VERISTAT

Regulatory Consulting & Planning For Clinical Development Success

Strategic and Tactical Regulatory Guidance, Clinical Program Design, and IND Support Through to Regulatory Approval

Veristat team members have supported nearly **50 IND submission projects.**

Regulatory planning for your clinical development program starts before and continues after you begin preparing your Investigational New Drug (IND) application. As you look to transition from lab to clinic, Veristat can help. Our regulatory, scientific and communications experts provide strategic regulatory planning, cross-functional operational support and the practical real-world knowledge of how to present your clinical and product development goals to the regulatory agencies.

Broad Range of Regulatory Consulting and IND Preparation Expertise

Our teams have prepared regulatory strategies, developed clinical program designs and supported INDs for numerous programs to treat blood disorders, cancers, cardiovascular disease, endocrine disorders, genetic disorders, respiratory diseases, woman's health issues and wound healing.

Staff Experience:

100% of our medical writing quality control, regulatory, and publishing teams have IND experience

4 senior consultants have an average of 20+ years of experience developing regulatory strategies, program design and submission preparation

Providing Strategic Regulatory Support for Clinical Program Planning & Trial Design Through to Successful Regulatory Approval

Strategic Program Planning

- Develop the regulatory strategy and submission plan to support both US and global registrations
- Explore the possibility of pursuing expedited or alternate regulatory pathways for faster approval, and write the corresponding applications
- Write and review non-clinical development plans, including toxicology study outlines
- Assist in Contract Manufacturing Organization (CMO) selection, justification of specifications and method validation
- Write and review clinical development plans including trial design, sample size calculations, protocols, investigator brochures, electronic Case Report Forms (eCRFs), write Statistical Analysis Plans (SAP) or Interim analysis plans (IAP)
- Draft regulatory agency, board meeting, or investor presentations of the clinical development, Chemistry, Manufacturing and Controls (CMC), regulatory and/or statistical plans

IND Writing, Gap Analysis & Publishing

- Protocol & Investigator Brochures
- CMC Writing
- Non-Clinical

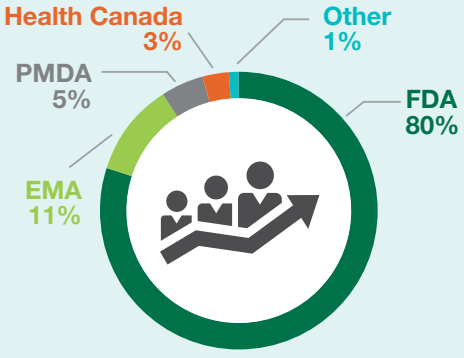
Regulatory Communications & Compliance

- Serve as Authorized Regulatory Representative and US Agent (pIND, IND, NDA, BLA)

Regulatory Agency Meeting Preparation & Support

- Prepare meeting logistics
- Facilitate or moderate the FDA meetings
- Track FDA clinical, Non-clinical and CMC development requirements from pre-IND through to marketing application and beyond
- Continual updates until final submission to regulatory agency – NDA, BLA, MAA, jNDA

Regulatory Agency Experience



Our Experts Drive Success

Over the past five years, I have personally had the privilege to work with a dedicated Agios team on the IND application, phase I study, and NDA submission for ivosidenib. I am thrilled to see TIBSOVO® receive FDA approval and look forward to seeing this therapy help improve the lives of patients with R/R AML."

Barbara Balser, VMD, Veristat Executive VP & Chief Scientific Officer at Veristat

CASE STUDY

Achieving Clinical Development Success

From IND to FDA Approval

Veristat supports the first targeted therapy for adult patients with relapsed/refractory acute myeloid leukemia and an IDH1 mutation

Situation: A company focused on cellular and precision medicines came to Veristat for help preparing their IND. Veristat worked on the IND and continued providing statistical and medical writing support for their phase I study which was used as the basis of the approval. Additionally, our team continued to support the preparation of the New Drug Application to submit to the FDA.

Impact: Our client received FDA approval for the first and only FDA-approved therapy for patients with Relapsed/Refractory Acute Myeloid Leukemia and an IDH1 Mutation. The FDA granted this application Fast Track and Priority Review designations and the therapy also received Orphan Drug designation. Today, we are helping this company expand this compound into new indications and bring new compounds into early phase trials.

Consult with Our Regulatory and Clinical Trial Planning Experts

To learn more about Veristat or how we can assist you with your regulatory strategy and clinical trial planning, reach out to us today.

www.veristat.com