FDA and CTTI Patient Engagement Collaborative (PEC) Meeting

September 14, 2023 | 12:30 – 2:30 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 discuss the FDA's Guidance Snapshot Pilot program and Guidance Recap Podcast, including their newest Patient Guidance Snapshot that covers FDA's guidelines for enhancing diversity in clinical trials. This meeting also included a discussion of CTTI's Diversity project that recently developed a set of recommendations along with a maturity model tool for organizations to track the development of their diversity infrastructure.

FDA Guidance Snapshots & Podcast Overview

- The FDA launched the Guidance Snapshot Pilot program and the Guidance Recap Podcast initiative in 2020. Guidance Snapshots are a communication tool that provide highlights from guidance documents using visuals and plain language tailored to a specific audience. The podcasts provide background information about the development of the guidance through interviews with FDA subject-matter experts. This pilot program is intended to increase general public awareness and engagement for FDA guidance documents.

- To support patient education and engagement in medical product development, the FDA further expanded this initiative, by publishing the first Patient Guidance Snapshot and podcast on FDA's final guidance, *Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs* (November 2020), in May 2023. The snapshot and the podcast explain why the guidance is important for patients, describe the FDA's recommendations for enhancing diversity in clinical trials, and explain how sponsors may implement FDA's recommendations.

Discussion

- *PEC meeting attendees gave the following suggestions regarding the FDA's Patient Guidance Snapshot program:*
    - *Add a background section outlining the purpose and scope of FDA guidance documents.*

- *Consider plain language to address the needs of patients with less formal education.*
- *Consider how these resources will be distributed to patients without internet access and those who can't read English – printing materials, providing printed transcripts, translating to various languages, and engaging local and national patient groups are some possible strategies.*

CTTI Diversity Recommendations

- CTTI's Increasing Diversity in Clinical Trials project aligns with their Transforming Trials 2030 vision (TT2030) – specifically the pillars related to making trials patient-centered & easily accessible and designed with a quality approach.
- CTTI's Diversity recommendations focus on organizational-level strategies that create sustainable support for clinical trial diversity, equitable access, and inclusion through commitment, resources, accountability, and partnerships.
- The Diversity Maturity Model focuses on eight elements of organizational-level infrastructure for improving equitable access to, and diverse participation in, clinical trials. These elements align with the Diversity recommendation's key themes, including:
  - **Commitment** of leadership and culture.
  - Bi-directional community **partnerships** and patient/patient group **partnerships**.
  - Commitment of **resources** through dedicated personnel and sufficient investments.
  - **Accountability** through data-driven strategies and continuous improvement.

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. The next PEC meeting will be held on November 9.

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.