

The RBM to RBQM Transformation: More Than The Method Or The Tool



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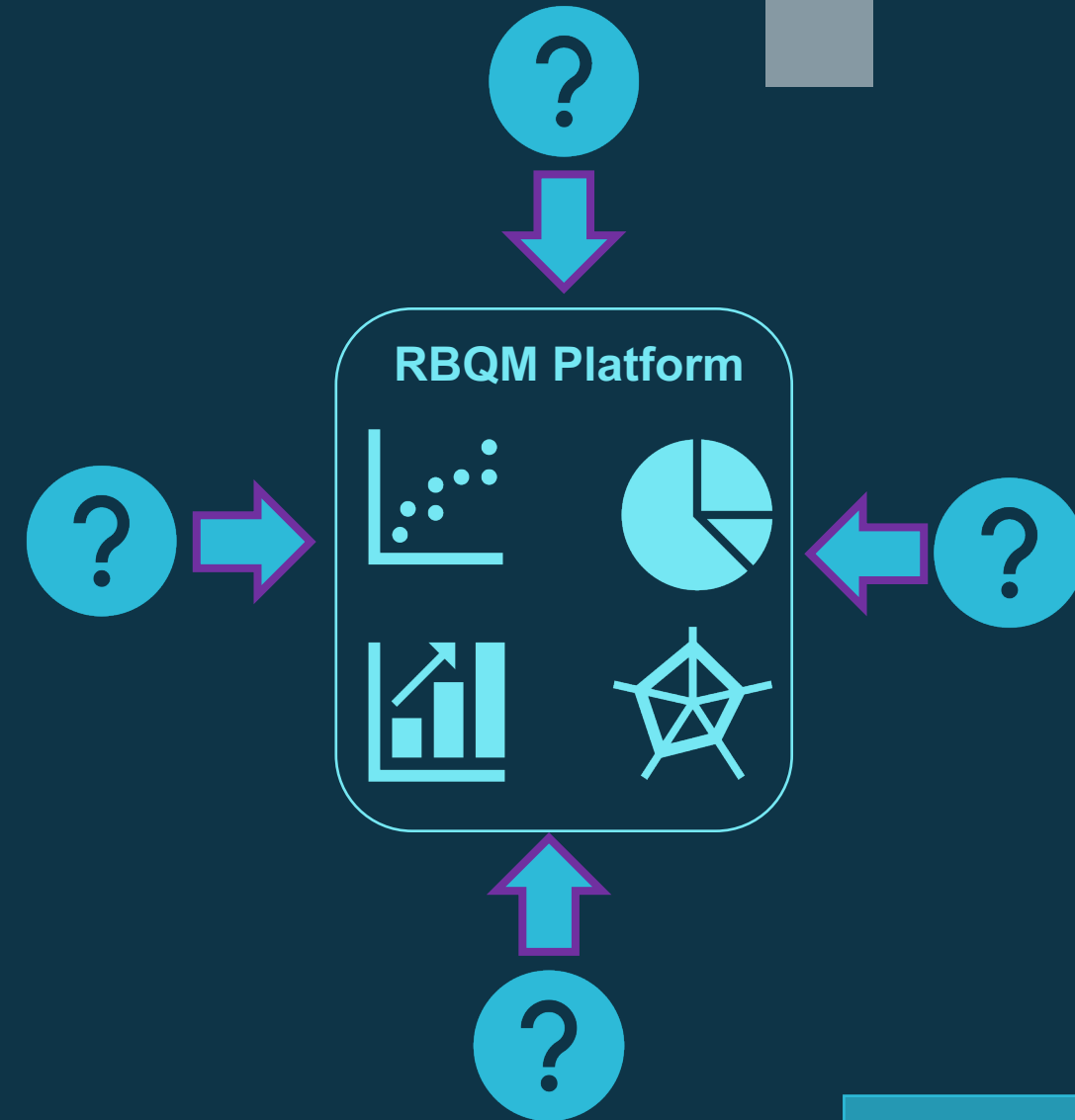
The RBM to RBQM Transformation: More Than The Method Or The Tool



Why is this Topic Important?



RBQM is essential 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 separate action plans for each risk

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?

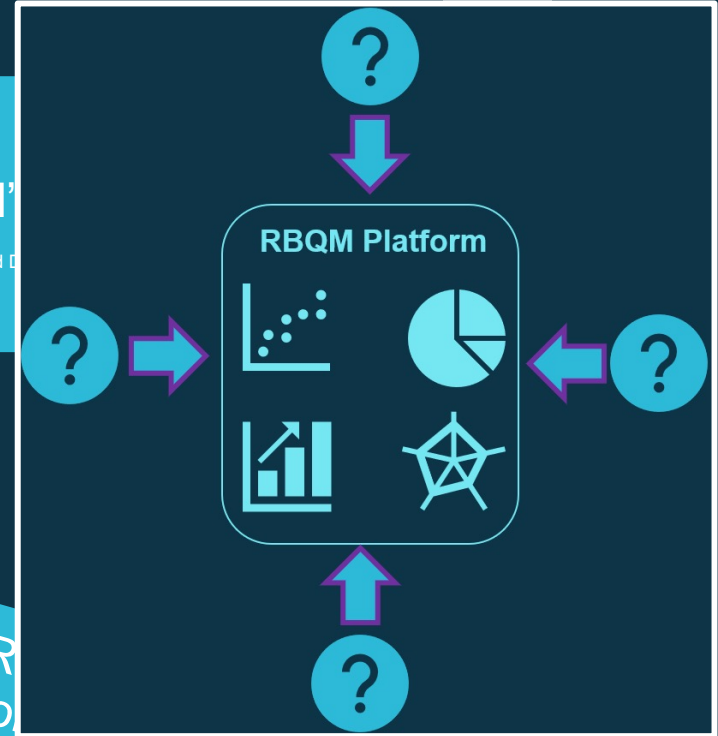
Better
monitoring
plans

More SDV

Less SDV

Risk
Assessment

R
Catego
ation



What data practices are needed to enable us to build quality into a Clinical Trial?

Infrastructure & Practices that Enable Quality

Acquisition

APIs

Easily
access data

Quality 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

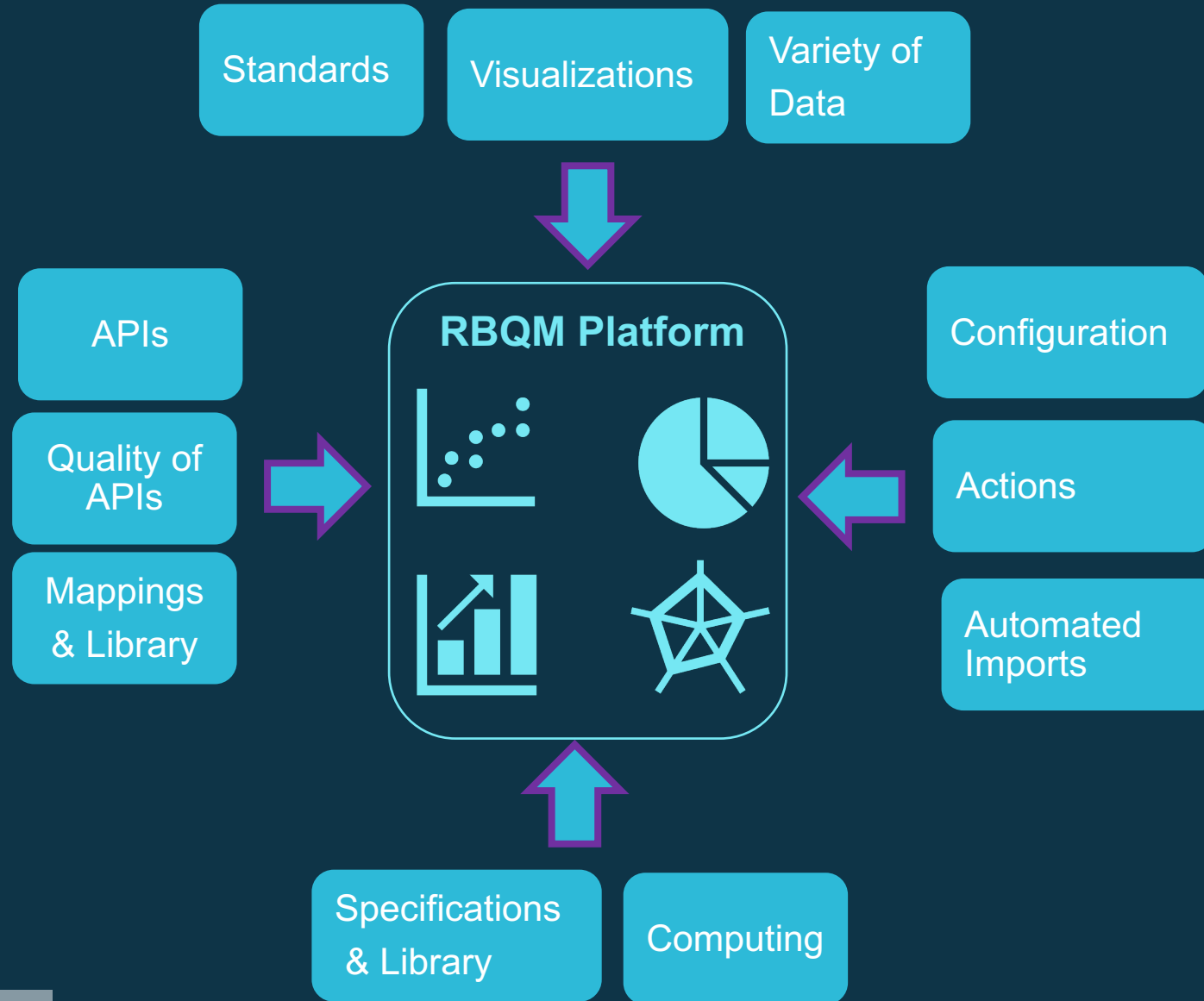
Actioning

Democratizing
the data

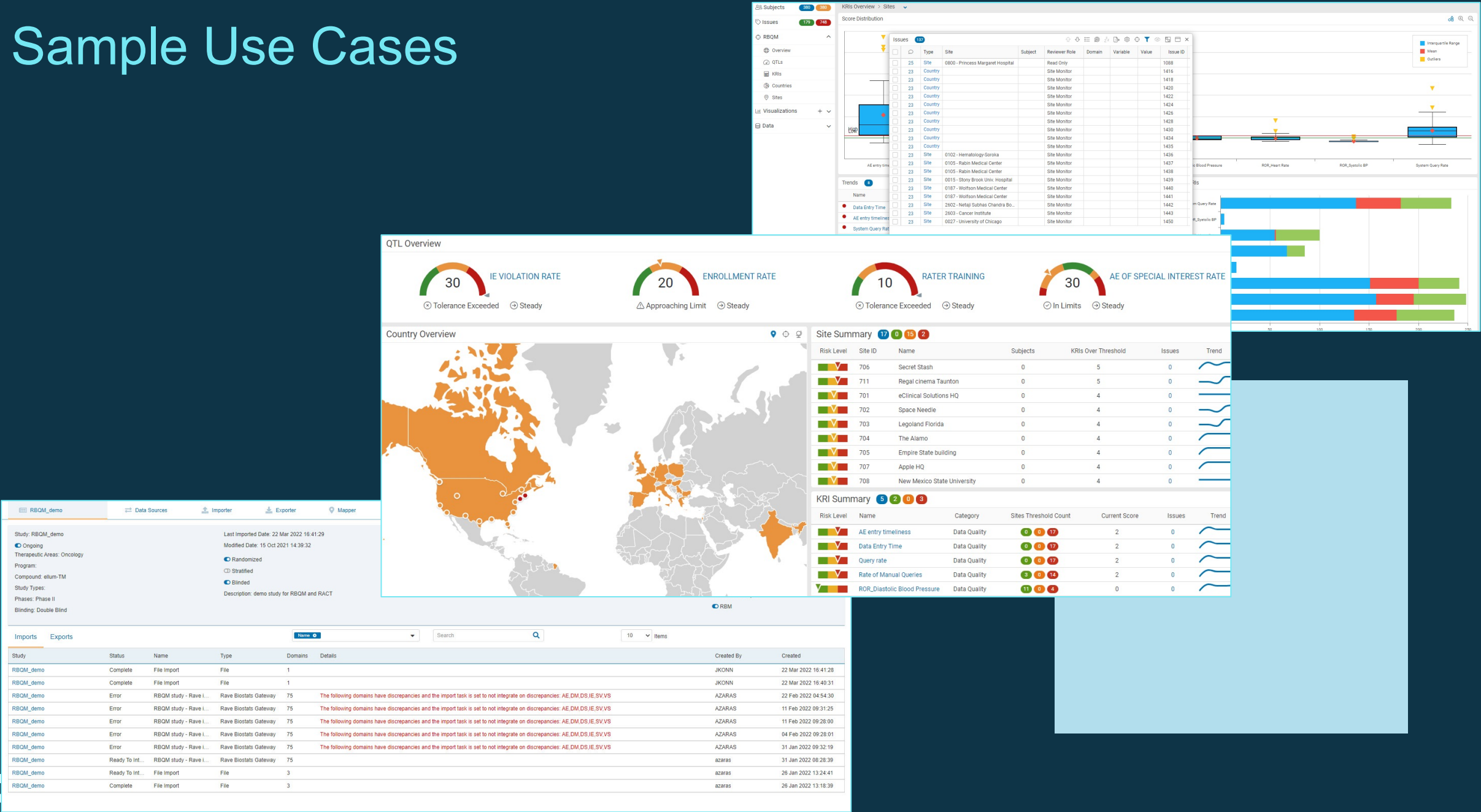
Computing

Techniques for
CSM

Infrastructure & Practices that Enable Quality



Sample Use Cases



Use Case: I have data from multiple vendors that will make up a QTL

RBQM_demo

Data Sources

Importer

Exporter

Mapper

Snapshots

Validator

Tasks

eDrive

Define XML

eForms

Data Central

Study: RBQM_demo

Ongoing

Therapeutic Areas: Oncology

Program:

Compound: ellum-TM

Study Types:

Phases: Phase II

Blinding: Double Blind

Last Imported Date: 22 Mar 2022 16:41:29

Modified Date: 15 Oct 2021 14:39:32

Randomized

Stratified

Blinded

Description: demo study for RBQM and RACT

Last Imported By: JKONN

Modified By: JBRUGGER

SDTM Standard:

ADaM Standard:

Define-XML Standard:

Active

Data Quality

Data Review

Clinical Analytics

Operational Analytics

Custom Analytics

RBM

Imports

Exports

Name

Search

10

Items

Study	Status	Name	Type	Domains	Details	Created By	Created
RBQM_demo	Complete	File Import	File	1		JKONN	22 Mar 2022 16:41:28
RBQM_demo	Complete	File Import	File	1		JKONN	22 Mar 2022 16:40:31
RBQM_demo	Error	RBQM study - Rave i...	Rave Biostats Gateway	75	The following domains have discrepancies and the import task is set to not integrate on discrepancies: AE,DM,DS,IE,SV,VS	AZARAS	22 Feb 2022 04:54:30
RBQM_demo	Error	RBQM study - Rave i...	Rave Biostats Gateway	75			
RBQM_demo	Error	RBQM study - Rave i...	Rave Biostats Gateway	75			
RBQM_demo	Error	RBQM study - Rave i...	Rave Biostats Gateway	75			
RBQM_demo	Error	RBQM study - Rave i...	Rave Biostats Gateway	75			
RBQM_demo	Ready To Int...	RBQM study - Rave i...	Rave Biostats Gateway	75			
RBQM_demo	Ready To Int...	File Import	File	3			
RBQM_demo	Complete	File Import	File	3			

APIs

Easily access data

Standards

Normalizing data

Visualizations

Understanding the data

Quality of APIs

Detailed access to data

Mappings & Library

Customizing the data

Configuration

Using the data

Automated Imports

Effort of data acquisition

Specifications & Library

Driving standards

Actioning

Democratizing the data

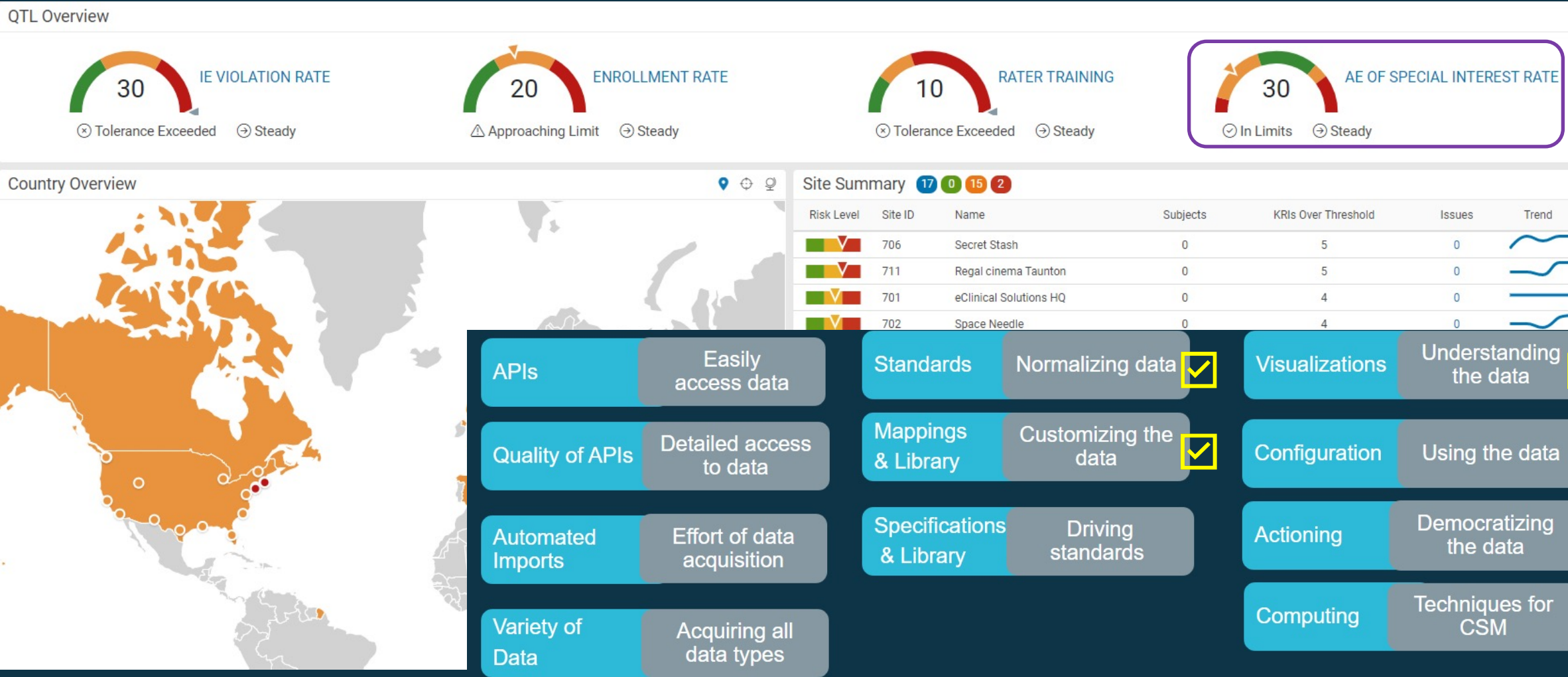
Variety of Data

Acquiring all data types

Computing

Techniques for CSM

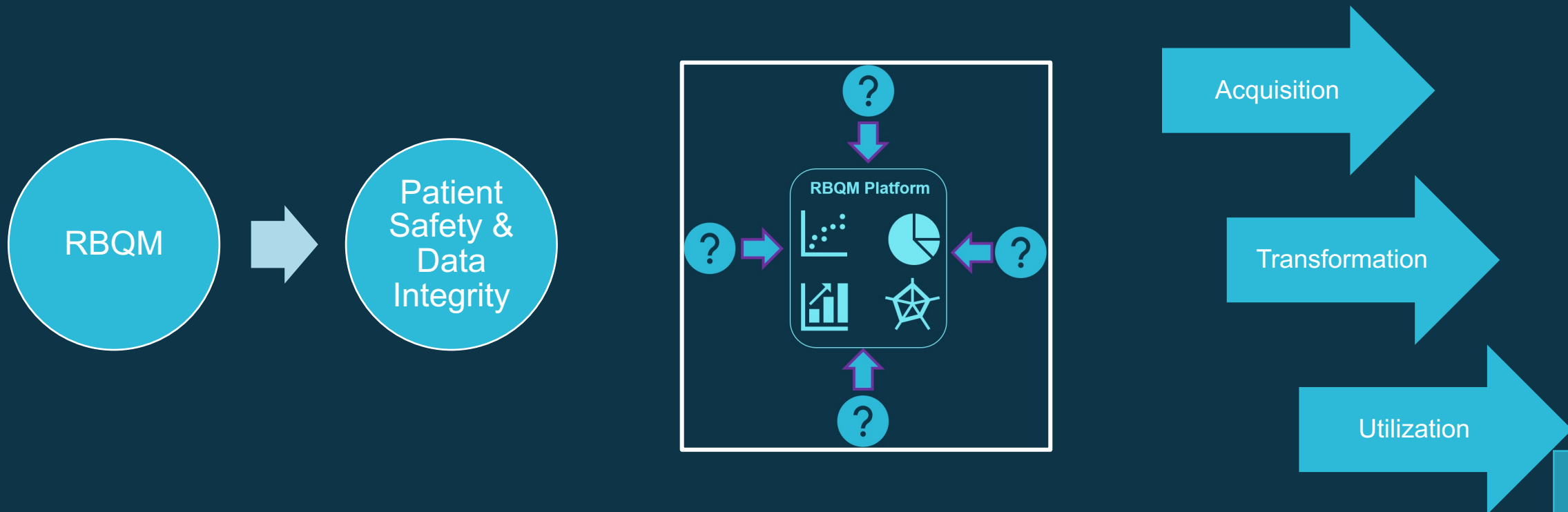
Use Case: I want to create an easy-to-understand QTL





In closing

- RBQM is essential to ensure Patient Safety and Data Integrity within a Clinical Trial
- Ask, "What infrastructure and practices are needed to enable us to build quality into a Clinical Trial?"
 - Compartmentalize infrastructure and practices into three categories Acquisition, Transformation, and Utilization



Thank You



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