



> FACT SHEET

Accelerate Neurology/Psychiatry Trial Success with Expert Guidance

The complexity of clinical trials in neuroscience therapeutic areas presents both challenges and opportunities in clinical research. Veristat's 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.

With a proven record of success, Veristat provides creative and strategic approaches to inform your decision-making, mitigate trial risks, prove safety and efficacy, and achieve approval success. Our regulatory and clinical development experts are poised to launch your CNS/Neurology trial.



Experience in the Past 5 Years:

200+

clinical trials and projects

20%

for rare and ultra-rare neurological disorders

70%

of global operations team members have neurology experience

7

marketing applications approved

Proven Success with Veristat: Neurology/Psychiatry Success Stories



Advancing Pediatric Gene Therapy from Natural History to Clinical Trial

A mid-size biotech company partnered with Veristat for a natural history trial in an ultra-rare pediatric neurological disease, which then progressed to a Phase I/II gene therapy clinical trial. Veristat provided comprehensive support, including regulatory consulting, biostatistics, data management, and site management. Their team streamlined site start-up, enhanced communication, supported international families requiring relocation and provided statistical expertise. The ongoing trial has treated over five patients with a goal of nearly 50 across North America and Europe. Veristat's flexibility and expertise in biologics trials (having conducted 40+ trials for 20+ sponsors) enabled them to serve as an implementation arm for the sponsor throughout this complex global rare disease study. [Learn more >](#)

Proven Success with Veristat: Neurology/Psychiatry Success Stories

2 Strategic Partnership Drives Successful NDA Submission

A biopharmaceutical company partnered with Veristat for NDA submission support for a therapy treating agitation in bipolar disorder and schizophrenia patients. After transferring from another vendor, Veristat discovered that submitted materials required substantial modifications to meet FDA requirements. Veristat's team implemented a strategic solution by communicating with the European vendor about CDISC compliance, developing the submission table of contents, reformatting documentation into FDA-validated templates, and leveraging in-house experts for quality assurance. Despite unexpected FDA information requests extending the timeline, the submission succeeded, earning FDA approval. This successful partnership continues as Veristat supports the client with additional indications and maintains three supplemental INDs for the same product. [Learn more >](#)

3 Overcoming Logistical Hurdles in Stroke Cell Therapy Trial

Veristat supported a Phase II study investigating intracerebral stem cell injections for ischemic stroke patients, providing comprehensive services including project management, clinical monitoring, and regulatory affairs. The team overcame numerous challenges: difficult recruitment due to invasive brain surgery requirements, complex HLA eligibility testing, patient privacy concerns amid high publicity, ethical questions regarding fetal stem cells, and critical logistical coordination for the temperature-sensitive treatment with 60-minute post-thaw viability. Their expertise ensured on-time, on-budget delivery, resulting in positive Phase IIa data publication and the client selecting Veristat for all their cell and gene therapy programs moving forward. [Learn more >](#)

Science-Based Focus That Delivers Results

Veristat delivers results accelerating new therapies through the clinical development and regulatory submission process for patients with no existing or limited treatment options. 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, partner with Veristat.

[veristat.com >](https://www.veristat.com)

