WHAT TO EXPECT AT

RBQM LIVE25

Who:

parexel

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Syneos Health

Deloitte.

Veeva

What:

The premier event for all things RBQM

When:

September 25, 2025,
9:00 AM EST to 12:00 PM EST

Where:

Anywhere with a Wi-Fi connection

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Why:

It's the only free, virtual event where your industry peers are sharing real case studies and news you can use.

The Agenda

One day. Three sessions. Industry experts take the virtual stage to explore the trends reshaping your role.

KEYNOTE PRESENTATION

Measuring the Impact: Quantifying the ROI of RBQM

Time: 9:00–9:45 AM EST

For years, the industry has embraced RBQM as a smarter, more efficient approach to clinical trial oversight. But what's the measurable return? In this keynote, experts from the Tufts Center for the Study of Drug Development (CSDD) will unveil new data modeling that applies Net Present Value (NPV) analysis to RBQM implementation, offering a first-of-its-kind look at the financial and operational value of doing things differently. With links to ICH E6(R3) principles, this session provides a compelling case for investing in a more proactive, data-driven approach to quality. Key learning objectives include:

- **Introduction to RBQM & NPV Analysis:** Learn the fundamentals of RBQM and how to evaluate its ROI using NPV analysis to quantify financial and operational impact.
- **New Data Modeling Insights:** Review the latest data modeling research analyzing the ROI of RBQM, featuring real-world data and case studies demonstrating its value.
- **Linking RBQM to ICH E6(R3) Principles:** Explore how RBQM aligns with ICH E6(R3) guidelines to improve trial quality, data integrity, and efficiency.
- **Financial & Operational Value:** Discover measurable benefits of RBQM—cost savings, improved data quality, shorter timelines, and better patient safety—making a strong case for adoption.
- **Practical Implementation Strategies:** Get actionable strategies for adopting RBQM, addressing common challenges, and integrating it into clinical trial operations.

PANEL DISCUSSION

Decoding ICH E6(R3): From Principles to Practice

Time: 9:45–11:00 AM EST

What does ICH E6(R3) mean for clinical trial oversight, and how are leading Sponsors and CROs preparing for it? This session provides a dual perspective on interpreting the new principles, evolving quality strategies, and embedding RBQM and integrated data review into trial operations. Moderated by Parexel, the discussion will explore practical approaches to implementation, collaboration, and staying ahead of regulatory expectations. Key learning objectives include:

- **Understanding ICH E6(R3) Principles:** Understand the updated guidelines and their impact on trial oversight, focusing on improving quality and efficiency through a risk-based approach.
- **Sponsor & CRO Perspectives:** Hear how Sponsors and CROs are applying the guidelines, adapting quality systems, and ensuring compliance.
- **Evolving Quality Strategies:** See how RBQM and integrated data review are being used to improve data quality and reduce risk.
- **Practical Implementation Approaches:** Explore real-world approaches, including change management, stakeholder engagement, and digital tools.
- **Collaboration & Regulatory Expectations:** Learn how Sponsors, CROs, and regulators are working together to meet evolving expectations and maintain compliance.

PANEL DISCUSSION

Harnessing AI for Risk Based EVERYTHING: Current Innovations & Future Directions

Time: 11:00 AM–12:00 PM EST

AI has become a pivotal tool in enhancing data quality, streamlining processes, and mitigating risks in clinical trials. This insightful session will delve into the practical applications of AI in RBQM and RBDM, before exploring how these two concepts come together fast. It's designed for professionals looking to leverage AI to enhance their RBQM and RBDM processes and ensure regulatory compliance while improving trial outcomes. This session will focus on real examples, describing not just the theory but the practical implementation that stems from connected thinking and connected delivery. Key topics include::

- **AI Integration in Everything:** Explore how AI enhances risk-based approaches by improving protocol design, risk identification, data cleaning, operational management, oversight and trial efficiency.
- **Real-World Applications:** Learn from case studies showcasing the benefits and challenges of AI-driven RB Everything in practice.
- **Change Management Strategies:** Discover how to effectively manage the shift to AI-powered RB Everything through stakeholder engagement, training, and issue resolution.
- **Future Trends:** Get a forward-looking view of AI's role in RB Everything and how to prepare for upcoming innovations and methodologies.

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Meet the Speakers

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Ken Getz

Executive Director & Professor, Tufts CSDD

Ken leads empirical research on drug development trends, protocol design, and clinical trial operations. He's also the founder and chairman of CISCRP, a nonprofit advancing public and patient awareness of clinical research, and a widely published speaker and columnist.

Abby Dirks

Data Scientist, Tufts CSDD

Abby leads research on clinical trial trends, including site burden, decentralized trials, and workforce dynamics. She holds a Master's in Health Informatics & Analytics from Tufts and is skilled in data cleaning, statistical analysis, data visualization, and Python and R.

Cris McDavid

Senior Director, Global Clinical Operations, Parexel

Cris is a seasoned clinical research leader with over 20 years of experience. An expert in RBQM and centralized data monitoring, she has a proven track record of leading global teams, optimizing clinical trial processes with advanced analytics, and driving innovation across biotech and pharma partnerships.

Dawn Anderson

Managing Director, Life Sciences Clinical Transformation Leader, Deloitte

Dawn is a senior life sciences executive with over 25 years of experience in clinical development, operations, and business transformation. She specializes in helping global pharma, biotech, and MedTech organizations solve complex challenges through process optimization, digital innovation, AI-driven solutions, and cross-functional collaboration.

Leonie Christianson

Business Consultant, Syneos Health

Leonie is a global clinical research leader with expertise in clinical data management and operations. Known for shaping product roadmaps, aligning digital investments with strategic goals, and solving complex challenges, Leonie drives business transformation and leads cross-functional teams.

Drew Garty

Chief Technology Officer, Veeva

Drew Garty's career in pharmaceutical technology spans over 25 years and includes significant expertise in EDC, clinical site monitoring, and clinical trial management solutions. Drew's innovative solutions in risk-based monitoring earned him a prestigious industry "Clinical Innovator of the Year" award in 2015 and has authored multiple patents. Drew joined Veeva in 2016 to lead the ground-up design of Veeva's clinical data management solutions. In his current role of Chief Technology Officer for Clinical Data, Drew collaborates with customers, partners, and the industry to set the vision and direction of Veeva's Clinical Data product family.

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How to Access the Content

RBQMLive is a **free, virtual event**. Once you **register**, you'll receive a link to join from your computer—whether you're tuning in from the office or your couch.

After the event, we'll send you a separate link to **access all sessions on demand** so you can revisit key insights or share them with your team.

A Word from Our Sponsors: CluePoints

2025 marks the fifth annual RBQMLive. Each year, it gets bigger, bolder, and more impactful. CluePoints is proud to lead this initiative. As RBQM innovators, we understand what Sponsors, CROs, and others are looking for. We curated this agenda with you in mind, and we hope you enjoy it.

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Follow CluePoints on social for live updates.