

Leading Teams Through Clinical Data Transformation with Storytelling

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ABSTRACT

In an increasingly fast-paced and demanding development landscape, leaders are challenged to optimize technology, workflows, and skills to effectively manage trial complexity in less time and with fewer resources. As part of this, organizations must also embrace a new vision and mindset for the future. While exploring and implementing new ways of working, story sharing can illustrate the transformative potential of data science optimization and empower team members to 'think big' so they can develop innovations of their own. This session will explore the instrumental role of storytelling in the strategic toolkit of modern data leadership. Attendees will learn practical strategies for helping teams working with clinical data not only confidently navigate change, but also become champions of change. At this critical time in drug development, incorporating personal stories, vision stories and case studies into change management can enhance organizational purpose and successfully mobilize future-ready teams.

INTRODUCTION

This paper will explore clinical data transformation drivers across the industry and the instrumental role of storytelling while leading through this evolution. Additionally, approaches for incorporating personal stories, vision stories, and case studies to enhance organizational purpose and inspire teams to confidently navigate change will be highlighted.

INDUSTRY TRANSFORMATION DRIVERS

Data is the critical asset of life sciences, and how that data is managed - from acquisition to insight - plays an instrumental role in clinical development success. Summarized below are four key drivers that serve as catalysts for an evolved approach to clinical data management and are shaping a clinical data vision for modern clinical trials.

1. INCREASING VOLUME AND COMPLEXITY OF CLINICAL TRIAL DATA

The availability of patient-generated data from electronic health records, wearables, and other remote monitoring devices has led to an exponential increase in both data volume and variety. Additionally, personalized medicine, difficulty accessing patient populations in rare diseases, and the need to reflect diversity within clinical trials are all factors driving an uptake of innovative trial approaches including adaptive designs, enrichment strategies, and master protocols. Adoption of these designs can improve trial efficiency and patient outcomes, but also lead to increased data complexity, and, in turn, demand new skills from clinical programmers, clinical data reviewers, data managers, and biostatisticians.

2. INCREASED MOMENTUM TOWARDS PATIENT-CENTRIC TRIALS

The trend towards patient-centricity in clinical trials has significant implications for biometrics functions. Decentralized and hybrid trial models, which aim to 'meet the patient where they are' involve the remote collection of real-world data from patients, and the use of wearable technology and other digital tools. This momentum brings with it a requirement for biometrics teams to manage and analyze large volumes of data from multiple sources, often in real time. The sheer volume of data requires a greater focus on what data is truly 'critical' with biometrics teams applying risk-informed approaches, and robust technologies and workflows to manage external data that is collected outside EDC (Electronic Data Capture).

Data scientists also need to think beyond traditional clinical trial endpoints and consider outcomes that reflect the patient's experience with the disease or treatment. Ensuring participant diversity has also become a pressing priority and data-driven strategies are key to overcoming underrepresentation by providing real-time insights about enrollment. At the same time, the imperative to give patients with unmet needs faster access to new medicines, is ushering in adoption of 'complex' clinical trials. For example, master protocols, enrichment strategies, and innovative adaptive designs are now commonly used approaches for generating clinical data with greater operational efficiency and reduced patient burden.

3. RISK-BASED STRATEGIES

Against the backdrop of trial complexity, incorporating risk-based approaches enables clinical teams to focus their resources on the most critical data, ensure overall quality, patient safety and comply with ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) and regulatory guidance. As well as meeting these requirements from regulatory agencies to use effective risk management practices, there is growing recognition of the value of risk-based approaches in improving efficiency and cost-effectiveness of clinical trial

operations while reducing the burden on teams. Incorporating RBQM (risk-based quality management) typically involves adopting innovative technology platforms, developing standard operating procedures (SOPs) and upskilling staff on RBQM practices.

4. ARTIFICIAL INTELLIGENCE, MACHINE LEARNING, AND AUTOMATION

The eClinical Solutions' Industry Outlook 2024 discovered that 50% of respondents felt that AI/ML was the industry trend set to have the greatest impact in the next 12 months on efficiency and outcomes. Yet, the vast majority of survey respondents highlighted that they were in the exploratory phases of AI (Artificial Intelligence) adoption. Clearly, there is a gap for the industry to bridge between exploring potential uses of AI/ML and realizing its value, so a collaborative industry-wide effort will be needed to overcome these barriers and realize meaningful results within this timeline.

CLINICAL DATA TRANSFORMATION AND STORYTELLING

Storytelling is universal to human experience, helping us to make sense of the world, communicate and connect with others and deepen emotional engagement. All these elements are also critical for leaders to help engage with teams, influence, and build trust. At the same time, the rapid pace of change demands exceptionally effective leadership. Storytelling offers a compelling strategy helping clinical data leaders to navigate this pivotal moment of transformation. Through storytelling skills, leaders can better align their teams around a compelling vision, to foster a shared understanding and commitment to innovation.

THE CORE ELEMENTS OF A GREAT STORY

The key elements of a compelling story reflect many of the critical components needed to lead teams through transformation.

Characters

Leaders need to assemble the key players within the team to drive clinical data transformation, including traditional and newer roles within a clinical data science framework. Their roles closely intersect and collaborate to drive the necessary change.

Setting

Any transformation journey begins with a rigorous assessment of existing processes, technologies, and skill sets to identify gaps based on the organization's needs. Deeply understanding the current state is imperative to navigate the path forwards.

Conflict

Clinical data transformation requires leaders to navigate the tension between innovation and tradition and overcome the inherent challenges of pushing boundaries.

Plot

To build momentum and drive change, leaders need to build trust within their teams for the transformation initiative. We need to clearly illustrate how team members across the data science disciplines stand to benefit from changes. By highlighting incremental victories, and sharing stories and examples about these, as leaders we can instill confidence and show tangible progress towards the overarching goal.

STORYTELLING TECHNIQUES TO INSPIRE AND ALIGN TEAMS

In a recent article in the Harvard Business Review, Frei and Morriss discussed the role of storytelling in several successful business transformations and break down the core components for success. They stressed the need to understand your story so deeply that you can describe it in simple terms, recognize what has gone before to provide continuity, lay out the rationale and imperative for change, and chart an optimistic path forward. In our experience at eClinical Solutions, we have leveraged several aspects of this approach both internally and externally to help drive transformation.

Focus on why

Change is a strategic imperative, since traditional methods of handling the volume, variety and velocity of data that we face are not scalable.

Simplify the complex

Our industry is deeply complex, but focusing on tangible outcomes allows us to simplify our message.

Know the numbers

Numbers matter in a compelling story and allow us to clearly communicate results.

Convey optimism

The road ahead may be challenging, and progression is not always linear, but as leaders it is critical that we bring our teams together with enthusiasm and celebrate the wins on the way.

Communicate and overcommunicate

The same message can be retold in multiple formats, in 1:1s, team meetings, town halls, and in thought leadership presentations. When a story is retold, it sticks and empowers team members to join us as champions of transformation.

Beyond these core principles, several kinds of storytelling, including personal stories, vision stories, and case studies help us as leaders to motivate teams and inspire a greater sense of purpose during clinical data transformation.

PERSONAL STORIES

Personal narratives from individuals about overcoming challenges foster a sense of connection and shared commitment. By sharing our own and others' stories of overcoming challenges, leaders can illustrate the power of resilience and growth to connect with team members on a personal level and create a metaphor for overcoming obstacles during the process of clinical data transformation.

VISION STORIES

Leaders can use vision stories to paint a vivid picture of the future state where technology, processes and people come together more seamlessly to advance clinical development through innovative data transformation.

CASE STUDIES

Case studies are vital internally and externally to highlight challenges faced, the strategies implemented, and the measurable outcomes achieved in any given clinical data transformation project. Sharing practical insights and providing forums for teams to share their experiences with one another helps all functions to learn from one another's successes and failures, to cultivate a deeper understanding of effective approaches. It is also helpful to provide examples of 'what good looks like.'

CONCLUSION

Leaders must know how to tell the story, to realize the vision. The rewards of success are high, including positive impacts not only on productivity measures such as decreased cycle times and increased efficiency, but also employee retention and wellbeing, while creating champions within our own organizations and beyond.

RECOMMENDED READING**[Storytelling that drives bold change, how to craft a narrative that matters](#)**

Harvard Business Review, December 2023

Frances X. Frei and Anne Morriss

[Industry Outlook 2024: Driving Clinical Data Transformation, eClinical Solutions](#)

eClinical Solutions, January 2024

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