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PRESS RELEASE

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CTTI Seeks to Speed Use of Mobile Technology in Clinical Trials through Novel Endpoint Recommendations

New CTTI Recommendations and Tools Equip Stakeholders to Integrate Mobile Technology into Clinical Trials

Durham, NC - Mobile technologies hold enormous promise for clinical research, but uncertainty about how to use the data captured by these devices has slowed progress. Newly released [recommendations](#) and tools from the Clinical Trials Transformation Initiative (CTTI) aim to change this by providing a pathway for using information gathered from mobile technologies to accelerate the development and evaluation of urgently needed therapies.

Mobile technologies such as remote sensors and wearables can be used to make trials faster, more efficient, and more inclusive. They can also spare patients from burdensome clinic visits while capturing new kinds of data that offer a better picture of how patients experience their disease or condition in their daily lives.

"Technology-derived endpoints offer the benefit of capturing information about patients' experience in 'real-world' settings," said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research. "These tools have the potential to capture data that can be used to develop endpoints and evaluate therapies in the patient population."

Responding to this potential, CTTI experts have crafted a set of recommendations and tools designed to help diverse stakeholders identify and develop novel endpoints based on data from mobile technologies for use in regulatory clinical trials.

"By engaging with experts who have been early champions of mobile technology in trials and combining that with patient insights, CTTI has created practical recommendations and action-oriented tools that have the potential to really accelerate the use of mobile technology in clinical trials," noted Craig Lipset, Pfizer's head of clinical innovation. "In particular, the use cases provide a realistic pathway for incorporating novel endpoints through technology into clinical development programs. CTTI's recommendations show we may be closer than previously believed to realizing the benefits of these novel endpoints, creating a sense of urgency to act."

In partnership with a group of investigators, regulators, patient representatives, technology developers, and research sponsors, four use cases were written to better guide the development and use of novel endpoints as part of clinical trials for Parkinson's disease, heart failure, diabetes, and Duchenne muscular dystrophy.

“The Michael J. Fox Foundation was pleased to participate in CTTI’s efforts to develop novel mobile endpoints for use in clinical trials,” said Lauren Bataille, senior associate director of research partnerships at the Foundation. “We look forward to leveraging these assets to support Parkinson’s research collaborations and speed the developments of measures that matter to patients.”

CTTI’s Novel Endpoints recommendations are the first to be released as part of a larger body of work to address multiple challenges to using mobile technology in clinical trials. CTTI’s [Mobile Clinical Trials Program](#) includes additional projects on legal and regulatory considerations, stakeholder perceptions, and scientific and technical issues related to the use of mobile devices. Recommendations from these projects will follow over the next year.

Established by Duke University and the FDA as a public-private partnership in 2007, CTTI comprises over 80 member organizations working to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. More information about CTTI and its projects is available at www.ctti-clinicaltrials.org.

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