CASE STUDY

BOOSTED CLINICAL EFFICIENCY WITH FSP

Improved clinical efficiency by deploying a global SME team for data management & biometrics, leading to improved data quality & faster regulatory responses

Company Overview
One of the top 10 biopharmaceutical companies in oncology, dedicated to developing innovative therapies for cancer patients.

Industry
Biopharmaceutical

Number of Employees
20,000 + employees

Location
Cambridge, MA, USA

BACKGROUND

A pharmaceutical company shifted its focus to the expanding field of neurology research and development. As they progressed into new research and initiated advanced clinical trials, they faced challenges in data management, statistical programming, ensuring data consistency, and overarching project management.

CHALLENGE

The sponsor faced challenges in executing clinical trials for a diversified portfolio. The primary dilemma was whether to wholly outsource projects to third-party vendors or to maintain an internal stronghold, especially concerning data management and data visualization. They were in dire need of a solution that was not only scalable as per the demands of the project but also sufficiently flexible to accommodate their internal teams.

SOLUTION

Understanding the gravity of the challenge and recognizing the critical need, Maxis Clinical Sciences promptly rolled out a comprehensive strategy. A robust team, comprising 50 Subject Matter Experts (SMEs) was stationed at strategic locations across the globe. This team was an ensemble of top-notch professionals, including SAS Programmers, experts proficient in SDTM & ADaM standards, adept data management specialists, and developers with a command over tools such as Tableau, EDC, R, and Python.

But the intervention wasn't just about staffing. The SME team was seamlessly integrated into the client's existing teams, working in tandem on high-priority drug development projects. Their primary areas of focus encompassed biometrics, meticulous clinical study management, vigilant site monitoring, and a deep dive into scientific & medical writing and clinical data management.

MAXIS CLINICAL SCIENCES

24/7

Global teams available 24/7

Timely deployment of qualified team

Reduction in manual effort through automation

Improved data quality

OUTCOME

The integration of the MCS team transformed the pharmaceutical company's clinical trial processes. They now had dedicated teams available round-the-clock, ensuring no lag due to global time differences. The data management process underwent a revolutionary shift with enhanced features like efficient data ingestion, rigorous validation, precise aggregation, adherence to CDISC standards, and a focus on meta-data management.
Furthermore, the company witnessed a marked improvement in reporting clinical trial data. The reporting became more consistent, repeatable, and streamlined.

KEY PERFORMANCE INDICATORS

- Swift deployment of a highly skilled professional services team.
- A tangible reduction in effort and time, credited to advanced automation processes.
- Exemplary efficiency in managing clinical trial data, encompassing numerous studies within the portfolio.
- A notable decrease in response time to regulatory authorities, expediting the entire regulatory process.
- Enhanced satisfaction among clinical stakeholders due to timely and accurate data reviews.

"We ran into challenges with our neurology research. Working with Maxis Clinical Sciences made a big difference. Their skills in handling data and managing projects really helped us move ahead."

-- Research Lead

ABOUT MAXIS CLINICAL SCIENCES

Maxis Clinical Sciences is a pioneering integrated research competence center and specialized management consulting organization. We are dedicated to advancing drug development, healthcare equity, and digital transformation in the healthcare and life sciences sectors. As a strategic partner, we deliver customized, innovative solutions that align with our clients' unique goals. We are not merely providing resources; we are instigating transformation.

Visit our website to learn more: www.maxisclinical.com