

6TH RISK-BASED QUALITY MANAGEMENT SUMMIT

The most detailed problem-solving space for change management, QbD implementation, metrics, E6(R3) inspection readiness, and data risks.

From Blueprint to Breakthrough: Implementing Quality by Design that Delivers



Karen Ragnauth
Director, Clinical Quality
Oversight & Risk Management
SHIONOGI



N. Kofi Addo
Manager, Clinical Quality
Control Oversight, Risk
Management
SHIONOGI

Detecting Fraud in Clinical Trial Data



Rachel Dossman
Director, Clinical Process
Compliance, Clinical
Development Operations
ABBVIE



Anne Hale
Head, Central Monitoring
and Study Risk Management,
Clinical Development
Operations
ABBVIE

ICH E6(R3) in the Real World: Post-Adoption Lessons and the Road Ahead



Olivio Feiro
Director, Risk Management
and Analytics
CSL BEHRING



Maria Florez
Senior Researcher
**TUFTS CENTER FOR THE STUDY
OF DRUG DEVELOPMENT**

Build Metrics that Influence Leadership Decisions



Marcin Kronhardt
Associate Director, Data
Management Science
BIOMARIN

The Change Management Imperative: Driving Lasting RBQM Adoption from the C-Suite to the Site



Alanna Steffen
Senior Manager, Clinical
Operations
COOK MEDICAL

“The sessions were great and shared multiple experiences, perspectives, and practical applications for current day challenges.”

– Head, Risk Evaluation & Adaptive Integrated Monitoring, **MERCK**

“I'd recommend this event to colleagues! Great conversations, networking, and idea sharing.”

– Manager, Central Monitoring & Data Analytics, **GSK**

“All sessions brought unique perspectives and I left with new ideas from each one.”

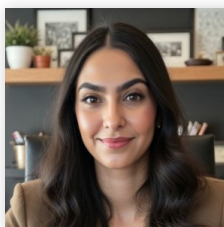
– Head, Centralized Monitoring, **BRISTOL-MYERS SQUIBB**

FEATURED SPEAKERS



N. Kofi Addo
Manager, Clinical
Quality Control
Oversight, Risk
Management

SHIONOGI



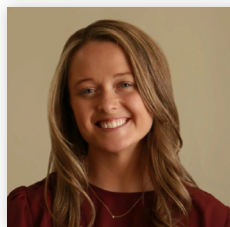
Lena Al-Rashed
Senior Compliance
Manager

ABBVIE



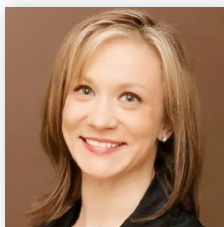
Joshua Cox
Vice President,
Clinical Data
and Analytics
Capabilities

ELI LILLY



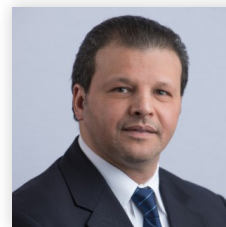
Abigail Dirks
Data Scientist

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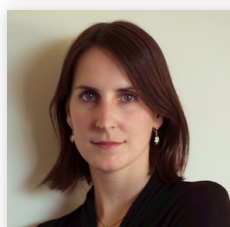
Rachel Dossman
Director, Clinical
Process Compliance,
Clinical Development
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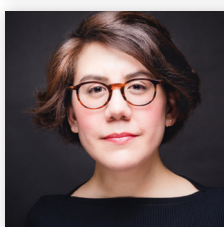
Kal Elhoregy
Senior Director,
Global Risk
Management &
Pharmacovigilance
Compliance

AMNEAL



Olivio Feiro
Director, Risk
Management and
Analytics

CSL BEHRING



Maria Florez
Senior Researcher

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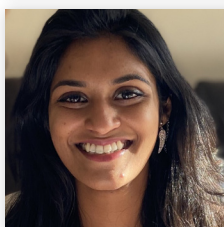
Nuvala Fomban
Senior Director, Risk
Management and
Central Monitoring

**BRISTOL MEYERS
SQUIBB**



Kristin Giessler
Senior Manager,
Risk-Based Quality
Management
Operations

TAKEDA



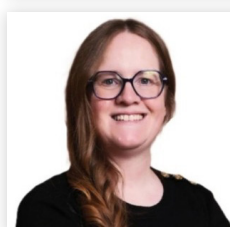
Pujitha
Gourabathini
Manager, Quality
Assurance, Risk
Management

BD



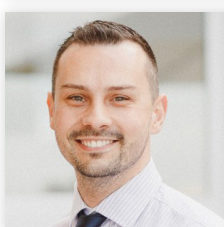
Anne Hale
Head, Central
Monitoring and Study
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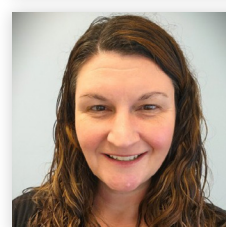
Nechama Katan
former Director,
Innovative Data
Analytics

PFIZER



Marcin Kronhardt
Associate Director,
Data Management
Science

BIOMARIN



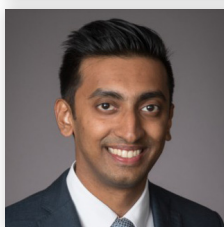
Lyndi Rice
Head of Novato
Quality Control

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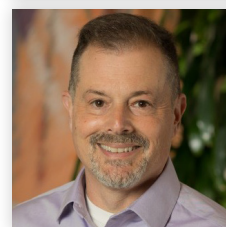
Karen Ragnauth
Director, Clinical
Quality Oversight &
Risk Management

SHIONOGI



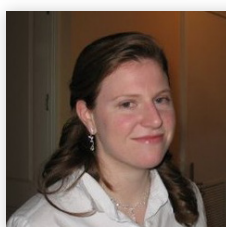
Sathya Ramnath
Senior Manager,
Risk-Based Quality
Management

GILEAD



Jonathan Rowe
Head of R&D Quality,
Operations and Risk
Management

ZS



Alanna Steffen
Senior Manager,
Clinical Operations

COOK MEDICAL



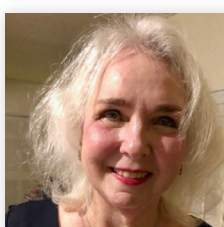
Vadim
Tantsyura
Executive Director,
Global Head of
Data Management

NUVATION BIO



Ted Thendral,
Director
RBQM Central
Statistical
Monitoring (CSM)

DAIICHI SANKYO



Nancy Wintering
Assistant Director
of Research

**THOMAS
JEFFERSON
UNIVERSITY**

Clinical trial teams today are operating under extraordinary pressure. With ICH E6(R3) reshaping global expectations, sponsors and CROs must not only prove inspection readiness, but also embed Quality by Design principles, demonstrate ROI, and keep pace with disruptive technologies like AI and audit trail analytics. Cultural resistance, siloed adoption, and talent gaps only intensify the challenge—leaving organizations vulnerable to missed risk signals, wasted resources, and compromised trial quality.

The **6th Risk-Based Quality Management Summit** is your chance to cut through this complexity with clarity and practical strategies. By learning and networking with our expert faculty, you'll gain tools to move RBQM from theory to sustainable practice, align cross-functional teams on quality ownership, and secure executive buy-in with evidence-based business cases. Sessions will spotlight how to:

- Implement QbD that drives measurable outcomes across every trial phase
- Overcome cultural and change-management barriers to lasting RBQM adoption
- Harness AI, audit trail analytics, and advanced metrics for proactive risk detection
- Translate ICH E6(R3) compliance into operational and strategic wins
- Quantify the financial ROI of RBQM deployments with new Tufts CSDD research
- Build and staff the “dream team” needed for a post-E6(R3) world

...and much more! Join RBQM leaders January 13–14, 2026, in Philadelphia to get the latest regulatory insights, learn from real-world case studies, and future-proof your risk-based quality management strategy.

WHO WILL ATTEND

- RBM/ RBQM
- Study Monitoring
- Study Lead
- Central Monitoring/Site Monitoring
- Clinical Operations
- Clinical Research
- Clinical Quality
- Clinical Quality Assurance
- Clinical Research Compliance
- Clinical Protocol Lead
- Clinical Operations & Compliance
- Risk Evaluation & Adaptive Integrated Monitoring
- Risk/Risk Management
- Clinical Standards and Innovation
- GCP Quality Assurance
- Data Management
- Data Monitoring
- Research Quality
- Clinical Outsourcing Analytics
- Site Engagement
- Site Monitoring
- R&D Quality
- Trial Feasibility
- Clinical Business Operations
- Data Sciences
- Regulatory Affairs

DAY 1: Practical RBQM Implementation, Cultural Shifts, & Strategic Alignment	
8:00 AM	Registration & Networking Breakfast
8:45 AM	Chairperson’s Opening Remarks
9:00 AM	From Blueprint to Breakthrough: Implementing Quality by Design That Delivers
ICH E6(R3) has made Quality by Design (QbD) a regulatory imperative, but to truly reap the benefits, QbD must move beyond theory into a living, breathing framework that shapes every trial decision. Is your team ready? By translating QbD principles into concrete actions, you can reduce rework, strengthen patient safety, and deliver reliable, inspection ready data without slowing timelines. - Map QbD principles to each phase of trial design, from concept through close-out - Identify and prioritize CTQs early to prevent downstream quality issues - Integrate QbD with RBQM frameworks for a cohesive, risk-driven approach for operational efficiency and regulatory readiness - Leverage technology and analytics to make QbD a continuous, adaptive process rather than a one-time exercise Karen Ragnauth, Director, Clinical Quality Oversight & Risk Management, SHIONOGI N. Kofi Addo, Manager, Clinical Quality Control Oversight, Risk Management, SHIONOGI	
9:45 AM	RBM to RBQM to IQRM: A Modern Evolution
RBQM promised smarter, more efficient trials, but what’s actually got ten in the way? Drawing data from ten small to large pharma companies, ZS exposes seven recurring pain points that stall progress and shows how an integrated, portfolio-wide approach can unlock real gains in productivity and GCP compliance. We’ll also explore the nirvana of Integrated Quality Risk Management (IQRM) and what leading sponsors are already achieving with it. - Pinpoint seven common obstacles that derail RBQM in practice - Explain how integrating RBQM from site to study to portfolio can double productivity while strengthening GCP adherence - Describe the vision and tangible benefits of moving from RBQM to IQRM based on large pharma implementations Jonathan Rowe, Head of R&D Quality, Operations and Risk Management, ZS	
10:30 AM	Break
11:00 AM	The Change Management Imperative: Driving Lasting RBQM Adoption from the C-Suite to the Site
In today’s regulatory environment, RBQM isn’t optional, but successful adoption is far from guaranteed. Too many organizations invest in tools and frameworks only to see them stall under cultural resistance, leadership disengagement, and outdated “business as usual” mindsets. The cost of failed adoption? Missed risk signals, wasted resources, and diminished trial quality. Join us to experience a complete change management roadmap—starting with building urgency, mobilizing champions, and securing leadership buy-in, then sustaining momentum through clear metrics, visible results, and organization-wide engagement. Through this you can master practical strategies to transform RBQM from a compliance project into a lasting cultural shift. - Recognize the most common adoption roadblocks and how to overcome them - Reframe RBQM concepts into language teams embrace - Build a network of cross-functional champions to lead peer-to-peer adoption - Maintain executive sponsorship by demonstrating ROI and strategic value - Keep RBQM visible, relevant, and embedded in daily operations long after rollout Alanna Steffen, Senior Manager, Clinical Operations, COOK MEDICAL	
11:45 AM	Panel: Break Down Silos and Drive RBQM Success Through Cross-Functional Collaboration
A 2024 survey by Tufts CSDD, CluePoints, and PwC found that, on average, companies have implemented RBQM in only 57% of their clinical trials. RBQM adoption often stalls when ownership is limited to a single function or small group of specialists. Effective, sustainable implementation requires broad engagement from clinical operations, data management, biostatistics, quality, and other key functions. Real-world lessons from CRO and pharma settings can give you clearer understanding of the organizational, cultural, and operational shifts needed to embed RBQM principles across teams. - Grasp the risks of siloed RBQM ownership and the benefits of cross-functional engagement - Implement strategies for bringing clinical operations, data management, and other leaders into the RBQM process early - Apply change-management tools to build trust and reduce resistance - Establish shared accountability for quality, efficiency, and cost outcomes - Integrate RBQM into existing workflows without undermining established best practices Vadim Tantsyura, Executive Director, Global Head of Data Management, NUVATION BIO Rachel Dossman, Director, Clinical Process Compliance, Clinical Development Operations, ABBVIE Kristin Giessler, Senior Manager, Risk-Based Quality Management Operations, TAKEDA	
12:30 PM	Lunch

1:45 PM	From Silos to Synergy: Building Inclusive, Quality-Driven Partnerships in the RBQM Era
In today’s evolving RBQM landscape, fractured relationships between sponsors, CROs, and sites can quietly erode both quality outcomes and diversity goals. Add in shifting inclusion mandates and decentralized trial models, and the stakes for alignment have never been higher. Your team needs to equip its clinical leaders with the strategies to transform tension into trust—aligning all parties on shared risk ownership, transparent communication, and inclusive Quality by Design (QbD) principles. - Define and align shared risk ownership across sponsors, CROs, and sites to eliminate role confusion and prevent blame-shifting - Integrate diversity and inclusion goals into QbD frameworks, even amid regulatory rollbacks - Translate inclusion principles into measurable risk and quality metrics that resonate with all stakeholders - Adapt recruitment and consent strategies to meet evolving regulatory requirements without compromising data quality - Foster cross-functional trust that accelerates decision-making and ensures trials remain both representative and compliant Nancy Wintering, Assistant Director of Research, THOMAS JEFFERSON UNIVERSITY	
2:30 PM	Focus on New Research Quantifying the Net Financial Return on RBQM Deployments
Groundbreaking research from the Tufts Center for the Study of Drug Development is shedding light on the true business case for Risk-Based Quality Management. Leveraging industry benchmarks and impact measures from actual RBQM implementation experience, Tufts CSDD modeled the Expected Net Present Value (eNPV) of RBQM investment in oncology drug development programs. The findings reveal substantial financial returns, providing long-awaited evidence to support adoption, scale, and continued investment. - Understand the eNPV modeling and direct cost ROI methods used to quantify RBQM’s financial impact - Identify the key drivers of value when RBQM components are implemented - Apply evidence-based insights to strengthen internal business cases for RBQM adoption - Anticipate future directions in measuring the ROI of RBQM deployments Abigail Dirks, Data Scientist, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT	
3:15 PM	Break
3:45 PM	Fireside Chat: Building the RBQM Dream Team: Strategies for Staffing in a Post-E6(R3) World
The most advanced RBQM processes mean little without the right people to execute them. Yet organizations across the industry are struggling to find professionals who understand both clinical trial operations and data-driven quality management—a rare “unicorn” skillset. With E6(R3) adoption accelerating the need for skilled RBQM practitioners, the pressure is on to build and train teams that can handle regulatory demands, embrace new tools, and collaborate seamlessly across functions. You will benefit from practical strategies to identify, recruit, and retain the right talent—while also upskilling existing staff. - Define the essential skills and roles needed for effective RBQM implementation - Explore models for distributing RBQM responsibilities across existing teams versus creating dedicated roles - Develop strategies for recruiting and retaining rare cross-functional talent - Learn approaches to upskilling site staff, CRAs, and data teams to support RBQM goals - Align staffing plans with evolving regulatory, operational, and technological demands Anne Hale, Head, Central Monitoring and Study Risk Management, Clinical Development Operations, ABBVIE Nuvala Fomban, Senior Director, Risk Management and Central Monitoring, BRISTOL MEYERS SQUIBB	
4:30 PM	Panel: Can AI Truly Predict and Prevent Risk?
AI is no longer a futuristic concept, it’s already embedded in tools that claim to predict and prevent trial risks before they escalate. But the reality is more complex: without the right human oversight, data integrity safeguards, and thoughtful implementation, AI can create as many problems as it solves. Can your team cut through the hype to examine where AI genuinely adds value, where its boundaries should be drawn, and how to launch high-impact pilots without compromising compliance or patient safety? - Evaluate AI’s real capabilities in detecting and predicting trial risks - Define the level and type of human oversight required for safe, effective AI use - Identify high-impact, low-risk AI pilot projects that deliver measurable results - Understand regulatory expectations and ethical considerations in AI-driven RBQM - Integrate AI insights into existing processes without disrupting team workflows Sathya Ramnath, Senior Manager, Risk-Based Quality Management, GILEAD Pujitha Gourabathini, Manager, Quality Assurance, Risk Management, BD Nuvala Fomban, Senior Director, Risk Management and Central Monitoring, BRISTOL MEYERS SQUIBB	
5:15 PM	Panel: Detecting Fraud in Clinical Trial Data
Fraud in clinical trials isn’t always obvious—but it can seriously compromise data integrity, patient safety, and regulatory compliance. From “professional patients” enrolling in multiple studies to duplicate enrollments across sites, fraudulent activity can distort outcomes and erode trust. Advances in statistical monitoring and data science now make it possible to detect these risks earlier and more accurately. Does your team have the tools to safeguard data integrity, protect patient safety, and stay inspection-ready? - Recognize common indicators of fraud, including duplicate enrollments and “professional patients” - Explore statistical monitoring and data analytics techniques for anomaly detection - Understand the capabilities and limitations of tools such as CluePoints and broader patient identity-matching systems - Integrate fraud detection seamlessly into RBQM processes and centralized monitoring strategies - Respond effectively when suspicious patterns are detected, balancing regulatory requirements with site relationships Rachel Dossman, Director, Clinical Process Compliance, Clinical Development Operations, ABBVIE Anne Hale, Head, Central Monitoring and Study Risk Management, Clinical Development Operations, ABBVIE	
Day 1 Concludes	

DAY 2: Operational Excellence, Regulatory Readiness & Future-Proofing RBQM

8:00 AM	Registration & Networking Breakfast
8:45 AM	Chairperson’s Recap of Day One
9:00 AM	Fireside Chat: ICH E6(R3) in the Real World: Post-Adoption Lessons and the Road Ahead

With the ICH E6(R3) adoption now in effect and global enforcement on the horizon, RBQM leaders face a pivotal moment: moving from theory to tested, operational practice. A 2025 DIA survey showed that 67% of trial sponsors feel only “partially ready” for full enforcement, so how are these changes playing out inside organizations and what early lessons can we take forward?

Learn from real-world post-implementation stories with forward looking strategies, highlighting what worked, what failed, and what’s still up for debate. Identify the most impactful process changes organizations have made in response to E6(R3).

- Pinpoint common implementation missteps and how to avoid them
- Develop a flexible RBQM plan that adapts to evolving enforcement interpretations
- Translate compliance mandates into operational wins for sites and sponsors

Olívio Feiro, Director, Risk Management and Analytics, **CSL BEHRING**
Maria Florez, Senior Researcher, **TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT**

9:45 AM	From Raw Data to Risk Insights: Embedding Audit Trail Analytics in RBQM
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Is your team ready to turn hidden process data into actionable intelligence? Audit trail analytics, spotlighted in ICH E6(R3), is rapidly becoming a must-have capability for Risk-Based Quality Management. By unlocking earlier issue detection, sharper site performance insights, and proportional risk-based responses, it empowers teams to elevate both compliance and operational efficiency.

Explore a practical three-domain framework—Clinical Relevance, Data-Driven Analytics, and Operational Integration—that shows exactly how to put audit trail analytics to work. Through real world examples and hands-on exercises, you’ll practice setting up an audit trail analysis for a common risk scenario, running root cause investigations, and embedding the results into everyday RBQM workflows for lasting improvement.

- Discover why audit trail analytics is essential for safeguarding data integrity and site performance
- Apply a proven three-domain framework to drive compliance and operational efficiency
- Place audit trail analysis into action for real-world risk scenarios
- Use root cause analysis techniques to uncover the “why” behind findings
- Translate insights into sustainable improvements that strengthen RBQM programs

Nechama Katan, former Director, Innovative Data Analytics, **PFIZER**

10:30 AM	Break
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11:00 AM	Panel: The Compliance Pressure Test: Risk-Proofing Your Organization for Inspections
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Regulators don’t just evaluate processes—they test your organization’s ability to respond under pressure. Whether in pharmacovigilance, clinical trials, or manufacturing, inspection readiness is a cross-functional challenge that exposes every weakness in risk ownership, communication, and documentation.Using collaborative exercises and live AI synthesis, the group will build a practical, inspection-ready risk strategy that can be adapted to their own organizations – a tangible framework you helped create.

- Identify the most common breakdowns in inspection preparedness across PV, GCP, and manufacturing functions
- Practice scenario-based problem-solving to strengthen risk response strategies
- Define clear roles and responsibilities for inspection day success
- Leverage AI tools to capture, refine, and document strategic outputs in real time
- Build a reusable compliance readiness framework tailored to cross-functional teams

Kal Elhoregy, Senior Director, Global Risk Management & Pharmacovigilance Compliance, **AMNEAL PHARMACEUTICALS**
Karen Ragnauth, Director, Clinical Quality Oversight & Risk Management, **SHIONOGI**
Lena Al-Rashed, Senior Compliance Manager, **ABBVIE**

11:45 AM	Master CTQs, KRIs, and QTLs for High-Impact RBQM
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Critical to Quality (CTQ) elements define what matters most in your trial, Key Risk Indicators (KRIs) monitor the ongoing health of those elements, and Quality Tolerance Limits (QTLs) set the boundaries for acceptable variation. Can your team align these three components to form a powerful, proactive RBQM framework that drives quality, safeguards patient safety, and ensures inspection readiness?

- Identify and prioritize CTQs that align with protocol endpoints, patient safety, and regulatory expectations
- Select KRIs that meaningfully measure risk to CTQs and provide actionable insights
- Set QTLs that act as early-warning signals, catching issues before they derail timelines or data integrity
- Foster collaboration between clinical, data management, and quality teams to manage CTQs, KRIs, and QTLs in unison
- Avoid “overengineering” by focusing on metrics and limits that are both meaningful and achievable
- Translate CTQ/KRI/QTL outputs into targeted monitoring strategies that keep RBQM agile and inspection-ready

Ted Thendral, Director, RBQM Central Statistical Monitoring (CSM), **DAIICHI SANKYO**

12:30 PM	Lunch
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1:45 PM	Structure Trials that Borrow Medical Device Human Factors and Risk Practices
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Human factors engineering is a cornerstone of medical device safety, ensuring usability and minimizing risks associated with user interaction. Clinical trials, however, often underestimate the impact of human factors on data integrity and patient safety. Principles from medical device usability engineering can be applied to RBQM frameworks to identify and mitigate risks related to human error in trial processes.

- Highlight the role of human factors in risk management for medical devices and its relevance to clinical trials.
- Learn practical methods for incorporating usability principles into RBQM risk assessments.
- Identify strategies to reduce human error and improve trial quality through proactive design and monitoring.

Pujitha Gourabathini, Manager, Quality Assurance, Risk Management, **BD**

2:30 PM	Build Metrics That Influence Leadership Decisions
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RBQM KPIs only matter if they shape leadership decisions and drive RBQM adoption. This is particularly true for small to mid-sized companies where resources and expertise can be a challenge. Do your KPIs go beyond operational checkboxes to tell a clear, compelling story about value, quality, and return on investment? Take a deep dive into selecting, designing, and presenting KPIs that drive executive-level decision-making and promote RBQM adoption. Learn how to choose metrics that matter to both scientific and financial stakeholders and present results in a way that supports strategic priorities.

- Select metrics that balance clinical relevance and cost efficiency
- Present KPIs in a way that drives strategic decision-making
- Link RBQM outcomes to broader business objectives to secure ongoing support

Marcin Kronhardt, Associate Director, Data Management Science, **BIOMARIN**

3:15 PM	Debate: Does SDV Still Deserve a Seat at the Table?
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Despite contributing less than 2% to overall data quality, Source Data Verification (SDV) remains one of the most expensive and resource-intensive elements of clinical trial monitoring. As the industry pushes toward risk-based methodologies, is SDV a legacy practice we can finally retire—or does it still serve a vital role in ensuring trial integrity?

Proponents will argue its continued necessity in high-risk areas, while challengers will make the case for smarter, targeted approaches that free up resources without compromising safety. Attendees will leave with a clearer understanding of whether and how SDV adds value or slows progress.

- Evaluate the real ROI of SDV in the era of risk-based monitoring
- Identify trial types, endpoints, and risk profiles where SDV remains critical
- Compare cost, efficiency, and quality outcomes between 100% SDV and targeted SDR
- Explore change-management tactics to move teams beyond entrenched SDV habits

Joshua Cox, Vice President, Clinical Data and Analytics Capabilities, **ELI LILLY**

Conference Concludes	
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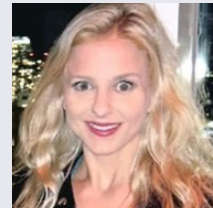
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