

More Than Mandates: RBM Today, Why It Matters, and How to Navigate the Change

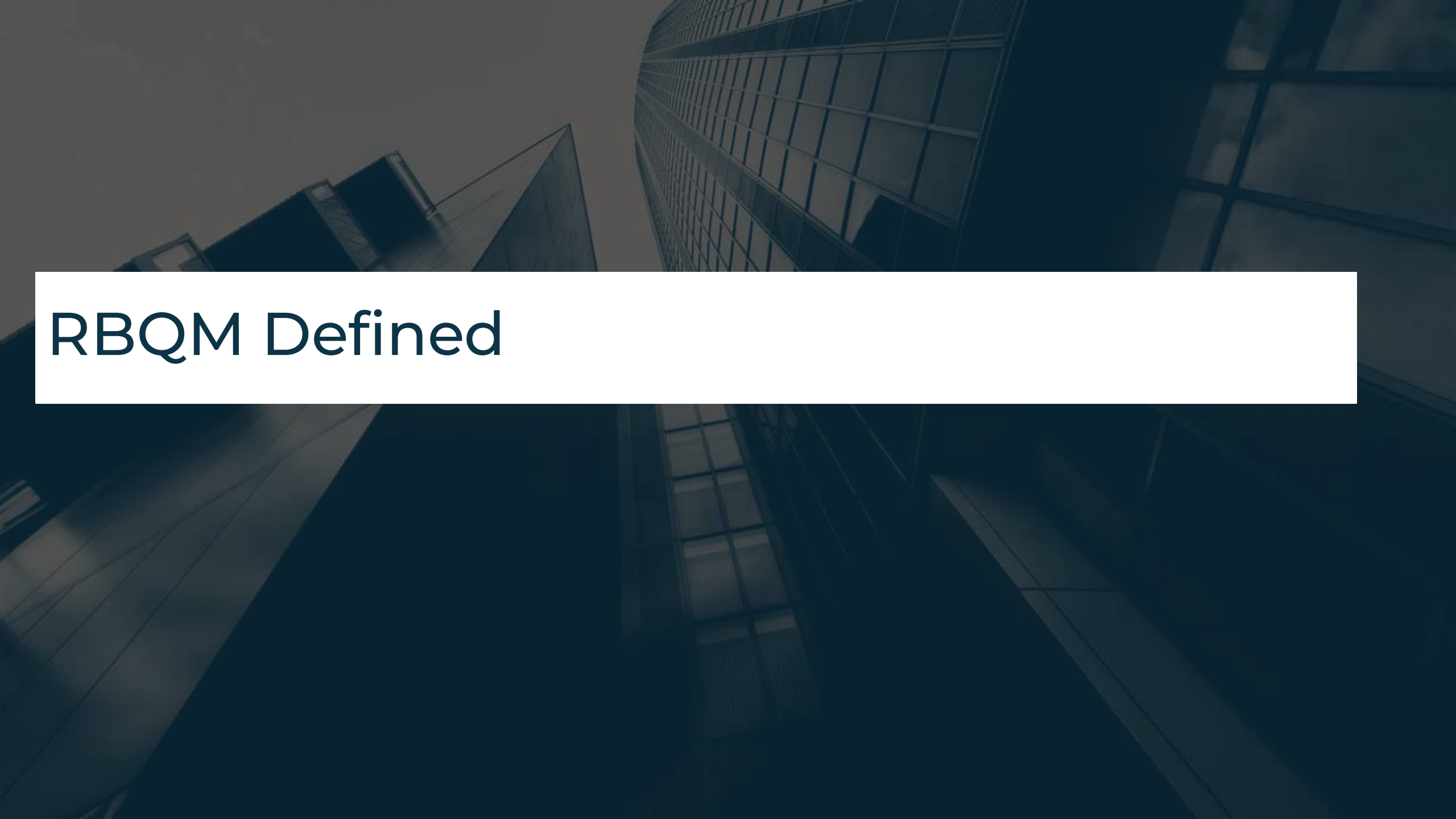


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Agenda

- RBQM Defined
- RBQM & Change
- RBQM & the “Clinical Trial ecosystem”



RBQM Defined

RBQM Defined



Risk Based Quality Management



Updated approach to Risk management within Clinical Trials to keep pace with industry practices and norms

ICH E6 (R2) made explicit the responsibility of the sponsor to understand the risks to quality in clinical trials via the use of a Risk-Based Quality Management (RBQM) approach

Early discussions

Link trial "inputs" to risk

Planning for risk

Risk scoring

Key Risk Indicators

Quality Tolerance Limits

- Critical process/data doc.
- Risk identification
- Risk evaluation
- Risk control
- Risk communication
- Risk review
- Risk reporting
- Data Quality
- Patient Safety

New Regulation

Better Patient Safety

Why RBQM?

Improved Data Quality

Decentralized Trials



RBQM & Change

RBQM & Change

Risk Based Quality Management

=

Change

Where is the change coming from?

What type of change is it?

Where is this change coming from?

Outside Forces

Market Changes

- Change in customer preferences
- Increased competition

Social Pressures

- Shift in values
- Crisis

Regulatory

- Guidelines
- Laws
- Patient Safety

Inside Forces

Performance

- Increased performance
- Decreased performance

Growth

- Need to scale
- New roles/departments

Complexity

- Complex process
- Complex product

Adaptive Change

Innovative Change

Radically Innovative Change

What type of change is this?

"We've seen stuff like this before"

Least Threatening

Change that has already been experienced before

Low cost, complexity, and uncertainty

Creates the least amount of fear & resistance for employees



"This is something new for this company"

Somewhat Threatening

Introduction of a practice that is new to the organization

Moderate complexity, cost, and uncertainty

Apt to trigger some fear and resistance for employees



"This is a brand-new thing in our company or industry"

Very Threatening

Introduces a practice that is new to the industry

Most complex, costly, and uncertain

Extremely threatening to managers confidence and employee job security and could tear at the fabric of the organization



Change Model

Lewin's Change Model

Most theories of organizational change originated with the work of social psychologist Kurt Lewin. Lewin developed a model with three staged – unfreezing, changing, refreezing to explain to initiative, manage, and stabilize planned change.



Creating Motivation for Change

- Announce the change!
- Managers try to instill in employees motivation to change, encourage them to let go of attitudes that are resistant to innovation.
- Employees need to become dissatisfied with the old way of doing things
- Manager need to reduce the barrier to change

Learning New Ways of Doing Things

- Employees are given the tools to change – new information, new perspectives.
- Managers can help by benchmarking results, model behavior, provide training.
- Change is more likely to be accepted if employees process the career readiness for the change

Making the New Ways Normal

- Employees may need help integrating the changed attitudes and behaviors into their normal way to doing things.
- Managers can encourage and reward employees for new behaviors
- New employees are onboarded with the new process



A low-angle, upward-looking photograph of several modern skyscrapers with glass facades. The buildings are dark and reflective, with the sky visible in the background. The perspective creates a sense of height and architectural scale.

RBQM & the “Clinical Trial ecosystem”

RBQM & the Clinical Trial ecosystem

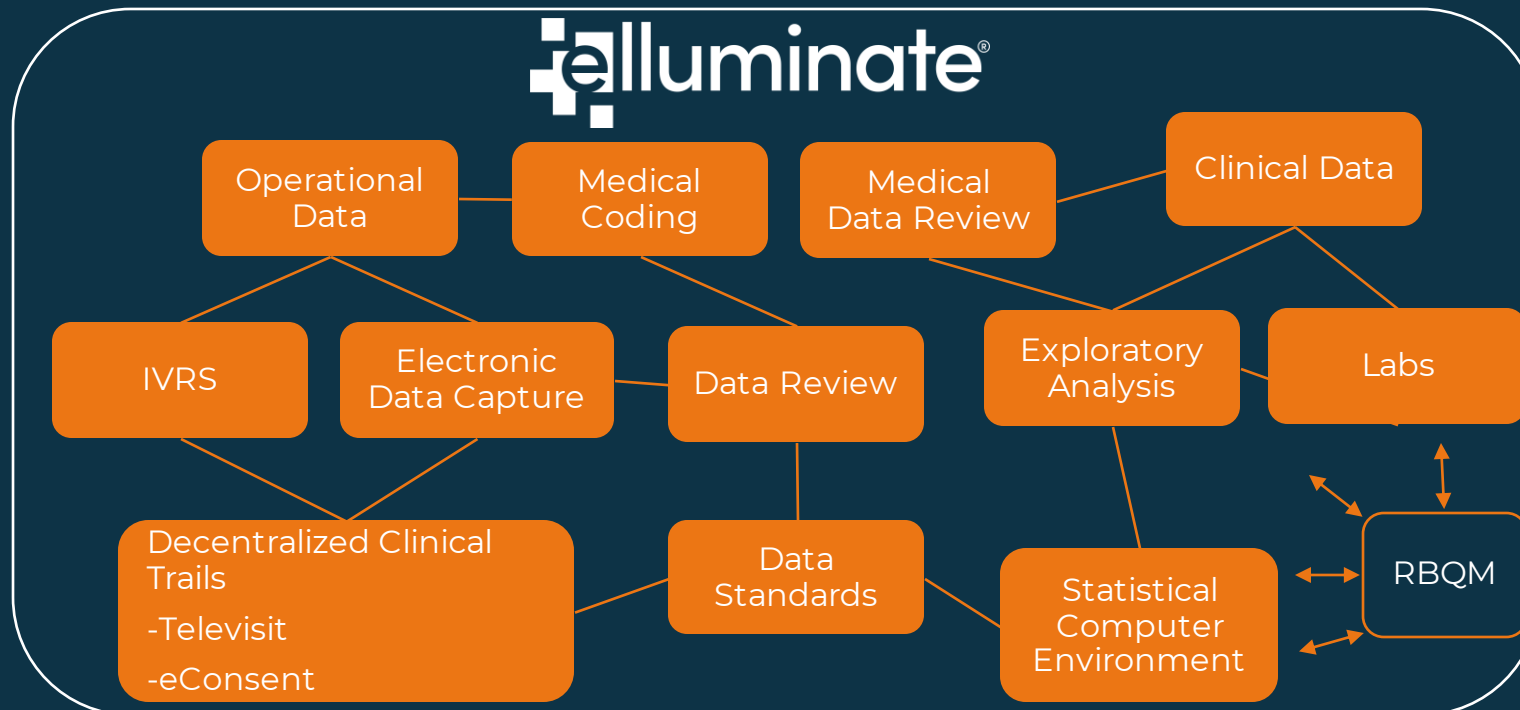
Every Sponsor organization will use a “product” to implement RBQM into their trial conduct.

If RBQM is a change that will be managed by a “product” what attributes should that product have that would:

-Decrease the complexity of the change



The Clinical Trial ecosystem



What attributes does your RBQM product need to make the change be more adaptive and less innovative?



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Data Acquisition

Data Transformation

Data Utilization

What attributes does your RBQM product need to make the change less complex?

Data Acquisition



- Understanding and monitoring risk within your trial requires...data.
- The process of acquiring data can make RBQM more/less complex
- What are the attributes of data acquisition that could make RBQM less complex to implement in an organization?

Access to a variety of data, clinical, operational, etc.

Data that is centrally located

Fully developed APIs to external vendor data

Automated imports of data

Scheduled imports of data

What attributes does your RBQM product need to make the change less complex?

Data Transformation

Adaptive
Change

Innovative
Change

Radically
Innovative
Change

- Data Transformation (standards, derived fields, mappings) can normalize disparate data into something common that can then more easily be used to calculate scores.
- What are the attributes of data transformation that could make RBQM less complex to implement in an organization?

Established &
agreed upon
standards

Mappings

Metadata
validation

Library of
standards

Standards that
are accessible to
all studies

What attributes does your RBQM product need to make the change less complex?

Data Utilization

- Data ultimately needs to be viewed, actioned, analyzed by users.
- What are the attributes of data utilization that could make RBQM less complex to implement in an organization?

Visualization

Computing Methods

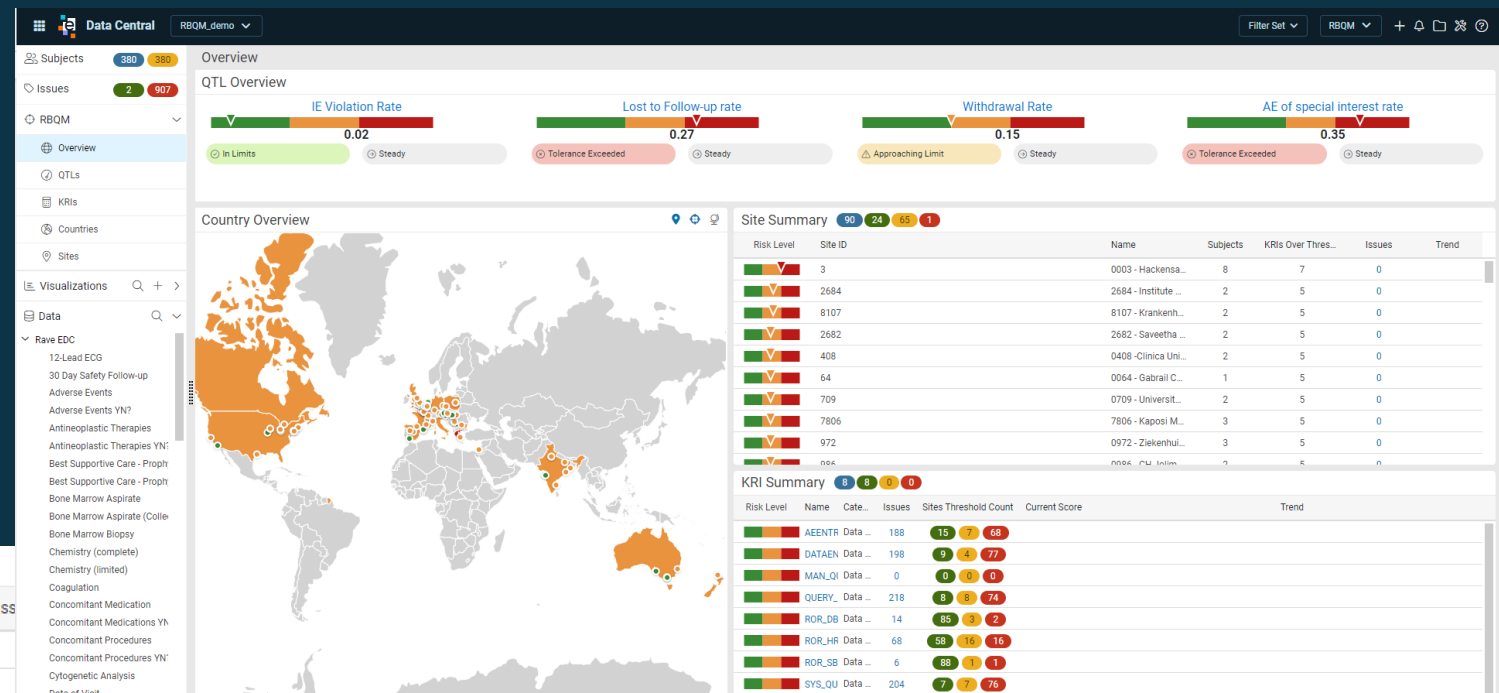
Configuration

Acting on the data
(assigning issues)

Adaptive
Change

Innovative
Change

Radically
Innovative
Change



In conclusion...

- RBQM = Change
- Change is hard!
 - Therefor it needs to be understood
- The change to RBQM does not need to be hard
- What attributes does your RBQM product need to make the change be more adaptive and less innovative?
- How does your RBQM 'product' fit into your Clinical Trial ecosystem?