SOLUTIONS MADE REAL THROUGH FOCUS ON PRECISION AND SPEED

Quality Data Rescue

A pharmaceutical company engaged Covance to rescue a global clinical trial for a multiple sclerosis drug. The study contract, originally awarded based on the ease of working with one single laboratory in the US, had already cost the company approximately $250,000 dollars (US) and, 10 months on, the central laboratory service provider had failed to deliver the quality service promised. The program, covering multiple protocols progressing through Phases I, II and III, involved over 645 patients across 109 investigator sites, in 2 countries.

Understanding the Challenge

- Ensuring that samples reached the laboratory within stability, to avoid patient re-draws
- Assuming full responsibility for sample collection and tracking, to save the client's own resources
- Streamlining data formatting before transfers, to deliver timely, quality data
- Providing a flexible, user-friendly, web-based reporting system backed up by competent, responsive support to help personnel meet their reporting goals

Rigorous Operations, Insights and Client Support Deliver Quality Reporting

Leveraging more than two decades of experience in multiple sclerosis trials, Covance quickly put together a cross-functional team whose first task was to review the client's requirements in terms of logistics and data management. Because the client's study had been compromised by substandard processes in both areas, the team's priority was to switch to the rigorous specimen collection and data reporting processes developed by Covance's central laboratory. From the outset, our project managers worked closely with the client's clinical team to ease the transition. By analyzing the study design and identifying the client's needs and previous issues, using insights from past experience, we were able to explore and suggest new ways to improve specimen management and data transfer.

With the previous provider, samples too frequently arrived at the lab out of stability and were not adequately tracked. We immediately started to label packages in line with Covance's rigorous automated tracking standards. As soon as we implemented this new process and proactively addressed shortcomings with couriers, tracking and sample collection timelines improved, ensuring testing within stability and reducing patient re-draws.

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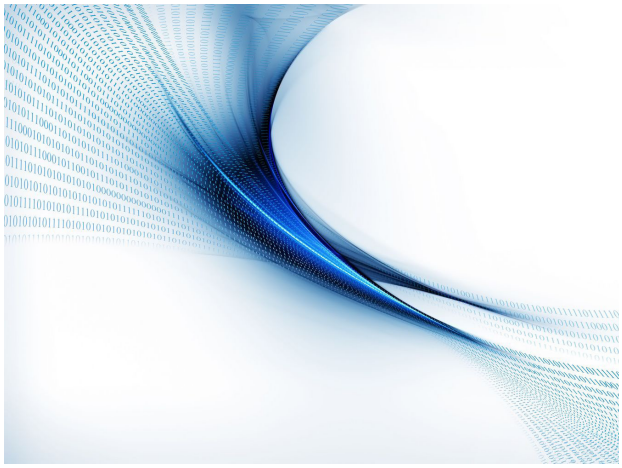
We then utilized our operational capabilities to enhance data reporting. By giving the client access to LabLink+, our web-based data monitoring and reporting tool, and supporting users through a dedicated trainer, we enabled them to monitor data and easily generate both standard and customized reports.

In order to expedite data transfers while preserving quality data, we tested, adjusted and finalized all data formats prior to their first transmission, putting an end to months of delays. In the end, by relentlessly focusing on delivering quality data, proactively implementing rigorous operational processes, supporting and communicating with the client at all times, the Covance multi-functional team succeeded in placing the study onto a proper path.

Navigating the various phases of a global clinical trial can be challenging. If you choose Covance's depth and breadth of experience, together we will explore new opportunities to deliver precision and maximize your chances of success.



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