



AI-Driven RBQM: Bridging Operational Excellence and Global Regulatory Demands

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The Clinical Trial Ecosystem Challenges

Increased protocol and regulatory complexity

Site selection, patient recruitment and retention

Massive amounts of data generated

Disparate data and technologies

More active stakeholders and lack of collaboration

Low RBQM adoption

Sites

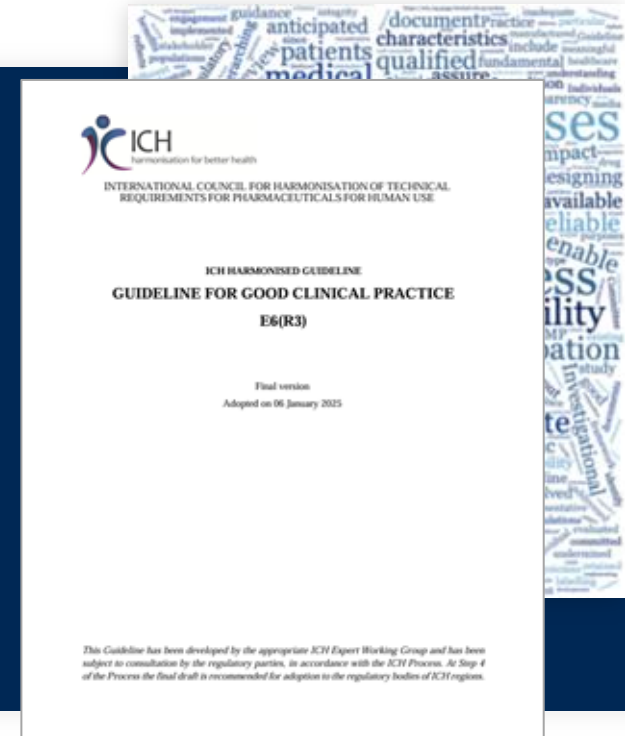


A Disconnected Ecosystem

creates data, processes and workflow silos that lead to quality, safety, and operational inefficiencies (costs, resources, timelines)

What are Regulators saying - ICH E6 (R3)

- Supports improved and more **efficient** approaches to trial design and conduct
- In line with advancing science and **technological** developments
- Use of technology in the conduct of clinical trials should be adapted to **fit participant** characteristics and the **particular trial design**
- Quality by design in clinical trial sets out to ensure that the **quality** of a trial is driven **proactively** by designing quality into the study protocol and processes



The Clinical Trial Ecosystem

Data Quality
fueled by
RBQM Principals

Identifying CTQs and Risk Based Strategy!!

Brain
Risk ID/Mgmt

Heart/Circulatory System
Data Platform

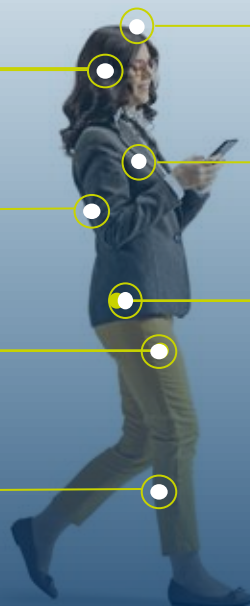
Blood
Data

Senses
Monitoring

Homeostasis/ Equilibrium
Self-regulation and
adjustment

Medicine
Mitigations

Immune System
Quality by Design Principles



Quality by Design Principles

Quality by Design – Trial's Immune System

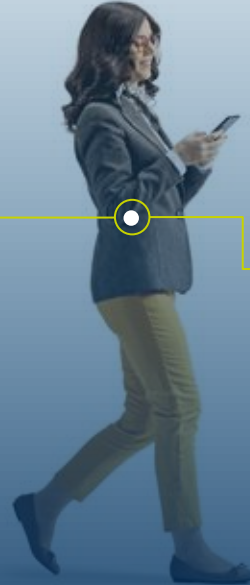
Quality by Design principles protect the integrity of the clinical trial by infusing quality into every aspect of the trial.

Innate immunity – strong foundation to ensure overall trial **health** (protocol design)

Fit(ness) for purpose data strategy

Reduce **patient** and site burden

Adaptive Immunity – historical insights



Risk Identification and Management

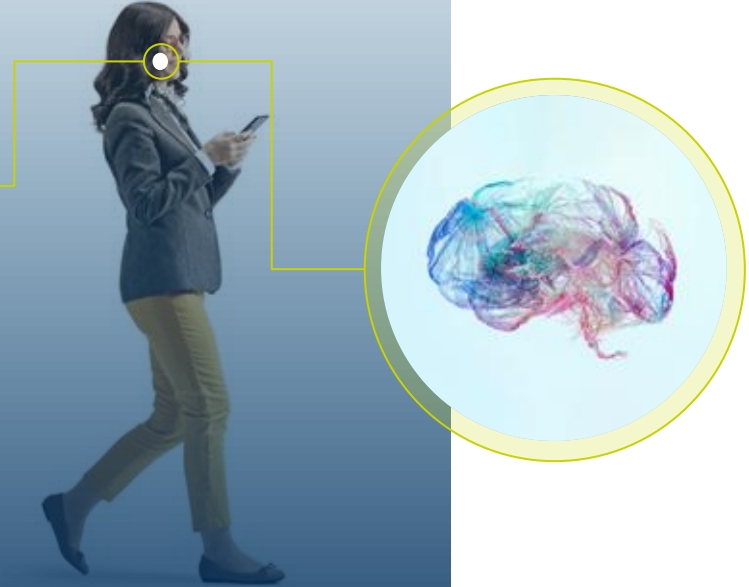
Risk Management –Trial's Brain

Understanding risks for a given protocol connecting to mitigation strategy, and a way to monitor/sense potential issues and risks, wherever they occur.

Central repository – use **intelligence and memory**

Sensing and collecting information from various parts of organization

Cross-functional and **regular exercise**



Data, Data, and More Data!

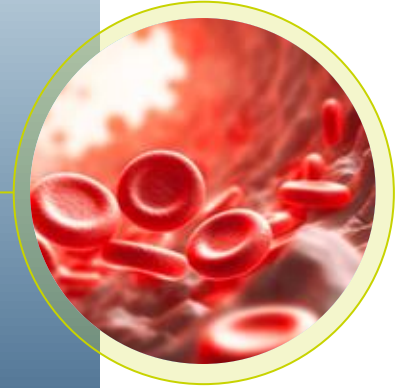
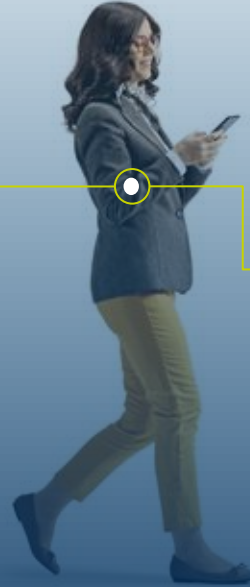
Data – Trial's Blood

Enriched data flows throughout the ecosystem, being cleaned and providing valuable insights to different stakeholders for faster decisions.

Lifeblood of RBQM

Data must flow to all parts of organization to **survive**

Data-driven **culture**



Data Acquisition and Aggregation

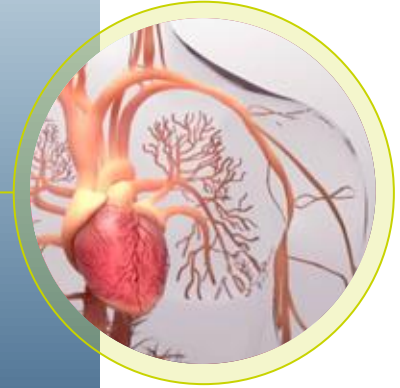
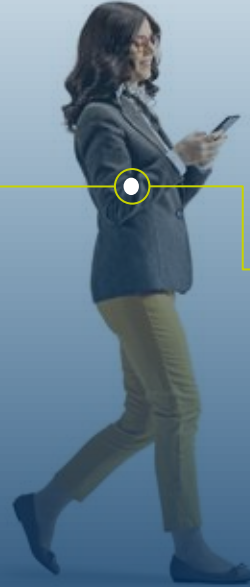
Data Platform – Trial's Heart & Circulatory System

Ensuring data aggregation, standardization and real time access is essential for risk management and maintenance of trial health and quality.

Aggregated data in one place –
no need for **life support**!

All **vital parts** of organization getting access
to the same data

Enriched and standardized data available in
all parts of the organization



Data and Risk Surveillance

Monitoring – Trial's Sensory System

Strategies for continuous monitoring of data integrity and quality, site performance, and patient safety via advanced analytics, smart visualizations, tools fit for purpose for each stakeholder.

Artificial Intelligence to automate workflows and risk identification

Local vs systemic problem

Red flag indicators



Mitigation Actions

Mitigation Actions - Trial's Medicine

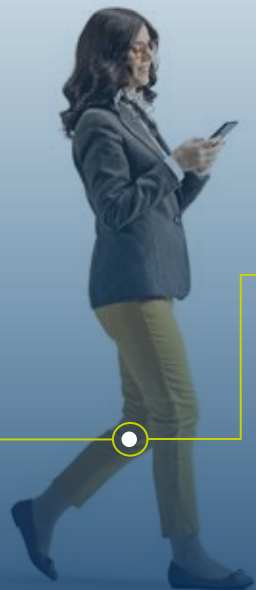
Layered, proactive, cross-functional approach to mitigate risks at various levels before they become issues.

Personalized medicine – tailored to risk type and level

Observe closer – increase central0 monitoring

Supportive therapy and training

Hospitalize and quarantine



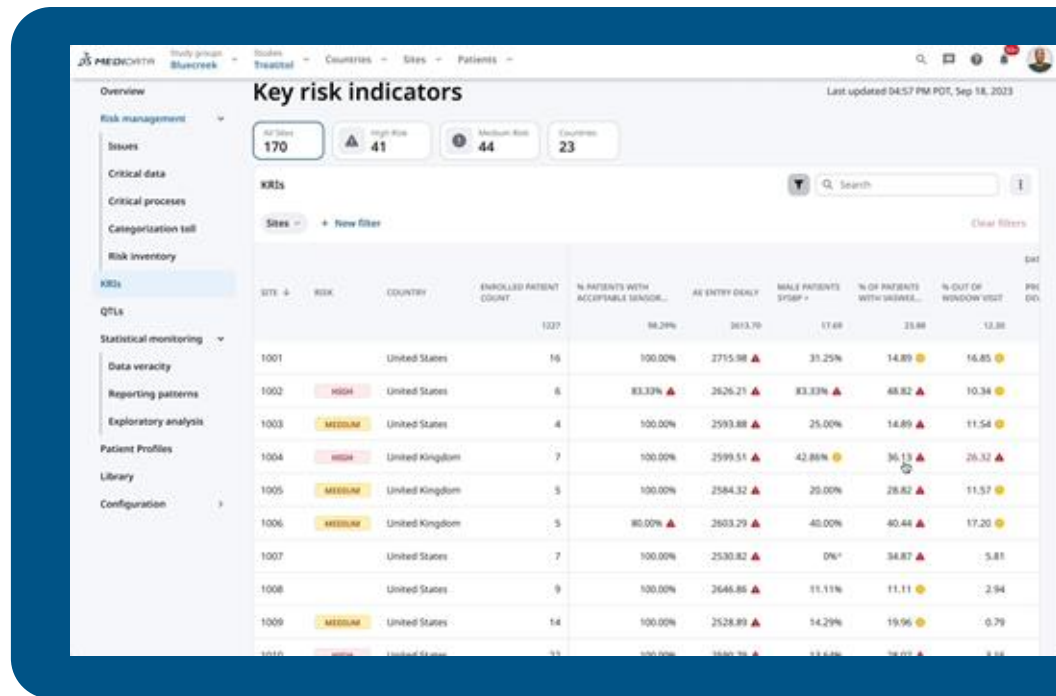
Monitor & Deliver: Risk-Based Quality Management

Manage site and trial risk comprehensively throughout the study

Execute efficient RBQM processes
with end-to-end workflows

Track and mitigate risks in real-time
with dynamic dashboards

Resolve emerging problems faster
with centralized issue management



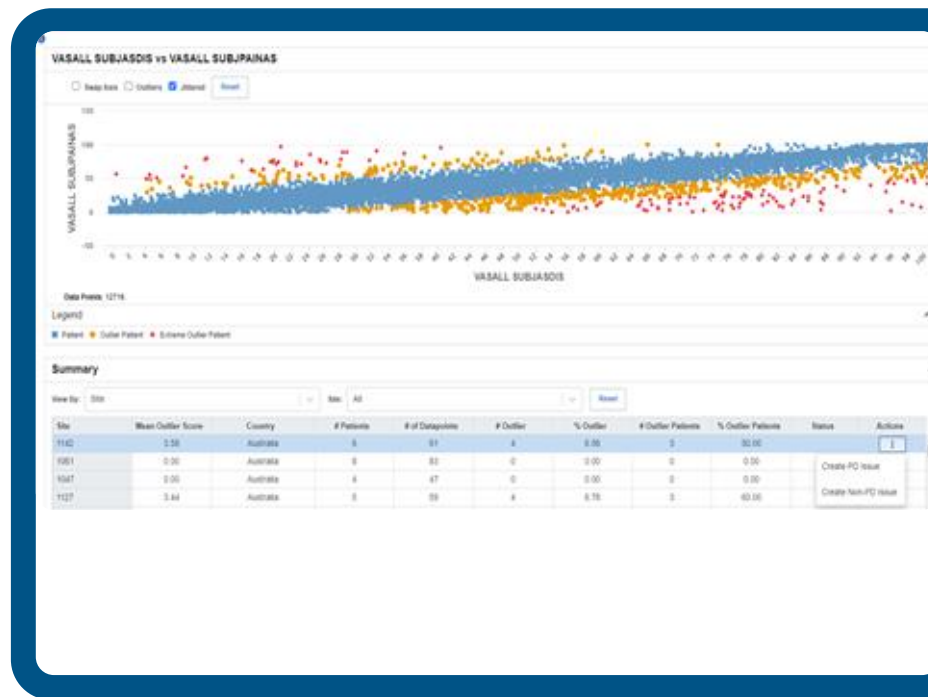
Identify Anomalies and Trends

Detect unusual patterns and outliers with centralized statistical monitoring

Detect data patterns, site performance issues, and potential misconduct with advanced analytics

Identify under/over safety events reporting at the study, site, or country level

Uncover anomalies and unusual associations with machine learning



Review Audit Trail

Analyze audit trail data with generative AI

Access and mine large audit data sets
in minutes

Automate analysis of the audit trail **with
GenAI to save time and effort**

Flexible, smart prompts and embedded chat
used to generate results

The screenshot displays the Medidata Treatitol interface for Protocol ID: 1646543. The 'Audit trail review' section is active, showing a chat conversation with a generative AI model. The chat history includes a prompt 'Show me queries for USA', a response 'Processing...', a follow-up question 'You are asking for audits of queries for sites in the USA, is that correct?', a confirmation 'Yes', and a final prompt 'Great, let me generate the dataset for you.' The chat is currently in a 'Processing...' state. To the right of the chat is a 'Data preview' table with columns for 'Account ID', 'Site', 'Country', 'Visit ID', 'Visit Date', and 'Visit Type'. The table contains 10 rows of data, with the 6th row highlighted. The interface also includes a sidebar with navigation options like 'Summary', 'Risk Assessment', 'Data capture', 'EDC tasks', 'Data connect', 'Data surveillance', 'RBQM', and 'Rave CTMS'.

Account ID	Site	Country	Visit ID	Visit Date	Visit Type
10141010	1014	USA	1014010	1014010	Baseline
10141010	1014	USA	1014011	1014011	Baseline
10141010	1014	USA	1014012	1014012	Baseline
10141010	1014	USA	1014013	1014013	Baseline
10141010	1014	USA	1014014	1014014	Baseline
10141010	1014	USA	1014015	1014015	Baseline
10141010	1014	USA	1014016	1014016	Baseline
10141010	1014	USA	1014017	1014017	Baseline
10141010	1014	USA	1014018	1014018	Baseline
10141010	1014	USA	1014019	1014019	Baseline

An RBQM Ecosystem that Works

Connected RBQM – a comprehensive cross-functional framework

Holistic Approach – quality built in at every stage

Proactive Risk Management – all hands on deck to prevent issues before they become significant

Stakeholder **Alignment** – team understanding of quality objectives and risk management strategies

Data-Driven Culture – access to all data for all stakeholders to drive better decisions

Data Homeostasis – data remains a robust foundation for decision-making and analysis



A Connected Ecosystem
driven by RBQM principles and data driven
culture delivers quality, safety and operational
efficiencies (costs, resources, timelines)

