

## **Workshop on Quality Risk Management: Making Clinical Trials Fit for Purpose**

*A Clinical Trials Transformation Initiative (CTTI)-sponsored Meeting*

*August 23–24, 2011*

*Hyatt Regency Bethesda*

*One Bethesda Metro Center*

*7400 Wisconsin Ave., Bethesda, Maryland 20814*

### **MEETING BACKGROUND**

At an expert meeting held in October 2010 for the CTTI monitoring project, representatives from a broad cross-section of the clinical trial enterprise—including regulators, government sponsors of clinical research, academicians, industry representatives, patient advocates, clinical investigators, and other interested parties—discussed clinical trial monitoring as one component of an overall quality framework. Panelists and participants agreed that an enlightened approach to ensuring trial quality is needed. Such an approach would apply risk management principles to clinical trials by prospectively identifying critical trial deliverables and important risks to each and then tailoring protocol design and delivery to mitigate those risks. To implement this change, participants agreed that all stakeholders in the clinical trial process must modify their view of risk and have a common understanding of quality-by design and quality risk management principles. This workshop is the first in a planned series intended to develop quality-by-design and quality risk management principles applicable broadly to clinical trials and development programs, as well as to identify and share best practices for implementing these principles.

---

### **MEETING OBJECTIVES**

- Develop quality-by-design concepts for the clinical trial process
  - Define consensus principles of quality risk management as applied in the drug development lifecycle and in conjunction with quality-by design concepts.
  - Review case studies of quality-by-design and quality risk management approaches applied in commercial and academic clinical trial settings, including tools and methodologies and potential best practices.
  - Discuss methods for evaluating the success of quality-by-design and quality risk management approaches in enhancing the quality and efficiency of clinical development.
  - Identify mechanisms to disseminate principles and best practices identified during the workshop to a broad array of stakeholders.
-



### SESSION III: CASE STUDIES

*Session Facilitators: Peter (lead), Fergus, and Ann*

*Session Objectives:*

- Highlight and discuss models/methods applied in the public and private sectors in creating quality-by-design and quality risk management approaches for clinical development.
- Evaluate strengths and weaknesses of these approaches and the desirability and/or feasibility of scaling up the widespread use of such designs.
- Identify best practices that could be broadly adopted by both commercial and academic researchers to reduce inefficiency and enhance quality of clinical trials.
- Discuss quality-by-design in the context of sponsor-CRO relationships.

*Building Quality into Clinical Development: The Academic Perspective*

1:00 – 1:20 pm      Rory Collins, Oxford

1:20 – 1:40 pm      Adrian Hernandez and Craig Reist, Duke University

*Building Quality into Clinical Development: The Pharmaceutical Industry Perspective*

1:45 – 2:05 pm      David Nickerson, Pfizer

2:05 – 2:25 pm      Jeff Kasher, Eli Lilly

2:25 – 2:45 pm      Andrew Lee, Genzyme

2:45 – 3:05 pm      Craig Wozniak, GlaxoSmithKline

3:05 – 3:25 pm      Andy Lawton, Boehringer Ingelheim

3:25 – 3:45 pm      Lynn Seely, Medivation

**BREAK: 3:45 – 4:00 pm**

*Building Quality into Clinical Development: Outsourcing*

4:00 – 4:20 pm      Regina Freunsch, Accovion GmbH

4:20 – 4:40 pm      Ken Getz, Tufts Center for the Study of Drug Development

*The Path Forward*

4:45 – 5:30 pm      Interactive discussion/brainstorming (all attendees)

*Reception*

6:00pm

## DAY 2 – AUGUST 24, 2011

### SESSION IV: EVALUATION OF QRM IMPLEMENTATION

*Session Facilitators: Peter (lead), Ann*

*Session Objectives:*

- Consider methods for evaluating the success of QbD and QRM approaches in various settings and time points in the development lifecycle.
- Identify gaps/areas of particular need and the challenges faced in measuring the success of QbD and QRM in development of drugs, biologics, and devices.

8:30 – 9:45 am      Panel discussion:  
Leslie Ball, FDA  
Fergus Sweeney, EMA  
Beat Widler, Roche  
Rory Collins, Oxford  
Ken Getz, Tufts Center for the Study of Drug Development

9:45 – 10:30 am      Interactive discussion/brainstorming (all attendees)

### **BREAK: 10:30 – 10:50 am**

### SESSION V: COMMUNICATION

*Session Facilitator: Ann (Lead), Peter*

*Session Objectives:*

- Determine how key findings and principles developed or discussed at the workshop can be communicated to all stakeholders to ensure public understanding of risk-based decision-making in drug, device, and biologic development and to ensure that effective and efficient QRM methodologies are adopted broadly.
- Discuss ideas from the workshop and potential next steps, including discussion of which of these should be incorporated into future CTTI workshops.

10:50 – 11:20 am      Panel discussion:  
Judy Leon, FDA  
Debra Madden, FDA Patient Representative  
Jacques Demotes, ECRIN  
Lee Zwanziger, FDA

11:20 am – 12:00 pm      Interactive discussion/brainstorming (all attendees)

### **WORKING LUNCH: 12:00 – 1:00 pm**

12:15 – 1:00 pm      The Path Forward:  
Leslie Ball, Fergus Sweeney, Briggs Morrison and Peter Schiemann