FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

MEDICAL WRITING

Ensure data accuracy and uniformity while maintaining full regulatory compliance

As a pharmaceutical or biotech company, you know the importance of clear, concise, and professional presentation of study findings from your development program for agency submissions or publications. Even if you know which documents and reports need to be written, internal capacity issues or aggressive corporate delivery timelines may prevent you from undertaking these responsibilities yourself. The Firma team understands your challenges and offers an experienced and knowledgeable team whose support can help you achieve your submission and reporting goals.

Our experienced team members provide value by embracing a partnership role and supporting your needs in everything from limited quality control (QC) review to comprehensively leading your submissions or publications. Our team members apply their direct experience from pharmaceutical and biotech positions, as well as direct agency interaction, to guide your regulatory submission strategy and deliverables.

Proven Medical Writing experience you can count on

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.

Our team consists of senior-level writers, support writers, project managers, editors, QC reviewers, and document specialists – almost all with at least 10 years of direct industry experience. In addition, two members of our staff have distinguished themselves by achieving the Medical Writer Certified® (MWC®) credentialing. With only approximately 50 MWC certified professionals total, having two experts available for your studies enhances the commitment and expertise exclusive to Firma clients.

150+
INDs supported

20+
505(b) NDAs supported

300+
Clinical study reports written

2
Medical Writer Certified (MCW) experts on staff (only 50 total in the US)

25+
Literature submissions, including literature-only submission approvals

MEDICAL WRITER CERTIFIED

Expert staff to manage your entire development pipeline, gap fill where needed, or rescue projects

Count on our project management experience, regulatory expertise, and proven industry reputation to help you:

- ▷ Manage your clinical projects whether the therapeutic area be acute, chronic, rare, or other
- ▷ Streamline and improve messaging with our dedicated QC team comprised of trained reviewers and editors
- ▷ Provide submission-ready documents with complete electronic formatting and internal linking

OUR EXPERTISE IS YOUR ADVANTAGE

Aligning our expertise by function, therapeutic area, or project phase allows us to strategically plan with the flexibility to quickly adapt to strategy changes. How can our expertise benefit you?

Increase revenue with faster time to market

Our team is positioned to expedite your writing and compilation timelines to meet the most demanding submission goals. With the right team in place, your submission can be accepted for review, without issues, meaning faster time-to-market and more revenue potential.

Restore study timelines and submission schedule

Our medical writing experts can rescue your medical writing projects, successfully finalizing and submitting documents on schedule to get your plans back on track.

Drive adherence without additional burden

With proper internal structure, streamlined processes and flexible work streams in place to support your writing initiatives, your communication can improve without the burdens of additional meetings, emails, and calls.

"With Firma, you can always count on working with a Dream Team of the best and most reputable experts in the industry. The Medical Writing team is responsive to our every need through all phases of development."— *Vice President of Development, mid-sized pharma*

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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.**