VERISTAT

IND Success Strategy: Building a High-Quality IND from Scratch with Strategic Gap Analysis

Veristat helps clients without internal regulatory expertise develop, compile, and submit complete, FDA-compliant INDs

Background

A sponsor without internal expertise needed to create and submit an Investigational New Drug (IND) application and approached Veristat for help. They required comprehensive regulatory support to ensure a compliant IND submission and a smooth development process moving forward.

Veristat applied its proven development model, which begins with strategic planning and a gap analysis, to guide the client through IND preparation and submission.

1 Sponsor Challenge

No Internal Expertise for IND Creation

The client required full support to compile an initial IND dossier. Without prior regulatory submission experience, they faced potential delays or a clinical hold due to incomplete or misaligned documentation.

SPECIFICATIONS

SUBMISSION TYPE
- IND – U.S.

CLIENT NEED
- Comprehensive IND expertise to address the lack of in-house resources

DEVELOPMENT PHASE
- Pre-IND through initial clinical trial

SERVICES PROVIDED
- Regulatory Gap Analysis
- IND Planning and Project Management
- Medical Writing Coordination
- Strategic Regulatory Review
- IND Document Authoring
- IND Publishing (eCTD)
- IND Submission and support during the review

Veristat Solution

End-to-End IND Planning, Medical Writing, and Submission Support

Veristat's model is purpose-built to support IND development from start to submission. The engagement began with a gap analysis of existing documentation and identification of key contributors across functions.

- The analysis uncovered missing information that could trigger FDA concerns.
- Veristat's recommendations bridged the gap between what had been completed and what FDA expects.
- Veristat collaborated with the client to address each point identified in the gap analysis.

Veristat also developed a deep understanding of the intervention's scientific rationale and assessed precedents in the competitive landscape.

Diving Deeper: Strategic Execution for IND Success

Veristat's responsibilities included:

- Project Management to define the IND content plan and timelines
- Publishing to receive documents and build the eCTD submission
- Strategic review of all sections
- Delivery of a complete, FDA-compliant IND

The client also required medical writing support, including coordination with third-party CROs and authorship of summary documents for IND Modules 1 and 2. Veristat's writing team:

- Integrated documents from external vendors
- Delivered:
  - ICH-compliant Clinical Study Reports (CSRs)
  - CTD Module 2 summaries
  - Technical reports for CTD Module 3
  - Tabular summaries of clinical and nonclinical data

Veristat also authored core IND documents, including:

- Investigator's Brochure
- IND Opening Protocol
- General Investigational Plan
- Quality Overall Summary
- Clinical Pharmacology Overview
- Clinical and Nonclinical Overviews

Veristat's model includes experienced project management and publishing services to build the IND for electronic submission. Success depended on assembling a cross-functional team of client SMEs and outsourced partners such as third-party medical writers, clinical pharmacology consultants and bioanalytical labs. Finally, Veristat supported conduct of the IND-opening clinical trial, including identification of a qualified MD to oversee the conduct of the IND opening clinical trial.

Impact

- Delivered a complete, FDA-compliant IND dossier on time by filling key roles on project development team
- Prevented potential delays and clinical hold by identifying and addressing critical documentation gaps early
- Coordinated input across internal contributors and third-party vendors
- Enabled the sponsor to initiate clinical trials with confidence
- Helped the team meet their internal corporate goals

Contact Veristat to Help Ensure Your IND Success

From strategic planning and scientific alignment to document authoring and submission, Veristat brings the regulatory expertise you need to move your program forward. Whether you're building your first IND or navigating complex submissions, our global team can help you meet FDA expectations with confidence.

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