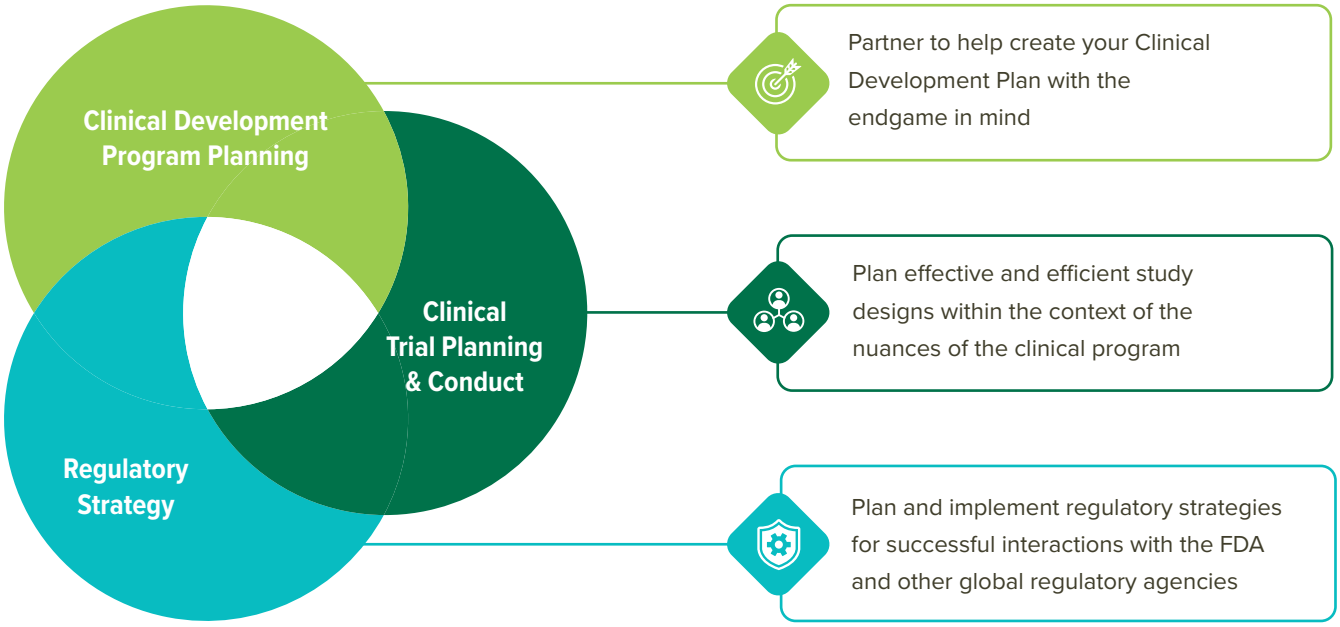
VERISTAT

Strategic Clinical Development Consulting

Veristat has helped pharmaceutical, biotechnology, and medical device firms solve the unique and complex challenges they face throughout the clinical development process. Our early, forward-looking planning can result in greater efficiency and a better understanding of key decisions and time points during your novel therapy development. Our expert regulatory, clinical, medical, and statistical consultants provide high-level strategic consulting services from IND planning to regulatory approval.

We never assume your problem is straightforward, where old solutions can be applied without careful consideration. Our approach marries strategic consulting with regulatory insights and technical expertise, bringing you informed recommendations and decisions that advance the development and approval process.



STRATEGIC CONSULTING SUCCESS STORIES

1. **Approvals for an Ultra-Rare Hematologic Malignancy**

   A small biotech company engaged Veristat early in clinical development for help with a novel biologic being tested for treatment of an ultra-rare and aggressive hematologic malignancy with no available effective therapies. Using the results of a single-arm Phase I/II study, Veristat and the sponsor company collaborated to present a thorough, well-planned strategy for demonstrating the benefits and risks of the targeted therapy in this patient population to regulatory authorities. Based on Veristat's significant experience, the sponsor engaged our team for strategic consulting, statistical and programmatic support, and medical writing to plan and execute the marketing application process, eventually leading to both FDA and EMA approval.

2. **Positioning a Sponsor's First Trial for Success**

   A clinical-stage biotech company approached Veristat to collaborate on study design and write the protocol for their first Phase I study for an immuno-oncology antibody in patients with advanced solid malignancies who have progressed on all available standard therapies. After completion of the trial planning stage, Veristat experts on the strategic consulting and regulatory strategists have maintained advisory roles assisting with protocol review committee meetings, clinical development plan, dose escalation and expansion, potential for accelerated pathways, risk mitigation, and more. Veristat is continuing to work with this client on initial planning for their next trial.

3. **A Nuanced Statistical Method to Determine Dosing Levels**

   A biopharmaceutical company came to Veristat at the start of their protocol development to write the dose escalation and expansion for a novel rare cancer therapy. Our experts utilized the Bayesian continual reassessment method, a dose escalation that uses a nuanced statistical method, to decide dosing levels. After writing the protocol and operational plan, our data management team built their EDC and continues to support this client in the early stages of their trial.

Bold Thinking that Delivers Results

Veristat is focused, dedicated and experienced in helping bring new therapies through the clinical development and regulatory submission process for patients who have no existing or limited treatment options available. Learn more about Veristat and how we can assist you with trial development, execution, and regulatory submission preparation.

www.veristat.com