



Advancing RBQM strategy to enterprise level: analytics, NLP and immersive technologies

PHUSE

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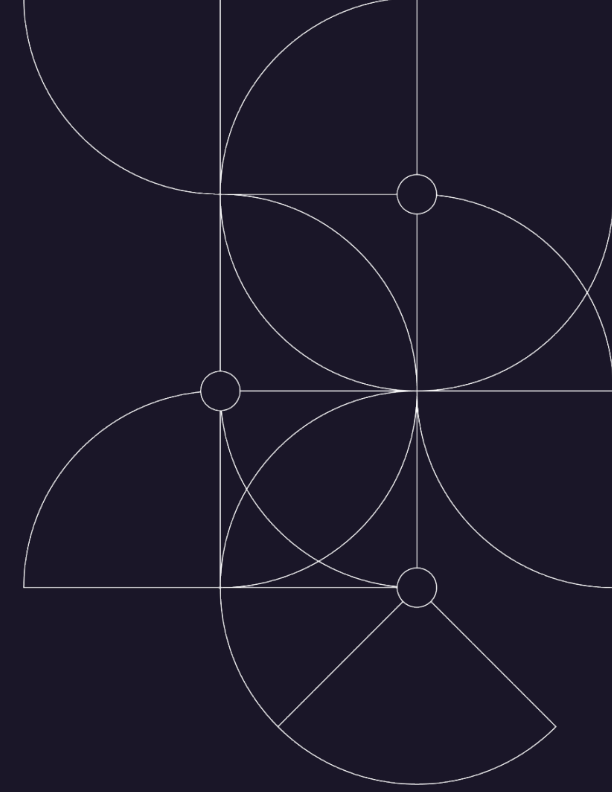
May 2022

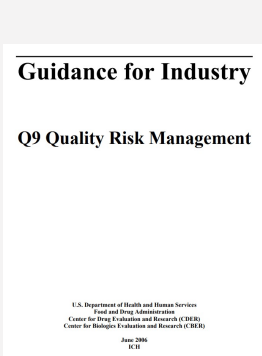
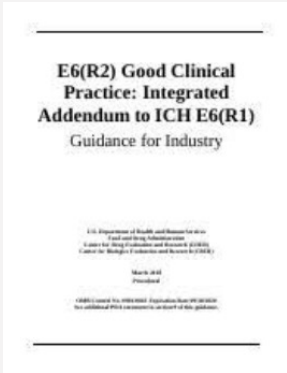
Impact where it matters.



Content

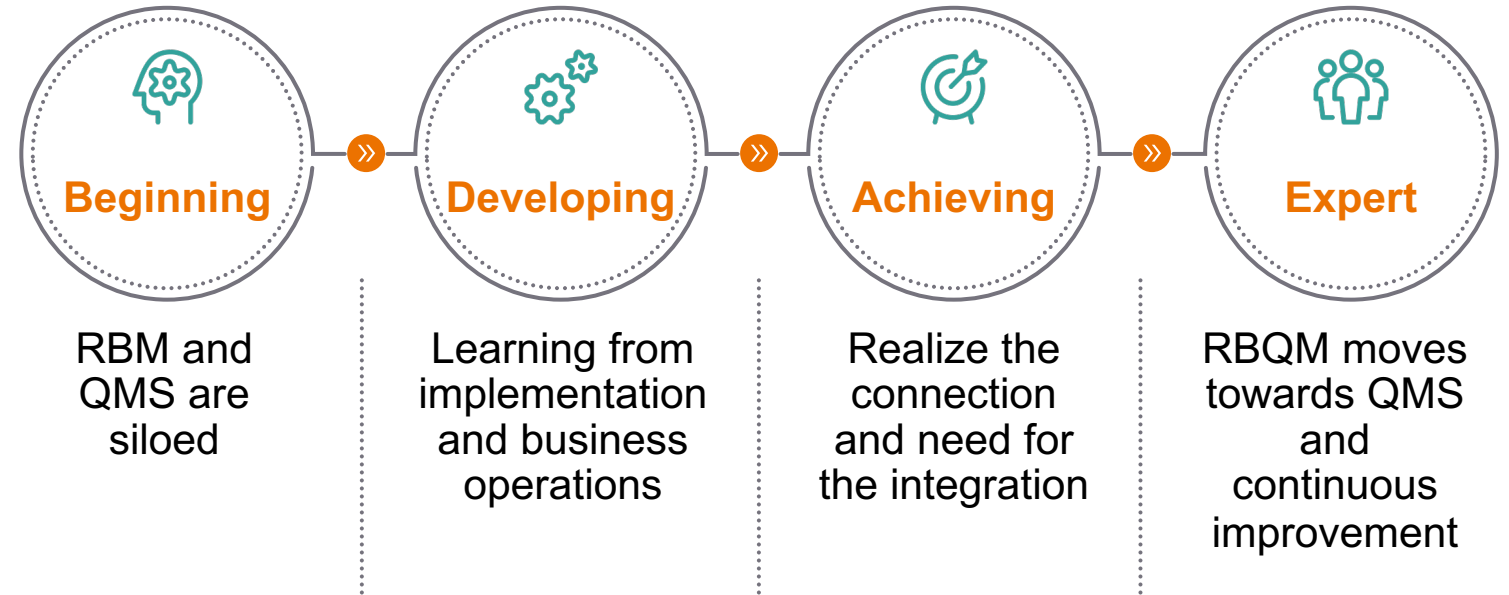
- RBQM Industry Evolution
- QMS: RBM and RBQM
- QMS Ecosystem and RBQM Integration
- Analytics: Quality Processes and Quality Events
- Continuous Improvement and Change Management
- Immersive experience for process re-design



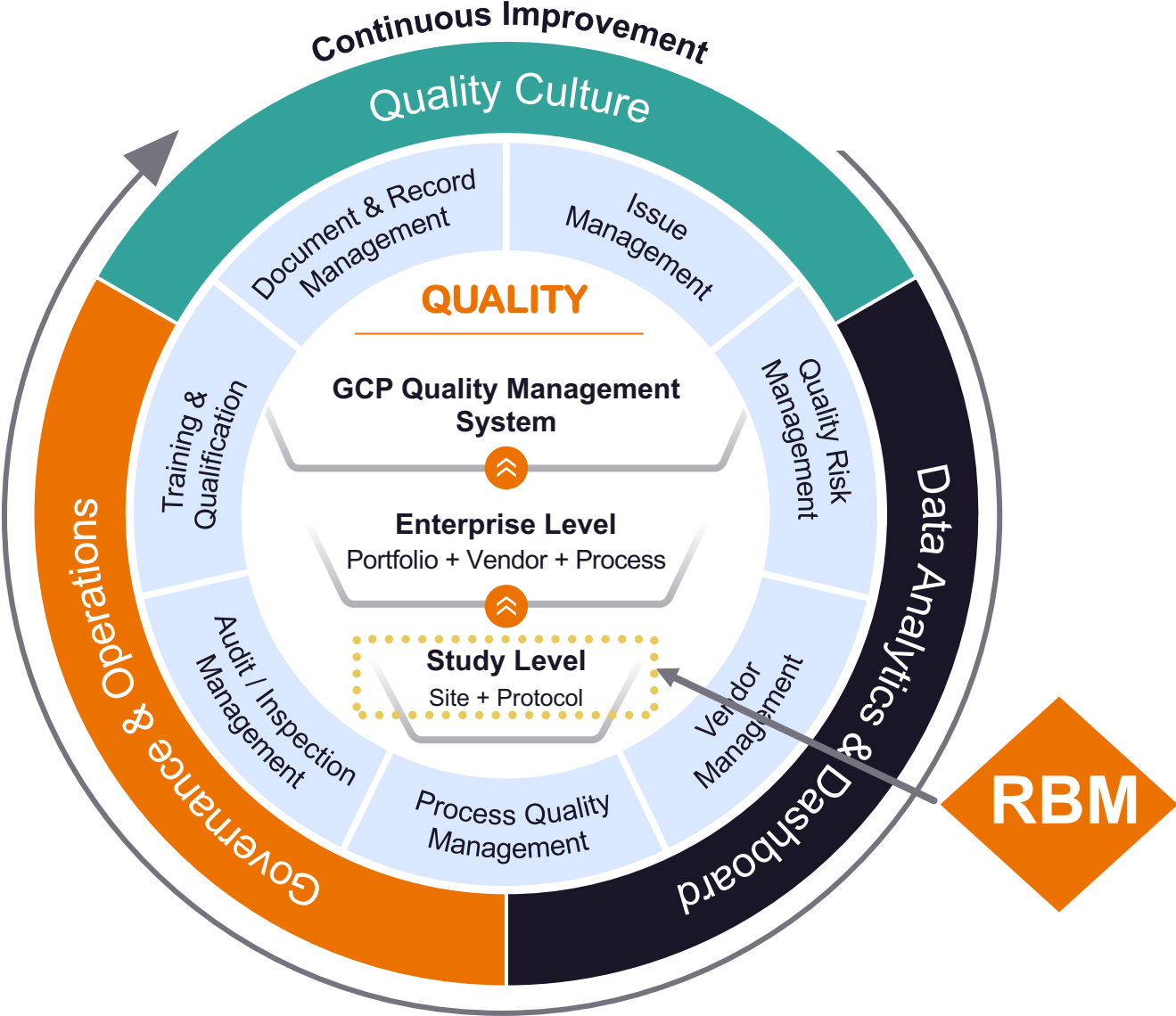


RBQM Industry Evolution:

RBM becomes integral part of QMS requiring capabilities and process change



QMS ecosystem



Quality Management System (QMS): RBM vs RBQM focus areas

RBM FOCUS:

- Assess and monitor study and site level risks
- Routinely manage and analyze study GCP risks
- Use statistical algorithms to detect risks and issues
- Improve resource allocation by focusing on the greatest risks

Examples:

- Data Entry Delays
- AE/SAE rates
- Protocol Deviations Rate
- Missed Assessment Rates

RBM

RBQM

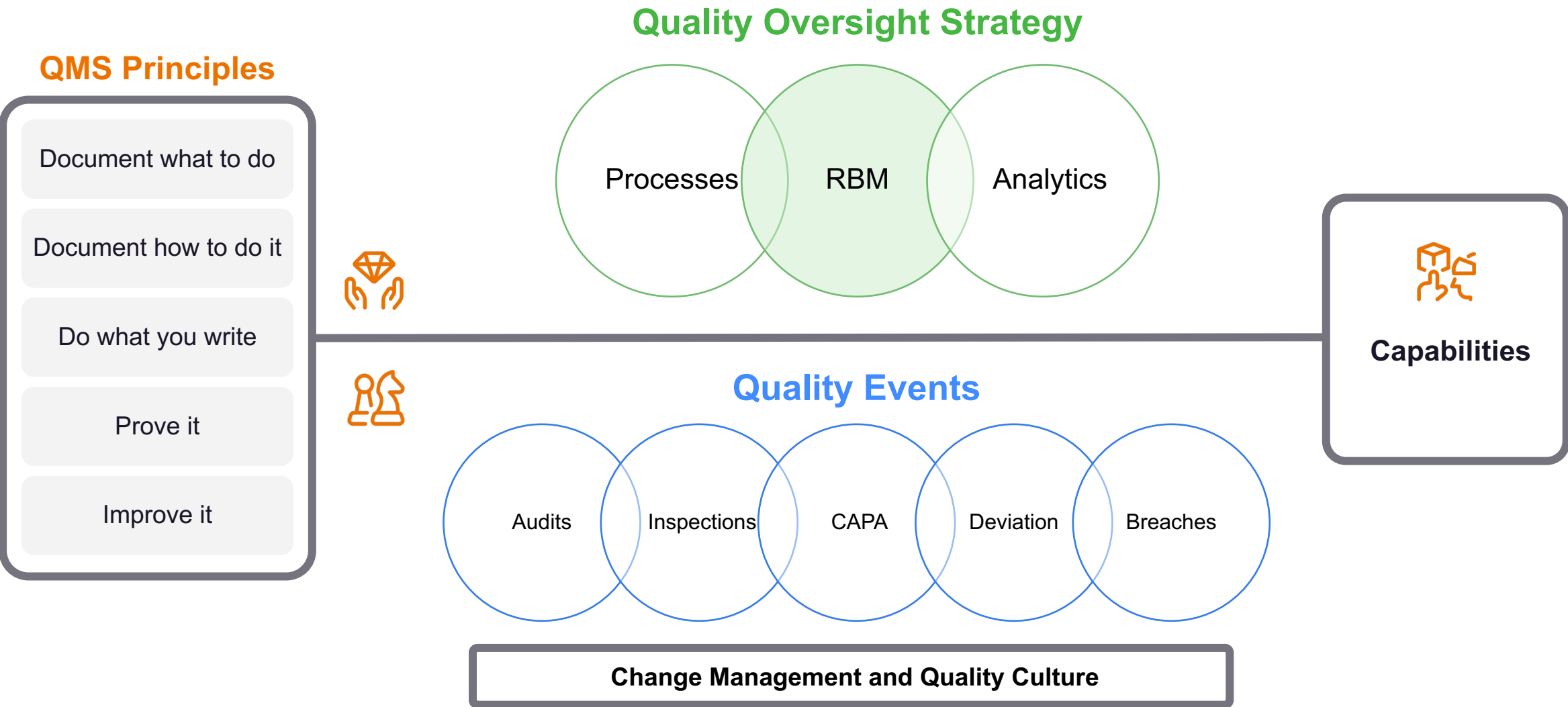
RBQM FOCUS:

- Assess underlying GCP process risks
- Provide actionable insight for the enterprise level
- Detect processes representing consistent risks across protocols, regions and portfolio
- Identify potential deficiencies in the preventive actions and control of the quality events

Examples:

- Process risks: IRT errors, Training compliance, PI oversight, monitoring adherence
- Performance risk factors: Avoidable protocol amendments, clinical supply delays etc.
- Quality events indicative of the enterprise level risks such as CAPA inefficiency, Breaches, Significant Deviations

Integrating with the internal QMS ecosystem



Capabilities: how to enable oversight of Quality Risks ?



1

GCP processes across enterprise: Studies, Sites, Regions and Portfolio level



2

Customized thresholds reflecting company processes and industry standards



3

Actionable insight and deeper understanding of the risks



4

Ability to control, evaluate and proactively monitor risks



5

Provide right level of oversight across different processes: quality, data management, compliance, monitoring etc.



6

Collaborate to establish foundation for continuous improvement and change management

Capabilities: analytics workflow design considerations

Key business questions



Key process risks



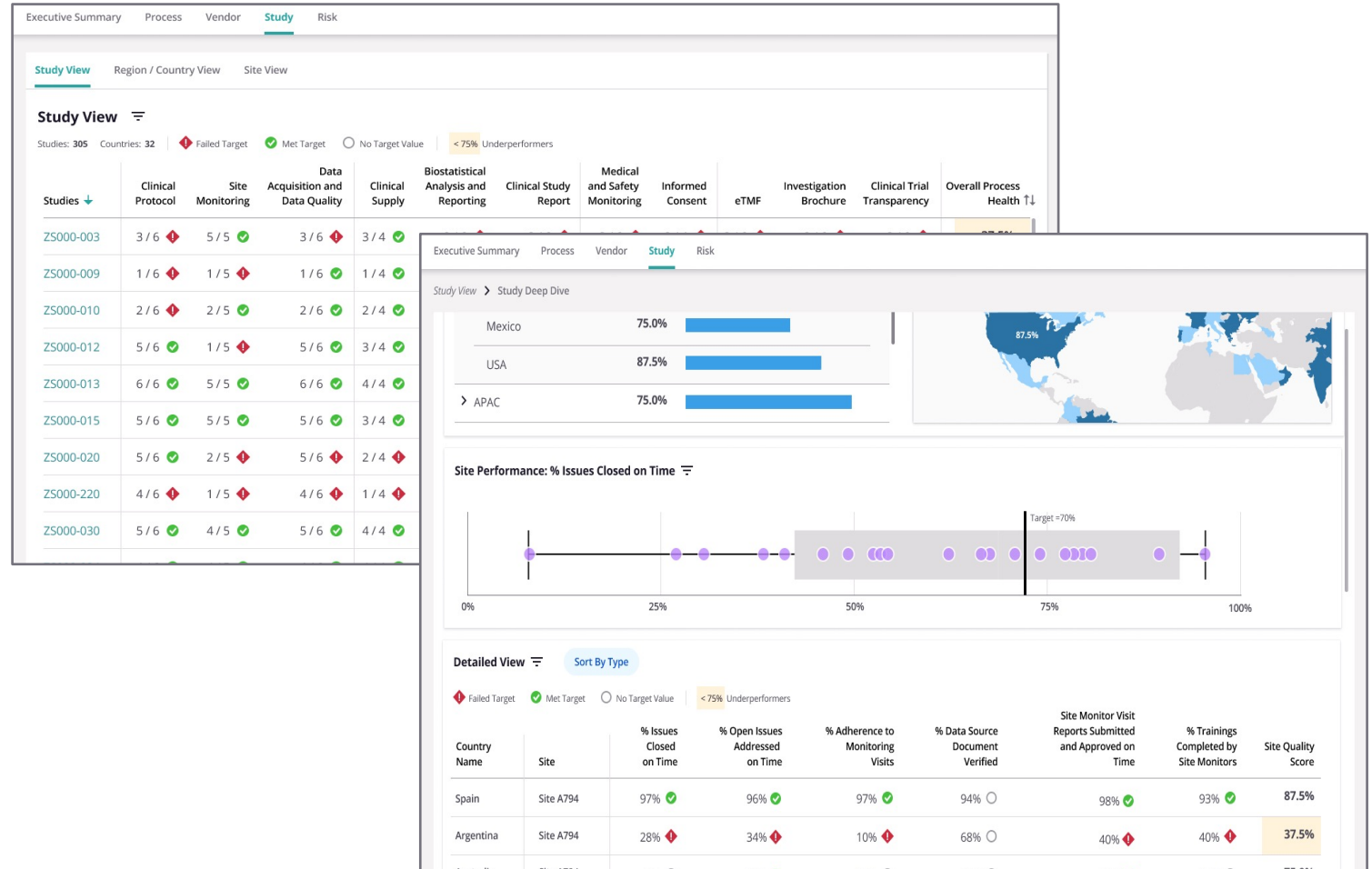
Variability of risks across levels (portfolio, region, study)



Change of risks over time



Additional processes impacted by risks



Metrics: How do you measure your processes?

ICH Major Areas:

- Design and Conduct
- Reporting and Records
- Subject Protection
- Compliance

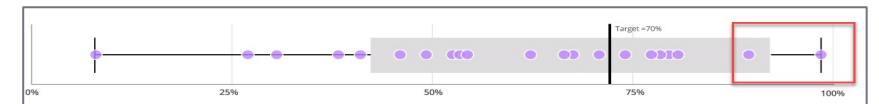
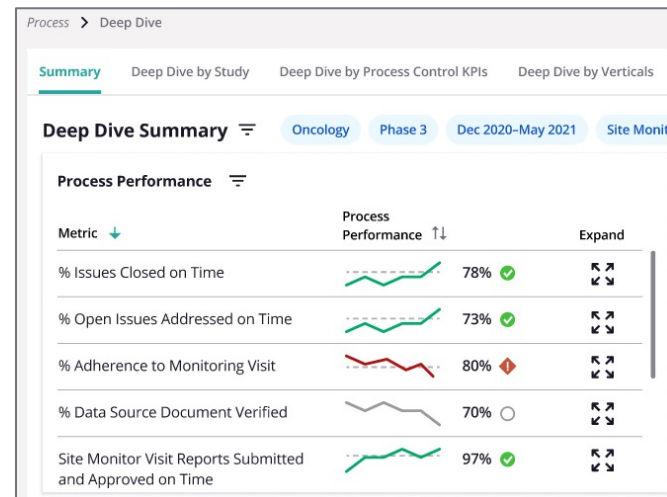
Metrics design:

- Processes are mapped to ICH area
- Metrics represent processes
- Balance of leading and lagging metrics within the process
- Quality events as multi-dimensional assessment of the processes
- Historical trends and outliers

Process: Global Level Summary Onco Phase 3 Dec 2020-May 2021

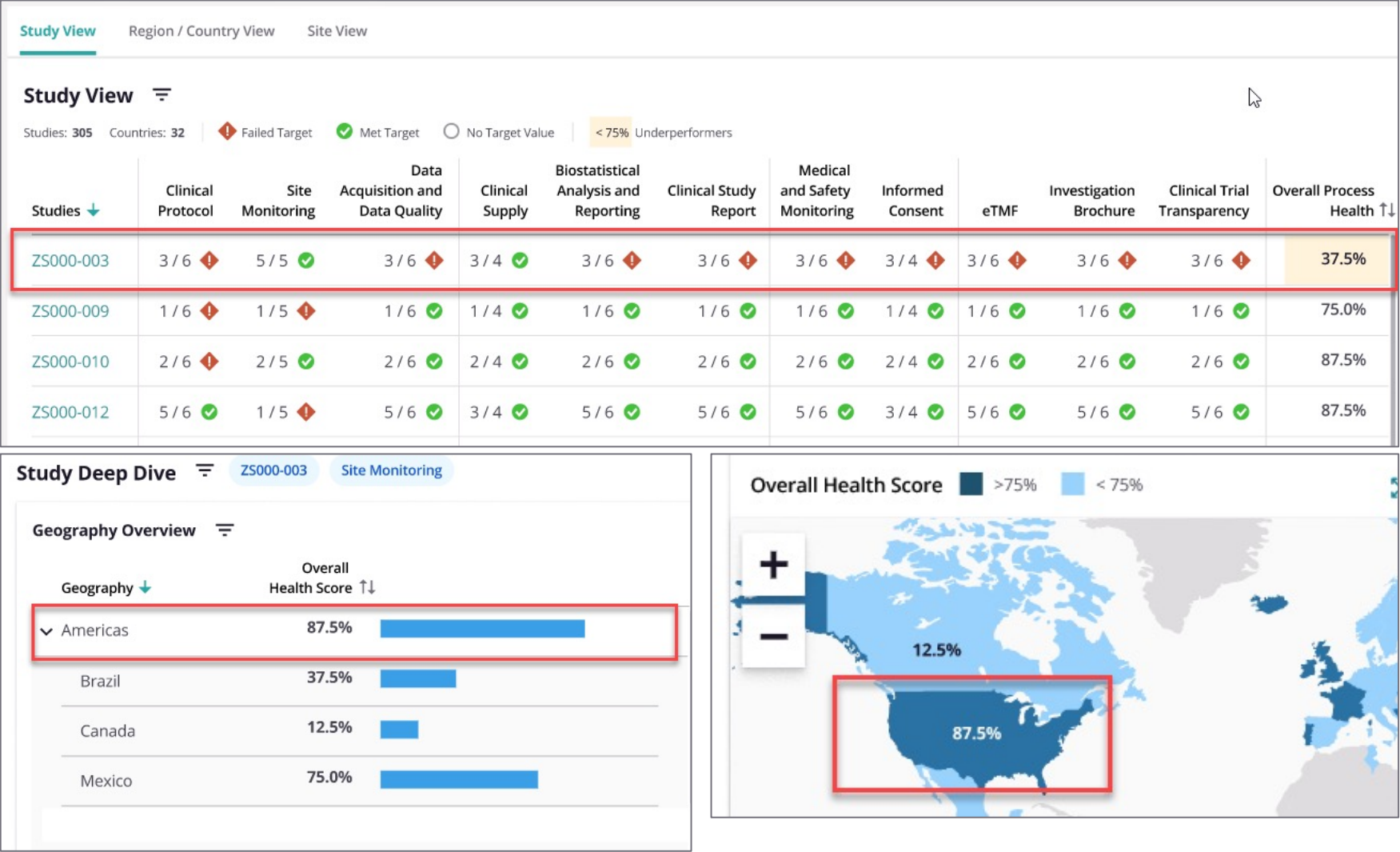
Studies: 305 Countries: 32 Failed Target Met Target No Target Value < 75% Underperformers

ICH Major Areas	Process	Process Control KPI	Training	Significant Protocol Deviation	Serious Breaches	Audit Findings	HA Inspection Findings	CAPA
Design & Conduct	Clinical Protocol Link	3 / 4 Met Target	2 / 2 Met Target	1 / 1 Met Target	1 / 1 Met Target	0 Met Target	0 Met Target	N/A No Target Value
	Site Monitoring Link	1 / 5 Failed Target	1 / 2 Failed Target	1 / 1 No Target Value	1 / 1 Failed Target	2 Failed Target	2 Failed Target	1 / 6 Failed Target
	Data Acquisition and Data Quality Link	2 / 2 Met Target	N/A No Target Value	N/A No Target Value	N/A Met Target	1 Met Target	1 Met Target	5 / 6 Met Target



Example of process risk review (1): Is it really study level?

- » Multiple process risks in the study
- » Is it really study level risks?



Example of process risk review (2): quality events perspective

» Quality Events risks:

- Important Protocol Deviations
- Serious Breaches
- Audits
- Inspections
- CAPA

Process: Global Level Summary ≡ Oncology Phase 3 Dec 2020-May 2021									
Studies: 305 Countries: 32		Failed Target	Met Target	No Target Value	< 75% Underperformers				
ICH Major Areas	Process	Process Control KPI	Training	Significant Protocol Deviation	Serious Breaches	Audit Findings	HA Inspection Findings	CAPA	Overall Process Health
Design & Conduct	Clinical Protocol 📄	3 / 4	2 / 2	1 / 1	1 / 1	0	0	N/A	87.5%
	Site Monitoring 📄	1 / 5	1 / 2	1 / 1	1 / 1	2	2	1 / 6	25.0%
	Data Acquisition and Data Quality 📄	2 / 2	N/A	N/A	N/A	1	1	5 / 6	75.0%
Record / Report	Clinical Supply 📄	1 / 3	1 / 2	3 / 6	0 / 1	1	5	3 / 6	25.0%
	Bio statistical Analysis and Reporting 📄	3 / 3	2 / 2	1 / 1	1 / 1	1	2	6 / 6	100.0%
	Clinical Study Report 📄	1 / 1	1 / 2	1 / 1	1 / 1	2	0	3 / 6	25.0%

Quality Events Story and Advanced analytics (AI/ML,NLP)

Challenges with quality events analytics

1



Lengthy and wordy

2



Subjectivity of classification and categorization

3

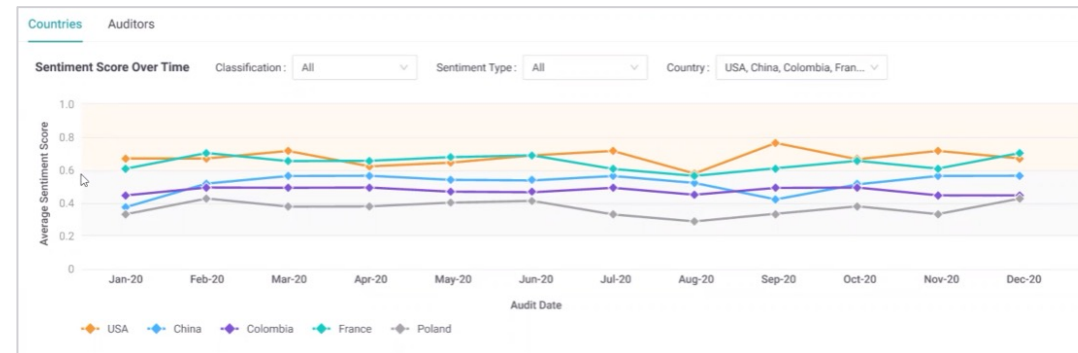
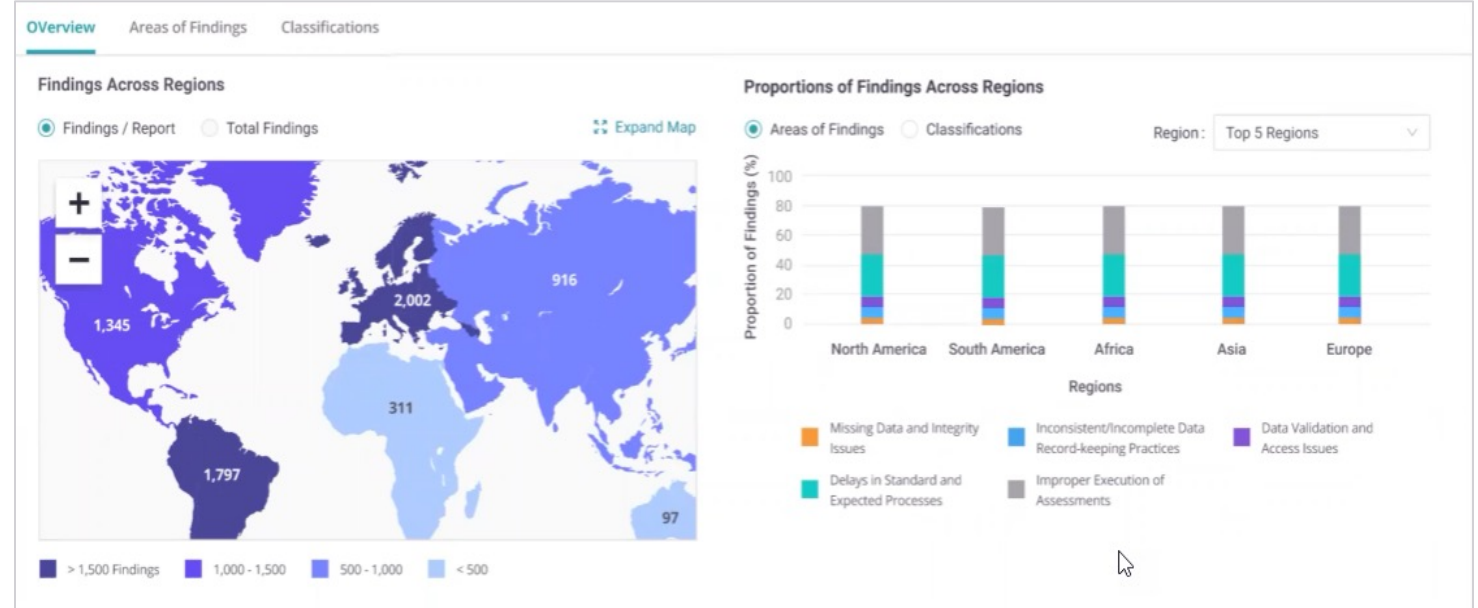


Inconsistent approach to categorization

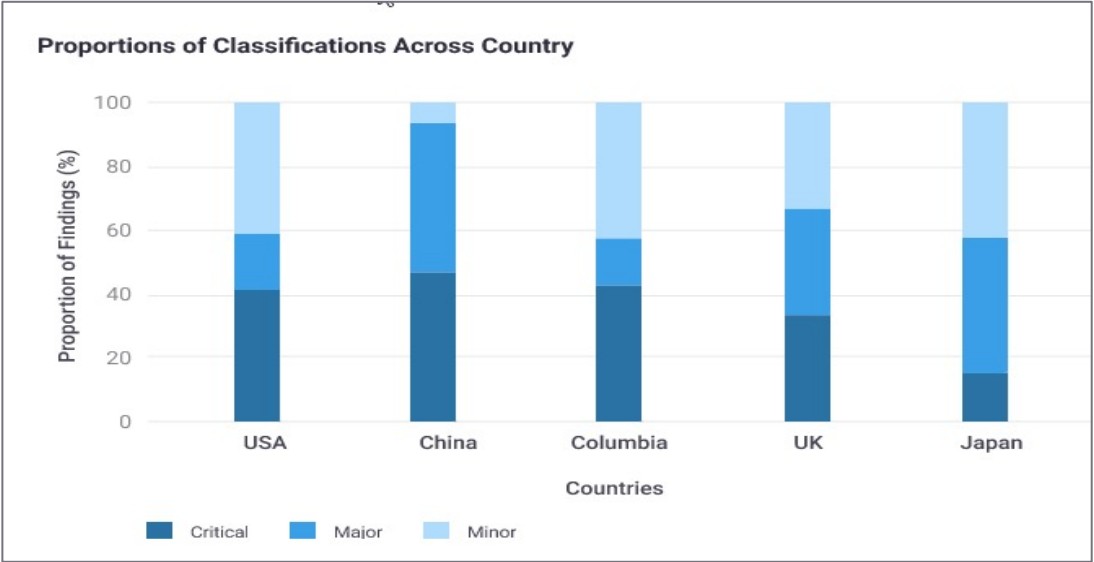
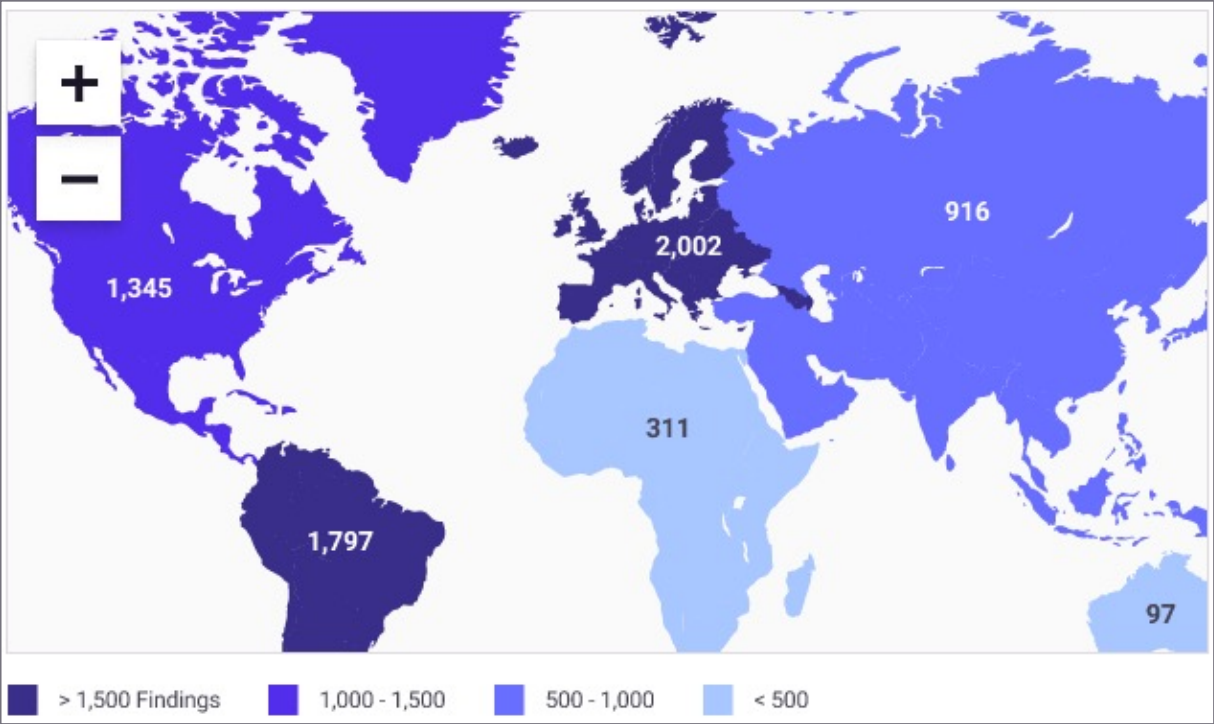
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Need for AI/ML to build analytics

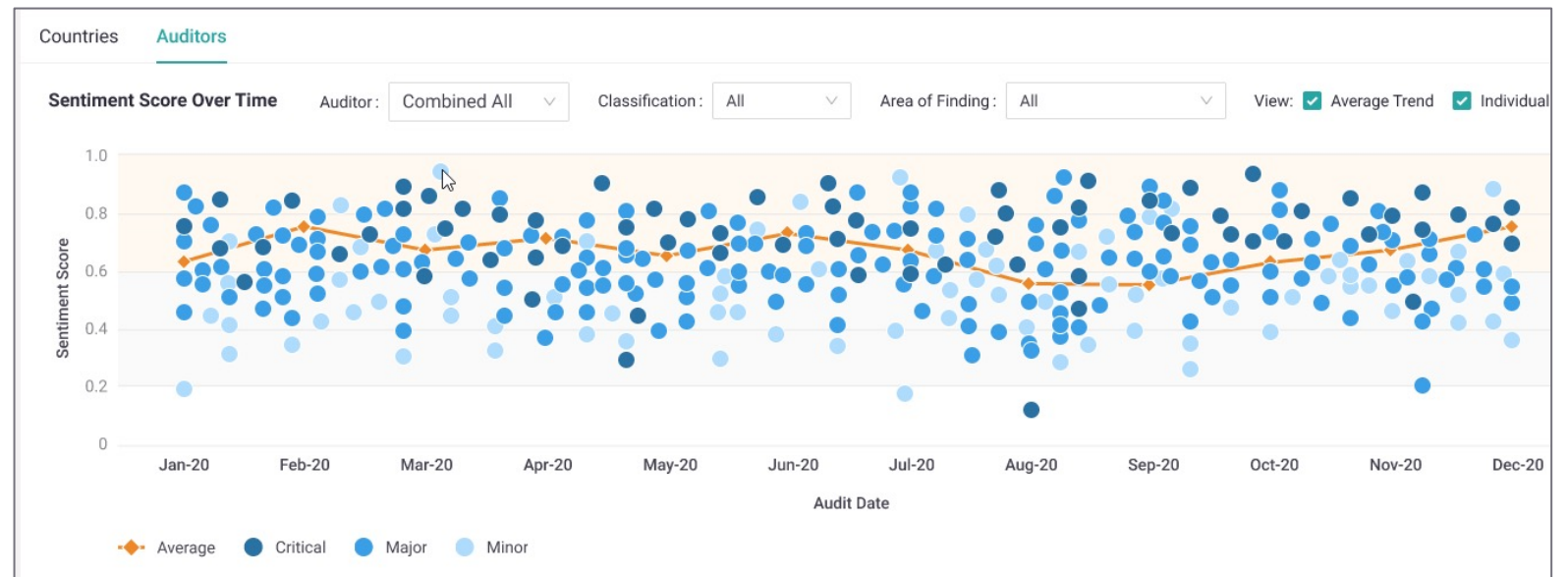


Insight from the quality events analytics: trends and patterns



Advanced analytics: Sentiment Score

Sentiment analysis of Audits, Inspections and other quality events records can help to reduce **subjectivity**, identify **isolated critical issues** requiring **immediate** action and **improve consistency** of the classification



High risk processes: collaboration and change management



Quality process risks require investigation and collaboration



Organization should demonstrate consistency in their approach and continuous improvement efforts



Continuous improvement require change management and establishing Quality culture

ICH Major Areas	Process	Process Control KPI	Training	Significant Protocol Deviation	Serious Breaches	Audit Findings	HA Inspection Findings	CAPA	Overall
Design & Conduct	Clinical Protocol	3 / 4 ✓	2 / 2 ✓	1 / 1 ✓	1 / 1 ✓	0 ✓	0 ✓	N/A ○	
	Site Monitoring	1 / 5 ✗	1 / 2 ✗	1 / 1 ○	1 / 1 ✗	2 ✗	2 ✗	1 / 6 ✗	
	Data Acquisition and Data Quality	2 / 2 ✓	N/A ○	N/A ○	N/A ✓	1 ✓	1 ✓	5 / 6 ✓	
Record / Report	Clinical Supply	1 / 3 ✗	1 / 2 ✗	0 / 1 ✗	0 / 1 ○	1 ✗	N/A ○	3 / 6 ✗	

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Janice Jane

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Add a comment. @mention to notify someone

Close

Post

ENABLING CHANGE MANAGEMENT

Investment into new processes and technology need to be balanced with investment into people. Change management is essential in driving continuous improvement requiring new behaviours

Can you follow your processes?



“

A process is thus a specific ordering of work activities across time and space, with a beginning and an end, and clearly defined inputs and outputs: a structure for action

- Davenport

Process redesign require collaboration and behaviour change

Uncover understanding



Define the why

Communicate the value of initiative to organization – from leadership to department heads



Drive understanding

Establish clarity and understanding around new way of working and role of individual



Enable action

Encourage trial and application through interactive experiences and gamification



Empower habit

Recognize and reward successes and create advocates

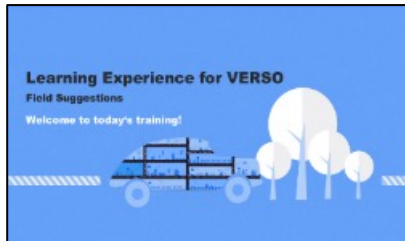
Immersive experience helps to envision end-to-end process journey and to collaborate

Facilitated virtual plenary presentation



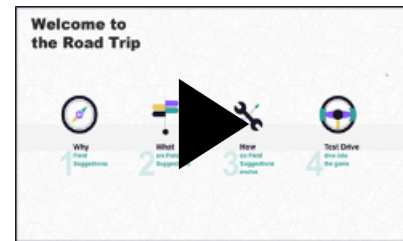
1. Introduction

A quick reiteration of the vision and journey that to advance engagement. Customized for each organisation.



2. Explanation

Open the 'black box' to clarify the workings of the tool and the transparency and support it creates between you and other functions.



Virtual team game



3. Game Simulation

Build knowledge and habits to operate in a new workflow using immersive, game-like environment and suggestions in interactive mode.



Virtual plenary discussion



4. Reflection

Reflect on the game, discuss best strategies and recap on the documentation points, consequences of actions, roles and impact over time.



Questions



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