Case Study

Accelerating Submission and FDA Advisory Meeting Support

Problem Identification

Strategic support and representation on behalf of client in FDA Advisory Committee meeting.

This drug is intended for use to potentially treat a rare but lethal genetically related neurodegenerative disease known as transthyretin-related hereditary amyloidosis, mostly occurring in a small number of people in Western Europe. At the time when our client, a major pharmaceutical company, acquired this compound through a merger, it was approved for use in EMEA. With the intent of rapid filing for approval in both the USA and Japan, our client was planning an accelerated submission of this compound to the FDA and the PMDA (the Japanese regulatory authority). This submission was to be based on two pivotal clinical trials on a small population and with pooled data analysis.

Our client sought a partner that could strategically support this accelerated approval in the form of guidance and knowledge transfer and also represent them in the FDA Advisory Committee meeting as a part of the submission team. The EG Life Sciences team was selected due to our proven track record of successfully partnering with clients to achieve accelerated submissions along with the advanced skill level of our programmers.

We assessed that supporting this submission would require a total of 3 highly skilled FTE's who could represent them in FDA Advisory Committee meetings as part of their team. These programmers supported our client's submission team, helping to resolve any query or request received by the regulatory authority.

Nature and Scope of Challenge

- Acquired drug with little documentation and knowledge transfer available
- High priority submission
- Client needed FDA Advisory Committee meeting support for programming and data queries

Problem Resolution

- Team of 3 programmers worked with client's team in representing them in on-site FDA Advisory Committee meeting.
- Programmers resolved queries in real time for regulatory authority working alongside client.

Value Proposition

This successful accelerated submission highlights our expertise and execution of programming and statistical support for our clients. EG Life Sciences group participated directly in the FDA Advisory Committee meetings as an extension of our client's team.

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