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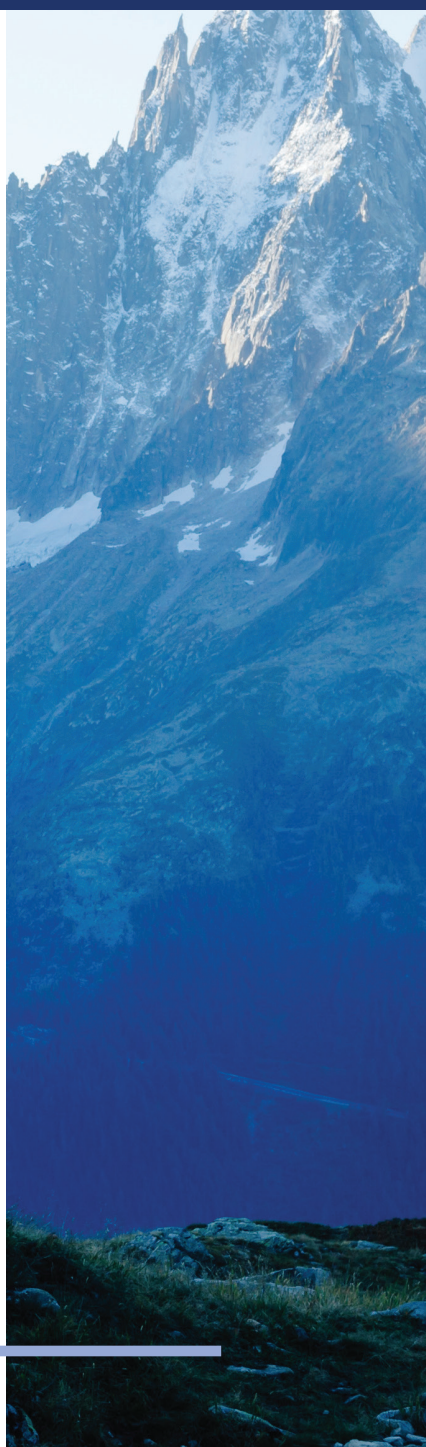
LIFE SCIENCES

FACET LIFE SCIENCES SAVES TIME AND MONEY FOR EUROPEAN DIAGNOSTICS SPONSOR



BACKGROUND

Founded in 2014, a European medical imaging diagnostics company sought guidance on the development of a novel Positron Emission Tomography (PET) radiopharmaceutical product. Data from over 800 patients had been collected from a variety of sources including medical centers, academic institutions, and independent investigators.

BUSINESS CHALLENGE

The company was struggling to make consistent and meaningful progress toward a marketing authorization in the United States and Europe. They were planning to conduct additional clinical trials that they thought would be needed for registration.

SOLUTION

The Facet Life Sciences team of experts reviewed the available data as well as literature found in the public domain, and argued that the data collected to date would be enough to seek approval in both major markets. They discussed the corporate objectives with the Sponsor and based on those goals, recommended a discussion with FDA before embarking on any additional studies.

RESULTS

In a Type C meeting regarding the development and review of the product, the Facet Life Sciences team confirmed with FDA that no additional trials were required for registration of the novel radiopharmaceutical product. This determination saved the company an estimated 2 years of additional development time and approximately $5 million in clinical trial operating costs.

Working closely with this Sponsor as their US Agent, the Facet Life Sciences experts subsequently established the requirements for the NDA and MAA filings. Both the NDA and MAA applications were prepared and successfully filed. The NDA was approved in 2016 and the MAA review is ongoing. The team is currently leading the NDA post-marketing submission activities, including labeling and promotional reviews, assisting with line extensions, and providing ongoing regulatory strategy guidance and content development (medical writing) support for the MAA. In addition, Facet Life Sciences oversees regulatory eCTD publishing activities for this Sponsor's portfolio of products through our publishing partner.

The Facet Life Sciences Team provided guidance and expertise to the Sponsor to help them understand and implement the most effective approach to achieve their goals. By asking the right questions and applying their extensive working knowledge of clinical development and regulatory processes, the Facet Life Sciences team was able to help the Sponsor save significant time, money, and resources.

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