Clinical Trials Advisory Panel

Bryan Luce, PhD, MBA, Chief Science Officer

PCORI Board of Governors Meeting

Washington, DC

September 23, 2013

Patient-Centered Outcomes Research Institute

Session Topics and Objectives

What are we going to cover today?

PCORI Clinical Trials Advisory Panel	• Review key information regarding the role and establishment of PCORI's Advisory Panel on Clinical Trials
Proposed Charter	• Presentation of proposed Charter
Timeline & Next Steps	• Timeline and next steps for the launch of Advisory Panel on Clinical Trials

Getting up to Speed

What does the authorizing legislation mandate?

- Appoint a Clinical Trials Advisory Panel that will:
  - Assure high methodological standards in design and conduct of clinical trials;
  - Advise the MC and Board on priority areas for development of clinical trial methodology; and
  - Advise PCORI on the readiness of trial results for dissemination or implementation.
- Specific duties:
  - Review proposed trials;
  - Oversight and analysis of funded trials;
  - Guidance on designs and protocols; and
  - Strategies for recruiting key patient subgroups.

Proposed Charter

Proposed Clinical Trials Charter

Purpose	The Clinical Trials Advisory Panel will advise PCORI, its Board of Governors, Methodology Committee and staff, in multiple aspects pertaining to the selection, design and implementation of clinical trials for patient-centered outcomes research conducted in typical community settings. PCORI Advisory Panels do not serve in an official decision-making capacity, but their recommendations and advice are carefully taken into consideration by the Institute.
Membership Term and Charter Duration	Two-year staggered terms (maximum two terms).
Composition	10-14 members [at least two who are patients/caregivers/representatives of patient advocacy organizations and at least half will have technical expertise in the conduct of clinical trials (clincial trialists, epidemiologists, biostatisticians, medical informaticists, ethical expertise in trials). Up to two Methodology Committee members can serve in addition to appointed members, ex-officio.]

Strategic Question for the Board

- Do you have any concerns or questions related to the purpose, composition, and role of the panel?

Appendix

Language in the Law

What does the authorizing legislation mandate?

- **EXPERT ADVISORY PANELS FOR CLINICALTRIALS**.—The Institute shall appoint expert advisory panels in carrying out randomized clinical trials under the research project agenda under paragraph (2)(A)(ii). Such expert advisory panels shall advise the Institute and the agency, instrumentality, or entity conducting the research on the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research. Such panels shall be available as a resource for technical questions that may arise during the conduct of such research.