Challenge

An EU-based pharmaceutical company was developing a new drug to treat a disease with unmet medical need in Europe and USA.

Since they were just starting their development program, they wanted to develop the regulatory strategy that would bring the much-needed medicine to the patients as fast as possible, and simultaneously in both the EU and USA. However, they were unfamiliar with the complex regulatory landscape in both regions and how are they intertwined.

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Phortas Solution

Our team of experts worked closely with the company to understand the clinical development program and the target population for the drug. We analyzed EU and USA regulations and unmet medical need aspects in both regions, including the current treatment landscape.

We prepared a comprehensive regulatory strategy incorporating both the EU and USA regulatory characteristics.
Special consideration was given to the EU and USA early access schemes (EMA PRIME, FDA INTERACT, etc.) that are specifically oriented to medicines for addressing unmet medical needs. The regulatory strategy gave the company clear way forward to bringing their product to the market as fast as possible.

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Outcome

Thanks to Phortas' regulatory expertise and guidance, the company got the full understanding of both regions' regulatory pathways. The company was fully satisfied with the depth of Phortas' analysis and appreciated a clear path forward for their product development.

Our consultancy's services saved the company time and resources as they did not have to spend time navigating the complex EU and USA regulatory landscape on their own.
We are proud to have helped our client in bringing a much-needed drug a step closer to the market.

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