



Optimizing Operational Efficiencies for Data Collection in HABP/VABP Trials

12 November, 2013

Crystal City Marriott
1999 Jefferson Davis Highway
Arlington, Virginia 22202 USA

Meeting Goal: Seek practical solutions to streamline the operational processes and build efficiencies for data collection in HABP/VABP trials

Meeting Agenda
Tuesday November 12, 2013
9:00 AM-4:00 PM

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

9:00-9:10 AM **Welcome & Introductions: Pamela Tenaerts, MD, MBA**, Executive Director, CTTI
Opening Remarks: Robert Califf, MD, Vice Chancellor, Clinical & Translational Research, DUMC; EC Co-Chair, CTTI

Session 1 Challenges in data collection for HABP/VABP trials

9:10-9:45 AM **Session Chair: Charles Knirsch, MD, MPH**, Vice President, Clinical Research Head, Specialty Care, Pfizer Inc.

Session goal: Understanding the issues surrounding data collection in HABP/VABP trials
Focus: Why reducing excessive non-critical data collection in HABP/VABP trials would improve data quality, and benefit investigators, sponsors, reviewers, and patients

Presentations:

Charles Knirsch, MD, MPH

HAP / VAP Clinical Trials Part 3: Can we reduce complexity and safety data collection to improve the quality of the data and inferences we make?

Richard Wunderink, MD, Professor of Medicine, Northwestern U, Feinberg School of Medicine

Challenges in data collection for HABP/VABP trials: Investigator's perspective

Sumathi Nambiar, MD, Acting Director, DAIP, FDA

Data collection in HABP/VABP trials: Regulatory perspective

Q&A and Discussion

Session 2 Regulatory requirements for AE data collection in registration trials

9:45-10:50 AM **Session Chair: Vance Fowler, MD, MHS**, Professor, ID Division, DUMC

Session goal: Discuss different regulatory requirements and the challenges of meeting these requirements for data collection for HABP/VABP registration trials that are globally conducted, and evaluate whether future work is needed to harmonize approach to AE collection

Focus: AE collection and adjudication of relatedness and seriousness; Reporting of SAE's and SUSARS and evaluation

Presentations:

Patrick Archdeacon, MD, Medical Officer, Office of Medical Policy, CDER/FDA

Safety data collection in late stage premarket and post-approval clinical investigations

Chris Wohlberg MD, PhD, Vice President and Safety Lead, Research and Specialty Care, Pfizer, Inc.

Managing safety data in multi-regional trials

Q&A discussion

10:50-11:00 AM **Break**

Session 3
11:00-12:05 PM

Strategies to simplify data collection using a QbD approach

Session Chair: Mark Behm, Sr. Director QA, AstraZeneca Inc.

Session goal: To simplify the recording, monitoring, and review to make HABP/VABP trials more feasible and economical

Focus: Reduction in the amount of data collected by identifying data that are critical to quality and those that may be essential to determine the benefit/risk of the treatment for registration, and those may be less informative

Presentations:

Mark Behm

Using QbD for data collection planning

Lisa G. Berdan, PA, MHS, Director- Global Megatrials, DCRI

Guiding principles for efficient data collection- 20 years of cardiovascular outcomes trials

Moderated Discussion:

Moderators:

Gary Noel, MD, FIDSA, FAAP, Child Health Innovation Leadership Dept. Janssen, J&J

Jean Mulinde, MD, Acting Sr. Advisor, DGCP/OSI/OC/CDER/FDA

Discussion topics:

A high-volume of data related to the following are collected in these trials:

- AE, SAE and Concomitant medications
- Inclusion exclusion criteria, Med history, Baseline characteristics
- Visits and assessments: Vital signs/PE, Clinical labs other assessments
- Exploratory data

1. Are there data/procedures, and the frequency at which they are routinely collected that don't significantly impact data analysis or subject safety for patients with HABP/VABP?
2. Can a focused set of data that are critical to assessment of drug efficacy and safety be proposed as required for a HABP/VABP trial?
3. How can safety data collection be streamlined without creating risk of missing unanticipated events?

12:00-12:05 PM

Breakout discussion instructions

Sabrina Comic-Savic, Sr. Director, GCP Compliance, The Medicines Co.

12:05-12:30 PM

Lunch

Session 3

continued

12: 30 -2:00 PM

Breakout group discussions

	Group 1	Group 2	Group 3
Discussion Leads	Sabrina Comic-Savic Charles Knirsch	Christina Reith Vance Fowler	Mark Behm Gary Noel
Writers	Pamela Tenaerts	Cheri Janning	Peter Hoffman
Topics	<ul style="list-style-type: none">• AE, SAE, and Concomitant medications• Inclusion and exclusion criteria, Med history, Baseline characteristics• Visits and assessments: Vital signs/PE, Clinical labs, Exploratory data		

2:00-2:15 PM

Break

Session 4
2:15-3:45 PM

Report out session
Session chair: Robert Califf, MD

Session goal: Breakout groups will share their discussion outcomes and present their recommendations to the entire team. The entire team will discuss recommendation and come up with a consensus

Presentations by breakout groups

Moderated Discussion:

Moderator:

Robert Califf, MD

Discussion topics:

1. *How can HAP/VABP trial processes and data collection be simplified to only report data that are critical to analyses of the efficacy and safety of the drug?*
2. *What is the feasibility of operationalizing some of the solutions proposed today?*
3. *The move to collecting critical but limited data requires a shift in current practices and expectation within academia, industry, and regulators:*
 - a. *What are the barriers to this shift?*
 - b. *How can we promote these changes in the HAP/VABP trial enterprise?*
4. *What culture changes need to be addressed among relevant medical specialties, advisory boards, and regulatory organizations to facilitate this shift, and how can the culture changes be promoted?*

3:45-4:00 PM

Next steps and adjourn
