VERISTAT

Medical Writing for Clinical Trial Documentation & Regulatory Submissions

Maximize Efficiency and Results with Veristat

Veristat provides medical writing support for the full lifecycle of a medical therapy's development, beginning with writing clinical trial and regulatory documentation to pre-clinical through marketing application and post-approval.

We offer rapid turnaround to meet tight timelines and flexible, efficient processes for any project large or small. Using in-house or sponsor-supplied document templates, we apply best practices for content, format, and style to meet global technical and regulatory requirements.

In the Last 5 Years

+400 Medical writing projects supported

+75 INDs and CTAs written

+50 Marketing Applications/ Authorizations written (NDAs, BLAs, MAAs, etc.)

Veristat excels in developing regulatory documents to support drug, biologic, device, and diagnostic marketing submissions to regulatory agencies worldwide. We understand the complexities of writing in a highly regulated environment and the challenges of varied requirements of different regulatory agencies.

Global Medical Writing Support From Start to Finish

Clinical Trial Documentation

- Investigator Brochures
- Protocols & Amendments
- Informed Consent Forms (ICFs)
- INDs/CTAs
- IMPDs/IMDs
- Clinical Study Reports
- Patient Narratives

Regulatory and Registration Documents

- Briefing packages
- NDA/MAA CTD clinical modules
- Responses EMA/FDA questions
- ISS/ISE
- PIP/PSP waivers
- Risk management plans
- Orphan designation applications
- OTC justifications
- Early access reports

Medical Communications

- Publications
- Literature reviews
- Systematic reviews
- Slides, posters & abstracts
- Conference reports
- Medical education material

Public Disclosures

- Registry postings (EudraCT, clinicaltrials.gov)
- Lay summaries
- Scientific summaries (CTIS)
- Lay protocol synopses (CTIS)

Case Study

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

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

Situation: A clinical-stage biopharmaceutical company developing medicines for psychiatric and neurological conditions engaged Veristat for strategic biostatistics and programming consulting. Our initial engagement expanded into medical writing and project management. The client needed help developing the Summary of Clinical Safety (SCS). The timeline was aggressive, with the target filing date 5.5 weeks from the final statistical output. The amount of data, summaries, and interpretation that needed client review was overwhelming to the team, especially with the marketing application components that required critical review.

Solution: Veristat focused on addressing three key factors for success:

1. **Comprehensive medical writing.** Veristat assigned an experienced medical writer who engaged our biostatistics and regulatory colleagues to translate laboratory values, adverse events, and all complex data into a 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. We worked 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 regular check-ins to support full transparency and identify and quickly resolve hurdles.

Impact: An expertly prepared SCS, a synchronized timeline, and a cadenced workflow reduced the review burden. Draft 1 and Draft 2 of the SCS were provided early so the client had more time to review a very large document.

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

> *"Thank you so much for writing our IND. It was a very tight schedule with so many components being built from scratch, and we wouldn't have achieved this milestone without you. You and the Veristat team are truly our best partner."*
>
> **President & CEO, clinical stage biotech**

Contact Veristat Today

Learn more about Veristat and how our clinical and non-clinical medical writers can assist you with your clinical trial documentation and regulatory submission writing needs.

veristat.com/medical_writing