

5 Key Things to Know About PCORI-Funded Research

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No COIs to Disclose



1. What Research Does PCORI Fund?

Patient-Centered Comparative Clinical Effectiveness Research (CER)

- **Goal:** CER addressing critical decisions faced by patients, clinicians, and other stakeholders across the US.
- Research that compares two or more treatments, services or health practices in real world populations and settings.



CER Funding Opportunities

Broad Pragmatic Studies

CER in any investigator-initiated topic area that informs healthcare decision-making and improves healthcare delivery and outcomes.

Up to \$12M

Phased Large Awards for Comparative Effectiveness Research (PLACER)

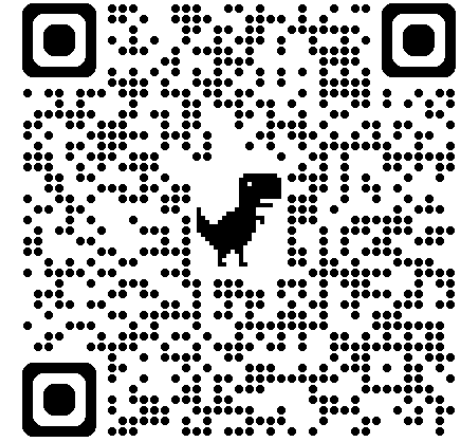
Large, meritorious randomized clinical trials with some risks that require a phased approach to maximize study success

Up to \$22M

Topic-Focused

CER in a topic area identified by patients and other community stakeholders as having evidence gaps and need for patient-centered CER

Variable



2. What is Patient-Centered CER?

Foundational Expectations for Partnership in Research



Representative
Involvement



Early & Ongoing
Engagement



Dedicated Funds for
Engagement &
Partner Compensation



Build Capacity To
Work as a Team



Meaningful Inclusion of
Partners in
Decision Making



Ongoing Review &
Assessment of
Engagement

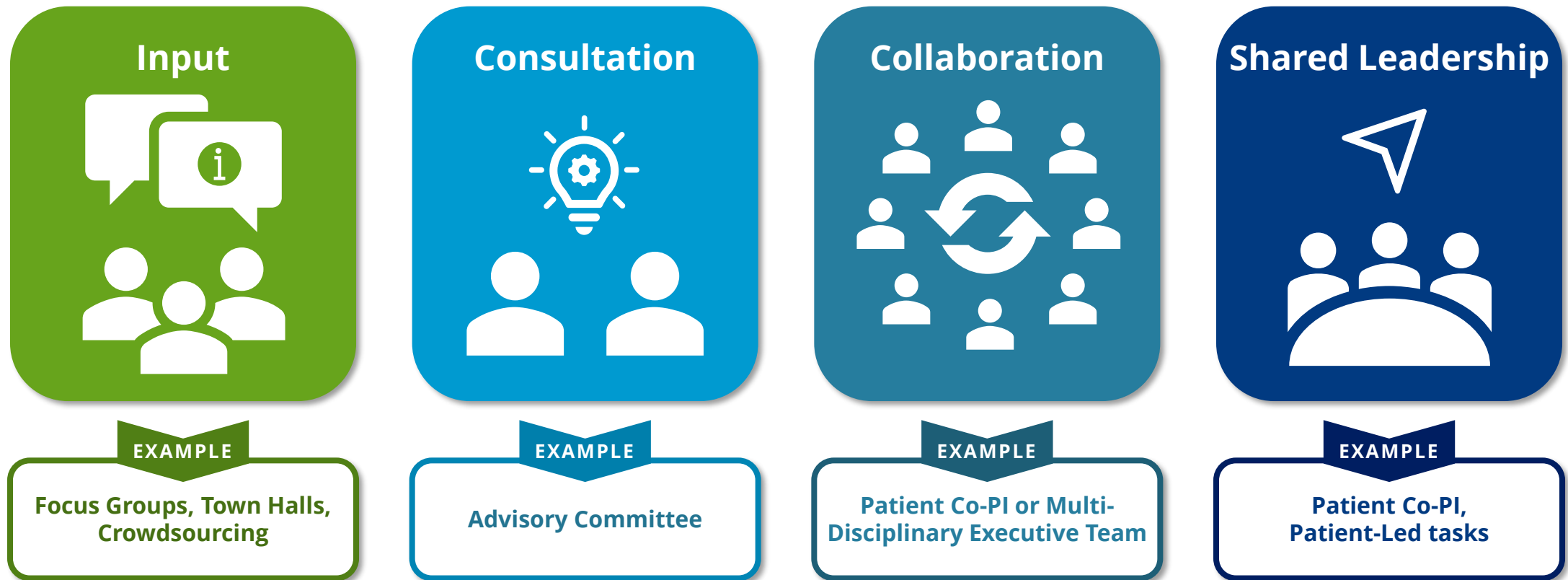
**Building Effective
Multi-Stakeholder
Research Teams**



More information: <https://www.pcori.org/Foundational-Expectations>

Meaningful Engagement in Research

Levels of Partners' Decision-Making Authority for Study Design & Implementation



3. Are PCORI Applications Reviewed Differently?

Letter of Intent
(3 page limit)

Full Application
(by invitation only)

- Fills a critical evidence gap
- Scientific merit
- Investigator/environment
- Patient-centeredness
- Potential for adoption into clinical practice
- Patient-stakeholder engagement

Merit Review

Programmatic
Review

Selection
Committee
Review



Scientists



Patients/
Caregivers



Healthcare
Community
Stakeholders

Funding
Decision

4. What Research Is Considered Responsive?

Informing health decision-making

Population

Patients for whom health condition has high prevalence, incidence, burden, or variations in care and/or critical evidence gaps exists

Intervention/ Comparators

Comparators have established efficacy or widespread use – uncertain which to choose and for whom?

Outcomes

Patient-centered, validated, health-related outcomes

Setting

Real-world settings and health care practices

Design

- Adheres to PCORI Methodology Standards
- Potential results are generalizable and ready to implement
- Powered heterogeneity of treatment effectiveness study aims where needed



5. What Does PCORI Not Fund?

- Studies designed to test the efficacy of unproven interventions/care strategies
- Development, testing, or validation of new instruments such as surveys, decision aids or clinical prognostication tools
- Pilot studies intended to inform larger efforts
- Studies whose principal focus is on quality improvement
- Studies describing epidemiology or natural history
- Aims studying pharmacodynamics, pharmacokinetics, or biologic mechanisms
- Studies that propose to compare new health policies or payment recommendations



Example of a PCORI-funded CER Study

EVIDENCE
THAT
MATTERS



Long-Term Randomized Controlled Trial Comparing Stimulant and Nonstimulant Treatment for ADHD

Organization – Research Foundation for the State University of New York

Study Design

Randomized non-inferiority trial involving 1000 youths age 6-16 with ADHD comparing

- Clinician starts extended-release stimulant, if two stimulants fail, can choose different stimulant, switch to non-stimulant, or augment with non-stimulant
- Clinician starts with norepinephrine reuptake inhibitor or alpha-2 agonist, if two non-stimulants fail, can choose different non-stimulant, switch to/augment with stimulant

Key Study Features

- Primary Outcome: Clinical Global Impressions-Improvement Scale (CGI-I) at 12 weeks
- Broad inclusion criteria for generalizability of results, including psychiatric comorbidities, sleep disorders, tic disorder, and autism spectrum disorders.
- Partnership Board: youths with lived experience, parents, school teachers, clinicians, patient advocacy groups, professional societies, medical educational industry members

More information

- Resources at <https://www.pcori.org/funding-opportunities>
 - Funding announcements
 - Submission instructions
 - Due dates
 - FAQs
 - Other applicant and awardee resources
- If you have a question about a potential project, reach out to pfa@pcori.org