CASE STUDY

Navigating Critical Regulatory Requirements in Alignment with Sponsors' Unique Challenges and Goals

BRACKEN

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OVERVIEW

Strategic navigation of regulatory requirements is essential for sponsors who hope to achieve commercial success in the United States. The FDA regulations and guidances are in place to assist sponsors, yet managing this process can be difficult.

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.

KEY SERVICES & DELIVERABLES

Regulatory services and deliverables vary greatly from client to client depending on the specific needs and interests. Some clients prefer just intermittent input from Bracken and continue preparing their strategy and documents with the aid of periodic Bracken/sponsor touchpoints. Other clients prefer more interaction and collaboration.

Still others engage Bracken to handle almost all the regulatory and strategic input and content submissions. These sponsors simply review key documents to ensure the path forward is the one they envisioned.

We at Bracken are happy to customize each engagement to suit each client's goals and needs.

TOOLS AND TECHNIQUES

Regulatory strategy

Content submission assistance

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TheBrackenGroup.com

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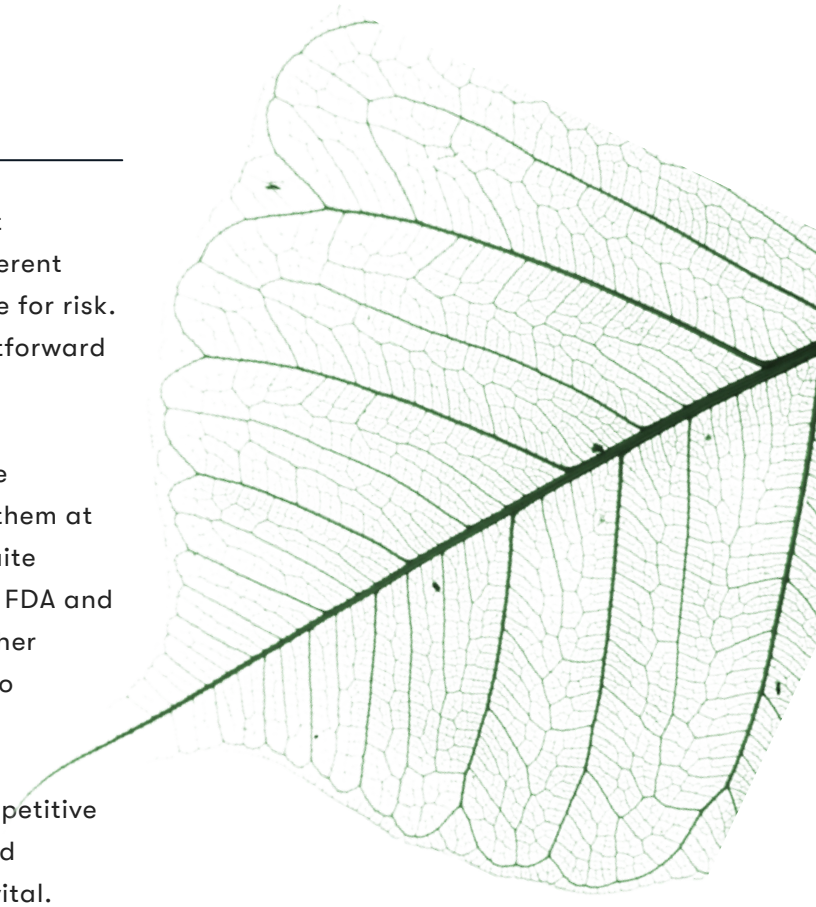
THE CHALLENGE
FINDING THE RIGHT CONSULTING



The first step for the Bracken team is to help the client understand the nuances of their situation and the different approaches available to them based on their tolerance for risk. Unfortunately, the path forward is not always straightforward and the process can be an iterative one.

Employing the guidances correctly, knowing which are appropriate for what therapeutic area, and applying them at the correct time in the development process can be quite challenging. In addition, new guidances are issued by FDA and other global health authorities on a daily basis. A further complication is the fact that the guidances are open to interpretation.

Experience with current programs, the regulatory competitive landscape, development trends, and the successes and challenges that others have met in the recent past is vital.

THE DETAILS

Recently, a sponsor approached Bracken as part of their quest to move forward with the COVID-19 Emergency Use Authorization (EUA) process. The sponsor asked Bracken to fill out a few forms for them. As the Bracken team examined the information provided, it became clear that one of the forms at hand was not the right one. In fact, the “right one” did not exist. As an alternative, Bracken suggested the sponsor supply a Reviewer’s Guide to more fully explain to the FDA their data package and their desired path forward.

The FDA appreciated receiving this more comprehensive document in addition to the standard form. But, shortly after the Reviewer’s Guide and form were submitted, the FDA issued a new form, which necessitated a new submission. While this development was somewhat frustrating for all concerned, having the Reviewer’s Guide available allowed Bracken and the sponsor to resubmit in record time.

THE BRACKEN SOLUTION

The development of products for COVID-19 was complicated at the time by the fact that understanding of SARS-Cov-2 was steadily evolving, necessitating frequent updates and changes from FDA.

In situations like this, Bracken is able to leverage extensive prior experience with FDA to predict changes that will likely result from the changing landscape.

With this in mind, Bracken collaborates with clients to develop a sound strategy that can withstand change. When changes do occur, we are prepared with the information necessary to satisfy FDA's updated requirements.

THE RESULT
EXPERT REGULATORY GUIDANCE

No matter at what phase of development a client engages with us, we at Bracken are always pleased to help the client in their journey toward solving their unique development and regulatory challenges, helping to direct and/or redirect the course, and positioning them for success.

THE TAKEAWAY

Success with regulatory requirements is at times process driven while at other times, strategic decision making is essential. In either case, nothing else happens if regulatory requirements aren't met. Sponsors who want to be sure of success can rely on the team at Bracken to get them there.

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