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CTTI Addresses Pregnancy Testing Challenges in Clinical Trials with New Recommendations and Online Tool

Creating pregnancy testing plans can support the inclusion of women in research and lead to safer, more efficient trials

Durham, NC – August 23, 2017 – The Clinical Trials Transformation Initiative (CTTI) today released [new recommendations](#) and an [online tool](#) to help research sponsors, investigators, and institutional review boards develop and review pregnancy testing plans, in an effort to conduct safer, more efficient clinical trials.

The U.S. Food and Drug Administration (FDA) expects clinical trials to include a population reflective of that which will receive the drug once marketed, which may include females of reproductive potential. However, there are no specific guidelines for how pregnancy testing should be conducted to prevent the unintended exposure of an embryo or fetus to a study's intervention, nor how risks should be clearly communicated to women. CTTI's new evidence-based recommendations and interactive online tool provide a standard way to plan for and make decisions about pregnancy testing in clinical trials, while also improving communication and transparency with trial participants.

"The absence of best practices to guide the development of pregnancy testing protocols often leads to prolonged negotiations and trial startup delays—an issue that many people don't realize exists," said Pamela Tenaerts, MD, MBA, executive director at CTTI. "Our new recommendations streamline and strengthen the process for determining pregnancy testing strategies for clinical trials, helping to save valuable time and resources."

"The CTTI online calculator provides a quick and easy way to estimate the potential outcomes of different pregnancy testing protocols when designing a clinical trial," said Evan R. Myers, MD, MPH at Duke University Medical Center, who helped develop the CTTI resources. "As part of a new initiative aimed at improving consistency in evaluating pregnancy testing protocols, Duke's institutional review board will use the calculator to help inform discussions with investigators, board members, and sponsors about the balance of benefits and burdens specific to study duration and the ages of women expected to enroll."

Upfront planning can also help to prevent unexpected challenges during a clinical trial, such as what to do if a positive pregnancy test occurs. The recommendations outline

specific steps researchers should take to plan for these possibilities and, ultimately, run more efficient trials. Additionally, CTTI suggests best practices to ensure women are adequately informed of the risks and implications before beginning the trial.

Patient advocates were involved in the development process, along with representatives from FDA and other government agencies, academic institutions, pharmaceutical companies, and other key stakeholders.

The new CTTI resources will be presented in a [free public webinar](#) on Thursday, August 24, 2017, at noon ET. Following, a recording of the presentation will be available on the [CTTI website](#).

About the Clinical Trials Transformation Initiative (CTTI)

The [Clinical Trials Transformation Initiative \(CTTI\)](#)—co-founded by Duke University and FDA—is a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high quality clinical trial system that is patientcentered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options. More information about CTTI and its projects is available at www.ctti-clinicaltrials.org.

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