FDA and CTTI Patient Engagement Collaborative (PEC) Meeting
February 23, 2023 | 12:30 – 2:30 pm ET

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 discuss revisions to the PEC Framework, share ideas for potential educational webinars for patient communities and PEC members, and review CTTI’s ongoing and completed projects.

Updating the PEC Framework
- Since the PEC Framework was written before the PEC was established in 2017, the FDA and CTTI are revising the document. The revised framework will be written in plain language and reflect the current purpose of the PEC.

- Major focus areas for revisions are:
  o Communication and Education;
  o Patient Engagement Activities; and
  o Roles and Responsibilities of the FDA, CTTI, and PEC members.

Discussion
- Meeting attendees gave the following suggestions for PEC Communication, Education, and Engagement Activities:
  o Record a video for the FDA website of patients, PEC members, and FDA staff discussing how patients, caregivers and advocates can get engaged with FDA activities
  o Host panels at conferences with FDA staff and patients to talk about patient perspectives

FDA Patient Engagement Brainstorming
*The FDA would like to hold a few educational public webinars for patients and asked PEC members to suggest topics that would be of interest to a general patient audience.*

A few of the topics suggested include:
- Understanding Patient-Focused Drug Development (PFDD) guidance
• Introduction to the various ways to interact with the FDA
• How to comment on open FDA public dockets
• What kind of patient feedback would be helpful on pending guidance and regulations
• Where on the FDA website to find information on diseases or specialty areas that patient communities can use

*The FDA also wants to organize a few internal educational sessions for PEC members and asked them to suggest topics that would be of interest.*

A few of the topics suggested include:

• Understanding “Right to Try” and “Expanded Access” (Compassionate Use)
• Learn more about Patient-Focused Drug Development (PFDD) guidance to patient advocates
• Introduction to FDA regulation of diagnostic tools and medical devices

**CTTI Topics of Interest**

• CTTI topics are selected by member organizations, requested by the FDA, or recommended by the executive committee or executive director (EC/ED).
• All CTTI projects include patient representatives as equal team members.
• Examples of CTTI projects include Quality by Design, Diversity in Clinical Trials, Digital Health Trials Hub, Novel Trial Designs, Patient Engagement, and Transforming Trials 2030.

**Discussion**

• Meeting attendees highlighted the importance of involving patients in clinical trial design and conduct in order to reduce participant dropout and save resources and money.
• All CTTI resources are free and publicly available on the CTTI website.

**Conclusion and Next Steps**

The FDA and CTTI will review the discussion points and ideas generated during this meeting. The FDA will share comments from this meeting with agency departments to facilitate engagement with patient communities and PEC members.

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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](https://www.pec.gov).