

Case Study: Roche

Roche is a leading Switzerland-based multinational pharmaceutical organization that operates on two of its main divisions: pharmaceuticals and diagnostics. The company associated with Digital Aptech to avail of our world-class data science services for smooth clinical data trial submission and approval of Polivy, a Lymphoma-fighting drug.

Avg. reading time: 2 min



Project Overview

- Our specialized big data experts, data visualization experts and data science professionals formed an actionable team and devised a unique plan
- We worked on incorporating biostatistical services for smooth data trial approval and accurate clinical report submission

[Read more](#)

Solutions

Since the founding of our company, we have been developing innovative medicines, treatments and diagnostics that continue to revolutionise healthcare.

[Learn more](#)

Innovation

Driven by our passion for what we do, our autonomy in how we find solutions, and the strength of our R&D structure we can take on the most complex challenges in healthcare.

[Learn more](#)

Client Background

- Roche has an illustrious past with more than 30 life-saving medicines on the list of World Health Organization Model Lists of Essential Medicines.
- Our team assisted the pharma giant on its goal to ensure assured clinical drug trial approval for one of its revolutionary drugs Polivy.



Challenges

- Clinical trial data submission is a crucial and complicated task comprising multiple rounds of investigation, data trial and investigations
- During clinical trial data submission, the FDA puts forward multiple questions and queries as part of the scrutiny. Accurate replies will ensure smooth drug approval
- A submission-ready and fully documented CSR is crucial for drug approval. It summarizes the overall outcome of a clinical study to the FDA. CSR ensures speedy drug approval

Services used



Biostatistics



PK/PD Modeling and Simulation



Regulatory Data Standards (CDISC) and Compliance



Clinical Trial: SDTM and ADaM



Statistical Consulting and Planning

The Solution Provided

Solution #1

We assisted Roche in trial data submission to the FDA for Polivy.



Solution #2

Digital Aptech, through its post-hoc analysis, aided in the queries that are conducted during drug data trials in the CDC. This was instrumental in faster approval.



Solution #3

We carefully developed and validated FDA-compliant and acceptable Clinical Study Reports for the Lymphoma drug.



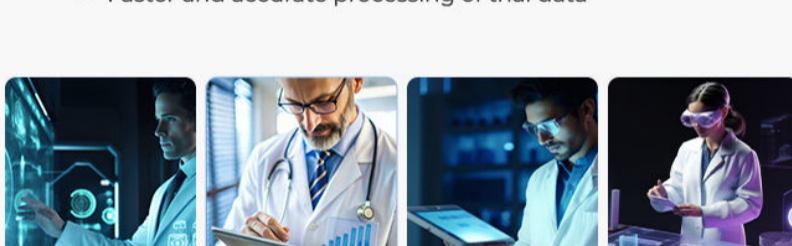
Solution #4

Our team also provided world-class and industry-leading design and analysis of clinical trials



Key Features and Benefits

- Carefully designed and detailed CSR for the drug
- Detailed post-hoc analysis
- Developing compliant data set submissions for the trials
- Faster and accurate processing of trial data



The results

- The inclusion of biostatistics and other integrated services enabled the organization to leverage the potential of data science
- Overall operations expenses of the company have been successfully reduced with the incorporation of integrated data science technology
- Streamlined data submission for clinical trials in accordance with regulatory body guidelines has encouraged smoother trial approvals

Conclusion

- Faster clinical data trials improved the company's overall productivity and brought down costs
- Smooth drug trial data submission meant more credibility of the pharma company
- Hassle-free data submission ensured on-time approval resulting in faster time to market of the drug in question
- Leveraging the power of big data assisted the business in transforming its decision-making
- Our services opened ways for the brand to use big data for other drug trials and data submissions



Ready to take your business to new heights?

Book a meeting with us to understand how we can Digitally Transform your brand

[Schedule a Meeting](#)

[Visit our website](#)

India

En-34 (9th Floor), Block-EN,
Sector - V, Salt Lake City,
Kolkata - 700091, West Bengal

USA

1904 Canyon Edge Dr. Austin,
Texas 78733

UK

10 Milton Cres, Ravenshead,
Nottingham NG15 9BD