WHITE PAPER

TATA CONSULTANCY SERVICES

Adopting a Design Thinking Approach for Successful Implementation of Risk-Based Monitoring

Abstract

Most drug manufacturers end up investing more than USD 2 billion and as long as 12 years[1] in the entire process of drug discovery all the way to marketing approvals. Clinical trials form a critical part of this process, and require oversight of participating investigators and sites to ensure protocol adherence, safety of patients, and integrity of data.

However, the conventional method of site monitoring has proven to be inefficient since it accounts for 40% of clinical trial costs[2], with a measly 7% return[3] on the impact of data. Furthermore, with the social distancing norms and travel restrictions triggered by the COVID-19 pandemic, traditional methods of site monitoring are proving even more ineffective. A design thinking approach for risk-based centralized monitoring can offer a solution to these challenges while paving the way for more efficient and cost-effective clinical trials.

[1] *DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics 2016;47:20-33*

[2] *Sertkaya A, Wong HH, Jessup A, Beleche T. Key cost drivers of pharmaceutical clinical trials in the United States. Clin Trials. 2016;13(2):117-126. doi:10.1177/1740774515625964*

[3] *https://www.transceleratebiopharmainc.com/wp-content/uploads/2013/10/TransCelerate-RBM-Position-Paper-FINAL-30MAY2013.pdf*

Critical Success factors – Technology and Experience Design

With the COVID-19 pandemic introducing lockdown restrictions and social distancing norms, the world around us has changed rapidly. However, technology can act as an enabler and bring normalcy. In this context, risk-based centralized monitoring (RBM) has emerged as a viable solution to ensure the continuity of clinical trials while travel restrictions are in place.

Risk-based clinical site monitoring relies on a model of centralized risk identification, control, review, reporting, and communication, without the need to visit the sites. It helps reduce costs and allocate more resources to patient safety and sites that require additional oversight. On the patient side, it reduces the effort needed in traveling to remote site locations, especially considering the current situation.

While it incorporates many aspects, data-driven smart analytics is at the core of any RBM solution. The solution must have the capability to ingest data from multiple data sources, standardize it, and present it to end-users for deriving actionable insights. For this to happen in time, technology is pivotal. However, another important, yet often ignored, aspect is the in-depth understanding of personalized user needs and a design that fulfills it.

Successful implementation of RBM requires a user-centric design approach, the right technology, a well-defined centralized monitoring process, and an integrated team of stakeholders aligned to a common goal.

Design Thinking – Creating the Right Start

Design thinking workshops can help bring all the stakeholders together and establish consensus around the expectations from an RBM solution. It provides a common platform where people from different regions and backgrounds can share their diverse experiences. Since each participant in the workshop has a unique vision of what the final product may look like, a comprehensive view can be created right from the start.

For instance, the vice president of a large American pharmaceutical firm shared an interesting perspective during their RBM journey. He envisioned a data-driven, smart analytics integrated solution powered by the latest AI and predictive technology, with minimal training cost and the highest level of user acceptance. Such a solution can completely transform the way RBM works in the organization. He, however, emphasized the need to make a simple and efficient system that is acceptable to the clinical research associate (CRA).

CRAs are one of the key stakeholders impacted by RBM implementation. Such a fundamental shift in the process of site monitoring calls for more in-depth technical expertise and understanding from CRAs. They would not only be required to handle the system efficiently but also possess thorough

knowledge of their trials, sites, and patients. This would ensure that CRAs can act as a critical link between the clinical team and the site team. Their role would also evolve to include decision-making aspect on risk analysis of a site, instead of just focusing on the compliance and accuracy of data on sites.

During our design thinking workshops, we interacted with multiple CRAs from different regions. All of them were from different backgrounds and had different stories to tell. A young CRA joined an organization with a dream to make a difference in the lives of the patients. She wanted to make the trial monitoring effective, especially in oncology trials, as one of her closest friends had cancer. She hoped for an intuitive system, with actionable insights, visual cues on the risk score of each site, timely reminders, enabling her to focus her time on high-risk sites, and protocol conduct-related problems.

Another CRA was extremely good at crunching numbers and using charts and figures to make decisions. She suggested that there could be a health indicator, or a scorecard of the sites based on their risks and current performances, just like her home budget health indicator offered a sense of how her home budget was performing.

Enabling collaboration, co-creation, and democratic design can make it possible for end-users to share not only functional requirements but also unique ideas based on the daily life activities. A design-thinking approach for RBM adopts the same philosophy. Using tools like persona detailing and journey sketching, a design thinker weaves a holistic tale to put all the pieces together.

Design done right is extremely powerful and bases itself on psychological principles. It takes into account the power of the subconscious mind in influencing choices, decisions, and many unspoken requirements based on past experiences, memories, dreams, and inspirations of the end-users.

For driving transformational changes according to the user needs, the focus cannot just be on the visual aesthetics; it needs to incorporate a more in-depth analysis of the unsaid needs of the user. The view must be telescopic and not microscopic.

Organizations that are just getting started with RBM can benefit significantly from design thinking workshops. These workshops can help them acquire stakeholder involvement and align everyone to a common goal. By putting together a team of experienced individuals, organizations can create a unique RBM journey.

Design Thinking – Key Aspects

Design thinking, when done right, can revolutionize the overall product experience in multiple ways. Let us look at a few key attributes:

- Involving stakeholders, influencers, and affected parties from day one and clearly defining the communication mechanism is critical.
- Design thinking operates on iterative experimentation, that helps arrive at solutions that are markedly and substantially enhanced.
- A one-time workshop at the beginning does not suffice. Follow-up visualization sessions and connects with the end-users are paramount for the consistent, continuous evolution of the product.
- Design thinking is a creative and collaborative process, and thus should not be siloed with the conference room meeting approach. Design thinkers need to don the hat of a leader and drive this initiative in an informal, fun way. The core intent of this exercise is to build a relationship of trust with the end users that translates into them sharing their unspoken, subconscious needs in addition to the functional ones.
- Empathy for the end-user is the core of the entire user-centered design process. It is imperative to be a keen listener and observer for understanding each user's inputs, mannerisms, behavior, and actions.
- An open and encouraging atmosphere and acceptance of all kinds of ideas and feedbacks are non-negotiable factors.
- Finally, it is vital to set the expectations of the users at the beginning and end of the session to bring a clear awareness and understanding of the product roadmap.

Conclusion

In the life sciences segment, creativity and design play a symbiotic role in enabling solutions powered by futuristic technology. In a world that is constrained by a pandemic, RBM solutions are the need of the hour. Design thinking helps transform the highly technical and jargon-heavy product experience into an easily understood and assimilated one that is mapped to patient needs and provides a 360-degree view of patient health. Quite figuratively, design thinking helps bring life to the sciences.

About The Author

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Shalini Arora heads TCS Interactive Lifesciences.
She is a passionate design thinker leading human centered design workshops across the globe. With over 23 years of IT experience she has performed various roles across strategy, User Experience Design COE enablement, and delivery for various lines of business. Shalini is a patent holder for an indoor positioning system using mobile technologies and bluetooth devices. She holds a master's degree in computer application and has also represented TCS at the open group conferences across the world.

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Digital Advantage for Life Sciences

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