VERISTAT

Think Bold.
Think Scientific.
Think Veristat.

From Strategic Planning and Trial Design to Trial Execution Through to Regulatory Approval and Commercialization

Veristat harnesses knowledge, expertise, and scale to provide superior solutions and progressive approaches to mitigate risks and achieve meaningful outcomes for biopharmaceutical and medical technology companies, and their patients.

Our highly qualified scientific-minded team of regulatory and clinical development experts offer creative, unique, and agile approaches to tackling the most complex challenges in program design, clinical trial conduct, and the regulatory approval process.

Our Impact – Improving Lives

Veristat teams supported marketing applications for **8 therapies that received regulatory approval in 2022.**

Dedicated Service Model Across Entire Development Spectrum

	PRE-CLINICAL	PHASE I-III	REGISTRATION	POST-MARKET
STRATEGIC CONSULTING	Bold thinking and science-based insights to plan your development program – from IND/CTA to NDA/MAA and beyond			
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	

Flexible Approach Based on Your Needs

We offer a flexible partnership engagement model that delivers the right scientific expertise – when you need it – throughout the entire development journey to help you avoid project/trial delays, missed milestones or deliverable failures.

Whether you're looking for a full-service partner with end-to-end solutions, support for a single service, or need specific experts to augment your in-house resources, Veristat can help.

Complexity Is Our Specialty

In the past five years, Veristat has supported more than 1,100 consulting, clinical trial and marketing application projects across various therapeutic areas. Our specialty is taking the complex to approval. Below is a snapshot of our overall study experience.

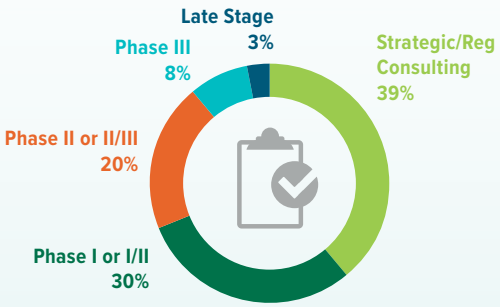
58% Drugs

31% Biologics

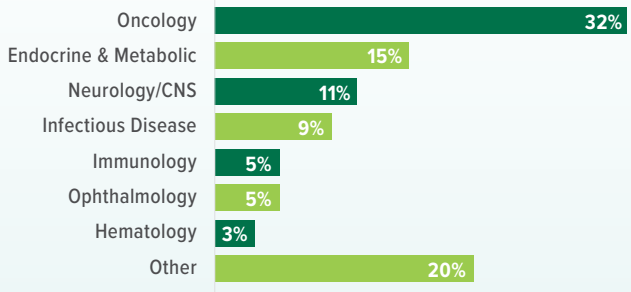
4% Vaccines

40% Rare Diseases

EXPERIENCE BY PHASE



KEY THERAPEUTIC AREAS



"Advancing complex therapies for challenging diseases is what motivates us every day. What distinguishes Veristat is the ability of our multi-disciplinary project teams to draw the appropriate connections amongst the fundamental constructs of the science, the practical and operational requirements of the clinical program, and the regulatory pathway. Those combined provide the evidentiary basis for product approval."

John Balser, Ph.D., President, Chief Statistical Officer and Founder, Veristat

Accelerating Complex and Novel Therapies to Market

Nothing is standard when developing treatments for patients suffering from (complex or) rare/ultra-rare diseases. Every step of these high-stakes programs – from study design through the regulatory approval process – is complicated and unique. Our global team of subject-matter and medical experts have knowledge from supporting:

In the past 5 years, Veristat teams have supported:

- **350+ rare/ultra-rare disease projects** and the preparation of **50+ marketing applications**
- **300+ projects** for **120+ sponsors** developing biologics
- **120+ cell and gene therapy projects** with more than **10 marketing applications**, including the first gene therapy approved in Europe.

Stepping in When Progress Has Stalled

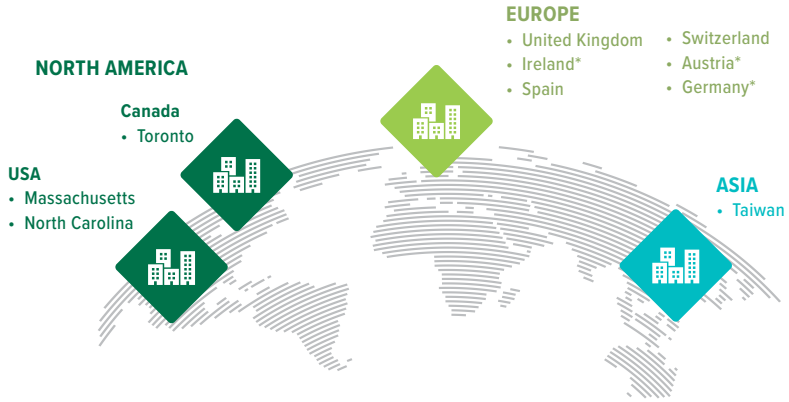
Nothing is more challenging than a setback in your development program. If milestones aren't being met, your vendors aren't communicating or following the protocol, or expertise is lacking, it might be time to bring in bold and scientific thinkers.

At Veristat we have a proven track record of getting clinical development programs back on track. We know the stakes are high and you can't afford to slow down. Let us help you move forward.

Continued Strategic Growth Globally

Veristat is expanding its global reach to maintain local knowledge of regulatory requirements to ensure development success. We focus where our clients need us. Our goal is to maintain personal connections with sponsors and deliver bold thinking, exceptional science and results – fast.

A Global Presence with 750+ Team Members



*Denotes legal entities, not physical locations in these countries

Driving Momentum with DCT Solutions

The post-COVID world has disrupted longstanding approaches to clinical research. The changing regulations and rapid adoption of decentralized clinical trial (DCT) solutions have and will continue to reshape the clinical trial landscape for years to come.

Veristat embraces the changing development landscape. By taking the best elements from traditional, hybrid, and fully virtual trial methodologies and incorporating them into a unified approach – we ease the burden on patients and reduce clinical trial delays.

Meet Veristat – Bold Thinking That Delivers Results

We understand that all the easy challenges have been conquered in your clinical development programs and you still need to navigate the process and scientific unknowns. To ensure your success, select Veristat as your partner.

Meet Veristat Today | www.veristat.com

FCT-VT-114 v.05 Mar-23

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