Patient-Centered Outcomes Research Institute

Funding Announcement:
Assessment of Prevention, Diagnosis, and Treatment Options

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About PCORI
Assessment of Prevention, Diagnosis, and Treatment Options

Opportunity Snapshot

_It was the most important health decision that she had faced in the 68 years of her life. She needed information about the risks and benefits of the treatment options she was asked to choose among. She needed information that applied to patients like her, and she needed information on a range of clinical outcomes that she felt were important to consider. Unfortunately, the information she needed was not available._

In this PCORI Funding Announcement (PFA), we seek to fund projects that address critical decisions that face patients, their caregivers, and clinicians every day without adequate information. These decisions must be consequential and be occurring now without key evidence about the comparative effectiveness of two or more options. Patients/caregivers must benefit from new knowledge in ways that are clear and important. The premise of this research is that new knowledge will support critical choices by patients, caregivers, and their clinicians—not that it will deliver a verdict that will lead us to dictate a choice. This knowledge will provide insight about the comparative benefits and harms of the options and provide information about outcomes that are experienced by patients and important to patients.

Every day, patients and their caregivers are faced with crucial healthcare decisions while lacking key information that they need. This information does not deliver verdicts or tell people what to do, but informs them of the trade-offs associated with the options they have—and enables them to make better decisions for themselves in collaboration with their clinicians—based on the facts, perhaps even personalized for them, and their own values, preferences, and goals.

The Patient-Centered Outcomes Research Institute (PCORI) is entrusted by the public to fund research that will matter to patients and their caregivers. PCORI has five national research priorities and a research agenda for the projects we will fund that is focused on producing knowledge that is useful to patients, their caregivers, and clinicians. This knowledge will also to be useful to health system leaders, payers, and regulators who make decisions that impact patients. PCORI seeks to change how research is done by emphasizing the role of diverse research teams that include varying perspectives. PCORI distinguishes itself by supporting research in which patients, caregivers, and practicing clinicians are actively engaged in generating the research questions, conducting the research, and using the results to understand and address patient needs.
Program Overview

Under this PFA for Assessment of Prevention, Diagnosis, and Treatment Options, PCORI seeks studies comparing the effectiveness of alternative strategies for prevention, treatment, screening, diagnosis, or management.

We are looking to fund projects that address critical decisions that patients and their caregivers face every day without adequate information. These decisions must be consequential and must be occurring now without key evidence about the comparative effectiveness of possible options. The potential of the research to benefit patients and their caregivers must be clear and important.

Research Areas of Interest

We are interested in the following broad topical areas:

- Studies that compare the effectiveness of two or more strategies for prevention, treatment, screening, diagnosis, or management that have not been adequately studied against alternative options. Topics are not limited to medical or surgical therapy and may include a range of strategies including self-care. Special emphasis is placed on studies conducted in typical clinical populations considering the full range of relevant patient-centered outcomes.

- Studies that compare the use of prognostication/risk-stratification tools with usual clinical approaches to treatment selection or administration.

- Studies that investigate the key determinants of the outcomes patients experience following treatment decisions, with attention to various patient factors, including demographic, biological, clinical, social, economic, and geographic factors that may influence the outcomes that follow a specific treatment. Strategies may focus on patient populations with a single condition or involve patients with a range of conditions.

Strategies addressing care for patients with rare conditions are of interest. Rare diseases are defined as life-threatening or chronically debilitating diseases that are of such low prevalence in populations that special efforts, such as combining data across large populations, may be needed to address them. The term low prevalence is defined as meaning conditions that affect fewer than 200,000 individuals in the United States or have a prevalence of fewer than 1 in 1,500 persons.
Background

Patients, caregivers, and clinicians often lack the appropriate evidence required to make the best choices regarding prevention, screening, diagnosis, monitoring, or treatment. This gap in knowledge may exist for a variety of reasons. Even when new therapies or technologies have been approved and marketed, there are often gaps in research comparing their effectiveness with that of another clinical option being offered. In some cases, prior research may not have included outcomes that are important to patients and their caregivers. In addition, the existing evidence base for prevention, diagnosis, and treatment options may not be relevant for certain patient populations, such as those at the extremes of age or with multiple comorbid conditions.

Comparative clinical effectiveness research (CER) compares the effectiveness and safety of preventive, diagnostic, and treatment options to create a foundation of information for personalized decision making. This research places emphasis on: the practical utility of the comparisons; the examination of all outcomes that may be important to patients; and the possible differences in outcomes across patient subgroups.

Prevention

Individuals, clinicians, policymakers, health plans and other payers need longitudinal comparative data to evaluate the benefits and possible risks of preventive measures. The U.S. Preventive Services Task Force (USPSTF) is formally charged with reviewing the evidence and making recommendations for or against use of clinical preventive services. The Task Force has found sufficient evidence to identify 45 clinical preventive services, including tobacco use counseling and screening for colorectal cancer, for which the evidence suggests a high certainty of net benefit in certain populations. The Community Preventive Services Task Force (Task Force), which complements the work of USPSTF and also uses evidence-based methods to formulate recommendations, examines community-based preventive services and has identified 109 services with evidence sufficient to support a recommendation for implementation. These include patient reminders for breast, cervical, and colorectal cancer screening and collaborative care for the management of depression. For a smaller number of measures, there is sufficient evidence of either a lack of benefit or actual harm to support recommending against use.

However, for numerous preventive strategies and services, these task forces have concluded that current available evidence is insufficient to recommend either for or against. The absence of such evidence leaves patients and clinicians in a state of uncertainty with respect to what to recommend or what to do. Many services lacking sufficient information are for conditions presenting a high burden of disease, such as screening for asymptomatic coronary artery disease or on strategies to prevent obesity and promote weight loss and physical activity in clinical and community settings.
**Diagnosis**

Diagnostics continue to evolve in tandem with advances in science and technology that enhance understanding of biological systems and disease. The rapid pace at which new diagnostics are introduced and the diversity of new technologies raise questions about the role and added benefit of these new options for guiding clinical decisions and changing patient outcomes. Examples include the role of molecular diagnostics in managing the care of patients with cancer. Some new diagnostic technologies have potential uses for a wide range of conditions, but the evidence base demonstrating benefit for these new indications fails to keep pace with use. For example, there is a continued desire for evidence to support the use of PET imaging, MRI, and CT for a number of conditions, including oncology and lower back pain. Finally, questions sometimes remain about the long-term safety of well-established modalities, even some modalities traditionally perceived as having relatively little risk, such as dental x-rays.

**Treatment**

To obtain and maintain regulatory approval and payer coverage in the United States, manufacturers of drugs and, to a lesser extent, devices must establish through clinical investigations the safety and effectiveness of their products. Evidence developed as a result of these pre- and post-market requirements yields important information for therapeutic decision making. However, given the breadth of treatment options and the dynamic nature of clinical practice, many research questions continue to be raised following approval. These questions go well beyond those typically addressed by regulatory agencies and focus particularly on the comparative real-world effectiveness of possible treatment choices for a wide variety of clinical options. There is a need for research that can better enable patients to make treatment decisions reflective of their individual values and preferences. In some situations, comparison to no treatment may be most relevant for patients. Because of the difficulty in recruiting certain patient populations, such as patients with multiple chronic conditions, the elderly, and children, there also may be gaps in evidence about treatment outcomes that are most appropriate for these groups.

**Definition of Patient-Centered Outcomes Research**

Patient-centered outcomes research (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:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system features 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.

Example Questions

The following research questions are meant as examples of the types of questions that your research may help answer. They are expressed from the perspective of an individual patient, emphasizing the notion that information must lend itself to tailoring for a range of individuals with varying characteristics and circumstances.

- A 48-year-old woman has recently completed radiation for a small growth in her breast. Her doctors currently see no signs of disease but recommend that she continue to be monitored for potential recurrence. What is her optimal management strategy?
- A 50-year-old woman is diagnosed with Parkinson’s disease. Given her personal characteristics, what is the comparative effectiveness and harms of the strategies available to her, especially with regard to cognitive and physical functioning?
- A 30-year-old woman, diagnosed with bipolar disorder, has a history of psychotic mania and episodes of suicidal thoughts. She now is pregnant. What are her options for protecting fetal development while managing her mental illness?
- An 8-year-old girl who is obese has signs and symptoms of metabolic syndrome. What is the optimal preventive and clinical management strategy for her and her parent(s) or caregiver(s)?
- A 64-year-old man was recently diagnosed with myelofibrosis, a rare disorder of the bone marrow that affects blood cell production. What strategies are available to help slow progression of the disorder and also help him maintain his stamina throughout the work day?
- A 43-year-old worker for an express package delivery firm developed very severe low back and left leg pain that began shortly after unloading a heavy package. Her family doctor recommended taking non-narcotic pain medications and suggested she see a physical therapist. She also called an orthopedist who recommended she might benefit from an MRI to evaluate whether she needed surgery. One of her neighbors is a chiropractor who treated two of her coworkers successfully for on-the-job back injuries. The chiropractor recommended that she avoid narcotic medications, stay active, and try a course of spinal manipulation for a few weeks before considering an MRI or surgery. An acupuncturist whom the worker has consulted for temporary relief of neck pain in the past also recommended a series of treatments. The
worker is perplexed and does not know which of the treatments are safe, what the risks are, and which might be of greatest benefit.

**Funding and Project Period Limits**

PCORI expects to fund projects totaling up to $12 million in total costs under this PFA, per cycle. Because the nature and scope of the proposed research is expected to vary widely from application to application, it is anticipated that the size and duration of each award will also vary.

Projects may not exceed three years in duration. Budgets may not exceed $500,000 in direct costs per year. It is expected that, within these limitations, project budgets and duration will vary substantially, depending on the study design, needs for recruitment and/or primary data collection, required length of follow-up, and analytic complexity. To that end, PCORI will reserve a portion of funding for smaller (less than $500,000 in total costs) and intermediate-sized projects (less than $1 million in total costs). PCORI encourages studies that can deliver findings promptly, including studies that take advantage of research infrastructure already in place and of longitudinal studies already underway. Currently funded CER studies may be considered for PCORI funding to support distinctive work related to extending follow-up, adding additional outcomes, or examining outcomes in key patient subgroups. Efficient use of research resources is a criterion that will be considered by merit reviewers and will also be reviewed by PCORI staff. The total amount awarded and the number of awards will depend on the quality, duration, and costs of the applications received.

Applicants wishing to propose prospective randomized trials or other complex studies that they believe will require more funding or longer duration may contact PCORI before the required deadline for the Letter of Intent to request permission to increase the budget beyond $500,000 in direct costs in any project year or to extend the study duration beyond three years. PCORI does not guarantee that permission will be granted, and applicants should expect that the deliberative process may result in delaying the submission for one or more cycles.

**Elements of PCORI Funded Research**

Now that you understand the research focus and priorities, you will need to determine if your organization and approach meet PCORI’s other eligibility requirements. To do that, please consider the following important issues.

**Key Elements**

Successful applicants for PCORI funds must:

1. **Have a research team that includes patients and/or caregivers, as well as clinicians, health system managers, or other potential end-users of the study findings, along with researchers.** Each member of the research team should participate actively in the design and
implementation of the study and the dissemination of its results. A key concept here is ensuring that the research remains true to the interests of those who would use it.

2. **Be familiar with the four questions of our patient-centered outcomes research definition;** applicants must clearly explain how their proposed research aligns with one or more of these questions.

   - “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 those options?”
   - “What can I do to improve the outcomes that are most important to me?”
   - “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

These questions articulate the needs of people as they make healthcare decisions.

3. **Demonstrate that the proposed research has the potential to provide important information that patients need to make decisions—but that is not currently available.** Consider what information patients, clinicians, or health systems may need to make or support better healthcare decisions.

4. **Propose to use PCORI resources efficiently in producing new knowledge.** We aim to stretch our resources as far as possible because we recognize the vast information needs of patients. Research budgets will be used as one component to evaluate the use of resources, as detailed in Review Criterion #8 (see PCORI Review Criteria). We are looking for approaches that are highly efficient without sacrificing methodological rigor. We are also interested in the potential for findings to be applied in multiple areas, independent of the disease studied.

5. **Make clear how you are accounting for individual differences among patient groups.** Average results are useful, but we are also very interested in providing evidence that can be tailored to patient subgroups based on their clinical and demographic characteristics. We want products of the research that are scalable and generalizable—and can be customized for specific sites.

PCORI is interested in research that can be rapidly disseminated and implemented into clinical and community settings, yielding prompt improvements in patients’ decisions and the outcomes experienced. To that end, projects of shorter duration and projects that take advantage of existing research infrastructure and data are of great interest. Applications must include a dissemination and implementation assessment that discusses prospects for dissemination and considers possible barriers as well. For projects that produce important findings deserving dissemination, PCORI will consider subsequent applications that evaluate additional dissemination and implementation efforts.
A variety of study designs and analytic methods may contribute valid new knowledge. These include evidence syntheses, randomized comparisons at either the individual or cluster level, or various observational approaches (eg, quasi-experimental studies). Qualitative methods may also be employed, either in mixed methods approaches or, potentially, as qualitative comparative studies. Evidence syntheses should follow rigorous standards accepted in the field, such as those published by the Agency for Healthcare Research and Quality (AHRQ) or the Institute of Medicine (IOM). Issues of possible heterogeneity of treatment effects must be considered and discussed. Any planned analyses of subpopulations should be discussed. Inclusion of previously understudied population groups, including the elderly, children (if appropriate), and vulnerable populations, is particularly important. Randomized evaluations must be generalizable either by virtue of considering entire populations or by efficiently recruiting highly representative study populations rather than selected volunteers. Observational comparisons must employ study designs and analytic methods that convincingly protect against selection bias and other threats to validity. Applicants should specifically discuss the need to measure factors such as differential adherence to chosen treatments that could create apparent differences in effectiveness in clinical populations. Regardless of the particular methods employed, proposals are expected to use rigorous methodology. Applicants are encouraged to refer to the contents of the PCORI revised Methodology Standards in developing their research plan. Adherence to the Methodology Standards is required. PFA applications will be required to comply with standards adopted by PCORI’s Board of Governors that have been approved by the Board at least six months prior to the PFA application due date. This time period, combined with the public comment period (45–60 days prior to adoption, as stated in PCORI's enabling legislation), will erase any knowledge advantage and maintain Methodology Committee application eligibility.

Comparisons must be to relevant alternatives—such as other interventions or clinical policies designed to address the same need in the same or a different healthcare system, to the previous approach used within the same system, or to “usual care.” The research will ideally provide information about the range of outcomes that are experienced by and important to patients. These outcomes may include quality of life, ability to participate in desired activities, degree of suffering from pain or other symptoms, ability to live independently, and satisfaction with health care.

Comparisons should examine the impact of the strategies in various subpopulations with attention to the possibilities that the effects of the strategy might differ across various populations. Populations of interest include those that are less frequently studied (eg, the elderly; children, if appropriate; patients with multiple chronic conditions; patients with rare conditions); other vulnerable populations, including those of low socioeconomic status, low literacy, and/or numeracy; and patient groups known to experience disparities in health care and outcomes, such as racial/ethnic minorities. Alternatively, the study may focus primarily on comparative strategies for communicating, disseminating, or implementing in one or more of these populations of interest.
Relevance to Patients

Research proposals should clearly identify the relevant patient population, the health decision(s) examined in the proposed study, and the patient outcomes that will be affected by the research, as outlined in PCORI Review Criterion #4. As patient-centered research, the focus should be on the identification of the primary concerns and questions of patients and their caregivers.

Patient and Stakeholder Involvement

Persons representative of the population of interest—referred to here as patients, their caregivers, and clinicians—should be engaged in all phases of the research process, as outlined in PCORI Review Criterion #7. Patients may include individuals who have or had the condition or who are at risk of the condition under study; it may also include patient surrogates or caregivers. In some instances, representatives of patient advocacy organizations may be appropriate research collaborators. Clinicians who face these decisions in collaboration with their patients are also relevant team members. Engagement should include participation in formulation of research questions; defining essential characteristics of study participants, comparators, and outcomes; monitoring of study conduct and progress; and dissemination of research results. In essence, patients and stakeholders must be important contributors throughout the research enterprise.

A key goal of patient engagement in research is to produce information that will best support health decisions for patients, their caregivers, and clinicians. As a result, patients and other key stakeholders must be meaningfully involved in the research team throughout the process. The members of the team will vary depending upon the research area or focus of study.

Dissemination and Implementation Assessment

PCORI is interested in funding studies that produce findings that can be readily disseminated and implemented—and are highly likely to be valued by patients and caregivers. To that end, it is important that potential facilitators and barriers to dissemination and incorporation into practice be assessed and anticipated.

Reproducibility and Transparency of Research

The ability to replicate potentially important findings from PCORI-funded studies in other datasets and populations is essential to building confidence in the accuracy of these findings. PCORI will support policies to promote sharing of study documentation (eg, study protocol, programming code, data definitions) so that other researchers may replicate the findings in other populations. For large studies—those with direct costs greater than $500,000 in any year—PCORI requires that applicants propose a plan for sharing of de-identified data, so that results may be reproduced by others in the same dataset.
Inclusiveness of Different Populations

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse population. However, the burden is on the applicant in such cases to justify the importance of the study given the absence of diversity. Alternatively, PCORI is interested in the inclusion of previously understudied populations for whom effectiveness information is particularly needed, such as “hard-to-reach” populations or patients with multiple conditions.

Protection of Human Subjects

PCORI adheres to, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form, as found on the National Institutes of Health (NIH) Web site: www.grants.nih.gov/grants/funding/phs398/phs398.doc.

Application Development and Submission Overview

Application Development

There are five steps to developing a PCORI application:

- **Step 1: Inform PCORI with the Letter of Intent**: submit a required Letter of Intent (LOI) by the deadline.

- **Step 2: Design the research plan**: As part of your application, you must state the specific aims of the project, the research question(s) to be studied, and how you will answer that question. In addition, applicants must:
  - Explain how the research plan aligns with PCORI review criteria.
  - Describe plans for dissemination and implementation.
  - Describe plans for supporting replication and reproducibility of research and data sharing.

- **Step 3: Document the people and places**: Determine and document who will be on the research team, what their roles will be, and where the research will be conducted. Describe plans for engaging patients and other relevant stakeholders as part of the research team in the research project.

- **Step 4: Develop the budget**: Determine, list, and justify the costs associated with the project.
• **Step 5: Submit the application**: Compile and submit your application using PCORI Online. For further guidance and resources, visit the PCORI Application Center (www.pcori.org/funding-opportunities/funding-announcements/application-center/).

**Review Criteria**

The PCORI review process for each complete, submitted application includes the three components listed below. This process typically takes about six months.

- Completeness, Compliance, and Eligibility Check
- Merit Review
- Business Review

Carefully read and thoroughly understand the PCORI review criteria before applying.

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<td><strong>RESEARCH STRATEGY: Background and Significance</strong></td>
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<td>1. Impact of the condition on the health of individuals and populations</td>
<td>Refers to the current impact of the condition on the health of individuals and populations. Is the condition or disease associated with a significant burden in the US population, in terms of prevalence, mortality, morbidity, individual suffering, or loss of productivity? A particular emphasis is on patients with chronic conditions, including those patients with multiple chronic conditions.</td>
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<td>2. Potential for improving care and outcomes</td>
<td>Refers to the potential that the proposed research may lead to meaningful improvement in patient health, well-being, or quality of care. Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations? Has it been identified as important by patient, caregiver, or clinician groups? Do wide variations in practice patterns suggest current clinical uncertainty? Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated, in ways that make it likely to improve care? Do preliminary studies indicate potential for a sizeable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated quickly and effect changes in current practice?</td>
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<td>3. Effects on healthcare delivery</td>
<td>Refers to the potential that the proposed research could lead to improvements in the efficiency of care for individual patients or for a population of patients. Does the research promise potential improvements in convenience or elimination of wasted resources, while maintaining or improving patient outcomes?</td>
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### RESEARCH STRATEGY: Relevance to Patients

| 4. Patient-centeredness | Is the proposed research focused on questions that affect outcomes of specific interest to patients and their caregivers? Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research? Is the absence of proposed measurement any important outcomes justified? |

### RESEARCH STRATEGY: Approach

| 5. Rigorous research methods | Refers to the use of appropriate and rigorous research methods to generate patient-centered evidence, including appropriate choice of study design and of analytic methods. How likely is it that the proposed study population, study design, and available sample size will yield unbiased, generalizable information with sufficient precision to be useful and reliable for patients, their caregivers, clinicians, and health system leaders? |

### RESEARCH STRATEGY: Inclusiveness of Different Populations

| 6. Inclusiveness of different populations | Does the proposed study include a diverse population with respect to age, gender, race, ethnicity, geography, or clinical status? Alternatively, does it focus on a population for whom effectiveness information is particularly needed? |

### PEOPLE AND PLACES

| 7. Research Team and Environment | The research team must be appropriately trained and experienced to carry out the planned studies. Does the study team have complementary and integrated research expertise in implementing the study? Are relevant patients and other key users of the study information (e.g., caregivers, clinicians, health system leaders, community, or policy makers) appropriately involved in the design and implementation of the study? Will the research environment contribute to the probability of success? Are features of the research environment, such as health system or community involvement or collaborative arrangements, described? Are institutional and community investment in the success of the research described? |

### BUDGET

| 8. Efficient use of research resources | Does the budget appear to be reasonable in relation to the potential contribution of the research? Does the justification address the efficiency with which PCORI resources would be used? Are there opportunities to make the study more efficient? Are there additional benefits to a PCORI investment in this study through the creation of common data or infrastructure that could support future research? |
Organizational Eligibility

Applications may be submitted by:

- Any private sector research organization, including any:
  - Non-profit organization
  - For-profit organization
- Any public sector research organization, including any:
  - University or college
  - Hospital or healthcare system
  - Laboratory or manufacturer
  - Unit of state or local government

All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States may apply, as long as there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals may not apply.

Submission Procedures

To apply with PCORI, you must register with PCORI’s online system and submit both a timely Letter of Intent and a timely application. To learn more about completing your application, please see the PCORI Application Guidelines (www.pcori.org/assets/PFAguidelines.pdf).

Submission Deadlines

This is a standing announcement, with three application deadlines per year. Applicants must submit a Letter of Intent and application to PCORI, in accordance with the published dates and times listed in the Application Center (www.pcori.org/funding-opportunities/funding-announcements/application-center/#anchor).
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions and improve healthcare delivery. PCORI will commission research that is guided by patients, caregivers, and the broader healthcare community and will produce high-integrity, evidence-based information.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a variety of forums and public comment periods to obtain public input throughout its work.

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.

Our History: PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI’s purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research or the support of new research.