IND Acceptance

Synteract Helps Biotechnology Company to Gain IND Acceptance

Highlights

- Synteract provided guidance to prepare and submit an IND under an aggressive timeline.
- It collaborated with the FDA on strategies to provide the most comprehensive, easy-to-review format.
- The IND was reviewed and accepted by the FDA within 30 days.

Introduction

A California-based biotechnology company, focused on the development of novel therapeutics, wanted to gain acceptance of an Investigational New Drug (IND) application for a drug to treat a specific type of leukemia.

Challenges

- The sponsor needed to file the IND under an extremely aggressive timeline that was barely a third of the time normally required.
- The IND submission was unique in that the clinical information submitted to the agency cross-referenced an existing IND.

Our Solutions

- **Synteract served as the regulatory advisor and authorized representative for the sponsor, coordinating all communications with the FDA before and during the IND submission process.**
- It approached the aggressive timeframe head-on with a strategy to assess all possibilities to streamline preparation of the IND and to make it more adaptable and reviewable to facilitate a speedy response from the FDA.
- **Synteract collaborated with the regulatory project manager (RPM) at the FDA to determine the best strategy for providing the most comprehensive preclinical and clinical information in an easy-to-review format.**

- A key and unique strategy, resulting from the conversations, was to create an electronic IND submission that would cross-reference information in the existing paper format IND, enabling FDA reviewers to easily refer to previously submitted paper information during the review process. A highly-detailed tracking sheet was inserted into the electronic submission that linked to each respective IND.

Program Success

- **The IND was reviewed and accepted by the FDA within 30 days.**
- With the FDA's approval, the biotechnology company was able to take the next steps toward treating this rare cancer by initiating open-label, Phase 1b/2 trials in AML patients, a major milestone for the company, product development and AML patients who may benefit from this novel treatment.

About Synteract

With employees across 21 countries, Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of therapeutic expertise in oncology, dermatology, and neuro degenerative indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Therapeutic-Expertise/Oncology or ContactUs@synteract.com.

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