



PRESS RELEASE

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CTTI Offers Path Forward for Using Decentralized Clinical Trials

New recommendations offer guidance on overcoming legal, regulatory, and practical hurdles for planning and conducting decentralized clinical trials

Durham, N.C.—September 26, 2018—The Clinical Trials Transformation Initiative (CTTI) will unveil [new recommendations](#) to speed the use of decentralized clinical trials (DCTs)—trials run through telemedicine and mobile health care providers—today at the [DPharm: Disruptive Innovations to Advance Clinical Trials](#) conference in Boston, Mass.

CTTI's evidence-based and practical recommendations address barriers—including varying state medical licensing laws and issues with the drug supply chain of custody—that could be hindering the widespread use of DCTs. Use of these recommendations could offer sponsors, CROs, and others many advantages, including improved recruitment and retention, greater participant diversity, and a more comfortable and convenient research experience for participants.

“CTTI's work in this space holds the promise of significantly reducing both the barriers to and the burdens of trial participation,” said Pamela Tenaerts, executive director at CTTI. “The potential benefits apply to trials in all disease areas, but could offer particular advantages in rare diseases, where patients are generally limited in number and are highly geographically dispersed.”

The recommendations also provide guidance on effective DCT protocol design, investigator delegation and oversight, use of mobile health care providers, and safety monitoring.

“The traditional method of conducting clinical trials, along with its exponentially increasing price tag, is not sustainable for the industry in the long run,” said Gary Grabow, head of research and development contracts at Genentech, a member of the Roche Group. “By implementing these new recommendations, we can help advance the use of mobile technologies in DCTs, move toward better and more inclusive clinical trials, and possibly address part of the price escalation.”

A key concept within the recommendations is that DCTs do not have to be fully decentralized, but can incorporate various procedures and activities that are common in traditional studies.

“These recommendations are grounded in the reality that running a DCT is not an ‘all or nothing’ approach,” said Leonard Sacks, associate director for clinical methodology with the Office of Medical Policy within the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research. “There is a broad continuum of hybrid approaches that provide sponsors and

CROs with varying opportunities to implement decentralized trials, even if it is their first time doing so.”

This is the third set of recommendations from CTTI’s Mobile Clinical Trials Program for FDA-regulated trials, which aims to drive the evolution of the clinical trials enterprise to keep pace with technological innovations. In 2017, CTTI announced recommendations for developing [novel endpoints](#) generated by mobile technologies and, in July, it unveiled new solutions for using [mobile technologies](#) for data capture in clinical trials. Recommendations addressing patient and investigator engagement regarding the use of mobile technologies in clinical trials will be released by early 2019.

The recommendations are being launched at DPharm’s 2018 conference during the 2:00 p.m. session titled, “Ready for Launch: CTTI’s Decentralized Clinical Trials (DCT) Recommendations and the Patient of the Future.”

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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