

Assessment of Prevention, Diagnosis, and Treatment Options

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Welcome!



David Hickam, MD, MPH
Program Director
Science



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Session Objectives

- Discuss PCORI's history, mission, and vision
- Describe the reason for this workshop
- APDTO program area specifics
- Merit Review Process
- Responsiveness of an LOI to the APDTO PCORI Funding Announcement
- Success of APDTO applications



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Introductions: APDTO Program Staff



Diane Bild
Senior Program
Officer



Yen-Pin Chiang
Associate
Director



Anne Trontell
Senior Program
Officer



Jackie Dillard
Senior
Administrative
Assistant



Stanley Ip
Senior
Program
Officer



Jess Robb
Program
Associate



Julie McCormack
Program Officer



Katie Hughes
Program
Associate



Jana-Lynn Louis
Program
Associate



Sandi Myers
Program
Assistant



Danielle Whicher
Program Officer

Layla Lavasani,
Program Officer



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APDTO Advisory Panel



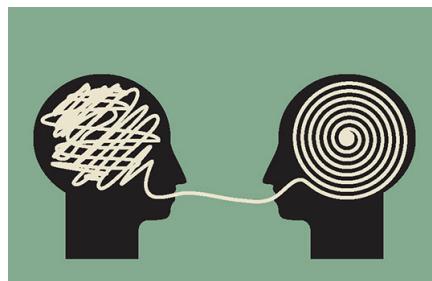
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Assessment of Prevention, Diagnosis, and Treatment Options

Comparative effectiveness research (CER) is designed to provide information that would inform critical decisions faced by:

- Patients
- Caregivers
- Clinicians
- Policy-Makers
- Health Care System Leaders



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APDTO cont'd...

- The critical decisions must be consequential and be occurring now in the absence of sound evidence about the comparative effectiveness of alternative approaches.
- There must be substantial potential that patients/caregivers will benefit from the new knowledge in ways that are important to them.
- The premise of this research is that the new knowledge will inform critical choices by patients and stakeholders in health care.
- This knowledge will provide insight about the comparative benefits and harms of the options and provide information about outcomes that are important to patients.



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FOCUS

Typical clinical populations

Comparison of
two or more
effective
strategies that
have not
adequately been
compared

Emphasis on
randomized trials
comparing clinical
interventions

Fills identifiable
and definable gap
in research

- May be population specific
 - Age of patient falls outside of existing evidence base
 - Comorbid conditions make existing research irrelevant



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Key Features of Our Funded Research

Impact of Health on Individuals and Populations

Improvability via Research

Inclusiveness of Different Populations

Addresses Current Gaps in Knowledge/
Variation in Care

Impact on Health Care System Performance

Potential to Influence Decision Making

Patient-Centeredness

Rigorous Research Methods

Efficient Use of Research Resources

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PCORI's Merit Review Criteria

1. Impact of the condition on the health of individuals and populations
Sample: Is there a clearly defined and justified evidence gap that affects an important patient population?
2. Potential for the study to improve healthcare and outcomes
Sample: Will new evidence produced by the project be used by decision makers?
3. Technical merit
Sample: Does the research plan describe rigorous methods that demonstrate adherence to PCORI's Methodology Standards?
4. Patient-centeredness
Sample: Is the research focused on questions that affect outcomes of interest to patients and their caregivers?
5. Patient and stakeholder engagement
Sample: Are the roles and the decision making authority of all research partners clearly stated?



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Unsuccessful Letters of Intent



- Cost Effectiveness Analysis studies are automatically disqualified
- Does not describe an important evidence gap
- Comparators are not clearly delineated
- Unclear about rationale for “usual care” comparator
- Outcomes are not well justified



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Steps in the Review of Proposals

- Investigators submit Letter of Intent (LOI).
- PCORI staff reviews LOIs for adherence to programmatic goals.
- Some LOIs are approved for full applications.
- All applications are reviewed by merit review panels comprised of scientists, patients, and clinical stakeholders.
- Program selects the most meritorious applications for funding.



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Strong LOIs

- Clearly identified
 - Population
 - Comparators
- 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



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Recap

In this session, we described:

- APDTO program area specifics
- Merit Review Process
- Responsiveness of an LOI to the APDTO PCORI Funding Announcement
- Success of APDTO applications



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Learn More

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Questions?

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Thank You!



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