



Research Agenda and Opportunities for Co-Funding

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Inter-agency Pain Research Coordinating Committee*

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Patient-Centered Outcomes Research Institute



Agenda for Today

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Introducing PCORI

2

Funding Mechanisms and Portfolio

3

Opportunities for Collaboration

PCORI Uses Engagement as a Path to More “Useful” Research



What Do We Mean by Comparative Clinical Effectiveness Research?



- Compares two or more options for screening, diagnosis, treatment
(one option may be “usual care”)
- Considers the range of outcomes important to patients
- Conducted in real world populations and real world settings
- Attends to differences in effectiveness and preferences across patient subgroups

PCORI's National Priorities for Research



**Assessment of
Prevention,
Diagnosis, and
Treatment Options**



**Improving
Healthcare Systems**



**Communication &
Dissemination
Research**

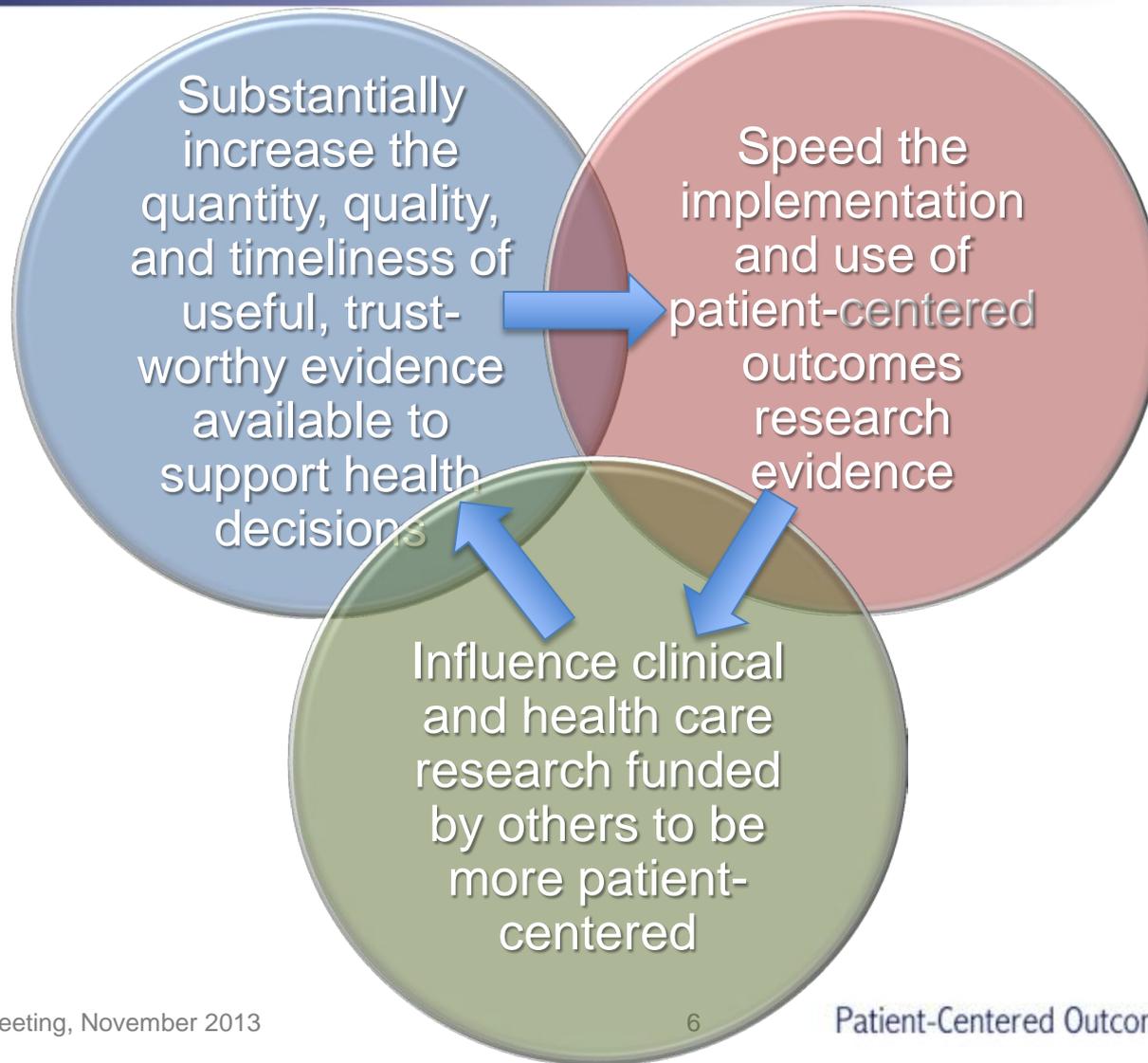


**Addressing
Disparities**



**Accelerating PCOR
and Methodological
Research**

PCORI's Three Strategic Goals



Agenda for Today

1 Introducing PCORI

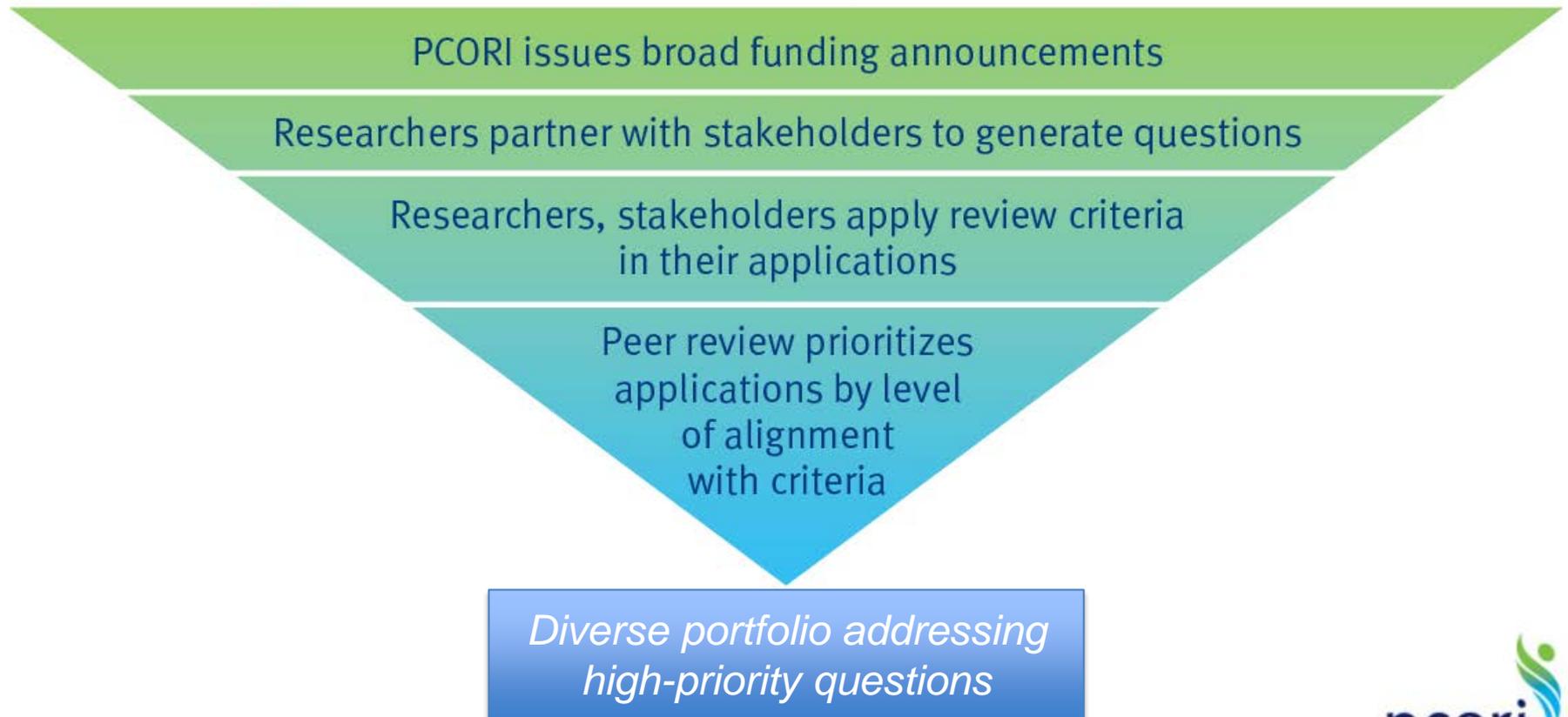
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Funding Mechanisms and Portfolio

3 Opportunities for Collaboration

Now Three Paths to PCORI Research Funding

#1: PCORI's Broad Funding Solicitations

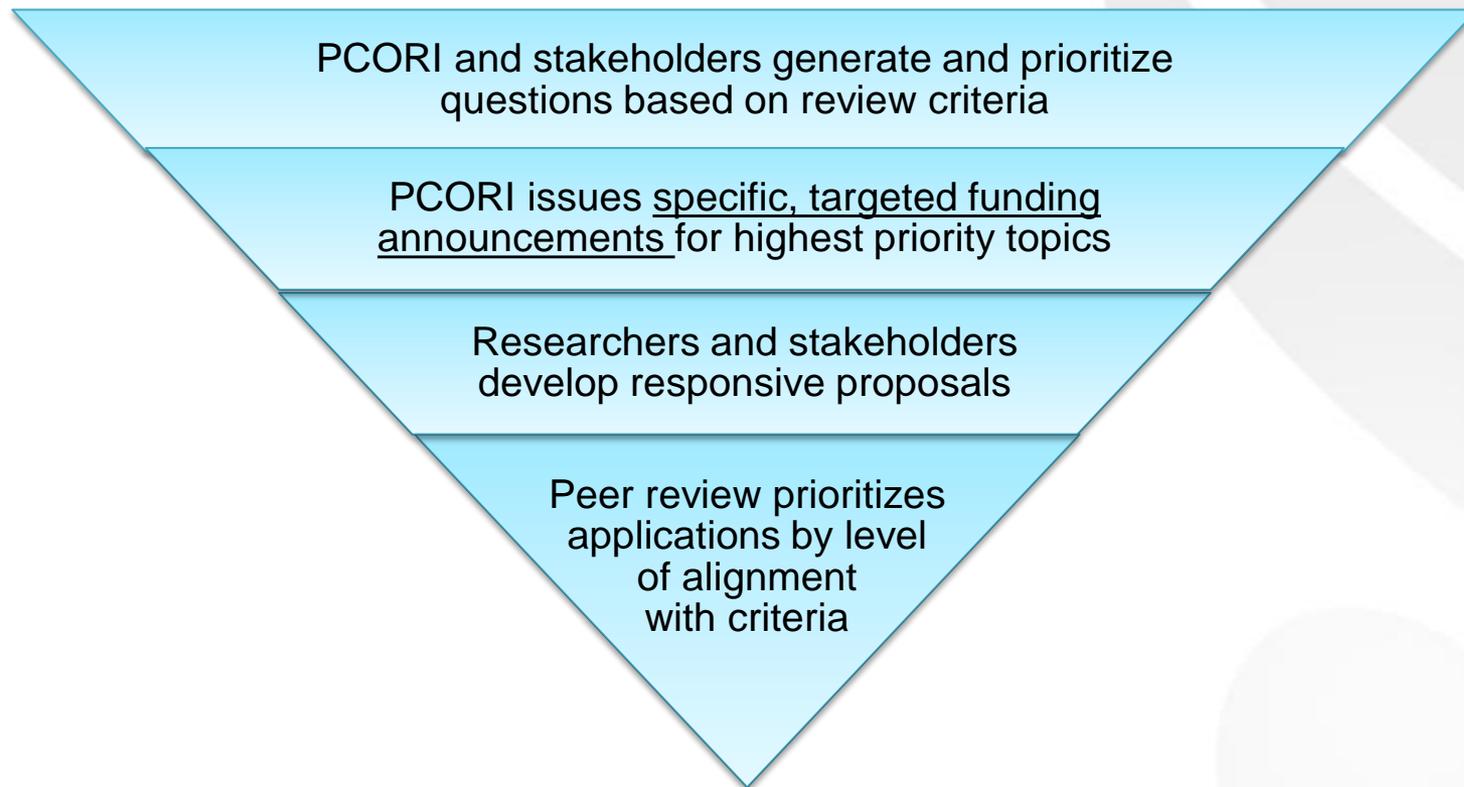


Pain-related Studies funded through PCORI's Broad Funding Announcements

- ④ Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial
- ④ Integrative Medicine Group Visits: A Patient-Centered Approach to Reducing Chronic Pain and Depression in a Disparate Urban Population
- ④ Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis
- ④ Optimizing Patient Engagement in a Novel Pain Management Initiative (OPEN)
- ④ Effects of a Patient Driven Assessment Process with Complex Pain Patients (PDAP)
- ④ Evaluation of a Patient-Centered Risk Stratification Method for Improving Primary Care for Back Pain
- ④ Patient Assisted Intervention for Neuropathy: Comparison of Treatment in Real Life Situations (PAIN-CONTRoLS)
- ④ Evaluation of a Health Plan Initiative to Mitigate Chronic Opioid Therapy Risks
- ④ Comparative Effectiveness of Postoperative Management for Degenerative Spinal Conditions
- ④ Long Term Outcomes of Lumbar Epidural Steroid Injections for Spinal Stenosis
- ④ Improving Palliative and End-of-Life Care in Nursing Homes

Three Paths to PCORI Research Funding

#2: Patient/Stakeholder-Led Targeted Announcements



Diverse portfolio addressing high-priority questions



PCORI's Research Prioritization Process

Topics Come from multiple sources

Gap Confirmation

Research Prioritization

Prioritized Research Topics

Board Topics

Workshops, Roundtables

1:1 interactions w Stakeholders

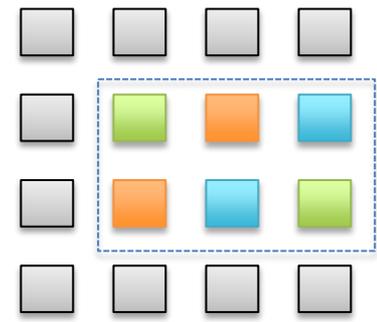
Guidelines Development, Evidence Syntheses

Website, Staff, Advisory Panel Suggestions

(PCORI Staff In Collaboration with AHRQ & others)

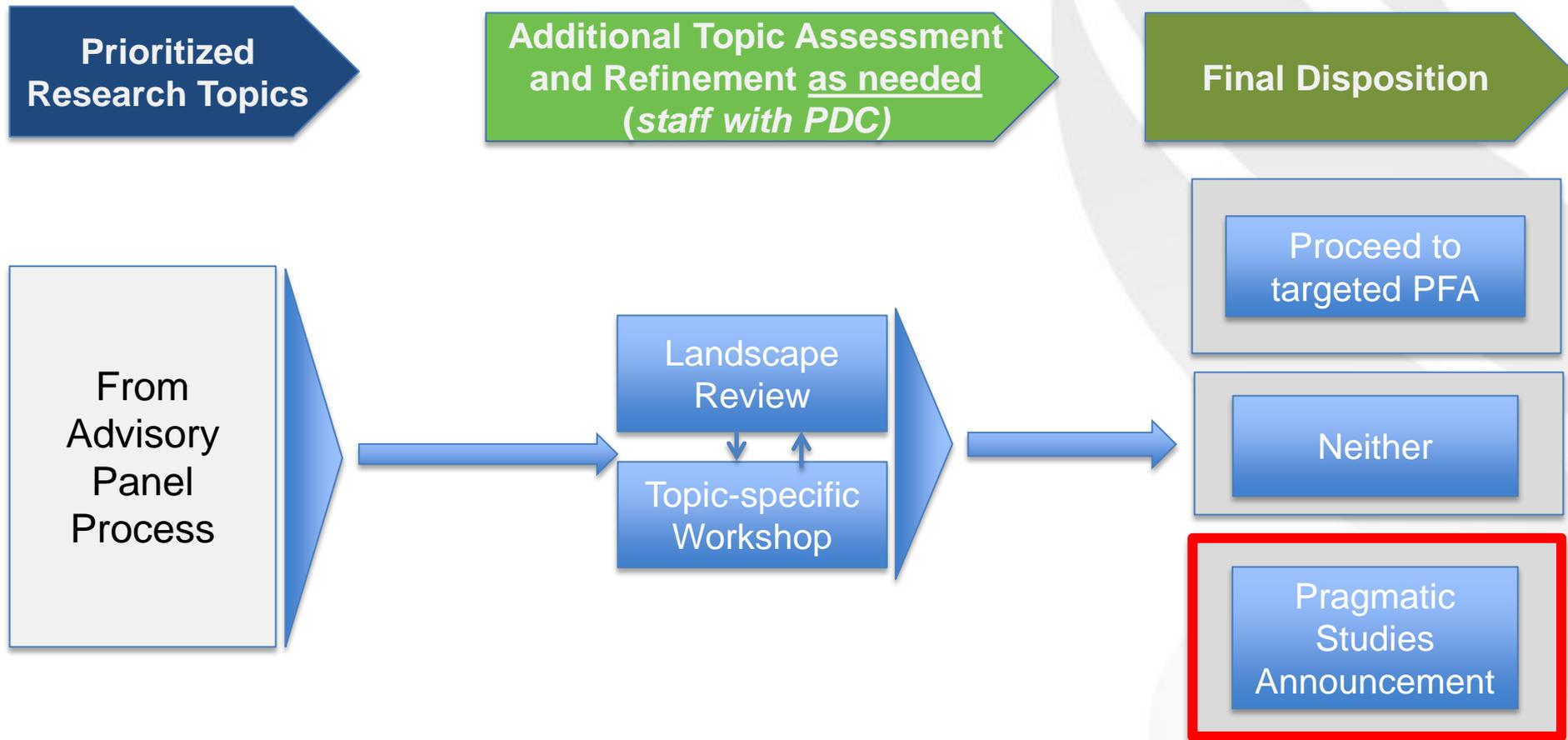
- Eliminating non-comparative questions
- Aggregating similar questions
- Assessing Research Gaps
- Preparing Topic Briefs

(Multi-stakeholder Advisory Panels)





Post-Prioritization Process: Board Approval is Required for Targeted Funding Announcements



PCORI's First Targeted Funding Announcements

- Identified several high-priority, stakeholder-vetted topics for targeted PFAs
- Leverages stakeholder input from before PCORI's existence
- Allows us to build on our engagement work

Research Topics:

- Treatment Options for Uterine Fibroids
- Safety and benefits of treatment options for severe asthma
- Fall Prevention in the Elderly
- Back Pain
- Prevention and management of obesity

Essential characteristics of Pragmatic Studies initiative

- Up to \$10 million in direct costs; 5-year duration. Larger or longer studies will be evaluated and may be funded
- Up to \$90 million available, two cycles per year
- Strong endorsement and involvement by relevant patient organizations, professional organizations, and/or payer or purchaser organizations
- Conducted in typical clinical care and community settings
- Broadly representative populations, sample sizes large enough to yield precise estimates of effect sizes and evaluate possible subgroup differences in treatment effects
- Measures health outcomes that are meaningful to the patient population under study

Comparators of interest in Pragmatic Studies

- Specific drugs, devices, and procedures
- Medical and assistive devices and technologies
- Techniques for behavioral modification
- Complementary and alternative medicine
- Delivery-system interventions
- Usual care or no specific intervention, if it is a realistic choice for patients (e.g., choosing not to have a procedure for cancer screening)

Topics of interest

- IOM 100 priority topics for CER
- AHRQ Future Research Needs Projects
- PCORI priority topics (as of 1/2014)
- *Investigator initiated topics will also be considered*

Pathway #3: Pragmatic Studies Announcement

Comparing effectiveness of alternative treatments or strategies for:

- Diagnosis and management of bipolar disorder in children and adolescents
- Management of breast ductal carcinoma in situ
- Reducing cardiovascular disease risk in underserved populations (e.g., racial and ethnic minorities, rural communities)
- Preventing the progression of episodic acute back pain into chronic back pain
- Integration of mental and behavioral health services into the primary care of the general population

Topics for Pragmatic Studies Announcement

Comparing effectiveness of alternative treatments or strategies for:

- Integration of mental and behavioral health services into the primary care of persons at risk for disparities in health care and outcomes
- Enhancing patients' adherence to medication regimens.
- Specific features of health insurance on access to care, use of care, and other outcomes that are especially important to patients
- **Adult patients with migraine headache**
- Symptomatic osteoarthritis (OA), including joint replacement

Topics for Pragmatic Studies Announcement

Comparing effectiveness of alternative treatments or strategies for:

- 🌐 Patients with autism spectrum disorder
- 🌐 Follow-up of pulmonary nodules identified by imaging studies
- 🌐 **People with opioid substance abuse**
- 🌐 Patients with multiple sclerosis
- 🌐 Proton beam therapy for patients with lung, breast, and prostate cancer

And:

- 🌐 IOM Top 100 Topics for CER
- 🌐 AHRQ Future Research Needs

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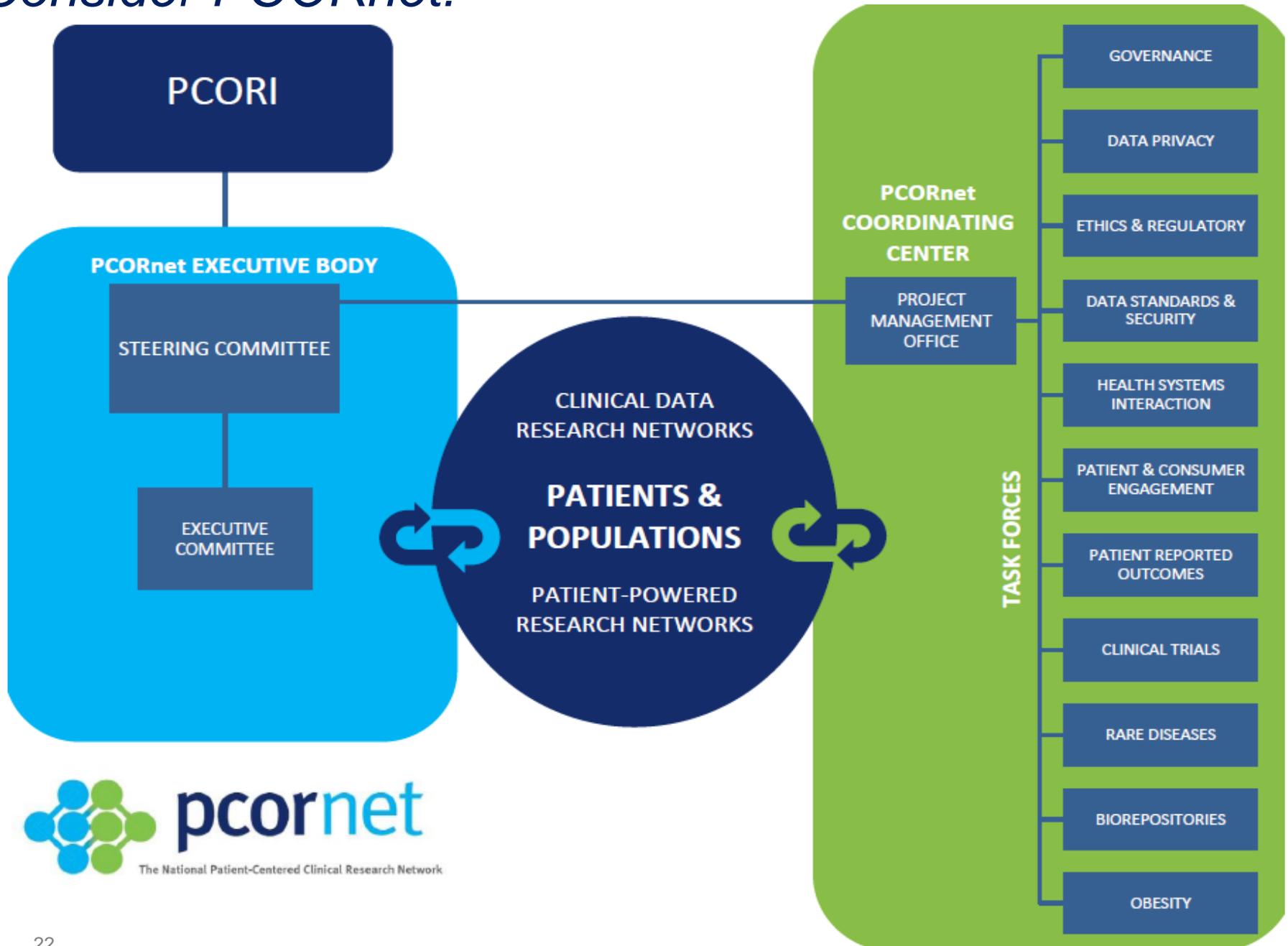
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Opportunities for Collaboration

Considerations for Collaboration

- PCORI's Board and its Strategic Plan express great interest in co-sponsoring and collaborative management with other funders
- Strong Board interest in “cross-cutting” topics such as pain
- Contracts/MOUs from PCORI to manage targeted PFAs – PCORI provides funding, Institute provides in-kind expertise
- Co-funded announcements – when mutual interests in a targeted PFA or pragmatic study make this feasible
- PCORI will be concerned to ensure that the innovations in terms of engagement and patient-centeredness are preserved in partnered relationships

Consider PCORnet!



Connect with PCORI



www.pcori.org



Patient-Centered Outcomes Research Institute