PRECISION DELIVERY AND OPERATIONAL EXCELLENCE RESTORE DATA QUALITY

Timely Accurate Reports

A pharmaceutical company engaged Covance to rescue a large global Phase III clinical trial program for a hepatitis drug, involving over 3,000 patients across 363 investigator sites, in 20 countries. The study contract, originally awarded on the basis of quality promises and low price, had already cost the company an estimated $3 million dollars (US) and, 2 years into the program, the central laboratory service provider had failed to deliver the quality expected by investigators.

Understanding the Challenge

- Cleaning up barely readable faxed reports and delivering them on time to investigator sites
- Reducing the unacceptable level of errors in reports – highlighted during company's audit – to enhance accuracy and usability
- Including data revisions in data transfers for greater clarity and timeliness
- Improving specimen tracking and audit trails to meet client's audit documentation requirements

Innovative Solutions and Communication Meet Client's Expectations

Leveraging more than two decades of experience in hepatitis trials , Covance quickly put together a cross-functional team of clinical and project management experts, specialized in hepatitis clinical trials. The client's study had been compromised by substandard processes; our priority was, therefore, to switch to the rigorous specimen management, site management and data reporting processes developed by Covance's central laboratory.

Because we understood that investigators' performance had been hindered by late and poorly presented reports, we faxed all laboratory reports in a timely fashion and addressed them to the right investigator, in a clean, readable format. By also reducing the keystroke error rate to less than one percent (as per company's audit confirmation), we instantly provided more accurate information for investigators.

In response to the company's request for clear trails and documentation for auditing purposes, we labeled each specimen, allocating it a unique barcode linked to our computerized audit trail system. By leveraging our operational capabilities, we provided easier,

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automated specimen tracking and enhanced documentation for audits. Finally, we included revisions in data transfers and met data review milestones, ensuring that the study got back on track faster.

In order to ensure a smooth specimen transition process, our project managers regularly communicated with the company, proactively anticipating and addressing incoming issues.

In the end, by relentlessly focusing on quality, listening to investigators' needs, leveraging operational expertise and communicating closely with the client, the Covance multi-functional team delivered the quality reports required and successfully recovered the study, while regaining investigators' trust.

Finding the right testing partner for your clinical trial can give you peace of mind. When you choose Covance's experience, together we will explore solutions that deliver data precision and compliance and stand up to the most stringent audits.

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

Covance is an independently held company with headquarters in Princeton, New Jersey, USA.
Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

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