VIRTUAL EVENT

Risk-Based Quality Management

DECEMBER 2-3, 2020
Delivered as a 100% Virtual Event in EST Time Zone

ELEVATE YOUR CLINICAL DATA QUALITY AND STREAMLINE THE PATH TO COMPLIANCE THROUGH RISK-BASED TRIAL MANAGEMENT & MONITORING

FEATURED SPEAKERS:

Ann Meeker-O'Connell,
Vice President,
Integrated QMS/OMS,
VERTEX PHARMACEUTICALS

Andy Lawton,
Director,
RISK-BASED APPROACH LTD

Mary Arnould,
Director,
ASTELLAS PHARMA

Steve Young,
Chief Scientific Officer
CLUEPOINTS

With leading insights on ICH guidelines, AI & machine learning, change management and beyond...

PROGRAM CHAIRS AND ADVISORY BOARD:

CO-CHAIR:

Christopher Biddle,
Associate Director, Risk Management,
and Central Monitoring,
JANSSEN

CO-CHAIR:

Esther M. Huffman O'Keefe,
Associate Director,
Monitoring,
REGENERON

ADVISORS:

John (Jay) Daly,
Clinical Study Risk Manager,
Clinical Data Operations,
Technology and Standards,
UCB BIOSCIENCES, INC.

Laureen Dorschel,
Clinical Data Manager,
UCB BIOSCIENCES, INC.

Craig Reist, Ph.D.,
VP & Chief Scientific Officer,
2M CLINICAL

Michael Walega,
Head of Centralized Monitoring,
BRISTOL MYERS SQUIBB

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Risk-Based Quality Management

Collaborate with Industry Thought-Leaders on the Following Topics:

- Change Management and Considerations from Leadership Teams
- State of the Industry Panel Debate
- Understand the Impacts of ICH E8 and What is Coming for ICH E6 Revisions
- Learn About the Evolution of Machine Learning and AI
- Tackle Long-Standing Challenges with New Technologies
- **BONUS:** Benchmark and Connect with Peers During the Live Speaker Q&A

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> **"The conference provided a professional, yet relaxing environment that allowed for great collaborations on how RBM is being utilized in the industry through the eyes of sponsors, CROs, and vendors. Very much look forward to future conference opportunities."**
>
> - Clinical Study Risk Monitor, **UCB Biosciences, Inc.**

> **"Excellent and informative conference."**
>
> - Senior Specialist, Central Monitoring, **Janssen**

> **"This conference brought together a broad range of experts and stakeholders committed to optimizing the clinical research process to accelerate drug and device approvals to benefit patients."**
>
> - President, **Target Health, Inc.**

> **"The ideal forum to be on the forefront of emerging strategies and approaches to clinical trial oversight."**
>
> - Manager, Clinical Monitoring, **St. Jude Medical**

DAY 1: WEDNESDAY, DECEMBER 2ND

All sessions marked with ** will be made available on-demand for 30 days following the event.
All times listed are in EST time zone.

10:25 am **Co-Chairs Welcome and Opening Remarks ****
Danica Schroth, Conference Director, **Informa Connect**

10:30 am **Leadership Perspective: Change Management ****
- Considerations from the leadership team
- Benefits seen through RBQM efforts
- RBQM's Role vs. Clinical's Role
- Overall Metrics of adoption
- Successes/Failures and Lessons Learned
- Issues management and incorporating everything from data management queries to comprehensive analysis etc.

Johann Proeve, Ph.D., Chief Scientific Officer, **Cyntegrity**
Nico Wegener, MD, Senior Clinical Project Manager, **Merz Pharmaceuticals**

10:55 am **State of the Industry**
Steve Young, Chief Operations Officer, **CluePoints**

11:15 am - Take a Break and Visit the Virtual Exhibit Hall

11:20 am **Panel Debate: State of the Industry from Stakeholders**
Moderator: Andy Lawton, Director, **Risk-Based Approach Ltd**

Panelists
Steve Young, Chief Operations Officer, **CluePoints**
Rosanne Petros, PMP, Associate Director, Clinical Research, **Merck Research Laboratories**
Esther Huffman O'Keefe, Associate Director, Monitoring, Global Clinical Operations, **Regeneron**
Stephanie Clark, Director, Risk Management - Central Monitoring,
The Janssen Pharmaceutical Companies of Johnson & Johnson

12:05 am **Regulatory Perspective: Concept of Quality in Clinical Trials****
- Review guidelines around Quality by Design
- Examples of alternative methods that should be considered (historical placebo controls, merging with EMR data or epidemiology data etc.)
- Recommendations to implement in your current RBM model
- Case Study from pharma – challenges faces, lessons learned from a study managed, submitted and inspected based on new guidelines

Andy Lawton, Director, **Risk-Based Approach Ltd**

12:25 pm - Grab some Lunch. Then come back to join in networking activities, watch product showcases, and connect with your key product and service providers in the virtual exhibit hall.

1:25 pm **Regulatory Perspective: Concept of Quality in Clinical Trials**
Ann Meeker O'Connell, Vice President, Integrated QMS/OMS, **Vertex Pharmaceuticals**

1:50 pm **Pivorting RBQM to Mitigate COVID-Borne Risks**
- Discuss how oversight needs have changed and how to address
- Discuss how to have around the clock coverage of risk review and mitigation even when can't be onsite
- Discuss how to drive consistency in response to a global risk using RBQM techniques

Kristin Stallcup, Senior Director, Xcellerate Customer Success, **Covance**

2:15 pm **ICH E6(R3) Review: RBQM Considerations within Annex 2 Applied to Non-Traditional Trials**
Steve Whittaker, Senior Consultant, **The Avoca Group**

2:40 pm **Live Speaker Q&A**
Facilitator: Lisa Henderson, Group Content Director, Applied Clinical Trials and Pharmaceutical Executive, **MJH Associates Inc.**

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10:25 am **Co-Chairs Review of Day 1**
Esther M. Huffman O'Keefe, Associate Director, Monitoring, Global Clinical Operations, **Regeneron**

10:30 am **The Evolution of Machine Learning and AI – Where Are We Headed? ****
- How is it revolutionizing central monitoring and risk management?
- Regulatory implications?
- How are organizations moving towards machine learning?
- What advancements are being made?
- Best practices or any lessons learned?
- Case study example?

Marion Wolfs, Head, Senior Director Risk Management & Central Monitoring, **The Janssen Pharmaceutical Companies of Johnson & Johnson**

10:55 am **New Technologies and their Impact on Long-Standing RBM Challenges ****
- How have long-term issues been solved (case study examples)?
- Comparison between smaller/new tech companies and larger companies
- Sponsor perspective – lessons learned/best practices for implementing any new tech
- Country Adoption
- Deployment within Countries

MaryAnne Rizk, Ph.D., Senior Vice President, Digital R&D Strategy, **IQVIA Technologies**

11:15 am - Take a Break and Visit the Virtual Exhibit Hall

11:20 am **Case Study: New Technologies and Their Approach to RBM at UCB ****
- Data Visualizations
- Protocol Complexity Assessments
- Risk Prediction
- Sponsor oversight of monitoring visit reports

John (Jay) Daly, Clinical Study Risk Manager, Clinical Data Operations, Technology and Standards, **UCB Biosciences, Inc.**

11:45 am **Panel: Innovative Approaches to Remote Monitoring During and Post-COVID-19 ****
Moderator: **Rosanne Petros,** PMP, Associate Director, Clinical Research, **Merck Research Laboratories**

John (Jay) Daly, Clinical Study Risk Manager, Clinical Data Operations, Technology and Standards, **UCB Biosciences, Inc.**

Mary Arnould, Director, **Astellas Pharma**

Stephanie Clark, Director, Risk Management – Central Monitoring,
The Janssen Pharmaceutical Companies of Johnson & Johnson

Artem Andrianov, Ph.D., MBA, Managing Director, **Cyntegrity**

12:25 pm - Grab some Lunch. Then come back to join in networking activities, watch product showcases, and connect with your key product and service providers in the virtual exhibit hall.

1:25 pm **An effective risk-based quality plan starts with data literacy**
Kristin Mauri, Solutions Services Director, **Remarque Systems**

When ICH e6 R2 was released in early Feb 2018 many in the industry thought that was going to be the catalyst to drive widespread adoption of RBQM. 3 years later, while there has been an increase in the uptake of RBM methodologies , we still see a large of amount of trials being run under old monitoring approaches and principles. What is preventing us from leveraging people, process and technology to move towards this more modern approach to clinical trial execution? During this session we will explore where we are as an industry in terms of RBM adoption, talk about what is holding us back, and discuss the organizational shift required to adopt RQBM as a standard for all trials.

1:50 pm **Successes in RBM and Quality for Audit and Inspection**
- What has been de-risked?
- What observations have been made?
- What issues were avoided?
- Discussion on how it can be further improved and streamlined

Jamie O'Neill, Senior Manager, Central Monitoring Operations, **Covance**

2:15 pm **Live Speaker Q&A**
Host: **Esther Huffman O'Keefe,** Associate Director, Monitoring, Global Clinical Operations, **Regeneron**

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