



Risk-Informed Data Strategies to Streamline Trial Complexity

- Tiina Erb
- Senior Portfolio Lead,
eClinical Solutions
- 17MAR2025



Poll Question 1

How far along is your organization in implementing risk-based methodologies in clinical trials?

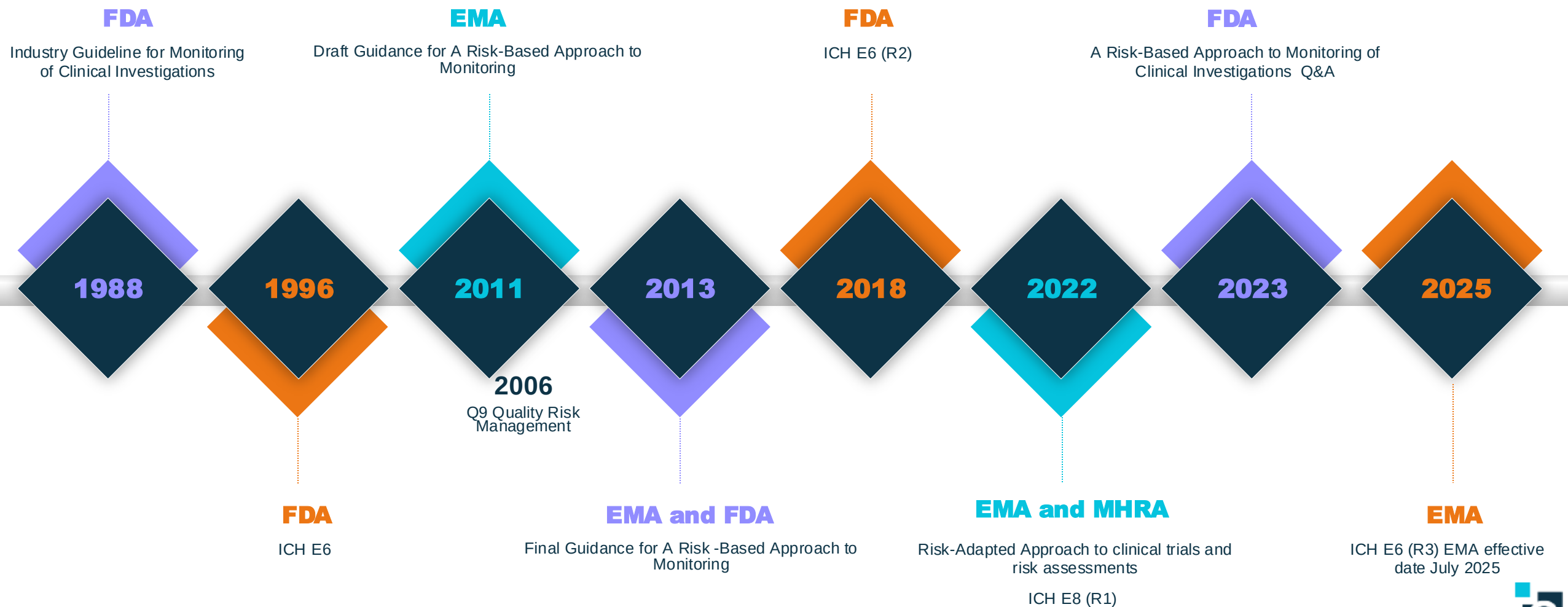
- We have not yet started implementing RBQM/RBM
- We are in the early stages of adoption
- We have partially implemented RBQM/RBM strategies
- We have fully integrated risk-based approaches into our clinical trials





Regulatory Journey & Industry Needs

Risk-Based Approaches are Evolving



Health Authorities Continue to Emphasize the Importance of Risk Management

FDA Guideline for Good Clinical Practice E6(R2) (2016)

- **During protocol development**, the sponsor should identify those **processes** and **data** that are **critical**
- Describes **7 steps or risk management**: critical data and process identification, risk identification, risk evaluation, risk control, risk communication, risk review, and risk reporting
- Risk should be considered at both the **system** and **trial level**

EMA General Considerations for Clinical Studies E8(R1) (2022)

- Proactive prevention of critical errors through implementing **QbD**
- **Prioritize** and **allocate resources** based on the risks
- **Proactive communication** of the critical to quality factors and risk mitigation
- Considerations and approach to identifying **Critical to Quality Factors**

MHRA Risk-Adapted Approach to trials & Risk Assessments (2022)

- **Multidisciplinary** team should be involved into risk assessment
- It is recommended that a risk assessment is undertaken for **all clinical trials**
- **Appropriate actions** for risks identified had been **documented** and **implemented**

Industry Need for Risk-Based Approaches

Increased complexity of clinical trials

- ❑ According to a survey for periods between 2001-2005 and 2011-2015, complexity of endpoints rose 86%, procedures to 70%, eligibility criteria to 61% and data points collected to 88%
- ❑ Protocols became more complex impacting cost and time

Growth in number of clinical trials

- ❑ 100% SDV becomes unrealistic and not much value added
- ❑ In 2000 there were 2,119 trials registered and in 2011, it increased to 115,909

Globalization of clinical trials

- ❑ Number of investigational sites increased by 63%, expanding all over the globe, especially in developing countries. It creates the need for variety in the approaches

Siloed approaches

- ❑ Fragmentation of roles without clear workflows require more holistic approach

Advancement in Technology

- ❑ Increasing use of cloud based, remote technologies and integration of EHR with EDC provide opportunities to be more efficient

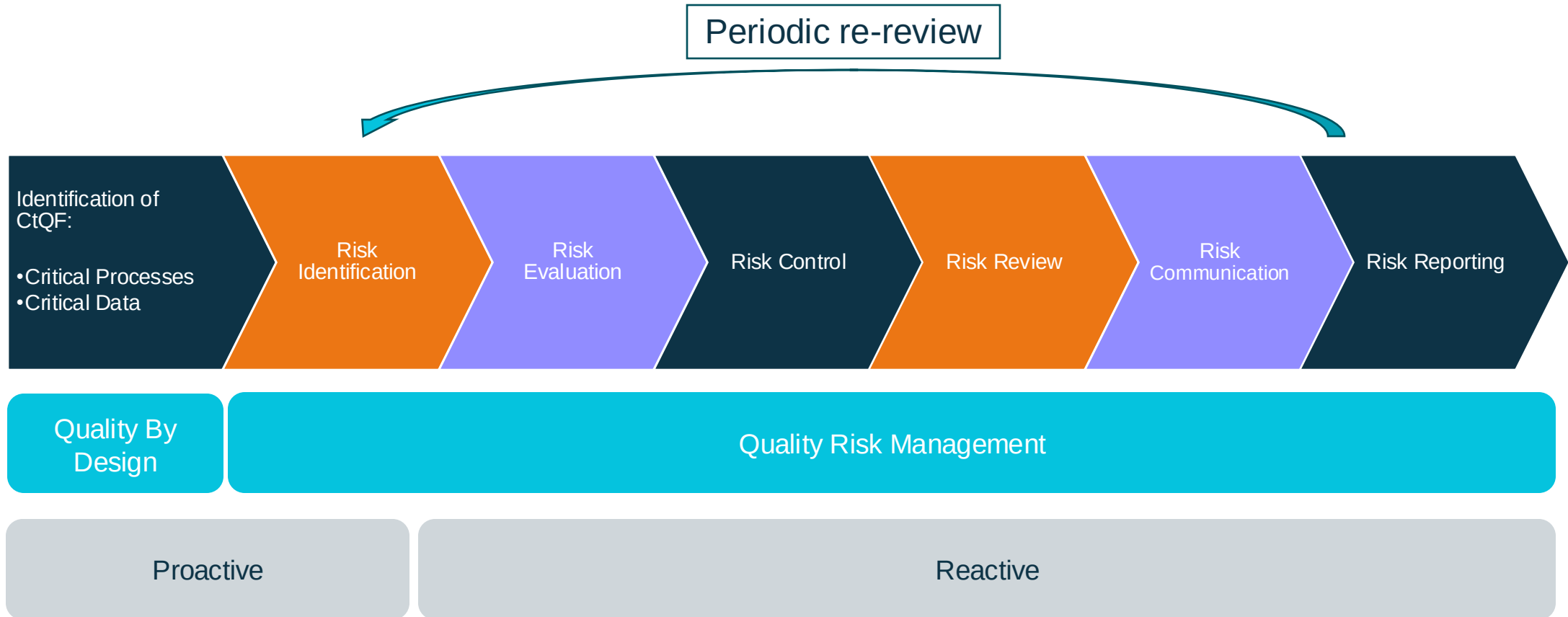


Risk Management Process

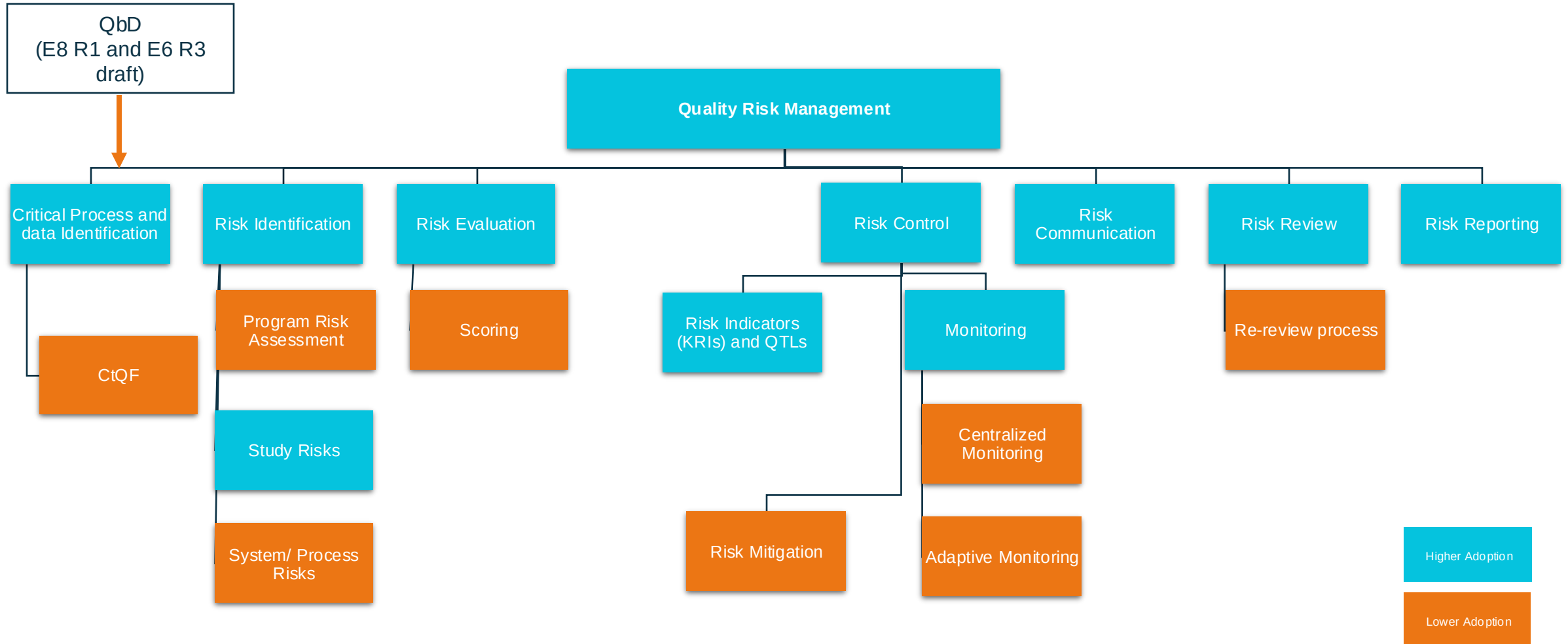
Key Steps & Elements of RBQM



End-to-end quality risk management



Elements of Risk-Based Quality Management

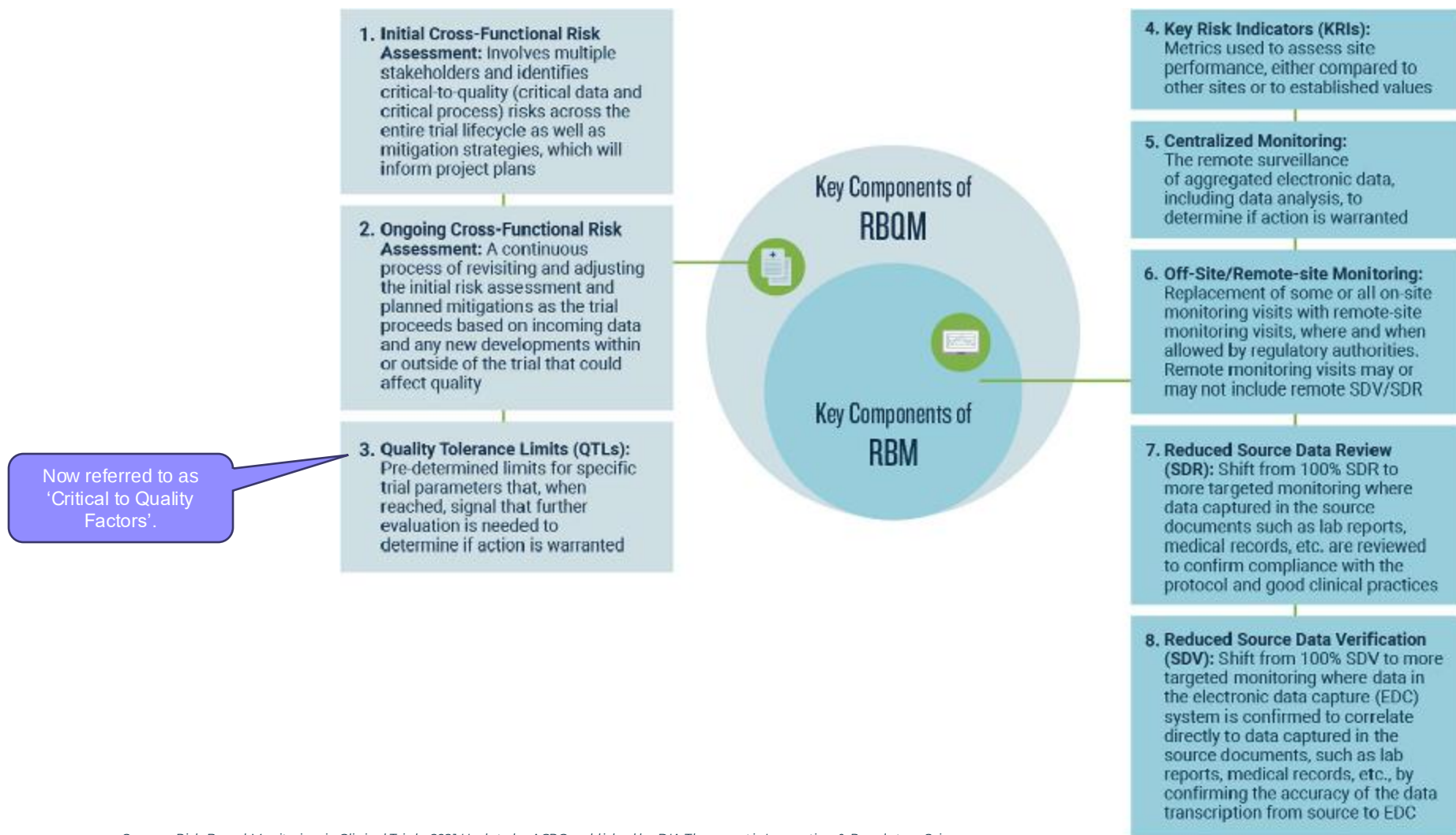




RBQM Ecosystem

Key components

Understanding the make up of RBM and RBQM



The difference between source data review (SDR) and source data verification (SDV) is as follows:

- Source Data Verification (SDV): Compares recorded data against the source documents to ensure a match.
- Source Data Review (SDR): Focuses on the quality of the source documentation itself, including areas that may not have an associated data field in the Case Report Form (CRF) or a system.

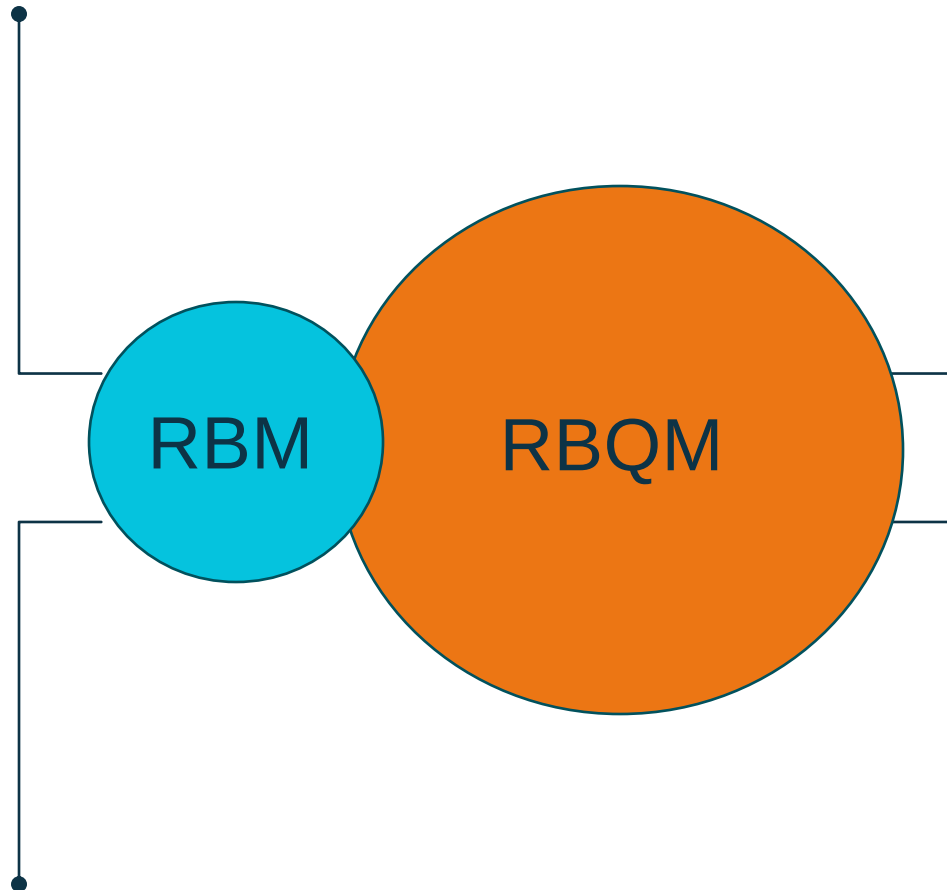
Focus Areas of RBQM and RBM

❑ RBM Focus:

- ❑ Assess and monitor study, countries within the 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



❑ RBQM Focus:

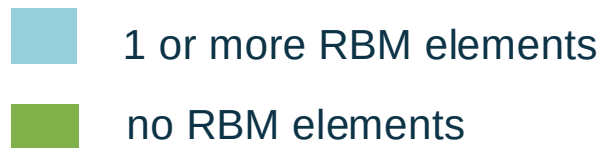
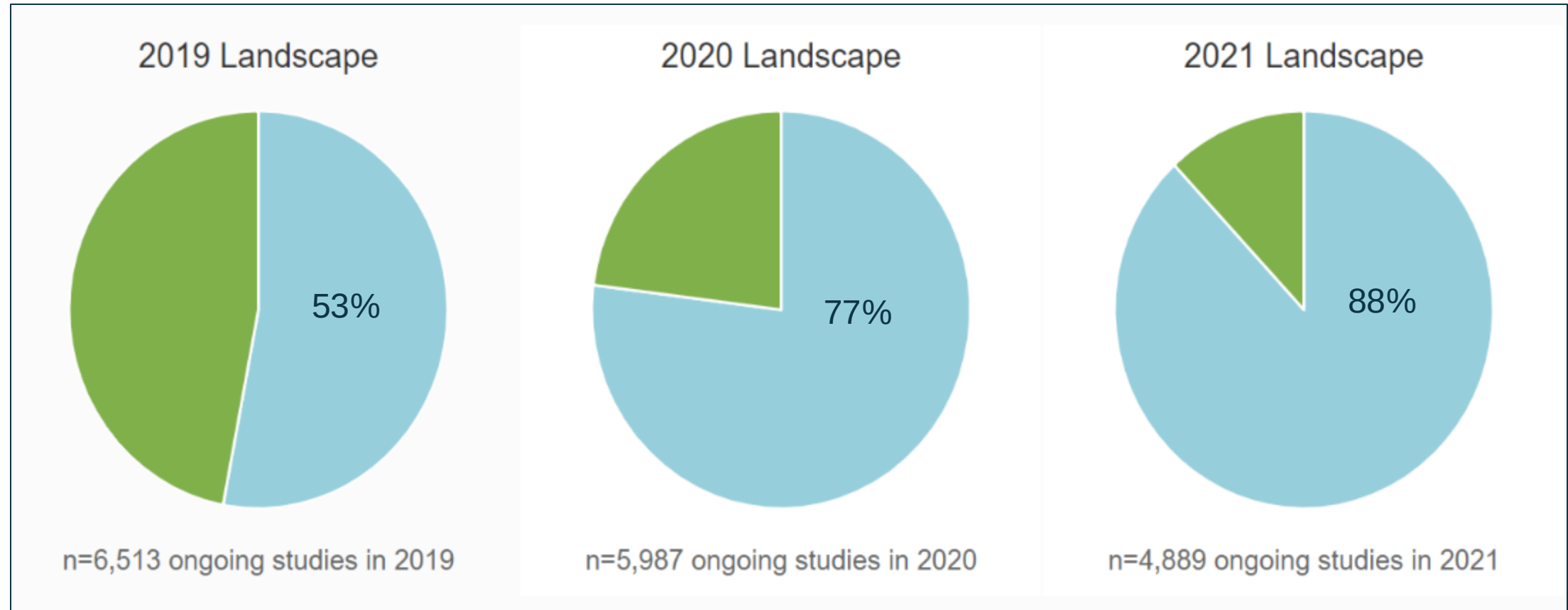
- ❑ Assess underlying GCP process risks
- ❑ Detect processes risks representing consistent risks across protocols, regions, vendors and portfolio
- ❑ Identify potential deficiencies in the preventive actions and control of the quality events

❑ 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

ACRO: Companies Implemented at least 1 Element of RBM

ACRO reported significant increases in the number of trials that utilized remote or risk-based components



Tufts Study : Industry Adoption of RBQM

Summary of Study Results

The Tufts Center for the Study of Drug Development conducted an online survey among pharmaceutical, biotechnology, and contract research organizations and gathered 206 responses on 32 distinct RBQM practices

- On an average companies implemented RBQM in 57% of their clinical trials
- Lower levels of adoption were observed among companies conducting fewer than 25 trials annually (48%)
- Higher level of adoption among companies conducting more than 100 trials annually (63%)
- Primary barriers to adoption include:
 - Lack of organizational knowledge and awareness,
 - Mixed perceptions of the value proposition of RBQM, and
 - Poor change management planning and execution

Summary of Trends

Tufts' CSSD assessment

- 32 components of comprehensive RBQM
- Spread across “Planning & Design (11)”, “Execution (11)” and “Documentation & Resolution(10)” phases
- 57% adoption overall by companies responded
- Adoption of components by sponsors with 100+ (63%) studies followed by 25 – 100 (59%)
- Tools adopted for Planning & Design and Execution phases
- Adoption of tools tracks close to adoption of components with 50% rate for 100+ studies and 43% for 25 – 100 studies
- EU adoption (64% & 43%) slightly higher than NA (54% & 45%) for components and tools respectively
- Substantial growth in the use of components & tools by 2027 (e.g. development of centralized monitoring plan, duplicate patient detection, QTLs, reduced targeted data management reviews etc.)
- Barriers are lack of knowledge, investment of time, lack of skills & lack of technology
- Opportunity to increase trust in RBQM within sponsors boils down to more successful implementations, communication & training

Poll Question 2

Which aspect of Risk-Based Monitoring (RBM) do you think has the most potential to improve clinical trial efficiency?

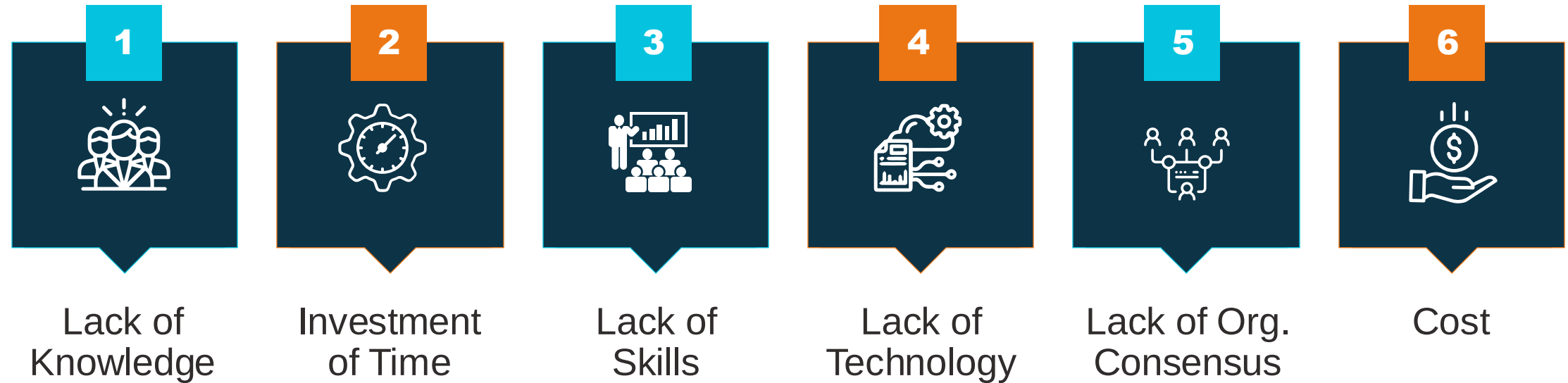
- Centralized and remote monitoring
- Automated data analytics and predictive modeling
- Improved stakeholder engagement and training
- Standardized risk assessment and mitigation processes

Adoption Challenges...

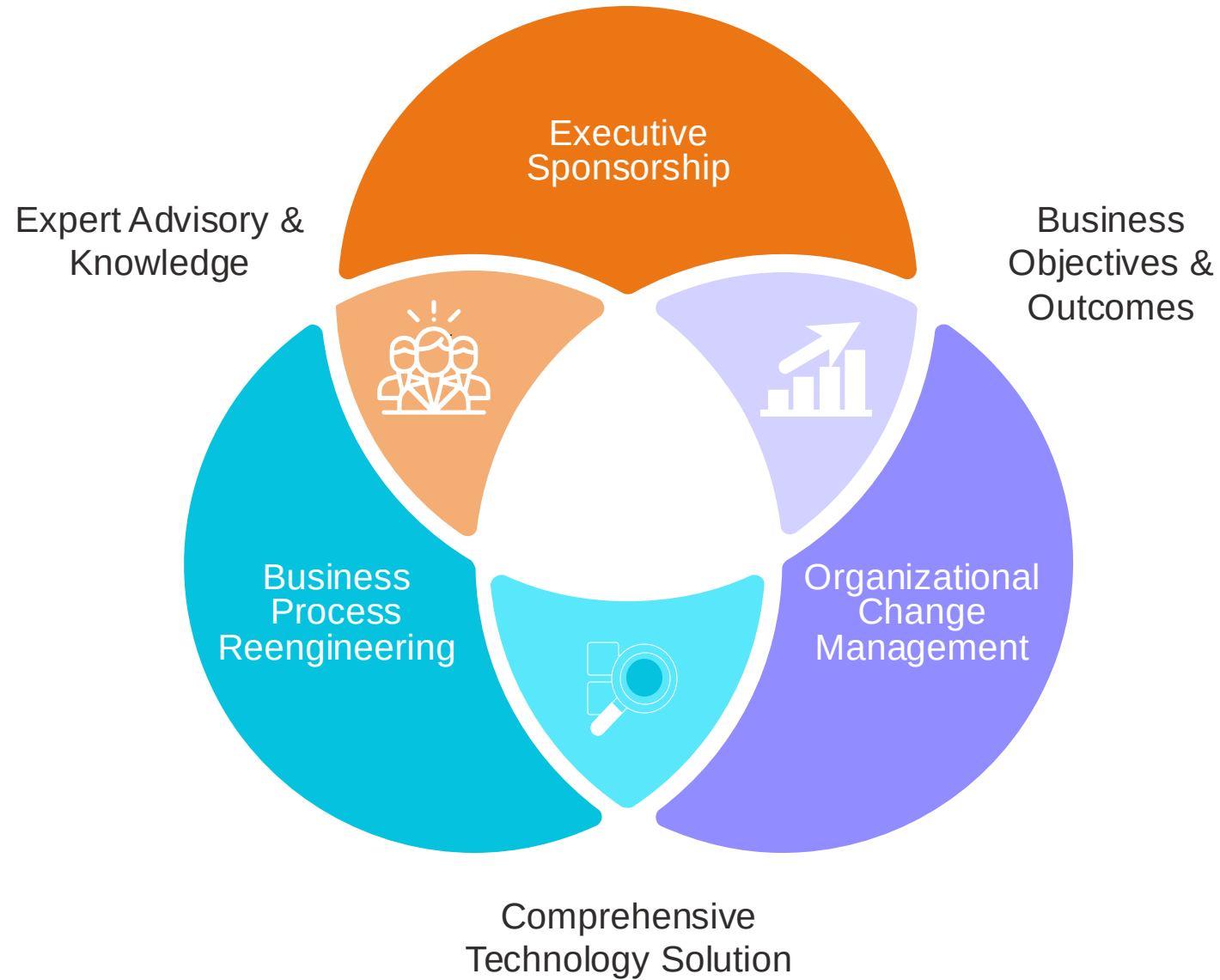
...and critical success factors for a successful adoption



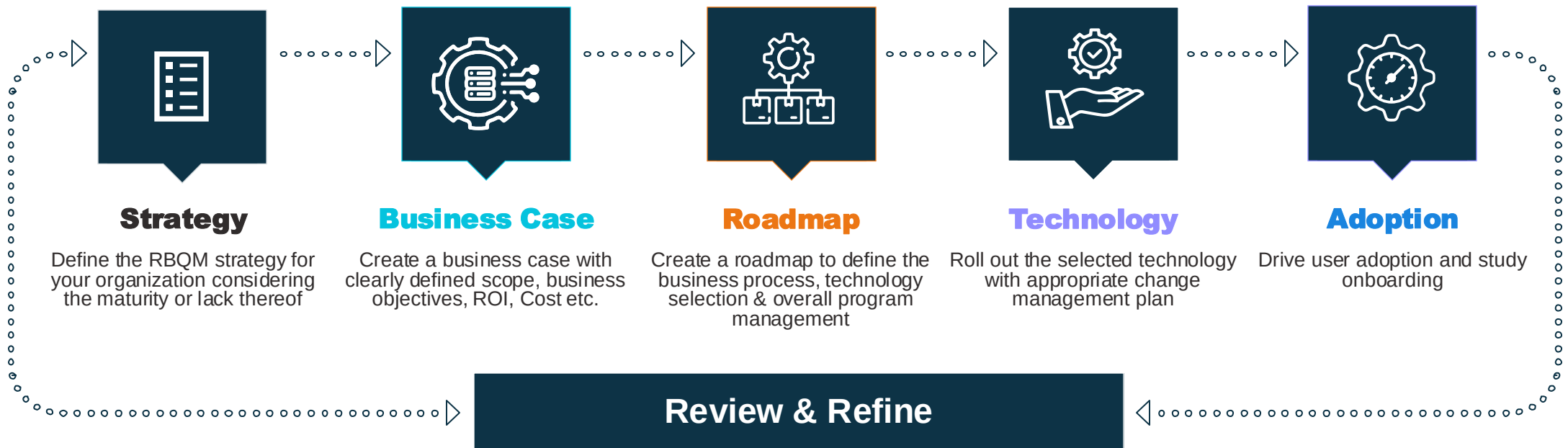
Industry Challenges : Top Barriers to Adoption



Critical Success Factors



Approach to RBQM Adoption



Poll Question 3

What is the biggest barrier to adopting Risk-Based Quality Management (RBQM) in your organization?

- Lack of organizational knowledge and awareness
- Mixed perceptions of RBQM's value
- Poor change management and resistance to adoption
- Technological and resource constraints

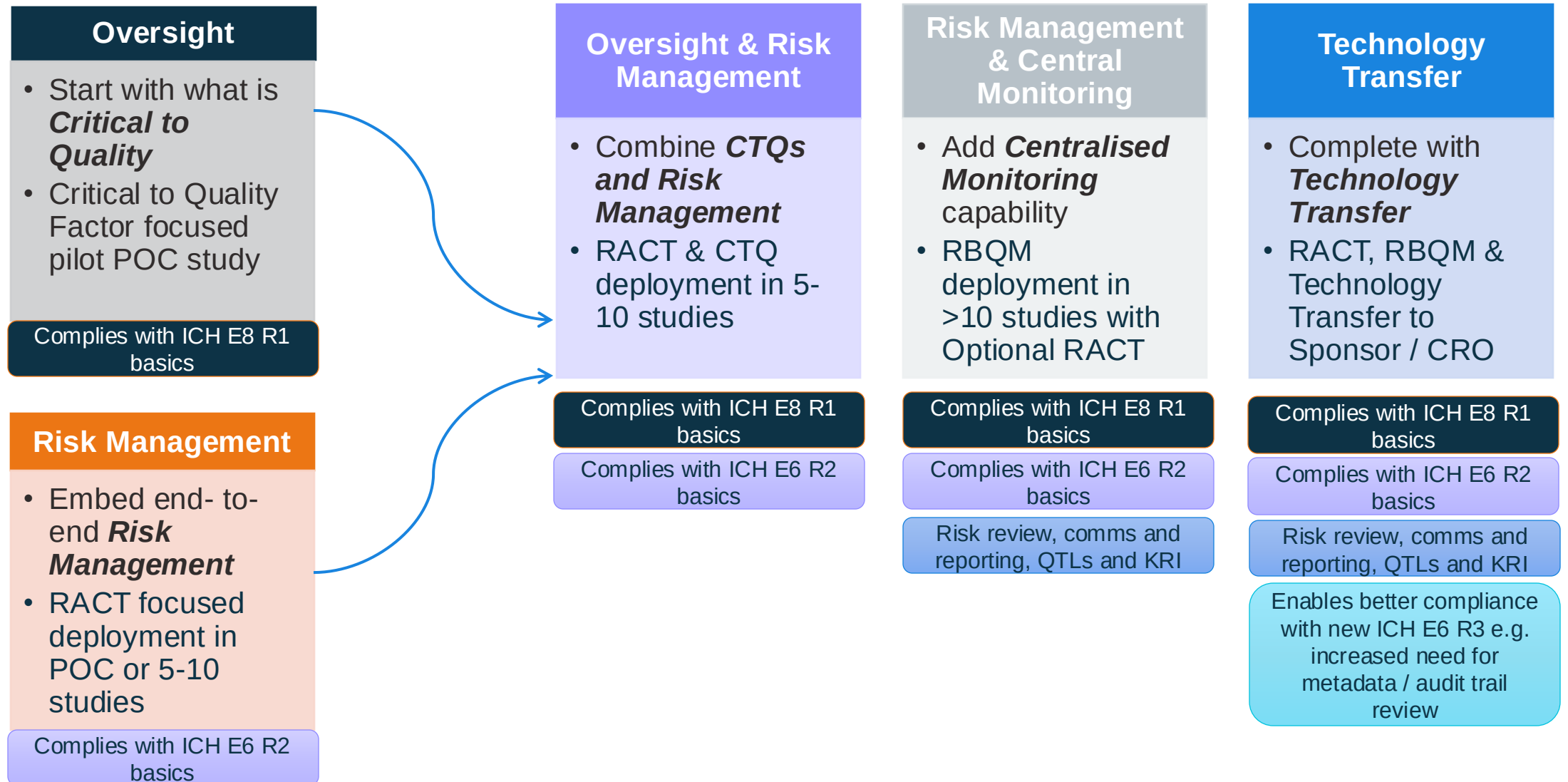


Looking Forward

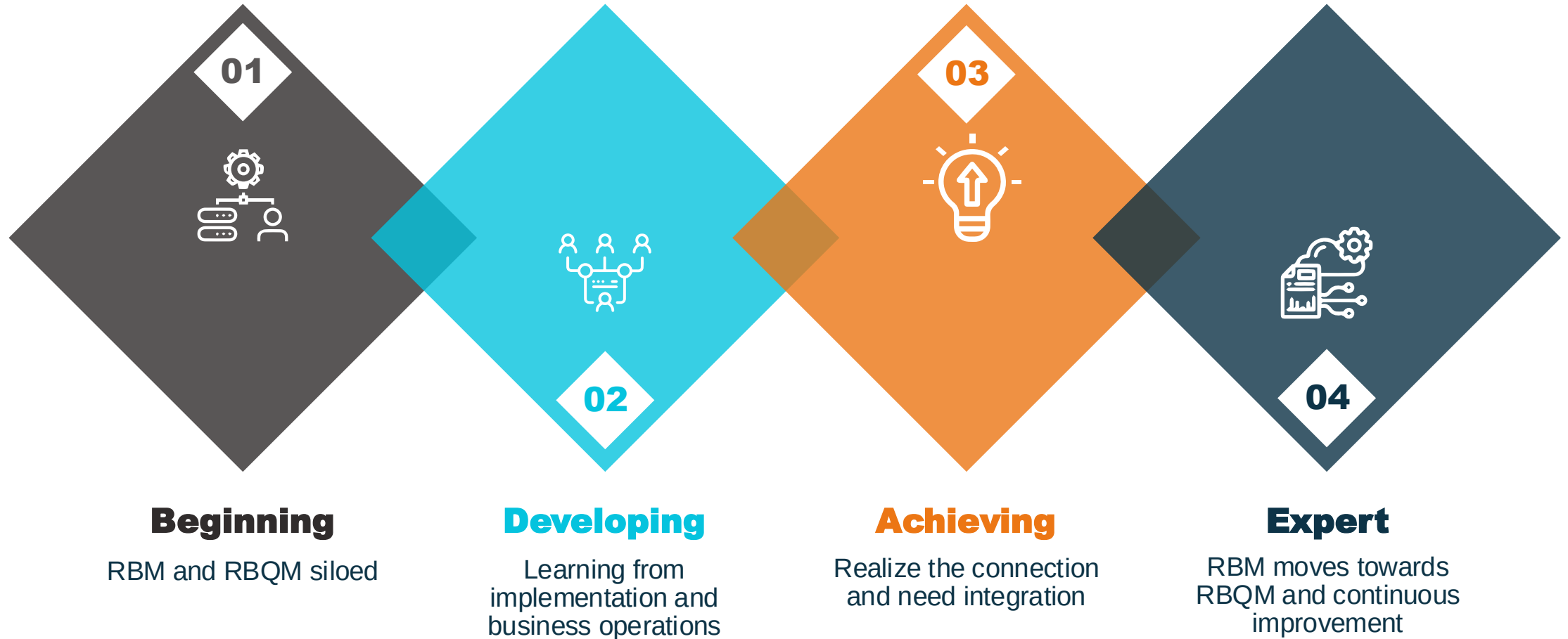
Phased Approach to Process
and Technology Adoption

Recommendation Adoption Approach

Phased Adoption & Implementation Tiers



RBQM Maturity Model



Poll Question 4

Where are you in your RBQM Journey?

- Beginning
- Developing
- Achieving/Implementing
- Expert - Making data-driven decisions

Challenges of Implementing a Risk-Based Approach

Barriers to Adoption

Change
Management

Organizational
Alignment

Technical and
Resource
Constraints

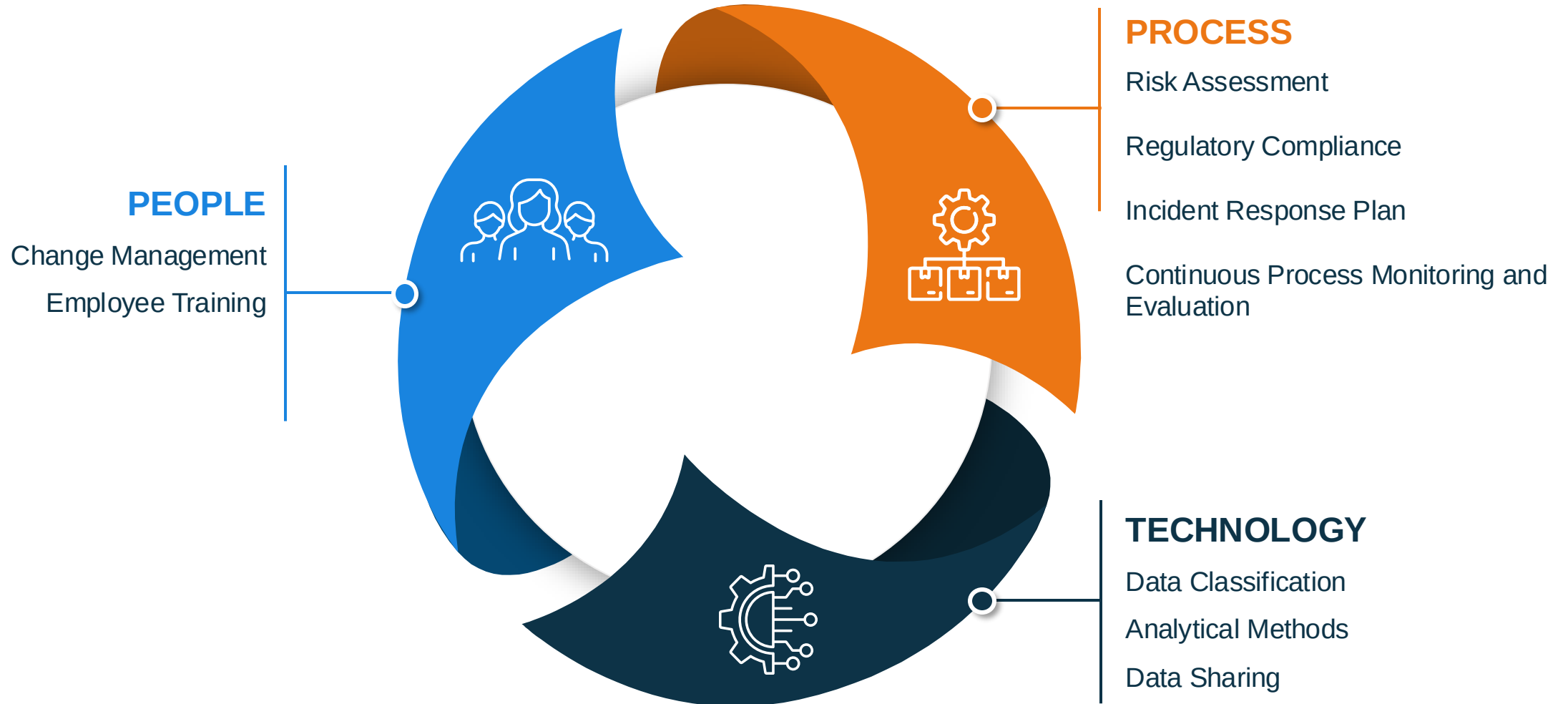
Trial Complexity

Evolving
Regulatory
Requirements

Organizational
Resistance

Organizational Changes

Secrets of Success



Steps to Start the Journey



**Acknowledge
what you have
in place**



**Take iterative
small steps**



**Remember the
journey is
continuous**

Standard Key Risk Indicators

AE Reporting Rate

SAE Reporting Rate

Discontinuation Rate

Data Entry Timeliness

Query Response Time

Missing Data

Can A Risk-Based Framework Transform Data Management?

Fundamental Shift

Proactive Risk Identification

▶ Organizations can develop strategies to mitigate risks before they impact the trial

Enhanced Data Integrity

▶ Focusing on high-risk processes and critical data ensures that the data collected is accurate and reliable

Regulatory Compliance

▶ Aligning with regulatory expectations for risk-based approaches helps ensure compliance

Efficient Resource Utilization

▶ Targeting monitoring efforts on critical areas enables resources to be used more efficiently

Improved Collaboration

▶ Cross-functional engagement between stakeholders leads to better oversight and management

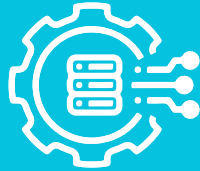


Right-sized Implementation

Incremental Return and Rewards



**Eliminating
Unnecessary
Queries**



**Improving Data
Integrity**



**Enhancing
Patient Safety**



Reducing Costs



**Streamlining
Trial Operations**



■ Questions?

Tiina Erb
Senior Portfolio Lead, eClinical Solutions
terb@eclinicalsol.com

