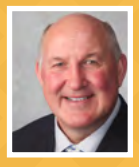
June 3-4, 2021 | Virtual Event

Risk Based Quality Management Summit

World Class Risk Evaluation and Adaptive Integrated Monitoring

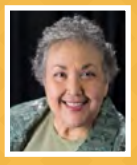
THE DISTINGUISHED 2021 SPEAKING FACULTY

KEYNOTE



Andy Lee, SVP, Head of Global Clinical Trial Operations, **MERCK RESEARCH LABORATORIES**

Jennifer Goewey, Associate Director, Risk Management-Central Monitoring, **JANSSEN R&D**



Celeste Gonzalez, Principal Specialist, Clinical Quality Assurance and Compliance, **BOSTON SCIENTIFIC**

Nechama Katan, Director Data Science Lead, **PFIZER**

Prajna Kumar, Senior Director, Clinical Development Quality Operations, **ALEXION**

Anne Lawrence, Executive Director Site Management Operations, **ABBVIE**

Andy Lawton, Consultant, **RISK BASED APPROACH LTD.**

Scott Litrakis, Head of Clinical Compliance and Risk Management, **BMS**

Suzanne Lukac, Associate Director Centralized Monitoring, **SEAGEN**

Esther Huffman O'Keefe, Associate Director – Monitoring, **REGENERON**

Angela Repa, Senior Director, Proactive Clinical Excellence, **BLUEBIRD BIO**

Catherine Sinclair, Director, Central Monitoring and Data Analytics, **GSK**

Shawntel Swannack, Central Monitoring, **GSK**

Phi Tat, Central Monitoring Manager, **PFIZER**

Katherine Taylor, Head of Risk Evaluation and Adaptive Integrated Monitoring (REAIM), **MERCK**

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WHY ATTEND?

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There is no doubt that the COVID-19 pandemic has shifted the clinical trials landscape and potentially changed it forever. Respectively, how has quality risk management changed and where do we go from here?

The RBQM Summit is your best opportunity to get the latest information available on whether regulators will continue to accept remote monitoring and digital technologies and how to think about maintaining a level of risk tolerance and agility in clinical trial oversight. The summit boasts an unrivalled lineup of expert speakers and complex discussion points.

The agenda includes two sessions on COVID-19 for a double lens on key takeaways. Phi Tat, Central Monitoring Manager, Pfizer will discuss lessons learned from RBQM management in vaccine trials and Jennifer Goewey, Associate Director, Risk Management-Central Monitoring, JANSSEN R&D focuses on their development of a data visualization dashboard to address the impact of COVID-19 on trials. Additionally, the heavy hitting agenda focuses on complex issues, including:

- ✓ How to ensure a comprehensive, end-to-end RBQM master plan
- ✓ Initiate a "culture of quality" toward proactive risk management
- ✓ Discern the realities of applying Six Sigma to clinical research
- ✓ Evaluate what happens when thresholds are exceeded and whether subsequent data are still valid
- ✓ Assess methods to remotely review data and examine changes in data monitoring post COVID-19
- ✓ Prepare for FDA inspection and exact a risk based audit strategy

WHO SHOULD ATTEND

- RBM/RBQM
- Study Monitoring
- Central Monitoring/Site Monitoring
- Clinical Operations
- Clinical Research
- Clinical Quality
- Clinical Quality Assurance
- Clinical Compliance
- Clinical Outsourcing
- Data Management
- Data Science
- Global Clinical Trial Operations
- Medical Writing
- Regulatory Affairs
- Risk Evaluation

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DAY ONE | THURSDAY, JUNE 3, 2021

8:30 *Registration & Log In*

9:00 *Chairperson's Opening Remarks*

9:15 **KEYNOTE**

Reach For World Class Enterprise Risk Evaluation and Adaptive Integrated Monitoring

You may need to completely disrupt your operating model, process, people and technology in order to arrive at world class risk management. Embrace a strategy that builds and strengthens core competencies to achieve next level performance.

- Be willing to allocate resources to highest risk areas
- Standardize and industrialize to build a platform for innovation.
- Determine core competencies and why that's relevant for your journey
- Key takeaways from regulatory inspections and future planning steps
- Develop the right tools and retain employees to reinvent monitoring for the future

Andy Lee, SVP, Head of Global Clinical Trial Operations, **MERCK RESEARCH LABORATORIES**

DEVELOP, IMPLEMENT AND MAINTAIN AN RBQM MASTER PLAN

10:00 **Secrets to Success for an End-to-End Comprehensive RBQM plan**

The key factor for successful RBQM implementation and ongoing management hinge upon setting up for success at the onset. In order to maximize the value of your RBQM plan you must be intentional with how the components fit together. Quality will suffer if a strategic, end-to-end approach is overlooked.

- Ensure you have the right components and understand their interdependencies
- Sharpen skills for risk identification, mitigation and response
- Ensure that risk assessments feed into monitoring programs

Anne Lawrence, Executive Director Site Management Operations, **ABBVIE**

10:45 *Break*

11:00 **PANEL | Maintain the Momentum of Proactive Risk Management**

The COVID 19 pandemic has forced industry to "walk the walk" when it comes to quality risk management. As we begin to move out of COVID, there is an opportunity to apply the lessons learned to maintain a level of risk tolerance and to be more agile in clinical trial oversight.

- Discuss whether regulators will continue to accept remote monitoring and digital technologies and engage authorities around other areas that may benefit from shifts away from current models
- Plan for and initiate a culture of quality to continue to shift toward proactive risk management
- How do we ensure better trial oversight through remote activity?
- Examine whether implementing quality by design for protocol development will enable parallel focus on innovative science and molecule development

PANELISTS:

Scott Litrakis, Head of Clinical Compliance and Risk Management, **BMS**

Angela Repa, Senior Director, Proactive Clinical Excellence, **BLUEBIRD BIO**

Prajna Kumar, Senior Director, Clinical Development Quality Operations, **ALEXION**

KEYS TO SUCCESSFUL QUALITY BY DESIGN (QBD)

11:45 **Continually Improve and Innovate in a "Culture of Quality"**

Dr. Joseph M. Juran developed the concept of quality by design (QBD) and many industries have embraced it. What does it mean for the biopharmaceutical and device industries? How far we have come and where we will be in the near future?

- Understand the baseline for using QBD by linking ICH6
- Determine the approach for identifying critical quality factors and methods for ideal metrics management
- Focus on what regulators expect in QBD

Andy Lawton, Consultant, **RISK BASED APPROACH LTD.**

12:30 *Lunch*

1:00 **Focus on a Systematic Approach to Risk Management Including Process Controls**

There is a tremendous opportunity to leverage the relationship between clinical and manufacturing functions to advance quality and risk management systematically. Biopharma manufacturing has leveraged process controls to ensure continuous quality improvement and quality by design over the last number of years.

- Discuss the realities of applying Six Sigma to clinical research
- Get closer to the issues that matter – what do you measure and when it goes out of control how do you address this? Do you apply root cause analysis?
- Determine what data is trending and how to best utilize this
- Examine adaptive design

Nechama Katan, Director Data Science Lead, **PFIZER**

1:45 **Avoid Setting Unreasonable Quality Tolerance Limits**

There is a strong correlation between placing reasonable thresholds and setting effective key risk indicators. Consider whether it's practical and timely to move away from attempting perfection to a space where you define quality and have acceptable errors inside.

- Set yourself up for success with QTLs and avoid unreasonable thresholds
- Evaluate what happens when thresholds are exceeded and whether subsequent data are still valid
- Consider why QTLs and KRIs must line up and how QTL management can be more robust

Celeste Gonzalez, Principal Specialist, Clinical Quality Assurance and Compliance, **BOSTON SCIENTIFIC**

2:30 **Ensure Scalability of Your Risk Based Quality Management Systems**

Building or buying new technology tools is not the most difficult aspect of implementing a successful RBQM system. Scalability of the usage of the tool is the hardest piece and it is critical to lay the foundation correctly to ensure success of the system.

- Identify the essentials for ongoing management of the tool
- Build in data standards and strive for standardization as you refine protocols
- Realize that standard protocols lead to standard data collection and leverage as much as possible from standardization to avoid excessive customization

Shawntel Swannack,Central Monitoring, **GSK**

3:15 *Day one concludes*

DAY TWO | FRIDAY, JUNE 4, 2021

8:40 *Log In*

9:00 *Chairperson's Review of Day One*

EVALUATE RISK IN MONITORING TYPES

9:15 **PANEL | Evaluate Shifts in Data Monitoring Pre and Post COVID-19**

Sponsors had been somewhat slow to adapt to technology-based approaches to monitoring trial data. In the wake of COVID, the absence of on-site monitoring has led to an acceleration in the adoption of these technologies.

- Clarify expansion of monitoring to include remote data monitoring, site, and central monitoring
- Assess methods to remotely review data
- Discuss how COVID-19 changed attitudes
- Consider new tools for remote data surveillance
- Support study teams in performing data-related risk assessments

PANELISTS:

Suzanne Lukac, Associate Director Centralized Monitoring, **SEAGEN**
Esther Huffman O'Keefe, Associate Director Monitoring, **REGENERON**
Catherine Sinclair, Director, Central Monitoring and Data Analytics, **GSK**

10:00 **Reduce Source Data Verification and Appraise the Site Monitoring Role in Risk Based Monitoring**

Closing the loop on risk based monitoring and ensuring that we evolve the site monitor's role to tie together the risk assessment and the central monitoring findings is a critical component to a successful RBQM program.

- Articulate the CRA's responsibility in the site monitoring role
- Discuss change management and where industry is in the curve
- Track the evolution of the role of the site monitor
- Reshape how your study gets audited

Esther Huffman O'Keefe, Associate Director – Monitoring, **REGENERON**

10:45 *Break*

ADAPT AND IMPLEMENT ROBUST RISK BASED QUALITY MANAGEMENT

11:00 **Analyze Expedited Development and Use of a New Data Visualization Dashboard to Address the Impact of Covid-19 on our Clinical Trials**

With the Covid-19 pandemic upon us, we had to create a quick and easy way to review data trends at multiple levels for our clinical trials.

- Understand why it was developed, focusing on central monitoring
- Hear about what was developed to support our trial teams
- Gain insight into how it is being applied to Deviation and Adverse Event Trending and other data reviews

Jennifer Goewey, Associate Director, Risk Management-Central Monitoring, **JANSSEN R&D**

11:45 **Gather Lessons Learned About RBQM from Vaccine Trials**

Discover more about the management of RBQM in vaccine trials and key takeaways.

- Examine frequency analysis
- Consider adaptive approach to risk
- Analyze QTL & KRI interaction
- Review the complete cycle for signal management to site follow up and back

Phi Tat, Central Monitoring Manager, **PFIZER**

12:30 *Lunch*

1:00 **Prepare for FDA Inspection and Exact a Risk Based Audit Strategy**

Learning from examples of 483 warning letters is a good way to know what to look out for and stay "inspection ready". Establish and maintain a single source of truth for study and site quality management, to ensure inspection readiness.

- Address risk-based approach and tools (RACT) used to optimize inspection readiness
- Delve into deviation management
- Hear about the most common FDA findings in inspections
- Consider what types of corrective actions could be necessary and why timeliness is important regarding the 483 response
- Implement end to end mock inspections and tactics for demonstrating audit trails

Katherine Taylor, Head of Risk Evaluation and Adaptive Integrated Monitoring (REAIM), **MERCK**

1:45 **Foster An Audit and Oversight Strategy for Vendor Quality Management**

Vendor oversight is a critical piece of the risk based quality management plan (RBQM). The sponsor is responsible for the quality performance of CROs, vendors and subcontractors.

- Develop a vendor oversight SOP
- Create documents for oversight and quality management of CROs, vendors and subcontractors
- Identify a vendor risk management plan

2:30 *Chairperson's Closing Remarks*

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