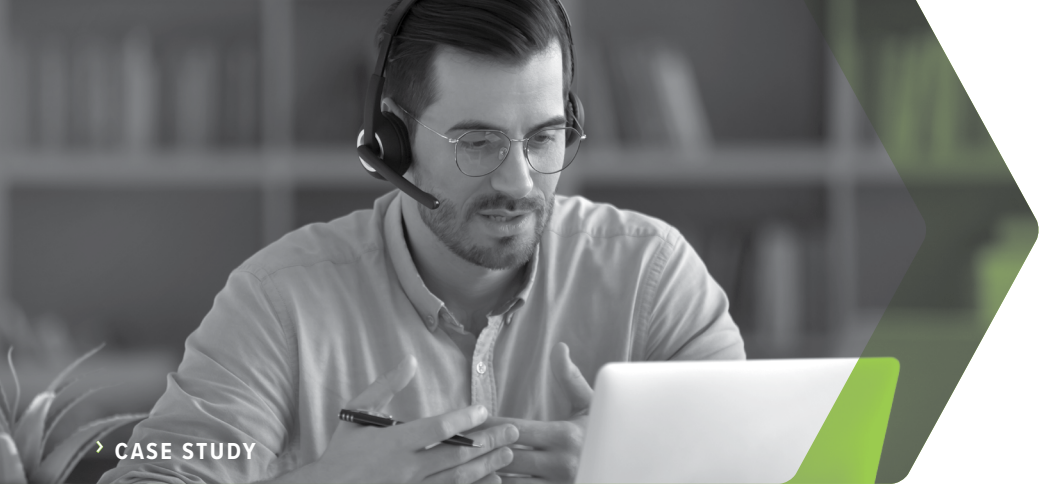

VERISTAT

Post-Submission IND Maintenance: Veristat as U.S. Agent and Strategic Regulatory Partner

Veristat supports FDA interactions and helps secure special designations like orphan, fast track, and priority review.

Background

Following a successful IND submission led by **Veristat (Link to other case study)**, the sponsor engaged Veristat for long-term IND maintenance and strategic regulatory input. The sponsor needed a U.S. Agent to correspond with FDA on their behalf and a team capable of supporting the multiple types of IND amendments frequently encountered during the drug development process.

1 Sponsor Challenge

Sustaining Regulatory Momentum Post-IND Activation

With their IND in effect and the initial trial underway, the client required a partner to maintain the IND, handle FDA communications, and help plan the next regulatory steps—all without internal regulatory staff.

Veristat Solution

Once the clinical development program had been initiated, Veristat took on the role of US agent for the IND for all FDA correspondence. Veristat also participated as a member of the development team to provide strategic input, including the timing and scope of FDA meetings when guidance was required.

To ensure ongoing success, Veristat supplemented the project team with specific regulatory skillsets, including:

- Regulatory strategy
- Project management
- eCTD publishing
- Statistical analysis
- Data management
- Medical writing

SPECIFICATIONS

PROGRAM STAGE

- Effective IND, early clinical development

SERVICES PROVIDED

- U.S. Agent Representation
- FDA Correspondence Management
- Strategic Regulatory Input
- FDA Meeting Planning
- Ongoing Project Support Across Functions

Putting Global Regulatory Strategy to Work

Veristat's approach to global regulatory strategy included:

- Strategic planning based on therapeutic area requirements and recent approval precedents
- Integration of client business priorities with industry best practices
- Agility to adapt to rapid changes in development

Veristat experts helped with multiple aspects of ongoing development, including:

- Building Clinical Trial Applications (INDs and CTAs)
- Supporting Agency meetings across ICH regions
- Preparing Marketing Applications for submission
- Preparing requests for special designations

Impact

- Provided U.S. Agent services and IND maintenance
- Enabled efficient FDA interactions and meeting planning
- Delivered regulatory strategy tailored to client priorities
- Positioned sponsor for access to expedited approval pathways

Regulatory Consulting for FDA & Global Regulatory Agencies

Veristat experts provide regulatory guidance to your product development teams to help ensure successful interactions with FDA as well as other global regulatory agencies.

Contact Veristat. Ensure Regulatory Success.

Veristat's global experts guide you through every phase of the regulatory process—from IND submission to market authorization—so you can focus on your science.

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