

[IN THE KNOW]

RBQM LIVE 2022



If you work in the clinical trial space, you're likely passionate about positively impacting human wellbeing. What if you could make longer, faster strides toward putting an effective medicine, therapy, or medical device on the market for current and future generations?

Risk-based quality management (RBQM) supports enhanced quality oversight for the entire clinical trial lifecycle, increasing the efficiency and timeliness of clinical trials and driving accelerated compliance and delivery.

On **September 8-9, 2022**, we invite you to join us in discussing the maturity of RBQM, its increasing value, and where we envision RBQM heading in the future. Here are five reasons why you can't miss RBQM Live 2022.

- 1 DISCOVER NEW WAYS TO LEVERAGE RBQM**
Innovative RBQM applications include quality oversight, safety review, business intelligence platforms, and randomization.
- 2 UNDERSTAND THE RISKS OF DECENTRALIZED TRIALS**
New independent entities are sources of study activity and data collection that could impact data reliability and patient safety.
- 3 DISCUSS THE LATEST INDUSTRY GUIDANCE UPDATES**
ICH E6 (R3) and E8 (R1) guidance updates and other global regulations are ever-evolving in the clinical space.
- 4 CONSIDER THE ROLE OF AI & ML IN RBQM**
Artificial Intelligence and Machine Learning can assist in identifying the program, organization, and industry trends.
- 5 HEAR FROM LEADING CLINICAL TRIAL & RBQM EXPERTS**
RBQM Live features presentations by clinical trial and RBQM experts and provides insights from critical thinkers like you.

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THE AGENDA

September 8, 2022

RBQM Maturity — Insights into Current Trends and Increasing Value

[**08:00 – 08:45 AM EST**] Keynote: How the Evolving RBQM Landscape Will Reinforce the Way We Improve Efficiencies & Add Value (Research Study Findings)

[**08:45 – 09:30 AM EST**] Compliance Is Key: ICH E6 (R3) & E8 (R1) Guidance Update — Getting in Front of the New Regulations

[**09:30 – 10:30 AM EST**] Panel: Interpreting QTLs Through the Lens of Where They Are Today & Their Future Evolution

[**10:30 AM – 12:00 PM EST**] RBQM Diversification: tSDV, tSDR, Dynamic Site Monitoring Strategies

[**12:00 – 1:00 PM EST**] Panel Discussion: Understanding the Risks of Decentralized Trials as Sources of Data Increase — How to Plan for Success Proactively

September 9, 2022

Advancing RBQM — Where Are We Heading in the Future?

[**08:00 – 09:15 AM EST**] Keynote: Fireside Chat: How Will AI & Machine Learning Play an Essential Part in the Future of RBQM?

[**09:15 – 10:15 AM EST**] Risk-Based Data Review & Medical Coding

[**10:15 – 11:30 AM EST**] Panel Discussion: Leveraging RBQM in New & Exciting Ways You Never Envisioned (Quality, Safety Review, etc.)

[**11:30 AM – 01:00 PM EST**] Panel: The New Risk-Based Norm — What Transformative Outcomes (from the Past Two Years) Are Here to Stay?



THE FUTURE OF RBQM AWAITS SEE YOU THERE

From clinical trial specialists and supporters to thought leaders and curious listeners, we welcome everyone to join the industry's leading, 100% virtual RBQM event.

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