# **Accelerating Patient-Centered Outcomes Research and Methodological Research**

**Jason Gerson, PhD** Associate Director, Science

February 19, 2015



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## Welcome!



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### In This Session

#### We will discuss:

- The Improving PCOR Methods (Methods) program area specifics
- Describe responsiveness in a Methods Letter of Intent (LOI)
- Describe responsiveness in a Methods application



### **PCORI CER Methods Program and Contracts Staff**

#### **CER Methods Program Staff**



Rachael Fleurence, Program Director, Methods and



Katherine McQueston, Jason Rotter, MHS MPH Program Associate,
Methods



Jason Gerson, Associate Director, Methods



Program Associate, Methods

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Emily Evans, PhD, MPH Program Officer, Methods

Maryan Zirkle, MD, MS, MA

Program Officer,

Methods and



#### **Post-Award Contracts Staff**



Stephen Jones Post Award Contracts Administrator, Contract



Shayan Hobbi Contracts Coordinator, Contracts



Rachel Benz Contracts Coordinator,

# Improving Patient-Centered Outcomes Research (PCOR) Methods

PCORI was created to support research that provides relevant information to patients and clinicians.

Research findings that can be trusted should be generated using valid, rigorous, patient-centered research methods.



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### **Program Mission/Objectives**

Fund studies to address gaps in methodological research relevant to conducting PCOR.

Disseminate and facilitate the adoption of new methods to improve the conduct of PCOR.

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### **Aspirations**

Improvement of existing methods that will benefit all stakeholders, including researchers planning investigations, policy makers weighing the value of healthcare interventions, and patients, clinicians, and caregivers facing healthcare decisions.



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### **Improving Methods Program: Overview**

- Awards: As of Fall 2014 cycle, 58 funded projects
- Merit Review:
  - Typically, we run 2 panels: (1) analytic methods, (2) methods of patient/stakeholder engagement
  - Competitive LOI screening process
  - Merit Review criteria for Methods different than other programs
- · Portfolio Management:
  - 3-month check-ins with PIs
  - 6-month interim progress reports
  - Listen in/participate in stakeholder advisory meetings
  - Evidence-to-Action Networks



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## Improving Methods for Conducting Patient-Centered Outcomes Research



# 58 Awards \$54.8 Million



## **Research Areas of Interest**

Development of methods for patient and other stakeholder engagement in research

Development and refinement of general analytic methods

Development and refinement of design-specific analytic methods

Research on issues related to human subjects protections

Research on novel methods, interventions, or strategies for increasing recruitment and retention of participants (e.g., patients, caregivers, clinicians, hospitals, and health systems) in PCOR/CER randomized trials, observational studies, and registries

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### **Special Topics of Interest**

 Research related to patient-centered outcomes (PCOs) and patientreported outcomes (PROs)

Research on methods for PRO development

n PRO nt Research on usefulness of patient-reported data in clinical care

Strategies for minimizing missing data

Research on the collection of PRO data for multiple purposes

Research on methods to elicit patient preferences Research on integrating PROs into clinical practice

Research on the use of PROs in registries



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### **Special Topics of Interest**

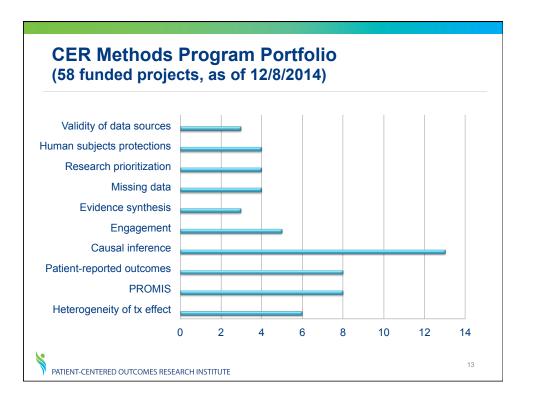
· Development of methods to support data research networks

Methods to establish optimal linkage of multiple data sources, such as electronic health records (EHR) Development and refinement of innovative ways to link to information captured from PROs

Methods to conduct patient-level disambiguation for deidentified linkage of data across networks

Methods related to missing and incomplete data within networks

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### **Revisions for Spring 2015 Funding Cycle**

- Decrease of award size from \$1,000,000 to \$750,000 in total direct costs
- The current PFA does not include a special emphasis on Patient Reported Outcomes Measurement Information System (PROMIS) related projects
- · New sections:
  - General analytic methods related to treatment adherence
  - Improving methods of recruitment into and retention of participants for PCOR/CER
- New Special Topic of Interest focusing on methods for networkbased data in research
- Currently, we are not supporting methods related to research prioritization and systematic reviews

### **CER Methods Program Vision**

- Create opportunities for information sharing across projects
  - Creation of learning networks by Methods area (e.g. patient engagement, PROs, causal inference)
  - Panel presentations at select conferences and annual meetings
  - Investigator-driven suggestions for collaboration and dissemination





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#### **Unsuccessful LOIs**

- Cost Effectiveness Analysis studies are automatically disqualified
- No clear identification of methodological gap to be addressed
- Lack of detail about proposed design, data, and analytic plan
- Disease- or condition-specific measure development/validation



### **Strong LOIs**

- · Clearly identified:
  - Methodological gap
  - Design, data, analytic plan
- Dissemination plan with identified stakeholder partner involvement
- Is a unique or novel study that doesn't duplicate projects already funded in portfolio





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### **Full Applications**

- · Very competitive
- · Lots of high quality projects
- "Pretty good" proposal is not competitive
- Needs to be different from previously funded studies



## **Questions?**

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## **Thank You!**

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