TRANSFORMING RISKS INTO RETURNS: XCELLERATE® MONITORING CASE STUDY

A large, multinational drug company engaged Covance to conduct a Phase III endpoint study randomizing more than 10,000 patients across roughly 40 countries and between 500 and 600 sites.

Understanding the Challenge

- Maintaining effective site quality and exceptional data and source document verification (SDV) despite the large number of sites and volume of data
- Proper resource planning
- Holding level of lost-to-follow-up (LTFU) below one percent

Delivering Solutions Using Xcellerate® Monitoring

Creating insight by leveraging our risk-based monitoring approach, we designed and implemented a quality dashboard to enable the project quality control team to identify sites exhibiting risk factors that might generate quality issues. To proactively and accurately determine a site's risk of generating issues, the team continually monitored such factors as enrollment data, data entry by site, query generation and resolution rates, protocol deviations noted by monitors and endpoint rates. If a significant issue was identified based on these data trends, remedial action was triggered for prompt execution.

To maximize resources, our modeling team enhanced current tools to predict eCRF flow and monthly backlog, based on enrollment and expected visits at a site level. Additionally, we built a resourcing model using actual patient recruitment and patient visit numbers to enable accurate and adaptive clinical and data management allocation. As a result, we were able to support sites by identifying where issues were clustered and instruct sites how to better complete data entry and reduce query loads. These efforts helped to maintain a data cleanliness level of more than 80 percent throughout the study.

One of the innovative Xcellerate® Monitoring approaches used for this trial was the implementation of Medidata's tSDV tool. This module allowed the project quality control team to track SDV and proactively implement additional monitoring and quality control visits of at-risk sites. Initiating the tSDV module provided ease in tracking SDV with a full audit trail.

Second, at the start of the study, the quality control team, along with our academic research organization (ARO) partner, implemented a study-specific retention and LTFU plan. By seeing early trends at a site-specific level, additional intervention to aid sites in following patients' post-discontinuation of study drug was implemented as appropriate. Driven by the central importance to the study, focus on LTFU was included in the informed consent form and database build.

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Finally, for precise delivery of endpoint adjudication, we developed a volume management and escalation plan that operated at different tiers of risk. This effort was guided by monitoring adverse events, serious adverse events and visit status.

Our relentless commitment to deliver precisely and advance our client's study as expeditiously as possible was confirmed by meeting targets for an on-time and on-budget database lock, as well as by achieving a less than 60-day cycle time from event identification to full adjudication. In addition, no critical findings were revealed during data audits and all patient retention goals were met.

In large outcomes trials, managing risk is critical. Identifying and effectively addressing it early on will help achieve scientific integrity and put you on the path to success.

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

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