

## CASE STUDY



# STREAMLINED BIOMETRICS WITH FSP FOR CLINICAL TRIALS

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 talent and data issues across multiple critical areas: statistical programming, biostatistics, data management, clinical data quality, standardization, and project management. And second, there was a clear need additional expertise to effectively manage clinical data quality processes, standardize clinical data, support clinical reviews, and reduce time to study-lock. These challenges were impacting their ability to maintain timely and efficient clinical trial operations.

## 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 utilizing 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 has strengthened our ophthalmology R&D operations. We were struggling with data management bottlenecks and project delays that were seriously impacting our timelines. The Maxis Clinical team stepped in and optimized our approach through their combination of onshore leadership and offshore delivery teams. What impressed me most was how seamlessly they integrated with our internal teams - it never felt like working with an external vendor. The results speak for themselves - faster database locks, improved data quality, and consistently clean regulatory submissions.*

**--Vice President, Clinical Operations**

## Learn More

Maxis Clinical Sciences combines deep FSP and clinical biometrics expertise with a global delivery model to drive efficiency and innovation in clinical trials. From clinical trial design and data management to biostatistics and real-world evidence generation, we provide comprehensive services and data analytics solutions that help life sciences organizations bring life-changing therapies to patients faster.

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