

FOR IMMEDIATE RELEASE:

New Recommendations from Public-Private Partnership Aim to Improve Clinical Trial Quality and Safety

Durham, North Carolina - May 20, 2011 - A public-private partnership comprising over 60 organizations has announced recommendations to improve clinical trials by ensuring quality with effective and efficient monitoring and improving safety through better methods of reporting unexpected serious adverse events to investigators.

The recommendations are the first to be issued by the Clinical Trials Transformation Initiative (CTTI), a partnership coordinated by Duke University Medical Center (DUMC), which was formed to modernize the way clinical trials are conducted and address priority areas of need identified by key stakeholders across the clinical trial enterprise.

The first completed CTTI Projects explore two topics central to the conduct of clinical research: 1) how clinical trials are monitored to ensure that participants are protected and results are reliable, and 2) changes to the systems in place for reporting unexpected serious adverse events for investigational new drugs.

Working groups gathered empirical information that was combined with expert opinion to inform the recommendations developed and presented at this week's Society for Clinical Trials annual meeting in Vancouver, BC.

"Our clinical trial system has lacked modern evidence-based national standards for conducting research, thus contributing to the increasing length, cost, and inefficiencies in the collection of safety and efficacy data for new and existing drugs, devices, and other medical products," said Rachel Behrman Sherman, MD, Associate Director for Medical Policy at the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA).

"We anticipate that these recommendations, when adopted, will streamline the current approaches and allow information needed to inform health care and regulatory decision making to be generated and shared."

CTTI was established in 2007 by FDA and DUMC as a public-private partnership to identify practices that through broad adoption will increase the quality and efficiency of clinical trials.

Today CTTI includes numerous U.S. and international government agencies, pharmaceutical and device industry representatives, clinical research organizations, patient advocates, investigator groups, academic representatives, and other interested parties.

Previous research has shown that monitoring practices to ensure quality in clinical trials represent approximately one quarter of the cost of a trial. However, little empirical evidence exists to delineate the relationship between current monitoring practices and improved patient safety and data quality.

For CTTI's first Project, which examined the range of current approaches for monitoring, an electronic survey was completed by 65 organizations that conduct clinical trials in academia, government, and industry.

The responses demonstrated that a wide variety of monitoring practices are currently being employed, the monitoring approach is correlated with the type of organization sponsoring the clinical trial, and the rationale for using a specific monitoring approach does not appear to be based on empirical evidence.

"These recommendations focus on the importance of prospectively building quality into the scientific and operational design, conduct, and analysis of clinical trials," said Martin Landray, PhD, FRCP, from the University of Oxford and one of the leaders of the monitoring project.

"They put patients at the center of the clinical trial enterprise, enhancing the safety of study participants and emphasizing the need for reliable results to the benefit of all those future patients whose health care depends on them."

The second project evaluated the U.S. system for reporting unexpected serious adverse events (SAEs) that are possibly related to the drug to study investigators researching new drugs.

CTTI participants evaluated alternative approaches for reporting SAEs and held focus groups with patients about their expectations for monitoring SAEs in the conduct of trials. A key finding was that study investigators

received a large volume of individual SAE case reports that were time consuming to process, but often not relevant to patients or perceived as valuable.

"The system for SAE reporting to investigators is a classic example of a widely recognized inefficiency that results in increased time and cost without adding value to the conduct of a trial," said Robert M. Califf, MD, chair of CTTI and vice chancellor for clinical research at Duke University.

"Through these recommendations we aim to suggest new standards that provide usable information to physicians and patients about the risk-benefit profile of these investigational products."

CTTI's ongoing and new projects focus on identifying best practices to design quality into a clinical trial, as well as best practices in organizing, evaluating, and communicating pre-market safety information.

Additional CTTI projects include improving the public interface for [ClinicalTrials.gov](https://clinicaltrials.gov) and evaluating the use of central institutional review boards for multicenter clinical trials.

More information about the CTTI projects and recommendations can be found on the [CTTI website](#).

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