Leadership Letter

On behalf of the Patient-Centered Outcomes Research Institute (PCORI), our Board of Governors, and staff, we are pleased to offer this report to the nation on our accomplishments and activities during the October 1, 2019 to September 30, 2020 fiscal year (FY).

In the year since our last Annual Report, the world changed in profound ways as the COVID-19 pandemic affected every aspect of how we live and work. However, the tumultuous year also provided many learning opportunities for our health and healthcare research ecosystem. Because of the commitment and resilience of our leadership, staff, and partners, we rapidly responded to research needs during the COVID-19 pandemic and made continued progress in meeting the mission Congress set for us in 2010: to fund comparative clinical effectiveness research that helps patients and those who care for them make better-informed healthcare decisions and move the results of that work into practice.

Amid this COVID-19 pandemic of unprecedented scale and impact, the nation is also focusing on the work we need to do to address racism and the continuing inequality of access and opportunity. These dual public health crises, which are disproportionately claiming the lives of people of color, have focused public attention on the root causes of long-standing health disparities in this country.

This has also been a year of transition for PCORI as we settled into our roles as Executive Director and Board of Governors Chairperson. We are grateful for the support of our partners and stakeholders as we continue PCORI’s important work in 2021.

Nakela L. Cook, MD, MPH
Executive Director

Christine Goertz, DC, PhD
Chairperson, PCORI Board of Governors

Influencing Others

- Engaging Patients as Research Partners
- Training Partners for Participation: Research Fundamentals
- Supporting Current Awardees during COVID-19 Pandemic
- New Resource to Facilitate Engagement
- Results from PCORI-Funded Research Reach Diverse Audiences Quickly
- Heightening Our Support for Sharing Research Results with Participants
- Virtual Annual Meeting Draws Record Attendance

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Nakela L. Cook, MD, MPH
Executive Director

Christine Goertz, DC, PhD
Chairperson, PCORI Board of Governors
A Year of Resilience and Hope

Congress authorized the establishment of PCORI in 2010 with a clear mission to fund comparative clinical effectiveness research (CER) that helps patients, caregivers, clinicians, and other healthcare stakeholders make better-informed healthcare decisions and improve patient care and outcomes.

PCORI worked tirelessly to fulfill this mission, always with an eye toward 2019, when Congress would decide whether to reauthorize the organization’s funding. When that happened in December 2019, PCORI prepared to embark on an exciting future: another decade of funding awards, a new Executive Director coming on board, and new research priorities and initiatives to take flight.

And then everything changed. The year 2020—with dual public health crises of the global coronavirus pandemic and increasing health inequities—was unparalleled in our country’s history. Amid a leadership transition, PCORI took concerted action to respond to both crises by quickly funding new COVID-19 research, a registry and study focused on frontline healthcare workers, COVID-19-related enhancements to existing projects, and research to address health disparities. These projects represent hope and promise of research results to aid in the national response to the pandemic and health inequities. PCORI seeks to integrate research with clinical care more effectively and make progress on creating a learning healthcare system.

From natural experiments growing out of the pandemic to leveraging data and technology for real-time information on care patterns, these trends and others will inform the next decade of PCORI’s work. That phase centers on three key elements: evidence generation; stakeholder participation; and PCORI’s pillars of engagement, innovation, and working differently. PCORI seeks to integrate research with clinical care more effectively and make progress on creating a learning healthcare system.

Reauthorization and a Bold Path Forward

In the law reauthorizing PCORI’s funding, Congress identified two new additional priority areas to pursue: research with respect to intellectual and developmental disabilities (IDD) and maternal morbidity and mortality. In the past year, PCORI formed work groups to examine and enhance its portfolio in these areas, received extensive stakeholder input on priority research questions, held breakout sessions on perinatal mental health and IDD at its Annual Meeting, and announced funding opportunities that encouraged research proposals on these topics. Directing more resources to maternal morbidity and mortality and IDD research will be top of mind as PCORI begins its forward-looking reexamination of the National Priorities and Research Agenda in FY 2021.

In November 2019, Joe V. Selby, MD, MPH, retired from his position as the organization’s founding Executive Director. Under his direction, PCORI became known as a leader in funding CER. Josephine P. Briggs, MD, a nationally recognized nephrologist and researcher, served as Interim Executive Director until a permanent replacement could be found.

In January 2020, the Board of Governors announced that Nakela L. Cook, MD, MPH, had been named as the next Executive Director. A cardiologist and health services researcher, Cook officially joined PCORI on April 15, 2020, from the National Heart, Lung, and Blood Institute, where she served as a Senior Scientific Officer and Chief of Staff.

In FY 2020, PCORI awarded $158 MILLION TO FUND 36 new comparative clinical effectiveness research studies.

Congress Authorizes Establishment of PCORI

In March 2010, Congress authorized the establishment of the Patient-Centered Outcomes Research Institute, an independent 501(c)(3) nonprofit organization. PCORI’s mission was formed:

- To provide information patients and those who care for them can use to evaluate prevention, diagnosis, and treatment options and make better-informed healthcare decisions.

In September 2010, the Acting Comptroller of the US Government Accountability Office (GAO) appointed the first 19 members to the new entity’s Board of Governors. In addition to the Directors of the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (or their designees), who represented stakeholders from across the healthcare spectrum and built the framework for PCORI’s work on patient-centered outcomes research.

Among the Board of Governors’ first steps was to establish PCORI as a nonprofit organization in November 2010. PCORI marked 10 years of service to the nation in FY 2020. Accomplishments for each year of that decade are spotlighted throughout this report.
Facing the Year’s Challenges

The year’s public health crises challenged PCORI to increase focus on inequities based on race, ethnicity, income, geography, and other factors that are drivers of health and healthcare disparities. After recognizing the impact of COVID-19 on the nation, PCORI senior leaders, staff, and Board of Governors pivoted to focus on what PCORI could do in coordination with ongoing efforts across government, industry, and other funders. The organization’s attention turned to critical dimensions of this pandemic, particularly the healthcare workers on the front lines: physicians, nurses, and all personnel—medical and nonmedical—who worked in hospitals, triage tents, drive-through testing stations, and clinics providing compassionate care to individuals with COVID-19. PCORI responded in innovative and decisive ways, with efforts focused on funding awards and sharing information.

Research Done Differently

As a research funder, funding awards was the most obvious way for PCORI to respond. In April, PCORI committed up to $50 million for the Healthcare Worker Exposure Response & Outcomes (HERO) registry and trial. The registry established a community of healthcare workers at risk of COVID-19 infection, identified individuals interested in engaging in clinical trials related to COVID-19, and created a dataset of basic clinical and environmental COVID-19 risk factors and clinical and emotional outcomes for analysis. At the end of FY 2020, 17,000 healthcare workers (and counting) had joined the registry. In May, on an accelerated timeline because of the pandemic’s urgency, PCORI began accepting submissions to a COVID-19 Targeted PCORI Funding Announcement (PFA), with a solicitation for projects that examined adaptations to healthcare delivery during the pandemic; the impact of COVID-19 on vulnerable populations; and the impact of COVID-19 on healthcare workforce well-being, management, and training. In August and September 2020, PCORI approved $34 million in funding for nine new studies under this PFA. These projects examine the effects on patients from state and local public health containment and mitigation policies, healthcare access and disparities in outcomes among racial and ethnic minorities and underserved populations, and the effects of policy changes relating to COVID-19 medication-assisted treatment on people with opioid use disorders. The projects also are examining different types and intensities of preventive interventions in reducing rates of COVID-19 and related hospitalization and mortality in staff and adult residents in congregate care settings. These projects are designed to provide actionable findings in no more than 12 months.

PCORI also committed $3.7 million to fund 25 projects through a special Eugene Washington PCORI Engagement Awards cycle to support the engagement and dissemination of patient-centered outcomes research in the context of the COVID-19 pandemic. In addition to new COVID-19 research, PCORI’s Board allocated funding for investigator-initiated requests for enhancements to existing projects in the context of COVID-19. This innovative mechanism leveraged work already in process to produce additional, timely results that could be used to combat the pandemic.

Over the spring and summer, PCORI reviewed more than 240 applications for enhancements on a rolling basis and committed $34.5 million to fund 116 enhancements across research, dissemination and implementation, and engagement awards. In response to the volume of high-quality research proposals for both the COVID-19 Targeted PFA and the enhancements, PCORI’s Board committed an additional $50 million to fund both research projects and enhancements in June.

The enhancements are unique to PCORI in that they seek to answer very specific questions as opposed to higher-level questions being tackled by other funders. For example, a research project examining the benefits and harms among various treatments for venous thromboembolism added an enhancement to examine whether patients hospitalized with COVID-19 are more at risk for blood clots than those hospitalized for other reasons. A Dissemination and Implementation project seeking to increase the use of a shared decision making aid for patients with lupus—who are at an increased risk of severe complications from COVID-19 and therefore might not want to access in-person care—used an enhancement to create a telehealth version of the decision aid for patients to use in virtual visits. An Engagement Award seeking to increase the engagement of African immigrants in health research added an enhancement to employ a creative method using photos to identify ways to engage African immigrants in COVID-19 prevention, testing, and treatment options. Outcomes of this project will have a national reach and can be tailored to other immigrant populations.

COVID-19 Response

As part of its response to the COVID-19 pandemic, PCORI awarded more than $120 million in research, research-related, and engagement projects. Included in this total is a COVID-19 Targeted PFA, which awarded:

$29 million in New Targeted Awards to fund 9 projects:

- $19.5M (6 projects) Impact of COVID-19 on Underrepresented Populations*
- $9.9M (2 projects) Impact of COVID-19 on Healthcare Workforce*

Adaptations to Healthcare Delivery

$5.4M (2 projects)

$19.5M (6 projects) Impact of COVID-19 on Underrepresented Populations*
- One study encompasses two priority areas (Impact of COVID-19 on Underrepresented Populations and on the Healthcare Workforce) and is reflected in both totals.

Building a Patient-Centered Research Organization

PCORI’s Board of Governors appointed Joe V. Selby, MD, MPH, as the organization’s Executive Director in May 2011. He helped create the organizational structure to carry out a national research agenda, identified strategic issues and opportunities for PCORI, and implemented programs authorized by the Board of Governors. PCORI also announced its first funding opportunity, a $26 million pilot grant program. Awardees in 24 states and the District of Columbia would produce evidence that informed PCORI’s development and enhancement of national patient-centered outcomes research (PCOR) priorities, supported the collection of preliminary data for an evolving Research Agenda, and supported the identification of research methodology to advance PCOR.

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Information Sharing

Recognizing its responsibilities to the broader healthcare community, PCORI worked to share information and resources that health systems could use during the pandemic.

From March through May, PCORI hosted a six-part webinar series, Confronting COVID-19: Finding Hospital Capacity and Improving Patient Flow. The webinars featured more than 20 leaders from hospitals and long-term care facilities, clinicians, and operations management experts discussing how they dealt with circumstances and sharing knowledge with the wider healthcare community and strategies for fine-tuning hospital capacity, staffing, and patient flow amid the coronavirus pandemic. Other webinar topics covered incident command management, how to deal with the Emergency Department, balancing elective and urgent surgeries, nurse staffing, discharge and recovery, and telehealth.

Also in May, PCORI launched its Horizon Scanning COVID-19 Supplement. The COVID-19 supplement scans for, identifies, monitors, and reports on emerging and available COVID-19-related treatments, diagnostics, preventive measures, management strategies, and systems changes with potential for high impact on patient outcomes—for individuals and populations—in the United States in the next 12 months.

The Health Care Horizon Scanning System COVID-19 Supplement produces three main products: Biweekly COVID-19 Scans, Status Reports that are published quarterly, and High Impact Reports that are published every four months.

Finally, the PCORI Annual Meeting—held virtually for the first time in 2020 because of the pandemic—featured a breakout session, Patient-Centered Telehealth under the Coronavirus Pandemic, in addition to several other sessions that touched on the effects of the pandemic on the healthcare landscape.

Together Toward Change

In response to both the health and healthcare disparities faced by racial and ethnic populations during the coronavirus pandemic and the unrest and violence over the summer of 2020, PCORI released a statement in June, Together Toward Change, highlighting the work needed to address racism and the continuing inequality of access and opportunity.

As PCORI begins the process of identifying our National Priorities for Health and launching our next decade, it does so with a renewed commitment to engaging diverse stakeholders, developing and investing in partnerships with communities, and identifying and promoting innovative models for patient-centered learning healthcare systems that are responsive to the needs of their patients and the communities they serve.
New Funding Initiatives

In addition to coronavirus-related opportunities, PCORI introduced several new funding opportunities in FY 2020.

The Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA, which opened for Letters of Intent in June 2020, seeks to answer research questions on high-burden, high-impact health topics in real-world clinical settings that reflect how most American health care is delivered.

Bold, innovative, and large-scale clinical trials funded through this PFA might carry some risk of failure along with significant potential benefits. To be scientifically and fiscally responsible in balancing the potential for risks and rewards, PLACER is using a phased funding approach new to PCORI. A smaller, initial phase of funding will be used to inform whether the trial is feasible and can achieve its intended aims as planned. If careful review of the planning phase accomplishments indicates likely success of the full-scale trial, continued study funding will proceed.

PCORI believes this phased approach will result in greater numbers of large, impactful studies and enable PCORI funding to reach more researchers.

As in past years, PCORI also opened Targeted PFAs to respond to priority research areas. The selected topics were suicide prevention for youth, observational analyses of second-line pharmacological agents in type 2 diabetes, and rare disease using the infrastructure of PCORnet®, the National Patient-Centered Research Network. Over the past two decades, suicide rates for youth aged 15 to 24 spiked by almost 50 percent, and effects of the COVID-19 pandemic could exacerbate this crisis. PCORI’s PFA seeks to fund studies comparing the effectiveness of brief interventions to prevent suicide in youth. Brief interventions—often the first line of help patients receive when concern about suicidality develops or increases—are designed to ease the immediate suicide risk and to direct patients to longer-term treatment.

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New Awards Begin, Methodology Standards Adopted

Fiscal year 2013 marked the launch of PCORI’s Engagement Awards, an initiative designed to grow a national community of healthcare stakeholders to advance PCOR. The Board also adopted 47 initial Methodology Standards developed by the Methodology Committee to guide the conduct of PCOR. The year also saw the formation of multi-stakeholder advisory panels that were charged with providing guidance and recommendations to PCORI’s Board, Methodology Committee, and staff on planning, developing, and enhancing PCORI’s work. Each panel has a specific focus:

- Clinical effectiveness and decision science
- Clinical trials
- Health delivery and disparities research
- Patient engagement
- Rare disease

Because of the emergence of a new class of medications—such as SGLT2 inhibitors and GLP-1 receptor agonists—to treat type 2 diabetes, PCORI issued a PFA to fund observational studies that compare the effectiveness of these newer agents versus older second-line pharmacological agents in type 2 diabetes among individuals at moderate cardiovascular risk.

The rare disease PFA was limited to current awardees receiving funding from PCORI as part of the PCORnet® initiative. It aims to answer important research questions about the care of patients with rare diseases, and to enhance the capabilities for multisite rare disease research by creating partnerships and linkages to facilitate future studies for the rare disease community. Awards for PLACER and each Targeted PFA will be announced in 2021.
**FY 2020 Milestones**

**October**
- NIH announces PREVENTABLE, a $90 million study that will harness PCORnet data to efficiently assess statins’ abilities to prevent dementia and other disabilities in older adults without cardiovascular disease

**November**
- Board approves $70 million to support 21 research studies and projects to speed the uptake of research results into practice on health topics including opioid use disorders, hearing loss, mental health issues, diabetes, and asthma
- Joe V. Selby, MD, MPH, retires as founding Executive Director
- Josephine P. Briggs, MD, named PCORI Interim Executive Director

**December**
- PCORI launches Engagement Tool and Resource Repository for Patient-Centered Outcomes Research, a searchable, peer-to-peer collection of engagement-related tools and resources developed and used by PCORI awardees
- Bipartisan legislation in Congress, signed by the president, reauthorizes PCORI’s funding through 2029

**January**
- Board approves $12 million to fund four new research studies on hearing loss, pediatric trauma care, care transitions, and reducing hospital readmissions among patients with pneumonia or sepsis
- Board announces that Nakela L. Cook, MD, MPH, will join PCORI in April as its second Executive Director

**March**
- Board commits up to $150 million for funding opportunities on PLACER, type 2 diabetes, and rare disease research using the PCORnet infrastructure
- Board approves $16 million to fund four new research studies on maternal depression, HIV prevention, prostate cancer, and care transitions; also approves three implementation projects
- Six-part PCORI-sponsored webinar series, Report from the Field: How We Are Managing Incident Command, launches, featuring health system leaders discussing their response to the coronavirus pandemic

**April**
- Board of Governors approves up to $110 million in COVID-19-related funding for enhancements and adaptations to current projects, new projects, and HERO program
- Engagement Awards COVID-19 Special Cycle opens for proposals supporting engagement in and dissemination of research
- Nakela L. Cook, MD, MPH, officially joins PCORI as its second Executive Director

**May**
- PCORI posts COVID-19 Targeted PFA for research into adaptations to healthcare delivery; impact on vulnerable populations; and impact on healthcare workforce well-being, management, and training

**June**
- PCORI releases statement, Together Toward Change, addressing structural racism in health care and health services research
- PCORI posts first biweekly COVID-19 Horizon Scan covering topics related to the coronavirus that could potentially affect health care in the United States in the next 12 months
- PCORI Board approves up to $50 million for additional COVID-19 funding opportunities and enhancements to existing studies
- Board approves $25 million to fund 10 comparative effectiveness research studies, $1.4 million for one implementation project

**August**
- PCORI launches Research Fundamentals, an online training tool to help people partner with health researchers
- PCORI publishes first quarterly Horizon Scanning COVID-19 Supplement Status Report
- PCORI announces $23 million in funding for seven COVID-19 targeted research awards

**September**
- Thirty-four people representing sectors from across the healthcare community named to join PCORI’s five multi-stakeholder advisory panels
- PCORI announces $7 million in funding for two additional COVID-19 targeted research awards
- Sixth PCORI Annual Meeting, held virtually, sees attendance jump by 160 percent from previous year
- GAO announces appointments of seven new members to PCORI Board of Governors
Producing Evidence for Informed Healthcare Decisions

PCORI continued to track rapid growth in the number of completed projects in its funded research portfolio in FY 2020. These projects are generating evidence that enables patients and those who care for them to make decisions that best reflect individual circumstances and preferences.

Knowing that research results are only useful if they are shared widely, PCORI continued making funded results readily available, posting 68 lay and professional results summaries on our website in FY 2020. PCORI also published two Evidence Updates—findings from systematic reviews and our funded research studies in concise, accessible formats. These Evidence Updates covered urinary incontinence and the increased risks of blood clot and stroke among transgender women taking estrogen.

PCORI also expanded its reach with the uptake of funded research results in 41 evidence-based clinical recommendations, 112 policy documents, and 191 citations in meta-analyses and systematic reviews in FY 2020.

It often takes years for new evidence from clinical research to influence healthcare delivery. Many times, these findings never reach patients and families who could benefit from the information. To bridge this gap, PCORI funds Dissemination and Implementation (D&I) Awards. This funding supports the expansion of research projects, their interventions, and their findings at new sites and in new settings.

Here is a snapshot of some of the year’s completed research projects and several studies that are now broadening their reach with D&I Awards.

Improving Antibiotic Prescription Practices in Pediatric Populations

Antibiotics are commonly prescribed to treat ear, sinus, and throat infections in children. Narrow-spectrum antibiotics, which target a few types of bacteria, and broad-spectrum antibiotics, which target many types of bacteria, may both work well in treating these infections. But using broad-spectrum antibiotics when they are not necessary contributes to the emergence of antibiotic-resistant bacteria and increases the risk of harmful side effects.

A study led by Jeffrey Gerber, MD, PhD, at the Children’s Hospital of Philadelphia found a greater risk of side effects with broad-spectrum antibiotics, with no difference in symptom resolution between the two types in treating children with ear, sinus, and throat infections. But clinicians still prescribe broad-spectrum antibiotics more than twice as often as they’re needed.

Through a D&I Award, Gerber’s team is using a multi-part program to improve antibiotic prescribing at healthcare visits for children with ear, sinus, and throat infections across three states. The program is called Prescribing Antibiotics for Respiratory Tract Infections. The program educates clinicians about appropriate prescribing and patient communication and tracks clinicians’ prescribing rates. The D&I Award will expand the program to 115 sites across five health systems in three states.

To diagnose acute respiratory tract infections in children, clinicians often use a physical exam or lab test that may not be possible with telehealth. Through supplemental COVID-19 enhancement funding, Gerber’s team is supporting the program’s adaptation to telehealth, providing clinicians information about prescribing antibiotics in this new practice setting.

PCORnet Launched with PCORI’s Strong Support

In FY 2014, PCORI’s leaders announced the funding of a new initiative, PCORnet, an integrated national clinical research network that could help conduct patient-centered CER and related studies faster, more easily, and more efficiently.

Launched with an initial $100 million in funding from PCORI, PCORnet is intended to transform how research is done by harnessing the power of electronic health record information covering tens of millions of patients, along with claims data and other information.

PCORI also produced an Engagement Rubric, which provides guidance on methods for engaging stakeholder partners throughout each phase of the research process, and an Evaluation Framework, which helped PCORI evaluate the effectiveness of its work.
National Priorities for Research and Research Agenda

PCORI’s National Priorities for Research and Research Agenda guide our funding of CER. Work groups comprising the Board of Governors, members of our Methodology Committee, and staff developed this framework:

Assessment of Prevention, Diagnosis, and Treatment Options
Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

Improving Healthcare Systems
Comparing health system–level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

Communication and Dissemination Research
Comparing approaches to providing CER information, empowering people to ask for and use the information, and supporting shared decision making between patients and their providers.

Addressing Disparities
Identifying potential differences in prevention, diagnosis, or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

Supporting Smokers Making Decisions about Lung Cancer Screening

Lung cancer is the third most common cause of cancer and the number one cause of cancer deaths in the United States. However, screening using low-dose computed tomography can detect lung cancer early and save lives. But screening also has possible harms, including radiation exposure from the tests and false positive tests.

A PCORI-funded study led by Robert J. Volk, PhD, at the University of Texas MD Anderson Cancer Center tested a video-based decision aid about lung cancer screening for people who seek help quitting smoking through tobacco quitlines against a standard educational brochure. Quitlines are telephone-based confidential smoking cessation services.

As the research team reported in *JAMA Network Open*, people who used the decision aid had a better understanding of their screening options and the trade-offs. They also felt more prepared to talk about screening with their health provider. Many went on to be screened.

Now, a D&I Award is broadening its reach to eight state tobacco quitlines that will reach thousands of new high-risk smokers. The project team will train staff to identify callers who are eligible for lung cancer screening and refer them to the decision aid and will also develop a guide of best practices for use by other quitlines.

The quitline service providers taking part in this project operate 37 other state quitlines, and the project includes resources and guides they may use to expand the program to these other sites.
Helping Women Select Their Best Treatment for Lupus

Lupus, an illness in which the immune system attacks parts of the body, can cause a kidney disease called lupus nephritis that is more common and more severe in racial and ethnic groups than in the general population. Multiple immune-blocking medications can treat lupus nephritis, but they differ in how well they work, side effects, and costs.

In a study led by Jasvinder Singh, MD, MPH, at the University of Alabama at Birmingham, women with lupus nephritis looked at either a pamphlet about lupus or an online decision aid tailored to women’s personal situations before deciding whether to start or change treatment with immune-blocking medicine. Compared with women who read the pamphlet, women who used the decision aid felt less doubt about their medicine choices.

Now, through a D&I Award, the team is updating the decision aid to include broader information about lupus beyond its effect on the kidneys. They are working to integrate the decision aid as part of patient care in 15 lupus clinics serving diverse populations. They have had early success, delivering the decision aid to more than 500 lupus patients—45 percent of whom are African American—via touchpad tablets at an in-person clinic.

The D&I Award was followed with supplemental funding for an enhancement that adapts the decision aid for use with telehealth so that lupus patients, who may be at an increased risk for severe complications from COVID-19, can use the decision aid at home using either a smartphone app or website. The research team is working with clinics to have patients view the decision aid at home and alert the clinic when the patient completes the decision aid.

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Averting Falls in Older Adults

Every second of every day, an adult age 65 or older falls in the United States, making falls the leading cause of injury and injury-related death in this age group. To assess the delivery and implementation of effective strategies for preventing these injuries, PCORI and the National Institute of Aging of the NIH supported the STRIDE Study.

The project, led by Shalender Bhasin, MD, of Harvard Medical School; Thomas Gill, MD, of Yale Medical School; and David B. Reuben, MD, of UCLA Medical School, randomly assigned more than 5,000 older adults across 10 healthcare systems serving diverse populations to receive either a personalized falls prevention program or general fall prevention information. As reported in the July 2020 issue of the *New England Journal of Medicine*, the study found that the personalized approach, in which nurses tailored falls prevention plans for older adults at high risk and administered these plans for at least 20 months, resulted in an 8 percent to 10 percent reduction in serious fall injuries, but this effect was not statistically significant.

The paper notes potential barriers to care, such as transportation availability, copayments, and lack of engagement in reducing some risk factors, such as eliminating medications that increase falls risk, are among possible reasons for the small effect size seen in the trial. Lessons learned from STRIDE can help inform the design and implementation of future clinical trials of fall injury risk reduction in various healthcare delivery settings.

Preventing Blood Clots through Education

Blood clots are a common cause of sickness and death among patients in the hospital—but they are also largely preventable, with highly effective medicines available. Hospitalized patients are at elevated risk of venous thromboembolism (VTE), but according to several studies, these patients miss about 12 percent of their blood-thinner doses, most often because they refuse to take them when offered.

In the original PCORI-funded study, Elliot Haut, MD, PhD, of Johns Hopkins University and colleagues tested an educational program that helps hospitalized patients make informed decisions about medications to prevent VTE. As published in *JAMA Network Open*, the single, web-based nurse education module program reduced the number of times patients did not take blood clot prevention medication by 42 percent. Since then, the team has received not one, but two D&I Awards. The first supported the program’s expansion to the inpatient population at The Johns Hopkins Hospital, a large teaching hospital, and Howard County General Hospital, a medium-sized community hospital. The program had similar success at both hospitals. Now, the second D&I Award, made in FY 2020, is expanding the program to 10 trauma centers across the country, where it could reach an estimated 32,000 patients each year.

**PCORI’s Funding Portfolio: A Closer Look**

<table>
<thead>
<tr>
<th>Most Studied Conditions*</th>
<th>Populations of Interest*</th>
</tr>
</thead>
<tbody>
<tr>
<td>$598 Million</td>
<td>$1.3 Billion</td>
</tr>
<tr>
<td>Mental/Behavioral Health</td>
<td>Racial and Ethnic Groups</td>
</tr>
<tr>
<td>$375 Million</td>
<td>$807 Million</td>
</tr>
<tr>
<td>Cancer</td>
<td>Low-Income</td>
</tr>
<tr>
<td>$352 Million</td>
<td>$805 Million</td>
</tr>
<tr>
<td>Cardiovascular Diseases</td>
<td>Women</td>
</tr>
<tr>
<td>$336 Million</td>
<td>$736 Million</td>
</tr>
<tr>
<td>Neurological Disorders</td>
<td>Older Adults</td>
</tr>
<tr>
<td>$249 Million</td>
<td>$570 Million</td>
</tr>
<tr>
<td>Multiple/C- Morbid Chronic Conditions</td>
<td>Individuals with Multiple Chronic Conditions</td>
</tr>
<tr>
<td>$244 Million</td>
<td>$418 Million</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>Rural Areas</td>
</tr>
<tr>
<td>$220 Million</td>
<td>$401 Million</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>Children</td>
</tr>
<tr>
<td>$209 Million</td>
<td>$384 Million</td>
</tr>
<tr>
<td>Nutritional and Metabolic Disorders</td>
<td>Urban Populations</td>
</tr>
</tbody>
</table>

* Awards since PCORI’s inception listed by primary condition. For more information, visit www.pcori.org/research-results.

**Sharing Research Results Quickly, Effectively**

Recognizing the importance of sharing relevant and potentially transformative research widely, effectively, and quickly, PCORI began building its Dissemination and Implementation program, awarding the first five implementation awards to teams that had completed PCORI-funded research projects. PCORI also launched a funding initiative specifically to support implementing effective shared decision making approaches in practice settings. The year 2017 also marked the first posting of findings from our funded studies in versions customized for patients and providers, as well as the creation of information products developed in collaboration with stakeholders.
Influencing Others

PCORI has become a leader in influencing clinical research by engaging patients and other healthcare stakeholders in all aspects of its work. This pioneering approach to patient engagement has had ripple effects across the research ecosystem. Efforts to engage, train, equip, and support stakeholders and research partners while adapting to the needs of the moment kept PCORI at the fore in FY 2020.

Engaging Patients as Research Partners

PCORI has seen that taking the questions that matter to patients as the starting point and bringing patients into the clinical research process as partners has dramatic benefits for clinical research. When patients are brought into the discussion of a possible clinical research study, they inject a sense of urgency and guard against complacency. Someone coping with cancer or a parent caring for a sick child may judge progress differently than a researcher; so having patients join the discussion is beneficial for all involved. Patient-centeredness also sometimes changes the research questions. Laboratory measurements used in clinical trials generally matter less to patients. People living with a health condition often ask whether a treatment can reduce the burden of disease on themselves, their caregivers, and families. Cure, longer survival, and other traditional clinical outcomes are important, but sometimes not the patient’s primary focus. Including them at the table lets researchers know what outcomes are most important to patients. Also, meaningful patient input can help researchers develop a better strategy for implementation. Patients bring creative thinking and useful ideas and help researchers improve study design and conduct. Patients and caregivers have lived experience that makes research more relevant and useful, as well as diverse backgrounds, professions, interests, and talents that bring value to research efforts.

Training Partners for Participation: Research Fundamentals

While PCORI knows that partners, patients, and stakeholders bring a wealth of knowledge and expertise to a project, it has also learned that partnering successfully in the research process can be facilitated by having information about the process and the confidence to contribute. In FY 2020, PCORI launched a free online training to support stakeholder partners in contributing to research. Research Fundamentals is a self-paced, on-demand training that uses evidence-based approaches and plain language to describe and explain PCOR. It is designed to help anyone—patients, caregivers, and other stakeholders—learn about the research process, regardless of their level of experience.

The training includes resources that provide an overview of PCOR and engagement, as well as learning modules that take users through the research cycle from beginning to end. It was developed based on extensive research and with input from experienced stakeholder partners and integrated their voices throughout to create a learning package that responds to research partners’ needs and encourages them with varied learning styles and goals.

Supporting Current Awardees during COVID-19 Pandemic

In early April 2020, PCORI launched its COVID-19 funding enhancement effort, making available funds for proposals that addressed the public health crisis through enhancements to currently funded research, engagement, and D&I Awards. By the end of 2020, PCORI awarded $34 million to fund 116 enhancement projects.

Later that month, PCORI committed up to $21 million in Eugene Washington PCORI Engagement Awards funding to a special opportunity supporting projects that help communities increase their ability to participate across all phases of PCOR/CER while responding to societal changes resulting from the COVID-19 pandemic. These funds also were awarded to organizations and community groups to actively disseminate PCORI-funded research results during the pandemic.

Moving Results into Practice

As PCORI began producing results, our unique approach to research began to reach health practice. Twenty-eight new citations of our funded research results were published, and findings were cited on online resources that healthcare providers and patients rely on when making health decisions and on websites dedicated to specific health topics.

Additionally, PCORI’s Board approved a policy on Data Management and Data Sharing, advancing our commitment to open science by encouraging others to use data from our funded studies to verify and build on those findings to generate new evidence.
New Resource to Facilitate Engagement

As the nation dealt with the ramifications of the coronavirus pandemic, PCORI awardees began adapting everything from the questions they sought to answer to the way they conducted activities as most in-person activities transitioned to a virtual format.

PCORI’s Engagement Tool and Resource Repository emerged as a valuable resource for people unsure how to best engage in the new, virtual environment. The repository is a rich and growing trove of information generated and shared by PCORI awardees that includes more than 300 resources available to help research teams navigate uncharted territory. Resources that proved especially promising during the pandemic focused on using social media, including patients as published authors in the scientific writing process, and using a web-based platform to engage and connect with patients and caregivers.

Results from PCORI-Funded Research Reach Diverse Audiences Quickly

Research findings historically have taken far too long to have an impact on clinical practice and health outcomes. PCORI funds Dissemination and Implementation projects to speed the time from published results to implementation, shortening the time for critical research results to reach patients, clinicians, and other decision makers. In FY 2020, PCORI saw early data showing its funded projects’ results are reaching large, diverse audiences quickly.

Upon project completion, awardees submit detailed research reports on their findings, and PCORI publishes lay-language and professional summaries of projects’ findings on its website within 90 days. In the final quarter of FY 2020, lay and professional results summary pages on our website were viewed approximately 30,000 times.

In addition to these reports and summaries, PCORI-funded researchers are also publishing in peer-reviewed journals. As of December 2020, 352 comparative clinical effectiveness research papers were published, up from 326 just three months earlier.

An analysis of PCORI’s funded studies from 2013 to 2020 found that almost 60 percent published results within 30 months of the project’s completion date. In contrast, an analysis in The BMJ found that typically only about one-third of research studies publish their results over that same period, and only about two-thirds of them ever publish their results, a lag we want to change.

Open access—the practice of making peer-reviewed scholarly research and literature freely available online to everyone, without a paywall or subscription—is one way to ensure wide access to results papers. To promote open access and make research results more accessible, PCORI pays the fees to provide free public access to peer-reviewed journal articles that present findings from PCORI-funded research. PCORI-funded researchers have given more than 5,000 presentations, including invited talks, peer-reviewed presentations, webinars, and more. Nearly two-thirds of PCORI-funded projects’ researchers have given at least one presentation so far, with more than 40 percent including a patient or another stakeholder partner as a co-presenter.

These are all indicators that the results from PCORI-funded studies are on track to be useful and make an impact that will only expand as the funded research portfolio continues to expand.

Heightening Our Support for Sharing Research Results with Participants

When people contribute to research that will inform and influence decisions about health care, it’s important that they hear about the results they’ve helped make possible. PCORI has always encouraged PCORI-funded researchers to return aggregate study results to their participants, and in FY 2020 PCORI made process improvements to emphasize the importance of this practice and provide a clearer, more consistent message to PCORI awardees about returning aggregate results to their study’s participants. PCORI also made changes to improve support of this process. Awardees can now request up to $2,500 to support results return activities. This funding encourages researchers to share aggregate results while allowing PCORI to review researchers’ plans for results return early and help better track return activities. PCORI also asks investigators to provide details of these activities in their Draft Final Research Report.

Several journal articles show that despite viewing the practice as an important part of conducting research, investigators often do not follow through, citing cost, logistics, and review policies as barriers. And not all funders encourage their supported researchers to undertake return activities. Through PCORI’s heightened support for and prioritization of this important work, the organization aims to be part of the solution and support PCORI-funded investigators to complete this step in their research.

Virtual Annual Meeting Draws Record Attendance

PCORI held its sixth Annual Meeting virtually on September 16 and 17. Reimagined because of the ongoing coronavirus pandemic, the event attracted more than 2,300 attendees. Patients, caregivers, researchers, and members of the healthcare community convened to share and learn about our community’s progress in advancing a patient-centered approach for research, generating useful results, and supporting dissemination and implementation of findings to improve care.

From the opening keynote by Liz Salmi, a patient turned co-investigator who talked about the blurring of lines between stakeholders and researchers, to the closing keynote by Lisa Cooper, MD, MPH, who discussed racism and discrimination in health care, the meeting included presentations on some of the timeliest topics in the healthcare landscape.

Sessions covered COVID-19-related research, telehealth, caregiving, maternal health, intellectual and developmental disabilities, big data, and more. PCORI Executive Director Nakela L. Cook, MD, MPH, moderated a special plenary roundtable with a group of distinguished panelists on core causes of health and healthcare disparities and concrete actions PCORI, patients, caregivers, and the broader healthcare community can take to address racism, discrimination, and bias to improve health outcomes for all Americans.

2019

Change in Leadership

Founding Executive Director Joe V. Selby, MD, MPH, informed PCORI’s Board of his plans to retire. Josephine P. Briggs, MD, joined PCORI as Interim Executive Director from November 2019 to April 2020. Her tenure as Interim Executive Director ended in April 2020 with the arrival of Nakela L. Cook, MD, MPH, as PCORI’s second Executive Director.

In February, the Board adopted an update to the PCORI Methodology Standards developed by the Methodology Committee to address the need for a more systematic approach to prioritizing research topics and determine which research designs can provide information that is both useful and timely to patients, caregivers, clinicians, and other healthcare system stakeholders. With that update, PCORI Methodology Standards grew to 65 addressing 16 topic areas.
Administration and Governance

PCORI’s work is guided by a 23-member Board of Governors that represents a broad range of perspectives and collective expertise in clinical health sciences research.

Board Amends PCORI Bylaws

In FY 2020, the Board of Governors approved several amendments to the PCORI bylaws. In May 2020, the bylaws were amended to align the bylaws language with the reauthorizing law, including relating to the appointment of Board members by the Comptroller General of the United States (GAO) and the shift in authority for the appointment of Methodology Committee members from GAO to the PCORI Board.

Additionally, the bylaws were amended to accurately reflect the citation to PCORI’s authorizing law, as amended by the reauthorizing law, and to enhance clarity. Relevant Board and Board-related committee charters were also amended in FY 2020, which included a revised governance framework and membership structure to support the transition of the appointment process from the GAO to the PCORI Board.

In July 2020, as part of its emergency planning processes and response to COVID-19, the Board amended the Bylaws to allow for the appointment of assistant officers by the Board Chairperson if the lead officer is absent, unwilling, or unable to perform the duties of that position for any reason.

Because all Board members serve on PCORI’s Board and Board-related strategy committees, new committee Chairs and Vice Chairs were appointed in September 2020 by the Board to fill vacancies created by the departure of former Board members. In addition, in January 2021, each new Board member was appointed by the Board to serve on one or more committees.

Improving Research Methods

Developing and improving the science and methods of patient-centered outcomes research is a central part of PCORI’s work. PCORI has developed:

- 65 Methodology Standards in 2 broad categories (cross-cutting and design-specific) and 16 topic areas

Board of Governors Welcomes New Members, Bids Farewell to Outgoing Colleagues

In September 2020, the Comptroller General of the United States, who serves as the head of the GAO, announced the appointment of seven distinguished leaders representing stakeholders from across the healthcare community to fill open seats on PCORI’s Board of Governors. The new members are Kate Berry; Tanisha Carino, PhD; James Huffman; Connie Hwang, MD, MPH; Eboni Price-Haywood, MD, MPH, FACP; James Schuster, MD, MBA; and Danny van Leeuwen, MPH, RN. Additionally, Barbara McNeil, MD, PhD, was appointed to a second term.

PCORI welcomed these new members while bidding farewell to four Board members who completed their terms of service in 2020: Larry Becker, Gail Hunt, Freda Lewis-Hall, MD, and Grayson Norquist, MD, MSPH. Each of these individuals made indelible contributions to PCORI, working with their fellow governors to help shape and guide our approach to research done differently and establish the foundation for research relevant to patients and the broader healthcare community.

Also in FY 2020, the Methodology Committee leaders swapped roles. Steven Goodman, MD, MHS, PhD, who had been Vice Chair, became Chair. Robin Newhouse, PhD, RN, who had been Chair, became Vice Chair, providing continuity to the committee which, among other duties, develops and updates the PCORI Methodology Standards for adoption by the Board after public comment.

PCORI Meetings Go Virtual in 2020

As social distancing guidelines discouraged in-person gatherings, PCORI established protocols and best practices for virtual Board, advisory panel, merit review, and other meetings. PCORI coached meeting organizers to manage chats, question-and-answer sessions, discussions, engagement tools, and technical rehearsals with the goal of equipping meeting organizers and back-up AV techs with structured and consistent meeting processes, templates, guides, and scripts to simplify planning and execution.
**Appendices**

**FY 2020 Actual and FY 2021 Budget**

**Revenue**
- FY 2020 Actual: $455,047,029
- FY 2021 Budget: $524,839,255

**Expenses**
- Program Services: $322,918,184
- Program Support Services: $15,322,058
- Administrative Expenses: $22,688,156
- Total Expenses: $360,946,398

**Change in Net Assets before Unrealized Gain/Loss on Short-Term Investments**
- FY 2020: $29,135,190
- FY 2021: $15,322,058

**Conflicts 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 in matters related to the Institute or the conduct of activities under this section.” Below are the associations reported by PCORI’s Board of Governors, Methodology Committee, and executive staff. Disclosures reflect those reported to PCORI as of March 25, 2021.

**Board Members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Associations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kara Ayers, PhD</td>
<td>Research; $187 Million, Research Infrastructure; $40 Million, New Initiatives/Emerging Issues; $50 Million, Engagement; $11 Million</td>
</tr>
<tr>
<td>Lawrence Becker</td>
<td>Personal Associations: – Cincinnati Children’s Hospital Medical Center, Employer – McGraw-Hill, Advisory Board Member (Compensated Position) – TriHealth, Employer, Parent – University of Cincinnati, Employer</td>
</tr>
<tr>
<td>Jennifer DeVoe, MD, MPhil, MCR, DPhil</td>
<td>Financial or Business Associations: – America’s Health Insurance Plans, Evolv</td>
</tr>
</tbody>
</table>
Naomi Aronson, PhD  
As of January 25, 2021  
Financial or Business Associations:  
* Blue Cross Blue Shield Association, Employer
  
Personal Associations:  
* EXCITE International, Board Officer  
* FDA Heart Failure Collaboratory, Member  
* Health Technology Assessment International, Health Policy Forum, Member  
* National Academy of Medicine Genomics Roundtable, Member  
* National Evaluation System for Health Technology Coordinating Center (NESTCC), Governing Committee  
* NEHTA, Network for Excellence in Health Innovation, Core Member  
* New drug development Patented (PERQOS), NRT Center for Biomimetic Innovation, Member  
* Tapistry Networks, Committee/Work Group Member  

Ethan Basch, MD, MSc  
(Resigned from Methodology Committee May 14, 2020)  
As of January 27, 2020  
Financial or Business Associations:  
* Careview, Advisory Board Member (Compensated Position)  
* Journal of the American Medical Association, Editor  
* Memorial Sloan-Kettering Cancer Center, Consultant  
* Navigating Cancer, Consultant  
* Sivian Healthcare, Advisory Board Member (Compensated Position)  
* University of North Carolina, Chapel Hill, Employer
  
Personal Associations:  
* American Society of Clinical Oncology, Board Member  
* The Alliance for Clinical Trials in Oncology Foundation, Chair/Chairperson or Board Officer
  
Arlene Bierman, MD, MS  
(Joining the Methodology Committee as the AMRO Director designee January 12, 2021)  
As of February 18, 2021  
Financial or Business Associations:  
* None Reported.
  
Stephanie Chang, MD, MPH  
(Former Associate Director, Service on Methodology Committee ended October 16, 2020)  
As of November 16, 2019  
Financial or Business Associations:  
* Agency for Healthcare Research and Quality, Employer
  
Personal Associations:  
* Arlington Free Clinic, Volunteer Physician  
* Guidelines International, Trustee
  
David Flum, MD, MPH  
As of December 24, 2020  
Financial or Business Associations:  
* None Reported.
  
Cynthia Girman, DoPH  
As of January 11, 2021  
Financial or Business Associations:  
* Abbvie, Inc., Consultant  
* Amgen, Consultant  
* Boehringer Ingelheim, Consultant  
* Capsida, Consultant  
* Celgene Consulting, LLC  
* Complete Health Economic Outcomes Research Solutions, Consultant  
* Epstein Health, Consultant  
* Gilead Sciences, Consultant
  
- Greenleaf Health, LLC, Consultant  
- Horizon, Consultant  
- Janssen Pharmaceuticals, Inc., Consultant  
- Passage Bio, Consultant  
- Pfizer, Consultant  
- Regeneron, Consultant  
- Takeda Pharmaceuticals, U.S.A., Inc., Consultant  
- Therateau Pharmaceutical, Consultant  
- Tria Health, Consultant  
- UBC, Consultant  
- Unisys Sciences, Consultant
  
Personal Associations:  
* International Society of Pharmacoeconomics, Board Member  
* University of North Carolina, Dept of Epidemiology, Professor
  
Steve Goodman, MD, MHS, PhD  
(Chair)  
As of January 20, 2021  
Financial or Business Associations:  
* American College of Physicians, Editor  
* Carbell, Consultant  
* Gilead, DSMR Member  
* IQVIA, DSMR Member  
* Blue Cross Blue Shield Technology Evaluation Center, Medical Advisory Panel, Advisory Panel Member (Compensated Position)  
* Stanford University, Employer
  
Personal Associations:  
* None Reported.
  
Mark Hollander, MD, MS, MPH  
As of January 10, 2020  
Financial or Business Associations:  
* Blue Cross and Blue Shield Association, Consultant  
* Oregon Health and Science University (OHSU), Faculty  
* Portland Health Care Systems, Employer
  
Personal Associations:  
* American College of Physicians, Member  
* Cochrane, Member  
* Society for Medical Decision Making, Member
  
Michael S. Lauer, MD  
As of November 29, 2020  
Financial or Business Associations:  
* Johns Hopkins University School of Medicine, Employer  
* Kaiser Permanente Southern California, Employer  
* King's College London, Consultant  
* NIH National Cancer Institute, Consultant  
* UCLA School of Medicine, Consultant  
* University of California Irvine, Consultant  
* University of Colorado Denver, Advisory Board Member (Compensated Position)  
* University of Maryland Baltimore, Advisory Board Member (Compensated Position)  
* Washington University in St. Louis, Consultant
  
Sally C. Morton, PhD  
As of November 25, 2020  
Financial or Business Associations:  
* Arizona State University, Employer  
* Virginia Tech University, Employer
  
Personal Associations:  
* American Association of Medical Colleges, Advisory Council Member (Non-compensated Position)  
* American Association of Medical Colleges, Advisory Council Member (Compensated Position)  
* National Institutes of Health: National Heart, Lung, and Blood Institute (NHLBI), Advisory Board Member  
* St. Michael's Hospital: University of Toronto, Advisory Council Member (Non-compensated Position)
  
David O. Meltzer, MD, PhD  
As of March 8, 2021  
Financial or Business Associations:  
* American Speech-Language-Hearing Association, Consultant  
* Baptist Memorial Health Care, Consultant  
* Brown University, Consultant  
* Cedars-Sinai Medical Center, Consultant  
* Cedars-Sinai Medical Center, Employer  
* Department of Veteran Affairs, Palo Alto, Consultant  
* Duke University, Advisory Board Member (Compensated Position)  
* Familiar Hypertransfusionemia Foundation, Consultant  
* Johns Hopkins Center for Health Research, Advisory Board Member (Compensated Position)  
* Mayo Clinic, Consultant  
* National Academy of Medicine Genomics Roundtable, Member  
* Stanford University, Employer
  
Personal Associations:  
* Comprehensive Care Organization, Chair or Other Board Officer  
* Society of General Internal Medicine, Member
  
Robin Newhouse, PhD, RN  
(Vice Chair)  
As of December 11, 2020  
Financial or Business Associations:  
* American Nurses Association, Book Author  
* Indiana University, Employer
  
Personal Associations:  
* AcademyHealth, Member  
* American Academy of Nursing, Member  
* Envision Healthcare, Employer, OHIO  
* National Academy of Medicine, Member  
* Trust U Chicago, Employer, Child
  
Neil R. Powe, MD, MPH, MBA  
As of November 23, 2020  
Financial or Business Associations:  
* American Society of Nephrology, Editor  
* Centers for Disease Control and Prevention, Grants  
* National Institutes of Health, Grants  
* University of California San Francisco, Employer
  
Personal Associations:  
* AcademyHealth, Member  
* American Clinical and Climatological Association, Member  
* American College of Physicians, Member  
* American Public Health Association, Member  
* American Society for Clinical Investigation, Member  
* American Society of Nephrology, Member  
* Association of American Physicians, Member  
* Institute of Medicine, Member  
* Journal of the American Medical Association, Advisory Council Member (Non-compensated Position)  
* Robert Wood Johnson Foundation, Advisory Board Member  
* Society of General Internal Medicine, Member
  
Adam Wilcox, PhD  
As of January 20, 2021  
Financial or Business Associations:  
* American College of Physicians, Editor  
* Carbell, Consultant  
* Gilead, DSMR Member  
* IQVIA, DSMR Member  
* Blue Cross Blue Shield Technology Evaluation Center, Medical Advisory Panel, Advisory Panel Member (Compensated Position)  
* Stanford University, Employer
  
Personal Associations:  
* None Reported.
Approved Research Awards and Contracts

Research Awards (Cycle 1 2019 Contracts)

<table>
<thead>
<tr>
<th>Research Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Amount Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparitive Effectiveness PTSD Trial of Sequenced Pharmacotherapy and Psychotherapy in Primary Care</td>
<td>University of Washington School of Medicine</td>
<td>John Fortney</td>
<td>$6,887,962</td>
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<tr>
<td>A Sequential Multiple Assignment Randomized Trial (SMART) Assessing Medication and CBT Sequencing</td>
<td>Children's Hospital Los Angeles</td>
<td>Bradley Peterson</td>
<td>$6,537,642</td>
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<tr>
<td>Comparative Effectiveness of Trauma- and Non-Trauma-Focused Treatment Strategies for PTSD and SUD</td>
<td>Center for Veterans Research and Education</td>
<td>Shannon Kehle-Forbes</td>
<td>$6,131,713</td>
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<tr>
<td>Comparative Effectiveness of Unobserved Versus In-Office Inductions for Medication Assisted Treatment</td>
<td>University of Colorado Denver</td>
<td>Linda Zittleman</td>
<td>$5,074,722</td>
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<td>Improving Communication and Healthcare Outcomes for Patients with Communication Disabilities: the INTERACT Trial</td>
<td>University of Colorado Denver</td>
<td>Megan Morris</td>
<td>$4,229,994</td>
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<td>Care in the CPP Program Versus Care in the CPP Program vs. Care in Traditional Care Coordinator Program</td>
<td>University of Chicago</td>
<td>David Meltzer</td>
<td>$4,200,000</td>
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<tr>
<td>Pediatric Trauma Care Models— Impact on Family Experience, Traumatic Stress, and Financial Hardship</td>
<td>The Regents of the University of California, Davis</td>
<td>James Marcin</td>
<td>$4,199,464</td>
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<tr>
<td>Comparing Two Approaches to Care Coordination for High-Cost/High-Need Patients in Primary Care</td>
<td>HealthPartners Institute</td>
<td>Leif Solberg</td>
<td>$4,056,191</td>
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<td>Patient-Clinic Community Integration to Prevent Obesity among Rural Preschool Children</td>
<td>The Gashiinger Clinic</td>
<td>Lisa Bailey-Davis</td>
<td>$3,848,909</td>
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<td>Opioid-Sparing Pain Treatment in Myeloma And Lymphoma Patients Undergoing High-dose Chemotherapy (OPTIMAL-HiChem)</td>
<td>Memorial Sloan-Kettering Cancer Center</td>
<td>Gary Deng</td>
<td>$3,680,871</td>
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<td>Comparative Effectiveness of Readmission Reduction Interventions for Individuals with Sepsis or Pneumonia</td>
<td>UPMC Center for High-Value Health Care</td>
<td>Namita Ahuja Yende</td>
<td>$3,680,452</td>
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<tr>
<td>Comparative Effectiveness of New Treatments for Prostate Cancer</td>
<td>Weill Cornell Medicine</td>
<td>Jim Hu</td>
<td>$3,411,846</td>
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<td>Evaluation of Unilateral Versus Bilateral Hearing Aids for the Treatment of Age-Related Hearing Loss</td>
<td>Duke University</td>
<td>Sheri Smith</td>
<td>$2,618,573</td>
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<td>Broad Implementation of Outpatient Stewardship (BOS) Study</td>
<td>The Children's Hospital of Philadelphia</td>
<td>Jeffrey Gerber</td>
<td>$2,499,077</td>
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<td>Comparison of Direct to Consumer Delivery Models for Hearing Devices</td>
<td>Northwestern University</td>
<td>Sumitraij Dhar</td>
<td>$2,460,670</td>
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<td>HearCare: Hearing for Communication and Resident Engagement</td>
<td>University of Pittsburgh</td>
<td>Catherine Palmer</td>
<td>$2,232,944</td>
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<td>Enhancing the Care Transitions Intervention with Peer Support to Reduce Disparities</td>
<td>University of South Florida</td>
<td>Kyalei Conner</td>
<td>$1,689,611</td>
</tr>
</tbody>
</table>

Research Project Title | Organization | Principal Investigator | Amount Awarded

PCOR Advisory Panels

Members of PCORI's advisory panels and their conflict of interest disclosure statements are available at www.pcori.org/advisory-panels.

PCOR Peer Reviewers

Names of the individuals contributing to any PCORI peer-review process and their conflict of interest disclosure statements are available at www.pcori.org/research-results/peer-review/who-are-our-peer-reviewers.
<table>
<thead>
<tr>
<th>Research Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Amount Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using the Child Health Ratings Inventories (CHRIS) to Improve Diabetes Care for Children</td>
<td>University of California, Irvine</td>
<td>Sherrie Kaplan</td>
<td>$1,429,999</td>
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<tr>
<td>Implementation of Effective Home Oxygen Weaning Strategies in Premature Infants</td>
<td>University of Massachusetts Medical School</td>
<td>Lawrence Rhein</td>
<td>$1,262,793</td>
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<td>Effective Dissemination Approach for a Successful Asthma Self-Management Support Intervention</td>
<td>University of Utah</td>
<td>Flory Nkoy</td>
<td>$1,170,927</td>
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<tr>
<td>Reducing Treatment Risk in Older Patients with Diabetes: Comparative Effectiveness of Academic Detailing with and without Pre-Visit Patient Preparation</td>
<td>Kaiser Permanente Division of Research</td>
<td>Richard Grant</td>
<td>$1,142,882</td>
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<tr>
<td>Toward a New Generation of Matching Methods for Comparative Effectiveness Research</td>
<td>Harvard Medical School</td>
<td>Jose Zubizarreta</td>
<td>$1,048,691</td>
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<td>Using Topic Segmentation to Enhance Concept Parsing and Identification of Negations</td>
<td>Brigham and Women’s Hospital</td>
<td>Alexander Turchin</td>
<td>$1,030,987</td>
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<td>New Causal Inference Methods for Cluster Randomized Trials with Post-Randomization Selection-Bias</td>
<td>Duke University</td>
<td>Fan Li</td>
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<td>Incomplete Stepped Wedge Designs: Methods for Study Planning and Analysis</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>John Preisser</td>
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Research Project Title

<table>
<thead>
<tr>
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<th>Organization</th>
<th>Principal Investigator</th>
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<tbody>
<tr>
<td>Comparing Two Ways to Mitigate the Impact of the COVID-19 Pandemic on Mental Health Among Adults from Underserved and Racial Minority Community</td>
<td>The Research Foundation For The State University of New York</td>
<td>Yu-Ping Chang</td>
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<td>Comparative Effectiveness of Single-Site and Scattered-Site Permanent Supportive Housing</td>
<td>University of Southern California</td>
<td>Benjamin Henwood</td>
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<td>Evaluating the Implementation and Effectiveness of an Automated Remote Monitoring Program for COVID-19 Patients</td>
<td>University of Pennsylvania Perelman School of Medicine</td>
<td>Mucio Delgado</td>
<td>$2,474,111</td>
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<td>Impact of COVID-19-Related Medication Assisted Treatment Policy Changes on Patients with Opioid Use Disorders</td>
<td>Boston VA Research Institute, Inc.</td>
<td>Risa Wesberg</td>
<td>$2,300,203</td>
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<tr>
<td>COVID-19 Project ECHO for Nursing Homes: A Patient-Centered, Randomized-Controlled Trial to Implement Infection Control</td>
<td>Pennsylvania State University Hershey Medical Center</td>
<td>Jennifer Kraschnewski</td>
<td>$2,253,190</td>
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<tr>
<td>Implementing Team-based Outpatient Palliative Care in Parkinson Foundation Centers of Excellence</td>
<td>University of Rochester</td>
<td>Benzi Kluger</td>
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<td>Innovative Implementation of a Robust Executive Function Intervention Delivered in Schools</td>
<td>University of Colorado Denver</td>
<td>Laura Anthony</td>
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<td>Learning Collaborative to Improve the Quality of Hip and Knee Replacement Surgery Decisions</td>
<td>Massachusetts General Hospital</td>
<td>Karen Sepucha</td>
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Research Awards (Cycle 2 2019 Contracts)

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<th>Research Project Title</th>
<th>Organization</th>
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<tr>
<td>Comparing Patient-Reported Impact of COVID-19 Shelter-in-Place Policies and Access to Containment and Mitigation Strategies</td>
<td>The Regents of the University of California, San Francisco</td>
<td>Mark Fletcher</td>
<td>$4,979,798</td>
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<tr>
<td>Best Practices to Prevent COVID Illness in Staff and People with Serious Mental Illness and Developmental Disabilities in Congregate Living Settings</td>
<td>Massachusetts General Hospital (The General Hospital Corp.)</td>
<td>Stephen Bartels</td>
<td>$4,972,283</td>
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<td>Protecting the Mental and Physical Well-Being of Frontline Healthcare Workers During COVID-19</td>
<td>RAND Corporation</td>
<td>Lisa Seidel Meredith</td>
<td>$4,893,467</td>
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<tr>
<td>Randomized Trial Comparing Mti-Targeted Transperineal Versus Transrectal Prostate Biopsy</td>
<td>Joan &amp; Sanford I. Weill Medical College of Cornell University</td>
<td>Jim Hu</td>
<td>$4,249,008</td>
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<td>Comparative Effectiveness of Mobile Integrated Health versus Chronic Care Model Nurse Managers</td>
<td>Joan &amp; Sanford I. Weill Medical College of Cornell University</td>
<td>Rainu Kaushal</td>
<td>$4,205,943</td>
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<td>Comparative Effectiveness of Perinatal Psychiatric Access Programs on Treatment Engagement</td>
<td>Rutgers Biomedical and Health Sciences</td>
<td>Thomas Mackie</td>
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<td>Comparing Mobile Health Strategies to Improve Pre-exposure Prophylaxis Use (PrEP) for HIV Prevention</td>
<td>Public Health Foundation Enterprises, Inc.</td>
<td>Albert Liu</td>
<td>$3,758,429</td>
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<td>Evaluating the Comparative Effectiveness of Telemedicine in Primary Care: Learning from the COVID-19 Pandemic</td>
<td>Joan &amp; Sanford I. Weill Medical College of Cornell University</td>
<td>Jessica Ancker</td>
<td>$2,953,754</td>
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Research Awards (Cycle 3 2019 Contracts)

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<tr>
<td>Comparative Effectiveness Trial of Perioperative Telemetry Monitoring for Functional Recovery and Symptoms</td>
<td>City of Hope</td>
<td>Virginia Sun</td>
<td>$4,209,999</td>
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<tr>
<td>Comparing Fingerstick Blood Glucose Monitoring versus Continuous Glucose Monitoring in Primary Care</td>
<td>HealthPartners Institute</td>
<td>Richard Bergenthal</td>
<td>$3,650,870</td>
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<td>Addressing Anxiety among Low-Risk Chest Pain Patients in the Emergency Department Setting</td>
<td>Trustees of Indiana University</td>
<td>Paul Musry</td>
<td>$3,358,251</td>
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<td>Online Cognitive Behavioral Therapy for Depressive Symptoms in Rural Patients with Cardiac Disease</td>
<td>University of Kentucky</td>
<td>Debra Moser</td>
<td>$2,888,855</td>
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<td>Comparing the Effectiveness of Two Approaches to Preventing Severe Hypoglycemia</td>
<td>Kaiser Foundation Health Plan of Washington</td>
<td>James Raiston</td>
<td>$2,733,300</td>
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<td>Comparative Effectiveness of Individual Versus Group-Level Interventions to Reduce HIV/STI Incidence</td>
<td>Brigham and Women’s Hospital</td>
<td>Bisola Ojikutu</td>
<td>$2,418,938</td>
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<td>Elders Preserving Independence in the Community (EPIC)</td>
<td>Cedars-Sinai Medical Center</td>
<td>Harriet Aronow</td>
<td>$2,306,797</td>
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## PCORnet Research Infrastructure Awards

<table>
<thead>
<tr>
<th>Research Project Title</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Amount Awarded</th>
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</thead>
<tbody>
<tr>
<td>HERO Registry &amp; Trial: Healthcare Worker Exposure Response and Outcomes</td>
<td>Duke University</td>
<td>Adrian Hernandez</td>
<td>$40,819,060</td>
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<tr>
<td>DRN OC Workplan and Implementation</td>
<td>Duke University</td>
<td>Adrian Hernandez</td>
<td>$2,616,621</td>
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<tr>
<td>The Greater Plains Collaborative (GPC)</td>
<td>University of Kansas Medical Center</td>
<td>Lemuel Waibman</td>
<td>$2,341,211</td>
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<td>Stakeholders, Technology and Research CRN (STAR)</td>
<td>Vanderbilt University Medical Center</td>
<td>Russel Rothman</td>
<td>$2,268,316</td>
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<tr>
<td>A PaTH Towards a Learning Health System</td>
<td>University of Pittsburgh</td>
<td>Kathleen McGue</td>
<td>$2,156,990</td>
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<tr>
<td>Chicago Area Patient-Centered Outcomes Research Network (CAPiCORN)</td>
<td>Northwestern University</td>
<td>Abel Kho</td>
<td>$2,001,951</td>
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<td>INSIGHT Clinical Research Network</td>
<td>Weill Cornell Medicine</td>
<td>Rainu Kaushal</td>
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<tr>
<td>PEDSnet: A Pediatric Learning Health System</td>
<td>The Children's Hospital of Philadelphia</td>
<td>Christopher Forrest</td>
<td>$1,859,695</td>
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<tr>
<td>New Leadership and Support</td>
<td>Duke University</td>
<td>Adrian Hernandez</td>
<td>$1,816,287</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>Accelerating Data Value Across a National Community Health Center Network (ADVANCE)</td>
<td>OCHIN</td>
<td>Jon Puro</td>
<td>$1,478,481</td>
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<td>DRN OC Workplan and Implementation</td>
<td>Duke University</td>
<td>Adrian Hernandez</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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<tr>
<td>Identifying and Predicting Patients with Preventable High Utilization</td>
<td>Joan &amp; Sanford I. Weill Medical College of Cornell University</td>
<td>Rainu Kaushal</td>
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<tr>
<td>Using PCORnet to Compare Blood Pressure Control Strategies</td>
<td>The Regents of the University of California, San Francisco</td>
<td>Mark Fletcher</td>
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<td>Variation in Case Management Programs and Their Effectiveness in Managing High-Risk Patients for Medicare ACOs</td>
<td>University of Wisconsin Madison</td>
<td>Maureen Smith</td>
<td>$465,500</td>
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<tr>
<td>Evaluation of PCORnet Coordinating Center</td>
<td>RAND Corporation</td>
<td>Dmitry Khodyakov</td>
<td>$432,641</td>
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## Research Project Title

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<thead>
<tr>
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<th>Amount Awarded</th>
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</thead>
<tbody>
<tr>
<td>Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers</td>
<td>Coalition for National Trauma Research</td>
<td>Elliott Haut</td>
<td>$1,394,373</td>
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<tr>
<td>Diabetes Medical Nutrition Therapy in Southeastern African-American Women</td>
<td>Meharry Medical College</td>
<td>Stephanie Miller-Hughes</td>
<td>$1,386,617</td>
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<td>An Efficient Distributed Learning Framework for Integrating Evidence in Clinical Research Networks</td>
<td>University of Pennsylvania</td>
<td>Yong Chen</td>
<td>$1,086,374</td>
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<tr>
<td>Missing Data When Transporting Treatment Effects from Clinical Trials to a Target Population</td>
<td>Brown University</td>
<td>Jon Steingrimsso</td>
<td>$842,900</td>
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<tr>
<td>Comparative Effectiveness of Biologic or Small Molecule Therapies in IBD</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>Michael Kappelman</td>
<td>$382,413</td>
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<td>Project Statement 1: Engagement Coordinating Center Awardee Organization/Institution - AcademyHealth</td>
<td>AcademyHealth</td>
<td>Elizabeth Cope</td>
<td>$314,050</td>
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<tr>
<td>New Coordinating Center Leadership</td>
<td>Duke University</td>
<td>Adrian Hernandez</td>
<td>$267,988</td>
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<tr>
<td>Bridging the GAP between Patients/Caregivers and COPD Research - The COPD PPRN BRIDGE Project</td>
<td>COPD Foundation, Inc.</td>
<td>Elisha Malanga</td>
<td>$149,264</td>
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<td>Enhancing Engagement, Research Participation, and Collaboration through the IBD Partners Patient Powered Research Network</td>
<td>Crohn’s &amp; Colitis Foundation, Inc.</td>
<td>Angela Dobes</td>
<td>$149,252</td>
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<tr>
<td>Diversifying, Expanding and Tracking Patient Engagement in Arthritis Research</td>
<td>Global Healthy Living Foundation</td>
<td>William Nowell</td>
<td>$122,233</td>
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</table>

## Our Vision

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

## Our Mission

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.