# Anti-Bacterial Drug Development: Issues in the Design of Trials in Patients with Unmet Need and in Patients with Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia

Sheraton Crystal City Hotel
1800 Jefferson Davis Highway Arlington, Virginia 22202
Telephone: (703) 486-1111

October 11 & 12, 2012

**Background**

Research and development of new antibacterial drugs has slowed. The prevalence of antibacterial resistance is rising, creating an urgent unmet public health concern. The goal of the 2-day workshop is to understand the challenges and develop potential solutions to facilitate drug development for treatment of patients with unmet need (i.e. patients with bacterial infections who have limited or no options for treatment).

The first day of the workshop will discuss approaches to facilitate drug development for areas of unmet need (e.g., more limited development programs). On the second day of the workshop we will focus on issues in clinical trial design for developing antibacterial drugs for treating patients with hospital-acquired or ventilator-associated bacterial pneumonia (HABP/VABP).

## Thursday October 11, 2012

9:00 am– 4:00 pm

Teleconference: 1-888-450-5996; Passcode: 382825

# Day 1: Exploring a new paradigm for antibacterial drug development in areas of unmet need

**Goal:** To define potential pathways for development of antibacterial drugs to address unmet medical need; to consider alternative sources of data to allow for assessment of risks and benefits; and to describe acceptable residual levels of uncertainty for treatments to fulfill unmet need.

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| 8:30 -9:00 am | **Continental breakfast** |
| 9:00-9:10 am | Welcome, introductions, and review of workshop goals |
| **Session 1:**<br>9:10-9:55 am | **The existing paradigm and the need for urgent action in antibacterial drug development**<br><br>Presentations: Edward Cox, John Bartlett, Emil Lesho |
| **Session 2:**<br>9:55 -10:45 am | **Targeted smaller development programs: Ideas on trial designs for bacterial infectious diseases in areas of unmet need**<br><br>Presentations: Charlene Reed, Kathryn O'Connell, John Rex, Vance Fowler |
| 10:45-11:00 | **Break** |
| **Session 2 Cont.**:<br>11:00 am-Noon | **Targeted smaller development programs: Ideas on trial designs for bacterial infectious diseases in areas of unmet need**<br><br>Moderated discussion led by Robert Califf |
| Noon-12:45 pm | **Lunch** |
| **Session 3**:<br>12:45-2:00 pm | **Innovative approaches to clinical trial design and data analyses**<br><br>Presentations: Edward Cox, Lisa LaVange<br>Moderated discussion led by Robert Califf, Lisa LaVange, Edward Cox |
| 2:00-2:15 pm | **Break** |
| **Session 4**:<br>2:15-3:45 pm | **Identifying potential solutions to development of drugs for unmet need**<br><br>Moderated discussion led by Robert Califf, Edward Cox<br>Panel: John Rex, John Bartlett, Deborah Collyar, Robert Guidos, Joseph Toerner |
| 3:45-4:00 pm | **Summary and next steps** |

**Friday October 12, 2012**
9:00 a.m. – 2:45 p.m.
Teleconference: 1-888-450-5996; Passcode: 382825

## Day 2: Issues in Clinical Trial Design for Drug Development to Treat Patients with Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia (HABP/VABP)

**Goal:** To outline current and possible future approaches to antibacterial drug development for hospital-acquired and ventilator-associated bacterial pneumonia.

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| 8:30 -9:00 am | **Continental breakfast** |
| 9:00-9:05 am | **Welcome and introductions** |
| **Session 1**:<br>9:05-9:20 am | **Review of HABP/VABP guidance and current approach**<br><br>Presentation: Joseph Toerner |
| **Session 2**:<br>9:20-10:35 am | **Endpoints in HABP/VABP clinical trials**<br><br>Presentations: John Powers, Richard Wunderink, George Talbot, Philippe Prokocimer |
| 10:35-10:45 am | **Break** |
| **Session 2 Cont**.:<br>10:45-12:15pm | **Endpoints in HABP/VABP clinical trials**<br><br>Moderated discussion led by Robert Califf, Edward Cox |
| 12:15-1:00 pm | **Lunch** |
| **Session 3:**<br>1:00-2:30pm | **Operational efficiency and design of HABP/VABP clinical trials**<br><br>Presentation: Charles Knirsch<br>Moderated discussion led by Robert Califf, Edward Cox |
| 2:30-2:45 pm | **Summary and next steps** |

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Arlington, Virginia - October 11 & 12, 2012

## Presenters, Panelists, and Moderators

**John Bartlett**
Professor of Medicine
Johns Hopkins Center for Global Health
Infectious Diseases Society of America

**Robert M. Califf**
Vice Chancellor for Clinical and Translational Research and Duke University Medical Center
Director, Duke Translational Medicine Institute

**Deborah Collyar**
President, Patient Advocates In Research

**Edward Cox**
Director, Office of Antimicrobial Products, CDER, FDA

**Vance Fowler Jr.**
Professor, Department of Medicine
Infectious Diseases, Duke University

**Robert Guidos**
Vice President, Public Policy & Government Relations, Infectious Diseases Society of America

**Charles Knirsch**
VP, Clinical Research Head
Specialty Therapeutics
Pfizer Inc.

**Lisa LaVange**
Director, Office of Biostatistics, CDER, FDA

**Colonel Emil Lesho**
Co-founder and Director of the Multidrug-resistant organism Repository and Surveillance Network (MRSN) at Walter Reed Army Institute of Research

**Kathryn O’Connell**
Medical Officer, Rare Diseases Program
Office of New Drugs, CDER, FDA

**John Powers**
Senior Medical Scientist, SAIC in support of Division of Clinical Research, NIH and Associate Clinical Professor of Medicine, George Washington University School of Medicine

**Philippe Prokocimer**
Chief Medical Officer
Trius Therapeutics, Inc.

**Charlene Reed**
Founder and Chief Executive Officer
Foundation to Combat Antimicrobial Resistance

**John H. Rex**
Vice President and Head of Infection
Global Medicines Development, AstraZeneca
Adjunct Professor of Medicine
University of Texas Medical School-Houston

**George H. Talbot**
Principal, Talbot Advisors LLC,
Infectious Diseases Society of America

**Joseph Toerner**
Associate Director for Medical Affairs,
Office of Antimicrobial Products, CDER, FDA

**Richard Wunderink**
Professor of Medicine, Pulmonary and Critical Care, Northwestern University Feinberg School of Medicine