



Navigating RBQM Change Management

Real World Strategies for Success

Jamie O'Neill, VP Customer Success, CluePoints

Company Confidential





Agenda:

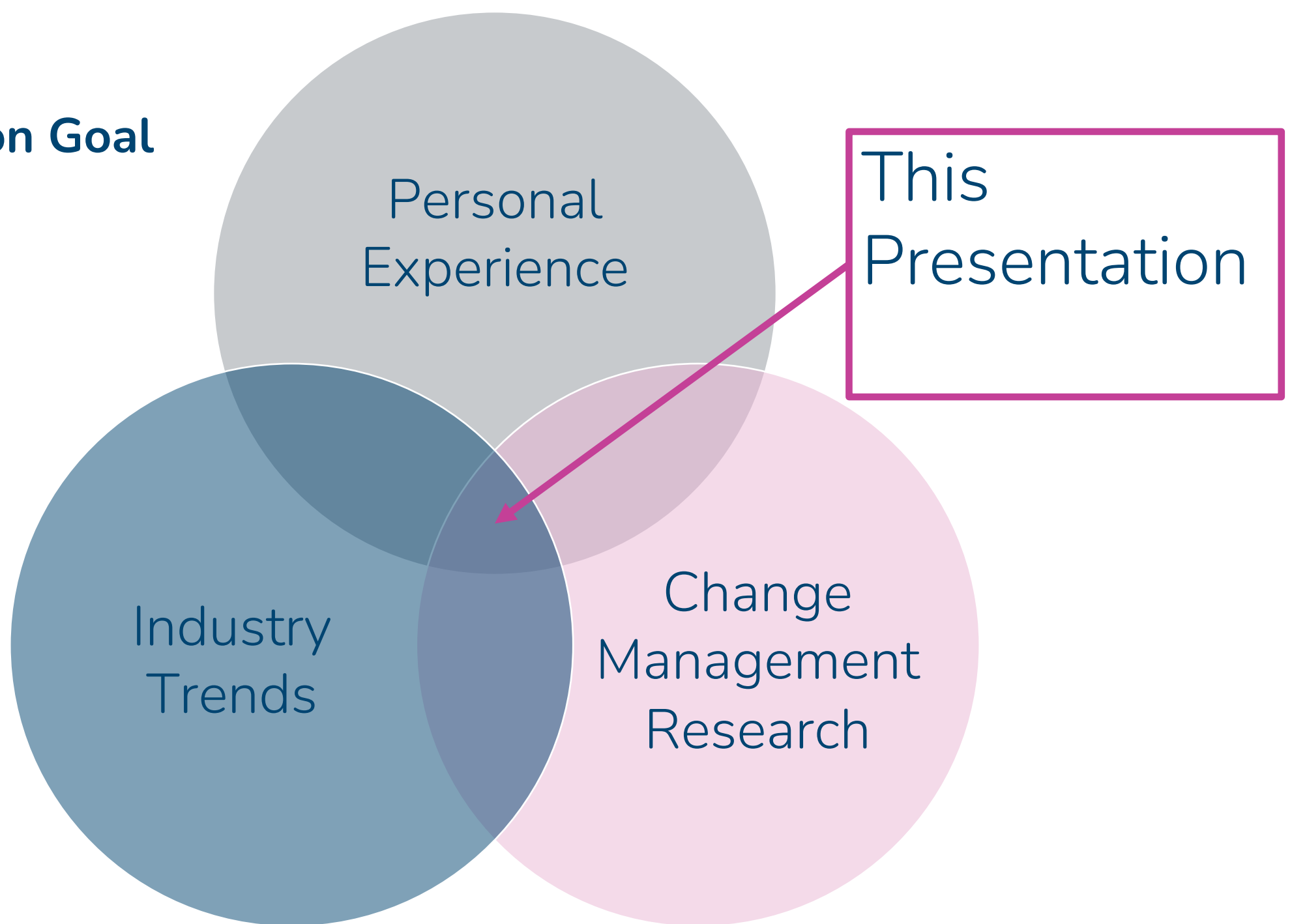
- Speaker Intro
- Presentation Goal
- RBQM and Change Management Landscape
- Company Preparation and Level Setting
- Change Management Planning
- Change Management Deployment
- Conclusion



Quick Intro

- Nearly 20 years in the Clinical Research Space
- 15+ years at large CROs
- 9 years in RBQM Space, serving 20+ different sponsors across the industry in their RBQM efforts
- 10+ years in ClinOps (CRA, ClinOps Lead, Project Manager), with direct Data Management experience
- Former RBQM business system owner at large pharma company
- Key support on RBQM SaaS installations of 4 top-10 pharma companies
- Supported RBQM work at multiple mid- and small-pharma companies
- Worked in 3 different independent SaaS RBQM technologies as vendor, sponsor, and CRO
- VP of Customer Success at CluePoints

Presentation Goal





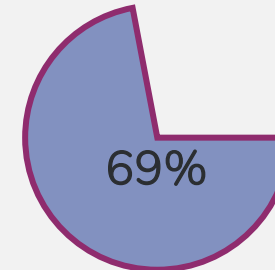
Why is RBQM Change Management so hard?

RBQM Change Management Landscape

Many impacted Stakeholder Groups:

• Central Monitoring	• BioStats
• ClinOps Leaders	• Protocol Writers
• CRAs	• Quality Assurance
• Data Managers	• IT/Systems Admins
• Project Oversight	• Data Flow architects
• Medical Monitors	• Safety

- Out of 206 respondents across sponsors and CROs, Tufts CSDD noted that 69% named a lack of cross-functional awareness as a key challenge for implementing RBQM¹



1) Tufts CSDD, *Impact Analysis & Insight into Critical Drug Development Issues*, Boston, MA: Tufts CSDD, Fall 2023.

RBQM Change Management Landscape



Can the Value of Centralised Monitoring Be Quantified?

“One of the expected benefits of CM is improved data quality. However, proving this is difficult because, if successful, there should be few data quality issues that matter. So, how can the value of CM be demonstrated when there is an inherent lack of supporting data? Confounding this question is the fact that clinical trial data quality is influenced by factors other than CM, thus making it difficult to tease out the successes that can be attributed to CM from the rest of the study conduct interventions.”²



**Centralized Monitoring:
Exploring the Considerations and
Challenges of Implementation**

“Ten years on, the industry is still struggling to drive consistency and standardisation in implementing the various elements of RBM methodology”³



2) PhUSE Centralized Monitoring Working Group, *Can the Value of Centralised Monitoring be Quantified?*, Kent, UK: PhUSE Limited, 2023.

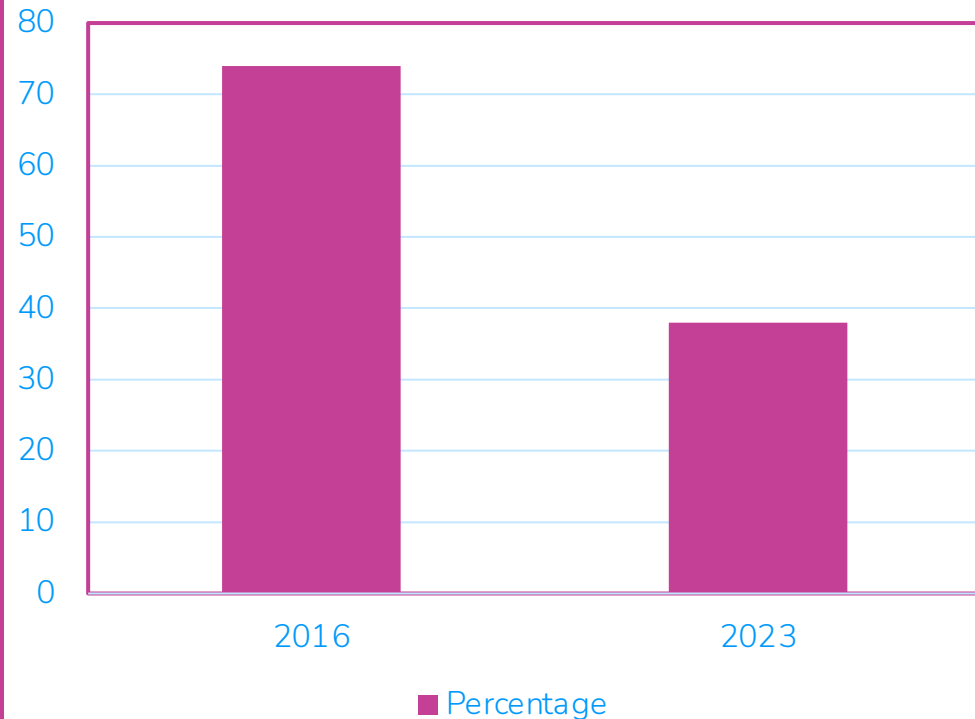
3) PhUSE Centralized Monitoring Working Group, *Exploring the Considerations and Challenges of Implementation*, Kent, UK: PhUSE Limited, 2022.

RBQM Change Management Landscape

Across all industries, change fatigue is getting worse.



Percentage of employees willing to change work behaviors to support organizational changes



4) Gartner, J. Turner, "What Will HR Focus on in 2023," 2022. [Online].

RBQM Change Management Landscape: Recap



Lots of Stakeholders and impacted departments



Difficult to define the change



Difficult to quantify the value



Increasing Change Management Fatigue

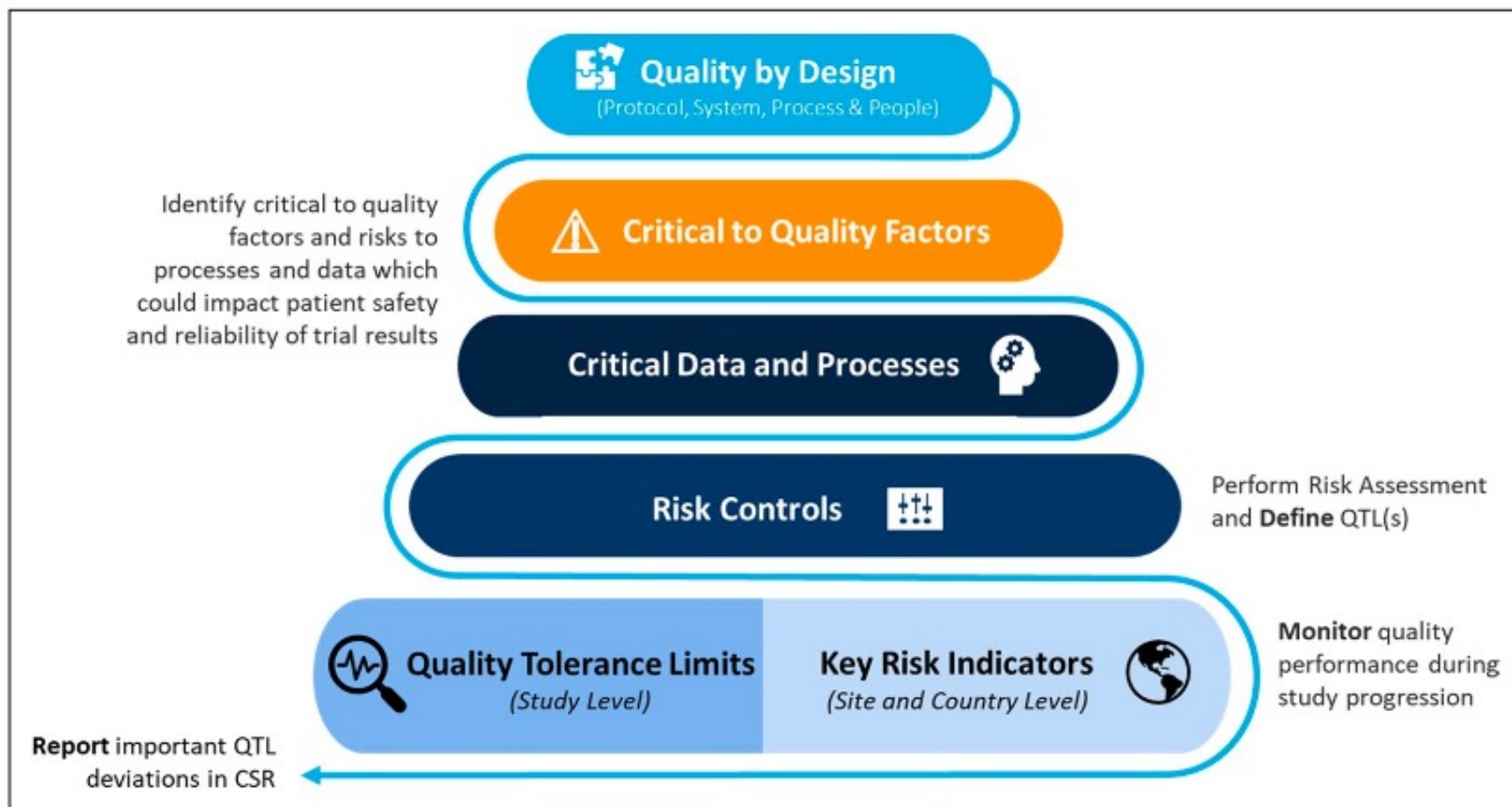


Part I: Company Preparation and Level Setting

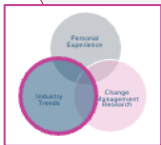
Preparation and Level Setting: Defining RBQM

Not a lot of companies here

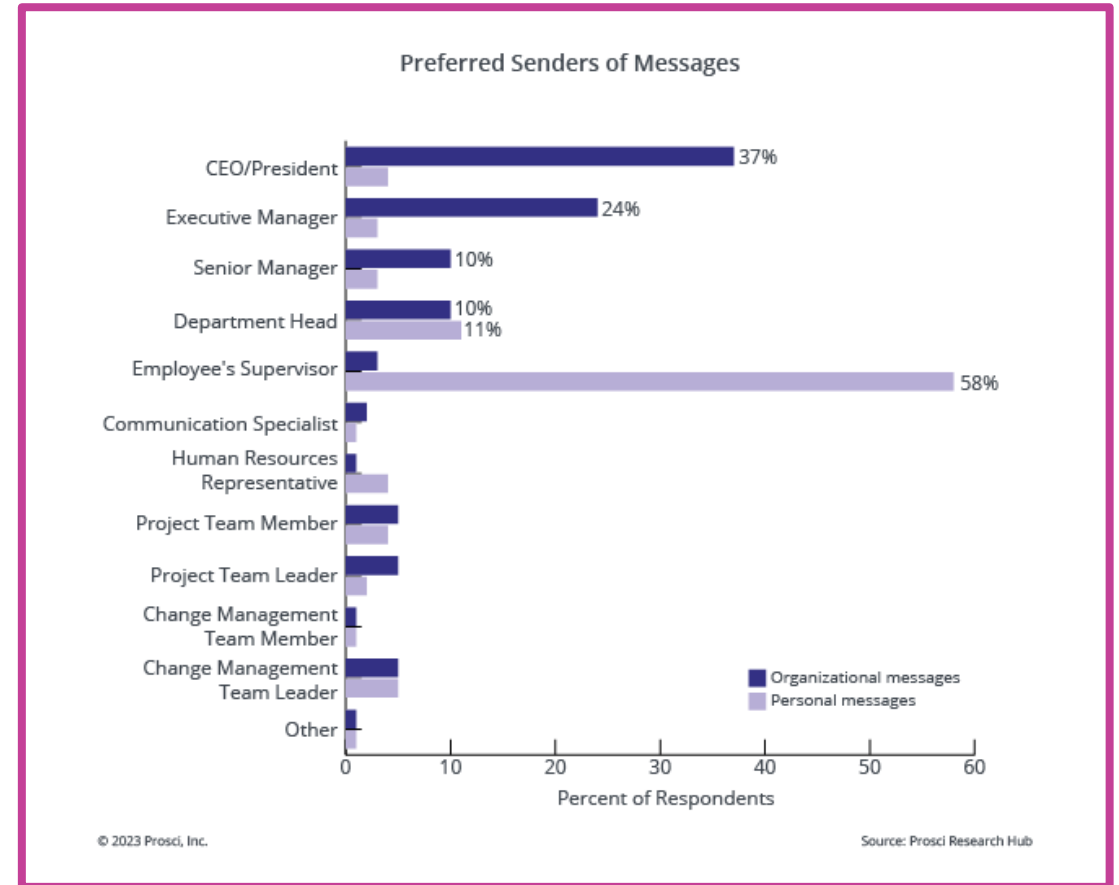
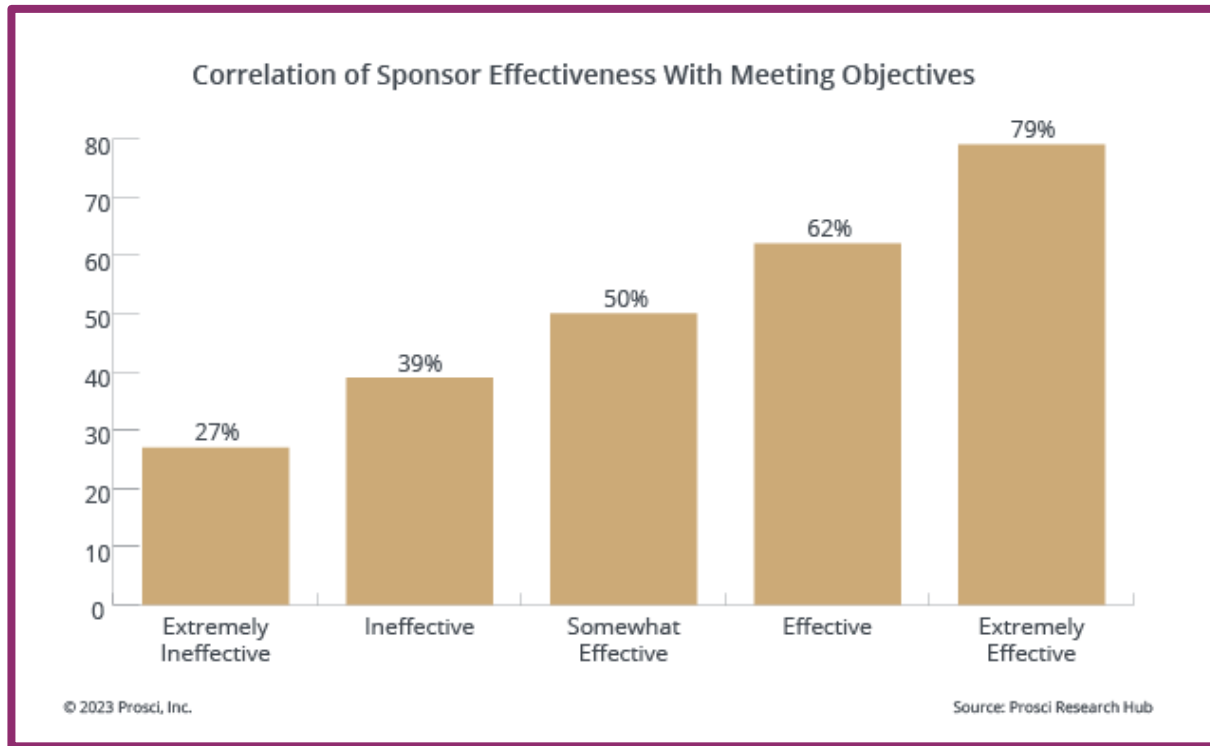
Lots of companies here



5) Bhagat, R., Bojarski, L., Chevalier, S. et al. Quality Tolerance Limits: Framework for Successful Implementation in Clinical Development. *Ther Innov Regul Sci* 55, 251–261 (2021). <https://doi.org/10.1007/s43441-021-00000-0>

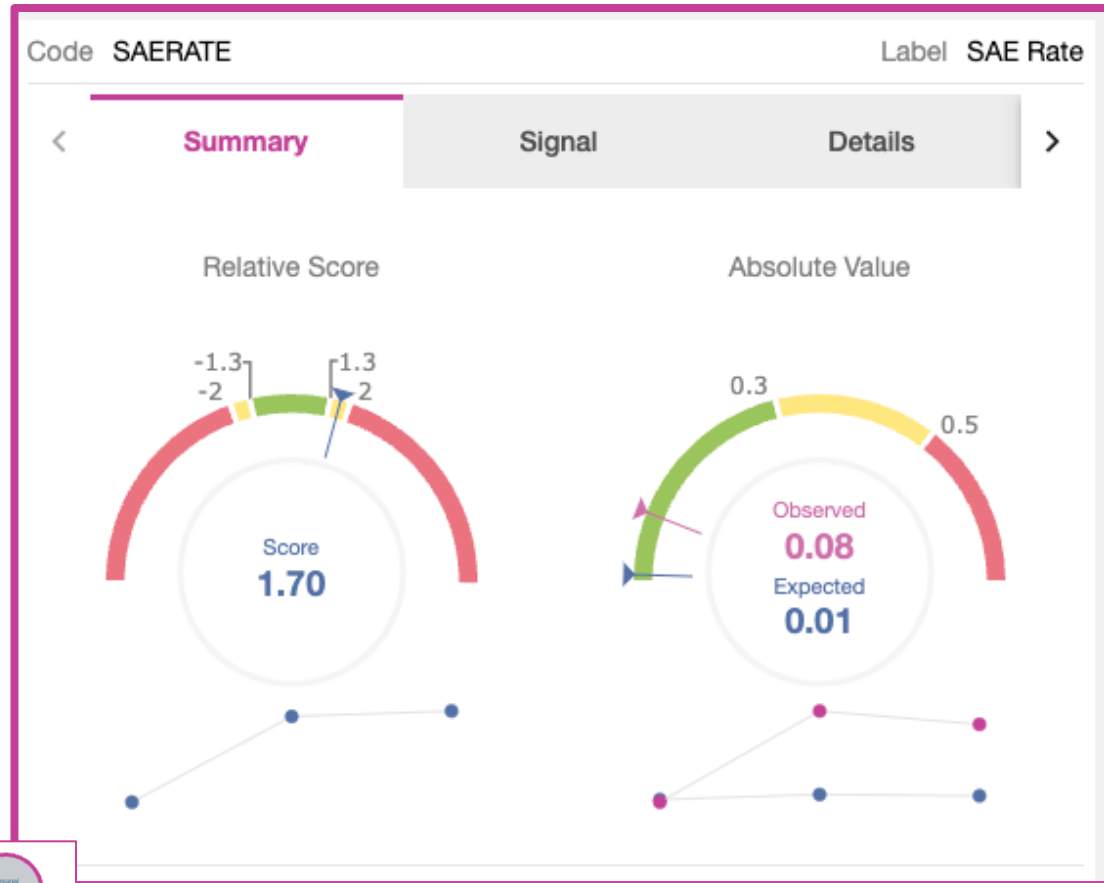


Preparation and Level Setting: Importance of Sponsorship

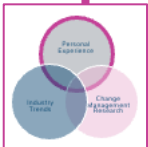


6) T. Creasey, *Best Practices in Change Management*, Prosci, 2023. <https://management-best-practices>

Preparation and Level Setting: Organizational Data Literacy



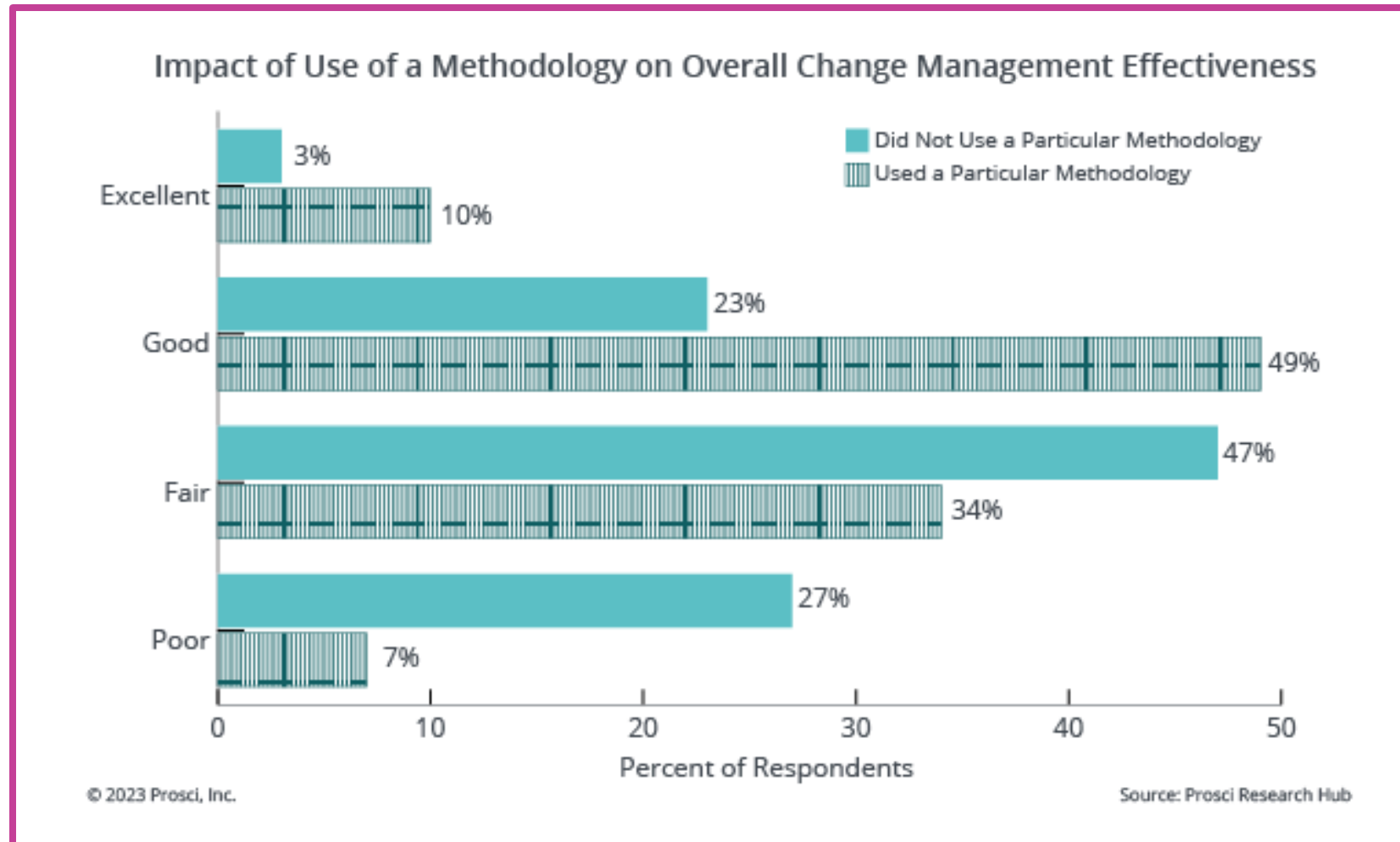
- Does your organization truly understand root cause analysis?
- Does your staff understand the capabilities of your vendor?
- Does your organization see the value of metrics not identifiable through traditional methods (e.g. EDC reports, line listings, etc.)
- How well can people "translate" your data?





Part 2: Change Management Planning

Change Management Planning – Methodology and ADKAR



6) T. Creasey, *Best Practices in Change Management*, Prosci, 2023. <https://htmanagement-best-practices>

Change Management Planning – Methodology and ADKAR

- The Prosci ADKAR* model:
 - Awareness
 - Desire
 - Knowledge
 - Ability
 - Reinforcement

THE PROSCI ADKAR MODEL

A Proven Framework for Individual Change

The Prosci ADKAR® Model is a results-oriented approach to managing change based on a simple truth: *company-wide change happens one person at a time.*

Providing a simple step-by-step approach, the ADKAR Model helps you and your team effectively manage individual change. You'll use proven strategies and tools to guide individuals through changes like a new system, an office move, or an acquisition, with methods for addressing any roadblocks along the way.

The ADKAR Model is one of the two foundational models of the Prosci Methodology, and the industry standard for change management practitioners worldwide.

[LEARN MORE](#)



* <https://www.prosci.com/>

Change Management Planning – Change Fatigue

Tell a Consistent Change Story

McKinsey research shows across industries that a transformation with a clearly articulated and widely shared change story is 3.7 times more likely to be successful than one without.

Wow!

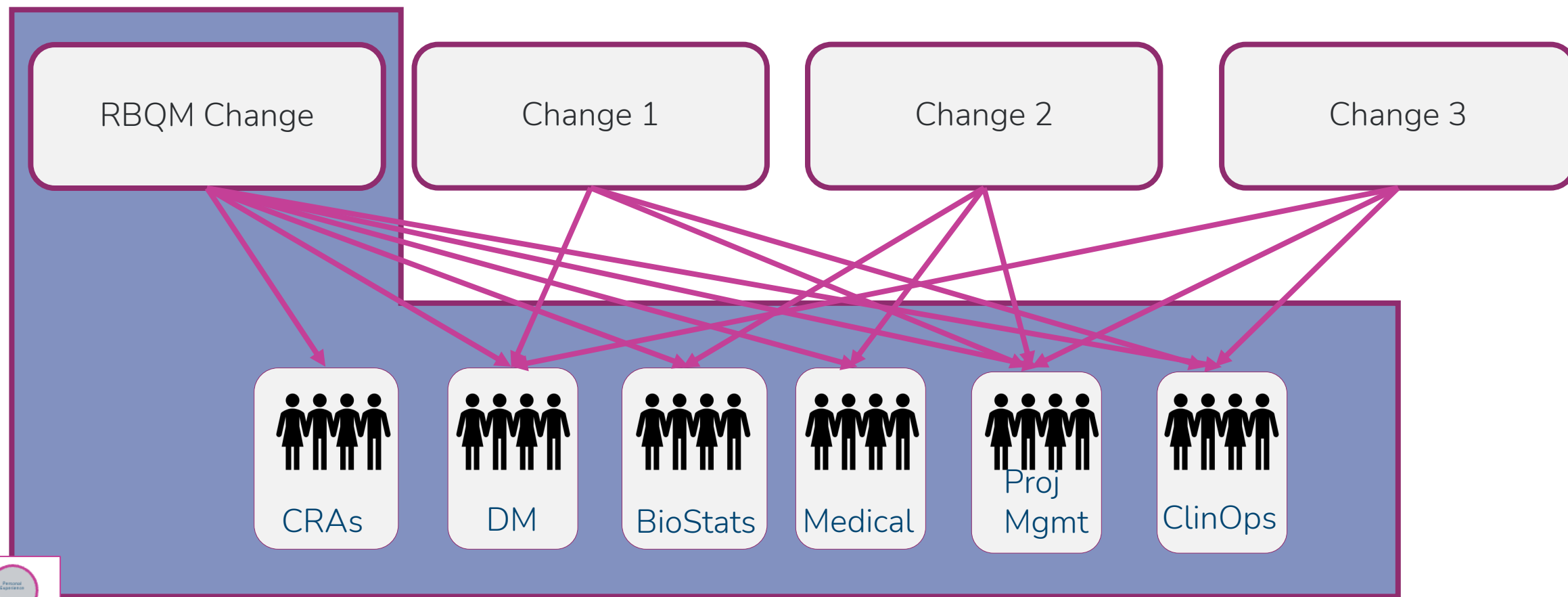
Define this early.

370%



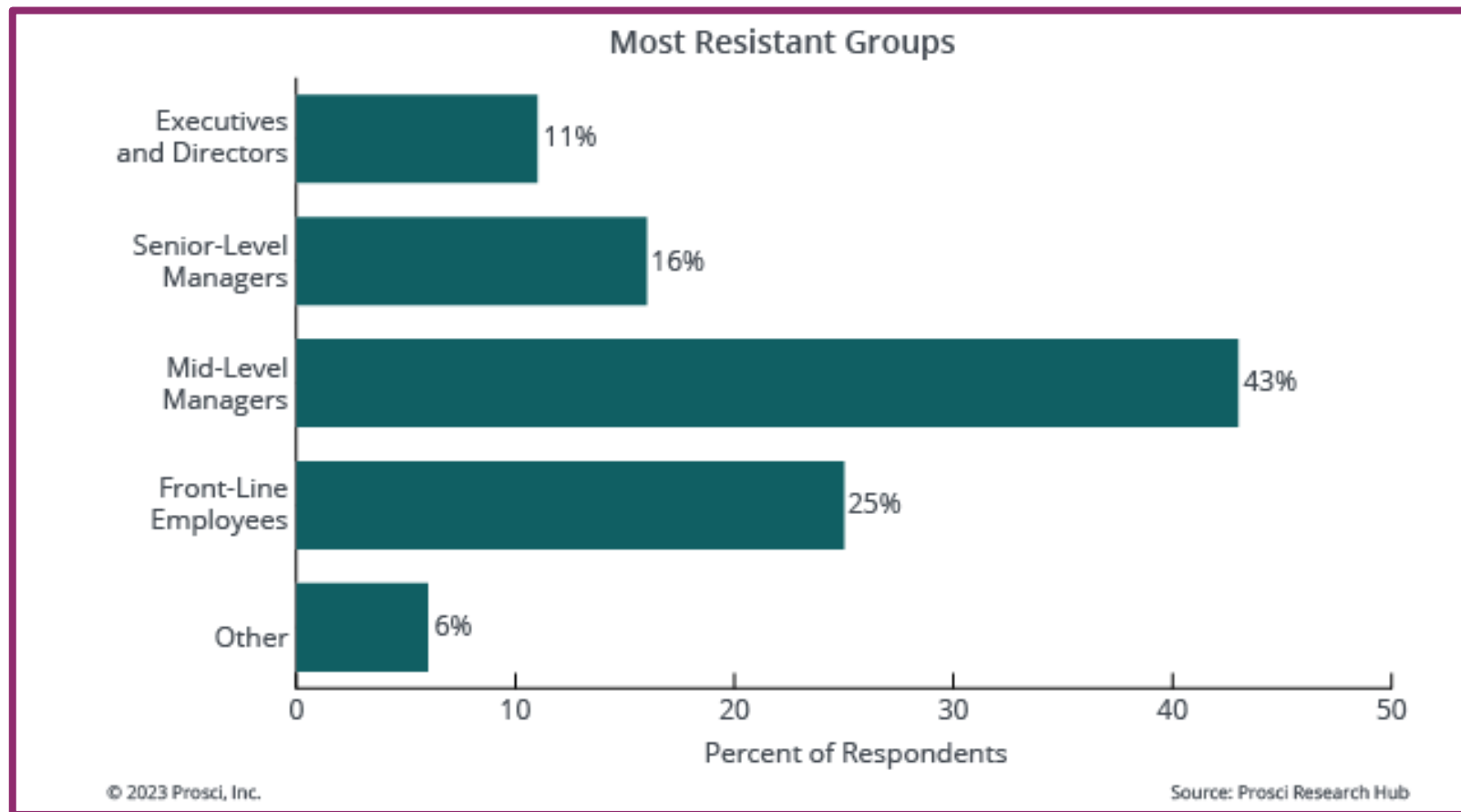
Change Management Planning – Change Fatigue

Landscape of change at End-User Level



Change Management Planning – Change Fatigue

Engaging Line Management

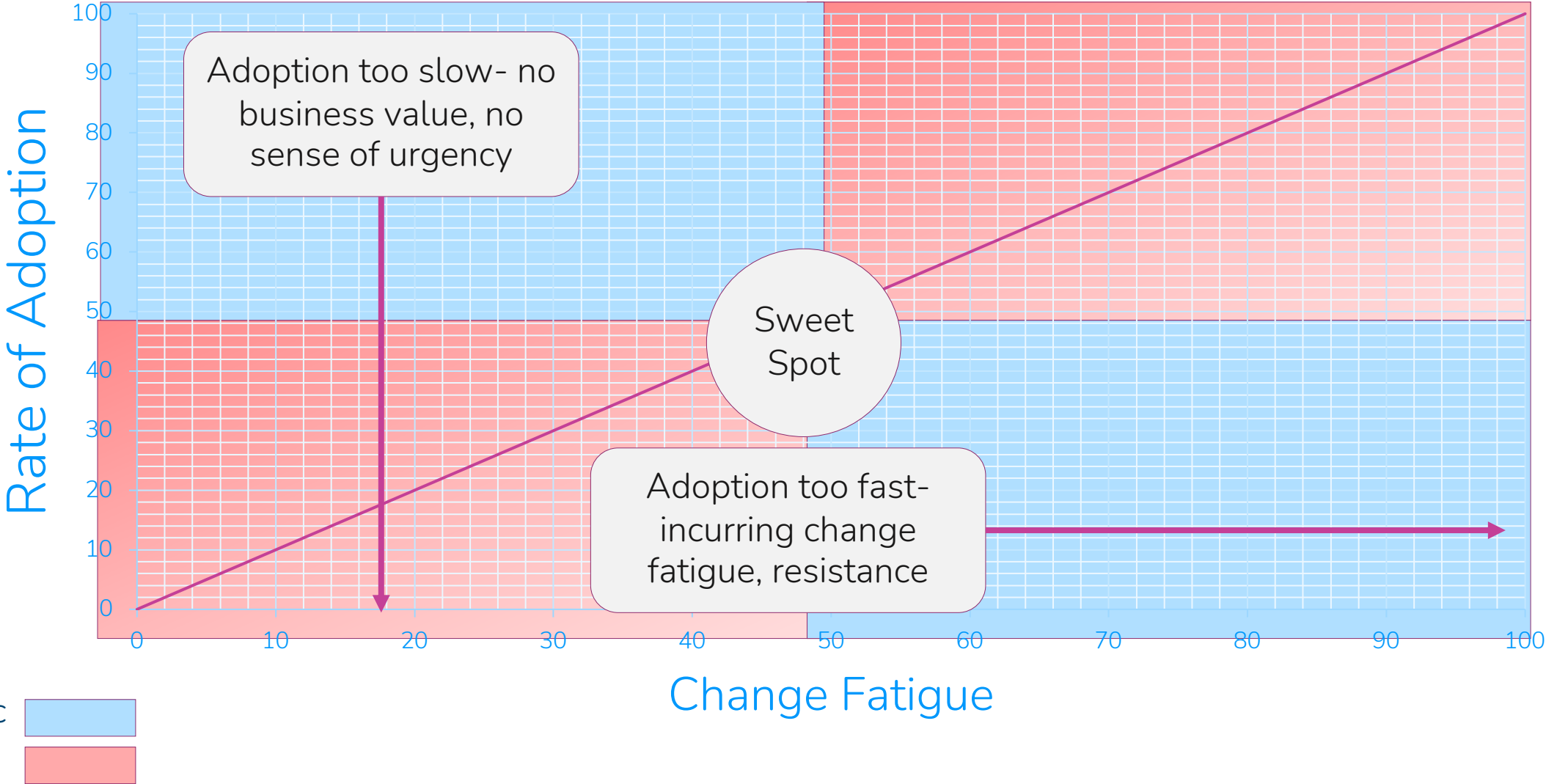


6) T. Creasey, *Best Practices in Change Management*, Prosci, 2023. <https://www.prosci.com/blog/change-management-best-practices>



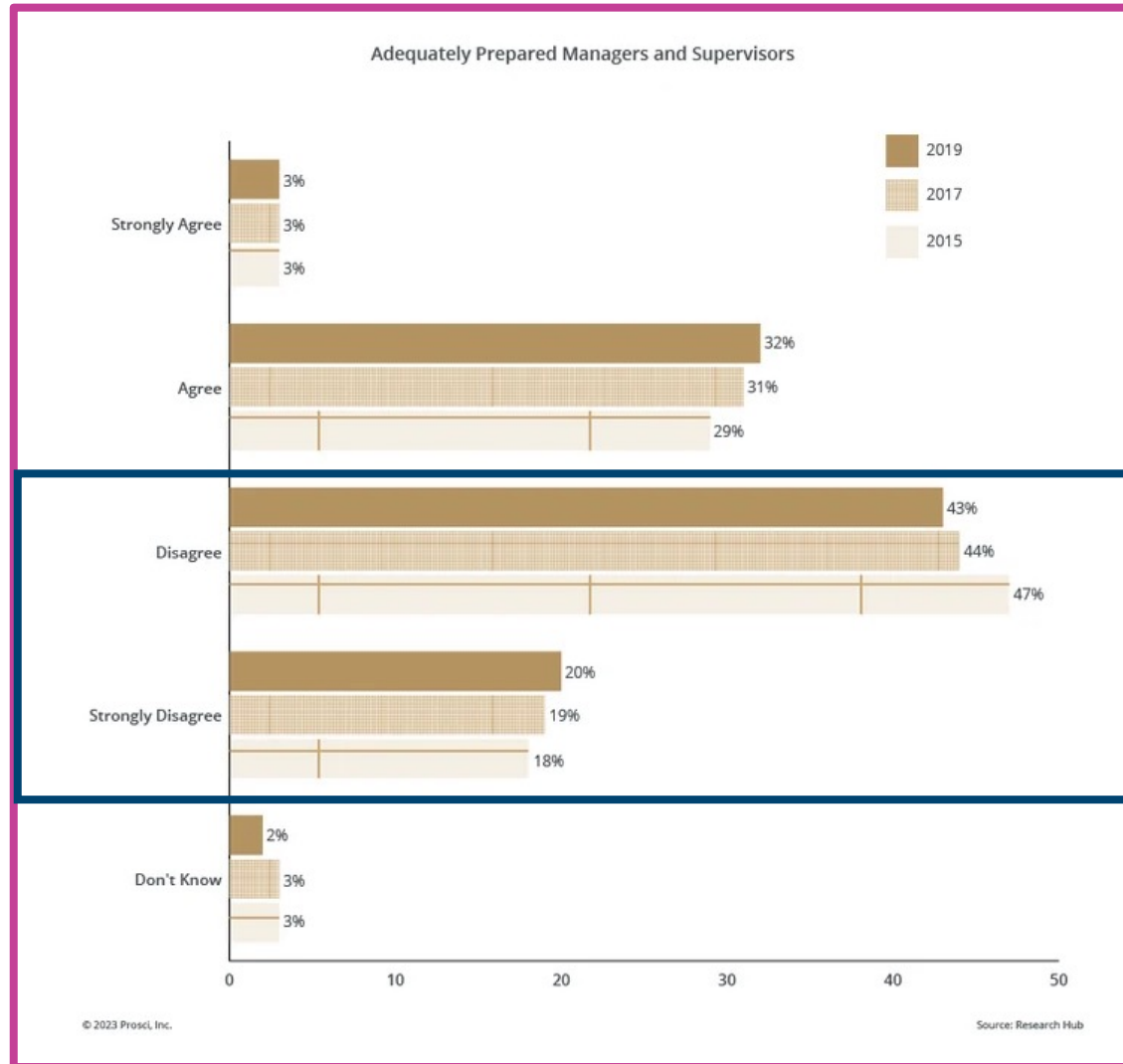
Part 3: Change Management Deployment

Change Management Deployment – Alignment with Ramp-Up



Unrealistic
Risky

Change Management Deployment – Change Enablers



People Managers will serve the following roles for the change:

- Communicator
- Liaison
- Advocate
- Resistance Manager
- Coach

In 2019, 63% of survey respondents noted that they either disagreed or strongly disagreed that managers and supervisors were prepared for a change.

People managers are critical to success.



Change Management Deployment – Adaptation

Delays to study start are extremely common

Approximately 40% of all clinical trials required a protocol amendment prior to FPI (n=3400)

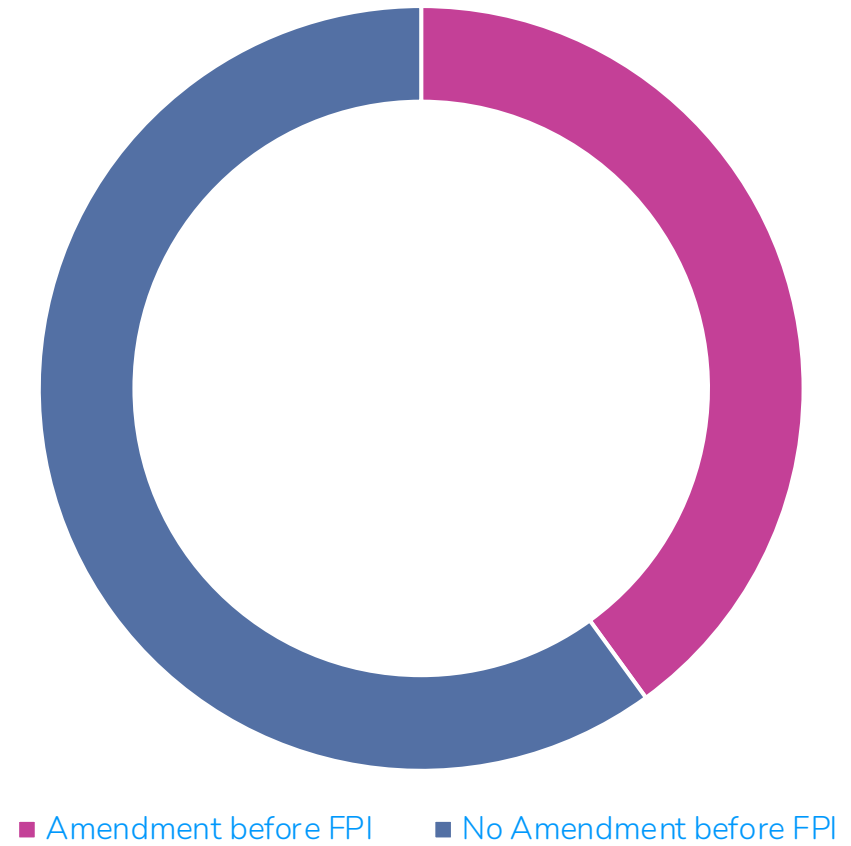
This number does not account for other delays, such as:

- Availability of study drug
- Site activation/start-up
- Regulatory approval
- Local/Country EC
- Availability of other clinical supplies
- Resourcing
- Enrollment



Be Prepared to Adapt!

Protocol Amendment Delay

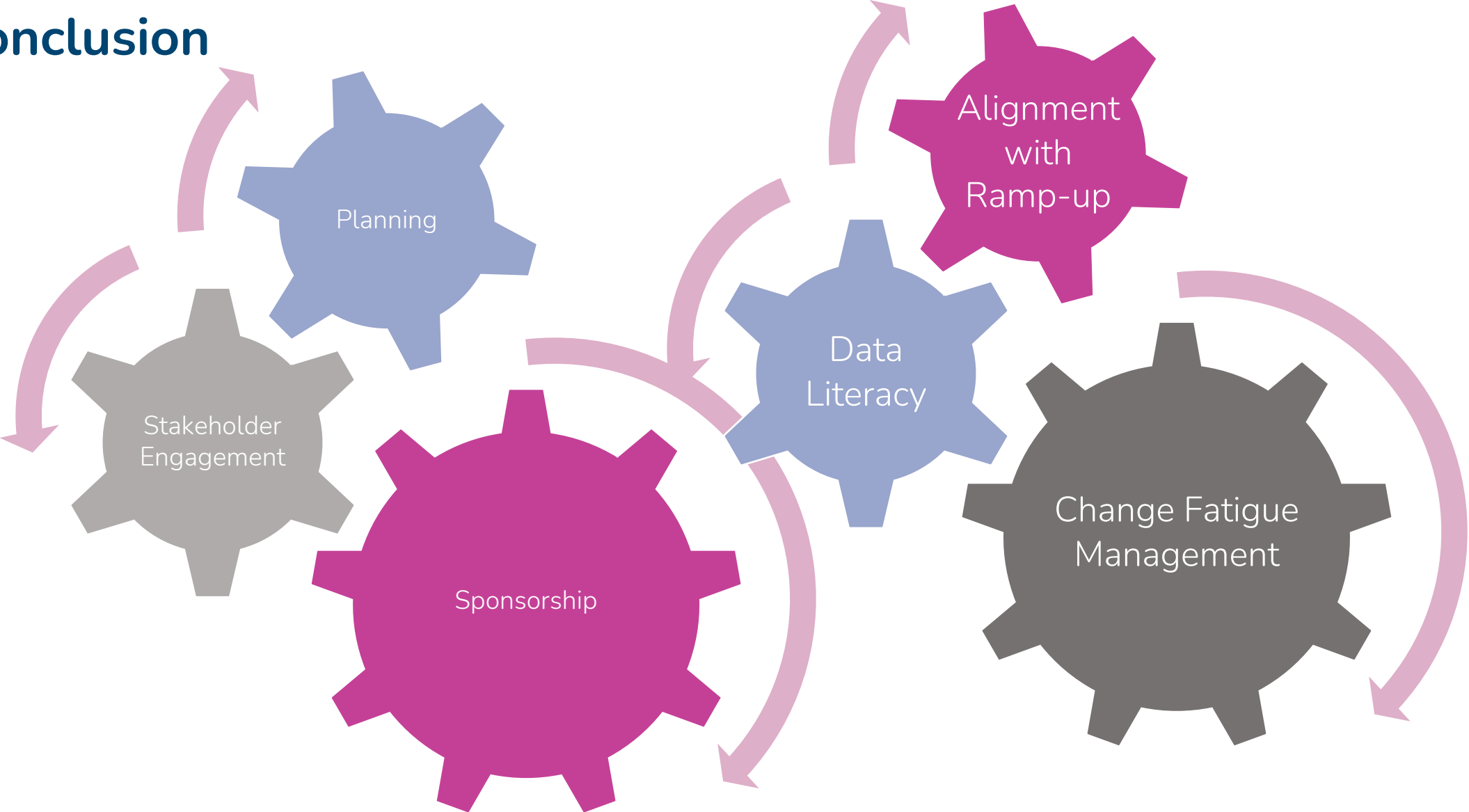


9) Tufts CSDD, "Measuring the incidence, causes, and repercussions of protocol amendments," *Drug Inf*, vol. 45, pp. 265-275, 2011.



Conclusion

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Thank You. Questions?

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