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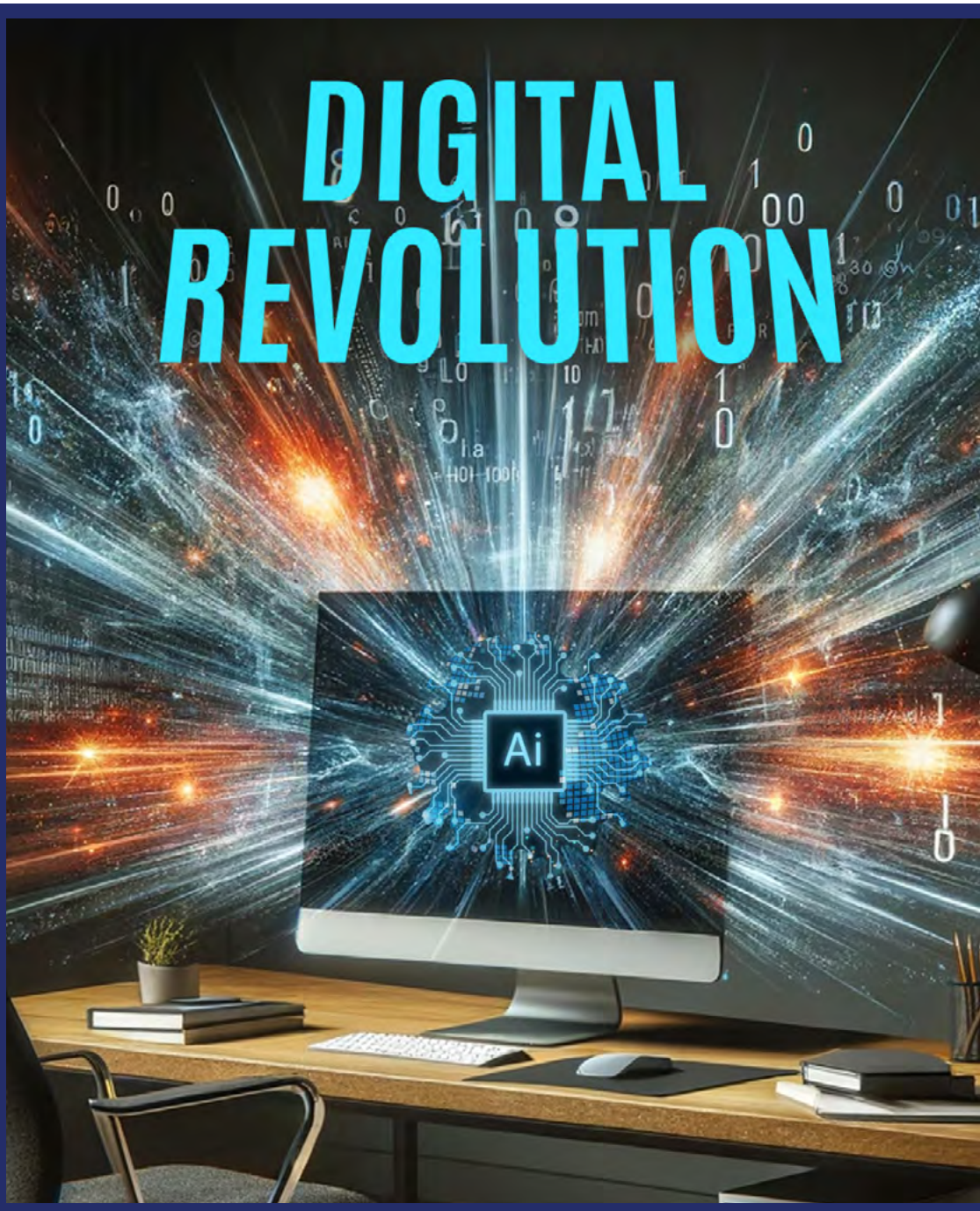
## INSIDE

### THEME ARTICLES



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# Contents

V39 N2
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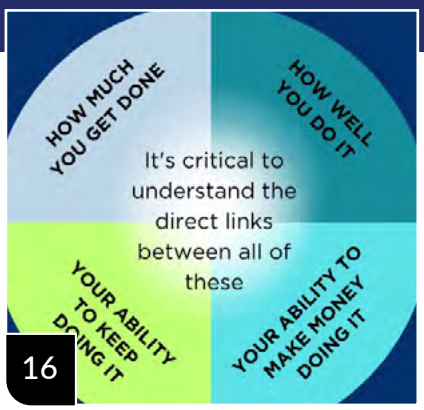
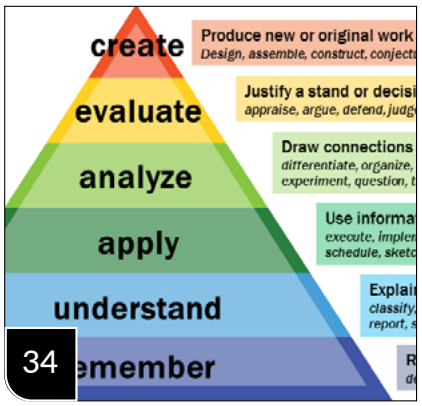
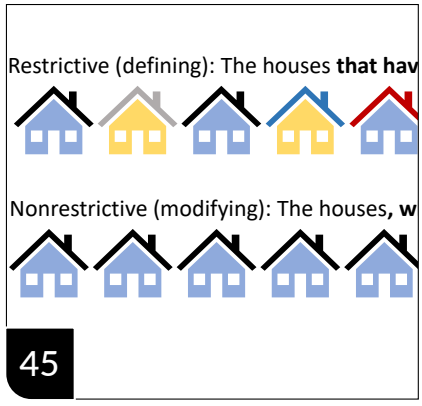


16



34



45

# MORE Contents

AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL
V39 N2 / 2024



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FROM THE GUEST EDITOR

# Introducing Artificial Intelligence and Machine Learning Tools Into the Medical Writing Workflow

**Kyla Ross, BS, MS /** Nonclinical Writer, Muskegon, MI

Artificial intelligence (AI) and machine learning (ML) tools have been used across all spectrums of the drug development process. The US Food and Drug Administration has accepted over 100 submissions that cite the use of AI that has assisted with clinical trial recruitment, drug discovery, and dose optimization. With these insights in mind, health authorities expect the use of AI and ML tools in regulatory processes and is working to provide meaningful oversight.[1,2] In medical writing, AI and ML sources have been essential to the writing process by formatting documents, designing study protocols, analyzing manuscripts, and communicating complex scientific information to lay audiences. The technological advances of AI and ML are rapidly evolving, and there is indeed a place for such technologies in the medical writer's resource toolbox.

AI and ML tools have made the regulatory submission preparation process more efficient and less tedious for both nonclinical and clinical processes by assisting in creating error-free, organized, and correctly formatted regulatory documents per health authority guidance. Other uses for AI and ML technologies in regulatory submission planning include outcome predictions, image analysis, and the design and conduct of clinical trials.[3]

In biomedical publications, AI has been used for manuscript preparation, citation management, proofreading, and formatting. Another AI/ML tool that is useful to medical writers is the technology's capability to analyze a manuscript and suggest journals for submission. Such utilization has ensured compliance with journal submission criteria, which increases the likelihood of manuscript acceptance. From a publishing workflow perspective, AI makes the editorial workflow more efficient by finding peer reviewers, reviewing statistical data, and screening manuscripts. AI/ML tools also detect plagiarism errors, provide quality assessments, and scout for experienced peer reviewers.[4] Non–English-speaking scientific writers have used AI to improve grammar, clarity, and syntax of manuscripts, namely, the methods, results, and reference sections, which can increase the likelihood of manuscript acceptance to notable scientific journals.[5]

Not only are AI and ML tools useful for regulatory and biomedical journal submissions, but it has also been used for scientific communications. AI algorithms can be used to develop lay summaries of complex scientific information to effectively communicate with the public in the forms of press releases, news stories, and product descriptions.[4,6,7]

Although AI and ML tools have been useful to medical writers, the technologies are shrouded in ethical concerns, which include properly citing the use of the technologies, bias, accuracy and reliability, informed consent violations, misinformation, and plagiarism.[5,6,8] Potential issues with job security and employee training have also been discussed.[4,9] Companies and medical writers who choose to implement AI and ML tools into their workflow should adopt a strict code of ethics and understand the regulations associated with their use. [1, 2]

In AMWA's Digital Revolution theme issue, a range of uses for AI and ML resources for medical writers are presented. The articles in this issue cover topics ranging from understanding the technology as it exists today to identifying the different types of software available. AMWA will continue to publish articles on the subject in the issues to come and vows to keep readers informed on technological resource availability, ethical responsibilities, and governmental oversight when it comes to AI and ML tools.

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AMWA JOURNAL V39 N2 / 2024

THEME ARTICLE

# Copilot — Essential AI Assistant to Medical Writers

**Noelle Ochotny, PhD, CMPP, and Mario Morel** / Foremost Medical Communications Inc, Toronto, ON, Canada

This article presents a conversation between a medical writer and a system administrator, who discuss their experience with the deployment and use of Microsoft Copilot for creating content. The medical writer is Noelle Ochotny, PhD, a certified medical publications professional who works as a freelancer in publications. The system administrator is Mario Morel, who specializes in digital collaboration, cybersecurity, and privacy. They work together and have recently integrated Copilot into their workflow. This article aims to communicate their insights on working with Copilot in a medical writing environment.

Among the available licensing options, Noelle and Mario have *Microsoft 365 E5*, supplemented with the *Copilot for Microsoft 365* add-on. Please be aware that the *Copilot for Microsoft 365* add-on was only made available to all Microsoft 365 business customers on January 15, 2024, 6 weeks prior to writing this article.

**Noelle Ochotny:** Mario, I consider Copilot to be indispensable. Copilot has definitely improved my efficiency since you deployed it a few weeks ago.

**Mario Morel:** I am glad to hear that Copilot is proving helpful to you. Nevertheless, my role involves ongoing assessment of any system we use in our organization, considering factors such as cost, cybersecurity, and privacy compliance. With that in mind, could you share a few of your experiences using Copilot in your daily work?

## TOP USE CASES FOR COPILOT

**Noelle:** One application is creating titles for articles or abstract submissions. Titles that are catchy, informative, and have relevant keywords for searchability can influence whether an article is read. Copilot assisted by rapidly producing several title options based on the content of an article. For those times when I need help generating ideas, Copilot provides a fresh perspective and proposes original and unique title options that I had not considered. Inspired by Copilot's options, I then easily create the title.

**Mario:** Intriguing. Do you have more examples?

**Noelle:** Copilot has been an effective tool in assisting me with writing presubmission letters. The process was expedited by requesting Copilot to generate an engaging statement that encapsulates the unique aspects of the research, all while having the manuscript open in Word. Subsequently, I asked for a 1-page summary of the research. Copilot was able to produce a satisfactory summary. Following some editing and tweaking, the letter was successfully crafted.

Another use case is rephasing. Occasionally, I have encountered awkwardly constructed sentences while editing a document. The authors wanted elegant prose. Interpreting these types of sentences can be time consuming. I prompted Copilot to provide me with 3 different renditions of a phrase. I selected the most suitable one, made a few edits and adjustments, then added it to the manuscript. This process is both faster and better.

**Mario:** Got it. Can you share one more use case?

**Noelle:** Copilot has been valuable in aiding me with creating abstracts. Clients require assistance with different types of abstracts for manuscripts, conferences, and more. I am impressed with Copilot's ability to understand the different contexts of each abstract type. I described the situation in my prompts and Copilot provided a good first draft. As always, I refine and improve the language, and, admittedly, this is easier to do from a strong initial draft.

I also prompted Copilot to generate a graphical abstract based on an actual abstract. Copilot offered several illustrations. Copilot's output served as a source of inspiration for me to create the final graphical abstract.

It is worth mentioning that creating detailed prompts is essential when interacting with Copilot. Initially, Copilot's responses were not specifically tailored to my situation. However, as I honed my skills in formulating more effective prompts, Copilot's performance improved.


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## CONFIDENTIALITY AND PRIVACY

**Mario:** I understand your recent concerns regarding the confidentiality of Copilot. To generate relevant content, Copilot needs access to sensitive information within a manuscript. I carefully read the Microsoft Copilot Privacy Statement. The main point is that *Copilot for Microsoft 365* adheres to Microsoft's standing commitments to privacy, security, and compliance for its commercial customers. For instance, the prompts, responses, and data accessed by Copilot are not used in the training of foundation large model languages. Essentially, Microsoft does not monitor your use of Copilot.

When you create a prompt, Copilot will only use the data, including emails, chats, and documents, to which you have authorized access. You can also restrict Copilot from conducting internet searches during a query. In these situations, Copilot uses only the data within your specific environment. This functionality can offer additional protection when using sensitive data in a prompt. Microsoft also applies additional restrictions to data inside the European Union boundary.

## LICENSING AND COSTS

**Noelle:** How much does a Copilot license cost?

**Mario:** Licenses determine the features of Copilot that are available for use. Features and pricing can vary by region and are subject to change.

**Noelle:** Fair enough. What is the minimum financial commitment required for a medical writer to have access to the version of Copilot that we use?

**Mario:** The minimum prerequisite license is a Microsoft 365 business or enterprise subscription. There are several options available: *Business Standard*, *Business Premium*, *E3*, and *E5*. Licensing fees range from $12 to $57 per use per month. Note that these subscriptions also include, at no additional cost, the Commercial data protection for Copilot, which facilitates private interaction (chat) with Copilot.

The version of Copilot that is compatible with Office tools is *Copilot for Microsoft 365*, which is an add-on priced at $30 per user per month. Therefore, the minimum expenditure for a medical writer would be $42 per month.

## BUSINESS DEVELOPMENT

**Mario:** Copilot has improved our business operations by helping to draft agreements. It accesses our data and can understand our business context. Copilot assisted me in writing draft terms for a service contract I was preparing for a customer. Thanks to this better prepared draft, our lawyer was able to review the contract quicker, which helped save money. With Copilot, we can create precise and relevant contracts with our customers, suppliers, and contractors, all while managing legal expenses.

**Noelle:** Copilot aided me in creating promotional materials, presentations, and sales proposals. Writing promotional documents is not my forte, although with Copilot's assistance, I can quickly create impactful documents… which is a relief.

**Mario:** I also built applications for automated handling of company emails using Copilot in conjunction with Power Apps. I provided a description of the app's intended functionality and Copilot generated the app. I reviewed and corrected any errors, and I now have a useful app at my disposal. I did not need to write any code… luckily.

## LOOKING AHEAD

**Mario:** We anticipate our next major improvement in productivity to stem from Copilot with Teams, given our extensive use of Teams in our daily work. Also, we plan to create use cases for Copilot with Excel, PowerPoint, Outlook, and SharePoint.

**Noelle:** Given that Copilot can securely access my data (eg, emails, files, chats), it progressively acquires a deeper understanding of my business operations. I anticipate that Copilot will evolve into an even more proficient assistant over time.

I plan to keep exploring and identifying more and better use cases. My hope is that we in the medical writing community will share our experiences and new ways to extract value from AI assistants. The previous 6 weeks have been very exciting while adopting this new tool, and I look forward to continued progress with Copilot in the upcoming 6 months.

## FINAL THOUGHTS

Using AI carefully and responsibly is essential. The improvements in efficiency have been so significant for us that we cannot imagine working without Copilot. From our experience, the process of learning about AI and integrating Copilot into our workflow was simpler and less expensive than we anticipated. In summary, we recommend that medical writers consider adding Copilot into their toolkit.

**Acknowledgment**

We used Microsoft Copilot in drafting this article.

***Author declaration and disclosure:*** *Foremost Medical Communications Inc. is a Microsoft AI Cloud Partner.*
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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

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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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

THEME ARTICLE

# Take the Leap! Steps to Integrate AI Into Your Work

**Jenni Pickett, PhD,**[1] **and Mandy Pennington, BS, MWC**[2] / [1]Whitsell Innovations, Inc, Chapel Hill, NC; [2]Freelance Medical Editor, Downingtown, PA

## ABSTRACT

The capability of artificial intelligence (AI) is rapidly increasing and is now sitting on the threshold of the medical writing field. This article presents an AI integration framework that breaks down adoption of this new technology into manageable steps that ensure an informed and thorough approach. Using this framework, individuals and corporations can leverage the benefits of this evolving technology while minimizing risks.

The first step, AI literacy, provides a foundation for informed decision making and appropriate expectations for AI capabilities. This knowledge inspires creative exploration of which use cases would be a suitable application of AI tools. Once the scope of potential uses is defined, risks can be assessed, including incorrect content generation, data leakage, and bias. AI tools can then be evaluated to find tools that can both satisfy the use cases and mitigate critical threats. The final step is to integrate the tools transparently with appropriate guardrails. Then the cycle begins again as AI technology evolves and new applications become possible.

As medical writers are ushered further into the AI era, clear and consistent advocacy for a synergy point between the efficiency of AI and the experience, ability, and humanity of a medical writer will maximize the impact of these innovative models.

The introduction of publicly available generative artificial intelligence (AI) tools has marked a significant turning point in integrating AI into medical communication. Mass-market releases of this new technology started with the launch of ChatGPT by OpenAI in November 2022,[1] which was quickly followed by other significant large language model (LLM) chatbots like Claude by Anthropic and Bard by Google. Generative AI demonstrated remarkable reasoning capabilities that previously required human medical writing expertise such as turning an unformatted data table into a summary paragraph that includes correct comparisons between groups. An upgrade to GPT-4 in late 2023[2] was the first of a wave of large multimodal models (LMMs) that could process and produce images and audio in addition to text.

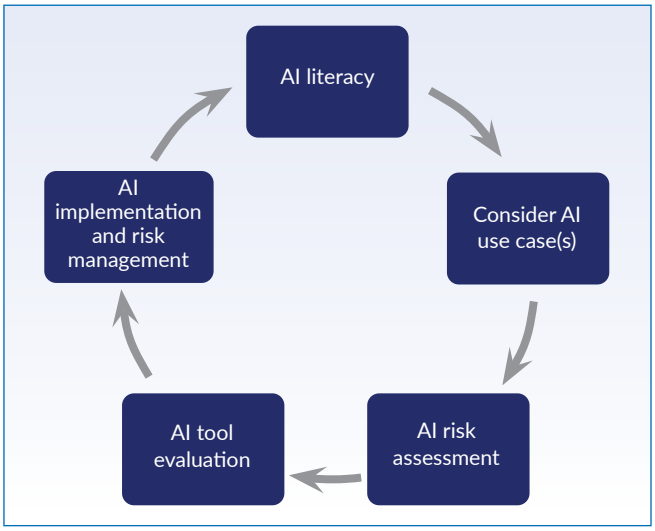


**Figure 1.** AI integration framework. AI, artificial intelligence.

This period of technological novelty brings with it a wave of AI anxiety among professionals, stemming from fears of job displacement and the reluctance to adapt to changes AI could bring to our daily work. Our psychological response to dramatic change mimics the stages of grief; we start with shock, denial, and anger, then progress to depression due to feelings of overwhelm and inadequacy. Despite these concerns, it's crucial to recognize the potential of AI to optimize drug development processes, reducing the time and expense of bringing new drugs to patients. Exponential growth in the number of AI-enabled drugs and devices may make it necessary for medical writers to adopt generative AI tools to keep up with the workload and do our part to bring treatments to patients faster. This hope for the future can bring us to the upside of the grief response curve, inspiring us to experiment with AI tools, increase our AI literacy, and eventually integrate AI into our work.

In the "Take the Leap! Steps to Integrate AI Into Your Work" presentation at AMWA's 2023 Medical Writing and


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Communication Conference in Baltimore, Maryland, a comprehensive framework for integrating AI was introduced that is relevant for leaders, employees, and freelancers (Figure 1). As medical communicators, it is up to us to set the foundation for a future in which the efficiency of generative AI is seamlessly blended with the expertise of medical communicators, harnessing the optimum capabilities of both.

## AI LITERACY

Successful application of LLM technology to medical writing hinges on our clear understanding of its benefits and risks. LLMs are a subset of AI, specifically within the field of generative AI. LLMs are created through machine learning, specifically deep learning using neural network architecture.

Machine learning is a way to build a computer program that is distinct from typical programming. It uses different hardware designed to perform many computational steps in parallel. Instead of having a programmer define each step for the computer to execute, a data scientist or machine learning engineer sets up a model for the computer to train itself based on provided data sets.[3]

LLMs such as GPT-4 from OpenAI are trained on massive amounts of data, allowing them to comprehend inputs and generate human-like responses. GPT stands for generative pretrained transformer, meaning a machine learning model that generates unique outputs, accesses a broad subset of human knowledge from its pretraining, and understands complex user requests using transformer technology. LLMs can perform tasks like writing, translating languages, coding, creating images, data analysis, and more.

An important step in AI literacy for medical communicators is understanding the difference between LLMs and other AI technologies. Many medical writing and editing AI tools are largely expert systems. Expert systems resemble the structure and consistency you get with highly detailed templates; they are deterministic and built with extensive human knowledge, which leads to predictable outputs. However, they require structured inputs and are less adaptable to varying tasks.

Conversely, LLMs resemble the flexibility and variability you get with simpler, open-ended templates. They are probabilistic, generating outputs based on likelihoods and patterns learned from their vast data sets. This nature makes them more adaptable and flexible but also introduces inconsistency in output and the need for human oversight for accuracy and context.

Writers may interact with LLMs in a standalone chatbot (like ChatGPT), as a functionality in software (like Copilot by Microsoft), or in an internet browser (like Chrome). LLM chatbots, whether standalone or within an application like Word, typically have an interface consisting of a blank box, which leaves the determination of what tasks are suitable and reliable entirely up to the user. AI literacy training to understand what tasks are appropriate for LLMs enables medical writers to leverage these tools effectively, allowing for productivity enhancements while maintaining the high standards of accuracy and context sensitivity crucial in the field.

Understanding how LLMs work helps users predict appropriate tasks. There are fundamental differences in how humans and LLMs write content. Human writers research, understand context, and cite specific sources. They bring a unique perspective and a depth of understanding to their writing, albeit with the possibility of errors and gaps, especially when dealing with unfamiliar topics. LLMs, on the other hand, do not read in the traditional sense. Instead, they are trained on text data broken down into tokens (words or parts of words). LLMs generate text based on patterns learned from their training data, predicting the next token in a sequence. This process can lead to innovative content generation, but it lacks the depth of understanding and context that human writers and editors bring. Moreover, LLMs often cannot trace back to specific sources and might create fake citations or inaccurate content, particularly on topics not well-represented in their training data.

Retrieval-augmented generation (RAG) technology, introduced to mass-market LLM tools in late 2023, assists LLMs by adding a retrieval step before generation. This retrieval step pulls out snippets relevant to the user request from writer-provided or Internet-based sources, which are then used and cited in the generation step.[4]

## CONSIDERING AI USE CASES

Armed with a general sense of how LLMs work, users can think of routine challenges in their work that LLMs could help with. However, avoid the feeling that an LLM can solve everything (AI solutionism) when other tools, such as expert systems or regular software would do a better job. Ideal use cases are those that can benefit from an LLM's unique capabilities.

Before evaluating use cases, users should understand that information shared with mass-market LLMs may be used to train a model owned by another entity. AI etiquette requires requesting permission before using someone's nonpublic content in any AI system and compliance with AI use policies (employer, client, publisher, etc). Because LLMs can provide inaccurate information, use case outputs should be externally verifiable.

LLMs and LMMs can augment users by taking on simple tasks, assist users step-by-step, and amplify users by expanding their skill set (box on next page).

### LLM Use Case "A-List"

**Augment:** delegate specific tasks to the LLM and review the outcome.

**Assist:** collaborate with the LLM—the model helps write, edit, and create content.

**Amplify:** the LLM provides new capabilities, such as coding, creating a data visualization, or teaching a new concept.

#### "Augment" Use Case Examples

- Formatting lists of abbreviations: fixing capitalization and spelling errors with awareness of proper nouns.
- Formatting references: aligning to a provided example style.
- Converting images to text: transform photos of handwriting, slides, or scanned documents to editable text.

#### "Assist" Use Case Examples

- Preparing slide scripts: generating a draft of a presentation script for a slide based on the slide title and key points.
- Creating images: convert text prompts to pictures for use in presentations or social media.
- Providing technical support: taking users step-by-step through common computer issues (if the LLM recommends entering an admin password or editing registry files, wait for a human to help).

#### "Amplify" Use Case Examples

- Creating a PubMed search string: converting a text request into Boolean operators.
- Writing macros for Microsoft Office: translating user requests into Visual Basic for Applications and taking the user through the steps to run the program.
- Performing basic data analysis: parsing large data sets and providing charts to visualize the data (users should be mindful that LLMs do not clean data automatically).

## AI RISK ASSESSMENT

Before using LLM-based tools, understanding potential risks and planning how to mitigate them is paramount. Establishing a risk profile will help identify tools that fit that profile. Risks related to LLMs can be due to training data limitations, human factors, functional limitations, and/or implementation challenges (Figure 2).

An LLM's knowledge is rooted in its training data. Gaps or weaknesses in training data can result in hallucinations (false information invented by the LLM), outdated outputs, or biased responses.

#### Examples of Training Data Limitations

- Data set does not include recent information (ie, after the training data cutoff), unless connected to internet browsing capability.
- Data set includes outdated practices and language; LLM is unaware which practices are now preferred or required.
- Data set is missing valuable context because it does not include nondigitized content (eg, conference presentations), content behind a paywall (eg, journal articles), or content in an inaccessible format (eg, regulatory guidances in PDF form).


**Figure 2.** Examples of risk categorization for LLM tools.

LLMs are very different from any technology previously available, which can introduce risks from human users.

#### Examples of Human Factor Limitations

- Automation bias, the assumption that machine-generated content is accurate.
- Distrust, leading to loss of interest from readers, attrition of employees, or client dissatisfaction.
- Providing the model with an incorrect or outdated source.
- Model damage from poisoned training data or manipulative prompts (prompt injection).

The machine learning process is the root of some risks related to the way LLMs function. LLMs are probabilistic systems that cannot be predicted or entirely understood.

#### Examples of Functional Limitations

- Opaque decision-making process.
- Inconsistency of output, even with identical prompts.

- Not able to cite sources (unless equipped with RAG technology).
- Can leak your inputs into other users' outputs (eg, proprietary data, protected health information).

Implementing AI systems presents challenges that should be considered as part of a risk assessment.

### Examples of Implementation Challengess

- Cost (including employee time and opportunity cost).
- Obsolescence as AI technology quickly advances.
- Finding legal, nonproprietary training data.

Risk evaluations should be captured together with planned risk mitigation steps in a risk management plan. The National Institute of Standards and Technology has created an AI Risk Management Framework and Playbook as a resource to complete this process.[5]

## AI TOOL EVALUATION

With a solid understanding of applicable use case(s) and a defined risk profile, it is time to select an appropriate tool to meet both criteria. When evaluating a tool, it is very important to understand which model the tool uses and what, if any, modifications have been made to the model – a tool based on an earlier LLM may be a lot less capable than the more recent models. For an expert system with LLM features, it is important to understand what features of the tool are based on the LLM and what features are based on more deterministic programming so you can determine if the tool matches your risk profile.

Because machine learning involves various degrees of learning, it can be helpful to think of LLM capabilities in layers (Figure 3):

- The foundation model, like GPT-4 in ChatGPT, is similar to the college education of a medical writer, providing a broad base of knowledge.
- Fine-tuning the model with additional specialty data sets like clinical study reports is similar to the specialized knowledge gained by a medical writer in a graduate or certificate program.
- Providing the model with access to your data is like on-the-job training.
- Finally, a collection of proven prompts in a prompt library mimics the efficiency gained with work experience.

When delegating a task to a beginning medical writer, you would provide more detail, instructions, and follow up than you would with an experienced medical writer. The same logic applies to LLM tools. If the tool has limited layers of capability, your prompt needs a lot of context and specific instruction, and your output may require substantial revision. If your tool has multiple layers of capability, your prompt can be more straightforward and the quality of the LLM output will require fewer edits.

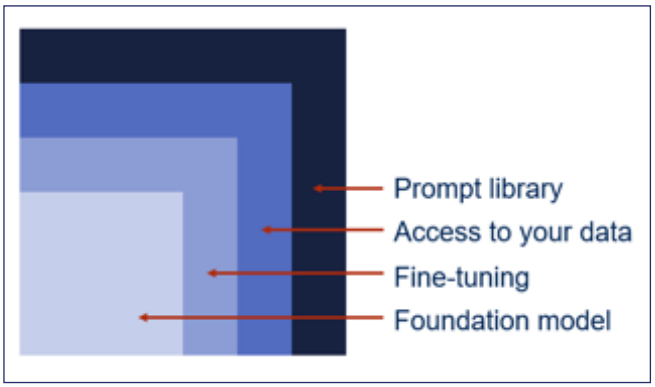


**Figure 3.** Potential layers of capability of an LLM tool. LLM, large language model.

## AI IMPLEMENTATION AND RISK MANAGEMENT

After choosing your use case(s), evaluating risks, and assessing and choosing an AI tool, the last step in the AI integration cycle is to integrate the tool into your work or organization. AI transparency is critical before, during, and after implementation. It is vital to address reservations that stakeholders may have and set guardrails for AI use.

Clearly communicate to partners and users what the AI tool is capable of, who will be authorized to use it, when it is appropriate to use AI, why this change is being made, and how to use it appropriately. AI policies to record and share these principles are becoming a common business practice. An AI policy can provide rigid guardrails to protect against the risks identified in your risk management framework.

Building a prompt library of successful, reliable use cases provides a set of flexible guardrails to further improve quality and reduce risk. The PLANTS acronym is a good starting point for building a prompt: persona, length, audience, nuance, type, and style guide (Figure 4).

Improve the probability of successful implementation by starting with 1 or 2 use cases that an LLM can consistently make easier. This feeling of productivity and success can spark more interest in trying other use cases. As you explore new use cases, record not only what works, but what does not work so that those failed prompts can be potentially revised or revisited as LLM capability improves. Sometimes a failed prompt can become successful when adding one or two examples inside the prompt (also known as one-shot or two-shot prompting).

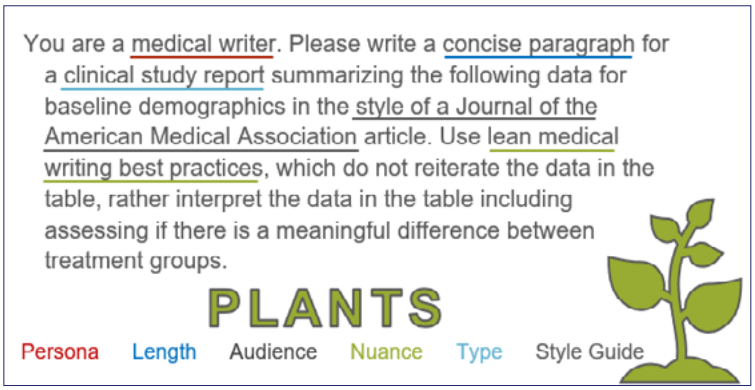


**Figure 4.** Using the PLANTS method to construct an LLM prompt. LLM, large language model.

## A VISION FOR THE FUTURE

Medical writers must have involvement in defining the optimal balance between human effort and AI assistance. At one extreme, staying with the status quo of 100% human effort in drug development means continuing to struggle to accelerate time to market and rising development costs, and potentially falling behind competitors. On the other extreme, replacing entire medical writing functions with AI also presents risks. Health authorities would reject applications after finding missing submission elements, fake references, and hallucinations. Teams would be left with a void of document leadership to break down tasks, set timelines, critically evaluate sources, and gain consensus.

Now is the time for medical writers to define and advocate for a synergy point that combines the expertise of medical writers with the efficiency of AI. The key is to be strategic, integrating AI where it adds value and ensuring that the core responsibilities of medical writing remain grounded in human expertise.

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TOPICAL FEATURE

PART 3 IN A 3-PART SERIES

# The Business of Medical Writing: Financial Acumen

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## ABSTRACT

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business. A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association national conference to discuss this topic. The topics of value proposition and business models; communication, leadership, and corporate responsibility; and financial acumen are reprised in this 3-part series. The series also includes thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path. This Part 3 manuscript focuses on financial acumen.

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business: the value proposition, the finances that drive strategy and decision-making, the financial goals, and effective communication.

A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association (AMWA) national conference to discuss this theme.[1]

The topics of value proposition and business models[2]; communication, leadership, and corporate responsibility[3]; and financial acumen are reprised in this three-part series, along with thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path. This Part 3 manuscript focuses on the importance of financial acumen and mastering fundamental financial concepts.

The authors' collective experience comprises the following medical writing work environments:

- Freelance business
- Small business/vendor
- Department leadership of small- to mid-size biotech company and large-sized pharmaceutical company

The moderator's (Joan Affleck - JA) prompt is provided for each topic, followed by each perspective on the topic. In some cases, text from the session has been paraphrased for optimal clarity in this medium.

## FINANCIALS

**JA:** ***When we talk about success in business, a lot of times we talk—or think—about the money. I want to spend a few minutes to talk about money: cash flow, balance sheets, quarterly earnings, budget forecasting. These are terms that many medical writers are not really familiar with and don't have a lot of practice with. So I would love to hear how you learned about those terms and practices and became comfortable with the financial aspects of business.***

**DD:** Well, I don't know if I ever became comfortable with them, but I certainly had to figure out how to work with them. It was really out of necessity when I started my business many years ago. And it was really to understand what made the whole thing a business—what defined a business legally and practically, how did you have to report your earnings, your obligations under tax requirements, and so on. There was a lot of education that had to happen because I came to [business] as a scientist from the bench; I didn't have business training. I learned from the ground up, by my bootstraps, found a good accountant, and certainly asked many, many questions. At the end of the day it really comes down to—especially in the freelance setting—understanding (1) what you can do in a unit of time and how to translate that into successful project work for a client maintaining quality at a certain cycle time and (2) how fast can you do the work well and maintain things to keep it profitable. We are providing a business product in a business setting, and the product is a written document; so, you need to think about that all at once—you can't really separate one from the other and hope for long-term success.


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**BB:** I'd love to say I learned from the best. But really, I learned from the worst. I always learn more from my mistakes than I do from my successes; I analyze them deeper to understand what went wrong. I have a long history, before working for myself, of working for small companies—and I worked for great people, brilliant people, nice people, talented people, but none of them knew how to run businesses. As I sit here today, out of all the companies I have worked for in my life, only two are still in business, and I'm glad to say that one of them is mine. What I've done is pay attention to the mistakes that people made that led to downfalls. And one of the big ones that I see—and I think this crosses the board from freelance to people who work on staff—is [continuity]: the direct link between how much you get done, how well you do it, and your ability to be able to keep doing it and generate revenue (Figure 1).

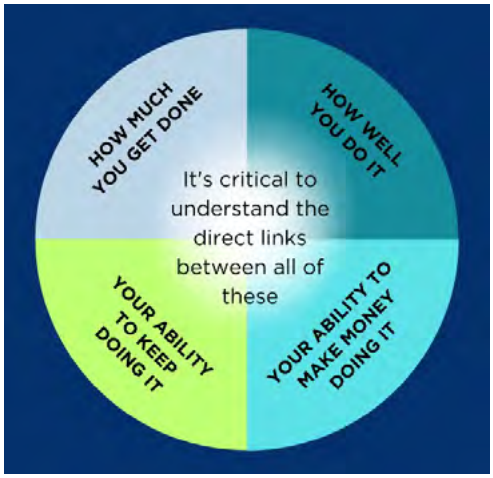



**Figure 1.** Linkage between productivity and revenue.

When you work for a company, it can be a little easier to lose track of this direct link between your productivity and your ability to get a paycheck because there are so many other people factoring into that ability to get the paycheck. As freelancers, especially if you work independently, if you don't work today, you don't get paid tomorrow; if you take a week off, it makes things a little bit harder next month when you don't have the same amount of revenue coming in. But where I see a challenge on the staff side is that many staff people lose that continuity. A lot of companies that have been my clients in the past have ultimately not succeeded because they spent so much more time working on projects than they had been scoped for. Yes, those projects turned out to be absolutely fantastic, but the company wasn't able to keep paying salaries at the end of the year or a couple of years down the line; it does have a ripple effect.

**JA:** ***Even in our shop it does. Jeanette, how about for you?***

**JT:** My first exposure was right before I started the business. I was in-house, happily writing, and my boss stepped away from the department, unfortunately. So I pretty quickly found myself in a position where I basically had no context for the financial aspects of the department; I had to step in and be able to produce things like quarterly reforecasting and an annual budget, and lots of other fun things, so it was really a feet-to-the-fire moment for me. I learned a lot in that process but also enough to know that it's not really the best way for people to learn that type of material; gradual exposure to it in a context where you can really understand how it connects to the day-to-day would be a much-preferred approach. So, fast-forward a few years to starting my own business and having to look at the balance sheet and all that: I really tried to take some of those concepts and infuse them into my operational team so that they understand. Just as an example, we have to look at time sheets, and anything that is marked as nonbillable, we need to actually make sure is nonbillable and check on why—or if that is something that is supposed to be billed to a project. Because, as Brian mentioned, if you don't check on those things, something that should be profitable can become unprofitable quickly, so you want your staff to really understand what that's about—that you really do need to look at things at that level of detail in order to be responsible about the company.

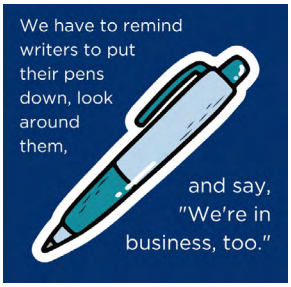
**DD:** Jeanette, that's a key point: in your company, you've decided proactively to really break down that barrier and share that information across your staff. Brian, you have to do that by design—that's what you follow to really manage the company's activities day-to-day. For me, we have some visibility into those things, but the company has a whole finance department that handles that information, and they don't often tell us the specific things that might or might not be helpful for us to know. It's hard sometimes in-house to see clearly without [such] visibility, so that's a challenge we have. Overall, we know what makes for a good product, and we know what makes for efficiencies—and we hope that indirectly we are making a positive impact.

**JA:** ***I think one of the key areas in talking about productivity and utilization is to get our staff comfortable with those terms and that it's not a threat to talk about those things; it's part of business because we have to be good financial stewards and good stewards of our people—our resources—as well. Any tips on how to do that? Dom, you mentioned being transparent about it. (Figure 2)***

**DD:** Yes, knowing what questions to ask about financial aspects is important, and I'm not sure if all medical writers ever really have the opportunity to figure out what they


**Figure 2.** Utilization means ensuring the expected amount of revenue is generated compared with all available billable hours in a time period while accounting for indirect and direct overhead costs.[4]

don't know [through discussion]. They'd have to think about that and say, "I can balance my checkbook, but if I'm writing a protocol, what does it really cost if we have to amend the document?" Understanding what those data are and what goes into the operational aspects of a clinical study, for example, are critical. Just thinking about [a clinical study] as a commodity really brings home the business component. We have to remind the writers to put their pens down and look around them and say, "We're in business, too."




**BB:** I spend a lot of time mentoring freelancers on the business aspects of freelancing. One of the biggest and most frequent questions that comes up is around estimating projects. I work on a project basis rather than on an hourly-rate basis, which is what drives that question. But it's interesting when someone comes to me with project parameters and they want to know how much they should charge. To me, that's not the question at all, and I get back to them with about 20 questions on the minuscule aspects of the project and the deliverable in order to wrap my mind around putting together that estimate. This is a muscle that freelancers need to constantly strengthen. When the questions you need to get answered to put an estimate together come naturally, that's when you're able to really estimate on a reliable and accurate basis.

**JT:** I've noticed a continuity between the freelance and the in-house experience [in terms of] the concept of accruals. Not only, prospectively, How much do you think this will take? But now that you've done it, Where are we with this? Sometimes there is a disconnect with the finance department not really understanding how much of the project is actually complete. Especially if the company is in a position where they are about to do an IPO or something like that, they might be tracking things down to the dollar, and so sometimes on both sides of the fence, I've had to provide information about things like, if the project is a unit, it's one-third done, and here's where I think we will be next month. This requires communication with whoever you are partnering with, whether that's in-house staff or a vendor, to know exactly where things are and if any difficulties have come up, in order to be accurate.

**JA:** ***I love that comment, Jeanette, and the idea of using these muscles in the corporate setting because, as Dom said, there are often other people—other departments—that have this as their primary work, [but] for writers, it's like a whole different sport. We haven't used those muscles at all! So it's a real call to action and embedding in our practice the idea of forecasting but then looking at the accruals. Great comments!***

## LOOKING TOWARD THE FUTURE

In Part 1 of this 3-part series, the authors discussed how this panel was an initial dialogue meant to "kick off a broader discussion of the many aspects of business leadership as it applies to our work as medical communicators."[1] The authors concluded that having a comprehensive business curriculum—namely, a pathway whereby medical writers can readily learn the skills needed to demonstrate leadership while also participating in decision-making activities

earlier in their careers—would benefit the writer toward the goal of developing a strategic mindset while learning fundamental business strategies and skills.[2]

In today's dynamic business environment, the ability for employees at all levels to interpret key financial indicators is more crucial than ever. Financial snapshots such as quarterly earnings reports provide invaluable insight into the health and trajectory of an organization. When employees have financial literacy baked into their corporate culture, they can not only grasp the current financial standing of the company but also gain a clearer vision of its future prospects and challenges.[5] This understanding empowers employees to make informed decisions in their respective roles, align their strategies with their company's objectives, contribute more effectively to the company's overall success, and, as a result, fuel their own success as well. Fostering financial literacy across all tiers of the organization can be a game-changer in steering its direction and ensuring sustained growth. An employee's ability to see the bigger financial picture can also be a boon to their career development, no matter what career path the employee ultimately chooses.

An important component of financial literacy within the corporate culture is fostering an understanding of where and how revenue is generated, and developing a clear picture of how each employee contributes to that process. Cash flow represents the lifeblood of a business,[6] and a healthy business should have enough cash flow to meet its expenses, repay debts, reward investors, and fuel growth. For a freelancer or small medical writing business owner, the goal would be to balance necessary nonbillable tasks with billable ones. Additionally, after a certain point, freelancers and small business owners may bring on vendors or partners to help maximize what they do best, which is generating revenue based on subject matter expertise and getting customers to return for repeat business.[3] For employees whose work contributes directly to the bottom line, this metric is otherwise known as utilization[4] (Figure 2)—in other words, a calculation that ensures a resource is contributing the expected amount of revenue compared with all available billable hours in a time period while accounting for their indirect and direct overhead costs. Examining this metric can help a freelancer or service provider understand whether they are charging enough for services, whether there is an appropriate number of staff, and whether the desired profit margin will be achieved. For an in-house writer, the concept of utilization differs slightly from the freelance or service provider scenario in that they are not directly generating revenue. However, most people in industry would agree that medical writers essentially sit in a place of revenue enablement (for example, medicinal products cannot get to market without documentation support for key clinical and regulatory stakeholders, and clinicians need to know about the results of clinical studies to determine a new treatment's place within the current armamentarium). Thus, utilization can be considered in a similar light in terms of how much time medical writing employees are investing on documents directly in support of revenue-enabling activities compared with purely administrative overhead. It all boils down to understanding what you can do with a unit of time and maximizing that contribution no matter the business model to help the company gain a competitive edge.[2,3]


The importance of understanding business concepts for all medical writers cannot be overstated, as it enables them to make informed decisions and drive their organizations toward success even in the face of volatility or change. Pairing training in general accounting and financial concepts such as accounting methodology (accrual vs cash methods), financial software, budgeting, forecasting, interpreting financial statements, and bookkeeping, and specific training on the revenue generation, cash flow, and other relevant financial overview of the company, with a goal toward a broad culture of financial literacy, can help all medical writers (freelance and staff alike) allocate resources efficiently, assess performance, and ensure the sustainability of their businesses or departments.

***Author declarations and disclosures:*** *D. De Bellis is employed by Merck & Co, Inc, and is a shareholder. J. Affleck, B. Bass, and J. Towles note no commercial associations that may pose a conflict of interest in relation to this article.*

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TOPICAL FEATURE

# Preventing Chaos: The Critical Role of the Submission Lead

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## ABSTRACT

Pharmaceutical product marketing applications represent the end result of years of development, significant financial investment, months of work, and the collaboration of a very large cross-functional team. Clearly, the Submission Lead for any marketing application team is a critical role. Experienced regulatory/medical writers often have the necessary array of skills to make excellent Submission Leads, whether they are overseeing only the writing activities or leading the entire submission team.

The Submission Lead serves as the "connector" by providing strategic and tactical oversight throughout the process to ensure on-time preparation of high-quality documents. By enabling the work in each stage of the submission, from initial regulatory submission strategy through publishing and submission, the Submission Lead ensures the development of a comprehensive and cohesive marketing application. Submission Leads wear many hats and ensure that the team is functioning well and communicating at all times. Teams benefit from a Submission Lead with extensive marketing application experience because they are better able to mitigate the challenges and risks that arise.

Submission Leads fluent in the strategy and content of the submission are able to drive discussions and prioritize team activities. Most importantly, as the project progresses, this strategy and content knowledge allows the Submission Lead to recognize potential cross functional impacts of each new development and to ensure the necessary parties are brought together to address those impacts. Like any large team effort, a clearly defined lead role and agreed processes are critical to achieve a high-quality, on-time marketing application that is accepted for review and ultimately results in regulatory approval.

Regulatory submissions are complex, and each has its own unique characteristics and challenges. New regulatory guidelines across regions and new innovative therapies and digital tools have added even more complexities that require dynamic planning, close coordination, and effective project management.

Marketing applications can take many forms, from initial applications for first-time marketing of a product and supplemental submissions to expand indications or dosage forms to generic or biosimilar applications. All require input from a broad, cross-functional team and inclusion of a large and diverse collection of source data and reports supporting the proposed product and its labeling to successfully gain approval. A successful, high-quality marketing application requires a well-balanced team comprising individuals from regulatory; commercial; chemistry, manufacturing, and controls; nonclinical; clinical; medical; statistic; programming; data management; safety; medical writing; and other fields. With so many individuals and areas of expertise involved, communication becomes critical.

Key to successful submission team functioning and delivering is a clearly identified overall lead (ie, the Submission Lead) and a lead for each function. These roles oversee and manage the team of individuals within their oversight area; ensure the open flow of communication to, from, and within that oversight area; and serve as the primary point of contact for that area. In our experience, regulatory/medical writers with submission experience are well suited to the Submission Lead role, whether overseeing all writing activities or leading the entire submission team. We attribute this to the fact that each regulatory/medical writer must interact with a broad range of functions to develop and deliver a document, be a good communicator, and establish and adhere to an agreed set of timelines. In addition, each regulatory/medical writer works in depth with both the underlying source data as well as high-level messaging, interpretation, and presentation.

## THE SUBMISSION LEAD ROLE

The Submission Lead plays a key role in coordinating submission teams, both internally and externally. The Submission Lead reaches out to team members for information and status updates, conducts regular meetings to keep everyone


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informed, and establishes appropriate contacts with outsourced vendors for timely exchange of information.

Furthermore, the Submission Lead, in conjunction with the Regulatory Lead,

- guides the team in developing a comprehensive electronic common technical document (eCTD) content plan and strategy;
- integrates perspectives of various functional areas, contributors, and subject matter experts into cohesive messaging to meet regulatory requirements per the eCTD;
- communicates expectations of regulatory reviewers to ensure that these are factored into the various summaries and reports;
- assists in authoring and reviewing documents to ensure consistency in messaging and adherence to regulatory guidelines for the product label; and
- identifies and monitors potential risks to the submission, working with the team to develop contingency and risk mitigation plans throughout the submission process.

Expanding upon basic skills required for authoring or leading a single document, leading a submission requires extensive project management skills as well as consultant-level submission expertise. Effective and relentless timely communication with all parties is vital, as is flexibility, securing consensus for any changes, and resolving issues as they arise. A Submission Lead serves as the "connector" by providing strategic and tactical oversight throughout the process to ensure on-time preparation of high-quality documents.

## THE SUBMISSION LEAD'S ROLE IN ENABLING THE WORK THROUGHOUT THE 5 STAGES OF A MARKETING APPLICATION

Embarking on a marketing application requires extensive planning and is carried out in stages (Figure 1).

### Stage 1: Regulatory Submission Strategy

The submission team (ie, Submission Lead and core team members) should be formed 9 to 12 months before the planned submission date to establish the overall goals and strategy for the submission at this stage, including the development of key messaging, target product profile [TPP], and plans for interactions with relevant regulatory authorities. To ensure confidence in the proposed strategy and plans, the Submission Lead or Regulatory Lead should review all previous interactions with the regulatory agencies, focusing on prior agreements and how they have been addressed. Standard of care and recent approvals for similar products and for any products in the proposed indication must also be identified and made available to the team.

Team meetings are initiated at this stage, starting with a formal kickoff meeting to ensure alignment on the goals and expectations for the submission, to review a high-level timeline, and to define roles and responsibilities. The Submission Lead should also establish a regular cadence of team meetings to begin following the kickoff meeting, perhaps monthly or biweekly and increasing in frequency to weekly closer to the planned submission date.

Key messages, which serve as guideposts for all content development, are important for the submission and labeling. There are many ways to approach this. Many sponsors use "storyboards," TPPs, draft labeling, a core data sheet, or other documents as tools for building and capturing key messaging. A significant pitfall with these approaches that the Submission Lead must watch for is that these key messages are often aspirational and disconnected from data. In addition, these internal documents can become formal documents that require time, effort, and prioritization from key team members and distract the team from preparation of the actual submission documents.

Presubmission meetings with regulatory agencies are also critical for successful submissions and are a key part of the Submission Lead's strategic input early in the project. For example, for US Food and Drug Administration (FDA) submissions, a key consideration is the option for an initial Type C FDA meeting to address pooling strategy, data set inclusion, and other submission plans. These meetings typically occur at least 6 months before the planned submission date. For submissions to multiple countries, a presubmission meeting with each country is necessary. This can greatly complicate planning and strategy as the timing of each meeting and each planned submission date must be accounted for in the timelines. More importantly, the


**Figure 1.** Marketing application development stages.

timeline and the content development of the documents must consider the potential for each country's regulatory authority to raise different (and sometimes conflicting) questions and requests during presubmission meetings. Presubmission meetings for marketing applications also typically require at least topline data from the final Phase III clinical trials and submission of a briefing document at least 1 month before the meeting. Therefore, the timing of these activities must be built into timelines as they may be on the critical path for completing drafts of key documents.

### Stage 2: Timeline and Content Planning

The submission timeline must be sufficiently detailed to confidently identify and track the critical path items. The content plan, which should account for timelines as well as for every file in the submission (including datasets, case report forms, analytical method reports, etc) is a critical living tracker and is reviewed with the team throughout the entire submission process. It is closely tracked by the publishing team to ensure each element is placed in the appropriate eCTD folder per regulatory requirements. Although maintaining the timelines and content plan may fall to different functions (eg, Project Management), the Submission Lead makes certain that all groups have a voice and a seat at the table and that every activity and deliverable has been taken into account.

Successful content planning and timeline development are largely dependent on knowing and identifying dependencies within and across modules. These dependencies range from the obvious (eg, study reports being dependent on final data and summary documents being dependent on well drafted study reports) to the more nuanced (eg, availability of finalized chemistry, manufacturing, and controls [CMC] stability data, nonclinical SEND datasets, or a population pharmacokinetic and exposure-response report). Ideally, the timeline and content plan are comprehensive, and the team has considered some alternate scenarios based on unexpected data outcomes, study completion delays, and regulatory authority feedback. This is a continuous process of maintaining an agreed plan and adjusting and incorporating new developments as they arise.

### Stage 3: Content Development

"Storyboards," the TPP, the draft labeling, a core data sheet, or other documents serve as the source for key messaging and a reference and guide for all content development. The Submission Lead enables authoring of submission documents by championing use of a system for coauthoring and subject-matter expert review. By maintaining familiarity with the data and reviewing documents for consistent messaging and presentation across the submission, the Submission Lead is able to advise and guide the writers and team. Throughout the process, Submission Leads may also guide writers on consistency of messaging and presentation, how to adjudicate difficult comments, assist writers with comment resolution meetings, and manage any conflict resolution on complex issues.

Since the advent of the CTD format, content is organized in a modular structure (ie, Modules 1 through 5). This structure simplifies and standardizes submissions but also requires transparency among disciplines, so appropriate cross references are included to locations with more detailed information. The Submission Lead is integral to enabling this transparency. In addition, successful development of each document requires comprehensive identification and agreement on the source data and documents to be used and referenced as well as when these documents and references will be available. Best practice is for the writer to generate a shell or prototype version of the document for team review to establish the overall structure and flow of the document as well as to confirm agreement on the sources to be addressed before attempting to author the first full draft of the document.

### Stage 4: Content Finalization

In collaboration with the functional areas, the Submission Lead ensures that the lists of reviewers and approvers are proactively defined and agreed upon per the sponsor's existing processes and governance. Before any reviews, the Submission Lead provides reviewers with best review practices training. As part of the development of the overall submission timeline, the Submission Lead or a delegate schedules reviews, comment resolution meetings, and approvals. Critical to the success of these reviews and approvals is ensuring that approvers and any other external-party or upper-management reviewers are included as early as possible in the process. Approvers, external parties, and management seeing the document for the first time at approval is a recipe for disaster, regardless of the quality of their input.

### Stage 5: Publishing

The Submission Lead plans for submission-level publishing in accordance with the content plan when developing the full submission timeline. Working with Project Management and Regulatory Operations, the Submission Lead ensures the content plan is being used to track document publishing status, missing components, and final review and approval of the published submission. It is especially important to ensure that all the supporting documents (eg, report appendices) are included and can be linked. Although these steps will always be the final steps in the process and are therefore rate-limiting to the submission, planning for these

end-of-submission steps from the very beginning is key. The Submission Lead ensures the whole team has visibility of the time required for these activities and that documents are being published as soon as they become available.

## RISKS AND MITIGATIONS

All submissions will encounter roadblocks, even with perfect, comprehensive planning. The key to a successful submission is anticipation of the risks and creation of an action plan to mitigate those risks. Often, this is done at the initial stage of planning by listing potential risks so that an appropriate contingency plan can be developed. The risks and mitigations associated with marketing submissions include

- ***Poor communication***
  Clear, open communication across the broad team is key to success and usually accomplished via weekly submission team meetings with an agenda provided to the team before the meeting, minutes, an action items log, a detailed timeline with dashboard, and a content plan. This is especially true for sponsors and their vendors but also for core teams that enable decision-making. Personality challenges/conflicts can always arise, so having standards of conduct and escalation paths may be necessary.
- ***An incomplete or disconnected team***
  At a minimum, a lead representative from each functional area is needed to support a submission. It is critical for these leads to have the ability to communicate both with those outside their area of expertise and experts in their discipline. Team dynamics make a submission pleasant or painful, so team members need to work together, value input, and have time available to dedicate to the program. Inclusion of multiple sponsor companies and vendors can make this more challenging.
- ***A lack of clear roles and responsibilities***
  Clear roles and responsibilities must be established, often with a Responsible, Accountable, Consulted, Informed chart (commonly referred to as a "RACI") to define and assign roles. A balance between reviewing outside of your expertise and "staying in your lane" is important to success and efficiency.
- ***A lack of oversight or engagement***
  Establishing a submission governance structure and risk log are important, as is involving senior managers from relevant functions early on. Getting it right the first time and avoiding late, drastic changes in approach and messaging can be accomplished by including approvers in Draft 2 reviews or earlier. Detailed planning and early engagement with a core team containing the key functional areas is critical.
- ***Inexperienced team members***
  Mentoring of inexperienced team members is an often-overlooked component of the job of the Submission Lead. The best way to learn is by doing, and everyone has a first submission (or new role) and may need some guidance or oversight. The Submission Lead can directly guide or mentor others as well as find other experts to help do so as well. A clear sign of a healthy, high-functioning team is when less experienced team members are provided with the support they need.
- ***A timeline that is only high-level or incomplete***
  Developing and agreeing upon a realistic detailed timeline is important. The critical path must be clear, and each functional area must have visibility to more than just its own timelines. Timelines also are living documents that need to adapt with changing circumstances as problems develop in execution of the agreed timeline. The Submission Lead works with other team members to keep timelines up to date and ensure communication of any changes, and their ramifications, across the team.
- ***Poor budget and timeline management***
  Regardless of how many contract organizations are involved in a submission, budgets of funds or time allocated toward specific activities need to be tracked and adjusted as needed. Teams need to understand when additional requests for data analyses or extra document draft reviews will affect budgets and timelines and when they will not.
- ***Results that are not as anticipated***
  A priori contingency planning helps teams avoid derailment when results are not as expected, making it easier and quicker to select and implement alternative scenarios and adapt accordingly. The Submission Lead needs to drive the revisions and facilitate bringing the key team members together to address these changes and agree on the path forward.
- ***Teams panic in a crisis***
  When submission teams are stressed and overworked, tempers can flare, and details can be missed. It is perhaps the Submission Lead's most important responsibility to be the "calm in the storm" and move ahead, keeping everyone aligned and engaged during these times.

## VALUE OF EXPERIENCE

Experience is the single most important skill necessary for a Submission Lead. Submission Leads get this experience by having had a key functional role within prior submissions. Most importantly, an individual who listens to and

learns from all of the submission team discussions—and not just those relevant to their function—will gain the experience necessary to lead the broader submission team. We believe the experience most needed for a Submission Lead is to have been through the submission process previously, including postsubmission regulatory defense through to approval. Why? Because that individual knows what the end looks like, what done looks like, and even what done *well* looks like. This enables the Submission Lead to provide the guidance and direction teams need as new issues arise, timelines shift, and the team struggles with critical periods of activity. Experience also enables the Submission Lead to strategically guide the team to a solid and detailed strategy, content plan, and timeline long before the actual submission work even starts. The Submission Lead has ideally faced these situations before; lived through various scenarios and solutions; and come out with a good sense of what works, what doesn't, and how to plan for and mitigate those inevitable pitfalls. Finally, the Submission Lead is in a position to keep the team focused and drive them to success. They do this by being focused; thinking in terms of scenarios; and ensuring the team is clear on their roles, responsibilities, actions, and agreed decisions.

## DISCUSSION

Pharmaceutical product marketing applications represent the end result of years of development, significant financial investment, months of work, and the collaboration of a very large cross-functional team. These marketing applications are a significant milestone in any product's development. The Submission Lead of any marketing application team fulfills a critical role that requires a daunting array of skills, including interpersonal/communication; project management; extensive drug development, regulatory, and marketing application knowledge; and leadership. The Submission Lead is essential to enabling a submission team's work and addressing all of the challenges and risks that typically arise during development of a marketing application. Experienced regulatory/medical writers often have this array of skills and make excellent Submission Leads, whether overseeing only the writing activities or leading the entire submission team.

Every team needs a capable leader. Without a clearly identified and capable leader, miscommunication and chaos can ensue. Submission Leads must be accountable and responsible to the submission team. The Submission Lead wears many hats and ensures that the team is functioning well and communicating at all times. There is no such thing as overcommunication on a submission project; submission teams need to keep the information flowing flawlessly. Although this role can be challenging, there is a huge sense of pride and achievement that comes from successfully leading a high-quality submission that meets its deadline and ultimately results in approval.

Leading and working with large multidisciplinary teams under tight timelines with complex results and interpretations is difficult, even for seasoned Submission Leads. Increasingly, more than 1 sponsor company as well as multiple vendors are involved. In addition, contract research organizations delivering the clinical studies, and other vendors supporting nonclinical, CMC, statistical programming and analysis, and other key submission components each constitute supportive but crucial roles. The Submission Lead must ensure that roles and responsibilities are clear, that communication is flowing across these disparate organizations, and that all activities are being accurately tracked.

Although much of the role of a Submission Lead may overlap with project management and an experienced Project Manager is an essential part of any large submission team, it is most efficient for an individual who can speak to the data, deliverables, and messaging to serve in the Submission Lead role. A Submission Lead fluent in the strategy and content of the submission allows them to drive discussions and prioritize team activities. Most importantly, as the project progresses, this strategy and content knowledge allows them to recognize potential cross-functional impacts of each new development and ensure the necessary parties are brought together to address those impacts.

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ORIGINAL RESEARCH

# Informed Consent Writing: Facing the Patient Is in the Interest of the Sponsor

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## ABSTRACT

This article analyzes the most common findings of the European Medicines Agency (EMA) and regulatory agencies regarding the quality of essential documents that led to delays in study approvals and major observations by EMA inspectors. The authors analyzed the content and length of informed consent forms used within clinical trials within the last 10 years and revealed a tendency toward increased length and complexity of the documents. Criteria for developing patient informed consent forms are suggested to implement in medical writing practice to make informed consent forms short and simple to read and understand by a layperson.

The quality of essential documents is one of the main factors affecting study approval by ethics committees (ECs)/institutional review boards (IRBs) and regulatory authorities (RAs). Deficiencies in the study protocol and/or informed consent form (ICF) content and structure might delay study approval by the EC/IRB and/or RA as well as negatively affect patient enrollment into the study, which would prolong study timelines.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) (R2) guideline[1] says that essential documents "serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements." Thus, the investigator's brochure, study protocol, and ICF(s) are always reviewed during the quality assurance audits or regulatory agency inspections.

According to the Annual Report of the Good Clinical Practice Inspectors' Working Group,[2] the most common findings of European Medicines Agency inspectors are issues related to essential documents: 7.5% of those findings were graded as critical and 59% as major.

In 2020, the American Medical Writers Association published data from an anonymized survey of reviewers at regulatory agencies evaluating the effect of study document quality on the regulatory review process.[3]

The main points of the survey were

- poor essential document quality can delay the study approval process or even lead to application rejection, and
- the most common issues related to document quality are
  - excessive length, repetition, and verbosity,
  - poor explanation of rationale, and
  - nonadherence to guidance and lack of clarity.

In addition, excessive document length, repetition, and verbosity were ranked as the main issues causing irritation for the reviewers or having a negative effect on regulatory review.

Thus, producing essential documents of high quality is a key factor affecting prompt study approval that would finally save sponsors' resources to allow for performing clinical trials within the predefined timelines and budget.

To achieve this goal, the essential documents produced by medical writers should meet the following criteria:

- provide clear scientific rationale for the study using available preclinical and clinical data, and
- be brief, clear, and unambiguous and avoid repetition.

In this article, we would like to share our observations and focus on items that should be considered when developing patient ICFs.

The main requirement referenced in ICH E6 (R2), section 4.8.6, states that information used in the ICF "should be as non-technical as practical and should be understandable to the subject."[1]

However, the current trend in modern clinical trials is toward a more complicated trial design with the involvement of various tests, procedures, questionnaires, etc, evaluated at multiple study visits. Such an approach also affects the length of patient ICF, which now contains a lot of medical information in addition to sections required by RA that are relevant to personal data protection, as per General Data Protection Regulation (GDPR)[4] for clinical trials


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conducted in the European Union (EU) or Health Insurance Portability and Accountability Act (HIPAA)[5] for clinical trials conducted in the United States.

The need to include all information required by RA in addition to data outlined in ICH GCP makes the ICF bulky and lengthy, which may lead to delay in regulatory review. We calculated the length of ICFs used within clinical trials run by patient safety indicators (PSI) within the last 10 years; the average length was 17 pages for pneumonia studies and 30 pages for breast cancer trials.

We have also noted a tendency toward increased length of ICF with time. Thus, for a series of clinical trials with the same investigational medicinal product (IMP) used for multiple myeloma treatment, a master version generated in 2016 was made up of 12 pages, an 18-page master version ICF was generated for another study with the same IMP in 2017, and in 2020, a master version ICF for the same drug and the same indication was made up of 25 pages.

Initially, we thought that the reason for the increase in the ICF length was the accumulation of safety data collected within 4 years of clinical trials with the IMP; however, our initial assumption appeared to be wrong.

When comparing the content of the ICF generated in 2020 against that issued in 2016, we found out that the 2020 version contained more detailed information on study procedures on a per-visit basis, which was an exact copy of the information available in the study protocol (eg, Eastern Cooperative Oncology Group [ECOG] status assessment), including medical terminology that makes no sense to a layperson (eg, "increase in blood level of creatine phosphokinase that could suggest heart damage").

It should also be pointed out that, in the ICF issued in 2020, safety information on the possible risks of glucocorticoid dexamethasone was described in a paragraph containing 15 lines as compared with a 6-line paragraph in the ICF from 2016.

When developing the master version ICF, the study sponsor should additionally keep in mind that in an international clinical trial, translation of the master version ICF into local languages will further increase the document's length, for example, the 25 pages of the master ICF for a multiple myeloma study translated into Spanish or Malay become a 42-page ICF for Argentina and Malaysia or Malay populations; translations to other languages resulted in the development of a 34-page ICF for Hungary and Taiwan and a 31-page ICF for Poland.

ICH E6 (R2), section 4.8.10, reads that the written ICF should include explanations of the trial procedures to be followed, including all invasive procedures. In practice, this requirement is considered to be an instruction to list all study procedures in the ICF.

However, the study protocol is developed to provide information on study procedures performed within the trial to the investigator/site team, and direct transfer of this information into the ICF seems unacceptable for a document developed for patients.

As an example, if the study protocol requires assessing patient ECOG status at each visit, it makes no sense to mention this procedure in the ICF, because ECOG status assessment in fact means the assessment of the patient's capability to perform activities and provide self-care; this assessment is done by the site team as part of the routine patient examination and does not require any additional procedure to be performed by the investigator or any additional action taken by the patient.

It should also be noted that some EU countries restrict the length of the ICF by local regulations. No longer than a 12-page ICF is allowed by the Czech Republic RA, which also requires that study procedures be provided in 1 table and on 1 page. The maximum length of ICF in Spain is 15 pages (written in Arial or Times New Roman font with a font size of at least 11 points, minimum line spacing of 1.5), which would probably mean no longer that 13 pages of the master ICF version in English.

The Spanish Agency of Medicines and Medical Devices (AEMPS)[6] has also introduced some reasonable requirements for the ICF that may be considered by medical writers when working on the master version of the patient ICF. These include:

- Infrequent adverse events can be summarized.
- Explanation of risks of common care procedures can be removed.
- In the case of marketed medicines, the wording "because it is a drug approved by the competent health authorities, there is information available to everyone in the drug information leaflet regarding the side effects of the drug XXX. Please talk to your study doctor in order to obtain this information" may be included.
- Lengthy wording describing study procedures in the related section should be replaced with a table: "The same tables that appear in the protocol should not be included; others that are simpler and easier to understand for the patient should be prepared."
- No need to repeat the same explanations for each visit, unnecessarily lengthening the document. Information regarding common routine examinations such as blood pressure, pulse, electrocardiogram, weight, height, etc, should be discarded.
- Exact activities to be carried out should be referenced, for example, as "blood sample collection" (details such as "determination of xxx biomarkers or quantifi-

cation of drug levels" are not necessary if it has already been explained that during some visits blood will be obtained for these purposes).
- Technical (medical) terms should be avoided (such as double-blind, randomization, etc); nontechnical description or direct explanation should be used instead.
- Data from animal studies should not be given when sufficient information is available for studies in humans.
- Risks and discomfort of the tests that are carried out as a result of participation in the study should be described. Excessive technicalities and wording containing excessive and unnecessary details should be avoided; however, it should be made clear if the time spent at the visits is prolonged due to additional procedures required by the study, such as questionnaires, kinetic samples, etc.
- If the risks and discomfort have been mentioned previously while describing study activities, they must NOT be repeated.

## CONCLUSION

The current trend is that clinical trial design is becoming more complex, and regulatory requirements make it necessary to include additional information in the ICF (eg, GDPR requirements), which leads to the development of lengthy ICFs. The requirements of ICH E6 (R2) guidelines are not strictly followed, which results in the development of ICFs containing information difficult to understand by patients, such as medical terms. Excessive length of ICFs may lead to delays in study approval by ECs/IRBs and/or RAs. It may be helpful to implement into medical writing practice the list of requirements for ICFs developed by local regulatory agencies (eg, AEMPS) with the objective to make the ICF as short as possible and simple to read and understand by a layperson.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

AROUND THE CAREER BLOCK

# From Public Health to Patient Education

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## ABSTRACT

Kelly Henderson, MScPH, defies the conventional path to medical writing with a rich background in journalism, teaching, public health, and humanitarian work. This article delves into Kelly's nonlinear career trajectory, providing insights and tips for individuals in similar circumstances aspiring to venture into medical writing.

## EARLY CAREER

**Journal (Petrus):** ***You did not come into the field of medical writing from a "traditional" background—can you tell us a bit about your academic and early professional background?***

**Henderson:** I actually started my career as a journalist and editor. That experience early in my career provided a good foundation—I know how editing works, how to work with authors, and how to write to deadlines. After a few years of that, I taught English as a second language at universities internationally. Teaching gave me a deeper understanding of how language works, how to communicate effectively, and how to write more simply and concisely to improve comprehension. It was probably my first experience with plain language.

I wanted to fulfill my dream of working in global health, so I took a break from teaching to get a postgraduate certificate in project management for international development and relief. This included a full year's course in program design and proposal development. It was the foundation for my grant writing expertise; I still use a lot of what I learned there today.

After that, I enrolled in the Master of Science in Public Health (MScPH) program at the London School of Hygiene and Tropical Medicine in the UK. While pursuing my MScPH part-time, I got my first humanitarian job working for a medical emergency relief organization at their UK headquarters. It was there that I implemented all of that program design and proposal development knowledge. A key part of my role was to write 6- and 7-figure grant applications for emergency primary health care projects in conflict- and disaster-affected countries like Afghanistan, Nepal, Pakistan, and Palestine. When I was transferred to Sub-Saharan Africa to work as a public health project manager, that grant writing work continued, and I took on medical writing work, too. I lived in Francophone Africa, and I was the only native English speaker on the team, so they relied on me to write donor proposals. Aside from the clinical staff, who were not tasked with this work, I was the only one with a public health education. I was relied on to do the collection and interpretation of epidemiological data and make it understandable for donors.

## TRANSITIONING TO MEDICAL WRITING

**Journal:** ***How did you translate this experience into a successful medical writing career?***

**Henderson:** The MScPH gave me a solid understanding of global health issues, familiarity with peer-reviewed journals, and comfort with technical medical terminology and statistics.

My public health work has given me deep insight into how health systems work internationally. It has also provided me with intercultural communication skills. I have conducted research internationally, and that has given me experience writing up and presenting results.

My experience writing grants as part of subsequent project management roles taught me how to write to an audience, interpret requests for proposals (RFPs) and donor motivation, and project-manage massive proposals that have multiple parts and numerous technical contributors. These can include a narrative, logical framework, timeline, and budget. It also taught me about results-based management (a particular method of program design that is common in the international development sector) and how to use that to design projects with an outcomes-first approach, which donors are more likely to fund. I learned a


ISSN 2163-5315

lot about different donors, from government to foundations to private funders. I learned how to adapt proposals and funding plans to different donor requirements to help get different aspects funded.

Believe it or not, most donor employees and grant reviewers do not have deep medical knowledge; they are not clinicians. I had to write in a way that made sense to them, in a way they understood, in plain language, and in alignment with their values and policies. It is a skill.

**Journal:** ***What are your tips for people who are interested in pursuing medical writing as a career but might not feel like they have the "right" scientific background?***

**Henderson:** A writer's job is to make things understandable for the reader. So, if you are a half-decent writer (and people have told you this), you are halfway there. It is simply a matter of applying your skills to the right environment.

- Look at what you already know how to do as a writer, editor, researcher, etc, and start from that point of strength.
- Learn about the different types of medical writing; talk to people doing it and figure out what piques your interest.
- Take a course or two, such as the AMWA courses or courses from schools that teach medical writing, and see what resonates with you.
- Start out freelancing, or subcontracting to another writer, and see how it works for you.
- Talk to agencies and companies in the sectors you want to work in, in the specialties that interest you.
- It may help to take some medical science courses so that you are familiar with the vocabulary and methodology and how research and implementation work.
- Personally, I can only write about topics or ideas that interest me or that have a deeper purpose, such as health promotion or patient education. Otherwise, I wilt and cannot get any writing done. I recognize that, and it drives the kinds of work I pursue. I recommend understanding what drives you as a writer and using it to your advantage.

## FROM GRANT WRITING TO PLAIN LANGUAGE SUMMARIES

**Journal:** ***You run The Grant Writing School, where you share your expertise to help people learn how to write better grants and secure grant funding. For medical writers interested specifically in grant writing, what are some of the top skills they need to develop?***

**Henderson:** That is a great question, and it is something I teach. It is not enough to be a good writer; you also need all the skills external to the task of writing to be successful at grants:

- How to read and understand RFPs and grant invitations
- How to write concisely, in jargon-free plain language. Not all donors are familiar with medical terminology. However, you can and should use correct terminology if it is a donor who works in that field and has their own level of expertise. It is about knowing the donor and gaining an understanding of how they work.
- How to understand the audience, which is the donors and reviewers, and what they are looking for
- How to build relationships with people at donor agencies; ultimately, you need them to know, understand, and like your project so they can become champions of it. That can make the difference between being funded or not.

**Journal:** ***In addition to grant writing, you have a special interest in plain language summaries and patient-facing materials. How are you finding the transition/expansion from one niche to another after 15+ years of specializing in grants?***

**Henderson:** It has been a challenge to find my niche and understand where I fit in. I realized I do not like pure science as a writing discipline. Plain language is a better fit, simply because it matches why I got into humanitarian aid and public health in the first place: I believe in health equity. I believe everyone has the right to good health, medical care, and knowledge. I believe in health literacy and that knowledge and information make for better and more informed patient decision-making.

## ON A CONTINUOUS JOURNEY

**Journal:** ***Have there been any specific challenges or things that have surprised you on this journey?***

**Henderson:** I should not be surprised by this, but it is the ongoing "siloization" of writing disciplines, types of writing, and writing outputs. To me, medical writing exists on a continuum: you start at the pure science end, which is crucial as you need to be accurate and specific about the work. This is where you have things like clinical reports or regulatory applications—writing that would be hard to understand without some medical or scientific knowledge and training. Next is the point where information is written to be understood outside the lab and by others with a science and medicine background: peer-reviewed journal articles, marketing materials to clinicians, clinician/pharmacist education, and so on. The final place on the continuum is having the patients, caregivers, and general public understand the

medical science and what it means for their daily lives. This includes general health literacy, where people can read and understand prescription instructions, over-the-counter drug inserts, how to give medications to people they care for, and so forth. It also means being able to understand enough to advocate for yourself because you know your history and understand what language to use to talk about it.

This is a simplistic view, but that is how I think we should view medical writing. It is a continuum of translation, from lab to regulator to clinician to public.

**Journal:** ***You are currently working on a Certificate in Medical Writing and Editing. How important is continuing education for you?***

**Henderson:** I think continuing education is important, not just to gain new skills, but to refine current ones. In the medical writing and editing course that I took at the University of Chicago, I learned that my years as an editor had served me well, and I actually remembered quite a lot. It reminded me that I know more than I had given myself credit for and gave me new ways to apply those skills. Education and learning are never wasted. If anything, you will learn more about what you do and do not like.

**Journal:** ***What is next in your medical writing journey?***

**Henderson:** I am continuing my global health grant writing work. I want to become a plain language medical writer and editor, and continue to advocate for health literacy.

***Author declaration and disclosures:*** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

AROUND THE CAREER BLOCK

# Leveraging Linkedin to Successfully Launch and Grow a Freelancing Career

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## ABSTRACT

When used to its full potential, LinkedIn can be a powerful networking and marketing tool for medical writers and other professionals. Bhavadharini Balaji, PhD, started her medical writing journey in late 2022 after completing 2 postdoctoral fellowships and working as a senior consultant at a global contract research organization. Today, she has a successful career as a freelance medical writer and mentor, with LinkedIn playing a substantial role in facilitating the transition.

In this article, Balaji shares her journey from academia to self-employment and discusses how LinkedIn has helped her gain knowledge, market herself and her services, and grow her business. Among many other advantages, Balaji highlights that LinkedIn can serve as a bridge, connecting medical writers with other professionals who can provide valuable insights and referrals, ultimately contributing to business growth. By crafting and curating content on LinkedIn that reflects one's expertise, passions, and unique selling points, freelancers can develop a personal brand that resonates with their target audience. As such, the social media platform has allowed her to create a compelling narrative, showcase her journey authentically, and make herself relatable through the sharing of insights and stories about her expertise, challenges, and successes. Nevertheless, having a strong social media presence is not enough to launch a career, with coaching, mentoring, and past in-house medical writing experience also playing important roles in Balaji's success.

Bhavadharini Balaji, PhD, is a former postdoctoral researcher turned freelance medical writer and mentor. With over 6,400 (as of May 10, 2024) followers on LinkedIn and a Top Academic Writing Voice badge, she is living proof that the social media platform can help accelerate your career when used right. Here, she shares her journey from academia to self-employment and discusses how networking, coaching support, and having a solid marketing strategy helped her get to where she is today.

**Journal (Petrus):** ***You started your medical writing journey fairly recently, in late 2022, having completed a Doctor of Philosophy (PhD) degree and 2 postdoctoral fellowships before that. Tell us a little bit about your academic background and when you realized that staying in academia as a postdoctoral researcher was not for you.***

**Balaji:** I completed my PhD, focusing on the epidemiology of diabetes (working closely with the International Diabetes Federation on one of their first projects on gestational diabetes mellitus) in 2017 in India. After that, I moved to Canada to undertake postdoctoral fellowships at McMaster University and the Women's College Hospital in Toronto, focusing on nutritional epidemiology. Despite investing considerable time in academia, I recognized limited growth opportunities compared with the industry. Eventually, the need for financial stability led me to the realization that taking up another postdoc was not the most viable path.

**Journal:** ***After this realization, when and how did you come across medical writing as a career, and how did you know that this was the right path for you?***

**Balaji:** Following my second postdoctoral research, I initiated efforts to transition into the industry. This involved networking, informational interviews on LinkedIn, and exploring roles held by individuals with PhDs in similar fields. Although initially hesitant about medical writing, a friend suggested it, and I decided to delve deeper. My first role as a senior consultant at a global contract research organization (CRO) was enriching, but the desire for greater diversity in my work motivated me to venture into freelancing. After a year of working full-time, I took a break to focus on setting up my freelance business. In about 3 months, I secured my first project and client.


ISSN 2163-5315

**Journal:** ***What were the initial steps to securing your first few projects and clients, and eventually growing your business?***

**Balaji:** After departing from my full-time role, I enrolled in coaching programs and engaged in extensive networking with other freelance medical writers. My first client reached out through a referral. Through the medical writing coaching program, I acquired skills in cold emailing and marketing on LinkedIn. Despite a brief dry period after my first project, perseverance in networking efforts eventually led to a thriving freelance business.

LinkedIn emerged especially as a pivotal marketing and networking tool to help me on my freelancing journey. Actively engaging with other medical writers on this platform expanded not just my knowledge base but also facilitated networking. LinkedIn served as a bridge, connecting me with professionals who provided valuable insights and referrals, ultimately contributing to the growth of my business.

In addition, I found that transitioning from academia to freelancing demanded a compelling narrative, a story that went beyond a traditional resume. LinkedIn allowed me to showcase my journey authentically and make it relatable. I found that sharing insights and stories about my expertise, challenges, and successes created a narrative that resonated with my audience, fostering a deeper, emotional connection.

**Journal:** ***What are your tips for new medical writers who are looking for clients or an employer but who may not have experience working on certain types of projects?***

**Balaji:** If you are new to medical writing and lack a portfolio, consider opportunities to gain experience, perhaps through internships at agencies or CROs. By starting in an in-house internship position, you can acquire critical skills on the job and gradually transition to freelancing with confidence. For instance, if you have not written scientific manuscripts or regulatory documents, gaining experience at a company first will provide the necessary skills before making the leap to freelancing.

**Journal:** ***For freelance medical writers, how important is it to expand their networks and market themselves to potential clients? You have a sizeable following on LinkedIn; how has this helped you land clients or expand your business in other ways?***

**Balaji:** Having a solid marketing strategy is crucial for a freelancer's success. At the start of my journey, I spent months actively posting content on LinkedIn, focusing on medical writing topics and sharing industry insights. Although engagement and numbers were not my primary focus, I noticed that clients often mentioned being referred to me by someone in their company whom I had never interacted with. This underlines the importance of being visible and engaged on the platform, marking your attendance, and fostering a sense of community.

Many individuals mistakenly believe that simply having an account and listing your past roles and education will attract job opportunities or interviews. However, this overlooks the platform's essence as a social networking space with a distinct professional focus. In order to leverage LinkedIn effectively as a freelancer, maintaining an active and engaging presence is paramount. Unlike other job-seeking platforms, LinkedIn thrives on continuous content. In this digital age in which visibility is key, especially for freelancers, the ability to craft compelling content and the ability to build and develop a distinctive personal brand becomes essential. By crafting and curating content that reflects one's expertise, passions, and unique selling points, freelancers can develop a personal brand that resonates with their target audience. The process of personal branding goes beyond self-promotion; it is about building trust, establishing authority, and creating a recognizable identity in the professional sphere.

## Recommended Readings


Liber B. 15 ways to leverage LinkedIn for your professional networking strategy. LinkedIn. Published May 13, 2019. Accessed January 18, 2024. https://www.linkedin.com/pulse/15-ways-leverage-linkedin-your-professional-networking-briony-liber/

Complete guide to LinkedIn: the ultimate guide to networking on LinkedIn. Learn how to use LinkedIn for business and the best practices to increase your LinkedIn presence in 2023. Premier Connect. Published August 14, 2023. Accessed January 18, 2024. https://premierconnect.io/complete-guide-to-linkedin/

Dublino J. How to network on LinkedIn like a pro. Business.com. Updated February 2, 2024. Accessed April 5, 2024. https://www.business.com/articles/linkedin-networking-tips/

Clayton R. 10 steps to building a powerful freelancer brand on LinkedIn. Payoneer. Published May 22, 2022. Accessed January 18, 2024. https://blog.payoneer.com/e-sellers/industry-tips-sellers/build-powerful-freelancer-brand-on-linkedin/

When potential clients peruse profiles, engaging content and a well-crafted personal brand can instill confidence, making the freelancer not just a service provider but a trusted partner. The continuous process of building an audience and developing a personal brand on LinkedIn serves as an ongoing investment in the freelancer's professional growth and success.

**Journal:** ***In addition to your medical writing business, you are also offering one-on-one mentoring to other new writers. How important was having a mentor or coach for you personally, and in what ways are you supporting your mentees?***

**Balaji:** Having received invaluable mentorship during my initial foray into freelancing, I recognize its significance. Offering one-on-one mentoring evolved organically as I started sharing insights and advice on LinkedIn about medical writing. New writers and grad students began reaching out, seeking guidance on freelancing, finding their niche, and securing clients. It seemed only fair to share the knowledge I had gained, create a supportive community, and give back to others, just as I had received mentorship and advice when I needed it most.

**Journal:** ***Any final words of wisdom?***

**Balaji:** I'll reiterate what I mentioned earlier: the power of LinkedIn visibility cannot be understated. LinkedIn's potential for visibility transcends the mere creation of an account—it's an active engagement tool that can significantly impact a freelancer's journey, just like it has impacted mine.

***Author declaration and disclosures:*** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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CE CRAFT CORNER

# Optimizing Continuing Education for Health Professionals: Incorporating Instructional Design Principles and Frameworks for Effective Learning

**Claudia Prahst, PhD** / CP Medical Writing, Marblehead, MA

## ABSTRACT

Medical writers who work in continuing medical education (CME) and continuing education (CE) are tasked with crafting resources for clinicians to stay up to date with the most recent advances in medicine. These CME/CE activities are designed to improve knowledge, competence, performance, and/or patient outcomes. For CME/CE to achieve these desired outcomes, medical writers can follow principles of instructional design during CME/CE development. At different stages of CME/CE development, medical writers can incorporate various conceptual frameworks and models. Commonly used frameworks to develop CME/CE activities include the plan-do-study-act cycle, Bloom's taxonomy, and Moore's levels. Medical writers can use these frameworks and models to help create learning experiences that are engaging and learner-centered, resulting in changed clinical behavior and improved patient outcomes.

Because the medical field continuously advances, clinicians may struggle to stay up to date with the latest developments in medicine. One way for them to stay informed is by relying on continuing medical education (CME) and continuing education (CE).[1] CME/CE that fulfill their purpose of changing clinical behavior is therefore critical for patients to benefit from advances in medicine. Unfortunately, CME/CE have not always used research findings from the learning sciences nor changed clinical behavior.[2] To ensure that CE fulfills its purpose, medical writers need to design CME/CE in a way that is engaging and learner-centered. Medical writers can help optimize learning by incorporating conceptual frameworks and models into the design of the CME/CE activity.

## USING A FRAMEWORK

A framework commonly used for designing CME/CE activities is the plan-do-study-act (PDSA) cycle, an approach structured to continually assess and improve.[3] The 4 steps of the PDSA cycle are to (1) plan, (2) do, (3) study, and (4) act (Figure 1).

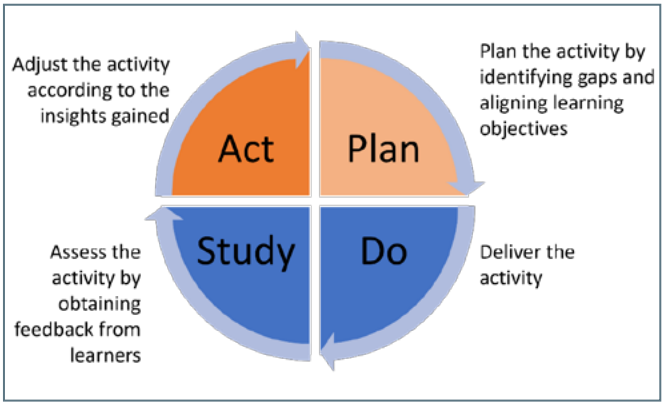


**Figure 1.** Steps of the PDSA Cycle.[3]

In the plan phase, practice gaps and educational needs are identified by performing a needs assessment. Practice gaps are defined as differences between health care processes or outcomes seen in practice and the processes or outcomes achievable using current professional knowledge.[4,5] The insights gained in the plan phase are then used to design the CME/CE activity.[1] The plan phase is followed by the do phase, in which clinicians take part in the CME/CE activity. Once the CME/CE activity has taken place, the educators evaluate the activity for its effectiveness in the study phase. The evaluation involves gathering information by asking learners to answer test questions, take surveys, or respond to open-ended questions. Finally, the insights obtained in the study phase can be integrated into the activity in the act phase to make future activities more impactful and useful for subsequent groups of learners.[3]

Another model often used in CME/CE is the analysis, development, design, implementation, and evaluation (ADDIE) model.[6] This 5-step model closely resembles the PDSA cycle. Both the PDSA cycle and the ADDIE model continually incorporate feedback into the activity to strengthen the relationship between education and clinical behavior.[7] This article goes into more detail about each phase of the PDSA cycle.


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## WRITING THE NEEDS ASSESSMENT

In the plan step of the PDSA cycle, current gaps and underlying educational needs are identified in a needs assessment.[8] When writing a needs assessment, medical writers are often asked to identify and research gaps in practice and to develop learning objectives and desired outcomes. These are then summarized in an alignment table. An example of such an alignment table is shown in Table 1.

Practice gaps are identified by comparing the actual clinical practice with the ideal clinical practice, also known as the professional practice gap.[8] Gaps can be identified from several sources including medical literature, interviews with subject matter experts, and surveys among clinicians. Inferred gaps are often derived from guideline updates, drug approvals, and novel technologies, such as diagnostic tests. Verbalized gaps can be identified through interviews or surveys, making them a valuable source. Finally, statistical gaps can be derived from epidemiologic data or morbidity and mortality reports.[8] When identifying gaps while planning CME/CE, medical writers need to keep the end in mind, namely, improved patient outcomes and how these outcomes can be achieved.[1] Once these practice gaps have been identified, the medical writer looks for educational needs by examining the problems. Examining the problems helps to identify deficits in knowledge, strategy, skill, performance, or systems that could contribute to the problems.[9]

Sometimes writers are asked to develop learning objectives based on practice gaps they have identified, but it has become common for writers to be asked to gather evidence to justify learning objectives that have been drafted in advance by the employer or client. In CME/CE, learning objectives are often developed using Miller's definition which delineates the progression from acquiring knowledge to translating knowledge into ability and implementing skills, abilities, and strategies into practice. Miller's definition, helps describe the knowledge, competence, and performance that learners should develop as a result of the CE activity.[10] When developing learning objectives, medical writers need to consider that the objectives should be designed to close the identified practice gaps and address the educational needs. The medical writer also needs to consider which behaviors the learners need to improve in real life to deliver better care for patients. A helpful framework for designing learning objectives is Bloom's taxonomy. This framework classifies different levels of thinking and ranges from remembering facts and concepts to creating new or original work. Bloom's taxonomy is, therefore, a helpful framework to use when designing learning objectives. As shown in Figure 2, action words from the appropriate learning level should be used to develop learning objectives for the learner to understand which changes they should expect after completing the activity.[3]

## CHOOSING THE EDUCATIONAL FORMAT

To ensure the learning objectives are appropriate, the medical writer should ask about the educational format before writing the needs assessment. The educational format

**Table 1.** Example of an Alignment Table

| Practice Gap | Learning Objective | Desired Outcomes |
|---|---|---|
| Many patients with newly diagnosed advanced NSCLC do not receive biomarker testing. Oncologists may not be aware of current guideline recommendations for the pretreatment evaluation of patients with advanced NSCLC. | Describe the role of biomarker testing in patients with newly diagnosed advanced NSCLC. | Learners will improve their knowledge of the role of broad molecular profiling in identifying the most appropriate therapy for individual patients with newly diagnosed advanced NSCLC. |
| Many patients with newly diagnosed advanced NSCLC do not receive appropriate therapy despite biomarker testing. Oncologists may need education on available targeted therapies for advanced NSCLC. | Integrate recent clinical trial data on FDA-approved targeted therapies into the management of patients with newly diagnosed advanced NSCLC. | Learners will be able to use current evidence-based guidelines to make informed treatment decisions for patients with newly diagnosed advanced NSCLC. |
| Oncologists may have limited knowledge regarding clinical trial data on emerging targeted therapies for advanced NSCLC. | Evaluate clinical trial data for investigational agents under development and their potential role in the context of existing NSCLC treatment paradigms. | Learners will improve their knowledge of investigational therapies in advanced NSCLC and incorporate this knowledge into treatment decisions. |

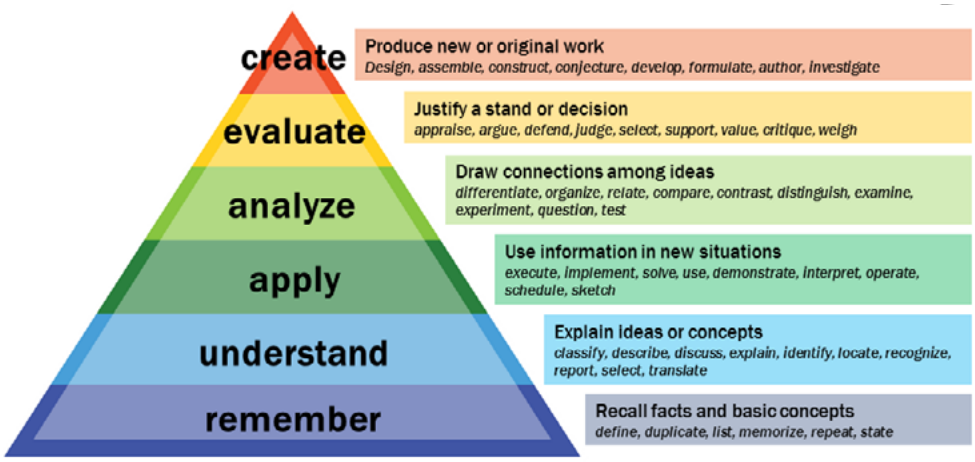


**Figure 2.** Bloom's taxonomy. Adapted from the Vanderbilt University Center for Teaching.[11]

should match the objectives with the learning method. For example, if the learner needs to learn a new skill, the main teaching method should not simply ask the learner to read about the skill. Instead, the method should ask the learner to practice the skill through simulation or real-life experiences.[12] Several factors contribute to better learning in adults, including active contribution during the activity and the opportunity to practice what they are learning. Receiving feedback from faculty and peers during the activity in a setting that allows them to reflect on their learning helps solidify what they learned.[13] Depending on the level of the learning objective, commonly used instructional methods include lectures, case studies, and simulations (Table 2).[12]

**Table 2.** Interface of Learning Objectives and Teaching Strategies[12]

| Level | Teaching Strategy |
|---|---|
| **Create** | Projects, problems, case studies, creative exercises, develop plans, simulations |
| **Evaluate** | Case studies, projects, exercises, critiques, simulations, appraisals |
| **Analyze** | Problems, exercises, case studies, critical incidents, discussion, questions, test |
| **Apply** | Exercises, practice, projects, simulations, role play, microteaching |
| **Understand** | Questioning, discussion, test, assessment, learner presentations, writing |
| **Remember** | Lecture, visuals, video, audio, examples, illustrations, analogies |

In recent years, multimedia and gamification have emerged as training platforms for CME/CE.[14] Gamification platforms, such as educational games, mobile applications, and virtual patient simulations, can be used to increase engagement and enhance collaboration.[14]

## EVALUATING THE CME/CE ACTIVITY

Once the activity has taken place, a framework can be used to assess for how effectively the activity achieved changes in the learner's knowledge, competence, and performance, as well as patient outcomes.[15] Several frameworks are used to evaluate CME/CE activities, including the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework, the Kirkpatrick-Barr framework, and Moore's levels. The RE-AIM framework evaluates the impact of the activity on public health, whereas the Kirkpatrick-Barr framework and Moore's levels assess the learner's educational outcomes.

Moore's levels are the most commonly used framework for evaluating outcomes in CME/CE. This framework assesses the educational outcome on 7 levels, ranging from participation to community health (Table 3).[3,15] Moore's levels were developed to combine assessment efforts with planning and teaching throughout the learning process. Participation and satisfaction are easy to assess using feedback surveys. However, these factors do not provide information on how much the participant learned during the activity and whether the acquired knowledge is integrated into clinical practice. Improvements in learning and knowledge gaps can be evaluated in different ways by asking the learner to answer pre- and posttest questions. Competence can also be assessed by analyzing reflective statements after the activity, and commitment to change can be gauged by semistructured interviews.[3] Finally, improvements in patient and community health can be estimated at a later time by studying administrative databases and epidemiological data and reports.

## SUMMARY

Medical writers who work in CME/CE develop resources for clinicians to stay up to date with the most recent advances in medicine. Effective CME/CE are vital to change clinical behavior and improve patient outcomes. By incorporating instructional design principles and frameworks, medical writers can design CME/CE in a way that engages and centers on learners. Using frameworks that support continual improvement of CME/CE, such as the PDSA cycle or

**Table 3.** Moore's Outcomes Levels[15]

| Level | Framework | Description | Potential Data Sources |
|---|---|---|---|
| 1 | Participation | Number of participants | Attendance records |
| 2 | Satisfaction | Degree to which expectations of setting and delivery were met | Questionnaires completed by participants after the activity |
| 3A | Learning: declarative knowledge | Degree to which participants state what the CME activity intended for them to know | Pre- and posttests of knowledge; self-report of knowledge gain |
| 3B | Learning: procedural knowledge | Degree to which participants state how to do what the CME activity intended for them to know how to do | Pre- and posttests of knowledge; self-report of knowledge gain |
| 4 | Learning: competence | Degree to which participants show, in an educational setting, how to do what the CME activity intended for them to be able to do | Observation in educational setting; self-report of competence; self-report of intention to change |
| 5 | Performance | Degree to which participants do what the CME activity intended for them to be able to do in their practices | Observation of performance in patient care setting; patient charts; administrative databases; self-report of performance |
| 6 | Patient health | Degree to which the patient outcomes improve due to changes in participants' practice behavior | Health status measures recorded in patient charts or administrative databases; patient self-report of health status |
| 7 | Community health | Degree to which outcomes of a community improve due to changes in participants' practice behavior | Epidemiological data and reports; community self-report |

*Abbreviation: CME, continuing medical education.*

ADDIE model, can help achieve this goal. These frameworks include developing a needs assessment to identify gaps and align learning objectives. Using a framework to continually evaluate CME/CE activities after they have taken place helps to improve the activities and shows the value of CME/CE for patients and the health care community.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

CONSCIOUS WRITING

# Five Pitfalls to Avoid When Crafting the Study Question for a Research Manuscript

**Crystal R. Herron, PhD, ELS** / Redwood Ink, LLC, San Rafael, CA

## ABSTRACT

The study question is the most fundamental part of a research manuscript. This question engages readers by piquing their curiosity and guiding them into the next part of the story. Yet, many medical writers will craft a study question that fails to accomplish one or both of these tasks, which weakens the story. To craft a persuasive study question, medical writers can use a helpful formula that ensures they accomplish both tasks. This formula will also help medical writers overcome five common pitfalls that weaken the question and the research story. These pitfalls include focusing on the objectives of the study, only stating what was done in the study, reversing the order of the formula in the study question, focusing on the hypothesis of the study, and summarizing the key findings of the study.

In the medical field, most research manuscripts follow the IMRaD format—Introduction, Methods, Results, and Discussion.[1] This format has become a valuable formula for crafting research manuscripts that have a consistent story structure. However, the IMRaD abbreviation fails to call attention to the most fundamental part of the research story: the study question.

The study question has the important job of engaging readers in the story. This question piques readers' curiosity by stating a gap that the study aims to fill. The study question is also the guiding star to which every other section in a research manuscript needs to point. The Introduction guides readers through the study's background to frame the question. Then the Methods explain the approach used to answer the question, and the Results describe data that help to answer the question. Then the Discussion frames the data and that answer in the context of what is already known.

The importance of the study question is more clearly highlighted in the STACR story structure—Setup, Tension, Action, Climax, Resolution—that maps onto the IMRaD story structure of a research manuscript (Figure 1).[2] The STACR structure emphasizes the importance of the study question as the Tension part of the structure. This emphasis helps medical writers ensure that they craft a good Tension—or study question—for a research manuscript.

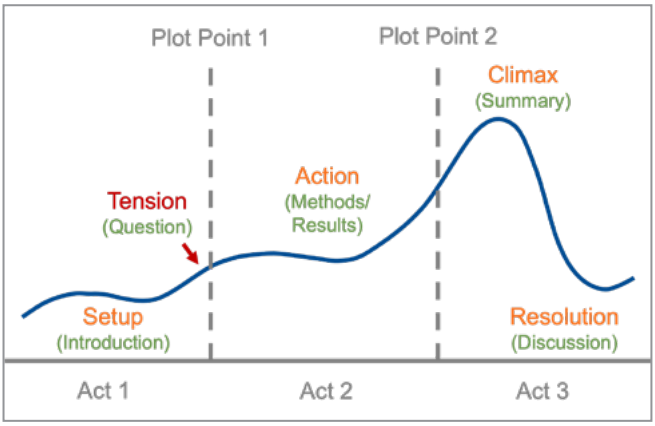


**Figure 1.** The STACR and IMRaD story structures. The STACR (Setup, Tension, Action, Climax, and Resolution) story structure maps onto the standard IMRaD (Introduction, Methods, Results, and Discussion) story structure of research manuscripts. The Tension (red) is the study question that sparks readers' curiosity and motivation to keep reading the story.

## WHAT MAKES A GOOD TENSION?

A good Tension states the gap you aim to fill in the study by framing a question and then lays out an approach to answer that question. In essence, a good Tension boils down to the formula, "To learn X, we did Y."[3] The "to learn X" part frames a question that sparks readers' curiosity and motivates them to keep reading the story. The "we did Y" part lays out an approach that helps to guide readers into the Action part of story. This combination is a powerful way to persuade readers and lead them through the research story.

The "To learn X, we did Y" formula is readily apparent in the following example:

**Example 1**

To determine the effectiveness of methotrexate in treating chronic kidney disease, we examined serious adverse events in adults with chronic kidney disease who were treated with high and low doses of methotrexate.


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In other words, "To learn whether methotrexate effectively treats chronic kidney disease, we did an analysis of serious adverse events in adults with chronic kidney disease who were treated with this drug."

Importantly, the "To learn X, we did Y" formula is not always so clear-cut. For example, this formula can also be found woven into the following example:

**Example 2**

In this study, we sought to develop a diagnostic scoring system for assessing extubation readiness in patients undergoing neurosurgery. To develop this system, we surveyed physicians to understand what factors influenced their decisions to delay extubation in patients who were mechanically ventilated during neurosurgery. We then developed a diagnostic scoring system and evaluated its usefulness in predicting extubation success in patients undergoing neurosurgery.

In other words, "To learn information to develop a system, we did a survey of physicians and then developed and tested a system."

## WHAT ARE COMMON PITFALLS IN CRAFTING TENSIONS?

The "To learn X, we did Y" formula is a helpful tool for crafting a persuasive Tension for your research manuscript. But many medical writers stumble over common pitfalls when crafting the Tension (Figure 2). These pitfalls weaken the Tension, which weakens the story.


**Figure 2.** Common pitfalls that weaken the study question in a research manuscript.

### Pitfall 1: Focus on the Objectives

Many medical writers craft Tensions that only use the "to learn X" part of the formula. In these cases, medical writers focus on highlighting the objectives with phrases like "we aimed to" or "we sought to." Although these phrases spark readers' curiosity, they do not guide readers into the story. Without the "we did Y" part of the formula, readers are forced to jump from the Tension into the Action of the story without a clear bridge to get there.

To strengthen the power of the Tension, include the "we did Y" part of the formula.

**Example 3**

***Avoid:*** In this study, we aimed to understand the perspectives of physicians who use the intervention to manage acute heart failure.

***Preferred:*** To understand the perspectives of physicians who use the intervention to manage acute heart failure, we collected quantitative and qualitative feedback from physicians after usability testing of the intervention.

**Example 4**

***Avoid:*** Our objective was to review published randomized controlled trials on the safety and effectiveness of nonpharmacologic treatments versus no treatment for children with functional constipation.

***Preferred:*** In this study, our objective was to evaluate the safety and effectiveness of nonpharmacologic interventions for children with functional constipation. For this evaluation, we completed a systematic review and meta-analysis of randomized controlled trials that tested nonpharmacologic treatments in children with functional constipation.

### Pitfall 2: Only State the Approach

Some medical writers craft Tensions that omit the "to learn X" part of the formula and only use "we did Y." This approach focuses on what was done in the study with phrases like "we measured" or "we assessed." These phrases help to guide readers into story. However, without the "to learn X" part of the formula, you are assuming that readers know the question. And assuming is risky. You are also not sparking readers' curiosity, draining the persuasion from the Tension in your manuscript.

To pique reader's curiosity and motivation to keep reading the story in the manuscript, include the "to learn X" part of the formula in the study question.

**Example 5**

***Avoid:*** In this study, we analyzed the relationship between neuropsychological function and disease biomarkers in people with Alzheimer's disease.

***Preferred:*** To determine the relationship between neuropsychiatric symptoms and glial markers in Alzheimer's disease, we analyzed the association between neuropsychological function and disease biomarkers in people with Alzheimer's disease.

**Example 6**

***Avoid:*** In this study, we analyzed data from an observational prospective trial that included patients who underwent different surgical procedures at a single center.

***Preferred:*** In this study, we aimed to dissect the risk factors for postoperative delirium that affect older patients' length of stay in the intensive care unit and in the hospital. To this end, we analyzed data from an observational prospective trial that included patients who underwent different surgical procedures at a single center.

## Pitfall 3: Reverse the Formula

Some medical writers include both parts of the formula, but they reverse the order to "we did Y to learn X." Although this format includes both parts of the formula, the reversed order does not follow a logical flow, which can create more cognitive work for readers or even confuse them. This logical flow relates to the question-answer format. We need to ask a question before we answer it. But the "we did Y to learn X" order states the answer—or the approach to finding the answer—before stating the question.

To craft a study question that logically guides readers into the story, use the "to learn X, we did Y" order.

**Example 7**

Avoid: In this study, we analyzed data from an ongoing cohort study of women of reproductive age to examine the potential association between adverse pregnancy outcomes and energy drink intake during pregnancy.

***Preferred:*** To examine the potential association between adverse pregnancy outcomes and energy drink intake during pregnancy, we analyzed data from an ongoing cohort study of women of reproductive age.

**Example 8**

***Avoid:*** In this study, we evaluated data on patients who had positive test results for SARS-CoV-2 and underwent a computed tomography scan or radiograph of the chest while in the hospital. Our goal was to calculate the rates of intrathoracic complications in patients with COVID-19, determine the clinical predictors of these complications, and assess the association of these complications with patient outcomes.

***Preferred:*** In this study, our goal was to calculate the rates of intrathoracic complications in patients with COVID-19, determine the clinical predictors of these complications, and assess the association of these complications with patient outcomes. To achieve this goal, we evaluated data on patients who had positive test results for SARS-CoV-2 and underwent a computed tomography scan or radiograph of the chest while in the hospital.

## Pitfall 4: Feature the Hypothesis

Some medical writers will omit the "To learn X, we did Y" formula entirely and only state the hypothesis. Hypotheses are an important part of the scientific method, and many fields believe that a hypothesis must be stated to consider the work research. But hypotheses convert your question into a prediction that lacks persuasion. Without the study question, you do a disservice to the study by not piquing readers' curiosity.

To craft a persuasive Tension, state the study question with the "To learn X, we did Y" formula, and then you can follow that question with your hypothesis.

**Example 9**

***Avoid:*** We hypothesized that physical activity in young adulthood would be associated with a lower likelihood of nonalcoholic fatty liver disease in middle age.

***Preferred:*** In this study, we aimed to identify the association between physical activity in young adulthood (ages 18 to 25 years) and the prevalence of nonalcoholic fatty liver disease in middle age (ages 43 to 55 years). To this end, we analyzed data from an ongoing prospective observational cohort trial. We hypothesized that physical activity in young adulthood would be associated with a lower likelihood of nonalcoholic fatty liver disease in middle age.

**Example 10**

***Avoid:*** We hypothesized that ventricular volume expansion would be greater in patients who carry genetic mutations for frontotemporal dementia than patients who do not carry these mutations.

***Preferred:*** In this study, we set out to determine the utility of ventricular expansion as a measure of early or presymptomatic disease in genetic frontotemporal dementia. For this purpose, we examined the ventricular volume expansion in patients who did and did not carry genetic mutations that cause frontotemporal dementia over 1 year. We hypothesized that ventricular volume expansion would be greater in

patients who carry genetic mutations for frontotemporal dementia than patients who do not carry these mutations.

### Pitfall 5: Summarize the Key Findings

Another common pitfall is not related to the "To learn X, we did Y" formula but rather to what comes after the formula. Some medical writers will use the "To learn X, we did Y" formula and then immediately follow the formula with a summary of the key findings (and even the conclusions) of the study. They believe that including this summary in the Tension is a conventional standard. But including this summary in the Tension is a missed opportunity to tell a compelling story. When you summarize the key findings immediately after the study question, you are giving away the story. Rather than entice readers to keep reading the manuscript, you immediately satisfy their curiosity, thereby draining their enthusiasm to keep reading the paper.

If you find yourself wrapped up in convention and hesitating to adopt this practice, you can find more formal support in the *AMA Manual of Style*. In section 19.1.2, the manual discourages writers from summarizing the study findings at the end of the Introduction section: "Results or conclusions do not belong in the Introduction section of a manuscript."[4]

To craft a Tension that captures readers' attention, resist the temptation to summarize the study findings immediately after the study question. Instead, reserve these details for the Climax part of your Discussion section.[2]

**Example 11**

***Avoid:*** To determine whether 6q deletions are associated with breast cancer outcomes, we probed for 6q with a microarray containing tissue from more than 1000 patients with breast cancer. We found that the 6q deletion was often present in breast cancer tissue, but the deletion was not associated with the prognosis of patients with breast cancer. Thus, analysis of the 6q deletion may not be a valuable proxy to predict clinical outcomes in patients with breast cancer.

***Preferred:*** To determine whether 6q deletions are associated with breast cancer outcomes, we probed for 6q with a microarray containing tissue from more than 1000 patients with breast cancer.

**Example 12**

***Avoid:*** To assess the association between bleeding and a new diagnosis of cancer, we examined the number and proportion of new cancers diagnosed in patients with gastrointestinal or genitourinary bleeding after beginning treatment with antithrombotic drugs for atherosclerosis. We found that gastrointestinal and genitourinary bleeding were associated with patients at a high risk of being given a new cancer diagnosis, particularly for gastrointestinal and genitourinary cancer. These findings support that health care providers should carefully search for undiagnosed cancer in patients receiving antithrombotic drugs.

***Preferred:*** To assess the association between bleeding and a new diagnosis of cancer, we examined the number and proportion of new cancers diagnosed in patients with gastrointestinal or genitourinary bleeding after beginning treatment with antithrombotic drugs for atherosclerosis.

## SUMMARY

The study question is the most fundamental part—the guiding star—of a research manuscript. This question engages readers by sparking curiosity and creating tension in the research story. By avoiding common pitfalls in crafting a study question, medical writers can create a good Tension that persuades readers to keep reading and guides readers into the next part of the story.

***Author declaration and disclosures:*** *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA JOURNAL V39 N2 / 2024

FREELANCE FOCUS

# 2023 Jam Session for Seasoned Freelancers Plays to a Packed House

**Brian G. Bass, MWC** / Bass Global, Inc, Fort Myers, FL

The Jam Session for Seasoned Freelancers held during the American Medical Writers Association's (AMWA's) 2023 Medical Writing & Communication Conference was packed with people and important discussions. Chief among those discussions was the use of artificial intelligence (AI) by freelancers and the role AI plays, does not play, should play, and should not play in medical communication.

## WHAT SHOULD FREELANCERS BE DOING ABOUT AI?

Seasoned freelancers attending the session continue to be at odds with the technology. There is no doubt AI is here to stay, and all medical communicators (not just freelancers) must make peace with it. But how?

AI is being used to conduct literature searches, generate images, and draft initial content that can then be used to guide further literature research and writing. It may be most useful for developing content in the area of disease states. There was an informal consensus that freelancers, and anyone, for that matter, should not share proprietary or confidential information with AI. It should be assumed that all information given to AI will be assimilated into its knowledge base and potentially shared with others. Whether medical writers and editors are freelancers or employees, education and guidance are needed on what to do and what not to do when working with AI content generators.

There was discussion around the potential utility of AI for writing large documents for which development timelines are traditionally lengthy, such as clinical study reports. It was suggested that AI might be able to write a clinical study report much faster than humans, and that this could adversely affect what freelancers can charge. However, it was noted that AI-developed content will not exclude human involvement. Freelancers may be able to charge more when using AI to create large documents because of the additional work needed to perform the functions that AI is not currently able to do or do well, such as verifying sources, references, and making annotations. Humans are also still needed to review and rewrite AI content. In some areas of medical communication, AI may also enable freelancers to increase revenue by enabling them to do more billable work faster.

Reminiscent of the fear that offshoring of medical writing and editing functions might cause people to lose their jobs, there was discussion that AI might eventually pose a similar risk. It was suggested that writers and editors who work for content mills are the ones who would most likely suffer because content mills are not typically concerned with the quality, accuracy, and ethical issues that arise with AI-generated content. For those who are concerned about quality, accuracy, and ethics, the use of AI in medical communication will likely always be AI-assisted writing rather than solely AI writing.

Session attendees identified a number of resources for content and image AI generators. Some are free and some are fee based. Mentioned were both the free and subscription-based versions of the well-known ChatGPT (https://chat.openai.com) and also OpenEvidence (https://www.openevidence.com/) for searching medical literature, Claude AI (https://claude.ai) for generating text, and DALL·E (https://openai.com/dall-e-3) for generating images.

> **"The value proposition for freelancers lies in the quality of the AI-human pairing."**

The bottom line for session attendees was that freelancers must embrace AI rather than fear it and find the best use of AI for their and their clients' needs. The value proposition for freelancers lies in the quality of the AI-human pairing.

## IS FREELANCING DANGEROUS TO YOUR HEALTH?

Another important topic discussed during the Jam Session for Seasoned Freelancers was the effect of freelancing on one's physical and mental health. Freelancing is not a full-contact sport, or at least it shouldn't be. But as session attendees discussed, freelancing can still take its toll.


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Fatigue from the pace and constant stress was at the top of the list for some seasoned freelancers. For others, long hours sitting at a desk and staring at a computer screen result in chronic dry eyes, stiff necks, and can exacerbate arthritis. The intensity was palpable when attendees began discussing the psychological effects of freelancing. Despite freelancers having the freedom to take off from work whenever they like, the lack of work-life balance and the ease with which freelancers can become workaholics were common threads of discussion. Even for seasoned freelancers who are busy all the time, the fear that at any moment there might not be enough work is like a carrot on a stick driving them continually to do more.

Digging deeper, session attendees grieved the loss of once-loved passions and hobbies. It was ironic that people who devote their careers to helping others are so bad at taking care of themselves. As one seasoned freelancer noted, "we are caregivers to everyone but ourselves."

> **"We are caregivers to everyone but ourselves."**

To overcome, or at least address, some of the health-related concerns of freelancing, session attendees recommended self-help books, making health—and better yet, themselves—a priority, and investing in disability insurance if possible. One attendee noted that retiring was cathartic. Regrettably, retirement wasn't yet an option for most people in the room.

In the end, seasoned freelancers agreed that freelancing was the best career choice they ever could have made, and they would never go back to a staff position.

## WHAT WAS WITH 2023?

Last year was an odd year for many seasoned freelancers—slower than usual, but why? Although many attendees may have come to the Jam Session thinking they were the only one experiencing a bit of a slowdown last year, they soon learned they weren't alone.

Several suggestions for what may have contributed to 2023 being a slower year were provided:

- Belt tightening by pharmaceutical companies reducing workflow to freelancers' medical communication clients, and, thus, to them.
- Reduced pharmaceutical funding stalling current and/or planned communication initiatives.
- Rising interest rates making venture capitalists jittery and slowing investment, causing smaller pharmaceutical and biotech companies to tighten their belts.
- Overall market uncertainty.

Of course, not every freelancer experienced a business slowdown in 2023, and not everyone whose freelance business did experience a slowdown was slower all year. One area of freelance medical communication that was as busy as ever in 2023 was regulatory writing. Session attendees specializing in regulatory writing agreed there was no slowdown in their business in 2023, and there was no sign of a slowdown in sight.

> **"Top freelancers will always have work as long as there is work to be had."**

One thing is for sure—top freelancers will always have work as long as there is work to be had. Seasoned freelancers embrace change and uncertainty. They have lived and worked through many market fluctuations. Thanks to this experience, they know not to be worried. Instead, session attendees agreed that 2023 was a good year to take extra time off, enjoy some peace and quiet, and get ready for 2024. In other words, enjoy it while it lasts!

***Author declaration and disclosures:*** *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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IN THE SERVICE OF GOOD WRITING

# It's All Relative (Clauses)

**Laurie Endicott Thomas, MA, ELS** / Independent Medical Writer, Madison, NJ

## ABSTRACT

Are you baffled by when to use *which* and when to use *that*? When is it okay to drop *that*? When should you say *who* (vs *whom*), and when should you say *whoever* (vs *whomever*)? This article explains the grammar and usage of relative clauses and noun clauses. Like other clauses, a relative clause has its own subject and predicate. However, the relative clause serves as an adjective, modifying a noun in some other clause. The relative clause is linked to its referent by a relative pronoun (eg, *that, who/whom, which*, or *whose*). Similarly, an adverb clause can be introduced by a relative adverb (eg, *when, where, why*). The words that serve as relative pronouns and relative adverbs can also serve as complementizers. A complementizer is a word that creates a noun clause that serves as a subject or object in some other clause. Knowing these principles can help you untangle long, complicated sentences. Thus, you can make your text more readable. A sentence diagramming app can help you visualize and understand the syntactical relationships.

The purpose of this article is to help you learn some tips and tricks for combining little sentences to make a bigger sentence, and for breaking up long, complicated sentences into bite-sized pieces. In particular, it explains how a relative pronoun can be used to turn a simple sentence into a relative clause (adjectival clause) that modifies a noun in some other clause and how relative adverbs introduce adverbial clauses. It also explains how you can turn a simple sentence into a noun clause that can serve as a subject or object in some other sentence. It will also give you some tips on how to make sure that your adjective clauses say what you want them to say.

## WHAT ARE CLAUSES?

Consider these 2 simple sentences.

- Sarah speaks 5 languages. Sarah works as a translator.

A simple sentence consists of a single independent clause. A clause is a word string that consists of a subject and a predicate. If a clause can stand on its own as a complete sentence, it is independent. Every complete sentence contains at least one independent clause. Two independent clauses can be conjoined to form a compound sentence. There are 3 common ways to conjoin 2 independent clauses: a semicolon, a colon, or a comma and a coordinating conjunction.

- Sarah speaks 5 languages; she works as a translator.
- Sarah works as a translator: she speaks 5 languages.
- Sarah speaks 5 languages, and she works as a translator.

Because both independent clauses have the same subject (Sarah), you could use the coordinating conjunction *and* to combine the 2 predicates into a compound predicate:

- Sarah speaks 5 languages *and* works as a translator.

You can also use a subordinating conjunction to turn one of those independent clauses into a dependent clause. The result is a complex sentence. A complex sentence contains at least one dependent (subordinate) clause in addition to an independent clause. In the following example, a subordinating conjunction (*because*) was used to create a subordinate clause that acts as an adverb:

- Sarah works as a translator *because* she speaks 5 languages.

Adverbial clauses express a time, a place, a reason, or a condition for action described in the main clause.

## WHAT ARE RELATIVE CLAUSES?

You could also create a complex sentence by turning one of those independent clauses into a relative clause that is embedded in the other sentence. To do that, replace the subject of one of those sentences with the relative pronoun *who*. A relative pronoun is a pronoun that serves as the head of an adjectival clause that modifies a noun in some other clause. (The head of a phrase or clause is the word that


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determines the grammatical category to which that phrase or clause belongs. The head is not always the first word in that phrase or clause.) The *who* clause is a dependent clause because it cannot stand on its own as a complete sentence. It is a relative clause because it relates to one of the nouns in another clause:

- Sarah, *who* speaks 5 languages, works as a translator.
- Sarah, *who* works as a translator, speaks 5 languages.

Knowing these grammatical tricks gives you flexibility. This knowledge enables you to combine small, choppy sentences into a larger but smoother sentence. It also enables you to break down a long, complicated sentence into shorter, simpler sentences that are easier to read. By decreasing sentence length, you improve your text's readability score, thus improving its ranking in search engine results.[1]

## WHAT ARE RELATIVE PRONOUNS, ADJECTIVES, AND ADVERBS?

Interrogative pronouns (*what, which, who/whom*) and the interrogative adjective *whose* (which is also a possessive adjective) are used for asking questions. Similarly, *that, which, who/whom*, and *whose* can be used as relative pronouns:

- **That:** used to refer to people, animals, or things as the subject or object of the relative clause.
- **Who:** used to refer to one or more persons as the subject or a predicate complement of the relative clause.
- **Whom:** used to refer to one or more persons as a direct or indirect object or the object of a preposition in the relative clause.
- **Which:** can be used as a relative pronoun or relative adjective, to refer to or modify animals or things as the subject or object of the relative clause; note that *which* can also be the object of a preposition (eg, *for which* or *at which*)
- **Whose:** is a possessive relative pronoun, sometimes classified as a relative adjective.

I prefer to use *who/whom*, as opposed to *that* or *which*, for clauses that refer to human beings. Note that *whose* can have an inanimate referent:

- Nothing is more powerful than an idea *whose* time has come.

A relative clause can also be headed by a relative adverb (*where, when*, or *why*).

## BOUND (ADJECTIVAL) CLAUSES

The words that are commonly used as relative pronouns can serve as the head of 2 different types of clauses: bound and free. The bound ones are the adjectival clauses that modify a particular noun in another clause. As you will see below, the free clauses can stand in for nouns (subjects or objects) in another clause.

Here's a sentence that contains a bound (adjectival) clause:

- They killed the goose that *laid the golden eggs*.

*They killed the goose* is an independent clause. It can stand on its own as a sentence. In contrast, *that laid the golden eggs* is a clause but not a complete sentence. It does contain a subject (*that*) and a predicate (*laid the golden eggs*). Therefore, it is a clause. However, the clause's subject is a relative pronoun that links the clause to the word *goose*, which is the direct object in the main clause.

Figure 1 is a diagram that I created with the Sentence Diagrammer app. (I added the labels and boxes.) The diagram shows the conjunctive role of the relative pronoun and the adjectival nature of the relative clause. Note the dotted diagonal line that runs from *goose* to *that*. The line is dotted to show that the relative pronoun (*that*) serves as a conjunction. The line starts off as diagonal (parallel to the solid line for an ordinary adjective) to show that the relative clause is a modifier. Because it is modifying a noun, it is adjectival.

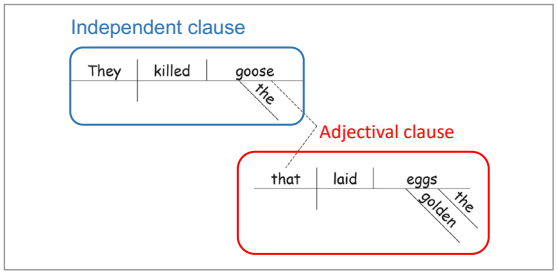


**Figure 1.** Diagram of a sentence with an adjectival clause.

The referent of a relative clause is normally a particular noun in some other clause. However, English speakers often use a relative clause to refer to a whole sentence or to more than one sentence. In that situation, *which* is always used as the relative pronoun:

- I don't have to work tomorrow, which is great because the weather forecast is good.

In English, adjectives normally go directly *in front of* the noun they modify. In contrast, adjectival phrases and clauses normally go directly *after* the noun that they modify. You may have to make some adjustments to put the adjectival phrase directly after the noun. Sometimes, you can do this by replacing a prepositional phrase with an attributive noun:

☹ A clause is a *string of words* that consists of a subject and a predicate.

😊A clause is a *word string* that consists of a subject and a predicate.

If you have more than one relative clause modifying the same noun, use a coordinating conjunction to connect them. You could drop the *that* to give the relative clause a compound predicate, but I prefer to repeat the relative pronoun to make the sentence easier to parse.

- Testosterone is a hormone *that is made mainly in the testes* but *that is also made by the adrenal glands*.

## RESTRICTIVE VERSUS NONRESTRICTIVE RELATIVE CLAUSES

Relative clauses can be restrictive (defining) or nonrestrictive (modifying). The difference is important because it affects meaning. A restrictive clause is used to define what you are talking about: to specify that you are talking about only a subset of the set that the noun represents. For example, consider the following sentence:

- The vaccine covers the pneumococcal strains *that cause invasive disease*.

This sentence is talking about only a subset of pneumococcal strains. It tells us nothing about the strains that don't cause invasive disease. Are they covered by the vaccine? Maybe, but maybe not. If you want to specify that the vaccine covers *only* the invasive strains, add the word *only*:

- The vaccine covers *only* the pneumococcal strains *that cause invasive disease*.

You might also want to stress that the vaccine provides full coverage:

- The vaccine covers *all* the pneumococcal strains *that cause invasive disease*.

In contrast, a nonrestrictive (modifying) clause is parenthetical: it adds nonessential information. You could delete the nonrestrictive clause without changing the scope of what the sentence is talking about.

- The pancreas secretes insulin, *which plays a key role in controlling blood sugar*.

The *which* clause tells you something about insulin, but it doesn't limit the discussion to a subset of insulins. Because nonrestrictive clauses are parenthetical, they are set off from the rest of the sentence by commas, parentheses, or dashes.

For an illustration of the difference between nonrestrictive and restrictive relative clauses, see Figure 2.

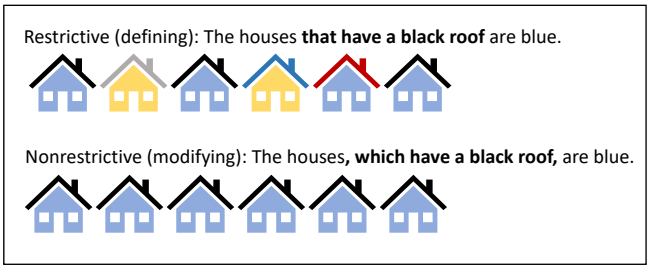


**Figure 2.** *Restrictive and nonrestrictive clauses*. The restrictive relative clause *that have a black roof* limits the scope of the discussion so that the sentence is talking only about the houses with a black roof. In the top row, all of the houses that have a black roof are blue. There is also a blue house that doesn't have a black roof. However, the sentence says nothing about it because the sentence is restricted to talking about houses with a black roof. In contrast, the nonrestrictive relative clause "*which have a black roof*," doesn't limit the scope of the discussion to a subset of houses. Rather, it just tells you something about all of the houses. All of the houses in the bottom row are blue, and each has a black roof. So, you could simply say, "The houses are blue" without mentioning the roofs.

When you are writing, you presumably know whether you intend a clause to be restrictive or nonrestrictive. If it is nonrestrictive, set it off with commas, parentheses, or dashes, for clarity. If it is restrictive, don't set it off with those punctuation marks (Table 1). If you are editing someone else's writing, you may have to guess from context whether a relative clause is intended to be restrictive or nonrestrictive. If you are in any doubt, query the author.

**Table 1.** Restrictive and Nonrestrictive Relative Pronouns

| | Referring to Human Beings | Referring to Something Nonhuman | Possessive (Human or Not) |
|---|---|---|---|
| Restrictive | who, whom, that[a] | which,[b] that | whose |
| Nonrestrictive[c] (with commas) | who, whom | which | whose |

[a] It's better to use *who* or *whom* instead of *that* when the relative clause is describing a person or group of persons.
[b] You could use ***which*** in a restrictive sense, as long as you don't set it off with punctuation. But it is better to reserve the use of *which* for nonrestrictive relative clauses.
[c] Nonrestrictive relative clauses are set off with commas, parentheses, or dashes.

## UNBOUND (NOUN) CLAUSES

As you have seen, relative clauses serve as adjectives, modifying the noun to which they are bound. However, there are some clauses that look like relative clauses but do not modify anything external to themselves. Instead, they are noun clauses embedded in another clause. The word responsible for turning the word string into a noun clause is called a complementizer. The words that commonly serve as relative pronouns (*who/whom, which, that*) can also serve as complementizers. So can the compound relative pronouns (*whoever, whichever*), the interrogative pronouns and adjectives (*who/whom, what, which, whose*), some subor-

dinating conjunctions (eg, *if, whether*), the relative adverbs (*how, when why*), and a preposition plus a relative pronoun (eg, *for whom*). A noun clause can serve as a subject, object, or predicate complement within some other clause:

- *Whom you know* [subject] is as important as *what you know* [object of a preposition].
- I will see *what I need* [direct object].
- This is *what I need* [predicate complement].

The Reed-Kellogg system of diagramming sentences uses a pedestal (a long vertical line with a triangular base) to insert the noun clause into the host clause (Figure 3).

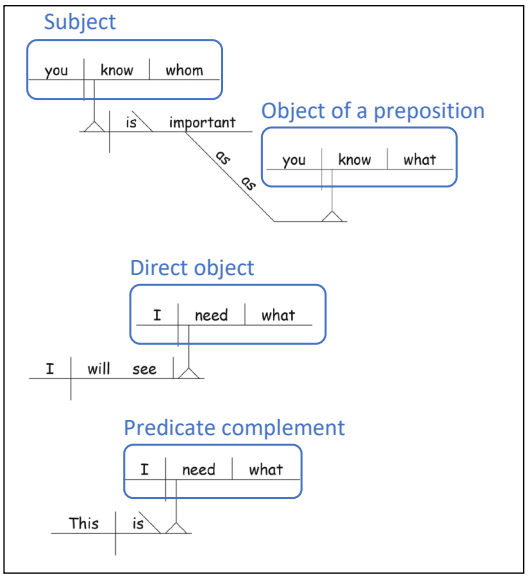


**Figure 3.** Examples of complementizers. The words that normally serve as relative pronouns (*who/whom, which that*) can also serve as complementizers. A complementizer is a word that is turning a word string into a noun clause that is a subject, a predicate complement, or an object within another clause. The compound relative pronouns (*whichever, whoever*) and interrogative pronouns and adjectives (eg, *how, when, where, whose*) can also serve as complementizers, as can some subordinating conjunctions. In Reed-Kellogg sentence diagrams, noun clauses are put up on pedestals (a vertical line with a triangular base).

## WHO OR WHOM?

Many people get confused about when to say *who* and when to say *whom*. They have the same trouble with *I* and *me*. This confusion results from the fact that English speakers have stopped marking nouns for case. Case refers to the role that a noun or pronoun is playing in a sentence. In English, there are only 2 cases:

- The nominative case (I, we, you, he, she, they, who, whoever) is used for the subject of a clause or for its predicate complement (Figure 4).
- The objective case (me, us, him, her them, whom, whomever) is used for direct and indirect objects and the objects of prepositions (Figure 5).

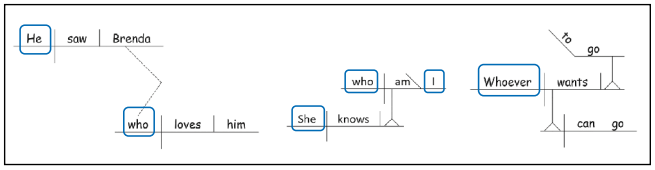


**Figure 4.** Nominative case. If a pronoun is the subject of a clause, use the nominative case (*I, we, you, he, she, they, who, whoever*). Also use the nominative case for predicate complements (pronouns linked to the subject by a linking verb [copula], such as *to be* [*am, is, are, was, were*, etc]). The diagonal line after the word *am* indicates that *am* is a linking verb.

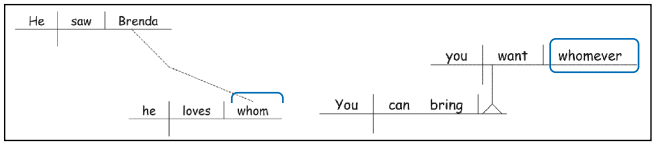


**Figure 5.** Objective case. If a pronoun is an object (direct or indirect object or the object of a preposition), use the objective case (*me, us, you, him, her, them, whom, whomever*).

When in doubt, diagram the sentence. Sentence diagramming apps can help you visualize the sentence structure, but they might not correct your grammar. If the pronoun is the subject of a clause (ie, it falls before the line that separates subject from predicate), use the nominative case. If the pronoun falls after that line, use the objective case unless the verb in the predicate is a linking verb (indicated by a slash after the verb).

## REDUCED RELATIVE CLAUSES

A reduced relative clause is a relative clause that is not marked by an explicit relative pronoun. English speakers often drop the relative pronoun. For example, Ira Gershwin's lyrics in the song *The Man I Love* are about "the man [whom] I love." If you drop a relative pronoun and its finite verb (eg, *that is* or *that were*), you may transform the relative clause into a participial phrase. By dropping those words, you can decrease your word count. Yet as I explained in an earlier installment of this column,[2] that practice can lead to garden path effects. A garden path sentence is grammatically correct and unambiguous, but it initially lures one into a false interpretation, which is irritating.

- The horse raced past the barn fell. (The horse that was raced past the barn fell.)

## CONCLUSION

Some of the problems posed by relative pronouns involve meaning, and some just involve grammar. These are the points that involve meaning:

- When you spot a relative pronoun (eg, *that, which, who, whoever, whom, whomever, whose*), ask yourself whether it is the head of an adjectival clause (relative clause) or a noun clause. If it is the head of an adjectival

clause, figure out what noun the clause is modifying. Try to position the clause directly after that noun to clarify the meaning.
- Set nonrestrictive relative clauses off with commas, parentheses, or dashes. Do not set off restrictive relative clauses with punctuation. If you are editing someone else's work and have any doubt about whether a relative clause is restrictive or nonrestrictive, query the author.
- In restrictive relative clauses that modify something nonhuman, use *that* instead of *which*, to emphasize the restriction.
- To avoid dehumanizing language, use *who/whom* instead of *that* or *which* when the relative clause refers to one or more human beings.

Once you learn how to diagram sentences, some baffling grammatical rules start to make more sense.

- When in doubt about whether to use *who* vs *whom* (or *whoever* vs *whomever*), diagram the sentence. If a pronoun is the subject of a clause or the predicate complement of a subject, use the nominative case (*who/whoever*). Otherwise, use the objective case (*whom/whomever*).

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PRACTICAL MATTERS

# Help Your Clients Create More Readable Patient Education Materials

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Improving readability is a challenge for many of our clients who create patient education materials.[1] Most studies addressing this problem focus on the language level of written content. Both digital and print materials produced for public audiences are typically more appropriate for health care providers and students than for patients, families, and caregivers, and this appears to be a global problem.[2-4]

As a medical communicator, you can help! Even if you don't have specialized training in health communication or creating patient education, the simple tips below can help you improve the readability of materials prepared for the public.

## TIP 1: MAKE SURE EVERY PIECE HAS JUST ONE MESSAGE

**Limiting each piece to a single message enhances readability by helping you limit the document's length. It allows patients and other users to focus on the important information instead of having to figure out what's essential and what isn't.**

What does your client want to convey on that web page or information sheet? Ask this question when you start a project that includes material for the public. Gently guide them towards *one* answer, such as "learning the benefits of a Mediterranean diet."

If they want to convey multiple messages, ask which are the most important. Suggest segmenting the information. For example, a patient education slide set can be delivered in 3 segments, each with its own message.

If you are editing for readability, strike out every detail that does not directly support the message your client wants to convey. I usually add a constructive comment when I delete material, such as "This would be great in a separate brochure," or "What about moving this to the 'After Your Surgery' webpage?"

### Why not just use AI?

First, these tips are not about improving readability by changing the words you use. Readability starts far upstream of word choice.

You may also balk at placing your organization's existing content in an artificial intelligence (AI) generator. When AI creates content, it does so by scraping the Internet for what others have written. Your words aren't private or protected—you've just shared them with the world.

## TIP 2: PLACE THE MESSAGE PROMINENTLY

**Place the piece's message prominently, usually in the title as well as at the start. This ensures your audience gets the message even if they only glance at the information. They will know what the piece is about and can come back to it later when they need the information or have more time.**

The title of your patient education piece, whether print or digital, should be the main message in everyday language. Instead of "COVID-19 Rapid Antigen Test"—which is a label, not a message—write "How to Do a Home COVID Test."

The first paragraph should also state the main message. "These instructions help you test for COVID-19 at home" or "This information tells you how to use your asthma inhaler."

In digital materials, the main message should appear immediately, eg, "Make an appointment" or "Learn your diabetes risk." Users should never need to scroll through content to discover the message.

In the days of newspapers, less urgent or interesting content was placed "below the fold" on the front page, so readers had to flip the paper over to read it. Don't make users hunt for the main message.

## TIP 3: USE CLEAR VISUAL CUES

**Visual cues draw the eye. They serve as signposts that are especially important to users with lower vision or less confidence in handling print or digital information.**

Highlight the material's title with bold type, a larger type size, a different color, or a heading such as "What You Need to Know." Avoid using all caps or underlining, as both of these devices obscure the variations in letter shapes that help users recognize words quickly.[5]

Add subheadings throughout the document. Use coordinating but different type size and font.


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A strategy from sales and ad copywriting is to make the subheads tell a story.[6] If you read one after the other, you have a coherent narrative. For example, a handout titled "Getting Ready for Surgery" can have subheads like "Prepare the night before," "Get ready at the hospital," "Ask questions," and "Know what to expect after surgery."

If you are writing a series of tips or steps, repeating the word "tip" or "step" indicates the sections of a document.

## TIP 4: MAKE CONTENT LOOK EASY TO READ

**Material that looks challenging to read will be abandoned, potentially in favor of "Dr Google." Remember that your audience may have access to a great deal of attractively presented, user-friendly, but inaccurate information.**

To assess how inviting a print piece is, I like to place it on a desk and stand over it, with enough height that I can't actually read the words. This gives me a sense of how the piece looks when it's handed off to a user for the first time.

I bring digital content up on my phone. This is how most people will view it, and you can instantly evaluate its user-friendliness. If you have any difficulty reading or navigating it compared to your own go-to digital content, talk with your web designer about optimizing the content for mobile use.

Questions to ask:

- Does the document or digital content look easy to scan at a glance? Or do you see big blocks of text, as you would in an academic journal? If it's the latter, some text needs to be cut and subheads added. Check a favorite news website to see what paragraph length users are accustomed to. It's usually a sentence or two.
- Is it visually busy? It should feel good to keep your eyes on the document or page. You should not have the sensation of visually skipping around.

## TIP 5: WHEN IN DOUBT, CUT IT OUT

**Help clients identify the "need to know," and remove the "nice to know" or save that for another audience.**

Is the information "need to know"? If patients, families, and caregivers can act on it, the answer is yes. If it's not actionable, it's nice to know, but not essential.

I once encountered a brief discussion of the sella turcica in a brochure on pituitary gland disorders. Was it interesting? Sure! Could patients do anything with it? No. Out it went.

What is "need to know" varies with your audience. For example, some clients include information on anatomy (like in the above example) or pharmacokinetics. However, the hard fact is that users don't usually need to understand these topics in order to participate in their health care any more than I need to understand exactly how the siping on winter tires works in order to choose the best ones for my needs.

Keeping sentences between 10 and 12 words is helpful for users. This is challenging for those of us who spent a lot of time in school, where sentences can run into entire paragraphs. The average sentence length I see in draft content written by clients is at least 20 words and often more than 40.

Again, look at popular digital content to see what the public is used to. **Bonus tip:** If you see a conjunction or a semicolon in a sentence, that sentence can likely be broken into at least 2 shorter ones to improve readability.

## TIP 6: SWITCH HIGH-LEVEL WORDS FOR EVERYDAY WORDS

Using words that you would use in talking to a neighbor or family member makes content friendlier for the public. It also helps you avoid words that many of our users have never seen in print. Remember that as knowledge workers, medical communicators see many more words, and many more complex and challenging words, than most people. It's our job!

For some of us, it's easy to come up with alternatives to high-level words like "salutogenic." For others? Not so much, especially if you're accustomed to writing for health care providers.

Now is the time to actually read the content of your patient education document. (You may want to print digital content to do this.) Take a pen in your favorite color and simply strike through the following:

- ☐ Words of more than 3 syllables
- ☐ Medical, scientific, nursing, and technical terms
- ☐ Words you use when talking to colleagues, but not to your next-door neighbor (eg, "follow-up," "resource" as a verb)
- ☐ Non-English words ("in vivo," "tamponade")

Now, replace those words with common English words. Consulting thesaurus.com is perfectly OK! I often revise the rest of the sentence a bit to make the new word fit—it's seldom a one-for-one substitution.

## RESOURCES

I hope these tips will help you make clients' patient and family education materials more readable, even if you're not a readability or patient education expert. Here are some resources for further help.

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REGULATORY INSIGHT

# Say the Right Thing: Developing a Program Lexicon for Cross-Functional Teams

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## ABSTRACT

Achieving consistency in terminology and speaking with one voice in clinical documents is challenging for several reasons. Cross-functional team members, including medical writers, may use different terminology to describe the disease, condition, and study features, as well as to compare and interpret clinical data. Inconsistent use of terminology in clinical documents can negatively impact the overall quality, efficiency of development, and clarity of messaging and may lead to longer regulatory reviews, extensive questions from regulators, delays in approval, and the possible rejection of a regulatory submission.

The development and use of a program lexicon can alleviate some of these challenges. The lexicon is created by the lead medical writer with input from all involved functional areas. The purpose of the lexicon is to provide detailed program-specific guidance for appropriate terminology to create accurate and consistent content within and across documents for use by all contributing authors and reviewers from document initiation to finalization. For regulatory medical writers, a lexicon is an integral part of the focused authoring approach in using consistent comparison language. The lexicon identifies the terminology that should be used, should not be used, if any exceptions are allowed, and examples.

Medical writers often drive the development, implementation, and periodic updates of the lexicon to maintain it as a living document. Once developed and used, the lexicon can facilitate faster authoring, review, and quality control of regulatory documents, and meeting tight timelines for regulatory responses or submissions. By standardizing terms and definitions, the lexicon also facilitates automation, structured authoring, and content reuse. Finally, the lexicon can be included as a source file for artificial intelligence tools to produce first drafts of documents that meet regulatory requirements.

Regulators have identified poor document quality as an issue that negatively impacts review of submitted clinical documents, and they specified a "lack of clarity" as one of the most frequently identified document quality issues.[1] Using consistent terminology and style conventions within and across clinical documents supports the development of clear, high-quality documents.[2-4] A program lexicon is a valuable tool that assists medical writers and cross-functional teams to effectively use consistent terminology and speak with one voice across clinical documents.

## IMPORTANCE OF CONSISTENT TERMINOLOGY IN CLINICAL DOCUMENTS

Clinical documents are an integral part of the development process for pharmaceutical products (drugs, biologics, and devices). The complex content of these documents is often developed by diverse authoring teams under condensed timelines to support a regulatory submission.[4] Developing high-quality clinical documents that are consistent, concise, clear, accurate, well-organized, and specific to their indication(s) and audience is critical in supporting a smooth regulatory review.

Consistent terminology in clinical documents helps the reader focus and comprehend the overall purpose and key messaging while avoiding distraction. This is especially important for complex studies with multiple comparisons for multiple treatment and age groups, time points, end points, statistical approaches, and other variables.

Inconsistent use of terminology in clinical documents can negatively impact the overall quality, efficiency of development, and clarity of messaging. Poor quality documents impede regulatory reviews and may lead to longer reviews, extensive questions from regulators, delays in approval, and the possible rejection of a submission.[1,4] Poor quality documents in a submission from an applicant may impact the review of other documents in subsequent submissions from the same applicant.[1] Additionally, if an applicant is developing submission documents that will be translated into various languages, ensuring that the initial documents are of


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high quality and using consistent terminology is critical for successful translation.[5]

## CHALLENGES TO USE OF CONSISTENT TERMINOLOGY

Achieving consistency in terminology and speaking with one voice in clinical documents is challenging for several reasons. Medical writers and other lead authors use materials from various sources of differing quality and combine all relevant information into clinical documents. These sources may use different terms to describe the same thing and accepted terminology may change over time.[6]

Medical writers work in cross-functional teams with many different authors, contributors, and reviewers who use different terminology to describe the disease, condition, and study features, as well as to compare and interpret clinical data. Cross-functional teams may struggle to find detailed and appropriate terminology for their program documents.

## USE OF A LEXICON

### What is a Lexicon?

A lexicon is a set of conventions that help facilitate consistent terminology use across a variety of clinical documents. The purpose of the lexicon is to provide detailed program-specific guidance for appropriate terminology to create accurate and consistent content within and across documents for use by all contributing authors and reviewers from document initiation to finalization. The lexicon identifies the terminology that should be used, should not be used, if any exceptions are allowed, and provides specific examples (Table 1). The lexicon may include the following

- terms for products, formulations, disease, and indications;
- standard terms for clinical trials;
- definitions for endpoints, assessments, and abbreviations; and
- cut-offs or rules for data interpretation and comparisons.

Lexicons are part of scientific communication platforms to provide the foundation for all communication around a product or disease and to ensure accurate and consistent language and terminology.[7] For regulatory medical writers, a lexicon is an integral part of the focused authoring approach in using consistent comparison language.[8] A lexicon should be a living document and reviewed and updated regularly as new guidelines and data emerge throughout the project or program's lifecycle. It can be developed to be specific to a document, regulatory submission, or program, or apply to several related programs.

**Table 1.** Example of a Lexicon

| Term to Use | Do Not Use | Examples/Rationale/Notes |
|---|---|---|
| Treatment | Intervention | eg, Study treatment. Also use treatment groups. |
| Study | Trial | eg, Clinical study. |
| Participant | Subject, patient | Use to describe participants in clinical studies.[a] |
| Comparable | Similar | Use comparable to describe results for endpoints in which statistical comparisons are made (ie, *P*-values and/or 95% CI). Usually for primary or key secondary endpoints for efficacy and safety.[b] |
| SARS-CoV-2 infection | COVID-19 infection | Use to describe the infection caused by the virus (SARS-COV-2), not the disease (COVID-19). |
| Viral error catastrophe | Viral error induction | eg, Drug A inhibits viral replication by inducing viral error catastrophe. |
| *Clostridioides difficile* | *Clostridium difficile* | Exception: Clostridium genus is used for all other species except difficile, eg, *Clostridium perfringens* bacteria causes food poisoning. |

*CI, confidence interval; COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.*

*[a]Patients may be used when describing results of real-world evidence or data studies.*

*[b]For results pertaining to objectives with hypothesis testing, use superior, noninferior, or other language as specified in hypothesis.*

### Standard Operating Procedures/Templates/Style Guides Compared With Program-Level Lexicons

Cross-functional team members may ask the medical writer why another guidance document or convention sheet is needed if the team has standard operating procedures, overall style guides, and standard document templates. Although these tools are invaluable in providing high-level guidance for the authoring of clinical documents, they are not intended to provide specific guidance for documents at the program level. Ensuring that an updated program-specific lexicon is available before initially drafting a regulatory document for a clinical development program will save time and effort downstream during document authoring, review, and at team consensus meetings.

## DEVELOPMENT OF A LEXICON

Medical writers often drive the development, implementation, and periodic updates of the lexicon to maintain it as a living document (Figure 1). The medical writer should meet with the project team early on in a project to explain the value of a lexicon, and if available, provide examples from other programs. The medical writer can then lead a discussion with the project team regarding what terminology, definitions, rules for data interpretation, and any exceptions to these should be included in the initial draft program lexicon. The team developing the lexicon can identify appropriate terminology from various sources such as guidelines, clinical conventions, previous program documents (eg, protocol,

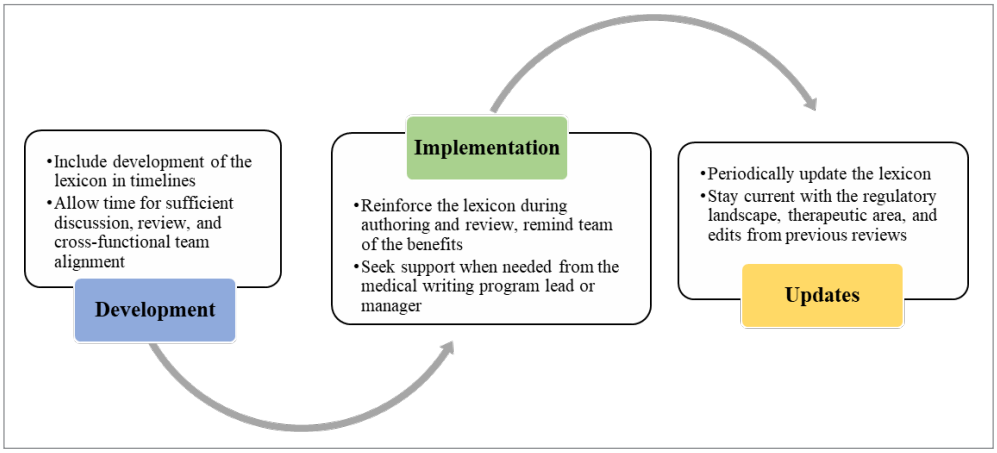


**Figure 1.** Development, Implementation, and Updates of Lexicons

investigator brochure), literature, statistical rules, etc. The draft lexicon can be in whatever format is best for the team (Word document, Excel document, PowerPoint, etc) and be stored in a central location (team site, OneDrive, OneNote, etc) accessible to cross-functional team members.

The medical writer should allow time for sufficient discussion, review, and cross-functional team alignment of the lexicon. Once the initial draft is produced, it should be reviewed by the project team and any other individuals that the project team would like to consult. The program lexicon can be used for development of multiple types of documents during the lifecycle of the program (eg, protocols, investigator brochures, diversity plans, clinical study reports, common technical documents, product label, response documents, publications, marketing materials, etc). Because there may be different teams working on different regulatory documents, the medical writer may need to continue to remind new team members of the benefits of a program lexicon and reinforce the use of the lexicon before initial document development. The medical writer should seek support when needed for implementing the lexicon from the medical writing program lead or manager. It is also important during quality control (QC) review to inform the editor that the team has used a program-level lexicon for authoring the document and provide the lexicon as one of the sources for the review.

The team should review and update the program lexicon on a periodic basis throughout the program life cycle. For example, the lexicon may be reviewed at the initiation of development of documents for each new regulatory submission. The medical writer should manage the review cycles for the program lexicon. Depending on the clinical landscape in the product's specific therapeutic area, the lexicon may be static or may change on a regular basis over the lifecycle of the program.

## BENEFITS OF A LEXICON

The program lexicon is a tool that supports teams in creating accurate and consistent content within and across documents in a program. The development and use of a lexicon can alleviate challenges with lack of consistency for clinical documents. Once developed and used, it can proactively avoid conflict within an authoring team over terminology, data interpretation, and presentation. Thus, the team can focus their attention on including meaningful study results and interpretation and the right level of detail. The lexicon can facilitate faster authoring, review, and the QC of regulatory documents and meeting tight timelines for regulatory responses or submissions.

Regulators have recognized the value of medical writers in improving the quality of clinical documents that they write.[1,9] The lexicon empowers the medical writer as the document leader during authoring in using preferred terminology that has been aligned on within the team. For multiple submissions occurring over time, different medical writers and others may be involved in developing the documents and having an up-to-date program lexicon can help ensure consistency. Finally, by standardizing terms and definitions, the lexicon also facilitates automation, structured authoring, and content reuse.[10,11] With many teams using tools for artificial intelligence, the lexicon can be included as a source file for data ingestion to produce first drafts of documents that meet regulatory requirements.[10,11]

***Author declaration and disclosures:*** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

CONFERENCE

Session Report

# Developing Plain Language Informed Consent Forms for Multinational Clinical Trials

**Speaker**
**Haroon Mohammad, PhD**
*Medical Writer and Consultant, Whitsell Innovations, Inc, New Orleans, LA*

**By Anna Shurtleff Smith, BSN-RN, MPH**

Guidance documents and regulations pertaining to obtaining informed consent from participants in clinical trials have been in place for <60 years. These regulations were developed in part due to atrocities conducted on individuals in the past under the guise of clinical research. Informed consent forms (ICFs) are required for clinical trials and can be found at all phases of clinical trial phases throughout the world. Although ICFs are required documents, medical writers have a responsibility to ensure ICFs are clear, concise, and easy to understand. As a result of the growth of multinational clinical trials and importance of plain language writing, medical writers are on the frontlines of this integration.

## WRITING CHALLENGES FOR MULTINATIONAL ICF DOCUMENTS

ICFs have been found to trend toward being lengthy and difficult documents to read and understand. In the United States, the average adult reads at an eighth or ninth grade reading level. However, it is recommended by the United States Department of Health and Human Services that any plain language materials be at a fifth to sixth grade reading level. It is common for sponsors of clinical trials to want ICFs to be written at a sixth to eighth grade reading level. An additional challenge for writers is integrating guidelines from the *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E6 (R2)* and relevant regulatory agencies into the document while maintaining the plain language writing objective.

## TWENTY COMMON KEY ELEMENTS TO INCLUDE IN A MULTINATIONAL ICF

Although each country may have a few differing elements to an ICF, the following items illustrate 20 key elements to include in most multinational ICF documents.

### Why is This Clinical Trial Being Done?

- Research. Explain to participants what the research means and how what their participation in the study is part of the research.
- Purpose of the trial. Provide a one sentence objective. Is the objective to investigate safety, efficacy, different dose, different route of administration, or a new indication?

### What Will Happen During the Clinical Trial?

- Investigational product and random assignment. Provide 1 to 2 sentences describing the investigational product, controls, and probability for random assignment.
- Experimental aspects of the trial. Identify or explain specific parts, tests, or procedures required by the clinical trial protocol that would not be part of a participant's normal care outside of the clinical trial (eg, collecting blood samples for a pharmacokinetic study or to check for specific biomarkers, completing questionnaires or quality of life surveys).
- Trial procedures. Although it can be easy to copy and paste from protocols, it is important for the writer to adjust this to a participant audience. Examples: what will the sample be used for? When will the procedure take place?
- Participant responsibilities. Describe what the participant is required to do to remain in the trial.
- Expected duration. Supply the number of and duration of clinical trial site visits and procedures.
- Approximate number of participants. Explain the expected number of participants who will be enrolled in the clinical trial with them, and which phase of the clinical trial they will participate in.
- Risks, discomforts, and inconveniences. Include adverse events, potential for stopping or changing current treatments and potential effects, and potential unintended disclosure of private information, data, and/or trial-specific procedures. Examples: loud sounds when undergoing magnetic resonance


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imaging, taking time off work or school, and organizing child care.

### Are There Any Benefits or Costs to Participate in This Clinical Trial?

- Expected benefits. Explain any direct impacts or benefits to participants, to other patients, or to society at large.
- Alternative procedures or treatments. Present participants with the current standard of care and what options they have besides the clinical trial. For example, there might be a surgery option that is not being offered to patients in the clinical trial.
- Anticipated expenses. Clearly state who will be paying for the clinical trial drugs, visits, and procedures.
- Anticipated compensation or reimbursement. Describe any prorated payments, reimbursements, or vouchers provided by the sponsor to participants for clinical trial–related expenses (eg, transportation, lodging, meals associated with clinical trial site visits). Including this as a benefit can be viewed as coercion.

### How Will Participants Be Protected During the Clinical Trial?

- Participation is voluntary. Participants can choose not to join or withdraw at any time, without penalty, from the clinical trial.
- Compensation or treatment for trial-related injuries. Include what form of compensation will be included for clinical trial–related injuries. This cannot include legal language that tells participants the sponsor is not responsible.
- Permission to access participant's medical records. Explain to participants who will be given permission to access their medical records (eg, clinical trial staff, regulatory agencies, and/or ethics committee).
- Confidentiality or protection of participant's information and data. Address how the participant's personal information will be protected.
- Sharing new information that may impact willingness to participate. Disclose to participants how significant new findings identified during the course of the clinical trial (eg, a new treatment option or adverse events), which may impact the participant's willingness to continue to participate, will be provided.
- Individual(s) to contact for trial information and trial-related injury. Include contact for investigator, ethics committee or institutional review board, and emergency contact.
- Reason(s) that trial participation may be terminated. Must give actual information, not just a general statement.

## INCORPORATING THE COMMON KEY ELEMENTS INTO A PLAIN LANGUAGE ICF

Including the aforementioned 20 elements will ensure that the ICF incorporates regulatory requirements, but it does not ensure that the document has a plain language focus. Writers who are knowledgeable on their intended audience can weave in the 20 elements with words the audience can identify with. How a document is structured, the flow of the document, incorporating a conversational tone, and having one key message per paragraph helps the reader more easily process information. Key messages that are concise and correctly conveyed provide the readers with a better grasp of the materials.

Additionally, font size and style that reflect the needs of the reader help enhance the writer's message. It is recommended that writers maintain adequate white space by working toward a 50/50 balance between printed and unprinted areas on each page. There are a variety of user readability tools (eg, Suitability Assessment of Materials instrument, Participant Education Materials Assessment Tool) that can be incorporated into the quality control process of a document.

Ultimately, medical writers are on the front lines of helping translate the essential information required in an ICF into plain language for participants to consume. Being able to creatively interlace essential regulatory information with plain language is a growing competence required among medical writers.

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AMWA JOURNAL V39 N2 / 2024

CONFERENCE

Session Report

# Plain Language With a Page Limit: Strategies for Writing Two-Page Protocol Synopses and Other Deliverables

**Speaker**
**Zack Fey, BS**
*CISCRP, Boston, MA*

**By Hanna Johnson, PhD**

Regulatory writers often work on lengthy technical documents tailored to an expert audience, such as investigator's brochures, clinical study protocols, and clinical study reports. But with recent regulation from the European Union (EU), a new deliverable—the plain language protocol synopsis (PLPS)—entered the picture. With it came questions: who is this document for? Is it required? And most importantly, how can a writer summarize a complex study protocol, using plain language, in just 2 pages? Zack Fey, a medical writer at the Center for Information and Study on Clinical Research Participation (CISCRP), has written countless PLPSs since the regulation took effect. At the 2023 AMWA Annual Conference, he shared his expertise, including best practices for writing in plain language, challenges introduced by the new regulation, and strategies for using plain language with a page limit.

## PLAIN LANGUAGE BEST PRACTICES

Plain language, broadly defined as writing that is easy to read and understand, is increasingly implemented in medical writing. It is particularly valuable in clinical research, in which it can improve transparency for regulatory authorities and promote understanding and engagement for research participants. Given the increasing demand and potential benefits, medical writers may be tasked to write in plain language and should be familiar with its principles. Accordingly, Fey shared the following best practices for developing plain language documents:

- **Word choice**
  - Aim for a sixth to eighth grade reading level
  - Use the active voice
  - Define complex terms with simple terms ("familiarizing")
- **Organization**
  - Order information from broad to narrow (inverted pyramid structure)
  - Break large blocks of text into smaller paragraphs ("chunking")
  - Limit cross-referencing between sections
- **Design elements**
  - Use ample white space around elements
  - Use a large font size
  - Use visual aids, including graphics and icons

## EU CTR 536/2014

Plain language makes a document more accessible but also usually makes it longer. White space, graphic elements, and additional definitions take up space, which can be a problem when trying to adhere to a page limit. Nowhere is this challenge more apparent than in the conditions of EU Clinical Trials Regulation (CTR) 536/2014, which, effective January 2022, (1) requires that clinical trial applications be accompanied by a 2-page protocol synopsis and (2) suggests that the synopsis be written in plain language. Applicable to all new clinical trials conducted in EU member states, the regulation further stipulates that the protocol synopsis must include the following 9 elements:

- Trial title
- Rationale
- All objectives
- All primary endpoints
- All secondary endpoints
- Population
- Trial design
- Interventions
- Ethical considerations

According to Fey, the target audience of the PLPS remains unclear and may vary by sponsor. Furthermore, because of the regulation's wording, there is some question as to whether the use of plain language is required, recommended, or merely suggested. Nonetheless, Fey noted that many of the sponsors who work with CISCRP have begun including a PLPS in their clinical trial applications, allowing Fey's team to develop and refine their strategies—along with a comprehensive template—for these documents.


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## BALANCING ACCESSIBILITY AND LENGTH

The PLPS poses a challenge for writers accountable to EU CTR 536/2014, but its difficulties are relatable for any writer who strives to balance clarity with conciseness. Nevertheless, skilled medical writers can adhere to principles of plain language while also limiting document length. Fey shared the following 5 tips for balancing these interests in a PLPS:

- **Use tables and other visual aids:** Tables and graphics are visually engaging and can break up otherwise large blocks of text, making a document more inviting to readers. Well-designed ones can also present a lot of information compactly, saving space.
- **Use bulleted lists where possible:** Bulleted lists are easier to navigate than lists in a body of text, making the information contained more accessible. They also allow for more brevity than full, grammatical sentences, which can reduce word count.
- **Condense similar secondary endpoints:** Secondary endpoints can be numerous and often have similarities. If this is the case, some may be able to be grouped together in a bulleted list or table. This approach consolidates related information, limits cross-referencing, and saves space.
- **Use color (and be consistent in its meaning):** Color coding makes text visually appealing and informative at a glance. When colors are used to convey meaning, they can also reduce explanatory text.
- **Add a third-page glossary:** If definitions are taking up too much space in a PLPS, they can be housed in an optional third-page glossary. This approach preserves important definitions in an easily referenceable format while saving space in the core document.

## CONCLUSION

Although writing in plain language often adds length, it can still be done when space is limited. As Fey explained, many principles of accessibility are applicable—and even conducive—to writing with a page limit. The key, Fey emphasized, is finding the right balance between accessibility and length.

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

CONFERENCE

Session Report

# Putting Your Plain Language Writing to the Test: Getting the Most Out of User Testing

**Speaker**
**Samuel Entwisle, PHD**
*Medical Writer, CISCRP, Boston, MA*

**By Anna Shurtleff Smith, BSN-RN, MPH**

Plain language writing has an essential responsibility in medical writing. It invites patients and nonmedical/scientific audience into medical and scientific conversations. Medical writers help write these invitations in a way that ensures the identified audience enters the conversation. User testing helps medical writers learn more about the intended audience and how to create engaging documents.

## ROLE OF USER TESTING IN HEALTH COMMUNICATION

At its foundation, user testing seeks feedback from individuals that represent the intended audience. It allows patients and the nonmedical/scientific audience members to provide feedback on documents, media, or other forms of communication.

## PATIENT CENTRICITY FOCUS

Research has shown that patient centricity, the act of allowing the patient to be actively engaged in their health decisions, improves health outcomes. Patient centricity in action is the reciprocal back and forth between the individual(s) or organization developing patient-facing documents and the patients/individuals working in the intended communities. With the growing appreciation for increased diversity among clinical trial participants, creating documents that invite engagement from diverse populations is essential. User testing systems can provide vital insights and perspectives that keep patient centricity front and center. Although user testing is part of developing a patient-centric document, user testing alone does not ensure a patient-centric document.

## REVIEW PANELS

Dr Entwisle explained the Center for Information and Study on Clinical Research Participation's (CISCRP) approach to review panels. Review panels are individuals invested in the intended community who provide a viewpoint on behalf of the community. Panels consist of 3 to 5 people from the intended audience who have been recruited through multiple channels (eg, established relationships with patient/patient advocacy groups, advertising, mailing list). Review panels include

- Health professionals
- Patient advocates
- Patients
- General public (nonexpert)

Most medical writing deliverables in CISCRP go through user testing in these review panels.

Based on feedback from previous review panel participants, draft 2 (sponsors see and provide input on draft 1) is used for the review process. This helps panelists to focus on the content rather than copyediting the document. Review panelists are compensated for their time.

## TESTING INDIVIDUAL SUMMARIES

CISCRP has used 2 different iterations of their review panel survey. In the first iteration, a short-answer question–based format was utilized. Although the first iteration provided extensive and thoughtful feedback, it could have biased toward negative feedback. A few years later, the survey was adjusted to include rating/multiple choice questions with a few short answers. The addition of rating/multiple choice questions into the survey provided a more complete picture of participant feedback on the document and comparison of trends. Their current user testing system provides panelists with a survey to help guide the focus of the information being collected.

Feedback from the survey can be categorized into three main categories:

- Specific suggestions or areas of confusion—easy fix.
- Expressed confusion or revealed misunderstanding—we do our best.
- Document-level criticism (eg, "It's too long!") —pin for later.


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Although panelists hold a very important role in document development (Figure 1), there are two main reasons that feedback should not be incorporated: if the feedback contradicts other suggestions and/or established best practices or it deviates from templates/regulations or established precedent. Additionally, during the development process, building in regular template updates into the document maintenance process was found to allow for new suggestions to be incorporated in a timelier manner.

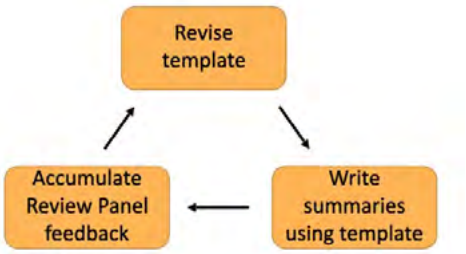


**Figure 1.** Document development stages incorporating feedback.

## LIVE FEEDBACK

Another way to gain insight from the intended audience is to do live feedback sessions to help tease out deeper insights compared with survey responses. This can involve virtual meets in which panelists are given two trial results summaries to review before the meeting. Participants are encouraged to compare the summaries and provide feedback.

## RETROSPECTIVE REVIEW PANEL

Retrospective review panels, which focus on looking over published trial result summaries, are currently being piloted. These review panels require a large group of around 20 individuals who are provided with specific topics related to trial result summaries. Examples of the potential areas to research are listed below:

- Did certain sections contain too much detail? Too little?
- What demographic data would you like to see?
- Comprehension questions about complex topics (eg, PK, bioequivalence)
- Word preferences (eg, "health problems" vs "medical problems" vs "unwanted effects")
- Graphics preferences (pie charts vs bullet lists)

## USER TESTING FOR ALL MEDICAL WRITERS

User testing helps improve and verify the quality of plain language materials. It also helps medical writers develop and enhance best practices while giving patients and other key stakeholders a voice. When writing a plain language material, medical writers can ask to see if user testing has been done on the sample documents or templates they are being provided. This information can help guide medical writers focusing on plain language materials to create engaging documents for their audience.

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CONFERENCE

## Product Showcase

# Yseop's Copilot

**Moira Calder** / Company Owner, ProNouns Editorial Services, Edmonton, AB, Canada

Artificial intelligence (AI) as a concept and, perhaps, goal has been with us for decades. Machines that can think (artificial general intelligence, or AGI) still exist only in science fiction. However, recent developments in large language models (LLMs) and enhanced computer capability to contextualize the meanings of words and to generate (dynamically produce) text have moved AI to the forefront of consciousness in all information-based industries, medical writing included. It is expected to become a permanent, powerful, and pervasive fixture in how we interact in and with the world of publishing.

It is not surprising, then, that the AMWA 2023 conference had a strong focus on AI-based productivity applications, some still at the beta stage or in development. Company representatives and a venture capitalist I met seemed eager to hear about writing community concerns and desired features in AI applications. The issues that I discuss here, except where noted, were raised by presenters and participants at the Product Showcase hosted by Yseop on its new Copilot application.

Yseop's first products addressed financial report writing. They are expanding their line to clinical study reports (CSRs), considering medical writing a fast-growing and competitive industry. The company name is the French word for *poetry* spelled backwards and is pronounced "easy op." This product interacts with Microsoft Word but is distinct from Microsoft's proprietary Copilot AI app.

As the presenters explained, expert systems—alternative terms include symbolic AI, rules-based AI, and deterministic AI—manipulate structured data, primarily converting tables to text, to produce a reasonable first draft, which can then be checked and edited. Generative AI, on the other hand, relies on prediction, with responses derived from probabilities based on pretrained models. The aim in using generative AI is to process nontabular materials. Yseop's Copilot comprises an expert system plus generative AI based on an LLM using open-source data. Clients host their own data behind a secure wall, which provides data protection.

Proprietary applications differ from open systems in the setting of constraints and parameters (eg, producing only CSRs) and training the system on synthetic or on client-owned or -selected data. It generates a specific type of document using specified input, addressing concerns of data traceability and reliability. The goal is to speed up the regulatory submission process through faster report writing. Yseop presented data indicating not only time saved on CSRs but also fewer manual errors.

Yseop's longer-term goal is to cover as much of the submission process as possible with separate products, referred to as automation packs. Clients would buy packs à la carte as needed, with a possibility of bundling for larger clients also mentioned.

For designated software to be acceptable in highly regulated industries such as biopharmaceuticals, the producer must address data traceability, reliability, and security, as noted above. Further issues related to AI-based software adoption included

- verification of the integrity of the data set;
- ensuring that desired changes made to the data set are reflected in the generated text;
- responsibility for verification of output;
- version control with single or multiple authors;
- editing at the section and the report level;
- compliance with submission guidelines;
- interface ease of use, including how intuitive it is and how much training is needed;
- types of files that can be accommodated;
- software programs that the application can interact with, eg, MS Word, rich text, PDFs;
- customization options, for example, style guides;
- use of languages other than English for report generation and/or translation;
- potential customers for the product; and
- packaging and pricing of applications and components.

Copilot is at least initially being developed for larger companies. This points to questions outside the scope of the


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software presentation regarding access and economics. Will small and medium-sized enterprises have equal access to generative AI products in the short term? In the longer term? If not, will this affect their ability to compete and grow their markets? Will freelance work be devalued or eliminated?

Also not discussed, at least not within my earshot, were possible noneconomic impacts. This is not surprising, given the newness of this technology. McLuhan articulated that mediated communication fundamentally alters how we relate to the world, so perhaps next year, when we will have gained more experience with generative AI, this will be the dinner table topic of discussion.

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## Product Showcase

# Draftsmith by PerfectIt

**Michael G. Baker, PhD**[1] **and Katie Kelm, PhD**[2] / [1]Editor-in-Chief; [2]PPD, Part of Thermo Fisher Scientific, Chapel Hill, NC

The creators of PerfectIt have introduced Draftsmith, a new tool that provides text suggestions for improvement of original written material. Specifically, it uses ChatGPT to help writers refine their draft material before it is sent to a copy editor. The product is a Microsoft Word 365 add-in available from the Microsoft Store, and thus a Microsoft account is required to install it.

As a Word add-in, Draftsmith fully integrates with Word. With track changes turned on, any changes made are tracked with the writer's username. Notably, the product does not work with Google Docs, other similar Office applications, or earlier versions of Word.

Once installed, the writer signs in to Draftsmith by clicking any button on its tab on the Word ribbon and enters the email address and password created during account setup. Each button on the tab opens a set of suggestion buttons in the Draftsmith tab. The grouped buttons (see Figure 1) generally follow the draft writing process:

- Pre-Edit group: Fluency Enhancer and Dictation Fixer
- Revise group: Engagement Tuner, Word Count Trimmer, and Empathy Tuner
- Simplify group: Readability Tuner and Plain English Converter
- Review group: Editing Helper

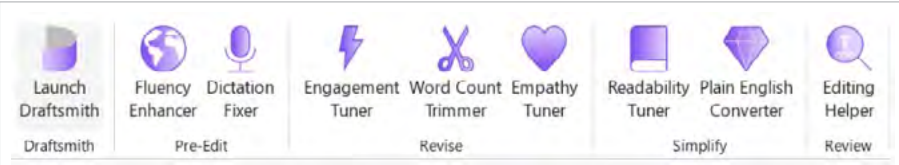


**Figure 1.** Draftsmith tab buttons

When a tab button is selected, 3 default functions for that writing stage are shown in the panel, with the currently active function outlined with a darker border (see Figure 2).


**Figure 2.** Function buttons on the Draftsmith panel

When a button is clicked, Draftsmith selects the sentence in which the cursor is placed and applies the function to that sentence, offering suggestions for changes in the lower part of the panel. To replace the selected sentence with Draftsmith's suggestion, the writer clicks "Replace Text." The change is made in the writer's document and Draftsmith automatically moves to the next sentence. If the suggestion is not wanted, the writer clicks the Next button to skip to the next sentence. If the writer wants to see a different suggestion, the "refresh" icon is selected.

For anyone concerned about the ethics of authoring using artificial intelligence (AI), PerfectIt notes that Draftsmith works in a secure environment using secure Microsoft backend servers. Only single sentences (or selected text, up to 400 words) are ever sent for checking. No data are saved, stored, or used for training AI.

Draftsmith is priced for ad hoc use—subscriptions can be purchased monthly (eg, while self-editing or working on a specific project) without committing to an annual subscription. For more regular use, an annual subscription option is available.

Overall, as a tool for medical writers, Draftsmith can be particularly useful for simplifying dense sentences/paragraphs, rewording complex concepts, and reducing word count. The direct integration with Word may be considered a game changer, as using ChatGPT independently requires frequent toggling between Word and the browser window and copying/pasting. Thus, Draftsmith may save the writer valuable time and enhance productivity.

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## Product Showcase

# PleaseReview by Ideagen

**Michael G. Baker, PhD**[1] **and Kelly Schrank, MA, ELS**[2] / [1]Editor-in-Chief; [2]Freelance Medical Editor, Bookworm Editing Services, LLC, Oneida, NY

Ideagen, a UK-based software firm, has launched its rebranded collaborative document coauthoring, review, and redaction software, Ideagen PleaseReview.

PleaseReview is software as a service providing a browser-based platform that allows a team of owners, authors, and reviewers (from 2 to 200) to work on a document from start to finish in an audit-ready environment. The main selling point of such a system is the potential to create higher quality documents on a shorter timeline.

PleaseReview enables simultaneous parallel and offline review and coauthoring by multiple participants, wherever they are located, whether internal or external to the sponsoring organization. All accepted comments and changes are automatically incorporated into the master document, removing the need to copy and paste. Collaborating within a single document provides an efficient and transparent process that can reduce costs associated with document review.

Collaborators can participate in discussion threads about edits, redact content, and navigate documents by comments or mentions. The software provides version control and a reconciliation report (available in Word, Excel, or the browser) that captures changes throughout the document's lifecycle. Owners have a dashboard for tracking the review process (see YouTube video), and they can customize the emails sent out to reviewers asking them to review a document. PleaseReview can be integrated with Veeva Vault, Oracle, Documentum, or other content management systems, and reviewers do not need to be users of those systems. For those working on a document offline, the edited document can be uploaded once the user is back online.

Features of PleaseReview include the ability to

- handle Word, Excel, PowerPoint, PDF, images, and more,
- provide secure document access anywhere, anytime from multiple devices,
- ensure full document version control,
- coauthor, edit, and review in real time,
- maintain total configurability of the permissions and capabilities of all contributors,
- have automated progress tracking and reminders,
- review documents in their original format,
- automatically capture comments, suggested changes, and discussion threads,
- control access and visibility of documents and sections,
- categorize redactions according to type,
- automatically generate justification reports,
- integrate with leading quality management systems, such as Q-Pulse,
- categorize comments for a more structured review process, and
- set up review templates to speed up review creation.

For medical communicators, perhaps the main advantages center on version control and collaborative editing and commenting. Ideagen claims an average time savings of 65% in content collaboration process, with review costs cut by 35% by reducing document collaboration time.

***Author declaration and disclosures:*** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

*Please note that author Kelly Schrank has not used this software but attended a product information session presented at the 2023 AMWA Conference.*

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AMWA NEWS

# FROM THE PRESIDENT

## It's Summer!

**R. Michelle Sauer, PhD, ELS** / 2023-2024 AMWA President

As I write this column, I'm reminded of "In Summer"—the quintessential ballad of an adorable snowman singing about the joys of a season that is, in fact, deadly to him. My children love to watch Frozen, and I can't help but hum along as Olaf identifies all of the wonderful elements of the season. I live in southern Texas; thus, my summers are scorching. As soon as I saw May on the calendar, I remembered that summer is NOT my favorite season.

However, I find myself looking for *glimmers* as the thermostat is rising. Although *triggers* are events that bring negative feelings, *glimmers* are events that bring hope, joy, or contentment. One glimmer is that registration for the 2024 Medical Writing & Communication Conference will be opening soon. As I reviewed the initial lineup of open sessions, I was energized and hopeful. Once again, the Annual Conference Committee had the tough job of selecting content from a wealth of strong session applications. The breadth of the medical communication field continues to grow, but as you look at the program, I know you will find content that is not only vital to your career but is also timely. Technology sessions were a huge hit last year, and we listened to member feedback. We made sure those sessions had minimal conflicts, and I cannot wait to see the new advancements and learn alongside you this year.

Another glimmer appears as I see the new diversity, equity, and inclusion (DEI) page on the AMWA website. The Board of Directors (BOD) has dedicated time and resources to ensure that AMWA works in a proactive fashion to deliver resources to our members. In April, the BOD approved a strategic plan for DEI initiatives that builds upon previous work. For this plan to succeed, AMWA will need your help. Please continue to let us know how we improve. We had a robust response to the membership survey that was sent in early 2024, and we are currently using that data to build our future plans and our budget. The BOD also approved the formation of a DEI Committee. I look forward to overseeing the formation of this new committee and the work that will be done to ensure that AMWA becomes an even more welcoming environment and fosters a sense of belonging for all medical communication professionals at the national and chapter levels.

Speaking of local chapters, I thoroughly enjoyed my local Southwest Chapter's Regional Conference this past April. I am so grateful for the time and effort of all of our local chapter leaders. Your dedication and generosity enable wonderful regional events that provide networking opportunities, timely education, and laughter. For those who can, I highly encourage you to get involved in your local chapters. There is always a need for someone to aid in the organization of a local or regional event or to assist with administrative tasks. Chapters provide such value, but they do require work. By working together, great things can happen. Many of the great ideas brought to the national level are inspired and fostered by the chapter "laboratories." I am so grateful to and inspired by all of the chapter leaders of our organization. As I have met with you and read your chapter reports, I continue to learn and can't wait to see what is next.

While progress and work are important, so is rest. It is summertime, so I hope you have some fun planned, too. I am looking forward to my week in August when I leave my cell phone and computer behind. It's a week of disconnection, and it truly helps me reset. I will be with the ones I love and enjoying some sand and sea. The first time I did a week without technology enabled a learning curve. The second time I escaped, I had better backup plans to reduce any "emergency interruptions." And, having done this twice before, I am assured that the world will indeed keep spinning even if I am not working. I will return with great memories, a tan, and a mindset that will prepare me for the next challenges, whatever they may be.

So in closing, I hope you have had a wonderful spring and find your glimmers outnumber your triggers this summer. Please be sure to reach out to me with any concerns or ideas, as I want to be available and responsive (except for one week in August). Together, we make AMWA stronger.

***Author declaration and disclosures:*** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA NEWS

# 2023 Annual Business Meeting for AMWA Members

## October 28, 2023, 1:07 PM Eastern time

**Kimberly M. Korwek, PhD** / 2022-2023 AMWA Secretary

The 2023 Annual Business Meeting was called to order on October 28 by Dr Elise Eller, President. Dr Eller provided a highlight of the accomplishments of the organization over the past year. Membership in AMWA continues to grow. The organization met its strategic goals thorough various accomplishments such as the Value of Medical Writing initiatives; diversity, equity, and inclusion initiatives; establishment of the Health Communication Curriculum Development Task Force; and initiation of the Apprenticeship Program Framework initiative. Dr Eller also expressed her gratitude to the Board of Directors (BOD), committee and task force members, volunteer leaders, and staff for their dedication and service to AMWA over the past year.

Dr Julie Phelan, treasurer, presented the financial report for the fiscal period of July 1, 2022, to June 30, 2023. The organization continues to be in an excellent financial position.

Dr Eller presented the slate of officers for the 2023-2024 AMWA BOD. In accordance with AMWA bylaws, this slate of officers was presented by the Nominating Committee to the AMWA BOD for approval. Membership was notified of this slate 60 days before the annual meeting. The AMWA bylaws contain a provision for additional nominations to be made in writing; no additional nominations were received. Nominees who are unopposed are elected automatically at the annual business meeting. Dr Eller declared the following slate to be the elected officers for 2023-2024, led by R. Michelle Sauer Gehring, PhD, who as President-Elect automatically assumes the office of President:

- President-Elect: Shawn Watson, PharmD, PhD, BCPS
- Secretary: Kimberly Korwek, PhD
- Treasurer: Julie Phelan, MD, MBA

Dr Eller passed the gavel to Dr Sauer Gehring to assume the office of President. Dr Sauer Gehring thanked Dr Eller for her leadership over the past year and provided highlights of her inaugural address. Dr Sauer Gehring introduced the 2023-2024 AMWA BOD:

### Officers

- Immediate Past President: Elise Eller, PhD
- President-Elect: Shawn Watson, PharmD, PhD, BCPS
- Secretary: Kim Korwek, PhD
- Treasurer: Julie Phelan, MD, MBA

### Chapter Advisory Council Chair

- Erik MacLaren, PhD

### At-Large Directors

- Joan Affleck, MA, MBA
- Katrina Burton, BS
- J. Kelly Byram, MS, MBA, ELS
- Sarah Dobney, MPH
- Jen Minarcik, MS
- JoAnna Pendergrass, DVM
- Genevieve Walker, PhD
- Qing Zhou, PhD

**2023-2024 Executive Committee.** From left: Elise Eller, Julie Phelan, Shawn Watson, Susan Krug, Kimberly M. Korwek, and R. Michelle Sauer Gehring.


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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

AMWA NEWS

# The Fifth Annual AMWA Executives Forum: Advances in Technology and the Future of Medical Writing

**Shiri Diskin, PhD[1]; Lisa Chamberlain James, PhD[2]; Aubri Charboneau, MSCR, PharmD, PhD[3]; and Daniel Wood, PhD[4] /** [1]Bioforum Group Ness, Ziona, Israel; [2]Trilogy Writing and Consulting, Cambridge, UK; [3]Jazz Pharmaceuticals, Inc, Chesterfield, VA; [4]CSL Behring, King of Prussia, PA

The Fifth Annual Executives Forum of the American Medical Writing Association (AMWA) was held on October 25, 2023, in Baltimore, Maryland, as part of the AMWA Annual Conference. The forum brought together leaders in medical writing departments from companies across the industry to enhance communication, share information and views, and formulate goals for the medical writing profession. Representatives from pharmaceutical companies, clinical research organizations, and specialized medical writing companies were present (Table 1). The forum was facilitated by Jenni Pickett, PhD, and headed by Julia Cooper, PhD, the head of the AMWA Executives Forum Committee. Breakout discussions were organized by Karen Rutkowski, PhD.

**Table 1.** List of Companies Represented at the Fifth Annual Executives Forum of the American Medical Writing Association

| | |
|---|---|
| ALK | Merck & Co, Inc |
| Amgen | Organon |
| Avidity Biosciences | Otsuka |
| BeiGene | PAREXEL |
| Bioforum | Pfizer |
| Bristol Myers Squibb | ProPharma Group |
| Certara | Regeneron Pharmaceuticals, Inc |
| CSL Behring | RRD International, LLC, Inc |
| Genmab | Synterex, Inc |
| Gilead Sciences, Inc | Syros Pharmaceuticals |
| GSK | Takeda |
| ICONplc | TFS Healthcare |
| Incyte | Trilogy Writing & Consulting |
| Johnson & Johnson | Whitsell Innovations, Inc |
| Jazz Pharmaceuticals | Zentalis Pharmaceuticals |

The forum's discussion topic was advances in technology and the future of medical writing. The forum aimed to identify ways to enhance the value of medical writers (MWs) and position them as innovative leaders using technology to develop medical and regulatory communication. The forum began with a presentation of the results of a survey conducted in 2023 that gathered information on the use of technology in medical writing departments. The survey results were reported by Rutkowski et al.[1] The core activity of the forum was small group discussions, each focusing on 1 of 5 key topics, including how AMWA could support the use of technology for MWs, what tools and training MWs and MW leaders may need, and whether rules need to be established to protect writer roles. The forum also addressed concerns about companies taking risks in content reproducibility or in verifying the accuracy of outputs when utilizing assistive authoring to generate content. Finally, the forum discussed the possibility of future meetings to discuss specific aspects of technology. In this article, we present the main points raised by forum attendees.

## CORE TOPICS

**Topic 1: How do medical writers retain their value in the face of advancing technology that may appear to make at least some aspects of their job unnecessary?**

Because change is inevitable, it is important to try to embrace the changes that are coming and for MWs and MW leaders to try to set a positive tone. Advances in technology will not make the role of the MW redundant; a good analogy can be taken from the world of aviation—autopilot technology is standard but has not removed the need for a human pilot. In the same way, advanced technology could help with the more mundane medical writing aspects and tasks, such as pulling together information for a first draft of a document.

Advanced technology has inherent limitations; for example, the current tools cannot understand nuances across documents. A human-in-the-loop (eg, a content strategist) is still very much needed in the process to ensure that data sources and tools are consistently monitored/controlled. This will create specific educational needs for MWs, as discussed below.


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There is no doubt that the role of MWs is evolving, and each process will need to be refined by individual working teams, with an assessment of the implications of choosing different paths and ways of working.

**Topic 2: How do we want technology to enhance the role of the medical writer? Is there an opportunity to use technology to enhance document content quality?**

Although there are already some tools that can support the role of the MW (eg, PerfectIt can help to produce a document that is compliant with a style guide), advanced technologies under development are expected to be able to go much further. However, the human-in-the-loop necessity (discussed above) means that advanced technologies should focus on providing a good first draft, with the required content drawn from various sources of 100% verified data and company-specific formatting requirements. MWs who start their work from a well-crafted initial draft will be more efficient and able to concentrate on the document's content rather than allocating time for data verification, formatting, and style guide adjustments. Advanced technology will not eliminate the writer but rather enhance the role of the writer as the content strategist.

In the new era of writing with advanced technologies, quality control (QC) becomes imperative to ensure accuracy, coherence, relevance, and appropriateness. This involves not only standard grammar and syntax checks but also verification that advanced technology-generated content is free of inaccuracies and false perceptions (referred to as "hallucinations"), ensuring a fusion of human and automated writing to maintain the highest standards of quality and reliability in written communication. Advanced technologies should include an option that discloses the source of extracted information. This enhancement would increase the tool's reliability and provide reassurance for stakeholders. Such transparency may reduce the need for extensive QC measures and minimize minor routine project management tasks, such as emailing preidentified reviewers for section-specific reviews.

In considering any positive aspects of an advanced technology, it is prudent to consider current concerns and aspects that MWs would not find helpful. Assigning mathematical tasks to automated systems might be straightforward, but for MWs, it is not advantageous to have advanced technology recalculate or conduct additional analyses. It is unacceptable for any tool to be "creative"—to add fictitious references/citations or generate output that is inconsistent with the input data, or any other information, such as "hallucinations." This emphasizes the need for review cycles and humans-in-the-loop, and the importance of leaving any conclusions and nuances of regulatory interactions or contextualization to the MW. However, given the caveats described, there is an opportunity to use technology to enhance document content quality. Advanced technologies are excellent at summarizing and condensing both data and information. Manual errors become nonexistent in parts/sections not written by a human, minimizing human error. Therefore, the need for data verification in QC can be reduced by using validated tables, leading to QC evolving in the direction of greater content- and context-related responsibility.

This shift would allow MWs to focus on key aspects of content contextualization, critical thinking, and document strategy. In the not-too-distant future, QC reviewers may assume responsibility for evaluating context and meaning, using more advanced tools and techniques to assess the accuracy, consistency, and relevance of the content.

**Topic 3: What types/specialties within medical writing will be most affected by technological advancements in the next 1 to 5 years?**

All existing medical writing–related roles, including writers, managers, leaders, document formatting specialists, and quality function roles, will be expected to adapt to new technological innovations. To facilitate the implementation, use, and maintenance of new technologies, new roles will need to be created and roles that are typically not associated with medical writing will find increased connectivity. Change will take time, but the uptake of new technology is rapid and ongoing, particularly within larger organizations. In contrast, smaller companies may experience more challenges in immediate adoption due to budget constraints or other resource limitations. Managing multiple iterations of technologies and processes could pose difficulties for smaller companies and clinical research organizations. Consequently, smaller companies may have to resort to working on client-provided platforms, using tools acquired by clients.

It will be incumbent upon medical writing leaders to manage expectations associated with the financial and time requirements needed to appropriately configure and maintain new tools. In some cases, these commitments may be significant. As elaborated below, upcoming innovations will demand enhanced soft skills such as project management, communication, and problem-solving. Effective communication with corporate leadership regarding return on investment, risk management, and alignment with organizational objectives will be critical. In addition to "managing up," medical writing leaders will also need to be mindful of the needs of their writing and document formatting teams. Managing potential pitfalls of implementation and uptake of new technologies will be key to fully capitalizing on the advantages they will bring. Implementing change

management strategies will contribute to ensuring a smoother transition to the new normal. This resonates with the insights shared below, emphasizing the importance of understanding document content structure, organization, and cross-document content strategy.

New roles with a technical focus will be needed to oversee the set-up of emerging tools and systems, ensuring compatibility with each other as well as with existing platforms such as clinical/safety databases and clinical trial management systems. Maximizing the value of new technologies will be facilitated by the seamless integration and compatibility of systems. Postimplementation troubleshooting will also need to be a key aspect of technical support. Success in these roles will require a balance between understanding medical writing requirements and the ability to liaise with the information technology department to effectively address inevitable technical challenges.

Content strategists and content architect roles could take responsibility for the creation/management of content that can be easily adapted and updated for different platforms, formats, and audiences. These roles will be needed to monitor and evaluate the system performance and quality of the content that is generated and to work with technical leads to make the appropriate adjustments and improvements. To ensure reproducibility and consistency of content across documents, there will be a need to establish and adhere to clear and consistent rules and guidelines for content creation, as discussed above.

Regardless of role, all medical writing professionals will need to be aware of the legal and ethical implications arising from the utilization of output created by advanced technologies. It will be important for everyone to have a broad understanding of how to protect the intellectual property rights of the content owners and how to comply with the regulations and standards of the relevant authorities and organizations.

**Topic 4: What new technologies or tech tools are medical writing leaders considering for their medical writing groups, and are there differences across specialties within medical writing?**

In line with survey results,[1] forum attendees reported that medical writing groups are considering several new technologies and tools to enhance their work. All acknowledged the need to implement technological tools, but several concerns were raised. These were mainly with respect to the use of generative tools, whose outputs need verification and can be subject to hallucinations in writing regulatory documents in the heavily regulated industry. Medical writing leaders are interested in tools that are tested and validated for content reuse and structured content management (SCM). The US Food and Drug Administration is considering rule-based systems as well as generative systems. Currently, medical writing groups are using SCM/structured content authoring systems, automated patient narratives, automated tools to support quality checking (eg, PerfectIt), plagiarism checker software, platforms such as PleaseReview to facilitate and manage review cycles, regulatory information management systems (such as Veeva Vault) to facilitate and manage collaborative authoring and large project workflows (eg, regulatory submissions), and Synchrowrite, a web-based tool that imitates Word but is not impacted by Microsoft technology upgrade pushes. Medical writing groups are considering the adoption of artificial intelligence (AI)–assisted authoring, utilization of advanced technologies for writing narratives, protocols, and clinical study reports, as well as internal authoring through generative pretrained transformers (GPT). These tools are anticipated to generate preliminary drafts, which can then be adapted and revised by MWs, as discussed above.

During the discussion on "wishful thinking," participants contemplated the idea of an advanced technology that harmonizes text across document sections, entire documents in a submission, or even across multiple submissions. Yet, the feasibility of such synchronization remains uncertain. Far from merely ensuring the identity of phrasing (ie, accurate copying), the notion is that harmonization of messaging across document sections or documents with different structures and contexts requires a human-level understanding that large language models are unlikely to attain.

Medical writing groups mostly use the same tools across specialties, with the main differences being the use of literature search-and-summary tools, which have mostly been adopted by MWs in the medical communication sphere, rather than in regulatory writing.

Looking forward, the large differences in the rate and extent of adoption of advanced technology were assumed by attendees to derive from company size.

**Topic 5: Which new skills will medical writers need to acquire to be effective in this technology-enhanced environment?**

MWs are crucial strategic partners in this evolving landscape, requiring new skills for effective collaboration and integration of new technologies in document development.

Strong leadership and communication skills will be critical as medical writing teams evaluate and integrate new technologies into document development workstreams. Medical writing leaders will need to be well acquainted with the concepts of return on investment and risk management (as described above) to share with key stakeholders and manage expectations. Senior-level writers may be required

to take on responsibilities such as developing and implementing advanced technologies, serving as superusers, and providing training to both junior MWs and cross-functional users (ie, good neighbors).

MWs will need to be adept at change management and actively foster continuous learning and improvement as new systems are implemented and iteratively updated over time. As digital champions, MWs will need a keen understanding of the evolving technologies, such as AI generative systems, content reuse, SCM, and internal GPT bots. Digital literacy will be crucial for MW leaders, enabling them to assess the most suitable technology for their company's stage and size, and effectively implement and collaboratively use new authoring technologies. For instance, an MW may need to write prompts for AI systems or bots, providing clear instructions to achieve the best results from the tool.

Strong critical thinking and content logic skills will be necessary for optimal use of new technologies, allowing MWs to holistically plan for standardization and reuse of content across documents as needed for a drug development program and across submissions. This planning extends from the study protocol to the statistical analysis plan, clinical study report, and summary-level documents, leveraging advanced technologies and/or SCM technologies. Collaboration with content owners (subject matter experts) in developing and managing standard content libraries within the new systems will be vital for enhancing document development efficiency.

**Topic 6: How will technological evolution affect the training of medical writers?**

Senior-level writers may need to serve as superusers/digital champions and be responsible for training junior MWs on how to use new technology for authoring documents. As technologies evolve quickly, MWs may require regular refresher training and guidance materials (eg, quick reference cards). Technologically savvy writers may carve out a new role to help develop and implement new systems, support change management, and provide ongoing training for MWs and cross-functional users.

**How can AMWA help?**

MWs have the opportunity to be advocates or champions of change, and organizations/associations like AMWA can actively contribute to this evolving landscape. AMWA has the potential to shape the future of medical writing by defining necessary skills and training MWs, outlining new roles, developing decision trees for advanced technology selection, creating a lexicon, and producing a toolkit to assist MWs in navigating the upcoming changes more smoothly. To support these transitions, AMWA could engage in several initiatives, including collaborating with quality assurance professionals to better define and document best practices for audits of advanced technology-generated content. Additionally, expanding training offerings to cover programming and engineering skills would empower MW professionals to create, edit, and manage content using emerging technologies. Furthermore, AMWA could offer training sessions covering the development of compelling business cases for advanced technology, provide insight into measuring and demonstrating the value and impact of technology, and deliver training on effective communication and persuasion strategies with stakeholders and decision-makers, and alignment of technology with organizational visions and missions. This multifaceted approach would help prepare both individual MWs and MW-focused companies to transition effectively into the new technological advancements.

Considering the multitude of advanced technology already available, AMWA could assist MWs in navigating this landscape in several ways:

- Provide an analysis of all the tools currently available.
- Develop a standard questionnaire for vendors to complete about their tools, including vendor sandboxes to showcase MW use cases for their tools.
- Establish a section on the AMWA website with a portal for vendors to update their information as their tool improves, allowing reviews from the medical writing community.
- Create a toolkit to aid managers in selecting advanced technologies, including tool profiles and comparisons of tools.
- Conduct a benchmarking exercise to determine key regulatory considerations, providing a metric for evaluating different advanced technologies.
- Publish successful business cases in the *AMWA Journal*.

Although some suggestions may not be feasible for AMWA to undertake, there is a clear need to develop training protocols for the evolving role of MWs in the context of advanced technology. Refining soft skills, articulating the benefits of advanced technologies to stakeholders, managing their expectations, and simultaneously honing change management skills and techniques are essential for MWs to thrive in the new era of AI and other advanced technologies. With the right training and skills (Figure 1), MWs will be equipped to become even stronger strategic partners in drug development teams.

## CONCLUSIONS

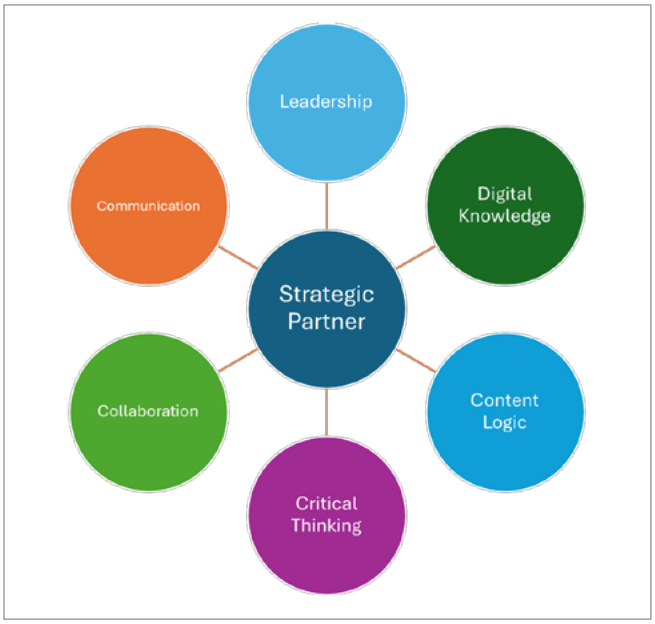


**Figure 1.** Key skills for a medical writer to be a successful strategic partner in a technology-enhanced environment.

Technological advancements are imminent and will undoubtedly affect the profession of medical writing. Far from being a threat, the upcoming changes should be viewed as an opportunity for the evolution of the profession. MWs—highly skilled, educated, and extensively trained professionals—are often underutilized by performing routine tasks such as accurate copying of materials from sources and document formatting. The careful adoption of appropriate tools can shift the balance, reducing the time and effort spent on tedious tasks and allowing a greater focus on document strategy and message formulation.

To allow for successful integration of such tools, leaders will have to adopt a positive approach and hone the training and capabilities of future generations of MWs. Beyond the current set of required skills (knowledge of regulations, scientific understanding, various soft skills), a senior writer will have to hone their critical thinking and appraisal skills, be an expert user, and even be a contributor to the development of sophisticated technological writing tools. AMWA can assume a facilitating role in the responsible and effective adoption of advanced technologies by MWs through advocacy and education activities.

**Acknowledgment**

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**Reference**

1. Rutkowski K, Shapiro K, Sheppard L. Understanding the impact of technology on medical writing: AMWA survey results from June 2023. *AMWA J.* 2024;39(1):56-59. doi:10.55752/amwa.2024.331

AMWA JOURNAL V39 N2 / 2024


# Innovate, Inform, and Inspire: Jazz Up Medical Communication

**Michele W. Sequeira, MS, MBA, MWC** / 2024 Annual Conference Committee Chair

Don your Mardi Gras colors—purple, green, and gold—to get ready for the AMWA 2024 Medical Writing & Communication Conference in New Orleans, Louisiana, October 23 through 26. The Annual Conference Planning Committee, AMWA Staff, and many, many contributors have been working hard to deliver a great conference in the Big Easy.

## A JAZZY SELECTION OF EDUCATIONAL OPPORTUNITIES

The Annual Conference Planning Committee reviewed more than 120 proposals (60% more than last year) for educational sessions. We'll have another packed schedule this year with room for only about 50 sessions.

The Committee read, evaluated, and discussed more than 90 thoughtful and well-written proposals for educational sessions. We could accept only 50 of them, and we're thrilled with the ones we selected. We think attendees will be, too!

The program will have sessions for beginners, mid-career, and experienced medical communicators. The Committee made every effort to match the session content to the areas that AMWA members need:

- ✦ Core Knowledge and Skills
- ✦ Regulatory Writing
- ✦ Health Communication
- ✦ Career Development
- ✦ Scientific Publications
- ✦ Freelancing
- ✦ And more!

In addition to the educational sessions, we'll have more than 18 workshops for deeper dives into specific topics relevant to medical communicators.

This year, we needed to innovate: because New Orleans is a popular place, our conference schedule will be adjusted slightly. Our general sessions will move to Friday and Saturday and will feature terrific speakers, so attendees should plan to stay until the end.

Like previous conferences, though, most workshops will be held on Wednesday, the preconference day, to minimize conflicts with the sessions. Posters offer additional topics for learning and allow space for networking, too. And, of course, the schedule will allow time for networking, light snacks, and break time to keep attendees rested and refreshed.

The Annual Conference offers roundtables to give attendees the opportunity to simultaneously learn and network. This year's conference will be no different; we are planning to offer several informational and participatory roundtables.

Feedback from previous conferences suggested adding technology showcases to learn about the latest technology and tools, and last year's showcases were a success. This year again, these presentations will offer a chance to learn more about the products and services some of the sponsors offer, see demonstrations of their tools, and perhaps even take some for a test drive.

## PLAN YOUR TRIP NOW

New Orleans is one of the most iconic American cities, so get inspired to make your travel arrangements early. Book your room as soon as possible at the New Orleans Marriott Hotel to take advantage of the early bird discount. Visit the AMWA website to learn more.

And don't forget to reserve some time to visit the attractions, sample the food, and take in the historic sites of the Big Easy. Our conference schedule will allow some time to visit the city, but you'll probably want more!
I look forward to seeing you at the conference.

***Author declaration and disclosures:*** *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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## CALENDAR OF MEETINGS


**The International Society of Managing and Technical Editors**
"ISMTE 2024 North American Conference"
July 16-19, 2024
Pittsburgh, PA
https://www.ismte.org/events/EventDetails.aspx?id=1831378

**Asian Council of Science Editors**
"ACSE 2024"
August 18, 2024
Dubai, United Arab Emirates
https://theacse.com/2024/

**Academy of Communication in Healthcare / European Association for Communication in Healthcare**
"International Conference on Communication in Healthcare – ICCH 2024"
September 9-13, 2024
Zaragoza, Spain
https://each.international/eachevents/conferences/icch-2024/

**ACES: The Society for Editing**
"VCON24"
September 25-27, 2024
Virtual
https://aceseditors.org/conference

**Society of Clinical Research Associates**
"2024 Annual Conference"
September 27-29, 2024
Las Vegas, NV
https://www.socra.org/annual-conference/2024/2024-annual-conference-information/

**Council for Programs in Technical and Scientific Communication**
"2024 CPTSC 50th Annual Conference"
October 18-19, 2024
Menomonie, WI
https://conference.cptsc.org/

**American Medical Writers Association**
"2024 Medical Writing & Communication Conference"
October 23-26, 2024
New Orleans, LA
https://www.amwa.org/event/2024annualconf

**American Public Health Association**
"APHA 2024 Annual Meeting & Expo"
October 27-30, 2024
Minneapolis, MN
https://www.apha.org/events-and-meetings/annual

**National Association of Science Writers**
"ScienceWriters2024"
November 8-11, 2024
Raleigh, NC
https://www.nasw.org/events/nasw-science-writers-national-conference-sciwri24-annual-meeting-2024-raleigh-north-carolina


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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V39 N2 / 2024

THEME ARTICLE

# Communicating About and With Artificial Intelligence Applications

**J. Kelly Byram, MS, MBA, ELS** / Founder and CEO, Duke City Consulting, LLC, Albuquerque, NM

**Editor's Note**
Developments in artificial intelligence (AI) will continue to be of critical importance to medical communicators for the foreseeable future. Accordingly, *AMWA Journal* expects to continue to feature AI-related articles in upcoming issues.

Given how rapidly advancements are occurring in AI as they relate to medical communication, we are striving to be as timely as possible in bringing relevant articles to you. In this spirit, we are supplementing the Summer 2024 *Digital Revolution* theme issue with a timely article titled 'Communicating About and With Artificial Intelligence Applications' by J. Kelly Byram, based on a presentation made by the author at the most recent AMWA Medical Writing & Communication Conference.

This session provided attendees with an overview of the elements of artificial intelligence (AI) that medical communication professionals can use in their decision-making when communicating about and with AI applications. Knowing how to determine if an AI application is reliable and secure guides the professional in their assessment of applications they write about and their choice of applications they use in their practice. In turn, this ability to assess AI applications underpins professionals' abilities to identify and apply best practices for developing and writing about AI. Taken together, this understanding of how AI works, how applications are developed, and how to identify and ethically apply best practices will guide professionals in their communication about and with AI applications.

## AI FUNDAMENTALS

The field of AI emerged in the early 1940s, and one touchstone of the field, the Turing test of machine intelligence (designed to determine if a machine can think like a human)[1] dates to 1950. Although initially considered a single field of research, in the intervening decades, researchers have split the study of AI across multiple domains involving myriad disciplines. As a result, AI is defined many ways, but 2 particularly salient definitions are (1) a machine performing a task requiring human intelligence and (2) a machine replicating human intelligence. Both definitions, like the Turing test, evaluate AI in the context of human intelligence (including behavior); however, the AI applications that have been developed thus far lack human traits, such as empathy and creativity, and human reasoning in the frameworks of ethics and complex strategy.

### Machine Learning

Machine learning (ML) underpins many of the AI applications that medical communicators will communicate about and with. Patient triage, hospital management, and imaging applications approved by the US Food and Drug Administration use ML. What makes ML applications different from traditional software applications is that most ML does not use explicit or rule-based programming. In explicit programming, a program gives the computer specific commands or lines of code, that is, the function. ML uses statistical and mathematical modeling and incredible volumes of data to learn relationships between variables, that is, it determines the function. The model learns and refines itself as it ingests and processes data. Some common models used in ML include linear regression, logistic regression, Bayesian algorithms, and decision trees.[2]

### Deep Learning and Generative Pretrained Transformer Applications

Deep learning (DL), a type of ML that uses an artificial neural network modeled on the human brain and designed to emulate human processing, uses layers of connected nodes that process information and pass the transformed data up to the next layer. It learns from itself and can create new features on its own. It can learn nonlinear, high-dimensional relationships from data that are not just unstructured but multimodal. Throw it all in the mix—imaging, biometrics, audio, visual, and time series data. DL applications include target validation, identification of prognostic biomarkers, analysis of digital pathology CT data, and generative pretrained transformer applications (GPTs).

* This article is based on the presentation Communicating About and With Artificial Intelligence Applications by J. Kelly Byram, MS, MBA, ELS, at AMWA's 2023 Medical Writing & Communication Conference.


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Because DL creates its own algorithms, the models and applications created by DL can lack transparency. This black box effect enhances a distrust of AI in many population segments, and 60% of Americans overall indicated discomfort with the use of AI in their care.[3] It can help to keep this discomfort front of mind when writing for lay audiences.

State of the Science

We typically divide AI into 2 categories: weak and strong (Figure 1). Weak AI is what we have today—systems or machines that have learned how to perform specific tasks in a way similar to how a human would perform the task. Some systems display human intelligence; that is, they have the ability to learn and solve some types of problems, but not all.[4] Although today the mention of AI elicits discussion of GPT applications such as ChatGPT, AI has been a part of the knowledge professional's workflow for so long that it has been taken for granted as the power behind search engines, spam filters, and smart assistants such as Siri and Alexa. Strong AI, or sentience, is the flexible intelligence that can flit from one type of task to another and has advanced reasoning capabilities. HAL from *2001: A Space Odyssey* and Skynet from *Terminator* usually come to mind when discussing this type of AI. Unlike Siri and Alexa, references to HAL and Skynet usually evoke fear and dystopian angst. Depending on one's point of view, strong AI is either an aspirational goal or an existential threat.

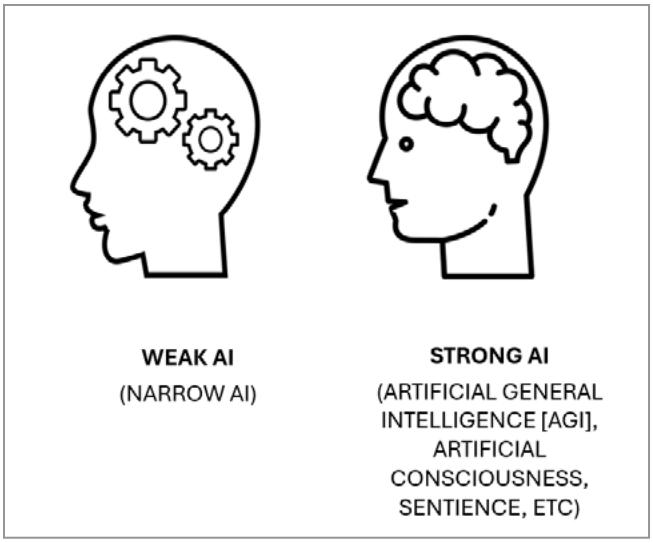


**Figure 1.** AI is typically divided into 2 categories: weak AI and strong AI. Although strong AI is the goal of the AI field, weak AI represents the current state of the science. AI, artificial intelligence.

### AI in Health Care

Three subfields of AI more commonly leveraged in health care research and practice include ML, DL, and large language models (LLMs) as GPT applications. These applications segment images to assist in the identification and segmentation of lesions, identify promising molecules and guide drug development, determine dosage, and assist in genomics and precision medicine, public epidemiology, emergency department triage, and hospital management.[5] Some of these models are standalone software packages, others are slick software-as-a-service applications integrated with electronic health records.

## COMMUNICATING ABOUT AND WITH AI APPLICATIONS

Medical writers and editors who work with AI development teams have been writing proposals for AI projects for years. As these projects come to fruition, more communicators will join the effort and find that the complicated and sometimes obscure methods used to develop AI applications can pose a challenge to effective communication about AI. Although many standard research design concerns (eg, hypothesis, sample size, data quality and representativeness, design rigor, multidisciplinary representativeness of the team, generalizability) also apply to AI model development, communicators must also interrogate designs for AI-specific matters (eg, portability of the model, validation and testing plan, human–AI team required for implementation, maintenance plan to address drift). For AI applications being developed for clinical use, the FDA's *Good Machine Learning Practice for Medical Device Development: Guiding Principles* document[6] provides excellent, clear guidance. Many of the points on their list of guiding principles should be considered in the research design development and proposal writing stages, in addition to the funder's explicit requirements.

When writing about AI-based health care apps, the importance of understanding how researchers develop these applications quickly becomes apparent, but, when writing with AI apps, one may ask why any of the technical aspects of AI matter to the end user. Generative AI applications are, after all, a tool—but every good craftsperson knows their tools. Communicators using generative AI in their practice likewise should understand the tools. In the medical writing and editing practices, this largely means understanding GPTs.

GPTs are a type of LLM. LLMs sit at the intersection of DL and natural language processing, an AI domain specific to teaching machines to understand and generate human language. LLMs use DL techniques applied to enormous data sets. Their objective is to understand and generate text based on what they have learned from the data they have ingested. Although their output sounds human, it is the output of a statistical model, like any other GPT. The text is the algorithm's best statistical prediction of what the next word (and then the next and the next) should be. Unlike earlier AI, like predictive text that suggests a word or brief

phrase, generative AI takes a holistic approach, creating a more complex model that understands the larger context of sentences and paragraphs and can generate paragraphs of cohesive and coherent human-sounding text. Some medical communication products especially suitable for generative AI production include patient education materials, medical guidelines, package inserts, patient-facing chatbots to answer medical questions, patient discharge instructions, and letters (to insurers, employers, etc),[7] and other plain language materials.

### Using Consumer GPTs to Generate Technical Content

Consumer versions of GPTs hit the market big with Dall-E and then ChatGPT in 2022. In the intervening time, the GPT offerings have only multiplied and expanded across tasks, including writing, image generation, programming, and data analysis. Developers train consumer GPTs on the Internet, meaning the GPTs ingest online content, good and bad. Although that is a large amount of data by anyone's standards, a consumer GPT's training is limited to the data to which it had access, including copyrighted material (in violation of copyright laws),[8] but without access to paywalled peer-reviewed content and with training cutoffs that may mean the most recent content is months or years old.† However, high-quality medical communication requires accurate, detailed, and current sources, so the quality of most content generated by consumer GPT applications may not meet those standards, especially for more complicated or technical topics.

The human quality of GPTs' language can cause users to trust the applications' content more than they should. GPTs provide inaccurate and biased information and plagiarize their sources—all issues ethical medical communicators cannot ignore. And, although the human-sounding quality of the content increases the value of GPT-generated content in many contexts, consumer GPTs have a limited ability to generate meaningful technical language.

### Using Proprietary or Enterprise Models to Generate Technical Content

To protect intellectual property, including research data and information about a novel technology or design, some companies have implemented proprietary or enterprise purpose-built models, trained on the research corpus specific to their industry and organization. Often these are sparse expert models (<100 billion parameters vs ChatGPT version 3.5's 175 billion parameters), which can be more accurate than larger general models because the data ingested are more specific to the users' needs.

Unlike consumer GPT applications, the models are trained with industry-appropriate information, including paywalled articles, then further trained on the organization's data. Data ingested by private generative models are only available to members of the organization. But, like consumer GPT applications, the tendency of the technology to prevaricate, hallucinate, and plagiarize persists in these models, too.

## CONCLUSION

Regardless of the type of AI application being used, whether it is an application for analyzing imaging or one for generating content for a patient education website, current AI applications are imperfect tools for our use. These tools augment human productivity, intelligence, and creativity if used strategically and well, which will result in a shrinking of the workforce.[9] As Erik Brynjolfsson, director of the Stanford Digital Economy Lab, summarized the situation for knowledge workers, "I think if done right, it's not going to be AI replacing lawyers. It's going to be lawyers working with AI replacing lawyers who don't work with AI."[10] Similar to earlier industrial revolutions, the Fourth Industrial Revolution brings technologies that will displace workers who perform work that new technologies can do faster and cheaper. But teams will always have a need for communicators with domain expertise or other exceptional skills who ethically and effectively use these tools in their practice.

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†After this presentation last year, more consumer GPTs have introduced real-time web search functionality. In practical terms, a GPT with real-time search capabilities may have been trained through September 2021, for example, but it can search the internet for information in real time. For many casual users employing a consumer GPT with real-time search functionality, the training date of the GPT has become a distinction without a difference.

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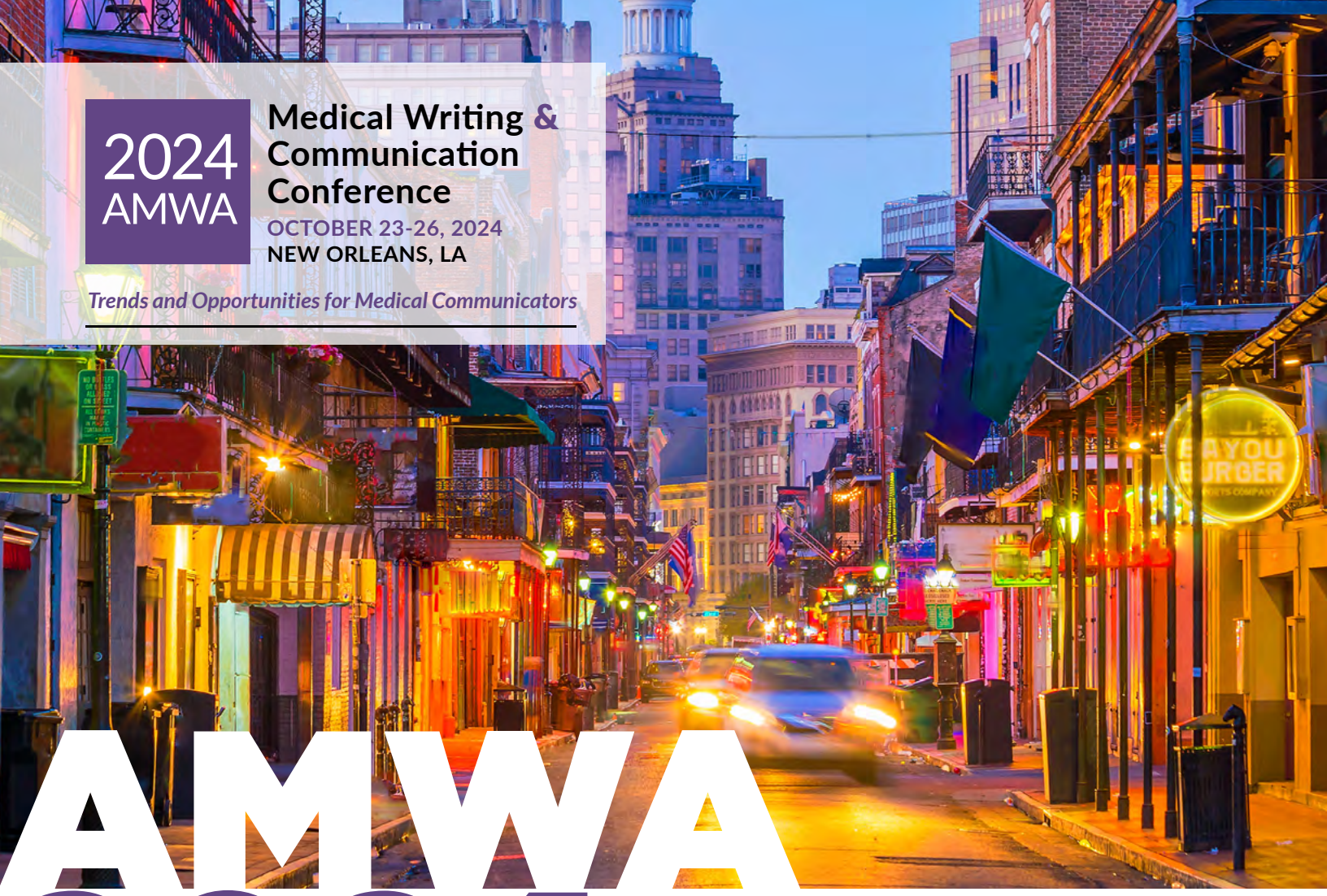

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