**MEDIA RELEASE**

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## CTTI Launches New Online Digital Health Trials Hub

*The Digital Health Trials Hub aims to offer sponsors, investigators, tech companies, CROs, and study teams a broad suite of solutions for designing and running patient-centered clinical trials.*

Durham, N.C. – April 6, 2022 – Today the Clinical Trials Transformation Initiative (CTTI) announced a new online Digital Health Trials Hub featuring enhanced recommendations and additional resources.

"This updated and expanded resource advances progress toward CTTI's bold Transforming Trials 2030 vision by helping sponsors, investigators, CROs and technology providers design and run clinical trials that are patient-centered, easily accessible, and designed with a quality approach," said CTTI Executive Director Sally Okun.

The new Hub combines resources that have been restructured from CTTI's four existing Digital Health Trials projects, completed from 2017 to 2019, along with improvements and new work from two project teams, Decentralized Clinical Trials Updates and Novel Endpoints Acceptance. By creating the Hub, CTTI's aim is to make the most relevant information more useful and accessible for those in the clinical trials enterprise who are designing and running patient-centered trials.

The materials in the new Hub are broken down into six core areas of Digital Health Trial design and conduct:

- Developing Novel Endpoints
- Planning Decentralized Trials
- Selecting & Testing Digital Health Technology
- Managing Data
- Interacting with Regulators
- Supporting Sites

Key enhancements and additions made to the Hub include significantly updated recommendations, revised reference documents, and two new resources – the Question Bank for Identifying Meaningful Outcome Measures and a Process Map for use of a digitally derived endpoint in an individual drug development pathway. Best practices for planning and conducting successful decentralized clinical trials (DCTs), which can be completely remote, similar to traditional "brick and mortar" trials, or anywhere in between, are also provided as part of the Hub.

"The way digital health trials are designed and conducted is always evolving," said Elizabeth Kunkoski from the Center for Drug Evaluation and Research (CDER) at the U.S. Food & Drug Administration (FDA). "With this constant evolution, there is a need for new and reliable tools to advance better, faster and more inclusive digital health trials."

Recommendations and resources for incorporating novel, digitally derived endpoints in clinical trials are offered within the Hub as well.

“The CTTI Hub has valuable information for sponsors and researchers developing novel endpoints that more comprehensively and accurately represent the patient experience,” said Quentin Le Masne, Global Digital Health at EMD Serono (Merck Group).

The enhanced resources featured in the Hub are the culmination of CTTI’s 2021 work to refresh and update its existing Digital Health Trials suite of recommendations and resources. This work unveiled several central themes of designing and running modern day digital health trials, including:

- The need for early engagement of both internal and external stakeholders;
- The importance of balancing flexibility and optionality against operational complexity and risk;
- The requirement for tailored approaches to trial design, execution, and oversight; and
- The desire for flexible support of sites in issues of budgeting, training, and communication.

The Hub was introduced during a free one-hour webinar that included presentations from Megan Doyle, Amgen, and Jörg Goldhahn, ETH Zurich; a stakeholder panel featuring Phil Green, CTTI, Elizabeth Kunkoski, FDA, Jeremy Wyatt, ActiGraph, and Reem Yunis, Medable; and a Q&A session moderated by Lindsay Kehoe, CTTI. A recording of the webinar is available on CTTI’s website.

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**About the Clinical Trials Transformation Initiative**

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership cofounded 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. Bringing together organizations and individuals from across the enterprise—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 30 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.