

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

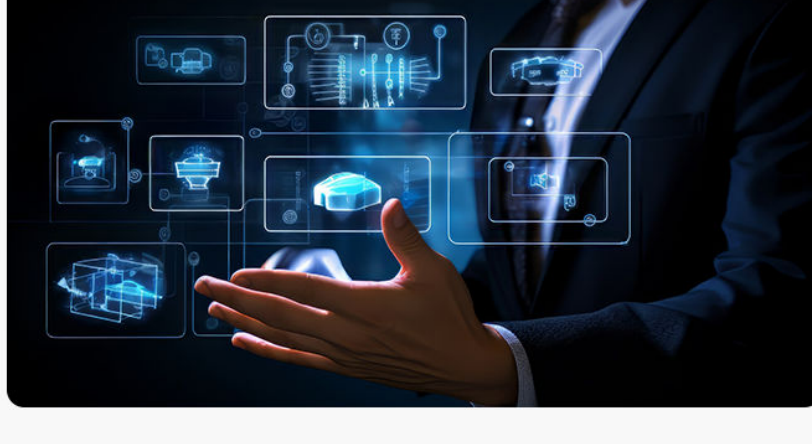
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Project Overview

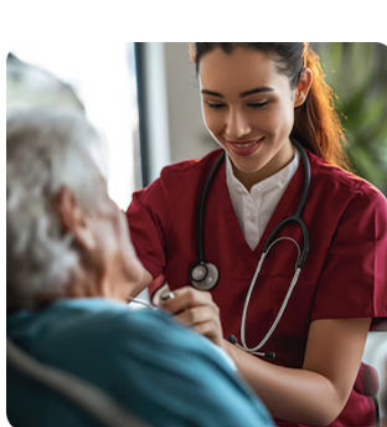
- Allergan was looking for faster and hassle-free data submission and our experts had to use biostatistics, Machine Learning and data science to make that happen
- We were tasked to develop a compliant CSR or Clinical Study Report which would ensure smooth approval from the central agency

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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



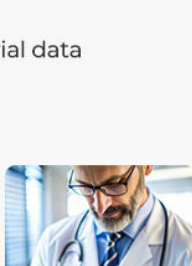
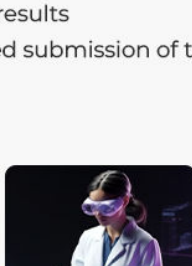
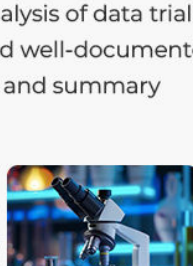
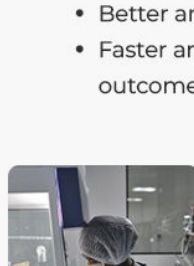
Solution #3

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 fast-track 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.



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