FDA and CTTI Patient Engagement Collaborative Meeting

Apr. 24, 2025 | 1 – 3 pm ET | Zoom Virtual Meeting

Disclaimer: *The purpose of this meeting was to facilitate a discussion of ideas, and as such, not all of the content below will be within the scope of the FDA or PEC. The views and opinions expressed in this meeting are those of the individual speakers and participants and do not necessarily reflect the official views of their organizations, the FDA, or CTTI.*

Meeting Overview

The purpose of this virtual meeting was to review the FDA's MedWatch Adverse Event Reporting Program and the CTTI Collaborative Engagement in Clinical Trial Design project. During the meeting, PEC members were asked to give their insights and perspectives on effective patient and caregiver engagement in clinical trial design.

MedWatch Adverse Event Reporting Program

- MedWatch enables public reporting of adverse events related to FDA-regulated products, including prescription drugs, over-the-counter medicines, biologics, medical devices, combination products, and cosmetics.
- Reports can be submitted by health care professionals, patients and consumers, highlighting serious events (e.g., deaths, prolonged hospitalizations, birth defects), medication errors, product quality issues, and potential errors and non-serious events.
- Once submitted, reports are reviewed by FDA safety evaluators, who analyze and compare them to identify safety signals, which may lead to safety alerts and public communications to inform consumers, patients and health care professionals.

Collaborative Engagement in Trial Design

- CTTI's Collaborative Engagement in Trial Design project aligns with the third pillar of the Transforming Trials 2030 vision that focuses on designing clinical trials using a quality approach.
- The project aims to develop a roadmap to help study designers engage all collaborative partners early and often, improving the overall quality of trial design and reducing errors in trial protocols.

- Six collaborative partner groups were identified for an Engagement Roadmap: patients and caregivers, investigators and sites, regulators, institutional review boards, tech/device/data companies, and payers.

Discussion:

- *PEC meeting attendees gave the following suggestions regarding effective strategies for engaging patients and caregivers in trial design:*
    - Partner with patient advocacy organizations
    - Engage patient communities as early as possible
    - Bring on patients who are professionals in clinical trials or patient advocacy to act as paid consultants throughout each trial design phase
    - Invest in education and awareness programs for patients in underrepresented groups who may not be otherwise empowered to get involved with trials

Conclusion and Next Steps

The FDA and CTTI will review the discussion points and ideas generated during this virtual meeting. The FDA will share comments from this meeting with agency departments to facilitate engagement with patient communities and PEC members. The fifth annual joint meeting between the PEC and the European Medicines Agency's (EMA) Patients' and Consumers' Working Party will be held on June 12, 2025.

The PEC is a public-private partnership between the FDA and the Clinical Trials Transformation Initiative (CTTI) that is not intended to advise or direct the activities of either organization. The PEC is primarily a forum to facilitate the exchange of information between patient community representatives and the FDA on areas of common interest, including regulatory discussions and strategies to increase patient engagement. Public summaries of all PEC meetings are available on the PEC website.