VERISTAT

Neurology Regulatory Submissions Simplified: Expertise You Can Trust

No two marketing applications are alike. Neurology programs bring added complexity: subjective outcomes, heterogeneous patient populations, and long-term follow-up requirements. Veristat applies proven strategies and integrated expertise in regulatory affairs, biostatistics, and medical writing to help sponsors navigate these challenges with confidence.

NDA/MAA Preparation Strategies for Neurology and Every Complex Submission

SAPs · Database Lock · CSR Analyses · ISS/ISE · CTD Dossier · Publishing · Agency Filing

Submission Strategy & Planning

- Build fully integrated sponsor–Veristat teams to avoid silos.
- Overcommunicate with centralized tools to keep stakeholders aligned.
- Establish master timelines with proactive scenario planning and clear ownership.

Data & Analysis Readiness

- Mitigate database lock delays through early risk workshops and scenario planning.
- Apply independent unblinding and automated QC checks to ensure clean workflows.
- Deliver rolling statistical outputs so medical writing can start earlier.

Medical Writing & Regulatory Engagement

- Assign document champions and use RACI matrices for efficient review governance.
- Apply submission-specific style guides to unify messaging across all modules.
- Schedule pre-submission agency meetings before clinical study report (CSR) finalization to minimize downstream rework.

Proven Neurology Track Record

- **10+ neurology NDA/MAA submissions** supported in the past five years.
- **30% rare or ultra-rare CNS disease programs**, requiring tailored regulatory strategies.
- **On-time NDA filing for a rare CNS therapy** despite a compressed nine-month timeline.
- **FDA priority review and approval achieved** for the first therapy in its indication.

From Challenge to Success

1 Case Study 1 – Rare CNS Therapy Under Pressure

A sponsor faced an aggressive nine-month NDA timeline requiring migration of 18 legacy studies and two pivotal trials. Final pivotal data arrived two months late.

Solution: Veristat used domain-based migration, parallel processing, and rolling outputs.

Impact: NDA was submitted on time and granted priority review, leading to first approval in this rare neurological disorder.

Before

- 18 legacy studies
- 2 pivotal trials
- Data 2 months late

After with Veristat

- Domain-based migration
- Rolling outputs
- On-time NDA
- Priority review & approval

2 Case Study 2 – Last-Minute FDA Requests

A sponsor preparing for simultaneous NDA, MAA, and NDS submissions received late-stage FDA requests for new analyses.

Solution: Veristat expanded resources, assigned document champions, and streamlined publishing.

Impact: All three submissions delivered within six weeks.

Partner with Veristat

Neurology submissions demand precision, foresight, and agility. Veristat's integrated teams deliver the rigor, creativity, and experience needed to overcome unpredictable timelines, complex endpoints, and regulatory challenges.

Advance your neurology program from data to approval with confidence.

veristat.com ›