



## PRESS RELEASE

Contact: Leanne Madre, Director of Strategy, CTTI  
Email address: [leanne.madre@duke.edu](mailto:leanne.madre@duke.edu)

---

### Clinical Trials Transformation Initiative Releases Recommendations to Enhance the Feasibility of Developing New Antibacterial Drugs

Durham, NC (Aug. 1, 2016) – The [Clinical Trials Transformation Initiative \(CTTI\)](#) today released [two new sets of recommendations](#) designed to advance clinical trials for an important and particularly challenging area of antibacterial drug development: hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP). This work is part of CTTI's [antibacterial drug development program](#), which includes a suite of projects tackling specific issues to improve clinical trials and bolster the pipeline for new antibacterial drugs.

CTTI's new recommendations outline innovative approaches to designing clinical trials for HABP/VABP, including early enrollment strategies and the streamlined collection of safety data. CTTI convened multi-stakeholder teams to analyze the challenges associated with HABP/VABP trials and develop the proposed solutions. The feasibility of these new approaches will be tested in an upcoming pilot study, the findings of which are expected to help drive adoption of streamlined practices for antibacterial drug development across the clinical trial enterprise.

"The CTTI project teams' work is the type of science that can benefit the overall field of antibacterial drug development by advancing the science of clinical trials for hospital-acquired and ventilator acquired pneumonia," said Edward M. Cox, M.D., M.P.H., Director of the Office of Antimicrobial Products from the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. "We look forward to continued progress of the CTTI effort and the results from additional studies that will evaluate proposed solutions to these challenges."

CTTI's latest recommendations appear as part of a [peer-reviewed supplement](#) in the journal *Clinical Infectious Diseases* that features collaborative and innovative approaches by CTTI and others to address this pressing public health concern and speed new treatments to patients.

"This supplement from *Clinical Infectious Diseases* is really impressive and broad, highlighting many of the problems within antimicrobial resistance, from how to improve the development of new drugs, to engaging with the private sector. I am delighted to see such a prestigious scientific journal engage with this issue in a holistic approach looking at policy as well as scientific actions that need to be taken" said Jim O'Neill, Chair of the AMR Review.

Antibacterial resistance is an international public health crisis, and new treatment options are urgently needed. HABP/VABP occurs in seriously ill patients and is associated with high rates of antibiotic resistance and mortality. Multiple comorbidities, the rapid time course of acute illness, and other factors make conducting clinical trials in this population especially complex. "As someone whose susceptibility to multiple infections and Pneumonias has plagued me for six decades, these recommendations signal a transformational breakthrough," said Stephen Mikita, patient advocate.

Established by Duke University and the FDA as a public-private partnership in 2007, CTTI comprises more than 70 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](http://www.ctti-clinicaltrials.org).

Funding for this program was made possible, in part, by the Food and Drug Administration through grant R18FD005292 and cooperative agreement U19FD003800. Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government. Partial funding was also provided by pooled membership fees from CTTI's member organizations.