FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

MEDICAL WRITING

Ensure data accuracy and uniformity while maintaining full regulatory compliance

CASE STUDIES

Clear, concise, and professional presentation of study findings is an important part of any development program. With a full complement of medical writing services, we can help you ensure accuracy and uniformity while maintaining full compliance with regulatory requirements and International Council for Harmonisation (ICH) or International Committee of Medical Journal Editors (ICMJE) guidelines.

Learn how three clients relied on Firma Medical Writing to produce timely, quality medical writing deliverables that meet regulatory requirements.

INCREASE REVENUE WITH FASTER TIME TO MARKET

Client: Mid-sized pharma company

Project Focus: Regulatory submissions

Request: Firma was contracted to assist with a two-part expedited 505(b)(2) new drug application (NDA). Services included:

- ▷ Extensive literature search and review of over 1,000 articles
- ▷ Summarization in support of the clinical message

Approach: Firma organized and deployed clinical pharmacology, efficacy, and safety sub-teams, in conjunction with creation of a team to conduct literature searches and a review of 1,000+ literature articles.

Results: For the first submission, Firma worked within extremely tight timelines to complete writing and compilation 1.5 weeks ahead of schedule. Allowing only a two-month timeline for the second submission, the Firma team completed writing and compilation on schedule. Both submissions were accepted for review, without issues, by the FDA, enabling the sponsor to reach agency approval ahead of several competitors and increase their revenue.

RESTORE STUDY TIMELINES AND SUBMISSION SCHEDULE

Client: Mid-sized pharma company

Project Focus: Narrative rescue

Request: After experiencing vendor quality issues and inadequate resource management, Firma was brought in to rescue several hundred narratives for a 120-Day Safety Update. Services included:

- ▷ De novo writing
- ▷ Narrative updates
- ▷ Rewrites
- ▷ Quality control (QC)

Approach: Within 24 hours of executing a client contract, a team of five writers and QC reviewers started the project. A writing manager served as a centralized point of contact and assisted in streamlining communication, tracking, and processes.

Results: The Firma team successfully finalized all narratives by the original client due date and the 120-Day Safety Update was submitted on schedule. This rescue collaboration allowed the client to maintain their regulatory requirements and project timelines.

DRIVE ADHERENCE WITHOUT ADDITIONAL BURDEN

Client: Global, mid-sized pharma company

Project Focus: Departmental optimization

Request: After experiencing challenges and inter-team issues with communication, process development, and resource management allocation from their existing vendor, Firma was contracted by the client to:

- ▷ Restructure and implement medical writing departmental processes
- ▷ Assist with functional service provider (FSP) vendor management

Approach: Firma rapidly assessed the client's internal structure and process gaps. Within just two months, plans were developed to create and streamline processes, realign work streams and create internal structure to support all writing initiatives. The entire client team restructure was in place by six months, and within eight months, new processes were initiated or under development.

Results: Firma established communication plans to ensure strict adherence and follow-up with meeting action items. Subsequently, communication improved without the burdens of additional meetings, emails, and calls, increasing team efficiency and departmental production.

FIRMA MEDICAL WRITING SERVICES

For more information on how we can help produce accurate and uniform medical writing deliverables with full regulatory compliance, email **sales@firmaclinical.com** or visit **firmaclinical.com.**