



Antibacterial Drug Development: Developing a Pilot Protocol for Hospital Acquired and Ventilator Associated Bacterial Pneumonia

April 22 & 23, 2013

Hyatt Regency Bethesda
7400 Wisconsin Avenue
Bethesda, MD 20814
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Meeting Goal: To seek solutions for challenges in study design and conduct of Hospital Acquired and Ventilator Associated Bacterial Pneumonia (HABP/VABP) studies by applying the quality by design (QbD) principles

Meeting Agenda

Teleconference: 1-855-244-8681 Passcode: 22290202

Monday April 22, 2013

11:30 - Noon Registration/Lunch

Noon-12:15 pm Introductions and Meeting Goals **Pamela Tenaerts**
Welcome remarks **Rachel Sherman**

Session 1:
12:15-12: 50 pm **The challenges of HABP/VABP trials:**
Session goal: understanding the challenges in HABP/VABP trials
Presentations:
Brad Spellberg: Summary of top challenges identified/ categorized earlier
Charles Knirsch: Operational challenges in HABP/VABP trial
& **David Friedland** conduct

Q&A

Break 10 min
12:50 -1:00 pm

Session 2:
1:00 -3:00 pm **How can QbD be used to address the challenges in HABP/VABP trials?**
Session goal: Understanding the risk-based QbD approach and discuss the advantages and challenges of adopting this approach for HABP/VABP trials
Presentations:
Martin Landray: Introduction to a QbD approach to clinical trials
Ann Meeker-O'Connell: Enhancing trial efficiency while promoting quality: A regulatory perspective.
Q&A

Moderated discussion
Presenters and Team Leads Applying QbD to HABP/VABP trials

Breakout Session Overview
Sabrina Comic-Savic Instructions on: Issues poll, breakout session discussion process, and reporting out

3:00-3:30 pm **Break and Issues poll**

Session 3
3:30 -5:30 pm **Breakout session: Seeking solutions to barriers of success**
Session goal: applying the QbD approach to develop alternate solutions and generate recommendations to overcome the issues
Breakout topics: 1) Patient Enrollment, 2) Efficacy and Safety Outcomes
3) Evaluable Population

Session 4
5:30 -6:00 pm **Breakout session: Seeking solutions to barriers of success**
Summary and report out slides preparation

6:30 pm **Team Dinner (all meeting attendees)**

Tuesday April 23, 2013
8:00 am – 2:00 pm

7:00 – 8:00 am	Breakfast
Session 1: 8:00-9:30 am	Breakout session: Seeking solutions to operational challenges <i>Session goal: Identifying factors that are critical to quality and develop strategies for efficient study conduct</i> Breakout topics: 1) Patient Enrollment, 2) Efficacy and Safety Outcomes 3) Evaluable Population (topics identified through issues poll will also be included)
9:30-10:00 am	Break Facilitators/recorders and key group members to summarize operational issues to report out
Session 2: 10:00-10:30am	Report out session Presentations by breakout group <i>Session goal: Breakout groups will share their discussion outcomes and present their recommendations to the entire team</i> Moderators: Vance Fowler and Brad Spellberg
Session 3 10:30 am –12 Noon	Building the trial elements <i>Session goal: the entire team will further discuss and enhance the recommendations from each group, the results of these discussions will be used to build the trial elements</i> Moderated Discussion: Brad Spellberg and Vance Fowler Patient Enrollment Efficacy and Safety Outcomes
Noon-12:15 pm	Break Working lunch will be served
12:15-1:45 pm	Moderated Discussion: continued Efficacy and Safety Outcomes continued Evaluable Population
1:45 -2:00 pm	Wrap up and next steps
