

12 NOVEMBER 2026

THE DECISION ROOM

A trial under pressure

An immersive, one-day leadership simulation for senior clinical trial leaders with direct responsibility for Risk-Based Quality Management.

Thursday, 12 November 2026
Frankfurt Innovation Center (FiZ), Frankfurt (M), Germany

Faculty Confirmed · Participation fee applies · Maximum 45 participants

Why this event now

RBQM programmes do not fail because teams lack more dashboards. They fail when evidence, accountability and decision rationale do not connect during real study conduct.

Interpret the signal

What further evidence is needed?
Who owns the decision? What should
deliberately not be escalated?

Determine the intervention

What evidence informed the
decision? Why this action? What
outcome is expected, and how will it
be evaluated?

Defend the decision

Can the response be shown to be
proportionate, traceable, and
protective of participants and critical
trial outcomes?

Register your interest

Applications reviewed within 2 business days

EVENT WEBSITE

The Decision Room

A full-day, in-person simulation. Not introductory training. Not a presentation-led conference.

Designed for

VPs and senior operational leaders with direct RBQM ownership across Clinical Operations, Quality/GxP, Central Monitoring, Medical Oversight, Data/Analytics, sponsor oversight and CRO delivery.

Participation is limited to 45 people to preserve seniority, interaction and cross-functional balance.

01

INTERPRET THE SIGNAL

Teams receive a mixed evidence package and must separate meaningful risk from noise, incomplete data, pressure, and conflicting interpretations.

Site-level anomaly

Protocol deviation drift

Recruitment pressure

Vendor lag

AI-supported alert

Medical ambiguity

Country continuity risk

Critical supply-chain dependency

02

DETERMINE THE INTERVENTION

New evidence contradicts some initial assumptions. Teams decide whether to act, adjust, pause, escalate, challenge, or deliberately do nothing.

Change monitoring intensity

Contact or retrain sites

Modify data review

Escalate to governance

Challenge the CRO

Revisit risk assessment

Reject an AI recommendation

03

DEFEND THE DECISION

The room shifts into inspection replay. Teams reconstruct what was known, why action was taken or not taken, and whether the response was proportionate.

Evidence considered

Decision rationale

Accountable owner

Expected effect

Effectiveness evaluation

Traceable evidence trail

The question is not whether risks were scored.

The question is whether study conduct changed - and whether the rationale can be defended.

2026 Decision Room Faculty

A cross-functional group of senior practitioners, moderators, and simulation challengers bringing clinical, operational, scientific, and leadership perspectives into the room.



Prof. Dr. Jochen Maas

House of Pharma Frankfurt

Decision Review Faculty
Simulation Challenger



Ida Holme, MD

Novo Nordisk

Decision Review Faculty
Simulation Challenger



Shehnaz Vakharia, MRQA

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Adam Baumgart

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Simulation Lead



Keith Dorricott, MBB

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Simulation Moderator



Johann Proeve, PhD

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Simulation Moderator



Julien Goncalves

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Simulation Moderator



Linda Bunschoten

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Program Host



Tamara Beck

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Event Operations Lead



Artem Andrianov, PhD

Cyntegrity

Executive Host

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Program

Arrival from 09:00 | Program 09:30–17:00 | Cocktail reception with light bites 17:00–18:00

09:00	Arrival and coffee	Arrival, registration, and time to settle in before the day begins.
09:30	Opening frame	Welcome, orientation, and context for the day's leadership simulation.
10:15	Act I — Interpret the signal	Teams receive the study context and first evidence pack, then assess what is signal, issue, or noise.
11:30	Decision checkpoint	Pause to reflect on evidence gaps, decision ownership, and what may need escalation.
12:15	Working lunch	Structured peer exchange over lunch; no formal presentation.
13:15	Act II — Determine the intervention	New evidence shifts the picture. Teams decide what should change, who should act, and what is proportionate.
14:45	Act III — Defend the decision	Teams reconstruct their reasoning and show how the decision trail can be defended.
16:00	Synthesis	Key takeaways on judgement, accountability, traceability, and implications for RBQM operating practice.
17:00	Cocktail reception	Informal networking with drinks and light bites.
18:00	Close	End of the event.

Participation

Attendance is limited to 45 senior leaders, with a maximum of three participants per organization.

INDIVIDUAL €490 per participant	TEAM OF 2 €882 total	TEAM OF 3 €1,225 total	MyRBQM ALUMNI / CUSTOMER €343 per eligible participant
INCLUDED Working lunch, coffee, tea, soft drinks and light refreshments throughout the day, plus an informal post-event cocktail reception with drinks and light bites.		SEAT CONFIRMATION Once an invitation has been issued, a seat will be held. Participation is confirmed upon receipt of payment. Discounts cannot be combined.	

Cancellation: 30+ days free · 15-29 days: 50% payable · 14 days or less: full fee payable · eligible substitutions accepted.
Prices are net and subject to applicable VAT. Travel and accommodation are not included.

Interested in joining the room?

Register your interest. We will respond within a maximum of 2 business days.

REGISTER INTEREST