



Contact: Laura Shannon, Communications Manager, CTTI
Email: laura.shannon@duke.edu

CTTI Selected to Support FDA Efforts to Increase Patient Engagement Through New Collaborative

New group will provide perspectives on new ways for patients and the FDA to work together

Durham, NC – Dec. 20, 2017 – Today the Clinical Trials Transformation Initiative (CTTI) is announcing it has been engaged by the U.S. Food and Drug Administration (FDA) to support its Patient Engagement Collaborative (PEC), an effort created in partnership with CTTI to bring together members of the patient community to discuss the best ways for patients to participate in the FDA’s regulatory discussions about medical products.

“Engaging patients as partners in the development of medical products is critical to the success of the clinical research enterprise, and CTTI is pleased to be hosting this new forum for patients and regulators to discuss and exchange ideas,” said Pamela Tenaerts, MD, MBA, CTTI Executive Director. “This is an important initiative that will benefit not only patients and regulators, but all stakeholders in the research enterprise.”

The Patient Engagement Collaborative is being created because of public feedback the FDA requested on Section 1137, Patient Participation in Medical Product Discussions, of the Food and Drug Administration Safety and Innovation Act (FDASIA). One suggestion was to create an outside group to give input on patient engagement across the FDA.

“The FDA is committed to expanding its efforts to engage patients in its regulatory decision-making processes and the new PEC will include a diverse group of representatives from outside the FDA who will help enhance the agency’s understanding of how to best engage across patient communities,” said Rachel E. Sherman, MD, MPH, FDA Principal Deputy Commissioner. “CTTI has a well-established network of patients and patient advocates, and we look forward to working with them in this important effort.”

The Patient Engagement Collaborative will bring 16 patients, caregivers, and patient group representatives together with the FDA several times a year to discuss topics such as communication, transparency, and new ways for patients and the FDA to work together. The new group will be hosted by CTTI, which has strong ties to the patient community.

Nominations to join the Patient Engagement Collaborative will be accepted until Jan. 29. [Learn more](#) about what is expected of members and how to apply in the Federal Register Notice.

About the Clinical Trials Transformation Initiative (CTTI)

The [Clinical Trials Transformation Initiative](#) (CTTI)—co-founded by Duke University and the U.S. Food and Drug Administration—is a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options. More information about CTTI and its projects is available at <http://www.ctti-clinicaltrials.org/>.

###