FDA and CTTI Patient Engagement Collaborative (PEC) Meeting
April 28, 2022 | 1:00pm – 4:00pm ET

Disclaimer: This 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 facilitate open brainstorming and discussion identifying opportunities for the PEC to assist the U.S. Food & Drug Administration (FDA) in improving patient-facing communications. This meeting included a discussion about critical issues for patient engagement identified at the previous PEC meeting held on January 27, 2022.

Discussion Themes
- Clarifying the role and scope of the PEC and FDA
- Generating ideas for an interactive FDA patient engagement decision tool
- Creating patient-friendly communications about the FDA review process and other strategies to reach those who are not involved in patient advocacy groups

Group Discussion: PEC Scope of Impact
- The discussion centered around clarifying some of the patient engagement issues brought up during the January 27, 2022, meeting that fall outside of the PEC’s scope of impact.

Group Discussion: FDA Patient Engagement Decision Tool
The PEC members previously suggested creating an interactive patient engagement decision tool to help patients, caregivers, and advocates determine the best way to engage with the FDA. Some ideas include:
- simplifying the tool’s language,
- providing direct links to relevant FDA resources, and
- including more options and descriptions for each outcome based on participants’ interest and willingness to engage.

Group Discussion: Enhancing Communications
The PEC is uniquely positioned to assist the FDA in improving their communications with patients and patient groups. Some of these areas include:
- Patient-friendly Resources on the FDA review process, informing patient groups about how the FDA operates and how patient groups can engage
- **Communication Strategies** to reach patients who are not involved in patient advocacy groups, including minority patients and those without access to specialist doctors
- **Education of Patients/Patient Groups** about ways they can provide feedback to the FDA about the patient experience

**Conclusion and Next Steps**

The FDA and CTTI will review the discussion points and ideas generated during this meeting. The second annual joint meeting between the PEC and the European Medicines Agency’s (EMA) Patients and Consumers Working Party (PCWP) will be held on July 15th.

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, including the last PEC-PCWP Joint Meeting in 2021, are available on the PEC website.