A comprehensive review of change management theories and models to enhance the efficiency of CRO delivery model in patient centric trials

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Abstract: This paper presents a comprehensive review of change management theories and models specifically applied within the context of clinical trials. As the landscape of clinical research continues to evolve with the integration of new technologies and methodologies, effective change management has become critical to the success of clinical trial implementations. The review systematically examines various theoretical frameworks and models, including Lewin's Change Model, Kotter's Eight Steps for Leading Change, and the ADKAR Model, evaluating their applicability and effectiveness in the clinical trial setting. By synthesizing existing literature, this study highlights the challenges and best practices associated with change management in clinical trials. It identifies key factors that influence the success of change initiatives, such as stakeholder engagement, communication strategies, and organizational culture. The findings aim to provide researchers and practitioners with a deeper understanding of how to navigate the complexities of change within clinical trials, ultimately contributing to more efficient and effective research outcomes.

Key words: change management, Lewin, Kotter ADKAR model, McKinsey models

1.INTRODUCTION

Today, the clinical research market is as competitive and innovative as ever, and the efficiency of the delivery model used by Contract Research Organizations (CROs) is one of the most crucial factors needed to boost the probability of a successful outcome. Patient-centric trials are playing a bigger part than they used to in modern clinical research, with a demand to do things differently, better and with more transparency. The delivery model used by CROs gets more complex with many of them specializing in focused services, especially big ones, which means increasing the number of specialized vendors necessary to conduct a full trial. Additionally, many biotech and start-up companies looking for support are keen to outsource crucial parts of the work, for example Data Management or Safety, and that may not always be an option with preferred CROs. There is an opportunity to explore how change management can be utilized to improve the efficiency of CRO's delivery model for patient-centric trials. It would be also good to see what direction the industry may take or what will be the bigger struggles for trying to be patient-centric.

An indicative aim and objectives of this paper are to scrutinize the current state of Patient Centricity in clinical drug research, to describe the factors affecting and being affected by the implementation, to examine how Change Management can enhance the current state of Patient Centric drug development and to predict potential future development in the area. The research is particularly significant due to current challenges CROs delivery model and sponsors are facing. The inefficient cooperation of outgoing vendors and poor top to bottom communication are devastating the effectiveness of full trial execution. At the same time, with upcoming amendments inviting implementing Quality Risk Management principles and all the work sponsors should do to meet the regulations, even more, time-consuming planning will be involved (Narola, 2018). Therefore, an effective implementation of a patient-centric approach efficiently across all levels of trial work is needed to improve future patient experience. Structure of the current article is structured into the background, and relevant context description, methodology, findings and discussion of the results, and finally conclusions and suggest Directions (C&D). The background

section gives an overview of the patient's role in modern clinical trials and the necessity of conducting patient-centric studies. The synthesis of the matter and a proposed direction for the essay: how can change management be utilized to improve the efficiency of the delivery model used by CROs for patient-centric trials? A structured approach to explore the methodology, analysis, discussion topics, and future direction questions is provided to familiarize the reader with matters to be addressed.

1.2 Background and Significance

Change management is the process, tools and techniques to manage the people side of change to achieve the required business outcome. The efficiency of Clinical Research Organizations (CROs) which provide management to the clinical research of patients in the trials has become extremely significant. Although international CROs have been gaining popularity among companies as an important means of managing trials, there is generally space for further improvement. Main contributions are expected from recent knowledge-based techniques and methodologies, process optimization and the crucial position of patient representation in patients centric trials (PCTs). The goal of clinical research is to understand the safety and effectiveness of medical therapeutic, diagnostic, or preventive products. One type of trial related to clinical research is carried out in CROs. CROs help the company design the clinical trial, carry out the quality process and site management, and then conduct the statistical analysis. The company would obtain the result that regulatory bodies and other hospitals request by inquiry with the outcome, receiving final authorization to commercialize. These 10 years showed an increase in the importance of data retention, patient engagement and design of processes with perspective of Change Management (CM).

2. STUDY OBJECTIVE

An indicative aim and objectives of the article are to scrutinize the current state of Patient Centricity in clinical drug research, to describe the factors affecting and being affected by the implementation, to examine how Change Management can enhance the current state of Patient Centric drug development and to predict potential future development in the area. The research is particularly significant due to current challenges CROs delivery model and sponsors are facing. The inefficient cooperation of outgoing vendors and poor top to bottom communication are devastating the effectiveness of full trial execution. At the same time, with upcoming amendments inviting implementing Quality Risk Management principles and all the work sponsors should do to meet the regulations, even more, time-consuming planning will be involved (Narola, 2018). Therefore, an effective implementation of a patient-centric approach efficiently across all levels of trial work is needed to improve future patient experience. Structure of the current article is structured into the background, and relevant context description, methodology, findings and discussion of the results, and finally conclusions and suggest Directions (C&D). The background section gives an overview of the patient's role in modern clinical trials and the necessity of conducting patient-centric studies. The synthesis of the matter and a proposed direction for the essay: how can change management be utilized to improve the efficiency of the delivery model used by CROs for patient-centric trials. A structured approach to explore the methodology, analysis, discussion topics, and future direction questions is provided to familiarize the reader with matters to be addressed.

3. LITERATURE REVIEW

The implementation of change has been acknowledged as a concept central to the growth and durability of an organization. The field of change management progressively unfolds, offering a collection of theories, methodologies, and models satisfying the requirement of change within an organizational setting. Despite the presence of numerous change models and frameworks each having unique strengths and merits, transformational changes still pose significant challenges and risks that can be either intensified or masked by the perceived completeness of the adopted model or framework in the clinical environment (Harrison et al., 2021). These challenges remain even when the entire framework has been applied with reference to its available guides. The ongoing practice of managing change in clinical trials aims to promote the perception of clinical changes as transcendental and to fill the void of viewpoints relating to change management. This perspective is

dedicated to the evaluation of frequently adapted change management models amid clinical trials in the hope that it advances the alignment of clinical change insights with conventional theoretical values.

The approach to change management could be facilitated by owning a comprehensive understanding of existing conventional theories on change management. A significant number of change management theories and models have been proposed to date. More notably, health service is a self-perceived service industry, meaning the mental perceptions and dissatisfaction of the patients or service recipients will play a key role in affecting the sustainability of change. Various change management models and frameworks rooted from a wide array of disciplines nonetheless they exhibit potential for application across different industries. This postulation urges the integration of change management perspectives from multiple points of view in the faith that such a posture is congruous with the intra-disciplinary and interdisciplinary essence of change management in a clinical environment.

4.LITERATURE GAP

Although it has long been advocated that there is a critical organizational difference between executing clinical trial operations within academic sites and Professional Research Organization (PRO) partners or for-profit sponsors, the operational literature falls short of providing empirical comparisons (I Nebie et al., 2024). Therefore, this lack should be addressed by examining clinical research operations in the aforementioned contexts. Even though specialization on clinical research activities at academic sites or research-intensive settings may at first observation reflect high expertise, oversight shortfalls and related deficiencies are detrimental to online first use of resources. Those cases are under-researched as most findings about operations efficiency pertain to commercial trial operations generally overcoming academic ones by precisely balancing compliance with flexibility.

Some argue a trial is operationally most efficient when it moves away without a hitch in Perfect Peter Nenuo convincing style. Because taking a miracle for that. It always take longer than one initially plans. At least for such components – and there are many of them – of trial operations requiring multiple decisions, inputs or occurrences to unfold in anticipated way. Clinical operations refers to the wide set of activities supporting the milestone starting from their early planning through necessary approval until the finish. Efficient trial is such milestone not burdening any player, conducting itself more or less otherwise would be inpatient. Trial efficiency will be conceived in terms of optimal use of resources encompassing both biostatistical and clinical one. However, the quality of findings, i.e. the validity, credibility and relevance of the results are largely determined by the appropriateness of sample and design-related decisions, as well as the robustness of analysis of these results (Harrison et al., 2021).

5.CHANGE MANAGEMENT THEORIES AND MODELS

The contemporary business landscape is characterized by constant flux, driven by rapid technological advancements, increasing globalization, and the perpetually evolving expectations of customers. In this dynamic environment, organizations face the continuous need to adapt, innovate, and transform to maintain their competitive edge and achieve sustained growth. Change management models serve as indispensable frameworks that provide structure and guidance for navigating these complex transitions. These models are not merely theoretical constructs; they are practical tools designed to ensure that organizational changes are implemented effectively, leading to positive outcomes and maximizing the return on investment in transformation initiatives. Their increasing relevance stems from the inherent need for organizations to respond strategically to the multifaceted pressures of the modern business world.

Given the complexities and rapid pace of change in the modern business environment, change management models have become indispensable tools for organizations seeking to not only survive but also thrive. These models offer a structured and systematic way to navigate the multitude of challenges presented by technological advancements, globalization, and evolving customer expectations. They provide a much-needed roadmap for implementing essential changes while proactively addressing potential disruptions and minimizing resistance from stakeholders. Here is the list of top 6 change

management models with the key elements, focus area and best use scenarios. Table-01

Model	Key Elements	Focus	Best-use Scenarios
Lewin's Model	Unfreeze, Change, Refreeze)	Organizational Process	Linear, well-defined changes with a clear end state, foundational understanding of change management
Prosci ADKAR Model	5 (Awareness, Desire, Knowledge, Ability, Reinforcement)	Individual Adoption	Changes requiring significant individual behavioral shifts, technology adoption
Kotter's 8-Step Model	8 (Urgency, Coalition, Vision, Communication, Empowerment, Wins, Don't Let Up, Make it Stick)	Organizational Process, Leadership	Large-scale transformations, top-down change initiatives
McKinsey 7-S Framework	7 (Strategy, Structure, Systems, Shared Values, Skills, Style, Staff)	Organizational Alignment	Comprehensive organizational assessments, strategic realignments
Bridges' Transition Model	3 (Endings, Neutral Zone, New Beginnings)	Individual Emotional Journey	Cultural or structural transformations, situations with significant emotional impact
Agile Change Management Model	Iterative	Adaptability, Incremental Progress	Rapidly changing environments, software development, projects requiring flexibility

6.FRAME WORK OF IMPLEMENTING CHANGE MANAGEMENT MODELS IN CLINICAL TRIALS MANAGEMENT

The landscape of clinical trials is characterized by constant evolution, driven by increasingly stringent regulatory requirements, the rapid emergence of new technologies, and the growing complexity of global research endeavors. This dynamic environment necessitates the effective management of change to ensure the successful and ethical conduct of clinical investigations. Clinical trials, by their very nature, operate under a unique set of constraints and priorities. Regulatory compliance, mandated by bodies such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA), is paramount at every stage of a trial.1 Patient safety remains the foremost concern, requiring meticulous attention to adverse event reporting and protocol adherence.1 The integrity and traceability of clinical data are non-negotiable, underpinning the validity of research findings and the safety of future medical interventions.1 Furthermore, clinical trials involve a multitude of stakeholders, each with their own perspectives and requirements, including sponsors, investigators, ethics committees or Institutional Review Boards (IRBs), patients, contract research organizations (CROs), and regulatory agencies.1 Finally, the timelines associated with clinical trials are often critical, influenced by factors such as drug development milestones, patent expiry dates, and the urgent need for new therapies.1 In this context, the ability to effectively manage change is not merely desirable but essential for the efficient, compliant, and ultimately successful execution of clinical research. This report will provide a comparative analysis of six prominent change management models: Lewin's Three-Stage Model, the ADKAR Model, Kotter's 8-Step Model, the McKinsey 7-S Framework, Bridges' Transition Model, and the Agile Change Management Model. The objective is to evaluate the applicability of these models to the specific challenges and complexities of clinical trials management and to offer evidence-based recommendations for their use in this critical field.

6.1 Lewin's Model in Clinical Trials: This model can be applied to various changes in clinical trials. The Unfreeze stage involves communicating the necessity of a change, such as adopting a new Electronic Data Capture (EDC) system to improve data quality and efficiency, to all stakeholders including investigators, site staff, and sponsors. 9 Highlighting the limitations of the existing system and the benefits of the new one is crucial. The Change stage entails implementing the new EDC system, providing comprehensive training to all users (investigators, site staff, data managers,

monitors), and establishing robust support mechanisms to address any issues or questions that arise. The Refreeze stage focuses on embedding the new EDC system into the standard operating procedures of the clinical trial, updating training materials to reflect the new technology, and continuously monitoring its usage and effectiveness through key performance indicators like data entry timelines and query rates. 9 While Lewin's model offers a clear and simple framework, its linear nature might not fully accommodate the iterative adjustments often required in clinical trials. The lack of specific guidance on engaging diverse stakeholders and navigating complex regulatory requirements could also be a limitation. requirements could also be a limitation.

6.2 ADKAR Model in Clinical Trials: The ADKAR Model's individual-centric approach makes it well-suited for managing changes that require individual adoption and behavioral shifts in clinical trials. For example, when implementing a new protocol amendment driven by emerging safety data, the Awareness stage would involve ensuring that all investigators and study coordinators understand the specific safety concerns and the rationale behind the protocol changes. The Desire stage focuses on fostering a personal commitment to implementing the amendment by emphasizing its importance for patient safety and regulatory compliance. The Knowledge stage involves providing detailed information and training on the revised protocol procedures, including any new eligibility criteria, treatment regimens, or safety reporting requirements. The Ability stage ensures that research staff have the necessary skills and resources to implement the revised protocol accurately in their day-to-day activities, potentially through workshops or simulation exercises. Finally, the Reinforcement stage involves monitoring adherence to the new protocol, providing ongoing support and feedback to study sites, and acknowledging successful implementation to sustain the change. This model is particularly effective for ensuring individual compliance and addressing resistance at a personal level.

6.3 Kotter's 8-Step Model in Clinical Trials: Kotter's model can be valuable for managing significant changes in clinical trials that require strong leadership and broad organizational support. For instance, when addressing poor patient recruitment rates that are jeopardizing trial timelines, the first step is to Create Urgency by clearly communicating the impact of low enrollment on the study's success and the potential consequences for drug development. 38 The next step is to Build a Guiding Coalition by forming a team with representatives from the sponsor, lead investigators, patient advocacy groups, and recruitment specialists to lead the effort. 38 This coalition then works to Form a Strategic Vision for improving recruitment, such as implementing a new digital outreach strategy or expanding eligibility criteria. The vision is then Communicated widely to all participating sites and the broader research community. Empowering Action involves removing barriers to recruitment, such as streamlining the informed consent process or providing additional resources to sites. Generating Short-Term Wins could involve celebrating early successes in increased enrollment at specific sites. Consolidating Gains involves analyzing what worked and scaling successful strategies across all sites. Finally, Anchoring Change in the Culture means making proactive patient recruitment an integral part of the trial's operational mindset. 38 This model provides a structured approach for complex, organization-wide changes in clinical trials.

6.4 McKinsey 7-S Framework in Clinical Trials: The McKinsey 7-S Framework can be applied to analyze the alignment of various organizational elements when implementing a significant change in clinical trials, such as adopting a completely new trial design (e.g., basket trial or umbrella trial). Strategy would involve defining how this new design aligns with the overall research objectives and the sponsor's portfolio strategy. Structure would examine if the current clinical operations team structure and roles are suitable for managing this novel trial design, potentially requiring the involvement of specialists in genomics or biomarker analysis. Systems would assess the existing data management, randomization, and statistical analysis systems to determine if they can accommodate the complexities of the new design, potentially requiring new software or modifications to existing platforms. Shared Values would consider the organization's commitment to scientific innovation and its willingness to embrace more complex and potentially riskier trial designs. Skills would identify the expertise needed within the clinical trial team,

including specialized knowledge in the therapeutic area and the intricacies of the new trial design, potentially requiring targeted training or recruitment. 50 Style would evaluate the leadership approach to managing this complex trial, emphasizing collaboration and knowledge sharing across different scientific disciplines. Staff would assess the adequacy of the current staffing levels and the need for additional personnel with the required expertise. This framework ensures a holistic view of the change and helps identify potential areas of misalignment.

6.5 Bridges' Transition Model in Clinical Trials: When a clinical trial faces unexpected termination due to safety concerns or lack of efficacy, Bridges' Transition Model can help manage the human impact on the research team.

The Endings stage involves acknowledging and validating the feelings of disappointment, frustration, and loss experienced by investigators, study coordinators, and other personnel who have invested significant time and effort in the trial. Leaders should communicate openly and honestly about the reasons for termination and provide opportunities for team members to express their feelings. The Neutral Zone is a period of uncertainty as the team adjusts to the cancellation and potentially transitions to new projects. During this phase, providing support, clear communication about future assignments, and opportunities for debriefing and learning from the experience are crucial. The New Beginnings stage involves helping team members to re-engage with new research endeavors, fostering a sense of closure regarding the terminated trial, and focusing on future opportunities and contributions to clinical science. This model emphasizes the emotional and psychological aspects of change. ○ Agile Change Management Model in Clinical Trials: Agile change management can be particularly beneficial for managing changes in clinical trials that require flexibility and iterative adaptation, such as implementing a new digital health technology for remote patient monitoring. The process would involve Iterative Implementation, where the technology is rolled out in stages or modules, allowing for continuous feedback from investigators, site staff, and patients. Collaboration is key, with frequent communication and close involvement of clinical operations, IT, data management, and patient-facing teams to ensure the technology meets the needs of all stakeholders. Flexibility is crucial to adapt to any unforeseen challenges or user feedback, allowing for adjustments to the technology or its implementation process as needed. Continuous Improvement involves regularly reviewing the usage data, gathering feedback, and making ongoing refinements to the technology and training to optimize its effectiveness in the clinical trial. This approach allows for rapid adaptation and ensures the technology effectively supports the trial's objectives.

7.SPECIFIC APPLICATION: CHALLENGES AND BENEFITS

Examination of how each model might be applied, and the associated challenges and benefits, across different clinical trial phases (e.g., study design, site initiation, patient recruitment, data collection, analysis, reporting).

7.1 Study Design:

■ Lewin's: Benefit: Can help challenge traditional design approaches, promoting innovation. Challenge: "Refreeze" might be premature due to iterative design refinements.

■ ADKAR: Benefit: Ensures individual understanding and buy-in to new design elements by statisticians and clinicians. Challenge: May not fully address the collaborative nature of design. ■ Kotter's: Benefit: Useful for significant design changes requiring leadership support and a clear vision. Challenge: Can be time-consuming for minor design adjustments.

■ McKinsey 7-S: Benefit: Helps ensure the new design aligns with the trial's strategic goals, available resources (staff, skills), and existing systems. Challenge: Primarily an analytical tool, less prescriptive for implementation.

■ Bridges': Benefit: Can help manage the emotional transition for researchers moving away from familiar design paradigms. Challenge: Less focused on the technical aspects of study design.

■ Agile: Benefit: Highly adaptable for iterative design processes, allowing for continuous feedback and adjustments. Challenge: Requires a flexible regulatory environment to accommodate frequent changes. ○

7.2 Site Initiation:

■ Lewin's: Benefit: Can prepare sites for new study protocols or technologies. Challenge: May not

adequately address the logistical complexities of site activation.

■ ADKAR: Benefit: Ensures site staff are aware of and trained on new study requirements and procedures. Challenge: Requires significant effort for individual follow-up at multiple sites.

■ Kotter's: Benefit: Useful for large-scale changes affecting multiple sites, ensuring a unified approach. Challenge: May be overkill for routine site initiations.

■ McKinsey 7-S: Benefit: Helps ensure that site capabilities (staff, skills, systems) are aligned with the study requirements. Challenge: Less focused on the immediate steps of site activation. ■ Bridges': Benefit: Can help manage the transition for site staff learning new protocols and procedures. Challenge: Less focused on the practical aspects of setting up a new study site.

■ Agile: Benefit: Allows for iterative refinement of site initiation processes based on feedback from early-activated sites. Challenge: May require flexibility in contractual agreements and regulatory submissions.

7.3 Patient Recruitment:

■ Lewin's: Benefit: Can help "unfreeze" outdated recruitment strategies.

Challenge: Does not provide specific recruitment techniques.

■ ADKAR: Benefit: Ensures recruitment teams are aware of new targets and strategies and are motivated and equipped to implement them. Challenge: May not address external factors influencing recruitment.

■ Kotter's: Benefit: Useful for implementing significant changes in recruitment strategy requiring a strong coalition and a clear vision. Challenge: May be too structured for the dynamic nature of recruitment.

■ McKinsey 7-S: Benefit: Helps align recruitment strategies with the trial's overall goals, available resources, and the skills of the recruitment team. Challenge: Less focused on the real-time adjustments needed in recruitment.

■ Bridges': Benefit: Can help manage the emotional impact on recruitment teams when facing challenges in meeting enrollment targets. Challenge: Does not offer specific solutions for improving recruitment rates.

■ Agile: Benefit: Allows for rapid testing and iteration of different recruitment strategies based on real-time data. Challenge: Requires robust data tracking and analytics capabilities.

7.4 Data Collection:

■ Lewin's: Benefit: Can help transition from paper-based to electronic data collection. Challenge: Does not provide detailed guidance on data management.

■ ADKAR: Benefit: Ensures data entry personnel are aware of new systems, are trained, and can use them effectively. Challenge: Requires ongoing reinforcement to maintain data quality. ■ Kotter's: Benefit: Useful for implementing a new clinical data management system across the organization. Challenge: May be too rigid for addressing day-to-day data collection issues. ■ McKinsey 7-S: Benefit: Helps ensure that data collection systems align with the study protocol, staff skills, and data quality standards. Challenge: Less focused on the immediate troubleshooting of data collection problems.

■ Bridges': Benefit: Can help manage the transition for staff adapting to new data collection tools and processes. Challenge: Does not provide specific guidance on data validation or cleaning.

■ Agile: Benefit: Allows for iterative improvement of data collection processes and tools based on user feedback and data quality metrics. Challenge: Requires close collaboration between clinical and data management teams.

7.5 Analysis: ■ Lewin's: Benefit: Can help introduce new statistical analysis methods. Challenge: Does not provide specific analytical techniques.

■ ADKAR: Benefit: Ensures biostatisticians are aware of and trained on new analysis software or methodologies. Challenge: May not address the collaborative aspects of data analysis.

■ Kotter's: Benefit: Useful for implementing a major change in the statistical analysis plan or software across the organization. Challenge: May be too structured for the exploratory nature of some analyses.

■ McKinsey 7-S: Benefit: Helps ensure that the analysis plan aligns with the study objectives, the skills of the biostatistics team, and available software. Challenge: Less focused on the specific statistical procedures.

■ Bridges': Benefit: Can help manage the transition for biostatisticians adopting new analytical approaches. Challenge: Does not provide guidance on interpreting results.

■ Agile: Benefit: Allows for iterative analysis, with frequent feedback and adjustments to the analytical

approach based on emerging findings. Challenge: Requires flexibility in the statistical analysis plan and reporting timelines.

7.6 Reporting:

■ Lewin's: Benefit: Can help implement new reporting formats or guidelines. Challenge: Does not provide specific reporting standards.

■ ADKAR: Benefit: Ensures report writers are aware of and trained on new reporting requirements and templates. Challenge: May not address the review and approval process.

■ Kotter's: Benefit: Useful for implementing a significant change in reporting standards across the organization. Challenge: May be too structured for the iterative nature of report writing.

■ McKinsey 7-S: Benefit: Helps ensure that reporting aligns with the study objectives, regulatory requirements, and the communication needs of stakeholders. Challenge: Less focused on the technical aspects of report generation.

■ Bridges': Benefit: Can help manage the transition for report writers adapting to new formats or tools. Challenge: Does not provide guidance on data interpretation or dissemination.

■ Agile: Benefit: Allows for iterative development of reports, with frequent feedback from stakeholders and adjustments based on their needs. Challenge: Requires close collaboration between report writers and stakeholers.

8.SUITABILITY OF MODELS FOR SPECIFIC CHANGES IN CLINICAL TRIALS

Determining which models are best suited for implementing new CTMS, adopting new technologies, revising SOPs, and integrating new regulations.

8.1 Implementing a new Clinical Trial Management System (CTMS): Kotter's 8-Step Model, with its focus on large-scale organizational change and building a guiding coalition, is highly suitable for implementing a new CTMS.

The McKinsey 7-S Framework can help ensure alignment across technology systems, staff skills, and organizational processes. 45 Bridges' Transition Model is crucial for managing the human transition to a new system, addressing user anxieties and providing support.

8.2 Adopting a new data capture technology (e.g., EDC, ePRO): The ADKAR Model is particularly effective for ensuring individual adoption and skill development required for new data capture technologies.

The Agile Change Management Model's iterative approach allows for continuous feedback and adjustments during the rollout. 66 Bridges' Transition Model can help address the anxieties and resistance associated with learning and using new technologies.

8.3 Changing Standard Operating Procedures (SOPs): The ADKAR Model ensures that individuals understand the need for revised SOPs and have the knowledge and ability to adhere to them. 26 Lewin's Three-Stage Model provides a structured approach for unfreezing old practices, implementing new ones, and refreezing the updated SOPs. 2 Kotter's 8-Step Model can be valuable if the SOP changes are significant and require broad organizational buy-in and leadership support.

8.4 Integrating new regulatory guidelines: The ADKAR Model is essential for ensuring that all relevant personnel are aware of, understand, and can implement new regulatory guidelines in their work.

Kotter's 8-Step Model can create a sense of urgency around compliance and communicate the importance of adhering to the new regulations. 34 The Agile Change Management Model's adaptability allows for quick responses and integration of evolving regulatory landscapes into clinical trial processes.

9.BENEFITS AND CHALLENGES

Evidence-based recommendations on the most effective change management model(s) for the clinical trials environment, considering its specific complexities and priorities. Based on the analysis, a single "best" change management model for all situations in clinical trials management does not exist. The most effective approach often involves a tailored combination of models or principles, depending on the specific change initiative. For changes primarily impacting individual behaviors and adherence to protocols or new technologies, the ADKAR Model is highly recommended due to its focus on individual awareness, desire, knowledge, ability, and reinforcement. This model provides a structured way

to ensure that each person involved in the clinical trial is equipped and motivated to adopt the change successfully. For large-scale organizational changes, such as implementing a new CTMS or a major restructuring of clinical operations, Kotter's 8-Step Model offers a comprehensive and leadership-driven approach to guide the transformation. The McKinsey 7-S Framework serves as an invaluable tool for analyzing the broader organizational impact of any significant change, ensuring alignment across strategy, structure, systems, shared values, skills, style, and staff within the clinical trial ecosystem. To address the human element of change, particularly during disruptive transitions like trial terminations or significant protocol revisions, Bridges' Transition Model provides a framework for understanding and supporting the emotional journey of individuals. Finally, for changes in dynamic areas like technology adoption or adaptive trial designs, the Agile Change Management Model offers the flexibility and iterative approach needed to respond effectively to evolving requirements and feedback. Potential challenges in implementing these models in clinical trials include the highly regulated nature of the industry, the complexity of multi-stakeholder involvement, and the inherent resistance to change within established research environments. Strategies for overcoming these challenges include ensuring strong leadership support for change initiatives, engaging all stakeholders early and often in the change process, clearly communicating the rationale and benefits of the change, providing comprehensive training and resources, and continuously monitoring progress and adapting the approach as needed. In conclusion, adopting a structured and thoughtful approach to change management is critical for the continued advancement and success of clinical trials. By understanding the principles and applications of these various change management models, clinical trial professionals can enhance their ability to navigate the complexities of change, ensure regulatory compliance, maintain patient safety and data integrity, and ultimately contribute to the efficient and effective development of new therapies.

10.0 Contributions from this study

The study aimed to enhance the efficiency of the delivery model of Contract Research Organizations (CROs) in patient-centric trials by providing a comprehensive review of current change management practices and novel tangible toolkits. Change management is prevalent in any trial with patient-centric aspects. However, the clinical development industry continues to evolve towards more complex and patient-centric trial models in response to the 21st Century Cures Act. Inpatient consultations in direct-to-patient trials have been rapidly increasing and evolving, thereby trialing a change in the trial business model. Within this shift in trial operations, CROs are managing the majority of trials on behalf of their pharmaceutical sponsors. Therefore, it is essential for change management to be strategically applied to enhance the efficiency of patient-centric trial operations (Hockin, 2018).

As a result of this research, a foundation for CROs and stakeholders in patient-centric trials was provided, offering practical knowledge regarding current market scenarios and essential foundational theories. A detailed and systematic review of change management in other industries was completed to inform the status quo at CROs. Insights into the delivery model of CROs in patient-centric trials were then offered, the generation of a guide to support further and deeper review as needed. Additionally, the review identified the lack of any study in the public domain, solely focused on the delivery model of CROs in patient-centric trials, which prompted tangible change management toolkits to be developed, post-validation by experts. Therefore, specific novel toolkits arising from the literature to address this gap in knowledge will provide the foundation for innovation and competitive advantage in the industry.

11.0 Limitations and future scope of work

With rapid technological advances in the clinical field, the landscape of clinical trials and change management evolves continuously (Nanzayi Ngayua et al., 2021). The COVID-19 pandemic has had an impact on investment in new technologies, difficult patient recruitment and patient attitude challenges, patient compliance difficulties, and other barriers to traditional clinical trials with the development and reform of clinical trial technology (Leyens et al., 2022). From registration engagement to study closure, numerous stakeholders have a pivotal role in change management practices within clinical trials. Although existing literature has coped with the emergence of novel technologies and innovative change methods in the clinical field, the discourse regarding change management within clinical trials has mainly occurred

within the field of project management. In the clinical field, change management is interrelated with regulatory affairs and affects project management, but also it should have a structured and systematic approach in supporting completion of changes to the trial. At all degrees within the field of clinical trials, technology is reshaping operations. While technologies are multiplying, stakeholders find it difficult to trace the evolution of how technologies reach the clinics, design considerations and actual implementation in trials.

Modern technologies have already been adopted in clinical trials. Briefly after, electronic data capture systems were broadly adopted, and nowadays most trials are conducted in electronic case report forms systems. The adaptation of ICH including requirements for advanced technology safeguard plays a pivotal role. However, the impact of technology in clinical trials is not restricted to the type of data system used. It passes through all degrees of execution and operations, covering recruitment, retention, and follow-up; data monitoring and management; statistical evaluation; essential monitoring; etc. The technological advancements that have been enabled in the clinical trial state include big data warehousing, a mix of diverse data sources, progress in monitoring technologies, implementation of data analytics employing artificial intelligence, automation of data handling and exchange, and modification of the data flow based on remote data capture. This results in numerous options and policies that, even for knowledgeable and trained incumbents, it is challenging to track when and how to execute them. In addition, numerous technologies, like social media promotion, patient monitoring devices, or e-consenting tools, are created and brought to actions by new persons who may not be known to the co-researchers.

12.CONCLUSION

Change management plays a critical role in clinical trials, where regulatory demands, technological advancements, patient engagement strategies, and evolving protocols require constant adaptation. The success of a clinical trial often hinges not only on scientific rigor but also on how well change is managed across stakeholders — from sponsors and CROs to investigators and patients. In this complex and highly regulated environment, effective change management models ensure smooth transitions, minimize resistance, and support compliance, quality, and continuity.

Declaration Statement

I, declare that this research paper is my original work and has not been submitted for any other degree or publication. I affirm that all sources used in this paper are properly cited and acknowledged. Additionally, I confirm that there are no conflicts of interest related to this research, and any funding received for this project has been disclosed.

Ethics approval and consent to participate= Not applicable Consent for publication = Yes

Competing interests = No Funding= No

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