



Patient Engagement Collaborative

Framework of the FDA/CTTI Patient Engagement Collaborative

1 Background and Purpose

Federal agencies, like the U.S. Food and Drug Administration (FDA) get their ability to regulate from laws (statutes) passed by Congress. The FDA is responsible for taking care of public health by reviewing the safety, effectiveness, and quality of human and veterinary drugs (drugs for animals), biological products (such as vaccines), and medical devices (such as blood glucose monitors) and making sure our nation's food supply, cosmetics, and products that give off radiation (such as X-Ray machines) are safe. In addition, the FDA helps the public get the correct, science-based information they need to use medical products and foods to continue to improve their health.

Founded by Duke University and the FDA in 2007, the Clinical Trials Transformation Initiative (CTTI) is a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. CTTI uniquely fosters an open forum for all stakeholders – from academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups – to come together as equals and work on challenges and opportunities in the clinical trials space. Uniting leaders, pioneers, and change agents across more than 500 organizations and approximately 80 member organizations, CTTI seeks to exchange ideas, build consensus, and develop solutions that can be used to drive real and positive change in clinical trials.

The Patient Engagement Collaborative (PEC) started in 2018 and is a joint project between the FDA and CTTI. The PEC is an ongoing, shared setting in which the patient community (PEC members), FDA, and CTTI discuss many topics for improving communication, education, and patient engagement related to medical product regulation.

The activities of the PEC may guide some FDA and CTTI activities. The PEC is not intended to advise or direct the activities of either organization. PEC meetings are not directly related to regulatory policy decisions and are non-committal. The PEC does not discuss specific medical products or treatments during PEC meetings and tries to avoid topics that are not part of FDA's authority, such as patient concerns about insurance coverage and medical costs. Please refer to ["About FDA: Patient Q&A"](#) to better understand what FDA does and what it regulates.

2 Rationale

For many years, the FDA and CTTI have included patients and patient points of view in their work. The PEC is a chance for the patient community to discuss and exchange views and perspectives (ideas and experiences). The PEC is not considered an [FDA advisory committee](#) and does not discuss specific medical products, investigational medical products, private company information, or regulations under review by the FDA.

The [Food and Drug Administration Safety and Innovation Act \(FDASIA\), section 1137](#), entitled “Patient Participation in Medical Product Discussions,” recognized the value of “...develop[ing] and implement[ing] strategies to solicit the views of patients during the medical product development process and consider[ing] the perspectives of patients during regulatory discussions...”

In 2014, the FDA asked for public comments ([FDA-2014-N-1698](#)) to gather information about how the FDA would carry out this project. After reviewing of the comments collected, many suggested creating an outside group (non-FDA staff) to provide ideas on possible forms of patient engagement across the FDA’s Centers. The member application process began in 2017, and the first PEC member meeting was held in 2018.

3 Activities

The PEC serves as a shared setting in which the patient community, FDA, and CTTI discuss a range of topics for enhancing communication, education, and patient engagement related to medical product regulation. The activities of the PEC may include, but are not limited to, the following:

Communication and Education

- Assist sorting out topics of shared interest to the PEC, CTTI, and the FDA
 - Examples may include, but are not limited to, clear ways for patients to engage, communicate, and understand FDA policies.
- Identify possible needs for communication tools and educational resources for patient communities (patients, caregivers and advocates)
- Contribute to the development of communication tools and educational resources, such as patient focused webpages, background information on the role of the FDA, etc.
- Increase awareness and take part in two-way education about medical product regulation in patient communities

Engagement

- Share information and experiences from patient communities on topics to inform patient engagement activities
- Explore new and creative ideas to enhance patient engagement
- Collaborate with the FDA/CTTI to inform their communities about public meetings and resources from the FDA/CTTI

4 Composition

The PEC is comprised of up to sixteen (16) wide-ranging representatives of the patient community, whose selection include, but are not limited to, sociodemographic factors (such as age, gender, ethnicity, education level, income) and disease experience.

Patient community representatives are selected through an application process, coordinated by the FDA and CTTI, 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 goal of the application process is to identify individuals who can represent a collective patient voice.

To avoid gaps in its activities and maintain group knowledge, the PEC maintains overlapping membership terms, rotating 8 members in/out annually. Membership terms are 2 years, with the possibility of extra time should that be necessary for project completion. Members may serve up to two terms.

5 Roles and Responsibilities

FDA and CTTI

The FDA and CTTI coordinate with PEC members to make sure the activities of the PEC are conducted in an organized and helpful process, including:

- Planning the activities of the PEC, which should include ongoing discussions of goals and values of membership
- Identifying important topics for upcoming discussions
- Obtaining a wide range of perspectives on issues discussed by the PEC by seeking the individual views of participants
- Ensuring PEC activities continue to promote and enhance the patient voice at FDA and CTTI
- Reporting the activities and outputs of the PEC to FDA and CTTI leadership
- Engaging appropriate individuals at the FDA and CTTI to participate in PEC activities
- Communicating FDA and CTTI feedback to the PEC members

PEC Members

PEC member information is publicly available on the [CTTI website](#). PEC members are encouraged to discuss ideas or concerns with their patient communities and communicate appropriate suggestions or ideas to the FDA and CTTI related to PEC activities (as described above).

PEC members are not expected to reach group agreement on issues discussed by voting or other similar procedures. PEC members are expected to:

- Conduct themselves in a professional way – in all cases, continued membership in the PEC requires helpful participation in, and regular attendance at, PEC meetings
- Share ideas and be respectful of the ideas and thoughts of other members

When discussing the activities of the PEC in non-PEC meetings (e.g., conferences or panels), members:

- must clearly state that any views expressed are their own
- can mention that they are a member of the PEC (e.g., presentations, bios, CVs, social media)
- cannot speak on behalf of the FDA or CTTI about PEC activities (many PEC activities are non-public)
- can speak about completed PEC projects which are already available to the public

6 Rules of Procedure

The FDA and CTTI will make sure the following Rules of Procedure are followed:

- Working meetings of the PEC are typically held virtually (teleconference or webinar) up to six times per year. Meetings may occur in person (in the Washington D.C. area) when determined necessary by the FDA and CTTI. Additional meetings may be organized as needed. Any needed adjustments and adaptations will be made for members with special needs to participate in a meeting.
- A draft agenda should be sent to all PEC members in advance of each meeting.

- From time to time, the FDA and CTTI may invite experts and observers to PEC meetings to make sure necessary stakeholders are informed. PEC discussions focus on information exchange between patient community representatives and the FDA on areas of common interest. No private medical company product information is discussed.
- Participants in all PEC discussions – whether members, observers, or outside experts – are expected to disclose potential conflicts of interest as they arise.
- High-level meeting summaries are available on the FDA and CTTI websites.

7 Revising the Framework

This Framework may require revisions as PEC membership, activities, procedures, and responsibilities might change over time. Current and former PEC members may make suggestions for future PEC Framework revisions.