

Challenge



An US-based pharmaceutical company was planning to conduct clinical trials for their new paediatric drug in Europe. However, they were facing difficulties in understanding the complex regulatory requirements for paediatric clinical trials in Europe.

They needed expert guidance on developing a Paediatric Investigational Plan (PIP) that would comply with EU regulations.

Phortas Solution



The company reached out to our EU-based regulatory affairs consultancy for assistance. Our team of experts worked closely with the company to understand their drug's clinical development program and their target market. As we have in-depth knowledge of the EU regulations applicable to paediatric clinical trials, we provided guidance on how to develop a PIP that would meet the requirements of the European Medicines Agency (EMA).

We provided a detailed plan for the paediatric clinical trials, including the study design, the target population, and the endpoints. We also advised on the required timelines, documentation and data that needed to be submitted to the EMA. We worked closely with the company to ensure that the PIP was of the highest quality and met all the necessary regulatory requirements.

Outcome



Our consultancy's services were instrumental in helping the company develop a successful PIP that met the requirements of the EMA. The company was satisfied with our services, and appreciated the flexibility and targeted expertise. They were able to conduct their clinical trials in Europe without any regulatory issues, and their drug was eventually approved for use in paediatric patients in Europe.

Our team's expertise and guidance were critical in ensuring that the company's clinical trials were conducted with the best possible outcomes for patients. Our consultancy's services also saved the company time and resources, as they did not have to spend time navigating the complex regulatory landscape on their own. Overall, it was a successful partnership that demonstrated the value of our consultancy's expertise and commitment to client satisfaction.