

TRANSFORMING RISKS INTO RETURNS: XCELLERATE® MONITORING CASE STUDY

A large multinational drug company engaged Covance to conduct a series of Phase III studies for a new cardiovascular medication. The studies involved roughly 10,000 patients across more than 260 sites in nearly 40 countries.

Understanding the Challenge

- ▶ Low incidence of cardiovascular endpoints
- ▶ Exceptionally large volume of complex data
- ▶ Need for quality and consistency across a large number of sites

Meeting and Exceeding Expectations

To best transform risks into returns, our cross-functional Xcellerate® monitoring team undertook a risk assessment before finalizing the design of our client's Phase III trial. For example, our analytics team created a model that forecasted the rate of endpoints. As a result, we identified the need for additional sites to increase the number of enrolled patients and decrease the risk of not meeting the statistical power of the study. We also reviewed the data collection instruments and monitoring processes to help focus the data and to more efficiently use resources. Finally, based on insight from past experiences, we proactively created a set of reports that helped manage project workload by integrating data across all sources. Bottlenecks in data cleaning and query resolution were identified and additional monitoring support was sent to targeted sites with a high potential for risk to enhance precision delivery and shorten timelines.

The holistic risk-based monitoring approach helped enable fit-for-purpose high-quality clinical data, resulting in successful applications for FDA and EMA approval. All databases were locked on time and the required study endpoint goals were met. Finally, proactively identifying sites for corrective action early on focused the team and enabled us to be properly prepared for audits and inspections.

Risk is a fact of life in drug development. But with risks being properly identified and effectively managed, it is possible to achieve more efficient use of resources, higher-quality data and greater value from your study.

Learn more about our drug development solutions at www.covance.com

Covance Inc., headquartered in Princeton, NJ, is the drug development business of Laboratory Corporation of America® Holdings (LabCorp®). Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

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