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.
DAY 1 – AUGUST 23, 2011

WELCOMING REMARKS
8:30 – 8:50 am
Robert J. Temple, M.D., Deputy Center Director for Clinical Science,
Center for Drug Evaluation and Research, FDA

SESSION I: PRINCIPLES FOR BUILDING QUALITY INTO CLINICAL TRIAL DEVELOPMENT

*Session Facilitators: Leslie and Peter (lead)*

*Session Objectives:*
- Review key findings from the Clinical Trials Transformation Initiative (CTTI) Monitoring Project Workstream #3.
- Discuss principles of quality risk management that may enhance the quality and efficiency of pharmaceutical and device development.
- Consider the key role of protocol design in quality-by-design approaches and in facilitating the application of quality risk management approaches in clinical trials.
- Review collaborative development of quality-by-design in the manufacturing sector and considerations (similarities and key differences) for building quality into clinical development.

8:50 – 9:10 am Monitoring Workstream #3 Key Findings: Briggs Morrison, Pfizer
9:10 – 9:35 am Learning from Quality-by-Design in the Manufacturing Sector: Fergus Sweeney, EMA
9:35 – 10:00 am Principles of Quality Risk Management: Beat Widler, Roche

10:00 – 10:20 am Interactive discussion (all attendees)

SESSION II: REGULATORS’ PANEL

*Session Facilitators: Fergus and Leslie (lead)*

*Session Objectives:*
- Discuss risk-based approaches to clinical oversight in a global regulatory environment.
- Discuss how regulatory agencies help ensure quality through inspections and other activities.
- Identify ways in which regulatory agencies can foster innovative approaches to build quality into clinical development.

10:20 – 10:40 am Kathleen Meeley, MHRA
10:40 – 11:00 am Pierre Henri Bertoye, AFSSAPS
11:00 – 11:20 am Tomoko Osawa, PMDA
11:20 – 11:40 am Ann Meeker-O’Connell, FDA

11:40 am – 12:00 pm Panel Q&A

LUNCH (PROVIDED): 12 – 12:45 pm
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 Freunscht, 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