

STREAMLINED BIOMETRICS WITH FSP

Reduced cycle time from protocol to data lock by leveraging functional outsourcing with required services accelerators



Company Overview

Medical device subsidiary of a top-5 pharmaceutical company with > USD 10 billion annual revenue, providing innovative solutions for enhanced vision & ocular health, including contact lenses, intraocular lenses, & surgical equipment.

Industry

Medical Device

Number of Employees

10,001+ employees

Location

Jacksonville, FL, USA

BACKGROUND

A renowned medical device subsidiary, operating under the umbrella of a global pharmaceutical giant, set its focus on the ever-evolving domain of ophthalmology R&D. With the progression of research and the introduction of new clinical trials, the organization found itself grappling with resource constraints. The specific challenges spanned across data management, statistical programming, data standardization, and overarching project management.

CHALLENGE

The heart of the matter was twofold: first, the organization lacked the specialized expertise required for meticulous clinical data management. And second, there was a clear need for well-established processes that could ensure data accuracy, all while maintaining strict regulatory compliance. In essence, they needed both the right people and the right processes in place - and they needed them quickly.

SOLUTION

Understanding the core challenges, Maxis Clinical Sciences proposed the implementation of the Functional Service Provider (FSP) model. Since 2013, a robust agreement was established, under which a dedicated team of 40 seasoned professionals were deputed to assist the company. This specialized team undertook pivotal roles, right from the foundational task of clinical database design to its management in adherence to CDISC standards. Additionally, they extended their expertise in statistical programming, ensuring data accuracy and timely delivery. Maxis Clinical Sciences, with its deep industry insights, ensured the provision of the necessary expertise in a manner that was both time-efficient and cost-effective. Collaboratively, both entities carved out well-defined processes and chalked out clear roles & responsibilities for each function, guaranteeing a seamless operation.



Reduction in cycle-time



Successfully renegotiated a 5-year agreement



Deployed 40 qualified professionals



Improved efficiency

OUTCOME

The collaboration yielded results that not only met but exceeded expectations. The strategic approach to harnessing the FSP model led to a significant reduction in cycle time. This efficiency enabled the sponsor to deliver pivotal results well ahead of schedule, positioning them at a vantage point where they could submit their dossiers to regulatory bodies much before their market competitors.

Upon the culmination of the initial 36-month agreement, the tangible results and seamless collaboration paved the way for the successful renegotiation of a subsequent 5-year agreement. Maxis Clinical Sciences emerged as a valued partner, recognized for its service excellence.

KEY PERFORMANCE INDICATORS

- Swift and agile implementation of the comprehensive solution backed by a highly skilled professional services team.
- Notable reduction in the time required to aggregate, review, and clean clinical data.
- Enhanced efficiency in handling clinical trial data spanning multiple studies across the portfolio.
- Drastic minimization in the risk associated with reporting errors, attributed to the adoption of a unified data source.
- Improved response time catering to regulatory queries and meeting the clinician's data review requirements.



"Partnering with Maxis Clinical Sciences streamlined our data challenges. Their expertise and precision stood out, making our processes smoother and more efficient. A top recommendation for anyone in our industry."

-- Director of Research Operations

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