

FDA and CTTI Patient Engagement Collaborative (PEC) Meeting

February 13, 2024 | 2:00 – 4:00 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 role of the Center of Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) at the FDA and opportunities for patient engagement with OTP. The meeting also included an activity to understand Patient Engagement Collaborative (PEC) members' current familiarity with CBER, OTP, and regenerative medicine therapies – including gene therapies and cellular therapies.

CBER OTP: Patient Engagement Activities and Opportunities

- The Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) regulates biological products such as vaccines, blood products, tissues, gene therapies, and cellular therapies.
- CBER OTP regulates regenerative medicine therapies (RMTs) that aim to restore or replace damaged or diseased cells, tissues, or organs by using gene editing, biological or bioengineered materials.
- CBER OTP engages with patients and patient advocates through various activities and opportunities, such as public workshops and patient listening sessions.
- PEC members can help OTP refine their resources and events surrounding gene editing and other RMTs by sharing their insights and interests, suggesting topics for future [RegenMedEd](#) webinars, and assessing new website content.

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 meeting will be on April 11.

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](#).