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