



PRESS RELEASE

Contact: Leanne Madre, Director of Strategy, CTTI
Email address: leanne.madre@duke.edu

February 16, 2017

Clinical Trials Transformation Initiative Releases New Recommendations to Improve Studies of Antibacterial Drugs for Children

Durham, NC - The Clinical Trials Transformation Initiative (CTTI) has released [new recommendations](#) to improve the quality and efficiency of research studies used to develop antibacterial drugs for children. In addition, many of the suggested strategies and practices could be applied to streamline clinical trials of other types of drugs and medical devices for children.

“Medically, children are not just little adults, and they need access to treatments that have undergone appropriate evaluation for safety and efficacy in children,” said Daniel Benjamin Jr., MD, PhD, MPH, a pediatric infectious diseases specialist at Duke University. “The CTTI recommendations address many of the common challenges of conducting this research, and if applied widely, can help deliver much-needed information and treatments to benefit our young patients.”

These recommendations resulted from a collaborative effort among research sponsors, parents, investigators, clinicians, and regulators from the US and the EMA (European Medicines Agency), who provided practical suggestions for the timing of pediatric trials, streamlining trial design, facilitating informed consent, and fostering global and community partnerships to conduct trials that can improve children’s health.

The time from approval of a new antibacterial drug for use in adults to pediatric labeling can be 5 years or longer, potentially delaying appropriate use of medicines for this vulnerable group. Antibacterial resistance is on the rise in children, and the very young can be particularly susceptible to severe illness or death from these pathogens. Despite the great need for more treatment options, many trial sponsors have challenges enrolling pediatric patients in antibacterial drug trials.

“These recommendations encourage consultation with the FDA on pediatric study plans early in drug development and emphasize the potential utility of global study networks and streamlining trials,” said Sumathi Nambiar, MD, MPH, Director of the Division of Anti-Infective Products at the U.S. Food & Drug Administration (FDA). “Our mutual goal is to provide data in the drug labeling that will better inform the safe and effective use of antibacterial drugs in children.”

The CTTI recommendations are meant to help researchers design trials that are less burdensome for families, as well as to support improved practices for approaching

parents for consent during the stressful time of a child's illness. These recommendations are based on research that showed 80% of clinicians surveyed identified parent concerns about their child participating in research to be a barrier for completing research studies with children. This emphasizes the need for better engagement with parents throughout a clinical trial, including during the initial design stage. "This work matters to the lives of families like mine," said Breck Gamel, a parent participant in the CTTI effort. CTTI studied other clinician concerns as well, which helped to identify educational gaps in pediatric labeling and the need for better engagement with other healthcare providers.

Established by Duke University and the FDA as a public-private partnership in 2007, CTTI comprises over 90 member organizations working 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.

###