spaulding clinical℠
RESEARCH BEYOND RESULTS

Rapid Data Case Study:

Study Executed in One-Third of the Industry-Average Timeline

Situation:

In May 2019, one of the largest pharmaceutical companies, with a large diversity of drug product, was overwhelmed with a heavy workload with extremely long timelines. They were insourcing, doing their own work on the backend data management — including the eSource database build at the beginning of a trial through the closeout — and CSR writing. A database build was running two to three months, and last subject last visit (LSLV) to the final clinical study report (CSR) was taking three to four months. Beyond capacity concerns, the bottom line was that they needed their Phase I data results faster in order to make informed downstream decisions sooner.

Challenge:

Their client's internal teams were struggling and hadn't been able to achieve close to the speed of data they needed externally from partners, or internally from their busy teams. But every external client they approached to bring the product forward informed them the timelines for LSLV to final CSR would be 90 to 120 days.

Solution:

Every Spaulding Clinical study starts with an outcome in mind. Spaulding Clinical identified that following the standard linear study progression model was not conducive to providing the accelerated results of high-quality data the client required. The entire process from database build to CSR writing had to be evaluated in order to identify inefficiencies and potential bottlenecks. Through innovation and refinements, Spaulding Clinical developed a rapid data model that achieved LSLV to final CSR in 45 days, against the industry average of 90 to 120 days.

"We've worked with many of the CROs you could guess (and I worked at one of them for over a decade), and I can honestly say you have had the highest quality with the fastest timelines (and don't forget the best price)!"

Our Rapid Data Model in Action

In November 2019, a small biotech startup urgently needed to file an NDA in December, facing a high-pressure deadline to commercialize their product and get it into the marketplace prior to January. Using their rapid data timeline model and process, Spaulding beat the deadline, helping the company get their product to market by January 2020. "The Spaulding data management, biostats, and programming group has been AWESOME throughout our project," the client stated. "Personally, I've been in biotech/pharma for almost 23 years, and I've never seen a biostats/programming CRO as responsive/amazing/accurate and easy to work with as Spaulding. I will definitely remember Spaulding as a top option for future projects."

Rapid Data Model Highlights:

- **Data Collection:** Results start with collecting clean, high-quality data in real time. Spaulding Clinical leveraged their electronic data capture (EDC) solution to collect data bedside and passively import data from instruments and their in-house clinical laboratory. Bedside data collection and passive imports allowed Spaulding Clinical to run paperless studies, practically eliminating data entry errors. Using unique rapid data model processes, Spaulding Clinical was able to ensure data cleanliness was maintained, allowing database lock 14 days after LSLV instead of months later.
- **Safety Programming:** All CDISC-compliant SDTM safety-related programming is completed from CDISC/CDASH-compliant data extractions from the EDC during study conduct. CDISC-compliant ADaM and safety tables, figures, and listings (TFLs) are programmed per the approved Statistical Analysis Plan (SAP). Draft safety TFLs are provided days after LSLV for client review.
- **Pharmacokinetics (PK) Programming:** The rapid completion of PK programming is pivotal to reducing overall timelines. Spaulding Clinical developed a unique method to streamline this while maintaining strict safety guidelines, resulting in PK TFLs production in days.
- **CSR Development:** With these proprietary methods, Spaulding Clinical is able to finalize PK and safety TFLs rapidly after database lock – within 30 days, excluding client review time.

"It's really been a pleasure working with everyone at Spaulding. I found it even easier and faster than working within [our organization] and, more importantly, the quality was beyond compare. I've requested more outsourced studies as a result, so I hope we can work together soon, too."

Results:

Leveraging their EDC system, Spaulding Clinical was able to provide clean, accurate data to the client in real time. A shift from a linear data model to a newly defined rapid data model allowed Spaulding Clinical to provide high-quality TFL outputs for review significantly faster than client expectations. Earlier review cycles created an environment where PK and safety TFL finalization was possible days after database lock.

Ultimately, Spaulding Clinical's rapid data model resulted in a final CSR within 45 days of LSLV. This achievement allowed the client to make informed decisions about their drug with confidence months earlier than would have otherwise been possible, leading to an overall reduction of the drug development timeline.

Contact Spaulding Clinical

About Spaulding Clinical Research

Spaulding Clinical opened in 2008 and was built upon fully electronic data and integrated, purposefully engineered systems for conducting Phase I trials. Spaulding runs a 200-bed facility in West Bend, Wisconsin, and conducts and analyzes First-in-Human, clinical Proof-of-Concept, cardiovascular safety (TQT, concentration effect), and NDA-enabling clinical pharmacology studies. Spaulding Clinical provides expertise on study design, medical writing, clinical data management, biostatistics, and PK/PD analysis.

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