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FOR IMMEDIATE RELEASE
June 15, 2015

New Recommendations to Improve Quality in Clinical Trials

DURHAM, NC – The Clinical Trials Transformation Initiative (CTTI) has issued [recommendations](#) to improve the quality and efficiency of clinical trials by helping sponsors to focus on study activities that are essential to the safety of trial participants and the reliability of study results, and to reduce or eliminate those activities that are not.

Recognizing that time and resources are finite, CTTI encourages sponsors to build quality into the scientific and operational design and conduct of a clinical trial. CTTI defines “quality” in clinical trials as the absence of errors that matter to decision making—that is, errors which have a meaningful impact on the safety of trial participants or reliability of the results (and thereby the care of future patients).

“CTTI’s recommendations put the patient perspective at the center of the process by proactively identifying and managing those aspects of clinical trials most likely to negatively impact trial participants. Patient advocates readily understand the need to focus on errors that matter rather than spreading effort and attention thinly across all potential errors,” said Nancy Roach, founder and chair of the board of Fight Colorectal Cancer.

CTTI recommends sponsors create a culture that values and rewards critical thinking and open dialogue about quality, and that goes beyond sole reliance on tools and checklists; focus effort on activities that are essential to the credibility of the study outcomes; involve the broad range of stakeholders in protocol development and discussions around study quality; and prospectively identify and periodically review the critical to quality factors.

A [toolkit](#) is available to help sponsors implement the recommendations. Included in the toolkit are resources that can facilitate proactive, cross-functional dialogue and decision-making about trial design and planning. For example, the Critical to Quality Factors document can help sponsors to focus on the critical to quality factors when designing clinical trial protocols. The critical to quality factors are not intended to be a simple check-list but to stimulate discussion and prioritization of the most critical determinants of a trial’s quality and formulation of an appropriate plan to define, avoid, mitigate, monitor and address important and likely risks to study quality.

“CTTI’s recommendations emphasize the importance of prospectively building quality into the scientific and operational design of clinical trials, rather than relying only on retrospective monitoring, inspection or scientific review. This systematic, proactive, and focused approach is

compatible with FDA guidance on risk-based monitoring,” noted Robert Temple, M.D., Deputy Center Director for Clinical Science at the U.S. Food and Drug Administration (FDA).

The recommendations and toolkit will be formally unveiled during a presentation at the DIA annual meeting.

CTTI was established by Duke University and the FDA as a public-private partnership in 2007, and now comprises over 60 member organizations working to identify and promote practices that will increase the quality and efficiency of clinical trials. More information about CTTI and its projects is available at www.ctti-clinicaltrials.org.

Financial support for the work was provided by a grant from the FDA awarded to Duke University for the Clinical Trials Transformation Initiative, as well as pooled CTTI member funds and in-kind contributions.

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