MEDIA RELEASE

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CTTI Releases New Recommendations and Resources for Using Real-World Data to Plan Trial Eligibility Criteria and Recruit Participants

Comprehensive work highlights the opportunities for using RWD sources to enhance the quality and efficiency of clinical trials

Durham, N.C.—October 17, 2019—During a public webinar today, the Clinical Trials Transformation Initiative (CTTI) will release new recommendations and resources on how to use real-world data (RWD) to evaluate trial eligibility criteria and recruit potential research participants.

"Until now, there have been few resources available to help sponsors and others optimally integrate the use of RWD into their trial design," said Pamela Tenaerts, executive director at CTTI. "The work we are launching today fills that gap—our new recommendations provide a clear path for using EHRs and claims data to help plan eligibility criteria and recruit for clinical trials in a way that enhances quality and efficiency."

"This is the most comprehensive set of work available to sponsors and researchers who are seeking practical tips and tools for applying RWD in a way that enhances eligibility criteria and recruitment," added Cathy Critchlow, vice president at Amgen. "If you aren't already using RWD in these areas, now is the time to consider it. For many, it can be a low-risk, high-reward approach that can bring increased efficiency, shorter timelines, and better patient access to your research effort."

In context of CTTI's work, RWD are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, such as electronic health records (EHRs) and claims and billing data. Recent regulation, including the 21st Century Cures Act and Prescription Drug User Fee Act VI Commitment Letter, supports the use of RWD in clinical trial design and has generated interest in using RWD to enhance the quality and efficiency of research.

"The FDA encourages sponsors to design trials with broad eligibility criteria to ensure the clinical trial population reflects the diversity of patients who may ultimately use the medical treatment," said Jacqueline Corrigan-Curay, director of the Office of Medical Policy (OMP) within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). "A sponsor can take many approaches to achieve this goal, and CTTI's new work offers a potential roadmap to help sponsors use RWD to design and successfully implement more inclusive clinical trials."

The new recommendations and resources were developed by stakeholders across the clinical trials ecosystem. Three case studies, included as part of the resources, offer a deep dive into the specific challenges faced by sponsors, and how they can be addressed. For example, sponsors

have used RWD to challenge eligibility assumptions based on anecdotal evidence, pressure-test the viability of sites to ensure the accuracy of a protocol's anticipated enrollment rate, and determine whether a protocol amendment to change the enrollment criteria is worth the investment.

CTTI's RWD project is one in a growing portfolio of work on embracing novel trial designs and improving quality in trials. Other related CTTI efforts include:

- Co-leading a proof-of-concept study to assess the feasibility of using the FDA Sentinel System infrastructure to conduct randomized clinical trials.
- Recommendations on how to assess and design registries so that the data can meet expectations for the FDA review of new products.
- Recommendations and a robust toolkit to help drive a Quality by Design (QbD) approach, which engages a broad range of stakeholders and focuses resources on the errors that matter to decision making.

The webinar – led by Sudha Raman, Duke University, and Jack Sheehan, Johnson & Johnson/Janssen – is open to the public and begins at noon ET.

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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. 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 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.