eClinical
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Case Study

Advancing Clinical Data Transformation with Strategic FSP Services

PROJECT BACKGROUND

A US-headquartered biopharmaceutical company with a track record of successful development in novel therapies for rare diseases selected eClinical Solutions as a technology partner to support their portfolio of trials at various phases. The client implemented the elluminate Clinical Data Cloud® to manage the proliferation of clinical trial data from a variety of sources and increasingly complex data workflows. Key initial elluminate use cases for the client were:

- Real-time access to data for more efficient review and visualizations to support analysis and inform stakeholders across clinical teams.
- Boost efficiency and avoid overburdening teams with routine tasks.

COMPANY PROFILE

- Mid-sized US-Headquartered Biopharma
- 500 + employees

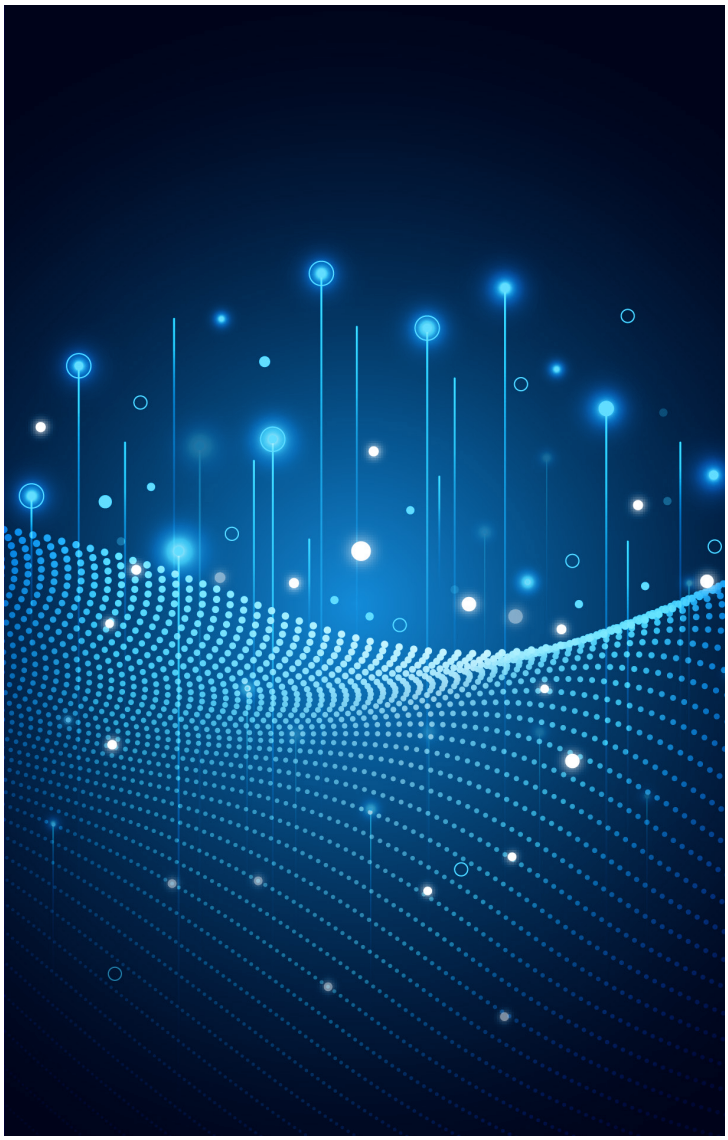
PRODUCTS

- elluminate Clinical Data Cloud
- Biometrics Services

THE CHALLENGE

With trials becoming more data intensive and complex, full-service outsourcing, and traditional offshored FSP models, which primarily provide operational resources, often lack the technological knowledge and strategic insight needed to handle the intricacies of modern trials. This results in inefficiencies, data silos, and delayed decision-making, compromising trial integrity and outcomes.

Having worked with eClinical Solutions for several years and successfully implementing elluminate, the client decided to shift its outsourcing strategy. The team wanted to further expand the organization's use of elluminate, alongside increasing its biometrics capacity to handle the increasingly complex activities involved in its portfolio of early and late-stage trials.



Client Objectives:

- Scale their biometrics capability with knowledgeable, elluminate-experienced data management professionals without increasing their internal headcount.
- Access external data expertise to support their demanding reconciliation activities and remove bottlenecks.
- Ensure the flexibility to scale capacity up and down depending on the study requirements.
- Further their adoption of elluminate, access best practices and optimize workflows.

About Functional Service Provider (FSP) Solutions:

FSP models involve outsourcing specific functions or tasks to specialized providers, rather than the entire project or trial. These specialized models are growing in popularity, enabling sponsors to benefit from flexibility, scalability, and access in-demand skillsets.

SOLUTION

eClinical Solutions proposed a strategic FSP model which would allow the client to fulfil both its operational data management deliverables while further optimizing the use of elluminate.

A team was assigned including external data specialists, data managers, data engineers, medical coders, and an experienced FSP Manager to oversee the engagement. The FSP Manager promotes sharing of information and consistency across project activities and serves as an escalation point for the client and within the FSP team. Additionally, Senior Data Managers serve as a primary point of contact for data management, ensuring quality deliverables for their assigned study and that the study is inspection-ready at any given time.

The eClinical Solutions team supports several late phase and long-term follow up studies working with client systems and SOPs (Standard Operating Procedures). In collaboration with the client, the eClinical team tailors its approach to meet the requirements of each study protocol and to achieve quality deliverables in line with milestones.

The assigned team draws on its extensive experience with elluminate to not only deliver operational data management activities but propose process improvements.

The team has provided input into the organization's clinical data related SOP and KPI (key performance indicators) development.



THE RESULTS

Through the engagement, the client has been able to benefit from a team of biometrics and elluminate experts, applying the insights gained from services and technology expertise to refine and enhance workflows.

The efficient biometrics services and ongoing technology adoption has enabled the client to address immediate trial needs while advancing towards a clinical data science framework and establishing the foundations for AI-enabled productivity.

The engagement has resulted in strong client satisfaction and potential for further expansion.

Success Factors

- Strong existing technology partnership with the client built on mutual trust enabled seamless start up for the FSP engagement.
- eClinical Solutions' Biometrics Services team's deep experience in elluminate enables hands-on support for optimization and workflow refinement.
- eClinical Solutions' data management and biometrics experts are equipped with the skills and knowledge to advance clinical data transformation –including risk-informed strategies, AI/ML applications, and emerging data sources.