Enhancing Clinical Study Monitoring with SmartSignals® Unified Platform

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Clinical study monitoring is crucial for ensuring the quality and integrity of data collected during research. Traditional monitoring methods consume a significant portion of a study's budget but only lead to marginal improvements in data accuracy. With the rising costs and complexity of clinical research, the pharmaceutical industry needs more efficient and flexible approaches.

The Inefficiencies of Traditional Monitoring

Traditional clinical study monitoring relies heavily on full on-site monitoring and extensive verification of EDC entries against source documents. These activities require substantial monitoring resources and involve extensive travel. Studies by Transcelerate and the British Journal of Clinical Pharmacology have shown that less than 1.5% of clinical study data is typically updated due to source data verification. Even 100% SDV does not result in error-free study data, with the error rate only marginally better than when applying reduced SDV.

Remote and Reduced Monitoring: Building Blocks for Future-Proof Strategies

CROs and sponsors are increasingly adopting remote and reduced monitoring to manage costs while maintaining data quality. This approach involves a better understanding of critical data and processes and the risks that must be handled during a clinical study.

With this understanding, CROs and sponsors can develop a targeted monitoring approach that focuses on what matters most and tailors the approach based on the needs of individual investigator sites. Some sites may require full on-site monitoring or source data verification, while others can benefit from reduced on-site monitoring in favor of a more holistic review of data, metrics, and risk indicators.

Adoption Challenges

Despite the introduction of risk-based approaches before the COVID-19 pandemic, the adoption of remote and reduced monitoring was limited due to fears of overlooking issues and uncertainties about regulatory acceptance. Variations in country-specific regulations, such as data privacy and remote access to health records, also posed barriers to widespread adoption.

The COVID-19 pandemic forced the industry to pivot, making remote and reduced monitoring the new "normal" as clinical studies continued under lockdowns and travel restrictions. While agencies have returned to stringent regulatory requirements, they now recognize risk-based approaches, including reduced and remote monitoring, as viable concepts and refer to them in recent regulatory guidances.

Future-Proof Study Monitoring with Signant SmartSignals® Unified Platform

Our targeted monitoring module allows CROs and sponsors to build a powerful monitoring strategy driven by configurable algorithms. These algorithms determine which patients, forms, or data points require verification and can be combined to develop a monitoring approach where sites are assigned rules triggering either higher or lower data verification based on their risk profile or performance during the study.

CRAs rely on a dynamic monitoring workflow report that identifies the patients, forms, and data requiring verification based on these algorithms. This report enables them to easily verify the required data and track their activities.

Our document upload module provides an easy-to-use interface for site users to upload and maintain copies of source documents, making them available to CRAs for remote verification. CROs and sponsors can use this capability to reduce on-site monitoring in favor of remote verification, thereby reducing travel costs and time on-site. CRAs can also use this to optimize the preparation and follow-up of their on-site monitoring activities, increasing their efficiency while at the investigator site.

Conclusion

Signant's SmartSignals® Unified Platform offers a powerful and flexible approach to clinical study monitoring through its integrated remote and reduced monitoring capabilities. This allows CROs and customers to better manage costs and target their monitoring efforts toward the investigator sites, patients, and data that matter most.

About the Author

Jan Breemans advises Signant Health and its customers on the value and use of eclinical solutions and data analytics in the oversight of their clinical development programs. With over 20 years of experience on the sponsor side, Jan has gained substantial expertise in data management and analytics, project management, and clinical systems management. He holds a Master's degree in Biochemistry and a post-graduate qualification in Relation and Communication Management.

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