

Additional notable demonstration projects under way during the year focused on critical areas of infrastructure enhancement, and several others were designed to show how CDRNs can conduct collaborative research with health systems leaders. This research aims to demonstrate the capacity of PCORnet to provide research findings to support health systems in making critical changes that lead to improved patient outcomes.

**Supporting Open Science**

As part of our commitment to making research more inclusive, patient-centered, and transparent, we moved ahead on several fronts aimed at advancing “open science,” which seeks to make study results and data more widely available. First, we began requiring our awardees to deposit final accepted journal manuscripts resulting from our funded studies in the federal PubMed Central database, following the practice of other major research funders. This database

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**PCORnet ACCOMPLISHMENTS TO DATE**

PCORnet is a distributed research network that unites patients, clinicians, health systems, and health plans in an effort to expedite research that can improve health care and patient outcomes. PCORnet includes:

| 145 million | patients who have had a medical encounter in the past five years |
| 33 | engaged, collaborating partner networks |
| 130+ | partnerships with health systems and patient groups |
| 150+ | common and rare conditions |
| $50 million | in PCORI-approved funding to support demonstration projects |
makes those papers freely available, typically within 12 months after their publication. For selected published papers, we also agreed to cover the fees many journals charge for free real-time public access; more details can be found starting on page 17.

We also drafted a policy on access to, and sharing of, data from our funded studies. This proposed policy sets forth expectations and guidelines for our awardees to follow in managing their data. The goal is to facilitate reproduction of original analyses of findings as a means of validating their scientific integrity and to allow researchers to conduct additional analyses using data from PCORI-funded studies.

In drafting the policy, we received input from several groups. In addition to PCORI's Research Transformation Committee, which is made up of members of our Board and Methodology Committee, we created an external advisory group composed of leading open science experts. We also conferred with other funders and regulators of clinical research, including the National Institutes of Health, the Gates Foundation, and the European Medicines Agency. We then prepared the draft policy for public comment.

We also planned a pilot project designed to bring some of our awardees together with selected data repositories as a first step toward seeing how our proposed data-sharing policy could work in practice. Through this pilot, we expect to learn which features and capabilities of repositories are most critical for effective data sharing and what the associated costs to both PCORI and our awardees might be. The final data-sharing policy will take into account what we learn from the pilot project.

Helping Patients with Chest Pain Make Decisions in the Emergency Department

ROCHESTER, MN—Chest pain accounts for about 6.5 million visits to US emergency departments (EDs) every year. Most of these patients are not diagnosed with a heart attack, yet many who test negative in the ED are still admitted to the hospital for further testing.

A Mayo Clinic study tested a simple decision aid to help such patients and their doctors decide whether to undergo the additional tests. The aid was a sheet of paper giving the individual patient's risk for future heart attacks and explaining testing options.

The study included 898 patients considered low risk for heart problems after tests in EDs at six hospitals. The researchers randomly assigned patients to either usual care or that care plus the decision aid. Just 37 percent of patients who used the aid opted for further testing, compared with 52 percent who received only usual care. To find out whether patients went on to experience major heart problems, a researcher called them 45 days after the ED visit.

The result: the choice to forgo additional testing did not translate into more heart problems in the following days.

See more at pcori.org/research-in-action

Improving Research Methodology

In FY 2016, PCORI's Methodology Committee worked on a series of updates and revisions to the Methodology Standards our Board had adopted in November 2012 to guide the development and conduct of patient-centered CER that produces valid, useful evidence leading to improved patient care and outcomes.

The initial set included 47 standards in 11 categories. This year, the Methodology Committee began working toward adding a new category—Standards on Research Designs Using Clusters. The updated standards were posted for public comment, and we began revising them in response to the feedback received. The committee also prepared some revisions to the accompanying Methodology Report to reflect the updated standards, as well as broader methodological advances and emerging challenges for PCOR. Our Board is expected to consider adopting the revised standards during FY 2017.

Along with revisions of the standards and report, the Methodology Committee also worked to ensure that our Board and our scientific advisory committees have an adequate supply of expertise in support of PCORI’s mission. As a result of the committee’s outreach efforts, the number of Board members with methodological expertise increased this year.
Committee continued to work with PCORI’s Board, leadership, and stakeholders, including our advisory panels on clinical trials and rare disease, to advance understanding and appropriate use of methods for PCOR. The committee identified several priorities for new standards to be developed in FY 2017 (complex interventions, qualitative methods, data management and data quality, individual participant data, and network meta-analysis) and began work on complex interventions.

Reviewing and Strengthening Evidence

This past year, we began putting into place a major expansion of our Evidence Synthesis initiative, our latest approach to making authoritative, relevant, useful information from CER studies available to help patients and caregivers make better-informed decisions. This initiative complements the hundreds of patient-centered research studies we’ve funded.

The program includes rigorous reviews of the best evidence available on topics of critical concern to patients and other stakeholders. The goal is to synthesize all relevant completed studies, from all funders, on a specific clinical question to provide evidence that is stronger than the results of each individual study.

We made plans to implement the initial effort as part of our long-standing collaboration with the Agency for Healthcare Research and Quality (AHRQ). We also began making plans to fund projects that reanalyze data from already-completed studies to discover which specific groups of patients gain the most, or are at greater risk for harms, from an intervention. And once we have synthesized the evidence, we plan to disseminate it through products designed to meet the needs of our various stakeholders.

It’s important to have the patient voice from the very beginning. Ultimately, that’s the purpose of healthcare service delivery—it’s to improve health.

KIMBERLY JINNETT, PHD, Research Director, Center for Workforce Health and Performance

RESEARCH PROJECT SNAPSHOT

To Fight Serious Infections in Children, Pick the Easier Way

PHILADELPHIA, PA—Each year, thousands of children in the United States get serious infections that are treated in a hospital with intravenous antibiotics. When those children are ready to go home, doctors face a choice. The child can receive a peripherally inserted central catheter (PICC) line, which lets parents administer antibiotics intravenously at home for several weeks. Or the doctor can prescribe oral antibiotics.

By examining data from the medical records of more than 15,000 children, Ron Keren, MD, MPH, a pediatrician at Children’s Hospital of Philadelphia, and his team have now demonstrated that for complicated appendicitis, children on oral antibiotics did at least as well as children receiving the medications intravenously through a PICC line.

The study had previously reported that oral antibiotics were as effective as intravenous ones for the bone infection osteomyelitis. Oral antibiotics avoid such problems as infection, clotting, and displacement of the PICC line.

See more at pcori.org/research-in-action

Project Title: Comparative Effectiveness of Intravenous versus Oral Antibiotic Therapy for Serious Bacterial Infections

Principal Investigator/Awardee: Ron Keren, MD, MPH, Children’s Hospital of Philadelphia

Goal: Using information from a large database of children’s hospital patients, compare the effectiveness and safety of two methods for delivering home antibiotic treatment for serious bacterial infections

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
FY 2016 marked a year of continued progress in our efforts to ensure that patients and other healthcare stakeholders are fully engaged in our work and that of our awardees. This approach—which we call “research done differently”—has been a core commitment for PCORI since our creation. By working closely from the start with the end users of the results of our work, we seek to ensure that the studies we fund ask the right questions, measure the outcomes most important to patients, and produce relevant and useful results that will be adopted into practice.

We convened scores of stakeholders throughout the year to provide input on potential research opportunities and to help us prioritize specific research topics and questions for potential funding. We made awards to expand the community of patients and other healthcare stakeholders prepared to become involved in patient-centered research, and we saw our first research award to a project developed through our Pipeline to Proposal program.

And as our earliest-funded research studies began to yield results, we established a comprehensive program to broadly disseminate the findings to the healthcare community in forms and formats designed to promote their implementation and appropriate use.
Working with the Healthcare Community to Shape Our Research Portfolio

We continued to work with patients, clinicians, researchers, and others across the healthcare community to prioritize the topics and questions that our funded studies should address. We convened more than 200 representatives of patient and other stakeholder organizations for a series of workgroups, roundtables, advisory panel meetings, and other gatherings to advise us on high-priority topics to consider in our research funding announcements.

Stakeholders put palliative care, prevention of opioid abuse, and management of sickle cell disease at the top of their lists. In response, we convened several stakeholder groups to talk to us about their unique needs and perspectives, give us feedback on our current research portfolio, and suggest new topics for us to consider. The groups included primary care physician and aligned societies, medical specialty societies, nursing specialty societies, employers, insurers, and industry representatives.

Expanding the Community Prepared to Partner with Researchers

In FY 2016, we expanded our programs that provide funding to patients, researchers, and other stakeholder organizations for a series of workgroups, roundtables, advisory panel meetings, and other gatherings to advise us on high-priority topics to consider in our research funding announcements.

Of our previously funded Engagement Awards projects, 18 were completed in FY 2016. These resulted in widely available training curricula on PCOR/CER and numerous peer-reviewed journal articles and other reports. For example, one innovative, online training strengthens the capacity of community health.

Eugene Washington PCORI Engagement Awards

This program supports projects that integrate patients and other stakeholders into healthcare research or create new channels to disseminate study results. In FY 2016, we issued 100 Engagement Awards, totaling $20 million, to a broad variety of stakeholder organizations.

Awardees included organizations of patients, clinicians, training institutions, hospitals, and industry. About half of the awards went to projects focused on creation of knowledge, training, or development programs, or laying the groundwork for the dissemination of evidence. The other half provided funding for meetings and conferences that align with PCORI’s goals and facilitate expansion of PCOR and CER.

The patients’ voice matters in the doctor’s office. PCORI research is showing how important patients’ voices are in research, too.

TERRY SUMMERLIN, MA, Volunteer, Arthritis Foundation, and Patient Caregiver
centers to participate in PCOR/CER. With another award, a conference brought together Utah researchers, patients, employers, and insurers to develop a network promoting patient and community engagement in PCOR.

**Pipeline to Proposal Program**

These awards aim to strengthen relationships between researchers and patients, along with other stakeholders, to build capacity for community participation in research. The program supports community partnerships to create and develop research questions that eventually lead to patient-centered research proposals. In FY 2016, the three-tiered program funded 112 partnerships, both new projects and ones moving on to the next phase (see table).

Two projects within our first cohort successfully submitted a Letter of Intent to a PCORI Research Funding Announcement and were invited to submit a proposal. One of these—a New Mexico project on culturally appropriate programs for Latinos with diabetes—became the first Pipeline award to result in a PCORI-funded research study.

We also developed a plan for our first Independent Tier III awards. In FY 2017, we will begin making these awards to groups that have already identified their partners and developed CER questions. The awards will give these groups the opportunity to receive training on patient engagement to strengthen their PCOR proposals.

**Educatig Researchers and Other Healthcare Professionals**

To promote effective engagement of patients and others across the healthcare community in research, we expanded our Continuing Medical Education (CME) portfolio and other training resources. A new course helps researchers apply the PCORI Engagement Rubric’s principles to planning, conducting, and disseminating healthcare research. The rubric, first posted in 2014 and updated last year, provides guidance for investigators on how to engage patients, caregivers, patient or caregiver organizations, and other stakeholders into the research process. It includes promising practices identified in studies from our portfolio, a variety of options

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**PIPELINE TO PROPOSAL AWARD TIER STRUCTURE**

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**Engagement Project Spotlight**

**Improving Advanced-Illness Care in African Americans**

WASHINGTON, DC—Research shows that African Americans tend to receive substandard advanced-illness care, which can include inadequate symptom management, poor patient-provider communication, care inconsistent with their preferences, and higher rates of hospitalization. This is thought to be due to patients’ mistrust of the healthcare system and negative experiences in clinical encounters. Interventions to address these disparities often fail because of insufficient patient and community engagement.

Faith-based organizations serve as a trusted leader within the African-American community. The Coalition to Transform Advanced Care (C-TAC) has partnered with several churches, researchers from Johns Hopkins Medicine, and other groups. They plan to develop a nationally representative, community-led network of African-American churches trained to participate in patient-centered outcomes research that addresses disparities in advanced-illness care among African Americans. With this project, the partnership is hosting two national and two regional workshops.

**Project Title:** UNITED in Faith, Health, and Strength

**Principal Investigator/Awardee:**

The Reverend Dr. Tyrone Pitts, D. Min, Coalition to Transform Advanced Care (C-TAC)

**Goal:** To host national and regional workshops to develop a nationally representative, community-led network of African-American churches and other faith-based organizations trained in patient-centered outcomes research and ready to participate in research that addresses health disparities for those with advanced illness.
for incorporating engagement effectively, and examples of successful engagement plans.

We also sought to address a need identified through ongoing reviews of our portfolio: many of our funded projects involve the collaboration of research teams at more than one institution, but researchers typically have little training in how to direct or participate in such efforts.

Because such collaborations are often necessary to address difficult healthcare questions, we launched a team-science initiative. The effort addresses team members’ roles in performing collaborative science and enables diverse team members (e.g., patients, researchers, other stakeholders) to obtain the necessary skills to work interdependently.

Ramping Up Our Dissemination and Implementation Efforts
We know the results of studies we fund will be useful only if they reach those who need the information to make better-informed health and healthcare decisions. So, during FY 2016, as some of our earliest studies reached completion, we established our Dissemination and Implementation (D&I) program. Its first task was to put in place a structure for translating findings from our funded studies into easily accessible materials for a range of decisions.

CONTINUING EDUCATION PROGRAMS

In FY 2016, PCORI offered four online continuing education programs:

- The Role of Patient-Centered Outcomes Research in the Current Healthcare Landscape
- PCORI Methodology Standards
- Osteomyelitis in Children
- Guidance from the PCORI Engagement Rubric

Participants claimed 6,380 CME/CE certificates from these courses.
professional and public audiences. This activity is performed in conjunction with our peer review of study final reports and, like that process, is mandated by our authorizing law.

We see this undertaking as more than a legal requirement, however. It is an essential element of our mission to serve our stakeholders and the public transparently by ensuring that the results of all of the projects we fund are easily available to anyone who wants to access them.

Translating and Making Research Results Widely Available
Under our authorizing law and the process our Board of Governors adopted to implement it, summaries of the findings from our funded projects must be posted to our website within 90 days of our accepting awardees' peer-reviewed final research reports. We will post 500-word professional and lay-language summaries presenting each study and its findings, with Spanish, audio, and downloadable versions of the lay-language text.

To facilitate this challenging process, our D&I program contracted with the American Institutes of Research to set up the PCOR Translation Center to prepare the summaries of results in collaboration with the investigators, as well as to revise our online summaries of projects still under way to make them more useful and accessible to the public. The center assembled a technical expert panel to advise on health literacy, content usability, and other translation issues.

As part of our mission to engage patients at all points during the research process, acknowledge the contributions of study participants, and help patients receive the greatest possible benefit from their research participation, we will supply our awardees with the 500-word public abstract that we produce, so they can provide that abstract to study participants and project partners. A substantial majority of PCORI awardees that we surveyed were already making plans to provide study results to patients and other partners, via presentations, website postings, and newsletter articles, as well as distribution of summaries.

The D&I program oversees PCORI's policy to promote public access to journal articles reporting the major findings of the studies we fund. Under this policy, awardees may request funds to cover the fees many publishers charge to allow free access to journal articles.

Using PCORI Evidence: Getting Started
In January 2016, the D&I program launched dissemination awards, which enable PCORI-funded investigators to themselves further disseminate and promote implementation of promising research findings. Research teams that have completed PCORI-funded projects can apply for additional funding to improve their findings'
usefulness, uptake, and impact among targeted users. By the end of FY 2016, merit review had evaluated the first set of applicants to this award program.

During the past year, PCORI also substantially strengthened our ongoing collaboration with the Agency for Healthcare Research and Quality (AHRQ) to disseminate PCOR findings. We provided input on the process AHRQ was developing for accepting and reviewing nominations of findings for dissemination, and we submitted several findings as part of the agency’s initial set of nominations.

In planning for our second PCORI Annual Meeting, we expanded on the first meeting’s success by further exploring the role of patient-centered research in enhancing clinical and self-care, and emphasizing results emerging from our earliest-funded research.

Patients appreciate engagement because it feels personal and it lets them know someone cares. And we really do care.

TOYA BURTON, DC, MPH, Chiropractor and Health Educator, Whatley Health Services, Inc.

Reaching Out through More Channels
In FY 2016, we expanded our outreach through a variety of channels. We continued to provide new content on our website, featuring our activities and highlighting the exciting projects that we have funded.

We put energy into making a place for PCORI on social media platforms. We developed daily and weekly content for Twitter, Facebook, and LinkedIn. With a variety of campaign efforts, we drove the number of PCORI’s Twitter followers to more than 10,000. Our cumulative Twitter reach (the number of Twitter users who had potential access to our posts) was over 114 million.

We used Twitter, Facebook, and LinkedIn to drive Annual Meeting registration and extend meeting reach through live online conversations. Meeting hashtag (#PCORI2015) generated 6,825
tweets with a Twitter reach of 19.2 million. We also used social media to crowdsource the topic for one of the meeting’s breakout panels. The winning topic, The Value of PCOR in the Real World, received more than 800 votes. This resulted in a standing-room-only session, with another 700 watching via webcast.

In other uses of social media, we also hosted Twitter chats on Alzheimer’s disease, autism research, and, in partnership with Health Affairs, patients’ and consumers’ use of evidence. We live-tweeted Capitol Hill briefings on mental health and Alzheimer’s disease research. We also used Twitter to promote PCORI involvement in two federal health initiatives: the Cancer Moonshot and Precision Medicine.

During the past year, the list of subscribers to our email alert and newsletter continued to grow to more than 15,000 and remained an important source of generating website traffic.

As more of our funded research projects began to generate results, we were pleased to see that work gain substantial attention in both consumer and professional media, including leading medical journals. Almost 200 journal articles associated with PCORI-funded projects were published during the year.
We continued this past year to assess PCORI’s progress toward our major strategic goals of increasing the quantity and quality of evidence available to answer important health questions, speeding uptake of study findings, and influencing other organizations to incorporate patient and other stakeholder engagement in research and to become more patient centered.

We also continued to measure the effect of engagement in research, learning more about how involving patients and other healthcare stakeholders in the projects we fund improves the way those studies are designed and conducted and the usefulness of those results.

Tracking Our Progress
To help us track progress toward our strategic goals, PCORI’s Evaluation Framework organizes the questions we ask about how our approach to research ultimately affects the impact of the studies we fund on health decisions, care, and outcomes. In FY 2016, we collected information from a variety of sources—from PCORI merit reviewers to awardees and research partners to users of research evidence—to begin answering the questions posed in the framework.

Using Evidence to Improve Processes and Assess Impact
For example, to track the influence of our work, we conducted interviews with researchers and others at Johns Hopkins University, the University of Pittsburgh, and elsewhere who were incorporating patient-centeredness into research and creating training programs for patient-centered comparative clinical effectiveness research (CER). We also examined publications, academic and continuing education courses, social media, and statistics about page views and downloads from our website. We found that use of the PCORI Methodology Standards is increasing, and that many awardees and other researchers report that they plan to engage patients and other healthcare stakeholders in their future studies.

We also improved the dashboard we use for quarterly reporting on our progress to our Board of Governors in their public meetings, increasingly incorporating measures of progress toward our goals along with earlier measures of output and process. As PCORI-funded projects have begun generating results and share findings, we are closely tracking how these results contribute to healthcare decision making. Our FY 2016 dashboard, for example, focused on published results from our first completed studies, measures of their dissemination and uptake, and examples of PCORI’s influence on research. The dashboard will continue to evolve to reflect progress toward our goals.

Examing Our Portfolio and Processes

To guide PCORI’s funding decisions, we regularly examine our research portfolio and ask how our work meets gaps in needed evidence. We also study our application, merit review, and engagement processes to see how well we are meeting our goals and to identify areas for improvement. These analyses provided information that led to improvements in our processes.

To help us examine our research portfolio to report what PCORI funds and evaluate PCORI progress, we finalized a taxonomy that categorizes our funded projects by disease/condition, populations studied, study design, comparators, health outcomes measured, and many additional characteristics. We used this taxonomy to analyze the contents of our current portfolio and begin building a foundation for characterizing PCORI’s contribution to patient-centered CER.

Our taxonomy also helps us to identify gaps in knowledge that our funded research might fill. Staff have used the taxonomy to see how PCORI research projects align with the Institute of Medicine’s 100 Initial Priority Topics for Comparative Effectiveness Research, to identify studies that can address stakeholders’ key questions and needs for evidence, and to support our advisory committees as they help us to prioritize our research agenda. Staff looked at how our portfolio compares with work funded by other sources. Such analysis ensures that the work we support efficiently meets information needs of patients, clinicians, and other healthcare stakeholders without duplicating research funded by other organizations.

To improve our application and review processes, we used information from ongoing surveys as well as focus groups to make refinements during FY 2016. For example, applicant survey results contributed to our decision to streamline materials on our website and reduce the length of our research funding application. We also used the information to help us fine-tune our merit review process, such as changing from online training modules to a downloadable manual.

Feedback from reviewers who had previously served on review panels was particularly helpful in redesigning training, permitting us to further differentiate materials for new reviewers from those for more experienced reviewers. We now point out any changes in the merit review process for returning reviewers and assign mentors for patient and stakeholder reviewers during their first review. We also completed an in-depth analysis of reviewer critiques of funding applications. Knowing the ways in which reviewer comments improved resubmissions will help improve communications with applicants.

Our analyses also helped us communicate more effectively about our funding process with patients, clinicians, and
other healthcare stakeholders, supporting our efforts to do our work transparently. This effort also facilitates ongoing stakeholder input into our funding process and research agenda by identifying areas that are already well funded and helping us prioritize areas of focus for dissemination of research findings as studies are completed.

This year, we also learned more from patients, caregivers, researchers, clinicians, employers, insurers, and drug and device makers about the kinds of research that can help in their decision making, how they judge whether research results can be trusted and used, how they obtain their research information, and whether they think engagement in research improves the usefulness of results.

We put our findings to use in communicating about the different way PCORI-funded research is conducted, relative to research funded by others. We published our results as three companion papers in the *Journal of Comparative Effectiveness Research*, and we held public webinars to share findings from different stakeholder groups. We learned that clinicians are a trusted source of health information for most patients, but many clinicians do not think they get research results quickly enough to support the many clinical decisions they must make. This finding underlines the importance of initiatives to widely and effectively disseminate the results of our funded research.

**Meaningful Stakeholder Contributions to Research Projects**

In other work during the past year, we learned more about researchers’ experiences with engagement in our funded studies. We also continued to ask patients and other stakeholder partners to report their experiences. We used this information to answer questions about how engagement in research is implemented across diverse projects and what impact it has on the project and the research team.

We heard from both researchers and their stakeholder partners that the partners made meaningful contributions to studies. These included refining research questions; helping select the study design, interventions, comparators, and outcomes; and collecting data. As PCORI’s projects progress, we increasingly hear that patients and other stakeholders are influencing later phases of research, such as data analysis, interpretation of results, and dissemination. For example, some partners coauthored journal articles or presented study findings in their community and at national conferences.

We also heard from researchers and their partners about challenges they have encountered in their partnerships, as well as strategies that facilitate research engagement.

This past year, we also began to classify our studies according to engagement practices. Different types of stakeholders are involved in different projects, and PCORI projects demonstrate engagement with these partners in a range of study phases, from formulating research questions, to deciding on outcomes to measure, through helping to get the word out about study findings. Patient and other stakeholder partners are also involved to different degrees. At the highest level are stakeholders who serve as co-investigators along with researchers. On other projects, they participate in a variety of other ways, such as providing consultation through advisory boards.

Our review of the rich mix of types of engagement led to a method for assessing how the impact of research engagement differs by type of engagement. As projects continue to be completed, this method will help us understand how different models contribute to uptake and use of research findings and how patient-centered CER contributes to improving health outcomes.

**Review by the Government Accountability Office**

Under our authorizing law, the
US Comptroller General must review PCORI’s activities at least every five years. The first of these Government Accountability Office (GAO) reviews, released in March 2015, found PCORI had met its initial legislative requirements for establishing priorities and processes for funding CER, developing dissemination plans for research findings, and creating evaluation plans for assessing progress on achieving its strategic goals.

In 2017, the GAO will be conducting its mandated review of PCORI, due to Congress by March of 2018. PCORI staff will be working to ensure the highest level of responsiveness to GAO’s requests for information.

**Improving Governance and Operations**

This past year, the PCORI Board of Governors did not adopt any amendments to the PCORI Bylaws. To reflect the growth and development of PCORI, our Board approved updates to several core corporate and governance policies that had been adopted in PCORI’s early years. In September 2016, the Board approved a revised Delegation of Authority and Expenditure Approval Policy as recommended by the Finance and Administration Committee (FAC). This policy specifies who has the authority to execute agreements or otherwise bind PCORI and who can authorize payment execution, subject to Board-approved budget, expenditure limits, and applicable controls and approval requirements.

Also in September, again as recommended by the FAC, the Board allowed PCORI’s initial Record Retention Policy, adopted in 2011, to terminate. The Board granted PCORI executive staff the authority to approve an updated version of the policy and appropriate amendments in the future. With input of the FAC, PCORI staff created, and executive staff approved, a new Record Retention Policy. It reflects current legal requirements and provides additional details on retention of core operational and governance records.

In addition, the Board approved amended charters for its three strategy committees—the Engagement, Dissemination, and Implementation Committee; Research Transformation Committee; and Science Oversight Committee—and also the Methodology Committee, Selection Committee, and several advisory panels. The revisions clarify responsibilities and make the charts’ language consistent, where applicable. All committees review their charters annually and may recommend revisions to the Board.

Finally, in accordance with PCORI Bylaws and charters, the Board approved recommended nominees for chairs, vice chairs, and members of various PCORI committees and advisory panels.
As PCORI marks the start of our seventh year as the nation’s primary funder of patient-centered comparative clinical effectiveness research (CER), we look forward to a full plate of activities building on the substantial progress we made during FY 2016. We do so knowing that our work has never been more relevant, as the fast-moving changes affecting our healthcare system make it more important than ever that patients and those who care for them have the information they need to make critical choices about their care options.

Our focus in the coming year will be the growing collection of results that will be emerging from our completed primary CER studies, starting with those we funded during our first round of such awards in 2012. We expect up to 150 such studies to have completed their research by year’s end. We will start posting professional and lay language summaries of the results of the studies on our website after the projects have completed the required peer review. We also will post summaries of the outcomes of all the 50 PCORI Pilot Projects we funded to explore how to best conduct patient-centered CER.

In addition, we expect our funded research to yield a rapid increase in scientific articles appearing in major professional journals, joining the scores of such articles already published and listed on our website. We also have started covering the costs of making articles summarizing the main results of completed studies free of charge as soon as they are published. We also expect to see more examples of how our work is changing the conversation about the way health research is conducted in the United States and, in the process, having an impact on the culture of research itself in academic, government, and industry settings.

We will, of course, continue to fund new research designed to help patients and those who care for them make better-informed healthcare decisions. In FY 2017, we expect to make available about $400 million in funding for research projects. As in recent years, we will emphasize large focused studies of...
critical patient-centered research questions that stakeholders tell us are important to them. By year’s end, we expect about half of our total portfolio to be invested in such studies. Topics in the pipeline for consideration include surgery for rotator cuff tears, treatments for opioid-use disorders, hospital discharge care for patients with traumatic brain injuries, and symptom management for patients with advanced illness.

In an exciting FY 2017 milestone, PCORnet will become a truly national resource for conducting large-scale patient-centered health research more efficiently, faster, and at lower cost than has been previously possible. PCORnet’s resources and capacities will become available to all interested researchers and research funders, under a set of governance policies and processes designed to ensure that our investment of public funds in this transformative effort continues to serve the public interest. The PCORnet Front Door will enable outside research teams to access the network’s resources. Soon after, the PCORnet Commons, a platform for collaboration and resource sharing, will be launched.

Development of the PCORnet networks will be largely complete at the end of FY 2017. The six newest networks will have developed their data resources, and all will have conducted individual and joint research projects. The two PCORnet demonstration studies related to obesity are on track to provide their initial results during this year. PCORI also anticipates committing additional funding for PCORnet research initiatives.

Finally, to advance PCORI’s goal of a sustainable national patient-centered research network, a group of PCORnet researchers will work on a plan for the network’s long-term sustainability.

As part of our effort to support the burgeoning open-science movement, we expect to finalize PCORI’s Data Sharing Policy, so that data resulting from our funded studies can be made available to others to build on that work to further benefit patients. We also expect to see the first products of our Evidence Synthesis program, which will undertake thorough reviews of completed studies, funded by PCORI and others, to produce summaries of the resulting evidence to help patients and their clinicians make better decisions.

And we will release the first major update to our Methodology Standards, important guideposts for ensuring the quality and patient-centeredness of CER. The Methodology Committee plans to add a 12th category of standards, for causal inference methods, and update the Methodology Report, which details the context and rationale for the standards.

In FY 2017, the Government Accountability Office (GAO) will initiate its second review of our work, which is mandated by our authorizing law. Throughout the year, PCORI staff will be working to ensure the highest level of responsiveness to GAO’s requests for information. The report is due to Congress by March 2018.

Finally, we know that none of what we have done or hope to achieve in the coming year and beyond would be possible without the help of patients and others across the healthcare community who have been willing to engage with us from the beginning. We look forward to their ongoing guidance and support with tremendous appreciation.

“We ultimately are in this business to help patients, and their caregivers, and their families to overcome the challenges of the disease or condition they live with. So by including them in research, it enriches our research. It lets us grow as professionals and makes patients healthier and happier.”

NATALIA LOSKUTOVA, MD, PHD
Director of Evaluation, The American Academy of Family Physicians National Research Network
FY 2016 and FY 2017 Budgets

Note: Our authorizing legislation requires that our Annual Report include PCORI’s budget for the year following the period covered by the report. The independent audit of our FY 2016 financial report, provided to Congress by the US Government Accountability Office, is available here: www.pcori.org/sites/default/files/PCORI-2016-Financial-Report-and-Audit.pdf

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**FY 2016 Operating Expense** (Actual)

- Administrative Support: 7%
- Program Support: 3%
- Program Expenses: 90%

**FY 2017 Operating Expense** (Budgeted)

- Administrative Support: 7%
- Program Support: 3%
- Program Expenses: 90%

**FY 2016 Awards Funding Commitment** (Awards Approved)

- Total: $393M
  - Engagement: $23M (6%)
  - Infrastructure: $43M (11%)
  - Research: $327M (83%)

**FY 2017 Awards Funding Commitment** (Planned)

- Total: $483M
  - Engagement: $27M (6%)
  - Infrastructure: $34M (7%)
  - Research: $422M (87%)
APPENDIX TABLE OF CONTENTS

I. PCORI Conflict of Interest Disclosures ................................................................. A1
II. Approved Research Contracts and Awards ......................................................... A7
CONFLICT OF INTEREST DISCLOSURES

The Patient Protection and Affordable Care Act, which authorized the establishment of the Patient-Centered Research Institute, requires PCORI to disclose any conflicts of interest of its Board of Governors, Methodology Committee, and executive staff. The Act defines “conflict of interest” as: “an association, including a financial or personal association, that have the potential to bias or have the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities under this section." Below are the associations reported by PCORI’s Board of Governors, Methodology Committee, and executive staff. Disclosures reflect those reported to PCORI as of March 31, 2017.

BOARD OF GOVERNORS

Sharon P. Arnold, PhD
As of February 27, 2017
Financial Associations
• Agency for Healthcare Quality Research, Employer
• Pfizer, Stock, Self
• Proctor and Gamble, Stock, Spouse
• Roche Holding AG, Stock, Self
• McKesson Corporation, Stock, Self
• Merck, Stock, Self
• Express Scripts, Stock, Spouse
• Bristol-Myers Squibb, Stock, Spouse
• Amgen, Stock, Self
• Abbott Laboratories, Stock, Self
• Gilead Sciences, Stock, Child
• Eli Lilly and Company, Stock, Self

Personal Associations
None reported

Debra Barksdale, PhD, RN
As of February 4, 2017
Financial Associations
• Virginia Commonwealth University, Employer
• Josiah Macy Jr. Foundation, Conference Planning Committee

Personal Associations
• American Academy of Nursing, Member
• American Association of Colleges of Nursing, Member
• National League for Nursing, Member
• National Organization of Nurse Practitioner Faculties, Member
• Robert Wood Johnson Executive Nurse Fellows Alumni Society, Member

Kerry Barnett, JD (Vice Chairperson)
As of December 22, 2016
Financial Associations
• SAIF Corporation, Employer
• Gastroenterology Medical Practice, Employer, Sibling

Personal Associations
• Cambia Health Solutions, Former Employer

Lawrence Becker
As of December 22, 2016
Financial Associations
• N3/Xerox Corporation, Employer
• Aetna, Stock, Self
• Amgen, Stock, Self
• Amino, LLC, Advisory Board Member (Compensated Position)
• Bristol-Myers Squibb, Stock, Self
• GE Healthcare (Managed Portfolio), Stock, Self
• GlaxosmithKline, Stock, Self
• Johnson & Johnson, Stock, Self
• LSB Consultants, LLC, Owner, Spouse
• Pfizer, Inc., Stock, Self
• SPDR Biotech, Stock, Self
• The Travelers Companies, Inc., Stock, Self
• University of Rochester Medical Center, Employer, Sibling
• Ventas (Managed Portfolio), Stock, Self

Personal Associations
None reported

Francis S. Collins, MD, PhD
As of January 24, 2017
Financial Associations
• National Institutes of Health, Employer

Personal Associations
• American Academy of Nursing, Member
• American Association of Colleges of Nursing, Member
• National Academy of Medicine, Member
• National Academy of Sciences, Member

Allen Douma, MD
As of January 27, 2017
Financial Associations
None reported

Personal Associations
• Jefferson Regional Health Alliance, Board Member

Alicia Fernandez, MD
As of March 7, 2017
Financial Associations
• University of California, San Francisco, Employer

Personal Associations
None reported

Christine Goertz, DC, PhD
As of January 27, 2017
Financial Associations
• Palmer College of Chiropractic, Employer
• American Chiropractic Association, Consultant
• Healthwise, Inc., Consultant
• Prezcor, Inc., Stock
• Quality Insights of Pennsylvania, Consultant
• Quality Insights of Pennsylvania Technical Expert Panel #131, Pain Assessment, Member
• Quality Insights of Pennsylvania Technical Expert Panel #182, Functional Outcome, Chair
• RAND Corporation, Consultant
• Spine IQ, CEO

Personal Associations
• American Chiropractic Association, Member
• American Public Health Association, Board Member
• Chiropractic & Manual Therapies, Editorial Board Member
• Journal of Manipulative and Physiological Therapeutics, Editorial Board Member
• Quad City Health Initiative, Member

Leah Hole-Marshall, JD
As of February 24, 2017
Financial Associations
• Washington Department of Labor and Industries, Employer
• Fidelity Select BioTech, Stock, Spouse

Personal Associations
None reported
Russell Howerton, MD  
As of February 26, 2017  
Financial Associations  
• Wake Forest Baptist Health, Employer  
Personal Associations  
• Cornerstone Health Enablement Strategic Solutions (CHESS), Chairperson

Gail Hunt  
As of March 16, 2017  
Financial Associations  
• National Alliance for Caregiving, Employer  
Personal Associations  
• American Society on Aging, Member  
• Center for Aging Services Technology, Commissioner  
• Coalition to Transform Advanced Care (C-TAC), Member  
• Community Health Accreditation Program, Standards Quality Board, Member  
• Gerontological Society of America, Member  
• International Alliance of Patient Organizations, Member  
• International Federation on Aging, Member  
• Long Term Quality Alliance, Board Secretary  
• National Center for Creative Aging, Board Member  
• National Complex Care Advisory Board (United Healthcare), Board Member  
• National Council on Aging, Member  
• NQF Alzheimer’s Disease and Related Dementia Committee, Prioritizing Measure Gap, Member  
• NQF Committee on Quality Measurement, Member  
• NQF Measure Application Partnership Coordinating Committee, Member  
• NQF Patient and Family Centered Care Committee on Quality Measurement, Chair  
• Partnership to Fight Chronic Disease, Member  
• ReACT, Member

Robert Jesse, MD, PhD  
As of March 20, 2017  
Financial Associations  
• Department of Veterans Affairs/ Veterans Health Admin, Employer  
• Virginia Commonwealth University Health System, Faculty  
Personal Associations  
• American Heart Association, Fellow  
• Richmond Metro Chapter, AHA, Board Member  
• American College of Cardiology, Fellow  
• Society of Cardiovascular Patient Care, Ex-officio Board Member

Harlan M. Krumholz, MD, SM  
As of March 1, 2017  
Financial Associations  
• Yale University, Employer  
• American Heart Association, Editor  
• Element Science, Inc., Advisory Board Member  
• Fuji Hospital, Consultant  
• HugoPHR (Patient Health Records technology through Yale), Owner  
• IBM Research, Advisory Board Member  
• ImageCOR, LLC, Owner  
• Johnson & Johnson, Research Agreement, Investigator  
• Massachusetts Medical Society, Editor  
• Medtronic Research Agreement, Investigator  
• Premier, Inc., Consultant  
• United Healthcare, Cardiac Scientific Advisory Board, Advisory Board Member  
Personal Associations  
• Cardiovascular Outcomes, Inc., Board Member

Richard E. Kuntz, MD, MSc  
As of March 29, 2017  
Financial Associations  
• Medtronic Inc., Employer  
Personal Associations  
• Case Western Reserve University School of Medicine, Board Member  
• Chiari & Syringomyelia Foundation, Board Member  
• Medical Device Innovation Consortium, Committee Member  
• Hennepin County Medical Center, Member

Sharon Levine, MD  
As of March 7, 2017  
Financial Associations  
• The Permanente Medical Group, Inc., Employer  
Personal Associations  
• Alliance of Community Health Plans, Board Member  
• American Medical Association, Member  
• California Medical Association, Member  
• Institute for Medical Quality, Board Member  
• Insure the Uninsured Project, Board Member  
• Medical Board of California, Board Member  
• Medicare Payment Advisory Commission, Commissioner and Chairman of the Commission, Spouse

Freda Lewis-Hall, MD  
As of February 28, 2017  
Financial Associations  
• Pfizer, Inc., Employer, Saving Plans, Retirement Plan  
• Bristol-Myers Squibb, Stock, Retirement Plan, Self; Stock, Self and Spouse  
• Eli Lilly and Co., Pension Plan, Self and Spouse  
• Tenet, Board of Directors/Trustees (Compensated Position)  
• Vertex Pharmaceuticals, Stock & Retirement Plan  
Personal Associations  
None reported

Steven Lipstein, MHA  
(Resigned from Board of Governors September 22, 2016)  
As of May 3, 2016  
Financial Associations  
• BJC HealthCare - President and CEO, Employer  
Personal Associations  
• Emory University, Trustee  
• Washington University in St. Louis, Trustee  
• Missouri Hospital Association, Trustee  
• St. Louis Regional Health Commission, Commissioner  
• Institute of Medicine, Member  
• Committee on Health Services, University of California, Board of Regents
Barbara J. McNeil, MD, PhD
As of January 12, 2017

Financial Associations
• Brigham and Women's Hospital/Harvard Medical School, Employer
• Harvard University Medical School, Employer
• BNY Mellon, Investments
• Marine Polymer Technologies, Consultant
• Warren Alpert Foundation, Board of Directors/Trustees (Compensated Position)

Personal Associations
• AGMednet, Board Member
• American Academy of Arts & Sciences, Member
• American Association for the Advancement of Science, Fellow
• American College of Radiology, Member
• American Medical Association, Member
• Blue Cross and Blue Shield Association, Member
• Boston Foundation for Sight, Board Member
• CMS Imaging Efficiency Measures Technical Panel, Member
• Massachusetts Medical Society, Member
• National Academy of Medicine, Member
• Society for Medical Decision Making, Member
• Society of Nuclear Medicine & Molecular Imaging, Member
• The Academic Medicine and Health Industry Forum, Member

Grayson Norquist, MD, MSPH
(Chairperson)
As of December 27, 2016

Financial Associations
• Emory University, Employer

Personal Associations
• Academy Health, Fellow
• American Psychiatric Association (APA), Fellow
• American Psychiatric Association Council on Quality of Care, Chair
• American Psychiatric Association Foundation, Board Member

Ellen Sigal, PhD
As of March 7, 2017

Financial Associations
• ISHARES CORE MSCI EAFE ETF, Stock, Self and Spouse
• ISHARES CORE S&P MIDCAP ETF, Stock, Jointly
• ISHARES INC MSCI JAPAN NEW, Stock, Jointly
• ISHARES MSCI EAFE ETF, Stock, Spouse and Jointly
• ISHARES MSCI EAFE ETF, Stock, Jointly and Spouse
• ISHARES RUSSELL1000 GROWTH ETF, Stock, Spouse and Jointly
• ISHARES RUSSELL 1000 VALUE ETF, Stock, Spouse and Jointly
• SPDR S&P 500 ETF TRUST, Stock, Jointly, Self and Spouse

Personal Associations
• DC Students Constructions Trades Foundation, Board Member, Child
• Duke University Cancer Center, Board of Overseers
• Foundation for the National Institutes of Health, Board Member
• Friends of Cancer Research, Chair
• GWU Milken Institute School of Public Health, Advisory Board Member
• MD Anderson Cancer Center, Advisory Board Member
• NY University Faculty of Arts and Science, Board of Overseers, Spouse
• NYU-DC Steering Committee, Advisory Board, Spouse
• Parker Institute for Cancer Immunotherapy, Advisory Board Member
• Reagan-Udall Foundation, Chair
• Sidney Kimmel Comprehensive Cancer Center Advisory Council, Advisory Council Member
• Stand Up 2 Cancer, Committee Member/Work Groups Member
• Stand Up 2 Cancer Catalyst Executive Committee, Committee Member
• The George Washington University, Medical Faculty Associates Board, Spouse
• The George Washington University Medical Center, Advisory Council Member, Spouse
• U.S. Holocaust Collections and Conservation Committee, Committee Member, Spouse

Kathleen Troeger, MPH
As of February 3, 2017

Financial Associations
• Hologics, Inc., Employer; Stock, Self and Spouse
• Pfizer, Pension, Self

Personal Associations
None reported

Harlan Weisman, MD, SM
(Resigned from Board of Governors September 22, 2016)
As of December 29, 2015

Financial Associations
• And-One Consulting, LLC, Managing Director and Paid Consultant
• ControlRad, Inc, Board Director. Stock and Stock Options
• BioMotiv, LLC, Scientific Advisory Board member (Compensation)
• Johnson & Johnson, Pension, Stock and Stock Options
• Mendham Investment Group, LLC. Member
• Hutchison Biofilm Medical Solutions, Board of Directors and Advisor (Compensation and restricted stock)
• 3D Bio Corp., Executive Chairman, Board of Directors and Stock
• Mycrobiomics, Inc., Co-founded, Board Director, Chief Scientific Stock Officer and Stock

Personal Associations
• American Heart Association, Fellow
• American College of Cardiology, Fellow
• American College of Chest Physicians, Fellow
• American Medical Association
• American Association for the Advancement of Science
• American Association for Medical Research
• Johns Hopkins Institute for Basic Biomedical Sciences, Advisory Council Member

Robert Zwolak, MD, PhD
As of February 2, 2017

Financial Associations
• Dartmouth-Hitchcock, Employer
• U.S. Department of Veterans Affairs, Employer
• Eva Corporation, Investments, Self
• Society for Vascular Surgery, Consultant

Personal Associations
• American Medical Association (AMA), Member
• American College of Surgeons, Member; Committee Member
• American Venous Forum, Member
• Society for Vascular Surgery, Member

A3
Naomi Aronson, PhD
As of February 10, 2017

Financial Associations
• Blue Cross Blue Shield Association, Office of Clinical Affairs, Employer

Personal Associations
• National Business Group on Health Committee on Evidence-Based Benefit Design, Member
• Center for Medical Technology Policy, Green Park Collaborative USA, Member
• Member Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Ox) Working Group, Tapestry Networks, Member
• NEW Drug Development ParadigmS Initiative (NEWDIGS), Member
• Medical Device Innovation Consortium (MDIC), Expert Advisor and speaker
• Scientific Oversight Committee (SOC) of the FDA Medical Device Epidemiology Network (MDEpiNET), Member
• Health Technology Assessment International Health Policy Forum, Member
• National Academies of Sciences Genomics Roundtable, Member
• EXCITE International, Advisory Board, Scientific Collaboration, and Chair; Payer Advisory Committee
• Steering Committee of the Quality Assurance Pilot for Cancer CDx Tapestry Networks, Member

Ethan Basch, MD, MSc
As of February 27, 2017

Financial Associations
• University of North Carolina Chapel Hill, Employer
• Memorial Sloan-Kettering Cancer Center, Employer

Personal Associations
• National Cancer Institute, Advisory Panel Member
• Journal of the American Medical Association, Editor
• The Alliance for Clinical Trials in Oncology Foundation, Chair/Board Officer
• American Society of Clinical Oncology, Chair/Board Officer

Stephanie Chang, MD, MPH
As of January 10, 2017

Financial Associations
• Agency for Healthcare Research & Quality, Employer

Personal Associations
• Arlington Free Clinic, Volunteer Physician
• Guidelines International Network, Trustee
• Journal of General Internal Medicine, Deputy Editor

David Flum, MD, MPH
As of January 30, 2017

Financial Associations
• Benchmark Medical LLC, Consultant
• Surgical Consulting, LLC, Expert Testimony

Personal Associations
• American Surgical Association, Member
• Elsevier, Editorial Board Member
• General Surgery News, Editorial Board Member
• British Journal of Surgery, Editorial Board Member
• Canadian Partnership Against Cancer, Knowledge Management Steering Committee, Advisory Council Member

Cynthia Girman, DrPH
As of January 24, 2017

Financial Associations
• CERobs Consulting, LLC, Employer
• Medtronic, Stock
• Celgene Corporation, Stock
• Teva, Stock
• Perrigo, Stock
• Gilead Sciences, Stock
• Merck & Co., Inc., Stock
• Sanofi, Consultant
• Regeneron, Consultant
• AstraZeneca Pharmaceuticals, Consultant
• Boehringer Ingelheim Pharmaceuticals, Inc., Consultant
• Roivant Sciences, Consultant
• Crestovo, Consultant
• Clinical Link, Consultant

Personal Associations
• Merck & Co, Inc., Former Employer
• University of North Carolina, Dept of Epidemiology, Professor
• University of North Carolina, Center for Pharmacoepidemiology, Advisory Board Member

Steven Goodman, MD, MHS, PhD
(Vice-Chair)
As of March 20, 2017

Financial Associations
• Stanford University, Employer

Personal Associations
• National Blue Cross Blue Shield Technology Evaluation Center, Medical Advisory Panel, Member
• American College of Physicians, Editor
• Society for Clinical Trials, Member
• American College of Epidemiology, Member

Mark Helfand, MD, MS, MPH
As of January 31, 2017

Financial Associations
• Portland VA Medical Center, Employer
• Oregon Health & Science University, Faculty
• Parker Waichman LLP, Consultant
• Consumer Union, Consultant

Personal Associations
• Society for Medical Decision Making, Past President
• U.S. Cochrane Center, Director
• American College of Physicians, Member

Michael S. Lauer, MD
As of March 5, 2017

Financial Associations
• National Institutes of Health, Employer
• Putnam College Fund, Stock
• Savings Investment Plan, Stock
• UptoDate, Inc., Employer, Spouse
• Johns Hopkins University, Employer, Spouse

Personal Associations
None Reported

David O. Meltzer, MD, PhD
As of December 29, 2016

Financial Associations
• University of Chicago, Employer
• CMMI, Grant
• National Institutes of Health, Grant
Brian S. Mittman, PhD
As of March 9, 2017

Financial Associations
- Kaiser Permanent Southern California, Employer
- Sepulveda Research Corp, VA Nonprofit Research Foundation, Employer
- Washington University in St. Louis, Consultant
- University of Southern California, Consultant
- University of California Los Angeles, Consultant
- Northwestern University, Consultant
- Merck, Speaker
- Cedars-Sinai Medical Center, Employer, Spouse
- Johns Hopkins University School of Medicine, Employer, Sibling
- University of Maryland School of Medicine, Employer, Sibling
- University of Kentucky, Advisory Board Member
- University of Maryland, Advisory Board Member
- Baylor College of Medicine, Speaker
- Univ of Texas Health Science Center at Houston, Speaker
- RTI International, Advisory Board Member, Self
- RTI International, Employer, Child

Personal Associations
- AcademyHealth, Advisory Council Member
- American Association of Medical Colleges, Advisory Council Member
- Kings College London Centre for Implementation Science/CLAHRS South London, Advisory Council Member
- Canadian Partnership Against Cancer, Knowledge Management Steering Committee, Advisory Council Member
- U.S. Department of Veterans Affairs, Former Employer

Sally C. Morton, PhD
As of December 22, 2016

Financial Associations
- Virginia Tech, Employer, Self
- Virginia Tech, Employer, Spouse
- University of Pittsburgh, Consultant

Personal Associations
- Agency for Healthcare Research and Quality, Committee Member
- American Statistical Association, Committee Member
- American Society for the Advancement of Science, Member
- Caucus for Women in Statistics, Member
- Society for Research Synthesis Methodology, Member
- National Academies of Sciences Genomics Roundtable, Member
- RAND Corporation, Former Employer
- RTI International, Former Employer

Robin Newhouse, PhD, RN (Chair)
As of January 20, 2017

Financial Associations
- Indiana University School of Nursing, Employer

Personal Associations
- American Nurses Credentialing Center's Research Council, Chair or Board Officer
- Academy Health, Chair or Board Officer
- American Academy of Nursing, Chair or Board Officer
- American Nurses Association, Member
- Sigma Theta Tau International Honor, Society of Nursing, Member
- Get Well Network, O'Neill Clinical Advisory Council, Member

Neil R. Powe, MD, MPH, MBA
As of January 3, 2017

Financial Associations
- University of California at San Francisco, Employer
- Centers for Disease Control and Prevention, Grants, Editor
- Parkland Center for Clinical Innovation, Advisory Board Member, Editor

Personal Associations
- RWJ Foundation, Member
- Institute of Medicine, Member
- American Society for Clinical Investigation, Member
- Association of America Physicians, Member
- Association of Professors of Medicine, Member
- American College of Physicians, Member
- American Society of Nephrology, Member
- Academy Health, Member
- American Public Health Association, Member
- American Epidemiology Society, Member
- American Clinical and Climatological Association, Member

Mary Tinetti, MD
(Resigned from Methodology Committee November 3, 2016)
As of December 14, 2015

Financial Associations
- Yale University, Employer
- Journal of the American Medical Association (JAMA), Employer

Personal Associations
- Association of Directors of Geriatric Academic Programs, Board of Directors
- Tideswell and American Geriatrics Society National Leadership Development Program, National Advisory Board

Adam Wilcox, PhD
As of January 31, 2017

Financial Associations
- University of Washington, Employer
- UW Medicine, Employer
- University of Michigan, Employer
- HRC-ManorCare, Employer
- Fred Hutchinson Cancer Research Center, Consultant
- Stanford University, Consultant
- Baylor College of Medicine, Consultant
- Columbia University

Personal Associations
- Agency for Healthcare Research and Quality, Committee Member
- American Board of Preventive Medicine, Exam Committee, Committee Member
- Intermountain Healthcare, Former Employer
- University of Utah, Former Employer
- National Institutes of Health, Committee Member
- American Medical Informatics Association, Member
- AcademyHealth, Committee Member
- eGEMs (Generating Evidence and Methods to improve patient outcomes), Editorial Board member
Joe V. Selby, MD, MPH  
As of November 22, 2016  
Financial Associations:  
• University of California, San Francisco, Employer (Child)  
Personal Associations:  
• None reported

Mary C. Hennessey, Esq.  
As of October 4, 2016  
Financial Associations:  
None reported  
Personal Associations:  
• Health and Human Services Advisory Council on Blood Stem Cell Transplantation, Member (Self)  
• American Health Lawyers Association, Member (Self)  

Jean R. Slutsky, PA, MSPH  
As of October 20, 2016  
Financial Associations:  
None reported  
Personal Associations:  
None reported

Evelyn P. Whitlock, MD, MPH  
As of October 10, 2016  
Financial Associations:  
None reported  
Personal Associations:  
• Kaiser Permanente, Northwest Health Plan and Hospitals, Former Employer (Former Senior Director of AHRQ-designated and funded Kaiser Permanente Research Affiliates Evidence-Based Practice Center)  

Regina L. Yan, MA  
As of September 22, 2016  
Financial Associations:  
None reported  
Personal Associations:  
None reported

A full list of staff is available at www.pcori.org/people
### APPROVED RESEARCH AND RESEARCH SUPPORT AWARDS

**October 1, 2015 to September 30, 2016**

#### PCORNET HEALTH PLANS

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Amount Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>HealthCore-Anthem Research Network (HCARN)</td>
<td>HealthCore</td>
<td>Kevin Haynes</td>
<td>$5,173,135</td>
</tr>
<tr>
<td>Project Data Link - Humana</td>
<td>Comprehensive Health Insights, Inc.</td>
<td>Vinit P. Nair</td>
<td>3,662,997</td>
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#### CROSS-PPRN DEMONSTRATION CONTRACTS

<table>
<thead>
<tr>
<th>Project Title</th>
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<th>Amount Awarded</th>
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</thead>
<tbody>
<tr>
<td>Healthy Mind Healthy You</td>
<td>Massachusetts General Hospital</td>
<td>Andrew Nierenberg</td>
<td>$3,999,360</td>
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#### PCORNET COORDINATING CENTER PHASE II

<table>
<thead>
<tr>
<th>Project Title</th>
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</thead>
<tbody>
<tr>
<td>PCORnet Coordinating Center Phase II (Duke University)</td>
<td>Duke University</td>
<td>Adrian Hernandez, Richard Platt</td>
<td>$29,041,034</td>
</tr>
<tr>
<td>PCORnet Coordinating Center Phase II (Genetic Alliance)</td>
<td>Genetic Alliance, Inc.</td>
<td>Sharon Terry</td>
<td>2,591,040</td>
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</table>

#### PCORNET HEALTH SYSTEM DEMONSTRATIONS

<table>
<thead>
<tr>
<th>Project Title</th>
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<th>Amount Awarded</th>
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</thead>
<tbody>
<tr>
<td>Automating Quality and Safety Benchmarking for Children: Meeting the Needs of Health Systems and Patients</td>
<td>Cincinnati Children's Hospital Medical Center</td>
<td>Kathleen Walsh</td>
<td>$670,898</td>
</tr>
<tr>
<td>Identifying and Predicting Patients with Preventable High Utilization</td>
<td>Joan &amp; Sanford I. Weill Medical College of Cornell University</td>
<td>Rainu Kaushal</td>
<td>1,198,793</td>
</tr>
<tr>
<td>The Impact of Patient Complexity on Healthcare Utilization</td>
<td>Oregon Community Health Information Network</td>
<td>Abigail Sears</td>
<td>985,686</td>
</tr>
<tr>
<td>Variation in Case Management Programs and Their Effectiveness in Managing High-Risk Patients for Medicare ACOs</td>
<td>University of Wisconsin-Madison</td>
<td>Maureen Smith</td>
<td>1,364,818</td>
</tr>
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</table>

#### PPRN DEMONSTRATIONS

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
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<th>Amount Awarded</th>
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</thead>
<tbody>
<tr>
<td>Comparative Effectiveness of Specific Carbohydrate and Mediterranean Diets to Induce Remission in Patients With Crohn's Disease</td>
<td>Crohn's and Colitis Foundation of America, Inc.</td>
<td>James Lewis</td>
<td>$2,500,000</td>
</tr>
<tr>
<td>Harnessing PCORnet to Study Comparative Effectiveness and Safety of Biologic Therapies</td>
<td>University of Alabama at Birmingham</td>
<td>Jeffrey Curtis</td>
<td>2,500,000</td>
</tr>
<tr>
<td>Healthy Hearts Healthy Minds: A PPRN Demonstration Pragmatic Trial</td>
<td>Massachusetts General Hospital</td>
<td>Andrew Nierenberg</td>
<td>2,488,754</td>
</tr>
<tr>
<td>Monitoring and Peer Support to Improve Treatment Adherence and Outcomes in Patients with Overlap Chronic Obstructive Pulmonary Disease and Sleep Apnea via a Large PCORnet Collaboration (O2VERLAP)</td>
<td>COPD Foundation, Inc.</td>
<td>David Mannino</td>
<td>2,479,303</td>
</tr>
<tr>
<td>Resilience Against Depression Disparities (RADD)</td>
<td>Regents of the University of California, Los Angeles</td>
<td>Bowen Chung</td>
<td>2,499,998</td>
</tr>
<tr>
<td>Using Single Subject (N-of-1) Designs to Answer Patient-Identified Research Questions</td>
<td>Cincinnati Children's Hospital Medical Center</td>
<td>Heather Kaplan</td>
<td>3,429,043</td>
</tr>
<tr>
<td>Project Title</td>
<td>Organization</td>
<td>Principal Investigator</td>
<td>Amount Awarded</td>
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<tr>
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</tr>
<tr>
<td>Comparative Effectiveness of Sentinel Lymph Node Biopsy for Ductal Carcinoma In Situ</td>
<td>Yale University</td>
<td>Shiyi Wang</td>
<td>$439,730</td>
</tr>
<tr>
<td>Development and Evaluation of a Patient-Centered Approach to Assess Quality of Care: Patient-Reported Outcomes-based Performance Measures (PRO-PMs)</td>
<td>University of North Carolina, Chapel Hill</td>
<td>Ethan Basch</td>
<td>930,695</td>
</tr>
<tr>
<td>Patient Osteoarthritis Careplan to Inform Optimal Treatment</td>
<td>University of Massachusetts Medical School</td>
<td>Patricia Franklin</td>
<td>6,378,861</td>
</tr>
<tr>
<td>Patient-Centered HCV Care via Telemedicine for Individuals on Opiate Substitution Therapy: A Stepped Wedge Cluster Randomized Controlled Trial</td>
<td>Research Foundation for the State University of New York</td>
<td>Andrew Talal</td>
<td>7,004,591</td>
</tr>
<tr>
<td>Comparing Interventions to Increase Colorectal Cancer Screening in Low-Income and Minority Patients</td>
<td>Indiana University</td>
<td>Susan Rawl</td>
<td>2,880,644</td>
</tr>
<tr>
<td>Comparing the Effectiveness of Clinicians and Paraprofessionals to Reduce Disparities in Perinatal Depression</td>
<td>Northwestern University</td>
<td>Darius Tandon</td>
<td>2,099,952</td>
</tr>
<tr>
<td>Comparing Effectiveness of Self-management and Peer Support Communication Programs amongst Chronic Obstructive Pulmonary Disease Patients and their Family Caregivers</td>
<td>Johns Hopkins University</td>
<td>Hanan Aboumatar</td>
<td>2,099,292</td>
</tr>
<tr>
<td>A Comparison: High Intense Periodic vs. Every Week Therapy in Children with Cerebral Palsy (ACHIEVE)</td>
<td>The Ohio State University</td>
<td>Jill Heathcock</td>
<td>2,663,962</td>
</tr>
<tr>
<td>Continued Anticonvulsants After Resolution of Neonatal Seizures: A Patient-Centered Comparative Effectiveness Study</td>
<td>University of Michigan</td>
<td>Renee Shellhaas</td>
<td>2,876,265</td>
</tr>
<tr>
<td>Design and Methodological Improvements for Patient-Centered Small n Sequential Multiple Assignment Randomized Trials (snSMARTs) in the Setting of Rare Diseases</td>
<td>University of Michigan School of Public Health</td>
<td>Kelley Kidwell</td>
<td>898,990</td>
</tr>
<tr>
<td>Engaging Patients and Caregivers Managing Rare Diseases to Improve the Methods of Clinical Guideline Development</td>
<td>Rand Corporation</td>
<td>Dmitry Khodyakov</td>
<td>1,015,936</td>
</tr>
<tr>
<td>Governance of Learning Activities in Learning Healthcare Systems</td>
<td>University of Pennsylvania</td>
<td>Steven Joffe</td>
<td>1,059,437</td>
</tr>
<tr>
<td>Healing through Education, Advocacy and Law (HEAL) in Response to Violence</td>
<td>University of Rochester</td>
<td>Catherine Cerulli</td>
<td>2,003,763</td>
</tr>
<tr>
<td>Improving Care for Veterans with PTSD: Comparative Effectiveness of Medications to Augment First-line Pharmacotherapy</td>
<td>University of California, San Francisco</td>
<td>Beth Cohen</td>
<td>1,222,183</td>
</tr>
<tr>
<td>Improving Methods of Incorporating Racial/Ethnic Minority Patients’ Treatment Preferences into Clinical Care</td>
<td>Cambridge Health Alliance</td>
<td>Benjamin Cook</td>
<td>1,059,782</td>
</tr>
<tr>
<td>Learning Within Health Care Delivery Systems: Design, Analysis, and Interpretation of Longitudinal Cluster Randomized Trials</td>
<td>University of Washington</td>
<td>Patrick Heagerty</td>
<td>1,031,006</td>
</tr>
<tr>
<td>Longitudinal Comparative Effectiveness of Bipolar Disorder Therapies</td>
<td>University of New Mexico Health Sciences Center</td>
<td>Christophe Lambert</td>
<td>2,186,437</td>
</tr>
<tr>
<td>Multi-Institutional Trial of Non-Operative Management of Uncomplicated Pediatric Appendicitis</td>
<td>The Research Institute at Nationwide Children's Hospital</td>
<td>Peter Minneci</td>
<td>2,875,543</td>
</tr>
<tr>
<td>Ostomy Telehealth for Cancer Survivors</td>
<td>Trustees of the University of Pennsylvania</td>
<td>Robert Krouse</td>
<td>2,080,650</td>
</tr>
<tr>
<td>Pragmatic Trial Comparing Telehealth Care and Optimized Clinic-Based Care for Uncontrolled High Blood Pressure</td>
<td>HealthPartners Institute</td>
<td>Karen Margolis</td>
<td>6,060,069</td>
</tr>
<tr>
<td>Resetting The Default: Improving Provider-patient Communication to Reduce Antibiotic Misuse</td>
<td>Children's Mercy Hospital</td>
<td>Kathy Goggin</td>
<td>2,095,392</td>
</tr>
<tr>
<td>Stratified Regression Models for Case-Only Studies</td>
<td>President &amp; Fellows of Harvard College</td>
<td>Murray Mittleman</td>
<td>1,049,980</td>
</tr>
<tr>
<td>Virtual Evidence-based Healthcare for Underserved Patients with Down Syndrome</td>
<td>Massachusetts General Hospital</td>
<td>Brian Skotko</td>
<td>2,080,284</td>
</tr>
<tr>
<td>Project Title</td>
<td>Organization</td>
<td>Principal Investigator</td>
<td>Amount Awarded</td>
</tr>
<tr>
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<tr>
<td>Augmentation versus Switch: Comparative Effectiveness Research Trial for Antidepressant Incomplete and Non-responders with Treatment Resistant Depression (ASCERTAIN-TRD)</td>
<td>Massachusetts General Hospital</td>
<td>George Papakostas</td>
<td>$14,210,781</td>
</tr>
<tr>
<td>Benefits of Stroke Treatment Delivered Using a Mobile Stroke Unit Compared to Standard Management by Emergency Medical Services: The BEST-MSU Study</td>
<td>Memorial Hermann Hospital-Texas Medical Center</td>
<td>James Grotta</td>
<td>$6,784,037</td>
</tr>
<tr>
<td>Blood Pressure Checks for Diagnosing Hypertension (BP-CHECK)</td>
<td>Group Health Cooperative</td>
<td>Beverly Green</td>
<td>$2,808,663</td>
</tr>
<tr>
<td>Cognitive Behavioral Therapy versus Yoga for the Treatment of Worry in Anxious Older Adults: A Randomized Preference Trial</td>
<td>Wake Forest University Health Sciences</td>
<td>Gretchen Brenes</td>
<td>$2,668,664</td>
</tr>
<tr>
<td>Comparative Effectiveness of Encounter Decision Aids for Early-Stage Breast Cancer across Socioeconomic Strata</td>
<td>Trustees of Dartmouth College</td>
<td>Marie-Anne Durand</td>
<td>$2,089,936</td>
</tr>
<tr>
<td>Comparative Effectiveness of Patient-Centered Strategies to Improve Pain Management and Opioid Safety for Veterans</td>
<td>University of Minnesota Twin Cities</td>
<td>Erin Krebs</td>
<td>$12,499,308</td>
</tr>
<tr>
<td>The Comparative Effectiveness of Probabilistic versus Patient Narrative: Enhanced Risk Communication for Pain Management Following Acute Care</td>
<td>University of Pennsylvania</td>
<td>Zachary Meisel</td>
<td>$2,110,029</td>
</tr>
<tr>
<td>Comparative Effectiveness of Treatment Options for Genital Herpes Infection in Pregnant Women to Reduce Adverse Pregnancy Outcomes</td>
<td>Kaiser Foundation Research Institute, a Division of Kaiser Foundation Hospitals</td>
<td>De-Kun Li</td>
<td>$2,799,498</td>
</tr>
<tr>
<td>The Comparative Effectiveness of Warfarin and New Oral Anticoagulants for the Extended Treatment of Venous Thromboembolism</td>
<td>University of California, San Francisco</td>
<td>Margaret Fang</td>
<td>$3,512,971</td>
</tr>
<tr>
<td>A Comparative Effectiveness Randomized Controlled Trial of Mindfulness Meditation versus Cognitive Behavioral Therapy for Opioid-Treated Chronic Low Back Pain</td>
<td>University of Wisconsin-Madison</td>
<td>Aleksandra Zgierska</td>
<td>$8,502,440</td>
</tr>
<tr>
<td>Comparative Effectiveness Trial between a Clinic- and Home-Based Complementary and Alternative Medicine Telerehabilitation Intervention for Adults with Multiple Sclerosis (MS)</td>
<td>University of Alabama at Birmingham</td>
<td>James Rimmer</td>
<td>$5,849,655</td>
</tr>
<tr>
<td>Comparison of Sleep Apnea Assessment Strategies to Maximize TBI Rehabilitation Participation and Outcome</td>
<td>Tampa VA Research and Education Foundation</td>
<td>Risa Richardson</td>
<td>$2,688,745</td>
</tr>
<tr>
<td>Comprehensive Disease Management Program to Improve Quality of Life in Disparity Hispanic and African American Patients Admitted with Exacerbation of Chronic Pulmonary Disease</td>
<td>Feinstein Institute for Medical Research</td>
<td>Negin Hajizadeh</td>
<td>$1,493,761</td>
</tr>
<tr>
<td>The Dabigatran, Apixaban, Rivaroxaban, Edoxaban, Warfarin Comparative Effectiveness Research Study (The DARE warfarin CER study)</td>
<td>Brigham and Women's Hospital</td>
<td>Joshua Gagne</td>
<td>$2,978,987</td>
</tr>
<tr>
<td>Developing and Validating Quantitative Measures to Assess Community Engagement in Research: Addressing the Measurement Challenge</td>
<td>Washington University School of Medicine</td>
<td>Melody Goodman</td>
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<td>Electroconvulsive Therapy versus Ketamine for Treatment Resistant Depression</td>
<td>Cleveland Clinic Foundation</td>
<td>Amit Anand</td>
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<td>Electronic Patient Reporting of Symptoms during Outpatient Cancer Treatment: A US National Randomized Controlled Trial</td>
<td>The Alliance for Clinical Trials In Oncology Foundation</td>
<td>Ethan Basch</td>
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<td>Engaging Patients and Providers in Collaborative Communication on HPV Vaccination (EPPIC-HPV)</td>
<td>University of New Mexico Main Campus</td>
<td>Gill Woodall</td>
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<td>Engaging Patients with Mental Disorders from Emergency Departments into Outpatient Care: A Comparative Effectiveness Workforce Study</td>
<td>Emory University</td>
<td>Benjamin Druss</td>
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<td>Expansion of Methods for Two-Stage Trial Designs for Testing Treatment, Self-Selection and Treatment Preference Effects</td>
<td>Yale University</td>
<td>Denise Esserman</td>
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<td>The HOMBRE Trial: Comparing Two Innovative Approaches to Reduce Chronic Disease Risk among Latino Men</td>
<td>Palo Alto Medical Foundation Research Institute</td>
<td>Lisa Rosas</td>
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<td>Home-Based Chronic Kidney Disease (CKD) Care in Native Americans of New Mexico: A Disruptive Innovation</td>
<td>University of New Mexico Health Sciences Center</td>
<td>Vallabh Shah</td>
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<td>Improving Causal Inference Methods via Statistical Learning with High-dimensional Data</td>
<td>Rutgers, The State University of New Jersey, New Brunswick</td>
<td>Zhiqiang Tan</td>
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<td>Leveraging Visual Analytics for the Identification of Patient Subgroups: Application to Improving the Prediction of Hospital Readmission in the Elderly</td>
<td>The University of Texas Medical Branch at Galveston</td>
<td>Suresh Bhavnani</td>
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<td>Linking UDIs to Insurance Claim: A Pilot Demonstration</td>
<td>Brigham and Women's Hospital</td>
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<td>A Multicentric Randomized Pragmatic Trial to Compare the Effectiveness of Fingolimod versus Dimethyl-Fumarate on Patient Overall Disease Experience in Relapsing-Remitting Multiple Sclerosis: Novel Data to Inform Decision Makers</td>
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<td>Optimizing Outcomes in Treatment-Resistant Depression in Older Adults</td>
<td>Washington University School of Medicine</td>
<td>Eric Lenze</td>
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<td>A Patient-Centered Framework to Test the Comparative Effectiveness of Culturally and Contextually Appropriate Program Options for Latinos with Diabetes from Low-Income Households</td>
<td>University of New Mexico Health Sciences Center</td>
<td>Janet Page-Reeves</td>
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<td>Randomized, Double-Blind, Crossover, Placebo-Controlled Trial of Amantadine, Modafinil, and Methylphenidate for Treatment of Fatigue in Multiple Sclerosis</td>
<td>Johns Hopkins University</td>
<td>Bardia Nourbakhsh</td>
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<td>A Randomized Pragmatic Trial Comparing the Complications and Safety of Blood Clot Prevention Medicines Used in Orthopedic Trauma Patients</td>
<td>University of Maryland Baltimore</td>
<td>Robert O'Toole</td>
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<td>Rituximab in Multiple Sclerosis: A Comparative Study on Effectiveness, Safety, and Patient-Reported Outcomes</td>
<td>Karolinska Institute</td>
<td>Fredrik Piehl</td>
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<td>Shared Care: Patient-Centered Management after Hematopoietic Cell Transplantation</td>
<td>Dana-Farber Cancer Institute</td>
<td>Gregory Abel</td>
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<td>Statistical Methods for Phenotype Estimation and Analysis Using Electronic Health Records</td>
<td>University of Pennsylvania</td>
<td>Rebecca Hubbard</td>
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<td>A Stepped-Care Intervention to Reduce Disparities in Mental Health Services among Underserved Lung and Head and Neck Cancer Patients and their Caregivers</td>
<td>University of Colorado Denver</td>
<td>Evelin Borrayo</td>
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<td>Warfarin versus Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism: A Randomized Comparative Effectiveness Trial</td>
<td>Duke University</td>
<td>Thomas Ortel</td>
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<td>Comparative Effectiveness of Breast Cancer Screening and Diagnostic Evaluation by Extent of Breast Density</td>
<td>University of California, Davis</td>
<td>Diana Miglioretti</td>
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<td>Comparison of Operative versus Medical Endocrine Therapy for Low Risk DCIS: The COMET Trial</td>
<td>The Alliance for Clinical Trials In Oncology Foundation</td>
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<td>Determining the Optimal Treatment Strategy for Patients Who Have Chronic Migraine with Medication Overuse</td>
<td>Mayo Clinic Arizona</td>
<td>Todd Schwedt</td>
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<td>The Impact of Medicaid Health Homes on Patients with Diabetes</td>
<td>Icahn School of Medicine at Mount Sinai</td>
<td>Victoria Mayer</td>
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<td>Improving Self-Care Decisions of Medically Underserved African-Americans with Uncontrolled Diabetes: Effectiveness of Patient-Driven Text Messaging versus Health Coaching</td>
<td>University of Tennessee Health Sciences Center</td>
<td>James Bailey</td>
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<td>Integrated Smoking Cessation Treatment for Smokers with Serious Mental Illness</td>
<td>Massachusetts General Hospital</td>
<td>Eden Evins</td>
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<td>Natural Experiments of the Impact of Population-Targeted Health Policies to Prevent Diabetes and Its Complications</td>
<td>Tulane University</td>
<td>Lizheng Shi</td>
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<td>A Patient-Centered PaTH to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities</td>
<td>Pennsylvania State University Hershey Medical Center</td>
<td>Jennifer Kraschnewski</td>
<td>$2,249,522</td>
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<td>Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations (PESRAMHIP)</td>
<td>Brigham and Women’s Hospital</td>
<td>Elliot Israel</td>
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<td>Roflumilast or Azithromycin to Prevent COPD Exacerbations (RELIANCE)</td>
<td>University of Illinois at Chicago</td>
<td>Jerry Krishnan</td>
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In addition to research and research support awards, PCORI approved other awards, including Engagement Awards, in FY 2016. More information on those awards can be found on pcori.org.
Patient-Centered Outcomes Research (PCOR)

PCOR helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions, such as:

• Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?

• What are my options, and what are the potential benefits and harms of these options?

• What can I do to improve the outcomes that are most important to me?

• How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?

To answer these questions, PCOR:

• Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people

• Is inclusive of an individual’s preferences, autonomy, and needs, focusing on outcomes that people notice and care about, such as survival, function, symptoms, and health-related quality of life

• Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination

• Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology and personnel, and other stakeholder perspectives

Approved by PCORI Board of Governors, March 5, 2012