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ELIQUENT Outcomes | FDA End-of-Phase 2 (EOP2) Meeting Success for a Radiopharmaceutical Company

Objectives

A leading radiopharmaceutical company sought to secure a successful End-of-Phase 2 (EOP2) meeting with the FDA for their diagnostic imaging agent. A positive outcome from this EOP2 meeting would be a major inflection point, providing clarity on the Phase 3 (Ph3) program and regulatory pathway.

Background

The company specializes in the radiopharmaceuticals sector, focusing on diagnostic imaging agents. Previously, it had engaged with the FDA regarding the same molecule but for a different indication. The company sought assistance from Eliquent to expedite the submission of an EOP2 meeting request, aiming to discuss the regulatory strategy for a new, previously unaddressed indication. However, the company faced a pressing obstacle: the request had to be filed within days, while the accompanying background document was still incomplete. Expert guidance was essential to navigate the regulatory process and develop a compelling meeting package that underscored the unmet medical need of the new indication and supported their proposed Ph3 program.

Challenges

The primary challenge was navigating the restricted timeframe while ensuring the FDA meeting package effectively conveyed the significance of the imaging agent and its potential impact in the new indication.
Key concerns included:

- **Tight deadline:** The EOP2 meeting request had to be submitted within a matter of days.
- **Regulatory complexities:** Previously unaddressed indication requiring a well-structured argument.
- **Convincing justification**: The EOP2 background documentation needed to clearly convey the unmet clinical need and how the product addressed it. Additionally, it needed to present a clear Ph3 program to facilitate alignment between FDA and the company on the next steps.

Solutions

Expedited Submission

Facing a tight deadline, the company wanted to submit an EOP2 meeting request within a week. With limited time and an incomplete background document, they turned to ELIQUENT's Regulatory Affairs for guidance. Together, they coordinated efforts to prepare and submit the request on time, ensuring alignment with company timelines and regulatory expectations.

Strategic Briefing Book Development

To build a compelling case for the FDA, the company collaborated closely with ELIQUENT's Regulatory Affairs and Medical Writing teams to create a strong scientific narrative. They focused on demonstrating the mechanism of action and addressing the unmet clinical need for the diagnostic tool. With ELIQUENT's expert support, their documentation was refined into a well-structured, persuasive background document, clearly justifying the Phase 3 program to the FDA and the product's impact on patient care.

Guidance Throughout the Process

Navigating the FDA process can be complex, but with ELIQUENT's comprehensive Regulatory Affairs' guidance, the company identified key priorities and structured discussions for clarity. By strategically framing their engagement, the company positioned themselves for a productive FDA interaction, gaining the insights needed to advance their program.

Outcomes

The Client benefited significantly from clear FDA feedback, resolving potential regulatory obstacles and providing confidence in moving forward with the Phase 3 program and NDA pathway. This also strengthened their position for investor discussions. For patients it means the continuing development of a non-invasive diagnostic tool for an unmet clinical need. ELIQUENT demonstrated the ability to work efficiently to tight deadlines, delivering high-quality regulatory and medical writing support, giving clients the clarity and support needed to move forward with their programs.