Paper AR02

Navigating RBQM Change Management: Real-World Strategies for Success

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ABSTRACT

A successful change management strategy is essential to implementing and updating new RBQM processes and technology. Having led multiple RBQM platform implementations for over four years for large- and mid-size pharmaceuticals companies – from the vendor, CRO and sponsor point of view – the author will use his industry and implementation experience to deliver a presentation that will highlight some of the considerations necessary to successfully implement an RBQM change management strategy and will also provide first-hand lessons-learned. The author's presentation will introduce the audience to ADKAR (Awareness, Desire, Knowledge, Ability and Reinforcement) principles and stakeholder mapping in RBQM, ramp-up considerations, and right-sizing the changes necessary to implement RBQM procedures and technology. The author will deliver best practices such as: executive leadership visibility and sponsorship, line manager engagement, creating a sense of urgency, data literacy assessments, and understanding of what successful implementation looks like.

INTRODUCTION

Change management is hard. Risk Based Quality Management (RBQM) is a discipline that touches nearly every aspect of clinical development, and therefore has a multitude of stakeholders which will require change management. According to the Tufts Center for the Study of Drug Development (CSDD), 69% of survey respondents named a lack of cross-functional awareness as a key challenge for implementing RBQM [1]. A recent PhUSE whitepaper from 2023 argued that the value of Centralized Monitoring (CM) is hard to quantify, which obfuscates organizational goals related to RBQM [2]. A 2019 survey from ACRO found that change management was a significant challenge in facilitating the uptake of RBM [3]. The Tufts CSDD released benchmark survey data that reported that 78.2% of all respondents felt that implementing innovations supporting clinical trials took somewhat/much longer than expected, and that the most difficult adoption stage was full implementation (as opposed to initiation, evaluation, and the adoption decision) [4]. These factors create treacherous waters for RBQM implementations, specifically in the areas of change management.

This paper will outline some of the best-practices for navigating these waters.

PART I: PREPARATION AND LEVEL SETTING

Before undertaking a change management journey in the RBQM space, companies should consider several key factors which will greatly impact their chances of success.

DEFINING RBQM

Because RBQM has multiple components of varying complexity to implement (KRIs, QTLs, adaptive site monitoring, centralized monitoring, quality by design principles, reduced SDV, etc.), an RBQM-naïve organization may be best suited to prioritizing certain aspects of RBQM first before attempting to digest the entire ecosystem in their first pass. More experienced organizations may have their own challenges of determining ownership over those components; for example, organizations may ask "should QTLs be owned by the central monitoring team or by the Quality Assurance organization?" Without aligning on what RBQM means to the organization writ-large, there is a possibility for a communication breakdown when shifting an organizational mindset to align with RBQM principles.

EXECUTIVE SPONSOR ENGAGEMENT AND SPONSORSHIP

According to ProSci Research Hub, survey participants placed "active and visible sponsorship" as the most important contributor to their change's success, and active sponsorship has been number one at the top of Prosci's benchmarking reports since 1998 [5]. The implementing organization needs to have a visible, active, and influential executive sponsor. This person should not merely be a figurehead, but should be actively promoting the initiative, engaging line management, and using their influence to cross into different functional areas.

DATA LITERACY

Data literacy is a potential asset or hurdle to any organization looking to implement RBQM principles. If stakeholders are not able to interpret trends and outliers in their data into meaningful actions through root-cause analysis, the analysis of that data will be ineffective. Data literacy comes with experience, critical thinking, and partnership with experts (either vendor or CRO partners). Collaboration between functional areas is critical- as an example, if a central monitoring team is consistently raising issues through a specific KRI that the clinical operations team interprets as non-issues, then the clinical operations team will quickly learn to tune-out the central monitoring team's issues related to that KRI (and potentially other KRIs in the future).

PART 2: CHANGE MANAGEMENT PLANNING

Change management best practice involves developing a business case and an associated strategy that has secured executive support and sponsorship [6]. That business case should outline the capabilities and aim of what the organization is trying to achieve through implementation, and it should also be cross-functional and collaborative. This exercise should serve as the basis for identifying affected functional areas, executive sponsorship, and change enablers throughout the organization that will serve as stewards in the change management journey.

CHANGE MANAGEMENT METHODOLOGY – ADKAR AND BEYOND

ADKAR is a change management methodology that stands for Awareness, Desire, Knowledge, Ability, and Reinforcement. This methodology is widespread and extends well beyond the clinical research space; this methodology works well but is only one of many change management methodologies that have been developed. It is important that a) the change management initiative uses an established methodology, and b) the steps and actions for the initiative are aligned to that methodology in a way that aligns with the initiative's goals.

CHANGE FATIGUE

It is critical to understand the landscape of change at your organization. The battle against change fatigue in pharma is constant- a popular saying is "the only constant is change", however, change fatigue is worsening at an alarming rate across industries. According to Gartner's Workforce Change Survey in 2016, 74% of employees were willing to change work behaviors to support organizational changes, but that number dropped to 38% in 2022 [7]. Here are three ways to combat change fatigue in your organization:

1) TELL A CONSISTENT AND CONGRUENT CHANGE STORY

It is critical to understand the landscape of change at your organization. According to McKinsey research across industries, initiative transformations are 3.7 times more likely to be successful with a clearly articulated and widely shared change story [8]. It is critical to a) create a "What's In it For Me?" message, b) build strong desire (D in ADKAR) and c) answer the "why are we changing?" question. According to John Kotter, Harvard Professor, and author of several books on corporate change management, convincing people of the need for change is critical; "the purpose of this activity is to make the status quo seem more dangerous than launching into the unknown." Kotter states that enough urgency has been created when approximately 75% of all impacted managers are convinced that maintaining the current business-as-usual is unacceptable [9]. This change story should be unique to your organization and should leverage a sense of urgency to maintain momentum. Ideally this change story was created before the business case was developed, but if it was not clearly articulated at the start of the project, crafting the story with the help of impacted stakeholders is a crucial step.

2) UNDERSTAND THE CURRENT LANDSCAPE OF CHANGE AT THE END USER LEVEL

Often, in sponsor and CRO organizations, change initiatives are project-based. Projects are following the business-case outlined above and are executed along project deliverables. The project-based approach can overlook a simple fact- people are the driver of project success, and people have a limited capacity to manage change in their day-to-day workflows. Stakeholder interviews can shed light on the organizational change impacting a set of stakeholders; truly listening to their concerns and implementing this into an RBQM scale-up approach is crucial. The best approach for the project is not always the best approach for the people most impacted by the project.

3) ENGAGE LINE MANAGEMENT

It is critical to understand the landscape of change at your organization. According to Prosci's annual Best Practices in Change Management survey, 63% of people surveyed noted that they do not feel as though their organization adequately prepares people managers with the skills, training, and tools they need to lead during change [10]. Similarly, mid-level managers have been identified as the group most resistant to change, with 43% of participants identifying them as such. This is followed by front-line employees representing 25% of the resistance to change, meaning that line management and their direct reports represent nearly 70% of all change resistance in practice [11]. Failure to engage line management and to empower them to serve as communicators, liaisons, advocates, coaches, and resistance managers is a pitfall that can be avoided with active engagement early and often in the initiative.

PART 3: CHANGE MANAGEMENT DEPLOYMENT

Practically speaking, the change management plan should be a crucial part of the deployment of the project, but the change management work must start before the deployment date. Stakeholder mapping, interviews, landscape analysis, impact assessments, and planning are all activities that must be engaged early in the process. An awareness campaign (the A in ADKAR) should be multi-modal, as stakeholder interviews often produce results that say that end users prefer to learn about the project in different modalities (emails, townhalls, departmental meetings, intranet posts, etc.). Engaging all these methodologies is critical, but also time consuming.

ALIGNMENT WITH RAMP-UP PLAN

The deployment and Ramp-Up plan of the RBQM initiative is an important part of any implementation. How studies are onboarded, the rate of adoption, and phasing-out any old processes or systems all impact the communication strategies for any change management plan. This will also impact training approaches, materials, awareness campaigns, and the sense of urgency/change story outlined above. If an implementation moves too quickly, end users could end up withdrawn through change fatigue; too slow of an implementation could erode the sense of urgency needed to maintain momentum through a full-scale adoption. Similarly, a training plan that is not delivered in the appropriate window could be easily overlooked and forgotten if the trainee is not utilizing the new system/process shortly thereafter.

CHANGE CHAMPIONS, CHANGE ENABLERS, AND REPEATABILITY

Change Champions and Change Enablers are those that will allow you to grow at scale. These individuals will be scattered across the business and serve multiple roles: 1) the eyes and ears of any resistance that requires mitigation, 2) become superusers for the technology platform, 3) identify forums for engagement, and 4) serve as line management for others impacted by change. Ideally, these change enablers also facilitate training for the end user community, such that they are identified as subject matter experts in the technology and process. Change managers should create an effective network of change enablers, and carefully craft the ‘what’s in it for me?’ (WIFM) message to be exceptionally clear for the network to repeatedly broadcast this in the forums they identify.

BE PREPARED TO ADAPT

As noted in the introduction, most companies responding to Tufts CSDD survey noted that they believed they moved slower than their peers in implementation of new initiatives. Getz et al noted that in an analysis of 3400 clinical trials, more than 40% had amended protocols prior to the first subject visit, delaying trials by an average of 4 months [12]. As such, implementation speed may ebb and flow due to circumstances outside of the initiative’s control – a key pilot study could be delayed, an early adopter study could be cancelled during start-up, or pushback from study teams could cause the implementation initiative to shift priorities. The numbers suggest this is normal and change managers should be prepared to quickly change direction and messaging.

CONCLUSION

Simply put, there is no one-size-fits-all change management plan that is transferrable to all situations. A robust framework tied to a proven methodology portends the best chance for success, when paired with visible and active executive sponsor engagement. Factors to consider for change management planning include the size of the organization, functional roles, in-house expertise, competing initiatives relating to change fatigue, and rates of adoption. A thoughtful adoption strategy which incorporates these factors will serve organizations well as they embark or continue their RBQM journey, however, organizations should be prepared to adapt their strategy when necessary.

REFERENCES

[1] T. C. f. t. S. o. D. Development, Impact Analysis & Insight into Critical Drug Development Issues, Boston, MA: Tufts CSDD, Fall 2023.

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

[3] Association of Clinical Research Organizations, "Establishing Risk-Based Monitoring within a Quality-Based System as Best Practice for Clinical Studies," ACRO, Washington, DC, 2019.

[4] M. F. a. B. H. Kenneth Getz, Benchmarking and Optimizing the Process for Adopting Innovations Supporting Clinical Trial Execution, Boston, MA: Tufts Center for the Study of Drug Development, 2022.

[5] T. Creasey, Primary Sponsor's Role and Importance, Prosci Blog, Accessed 2023 (Published April 15, 2021).

[6] P. C. M. W. Group, Exploring the Consirations and Challenges of Implementation, Kent, UK: PhUSE, 2022.

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

[8] I. P. S. T. Gayane Gyujyan, A Health Check for Pharma: Overcoming Change Fatigue in the Pharmaceutical Industry, McKinsey and Company, 2014.

[9] J. Kotter, Leading Change, Harvard Business Review, 2011.

[10] L. Kempton, CLARC: The Role of People Managers in Change Management, Prosci, 2023.

[11] T. Creasey, Best Practices in Change Management, Prosci, 2023.

[12] R. Z. A. C. A. H. R. K. K. K. KA Getz, "Measuring the incidence, causes, and repercussions of protocol amendments," *Drug Inf,* vol. 45, pp. 265-275, 2011.

[13] E. M. Agency, "Reflection paper on risk based quality management in clinical trials.," 18 November 2013. [Online]. Available: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-risk-based-quality-management-clinical-trials_en.pdf. [Accessed 19 December 2023].

[14] T. BioPharma, "Section 5 The Next Frontier of RBM - Glossary: Key Terms Defined," 2017.

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