

## Overview of PCORI Funding Announcements (PFAs), Priority Topics, and Methodology Standards

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## Welcome!



**Steven Clauser,**  
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*Assistant Director,  
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## The Model of Comparative Effectiveness Research

### Research that

- Provides Improved Evidence for Healthcare Decision Makers
- Driven by the Needs of Stakeholders
- Focuses on outcomes that matter to patients
- Guided by Well Defined Evidence Gaps
- Conducted in “real world” settings
- Applies appropriate methods and data sources



## Our National Priorities for Research



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



**CER Methods**



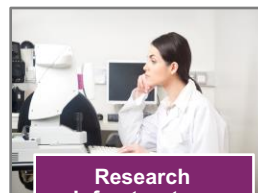
**Improving Healthcare  
Systems**



**Communication &  
Dissemination  
Research**



**Addressing Disparities**



**Research  
Infrastructure**



## Assessment of Prevention, Diagnosis and Treatment Options

- Decision Makers: Patients and their Clinicians
- Choices among Clinical Options
- Head to Head Comparisons
- Often focuses on “What” to do

No. of Funded  
Projects

APDTO  
**138**



Executed/Application  
Amount

**\$521,365,860**



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## Improving Healthcare Systems

- Decision Makers: Healthcare Managers
- Choices among Options for Organizing and Delivering Care
- Often involve Clinicians or Health Organizations as the Unit of Analysis
- Often focuses on “How” to do it

No. of Funded  
Projects

IHS  
**84**



Executed/Application  
Amount

**\$308,828,849**



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## Addressing Disparities

- Decision Makers: Members of Disadvantaged Populations and their Caregivers
- Choices among Options for Eliminating Barriers to High Quality Care
- Often Addresses Strategies for Improving Access among the Underserved

No. of Funded  
Projects

AD  
65



Executed/Application  
Amount

\$183,841,632



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## Communication and Dissemination Research

- Decision Makers: People who Implement Programs for Improving Quality of Care
- Choices among Options for Implementing Best Evidence
- Can Address Shared Decision Making or Dissemination Strategies

No. of Funded  
Projects

CDR  
43



Executed/Application  
Amount

\$79,352,444



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## Improving the Methodology of Comparative Effectiveness Research

- Decision Makers: Researchers who Desire to Use Better Methods
- Choices among Options for Measuring Outcomes and Analyzing Data
- Can Address Techniques for Improving Collaboration among Researchers and Partners

No. of Funded  
Projects

CER  
88



Executed/Application  
Amount

\$89,000,000



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## We Work to Improve Research Methodology

In any study, methods matter. That's why we've developed methodology standards that all research should follow, at a minimum.

### Methodology Standards: 11 Broad Categories

- Formulating Research Questions
- Patient-Centeredness
- Data Integrity and Rigorous Analyses
- Preventing/Handling Missing Data
- Heterogeneity of Treatment Effects
- Data Networks
- Data Registries
- Adaptive and Bayesian Trial Designs
- Causal Inference
- Studies of Diagnostic Tests
- Systematic Reviews



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## Broad PFA Budget and Period Limitations

### Budget

- Traditional PCORI Broad Awards direct costs capped up to \$1.5
- Indirect costs up to 40%
- Up to \$10,000 for scientific travel

\*Note that Large Awards are available in IHS Broad PFAs - Up to \$5 million



### Period of Performance

- Traditional Awards up to maximum of 3 years
- IHS Large Awards up to a maximum of 5 years
- Do not anticipate receiving a cost OR no-cost time extension



## Pragmatic Clinical Studies

Seeks to produce information that can be directly adopted by providers:

- Cross-Cutting funding mechanism across all the PCORI Research Areas
- Decision Makers: Everyone Involved with Health Care
- Most Projects are Randomized Controlled Trials
- Large Sample Sizes: Heterogeneity of Treatment Effects
- Topics of special interest from stakeholders, Institute of Medicine, Agency for Healthcare Research and Quality

### Overview

- Anticipated Awards per Funding Cycle: Six to Nine
- Funds Available per Cycle: Up to \$90 Million
- Maximum Project Duration: 5 Years
- Maximum Direct Costs per Project: \$10 Million



## Targeted Funding Initiatives

- Targeted funding initiatives; stakeholder-driven topics
  - Very specific research questions
  - Developed through:
    - Expert workgroups
    - Iterative review with Board Subcommittee
    - Review and approval by the Board of Governors
- Typically One-time Opportunities, although we have recently reissued targeted PFAs for Clinical Strategies for Managing and Reducing Long-Term Opioid Use for Chronic Pain and Treatment of Multiple Sclerosis



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## Questions?



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# Thank You!

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