Case Study

Validating Oncology Drug Indication for Approval with a Mid-sized Emerging Biopharma

IQVIA's expertise in clinical data sets the course for the identification, prioritization, and approval of oncology drug indication

Situation

A mid-size biopharma developed a new formulation of an existing, approved oncology drug and needed to quickly decide on the indications to pursue for approval. With limited resources and intense market competition, the company sought an independent evaluation from IQVIA to validate their internal prioritization of indications.

Challenge

The company faced significant constraints due to limited resources and a highly competitive environment, despite having spent a year internally prioritizing potential indications. They needed a strategic partner to navigate the complexities of prioritizing oncology product indications with precision, ensuring that their choices were both scientifically sound and operationally feasible. To avoid biases from their previous work, they sought a fresh, independent perspective to validate their internal prioritization process and deliver data-driven decisions.

Solution

Recognizing the company's critical need, IQVIA promptly arranged an early engagement workshop to provide expert guidance and support for the company's strategic decision-making process. IQVIA employed a comprehensive, data-driven approach to independently prioritize potential indications for the oncology product.

Initial assessment

An initial assessment took place with the goal of filtering potential indications based on scientific rationale, expected efficacy, and operational feasibility.

Establish a decision-making framework

Next, a rigorous decision-making framework was put in place to rank these indications, using criteria weighted according to their relevance to the biopharma company.

Drawing expert insights

Together with IQVIA's internal disease and biomedical experts, incorporating data on commercial sales figures, efficacy benchmarks, cost considerations, and the competitive landscape.

Collaborative Workshops

To ensure a customized approach, IQVIA also organized collaborative workshops to align on priorities and methodologies, providing tailored expert guidance throughout the evaluation process.

Results

IQVIA EMPLOYED A COMPREHENSIVE, DATA-DRIVEN METHODOLOGY TO INDEPENDENTLY EVALUATE AND PRIORITIZE INDICATIONS FOR THE COMPANY.

Validation of indications

IQVIA's strategic validation matched the company's internal ranking of indications, providing confidence and support for the clinical development plan.

Expedited executive approval

The independent validation helped secure executive approval for resource allocation in early clinical development.

Accelerating timeline

IQVIA completed the evaluation in 6 weeks, using only 12% of the time the company previously spent on a similar assessment over a year.

Enhanced insights

Beyond IQVIA's evaluation validating the sponsor's internal rankings, the results revealed additional factors which may have been overlooked, supporting the decision-making process.

"The deliverable helped validate some of our thinking and revealed a few things we may have overlooked." - Biopharma executive

Connect with IQVIA's industry experts today for tailored regulatory insights and guidance to optimize your drug development strategy.

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