HABP/VABP Pilot Study Planning Meeting

24 February 2015

Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Rd
Bethesda, Maryland 20852 USA

Meeting Goal: To determine the study design for the CTTI Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia (HABP/VABP) pilot study. The study will test the principles and recommendations identified in the CTTI Program on Antibacterial Drug Development (ABDD).
# Meeting Agenda
**Tuesday, February 24, 2015**
9:00 AM-3:30 PM

<table>
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<th>Time</th>
<th>Session</th>
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<td>8:00-9:00 AM</td>
<td><strong>Registration &amp; Breakfast</strong></td>
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| 9:00-9:15 AM  | **Welcome and Opening Remarks:** Pamela Tenaerts, CTTI  
**Session goal:** Provide CTTI overview and meeting objectives |
| 9:15-10:30 AM | **Session 1 CTTI Antibacterial Drug Development Program**  
**Session Chair:** Pamela Tenaerts  
**Session goal:** To review work of ABDD Streamlining HABP/VABP projects and an ongoing analysis of HABP/VABP trials costs. The focus will be on findings and recommendations that could be implemented as part of the pilot study.  
**Presentations**  
Edward Cox, Food and Drug Administration: Issues Facing Antibacterial Drug Development  
Rosemary Tiernan, Food and Drug Administration: CTTI Streamlining HABP/VABP Project  
Sara Calvert, CTTI: Preliminary Planning CTTI HABP/VABP Pilot Study  
Stella Stergiopoulos, Tufts Center for the Study of Drug Development: Calculating the Direct and Indirect Costs of a Phase III HABP/VABP Clinical Study  
**Questions and Discussion** |
| 10:30-10:45 AM | **Break**                                    |
| 10:45-12:00 PM | **Session 2 Proposed Study Designs for CTTI HABP/VABP Pilot Study**  
**Session Chair:** Vance Fowler, Duke University Medical Center  
**Session goal:** Present and obtain feedback on proposed HABP/VABP study designs.  
**Design A:** RCT of Intervention X vs. Intervention Y (two approved regimens) with operational streamlining  
**Design B:** RCT comparing trial enrollment and efficiencies in “traditional” vs. “streamlined” protocol  
**Design C:** Factorial Design – randomized to both Drug X vs. Drug Y and streamlined vs. traditional protocol  
**Design D:** Substudy, with expanded access and streamlining, added to existing HABP/VABP clinical trial  
**Discussion question:** Which of the trial concepts described would have the most impact on improving the feasibility of conducting HABP/VABP trials? |
| 12:00-1:00 PM | **Lunch (Provided)**                          |
| 1:00-3:15 PM  | **Moderated Discussion**                      
**Session Chair:** Vance Fowler  
**Session goal:** Determine most appropriate study design for CTTI HABP/VABP pilot study |
| 3:15 – 3:30 PM | **Next Steps and Adjourn**                   |