



Preparing for the “Q” in RBQM: The Framework for Risk-Based Quality Management



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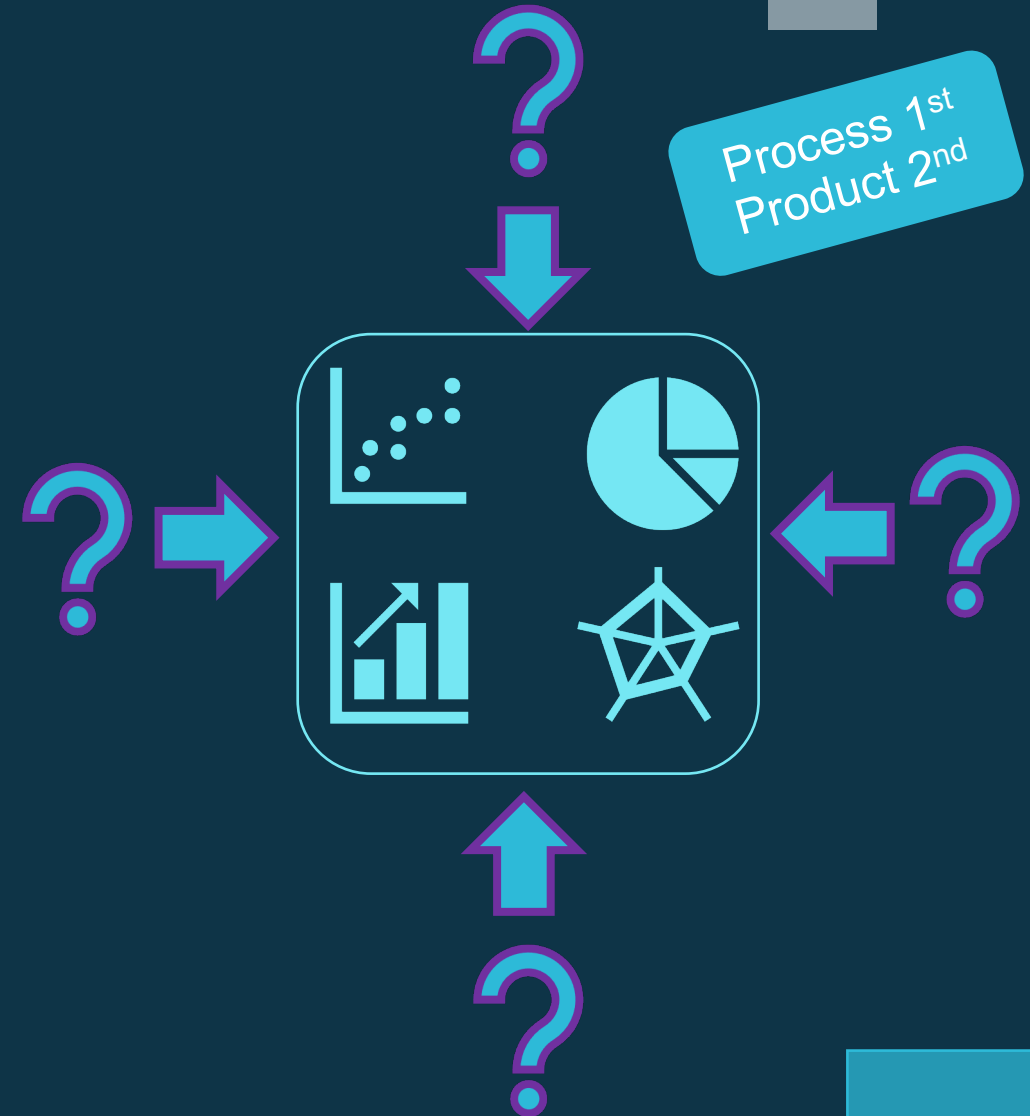
The RBM to RBQM Transformation:



Why is this Topic Important?



RBQM is a better way to ensure Patient Safety and Data Integrity within a Clinical Trial



The RBM to RBQM Transformation

RBM: (Risk Based Monitoring)

- Looking for risk everywhere
- Actioning all defects
- Managing all risks the same



- 100% SDV
- Addresses risk when they occur

RBQM: (Risk Based Quality Management)

- Defining risks early
- Accepting some risk
- Customizes monitoring plans
- Past trials should inform future trials



- Risk Assessment
- Risk Categorization
- Defining all risk
- Creating customized action plans for each risk
- Think about data & processes from a risk perspective

The RBM to RBQM Transformation – A New Mental Model?

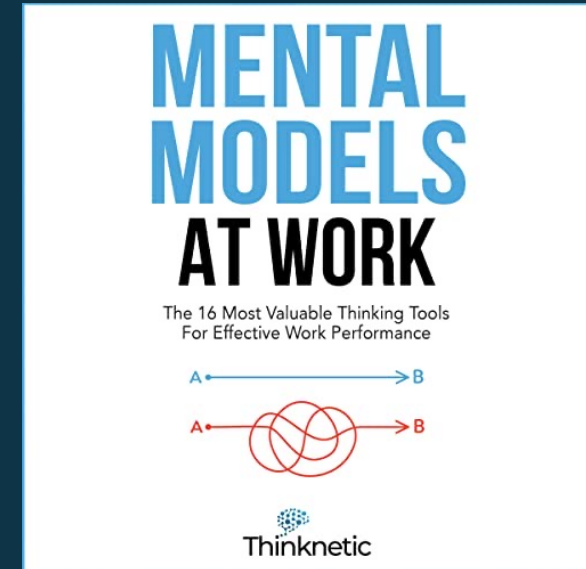
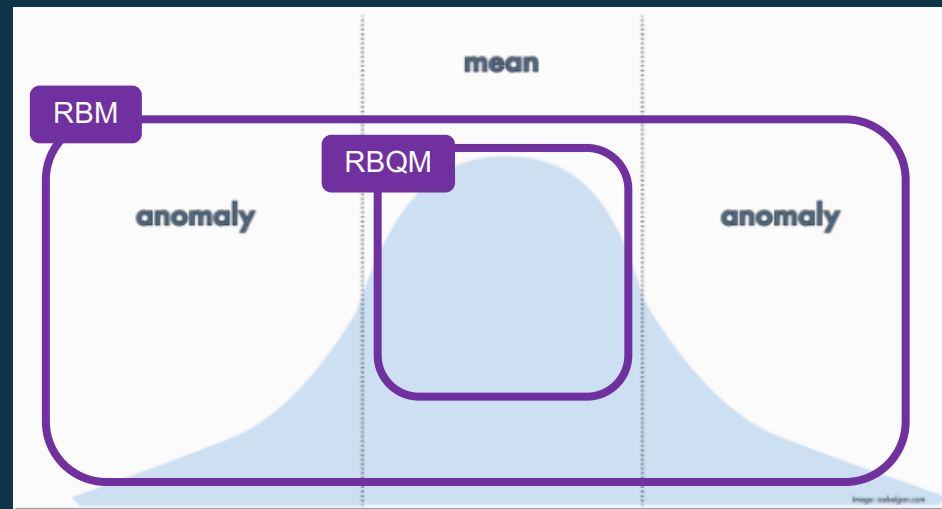
Mental Model: Mental models are personal, internal representations of external reality that people use to interact with the world around them.

Example of Mental Models

- Second Order Thinking: Considering the consequences of a decision
- Inversion: Look at what needs to be avoided to achieve a goal
- Map vs. Territory: Consider the limitations of representations of facts

Probabilistic Thinking: Considering the likelihood that any specific outcome will occur when making a decision.

Sounds like RBQM?



Quality As An Overarching Objective

"Monitoring alone cannot ensure quality. Rather, quality is an overarching objective that must be built into the clinical trial"

- Guidance for Industry Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring. U.S. Department of Health and Human Services Food and Drug Administration OMB Control No. 0910-0733 August 2013

Build quality into a Clinical Trial?

Better
monitoring
plans

More SDV

Less SDV

Risk
Assessment

Risk
Categorization

More
Meeting?!

What **data practices, standards, routines** are needed to **enable** us to build quality into a Clinical Trial?

And People!

Data Practices that Risk Based Quality Management

Acquisition

APIs

Easily access to data

Depth of APIs

Detailed access to data

Automated Imports

Effort of data acquisition

Variety of Data

Acquiring all data types

Transformation

Standards

Normalizing data

Mappings & Library

Customizing the data

Specifications & Library

Driving standards

Utilization

Visualizations

Understanding the data

Configuration

Using the data

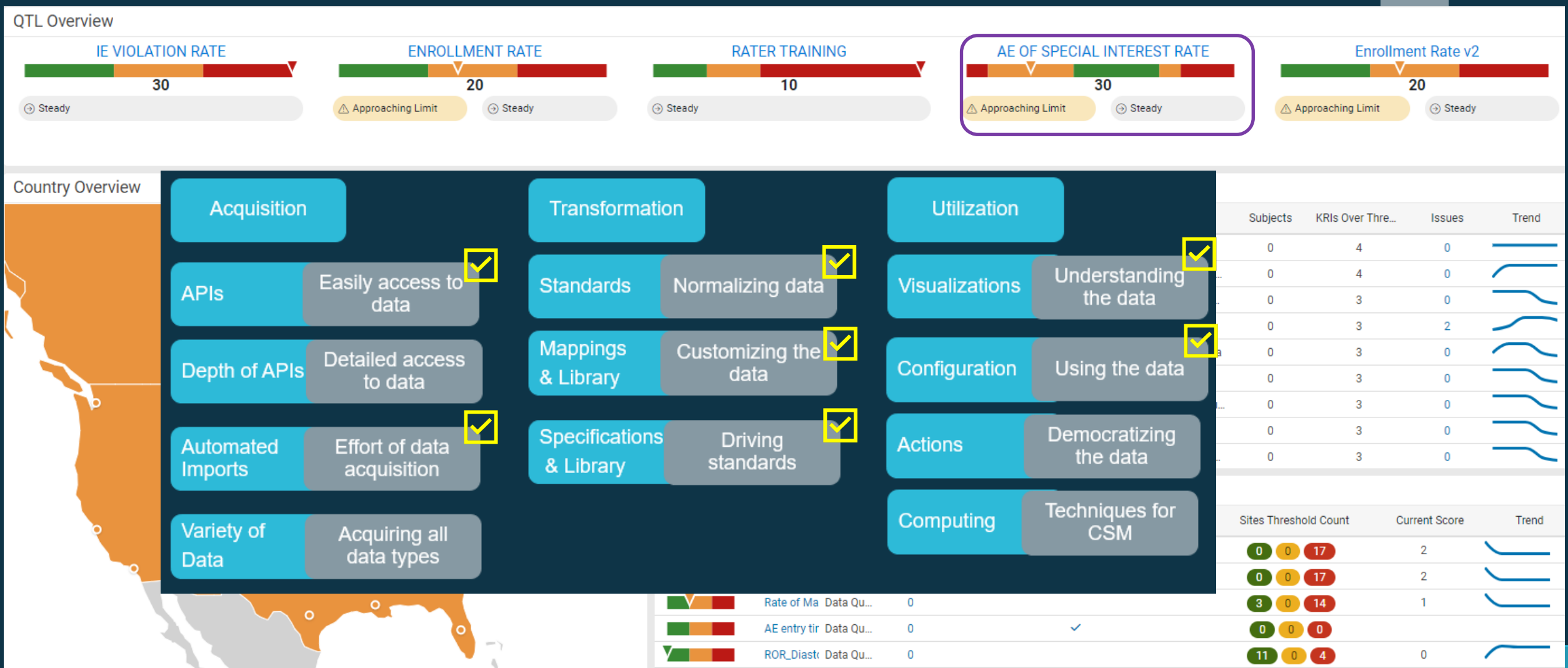
Actions

Democratizing the data

Computing

Techniques for CSM

Data Practices and Risk Monitoring enablement

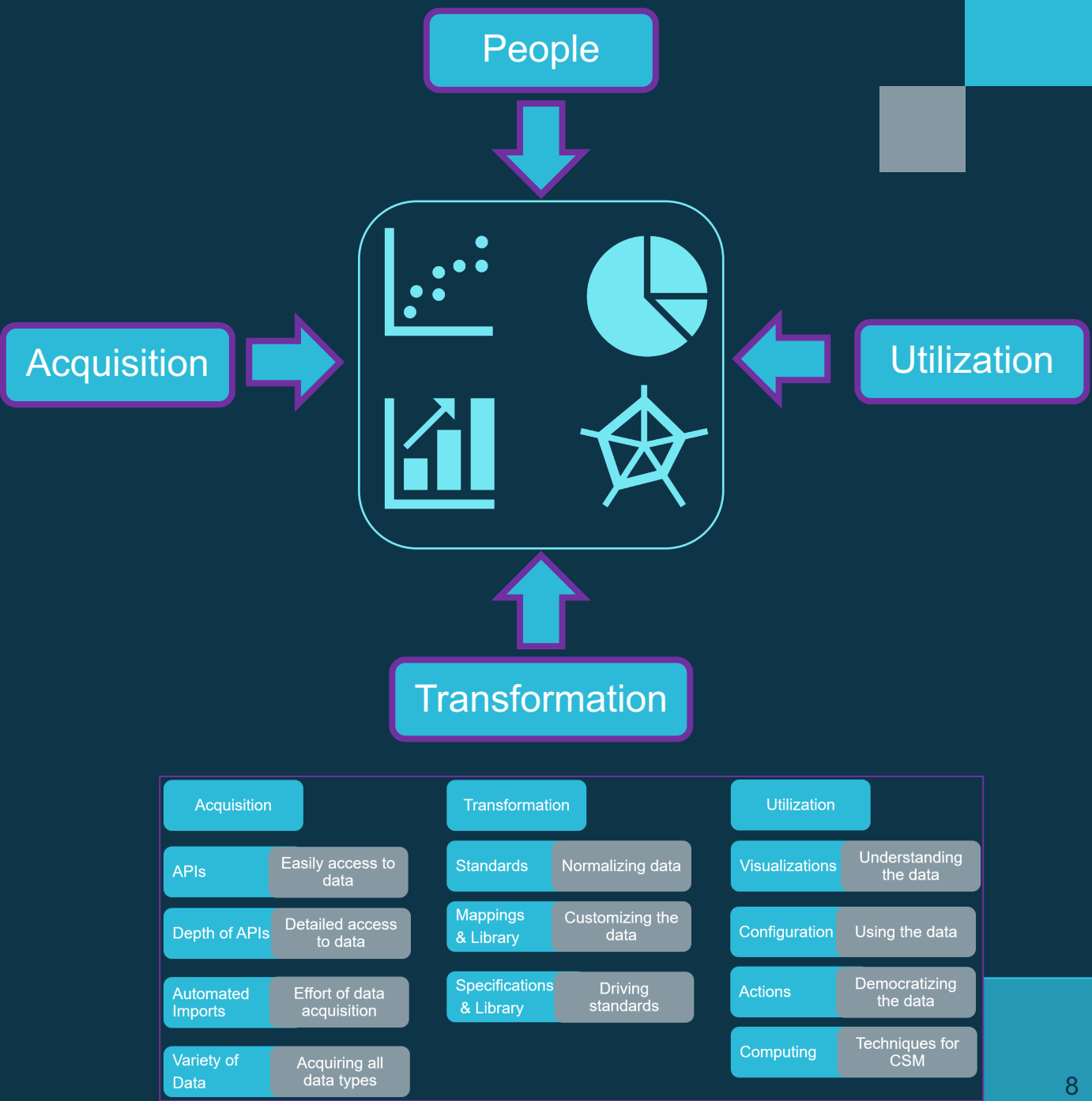
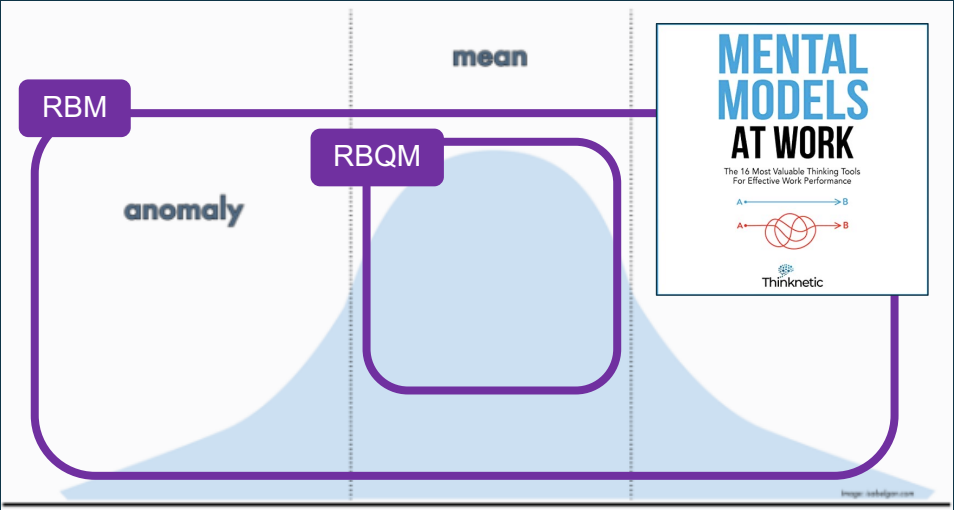


Conclusion

Process First Product Second

Data Practices, Standards, Routines

RBQM = Probabilistic thinking



Thank You

