CASE STUDY

Supporting a Client with a Novel Theranostic

SCENARIO

One of our pharmaceutical clients with a new theranostic needed support with the imaging aspects in the development of nuclear medicine and PET imaging aspects using 68Ga.

THE CHALLENGE

The business development team was familiar with the newly acquired product from a high level. The cross-functional development team, which included nonclinical, clinical, and CMC team members, was a bit unclear about the regulatory pathway options.

THE STRATEGY

Bracken staff embedded in the clinical team provided support in developing the clinical program for the diagnostic, including identifying the need for a new study to confirm the dosing (for both peptide mass and radioactivity).

Support also included developing the study and choosing core labs, as well as developing a unique read system to maximize the limited number of subjects. Shortly after that, FDA approval was secured.

The therapeutic trials required coordination with imaging as the end points have to be considered for therapy and to support the INDO for imaging. The clinical program is therefore complex and requires knowledge of diagnostics and therapeutics and the interplay between the two'. This led to an FDA Type C meeting in which the consultant participated.

Regulatory Expertise

Our team of expert consultants are here to help *you,* leveraging our knowledge for *your solutions.*

Our tailored services range from ad hoc consulting, to providing a virtual C suite (CEO, CFO, CMO, CSO) clinical and regulatory team ready and able to integrate with yours.

By employing a comprehensive and customizable multidisciplinary, problem-solving methodology, we are able to reduce risks and streamline development plans.

The regulatory landscape is tough to navigate---don't go it alone.

THE RESULT?
Built-in Imaging Expertise

The client has an inbuilt imaging expert to allow the successful development of the novel theranostic.

BRACKEN

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