



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
