



Driving CNS and Neurology Treatments to Approval

CNS trials are plagued with high failure rates at or before Phase III, requiring careful risk mitigation throughout trial design and execution with close regulatory agency collaboration. That is why Veristat has built a team of scientific-minded experts who have supported more than 250 CNS/neurology projects, including drug, biologic, and diagnostic trials in the past ten years. More than 30% of these treatments are for rare or ultra-rare neurological diseases or disorders.

In the past 10 years:



>250 CNS & Neurology Projects



>30 Biologic Therapies Projects



8 Marketing Application Approvals

Specialized Expertise from Consultation to Beyond Submission

Pre-Clinical/Trial Planning to Increase Speed

Our diverse trial experience allows us to confidently handle the most complex trials and patient populations with the attention and focus needed to navigate the neurological disease landscape. Veristat can determine if your study qualifies for an accelerated regulatory approval pathway and represent you in interactions with the US Food & Drug Administration (FDA), European Medicines Agency (EMA) and regional European regulatory bodies.

Study Design and Methodology that Will Work

Veristat's bold thinking 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 work with you to develop a customized solution, our goal being your success. We can help you select the right methodology – whether a decentralized trial, natural history study, or a central site model – to keep your program on track.

Marketing Application Preparation Experience by Phase and Publishing

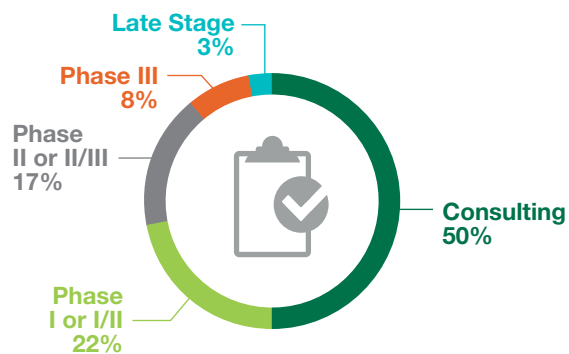
When your next milestone is to get your NDA, BLA, MAA, NDS or jNDA submitted on-time, trust our integrated team that has prepared more than 150 marketing applications that have led to over 80 approvals to date.

Post-Market Pharmacovigilance Ensures Safety

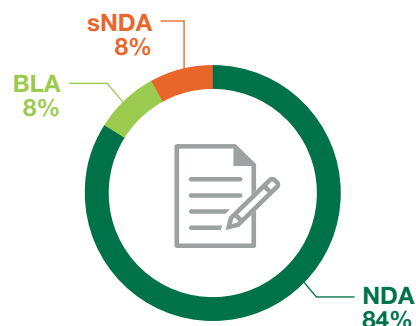
Our post-marketing pharmacovigilance support manages the safe use of your therapy and keeps it available to patients and their families.



Experience by Phase



Marketing Applications by Type



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.

www.veristat.com

