Case Study: Johnson & Johnson

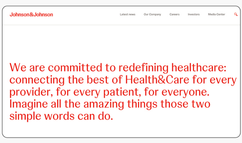
With an illustrious past of 135 years, US-based Johnson & Johnson is the world's largest and one of the most diversified consumer healthcare product manufacturers. At Digital Aptech, we assisted Johnson & Johnson in submitting FDA-compliant trial data for its B-cell lymphoma drug Teclistamab.

Avg. reading time: **2 min**

Project Overview

- Our data scientists and visualization experts collaborated with the biostatisticians at Johnson & Johnson to chalk out a detailed plan for clinical data trial submission
- We aimed to help the pharma giant in structuring a well-documented Clinical Study Report to be submitted to the FDA for the aforementioned drug

Read more



Client Background

- The organization boasts a wide portfolio of consumer healthcare items, prescription and pharmaceutical products, and medical devices/diagnostics products.
- Johnson & Johnson has been consistently striving to provide accessible and affordable healthcare solutions worldwide for a vibrant and healthier global community

Challenges

- After submission of trial data, the FDA conducts stringent scrutiny in which the organization seeking trial data approval is obligated to answer certain queries and questions.
- Clinical Study Reports are an essential part of the application for new drug approval.
- Clinical trial data submission and approval is a tedious and complicated process. Pharmaceutical organizations need to be careful, as any error or discrepancy could lead to outright rejection by the FDA.

Technology Stack 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

Our team of data science experts, data visualization engineers, and other big data professionals helped Johnson & Johnson to form articulate and accurate responses needed during the clinical trial

Solution #2

We worked in collaboration with the experts at the client's end to develop an FDA-compliant CSR or Clinical Study Report

Solution #3

Our biostatisticians used statistical planning, Statistical Report Writing, BA/BE analysis, PK and PK/PD analysis, PK/PD report writing, Toxicokinetics, etc to ensure faster drug approval

Key Features and Benefits

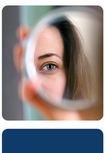
- Submission of FDA-compliant CSR
- Accurate responses to the FDA questionnaire, ensuring a lower rate of rejection
- Better analysis of data trial results
- Efficient post-hoc analysis

The results

- Our services accelerated the drug data trial process
- The expertise that we provided helped to ensure zero rejection and assured approval
- We helped the pharma giant streamline its business decisions and operations by letting it harness the power of big data.

Conclusion

- Johnson & Johnson benefitted largely from the hassle-free approval of the drug in question. It saved substantial funds, resources, and time with direct approval
- The direct approval also ensured faster large-scale production of the drug which enhanced the profit outlook of the company
- The credibility of the drug and the pharma company improved
- Johnson & Johnson decided to utilize AUI/ML and biostatistics to transform its other businesses



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