

**Developing Effective Quality Systems in Clinical Trials:
An Enlightened Approach**

A Clinical Trials Transformation Initiative (CTTI)-Sponsored Meeting
October 13–14, 2010
Bethesda Marriott Suites
6711 Democracy Boulevard
Bethesda, MD 20817

Complimentary shuttle to/from Grosvenor/Strathmore Metro Station (Red Line) from 7 am to 9 pm, Monday through Friday – Call – 301-897-5600 to schedule pick up.

Background:

The Clinical Trials Transformation Initiative (CTTI) has been conducting a project to identify effective and efficient methods to monitor clinical trials. In seeking to identify how best to ensure the reliability of study results and the protection of trial participants, the project team has recognized that quality cannot be “inspected into” a trial but rather must be incorporated from the outset in the trial’s protocol design and operational conduct. To be effective, monitoring should be one component of an overall quality framework that allows potential issues to be identified and addressed as early as possible.

Key Objectives:

- Describe, discuss, and evaluate novel approaches to clinical trial oversight
- Identify the critical aspects of clinical trials that should be the focus of risk-based approaches to creating quality systems
- Propose an integrated model of quality management that will promote more efficient approaches to design, conduct and oversight of clinical trials

Participants:

- Representatives from a broad cross-section of the clinical trial enterprise including regulators, government sponsors of clinical research, academia, industry, patient advocates, clinical investigators, and other interested parties
- Participants are expected to be actively engaged and ask questions both days

Duration: 1.5 days (Day 1: 9:00 a.m. – 5:30 p.m.; Day 2: 8:00 a.m. – 1:00 p.m.)

Meeting Facilitator: Martin Landray, University of Oxford Clinical Trial Service Unit

Day 1 - October 13 (9:00 am – 5:30 pm)

Location: Independence Ballroom (located on the 2nd level)

AGENDA TOPIC	PRESENTER	TIMEFRAME
Kickoff <ul style="list-style-type: none">• Review meeting objectives, review agenda, introductions	Martin Landray (University of Oxford, UK)	9:00 – 9:30
CTTI Background <ul style="list-style-type: none">• Overview of CTTI Monitoring Project and key findings to date	Martin Landray	9:30 – 10:00
Break		10:00 – 10:15

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<p align="center">Defining the Underlying Principles of Quality in Clinical Trials</p> <p>Quality Design of Clinical Trials <i>Presentation – 10:15 to 10:45 am</i> <i>Q&A – 10:45 – 11:00 am</i></p> <p>Quality Risk Management in Clinical Trials <i>Presentation – 11:00 to 11:30 am</i> <i>Q&A – 11:30 – 11:45 am</i></p> <p>Statistical Monitoring Applied to Research Trials <i>Presentation – 11:45 am to 12:15 pm</i> <i>Q&A – 12:15 – 12:30 pm</i></p> <p>Discussion</p>	<p>Rory Collins (University of Oxford, UK)</p> <p>Janet Woodcock (FDA, Center for Drug Evaluation and Research)</p> <p>Tomasz Burzykowski (International Drug Development Institute)</p>	<p>10:15 – 1:00</p> <p>10:15 – 11:00</p> <p>11:00 – 11:45</p> <p>11:45 – 12:30</p> <p>12:30 – 1:00</p>
<p>Lunch</p>	<p>Independence Ballroom</p>	<p>1:00 – 2:00</p>
<p>Approaches to Risk-Based Quality Management</p> <p>Quality by Design / Quality Systems <i>Presentation – 2:00 to 2:10 pm</i> <i>Q&A – 2:10 – 2:20 pm</i></p> <p>Clinical Data Mining as a Basis for an Information-Based Clinical QA Program <i>Presentation – 2:20 to 2:30 pm</i> <i>Q&A – 2:30 – 2:40 pm</i></p>	<p>Beat Widler (Roche)</p> <p>Grant Simmons (Novartis)</p>	<p>2:00 – 5:00</p> <p>2:00 – 2:20</p> <p>2:20 – 2:40</p>

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<p>Quality System Approaches Using Existing Data and Systems <i>Presentation – 2:40 to 2:50 pm</i> <i>Q&A – 2:50 – 3:00 pm</i></p>	<p>Eileen Magruder (Amgen)</p>	<p>2:40 – 3:00</p>
<p>Break</p>		<p>3:00 – 3:20</p>
<p>Quality Risk Management Tools <i>Presentation – 3:20 to 3:30 pm</i> <i>Q&A – 3:30 – 3:40 pm</i></p>	<p>Raffael Jovine (International Institute for the Safety of Medicines)</p>	<p>3:20 – 3:40</p>
<p>The NIH/NCI Data Quality Initiative <i>Presentation – 3:40 to 3:50 pm</i> <i>Q&A – 3:50 – 4:00 pm</i></p>	<p>Edward Helton (NIH/NCI)</p>	<p>3:40 – 4:00</p>
<p>An Academic Approach: Combining Quality by Design with Central Monitoring <i>Presentation – 4:00 to 4:10 pm</i> <i>Q&A – 4:10 – 4:20 pm</i></p>	<p>Martin Landray</p>	<p>4:00 – 4:20</p>
<p>FDA’s Risk-Based Inspection <i>Presentation – 4:20 to 4:30 pm</i> <i>Q&A – 4:30 – 4:40 pm</i></p>	<p>Leslie Ball (FDA, Division of Scientific Investigations)</p>	<p>4:20 – 4:40</p>
<p>Risk-Based Quality Management of Clinical Trials – A European Regulator’s View <i>Presentation – 4:40 to 4:50 pm</i> <i>Q&A – 4:50 – 5:00 pm</i></p>	<p>Gabriele Schwarz (BfArM)</p>	<p>4:40 – 5:00</p>
<p>Day 1 Wrap-Up Before leaving the room, participants must propose, in writing, 1–3 components of a quality management system that will promote more efficient oversight (monitoring) of clinical trials.</p>	<p>Martin Landray</p>	<p>5:00 – 5:30</p>
<p>Evening Reception</p>		<p>6:00 – 8:00</p>
<p>Location: Democracy Room (located on lobby level)</p>		

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Day 2 - October 14 (8:00 am – 1:00 pm)

Location: Independence Ballroom (located on the 2nd level)

AGENDA TOPIC	PRESENTER	TIMEFRAME
Kickoff Day 2	Martin Landray	8:00 – 8:15
<p>Round Table Discussion: Working Together to Deliver Quality</p> <ul style="list-style-type: none"> • Robert Temple/Rachel Behrman (FDA) • Fergus Sweeney (EMA) • Rory Collins (Oxford) • Briggs Morrison (Pfizer) • Felix Gyi (Chesapeake IRB) • Nancy Roach (Patient Advocate) <p>Panelists will present their thoughts on the following questions, followed by discussion:</p> <ol style="list-style-type: none"> 1. What are the essential elements of a quality management system for clinical trials; specifically, what activities and oversight are necessary for a quality clinical trial that protects participants and ensures data quality? 2. How do we measure the success of these quality management systems, in terms of quality, efficiency, and feasibility of adoption? 3. What are the biggest barriers to (a) adopting quality systems approaches to clinical trials, and (b) abandoning inefficient and/or ineffective methods? 4. Who do we need to influence to change the status quo? What are the optimal communication strategies and tools to facilitate widespread adoption of effective quality system models for clinical trials? 		8:15 – 10:45
Break		10:45 – 11:15
<p>Conclusions and Future Directions</p> <ul style="list-style-type: none"> • Define process steps and identify participants who will work to develop a consensus definition of a risk-based quality system • Define process for formalizing and disseminating the consensus definition • Define concrete steps to be taken to advocate adoption of quality system approach, and to identify participants who will coordinate these efforts 	Martin Landray	11:15 – 1:00