Case Study

Expedited Label Expansion for a Cancer Drug Using Real-World Evidence (RWE)

In a recent endeavor, a pharmaceutical customer sought to expand the labeling of its cancer drug to include a new patient population. However, the traditional route of conducting Randomized Clinical Trials (RCTs) was not feasible due to the low number of patients in this specific population. This presented a significant challenge: how to provide sufficient evidence to the FDA to support the label expansion without relying on RCTs.

Situation

Faced with this challenge, the customer turned to IQVIA's Regulatory Science and Strategy team for an innovative solution. The team recognized that an alternative approach was necessary to demonstrate the drug's efficacy and safety in the new population. Leveraging Real-World Evidence (RWE) became the cornerstone of their strategy.

Challenge

IQVIA's team identified and utilized RWE endpoints that provided robust real-world tumor response and safety data, which were critical for the regulatory submission. They developed a comprehensive regulatory strategy, including detailed protocol synopses and briefing packages for FDA meetings. Effective communication with the FDA was facilitated by IQVIA, with the team attending key meetings and promptly addressing regulatory feedback.

Result

IQVIA's Regulatory Science and Strategy team successfully navigated this challenge by leveraging Real-World Evidence (RWE). The key steps included:

RWE endpoints: IQVIA identified and utilized RWE endpoints that provided robust real-world tumor response and safety data, which were critical for the regulatory submission.

Regulatory strategy: IQVIA developed a comprehensive regulatory strategy, including detailed protocol synopses and briefing packages for FDA meetings.

FDA engagement: IQVIA facilitated effective communication with the FDA, attending key meetings and addressing regulatory feedback promptly.

As a result of these efforts, the FDA granted approval for the label expansion in approximately one year. This approach not only expedited the approval process, but also significantly reduced costs compared to conducting a traditional randomized clinical trial. Through the innovative use of RWE, IQVIA successfully navigated the regulatory landscape, providing a viable path for the customer to achieve their goal.

CONTACT US

RegulatoryScienceandStrategy@iqvia.com

iqvia.com