MEDIA RELEASE

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CTTI Provides Needed Clarity to Improve Qualification of Investigators

New recommendations and resources aim to help sponsors, CROs, and site teams work together to better qualify investigators and their delegates to conduct clinical trials

Durham, N.C.—November 15, 2018—During a public webinar today, the Clinical Trials Transformation Initiative (CTTI) will unveil recommendations and resources that propose a new approach for investigator qualification that goes beyond repetitive training and includes individual experience and protocol-specific preparation.

The new recommendations, developed by experts and leaders across the clinical trials enterprise, aim to 1) help sponsors and contract research organization (CROs) implement a more efficient and effective means of qualification and determine whether a site team is a good fit for a particular protocol, and 2) help investigators and their delegates better prepare and qualify themselves for a clinical trial.

“There is wide consensus across the enterprise that ‘one-size-fits-all’ approaches to investigator qualification simply are not working,” said Pamela Tenaerts, executive director at CTTI. “Our new recommendations and resources help stakeholders to recognize previous training and experience, identify gaps in knowledge and skills, and identify qualification aspects that go beyond applying Good Clinical Practice principles to the conduct of clinical trials.”

Current regulations from the U.S. Food and Drug Administration (FDA) require that sponsors and their delegates select qualified investigators. Good Clinical Practice (GCP) training is widely used as the industry standard for ensuring investigators are qualified, but there is little evidence that completion of GCP training alone sufficiently qualifies investigators and their delegates to conduct quality clinical trials.

“The most common deficiencies noted during investigator inspections are often directly related to GCP principles,” said Jimmy Bechtel, senior project manager at the Society for Clinical Research Sites. “Redundant GCP training also creates an unnecessary burden for site teams and limits the opportunity for more valuable, protocol-specific learning and preparation.”

By implementing CTTI’s recommendations, stakeholders can streamline processes and target training to exactly what is needed, when it is needed.

“Enabling quality in conduct of trials requires focus on site-specific and protocol-specific training needs,” said Sabrina Comic-Savic, vice president of quality assurance at The Medicines Company. “Supporting a culture of learning will result in site teams proactively looking for improvement opportunities, in order to optimize the conduct and the quality of trial data.”

The recommendations could also help stakeholders foster collaboration and provide ongoing support through formalized mentorship and knowledge-sharing platforms.

“These recommendations are intended to expand the focus of investigator qualifications beyond GCP training toward new approaches that will further help ensure that site teams have the appropriate skills and knowledge they need to run high-quality clinical trials,” said Jacqueline Corrigan-Curay, director of the Office of Medical Policy (OMP) within the Center for Drug Evaluation and Research (CDER) at the FDA.

The free public webinar begins at noon ET and will be led by Bechtel, Comic-Savic, and Kate Haratonik of Genentech—a member of the Roche Group.

Sponsors, CROs, and site teams should use the new recommendations in conjunction with CTTI’s Quality by Design recommendations on protocol development and CTTI’s Investigator Community recommendations for a holistic approach to conducting quality clinical trials—an approach that combines qualified site teams, well-designed protocols, and robust site-based research infrastructures to achieve better, higher quality clinical trials.

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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