Day 1

Tuesday, Sept. 28, 2021

10:00 AM **Summit Opening**
10:00 AM – 10:30 AM EDT

10:30 AM **Keynote: ICH E6(R3) Guideline for Good Clinical Practice Update**
10:30 AM - 11:45 AM EDT

M. Khair ElZarrad, PhD, MPH
ICH E6(R3) Rapporteur, FDA
Deputy Director, Office of Medical Policy
CDER, FDA

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

Keith Dorricott - Dorricott Metrics & Process Improvement Limited
Linda Sullivan - WCG-MCC

2:30 PM **Day 1 Closes**
2:30 PM EDT

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

- Identifying Common Risk Factors to Support Tiering Sites for Monitoring

  All sites are not created equal, does this matter?

  With the increasing number clinical trials being conducted, and the need to expand the number of sites getting involved in research; there is general recognition that a 'one size-fits all' approach to site monitoring is not fit for purpose.

  ICH E6 (R2) RBQM framework supports tailoring monitoring approaches to the specific risks of the study and the pending update to ICH E8 (R1) also points to recognizing sites as stakeholders in the study design and how communicating study risks to sites may support a more collaborative approach to study conduct.

  This workshop aims to evaluate if site tiering is a viable option for providing a better fit for purpose monitoring approach.

  We will consider common risk factors related to experience and past performance that could be used to create site tiers and explore the possibility of using the outcomes of the study risk assessment to engage the site in evaluating how these risks may impact them, and how this could be used as an input into the monitoring tier.

  This workshop will also evaluate the factors that could be used to adjust a site's monitoring tier throughout the study.

  Tammy Finnigan - Triumph Research Intelligence
  Elizabeth Robertson - Triumph Research Intelligence

- Managing Risk Across a Portfolio of Studies

    - How are organizations coordinating program and study risk identification/evaluation?
    - What are the criteria for when trial risks are brought to the program level?
    - How are mitigations defined at the program level?
    - Who is responsible for monitoring program level risks? Are there quality tolerance limits being defined to confirm effectiveness of mitigations?

    Joe Kunakorn - Janssen Pharmaceuticals, Inc.

- RBQM with CROs — Best Practice Discussion

    During this interactive discussion group session, participants will explore two aspects of implementing RBQM with CROs:

    - How to add RBQM to your CRO selection process, and
    - How to partner with your CRO to execute RQBM successfully (including how to avoid common mistakes and how to coordinate multiple service providers)

    The session will be segmented into two parts – each beginning with a live presentation of the topic and some best practices followed by Q&A and an open discussion about participants' experiences.

    Gary Tyson - Pharma Initiatives
    Matt Healy - Rho

- Oversight of Monitoring — Are Site Issues Mitigated? The Day in the Life of a Site QMS and the Gap in Monitoring

    Chuck Sather - Clinical Pathways, LLC
    Sandra Sather - Clinical Pathways, LLC

- RBQM Documentation Approaches: Lessons Learned and Points to Consider

    Vera Pomerantseva – ZS

Vendor Oversight Track

- Selection, Implementation and Use of KPIs in a Sponsor-CRO Collaboration

  Join us to discuss the opportunities and challenges on using KPIs in a Sponsor-CRO collaboration.

  - How can MCC metrics be used to help ensure the right things are measured?
  - How should the data be displayed?
  - How can the different audiences be catered for (study management, oversight, executive)?

  Stephen Crow - GW Pharmaceuticals (Greenwich Pharmaceuticals)
  Keith Dorricott - Dorricott Metrics & Process Improvement Limited

- From Reactive Spreadsheets to Predictive Applications: Modern Approaches to Effective Oversight

  In this interactive discussion group, participants will explore how different companies leverage data for effective oversight of vendors. Discussion group facilitators will share their experience and best practices in working with data and participants will be asked to share their own experiences through interactive polling, white board exercises and live dialog. The discussion will include:

  - Case study: Lokavant story — why we started with the data
  - Data possibilities and use cases
  - Current barriers to using data and technology
  - KRI and KPI selection
  - Data Accessibility

  Todd Johnson – Lokavant
  Alex Greenberg - Lokavant

- Oversight of Monitoring — Are Site Issues Mitigated? The Day in the Life of a Site QMS and the Gap in Monitoring

  Chuck Sather - Clinical Pathways, LLC
  Sandra Sather - Clinical Pathways, LLC

11:15 AM **Breakout Session #1 Readouts**
11:15 PM – 11:45 AM EDT

11:45 AM **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

  In this mini workshop, attendees will explore the critical attributes a vendor needs to possess for effective and quality-driven trial execution in 2021. During a review of these critical attributes, attendees will determine the adequacy of their assessment and selection of their vendors for providing QbD to the sponsor's quality standards and expectations.

  Attendees will also be guided through reflections of their practices to effectively evaluate the vendors RBQM model and plan, technology, processes and vendor staff selection criteria for their assigned RBQM roles.

  Additionally, attendees will evaluate their own practices for the training and equipping of their study teams and study leads in order to be qualified to participate in the vendor selection process.

  This will be an interactive, engaging, live virtual workshop.

  Leslie Sam - Wool Consulting Group

- The Value of and the Approach to a Retrospective Risk-Based Quality Management Analysis

  Many companies still struggle with getting their RBQM process off the ground, frequently due to not knowing how to 'sell' RBQM to their management. One rather successful way is to run a retrospective analysis of a completed study that had issues associated with it. This mini workshop will discuss the options available to set up a retrospective analysis of a study based on a straightforward protocol, discuss how to determine the risks, the key risk indicators and how to set the thresholds.

  The participants will hear about common findings in those retrospective analysis, learn about the golden KRIs and will be able to derive value for their organization based on the outcome of the workshop.

  Artem Andrianov - Cyntegrity
  Johann Proeve - Cyntegrity

- Linking Issues/CAPAs and Risks — Still a Challenge?

  Oleg Shevaldyshev - ICON (formerly PRA Health Sciences)

Vendor Oversight Track

- Using Metrics to ID Issues and Drive Improvement Activities

  The workshop is led by two industry experts in root cause analysis and critical thinking. It starts with the breakout groups reviewing and discussing a vendor's metrics report. What does the data tell you? What additional information do you need? What action might you take? Then the group will come together to discuss the themes and pull out principles for data review and analysis. We'll look at the next month's metric report and see what that tells us. We'll end with key takeaways, Q&A and discussion.

  Keith Dorricott - Dorricott Metrics & Process Improvement Limited
  Dawn Niccum - Inseption Group

- IT System Selection — How to Define and Estimate System Benefits Before Selection

  Gary Tyson - Pharma Initiatives

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  Leslie Sam - Wool Consulting Group

2:00 PM **Breakout Session #2 Readouts**
2:00 PM – 2:30 PM EDT

2:30 PM **Day 2 Closes**
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

- How to Define Critical Processes and Critical Data

  ICH E6 R2 expects companies to implement RBQM based on critical processes and critical data in their studies. Sometimes, however, it is rather difficult to identify those critical processes and critical data since almost everything in a study seems to be critical (or at least should be). This mini workshop will discuss how to identify those critical processes and critical data and help the workshop participants to get the process started.

  The participants will learn how to transform the critical processes and critical data into a risk statement which can commonly be understood by everybody in an organization.

  Artem Andrianov – Cyntegrity
  Johann Proeve - Cyntegrity

- The Central Monitor Says a Risk Threshold has been Breached … Now What?

  Steve Young - CluePoints

- RBQM Maturity Model — How to Manage Critical Implementation Components When They are Maturing at a Different Pace? Small to Large Sponsor/CRO, Implementation Adaptability

  Sandra Sather - Clinical Pathways, LLC
  Jennifer Lawyer - Clinical Pathways, LLC

- Oversight of RBQM with a CRO

  Continuing the learnings from Leslie Sam's session on Outsourcing Oversight of QbD, this mini-workshop delves into meeting the regulatory authority expectations for on-going vendor oversight of the sponsor's delegation of RBQM to their vendor. Attendees will evaluate the foundational requirements for vendor oversight (procedures, processes, training, vendor oversight plan), and determine the critical — to — quality duties, functions, and activities for their outsourced RBQM. Attendees will also evaluate their resourcing models and headcount that ensures there are enough staff, who are qualified for RBQM vendor oversight, assigned to their clinical programs. This will be an interactive, engaging, live virtual workshop with Liz Wool.

  Liz Wool - Wool Consulting Group, Inc.

- How to Measure Success in a Decentralized Trial

  Jennifer Price - THREAD Research

Vendor Oversight Track

- How to Use Metrics to Gain Insights About Site Activation and Patient Enrollment

  Keith Dorricott - Dorricott Metrics & Process Improvement Limited
Elvin Thalund - Oracle Health Sciences

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  Liz Wool - Wool Consulting Group, Inc.

- Decentralized Trials: How Do You Oversee, Manage New Vendors

  Pam Tenaerts - Medable, Inc.
  Keith Morgenstern - Medable, Inc.

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

11:45 PM **Break**
12:45 11:45 AM – 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