

Medical Writing Redefined: Exploring the Power of Artificial Intelligence



How Artificial Intelligence Is Transforming Medical Writing by Enhancing Accuracy, Efficiency, and Quality

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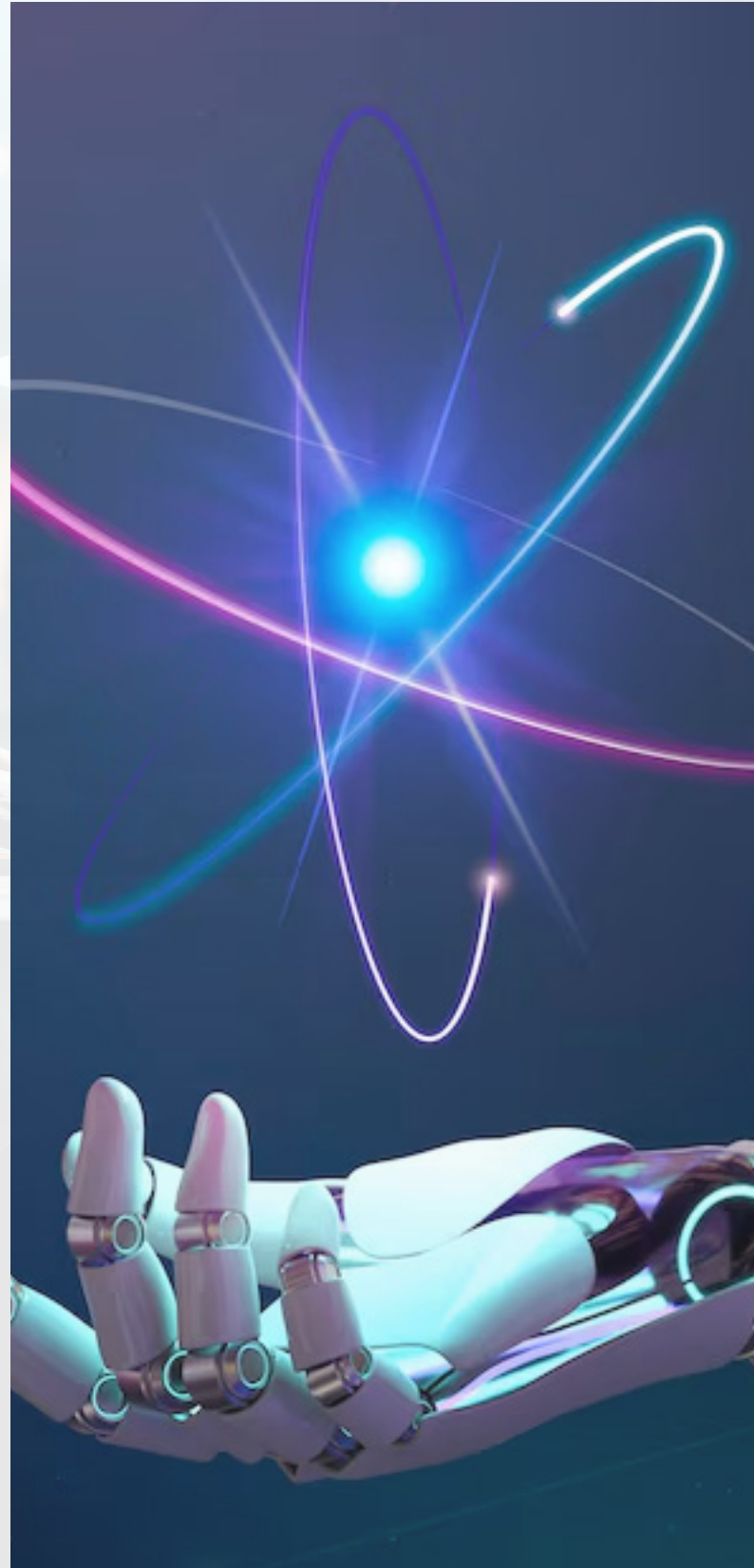
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EXECUTIVE SUMMARY

This white paper examines the integration of artificial intelligence (AI) in medical writing, highlighting current applications, challenges, and implementation strategies. The paper identifies both legitimate and deceptive applications of AI in medical writing. While AI enables efficient literature reviews and statistical analysis, concerns exist about paper mills producing fraudulent content, potentially accounting for up to 24% of medical publications. The implementation of AI in workflows must align with established guidelines from regulatory bodies such as the FDA, EMA, and MHRA, while following ICMJE recommendations for AI disclosure in medical manuscripts.

The paper concludes that while AI offers significant opportunities to enhance medical writing efficiency and accuracy, successful integration requires careful implementation, strong human oversight, and adherence to ethical guidelines to maintain high standards in medical communication.



INTRODUCTION

Technological advancements progress through cycles of disruption and gradual change. Communication has continuously evolved, from the printing press to modern tools like spell check and predictive text. Today, AI has reached a stage where non-experts can effectively use it without requiring coding skills or specialized medical knowledge [1].

In medicine, AI is playing an increasingly valuable role in medical writing, enhancing efficiency and productivity for researchers and healthcare professionals. It streamlines tasks such as data analysis, literature reviews, drafting, and editing. AI-powered tools process vast amounts of medical literature, extracting key insights and relevant information, saving time, and ensuring access to the most up-to-date data for accurate, well-informed content. Additionally, AI-driven algorithms structure and organize medical documents, ensuring compliance with established guidelines. By augmenting human capabilities, AI enhances the efficiency, quality, and impact of scientific publications, making it an essential tool in modern medical research and communication [2].

Key Objectives of This White Paper:

- Present current AI-driven tools used in medical writing
- Address ethical, regulatory, and quality-control considerations
- Provide a phased implementation framework and best practices
- Offer actionable recommendations for organizations and professionals



Current Applications of AI in Medical Writing

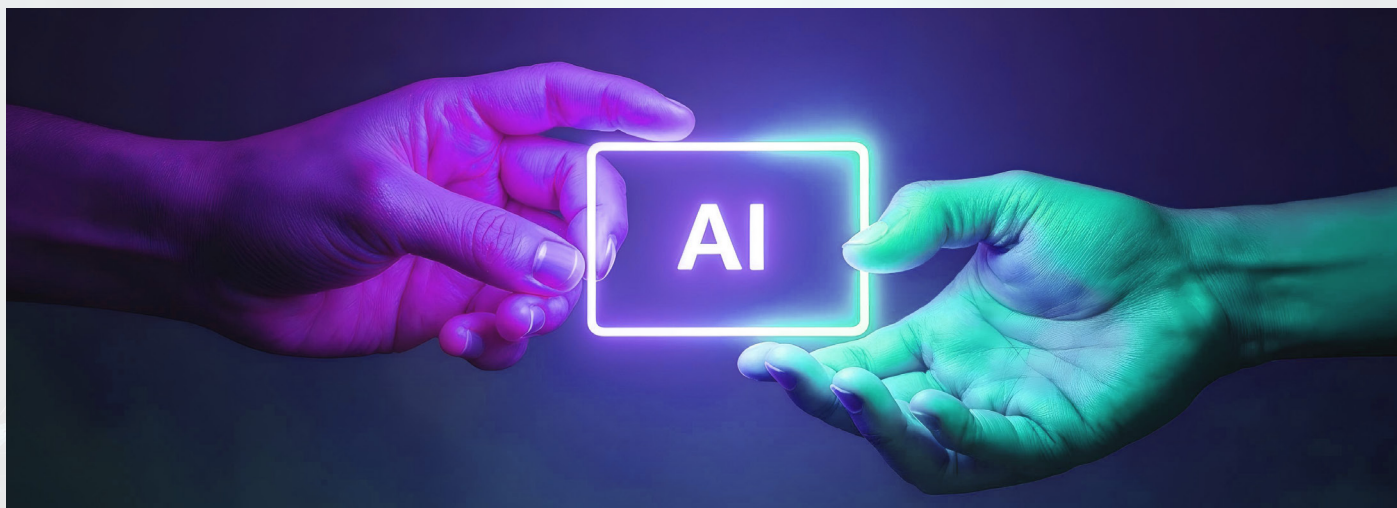
The adoption of large language models (LLMs) in natural language processing (NLP) has significantly expanded the range of data used for training and inference. Once trained, LLMs can be applied across multiple domains for practical tasks such as text generation, translation, summarization, content refinement, classification, sentiment analysis, and conversational AI/chatbots [3].

Medical writing has always been a meticulous and time-intensive process, demanding accuracy, technical expertise, and strict adherence to regulatory standards. With the integration of AI, the field is transforming at an unprecedented pace, empowering medical writers to work smarter, faster, and more effectively. Imagine an AI tool that can sift through thousands of clinical trial reports, extract key insights, and summarize findings in minutes—a task that would traditionally take days. AI-driven models now enhance literature reviews [4], generate structured drafts, and improve document formatting, ensuring compliance with industry guidelines. These tools also provide real-time grammar and style corrections, making medical content more precise and professional [5, 6]. Beyond drafting, AI streamlines regulatory document preparation, automating the structural outlines of clinical study reports (CSRs), safety narratives, and compliance documentation, with human oversight (**Article 26, EU AI Act**). Additionally, AI-powered quality control mechanisms help identify inconsistencies and reduce errors, ensuring alignment with industry standards.

AI also enhances accessibility in medical writing. Plain Language Summaries (PLS) and patient information materials can now be generated in a way that resonates with patients, keeping patient-centricity at its core. These AI-powered tools simplify complex medical data, making it more engaging and easier to understand. AI-driven translation tools further enhance accessibility by ensuring that medical documents reach a global audience with linguistic and cultural accuracy [7]. Furthermore, AI plays a pivotal role in statistical analysis, enabling researchers to interpret complex datasets, identify patterns, and generate evidence-based conclusions [8]. Conversational AI chatbots assist in patient education, while automated transcription tools convert medical discussions into structured text, ensuring comprehensive documentation [9].

Examples of Commonly Used AI Writing Tools:

- ChatGPT and Claude AI for real-time text generation
- Specialized medical writing software (e.g., Scite.ai, ResearchRabbit, Connected Papers, Connectedpapers) for literature mapping and citation tracking
- AI-enabled platforms for systematic literature reviews (e.g., EasySLR, Laser AI)

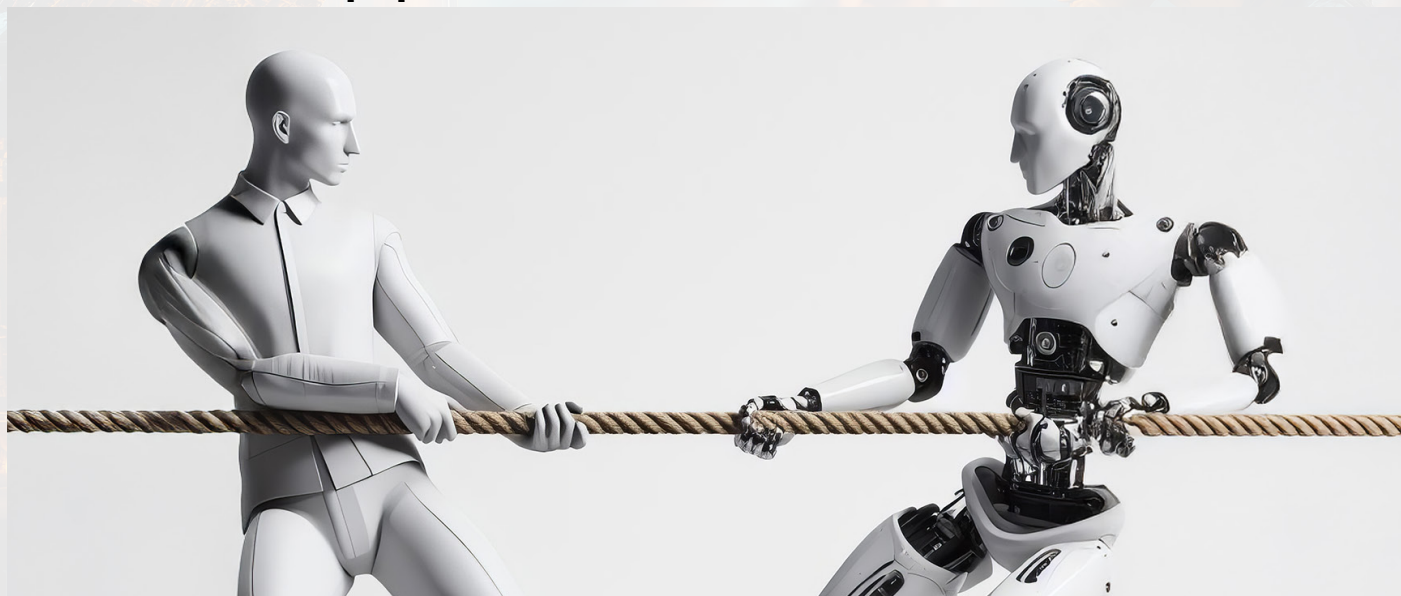


Ramoni et al. (2024) has divided AI applications in two categories [3]:

Legitimate Applications	Deceptive Applications
<p>Literature Summarization & Review</p> <ul style="list-style-type: none"> • Streamlines PubMed searches and research article summaries • Tools like IRIS.AI and Scite.ai provide visual mapping and citation tracking • Speeds up systematic literature review processes 	<p>Fake or “Paper Mill” Publications</p> <ul style="list-style-type: none"> • AI-generated research papers undermine scientific integrity • Paper mills produce fraudulent articles in bulk (up to ~24% in medicine) • Erodes trust in scientific literature
<p>Statistical Analysis Support</p> <ul style="list-style-type: none"> • Generates practical code (e.g., R language) for complex analyses • Helps overcome the shortage of expert statisticians • Requires user vigilance to avoid or correct errors 	<p>Detection of Fraudulent Papers</p> <ul style="list-style-type: none"> • AI-based tools (e.g., GPT-2 Output Detector, Copy leaks) identify fabricated text • STM’s Integrity Hub and publisher-specific detection software flag anomalies • Key checks: author information, manuscript content, and journal-related metadata
<p>Text Translation & Writing Improvement</p> <ul style="list-style-type: none"> • Provides real-time feedback on clarity, coherence, and structure • Helps align manuscripts with journal guidelines • Enhances writing skills, especially for non-native English speakers 	<p>Misuse Through Malevolent Intent or Negligence</p> <ul style="list-style-type: none"> • AI chatbots can inadvertently generate misleading or incorrect content • Untrained users may misuse advanced tools, leading to errors and misrepresentations

Challenges and Limitations

The implementation of AI in medical writing poses critical challenges involving plagiarism, authorship, and intellectual property. AI-generated text can appear credible while containing inaccuracies or plagiarized content, sometimes including fabricated references. Legal uncertainties arise over whether AI-produced materials qualify for copyright protection when no human creative input is involved. Moreover, some unethical practices exploit AI to generate paper mill content, falsified data, and manipulated results. Although detection tools such as machine learning (ML) algorithms can identify AI-generated passages, deceptive strategies—such as using “tutored phrases”—can evade scrutiny. These concerns highlight the urgent need for clear guidelines, ethical oversight, and vigilance to preserve the integrity of scientific literature [10].



Detection Tools and Limitations

- **Copyleaks, iThenticate, and GPT-2 Output Detector** can flag AI-generated or plagiarized text, but these tools have limited accuracy thresholds and may miss sophisticated, “humanized” AI output.
- **Continuous updating of detection methods is necessary** to keep pace with rapidly evolving LLM capabilities.

Unintentional Ethical Pitfalls

- Even the legitimate use of AI can lead to “**ghostwriting**” issues if authorship is not properly disclosed.
- **Inadvertent plagiarism** may occur if large portions of AI-generated text are included without thorough human review or proper citation checks.

Best Practices for Implementation

Successful integration of AI in medical writing requires a thoughtful, systematic approach. Organizations should adopt a phased implementation strategy, beginning with well-defined pilot projects and gradually expanding based on demonstrated success. Clear governance structures and defined roles and responsibilities help ensure proper oversight and accountability throughout the implementation process.

Proposed Phased Implementation Model



Preparation

- Identify specific use cases (e.g., literature reviews, clinical study reports)
- Assemble a cross-functional team (medical writers, data scientists, regulatory experts)
- Assess data governance and IT infrastructure



Pilot

- Select a limited-scope project to test AI tools
- Establish success metrics (e.g., reduction in drafting time, error rate)
- Provide training and hands-on support



Validation

- Conduct quality assurance and peer review of AI-assisted outputs
- Document any errors or gaps for iterative improvements
- Ensure regulatory and ethical compliance



Integration

- Scale up AI-assisted workflows once pilot objectives are met
- Define governance structures (roles, responsibilities, standard operating procedures)
- Maintain transparent documentation of AI involvement



Improvement

- Monitor performance metrics regularly
- Update AI tools and data sets to reduce bias and enhance accuracy
- Adapt to evolving regulatory guidelines

Quality assurance measures must be robust and comprehensive, including validation protocols, regular system audits, and strong human oversight mechanisms (**Article 26, EU AI Act**). The documentation and disclosure of AI involvement in content generation should be transparent, allowing for proper review and validation of AI-assisted work.

Training and support infrastructure play crucial role in successful AI implementation. Organizations should invest in comprehensive user training programs (**Article 4, EU AI Act**), maintain adequate technical support resources, and ensure regular updates and maintenance of AI systems. Continuous monitoring of system performance helps identify areas for improvement and ensures that AI tools continue to meet organizational needs (**Article 26, EU AI Act**).

Ethical Considerations and AI Guidelines

The integration of AI and ML technologies in healthcare holds tremendous promises for improving patient care, advancing medical research, and enhancing service efficiency. However, this potential also raises significant ethical considerations, including data privacy and security (**Article 26, EU AI Act**), algorithmic bias (**Article 5, EU AI Act**), transparency (**Article 50, EU AI Act**), clinical validation, and professional accountability, all of which demand proactive strategies. By confronting these challenges and upholding core ethical principles, healthcare stakeholders can protect patient welfare while unlocking the transformative benefits of AI and ML. Through best ethical practices and interdisciplinary collaboration, the healthcare community can usher in a new era of personalized, data-driven care that remains equitable and patient-centered [11].



The ethical implications of AI in medical writing extend beyond technical considerations, touching on fundamental questions of transparency, accountability, and scientific integrity. The Good Machine Learning Practice (GMLP) guidelines, jointly developed by the Food and Drug Administration (FDA), Health Canada, and the UK's Medicine and Healthcare Products Regulatory Agency (MHRA), provide fundamental principles for AI implementation in healthcare contexts [12]. The International Committee of Medical Journal Editors (ICMJE) has updated its recommendations to address AI use in medical manuscript preparation, requiring explicit disclosure of AI tool usage [13]. The European Medicines Agency (EMA) has issued guidance on AI in regulatory submissions through its Regulatory Science Strategy to 2025, which outlines specific considerations for AI in medical writing [14]. Additionally, the International Medical Device Regulators Forum (IMDRF) has published guidance on AI in medical documentation [15].

Recommendations

- Organizations seeking to leverage AI in medical writing should focus on developing clear strategies for implementation, establishing robust validation protocols, and maintaining strong human oversight of AI-assisted processes (**Article 26, EU AI Act**).
- Investment in training (**Article 4, EU AI Act**) and support infrastructure is essential, along with the regular assessment of AI tool performance.
- Staying current with regulatory requirements and industry best practices will help ensure successful integration of AI technologies.

Conclusion

The integration of AI in medical writing presents a significant opportunity to enhance efficiency, accuracy, and compliance in medical communication. While challenges remain, particularly in validation and quality control, organizations can harness the benefits of AI by following established best practices and maintaining rigorous oversight. As technology continues to evolve, organizations that successfully integrate AI tools in alignment with the ethical guidelines—while maintaining strong human oversight—will be well-positioned to meet the growing demands of medical communication in the digital age.



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