VERISTAT

A Creative Approach to Achieving an Aggressive NDA Timeline

On-Time Completion of an NDA Submission Despite Two-Month Database Lock Delay on the Pivotal Trials

Background

A mid-size biopharmaceutical company developing therapies for neurological disorders partnered with Veristat to prepare and manage an NDA for a rare CNS disorder. The submission required migrating legacy data for 18 studies and converting two ongoing pivotal studies—all within an aggressive nine-month deadline.

Sponsor Challenge

Final pivotal study data arrived two months late, compressing the timeline and delaying downstream work. Because integrated summaries and medical writing depended on final statistical outputs, every function faced schedule pressure.

Veristat Solution

Instead of migrating data study-by-study, Veristat used a domain-based approach (e.g., demographics, adverse events) to enable parallel processing.

STUDY DEMOGRAPHICS

STUDY PHASE
- NDA preparation and submission following Phase 3 pivotal studies

INDICATION
- Rare central nervous system disorder with no approved therapies

THERAPY TYPE
- Neurology

PRIMARY GOAL
- Complete NDA submission on a nine-month timeline despite pivotal study data delays

DATA SOURCES
- 18 legacy studies
- 2 ongoing pivotal studies (multi-regional)

SERVICES PROVIDED
- Legacy data migration to SDTM format
- Conversion of pivotal study data with database lock delays
- Statistical analysis planning for ISS and ISE
- ADaM programming and TLF production for ISS and ISE
- ISS, ISE, and Module 2 clinical summaries (M2.7.3, M2.7.4, M2.5)

Parallel Process Flow

- **SDTM Data Migration** by domain across all studies
- **Biostatistics & Programming** generated outputs per domain
- **Medical Writing** began integrated summaries as outputs became available

Close coordination across Veristat teams, the data management vendor, and the sponsor kept deliverables moving despite the delay.

Impact

Veristat submitted the NDA to the FDA on time—just three months after receiving the final pivotal study data. The NDA earned priority review and was approved in under six months. This was the client's first commercial product and remains the only approved treatment for this rare neurological disorder.

Meet Veristat

Veristat excels at guiding sponsors through complex NDA submissions. Our team overcomes data, timing, and regulatory hurdles to meet aggressive timelines and achieve approvals. From strategy to final agency interactions, we deliver the expertise needed to bring life-changing therapies to patients.

Contact Veristat Today

Learn how our neurology expertise can help you achieve submission success.

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