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CTTI Holds Special Event at the FDA to Launch Mobile Technologies Recommendations

New recommendations and resources address scientific and technical challenges, provide road map for using mobile technologies in clinical trials

Durham, N.C. – July 16, 2018 – In a special event at the U.S. Food and Drug Administration (FDA) today, the Clinical Trials Transformation Initiative (CTTI) will unveil recommendations for the use of mobile technologies in clinical research. The evidence-based recommendations and resources address an unmet need by outlining best practices for the use of mobile devices and applications to capture objective data—an approach that has the potential to increase the quality and efficiency of clinical trials.

“The clinical research community has long discussed an exciting future of using mobile technologies to collect objective, reliable data in clinical trials,” said Pamela Tenaerts, executive director at CTTI. “Today, we are excited to start making this vision a reality—sharing recommendations for capturing more informative real-world data from patients, reducing barriers to trial participation, and lowering costs associated with conducting clinical trials.”

During the daylong launch event, an impressive [lineup of more than 30 experts](#) will present the full set of recommendations and resources—including case examples and decision tools. These resources offer practical guidance for using mobile technologies in clinical trials, from selecting a technology at the beginning of a trial to preparing for FDA submission using data generated from the technology.

“The resources CTTI created offer sponsors and service providers valuable information to meet technical requirements, support collaborations, and understand each other’s needs and expectations,” said Owen Faris, clinical trials director in the Office of Device Evaluation at the FDA’s Center for Devices and Radiological Health. “CTTI’s recommendations will help complement FDA’s efforts to help to bridge a gap in the widespread adoption of mobile technologies for data capture in clinical trials.”

This is the second set of recommendations from CTTI’s [Mobile Clinical Trials Program for FDA-regulated trials](#). In 2017, CTTI announced recommendations for [developing novel endpoints generated by mobile technologies](#). Later this year, recommendations addressing patients’ and investigators’ needs regarding the use of mobile technologies in clinical trials and overcoming challenges to conducting decentralized trials in the U.S. will be released. CTTI’s work in this space is driving the evolution of the clinical trials enterprise to keep pace with technological innovations.

“To date, leveraging mobile technologies for data capture in clinical trials has been a daunting effort—mainly because much of the work is unprecedented,” said Seleen Ong, clinical sciences group lead for global product development at Pfizer. “With CTTI’s new recommendations, we now have a practical and user-friendly road map that has been jointly developed by regulators, sponsors, academic medical centers, technology companies, and other groups. We look forward to using this guidance to efficiently employ mobile technologies in clinical trials and pave the way for improving how we develop medicines.”

“The use of mobile technologies in clinical trials is a complex issue that requires multisector input in a comprehensive, systematic way—an approach ideally fitting for CTTI,” said Robert Califf, vice chancellor for health data science at Duke Health and adviser at Verily Life Sciences. “Their latest recommendations provide approaches for the enterprise to move forward with mobile technology innovations that will help improve data quality and reduce costs in clinical research.”

The launch will take place from 9:30 a.m. to 5:00 p.m. at the FDA’s White Oak Campus in Silver Spring, Md., and will [live stream](#) throughout the day. The event will culminate with an engaging panel discussion on the future of mobile technologies in clinical trials. Panelists include Francesca Cerreta of the European Medicines Agency; Ray Dorsey of the University of Rochester Medical Center; Pat Furlong of Parent Project Muscular Dystrophy; John Hubbard of Genstar Capital; and Leonard Sacks of the FDA.

About the Clinical Trials Transformation Initiative (CTTI)

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations—representing academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups—CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Many regulatory agencies and organizations have applied CTTI’s nearly 20 existing recommendations, and associated resources, to make better clinical trials a reality. Learn more about CTTI projects, recommendations, and resources at www.ctti-clinicaltrials.org.

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