Antibacterial Drug Development Working Group
Webinar Agenda
Thursday August 29, 2013

9:00-9:15 am	**Welcome** *Presenter:* **Pamela Tenaerts, MD, MBA** Executive Director, CTTI **Introductory Remarks** *Presenter:* **Rachel Sherman, MD, MPH** Co-Chair, CTTI; Associate Director of Medical Policy, CDER; and Director of Office of Medical Policy, FDA/CDER
9:15-9:30 am	**CTTI Antibacterial Drug Development Program Update** *An update on the program and workstreams* *Presenter:* **Pamela Tenaerts, MD, MBA** Executive Director, CTTI Q&A
9:30-9:45 am	**FNIH update** *An update from the FNIH HABP/VABP Working Group* *Presenter:* **George Talbot, MD** Co-Chair, HABP/VABP Working Group, and Acute Bacterial Skin and Skin Structure Infection/Community Acquired Bacterial Pneumonia (ABSSSI/CABP) Project Team, Biomarkers Consortium, FNIH Q&A
9:45-10:00 am	**Remarks from the Office of Antimicrobial Products** *Presenter:* **Edward Cox, MD, MPH** Director, Office of Antimicrobial Products, FDA/CDER Q&A
10:00-10:25 am	**HABP/VABP Patient Outcomes from Previously Conducted Trials** *Presenter:* **Daniel Rubin, PhD** Mathematical Statistician, Office of Biostatistics, FDA/CDER Q&A
10:25-11:25 am	**Moderated Discussion** *Moderator*: **Robert Califf, MD** Co-Chair CTTI, and Vice Chancellor of Clinical and Translational Research, Duke University Medical Center Discussion questions: • For developing a protocol for the pilot study, should all-cause mortality be used to develop a study design due to the current uncertainty surrounding clinical response endpoints? • What method(s) will be used to establish historical evidence of sensitivity to drug effect (HESDE) from modern clinical trial data? • Should recommendations also include any exploratory data collection on biomarkers with the purpose of collecting data that may aid in future development?
11:25-11:30 am	**Next Steps and Actions**