VERISTAT

Successful IND Submission Paves the Way for a Global Full-Service Phase I Clinical Trial Targeting Cancers

Veristat Guides Small-Sized Biotech Company to Next Development Milestone

Background

A small-sized biotechnology company engaged Veristat early in development for help with conducting a pre-IND meeting and IND submission for a therapeutic product platform targeting cancers of the reproductive system. The sponsor initially set their sights on reaching clinical trials as swiftly as possible, but navigating the complex regulatory environment proved challenging, and the project began to run over budget and behind schedule. To help the sponsor move forward as prudently as possible, Veristat provided strategic consulting, project management support, medical affairs services, and regulatory publishing expertise.

Study Demographics

Indication:
Therapy product platform targeting multiple cancers

Phase:
IND

Regulatory Agency:
FDA

Primary Services Provided:
- Project Management
- Medical Affairs
- Strategic Consulting
- Medical Writing
- Regulatory Publishing

SOLUTION

Veristat played a pivotal role educating the sponsor on the fundamental components of a successful IND submission, thereby fostering a more comprehensive and strategic approach. Our team persuaded the sponsor of the value in meeting with FDA, then took the lead in preparing and facilitating agency interactions, ultimately helping the sponsor save many months' time and receive valuable agency feedback to improve their clinical trial.

The sponsor had to rectify several CMC issues, but Veristat adapted quickly and seamlessly incorporated the late-breaking data into their submission, allowing the IND to be filed ahead of the revised schedule. During FDA's 30-day IND review period, our Regulatory experts efficiently facilitated and addressed agency requests and updated the protocol, resulting in a favorable outcome with no clinical hold.

IMPACT

Following FDA approval of the IND, the sponsor is now advancing with the Phase I clinical trial, which the Veristat global operations team has started.

ABOUT VERISTAT

Your Full-Service Clinical Trial & Regulatory Partner

Without a sound strategic plan tailored to your drug or biologic, your IND submission risks being delayed. To give you an advantage, Veristat's global experts guide you through the entire drug development and submission process to help you achieve clinical and regulatory success.

Lessons Learned

Early and successful interactions (meetings and written exchanges) with the appropriate regulatory authorities can reduce both costs and time to approval and mitigate potential clinical holds.

Veristat's flexibility to add team members from various functions streamlines projects and reduces timelines.

Contact Veristat Today

To learn more about Veristat or how we can assist you, reach out to us today.

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