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THEME ARTICLE

Reimagining Clinical and Regulatory Medical Writing With Generative AI

Ravi K. Ramachandran, PhD, Terris J. Linenbach, Christopher J. Ceppi, and Anita G. Modi / Peer AI, San Francisco, CA

ABSTRACT

The emergence of groundbreaking clinical targets and treatment modalities is fueling a surge in the number of clinical trials. This increased volume, coupled with the growing complexity of trials, is putting immense pressure on medicine's development process. One immediate area of opportunity for streamlining clinical trials is clinical and regulatory medical writing. Generative AI (GenAI) has the potential to revolutionize medical writing by automating routine tasks, improving consistency and quality, and enabling faster turnaround times. This frees medical writers from mundane work, allowing them to focus on strategic initiatives and exert greater influence within life sciences organizations. This article explores the current state of clinical and regulatory medical writing, the challenges posed by the increasing complexity of clinical trials, and how GenAI can be used to address these challenges. The article also discusses the ethical considerations of using GenAI in medical writing and the importance of human oversight and review. Overall, the article builds a compelling case for the use of GenAI in medical writing and outlines a roadmap for the future of this field.

HOW GENERATIVE ARTIFICIAL INTELLIGENCE CAN HELP MEDICAL WRITING

The emergence of groundbreaking clinical targets and treatment modalities, spurred by scientific leaps, is fueling a surge in the number of clinical trials aimed at evaluating the effectiveness of novel therapies.[1] By some estimates, the number of clinical trials running at any given time has grown by more than 200% since 2013,[2] putting the medicine development process under immense pressure.

Beyond an increase in clinical trial volume, trials are also becoming more complex. In some disease areas, an explosion in the amount of data available—due to advances in digital and analytics techniques, and more endpoints being used to validate efficacy and safety—has made trials more onerous to conduct. In other therapeutic areas, such as rare diseases, data may be sparse, but there is still a need to ensure appropriate power and repetitiveness in study results for approval. These are just two of the factors driving more complicated study designs that take longer to run and yield results that are arduous to analyze.

While the pharmaceutical industry grapples with an exponentially expanding workload in clinical trials, the essential workforce hasn't grown at the same pace.[3] The intricate nature of modern trials demands a robust cadre of skilled workers to both carry out and document the studies, and the current shortage impedes the smooth handling of critical, increasingly complex processes. To navigate this challenge, proactive strategies are key. Investing in training programs to cultivate new personnel, implementing automation and generative artificial intelligence (GenAI)–powered tools to support existing teams, and fostering industry-wide collaboration can bridge the talent gap and ensure efficient, cost-effective drug development.

Reducing time spent between research and regulatory approval with improved efficiency requires innovative solutions. One immediate area of opportunity for streamlining clinical trials and closing the resource gap is clinical and regulatory medical writing.

Using GenAI to Address Clinical and Regulatory Medical Writing Challenges

The emergence of GenAI, which relies on large language models to create new content, presents an opportunity to fundamentally transform clinical and regulatory medical writing. To grasp this groundbreaking change, we must first examine the existing landscape of medical writing, which will serve as our reference point.

A Problematic Status Quo

Clinical regulatory writers are an indispensable part of the clinical trial process. They create documents—such as clinical study reports, investigator's brochures, plain language summaries, development safety update reports, and common technical documents—that regulatory agencies

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must review in order to decide whether an intervention that has been studied in a clinical trial is safe and effective or not. A clinical regulatory writer's ability to effectively analyze, organize, and synthesize complex scientific information makes regulatory review easier, which means life-saving medicines and medical-grade devices get to patients faster. The challenge is that the volume and complexity of work needed to properly convey key findings forces medical writers to spend hundreds of hours producing the regulatory documents required for a given trial.

Caught in a double bind, medical writers must grapple with both meticulous writing for complex deliverables and lightning-fast turnaround times amid an explosion of clinical trials. As a result, writers are increasingly susceptible to burnout and job dissatisfaction as they shift from one time-intensive project to another with no time in-between.[4] Even at smaller biotech companies with one to two therapeutic assets of focus, the timelines for regulatory submissions still prove challenging given resourcing constraints, and burnout is still an issue.

To manage medical writer burnout, while accommodating a higher number of complex trials, trial sponsors are increasingly outsourcing medical writing assignments to contract research organizations or other agencies.[5] Outsourcing, however, can bring its own set of problems such as misaligned expectations and additional review rounds, leading to higher costs and more time spent on projects.

Although some trial sponsors have attempted to automate parts of the medical writing process, the tools that exist today perpetuate inefficiencies, because they are limited to automating very specific, repetitive tasks. Even with this technology, the typical medical writer may still be overburdened and continuously working under extreme time pressure.

How GenAI Is Revolutionizing Medical Writing

GenAI can significantly improve and expedite workflows for medical writers by taking on many of the repetitive, time-consuming tasks they currently manage, while also improving the quality of the documents that are produced. One analysis found that GenAI can both reduce medical writing time and augment quality management in such a way that increases staff productivity by up to 30%[6] and can save medical writers 80% of their time overall.[7]

The productivity and quality gains driven by GenAI are possible because the technology can go beyond the typical use cases for automation that exist today. Most of the existing tools excel at highly structured tasks but lack the deeper understanding of medical language and scientific concepts needed for impactful clinical and regulatory medical writing. This is where the capabilities of GenAI provide unique value.

By leveraging context-aware analysis of vast data sets, GenAI can produce content that is curated by the medical writer's deep understanding of the field. This intelligent authoring capability frees medical writers from tasks like data preparation, allowing them to focus on strategic work that is mission-critical for the sponsor.

GenAI's most important credential in clinical and regulatory medical writing is its ability to support complex document generation, adhering to specific formatting guidelines and implementing updates in real-time so the documents always reflect the relevant data set.

To do this successfully, GenAI platforms must be fit-for-purpose, because general models trained on vast amounts of "all" data are not suited to a highly regulated industry like biopharma. By contrast, specialized GenAI platforms that are purpose-built for biopharma use-cases and trained on biopharma data sets can ingest data and produce properly formatted, regulatory compliant documents that reflect that. Further and equally critically, they can also provide a synthesized, cohesive, and consistent narrative across an entire project. These purpose-built platforms can also be constructed around data protection, privacy and platform validation, ensuring the data they ingest is properly secured according to regulatory guidelines.

Beyond document creation, GenAI can be used to better manage processes around data inputs, including

- Ingesting and synthesizing data. GenAI can ingest, reconcile, and synthesize troves of data at a fraction of the time that it would take a human.
- Preparing data. GenAI can clean, transform, and organize data so it is ready for analysis. Rather than manually sifting through data, conducting quality checks on multiple screens, and reconciling divergent formats and sets of terminologies, medical writers can use GenAI so they can instead focus on exercising fine-tuned analytical skills and more substantively contribute to the clinical regulatory writing process.
- Detecting data anomalies. GenAI automates tasks like data entry and validation, reducing the risk of human error and improving overall accuracy. For example, GenAI can reduce time spent on quality control by detecting inputs that deviate from source documents.

Democratizing Medical Knowledge: Humans and GenAI Partnership Will Revolutionize Clinical and Regulatory Medical Writing

In a world with GenAI as an additional tool in their armament, medical writers can cut out much of the drudgery that comes with their jobs. Although they will continue to play a critical role in maintaining quality control, driving insights, and deriving a cohesive set of clinical regulatory

documents, human writers will be relieved from the tedium of ingesting and combing through data sets. Instead, writers can spend their time on more fulfilling tasks, such as strategic storyboarding, sourcing input from subject matter experts, and sharing key insights that will play a vital role in a medicine's approval.[8]

By pairing the ingenuity and creativity of humans with the efficiency and accuracy delivered through GenAI, the industry can transform regulatory medical writing in ways that we're just beginning to understand. At a minimum, this thoughtful implementation of GenAI will accelerate the authoring of documents supporting marketing applications to bring more life-saving medicines to market faster and support more patients.

Although the potential of AI to revolutionize clinical regulatory medical writing is vast (and already being realized to some degree, with the US Food and Drug Administration receiving over 100 product registration submissions that heavily relied on AI/machine learning in 2021 alone9), embracing this technology also necessitates acknowledging and addressing potential drawbacks, and the potential disruptiveness of GenAI in medical writing has not gone unrecognized.[10] Here are some key concerns and proposed solutions:

- ***Job displacement.*** Automation through GenAI may raise concerns about replacing medical writers. However, it's crucial to view GenAI as an augmentation, not a displacement. GenAI can handle the tedious, repetitive tasks, freeing up medical writers to focus on critical activities like strategic analysis, creative writing, and interpretation of complex data.[7] This shift toward higher-level skills can create new opportunities for medical writers within a transformed writing landscape.
- ***Data security and privacy.*** Handling sensitive patient data in clinical trials requires robust safeguards. To mitigate this concern, GenAI platforms should be built with data security and privacy at their core. This includes adhering to strict data protection regulations, employing cryptographic methods to secure data, and minimizing data collection and retention to the absolute minimum necessary.[6]

Using GenAI to Clear the Path to Scientific Discovery

The increased volume and complexity of clinical trials and stagnant labor pool mean that medicine developers need new methods of operating to increase the quality and efficiency in the reporting of data from clinical trials. Although some strides have been made in improving this process, clinical regulatory medical writers remain underserved and overburdened.

A new class of clinical and regulatory medical writing tools powered by GenAI have the potential to ease the strain of repetitive, mundane work taken on by medical writers while also improving the overall quality of documents submitted for regulatory approval. Organizations that devote resources to GenAI adoption and strategic implementation in clinical regulatory medical writing will clear the path to scientific discovery and accelerate time to market for innovative therapies.

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Author contact: *ravi@getpeer.ai*

References

1. Aronowitz S, Bleys J, Fleming E, Hsiao R. Transforming Biopharma R&D at Scale. McKinsey & Company; 2022. Accessed November 30, 2023.
2. Trends, Charts, and Maps - ClinicalTrials.gov. classic.clinicaltrials.gov. Accessed November 30, 2023. https://classic.clinicaltrials.gov/ct2/resources/trends
3. Spiegel K, Kryder C, Munno L. Medical Communicators' Guide to Regulatory Writing. American Medical Writers Association. Accessed December 6, 2023. https://info.amwa.org/a-medical-communicators-guide-to-regulatory-writing
4. Affleck J, Kryder C, Spiegel K, Winter-Vann A. Preparing for the future of medical writing in biopharma: AMWA's Inaugural Medical Writing Executives Forum. *Am Med Writers Assoc J*. 2019;34(1):45.
5. The Growing Role of CROs in Clinical Trials. PPD Inc. Published July 6, 2023. Accessed December 15, 2023. https://www.ppd.com/blog/growing-role-of-contract-research-organizations-in-clinical-trials/#:~:text=More%20than%20a%20third%20of
6. Neiser J, Srikumar K, Lee M, Engel C, Ganga K, Jayanth Dhruv, and Patel Keyur. Biopharma's Path to Value with Generative AI. BCG blog, Oct 9, 2023. Accessed December 21, 2023. https://www.bcg.com/publications/2023/biopharma-path-to-value-with-generative-ai
7. Cobb L, Haycock N. Narratives for a clinical study report: the evolution of automation and artificial intelligence. *Med Writ*. 2023;32(3):28-31. 10.56012/kcca1211
8. Chamberlin J, Cooper J, Affleck J, et al. *The Value of Medical Writing in the Regulatory Environment*. American Medical Writers Association; 2023.
9. Niazi SK. The Coming of Age of AI/ML in Drug Discovery, Development, Clinical Testing, and Manufacturing: The FDA Perspectives. *Drug Des Devel Ther*. 2023;17:2691-2725. 10.2147/dddt.s424991
10. The use of AI and AI-assisted technologies in writing for Elsevier. www.elsevier.com. Accessed December 21, 2023. https://www.elsevier.com/about/policies-and-standards/the-use-of-generative-ai-and-ai-assisted-technologies-in-writing-for-elsevier