VERISTAT

Agile Medical Writing Support Relieves the Burden of Review for a Growing Biopharma Company

How Veristat's Experienced Medical Writing and Project Management Teams Streamlined the Development and Review of a Critical Marketing Application Document

Background

A clinical-stage biopharmaceutical company that develops transformative medicines for individuals impacted by psychiatric and neurological conditions initially sought Veristat for strategic biostatistics and programming consulting expertise. Being actively involved in a number of clinical studies for its differentiated small molecule therapy, our client knew of Veristat's extensive experience in central nervous system (CNS) clinical trials, which are plagued with high failure rates and require careful risk mitigation throughout a trial's duration.

Our initial consulting engagement expanded into additional services within Veristat's regulatory affairs and biometrics groups. Two of these services were medical writing and project management – the featured solutions for this case study.

Study Demographics

Indication
A Serious Mental Health Disorder

Therapy Type
Small molecule (Non-NME)

Marketing Application Type
New Drug Application (NDA)

Primary Services Provided
- Medical Writing
- Project Management

MEDICAL WRITING AND PROJECT MANAGEMENT SOLUTIONS

Veristat's medical writing team was engaged to support a full New Drug Application (NDA) and multiple final and interim clinical study reports. One challenging aspect, as part of the client's first NDA submission, was the development of the Summary of Clinical Safety (SCS) (M2.7.4). The timeline was aggressive, with the target filing date of 5.5 weeks from the final integrated statistical output.

The client sought help from Veristat to develop the SCS and streamline its internal review. The amount of data and associated summaries and interpretation that needed to be reviewed by our client's small team was overwhelming, particularly when considering all of the other components of the marketing application that required development and critical review.

Veristat focused on addressing three key factors for success:

1. **Comprehensive medical writing.** Veristat assigned one of our experienced medical writers who collaborated with our biostatistics and regulatory colleagues to translate laboratory values, adverse events, explanatory factors, and all complex data into a scientifically rigorous summation while adhering to regulatory requirements.
2. **Strategically developed timeline and workflow.** Our team worked diligently to ease the review burden on the client by strategically breaking up sections of the SCS so that the client's review would be more focused and manageable. Rather than sending a complete Draft 1, we ranked each results section in terms of importance and developed a timeline for when those sections would be delivered for review. Veristat's Regulatory Project Manager took charge of establishing a project plan with specific timelines and stated responsibilities for all team members, arriving at a feasible workflow to better track progress. We were able to work within the client's electronic document management system so the process was seamless between our submissions and their reviews.
3. **Governance and communication.** We conducted daily and weekly check-in meetings with the client, as well as quarterly governance meetings with senior leadership, to support full transparency and identify and quickly resolve hurdles. These regular communication touchpoints helped to ensure we were delivering to our client's satisfaction while keeping the work on schedule.

IMPACT

With an expertly prepared SCS, a well-synchronized timeline, and a cadenced workflow, Veristat was able to significantly reduce the client's document review burden.

Both Draft 1 and Draft 2 of the SCS were provided to the client early so that their team had more time to work through a very large document. For the Final version, our lead medical writer traveled to the client's site to work on final edits together, further supporting efficiency.

Veristat successfully completed the SCS on time and within budget, facilitating client reviews at each milestone. Our client was able to successfully submit their NDA one day ahead of schedule.

We continue to work with the client in supporting FDA information requests associated with the NDA, in addition to writing other clinical regulatory documents.

ABOUT VERISTAT

Our team is expert in supporting the writing and management of your clinical trial documents, safety updates, and marketing applications to the regulatory agencies. We offer medical writing 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 global 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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