MEDIA RELEASE

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CTTI Releases Recommendations for Engaging Patients and Sites in Mobile Clinical Trials

New work aims to help sponsors, CROs, and other stakeholders consider sites and patients' insights in order to gain the full benefits of using mobile technologies in clinical research

Durham, N.C.—Feb. 21, 2019—During a public webinar today, the Clinical Trials Transformation Initiative (CTTI) will release new recommendations and resources for engaging patients and research sites when planning and conducting mobile clinical trials. By doing so, sponsors, contract research organizations, and other stakeholders can maximize the opportunities of mobile technologies to advance the development of new medical products.

"Acceptance and adoption by key stakeholders is critical to the widespread use of mobile technologies in clinical trials," said CTTI Executive Director Pamela Tenaerts. "However, very little was known about patient and sites' perspectives until our work shed light on what they see as significant benefits and barriers. Our new recommendations account for these perspectives and provide a valuable resource for optimally deploying mobile clinical trials.

"Further, they build on previous CTTI work—including our Quality by Design and Patient Groups and Clinical Trials recommendations—that emphasizes the involvement of many stakeholders, including patients and sites, in trial design. Engaging these groups early and often is the key to running better trials."

CTTI conducted surveys and in-depth interviews to better understand the perceptions of patients and clinical investigators, and convened experts and leaders across the clinical trials enterprise to develop actionable recommendations and resources.

The resulting recommendations are designed to assist research sponsors in:

- Engaging patient and site perspectives in planning clinical trials using mobile technologies, including protocol design, technology selection, and pilot testing;
- Maximizing value and minimizing burden for study participants, including setting patient expectations, protecting privacy, returning individual data, enhancing patient-site interactions, and providing technical support; and
- Addressing challenges for investigative sites, including contracting, budgeting, and training.

"One of the key takeaways of CTTI's work is the importance of engaging both patients and sites early, often, and throughout a mobile clinical trial," said Angela Botto-van Bemden, director of Osteoarthritis Programs at the Arthritis Foundation. "These new resources provide practical tools for communicating with stakeholders and ensuring their needs are factored into critical decisions, from technology selection to trial design to data dissemination."

The recommendations focus primarily on elements that are either unique or particularly important to trials that incorporate mobile technologies. The use of these technologies has the potential to enhance clinical trial quality and efficiency by allowing remote participation, increasing protocol adherence, and facilitating participation by a more diverse population.

"CTTI's recommendations and resources are designed to take our understanding of patient and site needs in mobile clinical trials to the next level," said William Wood, associate professor at the School of Medicine at the University of North Carolina at Chapel Hill. "With these new insights, sponsors and researchers can plan and conduct mobile trials that work better for everyone involved, streamlining the clinical research process and accelerating the development of critical new therapies."

The recommendations are the fourth set generated through CTTI's Mobile Clinical Trials (MCT) Program. In 2017, CTTI announced recommendations for developing novel endpoints generated by mobile technologies and, in 2018, it unveiled new solutions for using mobile technologies for data capture in clinical trials, and recommendations for planning and conducting decentralized clinical trials.

"This is the final piece that completes CTTI's comprehensive research into the use of mobile technologies in regulatory decision-making trials," said Virginia Nido, global head of product development industry collaborations at Genentech, a member of the Roche Group. "The focus on patient and site perspectives sets this work apart, and reflects CTTI's commitment to engaging patients and other stakeholders in every stage of the clinical research process."

These recommendations also align with the 21st Century Cures Act, the FDA Reauthorization Act of 2017 (FDARA), and the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI).

The free webinar begins today at noon ET and will be led by Nido and patient advocate Cynthia Geoghegan.

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 more than 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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