VERISTAT

Global Expertise to Mitigate Risks and Accelerate Biologics through Development Milestones

Advancing biologics from start to finish is highly complex and full of challenges, requiring scientific strategies and implementation. It pays to have a trusted partner by your side. Veristat's global team leverages lessons learned over the course of our work, supporting over 375 clinical trials and consulting projects and 20 marketing applications for biologic therapies in the past five years.

In the past 5 years: **375+**
Clinical Trials and Consulting projects

- **40%** are for Rare Diseases
- **45+** Full-service Clinical Trials
- **40** IND/CTAs and 20+ Marketing Applications Prepared

Expertise Across the Most Complex Biologic Treatment Types

Our expertise is offered as a comprehensive, all-inclusive solution or as functional support throughout the entire clinical development and regulatory approval process to keep your program on track. Veristat ensures that your clinical trial or program design supports your regulatory strategy, whether you plan to run a single pivotal trial or multiple trials.

Expertise Across the Most Complex Types of Biologic Treatments

- Biosimilars
- Cell Therapies
- Gene Therapies
- Immunotherapies
- Monoclonal Antibodies
- RNA Therapies
- Vaccines
- And more...

Flexible Collaboration Across Entire Development Lifecycle

	PRE-CLINICAL	PHASE I-III	REGISTRATION	COMMERCIALIZATION
STRATEGIC CONSULTING	Scientific strategic insights to plan for development program success – from IND/CTA to post-approval			
REGULATORY AFFAIRS	Regulatory expertise that delivers the roadmap, gap analysis, agency interactions and registration/maintenance support to achieve success			
BIOMETRICS		Data and Statistical experts to plan the collection, analyses, standardization, and reporting of your clinical trial data		
CLINICAL OPERATIONS/ MEDICAL AFFAIRS		Integrated clinical trial conduct solutions including feasibility, site selection, patient recruitment & retention, site management, site monitoring, patient safety services and a flexible virtual/decentralized trials approach		
MEDICAL WRITING		Scientific-minded medical writers to develop protocols, clinical study reports, all modules of regulatory dossiers for global regulatory authorities, as well as scientific manuscripts to disseminate scientific and clinical data		
PHARMACOVIGILANCE			Safety and PVG specialists focused on managing the post-market safety risks of your approved medical therapies	
MARKET SOLUTIONS/ COMPLIANCE			Market Access, Reimbursement, Healthcare Compliance, Public Affairs and Quality Assurance expertise to ensure the commercial success of your product	

Driving Success for Our Clients

Example 1: Clinical-stage biotech developing pancreatic cancer therapy

- Successful execution and closure of Phase II study based on the recommendation of the Safety Review Committee
- Full-service support continued into the Phase III study, targeting an NDA submission

Example 2: Biotech developing gene therapy for rare metabolic disease

- Successfully resolved critical patient, lab, and manufacturing logistics in Phase I/II clinical study
- Veristat continues to work with sponsor managing post-transplantation patient requirements through a long-term follow-up study

Example 3: Mid-size biotech developing novel gene therapy targeting an ultra-rare neurologic disease in a pediatric population

- Successfully served as implementation arm of the sponsor in ongoing natural history study
- Full-service support continued for Phase I/II clinical trial. Currently, more than five patients have received the gene therapy with the goal of treating 50 patients

Contact Veristat Today

Speak with our clinical trial and regulatory experts to accelerate your next study or program to success.

veristat.com/full-service-cro-biologics