› CASE STUDY

VERISTAT

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

Veristat guides a small biotech to next development milestone

Background

A small biotechnology company developing a therapeutic platform for cancers of the reproductive system engaged Veristat early for pre IND planning and IND submission support. While the sponsor aimed to move rapidly into first in human studies, complex regulatory requirements and emerging CMC needs began to strain timelines and budgets, putting program momentum at risk.

Sponsor Challenge

The sponsor needed a partner to orchestrate and engage on FDA interactions under tight timelines, maintain scientific and documentation rigor across modules, and integrate late breaking CMC data, without missing submission windows or increasing the risk of a clinical hold. Coordination across project management, medical affairs, medical writing, and publishing was essential to keep the program on track.

STUDY DEMOGRAPHICS

STUDY PHASE
- IND

INDICATION
- Therapeutic platform targeting multiple cancers

REGULATORY AGENCY
- FDA

SERVICES PROVIDED
- Strategic Consulting
- Project Management
- Medical Affairs
- Medical Writing
- Regulatory Publishing

Veristat Solution

Veristat educated the sponsor on critical IND components and the value of early, structured FDA engagement. The team led preparation for late-breaking pre-IND interactions with the FDA, shaping clear regulatory messaging and securing timely agency feedback to refine the protocol. When CMC issues surfaced close to submission, Veristat adapted quickly, incorporating late-breaking data while preserving consistency across the submission. Our regulatory publishing experts assembled, QC'd, and filed the package ahead of the revised schedule. During FDA's 30-day review, Veristat coordinated prompt responses and protocol updates, resulting in a favorable outcome with no clinical hold.

Impact

- **IND cleared—no clinical hold**—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.
- **On-time filing despite a revised schedule** via agile regulatory publishing and added cross-functional capacity.
- **Late-breaking CMC integrated without delay** through scalable resourcing and tight document control.

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Meet Veristat

The Global CRO and Consultancy that Accelerates Success

From early regulatory strategy through global study execution, Veristat aligns our integrated expertise to keep programs on time and submission-ready.

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