FDA and CTTI Patient Engagement Collaborative Meeting

Nov. 20, 2025 | 1 pm – 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 meeting was to discuss CTTI's "Reimagining Trial Participation: Patients as Consumers" model. During the meeting, PEC members were also asked to give their perspectives on the use of generative AI in clinical trials.

Reimagining Trial Participation: Patients as Consumers

Members of the PEC discussed CTTI's "Reimagining Trial Participation: Patients as Consumers" model and gave their perspectives on which portion of the model CTTI could address:

- **Patient-Centric Approach:** CTTI's Reimagining Clinical Trials project created a framework for approaching clinical trial patient engagement through the lens of consumer marketing, shifting from a researcher-focused model to one centered on patient needs, motivations, and long-term engagement.

- **Segmented Engagement:** The proposed framework segments patients into four distinct groups, each requiring tailored communication and engagement strategies.

- **Best Practice Repository:** PEC members suggested that CTTI could start by collecting and sharing effective practices and case studies from organizations succeeding at different stages of patient engagement.

- **Collaboration and Trusted Messengers:** PEC members emphasized the importance of building trust and fostering collaboration with patient leaders, healthcare professionals, and community health workers, especially in underserved communities. They also highlighted the importance of sustaining community engagement beyond direct trial recruitment efforts.

Generative AI in Clinical Trials: Exploring Patient Perspectives

Members of the PEC were asked to give their perspectives on the use of generative AI in clinical trials:

- **Data Accuracy, Bias, and Representation:** Patients are particularly worried about inaccuracies in the data used for AI algorithms, potential biases arising from underrepresentation of certain groups, and the perpetuation of health disparities.

- **Informed Consent Discussions:** Many patients fear that AI could reduce personal interaction with clinicians and lead to misunderstandings, especially if AI-generated explanations of informed consent documents are inaccurate or biased. Patients prefer clear, plain-language communication from researchers rather than relying on AI for critical trial information.

- **Potential Value of Generative AI Outside of Clinical Trials:** Patients see value in AI for improving diagnostics, revealing patterns in existing data, and identifying potential new treatments.

- **Responsibility and Oversight:** Participants raised important questions around liability, regulatory responsibility, acceptable error rates, and the risk of over-reliance on AI.

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. CTTI will send calendar invites for the 2026 PEC Meetings.

> 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](#).