



Framework of the CTTI/FDA Patient Engagement Collaborative

1 Scope

The Patient Engagement Collaborative (PEC) is an ongoing, collaborative forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at the U.S. Food and Drug Administration (FDA).

The PEC is a joint endeavor between Clinical Trials Transformation Initiative (CTTI), a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials, and FDA. The PEC is hosted by CTTI.

The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization.

2 Rationale

FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The Food and Drug Administration Safety and Innovation Act (FDASIA), section 1137, entitled "Patient Participation in Medical Product Discussions", added section 589C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c). This provision "directs the Secretary of Health and Human Services to: develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions." On November 4, 2014, FDA issued a Federal Register notice establishing a docket ([FDA-2014-N-1698](#)) for public commenters to submit information related to FDA's implementation of this provision. Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers.

3 Activities

The activities of the PEC may include, but are not limited to, the following:

- Serving as a forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at FDA.
- Conducting meetings on topics identified by the PEC, examples of which may include, but are not limited to, systematic patient engagement, transparency and communication, and clarification of FDA policies.
- Facilitating collection of information from patients and advocates.
- Providing considerations for implementing new strategies to enhance patient engagement at FDA.

- Proposing new models of collaboration in which patients and patient advocates are partners in aspects of the medical product development and review process.
- Assisting with relevant outreach to educate and increase awareness among the patient community about clinical trials and medical product development, including providing suggestions on appropriate methods.

4 Composition

The PEC includes as members up to sixteen (16) diverse representatives of the patient community. Designated individuals from FDA and CTTI also participate with the PEC.

Patient community representatives are selected through an open application process, coordinated by CTTI and FDA, to facilitate a broad range of perspectives and experiences. Selected members may include patients with personal disease experience; caregivers who support patients, such as parents, children, or other family members; and representatives from patient groups. The ultimate goal of the application process is to identify individuals who can represent a collective patient voice for their constituency.

To help ensure continuity in its activities and organizational knowledge, the PEC maintains staggered membership terms for patient community representatives. Membership terms are determined during the process of selecting members. Members may serve up to two terms, with the possibility of extensions.

The PEC is led by two Co-Chairs:

- FDA Co-Chair.
- Patient Community Co-Chair.

The Patient Community Co-Chair is selected from among the PEC patient community representatives. To encourage diversity of perspectives, a new Patient Community Co-Chair is selected every two years (or as needed to fill the role). Individuals may serve in the Patient Community Co-Chair role for a maximum of two years.

5 Responsibilities and Rules of Procedure

The Co-Chairs ensure that the activities of the PEC are conducted in an efficient and effective manner. Their responsibilities include the following:

- Coordinating with CTTI to plan the activities of the PEC, which should include ongoing discussion of goals, effectiveness, and membership.
- Together with CTTI, preparing an annual work plan that identifies the planned meeting schedule, topics, and activities for the year ahead.
- Co-leading all meetings of the PEC, ensuring that the Rules of Procedure are followed.
- Eliciting a wide range of perspectives on issues discussed by the PEC, by seeking the individual views of participants. The PEC is not expected to reach consensus by voting or other mechanisms on issues discussed.
- Ensuring PEC activities continue to enhance the patient voice in medical product development and regulatory decision-making.

Both Co-Chairs attend and lead the meetings of the PEC. However, meetings can be led by a single Co-Chair when necessary, and by agreement of both Co-Chairs.

The FDA Co-Chair (or designee) is a liaison to FDA. Responsibilities may include reporting the activities and outputs of the PEC to FDA leadership, engaging individuals at FDA to participate in PEC activities, and reporting back to the PEC on feedback from FDA.

The Co-Chairs ensure compliance with the following Rules of Procedure in organizing and reporting meetings of the PEC:

- Meetings of the PEC are typically held quarterly, either in-person (in the Washington D.C. area) or by webinar, as determined by agreement between the Co-Chairs, CTTI, and FDA. Additional meetings may be organized as needed.
- A draft agenda should be distributed to all PEC members in advance of each meeting.
- Outside experts and observers may be invited to meetings of the PEC; however, all such invitations must first be approved by the Co-Chairs.
- PEC discussions emphasize information exchange between patient community representatives and FDA on areas of common interest. No confidential commercial information is discussed.
- Participants in all PEC discussions—whether members, observers, or outside experts—are expected to disclose potential conflicts of interest.
- Meeting agendas, minutes, and meeting-related materials are provided to FDA and CTTI, and made public.

CTTI has final responsibility for determining the annual work plan, and provides the necessary administrative support to the Co-Chairs to carry out their responsibilities.

PEC members are expected to conduct themselves within the norms of professional behavior. In all cases, continued membership in the PEC requires constructive participation in, and regular attendance at, PEC meetings.

When discussing the activities of the PEC, members must make clear that any views expressed are their own.

6 Revising the Framework

This Framework is established with the understanding that it will require review and revision as the PEC and the broader research enterprise continue to evolve. Suggestions for future iterations of the Framework are invited from all current and former members, and should be directed to the Co-Chairs.