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CASE STUDY

GSK ISS Leverages ideaPoint, to Gain Critical Time and Resource Efficiencies

GlaxoSmithKline (GSK) Investigator-Sponsored Studies is a research effort committed to collaborating with external partners such as investigators, healthcare institutions, or universities to conduct clinical studies dedicated to bettering health and quality of life. GSK's ISS program offers support in a multitude of forms including products, funding, or both with approval of proposed high- quality ethical methodology and sound research objectives in congruence with medical science or patient care.

The ISS Challenge

As Medical Affairs continues to prove a quickly evolving business and a prominent area of focus for many life sciences companies, keeping pace with the increasing number of incoming investigator requests and regulatory guidelines is paramount.

For GSK and many others involved in the business of approving and funding investigator initiated studies, the task of evaluating requests often presents numerous difficulties. Fostering positive communication with external investigators, delegating requests to appropriate subject matter experts, and tracking and reporting on key milestones is critical in the support of investigator - initiated studies, which leaves no room for inefficiency.

For GSK ISS, process inefficiencies were growing as multiple systems and workflows were at play throughout the organization and across different therapeutic areas. Methods of communication had weakened (faxes, emails) and quickly proving detrimental to investigator response times and ultimately, the relationships themselves.

Business Challenges

While GSK ISS recognized the need to find a better solution for internal procedures, the number of requests had grown out of control, quickly reaching 70 studies per team. In addition, without a standardized process, study management had become burdensome, and, as a result, GSK ISS needed to quickly solve the division's numerous technology and business challenges.

• **Time Optimization**–How could GSK successfully evaluate and respond to the extensive number of proposed studies in a timely manner?

• **Process Standardization** –How could they establish a single, unified process for all enterprise-wide studies across different therapeutic and geographic areas throughout the world?

• **Data Standardization**–How do they efficiently migrate, consolidate, and archive data across a variety of disparate systems?

• **Communication Optimization**–How could they establish effective, consistent communications with external investigators throughout the evaluation process?

• **Security Optimization**–How could they enable privacy, security, and compliance throughout the entire process?

• **Transparency** –How could GSK make study information secure yet easily available to hundreds of relevant subject matter experts, while also streamlining appropriate delegation of requests by variant regions, therapeutic areas, etc.?

While GSK's ISS management and collaboration activities continued to flourish and expand, the necessity for a more standardized and simplified study management platform became even more pressing. After evaluating a range of commercially available software solutions, GSK selected ideaPoint. Not only did ideaPoint have a track record of success at 15 of

the top 25 pharmaceutical companies worldwide, but ideaPoint provided GSK with the flexibility, and enterprise scalability to store, manage and track the hundreds of investigator studies in one unified system. ideaPoint also met GSK's strict privacy and compliance requirements for their ISS program, providing a single, unified system for the secure submission and evaluation of hundreds of study proposals.

The Results

The ideaPoint solution was successfully implemented at GSK replacing a number of homegrown and commercial systems that were currently deployed as part of their study management and collaboration activities. In effect, ideaPoint's ISS management platform provided GSK ISS with:

• Successful migration of multiple data repositories

• Successful decommissioning of the previous implemented systems

• Standardized workflow combined with secure role-based access to enhance process flow and security

• Dramatic acceleration of decision making process and response time

• Complete visibility of investigator's engagements, performance data, and cycle times and other key insights

• Comprehensive search and reporting

• Fulfillment of Quality, Risk, and Compliance Obligations (CIA, ABAC, RRA)

GSK's partnership with ideaPoint has proven successful in encouraging positive communications with external investigators and providing a more unified process. In an industry that is constantly evolving and inviting new innovative ideas and opportunities, the business benefits provided by the ideaPoint Platform are clear:

• Intuitive, easy-to-use system that is deployed and leveraged at the enterprise level

• Quantifiable business process improvements and efficiencies

• Enhanced global visibility, compliance, and data integrity

• GSK become the partner of choice for ISS studies in vaccines, oncology, and multiple therapeutic areas

> "We are taking on more projects than ever before –the visibility enterprise-wide has streamlined our process. The system is very quick and intuitive." - GSK Core Business Services Manager

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