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

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.
“PCORI is going to have a big ripple effect across research across the country that’s going to make a lot of comparative effectiveness and health services research much more patient-centered, even research not funded by PCORI. I’m excited about that.”

LEAH KARLINER, MD, PCORI Reviewer, Associate Professor in Residence, UCSF School of Medicine

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By the time the meeting ended, it was clear that we had accomplished a great deal in those three years, and that we couldn’t have done it without the leadership of the person who was marking his last meeting that day as PCORI Board Chair—Dr. Eugene Washington.

Under Gene’s guidance, PCORI established its National Priorities for Research and its Research Agenda, adopted its first methodology standards, initiated research funding, and built from the ground up a research organization with a core commitment to integrating the needs and concerns of patients and others from across the healthcare community throughout the research process. He also helped Board members to look beyond our individual perspectives and interests to take a patient-centered focus in everything we do.

As Gene reminded us often, we have launched a “movement” to change the way comparative clinical effectiveness research (CER) is done, with a goal of producing trustworthy, useful, evidence-based information that will promote improved clinical decision-making and, ultimately, improve outcomes.

Our Board Chair’s responsibilities have now transitioned to someone else, but our focus remains the same. As we open the next chapter in PCORI’s development, our core commitment to fulfilling our mandate and mission is stronger and clearer than ever. We know the tasks before us in the coming year, and the years beyond that, may be even more challenging and ambitious than those we faced in getting PCORI off the ground.

We are now positioned to ramp up dramatically our investment in patient-centered CER designed to produce information that can change practice and improve outcomes, especially in high-burden diseases and conditions. We will seek to advance our vision of patient-centered research across the research community by promoting the broad use of our methodology standards and showing the value of our approach to engaging patients and others throughout the research process. We will continue to support development of the infrastructure needed to ensure that patient-centered CER can be conducted more effectively and efficiently. We will start to see the results of our initial funded studies, which focused on assessing the best ways to do this kind of work. And we will establish the framework for what we know must be a comprehensive plan to promote the dissemination and uptake of the results of our primary CER studies.

It’s a full agenda. But seeing how far we’ve come in a few short years, it’s one we fully embrace. We hope you will as well.

Grayson Norquist, MD, MSPH
Professor and Chairman, Department of Psychiatry and Human Behavior, University of Mississippi Medical Center Chair, PCORI Board of Governors

Steven Lipstein, MHA
President and Chief Executive Officer, BJC HealthCare, St. Louis, MO Vice Chair, PCORI Board of Governors
When PCORI was authorized by Congress in 2010, we had the broad and complex mandate outlined by our enabling legislation and the expertise of our Board as guides to building a new organization from the ground up. Three years later, we have grown into an innovative funder of research living up to our commitment to “research done differently.” Central to that vision is supporting CER that will be useful to patients and other clinical decision makers by ensuring that their questions and concerns are the focus of our work.

In the past year, our Board of Governors identified three goals that form the core of our Strategic Plan to guide efforts to fund and disseminate research that will provide patients and those who care for them with information they can use to make decisions that reflect their desired health outcomes. Our work in 2013 directly served each of these strategic goals.

First, we aim to increase substantially the quantity, quality, and timeliness of useful, trustworthy information available to support health decisions. We funded more than $200 million in research projects in 2013. Through broad and topic-specific funding announcements, we grew our research portfolio by more than 120 projects with the potential to improve how clinicians, family caregivers, and patients treat common and burdensome conditions. We plan to grow this portfolio even more in the next two years, investing a projected total of $1 billion in new CER projects.

Second, we will speed the implementation and use of patient-centered outcomes research (PCOR) evidence. To this end, we rely on robust programs for engaging patients and other healthcare stakeholders in all aspects of our work, including requiring funded investigators to involve these stakeholders as meaningful partners in shaping the research and advancing dissemination efforts. With this approach, we believe the results of the studies we fund are more likely to be used in everyday practice.

Finally, we will seek to influence clinical and healthcare research funded by others to be more patient-centered. We hope to cement such a legacy by demonstrating the positive impact of engagement in research, promoting the broad dissemination and uptake of the methodology standards we issued in 2012 and continue to enhance, and laying the groundwork for a national data infrastructure that will support patient-centered CER.

Broad public input remains a key ingredient of our approach. We are consistently impressed and humbled by the energy, enthusiasm, and sophisticated dedication displayed by the patients, caregivers, scientists, clinicians, and many others across the healthcare community who engage in our work. We thank them for their commitment to our mission and we look forward to collaborating on next steps as we continue to build a national research institute dedicated to improving patient care.

Joe V. Selby, MD, MPH
Executive Director

Anne C. Beal, MD, MPH*
Deputy Executive Director

Bryan Luce, PhD, MBA
Chief Science Officer

Regina L. Yan, MA
Chief Operating Officer

*Dr. Beal left PCORI in early March 2014

Looking back at our progress and achievements in 2013, it’s clear that this was the year PCORI left behind its start-up status and began to fulfill its promise as a true national research institute.
During PCORI’s early period of growth and development, we often referred to our approach to the comparative clinical effectiveness (CER) research we fund as “research done differently.” Our core belief is that engaging the broad healthcare community in the research described in our legislative mandate, with a consistent patient-centered focus, will make it more likely that the results of that work will be useful, trustworthy, and taken up in practice. Only in this way can we be confident of achieving our mission of improving outcomes important to patients and those who care for them.

In 2013, we took a series of coordinated steps to put this early thinking into action, building on a solidified organizational infrastructure and such foundational elements as our National Priorities for Research and Research Agenda and our methodology standards. We worked closely with our Board of Governors to detail our Strategic Plan, the roadmap for our research plans over the next few years, organizing our research activities around three strategic goals. We substantially expanded our research portfolio as well as our support for projects that will advance development of the methods and infrastructure needed to grow the nation’s capacity to undertake high-quality patient-centered CER. And we further refined our efforts to engage stakeholders from across the healthcare community in our work as members of PCORI-funded research teams, reviewers of applications for our research funding, and as partners on the PCORI Advisory Panels that help to prioritize research topics for potential funding.

Together, these complementary elements represent

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**THE LATEST STEPS ON THE PATH TO FULFILLING PCORI’S PROMISE**

**JANUARY**
- Public webinar on the Patient-Researcher Matching Challenge
- Application process opens for first four Advisory Panels
- Robin Newhouse becomes Vice Chair of Methodology Committee
- Online application system opens for PFA Cycle III
- Application process opens for first PCORI Advisory Panels
- Joint webinar with Health 2.0 to promote Matchmaking App Challenge

**FEBRUARY**
- Board meeting, San Francisco, CA
- Outlined in HealthAffairs and briefing PCORI’s process for engaging community in research topic generation and prioritization
- Announced first series of ad hoc workgroups to prioritize targeted research topics

**MARCH**
- Workgroup meetings to refine targeted funding announcements under five topic areas
- Board approves Advisory Panel selection process and membership
- Regional workshop on rural health, Wichita, KS

**APRIL**
- Latina stakeholder roundtable, Washington, DC
- PCORI Advisory Panels kickoff and training
- PCORI announces development of PCORnet, the National Patient-Centered Clinical Research Network

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**THE YEAR’S HIGHLIGHTS**
significant progress in our efforts to fund research that is timely, relevant, useful, and will increase the nation’s capacity to further support patient-centered CER.

This report describes our achievements from January 1 through September 30, 2013. The shortened period reflects Board approval, on September 10, of an amendment in PCORI’s Bylaws to shift from a calendar year accounting to a fiscal year that runs from October 1 to September 30. It was a period of important investments in research that will lead to new evidence to inform patients, family caregivers and other clinical decision makers, while simultaneously pursuing an engagement strategy that sets the foundation for even greater research investments in 2014 and beyond.

What “Research Done Differently” Looks Like

We expanded our research portfolio substantially in 2013 through funding cycles under our broad National Priorities for Research and our first topic-specific funding opportunities, and a major research infrastructure announcement (a summary of our research activities begins on page 8). But, as we ramped up our funding commitments, feedback from applicants and members of our review panels showed that our approach to research and the criteria we use to evaluate research proposals were not as intuitive to investigators as they could be. As a learning research organization committed to ongoing self-evaluation, we count on feedback to continuously improve our processes, so we knew we had an obligation to provide clearer guidance on what constitutes patient-centered CER and what we mean by engagement. As a result, we sought...
to provide greater clarity for those scientists who had not previously been asked to pursue these strategies, and for patients and other stakeholders who had never before been invited to participate in the research enterprise in this way.

We sought to help researchers better understand what we’re seeking by updating, streamlining, and refining our funding announcements and application guidelines. We also deployed a range of support resources for applicants, such as improved online training, enhanced programmatic and technical help desk support, and examples of plans to engage patients and other stakeholders. The results were encouraging. The percentage of proposed research projects selected for funding more than doubled from our initial cycle (in December 2012). Additional applicant support resources were in development at year’s end.

**Advances in Engaging the Healthcare Community**

We also took significant steps to act on our core belief that meaningful engagement by patients and other stakeholders in our work will build a community of passionate and knowledgeable individuals whose insight and experience will lead to the generation of more relevant and useful research results.

We worked to improve our merit review process, in which patients and other healthcare stakeholders join scientists in assessing the funding applications we receive. We convened our first four multi-stakeholder advisory panels to bring voices from across the healthcare community into our efforts to prioritize the research topics we consider for funding. We continued to hold a series of large and small stakeholder workshops, roundtables, and other events in Washington, DC, and elsewhere around the country. And we announced plans for the Eugene Washington PCORI Engagement Awards, designed to promote more integration of a range of stakeholders in the research process by providing training and funding to form small networks of activated constituencies.

**Further Refining Our Funding Initiatives**

Guided by our Strategic Plan, we look ahead with plans to sharply increase our budget for rigorous and useful patient-centered CER. Over the next two years, we plan to award up to $1 billion to fund additional research, including a new initiative to solicit larger pragmatic clinical studies designed to answer critical research questions raised by patients, clinicians, and other key healthcare stakeholders. And looking ahead to our mandate to provide the results of our

“**[Patients] are why research is done, and we all want meaningful research done that actually furthers the conversation and improves health outcomes. What I see as a benefit [of patient engagement in research] is that we start having more transparent research, that we have higher quality research. And not only that, research results actually have the impact that they’re meant to have.**”

BRAY PATRICK-LAKE, Patient advocate
work to patients, clinicians, and other stakeholders in ways they can best use it, we’re developing a detailed blueprint to guide the dissemination and implementation into practice the findings of the research we fund.

We also launched a signature initiative, PCORnet, the National Patient-Centered Clinical Research Network, a collaborative effort to expand the nation’s capacity to conduct a range of CER studies by establishing the infrastructure to better utilize clinical data gathered in real-world settings, including clinics, hospitals, and health systems. We look forward to this being a major piece of our legacy and an important step toward accelerating efficient, timely, and cost-effective comparative research.

The progress that we have achieved so far, and the promise of our future success, are made possible by the support of and input from the healthcare community we were established to serve. We thank all of you who have contributed to this work and look forward to continuing our journey together to improve the quality of care patients receive.

“When I have the opportunity to have access to more research of this type it helps tremendously when I’m sitting down with patients. It helps me decide which care I’m going to provide but it also helps me educate families better about their course of treatment.”

RONALD MEANS, Psychiatrist
A GROWING PORTFOLIO OF RESEARCH DESIGNED TO ANSWER PATIENTS’ QUESTIONS

This past year saw us significantly and strategically expand our portfolio of CER projects that will help patients and those who care for them make better-informed health and healthcare decisions. In the process, we took a number of steps to improve our application process, refine our review process, and strengthen our focus on engaging the broad healthcare community in all aspects of our work.

Seeking the Research Community’s Best Ideas
We completed one cycle of funding for projects under four of our five National Priorities for Research, our inaugural cycle of funding under our fifth priority, which focuses on supporting CER by advancing methods and infrastructure, and another round of funding under all five broad priorities.

Funding under these research priorities is allocated to investigator-initiated research questions with no specific assigned topics within the priority areas. The first broad cycle of funding approved by our Board of Governors in May included 51 awards, totaling $88.6 million, and the second in September included 71 awards, totaling more than $114 million. Together, these 122 projects and combined $202 million in approved funding address important questions surrounding many of the most prevalent and burdensome health conditions. The health topics most commonly addressed in our research portfolio include cardiovascular disease, the leading cause of death in the United States; cancer, which affects more than 13 million Americans every year; and mental illness, which affects one in four Americans.

Funding under our Accelerating Patient-Centered Outcomes Research and Methodological Research priority is designed to improve the nation’s capacity to conduct patient-centered CER by improving analytic methods; enhancing data infrastructure; and training researchers, patients, and other...
stakeholders to participate in this research. We approved funding for 19 projects focused on research methods in FY 2013, including studies of ways to apply data collected from new sources, such as electronic health records and social media sites, for clinical research; methods to engage patients and caregivers from underserved communities as active partners in patient-centered health research; and ways to improve existing methods for studies with few outcome events, such as treatments for rare diseases and newly marketed therapies.

The results of these studies, and other methods research we will support in the future, will complement our mandate to establish and advance the adoption of standards for patient-centered CER, a task that PCORI’s Methodology Committee and science staff continued to work on throughout the year. More detail on this effort is below.

We were particularly pleased to be able to announce our National Patient-Centered Clinical Research Network initiative in April. This resource, known as PCORnet, is envisioned as a national learning network, guided by patients, clinicians, and healthcare delivery systems, and designed to facilitate rapid and efficient CER that answers practical questions in real-world clinical settings. We plan to invest more than $100 million over 18 months to connect individual networks of patients and healthcare systems into a large interoperable, secure “network of networks” that can turn millions of patient encounters into valuable data points. To provide technical and logistical support for the project, we issued a competitive

“The researchers were asking questions from a medical perspective. I said, ‘Patients don’t think like this. You’ve got to change your terminology. You’ve got to put it in a patient world, not a medical world.’”

DUANE SUNWOLD, PCORI Pilot Project Patient Partner
RFP and awarded a $9 million contract for a Coordinating Center to a multi-institution consortium led by the Harvard Pilgrim Health Care.

**Establishing our First Advisory Panels**

We made good on our commitment to engaging the broad healthcare community in our work in numerous ways, but one major step was establishing our first four multi-stakeholder advisory panels, three of them created to support our growing research portfolio.

These panels have a diverse membership that includes representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine. The panels help us refine and prioritize research questions for potential funding, provide needed scientific and technical expertise, and offer input on other issues relevant to our mission. Their recommendations and advice help to inform programmatic decisions made by our staff and Board.

As we worked to establish each panel, it became clear that there was overwhelming interest in this effort from stakeholders representing all segments of the healthcare community and all areas of the country. Our open call to fill 84 panel slots returned nearly 1,300 applications. The result is that each panel includes a diverse range of stakeholders who can identify questions important to patients and those who care for them.

The panelists first met in April and immediately began to play an important role in prioritizing topics submitted by patients and stakeholders that would be considered for development into future targeted funding announcements. As the year ended, we were making plans for two additional panels, on Clinical Trials and Rare Disease, each of which is called for in our authorizing legislation.

**Stakeholder Input Guides Targeted Research Funding**

We supplemented the broad funding announcements that seek the research community’s best ideas for patient-centered CER studies with the first of our targeted funding announcements, which use patient and stakeholder input as a resource for helping us to select high-impact topics for funding. We developed this approach because we recognized that, even with the collaboration of patients and other stakeholders, topics generated through a traditional investigator-initiated process could miss important questions that matter to patients and other clinical decision makers.

Through an iterative prioritization process developed with stakeholder input, we identified five initial high-priority topics for research funding. The first two led to an announced $30 million partnership with the National Institute on Aging (NIA), part of the National Institutes of Health (NIH), to support a

**OUR FIRST ADVISORY PANELS**

- Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options
- Advisory Panel on Improving Healthcare Systems
- Advisory Panel on Addressing Disparities
- Advisory Panel on Patient Engagement
study aimed at preventing injuries from falls in older adults, and a call for up to $17 million in research on ways to address the persistent disparities in controlling asthma among African-American and Hispanic/Latino populations in the United States.

PCORI staff continued to work on developing funding announcements for three topics initially identified for targeted research: treatment options for uterine fibroids, chronic back pain, and obesity. The number of topics will increase dramatically as our initial advisory panels proceed with their prioritization work and as we establish new panels, including the two outlined in our authorizing legislation on Clinical Trials and Rare Disease.

A full list of executed research contracts is on page A-1.

**Other Programmatic Support Activities Funded in 2013**

In addition to primary research funding, we awarded a number of contracts through a competitive RFP process for a range of activities designed to support our research initiatives. These included:

- Science Review Officer Support (Awardee: Science Applications International Corporation)
- Scientific Surveys of Patients and Health Providers to Help Refine Research Agenda (Awardee: American Institutes of Research)
- A Feasibility Study to Determine Whether Clinical Evidence Gaps Can be Identified From Existing National Guideline Clearinghouse Syntheses of Clinical Practice Guidelines (Awardee: Agency for Healthcare Research and Quality)
- Topic Brief Support: Synthesizing Information from Evidence-based Practice Centers to Help Inform PCORI’s Prioritization and Selection of Topics for Possible Funding (Awardee: Agency for Healthcare Research and Quality)
- Workshop on Observational Studies in a Learning Health System (Awardee: Institute of Medicine)
- PCOR/CER Roadmap for State Policymakers (Awardee: National Academy for State Health Policy)
- Understanding Options to Reduce Disparities in Cardiovascular Disease through Comparative Effectiveness Research (Awardee: RTI International)

A full list of these executed contracts, along with a description of our RFP process, is on page A-1.
Continuing to Strengthen Methodological Standards for CER

Our science staff worked with members of our Methodology Committee to complete the revision of the draft Methodology Report released for public comment in 2012; and the updated report was reviewed and endorsed by the Board in November 2013. Central to the Methodology Report is the first set of methodology standards for comparative clinical effectiveness research. The Board had adopted a set of methodology standards, as required by our authorizing legislation, in late 2012 after reviewing and incorporating public comments, with applicants for PCORI research funding required to adhere to those standards starting with Cycle III proposals (those with a May 2013 application deadline). The revised Methodology Report is designed to put those standards in context as well as outline a framework for the translation tables researchers may use to determine the best methods to consider in designing different types of studies (a step required by our authorizing legislation). As part of the report, PCORI staff and Methodology Committee members were working with a range of experts to develop a series of patient-, researcher-, and clinician-focused narratives offering real-world examples of “why methods matter.”

Even as the revision was being completed, PCORI staff and Methodology Committee members were crafting a plan to promote broad use and dissemination of the report and standards, encouraging members of the healthcare community to adopt them as their own while working with PCORI to continue to expand and improve them. Enabling

PCORI METHODOLOGY STANDARDS

- Formulating research questions
- Patient-centeredness
- Data integrity and rigorous analyses
- Preventing and handling missing data
- Heterogeneity of treatment effect (HTE)
- Data registries
- Data networks as research-facilitating infrastructures
- Casual inference methods
- Adaptive and Bayesian trial designs
- Studies of diagnostic tests
- Systematic reviews

There’s a great opportunity to improve the studies we fund so that the follow these minimal standards. When they’ve been followed, the studies are rigorous. When they’re rigorous, they produce trustworthy results. When they produce trustworthy results, people will use them in the clinical arena. And that’s why methods matter.

ROBIN NEWHOUSE, PhD, RN, NEA-BC, FAAN, PCORI Methodology Committee Chair
broad use of the standards required that we provide training (by PCORI and partnerships with PCORI) and embed tools for reviewers and applicants as they evaluate and apply the methodology standards. PCORI staff are monitoring and evaluating the application of the methodology standards in funding proposals.

**Improving Our Proposal Review Process**

Our process for reviewing research proposals, involving teams of scientists, patients, and other healthcare stakeholders, is not only central to our efforts to build a robust research portfolio but one of the most visible examples of how seriously we take engagement in pursuing our goals.

We implemented a number of refinements to our merit review process during the year, many in response to ongoing participant feedback. These included enhanced training materials to guide reviewers through the process more effectively; streamlining review criteria from eight to five to assist applicants; better defining these criteria to make the evaluation of applications more straightforward; revising the requirements for written critiques and streamlining the process reviewers use to submit critiques; and improving communication with all who indicate an interest in reviewing.

In addition, to improve the overall structure of our review process, we transitioned to the use of standing merit review panels to help ensure a consistent, thorough, and rigorous review process. This step was taken to help reviewers develop a sense of community; gain experience, confidence, and efficiency in reviewing applications; and plan time commitments more efficiently. However, even with this shift, we continued to welcome applicants for additional reviewers—scientists, patients, and other stakeholders, including payers, employers, industry and health system representatives, clinicians, and policymakers—to serve on an ad hoc basis.

**Improving Contracts Management and Administration**

As the number of research projects we approved for funding increased, we moved to improve the process by which we finalized and oversaw management of our resulting contracts with investigators. We set a goal of completing our post-award process, including programmatic and business reviews and executing final contracts, within 90 days of Board approval. By year’s end, we were able to meet our target for the majority of the awards.

We don’t make money as an insurance agency by denying care. But we make money by keeping the patient healthy. So which might be the option that keeps the patient most healthy?  

**VINIT NAIR, BPharm, MS, RPh,** Director, Drug Safety & Comparative Effectiveness, Humana, Inc.

**WHAT OUR ADVISORY PANELS DO**

PCORI advisory panels do not serve in an official decision-making capacity, but their recommendations and advice will be taken into consideration by our staff, Board, and Methodology Committee in:

- Modeling robust patient and stakeholder engagement efforts.
- Refining and prioritizing specific research questions.
- Providing other scientific or technical expertise.
- Providing input on other questions that may arise relevant to the Institute’s mission and work.

A GROWING PORTFOLIO OF RESEARCH DESIGNED TO ANSWER PATIENTS’ QUESTIONS
ENHANCING ENGAGEMENT AS A PATH TO HIGH-QUALITY, USEFUL RESEARCH

From our earliest days, we have worked diligently to engage patients and other healthcare stakeholders in all aspects of our work. There are many examples of how we kept this commitment in 2013.

We involved scores of patients, researchers, caregivers, clinicians, payers, employers, policymakers, and others in our research proposal review process. We held the inaugural meetings of our first advisory panels. We relied on public input as we continued the process of revising our report on methodological standards in research. As the year ended, we were planning additional initiatives to support engagement as a critical component of our approach to research, including a rubric for patient and family engagement in research and developing a capacity for monitoring and evaluating the impact of stakeholder engagement in our funded projects.

Our Advisory Panel on Patient Engagement
As noted earlier, three of the advisory panels established in 2013 support efforts to prioritize specific topics for research funding. The fourth, our Advisory Panel on Patient Engagement, is designed to help us advance best practices in patient engagement and promote a culture of patient-centeredness in all aspects of our work. That panel held its first meeting in April and immediately started providing input on ongoing engagement activities as well as suggesting new initiatives, including a PCORI Ambassadors program to train interested patients and other stakeholders as members of a community that can participate in and advance patient-centered outcomes research now and in the future.

Connecting with Those We Were Established to Serve
We take seriously our commitment to staying in close touch with the healthcare community to solicit feedback and guidance on our programmatic initiatives.

We regularly hosted, co-hosted, or participated in events involving a wide array of audiences to seek input on the real-world health and healthcare questions and concerns they encounter. We convened hundreds of stakeholders through more than 40 workshops, roundtables, and open Board meetings, with several thousand more joining though associated webcasts, webinars, and teleconferences. We held smaller meetings with dozens of stakeholder groups.

OUR ENGAGEMENT GOALS
- Develop a knowledgeable community that can participate in CER/PCOR.
- Engage an informed community in the conduct of CER/PCOR.
- Promote dissemination of research findings so patients and other stakeholders have CER information they can use to make decisions that reflect their desired health outcomes.
on general and specific topics of concern. We organized an additional series of open access webinars to better explain and answer audience questions about our priorities, programs, and processes. And our staff delivered more than 130 talks at major professional association and advocacy group meetings, explaining our mission and activities to thousands of additional individuals.

The passion and enthusiasm of the people we meet deepens our commitment to community engagement as we strive to realize our vision of a healthcare system where patients and those who care for them have the information they need to make informed health and healthcare decisions that address their particular concerns and preferences.

Supporting Engagement with a New Funding Initiative

Even as we grew our research portfolio, we announced an innovative plan to direct additional funding to actively engage patient and other stakeholder communities that are not necessarily familiar with or involved in the traditional research process. This initiative, the Eugene Washington PCORI Engagement Awards, is designed to grow a national community of patients, clinicians, researchers, and other healthcare stakeholders who will advance patient-centered outcomes research. It was named in honor of our first Board Chair, who set the tone for our commitment to engagement as a defining principle.

Fittingly, the inspiration for these awards came during our first patient engagement workshop in October 2012. When we asked participants how we could better connect with patients and others interested in being involved in research, we heard

“Getting the entire community involved is very important. And the more we can do this and function as a family to really help our patients, the better it’s going to be.”

JAN TOWERS, PhD, NP-C, PCORI Reviewer

MAJOR ENGAGEMENT EVENTS

March 9-10: The Power of Partnership in Research: Improving Healthcare Outcomes in Rural Settings (Wichita, KS)

July 9: Patient and Clinician Views on CER and Engagement in Research: A Panel Discussion on New PCORI Survey Results

August 1: The Power of Partnership in Research: Improving Healthcare Outcomes in Underserved Communities (Memphis, TN)

August 14: Setting Standards for Patient-Centeredness and Patient Engagement in Research

September 19: Promising Practices of Meaningful Engagement in the Conduct of Research

September 20-21: Advisory Panel on Patient Engagement

Chair, who set the tone for our commitment to engagement as a defining principle.

Fittingly, the inspiration for these awards came during our first patient engagement workshop in October 2012. When we asked participants how we could better connect with patients and others interested in being involved in research, we heard...
[PCORI has] made it very clear that we are partners in this. It isn’t that they’re the researchers and we’re just the parents. [It’s] that we’re equals in this. This is such a unique opportunity ... to help researchers understand what it’s really like to live with something like this day in and day out.

ANDREA JENSEN, Parent Caregiver

The Engagement Awards are designed to leverage that passion by offering targeted funding to dozens of groups of patients, providers, and other healthcare stakeholders interested in supporting the expansion of CER and the implementation of its results. Projects will be funded across three categories, Knowledge Awards, Training and Development Awards, and Dissemination Awards, which align to PCORI’s overall engagement goals. The first step in this initiative was an initial set of Pipeline to Proposal Awards to help patients, clinicians and others form new partnerships with the goal of eventually working with researchers to submit full-scale research study proposals to PCORI or other CER funders. A round of pilot awardees solicited through a competitive RFP to be announced by year’s end.

A similar initiative was the PCORI Challenge, a competition to find innovative ways to connect patients and researchers as partners in patient-centered outcomes research. The Challenge awarded prizes for both concepts and more fully developed prototypes of “matching” tools that could effectively help patients and researchers interested in collaborating to find one another and work together. Two winners and eight runners-up shared $150,000 in prize money. We plan an additional challenge in 2014 to expand on our first effort of concepts and prototypes.

A Continuing Focus on Communication and Outreach
Digital communication was a core element of our promotion and outreach efforts. We grew our online and social media presence dramatically during the year. Our website recorded a total of 476,324 visits, with 218,982 unique visitors and nearly 1.7 million page views from January 1 through September 30—substantially more than in all of 2012. We also more than doubled the size of our opt-in email list to 10,160 (and regularly reached another 15,000 people through selective alerts to applicants), and saw our Twitter following more than triple to 2,848; our cumulative reach on Twitter was just short of 30 million impressions. A major website redesign project will be completed by mid-2014.

OUR WEB PRESENCE

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<th>Metric</th>
<th>Value</th>
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<td>Total visits to pcori.org</td>
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<tr>
<td>Unique visitors</td>
<td>218,982</td>
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<td>Page views</td>
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</tbody>
</table>

Jan. 1 to Sept. 30, 2013

2,848 number of @PCORI Twitter followers as of Sept. 30, a more than 200 percent increase from a year earlier.
As we move into 2014 and beyond, we enter a period intended to maximize PCORI’s potential as a research funding institution focused on CER that answers patients’ questions. For each of our initiatives, whether funding studies, promoting engagement as a path to rigorous and useful research, or improving methods and infrastructure, we’re confident that we are well-positioned to continue to meet the ambitious mandate set out by our authorizing legislation.

A Call for Large Pragmatic Clinical Studies
The next two years will be marked by a substantial increase in our research investment, as we commit up to $1 billion in research contracts. These funds will support the broad and targeted funding announcements we have supported to date and a new path to funded research topics focusing on pragmatic clinical studies and large simple trials.

This new initiative recognizes that many critical CER questions require larger and sometimes longer funding commitments than the three-year awards, with a maximum of $1.5 million in direct costs, allowed in our current broad announcements. We plan to release a call for funding in early 2014 inviting researchers to propose projects of up to $10 million in direct costs that address clear comparative questions raised by patients, clinicians, health systems, and other key stakeholders. Questions of particular interest will include those identified as high priorities for research by the Institute of Medicine, the Agency for Healthcare Research and Quality, key stakeholder organizations, and our advisory panels. To further ensure the “real-world” relevance of these studies, applicants will be required to engage patient and clinician organizations in the design and conduct of their projects.

These studies will be large enough and lengthy enough to better capture relevant outcomes and to allow examination of possible differences in effectiveness in key patient subgroups. We believe this initiative will round out our portfolio and provide the research community, in partnership with patients and other healthcare stakeholders, a robust way to help identify—and answer—critical healthcare questions.
I’m hoping this allows us to make certain that the places we make investments align with the places in which patients find actual value.

Trent Haywood, Blue Cross Blue Shield

This approach will complement the two paths to research funding that we have pursued—broad announcements issued under our five National Priorities for Research and a steadily growing number of targeted announcements seeking proposals to address high-impact clinical topics. We expect the balance of our portfolio to increasingly shift toward targeted funding over time.

In the next year, we also expect to start seeing the initial results of our Pilot Projects, awarded in 2012 as a prelude to our funding of primary research. These projects are designed to collect data that can be used to advance the field of PCOR by studying methodologies for engaging patients and other stakeholders in CER and identifying gaps where such work needs further development.

The Potential Transformative Power of PCORnet

Among the most exciting programs we expect to take shape in 2014 is our effort to support the development of sustainable infrastructure to significantly increase the amount of useful CER evidence available to healthcare decision makers. We will pursue this goal by investing more than $100 million in PCORnet, our envisioned national data patient-centered clinical data network that will speed the production of reliable comparative outcomes research.

PCORnet will enhance our country’s capacity to conduct CER efficiently by creating a large, representative electronic data infrastructure, based on electronic health records and patient-reported data. Researchers will be able to utilize and learn from clinical data gathered from multiple networks and settings under protocols that are developed under the guidance of patients and other stakeholders and are designed to protect data confidentiality and privacy.

We are confident that by creating a highly representative national network for conducting clinical outcomes research,
PCORnet will support the kinds of studies needed to answer the kinds of clinical questions seen in real-world settings.

**Continuing to Invest in Engagement as a Path to Rigorous and Useful Research**

Even as we continue to grow our research portfolio, we will expand and refine the range of initiatives we employ to engage stakeholders from across the healthcare community as a critical means of helping to ensure that the research we fund is meaningful, relevant, and useful.

We expect our Engagement Awards and Pipeline to Proposal awards to have a significant impact on our efforts to make participation in research accessible to more patients, front-line caregivers, and others who are not necessarily part of the traditional research enterprise. We will continue to ensure that the perspectives and concerns of clinicians, payers, employers, industry and policymakers, along with those of patients and caregivers, are represented in the processes we use to seek and prioritize topics for research funding. And we will look forward to sharing the lessons we have gathered from our Pilot Projects, lessons that we expect will not only bolster the case for giving patients and other stakeholders a prominent and meaningful voice in research, but will help to show all of us how to do so effectively.

**Looking to a Legacy of Learning and Lasting Impact**

The legacy we will leave for the healthcare community will be tied not only to the quality and utility of the patient-centered CER we fund, but also to how effectively we disseminate our body of work and promote its use by clinical decision-makers.

To that end, in the coming year we are planning a series of activities to engage the healthcare community in our efforts to promote use of the PCORI Methodology Report as a standard reference for conducting the kinds of studies that we support and that we hope others will as well. The revised report and standards incorporate input from a wide range of experts and stakeholder groups; we hope the profession will embrace this resource as its own, helping to improve, refine, enhance,
and follow the standards over time, just as we require our applicants to follow them.

A second program that we hope will gain traction in the healthcare community is a detailed blueprint we are creating for disseminating and implementing findings from the primary CER studies we fund in close coordinating with the Agency for Healthcare Research and Quality, which our authorizing legislation designates as PCORI’s primary dissemination partner. The oft-cited lengthy gap between the generation and use of critical evidence is a challenge healthcare has faced for decades; seeking to close that gap, even if in a modest way, is one of our core goals.

We held a stakeholder roundtable in July to seek input on developing a request for proposal to develop a blueprint for dissemination and implementation efforts. AHRQ presented at the workshop and will continue to work with PCORI as this framework is developed. We plan to have a draft blueprint ready for a workshop and public comment in the fall of 2014, and to release a final blueprint in January 2015.

As we pursue these and other initiatives in the coming year, we will do so in the context of expanding the formal mechanisms needed to evaluate the impact of our work. After all, as proponents of evidence-based practice, we’re eager to find out the extent to which our approach to research in fact meets our goals.

**Keeping a Focus on Our “True North” – Patients**

In all our efforts, we greatly value the support and guidance we've received from you—the patients, caregivers, clinicians, healthcare systems, researchers, industry, payers, consumers, and others across the diverse healthcare community whom our authorizing legislation directs us to serve. We hope you’ll remain generous with your time and expertise as we move forward.

Our mission is clear—to support and promote CER that helps patients and those who care for them make better-informed health and healthcare decisions as a path to improving practice and health outcomes. We now have a research portfolio in place that significantly advances us toward this goal and an innovative and important engagement structure that supports it. The coming year promises to be as busy and exciting as the last. We look forward to continuing to collaborate with you.

> Patient-centered research really allows for true transformation [by] bringing the month-to-month, year-to-year work into a research perspective and that chance to get to rapid cycle research, turning around the results and really sharing with others what’s effective and what works.

**ALBERT TERRILION,** National Association of City and County Health Officials
CELEBRATING PCORI-FUNDED RESEARCH

PCORI has developed a series of feature stories celebrating our patient-centered research enterprise and its unique contributions to clinical care in addressing questions faced by patients and other healthcare decision makers. The stories are distributed nationally and appear in a variety of print, broadcast, and online publications. The series is part of our broad communications and engagement effort to let all interested patients and healthcare stakeholders know about our expanding work and the opportunities for participation. Selected excerpts are below.

Guiding Men through Prostate Cancer Treatment Options

TAMPA, FL—Barbershop owner and community health advocate Emerson L. Tillman interacts with men in this Gulf Coast community all day long. And while he does, men often share their health concerns.

“People tell their barbers things they don’t tell their wives or their doctors,” says Tillman. “In my outreach efforts to barbershops and also churches, I encounter many men who have been treated for prostate cancer. These men share their experiences with me and express their concerns about their quality of life. I engage men in conversations about health issues related to prostate cancer treatment because there is not much information available to them.”

Which Medicine Is Best for Children with Epilepsy?

ATLANTA, GA—When a child is diagnosed with epilepsy, a parent’s first concern is to stop the seizures. But soon most of the current medications work equally well at stopping seizures. But little is known about how their cognitive effects may differ. So, doctors usually base treatment decisions on other factors. “There are no evidence-based guidelines,” says David W. Loring, PhD, professor of neurology and pediatrics at Emory University in Atlanta, Georgia.

Improving Quality of Life for Latinas with Breast Cancer

WASHINGTON, DC—Ivis Sampayo was just 38 years old and the mother of two young boys when she was diagnosed with breast cancer. She underwent surgery and nine months of chemotherapy, which made her ill and caused her hair to fall out. Her husband was very supportive, but “there were things I kept from my husband because I didn’t want to frighten him more,” she says.

Sampayo’s ethnic background likely played a role in her reticence. Although she was born in New York, her parents came from Puerto Rico. “The cultural heritage is to protect our family,” she says. “So, you keep a lot inside. I still do.”

Sampayo had strong family and social support and good access to care. But that’s not the case for many of the 8.5 million Latinas in the United States who are diagnosed with cancer, researchers say.

Now, Sampayo is a co-investigator on a new PCORI-funded study aimed at finding out whether participating in culturally relevant support groups—called “workshops” to avoid any cultural stigma—improves quality of life for Latina breast cancer survivors and their caregivers. Kristi Graves, PhD, of Georgetown University in Washington, DC, is leading the study.

The Decision is Yours: Engaging Patients in Depression-Treatment Choices

ANCHORAGE, AK—The best medicine in the world won’t work if you don’t take it. Would patients with depression be more likely to follow their treatment plans if they had more input into clinical decisions?

Depression rates are high among Native Americans in South Central Alaska—20 percent of women and 13 percent of men, in one recent survey. Contributing factors include economic hardship and the limited daylight during many months of the year, says Renee Robinson, MPH, PharmD, of the Southcentral Foundation, a tribally owned nonprofit healthcare system headquartered in Anchorage. But despite the foundation’s vigorous screening efforts and integrated program of behavioral health services, depression treatment wasn’t working well. The staff felt that they were missing something.

“We found that a lot of prescriptions for antidepressants weren’t being filled, or refilled,” says Robinson. “When we talked to [patients], we realized that many didn’t know that antidepressant drugs take a while to work—people thought they acted quickly, like antibiotics—and that depression treatments besides medication are available.”
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 2013 financial report, provided to Congress by the U.S. Government Accountability Office, is available here: www.pcori.org/assets/2014/04/PCORI-Financial-Report-093013.pdf.

The Patient-Centered Outcomes Research Institute is funded through the Patient-Centered Outcomes Research Trust Fund (PCORTF). At the beginning of the federal government's 2014 fiscal year (October 1, 2013 to September 30, 2014), the PCORTF received $150 million in federal appropriation and $86 million in transfer from the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds. The Treasury Department transferred 20% of these funds to the U.S. Department of Health and Human Services to carry out activities designated by the law, including dissemination of PCORI-funded research findings and to build capacity for comparative clinical effectiveness research.

### 2014 BUDGET

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**OPERATION REVENUE**

**PROGRAM EXPENSE**

- Research Expense & Engagement Awards: $106,206,944
- Methodology Committee: $2,745,000
- Science/Program Development & Evaluation: $23,259,838
- Engagement: $7,634,436
- Contracts: $12,594,812
- Total Program Expense: $152,441,030

**ADMINISTRATIVE EXPENSE**

- $30,100,587

**TOTAL OPERATION EXPENSE**

- $182,541,617
- Non-operation Interest Income: $323,000

**NET INCOME**

- $230,304,850

![2014 Budget Distribution](image1)

![2014 Research Funding Projections](image2)
Board of Governors
Debra Barksdale, PhD, RN
Kerry Barnett, JD
Lawrence Becker
Carolyn M. Clancy, MD
(resigned August 2013)
Francis S. Collins, MD, PhD
Allen Douma, MD
Arnold Epstein, MD
Christine Goertz, DC, PhD
Leah Hole-Marshall, JD
Gail Hunt
Robert Jesse, MD, PhD
Richard Kronick, PhD
(replaced Carolyn Clancy)
Harlan Krumholz, MD
Richard E. Kutz, MD, MSc
Sharon Levine, MD
Freda Lewis-Hall, MD
Steven Lipstein, MHA (Vice Chair)
Grayson Norquist, MD, MSPH (Chair)
Harlan Weisman, MD

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Gail Hunt
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Allen Douma, MD
Gail Hunt
Robert Jesse, MD, PhD
Sharon Levine, MD
Grayson Norquist, MD, MSPH (Chair)
Harlan Weisman, MD
Board of Governors Committees listings reflect 2013 committee assignments.

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David Flum, MD, MPH
Sherine Gabriel, MD, MSc
Steven Goodman, MD, MHS, PhD (Vice Chair)
Mark Helfand, MD, MS, MPH
John Ioannidis, MD, DSc
Michael S. Lauer, MD
David O. Meltzer, MD, PhD
Brian S. Mittman, PhD
Robin Newhouse, PhD, RN (Chair)
Sebastian Schneeweiss, MD, ScD
Jean R. Slutsky, PA, MSPH
Mary Tinetti, MD
Clyde Yancy, MD, MSc
Committee as of Dec. 31, 2013.

Methodology Committee Working Groups
Patient-Centeredness Working Group
Ethan Basch, MD, MSc (Chair)
Mary Tinetti, MD (Co-Chair)
Naomi Aronson, PhD
Brian S. Mittman, PhD

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Clyde Yancy, MD, MSc

Research Methods Working Group
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Michael S. Lauer, MD
Sebastian Schneeweiss, MD, ScD

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David Flum, MD, MPH
Sherine Gabriel, MD, MSC

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Eugene Washington
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Gail Hunt
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Allen Douma, MD
Howard E. Holland, Director, AHRQ Office of Communications and Knowledge Transfer
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Harlan Krumholz, MD
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Joe Selby, MD, MPH
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Art Levin, MPH, Consumer Advocate, Center for Medical Consumers
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Michele Orza, ScD, Senior Advisor
Desiree Frank, Executive Assistant
Anne Beal, MD, MPH
(*left PCORI in March 2014)
Deputy Executive Director, Chief Officer for Engagement
Orlando Gonzales, MPA, Chief of Staff for Engagement
Denise Earlington, Executive Assistant

Anne Beal, MD, MPH* (*left PCORI in March 2014)
Deputy Executive Director, Chief Officer for Engagement
Orlando Gonzales, MPA, Chief of Staff for Engagement
Denise Earlington, Executive Assistant

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Katie Jones, MS, Special Assistant to the Chief Operating Officer
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Sean Grande, Project Associate

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Lauren Holuj, MHA, Program Associate
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Ayodola Anise, MHS, Program Officer
Cathy Gurgol, MS Program Officer
Katie Lewis, MPH, Program Coordinator
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Victoria Szlydowski, Program Coordinator
Tsahai Tafari, PhD, Program Officer, Scientific Review
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Courtney Clyatt, MA, Senior Program Associate
Aingyea Kellom, MPA, Program Associate
Kristen Konopka, MPH, Program Associate

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Susan Sheridan, MBA, MiM, Director, Patient Engagement
Greg Martin, Deputy Director, Stakeholder Engagement
Suzanne Schrandt, JD, Deputy Director, Patient Engagement

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Paul Moses, Systems Support Specialist

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Brittany Jones, Administrative Services Specialist
Carly Vieira, PHR, Human Resources Manager

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Kelton Chapman, Assistant Manager
Jordan Elliker, Project Coordinator

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Katherine Hughes, MA Contracts Specialist, Pre-Award
Kirstin Margosian, MA, Contracts Specialist, Pre-Award
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Mychal Weinert, Contracts Analyst

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Merenda Tate, MBA, MHRM, Assistant Controller, Treasury Operations
Chao Wang, CPA, CGMA, MBA, Assistant Controller, Accounting Operations

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Tommesha Allen, Senior Administrative Assistant
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Christine S. Stencel, MA, Associate Director, Media Relations

Meetings and Events
Mark Q. Freeman, Manager
Kelton Chapman, Assistant Manager
Jordan Elliker, Project Coordinator

Staff as of Sept. 30, 2013

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II. PCORI Conflict of Interest Disclosures ........................................................................ A6-A10
## Research Contracts Awarded January 1, 2013 - September 30, 2013

**Table: PFA CYCLE II CONTRACTS**

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Contract Amount</th>
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<td>Effectiveness of DECIDE in Patient-Provider Communication, Therapeutic Alliance &amp; Care Continuation</td>
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<td>Using Telehealth to Deliver Developmental, Behavioral, and Mental Health Services in Primary Care Settings for Children in Underserved Areas</td>
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<td>Patient-Centered Trauma Treatment for PTSD and Substance Abuse: Is it an Effective Treatment Option?</td>
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<td>Health System Intervention to Improve Communication about End-of-Life Care for Vulnerable Patients</td>
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<td>Randomized Controlled Trial of a Patient Activation Tool in Pediatric Appendicitis</td>
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<td>Improving Healthcare Systems for Access to Care and Efficiency by Underserved Patients</td>
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<td>Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-Insulin Treated Diabetes</td>
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<td>Using Technology to Deliver Multi-Disciplinary Care to Individuals with Parkinson Disease in Their Homes</td>
<td>University of Rochester</td>
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<td>Long Term Outcomes of Lumbar Epidural Steroid Injections for Spinal Stenosis</td>
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<td>Comparing Patient-Centered Outcomes after Treatment for Uterine Fibroids</td>
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<td>Comparative Risks and Benefits of Gender Reassignment Therapies</td>
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<td>Nueva Vida Intervention: Improving QOL in Latina Breast Cancer Survivors and their Caregivers</td>
<td>Georgetown University</td>
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<td>Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology</td>
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<td>Developing Quality Metrics from Patient-Reported Outcomes for Medical Rehabilitation</td>
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<td>Shared Decision Making in Parents of Children with Head Trauma: Head CT Choice</td>
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<td>Bringing Care to Patients: A Patient-Centered Medical Home for Kidney Disease</td>
<td>University of Illinois, Chicago</td>
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<td>Patient-Defined Treatment Success and Preferences in Stage IV Lung Cancer Patients</td>
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<td>A Patient-Centered Approach to Successful Community Transition after Catastrophic Injury</td>
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<td>Comparative Effectiveness of a Decision Aid for Therapeutic Options in Sickle Cell Disease</td>
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<td>PAtient Navigator to rEduce Readmissions (PAiTNER)</td>
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<td>Sustainable Methods, Algorithms, and Research Tools for Delivering Optimal Care Study (SMART DOCS)</td>
<td>Stanford University School of Medicine</td>
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<td>Patient Valued Comparative Effectiveness of Corticosteroids Versus Anti-TNF Alpha Therapy for Inflammatory Bowel Disease</td>
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<td>Northwestern University</td>
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<td>Implementation of Patient-Centered Contraceptive Provision in Community Settings</td>
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<td>Patient Outcomes of a Self-care Management Approach to Cancer Symptoms: A Clinical Trial</td>
<td>University of South Florida</td>
<td>Susan McMillan</td>
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<td>Holly Mead</td>
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## PFA CYCLE II CONTRACTS (continued)

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<th>Organization</th>
<th>Principal Investigator</th>
<th>Contract Amount</th>
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<tr>
<td>Improving Communication for Chemotherapy: Addressing Concerns of Older Cancer Patients and Caregivers</td>
<td>University of Rochester</td>
<td>Supriya Mohile</td>
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<td>Individualized Care Plans for Hematopoietic Cell Transplant Survivors</td>
<td>National Marrow Donor Program, Inc.</td>
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<td>A Patient-Centered Intervention to Increase Screening of Hepatitis B and C among Asian Americans</td>
<td>University of California, San Francisco</td>
<td>Tung Nguyen</td>
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<td>Redesigning Ambulatory Care Delivery to Enhance Asthma Control in Children</td>
<td>University of Utah</td>
<td>Flory Nkoy</td>
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<td>Researching the Effectiveness of a Decision-Support Tool for Adult Consumers with Mental Health Needs and their Care Managers</td>
<td>Family Service Agency of San Francisco</td>
<td>Shobha Pais</td>
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<td>Generating Critical Patient-Centered Information for Decision Making in Localized Prostate Cancer</td>
<td>Vanderbilt University</td>
<td>David Penson</td>
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<td>Patient Priorities and Community Context: Navigation for Disadvantaged Women with Depression</td>
<td>University of Rochester</td>
<td>Ellen Poleshuck</td>
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<td>Impact of Radiation Therapy on Breast Conservation in DCIS</td>
<td>Dana-Farber Cancer Institute</td>
<td>Rinaa Punglia</td>
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<td>Interactive Personal Health Records: Use of a Web-Portal by Patients with Complex Chronic Conditions</td>
<td>Kaiser Foundation Research Institute</td>
<td>Mary Reed</td>
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<td>Navigator Guided e-Psychosocial Intervention for Prostate Cancer Patients and their Caregivers</td>
<td>H. Lee Moffitt Cancer Center &amp; Research Institute</td>
<td>Brian Rivers</td>
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<td>Evaluating the Impact of Patient-Centered Oncology Care</td>
<td>National Committee for Quality Assurance</td>
<td>Sarah Scholle</td>
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<td>Rural Options At Discharge Model of Active Planning (ROADMAP)</td>
<td>University of Montana</td>
<td>Tom Seekins</td>
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<td>Reducing health disparity in chronic kidney disease in Zuni Indians</td>
<td>University of New Mexico Health Sciences Center</td>
<td>Vallabh Shah</td>
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<td>Mrs. A and Mr. B</td>
<td>University of Pennsylvania</td>
<td>Margaret Stineman</td>
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<td>(P4f) Patient Participation Program for Pulmonary Fibrosis: Assessing the Effects of Supplemental Oxygen</td>
<td>National Jewish Health</td>
<td>Jeffrey Swigris</td>
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<td>Comparing Traditional and Participatory Dissemination of a Shared Decision Making Intervention</td>
<td>Carolinas Medical Center</td>
<td>Hazel Tapp</td>
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<td>Padres efectivos (parent activation): Skills Latina mothers use to get healthcare for their children</td>
<td>University of North Carolina, Chapel Hill</td>
<td>Kathleen Thomas</td>
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<td>Collaborative Care to Reduce Depression and Increase Cancer Screening among Low-Income Urban Women</td>
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<td>Ovarian Cancer Patient-Centered Decision Aid</td>
<td>University of California, Irvine</td>
<td>Lari Wenzel</td>
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<td>Reverse Innovation and Community Engagement to Improve Quality of Care and Patient Outcomes</td>
<td>Johns Hopkins University</td>
<td>Albert Wu</td>
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## INAUGURAL METHODS CONTRACTS

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<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Contract Amount</th>
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<tbody>
<tr>
<td>Advancing Stated-Preference Methods for Measuring the Preferences of Patients with Type 2 Diabetes</td>
<td>Johns Hopkins University</td>
<td>John Bridges</td>
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<td>Understanding Treatment Effect Estimates When Treatment Effects Are Heterogeneous For More Than One Outcome</td>
<td>University of South Carolina</td>
<td>John Brooks</td>
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<td>The Handling of Missing Data Induced by Time-Varying Covariates in Comparative Effectiveness Research Involving HIV Patients</td>
<td>Stanford University</td>
<td>Manisha Desai</td>
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<td>Integrating Multiple Data Sources for Meta-Analysis to Improve Patient-Centered Outcomes Research</td>
<td>Johns Hopkins University</td>
<td>Kay Dickersin</td>
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<td>Facilitating Patient Reported Outcome Measurement for Key Conditions</td>
<td>Dartmouth College</td>
<td>Elliott Fisher</td>
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<td>Methods for Comparative Effectiveness and Safety Analyses in a High-Dimensional Covariate Space with Few Events</td>
<td>Brigham and Women's Hospital</td>
<td>Jessica Franklin</td>
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<td>Building PCOR Value and Integrity with Data Quality and Transparency Standards</td>
<td>University of Colorado Denver</td>
<td>Michael Kahn</td>
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<td>Statistical Methods for Missing Data in Large Observational Studies</td>
<td>Emory University</td>
<td>Qi Long</td>
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<td>Measuring Patient-Centered Communication for Colorectal Cancer Care and Research</td>
<td>RTI International</td>
<td>Lauren McCormack</td>
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<td>Creating Locally Relevant Health Solutions with the Appreciative Inquiry and Boot Camp Translation Method</td>
<td>University of Colorado Denver</td>
<td>Donald Nease</td>
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### INAUGURAL METHODS CONTRACTS (continued)

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<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Contract Amount</th>
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<tr>
<td>A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information</td>
<td>Fred Hutchinson Cancer Research Center</td>
<td>Scott Ramsey</td>
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<td>Developing Patient-Centered Outcomes for Dementia: Goal setting and Attainment</td>
<td>University of California Los Angeles</td>
<td>David Reuben</td>
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<td>Sensitivity Analysis Tools for Clinical Trials with Missing Data</td>
<td>Johns Hopkins University</td>
<td>Daniel Scharfstein</td>
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<td>Causal Inference for Effectiveness Research in Using Secondary Data</td>
<td>Brigham and Women's Hospital</td>
<td>Sebastian Schneeweiss</td>
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<td>Improving the Use of Patient Registries for Comparative Effectiveness</td>
<td>Brigham and Women's Hospital</td>
<td>Daniel Solomon</td>
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<td>Evaluating Methods to Engage Minority Patients and Caregivers as Stakeholders</td>
<td>University of Texas Health Science Center, San Antonio</td>
<td>Barbara Turner</td>
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<td>Filling Two Major Gaps in the Analysis of Heterogeneity of Treatment Effects for Patient-Centered Outcomes Research</td>
<td>Johns Hopkins University</td>
<td>Ravi Varadhan</td>
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<td>Integrating Causal Inference, Evidence Synthesis, and Research Prioritization Methods</td>
<td>Tufts Medical Center</td>
<td>John Wong</td>
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<td>Development of a Causal Inference Toolkit for Patient-Centered Outcomes Research</td>
<td>Medical Technology and Practice Patterns</td>
<td>Yi Zhang</td>
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### PFA CYCLE III CONTRACTS

<table>
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<th>Project Title</th>
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<th>Principal Investigator</th>
<th>Contract Amount</th>
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<tr>
<td>An Integrative Multilevel Study for Improving Patient-centered Care delivery Among Patients with Chronic Obstructive Pulmonary Disease</td>
<td>Johns Hopkins University</td>
<td>Hanan Aboumatar</td>
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<tr>
<td>Balancing Treatment Outcomes and Medication Burden among Patients with Symptomatic Diabetic Peripheral Neuropathy</td>
<td>Kaiser Foundation Research Institute</td>
<td>Alyce Adams</td>
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<tr>
<td>CASA: Care and Support Access Study for implementation of a Palliative Approach with HIV Treatment</td>
<td>University of Maryland Baltimore</td>
<td>Carla Alexander</td>
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<td>A Community-Based Executive Function Intervention for Low Income Children with ADHD and ASD</td>
<td>Children’s Research Institute</td>
<td>Laura Anthony</td>
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<td>Eliminating Patient Identified Socio-legal Barriers to Cancer Care</td>
<td>Boston Medical Center</td>
<td>Tracy Battaglia</td>
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<tr>
<td>Increasing Health Care Choices and Improving Health Outcomes Among Persons with Serious Mental Illness</td>
<td>Yale University</td>
<td>Chyrell Bellamy</td>
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<td>Improving Patient Decisions About Bariatric Surgery</td>
<td>University of Michigan</td>
<td>Nancy Birkmeyer</td>
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<td>On the Move: Optimizing Participation in Group Exercise to Prevent Walking Difficulty in At-risk Older Adults</td>
<td>University of Pittsburgh at Pittsburgh</td>
<td>Jennifer Brach</td>
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<td>Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill</td>
<td>University of Southern California</td>
<td>John Brekke</td>
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<td>Patient Centered, Risk Stratified Surveillance After Curative Resection of Colorectal Cancer</td>
<td>The Alliance for Clinical Trials In Oncology Foundation</td>
<td>George Chang</td>
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<td>Reducing Unintended Pregnancies Through Reproductive Life Planning and Contraceptive Action Planning</td>
<td>Pennsylvania State University Hershey Medical Center</td>
<td>Cynthia Chuang</td>
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<td>Shared Decision Making and Renal Supportive Care</td>
<td>Baystate Medical Center</td>
<td>Lewis Cohen</td>
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<td>Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources</td>
<td>University of Wisconsin Madison</td>
<td>Elizabeth Cox</td>
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<td>Patient-Centered Support for Contraceptive Decision Making</td>
<td>University of California San Francisco</td>
<td>Christine E. Dehlerendorf</td>
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<td>Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis</td>
<td>University of Washington</td>
<td>Dawn Ehde</td>
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<td>A Helping Hand to Activate Patient-Centered Depression Care among Low-Income Patients (AHI)</td>
<td>University of Southern California</td>
<td>Kathleen Ell</td>
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<td>Integrative Medicine Group Visits: A Patient-Centered Approach to Reducing Chronic Pain and Depression in a Disparate Urban Population</td>
<td>Boston Medical Center</td>
<td>Paula Gardner</td>
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<td>Comparative Effectiveness of Broad vs. Narrow Spectrum Antibiotics for Acute Respiratory Tract Infections in Children</td>
<td>Children's Hospital of Philadelphia</td>
<td>Jeffrey Gerber</td>
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<td>Cervical Spondylotic Myelopathy Surgical Trial (CSM-S Trial)</td>
<td>Lahey Clinic</td>
<td>Zoher Ghogawala</td>
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<td>Collaborative Assessment of Pediatric Transverse Myelitis: Understand, Reveal, Educate (CAPTURE) Study</td>
<td>University of Texas Medical Center Dallas</td>
<td>Benjamin Greenberg</td>
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<td>Post-Treatment Surveillance in Breast Cancer: Bringing CER to the Alliance</td>
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<td>Patient-centered Research into Outcomes Stroke patients Prefer and Effectiveness Research (PROSPER)</td>
<td>Duke University</td>
<td>Adrian Hernandez</td>
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<td>Changing the Healthcare Delivery Model: A Community Health Worker/Mobile Chronic Care Team Strategy</td>
<td>George Washington University</td>
<td>Richard Katz</td>
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<td>Patient Centered Comprehensive Medication Adherence Management System to Improve Effectiveness of Disease Modifying Therapy with Hydroxyurea in Patients with Sickle Cell Disease</td>
<td>University of Pittsburgh</td>
<td>Lakshmanan Krishnamurti</td>
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<td>Comparative effectiveness of PEer-Led supplemental O2 Infoline for Patients and Caregivers (PELCAN)</td>
<td>University of Illinois at Chicago</td>
<td>Jerry Krishnan</td>
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<td>Quality of life in Allogeneic Hematopoietic Stem Cell Transplant Patients Is Improved when Their Caregiver's Distress Is Reduced</td>
<td>University of Colorado Denver</td>
<td>Mark Laudenslager</td>
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<td>Comparing Effectiveness of Treating Depression With &amp; Without Comorbidity to Improve Fetal Health</td>
<td>Kaiser Foundation Research Institute</td>
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<td>Northern-Manhattan Hispanic Caregiver intervention Effectiveness study (NHICE)</td>
<td>Columbia University Health Sciences</td>
<td>Jose Luchsinger</td>
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<td>Comparison of Peer Facilitated Support Group and Cognitive Behavioral Therapy for Hoarding Disorder</td>
<td>University of California San Francisco</td>
<td>Carol Mathews</td>
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<td>Improving Communication in the Pediatric Intensive Care Unit for Patients Facing Life-Changing Decisions</td>
<td>Ann and Robert H. Lurie Children's Hospital of Chicago</td>
<td>Kelly Michelson</td>
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<td>Randomized Trial to Increase Adherence to Cervical Cancer Screening Guidelines for Young Women</td>
<td>University of California San Francisco</td>
<td>Anna-Barbara Moscicki</td>
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<td>Improving Health Outcomes among Native Americans with Diabetes and Cardiovascular Disease</td>
<td>University of Colorado Denver</td>
<td>Joan O'Connell</td>
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<td>Building a Multidisciplinary Bridge Across the Quality Chasm in Thoracic Oncology</td>
<td>Baptist Memorial Hospital-Tipton</td>
<td>Raymond Osarogiagbon</td>
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<td>Impact of Patient Navigators on Health Education and Quality of Life in Formerly Incarcerated Patients</td>
<td>St. Luke's-Roosevelt Hospital Center</td>
<td>Georgina Osorio</td>
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<td>Contralateral Prophylactic Mastectomy and Breast Cancer: Clinical and Psychosocial Outcomes</td>
<td>University of Texas MD Anderson Cancer Center</td>
<td>Patricia Parker</td>
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<td>Telehealth Self-Management Program in Older Adults Living with Heart Failure in Health Disparity Communities</td>
<td>Feinstein Institute for Medical Research</td>
<td>Renee Pekmezis</td>
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<td>The Impact of Burnout on Patient-Centered Care: A Comparative Effectiveness Trial in Mental Health</td>
<td>Indiana University Purdue University at Indianapolis</td>
<td>Michelle Salyers</td>
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<td>Improving Informed Consent for Palliative Chemotherapy: Development of a Regimen-Specific Multi-Media Informed Consent Library To Promote Patient-Centered Decision-Making about Treatment of Advanced Gastrointestinal Cancers</td>
<td>Dana-Farber Cancer Institute</td>
<td>Deborah Schrag</td>
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<td>Evaluating the Navajo Community Outreach &amp; Patient Empowerment (COPE) Program</td>
<td>Brigham and Women’s Hospital</td>
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<td>Individualized Patient Decision Making for Treatment Choices among Minorities with Lupus</td>
<td>Univ of Alabama-Birmingham</td>
<td>Jasvinder Singh</td>
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<td>UCSF CT Radiation Dose Registry to Ensure a Patient Centered Approach for Imaging</td>
<td>University of California San Francisco</td>
<td>Rebecca Smith-Bindman</td>
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<td>Patient-Centered Outcomes Recovery from Treating Peripheral Arterial disease: Investigating Trajectories (PORTRAIT)-Phase II</td>
<td>St. Luke’s Hospital</td>
<td>Kim Smolderen</td>
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<td>Tools and Information to Guide Choice of Therapies in Older &amp; Medically Infirm Patients with AML</td>
<td>Fred Hutchinson Cancer Research Center</td>
<td>Mohamed Sorror</td>
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<td>Developing and Testing a Personalized, Evidence-Based, Shared Decision-Making Tool for Stent Selection in PCI</td>
<td>University of Missouri Kansas City</td>
<td>John Spertus</td>
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<td>Improving Childhood Obesity Outcomes: Testing Best Practices of Positive Outliers</td>
<td>Massachusetts General Hospital</td>
<td>Elsie Taveras</td>
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<td>Benchmarking the Comparative Effectiveness of Diabetes Treatments Using Patient-Reported Outcomes and Socio-Demographic Factors</td>
<td>Harvard University School of Public Health</td>
<td>Marcia Testa</td>
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<td>Improving Transitional Care Experience for Individuals with Serious Mental Illness</td>
<td>University of Texas Health Science Center San Antonio</td>
<td>Dawn Velligan</td>
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<td>Comparative Effectiveness of Surveillance Imaging Modalities in Breast Cancer Survivors</td>
<td>Group Health Cooperative</td>
<td>Karen Wernli</td>
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<td>Computerized PAINRelievel Protocol for Cancer Pain Control in Hospice</td>
<td>Univ. of Illinois at Chicago</td>
<td>Diana Wilkie</td>
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<td>Improving Delivery of Patient-Centered Cardiac Rehabilitation</td>
<td>University of California San Francisco</td>
<td>Mary Whooley</td>
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<td>Enhancing Genomic Laboratory Reports to Enhance Communication and Empower Patients</td>
<td>Weis Center for Research-Geisinger Clinic</td>
<td>Marc Williams</td>
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<td>A Comparative Effectiveness Trial of Optimal Patient-Centered Care for US Trauma Care Systems</td>
<td>University of Washington</td>
<td>Douglas Zatzick</td>
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</table>
PCORI’s RFP Evaluation Process

Technical and cost evaluation criteria are developed for each RFP solicitation and the weighted importance of each evaluation criterion is published in an RFP that is posted on our website. A notification is distributed via our email list and/or other vehicles as appropriate to the specific request. Submitted proposals are assessed in a careful process:

- The solicitation must comply with PCORI’s Conflict of Interest Policy; completion of a disclosure form is required.

- A PCORI Evaluation Team of procurement specialists and subject matter experts is convened and each technical proposal reviewed for merit by at least three reviewers who have been assessed for conflict of interest with the institution and personnel identified in all proposals under consideration.

- The cost proposals of the highest-scoring technical proposals are reviewed for reasonableness and accuracy.

- A Selection Committee of senior management identifies the potential contractor based on the “best value,” the combined technical and cost proposal scoring, and a verbal offer of award is made pending data collection, due diligence and acceptance.

- The verbal offer is followed by a Best and Final Offer negotiation and a contract is executed.

- Unsuccessful applicants are contacted and advised of their status. Unsuccessful applicants receive a formal debriefing upon request.

OTHER PROGRAMMATIC AWARDS (CONTRACTED THROUGH RFP)

<table>
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<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Contract Amount</th>
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<tbody>
<tr>
<td>Feasibility Study: To Determine Whether Clinical Evidence Gaps Can Be Identified from Existing National Guideline Clearinghouse Syntheses of Clinical Practice Guidelines</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>Topic Brief Support: Synthesizing Information from Evidence-Based Practice Centers to Help Inform PCORI’s Prioritization and Selection of Topics for Possible Funding</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>Scientific Survey Services</td>
<td>American Institutes for Research (AIR)</td>
<td>720,770</td>
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<tr>
<td>Topic Briefs: Assessment of Prevention and Treatment Options</td>
<td>Duke University</td>
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<td>National Patient-Centered Clinical Research Network Coordinating Center</td>
<td>Harvard Pilgrim Healthcare Inst. (HPHC)</td>
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<td>Illustrate Concepts of the Methodology Report Through Patient Narratives</td>
<td>Informed Medical Decision Making</td>
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<td>Topic Brief support: Improving Healthcare Systems</td>
<td>John Hopkins University</td>
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<tr>
<td>Landscape Reviews: Use of PRO’s in Electronic Health Records</td>
<td>John Hopkins University</td>
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<td>Workshop on Observational Studies in a Learning Health System</td>
<td>National Academies of Science</td>
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<td>PCOR/CER Roadmap for State Policymakers</td>
<td>National Academy for State Health Policy (NASHP)</td>
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<td>Comparative Effectiveness Research: Establishing Usability Criteria</td>
<td>National Health Council</td>
<td>50,000</td>
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<tr>
<td>Advisory Panel Support: Material Development of Topic Generation and Research Prioritization for Advisory Panel Meeting</td>
<td>NORC at the University of Chicago</td>
<td>71,534</td>
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<td>Understanding Options to Reduce Disparities in Cardiovascular Disease through Comparative Effectiveness Research PCO-CVOLDSR2013</td>
<td>RTI International</td>
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<tr>
<td>Science Review Officer (SRO) Support</td>
<td>Science Applications International Corporation</td>
<td>1,251,080</td>
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PCORI PATIENT-RESEARCHER MATCHING CHALLENGE

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Contract Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conceptual Model: ACTONNECT (Act Together and Connect for Patient-Centered Outcome Research)</td>
<td>Drexel University Office of Research Administration (ACTONNECT)</td>
<td>$10,000</td>
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<td>Conceptual Model: S.T.A.R. INITIATIVE</td>
<td>Healthcare Research Assoc. LLC</td>
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<td>Conceptual Model: Patient-Researcher Match</td>
<td>Lucid Bell</td>
<td>5,000</td>
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<tr>
<td>Conceptual Model: an online patient network</td>
<td>PatientsLikeMe, Inc.</td>
<td>5,000</td>
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<td>Prototype Model: WellSpringboard</td>
<td>Regents of the University of Michigan</td>
<td>40,000</td>
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<tr>
<td>Prototype Model: ResearchMatch</td>
<td>Vanderbilt University Medical Center</td>
<td>20,000</td>
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<tr>
<td>Prototype Model: Community-Driven Research</td>
<td>Estenda Solutions, Inc.</td>
<td>20,000</td>
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<tr>
<td>Prototype Model: Community Research Partners</td>
<td>Vanderbilt University Medical Center</td>
<td>20,000</td>
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</table>
PCORI Conflict of Interest Disclosures

The Patient Protection and Affordable Care Act, which authorized the establishment of the Patient-Centered Outcomes 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 decision 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 that fit within the definition of a “conflict of interest” specified by the law. Disclosures reflect those reported to PCORI as of February 25, 2014.

Board of Governors

Debra Barksdale, PhD, RN
As of January 11, 2014
Financial Associations:
• University of North Carolina at Chapel Hill (Employer)
• NIH/NINR (ended 12/31/12)
• Robert Wood Johnson Foundation—Executive Nurse Fellows Program

Personal Associations:
• National Organization of Nurse Practitioner Faculties—President
• American Association of Colleges of Nursing—Member
• American Nurses Association—Member
• National League for Nursing—Member
• American Association of Colleges of Nursing Practice Leadership Network—Member
• American Nurses Association—Member
• North Carolina Nurses Association—Member
• American Heart Association—Member
• American Academy of Nursing—Member

Kerry Barnett, JD
As of January 13, 2014
Financial Associations:
• Cambia Health Solutions (includes Blue Cross/Blue Shield and Other Affiliated Health Plans) (Employer)
• Cambia Health Solutions and Affiliates (Officer and Corporate Secretary)
• Gastroenterologist; partner in private group medical practice with ownership in ambulatory endoscopy center (Sibling)

Personal Associations:
None Identified

Lawrence Becker
As of January 8, 2014
Financial Associations:
• Xerox Corporation (Employer)
• Stock ownership:
  - Aetna, Inc.
  - GE
  - Johnson & Johnson, Inc.
  - Pfizer, Inc.
  - SPDR Biotech
  - The Travelers Companies, Inc.
  - Ventas
  - GlaxoSmithKline
  - Bristol-Myers Squibb
• LSB Consultants, LLC—company owned by wife
• Benfield Group
• The University of Rochester Medical Center (Employer of sibling)

Personal Associations:
• ERISA Industry Council—Board member
• The National Quality Forum—Board member
• Rochester Regional Health Information Organization—Board member

Carolyn M. Clancy, MD
(Resigned from Board August 23, 2013)
As of December 21, 2011; no changes since this disclosure
Financial Associations:
• Director, Agency for Healthcare Research and Quality (Employer)

Personal Associations:
• Institute of Medicine—Member
• American College of Physicians—Master
• George Washington University School of Medicine—Clinical Associate Professor

Francis S. Collins, MD, PhD
As of January 17, 2014
Financial Associations:
• Director, National Institutes of Health (Employer)

Personal Associations:
• Institute of Medicine—Member
• National Academy of Sciences—Member

Allen Douma, MD
As of January 22, 2014
Financial Associations:
None Identified

Personal Associations:
• AARP—Board member
• Jefferson Regional Health Alliance—Board member

Arnold Epstein, MD
As of January 14, 2014
Financial Associations:
• Harvard University—Faculty (Employer)
• Brigham and Women’s Hospital—Staff (Employer)
• New England Journal of Medicine—Consultant
• Partners HealthCare, Massachusetts General Hospital—Spouse’s employer
• Stock ownership:
  - ChemoTRx
  - LSI
  - Comcast

Personal Associations:
• Center for Health Care Strategies—Member of the Board of Trustees
• AcademyHealth—Member

Christine Goertz, DC, PhD
As of January 8, 2014
Financial Associations:
• Palmer College of Chiropractic—Vice Chancellor (Employer)
• American Chiropractic Association—Consultant
• Healthwise—Consultant
• Quality Insights of Pennsylvania—Consultant
• Prezacor, Inc.

Personal Associations:
• American Chiropractic Association (Member)
• American Medical Association—Measures Implementation and Informatics Performance Improvement Committee
• Health Care Professionals Advisory Committee—Alternate member
• Iowa Chiropractic Society—Member
• Journal of Manipulative and Physiological Therapeutics—Editorial Board
• American Public Health Association—member
• Women’s Leadership Council of the Quad Cities
• United Way—Member

Leah Hole-Marshall, JD
As of January 17, 2014
Financial Associations:
• Washington State Department of Labor and Industries—Medical Administrator (Employer)
• Stock ownership:
  - Fidelity Select Biotech

Personal Associations:
None Identified

Gail Hunt
As of December 23, 2013
Financial Associations:
• National Alliance for Caregiving—CEO (Employer)—The Alliance receives grants from healthcare-related groups

Personal Associations:
• National Center on Senior Transportation—Chair of the Board of Directors
• Long Term Quality Alliance—Secretary of the Board of Directors
• Center for Aging Services Technology—Commissioner
• Vinson Hall Corporation—Member of the Board of Directors
• Center for Advancing Health—Member of the Board of Trustees
• Advisory Panel on Medicare Education—Member
• American Society on Aging—Member
• National Council on the Aging—Member
• Gerontological Society of America—Member
• International Alliance of Patient Organizations—Member
• International Federation on Aging—Member
Robert Jesse, MD, PhD  
As of January 14, 2014

Financial Associations:
• Department of Veterans Affairs—Principal Deputy Undersecretary for Health (Employer)
• Virginia Commonwealth University Health System (Employer)

Personal Associations:
• American Heart Association—Fellow
• Richmond Metro Chapter of the American Heart Association—President
• American Board of Internal Medicine—Diplomate
• American College of Cardiology—Fellow
• Society of Chest Pain Centers—Board member

Richard Kronick, PhD  
As of January 17, 2014

Financial Associations:
• Agency for Healthcare Research and Quality—Director (Employer)

Personal Associations:
• National Quality Forum—Board Member
• University of California, San Diego—Faculty (unpaid leave of absence)

Harlan Krumholz, MD  
As of December 20, 2013

Financial Associations:
• Yale University—Professor of Medicine (Employer)
• VHA Inc.—Consultant
• United Healthcare—Chair, Scientific Advisory Committee
• Image COR, LLC—Founder
• American Heart Association—Editor
• Massachusetts Medical Society—Editor
• Institute of Healthcare Improvement—Chair, Scientific Advisory Group
• Medtronic, Inc.—Principal Investigator on grant through Yale University
• Centrix Technologies Pvt. Ltd.—Educational Lectures
• Premier, Inc.—Consultant
• Fujwai Hospital—Consultant

Personal Associations:
• American College of Cardiology—Board member
• CV Outcomes, Inc.—Secretary
• American Board of Internal Medicine—Board member

Richard E. Kuntz, MD, MSc  
As of January 28, 2014

Financial Associations:
• Medtronic, Inc. (Employer)
• Tengion—Board member (receives fee as Director)

Personal Associations:
• Minnesota Medical Foundation
• Case Western Reserve Medical School, Board of Visitors
• Chiari & Syringomyelia Foundation

Sharon Levine, MD  
As of January 14, 2014

Financial Associations:
• The Permanente Medical Group (Employer)
• American Medical Association—spouse’s employer

Personal Associations:
• California Association of Physician Groups (CAPG)—Board member, Executive Committee member
• California Medical Association/AMA, Member
• Medical Board of California—Board Member and Board President (2012–2013)
• Insure the Uninsured Project—Board member
• National Business Group on Health, Committee on Evidence Based Benefit Design—Member

Freda Lewis-Hall, MD  
As of January 17, 2014

Financial Associations:
• Pfizer, Inc. (Employer)
• Investments:
  • Pfizer, Inc.
  • Pfizer Savings Plan
  • Pfizer Supplemental Savings Plan
  • Pfizer/PharMacia Retirement Plan
  • Eli Lilly Defined Benefit Pension Fund
  • Bristol-Myers Squibb Defined Benefit
  • Bristol-Myers Squibb
  • Vertex Pharmaceuticals Inc.
• Pension Plan:
  • Bristol-Myers Squibb Savings Plan
  • Bristol-Myers Squibb 401(k) Profit Sharing Plan
  • Lilly Pension Retirement Plan
  • Vertex 401k Plan
  • Howard University Retirement Plan

Personal Associations:
• Power To End Stroke, American Heart Association—Board member
• Foundation for the National Institutes of Health—Board member
• Fellows of Harvard Medical School—Board member
• Institute of Medicine—Member
• Save the Children (STC)—Board Member
• NCATS Advisory Council—Council Member
• NCATS/Cures Acceleration Network Review (CAN)—Chair
• Clinical Trials Transformation Initiative (Executive Committee)

Steven Lipstein, MHA (Vice Chair)  
As of January 22, 2014

Financial Associations:
• BJC HealthCare—President and CEO (Employer)

Personal Associations:
• Emory University—Trustee
• Washington University in St. Louis—Trustee
• Missouri Hospital Association—Trustee
• Boston Children’s Hospital—Relative is employee
• St. Louis Regional Health Commission—Commissioner

Grayson Norquist, MD, MSPH (Chair)  
As of December 18, 2013

Financial Associations:
• University of Mississippi Medical School—Chair, Department of Psychiatry(Employer)

Personal Associations:
• American Psychiatric Association (APA)—Fellow
• APA Council on Research and Quality—Member
• American Psychiatric Foundation (component of APA)—Board of Directors
• AcademyHealth—Fellow
• Mississippi Coast Interfaith Disaster Task Force
• Mississippi Psychiatric Association—Member of Executive Board

Ellen Sigal, PhD  
As of December 23, 2013

Financial Associations:
• Stand Up To Cancer—Member of Scientific Advisory Committee

Personal Associations:
• Friends of Cancer Research—Founder and Chair of Board
• Reagan-Udall Foundation—Vice-Chair of Board
• Foundation for the National Institutes of Health—Chair of Public-Private Partnership Committee and Board member
• American Association for Cancer Research—Board member
• Duke University Cancer Center Board of Overseers—Board member
• Research America—Board member
• M. D. Anderson Cancer Center—Advisory Board
• The Sidney Kimmel Cancer Center, Johns Hopkins—Member, Advisory Council

Eugene Washington, MD, MSc  
Chair and Board Member (Resigned as Chair, September 2013; Resigned from Board, December 2013)  
As of February 1, 2013

Financial Associations:
• UCLA—Vice Chancellor and Dean (Employer)
• The California Wellness Foundation—Board member
• Johnson & Johnson—Director

Personal Associations:
None Identified

Harlan Weisman, MD  
As of January 14, 2014

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
• Coronado Biosciences, Inc., Stock and Stock Options
• Mendham Investment Group, LLC, Member

Personal Associations:
• American Heart Association, Fellow
• American College of Cardiology, Fellow

A-7
Methodology Committee

Naomi Aronson, PhD
As of December 28, 2013

Financial Associations:
- Blue Cross Blue Shield Association, Technology Evaluation Center (Employer)
- Under contract with Agency for Health Research and Quality

Personal Associations:
- Pew Charitable Trust, Technical Advisor, Medical Device Registry Project
- GAPNET Planning Committee
- Health Technology Assessment International Health Policy Forum
- Institute of Medicine Genomics Roundtable
- Steering Committee of the Chicago Area—DCEiDE Research Center
- National Business Group on Health Committee on Evidence-Based Benefit Design
- University of Toronto’s Internal Canada Foundation for Innovation—External Reviewer in 2012
- Center for Medical Technology Policy, Green Park Collaborative USA: Oncology Consortium; Metabolic Diseases Consortium
- Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Working Group, Tapestry Networks

Ethan Basch, MD, MSc
As of January 16, 2014

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

Personal Associations:
- National Cancer Institute—Board of Scientific Advisors
- International Society for Quality of Life Research—Board Member
- Alliance for Clinical Trials in Oncology—Chair
- American Society of Clinical Oncology—Task Force Chair

Alfred O. Berg, MD, MPH
As of January 4, 2014

Financial Associations:
None reported

Personal Associations:
- Member, Board on Population Health and Public Health Practice, Institute of Medicine
- Member, American Academy of Family Physicians
- Member, Society of Teachers of Family Medicine

David Flum, MD, MPH
As of January 14, 2014

Financial Associations:
- University of Washington—Department of Surgery (Employer)
- Surgical Consulting, LLC (Legal Consulting)
- Benchmark, LLC (Privately Owned Business), CMO
- Group Health Cooperative (Wife’s Employer)
- Shire (Received consulting fees and travel expense for Diverticular Disease Scientific Need/Working Group on 10/28/11)
- Applied Medical (received fee for symposium presentation on 10/25/11)
- American College of Phlebology (received honorarium and travel expenses for speaking at annual meeting 11/4/11)
- American Academy of Orthopaedic Surgeons—Speaker (4/12–13/2012; 8/5–6/2012)
- Nestlé—Speaker (9/21–23/2012; 1/10–14/2013)
- American College of Surgeons—Surgical Research Committee Chair (ongoing) & Outcomes Research Course Chair (11/7–10/2012)
- Australia New Zealand Hepato—Biliary Association—Speaker (10/30–11/7/2012)
- Kones International—Speaker at Int’l Conf. on Advanced Technologies & Treatments for Diabetes (2/26-3/1/13)
- NIDDK/NHLBI—Speaker at Bariatric Surgery Long-Term Outcomes Workshop (5/22/13–5/23/13)
- Foundation for Healthcare Quality—Speaker at Annual SCOAP Retreat (6/14/13)
- Pacira Pharmaceuticals—Consultant (4/22/13–present)

Personal Associations:
- American College of Surgeons—Fellow and Vice Chair of Surgical Research Committee
- Washington State Chapter—American College of Surgeons—Member
- American Society for Metabolic and Bariatric Surgery—Member
- American Surgical Association—Member
- Henry N. Harkins Surgical Society—Member
- Seattle Surgical Society—Member
- Surgical Outcomes Club—Member
- AcademyHealth—Member

Robert Zwolak, MD, PhD
As of February 25, 2014

Financial Associations:
- Dartmouth-Hitchcock Clinic (Employer)
- US Department of Veterans Affairs (Employer)
- Society for Vascular Surgery—Consultant
- US Department of Veterans Affairs (Employer)
- Dartmouth-Hitchcock Clinic (Employer)
- Henry N. Harkins Surgical Society—Member
- American Surgical Association—Member
- American College of Chest Physicians, Fellow
- American Medical Association
- American Association for the Advancement of Science
- American Association for Medical Research
- American College of Physicians
- American College of Surgeons—Fellow and Vice Chair of Surgical Research Committee
- American Society for Metabolic and Bariatric Surgery—Member
- American Surgical Association—Member
- AcademyHealth—Member

Personal Associations:
- Pertinent Previous: Institute of Medicine Development (2005–2008)
- Pertinent Previous: Institute of Medicine Forum on Innovation—External Reviewer in 2012
- Pertinent Previous: Institute of Medicine Forum on Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Working Group, Tapestry Networks (2005–2008)
- Pertinent Previous: Institute of Medicine Forum on Society to Improve Diagnosis in Medicine (2005–2008)

Investments:
- EVA Corporation, medical device manufacturer
- DEcIDE Research Center
- Center for Medical Technology Policy, Green Park Collaborative USA: Oncology Consortium; Metabolic Diseases Consortium
- Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Working Group, Tapestry Networks

Ethan Basch, MD, MSc
As of January 16, 2014

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

Personal Associations:
- National Cancer Institute—Board of Scientific Advisors
- International Society for Quality of Life Research—Board Member
- Alliance for Clinical Trials in Oncology—Chair
- American Society of Clinical Oncology—Task Force Chair

Alfred O. Berg, MD, MPH
As of January 4, 2014

Financial Associations:
None reported

Personal Associations:
- Member, Board on Population Health and Public Health Practice, Institute of Medicine
- Member, American Academy of Family Physicians
- Member, Society of Teachers of Family Medicine

David Flum, MD, MPH
As of January 14, 2014

Financial Associations:
- University of Washington—Department of Surgery (Employer)
Sherine Gabriel, MD, MSc  
(Resigned from Methodology Committee September 26, 2013)  
As of February 19, 2013

**Financial Associations:**
- Mayo Clinic (Employer)
- Genentech
- Hoffman-LaRoche
- National Institutes of Health

**Personal Associations:**
- FDA/CIDER Drug Safety and Risk Management Advisory Committee—Member (2010–present)
- Chair, FDA/CIDER Drug Safety and Risk Management Advisory Committee—Member (2011–present)
- External Advisory Board, University of Puerto Rico Post-doctoral Master of Science in Clinical Research Program, School of Medicine and School of Health Professions—Member (2006–present)
- Executive Board, Observational Medical Outcomes Partnership, Foundation for the NIH—Member (2008–present)
- Scientific Advisory Board, Excellence in Rheumatology—Member (2010–present)
- International Coordination Council, Bone and Joint Decade/Initiative—Member (2010–present)
- CTSA Academic-Industry Working Group—Chair (2010–present)
- Steering Committee, Actemra Cardiovascular Outcomes Trial (ENTRACTE), Roche—Member (2009–present)
- Pharmacoeconomics Advisory Board, Genentech—Member (2009–present)
- External Research Education Advisory Board, University of Kentucky CTSA—Member (2011–present)
- External Research Education Advisory Committee, Georgetown University—Member (2011–present)
- Oversight Board, Welcome Trust, HRB Dublin Centre for Clinical Research—Member (2011–present)

**Steven Goodman, MD, MHS, PhD (Vice Chair)**  
As of January 21, 2014

**Financial Associations:**
- Stanford University (Employer)
- National Blue-Cross/Blue Shield, Scientific Advisor to Technology Assessment Program
- The American College of Physicians, Associate Editor for Annals of Internal Medicine

**Personal Associations:**
- Editor, Clinical Trials: Journal of the Society for Clinical Trials
- Society for Clinical Trials—Member
- American Academy of Epidemiology—Member

**Mark Helfand, MD, MS, MPH**  
As of December 17, 2013

**Financial Associations:**
- Employer: Portland VA Medical Center, Portland, OR (Hospital and Clinics)
- Employer: Oregon Health & Science University, Portland, OR (Hospital and Clinics)
- Research Grants, Contracts, Consulting, Teaching:
  - US Department of Veterans Affairs (grants)
- Agency for Healthcare Research & Quality, US DHHS (contracts), Consumers Union (Consultant)
- Lectures at several universities in the US and abroad

**John Ioannidis, MD, DSc**  
(Resigned from Methodology Committee October 14, 2013)  
As of February 11, 2013

**Financial Associations:**
- Professor, Stanford University School of Medicine (Employer)

**Personal Associations:**
- Editor-in-chief, European Journal of Clinical Investigation
- Editorial member of 30 international peer-reviewed journals

**Michael S. Lauer, MD**  
As of February 6, 2014

**Financial Associations:**
- National Institutes of Health (Employer)
- Savings Investment Plan
- Putnam College Fund
- UptoDate Inc.

**None Identified**

**David O. Meltzer MD, PhD**  
As of January 17, 2014

**Financial Associations:**
- University of Chicago (Employer)
- Novartis
- CVS
- ABIM
- Peoplechart
- Cubist
- InHealth
- Centers for Medicare and Medicaid Innovation
- Grants from:
  - National Institutes for Health
  - Agency for Healthcare Research and Quality
  - Robert Wood Johnson Foundation
  - National Pharmaceutical Council
- Stocks holding in Acadia Pharmaceuticals and Valeant Pharmaceuticals

**Personal Associations:**
- ABIM, SGIM, SHM, MDM—Member
- University of Chicago

**Brian S. Mittman, PhD**  
As of January 27, 2014

**Financial Associations:**
- US Department of Veterans Affairs, VA Greater Los Angeles Healthcare System (Employer; wife’s employer)
- Sepulveda Research Corporation (VA Nonprofit Research Foundation, Employer)
- Kaiser Permanente Southern California, Department of Research and Evaluation (Employer)
- UCLA School of Medicine (Employer)
- Harvard University Dana Farber Cancer Institute (Consultant, NIH grant)
- Lewin Group (Speaking honorarium, AHRQ Chartered Value Exchange program)
- National Institutes of Health (Consultant, NIH/VA training program)
- Purdue Pharmaceuticals (Consultant, FDA Risk Evaluation & Mitigation Strategy CME program)
- RAND Corporation (Consultant)
- Novartis; Precision Health Economics (Consultant, Comparative Effectiveness Working Group)
- Stanford University (Speaking honorarium, RWJF training program)
- University of Iowa (Consultant, NIH and RWJF grants)
- Washington University in St. Louis (Consultant, NIH training grant)
- Westat (Consultant, AHRQ Health Care Innovations Exchange)

**Robin Newhouse, PhD, RN (Chair)**  
As of December 30, 2013

**Financial Associations:**
- University of Maryland—School of Nursing, Chair, Organizational Systems and Adult Health (Employer)
- Speaker Honorarium: Midwest Nursing Research Society, Southern Nursing Research Society, University of Arkansas, University of Michigan, University of Minnesota
- Consultation: VHA Inc.
- Righttime Medical Care (child’s employer)

**Personal Associations:**
- Review Committee for Student Posters, 2012 AcademyHealth Research Meeting—Chair
- American Nurses Credential Center—Research Council Member
- American Nurses Credentialing Center (Research Council Chair Elect)
- AcademyHealth (Board of Directors)
- Institute of Medicine (Standing Committee on Credentialing Research in Nursing)
- American Academy of Nursing (member)
- American Nurses Association (member)
- Council for the Advancement of Nursing Science (member)
- Sigma Theta Tau International Honor Society of Nursing (member)
- Southern Nursing Research Society (member)
- American Organization of Nurse Executives (member)
- Council for graduate Education for Administration in Nursing (member)
Sebastian Schneeweiss, MD, ScD  
As of January 2, 2014

Financial Associations:
• Brigham and Women’s Hospital
• Harvard School of Public Health
• WHISCON LLC
• Harvard Medical School (Teaching)
• AcademyHealth (Consultant)
• Abt Associates (Consultant)
• Neblett, Beard & Arsenaut (Consultant)
• Aetion, Inc. (Consultant and shareholder)

Personal Associations:
• International Society for Pharmacoepidemiology (Member and Fellow)
• International Society for Pharmacoeconomics and Outcomes Research (Member)
• American Society for Clinical Pharmacology and Therapeutics (Member)
• American College of Epidemiology (Fellow)
• American College of Clinical Pharmacology (Fellow)

Jean R. Slutsky, PA, MSPH  
As of March 21, 2012

Financial Associations:
• Agency for Healthcare Research and Quality (Employer)

Personal Associations:
None Identified

Mary Tinetti, MD  
As of January 14, 2014

Financial Associations:
• Yale University (Employer)
• National Institutes of Health
• Hartford Foundation
• Journal of the American Medical Association (JAMA)—Viewpoint editor
• MacArthur Foundation

Personal Associations:
• ADGAP—Board of Directors

Clyde Yancy, MD, MSc  
As of February 4, 2014

Financial Associations:
• Northwestern University, Feinberg School of Medicine (Employer)—Aligned with Northwestern Memorial Hospital Corporation and Northwestern Memorial Physician Group
• National Institutes of Health
• Food and Drug Administration
• Medscape, theheart.org
• FDA (Special government employee, Chair, Cardiovascular Devices Panel)

Personal Associations:
• American Heart Association—Former National President 2009-2010, Board Member (Chicago Metro), Committee member
• American Hospital Association—Committee member
• American College of Cardiology—Committee member; Author, Clinical Practice Guidelines
• American College of Physicians—Member
• Association of Black Cardiologists—Member, Educator
• Heart Failure Society of American—Member, Committee Member
• Heart Rhythm Society of American—Member, Educator

Jean R. Slutsky, PA, MSPH  
As of March 21, 2012

Financial Associations:
• Agency for Healthcare Research and Quality (Employer)

Personal Associations:
None Identified

Mary Tinetti, MD  
As of January 14, 2014

Financial Associations:
• Yale University (Employer)
• National Institutes of Health
• Hartford Foundation
• Journal of the American Medical Association (JAMA)—Viewpoint editor
• MacArthur Foundation

Personal Associations:
• ADGAP—Board of Directors

Clyde Yancy, MD, MSc  
As of February 4, 2014

Financial Associations:
• Northwestern University, Feinberg School of Medicine (Employer)—Aligned with Northwestern Memorial Hospital Corporation and Northwestern Memorial Physician Group
• National Institutes of Health
• Food and Drug Administration
• Medscape, theheart.org
• FDA (Special government employee, Chair, Cardiovascular Devices Panel)

Personal Associations:
• American Heart Association—Former National President 2009-2010, Board Member (Chicago Metro), Committee member
• American Hospital Association—Committee member
• American College of Cardiology—Committee member; Author, Clinical Practice Guidelines
• American College of Physicians—Member
• Association of Black Cardiologists—Member, Educator
• Heart Failure Society of American—Member, Committee Member
• Heart Rhythm Society of American—Member, Educator

Note: The names of the members of PCORI’s Advisory Panels and their Conflict of Interest disclosure statements are available on PCORI’s website: pcori.org/get-involved/advisory-panels
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:

1. Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?
2. What are my options and what are the potential benefits and harms of those options?
3. What can I do to improve the outcomes that are most important to me?
4. How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?

To answer these questions, PCOR:

1. 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;
2. 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;
3. Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
4. Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.