Case Study: Novartis

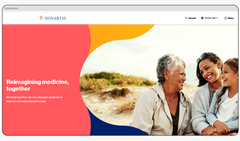
Switzerland-based Novartis is one of the top five largest pharmaceutical organizations worldwide. Our data science team assisted Novartis in facilitating hassle-free and quick trial data approval of its new drug for Myelogenous Leukemia, Gleevec, or Imatinib.

Avg. reading time: **2 min**

Project Overview

- Digital Aptech's team decided to leverage biostatistics, data science, data visualization and data engineering
- We worked in close association with the experts at Novartis for a data-driven approach and solution for faster and compliant FDA approval of the drug in question.

Read more



Client Background

- The pharma organization tirelessly works towards combining talent, science and technology to develop and deliver innovative products.
- We assisted the biotech giant in its efforts to achieve smoother, faster and hassle-free approval for the drug aimed at treating life-threatening cancer Myelogenous Leukemia.

Challenges

- Clinical trial data submission to the FDA and its approval is often a long, tiresome and sometimes challenging task.
- Any discrepancy or issues in data can straight away lead to rejection.
- The FDA, as part of its review of clinical trial data, needs the organization to answer certain queries and questions.
- An accurately developed CSR is vital in the overall drug approval process.

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

We assisted Novartis in the submission of appropriate responses with our top-notch post-hoc analysis

Solution #2

We also aided Novartis in developing FDA-compliant, submission-ready Clinical Study Reports for the drug in question.

Solution #3

Our resources teamed up with Novartis and devised crucial statistical planning for efficient clinical trial and report submission

Key Features and Benefits

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

The results

- Flight crews and pilots can easily track routes, flights, and distances traveled for each roster. They could also share the statistics with friends, co-workers and others via social media if required
- Users get a notification of the newly published roster or other modifications in changes with an auto-check facility
- Crews can effortlessly synchronize and integrate their rosters in Outlook, Google Calendar, Apple Calendar
- The app supports almost all major airlines of the world, as it uses Merlot, Jeppesen, Geneva, AIMS, etc.

Conclusion

- Hassle-free data submission ensured a reduced rate of rejection by the FDA
- Faster data submission also ensured faster manufacturing and time to market for the said drug
- The company managed to save substantial time and funds with a single attempt at clinical data trial approval
- Leveraging the power of big data assisted the business in transforming its decision-making process helping to optimize its production

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