VERISTAT

Advancing to Your Next Milestone – Global Regulatory Excellence Throughout the Entire Clinical Development Lifecycle

Navigating the global regulatory landscape in today's world is increasingly long and complex. Sponsors cannot afford mistakes or delays when it comes to preparing and submitting clinical trial applications and marketing applications to health authorities. Our integrated teams of regulatory, statistical, clinical, and medical experts work closely with you to understand your development goals to meet or exceed your regulatory timelines. Our experts help you:

- Develop the clinical development plan and regulatory roadmap
- Prepare and write clinical trial applications- INDs/CTAs/IMPD
- Perform CMC writing and gap analysis
- Apply for special designations for faster development or approval pathways
- Support Agency meetings, Briefing meetings, and Scientific Advice (SA) meetings
- Prepare and write Marketing Applications (NDA, BLA, NDS, MAA, etc.)
- Publish all clinical trial and regulatory dossiers/applications to regulatory agencies

Explore how Veristat has helped sponsors achieve regulatory success globally, and learn how our expertise can be tailored to support your specific needs.

1 Advancing to Phase I with Early Submission of the IND

Development Phase: Pre-IND and IND submission to FDA

Services Provided: Resourcing/FSP, Regulatory Consulting, Regulatory Project Management, Regulatory Publishing, Medical Writing, Data Management

Veristat supported a leading biopharmaceutical company in its IND submission for an antibody therapy targeting cancer. Having successfully collaborated on several other projects, the sponsor and our team had built a strong relationship. During the project, the client encountered staffing challenges, requiring us to adapt to changes in an agile fashion.

Veristat seamlessly executed a flawless submission and exceeded the proposed submission date by a quarter. FDA cleared the application, allowing for the sponsor to move forward with the Phase 1 clinical trial, moving towards benefiting patients.

2 Maximizing Resources and Timelines to Get Orphan Drug Designation, Priority Review, and Submission of Consecutive Marketing Applications to EMA and FDA

Development Phase: Marketing application submissions to FDA and EMA, as well as ODD applications

Services Provided: Regulatory Consulting, Regulatory Project Management, Regulatory Publishing, Medical Writing

A clinical-stage biopharmaceutical company sought Veristat to assist with multiregional submissions for a novel therapy targeting a rare genetic metabolic disease. Over several years, the sponsor and our team have collaborated on managing development programs in the US and Europe. Initially, Veristat supported the submission of a Marketing Application in Europe. Our teams were then able to repurpose the application for the New Drug Application submission in the US, optimizing resources to meet both timelines efficiently.

Veristat successfully helped the sponsor acquire orphan drug designations with both EMA and FDA as well as a rare disease designation and priority review with FDA. Veristat continues to support both submissions during the application review periods.

3 Achieving Early Submission of Marketing Applications to Three Regulatory Agencies

Development Phase: Marketing application submissions to FDA, MHRA, and EMA

Services Provided: Project Management, Regulatory Publishing, Medical Writing

A small biotech company developing a novel therapy to treat an autoimmune disease engaged Veristat for support publishing and writing a three-tiered marketing submission to FDA, MHRA, and EMA. Veristat strategically built the submissions to minimize customizations while supporting the three regions, and helped the sponsor achieve a rolling submission and priority review status with FDA.

As the submission deadline neared, the sponsor moved the submission date earlier due to a competitor submitting a marketing application for the same indication. Despite this challenge, our team successfully managed the execution of the marketing applications across all agencies. Veristat continues to provide the client with post-submission maintenance.

Contact Veristat.
Ensure Regulatory Success.

Our global experts guide you through the entire drug development and regulatory submission process to help you achieve regulatory success.

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