Charter of the
Advisory Panel on Clinical Trials

November 2013

Authority
The authorizing legislation for the Patient-Centered Outcomes Research Institute (“PCORI” or the “Institute”) provides that PCORI “shall appoint expert advisory panels in carrying out randomized clinical trials under the research project agenda” that is adopted by PCORI. The advisory panels for clinical trials are to “advise the Institute and the agenc[ies], instrumentalit[ies], or entit[ies] conducting the research on the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research.” The legislation also provides that such panels “shall be available as a resource for technical questions that may arise during the conduct of such research.”

Purpose
The Clinical Trials Advisory (CTA) Panel will serve as PCORI’s advisory panel on clinical trials and will advise PCORI, and agencies, instrumentalities, or other entities conducting research through the PCORI Methodology Committee. The nature of advice will include multiple aspects pertaining to the selection, research design, implementation, and technical issues of clinical trials for patient-centered outcomes research, including research conducted in typical community settings and relating to important patient subgroups and other parameters of research.

The CTA Panel Chair and the Methodology Committee chair may appoint Clinical Trials Advisory Subcommittees (“CTA Subcommittees”) to address specialized issues, specific clinical trials, and specific technical advice as described in this Charter.

PCORI Advisory Panels and Advisory Panel Subcommittees do not serve in an official decision-making capacity, but their recommendations and advice are carefully taken into consideration by the institute.

Function and Scope of Work
Randomized controlled trials provide high quality evidence for comparing alternative clinical interventions for specific clinical conditions. These clinical trials comprise an important component of clinical comparative effectiveness research. It is important that clinical trials be conducted using appropriate designs and methodologies.

The CTA Panel and CTA Subcommittees will provide guidance, as requested, on topics relating to clinical trials, which may include, but are not limited to:

- Advice to the MC on methodological standards in the design and conduct in clinical trials supported by PCORI;
- Advice to the MC on priority areas for development of clinical trial methodology;
- Baseline review of proposed trials and ongoing oversight of funded trials, including consultation to PCORI staff or study principal investigators on design, conduct and appropriate monitoring;
- Guidance on the selection of appropriate study outcomes that are patient centered, including patient-reported outcomes;
- Human subjects issues related to recruitment and informed consent in such trials;

• Strategies for designing clinical trials to maximize internal validity, efficiency, and generalizability and patient centeredness, in keeping with standards published by the methodology committee;
• Strategies for patient recruitment, eligibility and evaluation;
• Approaches to data analysis;
• Periodic evaluation of PCORI’s clinical trials portfolio;
• Areas where issuance of methodologic standards or investment in methodologic development or training might be helpful for PCORI funding recipients; and
• Advice to PCORI on the readiness of trial results for dissemination or implementation.

Composition and Structure
Membership on the CTA Panel is intended to allow for meaningful interactions amongst individuals with a variety of strengths, backgrounds, and areas of expertise. The panel will provide guidance to PCORI’s Board, Methodology Committee and staff. The Clinical Trials Advisory Panel will consist of 10 to 14 members appointed by the PCORI Board of Governors with the following composition:

- At least two Advisory Panel members will be selected from persons who are patients, caregivers, or representatives of patient advocacy organizations;
- At least half of appointed members will have technical expertise in the conduct of clinical trials, such as clinical trialists, epidemiologists, biostatisticians, or medical informaticists;
- One member will have special expertise in the ethical dimensions of clinical trials.

Consistent with the legislative mandate, the remainder will include other methodologists and individuals not already represented, including practicing and research clinicians, experts in scientific and health services research, health services delivery, and, as appropriate integrative health and primary prevention strategies. Members may also include technical, pharmaceutical, device, and other manufacturer or medical technology experts.

In addition to the 10-14 members, the Board may appoint up to two members of the Methodology Committee, ex officio.

Chair of CTA Panel
A Chair (and, a Co-Chair, if desired) will be appointed by the Board, in consultation with the Methodology Committee, to facilitate the Panel’s activities in conjunction with PCORI’s Chief Science Officer (CSO). The Chair is responsible for calling meetings and setting the panel’s agenda.

CTA Panel Members: Appointment and Term
PCORI’s Board of Governors will have final approval of the CTA Panel’s membership. Members initially will be appointed to staggered two-year terms, with the possibility of reappointment for a maximum of two two-year terms. Any member may resign at any time by giving written notice to the chair of the Clinical Trials Advisory Panel. Vacancies created by the resignation of appointed members will be filled at the discretion of PCORI’s Executive Director.

Management and support services will be provided by PCORI staff and contractors, consistent with PCORI policies.

CTA Subcommittees
The Chair of the CTA Panel and the chair of the Methodology Committee may appoint CTA Subcommittee(s) to examine special issues and to facilitate activities related to the purpose and scope of the CTA Panel. Special issues may include, but are not limited to, addressing specific methodological designs of applications that have already undergone PCORI’s merit review process, addressing specific clinical trials and methodologies, and providing technical advice. As appropriate, a CTA Subcommittee
will work with investigators to enhance the chosen designs to ensure that they are consistent with the standards generated by the Methodology Committee.

Membership of the CTA Subcommittees may be drawn from members of the CTA Panel as well as other individuals with appropriate expertise. CTA Subcommittees will work collaboratively with the CTA Panel and Methodology Committee. To the extent requested, CTA Subcommittees will provide reports to the CTA Panel, Methodology Committee, Board, and PCORI staff.

Panelist Applications and Selection
Panelist selection for the CTA Panel will be based on experience, background, ability to contribute to the scope of work described in this charter, and a prospective panelist’s commitment to advancing the mission and goals of the Institute.

PCORI will initiate an open call for applications to be considered for a position on the Clinical Trials Advisory Panel, including via the PCORI Web site and other modes of communication. PCORI may encourage selected individuals to consider applying based on their known expertise. Interested applicants will be required to submit an application online.

PCORI strives for inclusiveness and diversity in age, ability, gender, ethnicity, race, sexual orientation and gender identity, education, socioeconomic status, and geography in the selection of panelists.

Meetings
Meetings of the CTA Panel shall be conducted in an open forum and records of the proceedings kept in accordance with PCORI’s policies and procedures. All meetings will have an agenda, which will be issued to panelists and made available to the general public at least three business days prior to the meeting. However, if the CTA panel is addressing confidential information, the Chair of the panel may convene a meeting that is closed and members may be asked to sign a nondisclosure agreement.

A majority of the members of the CTA Panel shall constitute a quorum, and a roll call must be taken at the beginning of each meeting. In accordance with the Clinical Trials Advisory Panel’s advisory role, all votes and recommendations are nonbinding to the Institute.

Compensation, Travel, and Expenses
CTA Panel members and CTA Subcommittee members who are not full-time Federal employees are eligible for compensation, consistent with applicable PCORI policies and procedures. The amount of compensation shall be set by PCORI’s Executive Director, based on the nature and amount of services to be provided and consistent with applicable PCORI policies and procedures.

Travel and other expenses incurred during the conduct of PCORI business will be paid for by the Institute only if the expenses are reasonable and they comply with PCORI’s policies and procedures.

All payments will be made to individual panel members and not to employers, organizations, or third parties. Individuals serving on an advisory panel or subcommittee may decline compensation or reimbursement of expenses at their discretion.

Conflict of Interest
All CTA Panel members and CTA Subcommittee members shall abide by the Institute’s Conflict of Interest Policies. Members will be asked to disclose any potential conflicts upon joining the CTA Panel or CTA Subcommittee. The Institute’s Executive Director or designee shall be responsible for identifying
conflicts and determining what actions would be necessary to ensure that a panelist does not participate in matters in which such a conflict would or could exist.

In general, appointment to the CTA Panel will not lead to ineligibility for funding because all meetings will be public; members will not have access to confidential, nonpublic information; and panelists will provide input, but will not be responsible for final decisions.

Termination Date
This charter will remain in effect for one year beginning on the day of the first CTA Panel meeting. This charter will be reviewed on an annual basis. Amendments as needed may be made by the Board.