VERISTAT

Mastering a global approach to solving the complexities of successful medical writing

Veristat's medical writing experts are here to serve your content needs for clinical trial and essential regulatory documentation.

With substantial expertise in a wide range of therapeutic areas, including Rare Diseases, Oncology, Neurology, and Infectious and Metabolic Diseases, we ensure your content is effectively and efficiently communicated to sponsors, regulatory agencies, patients, and other key stakeholders.

Expert Medical Writing Support Throughout the Product Development & Commercialization Continuum

Clinical Trial Documentation

- Protocols & ICFs
- Clinical study reports
- Patient narratives
- Investigator brochures
- IMPD/INDs

Regulatory & Registration Documents

- Briefing packages
- NDA/MAA CTD clinical modules
- Responses to 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 materials

Public Disclosures

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

All documents are written in full compliance with EMA, FDA, PMDA, and ICH regulatory guidelines and follow Standard Operating Procedures in accordance with GCP, Declaration of Helsinki, GDPR, and ISO 9001 quality standards.

MEDICAL WRITING SUCCESS HIGHLIGHTS

Our Client

A global specialty pharmaceutical company that develops treatments for rare diseases engaged our team for medical writing support for two high-profile products. Our longstanding thirteen-year relationship built on trust and quality continues, with our team successfully fulfilling over 130 medical writing projects during this time.

Product 1

Enzyme replacement therapy for a rare genetic condition in adults and pediatric patients, for which an orphan drug designation was obtained.

EU Program Activities

- Writing the protocol for the pediatric study
- Writing Clinical Study Reports (CSRs) for pivotal studies
- Answering European Medicines Agency (EMA) D120/180 questions (RtQ) with speed and efficiency
- Preparing substantive consolidated Common Technical Document (CTD) of critical importance intended for submission to non-EU countries
- Writing the Post-Authorization Safety Study (PASS) report and updating the clinical overview on an annual basis

US Program Activities

- Writing the Phase 3 protocol, Investigator's Brochure (IB) update, and general investigation plan
- Writing the Biologics License Application (BLA)

Outcomes

- EMA approval obtained in 2018
- FDA approval obtained in 2023
- 22 projects completed by Veristat on time and on budget

Product 2

Enzyme replacement therapy for adults to treat a rare inherited disorder.

Global Program Activities

- Writing Clinical Study Reports (CSRs) for pivotal studies
- Writing the pediatric protocol for EMA and FDA, and the protocol for Japan's (PMDA) Pharmaceuticals and Medical Devices Agency

Outcomes

- EMA and FDA approval obtained in 2023
- 7 projects completed by Veristat on time and on budget

> *"I am writing to express my appreciation and gratitude. I have worked with many medical writers before in my career and find your medical writing team member one of the most efficient, thorough and elite in her work. I have been so impressed with her work and her eye for detail in picking up things. She is a delight to work with, and I appreciate the support and dedication she has shown working on the BLA project."*
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> Clinical Research Physician
> Global Specialty Pharmaceutical Company