VERISTAT

The Power of Publishing for an Efficient NDA Submission Process

Relieving the Strain of Regulatory Publishing During the Critical Regulatory Registration Stage

Background

A commercial-stage biopharmaceutical company that develops transformative medicines in neuroscience and immuno-oncology sought out Veristat for external support of NDA submissions, amendments to documents, and ad promo submissions for a therapy being developed for the acute treatment of agitation associated with bipolar and schizophrenia. Veristat's successful regulatory consulting services on a previous engagement made our team a top contender for the company's current need, and we were subsequently awarded this regulatory publishing assignment.

The project was transferred to Veristat from another vendor and virtually all of the content provided needed substantive review and modification in order to meet data submission requirements. Veristat's publishing lead and the sponsor's regulatory manager collaborated to establish a well-planned model for working together.

Study Demographics

Indication:
Bipolar disorder and schizophrenia

Primary Services Provided:
- Regulatory strategy
- Regulatory publishing
- Medical writing
- Project management

SOLUTION

The NDA was transferred to Veristat from the sponsor's former vendor in February of that year. The sponsor's regulatory manager worked closely with Veristat's project manager to construct a process roadmap and timeline that targeted an NDA submission for the end of that year.

As the process began, comprehensive modifications were necessary on the data sets provided by the former vendor to meet FDA submission requirements and specifications. To remedy the situation, Veristat's strategy involved:

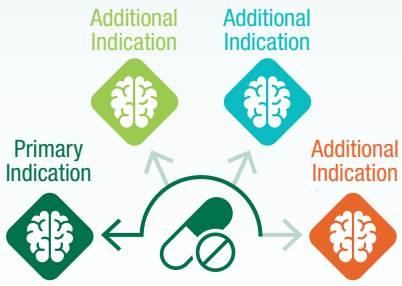
- Communicating with the sponsor's vendor contracted to conduct the pharmacokinetic (PK) studies in Europe and alerting them of the data inclusions and specifications necessary for the data sets to be CDISC-compliant and submission-ready.
- Initiating development of the submission table of contents for which Veristat's publishing lead served as the project administrator.
- Reformatting the majority of transferred documentation into Veristat's FDA-validated templates.
- Throughout the review process, Veristat was able to call upon our in-house regulatory strategists and biometrics experts to ensure continuous quality of all documents as they sequentially advanced through internal reviews.

The NDA was submitted to FDA by Veristat, and we served as the technical contact for the submission. Although the FDA had additional unexpected information requests which extended the target submission date, the Veristat and sponsor teams found ways to gain time back in the schedule wherever possible, and FDA approval was achieved.

IMPACT

With a flawless submission and time regained throughout the process, Veristat served as an extension of the sponsor's regulatory team, making it a successful partnership in every way.

Veristat continues to work with our client in pursuing additional indications, and currently supports the maintenance of three supplemental INDs for the same product in multiple psychiatric indications.



ABOUT VERISTAT

Our team is expert in supporting the publishing of your applications, amendments, supplements and reports to the regulatory agencies. We offer publishing as an independent service or as part of our end-to-end regulatory solutions, providing strategic regulatory consulting, developing all submission documents/dossiers, and publishing them to the regulatory agencies.

Contact Veristat Today

To learn more about Veristat or how we can assist you in determining if our expertise meets your needs, reach out to us today.

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