VIRTUAL EVENT

# Risk-Based Quality Management

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

# ELEVATE YOUR CLINICAL DATA QUALITY & 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 and 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
- Learn from a Small-Sized Pharma on the Scrappy Side of RBQM Models
- **BONUS:** Benchmark and Connect with Peers During the Live Speaker Q&A and Roundtable Discussions.

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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

Throughout the Conference there will be live keynote sessions, on-demand sessions and an opportunity for live Q+A with our speakers. The agenda below provides our recommended viewing order, but any sessions marked with ** will be available on demand. All times listed are EDT time zone.

10:25 am **Co-Chairs Welcome and Opening Remarks ****
**Christopher Biddle,** Associate Director, Risk Management, **Janssen**
**Esther M. Huffman O'Keefe,** Associate Director, Monitoring, Global Clinical Operations, **Regeneron**

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.

10:50 am **State of the Industry**
**Steve Young,** Chief Operations Officer, **CluePoints**

11:10 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**

12:00 pm **Regulatory Perspective: Concept of Quality in Clinical Trials****
**Andy Lawton,** Director, **Risk-Based Approach Ltd**
- 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

12:20 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.

1:20 pm **FDA Perspective: Concept of Quality in Clinical Trials**
**Ann Meeker O'Connell,** Vice President, Integrated QMS/OMS, **Vertex Pharmaceuticals**

1:40 pm **Presentation Title TBD ****
**Duncan Hall,** CEO and Founder, **Triumph Research Intelligence (TRI)**

2:00 pm **Live Speaker Q&A and Networking**
**Facilitator: Christopher Biddle,** Associate Director, Risk Management and Central Monitoring, **Janssen Research**

# DAY 2: THURSDAY, DECEMBER 3RD

Throughout the Conference there will be live keynote sessions, on-demand sessions and an opportunity for live Q+A with our speakers. The agenda below provides our recommended viewing order, but any sessions marked with ** will be available on demand. All times listed are EDT time zone.

10:25 am **Co-Chairs Review of Day 1 ****

**Christopher Biddle,** Associate Director, Risk Management, **Janssen**

**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? ****

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

- 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?

10:50 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

11:10 am - Take a Break and Visit the Virtual Exhibit Hall

11:20 am **Case Study: New Technologies and Their Approach to RBM at UCB ****

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

- Data Visualizations
- Protocol Complexity Assessments
- Risk Prediction
- Sponsor oversight of monitoring visit reports

11:40 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.**

**Esther Huffman O'Keefe,** Associate Director, Monitoring, Global Clinical Operations, **Regeneron**

**Mary Arnould,** Director, **Astellas Pharma**

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

12:20 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.

1:20 pm Track Presentation Available for Sponsorship

1:40 pm **Successes in RBM and Quality (Audit and Inspection) and Overall Data Quality at Sites ****

**Jennifer Bournique,** Associate Director, Riske Management & Central Monitoring,
**The Janssen Pharmaceutical Companies of Johnson & Johnson**

- What has been de-risked?
- What observations have been made?
- What issues were avoided?
- Discussion on how it can be further improved and **streamlined**

1:55 pm **Live Speaker Q&A and Networking**

Host: **Esther Huffman O'Keefe,** Associate Director, Monitoring, Global Clinical Operations, **Regeneron**

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