

- Study Operations
- Clinical Monitoring
- Pharmacovigilance
- Health Outcomes Research
- Medical Writing
- Document Management
- Electronic Publishing
- Biostatistics
- Statistical Programming
- Data Management
- Information Technology
- Quality Assurance
- Clinical Project Management

MEDICAL WRITING & DOCUMENT MANAGEMENT SERVICES

- ✓ *Easy-to-comprehend*
- ✓ *Well-structured*
- ✓ *Regulatory-compliant*

Achieving marketing approval for a new drug is a complicated, expensive, and lengthy process. Any delay of weeks or even days can make the difference in cost and time-to-market, but poorly structured documents or difficult-to-comprehend clinical results do not have to be the reason for this.

At ACCOVION, our medical writers are experienced scientists and native English speakers with proven expertise in timely and accurate preparation of study reports and submission dossiers in a wide range of therapeutic areas. Our reputation is based on years of delivering easy-to-comprehend, well-structured, and regulatory-compliant documentation – providing significant savings in time, money, and effort.



Flexibility and teamwork are the defining characteristics of our medical writing approach

✓ Flexibility and Teamwork

We conduct a briefing with all our clients to gain insight into their special requirements. Internally, we work closely with our physicians, statisticians, regulatory affairs and publishing experts to ensure that document planning and production deliver consistent data interpretation and presentation from study initiation through to analysis. This interactive approach allows us to address our clients' requirements early in the report writing process and to deliver clear and concise documentation enhanced by appropriate in-text tables, charts, and graphs.



ACCOVION combines scientific insight, language skills, writing techniques, table and figure design, and pharmaceutical regulatory knowledge to yield the highest quality of documents from draft copy through to the finished product. Our medical writers help shape and steer document review, maximizing every opportunity to streamline the use of your resources and time.

Medical Writing SERVICES

Medical Writing

Services:

- ✓ Investigator brochures
- ✓ Investigational medicinal product dossiers (IMPDs) for clinical trial applications
- ✓ Investigational new drug (IND) applications
- ✓ Preclinical reports and summaries
- ✓ Clinical study protocols for all development and postmarketing study phases
- ✓ Clinical study reports for all development and post-marketing study phases, including population pharmacokinetics, health outcomes research and pharmacogenomics
- ✓ Patient safety narratives
- ✓ Clinical summaries and overviews (expert reports) for worldwide regulatory submissions

We recognize that even draft documents are powerful communication tools within the cross-functional environment of your business and that medical writing quality at all steps enables fast comprehension of complex information and ideas.

This often reveals unexpected **new leads** or issues that require urgent resolution and the right skills to succinctly and objectively present the clinical relevance of the trial results without ambiguity.

✓ Continuity and Consistency

Our medical writers, familiar with all pharmaceutical regulatory documents, provide you with **continuity** across long-term projects.

They take an end-to-end results-oriented project design approach: planning the writing of final study reports while developing study protocols, and planning the writing of integrated summaries or clinical publications during the preparation of study reports.

Our synergistic and forward-looking approach accelerates your early decision-making activities on fundamental design and analysis issues, ensuring **consistency** across documents, and minimizing unexpected delays on the critical path towards finalization of individual documents and entire dossiers.



With ACCOVION's many years of experience using state-of-the-art publishing and document management software applications, such as CoreDossier™ and Documentum®, you can now have the benefit of **submission-ready** clinical study reports and entire regulatory dossiers.

Seamless assembly of PDF documents into electronic dossiers built according to **electronic NDA specifications for the FDA**, or to the new **XML-based eCTD specifications** ensures regulatory compliance, minimizes delays, and saves costs on the way to regulatory submission.

- ✓ Ensure compliance with regulatory technical specifications for e-submissions
- ✓ Combine maximum reader-friendliness and navigate through intricate dossier structures with hundreds of thousands of pages simply and easily
- ✓ Facilitate quality control and streamlining during document development and production
- ✓ Electronic publishing tools used for compilation, cross-referencing and hyperlinking of complex documentation
- ✓ Integration of component files into any format (such as Word, SAS transport files, ASCII files, TIFF files)
- ✓ One PDF document including a comprehensive table of contents hyperlinked to all document sections.
- ✓ Quality control of document assembly and hyperlinks – whether a single study report or an entire dossier – is built into our process.



Our expertise with the latest high-speed scanning and image enhancement technology (Ascent Capture®, Imaging for Windows®, ISIFile™) ensures that paper-based documentation such as case report forms and investigational site documents are incorporated into the publishing process.

Appendices to clinical study reports constitute the largest component of many regulatory submission dossiers and require extensive management and quality control of large quantities of documentation during report creation and dossier assembly. We ensure that GCP-relevant appendices are ICH E3-compliant and complete. And since appendices must be available in English for international regulatory submissions, we can arrange pharmaceutical translation services with a fast turn-around time. GCP-compliant physical archiving services of paper and electronic media according to your requirements can also be provided upon request.

Contact us to learn how you can experience Document Power from ACCOVION!

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