FDA and CTTI Patient Engagement Collaborative Meeting

Sept. 12, 2024 | 2 – 3:30 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 review work the FDA has done around participant-centered informed consent and enhancing clinical trial diversity and equity. The meeting included discussions around the FDA's draft guidance for participant-centered informed consent approaches and the FDA Office of Minority Health and Health Equity's (OMHHE) Enhance Equity Initiative and Racial and Ethnic Minority Acceleration Consortium for Health Equity (REACH).

A Participant-Centric Approach to Informed Consent

- The FDA emphasizes a participant-centric approach to informed consent, ensuring that participants understand all elements of the consent and do not feel unduly influenced to consent to trial participation.
- March 2024 FDA draft guidance on "Key Information and Facilitating Understanding in Informed Consent" encourages presenting key information first and organizing the consent to facilitate understanding, including the use of simple text, straightforward design, and visual aids.

Discussion

- *PEC meeting attendees gave the following suggestions regarding the FDA's participant-centered approach to informed consent:*
    - *The term "participant-partnered" might be a better descriptor of this informed consent approach because participants and patient communities are directly engaged in designing the informed consent strategy.*
    - *There are cultural differences across communities that must be addressed in the informed consent process to ensure true understanding and voluntary participation.*

Advancing Health Equity: An Overview of the FDA Office of Minority Health and Health Equity

- OMHHE's mission is to promote and protect the health of diverse populations through research and communication that addresses health disparities.
- OMHHE's Enhance Equity Initiative highlights research projects and communications resources to enhance equity in clinical trials, equitable data efforts, and equity of voices.
- OMHHE's Enhance Equity Research Hub is a public-facing data repository that allows individuals to search for OMHHE-funded projects by race, ethnicity, enhance equity aim, disease or condition of interest, or age group.
- OMHHE launched the REACH Consortium to **timely and efficiently** help respond to health equity needs.

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 Nov. 14.

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.