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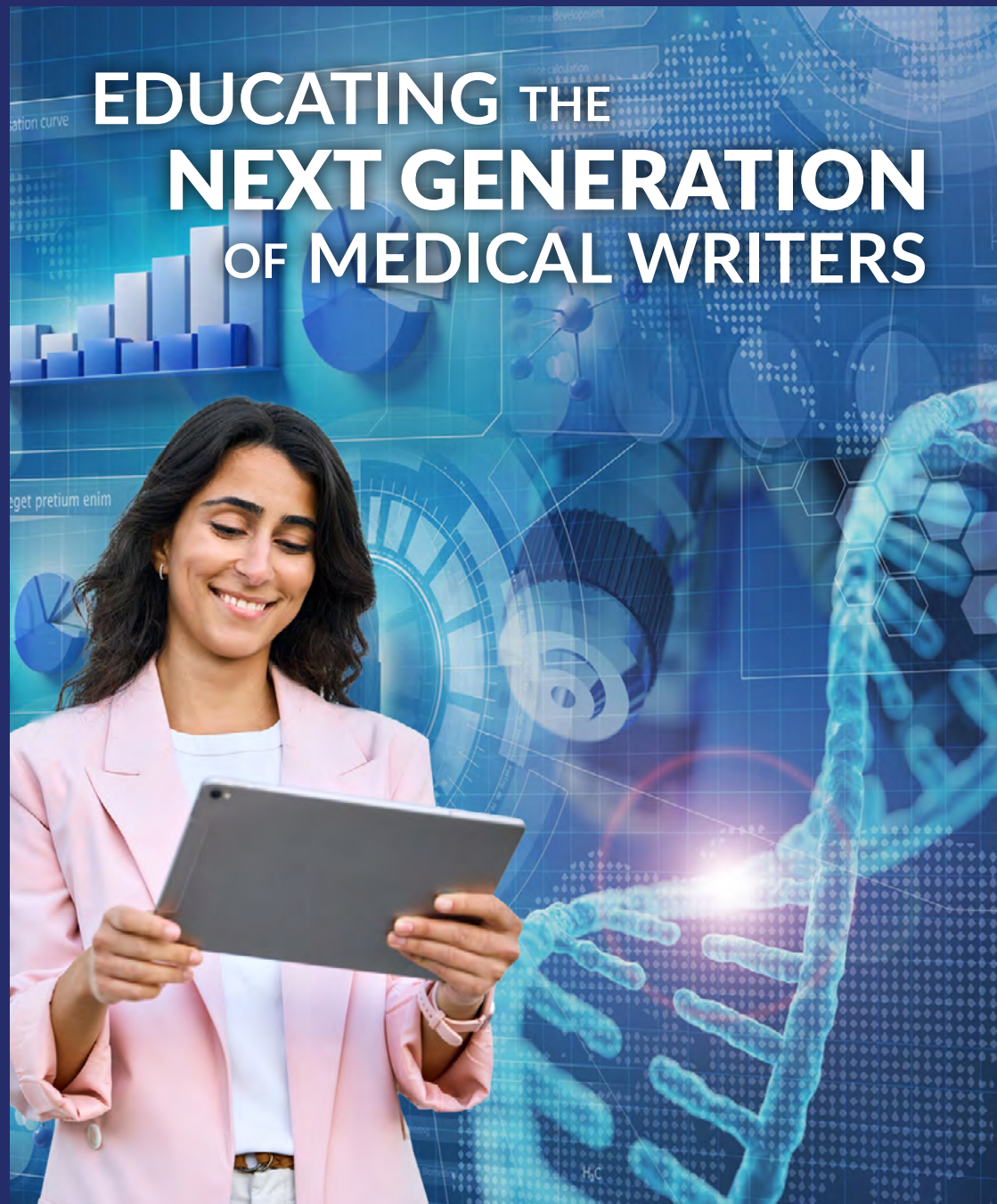
THEME ARTICLES

The Call of the Open Road: Is Medical Writing Right for You?

Training the Medical Writers of the Future Using a Structured Entry-Level Program: A Life Sciences Communications Agency Perspective

TECHNOLOGY TALK

Is the Hype Real? Real-Life User Experience of an Artificial Intelligence Tool for Clinical Study Report Production



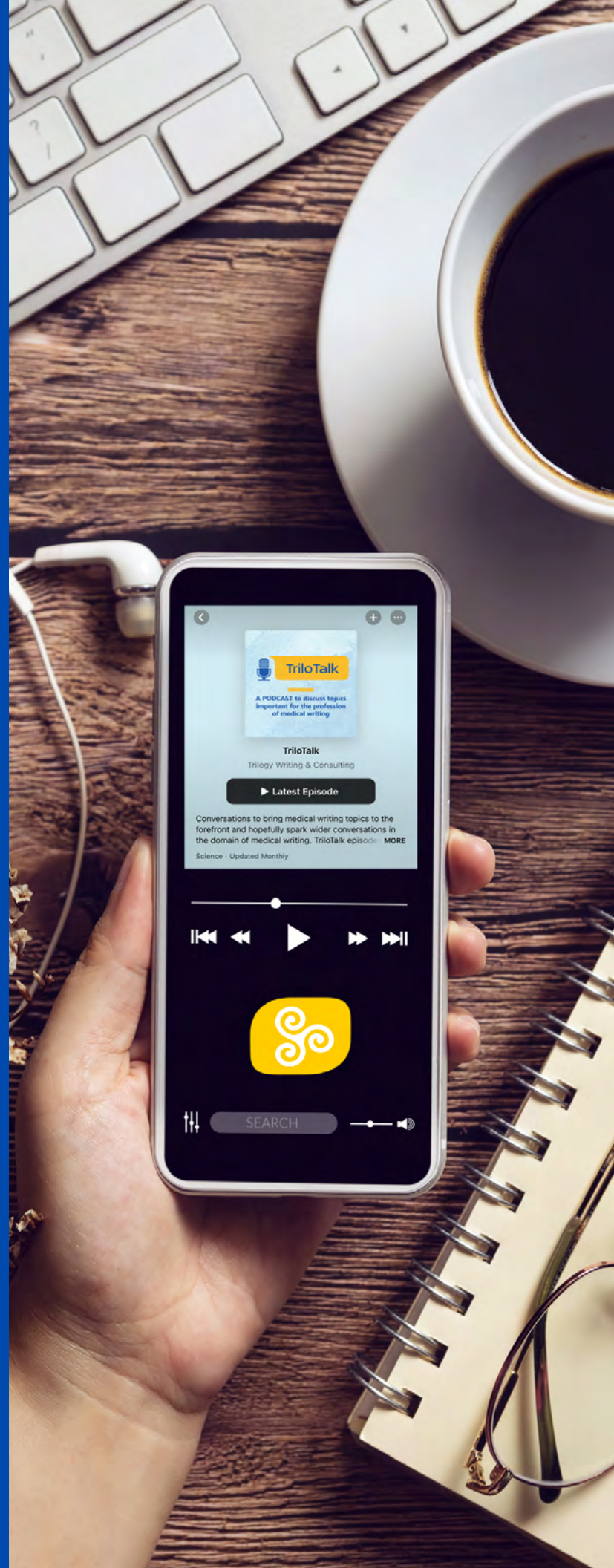
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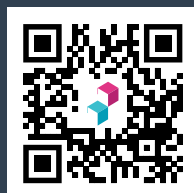
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FROM THE GUEST EDITOR



Cultivating Passion and Curiosity in Medical Writers: The Need for Dynamic and Agile Training Programs

Angela Russell Winnier, PhD / Senior Director of Medical Writing for Pfizer, The Woodlands, TX

My journey in writing began in 1999 as a science communicator right after grad school, before moving to regulatory writing in 2005 with minimal formal training. Early on, I was handed the ICH E3 guidance for clinical study reports and had to navigate through it on my own. My tasks varied daily, ranging from clinical data reporting to understanding submission procedures, including physically preparing documents for US Food and Drug Administration submission—the blue pronged folders are memorable. Fortunately, today's training resources and electronic submissions make the process much smoother.

When I interview new candidates, they often ask what I view as the key differentiators for top performing writers. Without hesitation, passion, curiosity, and agility. Love WHY we write, and embrace WHY we adapt. Medical writing is a dynamic and rewarding profession after all. We learn something new almost daily by navigating new therapeutic areas, emerging technologies, and evolving regulations and guidelines. We are invigorated by these challenges because we know our words matter to our patients. Our work is critical for advancing medical science and improving public health.

Over the last 20 years, the medical writing profession has evolved significantly as the industry has become more globalized, competitive, and regulated. Medical writers face an increasing volume and complexity of data, collaboration with mostly virtual stakeholders, and evolving advances in science and technology. Their training and professional growth needs are also increasing. Those of us trusted with their development need to consider the vast diversity of beneficial training topics (ranging from soft skills for matrix leadership to stakeholder management to generative artificial intelligence prompt engineering)—all while creating an environment that fosters curiosity, rewards agility, and remains driven by patient care.

In this issue, we explore how we foster a medical writer's career, from finding the right candidate, to providing education and training, to encouraging career progression and professional development. We aim for our training programs to be adaptable, mirroring the adaptability we expect from our writers as they encounter changing demands and challenges. We hope you are curious to learn more about the predictable characteristics of a candidate who finds joy in this role and the kinds of training approaches to nurture them at different stages of professional growth.

THEME ARTICLE

Advantages and Applicability of a Master Class Series as a Training Model for Mid-Career Medical Writers: Our Experience From the Perspectives of the Manager, Trainer, and Participants

Andriana Papaconstantinou, MSc, PhD¹; Anne McDonough, MPH²; Luba Binshtok, MScMed, PhD³ / ¹Senior Director, Medical Writing, Bioforum the Data Masters, Athens, Greece; ²Independent Medical Writer & Clinical Research Consultant, Newark-on-Trent, United Kingdom; ³Senior Medical Writer, Bioforum the Data Masters, Ness Ziona, Israel

ABSTRACT

Advancement of mid-career medical writers (MWs) to senior levels requires augmentation beyond the traditional training provided to MWs at all levels. In response to this need, online training and classes taught by more experienced writers in-house, external lecturers, or a mixture of both delivered through didactic presentations should be supplemented with methods that allow for interaction between the trainer and trainees and for a tailored approach.

We therefore designed an interactive, engaging, and dynamic training model that would draw on varied perspectives of colleagues. This Master Class Series was led by an external instructor and was based on a structured critique of regulatory document organization, content, and style. In this article, we share our experience from the perspectives of manager, trainer, and participant.

The Master Class Series was successful in part because of its dynamic content. The participants felt that this training greatly improved their understanding of the broader contexts in which documents are used and their ability to develop coherent documents. Participants further felt that their ability to implement a top-down approach in strategy documents and in applying lean writing principles was enhanced. They all agreed that they greatly benefit from exposure to each other's creativity in solving challenges in data and content presentation and concurred that it is very likely that they would sign up for a course with a similar model in the future. Our experience indicates that a Master Class Series is essential to the training of mid-career MWs.

engaging, and dynamic training model that draws on the varied perspectives of their colleagues was needed. With this goal, we developed a Master Class Series based on a structured critique of regulatory document organization, content, and style. In this article, we share our experience from the perspectives of the manager (AP), trainer (AM), and participant (LB).¹

THE MANAGER'S PERSPECTIVE: WHY WAS MASTER CLASS SERIES FOR MID-CAREER MWS NEEDED?

Hiring mid-career MWs presents various challenges, the greatest of which is the limited pool of experienced MWs looking for a position. Most companies prefer to invest in growth from within because the MW's skills are acquired on the job. For these reasons, promoting people that already know the company culture and its internal procedures provides a significant advantage. However, the advancement of MWs to senior levels requires augmentation beyond the traditional training provided to writers at all levels.

In response to this need, clinical research organizations and pharmaceutical companies dedicate significant resources to developing structured, high-quality training programs for their MWs. Such training programs include classes taught by more experienced writers in-house, external lecturers, or a mixture of both. Classes are often taught online as single or multiple sessions to large groups of participants who do not necessarily know each other and who have varied backgrounds and experience. Generally, such classes are based on a standard syllabus with limited flexibility to accommodate the needs of the participants that might become apparent during the course. They are

What training format is best suited for instilling in mid-career medical writers (MWs) both the knowledge and the mindset they need to become effective and independent? To move writers upward and forward, an interactive,

¹Initials in parentheses refer to the authors serving these 3 roles in the present manuscript. Hence, reference to "I" in each of the 3 sub-sections to this article refer to AP for the manager's perspective, AM for the trainer's perspective and LB for the participant's perspective.

delivered through didactic presentations with little or no interaction between the trainer and trainees.

As such, this type of training lacks sufficient interactivity and does not allow for learning through participation, engagement, and exposure to others' perspectives—approaches that are well known to have a wealth of advantages. To move senior MWs upward and forward, an interactive, engaging, and dynamic training model that would draw on varied perspectives of colleagues was needed. This is what we set out to accomplish when designing the Master Class Series.

From the managers' perspective, we did not want the participants' experience to be limited to the knowledge of their managers (which they get through other forms of training) nor did we want to take many hours from our project work to develop this Master Class Series. Thus, we chose to invite an external instructor.

The specific goals of this program were to

- provide MWs with the skills and mindset they need to become effective and independent, creating capacity as document leaders,
- enhance their ability to understand and use relevant guidelines,
- develop their holistic perspective of documents in the context of the sponsor's regulatory strategy, and
- help them identify the proper target audiences for each document and write the documents with those audiences in mind.

THE TRAINER'S PERSPECTIVE: HOW DID I DEVELOP AND CONDUCT THE MASTER CLASS SERIES?

I was excited about developing this Master Class Series for mid-career regulatory MWs. My experience delivering half-day and two-day workshops had provoked an interest in working with a small group of MWs over a longer period. I thought that leading a structured critique of their own documents and documents written by their peers was the best method to address the needs of MWs at this stage in their careers. Collaborating on this Master Class Series gave me an opportunity to test this proposition.

I began by conducting a needs assessment. The MW managers and I discussed the skills that they felt these newly promoted MWs could improve. I also proposed qualities and practices that I believe define good regulatory writing.

The managers and I decided on a series of two-hour classes, starting with an introductory session. Each of the four subsequent sessions focused on the review of a single document. The managers felt that 1 session per month was the best timing to keep the participants engaged and focused without detracting from their job responsibilities.

It also gave them enough time to prepare for each session and to incorporate what they learned into their everyday writing.

Over the five sessions, three themes that emerged in the needs assessment were addressed: style, document organization and content, and strategic leadership. In the introductory session, I led a discussion of the guiding questions for this Master Class Series:

- What makes an MW senior?
- How does a senior MW differ from a junior MW?

Or translated to a more practical level,

- What did you not do before that you do now?
- What did you use to do that you don't do now?

Answering these questions led to a lively discussion of all three themes. The introductory session concluded with preparation for the first review session with a few more questions:

- Who are the obvious and not-so-obvious audiences for this document?
- How do these individuals use this document?
- What do they need?

The group ended each document review session with a similar evaluation for the next document type.

Over the four review sessions, the participants and I continued to address the three themes. I designed a structure that enabled us to balance the big picture of documents as long as 100 pages with the finer details of clear, coherent, meaningful writing. The first part was a document review worksheet based on the topics discussed in the introductory session. The worksheet contained 14 questions, including whether the document tells a coherent story and if the key messages are clear. The participants completed this worksheet before each of the review sessions, and I used this same worksheet to prepare myself to lead each session. They also rewrote a short section (one to three pages) of the document, addressing style, content, and organizational issues. They sent me their rewritten sections a few days before the session so that I could lead a discussion of the problems they noted and their solutions.

Discussion of their "homework" inevitably led to brainstorming on how strategic leadership by the MW could prevent and resolve the issues noted. Key skills addressed included meeting planning and conduct, time management, communication, leading the team, and acting as an authority on relevant regulation, guidance, standards, and the needs and expectations of document users.

The Master Class Series was successful in part because of its dynamic content. Teaching mid-career MWs requires a more flexible approach than the static curriculum

appropriate for junior MWs. For example, I noted that many issues raised in the first review session were related to lean writing. Therefore, I started the next session with a short review of the rationale and implementation of these techniques.

THE PARTICIPANTS' PERSPECTIVE: WHAT DID THE MASTER CLASS SERIES DO FOR US?

To capture my fellow participants' experience in a systematic manner, I conducted a survey that solicited their opinions on the Master Class Series and what they learned. The survey comprised 5 open-ended questions and 11 five-level (fully agree, somewhat agree, neither agree nor disagree, somewhat disagree, disagree) questions (Figure 1). The main points are narrated below.

Becoming a senior MW typically requires a number of years in the profession that optimally (but not necessarily) coincide with the accumulated experience in writing regulatory documents. It is also expected that advancement to a senior level occurs after a sufficient exposure to a variety of regulatory documents and the ability to undertake projects with increasing scope of responsibility and leadership. Although the change in title is quick, the transition is gradual with the question, "are we there yet?" frequently occurring.

Much of the learning required for transition to this new proficiency level happens implicitly as the MW gains experience and understanding in the new role. MWs benefit from the experience and leadership of their managers and peers, they learn on the fly, and some are just naturally good at some new aspects of their roles. However, at times, writing a document is a lonely craft because typically projects are written by a single MW. MWs walk our own paths and rarely get the opportunity to discuss the principles, golden rules, and methods; to be exposed to alternative ways of thinking, writing, and leading; or to share the ways in which we are not there yet. This was the starting point for participants in this Master Class Series. We were all fresh senior MWs—with a shared feeling that we were not quite there yet.

The participants' collective experience with the Master Class Series can be boiled down to the following key points:

- We got to have a group discussion led by an experienced professional in an approachable, comfortable, and educational setting.
- Through hands-on writing exercises, we

shared our approaches to writing and tried the newly learned material.

- We were exposed to each other's creativity in solving data and content presentation challenges.
- We learned the techniques of lean writing, immediately implementable in ongoing projects.

Testimonials from Master Class Series participants highlighted these points (Figure 2).

The Master Class Series received highly positive feedback. Despite the differences in experience with the documents discussed, the participants agreed that it improved their understanding of the broader contexts in which documents are used and increased their ability to develop coherent documents. Most participants (80%) fully agreed with the following statements:

1. The training helped with our understanding and implementation of a top-down approach in strategy documents and in applying lean writing principles.

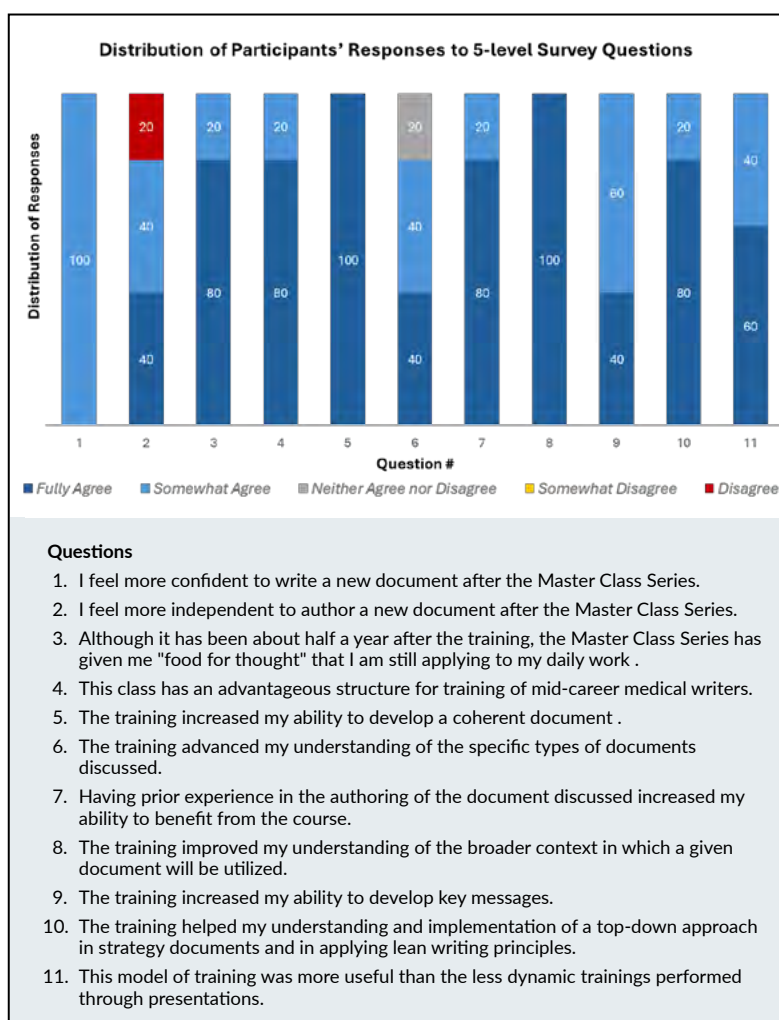


Figure 1. Participant survey results.

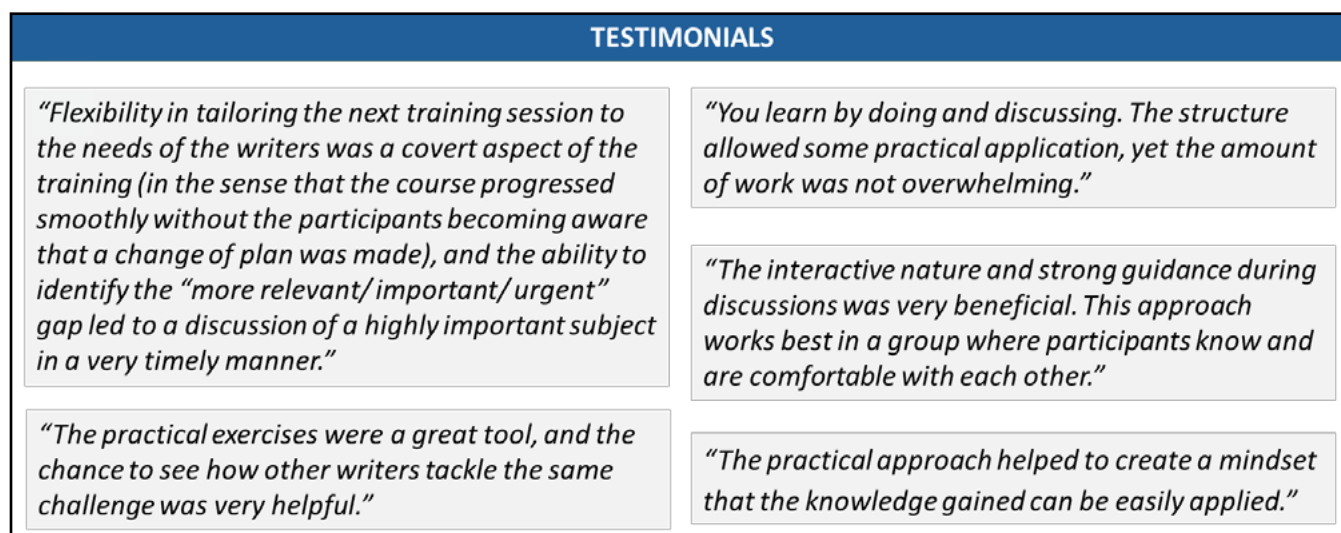


Figure 2. Participants' testimonials.

2. Having prior experience in the authoring of the documents discussed increased our ability to benefit from the class.
3. This class had a beneficial structure for the training of mid-career MWs.
4. Although after the survey was conducted approximately six months after the completion of the class, it has given us food for thought that we are still applying to our daily work.

The participants also felt more confident in writing new documents. All participants agreed that it is very likely that they would sign up for a course with a similar model in the future.

The topics that elicited higher response variability concerned the advancement of understanding of the document types discussed and the feeling of independence when writing a new document. One participant commented, "it seems that introduction to the types of documents was out of scope, unfortunately." These results reflect the impact of previous experience on the potential to benefit from such a class and the importance of providing a side-by-side introduction to the expected content of document types discussed in the Master Class Series for the participants new to such documents.

HOW COULD YOU DEVELOP A MASTER CLASS SERIES IN YOUR COMPANY?

The content, structure, and implementation of such a Master Class Series can be customized to meet the needs of your group. The starting point is a thorough needs assessment. Set the goals and content depending on the

participants' needs and experience level. Then decide the interval between sessions that is best for your group. The goal is to allow sufficient time for the participants to work on each assignment, applying the knowledge gained from the previous session(s), and for the trainer to have the time to tailor the next session to needs identified in the previous session(s), making it a dynamic form of training. Consider having an outside trainer who liaises with the managers before each session to renew and discuss the goals for the next session from their perspective. Keep the group size small; four to six is probably an optimal size. Larger companies could divide their MWs into small groups, perhaps by therapeutic area or document type. This type of interactive training could be offered in parallel with structured didactic training on the document types to be reviewed in the Master Class Series, especially if the participants are inexperienced with them. The only absolute is that a Master Class Series is essential to the training of mid-career MWs.

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Author contacts: andriana.papaconstantinou@bioforumgroup.com, Anne@McDonoughCR.com, luba.binshtok@bioforumgroup.com

THEME ARTICLE

The Call of the Open Road: Is Medical Writing Right for You?

Robin Whitsell, BA, BPh / Founder and President, Whitsell Innovations, Inc, Chapel Hill, NC

The questions I'm asked about medical writing are often "how do I become a medical writer?" or "what is the best background?" or "what kind of training is crucial to success?" I'd like to humbly suggest that these are the wrong questions. I think a better question might be, "how do I know I'll be happy as a medical writer?"

THE WHY

I began my career as a medical writer after almost 10 years in clinical development where medical writing responsibilities overlapped with my other job expectations. Conversely, one talented medical writer I know found this career following a prestigious postdoctoral fellowship. And still another gifted medical writer's first industry role was as a study coordinator at a clinical research site (and she had previously worked at two different nuclear power plants). There is very little overlap between our academic or career backgrounds. The one attribute we share is that we were attracted to medical writing by the very real opportunity to have an impact in the lives of patients.

In my experience, medical writers are often driven by a strong why, a sense of purpose that creates an ethical foundation for our work. When we think about the (nonfiction) stories we are telling, we know that, ultimately, our words impact other humans. Reflecting on our own individual why allows us to have a deeper well of patience and empathy for the challenges of our role.

For me, the two greatest gifts of being a medical writer are the relationships I have found within the industry (including the medical writing community) and the knowledge that my work has helped patients, especially those I call family and friends. Once you have clarity around your why, there are additional characteristics worthy of reflection.

ABILITY TO SOLVE PROBLEMS

If you don't enjoy complexity, medical writing may frustrate you. For medical writers, there is always something to learn and a problem to solve. Medical writers routinely face new ideas, new therapeutic areas, new technologies/systems, and new team dynamics. Each of these challenges becomes a puzzle to unpack, unwind, and understand. A level head

and tenacity are needed because it is common for a solution that worked in one situation to be less useful in a different situation, or a tactic that worked for one team to be less useful for a different team or even a different encounter with the same team. Hence, a critical trait for medical writing is a solutionist mindset—the new problem is a puzzle, not a roadblock, and solving each problem is intrinsically rewarding.

CURIOSITY

Between the ever-evolving science and the health authorities' efforts to drive innovation, intellectual laziness doesn't work for medical writers. In a 2023 survey of 800 C-Suite executives conducted by a for-profit education platform (EdX),^{1,2} 49% of the responding leaders questioned how relevant their workforces' current skills would be with the rise of artificial intelligence. Although an education platform would have a good reason to identify and report these results, the findings feel reasonable to me. Even very experienced medical writers face learning curves. With some of my company's recent clients, the science driving their innovations would have been relegated to science fiction when I was in college. We have to interrogate ideas with curiosity and openness. Job satisfaction as a medical writer means enjoying and thriving as a life-long learner.

WILLINGNESS TO LEAD WITHOUT ORGANIZATIONAL AUTHORITY

Though, arguably, everything would be better if teams did things exactly as advised by their medical writers, it is exceptionally rare (maybe nonexistent) for the medical writer to carry organizational authority over a team. Not surprisingly, according to Randstad's 2024 Workmonitor report,³ management and leadership skills were the highest training priority among workers in the United States. This is well-aligned with medical writing.

Our role requires time and timeline management, written and oral communication skills, and the ability to direct a team of document contributors. Most successful medical writers carry a deep sense of responsibility for their documents, their teams, and the patients they want

to help. Embracing document ownership, coupled with the skills of nonprosecutory levels of stalking, allows medical writers to extract the relevant contributions from team members, navigate team dynamics, and deliver high-quality documents. The balancing act of this leadership relies on tact, steadfastness, and leaning on communication and rapport soft skills.

COMFORT WITH DISCOMFORT

In a 2023 LinkedIn survey⁴ looking at desirable worker skills, the skill with the sharpest rise in demand over the study period was adaptability. Although the survey authors did not release a list of the specific roles they assessed, satisfaction as a medical writer is closely tied to this skill.

Like many industries, medical writers are impacted by technology, including the exploration of artificial intelligence—even as our value proposition might be questioned. What may be nonobvious is, despite how we feel about these changes, medical writers have to be ahead of each new advancement. We continually stare down learning curves to lead and support our teams as they navigate emerging technologies from regulatory information management systems to specific document requirements and workflows. Commonly, the medical writer is mapping out the best way to interact with the newest system deployed by our employers, even if that experience is frustrating for us. Medical writers might be the change agents of their teams.

Medical writers also have to exercise mental and emotional agility. They have to find ways to work with challenging circumstances and personalities. It's common for team members to feel a need to be seen as right and smart. Rather than being right, we have to embrace getting the document right. This can feel uncomfortable, especially when a document we have worked on is being critiqued less on its merit and more on how it aligns to the story a team member wants to tell or the way that the team member(s) want to tell it. Sometimes medical writers have to lead complex and difficult conversations and provide feedback to support delivering documents that will pass health authority muster. In a room full of very smart people, a medical writer has to remain unflappable and composed in order to build consensus without ruffling egos or compromising data integrity.

YOUR OPEN ROAD

In the *You're Wrong About* podcast,⁵ sled dog musher and author Blair Braverman corrected a misconception about the lead dog of a sled dog team and detailed how it parallels with leadership in the human world. She described how, contrary to the societal idea of the alpha dog, the dog leading a team was not necessarily stronger, more

vicious, or more dominant. Dogs, as pack animals, are more comfortable chasing another dog. Finding a dog who sees an open trail and experiences excitement is rare.

They could be shy, and they could be quiet... They're good at finding the trail, breaking the trail in deep snow, navigating, setting a pace, listening to cues from the musher, pushing through storms, (and they) like using their own instincts. And it's energizing for them in a way that other dogs on the team might find it exhausting to be making those decisions.⁵

Her explanation felt very much like being a medical writer. If you are passionate about your potential to help people, enjoy solving problems, embrace curiosity and the opportunity to continuously learn, are undeterred by leading without organizational authority, and facing challenges energizes rather than exhausts you, congratulations! You have found a career that can deliver these adventures. Medical writing is for you.

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Author contact: robin.whitsell@whitsellinnovations.com

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THEME ARTICLE

Training the Medical Writers of the Future Using a Structured Entry-Level Program: A Life Sciences Communications Agency Perspective

Michelle Utton-Mishra, PhD, CMPP¹; Melissa K. Purves, PhD, CMPP²; Linda Mascarenhas, MS¹; Valerie Moss, PhD, CMPP¹ / ¹Prime, London, United Kingdom; ²Prime, Knutsford, United Kingdom

ABSTRACT

Ensuring that associate medical writers are set up for success requires a well-planned entry-level program that integrates training sessions with on-the-job experience. We describe how we have crafted our program for entry-level candidates—starting from our interview process and moving to our training program, how we embed them into teams and provide on-the-job training, how our support network is structured, and how we measure success. Feedback from recent participants in our training program offers valuable hands-on insights. A robust foundation of publication training is key to the development of our medical writers, providing skills and helping them develop many of the key attributes that underpin success, including attention to detail, effective storytelling, and industry compliance. Our profession is not static, and training programs need to be agile and pivot quickly to accommodate evolving industry standards, new technologies, and fluctuating client and audience needs and challenges. Staying up to date with future developments in medical writing is crucial, and we do our utmost to train and support our team and future-proof our training, so our junior writers are well equipped to excel and have fulfilling careers in the life sciences communication industry.

INTRODUCTION

Medical writers play a pivotal role in ensuring that clinical research findings reach their target audience in a timely manner. As the health care communication landscape evolves, nurturing the new generation of medical writers is paramount. Developing an engaging, informative, and relevant training program for aspiring medical writers will prepare them for the varied aspects of their working life and ensure they have the best start to their careers.

Through comprehensive training, medical writers develop their skills to disseminate scientifically accurate, engaging, and industry-compliant information that will

contribute to knowledge of health care advances and ultimately benefit patients. It is essential, therefore, to understand and nurture the multifaceted role of a medical writer. The ability to pivot between diverse types of projects—with strategic acumen, a sharp eye for accuracy, proficiency with digital tools, and a flair for scientific storytelling—is no mean feat, particularly in the rapidly evolving life sciences communication industry. Given that the use of generative artificial intelligence (GenAI) in medical communication is progressing at a rapid pace, the skills of the medical writer must evolve too. Expertise in the critical evaluation of GenAI content will be an essential skill as, in the not-so-distant future, this task becomes a part of a medical writer's daily life. Leaders of entry-level training programs have a responsibility not to shy away from this new technology but to embrace it, train for it, understand how it impacts our clients and audiences, and incorporate it into training plans.

A medical writing career can be an inspiring and exciting one. With opportunities for continued learning and knowledge expansion through training and experience, there is rarely a dull moment in this field! To ensure that medical writers are set up for success throughout their careers, training programs should be tailored to all levels of ability and experience. This demonstrates the company's investment in staff and encourages an environment of shared responsibility for continuous learning and development. For example, in addition to our entry-level program (IGNITE), the authors' company also offers an internship program and training tailored to mid-level staff and those moving into leadership positions. These training programs are designed to build confidence in projects of increasing complexity, provide more in-depth training on strategic oversight, and ensure the development of broad leadership skills. To enhance understanding of the purpose and connection with the training, across all levels, we tailor it around our four company values: be brave, be human, be passionate, and be exceptional (Box 1).

Box 1



Be Brave – challenge the status quo, seize the learnings and step out of the comfort zone



Be Human – consider patients in all we do, act with trust, integrity and empathy and nurture an environment for everyone to succeed



Be Passionate – go one step beyond to build trusting and lasting partnerships, love what you do and inspire others



Be Exceptional – set the highest standards, be an expert, continuously learn

Here, we describe our entry-level program for the benefit of potential future medical writers and those wishing to set up a similar training program, sharing what training works well, offering feedback from our recent trainees, and offering insight into how we are developing the medical writers of the future.

OUR ENTRY-LEVEL PROGRAM

At Prime, our entry-level program, which encompasses 12 months of training and on-the-job experience, has been running in its current format for over five years across the United Kingdom, Europe, and the United States. The program is designed to train junior medical, market access, and patient writers, account executives, and editors to become the life sciences communication stars of the future (Figure 1). Regardless of department, our trainees attend all sessions and gain broad awareness of the skills needed across the field of life sciences communication through incorporation of elements of writing, editing, and client service projects into the entry-level training sessions. In this way, we equip all junior staff with skills and understanding relevant to many areas of the

Hear Hands-On Experience from an Associate Medical Writer



Video 1. <https://f.io/E6aeNhl9>

What are your top tips for someone starting a medical writing career? Firstly, to read published manuscripts and any other available material; secondly, to ask for feedback and be open to feedback—talk to your colleagues to put things into perspective; and lastly, to be exposed to as many different types of medical writing as possible. Interviewer and Hope, an associate medical writer.

life sciences communication world, providing a good introduction to collaboration and how to function within a high-performing team.

Our journey begins with our rigorous recruitment process. For aspiring writers, this process involves writing a mini review per a detailed brief with source materials; a live, timed writing test; and real-life scenario interview discussions. When successful candidates come onboard, they enter our program from their first day. We assign each candidate to a home team with a line manager in that same home team. They integrate into the workings of that team, getting up to speed with the team's ongoing work, shadowing colleagues, and taking on live tasks with supervision from their second week. We also assign each candidate a buddy (usually someone from a different team who has been through the entry-level program themselves) who can befriend, support, and answer any questions more casually than a line manager and be a friendly face around the office.

We start our training by bringing the candidates together in a live classroom setting. They have the opportunity to spend time with each other, which builds camaraderie among peers, and are introduced to many of our team, both for training and informal catch-ups over coffee. We aim to create an environment in which everyone feels nurtured, comfortable to learn, and encouraged to contribute. Our training program for medical writers is crafted by our senior scientific team, including our chief scientific officer. The training is delivered by a variety of individuals who have recent hands-on experience, including senior medical writers, and scientific directors. We also organize many sessions given by the wider team, including members of the client services, editorial, finance, digital, evidence and access, and patient engagement teams. This ensures



Figure 1. Overview of our entry-level training program. F2F, face to face.

our trainees have a fully rounded introduction to various aspects of life sciences communication. Our initial round of training sessions set the scene by introducing the job role and pharmaceutical development process, along with soft skills to build confidence. For example, introductory sessions include *An Introduction to: Pharma* and *An Introduction to: Drug Development*, also some role-specific sessions, such as *Spotlight on: Client Services*. After these initial settling-in sessions, the program expands to cover the many elements of life sciences communication in a blend of live, virtual, and self-led training sessions. Topics include:

- core publications skills (how to data or fact check, how to approach writing an abstract),
- digital production (marking up PDFs, working with the creative team, how to approach developing a poster), and
- patient engagement (spotlight on patient engagement and centrality).

In addition, we keep the program fresh and introduce contemporary subjects as they arise, such as the impact of GenAI on our industry and how to verify GenAI content, presented by in-house subject matter experts. We pair the topics with the most appropriate method of delivery, based on the length of the training and level of interactivity required. Straightforward topics are either delivered as virtual or self-led sessions, whereas more involved, interactive training is performed live. Having a range of delivery approaches means that, overall, sessions are well-attended, and trainees are engaged.

We are conscious that everyone may have different preferences for learning styles, so our curriculum comprises bite-size training materials, slides, videos, task-based learning, and discussion-based sessions. We ask that cameras are turned on for virtual and hybrid sessions, and ensure the format is as interactive as possible, including polls, asking questions throughout, and allowing ample time at the end for discussion. All sessions are recorded and shared, so anyone can return to materials at a later date or catch up on any topics they may have missed.

Line managers, buddies, and the program organizers work together to ensure everyone's needs are met and views heard. During the 12-month program, we organize group training days in which we ensure everyone meets face-to-face for live training sessions and some fun downtime. The trainees also have the opportunity to hone their presentation skills within a safe space by presenting to each other. The program leads track progress, successes, and challenges through regular meetings with line managers and trainees. A sense of community is encouraged among the trainees throughout. We feel the balance of background training,

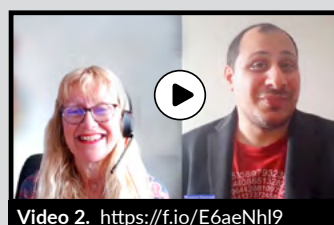
on-the-job project work, and genuine care that is taken supports company loyalty and encourages staff retention, with many of our trainees progressing to mid- and then senior-level positions within the company.

For an associate medical writer, the on-the-job training starts with a firm grounding in the need for accuracy and attention to detail. They will perform data checks in parallel with more senior colleagues until they feel confident and ready to go it alone. Publication writing training is built into the program early on as it gives a good foundation in the other skills needed for medical writing, including experience in interpreting data, ability to develop engaging long-form storytelling, and adhering to the compliance standards of the role. A medical writer supports the author to develop drafts of a publication, facilitating timely publication under author direction.¹ Understanding publication process is an important part of initial training and allows our associate medical writers to become publication professionals with a strong understanding of our own and client procedures, and a commitment to publication standards of excellence. We also hone scientific storytelling skills throughout all our training, ensuring our writers feel empowered to undertake multiple project types.

As our associate medical writers grow in confidence, they begin to engage in other publication projects, taking on client and author interaction responsibilities when

they are ready and attending kick-off calls, implementation of good publication practice, and development of deliverables such as graphical abstracts, infographics, video abstracts, and plain language summaries. Understanding the strategic relevance behind a publication plan and ensuring an omnichannel approach to reach the right audience, with the right material, at the right time, via the right medium, is discussed early in the entry-level program. The health care landscape in

Hear a Former Trainee Discuss His Life Sciences Communication Journey



How might the career of a medical writer change in the near future?

Writers will need to embrace a lot of different needs going forward, especially in an environment where there is strong demand for an omnichannel approach. [...] In addition, writers will need to continue to learn more about generative AI and how it can help them deliver more [...] as well as identifying where we can innovate using technology platforms [...], learning how to deliver not just science—but deliver science strategically. Interviewer and Moamen, associate scientific team leader and former member of our entry-level program.

which medical writers work thrives on interdisciplinary collaboration between a broad range of health care professionals, researchers, pharmaceutical colleagues, and patients. By collaborating with patients and professionals from various disciplines, our medical writers gain invaluable experience and learn to adapt their writing style to different audiences.

How to Measure Success

For our associate medical writers, we benchmark success against a set of objectives, some universal to the job role and others specifically tailored to each individual. These objectives cover research and writing ability, communication skills, team working, time management, industry compliance, and financial awareness (Figure 2). Progress toward objectives is reviewed regularly with line managers, and associate medical writers are encouraged to keep a record of their achievements in a centralized human resources system. Clearly defined promotion criteria that assess competency in the objectives outlined above are available to line managers and associate medical writers, ensuring that standards are transparent and there are no hidden hurdles. Similarly, associate medical writers have access to clear job descriptions for their current and next role, which helps them understand what they need to work toward as they progress through their career. This clear, information-first approach means that all associate medical writers have a good understanding of what is expected of them, which helps reduce the instances of performance concerns.

Occasionally, our associate medical writers experience challenges as they navigate the complexities of life sciences communication, and we have tried-and-tested approaches in place to help them overcome any obstacles. These approaches include access to buddy mentors who have been through the program themselves and can provide

guidance on how to navigate what is, for many, their first job after college. Secondly, our associate medical writers have access to a peer support network in the form of the other trainees (including other writers, editors, and account executives) who are part of their cohort. Learning to work as part of a team is a pivotal part of training. Our associate medical writers are encouraged to reach out to their buddies and peer group to discuss challenges and identify solutions; in most cases, challenges can be overcome through these informal discussions. We have observed first-hand how well this approach works, and how effective it is at developing problem-solving skills. Thirdly, all associate medical writers have a dedicated, experienced line manager with whom they have weekly touchpoints to discuss progress, as well as ad hoc catch-ups as needed. Line managers are trained to provide support and help their line reports to navigate potential challenges. Finally, all our trainees have regular meetings with the program heads who check in from an emotional and social support perspective. These catch-ups are usually informal and provide another opportunity to discuss concerns, explore challenges, and access support as needed.

Our approach has shown success since our entry-level program began in 2017, with 154 candidates entering the program to date. The vast majority of these candidates have completed the entry-level program and are highly trained, resilient, and well rounded, with a passion for life sciences communication and the ability to thrive in a fast-paced and evolving industry. We are proud that they have gone on to fulfilling and rewarding careers, and many are now passing on their skills to develop the medical writers of the future.

Ways of Working, Now and in the Future

We have seen many changes in life sciences communication since the start of our entry-level program, and it is

 Setting objectives	 Log training	 Performance reviews	 Feedback	 Progression
• Writing skills • Therapy area knowledge • Industry compliance • Communication skills • Team work • Timekeeping • Financial awareness	• Log training courses attended • Catch up on missed training sessions by watching the session recording • Revisit any training • Answer any quiz questions	• Discussion of achievements against set objectives • Work through any challenges • Competency levels assessed against objectives	• Regular feedback on sessions from trainees • Ideas for additional sessions	• Successful promotion when desired competency level reached

Figure 2. Setting colleagues up for success.

important that we continue to evolve to ensure we remain future-proof. For example, one of our cohorts was initiated in 2020, just before the COVID-19 pandemic. We had to quickly pivot to a virtual training program while ensuring that our new recruits had the same standard of formal training and on-the-job learning opportunities as those who started before the pandemic. Luckily, our team is very resilient; they adapted quickly and embraced these needs, taking every care to give our candidates the best experience possible. The challenges posed by the pandemic underscored the importance of community and added an element of joint accountability, with trainees expected to attend virtual meetings, specific training sessions, and all opportunities for online social events and informal get-togethers.

Four years on, we (along with many other industries) are now very much in a hybrid world. Our trainees are encouraged to come into the office for two to three days per week. We feel this offers the best of both worlds, with trainees exposed to in-person conversations that support their learning in an informal way and help them forge close relationships more quickly than in the fully virtual setting.

In the evolving medical writing landscape, embracing modular content creation is a crucial mindset shift for effective omnichannel communication. The omnichannel approach, delivering the right content to the right audience at the right time via the right channel, requires truly understanding the audience, their needs, and their preferred way to receive information. The ability to create content in modules that can be adapted across platforms is key with this approach and needs to be incorporated into processes and training programs to equip medical writers with the skills to maximize the reach and impact of data.

In addition, there has been a lot of interest in the use of GenAI to develop medical content, with the aim of streamlining workflows and quickly tailoring content to different styles and audiences. It is important that our writers understand both the risks and the benefits of emerging technologies, so we provide clear guidance on disclosures, transparency, and the importance of ensuring human oversight and validation within our training program.² GenAI may be used in a variety of ways in the future, but medical writers will remain the subject matter experts. Over time, they will gain skills in critical thinking, how to interpret data and provide context, and strategic content validation, skills that will be increasingly critical and require appropriate training as we move further into the GenAI era.

CONCLUSION

Supporting the next generation of highly skilled medical writers is a multifaceted endeavor that requires a comprehensive training approach encompassing strategic, scientific, and clinical knowledge; communication and storytelling skills; technological proficiency; and an understanding of industry compliance. A comprehensive training program will bring together all the necessary instructional elements and on-the-job experience to empower medical writers to shape the future of life sciences communication. We must continuously evolve our educational approach and our materials – from updating information to staying in line with industry standards to improving how we deliver our training sessions. We are always looking for new ways to enhance participants' engagement, build in interactivity and discussion-based sessions, monitor training achievements, and awareness of how to stay ahead of the latest industry trends. Exposing medical writers to the plethora of project types and approaches we can take to support our clients and inform our audiences will encourage them to “Be Brave” – to challenge established ways of thinking and suggest an alternative solution. This will not only result in forward-reaching communication that meet target audience needs and ultimately result in patients receiving the best care possible but will also ensure we always put our best foot forward to support successful medical writing careers.

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Author contact: Valerie.Moss@primeglobalpeople.com and Michelle.Utton-Mishra@primeglobalpeople.com

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THEME ARTICLE

Medical Writing and Editing Internships: Preparing the Next Generation of Medical Communication Professionals

Speakers
Barbara Gastel, MD, MPH, ELS(H)

Professor, Texas A&M University, College Station, TX

Joan Affleck, MA, MBA

Associate Vice President, Head of Medical Writing, Merck & Co., Inc., Rahway, NJ

Moderator
Erica Goodoff, ELS(D)

Senior Scientific Editor, The University of Texas MD Anderson Cancer Center, Houston, TX

By Sidonie Jones, MA, MPhil, PhD

This was a panel discussion with speakers Barbara Gastel and Joan Affleck and moderator Erica Goodoff. The panel discussed the importance of internships for training the next generation of medical writers, and there was a robust Q&A portion. The panel discussed internships targeted toward mostly graduate students (but open to students at various levels who show an interest in writing), but they also mentioned that internships for early career entry or mid-career change are important and do exist as well. The discussion came from three perspectives. Goodoff is part of a small team of medical editors, and she hires up to one intern per year; contact with and training for the intern is mostly her responsibility. The interns work remotely. Affleck heads a 200+ medical writing team at Merck, where they hire many interns in the medical writing department. This internship requires onsite presence. Gastel directs a professional science communication graduate program, in which she teaches and advises potential medical communicators and coordinates internship placements. She has also hosted interns, including international trainees.

THE IMPORTANCE OF INTERNSHIPS

Goodoff spoke about the benefits of internship programs. Training possible future team members, teaching both hard and soft skills to the interns, and mentoring and leadership experience for their team members are all benefits for the team. Affleck stated that an internship gives students an opportunity to learn about the industry and have exposure to experienced medical writers and editors and other departments, and this builds a large potential talent pool for not only the writing team but other departments as well. They all stated that the interns benefit from having the opportunity to build their resume, gain contacts and rec-

ommendations, and learn where and if they fit as a medical communicator. An internship can also lead to opportunities for future roles in the host institution or company. Although their programs differ in size and structure, the goals are the same: successfully training new medical communicators. Some of the key points from the Q&A session are detailed in the following portion.

Interns Should Be Compensated for Their Role

The work of medical communication is highly skilled, specialized, and important and should be compensated as such. This is beneficial to both the institution or company and to the intern to have them fully engaged. A fair base salary should be explicit for interns. Benefits can include such things as locating low-cost housing and transportation assistance for in-person internships. Internship programs foster relationships with colleges and universities to find the best interns, but these programs also can recruit through job boards, fairs, and other similar venues, if allowed by the host institution or company.

Onboarding Procedures Are Important

Interns should be introduced and integrated into the team through well-defined orientation and training materials. Expectations should be set with new interns as with any new employee. Learning the interns' interests and strengths and what they hope to gain can guide interns' assignments (eg, an intern with an interest in neuroscience may be given as many neuroscience-related assignments as possible).

Keep the Intern Engaged and Part of the Team

Interns should be included in team meetings, trainings, and activities and given regular assignments. This helps the

intern become acclimated to the team and institution or company. Regular meetings with the intern are essential, especially in a remote situation. Affleck's program requires that the interns keep a daily journal and send it to the mentor once a week. Her interns also build a portfolio and give a presentation as part of offboarding. Goodoff's program uses a similar procedure.

Bad Hiring Decisions

Goodoff spoke to making the best of a bad situation by having frank conversations about the intern's challenges, possibly assigning them different tasks, and trying to guide the intern toward alternate career goals and possible better career paths if they find that the job is not a good fit. Fortunately, this is not a frequent occurrence. Affleck spoke to preventing this through clear and specific job postings and stringent interviewing and hiring practices.

Overcoming Other Potential Challenges

Budget concerns and bureaucracy can be obstacles to an internship program. Recruiting early and being willing to negotiate the salary and hours for your intern can overcome these challenges.

Internships are one of the best ways to train a new generation of medical communicators. Hopefully, we can look forward to future development of these programs by different institutions and companies with the possible involvement of AMWA.

Sidonie Jones is an aspiring medical writer.

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

Author contact: sidoniejones@gmail.com

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TECHNOLOGY TALK

Is the Hype Real? Real-Life User Experience of an Artificial Intelligence Tool for Clinical Study Report Production

Julia Forjanic Klapproth, PhD / Senior Partner, Trilogy Writing & Consulting, Frankfurt, Germany

We all know that artificial intelligence (AI) is changing the world we live in, and the world of medical writing is no different. The explosion of AI is creating significant opportunities in identifying data signals, document creation, and supporting the work of medical writers. This article summarizes how the medical writers in my company, Trilogy Writing & Consulting, have been using a rule-based AI tool (that we purchase as a Software as a Service license) to augment their writing of clinical study reports (CSRs) and is a summary of a talk that I gave at AMWA's 2023 Medical Writing & Communication Conference in Baltimore, Maryland, on October 26, 2023.

First, a brief introduction to the tool we are using. It is called TriloDocs and is what is called an expert system. This is a form of AI that uses rules to simulate how a human would apply their expertise to do something. In this case, it is simulating how medical writers make decisions to select the information to be used in a CSR. The rules in the system were developed by experienced medical writers to recreate our thought processes.

The system does not apply machine learning or generative AI (à la ChatGPT). This was an important decision in developing the tool because it was critical that we could understand exactly how the system makes all its decisions; namely, why it chooses which data, which cutoffs it uses, and where the material comes from. The system was designed to be completely transparent about what it does and to inform the user about the decisions made.

The user works in a browser-based working environment in which they upload all source files (the protocol, statistical analysis plan, and the tables and figures) in Word or Rich Text Format. The system generates the output from these, and the source files are removed. Nothing is stored in the system. This was another important feature because the tool was not intended to be a repository of any kind. In fact, it functions much like a photocopier! You put the material in, it creates the output, and you take the material out.

The output itself is a Word file based on the Transcelerate template. This means the medical writers

continue to work in Word as usual, without needing to learn a new system. Using the Transcelerate template makes it as universal as is possible in an industry full of unique interpretations of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use E3 guideline.

We wanted a tool that would support how we work as medical writers. Its main purpose is to pull information together quickly and accurately—leaving the interesting part of writing to us. The initial draft it generates is not complete and is not intended to be sent to the team for review. The medical writer takes what it has pulled together and refines it, giving it the color and context needed to tell the full story. But by saving days' worth of time normally spent copying and pasting the source information together, we can better focus on the intellectual part of the exercise. This is critical in understanding the benefits and limits of an AI tool. AI cannot interpret data; it can only either repeat information that is already summarized, or it can describe data based on rules. Humans look at the signals and decide what they actually mean in the context of everything else we know.

TriloDocs does two main things in generating the initial draft of a report. The first is to compile the data-independent sections by pulling information from the protocol and statistical analysis plan. Some things are used verbatim and left for the medical writer (in collaboration with the rest of the authoring team) to decide how much to adapt it for this particular CSR. Some things are woven together from multiple sections of the source material. Anything that happened during the study and is thus not described in the protocol (eg, audits and their findings) will still need to be added manually by the medical writer.

It also writes text and produces in-text tables and figures for the data-driven sections (the results). The tool applies good medical writing methods by using lean text focused on the data signals and not just a repetition of the data from the tables. The text identifies data that are likely to have clinical relevance (ie, notable differences between

treatment groups) or indicates if there are no differences. It is the equivalent of having someone sit down with a highlighter pen and mark up all notable differences between groups on the tables—only now these data have been captured in the text already. The system does not make a judgment call on these differences, it simply identifies them, leaving the medical writer (together with the clinical team) to decide if they are important and if more detail or explanation needs to be added. In this way that initial draft is equivalent to giving the medical writer the tables with all the potentially interesting findings already laid out in text.

So, the output is not a complete final draft—it is a solid starting point that then requires the human element to refine it. That’s why an experienced medical writer is needed who can take the initial text provided, craft it (in collaboration with the clinical team) to interpret what those findings mean, and hone the report into a well-written document that tells the scientific story of what these data mean. In fact, the system was designed to be used by an experienced medical writer from the start. The user must have reviewed the source material and have an overview of the study intention and purpose to be able to guide the tool to generate a meaningful output. They must understand what to present in the report and inform the tool accordingly.

This happens by answering a series of questions posed by the tool about the study before creating the initial draft. After uploading the source files (protocol, statistical analysis plan, tables and figures), the medical writer steers the decisions that TriloDocs will make through these questions. The questions consider things that have implications for what should be considered important (like size of the population, is it a comparative study, how many treatment arms are there).

Because it only takes about half a day for a medical writer to generate that initial draft, they have much more time free to focus on discussing with the authoring team what the messaging is around the findings. By removing the grunt work, medical writers can now focus on the strategic input to the CSR. The role and the perception of the medical writer will be that of true subject matter experts in their own right who aid the team to craft well-honed content.

In addition, the tool reduces or eliminates the risk that teams will overlook important signals in the data. The rules were created to err on the side of showing more rather than less, leaving the teams to decide what needs to be retained. By always indicating in the text what the cutoffs were for selecting data (eg, how the most common adverse events were selected), the users and reviewers are fully informed about what has been presented.

Are there limitations to the tool? Definitely. It was designed by medical writers, so it only knows what we know in our combined knowledge base. If there is something

highly atypical (eg, a new type of analysis or an unusual data presentation), it may not have a rule to process that, in which case it informs the user that it did not know what to do and will leave that section blank. The writer will have to look at that material and populate the section manually. However, the rest of the report will be populated, so it still eliminates the drudgery of filling in the rest of the document.

Feedback from the medical writers using the tool has shown that they particularly appreciate the way the tool guides them to think about the context of the study and the report before they start writing. One writer said, “The way the tool guides me to consider different things meant I was thinking about aspects of the structure and presentation of the CSR that I wouldn’t necessarily do or even think of while writing manually.” We have also seen that the guided nature of generating the report means there is greater consistency in how things are reported. It prevents key things (eg, regulatory requirements) from being forgotten or overlooked in haste.

“ The part I loved about TriloDocs is that it read the prohibitively long, complex, and poorly designed lab tables and gave me a simple statement that there were no clinically significant findings. In my whole experience, this saved me the most time and effort and was a real blessing. ”

Another learning has been that the tool finds important signals that clinical teams miss. We have done several comparisons of the TriloDocs initial draft to reports that were previously written manually and had completed full team review. In many cases the draft results produced by the tool highlighted findings that had not been reported in the manually generated report. For example, in one pivotal study report two key safety findings had not been reported in the original report but had been summarized in the report generated by TriloDocs.

Another quote from a medical writer highlights how medical writers benefit from using the tool. “The part I loved about TriloDocs is that it read the prohibitively long, complex, and poorly designed lab tables and gave me a simple statement that there were no clinically significant findings. In my whole experience, this saved me the most time and effort and was a real blessing.” Using the tool saves the time normally needed for wading through the data, freeing up the writer to think about what the signals mean rather than struggling to find them. In addition, while humans get tired

and lose focus as they pour through hundreds of pages of data, an AI tool does not.

So, to consider the original question “Is the hype real?” I can say that from our experience, these tools are dramatically changing the way medical writers work. They enable us to focus on the messages by eliminating the tiring and error-prone tasks (copy and pasting, typing in the data, identifying signals, etc). Yet, the elimination of these tasks does not diminish the value and need for a medical writer. Very much like how automatic pilot systems on airplanes have not eliminated the need for pilots, this technology brings advantages to the user that allows them to focus on the essential (and human) aspects they bring to the role. The tasks we do will change, but in an industry in which medical writers are overloaded with work, removing some parts of

the job could be a welcome respite. Ultimately, we see how using AI tools will elevate further the medical writer’s role to a strategic level of focusing on critical thinking around the messaging of the documents. From here, the next step in TriloDocs development is to focus on populating Module 2 summaries, which will bring all these advantages to dossier writing and, ultimately, aid in getting drugs to patients faster—a goal we are eager to embrace.

Author declaration and disclosures: *The author notes that she is a partial owner of the rule-based AI tool mentioned in this article, but this does not pose a conflict of interest in relation to this article.*

Author contact: julia@trilogywriting.com




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Advance Your Writing Skills: Craft Effective Multiple-Choice Questions for Continuing Education Activities

Heidi Veillette, BSc, RT(R)(MR) / Veillette Communications, Calgary, Canada

ABSTRACT

Health care professionals are required to participate in continuing education activities to maintain their competency and improve their clinical skills. These educational activities are often developed by medical writers who create the course content and postactivity multiple-choice questions (MCQs). The MCQs align with the learning objectives and assess the learners' comprehension of the information and their ability to apply the knowledge in a clinical setting. The MCQs also help evaluate the educational outcome of the activity and guide future educational programs. Medical writers can craft high-quality MCQs for continuing education activities by following key recommendations that enhance knowledge and build skills in medical professionals, effectively contributing to improved patient care. This article offers an overview of the recommendations for writing effective MCQs for continuing education activities.

INTRODUCTION

Continuing medical education (CME) activities for physicians and continuing education (CE) activities for other health care professionals supplement knowledge, build skills, and integrate changes into the clinical environment.¹ These educational activities often include pre- and post-tests that identify learners' areas of strength and weakness and determine whether the activity's learning goals have been reached.²

The National Board of Medical Examiners (NBME), the organization responsible for developing national medical licensing exams and medical educational assessment tools, recommends multiple-choice questions (MCQs) as the optimal format for testing the knowledge of new information.³ These questions are a reliable assessment tool because they allow for quick marking of a large number of tests, remove interexaminer bias in marking, and provide data about performance in specific areas.² However, MCQs cannot evaluate creativity or fully mimic real-world situations in which learners must think of the correct answer without prompts.⁴

Medical writers who develop content for CME/CE activities are often responsible for writing the associated MCQs. Although writing an MCQ might seem straightforward, crafting an effective MCQ that appropriately tests the application of new knowledge takes careful consideration. A high-quality MCQ should prompt learners to use high-level cognitive thinking to answer correctly. Conversely, a poorly written MCQ can confuse learners with irrelevant information or cue savvy test-takers into guessing the correct answer.³ Medical writers can enhance the learning experience and improve the educational outcome of a CME/CE activity by following established MCQ writing recommendations from the NBME Item-Writing Guide and similar resources.

CONSIDERATIONS FOR MCQs IN CME/CE

An effective MCQ for a CME/CE activity must test at the same cognitive level as its associated learning objective.⁵ The NBME determined that the cognitive level of a learning objective can be separated into 2 basic categories based on the cognitive task required of the test-taker. These categories are recall of a fact and application of knowledge.³ The MCQs that test the recall of a fact simply assess rote memory, whereas MCQs that test the application of knowledge require the learner to interpret the new information and apply this information in a clinical setting.³ Most CME/CE activities include application-based learning objectives and require high-level MCQs.⁶

OUTLINE OF A MULTIPLE-CHOICE QUESTION

A basic MCQ consists of a stem and multiple answer options. The singular correct option is called the keyed response, and the incorrect options are called distractors.⁶ The appropriate number of answer options is debatable and can vary depending on the level of assessment and information tested.⁶

Stem

The stem can be a standalone question or a vignette with a lead-in statement or question. The stem should include all the relevant information and be as succinct as possible to avoid the learner having to read it multiple times.³ Ideally, the learner should be able to cover the answer options with their hand and come up with the correct answer on their own after reading the stem.^{2,3,7}

When crafting a stem, medical writers should ensure that the information is clear to avoid misleading the learner into answering incorrectly.⁶ Medical writers should avoid absolute terms (eg, *always*, *never*, *all*, or *none*) because few medical situations are absolute.⁶ Vague and imprecise terms (eg, *may*, *could*, *often*, and *usually*) are also not recommended because they are not consistently defined or interpreted by the learner.⁶ The learner may become confused trying to guess the writer's personal definition of the vague or imprecise term, which can lead to the learner guessing an incorrect option or arguing the merits of incorrect options.^{2,3}

The stem should be positively worded. Negative phrases (eg, *not*, *least likely*, and *except*) should be avoided in the stem. A negative phrase that is highlighted using bold and capitalized letters may still be misread by the learner, who may then choose an incorrect answer.³ Also, a negatively phrased question requires the learner to switch from looking for the best option to looking for the worst option. Choosing the worst option does not mimic typical reasoning in the clinical environment in which the standard approach is to rule out incorrect options.²

Vignettes

To test application-based skills in CME/CE activities, the optimal format for an MCQ stem is a clinical vignette. Clinical vignettes, the preferred format of several medical licensing examinations, can identify a learner who has memorized facts but is unable to apply the information effectively.^{5,6} To write a good vignette for an MCQ, a medical writer needs to be familiar with the learners' language and base knowledge on the subject. This way, the medical writer can ensure that the vignette gets to the point without including unnecessary information or explanations.

A clinical vignette presents information in a real-world scenario that the learner will likely experience in the workplace.² The scenario often begins with presenting relevant patient information, including signs and symptoms, diagnostic study results, and recent treatments. Then, the scenario finishes with a decision-making question.³ Vignettes can be effective without being lengthy. Succinct vignettes have short reading times, avoid confusing the learner with irrelevant facts, and often mimic a real-world conversation in the clinical environment.⁶

Answer Options

After the stem, the second part of an MCQ consists of the answer options, including the keyed response and distractors. The keyed response includes the important information that the CME/CE provider wants the learner to understand. The keyed response must be indisputably correct and referenced from a reliable source.⁶ Writing the keyed response is typically straightforward, whereas creating effective distractors can pose a challenge. The distractors must be plausible but less correct than the keyed response.³ For this reason, distractors should be related to or fall into the same category as the keyed response and represent common errors encountered by learners in the workplace.^{3,6}

The distractors and keyed response must have similar structure and grammar to prevent a savvy test-taker from detecting the keyed response without knowing the correct answer.² To craft high-quality answer options without structural or grammatical errors, medical writers should follow these three recommendations. First, the answer options should be the same length as each other. A common mistake when writing an MCQ is to add extra information in the keyed response as a last-ditch effort to teach.³ Second, all relevant information should be included in the stem so phrases are not repeated or defined in the answer options.² Third, the answer options should have a subject-verb agreement with the stem.³ Inconsistent use of plurals or tenses can lead learners to match the grammar of the keyed response to the stem.³

A good tactic to catch grammatical and structural errors is to read each answer option out loud after reading the stem to ensure the language is a good fit.³ A final note about answer options is that the choices of "all of the above" and "none of the above" should be avoided, as these phrases effectively turn the MCQ into a true-false question (Box 1).^{3,6}

Box 1. Guidelines for writing high-quality MCQs^{3,6}

Include	Avoid
• Clear, concise questions or statements • Only relevant information in the stem • One correct and referenced keyed response • Plausible distractors in the same category as the keyed response • Answer options similar in length and grammar • Key information the learner should take away from the activity	• Incomplete or unclear questions or statements • Negatively worded stem • Vague or imprecise words in the stem • Answer options with different lengths or grammar • Answer options with incorrect subject-verb agreement with the stem • "None of the above" or "all of the above" options

MCQs, multiple choice questions.

EXAMPLE PROCESS OF CRAFTING A HIGH-QUALITY MCQ

The following scenario demonstrates the creative process involved in crafting a poor MCQ and a good MCQ for a CME activity on liver imaging for radiologists. The medical writer must craft a high-quality MCQ to support the learning objective of: differentiate between hepatic adenoma and focal nodular hyperplasia on an magnetic resonance imaging (MRI) image. This high-level learning objective requires the radiologist to apply information about the radiological appearance of liver pathologies to determine the correct diagnosis. An effective MCQ should support this high-level learning objective with a clinical vignette that prompts the learner to apply knowledge.

Below are examples of a poor MCQ and a good MCQ for this learning objective. The poor MCQ example is a simple question that tests only information recall (Box 2). This MCQ requires recall of the pathophysiology of focal nodular hyperplasia but does not require the learner to apply this knowledge to a diagnosis.

Box 2. Poor MCQ

Which liver pathology is characterized by an overgrowth of liver cells?

- a. Adenoma
- b. Meningioma
- c. Endometriosis
- d. **Focal nodular hyperplasia**

MCQ, multiple choice question.

Additionally, this poor MCQ includes subquality answer options that could clue a savvy learner to choose the correct answer without knowing the information. For example, two of the distractors (b and c) are not liver pathologies, so they can be eliminated. Also, the keyed response (d) stands out from the other options because the phrasing directly matches the phrasing in the stem. The word hyperplasia in the keyed response is the medical term for the words overgrowth of cells in the stem, which is basic knowledge for a physician.

In contrast, the good MCQ example supports the learning objective with a clinical vignette (Box 3). The vignette includes relevant information about the patient's demographics and symptoms, along with a description of the radiological characteristics of the lesion. The language used in the vignette is tailored to the audience, and the concise lead-in question is a common question that radiologists would encounter in the clinical environment. The answer options are all plausible liver pathologies, and they are written concisely with no extra words to confuse the learner.

Box 3. Good MCQ

A 38-year-old woman without symptoms had an abdominal MRI with a hepatobiliary contrast agent to further characterize a liver lesion found incidentally on ultrasound. On the MRI images, the lesion showed hyperintensity to the surrounding parenchyma in the late arterial phase with rapid washout in the venous phase and isointensity on the 20-minute delayed series.

What is the most likely diagnosis of this lesion?

- a. Adenoma
- b. Hemangioma
- c. Hemochromatosis
- d. **Focal nodular hyperplasia**

MCQ, multiple choice question; MRI, magnetic resonance imaging.

ASSESSING EDUCATIONAL OUTCOMES

Results from the postactivity MCQ test should be assessed to evaluate the medical writer's MCQ writing skills, guide revisions of the current activity, and provide insights for developing future activities.^{2,3} The posttest MCQ assessment includes analyzing the quality of each MCQ and the overall quality of the activity. First, the quality of each MCQ can be assessed by observing the number of correct answers. An MCQ that is too easy or too difficult should be edited so the MCQ can appropriately test the learner's application of knowledge. Second, the answer options of each MCQ should be analyzed to determine their performance. For example, if any distractors were not chosen, then that distractor may not be plausible or may have a structural flaw.³ In such cases, the distractor should be rewritten to a higher standard.³

The overall quality and long-term educational impact of the CME/CE activity can be assessed using Moore's framework or Kirkpatrick/Barr's framework.⁸ Both frameworks combine the MCQ test results with surveys, learner-reported data, interviews, and clinical observations to assess levels of educational outcomes related to learner satisfaction, knowledge, competence, and performance.⁹ The highest levels of educational outcomes showing a lasting impact of the CME/CE activity include improvements in health care quality, and patient and community health outcomes.⁹

CONCLUSION

Medical writers are instrumental in the development of CME/CE activities by crafting MCQs that support the educational content. When writing an MCQ, medical writers should follow the established recommendations of what to include and avoid in the stem and answer options and ensure the MCQ matches the cognitive level of the

associated learning objective. By following these recommendations, medical writers can produce high-quality MCQs that use clinical vignettes to evaluate the learners' ability to apply new information from the activity to a clinical situation. Then, the results of the MCQ test can be used to assess the effectiveness of each question and the overall educational impact of the CME/CE activity. The CME/CE activities that have the greatest educational impact enhance knowledge and build skills in medical professionals, leading to changes in the clinical environment and ultimately improving patient care. Medical writers interested in further developing their MCQ skills are encouraged to review the resources provided below.

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RESOURCES

- NBME Item-Writing Guide
<https://www.nbme.org/item-writing-guide>
- ACCME CE Educator's Toolkit
<https://www.accme.org/ceeducatorstoolkit>

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Author contact: Heidi@VeilletteCommunications.com

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CONSCIOUS WRITING

The Essential Elements of the Discussion Section of a Research Manuscript

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

ABSTRACT

Many medical writers believe that the Discussion is the most difficult section of a research manuscript to write, largely because of its structural flexibility and open-ended nature. However, medical writers can build confidence in writing this section by ensuring that the Discussion includes the essential elements: a summary of the major findings, interpretations of the important findings, descriptions of the implications and applications of the findings, a discussion of the strengths and limitations of the study, details about recommended future directions, and statements of the significance and relevance of the work. These essential elements help to form an effective Discussion that showcases the study and highlights its impact to the field.

Many medical writers believe that the Discussion section of a research manuscript is the most difficult section to write. This difficulty is related to several factors. First, the Discussion describes the authors' interpretations of the findings, which requires careful thought and presentation. Also, the Discussion needs to explain these interpretations in the context of what is known in the field, which requires a thorough analysis of the literature and consideration of how the findings connect to that literature. Furthermore, the Discussion section does not follow a standard structure, which gives medical writers more creative freedom in writing this section. Although this creative freedom might be liberating for some medical writers, others may feel anxiety or even dread.

Although the Discussion is the hardest section to write, medical writers can find solace with recommendations on the essential elements to include in this section (Box). These recommendations are not prescriptive nor exhaustive, but they are a solid starting point for helping medical writers feel more confident and focused in crafting an effective Discussion.

ESSENTIAL ELEMENTS OF A DISCUSSION SECTION

Summarize the major findings

- Repeat the study question
- Synthesize the most important findings
- State how the findings answer the study question

Interpret the important findings

- Describe how important findings are interrelated
- Discuss unexpected and interesting findings
- Explain how important findings extend or support previous findings
- Explain how important findings contradict previous findings

Describe the implications and applications

- Describe the theoretical implications of the findings
- Describe the practical applications of the findings

Discuss the strengths and limitations

- Highlight the strengths of the study
- Acknowledge the limitations of the study

Recommend future directions

- Suggest next steps and future work

State the conclusions and impact

- Repeat the main outcome
- Describe the main contribution to the field
- Emphasize the relevance and significance to the field

SUMMARIZE THE MAJOR FINDINGS

The first paragraph of the Discussion is an opportunity to transition readers from a dense Results section into a discussion of the findings and interpretations. In this first paragraph, the main goal is to tie the important findings back to the study question.

Repeat the Study Question

To reorient readers to the overall purpose of the study and prepare them to navigate the Discussion, start with a statement that reminds them of the study question you posed at the end of the Introduction. This statement should include

the key aim(s) of the study, the main objective(s), and, when relevant, the hypothesis.

Synthesize the Most Important Findings

After restating the question, summarize the most important findings that answer the study question. In this summary, be careful not to rehash the findings. Instead, synthesize the findings in a way that supports the answer to the study question. If the manuscript is highlighting a new approach that was developed, describe the overall approach that was developed and validated.

State How the Findings Answer the Study Question

At the end of this first paragraph, state how the summarized findings answer the study question. This sentence helps to tie the key findings together in a nice package that shows cases how they are connected to the question and how they advance the field.

INTERPRET THE IMPORTANT FINDINGS

The bulk of the Discussion includes the authors' interpretations of the important findings and how they fit into what is known in the field. These interpretations can vary widely among studies and fields—which contributes to the common perception of the Discussion being the most difficult part of a research manuscript to write. However, the following recommended features can help authors ensure they include the essential elements of an effective Discussion.

Describe How Important Findings Are Interrelated

In the Discussion, describe any relationships in the findings. Are there any correlations or incongruence between different findings? Are there any patterns in the data? Could any of the findings influence other findings? Be sure to explain how these relationships could affect the outcomes or implications of the study.

Discuss Unexpected and Interesting Findings

Although many researchers anticipate the outcomes of their work, they may still uncover surprising, intriguing, or inconclusive findings. In the Discussion, describe these interesting findings and any findings that do not support the answer to the study question. Importantly, share why these findings are particularly interesting and what new questions arise as a result. Some examples include rationalizing unexpected outcomes, clarifying inconclusive findings, and interpreting data outliers.

Explain How Important Findings Extend or Support Previous Findings

Most research builds on previous work. Although the

Introduction should describe this previous work to frame the rationale for the study, the Discussion section frames how this previous work connects to the findings in the study. To discuss these connections, describe how the findings build on what is already known. For example, how do the study findings support or extend findings from previous work?

Explain How Important Findings Contradict Previous Findings

In addition to connecting the findings to previous work, the Discussion should also examine any disconnections from previous work. For example, how do the study findings contradict or refute previous findings? When highlighting these disconnections, speculate on why the findings might be contradictory. For example, was the approach different? Was the population or sample size different? Was the analysis different? Answering these questions is an opportunity to defend the work in this study and strengthen the significance of the findings.

DESCRIBE THE IMPLICATIONS AND APPLICATIONS

To ensure that readers fully appreciate the significance of the study, the Discussion needs to include a description of the potential implications and applications of the findings. In other words, how do the findings advance the field, and what can be done now that these findings have been revealed? This description will depend on the study and generally include theoretical implications and/or practical applications.

Describe the Theoretical Implications of the Findings

In the Discussion section, be sure to describe the theoretical implications of the findings. Theoretical implications are evidence-based speculations on how the findings impact research in the field. As the name implies, these implications describe how the findings advance the field but cannot yet be meaningfully applied in the real world.

Describe the Practical Applications of the Findings

In the Discussion section, describe any practical applications of the findings. Practical applications are evidence-based recommendations or solutions that can be used in the real world. These applications are often calls to action, such as new approaches to research, changes to clinical practice, or updates to government policies.

DISCUSS THE STRENGTHS AND LIMITATIONS

The Discussion section needs to highlight the strengths and limitations of the study. These details help readers to understand how definitive (ie, significant) the findings are.

Highlight the Strengths of the Study

Few journals specifically request that authors highlight the strengths of a study. And some authors feel uncomfortable or immodest about highlighting these strengths. But describing the strengths can help readers understand the value of the findings and significance of the study. When highlighting the strengths, consider all aspects of the study, including the conceptual framework, population, experimental techniques, and statistical analysis.

Acknowledge the Limitations of the Study

An important part of the Discussion is acknowledging the limitations of the study. Be sure to describe these limitations and, importantly, how they could have affected the outcomes, interpretations, and conclusions. For example, what problems occurred? What are the weaknesses or assumptions made in the methods? What gaps does the data leave open? Acknowledging these limitations gives the opportunity to share the rationale for doing the work despite the limitations or to suggest future directions of the work.

RECOMMEND FUTURE DIRECTIONS

The Discussion section should include recommendations for future work. These details describe what next steps could be done to build on or fill any gaps in the work and to further advance the field.

Suggest Next Steps and Future Work

In the Discussion, describe what could be done next by the research team or others in the field. For example, if the study needed to be repeated, what could be done differently? If the study created gaps in knowledge, what could be done to fill them? If unlimited resources were available, what could be done next?

STATE THE CONCLUSIONS AND IMPACT

At the end of the Discussion, readers have the full context of the study and how it fits into the existing literature. The conclusions paragraph is then final opportunity to highlight the significance of the work and leave readers with a lasting positive impression of the study.

Repeat the Main Outcome

Start by repeating the main outcome of the study, but do not summarize the findings again. Repeating the main outcome reminds readers of the most important result(s) of the study.

Describe the Main Contribution to the Field

Next, state how the main outcome answers the study question. This answer will show readers that the study accomplished its purpose of answering the question and filling a gap or need in the field.

Emphasize the Relevance and Significance to the Field

Finally, share how the study advances the field. Ending with this information highlights the relevance and significance of the work at the end of the manuscript, the prime position for leaving a lasting impact on readers.

THE ESSENTIAL ELEMENTS SHOWCASE THE STUDY

An effective Discussion showcases the findings and significance of the study in the context of what is already known. For a medical writer, this task can be difficult and overwhelming—especially with the structural flexibility and open-ended nature of the Discussion section. But with these essential elements at their fingertips, medical writers can sharpen their focus and build their confidence in crafting an effective Discussion.

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Author contact: *crystal.herron@redwoodink.com*

FREELANCE FOCUS



Melissa L. Bogen



Lori De Milto



Cathryn D. Evans



Alex Howson

Q1: What advice would you give to freelance medical writers, editors, or communicators who are new to medical writing and have limited writing experience?

If you have limited or no hands-on writing experience, the first question you should be asking yourself is, “Why do I want to be a medical writer?” If the answer is, “Because it pays well,” you probably should rethink the idea of being a medical writer; otherwise, if the answer includes, “Because I love reading and writing and sincerely wish to develop the skills to be a good writer,” then go forward.

Other crucial questions include, “Am I willing to do the work involved to learn how to write well, to study and discriminate the medical literature, and to immerse myself in medical and other health care topics? And do I honestly believe I would be an excellent writer and communicator?” If the answers to these questions are a resounding “Yes,” then great! Move forward.

The most essential things you need are experience and good writing skills—so practice, practice, practice; write, write, and write more. I recommend taking an onsite writing class (or several) at your local college or university—not an online class because learning is more valuable in the classroom with a teacher and other students. Although the AMWA Essential Skills booklets are supportive, they cannot teach you how to write; nor can they give you the hands-on experience necessary to ask someone to pay you to write an article, clinical report, or other writing tasks. Most companies or clients wish to work with an experienced medical writer, not a trainee. (However, some agencies may be willing to hire you as a contract writer as a trainee at a lower rate, although this is not too common.)

Try selecting a topic area in medicine (eg, heart disease, a specific cancer, psychiatric medicine, etc), write an interesting article or review, and submit it to your local throw-away journals or magazines for free, just to get experience and a few published articles in your portfolio. Do your marketing research; determine who is likely to accept such articles from you.

There are so many venues for publishing your writing. For example, if you wish to write for magazines devoted to the lay public, consider Writer’s Market 2024 (<https://writersmarket.com>). There you will find information about the

requirements of many journals/magazines, including how to submit your work, or how to receive an assignment.

I strongly recommend working in a full-time job as a medical writer before attempting to sell yourself as a freelance medical writer. Even if you take a position as an associate medical writer at a lower salary, it will be worth it because you will acquire many skills not possible from just taking a few courses and reading booklets about writing.

Medical writers can work in various media, for example, publishing, public relations, marketing communication, sales training, website copy, advertising agencies, pharmaceutical or biotech companies and their contract research organizations, continuing medical education for physicians, nurses, pharmacists, patient education, sales training, standard operating procedures (SOPs), and more. It is a good idea—once you have taken classes and acquired the skills and hands-on experience—to select certain media or therapeutic areas for which you feel an affinity and practice in those areas.

In the pharmaceutical and biotech industry, you need not only writing skills and experience, but also you should have a good understanding of the process of drug research and development (from bench to marketing), how the industry works, what requirements and guidelines the US Food and Drug Administration (FDA) and other regulatory agencies have, and how different departments relate with each other (eg, research, biostatistics, clinical studies, marketing, sales).

If you are earnest in the desire to be a professional medical writer, do your homework and write, write, write, and write some more!

—Cathryn D. Evans

Q2: What are the top software tools for new medical writers?

When I started as a freelance medical writer in 2005, I had a laptop, a cell phone, and Microsoft Office 2004. I tracked time with TaskTime4 or copious Post-It notes on my desk. Over the years, I’ve added many software tools to my technology stack. Some have enhanced my productivity, some have wasted time, and some have been fun to explore. Here are some tools I recommend to help streamline research, writing, and collaboration processes.

Regardless of your specialty in medical writing, you probably have to track and manage references and source material. I know too well how easy it is to get tangled in a reference knot, but not if you have robust reference management software! I've used Endnote since my graduate days to save time and ensure citation accuracy, but many alternative options exist. Mendeley and Zotero have free versions to help you organize, cite, and share your sources if required. You can create a searchable database of your references, generate bibliographies, and easily insert citations into your text.

Like many medical writers, I started with Microsoft Word, but a couple of years ago, I switched to the Google family of tools, which includes Docs, Sheets, and Forms. I've always been an Apple user, and these tools integrate more seamlessly with Mac products. Some clients use Microsoft, and some use Google. If you have to switch back and forth between these tools, you'll find that the interoperability between Google and Microsoft is reasonable. Like Microsoft tools, Google Docs also allows real-time collaboration with colleagues and clients, making it easy to incorporate feedback and track revisions. For longer documents like book manuscripts, I recommend Scrivener or Butter Docs. These tools are highly visual. They use cards and blocks that allow you to easily rearrange sections of your document across horizontal boards. Dropbox is a must-have for file sharing—spring for at least the business plan to maximize your storage limit. I also recommend meeting and calendar software. Your clients will thank you for making meeting scheduling and follow-up a breeze. I use Calendly to schedule meetings, otter.ai to create a transcript (with permission), and Zoom to conduct virtual meetings.

Applications like Grammarly or Hemingway Editor can help you polish your writing by identifying grammar, spelling, and style issues, and help to ensure your work is free from unintentional plagiarism. If your clients require you to create or recommend visuals, data visualization tools like Infogram, Canva, and Piktochart can help you build engaging charts, graphs, and infographics to supplement your content. I also like the Noun Project for customizable icons and royalty-free photos.

When juggling multiple clients or projects, it's easy to get overwhelmed by different project tasks and timelines. Software to help you keep tabs on different client requirements is vital. I currently use Click Up to create task lists and monitor progress, but many project management tools like Trello, Asana, Evernote, Basecamp, or Notion will help you stay organized with project items and track deadlines.

—Alex Howson

Here is a short list of what I use:

- Cloud-based backup, for example, Dropbox (<https://www.dropbox.com/backup>) or Carbonite (<https://www.carbonite.com>). Be careful about having

multiple backup systems as they sometimes mess one another up by moving folders.

- Computer security, for example, Webroot Antivirus (<https://www.webroot.com/us/en/home/products/av>)
- Accounting software for expenses, invoices, estimates, and time tracking, for example, QuickBooks (<https://quickbooks.intuit.com/oa/get-quickbooks>)
- Teleconference software, for example, Zoom (<https://zoom.us>) or Microsoft Teams (<https://www.microsoft.com/en-us/microsoft-teams/download-app>)
- PDF unlocking software, for example, Soda Unlock PDF (<https://www.sodapdf.com/unlock-pdf>)
- *AMA Manual of Style* (<https://academic.oup.com/amamanualofstyle>). The eleventh edition is the current edition, and it's continuously updated online. (As an AMWA member benefit, access is 20% off. See the complete list of affiliate partner discounts at https://www.amwa.org/page/Member_Benefits)
- Citation management, for example, EndNote (<https://endnote.com>)—15% off as an AMWA member benefit.
- PerfectIt Proofreading Software (<https://intelligentediting.com>)—30% off as an AMWA member benefit.
- Stedman's Online Medical Dictionary (<https://www.wolterskluwer.com/en/solutions/lippincott-medicine/medical-education/stedmans-online-medical-dictionary>)
- Adobe Acrobat (<https://www.adobe.com/acrobat/complete-pdf-solution.html>)

AMWA member Monica Nicosia, PhD, has published surveys in the past about essential digital tools for medical writers, and recently concluded a survey in March 2024.

—Melissa L. Bogen

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Q3: What is the role of generative artificial intelligence in medical writing?

Although I have used ChatGPT and BingChat frequently, I have not used them for serious medical writing projects, partly because these and several other ChatBot programs are still in development, changing rapidly—but more importantly, because I have found too much plagiarism, a limited scope of the responses, information rendered incomplete, too many errors in citations (which means I have to check everything), and no obvious advantage in terms of time spent.

One really does need to check the reference citations and go beyond the research data these programs provide—thus, in the end, although they may be fun and interesting, they do not reduce the time required to write a serious article, so far, at least. An experienced medical writer, I have

found, can do the job faster than when using artificial intelligence (AI) to assist. Nonetheless, at present it is useful to get a few helpful ideas here and there, and definitely the direction AI is going suggests that these programs might be much more helpful in the future. AMWA offers workshops or webinars given by people who use AI seriously and often so likely it is prudent to sign up for them. Time will tell...

—Cathryn D. Evans

When generative AI started making a big splash everywhere, I tried to bury my head in the sand and ignore it. I just didn't want to deal with it. But as I started learning about generative AI, I realized that if I wanted to survive and thrive in the era of AI, then I had to learn how to use it in my medical writing.

Generative AI, algorithms like ChatGPT, is a type of AI that can create content, ideas, outlines, images, videos, and more. Right now, most medical writers (freelancer and employed) and organizations working in the field are still trying to figure out the best ways to use AI in medical writing. But as the technology evolves and we all gain more experience using generative AI, its use and importance in medical writing will increase, probably exponentially.

Like all technology, generative AI has benefits and limitations. It can increase our efficiency, once we learn how to use it. But medical writers must use generative AI ethically and responsibly.

Medical writers can use generative AI to plan content, brainstorm ideas, summarize data and information, generate titles, ensure consistency, optimize content for search engine optimization, and more. Although generative AI can be a great starting place for a project, we should never use it to do the writing for us.

Generative AI can't replace our expertise, judgement, and critical thinking skills. Using it effectively requires much more than simply typing in a topic. Writers must know how to prompt the AI tool to deliver accurate and appropriate results and to carefully review and validate those results. This requires skill.

Problems with generative AI in medical writing include the lack of the most current information and the lack of subject matter expertise. Also, AI doesn't know the needs, perspectives, insights, or strategies of our clients. And we can't use proprietary information on ChatGPT or other AI tools because user prompts are incorporated into their algorithms.

Nearly all of my work requires interviews with subject matter experts or extensive use of information about my clients. Although most of this is not proprietary, much of it is not publicly available. So, I wouldn't feel comfortable using it in my prompts.

Also, generative AI can't produce creative or original content. It lacks the human touch. Information can be inaccurate and confusing, biased, and possibly racist.

Using generative AI in medical writing is a skill. Like any skill, practice will help you learn how to use generative AI ethically and responsibly. Experts say to just start experimenting with ChatGPT.

Learning new technology has always been a struggle for me. If I can learn how to use generative AI, then you can too.

—Lori De Milto

I have been noodling around with generative AI since ChatGPT emerged late in 2022. Mostly, I've been playing with tools like Claude, ChatGPT-4, Castmagic, and other platforms with generative AI capabilities to support content marketing and podcast production. This noodling feels like low-stakes fun. Although I have not (yet) used generative AI for client-facing medical writing, there is a lively discussion about its promise in my medical writing specialty, continuing education (CE) for health professionals. Proponents of generative AI emphasize its potential for creating initial drafts of CE content, such as overview articles and case studies, or for developing interactive elements to enhance learner engagement and knowledge retention, such as quizzes or polling questions.

Given the persistent concerns about quality control, content integrity, and bias in AI-generated content, I'm not alone in viewing generative AI in CE as best used for research assistance tasks and optimizing workflow efficiency. Here, generative AI shines. For instance, tools like Semantic Scholar, Scholar.ai, and Elicit scan and summarize relevant medical literature rapidly, speeding up parts of the research process. Similarly, tools like SciSpace generate multiple citations focused on a particular topic or research question and provide explanations, summaries, and insights for technical text, equations, and tables in research papers and other written content. Tools like ResearchRabbit can help you visualize connections between articles and authors, making it possible to drill ever more deeply into the literature to pull out granular nuggets of information that bring educational content alive. When writing about complex topics, summarizing software is a launchpad that helps you get a quick gist (eg, Quillbot, DeepL Write, Scholarcy, Genei.io). Generative AI can also polish your text and streamline the editing and revision process by identifying potential errors, inconsistencies, or areas in your work that require additional clarification.

Beyond these current tasks, CE medical writers will likely see more generative AI in their workflow and content creation. Undergraduate medical education already uses generative AI to personalize learning, create virtual simulations tailored to individual learning gaps, and develop assessments. CE will no doubt follow.

—Alex Howson

IN THE SERVICE OF GOOD WRITING

How To Read (and Write) a Book

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

ABSTRACT

Mortimer Adler and Charles Van Doren's classic *How to Read a Book* gives useful guidance. It explains how to evaluate whether a book is worth reading. It also gives you tips for getting the most out of the books that you read. Their advice on reading also suggests some tips for better writing. Pick an important topic and say something important about it. Do your research and organize your presentation. Keep your writing clear and simple. Make clear and reasoned arguments and anticipate the objections that your audience may raise. Above all, make sure that your title, front matter, back matter, and book cover tell the reader what your book is about and why it is worth reading.

In 1940, Mortimer Adler published the first edition of his classic book *How to Read a Book*.¹ In 1972, he and Charles Van Doren published an extensively updated edition.² As I was reading the 1972 edition, I realized that it also provides hints on how to make your writing more readable.

By 1972, millions of books had already been published. Some books are informative, and some are just amusing. You might read a detective novel just once, purely for entertainment. You might dip into a reference book from time to time to find bits of information. There are surprisingly few great books—books that are worth reading carefully, or even repeatedly. In an appendix, Adler and Van Doren provided a list of great books by 137 authors. Some of these are medical texts (see Box: Great Books on Medicine).

Adler and Van Doren wanted to teach you how to sort through books to find the ones that really matter, and how to get the most out of reading them. Yet their discussion also offers hints on how to improve your own writing. These hints can be organized by the levels of reading that Adler and Van Doren defined: elementary, superficial, analytical, critical, and syntopic. As I discuss each level of reading, I will offer my own rules for better writing.

ELEMENTARY READING

Elementary reading means the ability to translate the marks on a page into words in your mind. The major weakness of *How to Read a Book* is the authors' baffling denial of an obvious fact. Many American schools were (and still are) using a bad method for teaching reading. English is an alphabetic language. It is written with letters that stand for sounds. Thus, to teach English-speakers to read, you start by teaching the 26 letters of the English alphabet. Then, the students should learn the 70 rules for how those letters can be used to represent English's 44 phonemes (speech sounds). Roughly 85% of English words follow those rules.³ Once students learn the rules, which takes about three months,⁴ they will be able to read tens of thousands of words. Yet instead of teaching those phonetic rules, many educators ask students to memorize whole words (sight words), with-out regard to the letter-sound relationships.

Adler and Van Doren suggested that the ability to read develops, as if by magic, after children have memorized a few hundred sight words. They should have known that there is no such magic. They alluded dismissively to Rudolf Flesch's 1955 bestseller *Why Johnny Can't Read—And What*

GREAT BOOKS ON MEDICINE

In the appendix to the 1972 edition of *How to Read a Book*,² Mortimer Adler and Charles Van Doren provided a list of 137 authors whose greatest works are worth reading carefully and perhaps repeatedly. Some of these might be of particular interest to medical writers:

- Hippocrates – [Medical writings](#)
- Galen – *On the Natural Faculties*
- William Harvey – *On the Motion of the Heart and Blood in Animals; On the Circulation of the Blood; On the Generation of Animals*
- Claude Bernard – *Introduction to the Study of Experimental Medicine*
- William James – *The Principles of Psychology*
- Thomas Mann – *The Magic Mountain*
- Aleksandr Solzhenitsyn – *The Cancer Ward*

*You Can Do About It.*⁵ Flesch explained that children should be directly taught how to sound words out from left to right. Of course, many children learn to read well despite the use of the sight word method. Either they break the letter-sound code for themselves, or they learn it from a tutor. The rest remain mired in functional illiteracy.

Writers have a vested interest in the performance of public schools. Writing is pointless if your intended audience cannot read well. Fortunately, writers can use their power of the pen to demand that public schools use better methods of teaching reading. Writers must also compensate for their readers' poor reading skills. Many adults have never learned to sound out words. For this reason, writers should strive to obey the following two rules:

Rule 1: Try to use short, simple words that your readers already know, rather than using big words or words that readers have never seen before.

Rule 2: Write short, simple sentences.

If you obey those rules, your writing will be more accessible, in two important ways: it will be easier to understand, and it will be easier to find online. Search engines give a higher ranking to Web pages that have higher readability scores. (Some word processing programs can calculate the Flesch-Kincaid readability scores.)

INSPECTIONAL READING

Adler and Van Doren described two levels of inspectional reading. The first involves a quick inspection of the book's title, its table of contents, its index, and its cover. During this inspection, the reader asks the following questions: What is the book about? What kind of book is it (eg, fact or fiction, practical or theoretical)? What kind of material does the book cover? To help your readers answer those questions about your writing, obey the following rules:

Rule 3: Write about something interesting.

Rule 4: Make the framework of your book clear. Use meaningful chapter titles and meaningful subheadings in the text, and include a table of contents, as well as an index, if possible.

Rule 5: Make sure that the title and the cover of the book say what the book is about and why it is worth reading.

Rule 6: If you are writing an eBook, provide links that make it easy for readers to find the information they want.

The second level of inspectional reading involves reading a book through from beginning to end, without stopping to look up or ponder things that you don't immediately understand. To make this experience better for the reader, follow rules 1 through 5.

ANALYTICAL READING

During analytic reading of a book, the reader asks several questions: What kind of book is it (eg, fiction or nonfiction, practical or theoretical)? What is its unity (main message)? How do its parts fit together? What questions is the author asking? What problems is the author trying to solve? Your readers will find it easier to answer these questions if you followed rules 1 through 6.

The second phase of analytical reading involves coming to terms with the author. This means making sense of the key terminology that the author is using. A term is a word or expression that has a precise meaning in some contexts or is peculiar to a science, art, profession, or subject. Adler and Van Doren urged readers to "distinguish between the author's *vocabulary* and his [sic] *terminology*" [emphasis in original].² By *vocabulary*, they mean the words that are being used. By *terminology*, they mean the precise meaning that the author intends those words to convey. In other words, readers must struggle to figure out what the author really meant. Readers would rather not have to do so much work. As writers, we must strive to make it easy for our readers to understand what we mean. To achieve that goal, obey the following rules:

Rule 7: Whenever possible, use common words, and use them according to their standard meanings, as spelled out in a well-respected dictionary.

Rule 8: If you must use an uncommon word, define it the first time you use it.

Rule 9: If you must use a common word in an uncommon way, explain the meaning that you want that word to convey.

The third phase of analytical reading involves identifying and evaluating the arguments that the author has made. Adler and Van Doren explain that readers often must try to find the book's most important sentences. Then, the readers must try to piece together the argument that the author seems to be making. Your readers will find it easier to find and evaluate your arguments if you followed Rule 10.

Rule 10: If you need to explain why someone should believe something, or if you want to persuade them to do something, make your argument clear and simple.

Adler and Van Doren emphasized the importance of the classical trivium (grammar, logic, and rhetoric) for helping one develop skills in analytic reading. Grammar is the study of how words are altered and combined to form meaningful sentences in a given language. Logic is the study of how sentences are combined to form arguments. Rhetoric is generally described as the art of persuasion, but it provides the basis for critical thinking. You must learn some grammar

before you begin to study logic. You must learn something about logic before you can begin to study rhetoric.⁶ Yet by 1972, the National Council of Teachers of English had been working for nearly a decade to suppress grammar instruction in American grammar schools.⁷ Readers who have never studied the trivium will have poor skills in analytical reading. Thus, many readers have poor thinking skills. For this reason, writers must strive to keep their writing clear and their arguments simple.

After identifying and evaluating the author's arguments, the reader can then ask two other questions: Which problems has the author solved? Which problems has the author failed to solve? As Adler and Van Doren noted, some authors clearly address the possible objections to their conclusions. For example, in his *Summa Theologiae*, Thomas Aquinas headed many sections with a question. He then offered possible answers, followed by possible objections. He then expressed his own opinion by saying, "I answer that..." By taking this approach, Aquinas showed that he had given the topic careful thought. He also handled the foreseeable objections. You might not have the space to go into that much detail, but you should try to obey the following rules:

Rule 11: Do your homework, and make reasonable arguments based on the best available evidence.

Rule 12: Try to anticipate the most likely objections that a typical reader, and especially an intelligent reader, might raise.

CRITICAL READING

Adler and Van Doren felt that one should not agree or disagree with an author—or even suspend judgment—unless one truly understands what the author meant to say. They argued that suspending judgment is itself an act of criticism. It means taking the position that the author did not make an adequate case. You cannot render that judgment unless you understand what the author wrote.

Adler and Van Doren also urged readers to be civil. When you disagree with an author, you should do so reasonably, rather than for the thrill of conflict. They also stressed the difference between knowledge and opinion. When criticizing a work, it is fair to evaluate the author's grasp of the facts. You might point out where the author was uninformed, or perhaps misinformed. You might also point out illogical arguments or an incomplete analysis. Of course, your readers might do critical reading of your own work. If you followed Rule 11 and Rule 12, your readers might not share your opinions, but they will have little room for legitimate criticism.

SYNTOPICAL READING

Syntopical reading means reading several books on the same topic. In the first step, the reader compiles a tentative bibliography on the subject. Then, the reader can inspect those books to see whether they truly relate to the subject. By inspecting those books, the reader will get a clearer idea of the subject. Then, the reader will identify the most relevant passages. The reader must then apply steps similar to those in analytical reading:

- Reconcile differences in terminology among authors.
- Establish a set of issues that all authors seem to be addressing, directly or indirectly.
- Rate those issues as major or minor.
- Assess where the authors agree—and where they disagree—on those issues
- Analyze the discussion among the authors in a way that throws maximum light on the subject.

When you write a review article, you do much of this work for your intended readers. You should start by doing a thorough search of the literature. The goal is to compile all the evidence relevant to some important question. If you have studied statistics, you might do a meta-analysis, which is a statistical analysis that combines the results of multiple scientific studies. Fortunately, there are published guidelines (the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines)⁸ for the conduct of meta-analyses. You can also use commercial software to do the statistical analyses. As you compile the evidence, you should use proper bibliographic citations. (I strongly recommend using citation management software, such as Endnote.) Thus, your reference list will serve as a bibliography. As you analyze the evidence, you may have to reconcile differences in terminology. You would then identify the major and minor issues. Do the authors agree or disagree about these issues? What light does the combined input from these various authors shed on the subject at hand?

CONCLUSION

To write a great book, or even a great article, you must find an important topic and say something important about it. You must also follow the basic disciplines that you may have learned in grammar school and high school. Say something intelligent and say it intelligibly. To reach the broadest possible audience, you must apply the principles of plain language: use short, simple words in short, simple sentences. To appeal to a more specific audience, you must do your homework. Make sure that you know what you are talking about and make reasoned arguments based on the best available evidence. Use proper citations to help your readers find and evaluate the supporting evidence for them-

selves. Put your thoughts into an organized structure that will allow readers to identify your main points and evaluate your arguments with minimal effort on their part. Make sure that your title, your chapter titles and subheadings, and your promotional materials express what your book is about and how valuable it is.

Laurie Endicott Thomas is a freelance writer. She is also the author of several books, including Not Trivial: How Studying the Traditional Liberal Arts Can Set You Free.

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Author contact: *Lthomas521@verizon.net*

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REGULATORY INSIGHTS

European Union Regulation on Personal Data Protection in Medical Writing

Tatiana Revenco, PhD / Privacy Professional and Personal Development Lead, MyData-TRUST, Mons, Belgium

ABSTRACT

The European General Data Protection Regulation 2016/679 (GDPR) aims to harmonize data protection laws across European Union (EU) Member States. The goal of GDPR is to ensure respect of the fundamental right to protection of the personal data and privacy, to enhance security measures, including information technology (IT) for data protection, and to render natural persons control over their personal data. Importantly, companies, institutions, freelancers (including medical writers) located outside the EU and handling personal data of natural persons living on the territory of the EU must comply with GDPR.

Medical writers edit documents related to the activities in health sector that comprise personal data, specifically health data considered as sensitive data. Therefore, medical writing should put in place robust security measures and comply with the GDPR. This article is a clarification of the GDPR notions, principles, technical and organizational measures applied to the medical writing to guarantee protection of the personal data and respect of individual's rights and freedoms.

INTRODUCTION

The European Union (EU), consisting of 27 European member states (MS),¹ is governed by the European Parliament and the Council of the European Union. These two legislative bodies, comprised of EU MS representatives, are responsible for enacting legislations (that comprise regulations and binding legislative acts) that apply across all MS. The European General Data Protection Regulation 2016/679 (GDPR) was voted by the European Parliament and the Council of the European Union as a binding regulation for all EU MS, aiming to harmonize the national data protection laws of all EU MSs.^{2,3}

The GDPR respects all fundamental rights and observes the freedoms and principles recognized in the Charter of Fundamental Rights of the European Union and in the Treaty on the Functioning of the European Union. The objective of the GDPR is acknowledging the right to protect

personal data (PD) and respect individuals' privacy, freedom of thought, conscience, and religion, freedom of expression and information, as well as freedom to conduct a business. In addition, the GDPR aims to enhance security measures by leveraging information technology (IT) to protect PD and to render individuals' control over their own PD. In principle, companies, institutions and freelancers, including non-EU medical writers and those handling PD for EU residents, should comply with the GDPR. Medical writers usually edit the health system documents that contain sensitive PD. Thus, medical writing should employ robust protection of PD as required by the GDPR. This article clarifies GDPR notions, principles, and technical measures applied to medical writing to support PD protection and respect of the aforementioned individuals' rights and freedoms.

GDPR NOTIONS ASSOCIATED WITH MEDICAL WRITING

Requirements for the Management of Sensitive Data

PD are defined as any information related to a natural person. The person can be directly identifiable by name, surname, identification number, or other direct identifiers. Or the person can be identified indirectly by combining other personal information or factors such as physical, physiological, genetic, mental, cultural, and so on.³

When editing documents representing a particular clinical study, medical writers may manage PD, including demographic information (ie, age, gender, ethnicity, and race), health and genetic data, which is classified as sensitive PD.³ Sensitive PD falls under special categories of data and requires enhanced security measures with a comprehensive and multiple-faceted strategy.

Complying With GDPR When Processing PD

The GDPR defines actors of processing activities. A data controller is a natural or legal person, public authority, agency, or other body that, alone or jointly with partners, determines the purposes and means for processing PD. In the context of a clinical study, controllers are the sponsor or

investigational site; they determine the objectives and means of processing the study participant's data in the study protocol. The GDPR clearly defines the duties and liability of the controllers. As such, controllers should implement appropriate and efficient security measures to demonstrate compliance with the GDPR in processing activities.

Data controllers engage service providers or freelancers, including medical writers, who are defined as data processors. Although processors handle PD upon the instructions of controllers, they have responsibilities and obligations to provide sufficient guarantees to implement appropriate security measures in such a manner that processing will meet the requirements of the GDPR and ensure the protection of the data subject's rights.¹ The contractual bindings between controllers and processors must incorporate a data processing agreement (DPA) that explicitly outlines the responsibilities of both parties and ensures compliance with the GDPR (Figure 1).

GDPR PRINCIPLES APPLIED TO MEDICAL WRITING

The GDPR outlines key principles that serve as the foundation for data protection. These principles guide how organizations process PD.

Lawfulness, Fairness, and Transparency

The GDPR states that PD shall be processed lawfully, fairly, and transparently in relation to the data subjects.³ Accordingly, the processing of PD must have a valid legal basis, such as the consent of data subjects, the legitimate interest of controllers, or a legal or contractual obligation. Fairness is defined as the idea that PD processing should not exceed data subjects' expectations. Transparency means that the purposes and means of processing must be clearly defined and explained in a comprehensible language to the data subjects (ie, informed consent forms for a clinical trial,

plain language sections in the articles or patient advocacy communication, privacy notices for digital communication or any other types of communication).

Purpose Limitation

The GDPR restricts the collection of PD to specific and explicit purposes initially disclosed to the data subjects. It prohibits using PD in ways that are incompatible with those stated purposes. However, if a second purpose arises, it must undergo a thorough analysis to determine its compatibility with the initial purpose. If it is not compatible, additional steps for data re-use are necessary. However, further details on this topic are beyond the scope of this article.

Minimization

The GDPR states that “PD shall be adequate, relevant, and limited to what is necessary for relation to the purposes for which they are processed.”³ When writing for scientific publications, data minimization means that any additional information about an individual must be avoided or replaced with more generalized information.⁴⁻⁷ Examples of generalization or randomization of PD include: avoiding the use of date of birth, using a range of age to replace exact age, removing any unnecessary details on images (ie, from scans, biopsies, x-rays), double coding a patient code that was initially attributed by the investigational site, avoiding or generalizing (by a considerable geographical extent) the location and name of the investigational site, and removing or aggregating outliers.

Accuracy

The GDPR specifies that PD must be both accurate and, when necessary, kept up to date. Moreover, the regulation emphasizes that every reasonable effort should be made to promptly erase or rectify inaccurate PD, considering the purposes for which they are processed. Overall, a particular set of PD should be attributable, legible, contemporaneous, objective, and accurate. The accuracy of data is ensured by additional teams that perform quality control, and the correctness of data is used to do statistical analysis, elaborate figures, and create tables for any medical documentation, report, or publication.

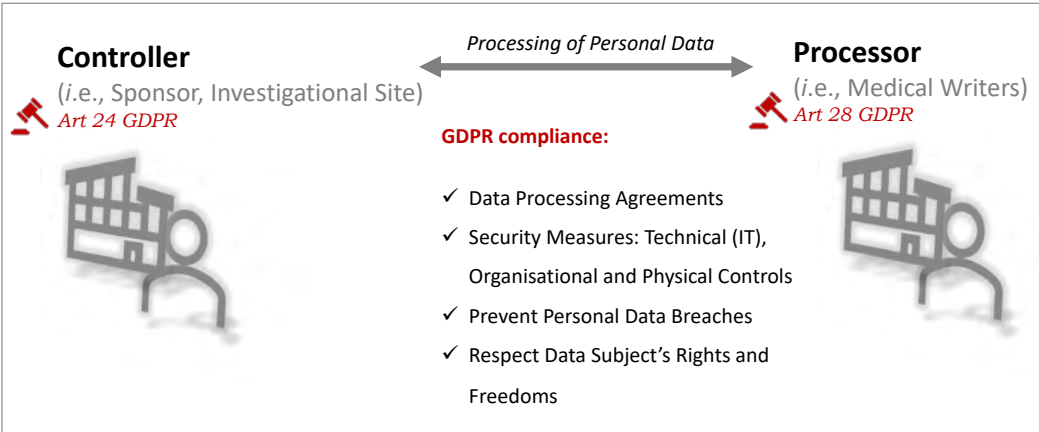


Figure 1. Responsibilities of data controllers and processors. GDPR, European General Data Protection Regulation 2016/679.

Limitations on PD Retention

The GDPR does not prescribe specific retention periods; it mandates that data are stored only as long as necessary in accordance with relevant regulatory provisions and the specific purposes of data processing. Organizations must therefore develop and adhere to a robust data retention policy tailored to their sector and operational needs. For instance, in clinical research, the storage duration of data depends on the type of investigational product and the relevant regulations. Clinical Trials Regulation apply when the investigational product is a drug, requiring data to be stored for at least 25 years, whereas the PD holding span for advanced therapy medical products is 30 years.^{8,9} On the other hand, as per medical device regulation, the estimated PD lifespan for clinical studies on performance evaluation of medical devices, including health applications, falls between 10 and 15 years.¹⁰ Without regulatory specifications, controllers should follow the commendable retention duration for a set of PDs from regulatory authorities. Otherwise, the controller may define the retention time by relying on the processing objectives.

Notably, the data controller is responsible for instructing processors on the duration of retention, retrieval, and deletion of PD upon termination of the data lifespan. In most cases, the storage period is limited to the provision of services mentioned in the contracts; otherwise, data protection agreements should address the data holding period.

APPLYING MEASURES TO PROTECT PD

Data controllers and processors must put security measures in place and ensure privacy by design and default.³ The goal of security measures is to prevent PD breaches and decrease the risks of threats to the rights and freedoms of data subjects. Security measures defined by the GDPR include

- the pseudonymization and encryption of PD;
- the ability to ensure the ongoing confidentiality, integrity, availability, and resilience of processing systems and services;
- the ability to restore the availability and access to PD on time in the event of a physical or technical incident; and
- a process for regularly testing, assessing, and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing.

Importantly, the GDPR doesn't impose either pseudonymization techniques or any other technical and IT specificities (ie, algorithms for encryptions, types of encryptions), rendering the possibility for controllers and processors to adopt the measures according to their type of processing activities, size, organization, and budget.

Pseudonymization is the processing of PD in such a manner that the PD can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the PD are not attributed to an identified or identifiable natural person.³

Investigational sites attribute a code instead of their names to avoid direct identification of study participants in clinical trials. The codes remain confidential by the sites, and the data controller (sponsor) and processors (service providers) do not have access to the key to the code. Thus, they handle pseudonymized data of study participants. Other pseudonymization techniques in medical writing include data generalization, transformation, encryption, and hashing.

To consider PD as effectively pseudonymized, four cumulative criteria should be met (Figure 2):¹²

1. No individualization is possible, yet the individual can be singled out using additional information (ie, key to the code).
2. The key to the code must be kept confidentially by the data exporter (who might be a data controller or data processor) and typically at the investigational sites of a clinical trial.
3. Appropriate safeguards must be implemented to avoid data breaches and render control over PD to the exporter.
4. A thorough analysis must ensure that it is impossible to single out the individual even in case of cross-reference, considering the availability of such data.

Pseudonymized data are not directly identifiable data. Nonetheless, medical writers might have access to instantly recognizable PD when editing documentation for real-world evidence, clinical study reports, safety reports, and case reports. Therefore, it is essential that medical writers (freelancers or companies providing medical writing services) set up transparent pseudonymization methodology and adapt security measures to protect PD (Table 1). Importantly, pseudonymized data should not be considered anonymized data. The GDPR defines anonymous data as “information which does not relate to an identified or identifiable natural person or to PD rendered anonymous in such a manner that the data subject is not or no longer identifiable,”¹¹ and anonymized PD does not fall in the purview of the GDPR. The EU Data Protection Working Party, an independent European advisory body on data protection

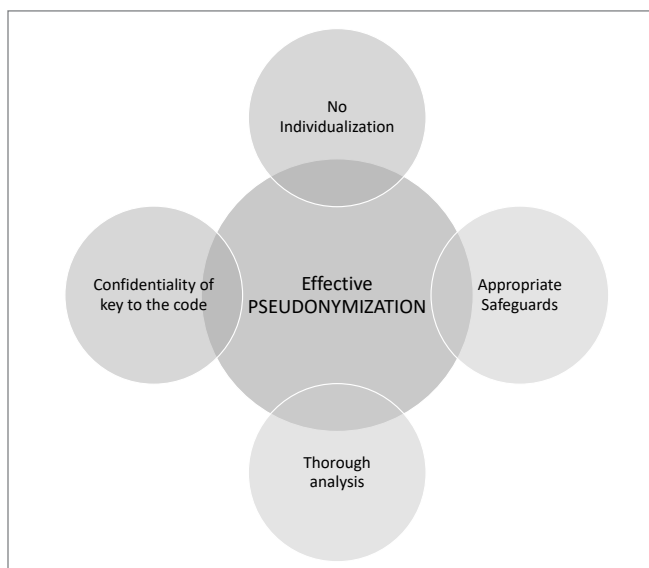


Figure 2. Four cumulative criteria to consider personal data effectively pseudonymized.

and privacy, analyzed several anonymization techniques and issued opinions regarding each method and the persistence of residual risk to identify the person.¹² In practice, it is impossible to achieve complete anonymization, and the success of reidentification in incomplete datasets is high.^{13,14}

Security measures can be categorized into technical, organizational, and physical security measures, underpinned by strong contractual agreements (Table 1). Technical controls involve IT-related measures designed to protect data from unauthorized access, alteration, or destruction. Organizational controls include policies and

procedures that govern how data are handled within an organization. Policies and procedures for data protection aim to manage:

- access to databases containing PD, that is, Electronic Case Report Forms (eCRFs), Electronic Data Capture (EDC), Trial Master File, safety data bases, as well as access to data during archival period;
- PD breaches, analysis of risks triggered by data breaches and evaluation of necessity whether the PD breach should be notified to Data Protection Authorities;
- data retention periods for different categories of PD based on the applicable regulatory requirements and the purposes of processing; the processes of data retrieval during storage and data deletion upon termination of the storage duration; and
- requests from data subjects.

The policies and procedures should be regularly reviewed and updated to reflect any changes in legal and regulatory requirements.

Physical controls refer to measures designed to safeguard the hardware and physical facilities in which data are stored. These controls protect critical components, such as servers, from physical threats and ensure the security of PD.

Contractual security is of utmost importance. Contractual frameworks serve as an instrument to demonstrate compliance with the GDPR by establishing clear responsibilities and expectations between parties involved in data processing (Figure 1). The DPA includes clauses on data

Table 1. Nonexhaustive Checklist of Organizational, IT, and Physical Security Measures to protect PD

Organizational Measures	Technical (IT) Measures	Physical Security Measures	DPAs
☐ Set up a data protection policy. ☐ Set up a data breach procedure describing step-by-step actions to contain the breach. ☐ Set up data retention, archival, and data removal or destruction procedures. ☐ Set up clear data management procedures that state how, to whom, by whom, and under what circumstances personal data can be accessed, erased, or sent back to the sponsor. ☐ Make personnel aware of the policies and procedures related to data protection. ☐ Regularly review and update data protection policies and procedures. ☐ Set up regular data protection trainings ☐ Raise privacy culture.	☐ Ensure control and restriction of access to the sources containing PD. ☐ Limit the number of users who may have access to PD. ☐ Limit time of access to PD. ☐ Use robust passwords to secure Internet connections. ☐ Install malicious software protection on workstations. ☐ Encrypt data and define ownership of the encryption keys. ☐ Define traceability methods to track the logs to the documents containing PD.	☐ Ensure the physical security of servers and platforms of data exchange. ☐ Ensure physical security of workstations. ☐ Set up procedures for managing paper format containing PD. ☐ Set up policies describing how to manage the physical maintenance of hardware. ☐ Set up procedures describing actions against the physical nonhuman source of risk (eg, earthquake zone).	☐ Use DPAs in contracts with controllers, processors, and freelancers who handle personal data. ☐ Clearly define responsibilities and liability of each party. ☐ Use adequate clauses to transfer data outside the EU to other countries.

DPA, data protection agreement; IT, information technology; PD, personal data.

protection obligations, breach notification procedures, and the implementation of security measures. Importantly, when PD are being transferred outside of the EU to countries that don't have an adequate level of data protection, contractual clauses ensuring appropriate data protection measures shall be used. For this matter, European Commission issued standard contractual clauses that can be used to legally frame data transfers to these countries.¹¹

CONCLUSION

Medical writers, whether working for companies or as freelancers, often fall into the category of data processors under the GDPR. As such, their responsibility extends beyond creating accurate medical content—it includes protecting the PD of EU residents. The GDPR provides a broad description of security measures that controllers and processors must implement. Hence, companies can adapt those measures according to size, organization, budget, and type of processing activities. The main goal of the GDPR is to ensure that the risks of data breaches, which might have harmful consequences for individuals, are decreased and that individuals' rights to data protection are upheld. Medical writing plays an essential role in the disclosure of medical information and results of clinical studies, as well as having access to an individual's data, including sensitive and directly identifiable data. Therefore, it is essential that the medical writing community raises awareness about data protection among its members and beyond and does not underestimate the role of medical writers in safeguarding privacy.

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Author contact: revenco.tanya@gmail.com

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AMWA NEWS



FROM THE PRESIDENT

Transitions

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

In medical writing, transitions are pivotal. They improve readability and, in many cases, clarify how story elements are related. They are connectors. I have been pontificating on the importance of transitions as I edit the current proposal on my desk. In looking for ways to draw the reviewer in, I use transitions to improve the flow of the document. I try out different transitions to see which ones will best show the reader how the research approach will answer the hypothesis and accomplish the objectives. So often, the original draft lacks transitions, and in finding those elements, I often find the heart of the grant.

Perhaps I am focused on literal transitions because I am also in the midst of a personal transition. After two decades in the academic employed sector, I will be joining the freelance sector. Thus, currently, I am trying out different transition possibilities. While I identified resources and elements that would enable this professional transition, I am in the process of testing different pieces to see which one will provide the best connection between phases of my career. And life continues to provide different and unexpected (but exciting) challenges, such as a move to a new state. I have been a member of the Southwest Chapter since 2008, and this fall, I will join the Rocky Mountain Chapter. That is one transition that was easy to select. Despite the different phases of my career, AMWA has been a constant, a pivotal connector.

At the national level, AMWA too continues to seek optimal transitions. The field of medical communication seems to be constantly in flux, and our needs as members change and evolve. Gone are the days of evergreen content, and the entry of artificial intelligence has spurred a new need and multiple opportunities alongside novel challenges. Yet

the Board of Directors (BOD) and AMWA staff continue to respond to the member feedback and seek ways to support members, chapters, and the field as a whole. As a member, you are integral to any successful transition. I am so grateful to everyone who fills out a survey, organizes a chapter event, writes a journal article, joins a committee, or volunteers at a meeting. Only with your support and feedback can we, as an organization, ensure we are transitioning in the right direction.

The BOD is working on approving the next set of priorities and setting the strategic direction of the organization. We are expanding the staff to meet the growing needs of the organization, and we are reviewing and expanding education content to ensure each of you can secure the transition you need to advance your career. With the recently approved Strategic Plan for Diversity, Equity, and Inclusion (<https://www.amwa.org/page/dei>), committees are reviewing and improving inclusive and accessible elements throughout the organization and its resources. If you are reading this article, I know you are invested in the future of AMWA. I encourage you to contact me directly or your local chapter leader (find your chapter here: <https://www.amwa.org/page/Chapters>). Let us know your needs and concerns. Help us create successful transitions.

In short, I know firsthand how hard it is to find the right literal or personal transition. However, you are not alone. Together, we can develop, test, and create transitions that are not just valuable connections; they are growth, and they are the future.

Author contact: michelle@rnaeditingllc.com

AMWA NEWS

AMWA Annual Financial Report, 2022–2023

Julie Phelan, MD, MBA / 2022–2023 AMWA Treasurer

Following is AMWA's financial report for the 2022–2023 fiscal year, which ended June 30, 2023.

Based on the number of attendees and positive evaluation results, we had a very successful 2022 Annual Conference and Executive Forum in Denver, Colorado. We produced profitable webinar programs, continued engaging executives, provided continued support for the value of medical writing projects, and initiated a new apprenticeship toolkit project. Significant progress was made on our Diversity, Equity, and Inclusion (DEI) and Health Communication Curriculum initiatives as we contracted with a DEI consultant to design interactive facilitated Board of Directors discussions and assembled a Health Communication Task force. We also continued marketing strategies to promote our major revenue-generating programs, increased membership, and created valuable and timely content and member resources.

FINANCIAL PERFORMANCE

Net income from program operations was \$178,000 versus a budgeted net loss from operations of (\$222,000). AMWA reported a net surplus for the 2022–2023 fiscal year of \$435,000 that was due to revenue exceeding budget, expenses under budget, and a significant investment income of \$257,000.

REVENUES

Overall, program revenues of \$2,127,000 exceeded budget expectations by 6%. This was largely because of conservative income budget estimates. Membership, annual conference, and education and certificate program income continue to be AMWA's major sources of revenue, providing 90% of AMWA's program revenue (Figure 1).

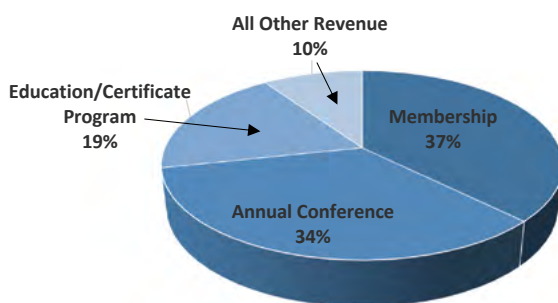


Figure 1. Sources of program revenue for the fiscal year that ended June 30, 2023.

EXPENSES

AMWA invests in programs, products, and services that bring value to members and the medical writing community. Overall, program expenses were under budget by 13% for the fiscal year. Total program expenses for the fiscal year were \$1,949,000, with 25% of the expenses being used to fund membership benefits, 29% of expenses were used to produce the annual conference, 16% of expenses funded educational programs including the Essential Skills Certificate Program and online education, and 4% was used to produce the journal (Figure 2).

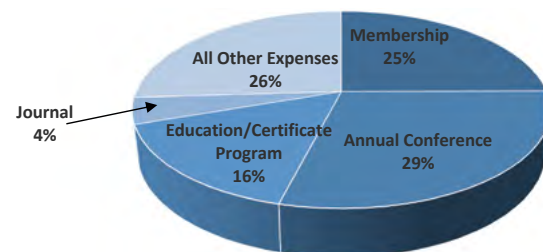


Figure 2. Sources of major program expenses for the fiscal year that ended June 30, 2023.

RESERVES

Reserves are the accumulation of funds over time that enable an organization to withstand an emergency or to invest in new mission-related initiatives. Unrestricted reserves of 6 to 12 months of annual operating expenses represent a standard target for not-for-profit organizations. Budgeted annual operating expenses are \$2,319,000 for the fiscal year beginning July 1, 2023, to June 30, 2024. AMWA's unrestricted short- and long-term investment reserve level of \$2,960,000 on June 30, 2023, provided sufficient reserves to cover 6 to 12 months of operations. AMWA's restricted Endowment and McGovern funds totaled \$229,000 and \$186,000, respectively.

FINANCIAL POSITION

An organization's financial position is reflected in its asset and liability holdings. AMWA is well positioned to pay its obligations and plan for the future. Total assets were \$4,774,000 as of June 30, 2023, and the organization's liabilities totaled \$942,000.

FINANCIAL STATEMENT AUDIT RESULTS

Mullins, PC, AMWA's independent auditors, expressed an unqualified opinion regarding their audit of the financial statements for the fiscal year that ended June 30, 2023. An unqualified opinion states that the financial statements present fairly, in all material respects, an entity's financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. AMWA continues to be in a secure financial position as it continues expanding member benefits and resources into the next fiscal year. The full audit report is available to AMWA members upon request.

Acknowledgments

I thank Calibre CPA Group, PLLC, for providing the financial data, and the members of the 2022–2023 Budget and Finance Committee for their review of reports and budgets: Karen Bannick McQuoid, Ana Bozas, Alice Pappas, Whitney Smalley-Freed, Laura Town, and Christine Wogan, as well as ex-officio members Elise Eller (2022–2023 AMWA President), Michelle Sauer Gehring (AMWA President-Elect), and Susan Krug (AMWA Executive Director).

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

Author contact: Julie@biomedisysinc.com

The advertisement features a blue textured background on the left and a dark wood-grain background on the right. A blue dumbbell is positioned diagonally across the center. In the top right corner, there is a logo of an open book with the text 'AMWA EDUCATION' and 'Write better. Write now.' below it. The main text 'Get FIT with AMWA' is in large white letters on the left. Below it, the words 'FAST', 'INTERACTIVE', and 'TRAINING' are stacked vertically in green, yellow, and green respectively. The website 'www.amwa.org/fit' is in green. On the right, a paragraph describes the series, followed by a list of topics and pricing information.

Get FIT with AMWA

**FAST
INTERACTIVE
TRAINING**

www.amwa.org/fit

AMWA EDUCATION
Write better. Write now.

AMWA's FIT Series helps medical communicators stay healthy. In only 15 minutes—jog your memory, tone your writing muscles, build your core skills, and stretch your knowledge.

Topics in the series include:

- ▶ Misplaced Modifiers
- ▶ Mean, Median, and Mode
- ▶ Dangling Participles
- ▶ Measures of Variability

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AMWA NEWS

2024 Walter C. Alvarez Award Recipient Otis Brawley, MD

Michele W. Sequeira, MS, MBA, MWC / 2023 Annual Conference Committee Chair

The Walter C. Alvarez Award is bestowed on a member or nonmember of AMWA to recognize excellence in communicating health care developments and concepts to the public.

As chair of the 2024 Annual Conference Committee, I have the honor of bestowing this year's Walter C. Alvarez Award upon Otis Brawley, MD.

Dr Brawley is the Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University. He is an authority on cancer screening and prevention and leads a broad interdisciplinary research effort focused on cancer health disparities at the Johns Hopkins School of Medicine, the Bloomberg School of Public Health, and the Sidney Kimmel Comprehensive Cancer Center.

Dr Brawley served as chief medical and scientific officer of the American Cancer Society from 2007 to 2018, overseeing the largest private cancer-research-funding program in the United States. He served as director of the Georgia Cancer Center at Grady Memorial Hospital in Atlanta from 2001 to 2007, and as professor of hematology, oncology, medicine, and epidemiology at Emory University from 2001 to 2018.

I first heard about Dr Brawley shortly after I started working as a medical writer at the University of New Mexico Comprehensive Cancer Center. I later came across his book, *How We Do Harm: A Doctor Breaks Ranks About Being Sick in America*, co-written with Paul Goldberg. The book struck me. It described Dr Brawley's experiences as a physician helping people cope with a medical system that they did not understand.

The stories in the book were heartbreaking. Some patients waited so long to seek cancer care that body parts literally fell off. Others were subjected to agonizing pain because they and their family members were unable to understand the complex medical information they were given. Dr Brawley's message was clear, and it applies to all of us: we must do better.

Dr Brawley is leading some of the efforts to address health care disparities. We, as medical communicators, can play a role in these efforts too; we can innovate to provide clear communication that informs and inspires patients and professionals alike. Please join me in congratulating Dr Brawley, our Walter C. Alvarez award winner, and listening to his talk on Saturday, October 26, at the 2024 Medical Writing & Communication Conference in New Orleans.

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

Author contact: Michele@SequeiraMedicalWriting.com



AMWA NEWS

2024 John P. McGovern Award Recipient Eliseo Pérez-Stable, MD

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

Each year, the president of the American Medical Writers Association (AMWA) has the honor of selecting the recipient of one of our organization's highest honors, the John P. McGovern Award. AMWA bestows this award to a member or nonmember of AMWA to recognize a preeminent contribution to medical communication. Previous recipients of the McGovern Award include Peter J. Hotez, MD, PhD; Paul A. Offit, MD; Lisa Sanders, MD, FACP; Ivan Oransky, MD; Cynthia Bauer, PhD; Julie L. Gerberding, MD, MPH; and Anthony S. Fauci, MD, among others (https://www.amwa.org/page/Award_Recipients#McGovern).

This year, the 2024 McGovern Award will go to Dr Eliseo Pérez-Stable in recognition of his work as the Director of the National Institute on Minority Health and Health Disparities and his prior contributions as a researcher at the University of California-San Francisco. His dedication to improving the health of minorities and the effective dissemination of strategies to decrease the disparities seen in health care are fascinating and inspirational. His career has centered on improving the health of individuals from racial and ethnic minority communities through effective prevention interventions, understanding underlying causes of health disparities, and advancing patient-centered care for underserved populations.

Dr Pérez-Stable has published more than 300 peer-reviewed papers and has been recognized as a leader in minority health care and disparities research. His work has directly impacted the lives of patients and colleagues. Dr Pérez-Stable developed the PhenX Social Determinants of Health Assessment Collection toolkit and The Science of Health Disparities Research textbook—resources that medical communicators across the country use. These projects and others demonstrate his leadership ability to gather input and consensus from a broad range of expertise. At a time when patient-centered care is needed and health disparities must be addressed, Dr Pérez-Stable's work is highly deserving of AMWA's McGovern Award.

Dr Pérez-Stable will deliver a keynote address at AMWA's 2024 Medical Writing & Communication Conference (register here: <https://site.pheedloop.com/event/AMWA2024/home>), which will be held in New Orleans from October 24-26, 2024.



AMWA NEWS

2024 Golden Apple Award Recipient Kathy Spiegel, PhD, MWC

Loretta Bohn, BA, ELS / 2023-2024 Chair, Member Awards Recognition Committee

The Golden Apple Award is given to an AMWA member in recognition of their consistent and outstanding excellence in leading AMWA workshops.

The 2024 Member Awards Committee is pleased to recognize a Golden Apple honoree. The Golden Apple Award is presented to a member of AMWA to honor consistent outstanding workshop leadership. The committee's selection for the Golden Apple Award is Kathy Spiegel.

Kathy Spiegel, PhD, MWC, received a bachelor's degree in chemistry from Duke University and a doctorate in pharmacology from Cornell University Medical College. After 11 years of basic bench research in Alzheimer disease at Parke-Davis, Kathy transitioned into medical writing, and then into clinical research in epilepsy and neuro-pathic pain, for a total of 18 years at Parke-Davis and Pfizer. She then spent 6 years as a freelancer, working at both clinical trial consulting and regulatory writing. In 2012, she accepted a full-time position as a Regulatory Writing Senior Manager at Amgen Inc, and in 2022 she spent a year as the Director of Medical Writing at Organon. Kathy's initial attempts at retiring failed, and she began consulting again in May 2023. She insists that she is now fully retired from medical writing and keeps busy working her small farm in Sharon Township, Michigan, as well as running a baking business and serving as her township's supervisor. She is also kept busy by her three dogs, four cats, one horse, her chickens (currently numbering only six), and four beehives. In selecting Kathy as this year's honoree, the Member Awards Committee and the AMWA Board of Directors were impressed with her long-term commitment to leading workshops for AMWA and her ability to keep her workshops engaging and her material timely and relevant. Kathy also served AMWA at the chapter level from 2008 to 2013 and at the national level on the Board of Directors from 2012 to 2019, including as President in 2017 to 2018. Kathy says that AMWA has been her home and family through all these years.



AMWA NEWS

2024 AMWA President's Award Recipient Barbara Gastel, MD, MPH, ELS(H)

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

I first met Dr Barbara Gastel in an AMWA workshop and was immediately drawn to her approachable, inclusive, and informative style. At the end of the 3 hours, I felt inspired and ready to tackle the world of medical communication. That was over 15 years ago, and since then, she and I have organized a regional chapter conference. Most recently, we served on a panel regarding the education of future medical communicators. She has continued to devote herself to the organization and her colleagues. In my opinion, no one deserves the AMWA President's award more.

Each year, the AMWA President selects someone who has made distinctive contributions to the association at the chapter and national level, and Dr Gastel has certainly made significant contributions since joining the organization in 1978. Her contributions include leading 9 different AMWA workshops in addition to countless open sessions at the national and chapter meetings. She authored *Elements of Medical Terminology*, a cornerstone of the AMWA Essential Skills Certificate, and has served on the Medical Writer Certification Committee since 2011. Her contributions to AMWA have been honored with a fellowship, the Golden Apple Award, the Harold Swanberg Distinguished Service Award, and the Southwest Chapter of AMWA's John P. McGovern Award for Excellence in the Field of Medical Communication.

Beyond the direct contributions and service, Dr Gastel has empowered countless students and members at all career stages. Early in her academic career, Dr Gastel was an assistant professor of science writing at the Massachusetts Institute of Technology. Her skillset as an educator eventually led her to Texas A&M University, my alma mater. For the last 35 years, Dr Gastel has not only taught students at the graduate, professional, and undergraduate levels, but she has created and improved multiple courses and programs focusing on science journalism, biomedical writing, and science editing. She currently serves as a professor of Veterinary Integrative Biosciences and of Humanities in Medicine.

Dr Gastel embodies the AMWA values of professionalism, expertise, continuous learning, and connection. She has cemented her reputation as a leader and professional through her generous service and provision of expert advice on a multitude of areas. Her expertise and wisdom have provided guidance as we navigate the ever-evolving landscape of medical communication. Her workshops and advice have empowered medical communicators to convey complex medical concepts with precision and empathy. Her collaborative spirit and willingness to serve have created and refined countless continuing education opportunities for AMWA members. Her ability to connect and share has made her a role model for so many in the AMWA membership. I am honored to be the one to hand her this much-deserved award.



AMWA NEWS

Member Awards Committee Announces Honors

Loretta Bohn, BA, ELS / 2023-2024 Chair, Member Awards Recognition Committee

The 2024 Member Awards Committee is pleased to recognize 3 new AMWA fellows. AMWA Fellowships are given to members for significant contributions to the goals and activities of the association. Nominees must be current members of AMWA and have been consistently active in AMWA during at least the past 5 years. This year's fellows are Melissa L. Bogen, Kim Jochman, and Kimberly Korwek.

Melissa L. Bogen, ELS, has been a full-time freelance editor since 1997. Her expertise is in editing, fact checking, and proofreading pharmaceutical sales training materials, multimedia programs for health care professionals, and medical manuscripts in a wide range of therapeutic areas. Melissa has in-depth knowledge of American Medical Association style as well as editorial production processes. An AMWA member since May 2000, Melissa has regularly presented at local and national AMWA conferences on the scope of medical editing, Microsoft Word tips and tricks, the differences between editing and proofreading, and fact checking and annotating for medical, legal, and regulatory affairs reviews. She has also presented breakfast roundtables on various topics, as well as a coffee and dessert klatch on "Chickens in Your Backyard" in 2011. Melissa has contributed to the *AMWA Journal* since 2003, having written website and book reviews, and has been a regular columnist for the *Journal's* Freelance Forum since 2014. Melissa recently joined the Board of Directors of the Empire State–Metro New York Chapter as the Website Coordinator. She says, "I believe deeply in the mission of AMWA and have been a staunch supporter of AMWA initiatives. I owe my career in part to AMWA."



Kim Jochman, PhD, RAC, is a senior director for medical writing and disclosure at Merck. She has been a regulatory medical writer since 2007, with experience across a broad range of document types, development phases, and therapeutic areas. In her current role at Merck, Kim leads the early talent programs in the Medical Writing and Disclosure department, including the summer internship program and the entry-level associate medical writer program. She also

leads and supports department-level and Merck-wide process improvement initiatives that help the organization function more effectively and efficiently. For the Carolinas Chapter of AMWA, Kim has been President-Elect, 2-time President, and Conference Committee lead and member; her current role is as the chapter's Volunteer Coordinator. Kim has developed and presented workshops and been a committee member for AMWA national conferences, created Knowledge Builders and a webinar, and actively participated in the working group on medical writing apprenticeships. Hailing from Apex, North Carolina, Kim lives with her husband, 14-year-old child, and 3 cats. In her spare time, she enjoys reading (especially historical fiction!), traveling, and attending musical theater performances.



Kimberly Korwek, PhD, is the Manager of Scientific Communications in the Clinical Services Group of HCA Healthcare, where she has worked since 2009. In that role, she manages the development of scientific publications—manuscripts, abstracts, presentations, and white papers—to share research findings with internal and external audiences.



Kimberly also manages a portfolio of comparative effectiveness research projects that use data collected in the course of clinical care to improve health care delivery and patient outcomes. An AMWA member since 2010, she has been a leader for the Southeast chapter, including terms as President, Chapter Advisory Council representative, and Webmaster. Kimberly has chaired the Annual Conference Program Committee and the Chapter Advisory Council, and she was a section editor for the *AMWA Journal* for 4 years. She joined the national Board of Directors in 2019 and is now in her second term as secretary. "It is a privilege to be able to serve AMWA, as the organization has provided so much to me in professional and personal development," Kimberly says.

AMWA NEWS

Officer Candidate Slate for the 2024-2025 Election

Roshawn (Shawn) Watson, PharmD, PhD, BCPS / 2023-2024 AMWA President-Elect

I am honored to serve as President-Elect for AMWA this year. This afforded me the privilege to chair the Nominating Committee, who propose a slate of officers for the upcoming governance year.

The process is as follows: any interested AMWA member is invited to submit a board interest form for consideration of one of three elected offices: President-Elect, Secretary, and Treasurer. The Nominating Committee then reviews the forms and qualifications of candidates who meet the eligibility criteria and collectively agrees on a candidate for each officer position to submit to the AMWA Board of Directors (BOD) for consideration.

The Nominating Committee currently consists of past AMWA presidents and board members, as well as members who have served in leadership positions in the medical communication field. I want to extend my gratitude to those who volunteered their time and expertise to serve alongside me as committee members:

- Cyndy Kryder, MS, MWS,
- Tenille L. Lawson, PharmD, BCPS,
- Brian Bass, MWC,
- Gail Flores, PhD,
- Theresa E. Singleton, PhD,
- Lorretta Bohn,
- Leslie Nielstat, ELS, and
- Susan Krug, MS, CAE (ex officio, nonvoting member).

We received multiple strong applications for the executive committee, and the Nominating Committee's insightful feedback and critical analysis allowed for robust discussion and a strong slate of officer candidates. I respectfully present the following candidates who were presented to and approved by the AMWA BOD at the June BOD meeting:

- **President-Elect:** Kimberly Korwek, PhD
- **Secretary:** Jennifer Minarcik, MS
- **Treasurer:** Julie Phelan, MBA, MD

PRESIDENT-ELECT

Kimberly Korwek, PhD, an AMWA member since 2010, has been on the AMWA BOD for five years and is currently serving her second term as AMWA secretary and the board liaison

for the Medical Compensation Survey Work Group. Korwek also served as chair of the 2022 Annual Conference Program Committee.

From 2019 to 2020, she was chair of the Chapter Advisory Council on the BOD and was a member of the Chapter Advisory Council from 2017 to 2019. From 2016 to 2019, Korwek was a section editor for the *AMWA Journal*, serving on the editorial board. She has also authored articles published in the *Journal*. Korwek was president of the AMWA Southeast Chapter (2016-2017), and president-elect (2015-2016). She also served as a chapter delegate to the AMWA Board (2016-2017) and the website coordinator for the Southeast Chapter (2018-2019). Korwek is the manager of scientific communication within the Clinical Operations group of HCA Healthcare. In this role, she is responsible for managing the portfolio of comparative effectiveness research projects that seek to use data collected during clinical care to improve health care delivery and patient outcomes. Korwek also manages the development of scientific publications, including manuscripts, abstracts, presentations, and white papers, to facilitate the distribution of research findings to internal and external audiences.



SECRETARY

Jennifer Minarcik, MS, an AMWA member since 2011, is in her fourth year of serving on the AMWA BOD and is the current board liaison to the AMWA Annual Conference Committee. From 2021 to 2023, she served on the BOD as Chapter Advisory

Council chair. As a member of the Delaware Valley Chapter, she served as the Chapter Advisory Council representative (2019-2020), treasurer (2018-2019), and president-elect, president, and immediate past president (2016-2018). Additionally, she has served as the chair of the Chapter Advisory Council Task Force (2016-2017), a member of



the National Communication Committee (2013-2017), an Engage Task Force committee member (2016-2017), and an Annual Conference committee member (2018). In addition to her service on various committees, Minarcik was an editor-at-large for the *AMWA Journal* from 2014 to 2017, and in 2018 joined the editorial board as the Social Media Section co-editor and became editor in 2019. Minarcik also presented sessions at the 2015 and 2016 National Conferences and was awarded an AMWA Fellowship in 2020. Minarcik is a freelance biomedical writer specializing in pharmaceutical sales training and promotional medical writing projects.

TREASURER

Julie Phelan, MBA, MD, an AMWA member since 2009, is in her eighth year as treasurer on the BOD and as chair of the Budget & Finance Committee (2016-2024). She served as a member of the Budget & Finance Committee (2015-2016), the Communication Committee (2014-2015), the 2015 Salary Survey Task Force, and the Online Community and Social Media Committees (2012-2014). At the chapter level, she was president of the Greater Chicago Area Chapter (2013-2016), serving previously as president-elect (2012-2013). She also served as membership chair for the chapter (2011-2015) and as a chapter delegate to the Board (2013-2016). She has authored articles for the *AMWA Journal* and is currently AMWA's registered agent. She was awarded an AMWA fellowship in 2017. Phelan is the founder and president of Biomedisys, Inc, a medical communication and strategy consulting boutique in Chicago, Illinois. She has more than 20 years of medical communication and business strategy experience including working as a biotechnology equity research associate analyst at Robert W. Baird & Co, medical and strategic advisor for an insurance corporation, and medical communication consultant.



PROCEDURE FOR ADDITIONAL NOMINATIONS

As required by AMWA's bylaws (Article IV.2e-f), these nominations were announced to the AMWA community by email more than 60 days before the annual business meeting. A nominee who is unopposed for any office is declared automatically elected at the annual business meeting. As stated in the bylaws, additional nominations for President-Elect, Secretary, or Treasurer may be made by any member provided the member meets the criteria set forth by the BOD. The criteria and process are listed below:

- Member dues must be current, and the member must be in good standing.
- The nomination must be submitted in writing to the secretary of AMWA at least 30 days in advance of the annual business meeting. This year's annual business meeting is scheduled on October 26, 2024.
- The nomination must clearly state the qualifications of the candidate and be signed by 50 members in good standing as of the date of the receipt of the nomination.
- The nomination must be accompanied by a letter from the candidate stating that she or he is willing to serve if elected.

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

Author contact: watson900@hotmail.com

Innovate, Inform, And Inspire: Jazz Up Medical Communication at the 2024 Medical Writing & Communication Conference

October 23-26, New Orleans

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

It's almost here! Get ready for the AMWA 2024 Medical Writing & Communication Conference in the Big Easy. This year's conference is scheduled for October 23 through October 26 at the New Orleans Marriott hotel. Register now for the conference at the Annual Conference website (<https://site.pheedloop.com/event/AMWA2024/home/>).

The Annual Conference will offer 49 educational sessions for beginners, midcareer, and experienced medical writers. The Annual Conference Committee carefully selected the sessions, as well as 63 roundtables and 19 posters, in the topic areas that AMWA members need: core knowledge and skills, regulatory writing, health communication, scientific publications, medical editing, generative artificial intelligence, and more. And to complete the conference schedule, we'll have networking sessions, vendor showcases, and workshops. Be sure to schedule yourself some break and snack times to keep yourself refreshed and energized.

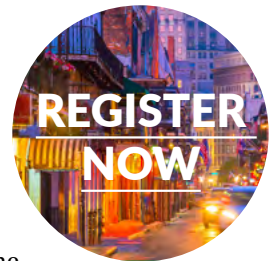
Both award winners this year focus their research on health disparities. The 2024 McGovern Award winner, Dr Eliseo Pérez-Stable, studies the underlying causes of health disparities and effective prevention interventions. The 2024

Alvarez Award winner, Dr Otis Brawley, is an authority on cancer screening and prevention and studies cancer health disparities. Both will share their perspectives on the importance and role of medical communicators in helping all people enjoy the medical progress our society is making.

Aside from the programming, the Annual Conference is a great opportunity to meet and socialize in person with other medical communicators from around the country. Each of us brings a unique set of experiences and skills to medical communication. Take advantage of the networking sessions, breaks, sunrise walks, and dinners to get to know fellow medical communicators. Ask questions and share your knowledge in our rapidly changing field.

And, of course, allow yourself some time to enjoy the iconic city of New Orleans. Visit some famous neighborhoods, enjoy fabulous food, and take in a tour or two.

Plan your conference schedule now and balance it with some fun New Orleans experiences. I look forward to seeing you at the 2024 Annual Conference.



AMWA NEWS

Sneak Peek of the AMWA 2024 Medical Communication Compensation Survey Results

Shari Rager, MS, CAE / Deputy Director, AMWA

As the leading professional organization for medical writers, editors, and communicators, AMWA has been conducting periodic compensation surveys since 1989. This research is designed to provide insights into income, and the factors that affect it, within the field of medical communication.

The **AMWA 2024 Medical Communication Compensation Survey** was conducted in March and April 2024 by an outside research firm, Association Research, Inc (ARI). ARI will deliver the final, comprehensive report to AMWA in Fall 2024. AMWA members will receive full access to the report as an exclusive member benefit. On the following pages, infographics highlighting select results from the full-time employed and full-time freelance medical communicator data sets (respectively) are presented.

Upon reviewing these top-level highlights, it is important to note that gross income for employees and freelancers cannot be directly compared due to a variety of factors. Gross income for employed medical communicators is reported prior to any taxes or other paycheck deductions. Gross freelance income as reported includes all revenue, including sub-contractors (if applicable), prior to any business expenses. Income for employed and freelance medical communicators varies according to many factors, including years of experience, employment level, employer/client type, level of education, area of work, and number of hours worked.

The published report will provide a comprehensive analysis and full results including quartiles, means, medians, and other statistical analysis. The infographics provided here only display a few highlights from the survey, including the mean, or simple average, value for gross income.

AMWA is grateful for the support of AMWA member volunteers in reviewing and updating the survey instrument and subsequent analyses. The review team included Gail Flores, PhD; Leena Knight, PhD; Stephen Palmer, PhD, ELS; Joanne Rosenberg, MS, ELS; Cynthia Saver, MS, RN; Linda Yih; Kim Korwek, PhD (Board liaison); and Shari Rager, MS, CAE (Staff lead). AMWA is also grateful to every medical writer, editor, and communicator who took the time to complete the survey. Your efforts allow AMWA to create the forthcoming AMWA 2024 Medical Communication Compensation Report and provide this and other valuable resources for the field of medical communication.

Employee:

Your employer deducts all taxes (federal, state, and Social Security) from your paycheck.

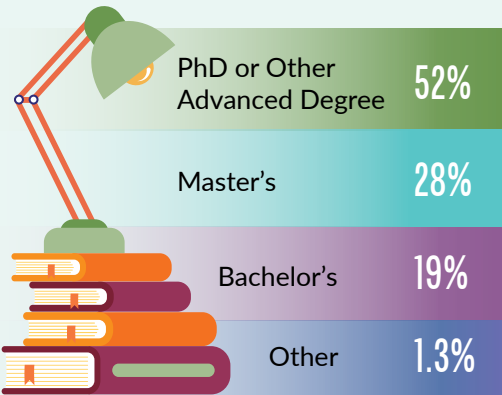
Freelance:

You pay your own taxes (federal, state, and Social Security). You may also describe yourself as an independent contractor, consultant, or self-employed. This status applies if you pay yourself a salary (and taxes) through your freelance company.

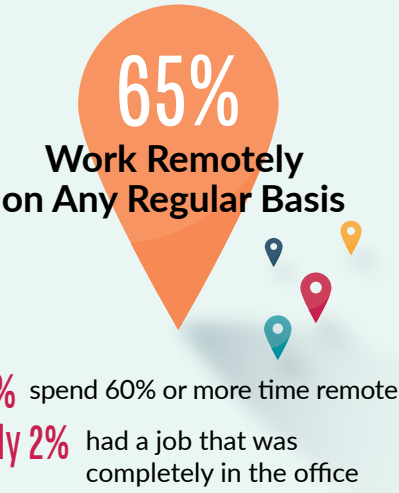
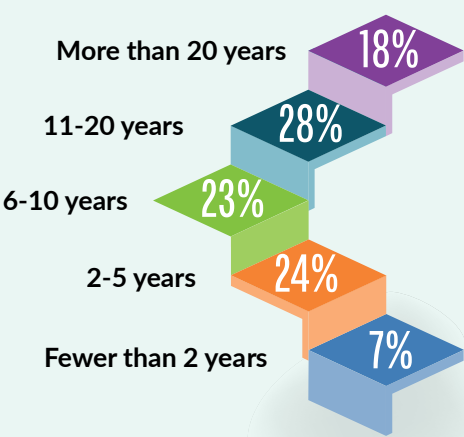
AMWA 2024 COMPENSATION SURVEY

Highlights for Full-time Employed Medical Communicators

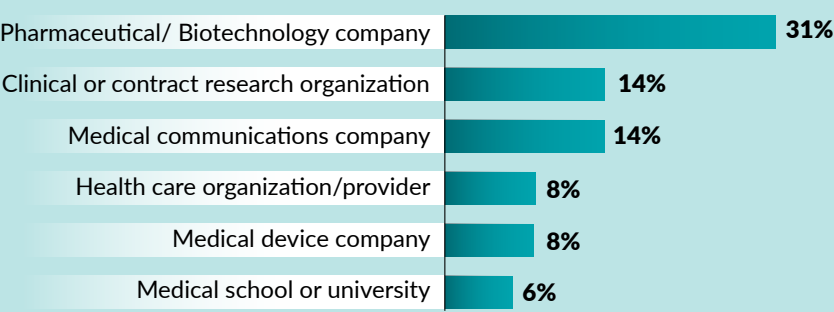
Highest Level of Education



Years of Experience



Employer Type



Mean Income for Full-time Employed Medical Communicators

By Type of Work



By Area of Work



Most Common Benefits Received

- ✓ Health insurance 96%
- ✓ Retirement savings plan 89%
- ✓ Life and/or disability insurance ... 85%
- ✓ Employer match to retirement ... 80%
- ✓ Pre-tax spending programs 74%
- ✓ Annual cash bonus 68%
- ✓ Professional development 66%

Explore the complete AMWA 2024 Medical Writing & Compensation Report at www.amwa.org.

**AMERICAN
MEDICAL WRITERS
ASSOCIATION**
The Resource for Medical Communicators

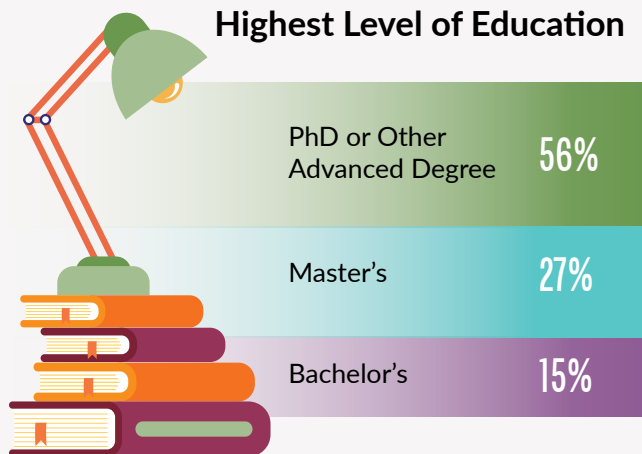
Income information is based on 2023 data reported in US dollars by 671 full-time employed respondents, including those working outside the US. All income data are presented as means. Income varies according to many factors, including years of experience, level of education, employment level, employer type, and area of work. Gross income for freelancers and employees cannot be directly compared due to these and other factors. Percentages were rounded. Totals may not equal 100%. Not all respondents answered all questions.

AMWA 2024 COMPENSATION SURVEY

Highlights for

Full-time Freelance Medical Communicators

Highest Level of Education



39% More than 20 years

28%

11-20 years

16%

6-10 years

17%

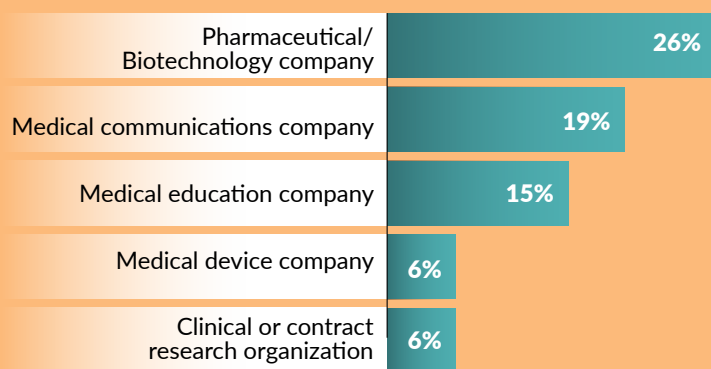
5 years or less

Years of Medical Communication Experience

Most Common Recurring Expenses



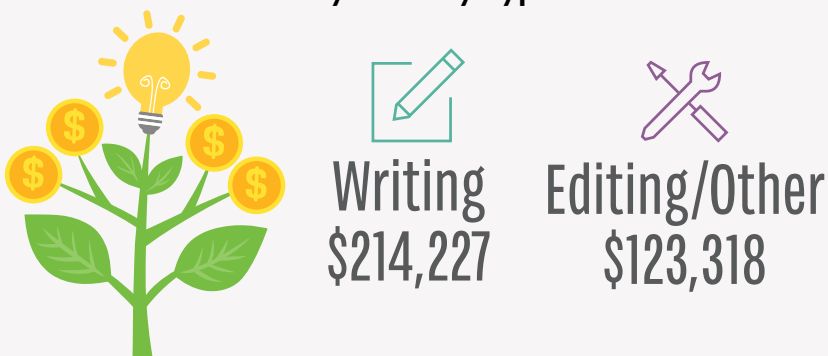
Primary Client Type



% reporting as top source of income

Mean Gross Income for Full-time Freelance Medical Communicators

By Primary Type of Work



By Primary Area of Work



Explore the complete AMWA 2024 Medical Writing & Compensation Report at www.amwa.org.

CALENDAR OF MEETINGS

**2024
AMWA**

Medical Writing & Communication Conference

OCTOBER 23-26, 2024
NEW ORLEANS, LA

Trends and Opportunities for Medical Communicators

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>

Alliance for Continuing Education in the Health Professions

"2025 Alliance Annual Conference"

January 8-11, 2025

Orlando, FL

<https://www.acehp.org/Your-Learning/Events/Call-for-Abstract-Submissions>

American Association for the Advancement of Science

"2025 AAAS Annual Meeting"

February 13-15, 2025

Boston, MA

<https://meetings.aaas.org/>

Drug Information Association (DIA)

"DIA Europe 2025"

March 18-20, 2025

Basel, Switzerland

<https://www.diaglobal.org/en/flagship/dia-europe-2025>

2024
AMWA

Medical Writing &
Communication
Conference

OCTOBER 23-26, 2024
NEW ORLEANS, LA

Trends and Opportunities for Medical Communicators

AMWA
2024

**Innovate, Inform, and Inspire:
Jazz up medical communication.**



REGISTER NOW!

October 23-26, 2024

www.amwa.org/conference

Plan to join us in New Orleans to explore innovation, expertise, and opportunities in medical writing and editing, including these key topics:

- Advanced-level content for experienced medical communicators
- Excellence in scientific publications
- Effective health communication strategies
- Exploring health equity and disparity issues
- Inclusive language training
- Regulatory writing topics
- Technology and innovation in medical communication
- Training and mentoring the next generation of medical communicators