Case Study

Accelerating Approval of Next-Generation Oncology Treatments for EBPs in JAPAC

IQVIA's depth of regulatory experience with novel therapeutics helps to increase chances of regulatory success and accelerates time to market

Situation

An emerging biopharma (EBP) client in Asia sought to accelerate the development of a theranostic for patients. The company hoped to gain marketing approval swiftly including in the US and Japan. The design for Phase 1 first-in-human trials began, but the company had considerations such as human off-and-on-target dosimetry, and absorbed and effective dose/dose optimization of radionuclide and ligand.

Challenge

Developing novel theranostic agents involves complex processes. To receive approval, it was crucial for the sponsor to consult with IQVIA to draw on their expertise in FDA requirements and specific regulatory interactions that could influence the acceptance of the Phase 1 clinical study design.

Harness IQVIA's extensive expertise

IQVIA assembled a team of experts in Japan and the US to tackle the sponsor's challenges and enhance their probability of technical and regulatory success by providing a detailed analysis of FDA requirements, evaluating impacts on the therapeutic program, and presenting strategic solutions.

IQVIA's strategic support enabled the EBP to navigate complex regulatory landscapes, optimize its Phase 1 study design, and expedite global marketing approval. This collaboration highlights IQVIA's critical role and capabilities in advancing innovative therapies for patients worldwide.

IQVIA's diverse cross-functional experts

Solution

IQVIA implemented a high-touch approach by being the only company to arrange face-to-face meetings with the sponsor multiple times, enabling thorough discussions on their goals and objectives. This direct engagement facilitated the brainstorming of tailored strategies to enhance the probability of success.

The team conducted a detailed analysis of the FDA's regulatory requirements for novel radiopharmaceuticals and assessed their potential impact on the theranostic program. A comprehensive presentation was delivered, outlining the different strategic approaches the sponsor might consider to achieve their objectives effectively.

Results

IQVIA's unique approach, integrating advanced technology with expert insights, delivered a tailored solution that streamlined the EBP's approval process.

Reduced risk and time to market through an innovative approach to the Phase 1 study design that accelerates data capture and dose optimization.

Increase efficiency in identifying the optimal dose using Physiologically Based Pharmacokinetic (PBPK) modeling to understand pharmacokinetics and intraperitoneal bio-distribution.

Reduced costs through simultaneous dose-response modeling analysis, minimizing the number of patients, and accelerating the availability of robust data.

Accelerated marketing approval by prioritizing and segregating approval processes for the novel therapeutic development.

Consult IQVIA's industry experts today to get insightful guidance on early clinical development strategies.

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