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

CTTI and the FDA Select Representatives for Patient Engagement Collaborative
New group will share ideas on innovative ways for patients and the FDA to work together in the regulatory decision-making process

Durham, NC – July 12, 2018 – The Clinical Trials Transformation Initiative (CTTI) and the U.S. Food and Drug Administration (FDA) announced newly selected representatives for the Patient Engagement Collaborative (PEC) today. The group of 16 patients, caregivers, and patient group representatives will meet with the FDA several times a year to discuss topics such as communication, transparency, and the best ways for patients to participate in the FDA's regulatory discussions about medical products.

The representatives are:

- Dawn Aldrich
- Ronald Bartek
- Karen Erickson
- Jeffrey Goldstein
- Anne Hall
- Melissa Hogan
- Elizabeth Joniak-Grant
- Nancy Lenfestey
- Isabelle Lousada
- Stephanie Monroe
- Lawrence "Rick" Phillips
- Philip Posner
- Lynne Quittell
- Adrienne Shapiro
- Theresa Strong
- Dave White

The representatives were selected from nearly 200 nominations received in response to a Federal Register notice published in December 2017. The selection committee, which included patient advocates and staff from CTTI and the FDA, worked to identify representatives with diverse perspectives and experiences who could meaningfully contribute and express the patient voice.

"We are excited to welcome these experts to the PEC and are confident that they will make a significant contribution to advancing patient engagement in research and development," said Pamela Tenaerts, CTTI executive director. "This group will play a critical role in ensuring that every step of medical product development accounts for patients' needs."

The PEC was created by the FDA and CTTI in December 2017 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,” said Andrea Furia-Helms, director, Patient Affairs Staff, Office of Medical Products and Tobacco, FDA. “This new diverse group of representatives will help enhance the agency’s understanding of how to best engage across patient communities.”

Since 2008, CTTI has included patient advocates on its Executive Committee, Steering Committee, and project teams and, today, nearly all of its 25 sets of recommendations mention inclusion of patients as a critical part of the clinical trials process.

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 www.ctti-clinicaltrials.org.

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