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Revolutionizing Clinical Trials: The Power and Potential of Risk-Based Monitoring

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Risk-based monitoring (RBM) is a modern approach to clinical trials, shifting from the traditional frequent on-site monitoring toward a more targeted and flexible strategy. RBM is designed to enhance the efficiency and effectiveness of trials while maintaining data integrity and patient safety.

RBM commonly is conflated with remote monitoring or is assumed to eliminate on-site monitoring. In fact, all clinical trials require some on-site monitoring, and remote monitoring is just one element of RBM. Additional misconceptions surrounding RBM include diminished data quality, disruptive process changes, or inconsistency across operations. Also, RBM is sometimes believed to diminish trial oversight, when it actually increases overall trial oversight. It balances "must do" data collection and "nice-to-have" data against site and patient burden — and, more importantly, patient safety.

AIM SMALL: TARGET SPECIFIC PRIORITIES

Targeted priorities, including monitoring, strive for more efficient allocation of resources to areas of higher risk and/or those with the most significant impact on patient well-being, shifting monitors' focus from routine on-site monitoring to focused risk-based monitoring. This approach emphasizes data quality through monitoring of critical data points, critical safety points, and adverse event reporting — reducing the likelihood of errors and inconsistencies during the trial.

Strategic application of remote monitoring enables timely access to data and enhances collaboration between investigators, CRAs, and other trial stakeholders. This, in turn, fosters an environment where on-the-ground personnel have more timely access to the people and other resources they need to perform their jobs at a high level. In this way, adopting remote monitoring in your RBM approach can promote clinical trial proactivity, efficiency, and transparency.

Rather than demanding that a monitor pore over the data to perform 100 percent source data verification (SDV), RBM implements technology and leverages other trial stakeholders — such as the data management and medical teams — to handle source data review. This frees up monitors to perform more value-added activities while serving to enhance data quality. While combining multiple elements of RBM can feel like a daunting strategic shift for the clinical research industry, the resulting efficiency and adaptability make RBM appropriate for trials of any size or complexity.

IMPLEMENTATION: WHAT DO YOUR SITES NEED TO SUCCEED?

In addition to remote monitoring and a flexible monitoring strategy, risk assessment is a key aspect of RBM. This comprehensive assessment of potential risk associated with the clinical trial must be performed for each participating site. It examines data quality, patient safety, and other operational aspects of the trial while also seeking to identify potential mitigation strategies.

The type and degree of risk varies depending on the clinical trial itself and the sites, which may differ in terms of personnel experience, resources, and capabilities. So, implementing RBM requires a tailored monitoring strategy fitted to each site-specific risk profile. In addition to determining each site's nuances, the assessment must reveal what is necessary to help the site perform well, be it training and technology or more effective change management and open communication.

This process can be logistically challenging and may involve inconsistencies across several sites, depending on their established processes. Moreover, ensuring seamless technology adoption — typically an element of RBM but, again, the type and complexity of the technology vary — across multiple stakeholders can be challenging due to inconsistent technological expertise. Thus, risk assessment does not provide a uniform solution.

EASE THE TRANSITION

All of this flexibility also introduces the challenge of change management when implementing RBM. Moving away from well-established monitoring parameters changes the mindset and processes for various stakeholders in the company. So, it involves overcoming resistance to change and managing the transition effectively through collaboration between the sponsor, each site, the CRO, and regulatory agencies.

Encouraging communication and collaboration between these parties ensures seamless exchange of information, maintaining crucial transparency throughout the clinical trial life cycle. RBM uses centralized monitoring and data collection, allowing trial data to be continuously reviewed remotely via advanced data analytics and visualization tools. This transparency and accessibility enable early detection of potential issues or anomalies in the trial data, contributing to greater data integrity.

RBM does not necessarily have to be implemented at the beginning of a clinical trial. However, early implementation reduces unnecessary burdens of risk and enhances efficiency and trial effectiveness from the program's outset. All stakeholders involved in the clinical trial process need to be educated and trained on the principles and practices of risk-based monitoring. So, the trial timeline must consider the need to provide adequate training and support to ensure consistent understanding and implementation of the new approach.

LOOKING FORWARD

RBM will continue to promote data transparency and integrity through centralized monitoring, documenting risk assessments and monitoring plans, as well as actions taken in response to the identified risks. That documentation enhances accountability and ensures clinical trials align with evolving regulator expectations. Notably, regulatory agencies such as the FDA have expressed support for risk-based monitoring approaches that ensure data quality and patient safety.

As RBM matures, it will contribute even more to enhanced data quality, focusing intently on trial data collection, filing, and associated processes to reduce the likelihood of errors and discrepancies. RBM also will be increasingly trusted as a cost- and time-saving tool as sponsors and sites become more proficient

in targeting monitoring activities to areas with higher risk and reducing on-site visits to lower-risk sites. Ideally, this creates a ripple effect, minimizing monitor and investigator workload (and, by extension, stress and burnout/turnover), helping them to feel informed and supported in all situations.

RBM approaches also will accelerate clinical trial timelines by identifying and addressing issues promptly – allowing sponsors to make faster, more well-informed decisions that lead to faster recruitment and data analysis. To learn more, contact the author and visit https://inseptiongroup.com.

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ABOUT THE AUTHOR

With a clinical research career spanning nine years, Olubukola ("Bukky") Oseni brings to inSeption Group regulatory, GCP, and study coordination expertise, as well as patient recruitment prowess and a commitment to advancing healthcare through rigorous clinical trials. Olubukola has successfully managed multiple trials across various therapeutic areas, from oncology to neurology. A collaborative and detail-oriented professional, she works effectively with cross-functional teams — including investigators, sponsors, and site staff — fostering productive relationships that drive successful trial outcomes. Additionally, her experience in risk assessment and mitigation strategies has been instrumental in identifying potential issues early in trials and implementing solutions to keep them on track.

ABOUT INSEPTION GROUP

inSeption Group is a full-service, global outsourcing organization built on a foundational culture of exceptional service and quality. This culture attracts a subset of people who take a personal responsibility to deliver on what has been promised. inSeption Group's ability to custom-build teams with these experts, while providing valuable continuity, distinguishes our approach from traditional outsourcing options.

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