

Update on the Patient-Centered Outcomes Research Institute

Joe Selby, MD, MPH

Executive Director

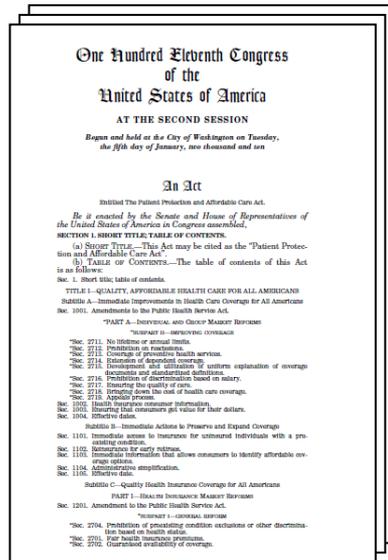
Brigham and Women's Hospital Research Day

December 7, 2012

Patient-Centered Outcomes Research Institute



PCORI's Purpose – from The Affordable Care Act



Purpose
Of
PCORI

“The purpose of the Institute is **to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions** by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed **through research and evidence synthesis** that considers variations in patient subpopulations **and the dissemination of research findings** with respect to the relative health outcomes, clinical effectiveness, and appropriateness of medical treatments, services.

Source: Affordable Care Act. Subtitle D—Patient-Centered Outcomes Research.

PUBLIC LAW 111–148—MAR. 23, 2010.

MISSION STATEMENT

(adopted July 17, 2011)

The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed health care decisions – and improves health care delivery and outcomes – by producing and promoting high integrity, evidence-based information - **that comes from research guided by patients, caregivers and the broader health care community.**



Taking the Patient and Stakeholder Perspective Seriously

- Patients and other relevant stakeholders must be included as members of research teams and involved in all aspects of the research project - from planning to dissemination
- Applications are evaluated and scored on patient-centeredness and on patient-stakeholder engagement as part of the review process
- 30% of reviewers on each review committee are trained patient or stakeholder reviewers.

PCORI's National Priorities and Research Agenda

Assessment of Prevention, Diagnosis, Treatment Options

- Comparisons of alternative clinical options; identifying patient differences in response to therapy; studies of patient preferences for various outcomes

Improving Healthcare Systems

- Improving system support of patient self-management, coordination of care for complex conditions, access to care; comparing alternative strategies for workforce deployment.

Communication & Dissemination Research

- Understanding and enhancing shared decision-making; alternative strategies for dissemination of evidence; exploring opportunities to improve patient health literacy

Addressing Disparities

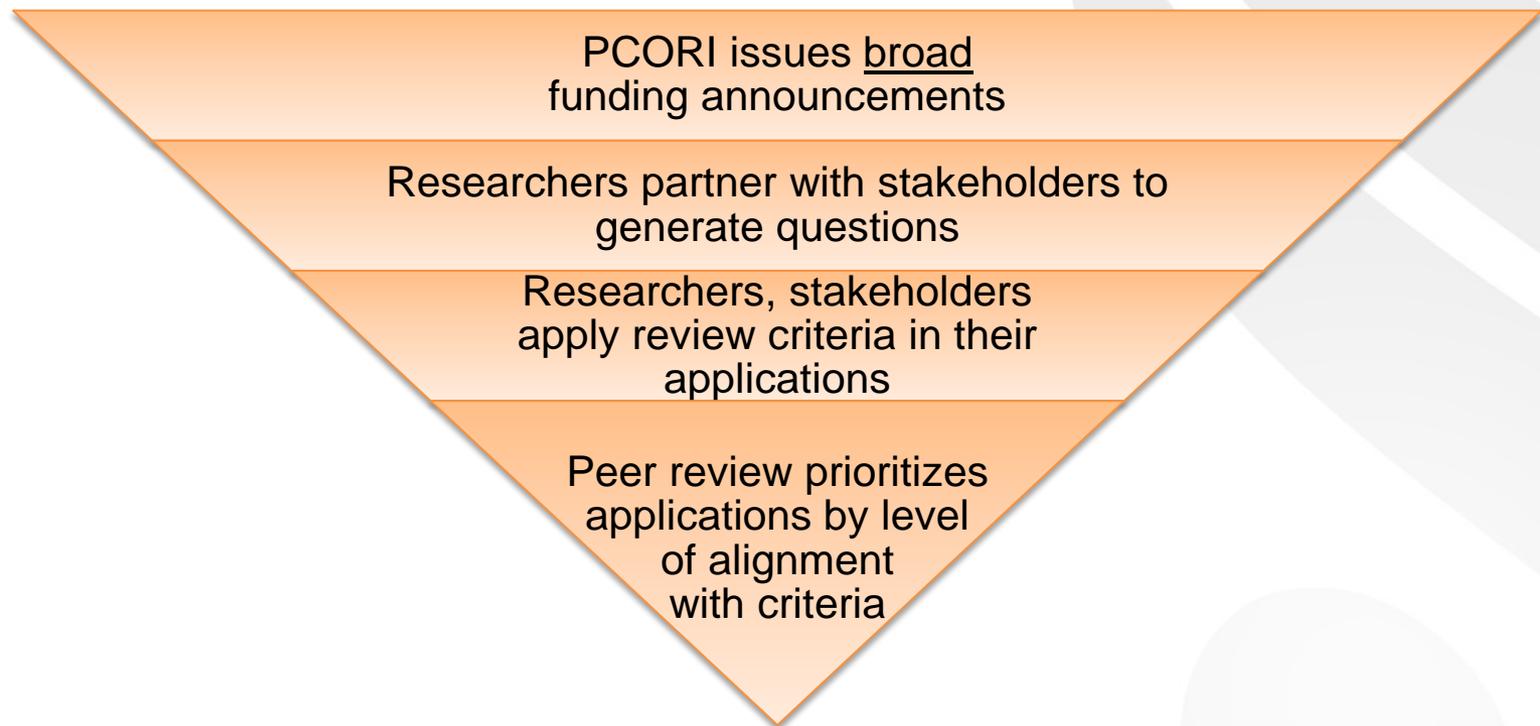
- Understanding differences in effectiveness across groups; understanding differences in preferences across groups; reducing disparities through use of findings from PCOR

Accelerating PCOR and Methodological Research

- Improving study designs and analytic methods of PCOR; building and improving clinical data networks

Two Complementary Pathways for Developing PCORI's National Research Portfolio

#1 Investigator-Generated Pathway to Research



Diverse Portfolio addressing high-priority questions

First PCORI Funding Announcements (PFAs) – May 2012

Research Agenda

PCORI Research Agenda-DRAFT

Research Agenda Process
The development of the PCORI Research Agenda was facilitated by the Research Agenda Workgroup, a subgroup of the PCORI Program Development Committee. The Research Agenda Workgroup also solicited and gathered input from the PCORI Board of Governors, Program Development Committee, and the Methodology Committee. Following identification of the five PCORI National Priorities, the Workgroup developed a framework for the translation of these priorities into the Research Agenda.

Framework for Translation of PCORI National Priorities into the Research Agenda

Priorities

- Improving Healthcare Systems**
 - PCORI Criteria:
 - Feasibility of Research via Research
 - Importance of Addressing the Population
 - Addressing Critical Gaps in Knowledge/Performance
 - Appropriateness of Research Approach
 - Potential to Influence Practice/Policy
 - Researcher's Research Skills
 - Researcher's Research Goals
 - Researcher's Research Methods
- Communication & Dissemination**
- Patient-Centered Outcomes Research**
- Assessing Public-Centered Research**

• The five National Priorities were analyzed to create the Research Agenda through a detailed evaluation of the Institute and PCORI specific criteria.
 • Each Research Agenda statement maps to one of the PCORI National Priorities (though it may be relevant to more than one) and to one or more of the Criteria.

This document represents version one of the draft Research Agenda. With time, the Research Agenda will move toward greater specificity and be refined based upon a significant due diligence process that will include discussions with a broad range of stakeholders. These discussions are currently proceeding via focus groups, PCORI leadership presentations to various audiences, and the public comment period. PCORI will also engage stakeholders through advisory panels and stakeholder meetings, and provide opportunities to provide input via PCORI's website. Additionally, PCORI is examining its initial round of funded grants (the PCORI Pilot Projects) to gauge community interests and needs and to determine and apply lessons learned from those initial funding opportunities. Based upon this due diligence process,

PFAs

Communication and Dissemination Research

The Patient-Centered Outcomes Research Institute is accepting applications for research to <enter short synopsis of purpose for the announcement>.

Apply for a PCORI Research Grant

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

Section One: The Application Process

If you are interested in applying for a grant under this program, follow PCORI's five-step process.



- ✓ **Review requirements.** Understand the overall requirements and timelines of the program.
- ✓ **Determine your fit.** Consider the applicant eligibility and research priorities to see if your organization and project fit this within this funding program.
- ✓ **Design the project.** Determine and document who will be involved, the research strategy, and the budget needs.
- ✓ **Inform us of your intent.** Send PCORI your notice of intent.
- ✓ **Apply for a grant.** Compile and submit your grant application.

1 Step 1: Review the Requirements
Opportunity Overview. The <Name of Funding Announcements> program calls for applications that <insert basic premise for the opportunity>. PCORI expects to award about <XX> grants totaling approximately \$<XX> million in <YEAR>. <Insert brief overview of the opportunity>.

System Registration. <ENTER THE PROCESS FOR REGISTERING WITHIN THE ONLINE NOTICE OF INTENT AND APPLICATION SYSTEM.>

The first four National Priorities: Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research;

Addressing Disparities Patient-Centered Outcomes Research Institute



Requirements of Applications to Broad PFAs

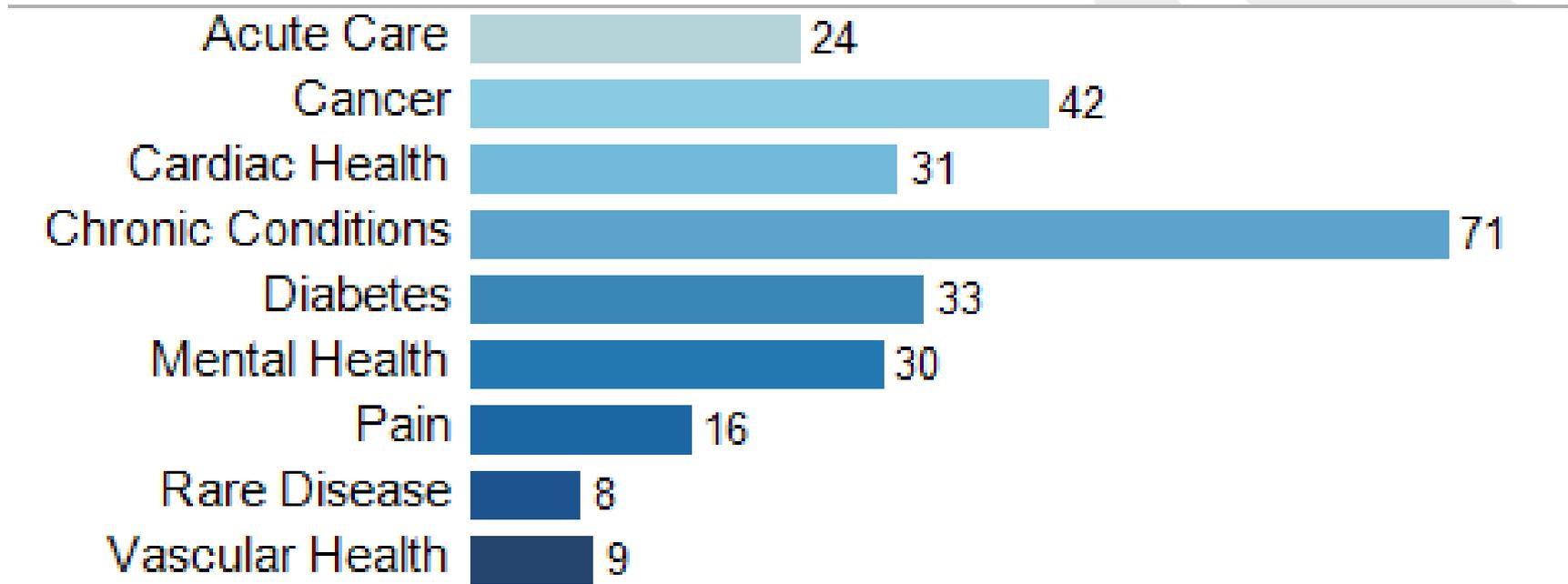
- Address a question relevant to patients and consider patient-relevant outcomes
- Be comparative
- Assess for differences in treatment effectiveness across subgroups of study population
- Include relevant patients and other stakeholders on research team
- Discuss potential for dissemination and implementation
- NOT include cost-effectiveness analyses or treat costs of care as an outcome that is compared

PCORI Review Criteria

1.	Impact of the Condition on the Health of Individuals and Populations
2.	Innovation and Potential for Improvement
3.	Impact on Health Care Performance
4.	Patient-Centeredness
5.	Rigorous Research Methods
6.	Inclusiveness of Different Populations
7.	Research Team and Environment
8.	Efficient Use of Research Resources

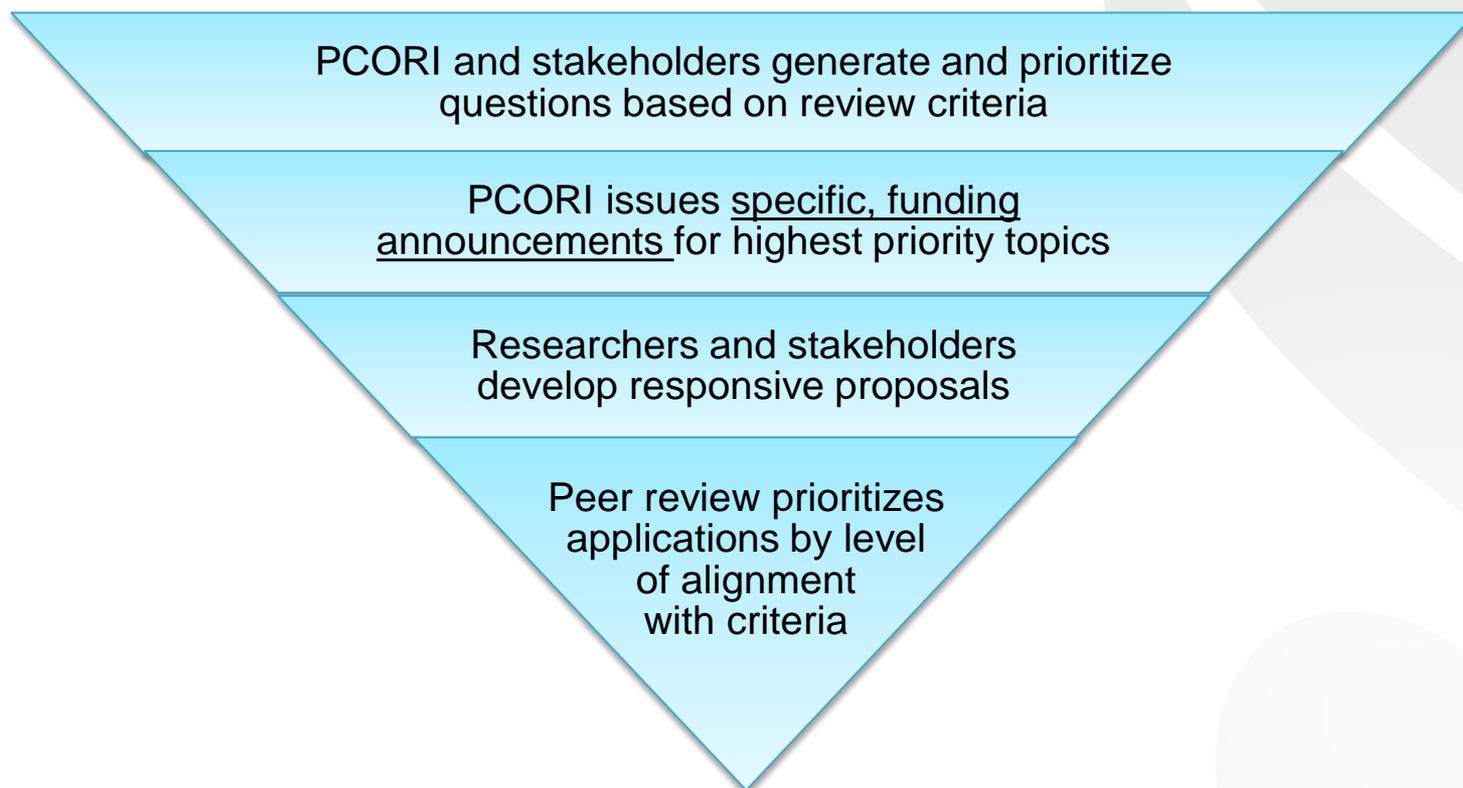
Cycle 1 Response to Broad PFAs Proposals Advanced to Phase II:

Condition Studied



Two Complementary Pathways for Developing PCORI's National Research Portfolio

#2 Patient/Stakeholder-Led Pathway to Research



Diverse portfolio addressing high-priority questions

Developing PCORI's Research Prioritization Process

Topic Generation

Gap Confirmation

Research Prioritization

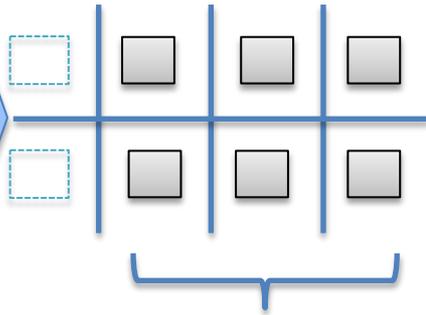
Final Selection Specific PFAs

(In Collaboration With AHRQ)

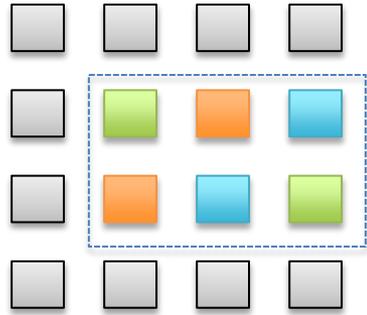
(Multi-stakeholder Advisory Panels)

(PCORI Board)

- Patients & Stakeholders:**
- Web Page
 - Social Media
 - Workshops
 - Guidelines and Systematic Reviews
 - Direct Communication with Stakeholder Groups
- PCORI**
- Continuous Portfolio Review
- Supported by AHRQ:**
- Systematic Review Gaps



Research Opportunities



PCORI Advisory Panels - 2013

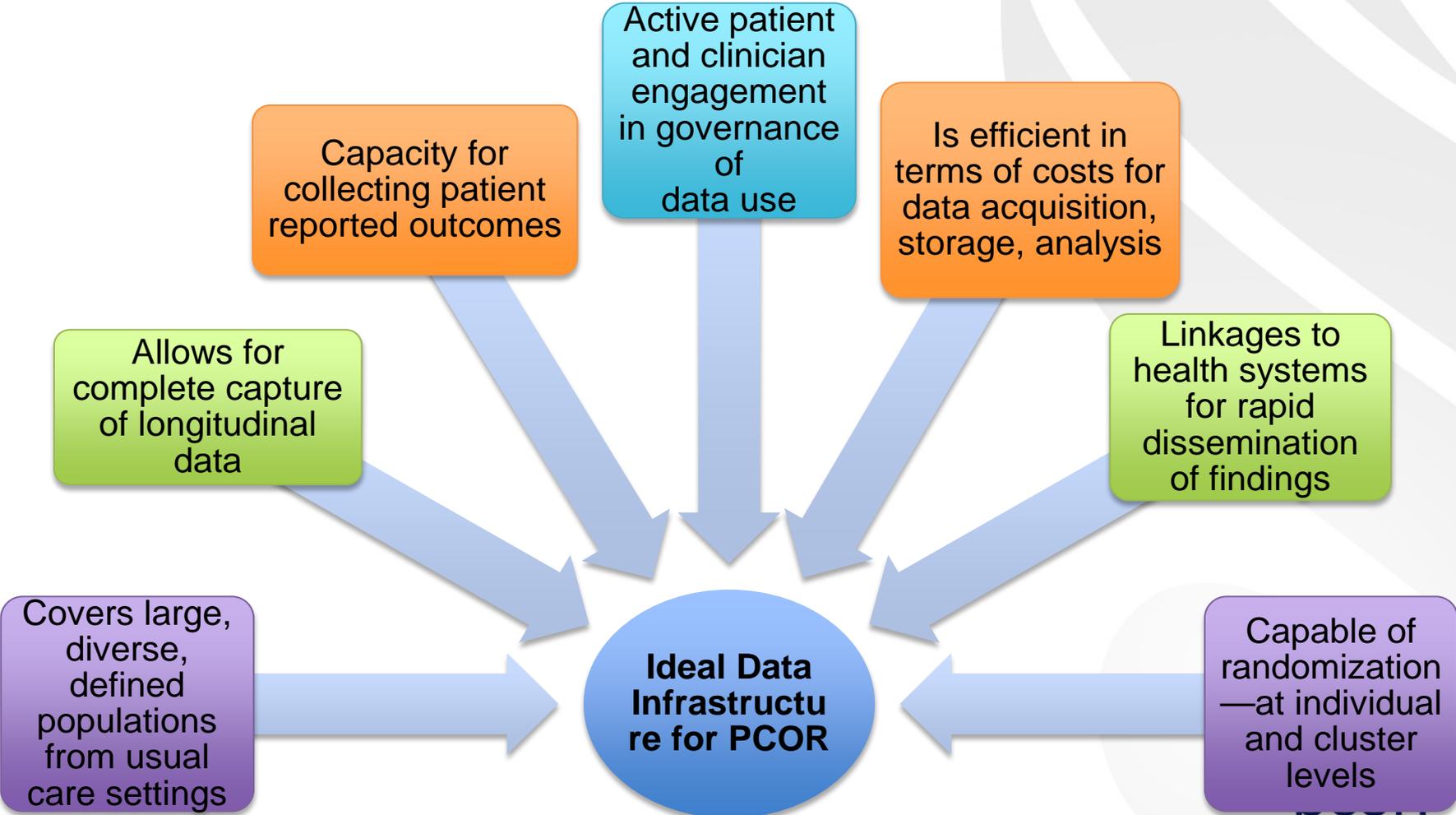
- Multi-stakeholder Advisory Panels will assist PCORI staff and Board in:
 - Modeling robust patient and stakeholder engagement efforts
 - Identifying, refining and prioritizing specific research questions
 - Provide other scientific or technical expertise – e.g., for clinical trials and for rare diseases
 - Other questions that may arise relevant to PCORI's mission and work – e.g., refinement of research agenda; dissemination of PCORI research findings

Targeted Funding Announcements

- May call for single or multiple projects
- May be organized as cooperative agreements or as “contracts”
- Will seek to identify opportunities to co-fund
- Will require that projects meet PCORI criteria for patient-centeredness and engagement

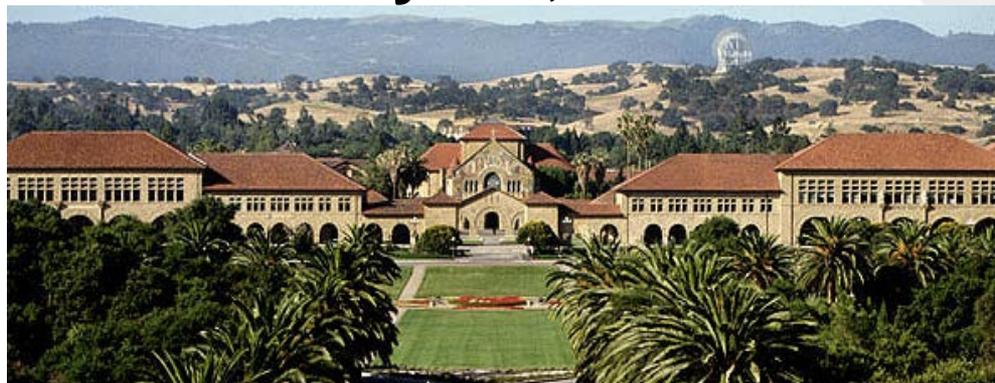
Building infrastructure for PCOR and a learning health care system

Desirable Characteristics of a Data Infrastructure for PCOR



Two Distinct (Complementary) Approaches to Building Research Infrastructure Emerge

PCORI National Workshop to Advance Use of Electronic Data July 2-3, 2012



Clinical Data
Networks

Patient-Powered
Research
Networks



Funders, Models, and Opportunities



ONC

- Meaningful Use
- EHR Certification programs
- SHARP Program
- BEACON Communities



FDA

- Sentinel
- OMOP



AHRQ

- DRNs
- PBRNs
- Registries
- SPAN
- PROSPECT
- EDM Forum



NIH

- CTSA
- Collaboratory
- CRN, CVRN
- ClinicalTrials.gov
- eMERGE Network
- PROMIS/ NIH - Snomed-CT, LOINC



VA

- VistA
- iEHR (2017)



IOM

2011 Report: *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care*

Payers



Specialty Societies



Industry



Innovators and Entrepreneurs



Patient-Centered **CANCERCOMMONS**e

Join Us at PCORI.org

