DIGITAL APTECH PRIVATE LIMITED

Case Study: Allergan

Allergan is a leading pharmaceutical company involved in developing and manufacturing drugs, biosimilars and medical devices. Digital Aptech assisted Allergan with FDA data submission and approval for whether Botox (Botulinum toxin-A) could be used for treating chronic migraine and

Avg. reading time: **2 min**

Project Overview

- Allergan was looking for faster and hassle-free data submission and our experts had to use biostatistics, Machine Learning and data science to make that happen
- We were tasked to develop a compliant CSR or Clinical Study Report which would ensure smooth approval from the central agency

Read more

Client Background

- Allergan is known to offer world-class products for dermatology, medical aesthetics, eye care, urology, women's health, central nervous system, anti-infective therapeutics and gastroenterology.
- Allergan has a rich and promising pipeline of new therapeutics and innovative technologies aimed at providing novel therapies that can bring a paradigm shift to treatment and healthcare.

Challenges

- CSR is a highly valuable document that could either make or break the data trial submission.
- Clinical Study Reports have to be compliant with all FDA policies and guidelines while accurately displaying and projecting all necessary drug trial data
- The entire data submission process can be quite tiresome, complicated and challenging. Passing the procedure requires professional and scientific expertise.

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

With the help of statistical consulting, planning, PK/PD analysis, and data visualization, we documented an accurate and standard Clinical Study Report

Solution #2

Our post-hoc analysis assisted the company in offering satisfactory replies to the crucial questions from the FDA related to the drug data trial

Solution #3

Experts from Digital Aptech provided an FDA-compliant trial outcome in the well-documented CSR.

Key Features and Benefits

- Submission of FDA-compliant CSR
- Efficient post-hoc analysis
- Better analysis of data trial results
- Faster and well-documented submission of trial data outcome and summary

The results

- The inclusion of Biostatistics and data visualization helped the company in efficient and faster decision-making
- Our expertise and world-class services helped the pharma giant streamline the drug development process
- The operational expenses of the company have been significantly reduced with the incorporation of integrated data science technology

Conclusion

- We assisted the pharma giant in receiving approvals for clinical data in a more efficient way, which accelerated its product development and delivery.
- It enabled product planning, development, and release to be hassle-free, smooth and highly streamlined.
- Allergan was able to improve its research and development and fastrack its product development and release in a smart and cost-effective way.
- With data science and statistical services from us, the pharma giant enhanced its operational efficiency with respect to particular drug development cycles while reducing expenses.

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