

Case Study: GSK

GlaxoSmithKline is a widely renowned global biopharma organization focused on combining talent, science and technology to bring a positive impact on global health. The company approached Digital Aptech to develop specialized software to help the brand successfully submit clinical trial data for Tykerb, a breast cancer drug

Avg. reading time: 2 min



Project Overview

- GSK connected with Digital Aptech to develop an appropriate dose-finding strategy that would help in accurate clinical data trial of a breast cancer drug
- The company wanted assistance in preparing and developing a CSR or Clinical Study Report that is crucial for drug trial and data submission

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Client Background

GSK is involved in vaccine R&D bringing in new vaccine technology as well as working on developing a new and differentiated pipeline of consumer healthcare products. We designed two specific software that helped in making clinical trials for Tykerb smooth, accurate and hassle-free



Challenges

- Clinical data trial submission is a long, tedious and often complicated process. Any error could potentially lead to rejection by the FDA.
- During trial data submission, the FDA conducts a scrutiny that includes the regulatory body raising multiple questions or queries.
- CSR or Clinical Study Reports are a crucial part of applications sent to regulators for new medical treatments

Technology Stack used



Python



R

The Solution Provided

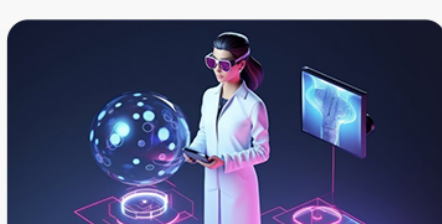
Solution #1

Digital Aptech assisted GSK in the hassle-free submission of trial data for Tykerb, a breast cancer drug developed by the organization



Solution #2

We assisted GSK to successfully fill out these queries through posthoc analysis that accelerated the approval



Solution #3

Our team developed two customized software, namely Drug Supply Modeling and Optimal Design. The Drug Supply Modeling software predicts the proper supply of drugs needed to cover patient demand in a single study with the risk of drugs running out for one patient. The Optimal Design software helps to identify the appropriate dose-finding strategies for drug development



Solution #4

CSR or Clinical Study Reports are a crucial part of applications sent to regulators for new medical treatments. We assisted GSK in developing CSR for the above-mentioned drug



Key Features and Benefits

- We successfully incorporated data science, statistical planning, consulting and programming services.
- We provided world-class statistical planning, consulting, programming, and other integrated services that helped the company to fast-track research and development for new and improved products.
- The Drug Supply Modeling Software helped GSK save \$1 billion



Conclusion

- The organization managed to improve its drug and device development while reducing the overall operational budget.
- Our world-class data science and Biostatistics services enabled the organization to utilize the power of big data.
- GlaxoSmithKline USA successfully streamlined its product planning, research and development, clinical trials, data submission, and release of products.
- The Optimal Design software played a vital role in the research and development of Tykerb.
- We assisted our client with data submission of clinical trials to multiple regulatory bodies in compliance with the data standards as laid down. This allowed GlaxoSmithKline to receive faster and hassle-free approvals



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