



Charter of the Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options

Purpose

The Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options (“APDTO Panel”) will advise and provide recommendations to PCORI’s Board of Governors, Methodology Committee, and staff to help plan, develop, implement, improve, and refine efforts toward meaningful patient-centered research. The APDTO Panel 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.

Members of the APDTO Panel will:

- Identify and prioritize critical research questions for possible funding under PCORI’s research priority assessment of the comparative effectiveness of alternative strategies for prevention, treatment, screening, diagnosis, and management of diseases; and
- Provide ongoing feedback and advice on evaluating and disseminating the research conducted under this priority.

The designated individual tasked with overseeing the APDTO Panel’s activities is the Scientific Program Director for APDTO or the individual designated by PCORI’s Chief Science Officer.

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 by PCORI.

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 a permanent expert Advisory Panel for Clinical Trials and a permanent expert Advisory Panel on rare diseases. Furthermore, PCORI appoints other permanent and ad hoc expert Advisory Panels when there is a demonstrated need.

Function and Scope of Work

Comparative clinical effectiveness research (CER) compares the effectiveness and safety of preventive, diagnostic, and treatment options to create a foundation of information for personalized decision making. This research places emphasis on: the practical utility of the

comparisons; the examination of all outcomes that may be important to patients; and the possible differences in outcomes across patient subgroups, both in terms of outcomes and preferences.

The APDTO Panel will:

- Identify and prioritize comparative research topics;
- Provide feedback to PCORI on specific research questions and study design relating to APDTO;
- Review and comment periodically on PCORI's research portfolio, including the identification of gaps in the portfolio, and the overall impact of the portfolio;
- Provide input on possible refinements to PCORI's research priorities;
- Consider study findings and advise on targets and strategies for PCORI dissemination efforts; and
- As needed, advise PCORI on potential refinements to its identified research priorities.

Composition and Structure

PCORI aims to involve patients, caregivers, clinicians, other stakeholders, and the organizations representing these stakeholders in a partnership of shared accountability for PCORI's research priorities and research agenda. Membership on the APDTO Panel will allow for meaningful interactions amongst individuals with different strengths, backgrounds, and areas of expertise.

The APDTO Panel will consist of 12 to 21 members appointed by the PCORI Board of Governors. No fewer than 25 percent of APDTO Panel members will be selected from persons who are patients, caregivers, or representatives of patient advocacy organizations. The remainder will include representation by clinicians and clinician organizations, organizational providers, employers, health insurance plans, the life sciences industry, policy makers, and clinical researchers.

A Chair (and a Co---chair if desired) will be selected by the Institute's Board of Governors to facilitate the APDTO Panel's activities in conjunction with the Institute's designated Scientific Program Director. The Chair may assemble subcommittees composed of APDTO Panel members to examine special issues and to facilitate activities related to the scope of work described in this charter.

Members will serve three-year terms. Terms shall be staggered with a goal of having a balanced number of members appointed each year and a diverse spread of members. To implement staggered terms, initially some members will be appointed for a one-year term, some for a two-year term, and some for a three-year term. Members will not serve more than one full three-year term. Panel participation will not be extended beyond the life of the APDTO Panel's complete work and charter. Any member may resign at any time by giving written notice to the chairperson of the APDTO Panel. Vacancies will be filled at the discretion of PCORI's Executive Director.

Management and support services will be provided by PCORI staff and contractors.

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 APDTO Panel.

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 APDTO 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.

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

Meetings

Meetings 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.

Meetings of the full panel will be called by the Chair with the agreement and consent of the designated Scientific Program Director, 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 an advisory panel shall constitute a quorum, and a roll call must be taken at the beginning of each meeting. In accordance with the APDTO Panel's advisory role, all votes and recommendations are nonbinding to the Institute.

Compensation, Travel, and Expenses

Members who are not full-time Federal employees are eligible for compensation. 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 may decline compensation or reimbursement of expenses at their discretion.

Conflict of Interest

All APDTO Panel members shall abide by the Institute's Conflict of Interest Policy. Members will be asked to disclose any potential conflicts upon joining the APDTO Panel. Each panel member 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 APTDO Advisory 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 until terminated by the Board of Governors. It is subject to review, reauthorization, amendment, or termination by the Board of Governors or its designee. This charter will be reviewed on an annual basis.

History:

Approved by the PCORI Board of Governors 4/1/2013

Amended and Approved by PCORI Board of Governors 5/6/2013

Amended and Approved by PCORI Board of Governors 12/3/2013

Amended and approved by PCORI Board of Governors 4/26/2016