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PRESS RELEASE

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New CTTI Recommendations Provide Path for More Efficient Clinical Trials Using Clinical Registries

Durham, NC - Newly released recommendations from the Clinical Trials Transformation Initiative (CTTI) have the potential to streamline clinical trials by using registry information. Registries are data collection tools typically used to better understand long-term trends in a specific population, such as patients with a particular disease or patients exposed to a certain treatment.

“High-quality registries are an increasingly important source of evidence for regulatory decisions and surveillance, conveying important information, for example, regarding real-world medical product use and outcomes throughout the total product lifecycle,” said John Laschinger, MD, of the U.S. Food and Drug Administration, who helped lead the CTTI work. “Use of high-quality registries as a vehicle for efficient conduct of randomized clinical trials is a proven concept that can be considered for future pre-market trials,” he added.

If registries are designed appropriately, the “real-world” data within them should often be able to meet the expectations of regulatory agencies, and support decisions about medical products. In this regard, CTTI addresses how to assess data quality, ensure patient protections, and link with other data sources. The recommendations apply to both existing and new registries. Following these best practices can assist in evaluating suitability of registry data for regulatory purposes.

“Conducting randomized clinical trials within registries can increase efficiencies in data collection and decrease site workload, potentially leading to significant cost savings,” said Sunil Rao, MD, principal investigator of the successful randomized registry-based clinical trial, SAFE-PCI for Women.

While the scope of this project was limited to registries, many of the principles and tools in these recommendations have the potential to be applied to using health care systems or other existing data sources, such as those available within claims databases, to facilitate more efficient clinical trials.

More information about the CTTI's recommendations on conducting clinical trials using registries is available in a webinar recording located on the CTTI website.

Created by Duke University and the FDA as a public-private partnership in 2007, CTTI now includes over 80 member organizations. Its mission is to develop and drive adoption of 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.

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