› CASE STUDY

VERISTAT

From Strategy to Submission

End-to-End Clinical, Biometrics, and Regulatory Support in Neurology

Background

Veristat became more than a service provider for a biopharmaceutical company developing transformative therapies for psychiatric and neurological disorders: we became a clinical development partner.

Our collaboration began with strategic consulting, providing statistical analysis planning and early phase protocol review, subsequently expanding to include programmatic review of analyses and the execution of *ad hoc* analyses for completed studies within the sponsor's development program. When selecting partners for their Phase 3 program and eventual New Drug Application (NDA), the sponsor returned to Veristat, asking us to provide Phase 3 protocol and statistical analysis plan development, biostatistics and programming services for Phase 3 studies and the NDA, medical writing of clinical study reports and NDA, regulatory strategy, publishing and project management, and legacy data CDISC migration for completed studies to support the NDA.

By combining consulting, medical writing, biometrics, regulatory strategy, publishing, and project management, Veristat provided a seamless continuum of expert services that carried this complex CNS program from pivotal study execution through data review and reporting of results, and ultimately FDA approval.

SPECIFICATIONS

SUBMISSION TYPE
- New Drug Application (NDA) – U.S.

INDICATION
- Psychiatric and CNS disorder

THERAPY TYPE
- Small molecule (Non-NME)

DATA SOURCES
- Two identical Phase III inpatient studies + long-term real-world extension

SERVICES PROVIDED
- Strategic Consulting
- Medical Writing
- Project Management
- Biostatistics & Programming
- CDISC Migration
- Regulatory Strategy
- Regulatory Publishing

COLLABORATION MODEL
- Multi-vendor, cross-functional partnership driven by Veristat's end-to-end delivery model

Sponsor Challenges

While planning and executing two identical Phase 3 studies with a single long-term extension follow-up, the goal of a fast transition from Phase 3 readout to NDA submission remained, placing pressure on all members of the team to ensure complete documentation, precision of detail, and readiness for regulatory scrutiny throughout Phase 3 study execution:

- **Data Complexity:** The CNS research relied on patient reported outcomes, caregiver assessments, and survey tools, where missing data can lead to complexities in both the analysis and interpretability of results.
- **Multi-Regional Clinical Trials:** Multiple sites and use of different sites between two otherwise identical studies can still risk inconsistencies in the protocol interpretation and reporting of safety findings, reducing confidence in pooled analyses.
- **Multiple Vendor Collaboration:** Alignment of expectations for data quality and cleanliness is required, including reconciliation of data from multiple sources, and was only reached through thorough research and conversations with the sponsor to ensure understanding and agreement to produce a high quality data product.
- **Integration Across Study Types:** The NDA needed to merge short-term inpatient efficacy data with long-term exposure, efficacy, and safety data while addressing adherence variability and comorbidities common to psychiatric and CNS disorders.
- **High-Visibility Deliverable:** With a first-in-class CNS therapy at stake, data accuracy, narrative consistency, and submission readiness had to be flawless.

Veristat Solution

- **Integrated Biostatistics Leadership:** Veristat assumed biostatistics and programming ownership for both Phase 3 CNS disorder studies, the long-term extension study, and the NDA integrated summary of safety and integrated summary of efficacy analyses, uniting statistical oversight, programming precision, and regulatory alignment.
- **Regulatory-Ready Estimand Strategy:** Authored estimand statements, ensuring all related regulatory comments on study protocols and statistical analysis plans were addressed with a clarity of analysis, complete and extensive imputation methods for sensitivity and supportive analysis, and consistency between Phase 3 protocols to allow ease of review and interpretation of the study findings.
- **Collaborative Multi-Vendor Data Resolution:** Veristat initiated a collaborative tone across multiple vendors through in-person meetings, turning a potentially contentious environment into a unified effort. Despite limited data access from global sites, political disruptions, and differing protocol interpretations, joint data-cleaning sessions with the sponsor and external vendors—including data management and safety teams—resolved cross-database discrepancies and enabled integration of study findings.
- **Data Consistency and Quality Oversight:** With data collected across multiple systems—including pharmacokinetics, laboratory parameters, electronic data capture, and questionnaires—Veristat led discussions and documentation of quality check conventions to preserve consistency across studies. A thorough understanding of the data, tailored query resolution, and alignment with safety management enabled efficient, well-informed responses to FDA questions.

Data Readiness Engineered for NDA Success

To prepare for the NDA, Veristat's biometrics and regulatory experts worked in lockstep with our sponsor and their outside vendors to transform raw study data into a cohesive, compliant submission package.

- Veristat directed large-scale CDISC migrations and integration of complex datasets and complicated pooling across in-patient, acute treatment settings and out-patient, long term exposures.
- Veristat's medical writers collaborated with the sponsor representatives to align efficacy and safety narratives across all CTD modules, presenting the data in the best possible context with succinct and clear messaging.
- Veristat's multidisciplinary team contributed to risk management planning, incorporating health disorder-specific adherence and safety considerations.

Operational Alignment that Drove Submission Excellence

Veristat played a key role in the sponsor's high-impact NDA kickoff meeting, a three-day, multi-stakeholder working session designed to synchronize every function and deliverable. With more than 40 contributors involved across organizations, Veristat partnered with the sponsor team to present key topic areas, establish overall NDA timelines, and adapt our team size and roles to meet the requirements of the NDA, helping to ensure focused, actionable collaboration. Focus groups were divided into dedicated working groups— each tasked with addressing a critical submission area. The meeting increased NDA development efficiency through:

- Guiding breakout groups on safety, efficacy, and risk-management planning, incorporating CNS disorder-specific adherence and safety considerations, ensuring unified communication across vendors and functions.
- Engaging directly with sponsor leadership, including the CMO and Head of Regulatory Affairs, to ensure oversight, plan for obstacles, and accelerate decision-making.
- Providing the structure and accountability needed to keep complex, multi-partner workflows on time and on message throughout the reporting, writing, and publishing of the NDA.

From clinical data to global submissions, Veristat helps neurology innovators bring therapies to market with precision, foresight, and speed. Our integrated clinical, regulatory, and biometric teams ensure every document, dossier, and submission is strategically aligned for successful marketing authorization worldwide.

Impact

One Team, One Direction + **Iterative, Not Redundant** + **Flawless Execution at Scale** + **Sustained Partnership**

Veristat's leadership and experience in NDAs helped transform a multi-vendor program into a coordinated, forward-moving partnership. By uniting the work of Veristat's statisticians, programmers, writers, and regulatory teams with other organizations, Veristat ensured that progress never stalled and that every deliverable was built efficiently.

- **One Team, One Direction:** Veristat provided a connective team linking clinical, biometrics, and regulatory partners, ensuring decisions were data-driven, communication stayed consistent, and no effort was duplicated.
- **Iterative, Not Redundant:** Through proactive data reviews and continuous alignment meetings, Veristat helped teams work in sequence rather than in silos, eliminating rework and maintaining submission momentum.
- **Flawless Execution at Scale:** With consistent oversight and clear governance, the NDA was submitted on schedule and approved without major queries, validating both data integrity and the integrated team model.
- **Sustained Partnership:** Following approval, Veristat continued to support the sponsor's early-phase and post-marketing programs, building on the same trusted foundation of collaboration and precision.

Meet Veristat

If you've struggled with missed deadlines and slow progress, talk to Veristat. We have a proven track record of starting—and accelerating—clinical development programs with the expertise to navigate the challenging path to regulatory submission and approval efficiently. Collaborate with experts who understand the value of speed without compromising quality.
It's not just business for Veristat, it's personal.

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