

FDA and CTTI Patient Engagement Collaborative Meeting

Sept. 16, 2025 | 10 am – 3 pm ET | David M. Rubenstein Conference Center at Duke in D.C.

***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 bring members of the PEC together to reflect on the structure and format of the PEC. PEC members also provided feedback on designs for Rare Disease Day graphics and collaborated with the FDA to evaluate a web-based application, ensuring its functionality, usability, and performance was user-friendly. CTTI also gave an update on the “Re-Imagining Trial Participation” project.

Brainstorming Session: Patient Engagement Ideas & Strategies

Members of the PEC reflected on the structure and format of the PEC and considered new strategies for the FDA to more effectively engage PEC members going forward:

- **PEC’s Role and Structure Are Evolving:** The PEC’s current focus is on communication, education, and outreach. There is ongoing consideration of how the PEC’s structure and operations should adapt moving forward.
- **Training and Education Are Crucial:** Providing comprehensive introductory education for PEC members and patient advocates is essential for enabling more meaningful engagement and productive participation.
- **Expanding Participation and Building Trust:** Suggestions for the structure of the PEC include broadening the PEC’s membership model to allow wider participation while maintaining application process for PEC leadership roles, fostering trust with patient communities through collaborative initiatives and workshops jointly run by PEC and FDA, and shifting PEC meetings to a more interactive format with educational resources being shared before meetings.
- **Collaboration and Special Interest Groups:** Engaging academic institutions and health professionals and creating special interest groups within the PEC could help address specific issues.

CTTI Project: Reimagining Clinical Trials

CTTI gave an update on their Reimagining Clinical Trials project, outlining the key barriers to clinical trial participation, proposed solutions, and potential next steps for the project team:

- **Patient-Centric Approach:** This project aims to reimagine clinical trials as a consumer experience by actively involving patients and communities in trial design, emphasizing patient learning, partnership, and tangible value for participants.
- **Barriers to Participation:** Key challenges to trial participation include lack of awareness, mistrust, complex language, financial toxicity, strict eligibility criteria, and insufficient physician engagement. Addressing these requires improved communication, education, and engagement strategies.
- **Strategies for Improvement:** Potential areas of focus for this project going forward include co-creating training guides for researchers, developing patient experience scoring models, conducting sponsor surveys to better understand financial challenges, and designing pilot programs for non-monetary incentives to trial participation.

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. The next PEC member meeting will be held on November 20, 2025.

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](#).