VERISTAT

Medical Writing for Clinical Trial Documentation & Regulatory Submissions

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.

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.

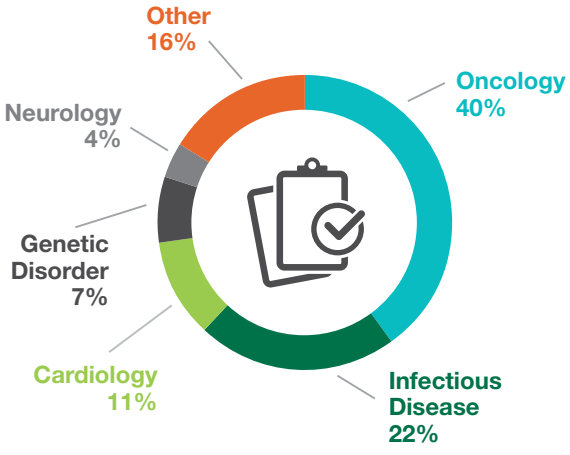
Experience writing documents for **>500** clinical trials

Veristat medical writers on average have **20 years** industry experience

>150 rare disease trials

>50 marketing applications

Medical Writing Experience by Therapeutic Area



MEDICAL WRITING CAPABILITIES

Develop Clinical Trial & Program Documentation

- ✓ Investigator Brochures
- ✓ Clinical Study Protocols
- ✓ Informed Consent Forms
- ✓ Clinical Study Reports
- ✓ Subject Narratives

Regulatory Submission Documents

- ✓ Global Regulatory Documents in eCTD Format – INDs, NDAs, IMPDs, MAAs
- ✓ Orphan Drug Designation Applications
- ✓ Agency/Advisory Panel Briefing Documents
- ✓ Risk Management Plans
- ✓ Development Safety Update Reports

Medical Communications & Writing Support for Thought Leadership

- ✓ Clinical Trial Registration & Results Postings on ClinicalTrials.gov
- ✓ White Papers to Supplement Submissions
- ✓ Literature Reviews
- ✓ Abstracts, Posters & Manuscripts for Scientific Meetings

VERISTAT MEDICAL WRITING LEADERSHIP

Kimberly Newton, MA

Senior Director, Medical Writing

Kimberly Newton oversees the medical writing team and develops project-specific strategies to increase the team's productivity and quality. She has nearly 25 years of regulatory affairs and medical writing experience across multiple large and mid-sized CROs. Over the course of her career, Kimberly has worked as a medical writer, led global medical writing teams, and supported countless medical writing projects for clinical trials and regulatory submissions. She has contributed to the writing of more than 20 Investigational New Drug Applications (INDs) and worked on more than a dozen marketing applications.

CASE STUDY

Writing Multiple Marketing Applications Simultaneously with Accelerated Timelines

How an Expert Medical Writing Team Completed Three Submissions Within Six Weeks of One Another

Situation: The client's product received Orphan Drug Designation in the United States and Europe, and Priority Review status in Canada. This meant our medical writing team needed to work quickly to complete the submission documents for the MAA, NDA, and NDS. Additionally, the client scheduled their Pre-NDA meeting with the FDA late in the process. The meeting was held two months prior to the NDA submission date goal and the outcome resulted in the FDA requesting additional analyses. Ultimately, the submission for the NDA was delayed one month as a result.

Solution: Veristat's submission project manager and the medical writing team developed a plan to bring in more resources to keep the NDA and NDS submission timelines moving forward. As a result of the agency's feedback, our medical writers had to produce addendums for five clinical study reports (CSRs) included in the submission (including the pivotal CSR). We had already completed the ISS, so considerable rework had to be done to add in the new analyses. Additionally, the final M2.5, M2.7.3, and M2.7.4 sections submitted with the MAA had to be revised based on FDA's feedback. Document authoring followed by eCTD-compliant electronic publishing at Veristat allowed us to further streamline the timeline at critical milestones, ultimately resulting in on-time submission of the MAA, NDA, and NDS by the client.

Impact: The MAA, NDA, and NDS were submitted to the regulatory agencies within six weeks of one another. The MAA was submitted on time and the NDA and NDS submissions were only delayed by one month. So far, the client has received a conditional approval from the EMA and is awaiting approval in the US and Canada.

> *"Thank you all so much for your hard work writing this protocol. It's proven to be a difficult task and we could not have had a better team pushing this through to the end."*

Clinical Trial Manager, Small Biopharmaceutical Company

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.

www.veristat.com/medical_writing