Case Study

Enhancing Clinical Development Plan and Regulatory Support for Small Emerging Biopharma in Neuroma Therapy

IQVIA's market analysis and regulatory expertise facilitated informed decision-making and streamlined interactions with the FDA

Situation

IQVIA partnered with a small emerging biopharma (EBP) company to refine their clinical development plan (CDP) for a new formulation of an existing drug, targeting foot neuromas in patients unresponsive to conservative treatments. The FDA had previously granted orphan drug designation to this therapeutic. IQVIA's support involved determining key outcomes for stakeholders, conducting a market assessment, and preparing for a Type C meeting with the FDA to align on the drug development regulatory requirements.

Challenge

The EBP faced challenges in determining outcomes that were vital to stakeholders, including payers, physicians, and patients, as aligning these diverse perspectives were crucial to the clinical development plan (CDP). Conducting a market assessment was also a significant hurdle, as it required in-depth analysis of unmet needs, market size, and competition to refine the CDP and ensure the product's viability. Additionally, managing the Type C meeting request with the FDA presented challenges, requiring precise preparation, clear communication, and strategic planning to meet the FDA's expectations and navigate the regulatory requirements.

Solution

IQVIA tackled the EBP's challenges with a targeted three-step approach. First, they conducted a robust market assessment to pinpoint key insights from stakeholders and define the drug's market positioning. Next, IQVIA developed multiple clinical development scenarios, offering a clear analysis of each pathway's pros and cons to guide strategic decision-making. Lastly, IQVIA expertly managed the preparation for the Type C meeting with the FDA, overseeing the process from drafting key documents to coordinating logistics. This thorough approach equipped the EBP to navigate the regulatory complexities and enhance its development plan.

IQVIA's expertise and understanding of FDA processes allowed the team to anticipate potential issues, enabling meticulous preparation, contributing to favorable meeting outcomes.

Results

IQVIA IMPLEMENTED A COMPREHENSIVE THREE-PART APPROACH TO ADDRESS THE EBP'S NEEDS.

Market imperatives and niche

IQVIA conducted primary research with payers and physicians, alongside secondary research on unmet needs, market size, and competitive landscape. This data was synthesized through internal and client brainstorming sessions, resulting in a detailed assessment that offered strategic recommendations for improving the CDP.

Identified key market needs and positioned the product to address these gaps.

Clinical development scenarios

IQVIA developed multiple clinical development scenarios, each outlining potential benefits and drawbacks, including the probability of success, required time, and investment for each option. This allowed the EBP to make informed decisions on the optimal path forward.

Provided several strategic pathways, each with its potential.

FDA Type C meeting preparations

With IQVIA's in-depth experience, the team was capable of crafting the right key questions for the FDA, preparing a comprehensive meeting request letter and briefing document, managing all logistics, and interpreting the FDA's responses. This thorough preparation facilitated smooth regulatory interactions and alignment with FDA expectations.

Highlighted FDA's specific concerns and outlined necessary steps for progression.

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

IQVIA

CONTACT US

iqvia.com/contact