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

8:00-9:00 AM **Registration & Breakfast**

9:00-9:15 AM **Welcome and Opening Remarks: Pamela Tenaerts**, CTTI

Session goal: Provide CTTI overview and meeting objectives

Session 1 CTTI Antibacterial Drug Development Program

9:15-10:30 AM **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**

Session 2 Proposed Study Designs for CTTI HABP/VABP Pilot Study

10:45-12:00 PM **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**