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CTTI Celebrates a Decade of Transforming Clinical Trials

Enterprise leaders convene at CTTI Celebration Symposium; discuss how CTTI's work has led to better clinical trials and share visions for the future

Feb. 5, 2017 – Durham, NC – In a public Celebration Symposium being held tomorrow in Bethesda, Md., leaders from across the clinical trials enterprise will gather to celebrate the 10-year anniversary of the Clinical Trials Transformation Initiative (CTTI). The exciting lineup of speakers includes leaders from all sectors involved in clinical trials—government, industry, academia, patient groups, and other groups. Presenters will share case studies illustrating the benefits of applying CTTI's clinical trial recommendations and moderate a vibrant exchange of ideas on the future of the clinical trials enterprise.

"CTTI was established by the U.S. Food and Drug Administration and Duke University to bring together diverse perspectives to develop actionable solutions that can advance the design and conduct of streamlined clinical trials," said Jacqueline Corrigan-Curay, director of the Office of Medical Policy within FDA's Center for Drug Evaluation and Research (CDER), and one of the symposium's guest speakers. "This event is a great opportunity to reflect on the considerable progress that has been made and get a preview into how CTTI's ongoing work will continue to shape clinical trials of the future."

CTTI has completed more than 25 projects in the past 10 years on critical issues affecting clinical trials. The symposium will highlight CTTI's leadership and impact in areas such as quality by design, patient engagement, and the use of a single institutional review board of record.

"Ten years ago, it was becoming clear that clinical trials were so expensive, slow, and cumbersome to conduct that inefficiencies in the research enterprise were threatening progress in therapeutic development," said Duke University researcher and former FDA Commissioner Robert Califf, who will present at the symposium. "CTTI's work over the past decade has provided much-needed resources and tools that are critical in reversing this trend, and they continue to tackle many of the key challenges affecting clinical trials."

CTTI's work has influenced or been cited by FDA, the European Medicines Agency (EMA), the National Institutes of Health (NIH), and other policymakers, and its resources are used every day by sponsors, investigators, research professionals, patient groups, and others to improve clinical trials.

“Today, we are proud to celebrate CTTI’s vital work on transforming clinical trials over the past decade,” said Pamela Tenaerts, CTTI executive director. “Through collaboration, evidence, and impact, CTTI has developed recommendations and resources that enable progressive change in the enterprise—as evidenced by having influenced and being referenced by the FDA, EMA, NIH, and many other organizations. Looking ahead, we will continue to question the status quo and work to bring about quality, efficient, and patient-focused clinical trials.”

In addition to Corrigan-Curay, Califf, and Tenaerts, scheduled symposium speakers include: Soo Bang, Celgene; Ron Bartek, Friedreich’s Ataxia Research Alliance; Julie Dietrich, Amgen; Ken Getz, Tufts University; Hallie Kassan, Northwell Health; Ann Meeker-O'Connell, Johnson & Johnson; Jerry Menikoff, Office for Human Research Protections; Bray Patrick-Lake, Duke Clinical Research Institute; Jeff Sherman, Horizon Pharma; and Robert Temple, FDA. Califf will also moderate a panel discussion on “The Future of Clinical Trials” featuring: Jodi Black, NIH; Paul Eisenberg, Amgen; Owen Farris, FDA, Center for Devices and Radiological Health; Pat Furlong, Parent Project Muscular Dystrophy; Peter Marks, FDA, Center for Biologics Evaluation and Research; and Peter Stein, FDA, CDER.

About the Clinical Trials Transformation Initiative (CTTI)

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 nearly 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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