



› CASE STUDY



VERISTAT

## Efficient Regulatory Publishing for a Large-Scale FDA Submission

Relieving Pressure During Preparation of a High-Volume sNDA

### Background

Following a previously successful NDA submission and approval in a psychiatry indication during which Veristat assumed responsibility for a transferred NDA preparation and submission, remediated submission-ready content, and served as the technical contact throughout FDA review (see related case study: [The Power of Publishing for an Efficient NDA Submission Process](#)), our client, a commercial-stage biopharmaceutical company, re-engaged Veristat to support a subsequent supplemental New Drug Application (sNDA).

### Solution

Veristat supported our client through an integrated regulatory strategy, publishing, and project management approach designed to maintain submission readiness and execution consistency across a large and technically complex dataset.

The sNDA represented a substantial publishing effort, comprising:

- 276 files
- 56,741 pages
- 21,748 bookmarks
- 27,989 hyperlinks
- 837 MB total submission size

Veristat's team worked closely with our client's regulatory affairs leadership to coordinate submission activities, manage timelines, and maintain alignment with FDA technical and formatting requirements. Dedicated hands-on project management enabled steady progress throughout the submission process.

### PROGRAM DEMOGRAPHICS

#### INDICATION

- Bipolar disorder

#### SUBMISSION TYPE

- Supplemental New Drug Application (sNDA) – U.S. FDA

#### PRIMARY SERVICES PROVIDED

- Regulatory submissions support
- Regulatory strategy
- Project management

## Outcome

The sNDA was successfully submitted to FDA ahead of schedule. Following submission, the client acknowledged the collaboration and execution:

“

*To both the Veristat and our internal teams, thank you so much! I appreciate the dedication and collaboration you all had to get this done on time (actually early!).”*

— VP, Regulatory Affairs, commercial-stage biopharmaceutical company

## Impact

- Successful FDA sNDA submission for a bipolar disorder indication
- Early submission despite significant volume and technical complexity
- Continued client engagement following a prior successful NDA submission and approval

This engagement reflects Veristat’s continued role supporting complex marketing authorization applications, including BLA/NDA and sNDA submissions, as well as MAA submissions across therapeutic areas.

## Clear Decisions. Coordinated Support.

Veristat is expert in supporting the publishing of regulatory applications, amendments, supplements, and reports to global health authorities. Publishing services are offered as an independent capability or as part of Veristat’s end-to-end regulatory solutions, providing strategic regulatory consulting, development of submission-ready documents and dossiers, and electronic publishing to regulatory agencies.

Veristat’s core services include integrated cross-functional support for NDA, BLA, and MAA programs—from early guidance through agency interactions, expert review, documentation updates, and coordinated project management and publishing.

We also adapt documentation for regional needs and can serve as the Marketing Authorization Applicant or Holder in the EU, UK, and Switzerland on your behalf until you have established a local commercial organization.

## Meet Veristat

### Full-Service CRO and Consultancy That Accelerates Success

If you’ve faced missed deadlines or slow progress, talk to Veristat. We have a proven record of accelerating clinical development programs with the expertise to navigate the complex path to marketing authorization efficiently. Partner with experts who understand the value of speed without compromising quality. From first-time approvals to regional expansions, our cross-functional teams help clients meet regulatory milestones with confidence.

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