› FACT SHEET

VERISTAT

Science-First Strategies to Advance Development and Approval of Rare/Ultra-Rare Disease Therapies

Getting Your Novel Therapies to Patients Everywhere

At Veristat, we see facilitating success for our sponsors of rare disease therapy clinical trials as a fundamental responsibility. We're a team of Science-First thinkers, never assuming a situation can be addressed as it has always been done before.

Supporting the development of rare disease therapies accounts for **35%** of Veristat's work

From regulatory pathway selection to patient recruitment and site selection to collecting and cleaning the data, we plan your trial with the utmost precision and innovative approaches. Our scientific experts account for your highly compromised study participants, leveraging the power of biostatistics to meet your trial's objectives, regardless of the complexities.

In the past 5 years:

>350

Rare Disease Clinical Trials & Consulting Projects

Including:

70+ **cell and gene therapy projects**

40+ **US and European marketing applications (NDAs/BLAs/MAAs, etc.) prepared**

Unparalleled Rare Disease Expertise from IND/CTA to Commercialization

Strategic and Regulatory Advice

We help determine if your study qualifies for an accelerated regulatory approval pathway and we'll represent you at US Food & Drug Administration (FDA) and European Medicines Agency (EMA) meetings.

Clinical Trial Design and Delivery

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. We offer a range of solutions – including decentralized trials, natural history studies, and a central site model – to keep your program on track.

Marketing Application Preparation

When your next milestone is to get your NDA, BLA, MAA, NDS or jNDA submitted on-time, trust our integrated team that has prepared more than 170 marketing applications to successful outcomes.

Post-Market Pharmacovigilance

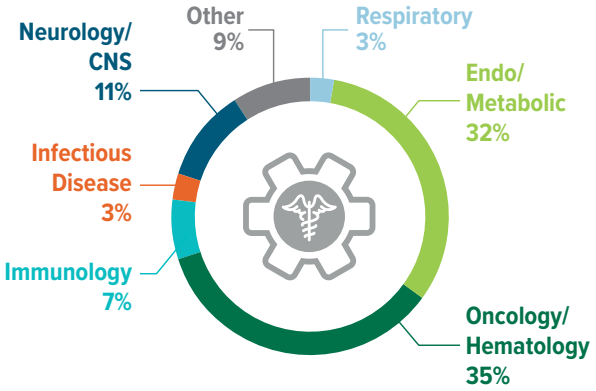
Manage the safe use and detect safety signals for your marketed products to keep them on the market and accessible to patients.

Market Solutions/Compliance

Ensure the commercial success of your product with the right expertise in market access, reimbursement, healthcare compliance, public affairs and quality assurance.

The work of Veristat's innovative regulatory, statistical, and medical writing experts was vital in supporting eight regulatory approvals in 2022, the majority for therapies designed to treat rare diseases.

Tailored, trusted expertise across a broad range of 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, Veristat

Meet Veristat

The Science-First CRO™ That Delivers Results

Our approach – marrying strategic consulting with regulatory insights and technical expertise – brings you informed decisions through the development and approval process. You collaborate with experts that care— like you do. It is not just business for Veristat, it's personal.

Let Veristat be the partner to provide tailored solutions for the clinical trial planning, execution, and regulatory submission of your rare disease treatment.

veristat.com/rare