Case Study

Label Expansion Supported by a Real-World Evidence (RWE) Study

In a recent project, a pharmaceutical customer aimed to expand the label of its product to include a new patient population. This expansion required robust regulatory engagement and clear communication with the FDA to ensure the evidence met regulatory requirements. The customer faced the challenge of navigating the complex regulatory landscape to gain approval for the label expansion without relying on traditional Randomized Clinical Trials (RCTs).

Situation

The customer sought to expand the label of its drug using a Real-World Evidence (RWE) study. The labeling expansion required the drafting and regulatory positioning of a real-world study protocol synopsis that would reliably and accurately assess the safety and effectiveness of the sponsor's product.

Challenge

The primary challenge was to provide sufficient evidence to the FDA to support the label expansion without the traditional RCTs. This involved several key steps:

1

Developing a comprehensive protocol synopsis

In-house IQVIA epidemiologists developed a detailed protocol synopsis to outline the study design and objectives. This synopsis was crucial for demonstrating the robustness of the RWE study.

2

Preparing a Type B meeting request and briefing package

IQVIA developed a thorough Type B meeting request and briefing package to discuss the regulatory justification of the proposed real-world data source, study design, and potential regulatory pathways with the FDA. This package ensured that all necessary information was presented clearly and effectively.

3

Addressing feedback from the Type B meeting

Following the Type B meeting, IQVIA prepared a Type D meeting briefing package to address and clarify the FDA's feedback. The Type D meeting was one of the first of its kind held with the FDA, demonstrating IQVIA's pioneering approach and deep regulatory expertise.

Result

IQVIA's Regulatory Science and Strategy team provided end-to-end support throughout the process. This included:

Protocol synopsis development	Type B meeting preparation	Type D meeting preparation	Regulatory meetings
IQVIA supported epidemiologists in creating a detailed protocol synopsis to outline the study design and objectives.	IQVIA developed a thorough Type B meeting request and briefing package, ensuring all necessary information was presented clearly.	Following the Type B meeting, IQVIA prepared a Type D meeting briefing package to address and clarify the FDA's feedback.	IQVIA attended both the Type B and Type D meetings alongside the customer, providing expert guidance and support.

The successful execution of these steps facilitated clear communication with the FDA, helping the customer navigate the regulatory process effectively. The Type D meeting, being one of the first of its kind, demonstrated IQVIA's pioneering approach and deep regulatory expertise. IQVIA continues to collaborate with the sponsor to provide and position the highest quality regulatory-grade data in its ongoing support of the product's path to regulatory approval.

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