



Charter of the Advisory Panel on Clinical Trials

Purpose

The Advisory Panel on Clinical Trials (CTAP) 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 CTAP will not serve in an official decision-making capacity, but its recommendations and advice will be taken into consideration by the Institute's Board of Governors, Methodology Committee, and staff.

PCORI's Chief Science Officer or his or her designee will support and oversee CTAP activities.

Authority

PCORI's Advisory Panels are governed by the provisions of Public Law 111-148, which sets forth standards for the formation and use of Advisory Panels.

PCORI's authorizing legislation allows the Institute to appoint permanent or ad hoc expert Advisory Panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda. Based on explicit directives in the law, PCORI has appointed this permanent expert Advisory Panel for Clinical Trials and an expert Advisory Panel on Rare Disease. Furthermore, PCORI appoints other permanent and ad hoc expert Advisory Panels when there is a demonstrated need.

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 CTAP and CTAP 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 CTAP 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 15 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 10-15 members, the Board may appoint up to two members of the Methodology Committee, ex officio.

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.

The members of the CTAP will be appointed to staggered three-year terms, with a goal of having a balanced number of CTAP members appointed each year and a diverse spread of members. To implement staggered three-year terms, the CTAP members shall be divided into three (3) groups such that the members in each group will serve the term assigned to that group, which shall be, respectively, terms of 1 (one), 2 (two), and 3 (three) year-terms. CTAP members will not serve more than one full three-year term. Panel participation will not be extended beyond the life of the CTAP's complete work and charter. Any member may resign at any time by giving written notice to the Chair of the CTAP. Vacancies will be filled at the discretion of PCORI's Executive Director. Any panel member who is appointed to fill a vacant position shall serve for the remainder of the term of the vacated position, if any, to retain the staggered-term structure for the CTAP.

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

CTAP Subcommittees

The Chair of the CTAP and the Chair of the Methodology Committee may appoint CTAP Subcommittee(s) to examine specialized issues, specific clinical trials, and/or specific technical advice as described in this Charter of the Advisory Panel on Clinical Trials

charter, and to facilitate activities related to the purpose and scope of the CTAP. 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 CTAP Subcommittee will work with PCORI program staff to enhance the chosen designs to ensure that they are consistent with the standards generated by the Methodology Committee.

Membership of the CTAP Subcommittees may be drawn from members of the CTAP as well as other individuals with appropriate expertise. CTAP Subcommittees will have a defined scope of work, and members will be appointed for the duration of the scope of work. CTAP Subcommittees will work collaboratively with the CTAP and Methodology Committee. To the extent requested, CTAP Subcommittees will provide reports to the CTAP, Methodology Committee, Board, and PCORI staff.

Panelist Applications and Selection

PCORI will initiate an open call for applications via the PCORI Web site and other modes of communication when it is seeking members for an Advisory Panel. Prospective panelists are invited to submit an application via an online portal to be considered for a position on the CTAP.

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.

The application review and panelist selection process for the CTAP 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.

The Institute's Board of Governors will have final approval of the CTAP's membership roster.

Meetings

Meetings of the CTAP 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 CTAP 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.

CTAP subcommittee meetings will typically be closed to the public as they will mostly address confidential information.

Meetings of the full panel will be called by the Chair with the agreement and consent of the Chief Science Officer (CSO) or the CSO's designee, who shall develop and approve the agenda and be present at all meetings. Notice of all meetings shall be given to the public at least three business days before the meeting is set to occur.

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

Compensation, Travel, and Expenses

CTAP members and CTAP 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 CTAP members and CTAP Subcommittee members shall abide by the Institute's Conflict of Interest Policies. Members will be asked to disclose any potential conflicts upon joining the CTAP or CTAP Subcommittee. Each panelist shall work with the Institute's Executive Director or designee to identify conflicts to consider appropriate actions so that a panelist does not participate in matters when a conflict exists.

In general, appointment to the CTAP will not lead to ineligibility for funding because 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 until terminated by the Board of Governors. It is subject to review, amendment, or termination by the Board of Governors. This charter will be reviewed on an annual basis.

History:

Approved by the PCORI Board of Governors 11/18/2013

Amended and approved by the PCORI Board of Governors 4/21/2015

Amended and approved by the PCORI Board of Governors 6/20/2017