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

OUR MISSION
The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.
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Those of us privileged to serve as part of PCORI’s leadership look back on FY 2015 as a year of important progress in serving our stakeholders as the nation’s leading funder of patient-centered comparative clinical effectiveness research (CER).

As our portfolio of funded CER and related projects topped $1 billion, we continued to shift our emphasis to larger studies of specific conditions that impose a substantial burden on the health of patients and the healthcare system as a whole.

We saw completion of the initial development phase of PCORnet, the National Patient-Centered Clinical Research Network, our initiative to help researchers harness health data and stakeholder partnerships to boost the pace and power of health research at lower cost than is possible today.

We saw our early research investments begin to bear fruit. Our Pilot Projects, the 50 studies we funded in 2012 to learn more about how our approach to CER might work, moved toward completion and initial analyses. Investigators on several of our early primary CER projects began publishing their initial findings in major medical journals.

Looking toward the day when our portfolio begins to produce a steady stream of results, we finalized and started implementing the process by which we will meet our legal mandate to assess the scientific integrity of our funded studies and make their results widely available to patients, clinicians, and the public. To that end, we began putting in place a comprehensive plan to disseminate and promote the uptake of the research findings and launched an initial set of continuing professional education activities on foundational aspects of our approach to research and the first results of our funded studies.

Finally, PCORI, the Board of Governors, and our staff were very pleased to see the US Government Accountability Office affirm in its initial review of our activities that PCORI met the requirements set forth in our authorizing law to establish priorities, programs, and processes that will let us fulfill our promise to produce evidence-based information that will enhance healthcare decisions. Given our progress in the past year, we are more confident than ever of delivering on that promise.

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

Kerry Barnett, JD
Vice-Chairperson, PCORI Board of Governors; President and CEO, SAIF Corporation
As we look back on fiscal 2015, we see a clear record of PCORI’s achievements, growing influence, and opportunities for progress. You will read about our work in the pages ahead, but here are a few highlights.

We are pleased to see how robust a collection of comparative clinical effectiveness research (CER) projects we have funded to date—the main reason Congress authorized our creation in 2010. About 72 percent of the more than $1 billion in funding our Board has approved for research and related projects supports patient-centered CER studies. The rest funds research to improve the science and methods of CER, as Congress also directed, and to develop PCORnet, the National Patient-Centered Clinical Research Network, to harness the power of data and partnerships to conduct critical patient-centered outcomes research faster, more effectively, and at a lower cost.

We have accelerated our ongoing efforts to fund more large studies targeting conditions that impose a high burden on patients and the healthcare system. These include comparisons of drugs, medical procedures, and other approaches to disease prevention, diagnosis, and treatment. The proportion of our research portfolio invested in such projects jumped from 17 percent in 2013 to more than 40 percent through the end of FY 2015; we project it will increase further in the next few years.

Perhaps as important a milestone as building our funded portfolio of patient-centered research is the growing evidence that our work is changing the conversation about how health research is conducted in the United States—and in the process, having an impact on the culture of research itself.

Since our creation, we have focused on the issues and outcomes most important to patients. We do that by engaging patients and their families—along with researchers, clinicians, insurers, health systems, and others across the healthcare community—in all aspects of our work. It is gratifying to see that approach reflected in the growing body of articles our awardees are publishing in top scientific journals and increasingly adopted as healthcare institutions, academic centers, and other organizations pursue their research, teaching, and training activities. We believe our leadership is one reason funders, policymakers, health systems, and industry increasingly seek to engage patients in their work.

Our goal is to see patient-centeredness become the norm in health research and delivery. We think we are on the way to making that a reality.

Joe Selby, MD, MPH
Executive Director

Bryan Luce, PhD, MBA*
Chief Science Officer

Jean Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer; Program Director, Communication and Dissemination Research

Regina Yan, MA
Chief Operating Officer

Mary C. Hennessey, Esq.
General Counsel

*Luce resigned as Chief Science Officer in September 2015.
As we completed our fifth year, PCORI moved into a new phase: we’ve begun to deliver on our promise to help patients and those who care for them make better-informed healthcare decisions.

This year, we celebrated the completion of our Pilot Projects, as well as the first of our early comparative clinical effectiveness research (CER) studies. With these and other projects beginning to yield results and publish scientific reports, we put into place procedures to evaluate and disseminate the findings. Our research portfolio expanded significantly during the past year, with approved funding for CER studies increasing by 64 percent over the previous year’s total. We increased our focus on funding large studies carried out in routine healthcare settings—projects we believe have great potential to quickly lead to improved patient care and outcomes. Continuing our commitment to engagement throughout the research process, we relied on patients, clinicians, and other stakeholders to suggest and hone the research questions that became our targeted funding announcements and high-priority topics for our pragmatic clinical studies.

PCORnet, the National Patient-Centered Clinical Research Network,

### FY2015 MILESTONES

- **October 2014**
  - PCORI announces plans to offer up to $4 million for Engagement projects through expanded Pipeline to Proposals awards program

- **November 2014**
  - Board approves new advisory panel (on Communication and Dissemination Research), and offers up to $9 million to fund a pair of obesity-related PCORnet demonstration research projects

- **December 2014**
  - GAO issues initial assessment saying PCORI’s work is following its legislative requirements
  - PCORI makes first Tier II Pipeline to Proposal Awards

- **January 2015**
  - Board approves providing up to $50 million for CER projects on Hepatitis C
  - PCORI and NIH partner on request for applications to study how to improve blood pressure control in high-risk individuals

- **February 2015**
  - Following public comment, Board adopts process for peer review and public release of research findings
  - Board approves $64.1 million for first five pragmatic clinical studies

- **March 2015**
experienced substantial expansion. Our Board of Governors approved funding for PCORnet’s next three-year development phase, adding several partner networks to those approved under Phase I. Three large research projects were launched to demonstrate how PCORnet can be used to harness electronic health data and partnerships. Participants in PCORnet also continued to develop tools and processes to facilitate research and data sharing.

As we expanded our research portfolio, we also grew our efforts to meaningfully engage stakeholders in all aspects of our work and the research we fund. One highlight was our framework, unique among funders, for supporting the compensation of patients and other stakeholders involved as partners in the research we fund. During the past year, we expanded our engagement award programs, which promote new relationships between researchers.

April 2015
- Board approves $120 million for 34 CER projects, including five more pragmatic studies
- PCORI approves 47 new Pipeline to Proposal Awards

May 2015
- Board approves $14 million for study of optimal aspirin dosing in heart disease, the first PCORnet research demonstration project
- PCORI begins offering CME/CE activities

June 2015
- Board approves $56.7 million for four new pragmatic clinical studies
- Board approves $9 million for two PCORnet research demonstration studies on obesity treatment and prevention
- Engagement Awards program passes $10 million mark in project support

July 2015
- Board approves $142.5 million for infrastructure development of 34 networks in second phase of the PCORnet initiative

August 2015
- Board approves $23.5 million for two studies on health disparities related to uncontrolled high blood pressure
- Board approves $83 million for 26 CER studies

September 2015
- Board approves $8 million for two CER studies
and other stakeholders aimed at the development of patient-centered CER proposals.

We began developing an extensive, integrated effort to disseminate the results of PCORI-funded research to stakeholders across the healthcare spectrum. This year, our Board adopted our process for peer review and public release of research findings. As part of our dissemination program, we began offering certified professional educational opportunities, making new evidence, as well as guidance on trustworthy methods for patient-centered CER, available across the healthcare community.

We continue to refine the processes by which we evaluate our own work, performing in-depth analysis of our operations and the results they yield. We were encouraged by the positive findings of the Government Accountability Office’s review of our first five years. We also began requiring our funded researchers to describe their engagement efforts to help us measure the impact of stakeholder involvement in all phases of research. An analysis of our merit review process showed that nonscientists are contributing effectively to the decision making.

As we look ahead, we are eager to bring more—and larger—research projects to completion, and make their results widely available to patients, caregivers, clinicians, and other healthcare stakeholders to improve care and outcomes. We are gratified to see that our patient-centered work is having an impact on the research community, with a growing number of clinical studies now including patient voices and healthcare leaders citing PCORI’s innovations in “Research Done DifferentlySM.”

I am excited to be a part of this larger conversation. We’re working to build partnerships and change how research is done.  

LINDA CARTER-FARRIER, Member, Community Advisory Council, Interactive Autism Network
This past year saw a number of major milestones in PCORI’s ongoing mission to fund patient-centered comparative clinical effectiveness research (CER) studies that will provide patients and those who care for them with the evidence needed to help them make better-informed healthcare decisions.

We advanced our research agenda by expanding our portfolio of patient-centered CER studies approved by our Board of Governors under our five National Priorities for Research, adopted in 2012. As our priorities and associated research agenda envisioned, our portfolio continues to shift toward a focus on larger studies of stakeholder-prioritized topics designed to improve care and outcomes in conditions that impose a major burden on patients, their families, and the US healthcare system as a whole.

Along with expanding our research portfolio, we took several steps during the year to support the infrastructure and methods needed to ensure that this critical research can be conducted efficiently and with scientific rigor.

In one such step, our Methodology Committee undertook a review of the research standards that it developed and our Board adopted in 2013, thus addressing our legal mandate to “develop and improve the science and methods” of CER. We also saw substantial progress in the development of PCORnet, the National Patient-Centered Clinical Research Network, our initiative to transform the nation’s capacity to conduct outcomes research more efficiently, more robustly, and less expensively than is now possible.
An Ongoing Shift to Larger, Targeted Studies

During FY 2015, our Board approved $357 million in funds for patient-centered CER studies, a 64 percent increase from 2014. This brought our cumulative funding total since 2012 to $1.20 billion for 468 patient-centered CER studies and infrastructure and methods projects to support CER.

Since our establishment, our commitment to engaging patients and other healthcare stakeholders has led us to fund many projects that address patient populations, topics, concerns, and outcomes that traditional research has not adequately studied. This same process supports our shift toward funding more, larger studies addressing topics and research questions designed to have a substantial clinical impact on conditions that impose a major burden on patients, their families, and the healthcare system as a whole.

Through our research prioritization process, we actively solicit potential topics for funding from the entire healthcare community. We then convene stakeholders, through our advisory panels, workshops, and work groups, to refine these topics and associated research questions. We recommend the highest priority research topics to our Board for approval to develop them into funding announcements.

We made that prioritization system more transparent during the past year, updating our website to allow the public to more easily track the progress of specific topics as they move through our multi-step process as we evaluate and approve research questions and prepare funding announcements.

Topics prioritized through this process are included in two types of calls for research projects: targeted funding

The initial phase of development of PCORnet was completed during the year, with participation by 29 research partner networks building a data network for health research governed by a unique collaboration between researchers, patients, health systems, and clinicians. Our Board approved funding for a series of studies designed to demonstrate PCORnet’s research readiness and, as the year drew to a close, selected 33 partner networks for funding during Phase II of the initiative, including continuing support for 27 of the networks that participated in Phase I.

Finally, we were pleased to see a growing body of scientific articles resulting from our funded studies published in major peer-reviewed journals. This included papers summarizing the progress of our Pilot Projects and reporting early findings from two studies approved during our initial funding cycles.
and pragmatic clinical studies announcements. Targeted funding announcements make designated amounts of support available for CER studies of specific research questions, clinical conditions in particular. We include other prioritized topics in funding announcements for our pragmatic clinical studies initiative. These large trials collect data in routine clinical care settings and are designed to produce evidence that patients and clinicians can quickly use to answer practical questions about care options.

During the year, our Board approved $29.5 million for two large targeted projects that aim to improve care for people infected with hepatitis C virus. The Board also approved development of targeted funding announcements addressing two topics: long-term opioid use for chronic pain and treatments for people with multiple sclerosis. Other high-priority topics under consideration included management strategies for treatment-resistant depression and obesity treatment options set in primary care for underserved populations.

Our Board also approved funding for 14 awards, totaling $176.6 million, for large pragmatic clinical studies. These covered high-priority topics including prevention of chronic lower back pain, treatment of hip fractures in the elderly, and proton versus photon therapy for breast cancer.

Through two cycles of broad calls for proposals under our national research priorities, we also continued to solicit the research community’s best ideas for CER studies. The Board approved $114.1 million for 53 such projects, including a special pool of nearly $7.4 million for studies of rare diseases, one of the specific areas of research focus our authorizing law emphasizes.

Enhancing Our Application and Merit Review Processes
Before our Board approves any research funding, proposals go through our unique merit review process, which involves the participation of patients and other healthcare stakeholders, alongside scientists, to select scientifically rigorous, patient-centered projects.

In FY 2015, our Merit Review team oversaw the evaluation of 576

"I feel my voice is heard and respected but more importantly, I listen very carefully to the other panel members and I have been continuously inspired by the other panel members’ insights, thoughts, knowledge. And as a result I feel that today I am an even stronger advocate of patient-centered approaches to outcomes research."

MARCIA RUPNOW, MS, PHD, Senior Director of Health Economics and Outcomes Research, Janssen Science Affairs

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FY2015 ANNUAL REPORT
applications submitted in response to 18 funding announcements. The team managed 28 review panels staffed by more than 500 scientist, patient, and other stakeholder reviewers. To make this unique process as effective as possible, we continued to provide specialized reviewer training and support, including instruction on preparation of proposal critiques.

We also implemented improvements designed to make our application process more efficient and less burdensome for those seeking our funding, increasing the chances they will submit a successful proposal. For example, we extended our competitive Letter of Intent (LOI) review process to cover applications under all five of our national research priorities, reducing the work for applicants and giving our staff more time to recruit reviewers with appropriate expertise. To relieve reviewer burden, we cut in half the number of applications assigned to each reviewer and allowed more time for reviews. And to encourage submission of high-quality proposals, we no longer specify that an application can be resubmitted only once.

Transforming the Nation’s Ability to Conduct Patient-Centered CER
This was a year of major accomplishment for PCORnet, the National Patient-Centered Clinical Research Network. This unique initiative is designed to make CER faster, more inclusive, and less expensive by securely harnessing the power of partnerships and data from electronic health records, claims databases, and patients themselves.

Growth. The end of the fiscal year marked the completion of the initial 18-month development phase of PCORnet, which involved 29 partner networks that our Board approved for funding in late 2013. These 11 health system-based Clinical Data Research Networks (CDRNs) and 18 Patient-Powered Research Networks (PPRNs), which were governed and operated by groups of patients and their partners, made substantial progress in building PCORnet’s basic structure and making it research-ready. As part of that effort, the partner networks collected data representing about 75 million patients and contacted more than 3 million individuals for in-depth surveys about their conditions, characteristics, and interest in participating in future studies.

Demonstration Research Projects. Following extensive evaluation and review, several PCORnet demonstration research projects got under way. These will serve as “proofs of principle” for the usefulness of PCORnet’s unique resources. The cost of such studies is expected to be much lower than that of comparable conventional studies.

The first study is a prospective randomized trial comparing the benefits and harms of low- and regular-strength daily doses of aspirin in patients diagnosed with heart disease. Seven CDRNs and one PPRN are participating.

The other two research projects focus on obesity. One is an observational study of the effects of antibiotic use during the first two years of life on body mass index of 5- and 10-year olds. The study will use...
clinical records on 1.6 million children from nine CDRNs. The other project, involving 10 CDRNs, aims to estimate the benefits and risks for adolescents and adults of the three most common bariatric, or weight-loss, surgical procedures.

Plans were under way for several additional research demonstration projects. In one, a collaboration with the NIH and CDC would compare the impact of population-targeted health policies on risk and complications of diabetes.

**PCORnet Governance Improvements.** Leaders of PCORnet’s partner networks worked closely with PCORI staff and the project’s Coordinating Center during the year to improve governance procedures. The goal was to streamline decision-making functions while maintaining appropriate representation by the individual networks and their partners and maintaining a core focus on patient-centeredness. A new PCORnet governance structure was approved in August.

As part of this effort, the PCORnet Commons, a collection of shared tools and processes to help the networks accelerate their research, was under development. In addition, PPRNs and CDRNs teamed up to create novel data-acquisition tools, develop measures of patient-reported outcomes, and define and disseminate computable phenotypes (electronic algorithms used to identify diseases). PCORnet governance was further developed to allow outside researchers, under rules and safeguards, to begin using PCORnet data for a wide range of studies.

**Data Sharing.** Crucial to PCORnet’s success has been the development of approaches to data sharing designed to allow researchers to conduct research using information gathered through different clinical systems and protocols.

PCORnet is a federated approach in which data stay with the CDRNs and PPRNs that collected them, protecting patient privacy. In FY 2015, mechanisms were developed and implemented that ensure data elements collected through this approach meet standard definitions and pass quality checks. Clinical organizations not connected to PCORnet have started using the common data model developed for PCORnet, suggesting it may become a standard for sharing information for CER studies across organizations.

**Phase II.** In July, our Board approved $142.5 million in funding for PCORnet’s second three-year development and implementation phase, deciding to continue to support most of the Phase I partners while adding six networks, including two PPRNs focused on communities rather than diseases or conditions. Phase II will focus on refining the network’s research and data infrastructures and capacity to conduct clinical trials, continuing to improve its governance structure, and advancing new opportunities for collaboration among and between partner networks as well as with additional research entities. It will also facilitate ongoing and additional demonstration projects designed to test-drive PCORnet’s research readiness while answering important patient-centered outcomes research questions.

**Improving Research Methodology**

In 2013, our Board adopted an initial set of 47 standards in 11 categories developed by our Methodology Committee to guide the development
and conduct of patient-centered CER that produces valid, useful evidence leading to improved patient care and outcomes. In FY 2015, the Committee, supported by PCORI staff, continued its work to disseminate those standards. The Committee collaborated with Baylor College of Medicine to create continuing medical education (CME) and continuing education (CE) modules that are available online for professional development. The CME/CE modules help multidisciplinary researchers acquire the knowledge and skills necessary to apply the standards to the design and conduct of studies.

The Committee also worked with Johns Hopkins University to create an academic curriculum for faculty who are teaching content related to CER. The academic curriculum includes teaching resources such as presentation materials, a teaching guide, and self-assessment questions. The curriculum, which can be accessed and downloaded from the PCORI website, is appropriate for graduate students, research personnel, and funding agency and patient advocacy organization staff, as well as others.

Concurrently, the Committee worked on a series of updates and revisions to the standards, proposing a new category—Standards for Designs Using Clusters—to be added to the 11 categories developed earlier. As required by our authorizing law, these standards will be finalized after public comment, a process expected to be completed in early 2016. The Committee also began considering complex interventions as a future new category of standards and developing guidance on definitions and components of usual care, decision-making sciences, patient-reported outcomes in electronic health records, innovative approaches to study design, and other aspects of research methods.

RESEARCH SNAPSHOT

**Picking the Easier Way to Fight Serious Infections in Children**

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

Ron Keren, MD, MPH, of the Children’s Hospital of Philadelphia is studying how oral and PICC-delivered antibiotics stack up in treating three serious childhood infections: osteomyelitis, a bone infection; complicated pneumonia; and perforated appendicitis. With osteomyelitis, the team found that the two methods were equally effective, but the children with PICC lines had three times the rate of complications.

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

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

**Principal Investigator:** Ron Keren, MD, MPH

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

PCORI’s Pilot Projects and Early CER Studies Move toward Completion

This past year saw the completion of all 50 PCORI Pilot Projects, studies designed to explore evidence-based methods and strategies to advance patient-centered outcomes research. All will undergo PCORI’s process for peer review and public release of our research results, as will all of the primary CER projects as our awardees finish analyzing their results and submit their final research reports. More information on our peer review process can be found on page 16.

In the meantime, researchers have been publishing a steady series of papers in peer-reviewed journals summarizing their initial findings. Some of these, from our earliest-funded cycles of primary research funding, suggest both the potential impact that patient engagement can have in adjusting study outcomes measures so they are more patient-centered, as well as the real-world impact CER can have on helping patients and clinicians make more informed healthcare choices. In addition, 26 of our Pilot Project teams were approved for Eugene Washington PCORI Engagement Awards to support their dissemination activities, including presenting findings at conferences, organizing meetings to share findings with key stakeholders, and developing online toolkits to support wider dissemination. More information about our Engagement Awards and our broader dissemination plans can be found on page 14.
As we have from the time PCORI was established, we hold fast to our commitment to meaningfully engage patients and other healthcare stakeholders in all aspects of our work.

By involving patients, caregivers, clinicians, employers, insurers, and representatives of health systems and industry throughout the research process, we make it more likely that the studies we fund ask the right questions, measure the outcomes most important to patients, and produce relevant and useful results that will be adopted in practice. We also strive to develop a nationwide community that is ready and able to participate in patient-centered comparative effectiveness research (CER).

This stakeholder-driven approach to CER, which we call “research done differently,” is changing the conversation about research and the culture of research itself, making it more responsive to the needs of those who depend on the studies we fund to make often difficult choices about the healthcare options they face daily.

Choosing High-Priority Topics
A stakeholder-driven approach is especially important as we continue to focus our portfolio on larger studies of topics that impose a substantial burden on patients, their families, and the healthcare system. As topics move through our research prioritization pathway, we hold large, multi-stakeholder meetings to help us refine and prioritize significant research questions. In FY 2015, we held eight workshops in which a diverse range of healthcare stakeholders helped us refine potential research questions to focus on in potential funding announcements on a series of high-impact topics (see table on next page).

Enhancing Engagement as a Path to Better Research
Helping Applicants Develop Strong Engagement Plans

Over the past year, we continued to develop practical tools to guide applicants in meeting our requirements for including patient and other stakeholder partners in research. Perhaps the most important tool we offer researchers is the PCORI Engagement Rubric, which provides guidance for applicants as they shape their engagement practices. It also guides our merit review process, as well as much of our overall engagement work.

This year, we made several changes to the rubric to help applicants. We now offer more information about how applicants can make strategic choices of engagement partners and ways in which those partners contribute to the study. We also added many more real-world examples of current studies’ engagement practices. The revised rubric, its third version, was scheduled to be released in October 2015.

To encourage PCORI-funded research teams to recognize the value of the time and effort that patient, caregiver, and other stakeholder partners offer to research projects, we released a unique framework on compensation of patient and other stakeholder research partners. It addresses compensation of patients, caregivers, and other stakeholders on the research time, rather than compensation of research subjects.

Our framework outlines factors to consider when making a project budget, and it recommends that research partners receive compensation at rates that reflect their level of engagement and are consistent with payments to other members of the research team.

Growing the Community That Can Participate in Research

In FY 2015, we expanded our award programs that reach out to patients, other stakeholders, and researchers to build a national community with both the expertise and desire to participate in patient-centered research. These awards do not fund research but emphasize creation of partnerships that may lead to high-quality research proposals.

Eugene Washington PCORI Engagement Awards

Our Eugene Washington PCORI

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<td>Build a community of patients, caregivers, and other stakeholders equipped to engage in PCOR/CER*</td>
<td>26</td>
</tr>
<tr>
<td>Meetings and Conferences</td>
<td>Exchange information about PCOR/CER</td>
<td>36</td>
</tr>
<tr>
<td>Knowledge Projects</td>
<td>Produce tools to increase knowledge of what stakeholders need to make healthcare decisions</td>
<td>5</td>
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<tr>
<td>Dissemination</td>
<td>Develop channels or facilitators for dissemination and implementation of PCOR/CER findings</td>
<td>3</td>
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<tr>
<td>Multiple</td>
<td>Span categories</td>
<td>3</td>
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<tr>
<td>Pilot Project</td>
<td>Disseminate results</td>
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*Patient-centered outcomes research and comparative clinical effectiveness research

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I’ve learned that when you do include patients, you get a new perspective. It’s a very different way of doing things.

DEBRA FISER, MD, Professor, University of Arkansas for Medical Sciences

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STAKEHOLDER WORKSHOPS

We convened eight stakeholder gatherings to help us refine research questions for potential funding announcements on high-impact topics.

Targeted Funding Announcements: Hepatitis C diagnosis and treatment; Treatment of multiple sclerosis; Treatment of major depressive disorder; Use of new oral anticoagulants; Long-term use of opioids for chronic pain: pharmacological treatment options and dosing strategies; Long-term use of opioids for chronic pain: nonpharmacological treatment options, risk-mitigation strategies, and opioid dependency

Topic being refined: Treatment options for chronic low-back pain

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EUGENE WASHINGTON PCORI ENGAGEMENT AWARDS

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*Patient-centered outcomes research and comparative clinical effectiveness research
Engagement Awards program supports projects that integrate patients and other stakeholders into healthcare research or that create new channels to disseminate study results. In FY 2015, we issued 73 Engagement Awards totaling $13.7 million to a broad variety of stakeholder organizations, including those relating to patients, clinicians, training institutions, hospitals, and industry. In addition, we made 25 awards, totaling $1.2 million, to support dissemination of results from Pilot Projects and collaborative projects undertaken by groups of Pilot Project investigators.

**Pipeline to Proposal Program**

Our Pipeline to Proposal Awards aim to strengthen relationships between researchers and patients and other stakeholders to build capacity for community participation in research. The program builds community partnerships to create and develop research questions that eventually lead to patient-centered research proposals. The Pipeline to Proposal Program has three tiers (see figure on this page).

In FY 2015, we awarded a total of $685,000 for 47 new Tier I projects in 20 states and Puerto Rico, with eight awardee organizations spanning multiple regions. These projects focus on 35 health issues, including cirrhosis, osteoarthritis, sickle cell disease, spinal cord injuries, and chronic pain.

We also awarded 27 Tier II awards, totaling $675,000, to teams that had received Tier I awards in 2013. Our first Tier III awards will be made in FY 2016.

**Convening Stakeholders to Advance Our Research Agenda**

We use a range of channels to stay in contact with our stakeholders. We hold meetings to provide information and gather input and attend meetings sponsored by other organizations. We also have a special program in

### PIPELINE TO PROPOSAL AWARD TIER STRUCTURE

<table>
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<tr>
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<th>Purpose</th>
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<tr>
<td>Tier I</td>
<td>Form partnership that may lead to research proposal</td>
<td>Up to $15,000</td>
<td>Up to 9</td>
</tr>
<tr>
<td>Tier II</td>
<td>Expand and advance partnership</td>
<td>Up to $50,000</td>
<td>Up to 12</td>
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<td>Tier III</td>
<td>Develop a research proposal</td>
<td>Up to $50,000</td>
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<tr>
<td>Goal</td>
<td>Proposal for PCORI-Funded Research</td>
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</table>
which we engage patients and other healthcare stakeholders who are passionate about patient-centered research.

As we have from PCORI’s beginning, our Engagement staff held about a dozen face-to-face and virtual meetings with key stakeholders and stakeholder groups. In addition to the workshops on potential topics for research funding, we held workshops and roundtables tailored to specific stakeholder groups, including public and private research funders, patient organizations, pharmacy benefit managers, and the life sciences industry.

As another form of outreach, our staff, Board, and Methodology Committee members tallied more than 235 speaking engagements. These events directly engaged patients and other stakeholders in settings that ranged from 25-person roundtables to meetings attended by more than 1,000 people.

To harness the enthusiasm of individual stakeholders and organizations for building a community that supports patient-centered research, PCORI’s Ambassador Program offers opportunities for training, partnership, and knowledge sharing. The program has 232

<table>
<thead>
<tr>
<th>PCORI TWITTER CHATS</th>
<th>Date</th>
<th>Co-Host</th>
<th>Reach*</th>
</tr>
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<tbody>
<tr>
<td>Patient Engagement in Research</td>
<td>Nov. 17, 2014</td>
<td>Health Affairs</td>
<td>13.4 M</td>
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<tr>
<td>Big Data</td>
<td>Feb. 18, 2015</td>
<td>Health Affairs</td>
<td>14.7 M</td>
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<tr>
<td>Mental Health</td>
<td>May 19, 2015</td>
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<td>33.3 M</td>
</tr>
<tr>
<td>Cancer Symptoms/Side Effects</td>
<td>Sept. 29, 2015</td>
<td></td>
<td>51.3 M</td>
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</tbody>
</table>

*potential total number of Twitter users who might have seen the chat (in millions)
Ambassadors, both individuals and organizations, across the United States. Over the course of the year, we held informational webinars for Ambassadors on healthcare and research topics. By participating in events hosted by a wide variety of organizations, our Ambassadors helped us make progress toward our goal of influencing others to be more patient-centered. We also planned our second in-person meeting of Ambassadors in conjunction with the first PCORI Annual Meeting in October 2015.

**Laying the Groundwork for Disseminating Research Findings**

Dissemination of our research findings is an important activity specified in our authorizing law. Getting results out broadly will help them find their way into individuals’ and organizations’ health decisions. With the research concluded in our Pilot Projects, and our first primary research projects nearing completion, we began developing an extensive, integrated effort to disseminate and promote implementation of the most important results of PCORI-funded research to stakeholders across the healthcare community.

In planning this effort, we have collaborated closely with the Agency for Healthcare Research and Quality (AHRQ), as outlined in our authorizing law. We also worked with the community of healthcare stakeholders, both individuals and organizations, with whom we and our funded investigators have been engaged since early in PCORI’s existence. We view these stakeholders—who have served as reviewers, advisory panel members, and participants on funded research teams—as key partners in ensuring that the evidence produced in our studies is effectively disseminated and used by those who need it most.

This past year, we revised our draft plan for dissemination activities, originally released in September 2014. We updated the plan based on input of 63 contributors during the public comment period. We developed a framework, along with a toolkit, for evidence assessment, audience identification, dissemination, implementation, and evaluation.

The first step in our dissemination process will be peer review of our primary research, to ensure scientific integrity and adherence to our methodology standards, as well as making the findings publicly available in a format useful to patients, clinicians, and other stakeholders. Our authorizing law mandates this process, which we will carry out under a framework adopted by our Board in February 2015. As the year came to a close, we were finalizing our plan for engaging an expert contractor to assist with implementing our peer review process. We were also familiarizing awardees with the process.

As we worked to put our peer review and public-release process in place, we initiated our suite of certified professional education activities. We began making educational material about patient-centered CER, and especially promising results from our early projects, available to the healthcare community. We developed these programs in partnership with the Baylor College of Medicine and Prime Education Inc., and launched the resulting continuing medical education (CME) and continuing education (CE)

> It’s key to consult people who have been successful and help them feel empowered to contribute. We can’t ask just one type of person, and we can’t just consult the literature. We really have to go above and beyond that.

**EARLENE AVALON, MPH, PhD, Director of Nursing Diversity Initiatives, Children’s Hospital Boston**

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**SOME ORGANIZATIONS FEATURING PCORI SPEAKERS IN 2015**

- Academy of Managed Care Pharmacy
- American Academy of Pediatrics
- American Cancer Society
- American College of Cardiology
- American Heart Association
- American Medical Association
- American Psychiatric Association
- American Society of Clinical Oncology
- Amgen
- Arthritis Foundation
- Association of American Medical Colleges
- Boehringer Ingelheim
- Brookings Institution
- Families USA
- Food and Drug Administration
- Janssen Pharmaceuticals
- Merck & Co.
- National Cancer Institute
- National Health Council
- Pfizer
programs in May through our website, free of charge. One set of these CME/CE modules guides researchers in applying the PCORI Methodology Standards (see page 12). We plan to make additional CME/CE programs available in coming months.

Communicating with Our Audiences
Digital communication remains central to our outreach efforts. In FY 2015, we continued to enhance our website and expand our email communication. We also dramatically increased our use of social media to both provide information about our work and to engage a wide range of stakeholder groups in conversation about PCORI activities and how we can better serve them.

Our enhanced social media efforts included using Twitter chats to reach out to patients and other stakeholders on topics of broad interest. We hosted two hour-long chats and co-hosted two more. Each attracted hundreds of participants, including patients, caregivers, clinicians, researchers, and members and staff from advocacy groups, specialty societies, and research funders. The more than 3,000 tweets posted during the cancer and mental health chats were especially helpful in providing our program staff with ideas for better focusing our research and engagement efforts. For the year, our cumulative Twitter reach (the total number of Twitter users who had potential access to our posts) was 164 million, more than four times that in FY 2014.

In addition to our own communications channels, we were pleased to see PCORI's work gain substantial attention during the year in both consumer and professional media, including leading medical journals.

RESEARCH SNAPSHOT

Moving Beyond Averages

BOSTON, MA—Bray Patrick-Lake, MFS, is not an average patient. In a clinical trial in 2008, she experienced nearly every possible adverse event but also received maximum benefit. So she teamed up with a researcher who applies mathematical models to move beyond averages to interpret clinical trial results in terms of what's best for individuals.

Patients with the same medical condition can differ from one another in many ways, says David M. Kent, MD, MS, of Tufts Medical Center in Boston. Which types of patients are most likely to benefit or suffer harm from a treatment? Examining a diabetes prevention study, his team found that higher-risk participants received the most benefit from intensive diet and exercise and the drug metformin.

To read more, go to pcori.org/research-in-action

A GROWING PRESENCE IN THE PROFESSIONAL LITERATURE

<table>
<thead>
<tr>
<th>Articles citing or mentioning PCORI work</th>
<th>FY 2014</th>
<th>FY 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>55</td>
<td>139</td>
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</table>

<table>
<thead>
<tr>
<th>Articles resulting from PCORI-funded research projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>80</td>
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</table>

<table>
<thead>
<tr>
<th>Articles by PCORI staff or about PCORI</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2014</td>
</tr>
<tr>
<td>39</td>
</tr>
</tbody>
</table>
As a learning organization, we evaluate all that we do so we can gauge progress toward our strategic goals and continually improve our processes.

Applying Our Evaluation Framework

In FY 2015, we shared an updated version of our continually evolving Evaluation Framework. In our initial version, we focused on making sure we understood and captured key stakeholder questions about PCORI’s approach and its impact on comparative effectiveness research (CER), on attaining our strategic goals, and ultimately on health decisions, care, and outcomes. We later re-organized our framework for greater clarity and described how we intend to address these questions, specifying for each where we will find the information we need, what we will measure, and how we will use those data.

We also revamped the dashboard we use for reporting quarterly to our Board of Governors what we are learning and how we are incorporating our findings into our work. This reflected a further shift in focus from building activities to the outputs from our processes. Our FY 2015 dashboard also began to reflect results from our first completed studies, measures of their dissemination and uptake, and our influence on research. Our dashboard,
We owe it to our patients to feel very confident that the treatments we’re giving them will lead to the best outcomes with the fewest side effects.

RON KEREN, MD, MPH, The Children’s Hospital of Philadelphia
taxonomy to describe and categorize the funded studies. With this taxonomy, we are analyzing projects by topic areas and mapping relationships among projects. We are building an evidence-rich foundation for characterizing PCORI’s contribution to patient-centered CER. In addition, we made plans to use our taxonomy to identify gaps in knowledge that our funded research might fill. Such analysis ensures that the work we fund meets information needs efficiently by addressing important questions without duplicating ongoing research.

Assessing Engagement in Research
This year, we began requiring all our research teams annually to answer detailed questions about engaging as research partners in their work. These include: whom are they engaging, and what impact has it had on the research? We also give patient and other stakeholder partners the opportunity to report their experiences on PCORI projects.

We have heard from both researchers and their partners that engagement resulted in meaningful stakeholder contributions to studies, including refining research questions, selecting the study design, and choosing interventions, comparators, and outcomes. We plan to use what we learn to identify and share promising practices in research and engagement.

Assessing Attitudes toward CER and Patient Engagement
To assess different healthcare communities’ knowledge of and attitudes toward health research, CER, and stakeholder engagement in research, we completed surveys of researchers, patients, caregivers, and clinicians. Findings point to several opportunities to speed incorporation of treatment comparisons into decision making. As we collected information from these stakeholders, we also assessed their familiarity with stakeholder engagement in research. The surveys point to specific facilitators and barriers of engagement in research, and we began using these findings to identify ways to enhance engagement.

To understand the views of other healthcare stakeholders not readily obtained via surveys, we held focus groups and interviewed representatives of individual healthcare payers, purchasers, and industry. We plan to use these results to enhance our engagement with these stakeholders and improve strategies for communicating relevant CER quickly and accurately.

RESEARCH SNAPSHOT

Finding the Keys to a Longer, Better Life after Stroke
DURHAM, NC—Every year, around 800,000 people in the United States have a stroke. Because about one-quarter of patients who’ve had one stroke have a recurrence, doctors often prescribe preventive therapies. Patients are uncertain about the best treatment for their individual cases, says Adrian F. Hernandez, MD, MHS, of Duke University.

“There’s not enough information about what’s really important in recovery,” says Lesley Maisch of Buffalo, NY, who had a stroke 7 years ago. Patients’ input convinced researchers to focus on an unusual outcome: time spent out of the hospital. Using data already collected on nearly half a million people treated for stroke, the Duke team reports, for example, that patients taking statins spent 28 more days out of the hospital over two years.

To read more, go to pcori.org/research-in-action

Project Title: Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER)

Principal Investigator: Adrian F. Hernandez, MD, MHS

Goal: Using new and existing data on the risks and benefits of anticoagulant, statin, and antidepressant therapy to develop a tool that will help post-stroke patients choose treatment best suited to their individual characteristics and preferences.
As with any organization dedicated to continual improvement, we refine our governance processes and operations on an ongoing basis in response to external input and internal analysis.

**Governance Update**

Our Board of Governors approved amendments to the PCORI Bylaws in April to reorganize the function of two key committees. Under the revised Bylaws, the responsibilities of the Audit and Conflict of Interest Subcommittee of the Governance Committee were transferred to the Governance Committee, and the charter for the Subcommittee was withdrawn. The revisions also reorganized bylaws sections addressing committees, added clarifying language on the staggered terms of Board and Methodology Committee members and on filling vacancies for members who resign mid-term, and confirmed that the Board, as well as the Board Chairperson, has authority to create and disband committees and working groups. The revised Bylaws also now recognize modern mechanisms of payment, such as funds transfers.

The Board also approved a set of PCORI Collaboration Principles to be incorporated into each of our three types of collaborative arrangements—co-funding, contracting for management, and staff detail. We collaborate with other research funders as one of our strategies for influencing research funded by others.
to be more patient-centered.

Finally, the Board approved the charter and membership for a new Advisory Panel on Communication and Dissemination Research, which will help us identify and prioritize critical research questions related to the work done under this national research priority. It also will provide advice on evaluating and disseminating the research conducted under our Communication and Dissemination Research program.

**Interacting with Applicants and Awardees**

Our Operations staff continued to focus in FY2015 on outreach to applicants and awardees to solicit information about our funding opportunities and application and project management processes. This effort included ongoing email communication with these key audiences, 56 training events for applicants and reviewers, and opportunities for applicants to meet with staff, one-on-one, to learn more about the application process and project management.

We also held three in-person workshops, attended by 571 researchers and research administrators from across the country, that provided tools and guidance for developing applications and improving project performance. We used information garnered at these workshops to enhance our funding announcements, online application system, and project management.

To gather additional feedback on how we could improve our application process, we contacted more than 500 past applicants through focus groups, surveys, and other outreach channels, and made key changes in response to their comments. For example, applicants wanted to know whether a topic they had in mind would be a good fit for a PCORI funding opportunity before devoting time to preparing a Letter of Intent (LOI). As a result, we developed a screening tool to indicate whether a research idea aligns with a funding opportunity. We also updated both the LOI and application guidelines and templates to make the process simpler, more standardized, and less burdensome overall to researchers seeking PCORI funding.

**Genetic Test Results: Parents and Doctors on the Same Page**

DANVILLE, PA—Mackenzie Clink was born missing part of her brain. She experienced seizures and developmental delays. The Clinks joined a study at Geisinger Health System in Pennsylvania to sequence Mackenzie’s genome to learn why her brain failed to grow normally.

Whole-genome sequencing is powerful, says Marc S. Williams, MD, who leads the study. But he was concerned that genetic reports are too technical for most parents, and even doctors, to understand. He envisioned reports that would enable families to become more involved in decisions, more satisfied with care, and more likely to stick with a treatment plan. Soon at Geisinger, all patients receiving genomic sequencing will receive the results in the new form of report that Williams’s team developed.

> **RESEARCH SNAPSHOT**

**Project Title:** Enhancing Genomic Laboratory Reports to Enhance Communication and Empower Patients

**Principal Investigator:** Marc S. Williams, MD

**Goal:** To develop and test an advanced, information-rich, and highly readable patient-facing genomic laboratory report, with the aim of improving communication between parents of children with rare genetic disorders and their care providers.

To read more, go to pcori.org/research-in-action

“[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.”

ANDREA JENSEN, parent caregiver
A Look Ahead

We look ahead to FY2016 as a year of continuing progress, focus, emerging results, and a growing record of impact.

Coming Together
We will open the year with our inaugural Annual Meeting, an opportunity to report to our stakeholders on our progress as the nation’s leading funder of patient-centered CER. We expect some 1,000 researchers, patients, clinicians, and others from across the healthcare community to join us in person—and many more via webinar—for three days of sessions summarizing early results and important works in progress.

Further Refining Our Research Portfolio
During the next year, we will continue to use our broad funding announcements to seek researchers’ best ideas for patient-centered CER projects on a wide range of topics. But we will continue to rapidly increase the proportion of our overall research portfolio dedicated to larger studies focused on topics and conditions that our stakeholder communities have identified—through our topic prioritization pathway—as imposing a high burden on patients, their families, and the healthcare system.

As FY2015 came to a close, topics moving through our prioritization process toward inclusion in one or both of these streams included treatments for new oral anticoagulants, treatment-resistant depression, treatment of multiple sclerosis, and strategies for managing and reducing long-term opioid use for chronic pain.

As in the past year, two major pathways—our targeted funding announcements and our pragmatic clinical studies initiatives—led to the larger, more focused research projects. We were delighted at year’s end to
welcome a new Chief Science Officer, Evelyn P. Whitlock, MD, MPH, who was to take up her new position in January 2016. Dr. Whitlock, a nationally recognized expert in evidence-based medicine, comes to PCORI having spent almost 25 years in research and leadership positions at the Kaiser Permanente Center for Health Research in Portland, Oregon. She was the founding director of the Kaiser Permanente Evidence-based Practice Center and also provided evidence-based support to the US Preventive Services Task Force.

More PCORnet Progress
PCORnet enters its second phase of development in FY2016 poised to start fulfilling its promise of becoming a robust national resource for conducting patient-centered outcomes studies faster, with more power, at lower cost than is possible now.

Building on its first 18 months of progress, PCORnet will continue to expand its data resources and promote increased collaboration among its 33 partner networks to demonstrate its capacity to conduct critical research. PCORnet also will enable collaboration with the wider healthcare community, including a framework for considering outside research proposals that could leverage network resources.

We expect to see the first three research demonstration projects using PCORnet—one on improving care for people with heart disease and two on prevention and treatment of obesity—mark a series of key milestones in the coming year, in recruitment, retention, data collection, and other activities. We look forward to additional projects designed to demonstrate PCORnet’s potential to transform health research, including several that build on collaborations between the partner networks and health systems and patient communities. And we are confident that as PCORnet continues to build its research readiness, it will demonstrate the value of a new model and culture of health research that leverages the power of data and partnerships to make health research more efficient, less expensive, and more patient-centered.

A Growing Body of Research Results Ready for Dissemination
Our awardees contributed a steady flow of papers to the scientific literature in the past year describing progress in their work and, in several cases noted earlier in this report, reporting initial results with potentially important implications for practice. That flow of papers—including those reporting at least initial results—should grow substantially in the coming year as more of our funded projects move toward completion. We expect more than 80 studies to be completed by the end of FY 2016. As we did in the past year, we will monitor the professional literature for opportunities to develop materials that will be part of our effort to promote dissemination of the evidence our studies produce to our stakeholder communities. At the same time, we will fully implement our process for peer reviewing all of our awardee’s primary research and making the results of that work available, as required by our authorizing law, in ways that patients, clinicians and the general public will find most useful. We plan to “test drive” this process with our Pilot Projects, which were completed during FY 2015.

On the Right Path
We enter our sixth year confident that we are appropriately and effectively investing the public funds entrusted to us in studies that will generate the kind of evidence patients and those who care for them need to make better-informed healthcare decisions.

PCORI is proud of what we’ve achieved in our first five years and clear on the tasks still ahead of us. But more than anything else, we are grateful to the patients, family caregivers, researchers, clinicians, and other healthcare stakeholders who continue to guide and participate in the important work entrusted to us—to advance a patient-centered approach to comparative effectiveness research that will improve patient care, outcomes, and the health of the nation.

“The diversity of the stakeholder representation is a very important part of the PCORI process. ... It’s been remarkable how collaborative and collegial the panel’s been in bringing forth those perspectives and weighing them as we think about what [topics] we should prioritize.”

ALAN ROSENBERG, MD, Vice President, Clinical Pharmacy and Medical Policy, WellPoint, Inc.
FY2015 and Projected FY2016 Budgets

Note: Our authorizing legislation requires that our Annual Report include PCORI’s budget for the year following the period covered by the report. The independent audit of our FY2015 financial report, provided to Congress by the U.S. Government Accountability Office, is available here: pcori.org/2015-Financial-Report

<table>
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<th>Operating Revenue</th>
<th>2015 Actual</th>
<th>2016 Budget</th>
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<tbody>
<tr>
<td>$422,893,090</td>
<td>$491,200,000</td>
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</table>

Program Expense:
- Research Expense & Engagement Awards: $214,304,095, $331,526,300
- Methodology Committee: $643,705, $1,636,000
- Science/Program Development & Evaluation: $23,497,283, $32,592,650
- Engagement: $8,445,443, $12,148,203
- Contract Management: $6,150,239, $6,674,025

Total Program Expense: $253,040,765, $384,577,178

Administrative Support: $23,918,080, $38,904,122

Total Operating Expense: $276,958,845, $423,481,300

Non-operating Interest Income: $173,851, $250,000

Net Income: $146,108,096, $67,968,700

2015 Actual Distribution:
- Clinical Effectiveness Research Program: 25%
- Improving Healthcare Systems Program: 7%
- Addressing Disparities Program: 13%
- Communications and Dissemination Program: 2%
- CER Methods and Infrastructure Program: 35%
- Unassigned: 9%

2016 Budget Distribution:
- Clinical Effectiveness Research Program: 29%
- Improving Healthcare Systems Program: 13%
- Addressing Disparities Program: 16%
- Communications and Dissemination Program: 16%
- CER Methods and Infrastructure Program: 13%
- Unassigned: 3%

2015 Actual Research Funding Projections:
- Clinical Effectiveness Research Program: 25%
- Improving Healthcare Systems Program: 7%
- Addressing Disparities Program: 13%
- Communications and Dissemination Program: 2%
- CER Methods and Infrastructure Program: 35%
- Unassigned: 9%

2016 Budgeted Research Funding Projections:
- Clinical Effectiveness Research Program: 29%
- Improving Healthcare Systems Program: 13%
- Addressing Disparities Program: 16%
- Communications and Dissemination Program: 16%
- CER Methods and Infrastructure Program: 13%
- Unassigned: 3%
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<th>Section</th>
<th>Pages</th>
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<tbody>
<tr>
<td>I. PCORI Conflict of Interest Disclosures</td>
<td>A1-A7</td>
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<tr>
<td>II. Approved Research Contracts and Awards</td>
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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 decisions on matters related to the institute or the conduct of activities under this section.” Below are the associations reported by PCORI’s Board of Governors, Methodology Committee, and executive staff. Disclosures reflect those reported to PCORI as of March 11, 2016.

BOARD OF GOVERNORS

Debra Barksdale, PhD, RN
As of December 28, 2015
Financial Associations
• Virginia Commonwealth University, Employer
• Mitre Corp, Veteran’s Choice Act Blue Ribbon Panel, (ended 9/31/2015)
• Seattle University College of Nursing, Seattle, Washington, Speaker
• University of Central Florida Nursing Leadership in Practice, Keynote Lecture
• National League for Nursing and the Independence Blue Cross Foundation, Conference Panelist

Personal Associations
• University of North Carolina at Chapel Hill, employment ended Jan. 3, 2016
• National Organization of Nurse Practitioner Faculties, Member
• American Association of Nursing, Member
• National League for Nursing, Member
• North Carolina Nurses Association, Member
• American Academy of Nursing, Member
• Robert Wood Johnson Executive Nurse Fellows Alumni Society, Member

Lawrence Becker
As of November 16, 2015
Financial Associations
• Xerox Corporation, Employer
• Stock ownership:
  • Aetna, Inc.
  • GE
  • Johnson & Johnson, Inc.
  • Amgen
  • Pfizer, Inc.
  • SPDR Biotech
  • The Travelers Companies, Inc.
  • Ventas
  • GlaxoSmithKline
  • Bristol-Myers Squibb
  • LSB Consultants, LLC (company owned by spouse)
  • The University of Rochester Medical Center, Employer (sibling)
  • Amino, LLC, Board of Advisors for Healthcare Quality Measurement (self)

Personal Associations
• ERISA Industry Council, Board Member
• The National Quality Forum, Board Member
• Rochester Regional Health Information Organization, Board Member
• Jewish Senior Life, Board Member

Alicia Fernandez, MD
As of January 6, 2016
Financial Associations
• University of California, San Francisco, Employer
• Stock ownership:
  • Prosetta Bioinformatics

Personal Associations
• Society of General Internal Medicine, member, Volunteer (Former Council Member)
• National Hispanic Medical Association, Member
• Institute of Medicine Roundtable on Literacy, Member

Christine Goertz, DC, PhD
As of March 11, 2016
Financial Associations
• Palmer College of Chiropractic, Employer
• American Chiropractic Association, Consultant
• Healthwise, Consultant
• Quality Insights of Pennsylvania, Consultant
• RAND Corporation, Consultant
• Prezcor, Inc., Stock Options

Personal Associations
• American Chiropractic Association, Member
• American Medical Association, Measures, Implementation and Informatics Performance Improvement Committee, Member
• Health Care Professionals Advisory Committee, Alternate Member
• Iowa Chiropractic Society, Member

Allen Douma, MD
As of January 15, 2016

Kerry Barnett, JD
As of November 5, 2015
Financial Associations
• SAIF Corporation, Employer
• Cambia Health Solutions (includes BlueCross/BlueShield and other Affiliated Health Plans), Former Employer
• Gastroenterologist, partner in private group medical practice with ownership in ambulatory endoscopy center, Employer (sibling)

Francis S. Collins, MD, PhD
As of March 7, 2016
Financial Associations
• National Institutes of Health, Director (Employer)

Personal Associations
• Institute of Medicine, Member
• National Academy of Sciences, 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
• Global Spine Care Initiative, Member

Leah Hole-Marshall, JD
As of November 19, 2015
Financial Associations
• Washington State Department of Labor & Industries, Employer
• Fidelity Select Biotech, Stock Ownership

Personal Associations
None reported

Gail Hunt
As of March 14, 2016
Financial Associations
• National Alliance for Caregiving, CEO, Employer
• International Alliance of Caregiver Organization, Secretariat, Member

Personal Associations
• Long Term Quality Alliance, Board Secretary
• Center for Aging Services Technology, Commissioner
• American Society on Aging, Member
• National Council on Aging, Member
• ReACT, Member
• Community Health Accreditation Program, Standards Quality Board, Member
• Gerontological Society of America, Member
• Partnership to Fight Chronic Disease, Member
• Institute for the Ages, Board Member
• C-TAC, Member
• National Complex Care Advisory Board (United Healthcare), Board Member
• International Alliance of Patient Organizations, Member
• International Federation on Aging, Member
• NQF Patient and Family Centered Care Committee on Quality Measurement, Co-Chair
• NQF Alzheimer’s Disease and Related Dementia Committee; Prioritizing Measure Gaps
• NQF Measure Application Partnership Coordinating Committee

Richard Kronick, PhD
As of November 5, 2015
Financial Associations
• Agency for Healthcare Research & Quality (AHRQ), Director, Employer

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

Harlan Krumholz, MD, SM
As of January 15, 2016
Financial Associations
• Yale University, Professor of Medicine, Employer
• United Healthcare, Cardiac Scientific Advisory Board, Chair
• ImageCOR, LLC, Founder
• HugoPHR, Founder
• American Heart Association, Editor
• Massachusetts Medical Society, Editor
• Medtronic, Inc., Principal Investigator on research agreement through Yale University
• Johnson & Johnson (Janssen), Principal Investigator on research agreement through Yale University
• Premier, Inc., Consultant
• Fuwai Hospital, Consultant
• Element Science, Inc., Consultant

Personal Associations
• WikiDoc Foundation, Board of Directors
• Cardiovascular Outcomes, Inc., Secretary

Freda Lewis-Hall, MD
As of November 11, 2015
Financial Associations
• Pfizer, Inc., Employer, Stock, Retirement (self)
• Pfizer Savings Plan, Stock, Retirement plan (self)
• Pfizer Supplemental Savings Plan, Stock, Retirement plan (self)
• Pfizer/Pharmacia Retirement Plan, Stock, Retirement plan (self)
• Eli Lilly Defined Benefit Pension Plan, Retirement plan (self and spouse)
• Bristol Myers, Inc., Stock (self and spouse)
• Bristol Myers Defined Benefits Plan, Retirement plan (self)
• Vertex Pharmaceuticals, Inc., Stock (self)
• Vertex Pharmaceuticals 401k, Retirement plan (self)
• Tenet Healthcare, Board of Directors, Stock, Deferred compensation plan (self)
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
• NCCATS Advisory Council, Council Member
• NCAT/Cures Acceleration Network Review (CAN), Chair
• Clinical Trials Transformation Initiative, Executive Committee

Barbara J. McNeil, MD, PhD
As of November 3, 2015
Financial Associations
• Brigham & Women Hospital, Employer
• Harvard University Medical School, Employer
• Edwards Lifesciences Corp., Investments, Consulting Fee, Board Member
• Marine Polymer Technologies, Consulting Fees, Medical Advisor
• BNY Mellon Professionally Managed Investment Account (diversified)
• Warren Alpert Foundation, Member, Board of Trustees
Personal Associations
• AgMednet, Inc., Board of Directors
• Boston Foundation for Sight, Board of Directors
• National Academy of Medicine, Member

American Academy of Arts & Sciences, Managing Board
• Food & Drug Administration, Advisory Committee to Review Status of FDA
• Blue Cross, Blue Shield Association, Technology Evaluation Committee, Member
• American College of Radiology, Member
• Society of Nuclear Medicine & Molecular Imaging, Member
• American Medical Association, Member
• The Academic Medicine and Health Industry Forum, Member
• CMS Imaging Efficiency Measures Technical Panel, Member
• Nuclear and Radiation Studies Board, Member (term ended November 15, 2015)
• American Association for the Advancement of Science, Fellow
• Society for Medical Decision-Making, Member
• Massachusetts Medical Society, Member

Grayson Norquist, MD, MSPH
As of December 23, 2015
Financial Associations
• Emory University, Employer
• University of Mississippi Medical Center, Former Employer
Personal Associations
• American Psychiatric Association (APA), Fellow
• American Psychiatric Association Foundation, Board Member
• American Psychiatric Association Council on Quality Care, Chair
• Academy Health, Fellow

Ellen Sigal, PhD
As of January 11, 2016
Financial Associations
• SPDR S&P 500 ETF TRUST, Common Stock (spouse), Managed by JP Morgan
• ISHARES CORE S&P MIDCAP ETF, Common Stock (spouse), Managed by JP Morgan
• VANGUARD FTSE EUROPE ETF, Common Stock (spouse), Managed by JP Morgan
• ISHARES MSCI EAFE ETF, Common Stock (spouse & Jointly), Managed by JP Morgan and UBS
• ISHARES RUSSELL 1000 GROWTH ETF, Common Stock (spouse & Jointly), Managed by UBS

Personal Associations
• Friends of Cancer Research, Chairperson (self)
• Reagan-Udall Foundation (self), Board Vice Chair and Acting Chair
• Foundation for the National Institutes of Health, Board Member
• Stand Up 2 Cancer, Scientific Advisory Committee Member
• MD Anderson Cancer Center, External Advisory Board
• Duke University Cancer Center, Board of Overseers
• Sidney Kimmel Comprehensive Cancer Center, Advisory Council
• Milken Institute School of Public Health, Board of Advisors
• The George Washington University Medical Center, Advisory Council (spouse)
• The George Washington University Medical Faculty Associates, Board of Trustees (spouse)
• New York University, Faculty of Arts and Science/Board of Overseers (spouse)
• Treatment Action Group (TAG), Board of Directors (child)

Harlan Weisman, MD, SM
As of December 29, 2015
Financial Associations
• And-One consulting, LLC, Managing Director and Paid Consultant
• ControlRad, Inc., Board Director, Stock and Stock Options
• BioMotiv, LLC, Scientific Advisory Board Member (Compensation)
• Johnson & Johnson, Pension, Stock and Stock Options
• Mendham Investment Group, LLC, Member
• Hutchison Biofilm Medical Solutions, Board of Directors and Advisor (Compensation and restricted stock)
• 3D Bio Corp., Executive chairman, Board of Directors and Stock
• Mycrobionics, Inc., Co-founded, Board Director, Chief Scientific Stock
Robert Zwolak, MD, PhD
As of January 15, 2016
Financial Associations
• Dartmouth-Hitchcock Clinic, Employer
• US Department of Veterans Affairs, Employer
• Society for Vascular Surgery, Consultant
• Various Academic Centers, Honoraria for Visiting Professorships
• Eva Corporation (medical device manufacturer), Investments
Personal Associations
• Intersocietal Commission for Accreditation of Carotid Stent Facilities, Board of Directors
• AMA/Specialty Society Relative Unit Update Committee, Member of Work Groups
• Society for Vascular Surgery, Health Policy Consultant, Past President
• American College of Surgeons, Member of Committees and Work Groups
• New England Society for Vascular Surgery, Member
• American Venous Forum, Member
• Society for Vascular Society, Member
• Geisel School of Medicine at Dartmouth, Professor (unpaid position)

METHODOLOGY COMMITTEE
Naomi Aronson, PhD
As of January 8, 2016
Financial Associations
• Blue Cross Blue Shield Association, Office of Clinical Affairs, Employer
Personal Associations
• National Business Group on Health Committee on Evidence-Based Benefit Design, Member
• 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, Member
• Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Ox) Working Group, Tapestry Networks, Member
• Pew Charitable Trust, Medical Device Registry Project, Technical Advisor
• Society to Improve Diagnosis in Medicine, Member
• American Gastroenterological Association Institute, Tech Summit, Faculty
• Brookings Expert Workshops: Breakthrough Therapy Designation
• Improving Productivity in Pharmaceutical Research and Development
• Defining and Measuring Innovation in a Changing Biomedical Landscape
• Clinical Cancer Research, 2015
• Incorporating Evidence from Clinical Experience in Regulatory Decision-Making: A Pragmatic Approach to Clinical Trials

Ethan Basch, MD, MSc
As of November 13, 2015
Financial Associations
• University of North Carolina, Chapel Hill, Employer
• Memorial Sloan-Kettering Cancer Center, Employer
Personal Associations
• National Cancer Institute, Board of Scientific Advisors
• Journal of the American Medical Association, Associate Editor
• Agency for Clinical Trials in Oncology, Chair
• American Society of Clinical Oncology, Task Force Chair

David Flum, MD, MPH
As of February 4, 2016
Financial Associations
• University of Washington, Department of Surgery, Employer
• Benchmark Medical, LLC, Partial Ownership
• Agency for Healthcare Research & Quality, US DHHS (contracts), Consumers Union (Consultant)
• Lectures at several universities in the US and abroad
Personal Associations
• Academy Health, Member, Committee Member
• American College of Physicians, Member
• Society for General Internal Medicine, Member
• Society for Medical Decision Making, Member, Committee Member
• U.S. Cochrane Center, Advisory Board
• International Society for Quality of Life Research, Member

Cynthia Girman, DrPH
As of January 8, 2016
Financial Associations
• Merck & Co., Inc., Retired Employee as of 12/31/2014
• Merck & Co., Inc., Stock ownership
• CERobz Consulting, LLC, President and Consultant
• Stock Ownership:
  • Merck
• Medtronic
• Celgene
• Teva
• Perrigo
• Gilead

Personal Associations
• Department of Epidemiology, University of North Carolina, Adjunct Associate Professor (unpaid position)
• Center for Pharmacoepidemiology, UNC, Scientific Advisory Board, Prior Member
• International Society of Pharmacoepidemiology, Member
• ISPE CER Special Interest Group, ICPE Education Committee, Member
• ISPE CER Special Interest Group, ICPE Education Counsel, Member
• International Society for Pharmacoeconomics and Outcomes Research, Member

Steven Goodman, MD, MHS, PhD
As of January 15, 2016

Financial Associations
• Stanford University, Employer
• National Blue Cross-Blue Shield Technology Evaluation Center, Member, Medical Advisory Panel
• American College of Physicians, Annals of Internal Medicine, Statistical Editor

Personal Associations
• Society for Clinical Trials, Member
• American College of Epidemiology, Member

Mark Helfand, MD, MS, MPH
As of January 15, 2016

Financial Associations
• Portland VA Medical Center, Portland, OR (Hospital and Clinics), Employer
• Oregon Health and Science University, Portland, OR (Hospital and Clinics), Employer
• Parker Waichman LLP, Consultant/Expert
• Consumer Union, Consultant

Personal Associations
• Academy Health, Methods Council, Member
• American College of Physicians, Member
• Research Grants, Contracts, Consulting, Teaching:
  • U.S. Department of Veterans Affairs
  • Agency for Healthcare Research & Quality, US DHHS (contracts)
  • Lectures at several universities in the US and abroad

Robert Kaplan, PhD
(Resigned from Methodology Committee February 2016)
As of November 6, 2014

Financial Associations
• Agency for Healthcare Research and Quality, Employer
• Proctor & Gamble, Stock
• Stryker Corporation, Stock

Personal Associations
• University of California, San Diego, Faculty (unpaid position)
• University of California, Los Angeles, Distinguished Professor Emeritus, Retired
• National Institutes of Health, Office of the Director, Former Employer
• University of Tennessee Health Science Center, Assistant Professor of Preventative Medicine (child)
• University of Tennessee Health Science Center, Assistant Professor of Preventative Medicine (child’s spouse)

Michael S. Lauer, MD
As of January 15, 2016

Financial Associations
• National Institutes of Health, Employer
• Savings Investment Plan
• Putnam College Fund
• UptoDate Inc., Employer (spouse)

Personal Associations
• None reported

David O. Meltzer, MD, PhD
As of January 15, 2016

Financial Associations
• University of Chicago, Employer
• CVS
• National Institutes of Health
• American Board of Internal Medicine
• Grants/Contracts:
  • CMMI
  • NIH
  • AHRQ
  • PCORI

• Robert Woods Johnson Foundation (RWJF)
• National Pharmaceutical Foundation
• Stock:
  • Acadia Pharmaceuticals

Personal Associations
• American Board of Internal Medicine, Board Member (spouse)
• Society of General Internal Medicine, Member
• Society for Medical Decision Making, Member
• University of Chicago

Brian S. Mittman, PhD
As of November 9, 2015

Financial Associations
• US Department of Veterans Affairs, Employer (self and spouse)
• Kaiser Permanente Southern California, Employer
• Sepulveda Research Corp., VA Nonprofit Research Foundation, Employer
• Speaking, teaching, peer review and advisory board honoraria:
  • American College of Clinical Pharmacy
  • American Thoracic Society
  • Merck
  • Westat
  • Harvard University
  • Indiana University
  • Mt. Sinai Medical School
  • Mayo Clinic Center for Clinical and Translational Science
  • Northwestern University
  • University of Pennsylvania
  • University of Utah
  • Washington University St. Louis

Personal Associations
• AcademyHealth, Member, Methods Council, Education Council; Various Advisory Groups; Delivery System Science Fellowship Program Advisory Committee
• Association of American Medical Colleges, Member, Advisory Panel on Research
• Kings College London Centre for Implementation Science/CLAHRC South London, Member, External Advisory Board
• Canadian Partnership Against Cancer, Knowledge Management Steering Committee, Member
• Oregon Health Science University, Member, National Advisory
Committee (ESCALATES Project)
• Academy of Management, Member

Sally C. Morton, PhD
As of November 8, 2015
Financial Associations
• University of Pittsburgh, Employer (self)
• RAND Corporation, Consultant, AHRQ Contract (self)
• RTI International, Consultant, AHRQ Contract (self)
• Contracts/Grants from:
  • AHRQ
  • National Institutes of Health
  • PCORI

Personal Associations
• AHRQ, Committee Member (self)
• American Association for the Advancement of Science, Past Chair, Section U (Statistics) (self)
• American Statistical Association, Committee Member (self)
• Caucus for Women in Statistics, Member (self)
• Society for Research Synthesis Methodology, Elected Member (self)

Robin Newhouse, PhD, RN
As of November 29, 2015
Financial Associations
• Indiana University School of Nursing, Dean and Professor, Employer
• Speaker Honorarium:
  • Midwest Nursing Research Society
  • Baylor College of Medicine
  • University of Minnesota
  • University of Maine
• Worldviews on Evidence-Based Nursing, Associate Editor
• Get Well Network, O’Neil Clinical Advisory Council
• RWJF Nurse Faculty, Scholar Mentor
• Righttime Medical Care, Employer (child)
• AHRQ Research Funding Awards, Serving as PI or Co-Investigator on various projects
• PhRMA Foundation Grant Funding, Serving as Co-Investigator on project

Personal Associations
• American Nurses Credentialing Center’s Research Council, Chair
• AcademyHealth, Board of Directors, Member
• 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
• Midwest Nursing Research Society, Member
• American Organization of Nurse Executives, Member
• Institute of Medicine, Committee Member
• University of Maryland, School of Nursing, Professor and Chair, Organization Systems and Adult Health (former employer through June 30, 2015)

Neil R. Powe, MD, MPH, MBA
As of January 15, 2016
Financial Associations
• University of California, San Francisco, Employer
• National Institutes of Health, Research Grants
• Centers for Disease Control and Prevention, Research Grants
• Robert Wood Johnson Foundation, National Advisory Committee
• Informed Medical Decisions Foundation/Healthwise, Medical Editor
• Parkland Center for Clinical Innovation, Board Member
• Vanderbilt University School of Medicine, Scientific Advisory Board

Personal Associations
• Professional Societies/Association Membership:
  • Institute of Medicine (IOM)
  • American Society for Clinical Investigation (ASCI)
  • Association of American Physicians (AAP)
  • Association of Professors of Medicine (APM)
  • Society of General Internal Medicine (SGIM)
• American College of Physicians (ACP)
• American Society of Nephrology (ASN)
• Academy Health
• American Public Health Association (APHA)
• American Epidemiology Society (AES)
• American Clinical and Climatological Association (ACCA)

Sebastian Schneeweiss, MD
(Resigned from Methodology Committee February 1, 2016)
As of January 15, 2015
Financial Associations
• Brigham and Women’s Hospital, Employer
• Harvard School of Public Health, Teaching
• Harvard Medical School, Teaching
• WHISCON, LLC, Consulting
• Neblett, Beard & Arsenaut, Consultant
• Aetion, Inc., Consultant and Equity Holder

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

Mary Tinetti, MD
As of December 14, 2015
Financial Associations
• Yale University, Employer
• Journal of the American Medical Association (JAMA), Employer

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

Adam Wilcox, PhD
As of February 10, 2016
Financial Associations
• University of Washington, Employer (self)
• UW Medicine, Employer (self)
• University of Utah, Adjunct Faculty Member (self)
• eGEMs (Generating Evidence and Methods to improve patient
outcomes), Senior editor (self)
• EDM Forum, AcademyHealth, Steering Committee Member (self)
• Agency for Healthcare Research and Quality, Study Section Member (self)
• American Board of Preventive Medicine, Exam Committee Member (self)
• University of Michigan, Employer (sibling)
• HCR ManorCare, Employer (sibling)

Personal Associations
• Frost and Sullivan, Consulting Expert (self)
• Intermountain Healthcare, Former Employer (self)
• BMC Medical Informatics and Decision Making, Former Section Editor (self)
• Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C., Former Consulting Expert (self)

Clyde Yancy, MD
(Resigned from Methodology Committee on February 4, 2016)
As of January 15, 2015

Financial Associations
• National Institutes of Health, Special Government Employee
• Medscape/theheart.org, Consultant
• PCORI Methodology Committee, Member (paid)

Personal Associations
• American Heart Association, Board Member, Chicago Metro board; Past National President (2009-2010)
• American College of Physicians, Member
• Association of Black Cardiologists, Member, Educator
• American Hospital Association, Committee Member, Health Equity
• Heart Failure Society of America, Committee Member
• Heart Rhythm Society, Member

PCORI EXECUTIVE STAFF
Note: Conflict of Interest disclosure statements for all PCORI staff are available at pcori.org/people

Joe V. Selby, MD, MPH
As of July 15, 2015

Financial Associations
• University of California, San Francisco, Employer (child)

Personal Associations
None reported

Bryan Luce, PhD, MS, MBA
(Resigned from PCORI staff September 30, 2015)
As of August 18, 2014

Financial Associations
None reported

Personal Associations
• AcademyHealth Methodology Council, Member

Jean R. Slutsky, PA, MSPH
As of July 23, 2015

Financial Associations
None reported

Personal Associations
None reported

Regina L. Yan, MA
As of July 2, 2015

Financial Associations
None reported

Personal Associations
None reported

Mary C. Hennessey, Esq.
As of July 9, 2015

Financial Associations
None reported

Personal Associations
• Health and Human Services Advisory Council on Blood Stem Cell Transplantation, Member
• American Health Lawyers Association, Member

A full list of staff is available at www.pcori.org/people

PCORI ADVISORY PANELS
Names of the members of PCORI’s advisory panels and their Conflict of Interest disclosure statements are available at pcori.org/advisory-panels
## APPROVED RESEARCH AWARDS AND CONTRACTS

Research Contracts Awarded October 1, 2014-September 30, 2015

### FALL 2014 CYCLE CONTRACTS

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Awarded Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Practical Intervention to Improve Patient-Centered Outcomes after Hip Fractures Among Older Adults (Regain Trial)</td>
<td>University of Pennsylvania</td>
<td>Mark Neuman</td>
<td>11,869,193.00</td>
</tr>
<tr>
<td>Anti-TNF Monotherapy versus Combination Therapy with Low Dose Methotrexate in Pediatric Crohn's Disease</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>Michael Kappelman</td>
<td>7,909,644.00</td>
</tr>
<tr>
<td>Bayesian Hierarchical Models for the Design and Analysis of Studies to Individualize Healthcare</td>
<td>Johns Hopkins University</td>
<td>Scott Zeger</td>
<td>839,941.00</td>
</tr>
<tr>
<td>Cancer of the Uterus and Treatment of Stress Urinary Incontinence</td>
<td>Women and Infants Hospital-Rhode Island</td>
<td>Katina Robison</td>
<td>2,799,710.00</td>
</tr>
<tr>
<td>Clinician Language Concordance and Interpreter Use: Impact of a Systems Intervention on Communication and Clinical Outcomes</td>
<td>University of California, San Francisco</td>
<td>Leah Karliner</td>
<td>2,107,210.00</td>
</tr>
<tr>
<td>Communication to Improve Shared Decision-Making in ADHD</td>
<td>The Children's Hospital of Philadelphia</td>
<td>James Guevara</td>
<td>2,109,999.00</td>
</tr>
<tr>
<td>Comparative Effectiveness of a Virtual Reality Platform for Neurorehabilitation of Hemiparesis</td>
<td>The Ohio State University</td>
<td>Lynne Gauther</td>
<td>2,086,594.00</td>
</tr>
<tr>
<td>Comparative Effectiveness of CARRA Treatment Strategies for Polyarticular Juvenile Idiopathic Arthritis</td>
<td>Hackensack University Medical Center</td>
<td>Yukiko Kimura</td>
<td>2,738,645.00</td>
</tr>
<tr>
<td>Comparative Effectiveness of State Psychotropic Oversight Systems for Children in Foster Care</td>
<td>Rutgers The State University of New Jersey, New Brunswick</td>
<td>Stephen Crystal</td>
<td>2,032,074.00</td>
</tr>
<tr>
<td>Comparative Effectiveness Trial to Reduce Child Maltreatment, Improve Client Outcomes and Examine Client Burden</td>
<td>Georgia State University</td>
<td>Daniel Whitaker</td>
<td>2,796,068.00</td>
</tr>
<tr>
<td>CPR Education for Families of Cardiac Patients before Hospital Discharge: Comparing Methods for Real-World Dissemination</td>
<td>University of Pennsylvania</td>
<td>Benjamin Abella</td>
<td>1,866,644.00</td>
</tr>
<tr>
<td>Developing Bayesian Methods for Noninferiority Trial in Comparative Effectiveness Research</td>
<td>Wayne State University</td>
<td>Samiran Ghosh</td>
<td>832,703.00</td>
</tr>
<tr>
<td>Does Outpatient Palliative Care Improve Patient-Centered Outcomes in Parkinson's Disease?</td>
<td>University of Colorado Denver</td>
<td>Benzi Kluger</td>
<td>1,965,022.00</td>
</tr>
<tr>
<td>GWTG Interventions to Reduce Disparities in AHF Patients Discharged from the ED (GUIDED HF)</td>
<td>Vanderbilt University</td>
<td>Sean Collins</td>
<td>2,083,575.00</td>
</tr>
<tr>
<td>Home or Away from Home: Comparing Clinician and Patient/Family-Centered Outcomes Relevant to the Care of Pediatric Acute Myeloid Leukemia during Periods of Neutropenia</td>
<td>The Children's Hospital of Philadelphia</td>
<td>Richard Aplenc</td>
<td>1,987,778.00</td>
</tr>
<tr>
<td>Impact of High Deductible Health Plans on Patients with Bipolar Disorder</td>
<td>Harvard Pilgrim Health Care, Inc.</td>
<td>James Wharam</td>
<td>1,396,820.00</td>
</tr>
<tr>
<td>Improving Outcomes of Opioid Addicted Prisoners with Extended Release Injectable Naltrexone Before Reentry</td>
<td>University of Pennsylvania</td>
<td>George Woody</td>
<td>2,015,347.00</td>
</tr>
<tr>
<td>Integrating Online Weight Management with Primary Care Support: Patient-Centered Strategies for Addressing Overweight and Obesity in Primary Care</td>
<td>Brigham and Women's Hospital</td>
<td>Heather Baer</td>
<td>1,956,231.00</td>
</tr>
<tr>
<td>Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture</td>
<td>Pennsylvania State University Hershey Medical Center</td>
<td>Christopher Sciamanna</td>
<td>13,950,066.00</td>
</tr>
<tr>
<td>Intervention and Outcomes in Duarte Galactosemia</td>
<td>Emory University</td>
<td>Judith Fridovich-Keil</td>
<td>2,628,116.00</td>
</tr>
<tr>
<td>Mapping and Resourcing Patient and Stakeholder Engagement Along 10-Step PCOR Continuum Framework</td>
<td>University of Maryland Baltimore</td>
<td>C. Daniel Mullins</td>
<td>1,234,890.00</td>
</tr>
</tbody>
</table>
## FALL 2014 CYCLE CONTRACTS (continued)

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Awarded Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matching Complex Patients to Treatments: Innovative Statistical Scoring Methods for Treatment Selection</td>
<td>University of Wisconsin-Madison</td>
<td>Menggang Yu</td>
<td>1,400,000.00</td>
</tr>
<tr>
<td>Measuring and Talking to Patients about the Accuracy of Data used in PCOR</td>
<td>Duke University</td>
<td>Meredith Nahm Zozus</td>
<td>1,398,807.00</td>
</tr>
<tr>
<td>Mobility: Improving Patient-Centered Outcomes Among Overweight and Obese Youth with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics</td>
<td>University of Cincinnati</td>
<td>Melissa DelBello</td>
<td>12,906,187.00</td>
</tr>
<tr>
<td>Pain Coping Skills Training for African Americans with Osteoarthritis</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>Kelli Allen</td>
<td>1,923,764.00</td>
</tr>
<tr>
<td>Patient Centered Adaptive Treatment Strategies (PCATS) Using Bayesian Causal Inference</td>
<td>Cincinnati Children's Hospital Medical Center</td>
<td>Bin Huang</td>
<td>1,400,000.00</td>
</tr>
<tr>
<td>Patient Reported Outcomes for Bladder Management Strategies in Spinal Cord Injury</td>
<td>University of Utah</td>
<td>Jeremy Myers</td>
<td>2,702,708.00</td>
</tr>
<tr>
<td>Pragmatic Randomized Trial of Proton vs. Photon Therapy for Patients with Stage II or III Breast Cancer</td>
<td>University of Pennsylvania</td>
<td>Justin Bekelman</td>
<td>11,830,530.00</td>
</tr>
<tr>
<td>Putting Patients at the Center of Kidney Care Transitions</td>
<td>Duke University</td>
<td>Leigh Boulware</td>
<td>5,600,108.00</td>
</tr>
<tr>
<td>Research Ethics in Patient-Centered Outcomes Research</td>
<td>Brigham and Women’s Hospital</td>
<td>Joel Weissman</td>
<td>1,358,916.00</td>
</tr>
<tr>
<td>Simplifying Survivorship Care Planning; Comparing the Efficacy and Patient-Centeredness of Three Care Delivery Models</td>
<td>Johns Hopkins University</td>
<td>Katherine Smith</td>
<td>3,939,504.00</td>
</tr>
<tr>
<td>The Patient-Reported Outcomes Project of HCV-TARGET (PROP up TARGET)</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>Donna Evon</td>
<td>2,405,179.00</td>
</tr>
<tr>
<td>Treatment Alternatives in Adult Rare Disease; Assessment of Options in Idiopathic Subglottic Stenosis</td>
<td>Vanderbilt University</td>
<td>Alexander Gelbard</td>
<td>2,741,972.00</td>
</tr>
<tr>
<td>Visual Displays of Qualitative Data to Advance PCOR</td>
<td>University of California, San Francisco</td>
<td>Daniel Dohan</td>
<td>1,373,141.00</td>
</tr>
</tbody>
</table>

## PCORnet PHASE II CONTRACTS

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Awarded Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerating Data Value Across a National Community Health Center Network (ADVANCE)</td>
<td>Oregon Community Health Information Network</td>
<td>Jennifer DeVoe</td>
<td>8,697,334.00</td>
</tr>
<tr>
<td>A PaTH Towards a Learning Health System (PaTH)</td>
<td>University of Pittsburgh</td>
<td>Kathleen McTigue</td>
<td>8,759,993.00</td>
</tr>
<tr>
<td>ABOUT Network (American BRCA Outcomes and Utilization of Testing PPRN)</td>
<td>The University of South Florida</td>
<td>Rebecca Sutphen</td>
<td>1,456,391.00</td>
</tr>
<tr>
<td>AR-PoWER (ARthritis Partnership with Comparative Effectiveness Researchers) PPRN</td>
<td>Global Healthy Living Foundation</td>
<td>Seth Ginsberg</td>
<td>1,646,998.00</td>
</tr>
<tr>
<td>Chicago Area Patient Centered Outcomes Research Network (CAPriCORN)</td>
<td>The Chicago Community Trust</td>
<td>Terry Mazany</td>
<td>8,007,000.00</td>
</tr>
<tr>
<td>Collaborative Patient-Centered Rare Epilepsy Network</td>
<td>Epilepsy Foundation</td>
<td>Janice Buelow</td>
<td>1,765,890.07</td>
</tr>
<tr>
<td>Community Engaged Network for All</td>
<td>Genetic Alliance, Inc.</td>
<td>Sharon Terry</td>
<td>1,682,019.00</td>
</tr>
<tr>
<td>Community Partnered Participatory Research Network Centers of Excellence</td>
<td>Regents of the University of California, Los Angeles</td>
<td>Kenneth Wells</td>
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<td>Continuation of the NephCure Kidney Network</td>
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<td>Ann Lucas</td>
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<td>Jessica Law</td>
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<td>Kaiser Permanente &amp; Strategic Partners Patient Outcomes Research to Advance</td>
<td>Kaiser Foundation Research Institute, a Division of Kaiser Foundation Hospitals</td>
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<td>Research to Advance Learning (PORTAL)</td>
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<td>Research Action for Health Network (REACHnet)</td>
<td>Louisiana Public Health Institute</td>
<td>Thomas Carton</td>
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<td>Andrew Nierenberg</td>
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<td>New York City Clinical Data Research Network</td>
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<td>OneFlorida Clinical Research Consortium</td>
<td>University of Florida</td>
<td>Elizabeth Shenkman</td>
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<td>patient-centered SCAIable National Network for Effectiveness Research</td>
<td>University of California San Diego</td>
<td>Lucila Ohno-Machado</td>
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<td>Patients, Advocates, and Rheumatology Teams Network for Research and Service</td>
<td>Duke University</td>
<td>Laura Schanberg</td>
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<td>PCORnet Patient-Powered Research Network Phase II: ImproveCareNow Network</td>
<td>Cincinnati Children's Hospital Medical Center</td>
<td>Peter Margolis</td>
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<td>PEDSnet: A Pediatric Learning Health System</td>
<td>The Children's Hospital of Philadelphia</td>
<td>Christopher Forrest</td>
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<td>Phelan-McDermid Syndrome Data Network (PMS_DN)</td>
<td>Phelan-Mcdermid Syndrome Foundation</td>
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<td>PRIDEnet: A Participant-Powered Research Network of Sexual and Gender</td>
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<td>Scalable Collaborative Infrastructure for a Learning Healthcare system</td>
<td>President &amp; Fellows of Harvard College</td>
<td>Kenneth D. Mandl</td>
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<td>The University of North Carolina at Chapel Hill</td>
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<td>COPD Foundation, Inc.</td>
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<td>The Greater Plains Collaborative</td>
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<td>The Health eHeart Alliance, Phase II</td>
<td>University of California, San Francisco</td>
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<td>The Multiple Sclerosis Patient-Powered Research Network, iConquerMS™</td>
<td>Accelerated Cure Project for Multiple Sclerosis</td>
<td>Robert McBurney</td>
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<td>The National Alzheimer’s &amp; Dementia Patient &amp; Caregiver-Powered Research</td>
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<td>Veronique Roger</td>
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<td>The Vasculitis Patient-Powered Research Network (V-PPRN)</td>
<td>University of Pennsylvania</td>
<td>Peter Merkel</td>
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PCORnet PHASE II CONTRACTS (continued)
### SPRING 2014 PRAGMATIC CLINICAL STUDIES CONTRACTS

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<td>Early Supported Discharge for Improving Functional Outcomes After Stroke</td>
<td>Wake Forest University Health Sciences</td>
<td>Pamela Duncan</td>
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<td>Enabling a Paradigm Shift: A Preference-Tolerant RCT of Personalized vs. Annual Screening for Breast Cancer</td>
<td>University of California, San Francisco</td>
<td>Laura Esserman</td>
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<td>Pragmatic Trial of More versus Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules</td>
<td>Kaiser Foundation Research Institute, a Division of Kaiser Foundation Hospitals</td>
<td>Michael Gould</td>
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<td>A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer</td>
<td>Fred Hutchinson Cancer Research Center</td>
<td>Scott Ramsey</td>
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<td>Targeted interventions to Prevent Chronic Low Back Pain in High Risk Patients: A Multi-Site Pragmatic RCT</td>
<td>University of Pittsburgh</td>
<td>Anthony Delitto</td>
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### SPRING 2015 CONTRACTS

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<td>3D Team Care for Cognitively Vulnerable Older Adults</td>
<td>University of Connecticut School of Medicine</td>
<td>Richard Fortinsky</td>
<td>6,204,645.00</td>
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<td>A Model for Improving Patient Engagement and Data Integration with PCORnet Patient-Powered Research Networks and Payer Stakeholders</td>
<td>HealthCore</td>
<td>Kevin Haynes</td>
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<td>Acute Community Care to Avoid Unnecessary Emergency Department Visits</td>
<td>Massachusetts General Hospital</td>
<td>Lisa Iezzoni</td>
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<td>Addressing Racial Disparities in Implantable Cardioverter Defibrillator Therapy Via Innovative Designs (VIVID)</td>
<td>Duke University</td>
<td>Kevin Thomas</td>
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<td>Advancing Patient Centered Outcomes Research in Survival Data with Unmeasured Confounding to Improve Patient Risk Communication</td>
<td>Trustees of Dartmouth College</td>
<td>Alistair O’Malley</td>
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<td>Causal Inference Guidelines for Pragmatic Clinical Trials</td>
<td>Harvard University School of Public Health</td>
<td>Miguel Hernan</td>
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<td>Comparative Effectiveness and Safety of Inhaled Corticosteroids and Antimicrobial Compounds for Non-CF Bronchiectasis</td>
<td>Oregon Health &amp; Science University</td>
<td>Kevin Winthrop</td>
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<td>Comparative Effectiveness of Decision Support Strategies for Joint Replacement Surgery</td>
<td>Massachusetts General Hospital</td>
<td>Karen Sepucha</td>
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<td>Comparative Effectiveness of Metabolic and Bariatric Surgery using Patient Reported Outcome Measures (PROMs)</td>
<td>Massachusetts General Hospital</td>
<td>Matthew Hunter</td>
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<td>Comparative Effectiveness of Therapy in Rare Diseases: Liver Transplantation vs. Conservative Management of Urea Cycle Disorders</td>
<td>Children’s Research Institute</td>
<td>Mendel Tuchman</td>
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<td>Comparing the Effectiveness of Guideline-Concordant Care to Active Surveillance for DCIS: an Observational Study</td>
<td>Duke University</td>
<td>Shelley Hwang</td>
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<td>Concept Mapping as a Scalable Method for Identifying Patient-Important Outcomes</td>
<td>Thomas Jefferson University</td>
<td>Kristin Rising</td>
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<td>Discontinuation of Disease Modifying Therapies (DMTs) in Multiple Sclerosis (MS)</td>
<td>University of Colorado Denver</td>
<td>John Corboy</td>
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<td>Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths</td>
<td>University of Massachusetts, Amherst</td>
<td>Michael Constantino</td>
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<td>Enhancing Patient Ability to Understand and Utilize Complex Information Concerning Medication Self-Management</td>
<td>University of North Carolina at Chapel Hill</td>
<td>Susan Blalock</td>
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### SPRING 2015 CONTRACTS (continued)

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<td>Enhancing the Cardiovascular Safety of Hemodialysis Care: a Cluster-Randomized, Comparative Effectiveness Trial of Multimodal Provider Education and Patient Activation Interventions</td>
<td>University of Michigan</td>
<td>Tiffany Veinot</td>
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<td>Making Better Use of Randomized Trials: Assessing Applicability and Transporting Causal Effects</td>
<td>Brown University</td>
<td>Issa Dahabreh</td>
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<td>Navigating High Risk Surgery: Empowering Older Adults to Ask Questions that Inform Decisions about Surgical Treatment</td>
<td>University of Wisconsin-Madison</td>
<td>Margaret Schwarz</td>
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<td>Optimizing the Effectiveness of Routine Post-Treatment Surveillance in Prostate Cancer Survivors</td>
<td>The Alliance for Clinical Trials In Oncology Foundation</td>
<td>Ronald Chen</td>
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<td>Patient-Centered Models of HCV Care for People who Inject Drugs</td>
<td>Montefiore Medical Center</td>
<td>Alain Litwin</td>
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<td>Patient-Centered Research for Standards of Outcomes in Diagnostic Tests (PROD)</td>
<td>University of Washington</td>
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<td>Posterior Fossa Decompression with or without Duraplasty for Chiari Type I Malformation with Syringomyelia</td>
<td>Washington University School of Medicine</td>
<td>David Limbrick</td>
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<td>Reducing Health Disparities in Unintended Pregnancies Among Hispanic Adolescents Using a Patient-Centered Computer-Based Clinic Intervention</td>
<td>University of California, San Francisco</td>
<td>Kathleen Tebb</td>
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<td>Rivaroxaban versus Low-Molecular Weight Heparin or Coumadin for Treatment of Venous Thromboemboli (VTEs) in Cancer Patients</td>
<td>The Alliance for Clinical Trials In Oncology Foundation</td>
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<td>THE PRIORITIZE STUDY: A Pragmatic, Randomized Study of Oral Regimens for Hepatitis C: Transforming Decision-Making for Patients, Providers, and Stakeholders</td>
<td>University of Florida</td>
<td>David Nelson</td>
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<td>Using a Teachable Moment Communication Process to Improve Outcomes of Quitline Referrals</td>
<td>Case Western Reserve University</td>
<td>Susan Flocke</td>
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<td>Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities</td>
<td>Johns Hopkins University</td>
<td>Lisa A. Cooper</td>
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<td>Collaboration to Improve Blood Pressure in the US Black Belt-Addressing the Triple Threat</td>
<td>University of Alabama at Birmingham</td>
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<td>Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)</td>
<td>Duke University</td>
<td>Matthew Roe</td>
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<td>Comparative Effectiveness of Pulmonary Embolism Prevention after Hip and Knee Replacement (PEPPER): Balancing Safety and Effectiveness</td>
<td>Medical University of South Carolina</td>
<td>Vincent Pellegrini</td>
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<td>Comparing Outcomes of Drugs and Appendectomy (CODA)</td>
<td>University of Washington</td>
<td>David Flum</td>
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<td>Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural FQHCs</td>
<td>University of Washington</td>
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<td>Integrating Behavioral Health and Primary Care</td>
<td>University of Vermont and State Agricultural College</td>
<td>Benjamin Littenberg</td>
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<td>PCORnet Bariatric Study</td>
<td>Group Health Cooperative</td>
<td>David Arterburn</td>
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<td>PCORNet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth</td>
<td>Harvard Pilgrim Health Care, Inc.</td>
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In addition to research contracts, PCORI approved a number of programmatic and research support awards in FY2015. More information on these awards may be found at www.pcori.org.
PATIENT-CENTERED OUTCOMES RESEARCH (PCOR)

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

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

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

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

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

To answer these questions, PCOR:

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

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

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

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

Approved by PCORI Board of Governors, March 5, 2012