

Accelerating Software Approval Through FDA's ISTAND Pilot Program

In a recent project, a customer developed innovative software designed to address an unmet need in evidence generation. The software had the potential to revolutionize the way data was collected and analyzed, offering new insights and improving decision-making processes in the healthcare industry. However, to bring this groundbreaking software to market, the customer needed to navigate the complex regulatory landscape and gain FDA approval.

Situation

The customer faced the challenge of securing FDA approval for its innovative software. This approval was crucial for the software to be recognized and trusted by healthcare providers and stakeholders. The customer sought to leverage the FDA's ISTAND (Innovative Science and Technology Approaches for New Drugs) pilot program, which supports the development of novel Drug Development Tools (DDTs) that fall outside the scope of existing qualification programs. The ISTAND program aims to facilitate the regulatory acceptance of innovative approaches that can enhance drug development and regulatory review processes.

Challenge

The primary challenge was to prepare a comprehensive Q-submission that would effectively demonstrate the software's value and potential impact. The goal was to secure FDA's support and expedite the review process. This involved several key steps:



Preparing background information and questions: Ahead of the protocol synopsis, the team collaborated to gather relevant and necessary information about the software, including its design, intended use, and any preliminary data.



Developing a comprehensive protocol synopsis: IQVIA's team worked closely with the customer to create a detailed protocol synopsis that outlined the study design and objectives. This synopsis was essential for demonstrating the robustness of the software and its ability to meet the unmet need in evidence generation.

Result

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



Q-submission preparation: IQVIA developed a detailed Q-submission that highlighted the software's capabilities and its potential to meet the unmet need in evidence generation. The submission included comprehensive data and analysis to support the software's efficacy and safety.



Regulatory strategy: IQVIA crafted a strategic approach to engage with the FDA, ensuring all necessary information was clearly presented. This strategy included detailed protocol synopses, briefing packages, and effective communication plans.



FDA engagement: IQVIA facilitated effective communication with the FDA, attending key meetings and addressing regulatory feedback promptly. This engagement led to the software being considered for the FDA's ISTAND pilot program.

As a result of these efforts, the FDA determined that the software could be entered into the ISTAND pilot program. This provided the customer with access to additional FDA support and significantly accelerated the review timelines, enabling a faster path to market. The successful execution of these steps facilitated clear communication with the FDA, helping the customer navigate the regulatory process effectively. The ISTAND pilot program's acceptance of the software demonstrated IQVIA's pioneering approach and deep regulatory expertise.