MyRBQM Solutions

Enhancing Clinical Trial Success through
Collaborative Risk Management and Training

Cyntegrity | 2025

www.cyntegrity.com

"INSPIRED BY NATURE'S PRECISION, POWERED BY AI TO TRANSFORM CLINICAL TRIALS"

Artem Andrianov, PhD
CEO & Founder

Cyntegrity®

Founded in 2013 by experts from **ERT**, **Bayer**, and **Carefusion**, Cyntegrity empowers clinical trials with **AI-augmented Risk-Based Quality Management (RBQM)** solutions, grounded in **Quality by Design (QbD)** principles.

Meet Our Leadership Team

We are passionate about what we do

Artem Andrianov, Ph.D.
CEO & Founder

Johann Proeve, PhD
Chief Scientific Officer

Linda Bunschoten
Chief Marketing Officer

David Lacagnina
Chief Business Officer

What We Do

With our presence in Europe and the USA, we partner with industry leaders globally to

- Optimize clinical trials with actionable insights
- Ensure compliance for regulatory inspections
- Streamline decision-making in M&A due diligence

Our proprietary My**RBQM**® Portal aligns with evolving **ICH E6 and E8** guidelines, addressing BioPharma's critical challenges:

- » **Patient Safety**
- » **Data Security & Reliability**
- » **Operational Inefficiencies**
- » **Misconduct**
- » **Compliance**

Fast Facts

Values:

- Quality
- Standards
- Compliance
- Transparency
- Interoperability

+50

Team of Experts
The best minds creating your Quality by Design strategy.

+140

Pharma & CRO Companies
Put their trust in Cyntegrity to streamline their clinical trials and ensure compliance.

+620

Global Clinical Studies
MyRBQM® expertise has already been applied in over 620 clinical studies.

Discover Our Solution

MyRBQM®

MyRBQM® Portal

The MyRBQM Portal is an AI-augmented cloud platform that facilitates GCP-compliant, end-to-end risk-based quality management.

» Integration Capabilities
» AI-Augmented Efficiency
» End-to-End Traceability

MyRBQM® Academy

Expert-led training and courses to foster a QbD culture, empowering teams for effective risk-based trial management and compliance.

» RBQM Belt Certification
» Instructor-led & e-Courses
» Webinars & Workshops

MyRBQM® FSP

Our Functional Services Support processes and activities to ensure the successful rollout of a cross-functional RBQM system.

» Protocol Risk Assessment & Mitigation
» RBQM SOPs & GAP Analysis
» Centralized Monitoring

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Use Cases

MyRBQM®

Quality by Design
Protocol Complexity Evaluation
ICH-Compliant Workflows by Design

GCP Audits
Critical Audit Areas Identification
Issue Detection
Compliance Risks Prediction

Risk-Based Quality Management
AI-Augmented Risk-Assessment
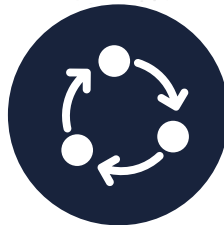Human-Supervised CSM
End-to-End Traceability

Regulatory Site Inspections
Remote & Virtual Inspections
Data Quality Across Study Sites
Resource Optimization

Clinical Operations
Centralized Monitoring
Adaptive Monitoring
Medical Monitoring

M&A Due Diligence
Quality of Clinical Data Report
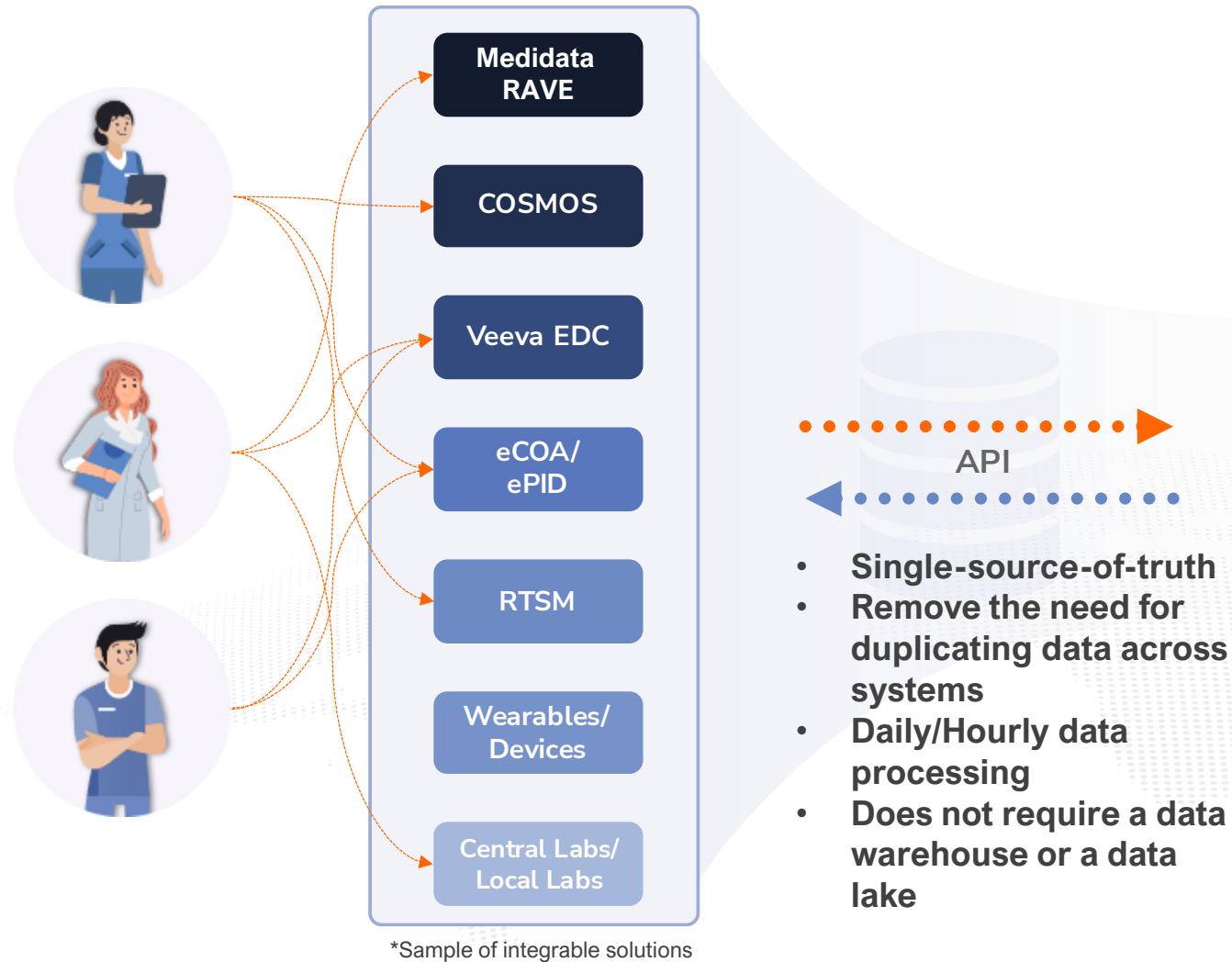Risk Assessment
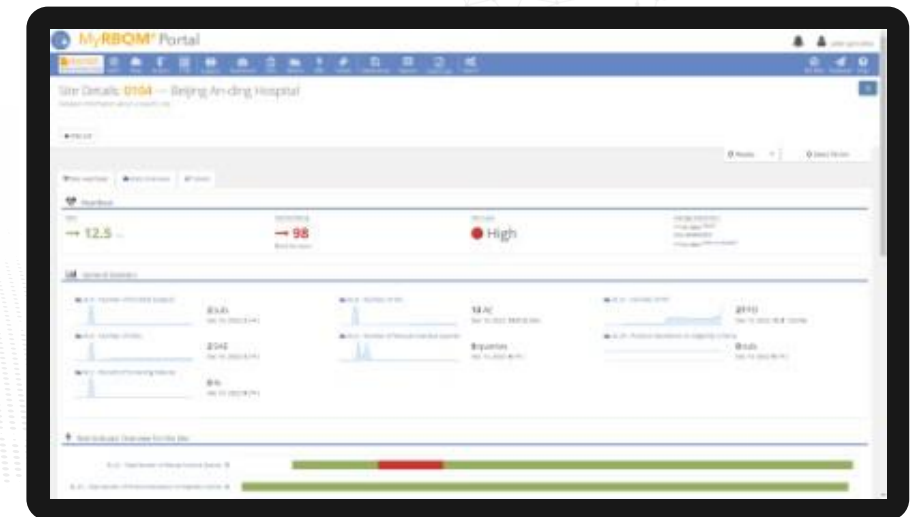Misconduct Detection

MyRBQM® Portal

Quality by Design in Action

Seamless Workflows

Quality by Design in Action

Medidata RAVE

COSMOS

Veeva EDC

eCOA/ ePID

RTSM

Wearables/ Devices

Central Labs/ Local Labs

*Sample of integrable solutions

API

- Single-source-of-truth
- Remove the need for duplicating data across systems
- Daily/Hourly data processing
- Does not require a data warehouse or a data lake

My**RBQM**® Portal

CRO Collaboration & Oversight

Data-Driven RBAC

Flexible Permissions and Data Access

Targeted Data Access
Grant tailored permissions based on roles and responsibilities, not guesswork

Dynamic Adjustments
Quickly update access as studies evolve—no IT bottlenecks
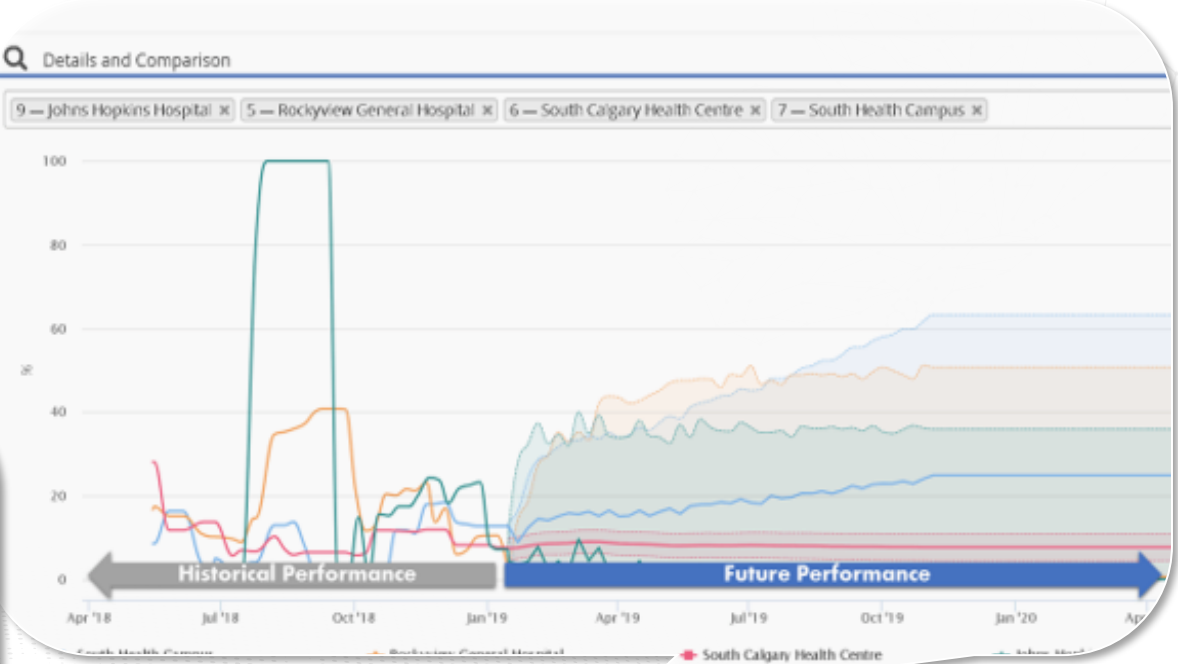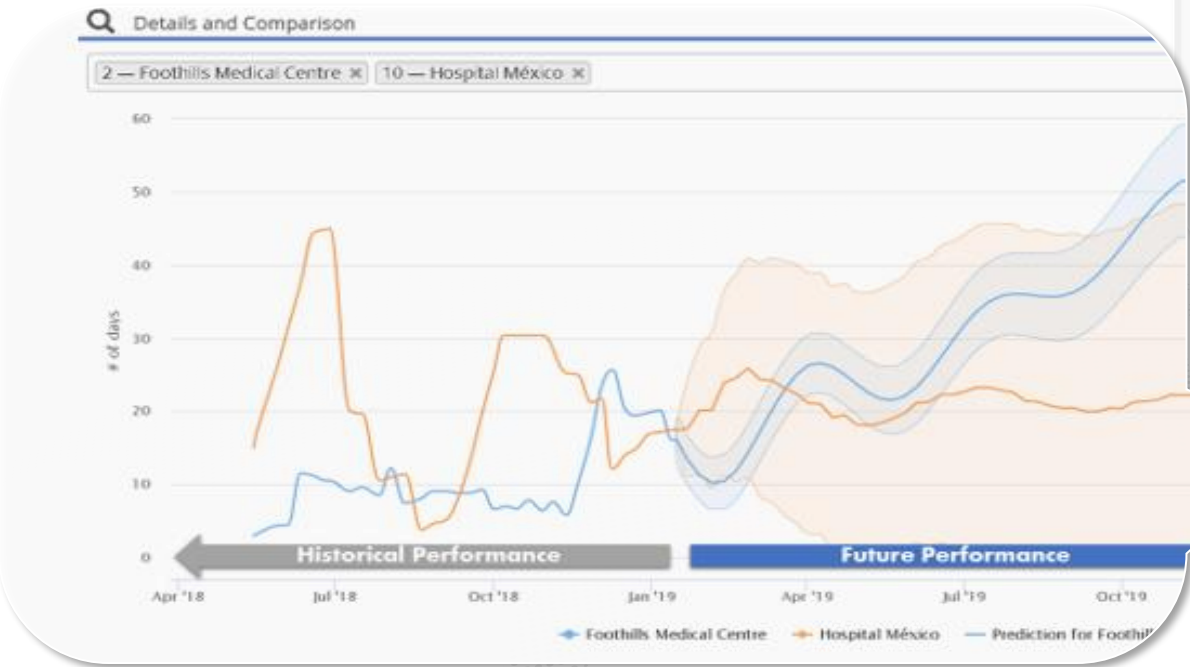
Regulatory Confidence
Meet strict privacy standards with secure, auditable access controls

Streamlined Operations
Reduce overhead and accelerate decision-making through clear, role-based transparency

Learn From the Past

Quality by Design in Action

Artificial Intelligence Based on Neural Networks

Address Today's Issues to Shape Future Solutions

Cross-Study Analytics

Visualization

▼ Filter by [30% Completeness ▼]

	Study 1	Study 2	Study 3	Study 4	Study 5	KRI_1 (avg)
Site 1	◐ 2	○ 1	○ 1	◐ 2	○ 1	○ 1
Site 2	○ 1	◐ 2	○ 1	● 3	● 2	● 3
Site 3	◐ 2	◐ 2	◐ 2	● 3	● 3	● 3
Site 4	○ 1	○ 1	◐ 2	○ 1	◐ 2	● 1
Site 5	● 3	○ 1	◐ 2	● 3	◐ 2	● 3
Site 6	○ 1	○ 1	○ 1	● 3	○ 1	○ 1
Site 7	◐ 2	● 3	○ 1	● 3	○ 1	● 3

Overview

The feature helps users **identify common behavioral patterns across sites** in selected studies and phases (e.g., 30%, 50% completes[1]).
It also provides key issue management statistics, including:
- Issue statistics for each KRI
- Average issue resolution time
- ICA and PA execution statistics

This enables users to identify problematic KRIs what issues require more resources (time).

Future plans: include AI-powered ICA effectiveness analysis and issue management summaries for specific KRIs.

Requirements

» The feature requires **synchronization of KRI calculations across studies.**
  Can be addressed using the recently introduced "Hide KRI" feature in MyRBQM. This allows creating a common study type (via Azure function) that spans a study program or all BU studies, enabling KRIs to be toggled on/off without worrying about calculation comparability.

» Additionally, **site and region synchronization** is essential to ensure consistent analysis for the same sites across different studies.

Outcomes

» Enables insights into patterns, such as **identifying common escalations in specific KRIs** (e.g., multiple sites experiencing escalations when study completeness reaches 30%).

» Highlights **trends in issue management**, such as identifying a KRIs that, on average, require X days to resolve escalations.

» Lays the **groundwork for** refining future study protocols or **modifying study designs** to mitigate highly probable issues.
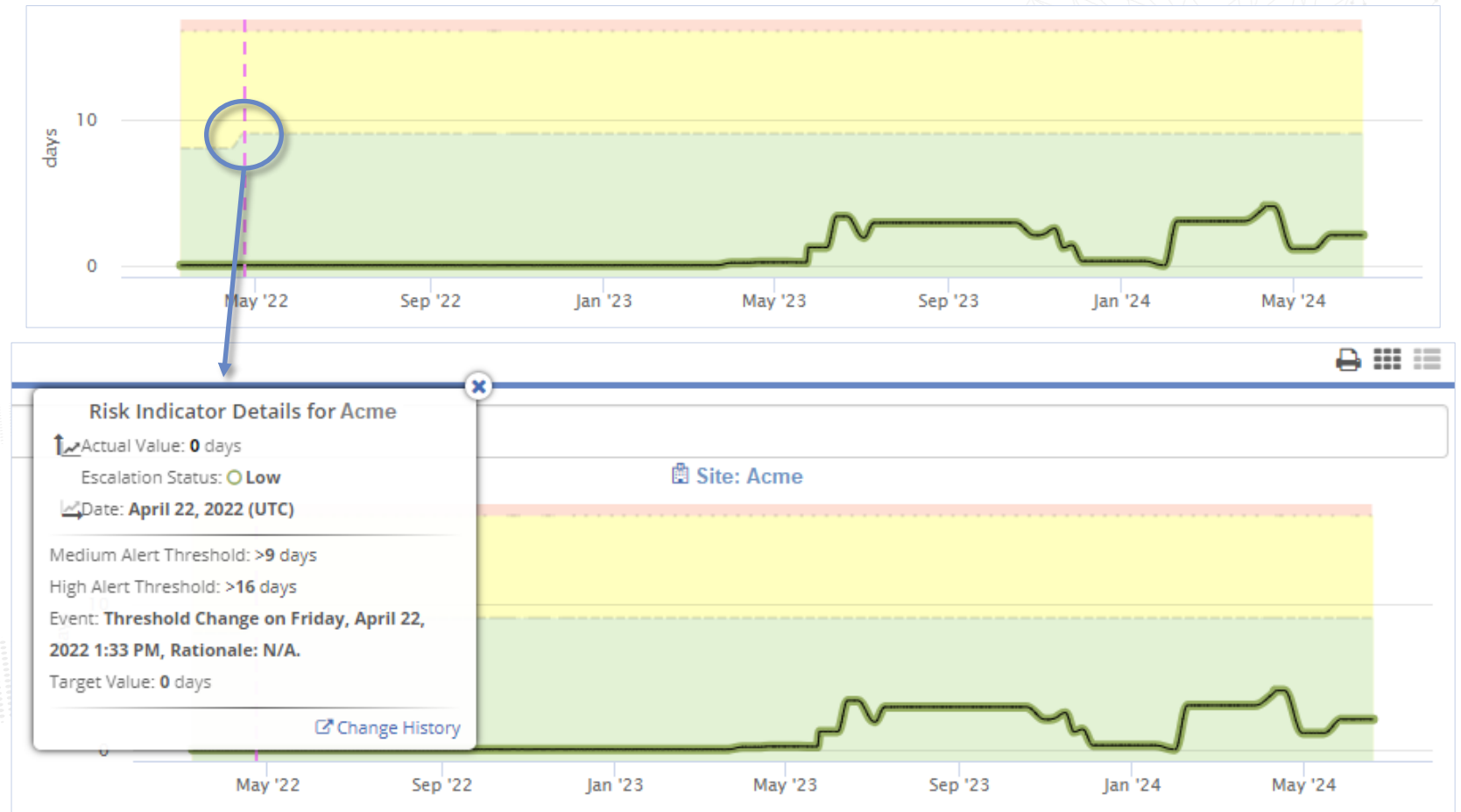
Rewind Time, Retain Context

Quality by Design in Action

MyRBQM Portal Facilitates Longitudinal Data Quality Audits

» **Vertical Lines**: Indicate changes in the Risk Indicator (RI) thresholds, reflecting updates based on revised risk assessments.

» **Tooltip**: Provides detailed information about each RI threshold change, ensuring you understand the context and rationale.

All information is preserved in its historical context: nothing is lost.

Risk Indicator Details for Acme

Actual Value: **0** days

Escalation Status: ○ **Low**

Date: **April 22, 2022 (UTC)**

Medium Alert Threshold: >9 days
High Alert Threshold: >16 days
Event: **Threshold Change on Friday, April 22, 2022 1:33 PM, Rationale: N/A.**
Target Value: **0** days

Change History

Site: Acme

High Performance Under Pressure

Quality by Design in Action

100 concurrent studies

Eventually: Is my system…..?

The Big Five

Transparent | Can the system provide a clear and accurate view of historical data?

Verifiable | Can the system verify the authenticity and context of each data point?

Auditable | Does the system allow for easy auditing of data transformations and processes?

Collaborative | Does the system support real-time collaboration among multiple users?

Reliable | Is the system designed to handle data efficiently and accurately, even under load?

Cyntegrity's MyRBQM® Portal:

» Tracks study progress with multi-timestamped datasets, providing a clear historical view of data changes.
» Ensures data authenticity and traceability with three timestamps per data point.
» Offers full audit trails by documenting all data transformations for reproducibility and compliance.
» Supports real-time teamwork with simultaneous updates and shared access to study data.
» Delivers consistent performance under heavy data loads with robust processing and optimized queries.

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Our Growing AI Capabilities

MyRBQM®

2017 — **Machine Learning** Predictive Analytics

2020 — Machine Learning predictive analytics for **all clinical research metrics**

2023 — **"Ask AI"** for clinical Risk Assessment & Mitigation, AI-augmented Regulatory Inspections

2025 — AI-enhanced **Medical Monitoring** and clinical **Due Diligence**

Q1 2025 — AI-enhanced **Protocol** Complexity Assessment & Optimization

The Value We Bring

Quality by Design in Action

Best in Class

ASSURANCE & SECURITY

Upholding the Highest Security & Industry Standards for Compliance
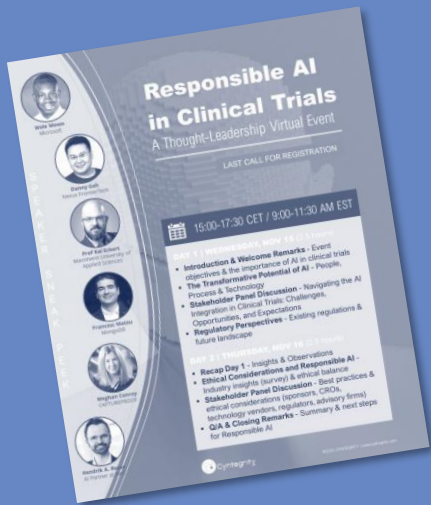
ISO 9001:2015

ISO 27001

GDPR COMPLIANT

SOC 2 TYPE 2

ICH GCP compliant

FDA 21 CFR PART11

Aligned to industry standards

STANDARDIZATION

Cyntegrity's RBQM solutions are aligned to the expected standards for clinical trials.

Thought Leadership

INNOVATION
Backed by Novel Technology & KOL Partnerships

Microsoft Solutions Partner

Healthcare AI
Certified software
MyRBQM Portal

Visit Cyntegrity at:
microsoft.com
microsoftISVpartner.com

Cyntegrity
Health Provider

Risk-based quality management: Cyntegrity uses Microsoft Azure to increase data integrity in clinical trials

Read the full story…

Strengthened Partnership. Since 2022, our alliance with Microsoft has deepened, highlighted by a successful Responsible AI event that showcased our leadership in ethical AI.

Collaborative Innovation. Joint AI initiatives with Microsoft, including sponsorship, reflect our shared commitment to responsible innovation.

EDUCATION

MyRBQM® Academy
The Industry Transformer

Operational Excellence

1,074

Students
enrolled into
MyRBQM
Academy

385

Clinical
research
organizations
trained

809

MyRBQM
Academy
graduates

Established in 2019, our MyRBQM Academy provides targeted education to help clinical research teams embrace the RBQM implementation process and contribute to its success.

www.academy.cyntegrity.com

Ask Our Customers

Quality by Design in Action

Bristol Myers Squibb™

Seqirus™
A CSL COMPANY

Biotest
From Nature for Life

ADAMAS

Daiichi-Sankyo

MERZ

ERGOMED

hal allergy

BIOMARIN®

TechObserver

VERICEL

CRO

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