
# Day 1

Tuesday, Sept. 28, 2021

10:00 AM **Summit Opening**

10:00 AM – 10:30 PM EDT

10:30 AM **Keynote: ICH E6(R3) Guideline for Good Clinical Practice Update**

10:30 AM - 11:45 AM EDT

**M. Khair ElZarrad**
E6(R3) Rapporteur, FDA
Deputy Director, Office of Medical Policy
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

11:45 AM **Break**

11:45 AM - 12:30 PM EDT

12:30 PM **Risk-based Quality Management Critical Thinking Workshop – What Can Go Wrong?**

12:30 PM - 2:30 PM EDT

During this 2-hour workshop, participants will view short, online e-learning training videos that review risk management concepts and apply the concepts in “hands-on”, virtual activities and interactive discussion. The topics covered in the workshop include:

- What is risk? How does it apply to clinical trials?
- Identifying and evaluating risks in clinical trials – starting with the critical data and processes
- Controlling risks, risks that become issues, implementation challenges

Learning Objectives:

- At the end of the workshop, participants will be able to:
- explain the concept of risk and its management
- describe risk management in clinical research and the relevance of ICH E6 (R2)
- identify critical data and processes
- use process maps to identify areas of risk by asking “what can wrong?”
- develop risk statements and quantify risk
- describe approaches to controlling risks in clinical research and
- mitigate some common implementation challenges.

## Day 2

Wednesday, Sept. 29, 2021

9:30 AM **Welcome**

9:30 AM – 9:45 AM EDT

9:45 AM **Breakout Session #1**

9:45 AM – 11:15 AM EDT

Quality-by-Design and Risk-Based Quality Management Track

- Oversight of Monitoring – Are site issues mitigated? The day in the life of a site QMS and the gap in monitoring
- Identifying common risk factors to support tiering Sites for monitoring.
- Managing Risk Across a Portfolio of Studies
- RBQM Documentation Approaches: Lessons Learned and Points to Consider

Vendor Oversight Track

- Oversight of Monitoring – Are site issues mitigated? The day in the life of a site QMS and the gap in monitoring.
- Selection, implementation and use of KPIs in a Sponsor-CRO collaboration

11:15 AM **Breakout Session #1 Readouts**

11:15 AM – 11:45 AM EDT

11:45 PM **Break**

11:45 AM – 12:30 PM EDT

12:30 PM **Breakout Session #2**

12:30 PM – 2:00 PM EDT

Quality-by-Design and Risk-Based Quality Management Track

- Outsourcing Oversight of QbD

Vendor Oversight Track

- Outsourcing Oversight of QbD
- IT System Selection - How to Define and Estimate System Benefits before Selection
- Using metrics to ID issues and drive improvement activities

2:15 PM **Breakout Session #2 Readouts**

2:15 PM – 2:30 PM EDT

## Day 3

Thursday, Sept. 30, 2021

9:30 AM **Welcome**
9:30 AM – 9:45 AM EDT

9:45 AM **Breakout Session #3**
9:45 AM – 11:15 AM EDT

Quality-by-Design and Risk-Based Quality Management Track

- Oversight of RBQM with a CRO
- RBQM Maturity Model – How to manage critical implementation components when they are maturing at a different pace? Small to large sponsor/CRO, implementation adaptability.
- How to measure success in a decentralized trial
- The central monitor says a risk threshold has been breached … now what?

Vendor Oversight Track

- Decentralized Trials: How Do You Oversee, Manage New Vendors
- Oversight of RBQM with a CRO
- How to Use Metrics to Gain Insights About Site Activation and Patient Enrollment

11:15 AM **Breakout Session #3 Readouts**
11:15 AM – 11:45 PM EDT

11:45 PM **Break**
11:45 PM – 12:30 PM EDT

12:30 PM **Champion Awards**
12:30 PM – 12:45 PM EDT

12:45 PM **Panel Session**
12:45 PM – 1:45 PM EDT

1:45 PM **Summit Close**
1:45 PM – 2:00 PM EDT