Patient Engagement Collaborative (PEC) Meeting Summary

April 29, 2020 | 12:00 – 3:30pm ET

OVERVIEW

This virtual meeting built upon prior Patient Engagement Collaborative (PEC) discussions of a potential patient outreach program to introduce patient engagement activities and opportunities at FDA. The meeting focused on brainstorming and outlining educational resources that could be developed to support a patient outreach pilot program, including:

- FDA 101: Myth vs. Fact
- Summary of Engagement Opportunities for Patients at FDA
- Medical Product Approval Overview

The PEC also spoke about other useful resources such as case studies. The case studies could be developed to highlight how patients engage with FDA and what the impact is.

DISCUSSION THEMES

- Frame educational resources from the patient perspective, addressing questions, concerns, and interests that patients have.
- Keep it simple: Too much detail is off-putting.
- Use visuals to convey the most important information.
- Maintain a patient-friendly voice and plain language.
- Emphasize why the information matters to patients, and why the patient role matters in the clinical research process.
- Ensure that minorities and vulnerable groups have the chance to be involved, and that the needs of underrepresented populations are understood and addressed.

CONCLUSION AND NEXT STEPS

PEC member's ideas, insights and information shared during this meeting will help inform ongoing efforts by FDA's Patient Affairs Staff (PAS) to develop educational resources for a pilot program. This program is envisioned as an approach to:

- Support two-way communication between patients and the FDA;
- Educate patient communities about FDA's activities; and
- Inform patients and caregivers about how they can provide their experiences and perspectives to enhance and strengthen FDA's public health work.

DISCLAIMER

The views expressed in this meeting summary represent the individual perspectives of the attendees and do not necessarily represent the official views of the FDA or CTTI or of any organization with which the attendees are affiliated. Discussions and responses are not intended to establish binding agreements pertaining to medical product development programs or to discuss proprietary information pertaining to specific development programs under FDA review.