CASE STUDY

FSP STRATEGY TO OPTIMIZE CLINICAL TRIAL SUCCESS

Increased trial success by implementing FSP, utilizing a US-based SME team to boost programming quality and create committed in-house teams

Company Overview

Subsidiary of one of the top 10 Life Sciences companies, a global leader in molecular diagnostics offering cutting-edge products, including nucleic acid isolation kits, real-time PCR systems, & next-generation sequencing technologies.

Industry

Biopharmaceutical

Number of Employees

10,000 + employees

Location

Pleasanton, CA, USA

CHALLENGE

The biopharmaceutical company, renowned for its pioneering research, confronted a significant challenge in its operational framework. Previously relying on a fully outsourced model for their clinical trial processes, the company embarked on a strategic shift towards a fully insourced model. This transition presented challenges:

- A palpable void in the in-house talent pool, especially in specialized roles.
- The pressing need for a solution that was not only flexible but could also scale in response to the evolving demands of clinical trials.
- The significant tenure of Subject Matter Experts (SMEs) and the expertise they bring to the table.

SOLUTION

Recognizing the complexities of the challenge, Maxis Clinical Sciences took a holistic approach. A robust team of 25 seasoned SMEs, stationed in the US and specializing in SAS programming and biostatistics, was curated and deployed. This team seamlessly integrated into the client's framework, becoming an integral part of the critical drug development projects.

Key strategies employed:

- A pronounced focus on biometrics to ensure data reliability and accuracy.
- Streamlined clinical study management processes to optimize trial outcomes.
- Enhanced site monitoring procedures to ensure adherence to clinical protocols.
- Scientific and medical writing services were strengthened to improve documentation quality.
- Clinical data management was revamped to ensure data integrity and compliance.

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MAXIS CLINICAL SCIENCES

Dedicated in-house team

Team members working since 2008

Improved programming quality

Ability to scale up & down as needed

OUTCOME

The joint efforts of the biopharmaceutical company and Maxis Clinical Sciences achieved the desired outcomes:

- Establishment of dedicated in-house teams, fostering a sense of ownership and commitment.
- A marked improvement in the quality of programming, ensuring data accuracy and reducing errors.
- Impressive team longevity, with some team members having been onboard since 2008, bringing stability and consistent expertise.

KEY PERFORMANCE INDICATORS

- Timely deployment of a qualified professional services team, adapting to the company's dynamic needs.
- The ability to scale resources up or down based on project requirements.
- Sustained high quality of resources ensuring project success.
- Robust Intellectual Property (IP) protection mechanisms in place, safeguarding company interests.

"Through Maxis Clinical Sciences' expertise, we have strengthened our in-house capabilities, driving clinical trial success and sustaining progress in therapeutic strategies."

-- CEO

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.

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