

Medical Writing

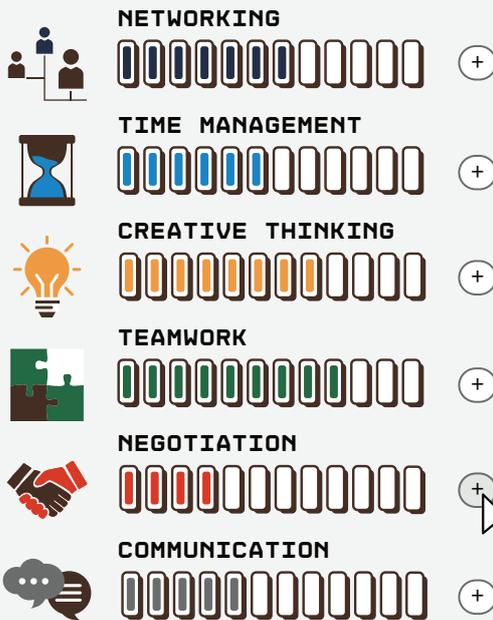
SOFT SKILLS FOR MEDICAL WRITERS

WELCOME TO LEVEL 6

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HARD SKILLS

SOFT SKILLS



MEDICAL WRITING DEMANDS A COMPREHENSIVE SET OF TECHNICAL SKILLS. HOWEVER, IT IS INCREASINGLY EVIDENT THAT INTEGRATING SOFT SKILLS CAN ELEVATE CAREER PROGRESSION.



ASSIGN
4 SKILLPOINTS

ALSO IN THIS ISSUE...

- Project facilitators: The yin to a medical writer's yang
- Geoff Hall Scholarship essay winners
- Information on animal experimentation

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EUROPEAN MEDICAL WRITERS ASSOCIATION



Medical Writing

is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers.

Members of EMWA receive *Medical Writing* as part of their membership. For more information, contact mew@emwa.org.

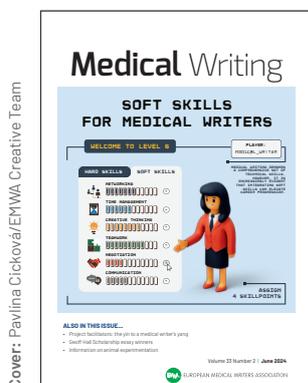
Medical Writing

THIS ISSUE June 2024 | Volume 33 Number 2

Soft skills for medical writers

“Medical writers can leverage AI to help them with the more technical aspects of their craft. This signifies a shift in how medical writers may work in the future with a focus on soft skills.”

Guest Editors Clare Chang and Nicole Bezuidenhout, p.3



| | | | | | |
|--|----|--|----|--|----|
| Editorial: | 2 | Unlocking the power of emotional intelligence in medical writers | 28 | The balancing act: Leading creative teams for clear, accurate science communication | 60 |
| Advance your medical writing career with essential soft skills | | <i>Ananya Bhowmick, Seema Abhijeet Kaveeshwar, Susmita Sahu</i> | | <i>Alexandra Hoegberg</i> | |
| From the Editor: | 5 | The 3 C's of medical writing: Communication, conflict management, and critical thinking | 34 | SPECIAL SECTION | |
| The skill of giving and receiving feedback | | <i>Asha Liju, Diana Daniel, Grishma Kanchan</i> | | Winners of the Geoff Hall Scholarship Essay Competition | 64 |
| <i>Raquel Billiones</i> | | | | <i>Louisa Ludwig-Begall, Florencia Garro</i> | |
| Outgoing President's Message: EMWA: An evolving organisation | 6 | The soft skills gap for remote workers: Different perspectives | 38 | <i>Editor: Lisa Chamberlain James</i> | |
| <i>Maria Koltowska-Hägström</i> | | <i>Hanna Kurlanda-Witek</i> | | REGULAR SECTIONS | |
| President's Message: The road ahead | 8 | Connecting through screens: Navigating relationships with patients and advocacy groups in a digital world | 42 | News from the EMA | 68 |
| <i>Sarah Tilly</i> | | <i>Catherine Richards Golini</i> | | <i>Anuradha Alahari</i> | |
| EMWA News | 10 | Building resilience: Navigating challenges and thriving among the demands of regulatory writing | 46 | Digital Communication | 74 |
| <i>Somsuvro Basu</i> | | <i>Phani Ayalavajjala, Roy D'Souza</i> | | <i>Nicole Bezuidenhout, Shannen Young</i> | |
| Spring Conference Poster Session Valencia, Spain | 12 | Managing protocol development with international teams: Soft skill perspectives from a global team of protocol writers | 50 | Veterinary Medical Writing | 79 |
| EMWA's 57th Conference | 14 | <i>Jonathan Mackinnon, Anuradha Alahari, Leo Daffue, Wiebke Griemberg, Mati Kargren, Chris Matthews, Kavita Muchandi, Gunnar Schilling</i> | | <i>Louisa Marcombes, Cemile Jakupoglu, Jennifer Freymann</i> | |
| FEATURE ARTICLES | | Mentors and mentees in medical writing: A very particular set of (soft) skills | 56 | Publications | 83 |
| Moving into medical writing from academia: A soft skills perspective | 16 | <i>Nicola Haycock</i> | | <i>Maddy Dyer</i> | |
| <i>Vivek Ranjan</i> | | | | Freelancing | 86 |
| Unlocking success as a book author: Navigating the essential social skills of writing gained through my PhD journey | 20 | | | <i>Adriana Rocha, Laura A. Kehoe</i> | |
| <i>Matteo Tardelli</i> | | | | Regulatory Matters | 88 |
| The hard truth about soft skills in medical writing | 24 | | | <i>Clare Chang, Yoko Komatsuzaki, Zuo Yen Lee, Julia Forjanic Klapproth</i> | |
| <i>Corinne Swainger</i> | | | | The Crofter: Sustainable Communications | 93 |
| | | | | <i>Louisa Ludwig-Begall, Sarah Kabani, Catarina Leitão</i> | |
| | | | | Good Writing Practice | 98 |
| | | | | <i>Wendy Kingdom, Amy Whereat, Michael Lewis Schneir</i> | |



Advance your medical writing career with essential soft skills

Medical writing demands a comprehensive set of technical skills, from mastering regulatory and ethical guidelines to honing exceptional writing abilities. The foundation of superior medical writing is built on the hard skills acquired through education, hands-on experience, and ongoing professional growth. However, it is increasingly evident that integrating non-technical or “soft” skills can elevate one’s medical writing skills and bolster career progression. In our rapidly evolving and interconnected world, soft skills are becoming indispensable. They empower individuals to manage complexities, collaborate effectively, and excel in the 21st-century workplace. As we navigate

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through changes driven by technological advancements (artificial intelligence [AI], amongst others), globalisation, and economic fluctuations, understanding and enhancing soft skills is crucial for medical writers who aim to stay ahead. This issue of *Medical Writing* delves into acquiring and correctly applying soft skills across the different areas of medical writing. It offers rich insights and inspiration for medical writers at every career level, while emphasising how these skills can make a significant difference in their professional journey.

The path into medical writing is neither easy nor direct. Many who complete their academic journeys struggle to break into the craft. As a regulatory medical writer with fresh eyes, **Vivek Ranjan** shares his insight on six key soft skills critical for his successful transition into the regulatory writing industry. Similarly, from PhD to author, **Matteo Tardelli** paints the picture of his transition from academia into the publishing industry – a journey many aspiring medical writers can relate to. Matteo explains how nurturing his skills in networking, resilience, and self-discipline during his PhD laid the foundation for his success in the dynamic world of publishing. He details practical strategies to



This issue of *Medical Writing* delves into acquiring and correctly applying soft skills across the different areas of medical writing.

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help you do the same.

But entering the field is just the beginning. To ensure a fruitful career, medical writers should continue to strengthen their soft skills. In the rising age of AI, medical writers can leverage AI to help them with the more technical aspects of the craft. This signifies a shift in how medical writers may work in the future with a focus on soft skills. To this end, **Corinne Swainger** provides an overview of essential soft skills for a medical writer. Among the many soft skills, **Ananya Bhowmick, Seema Abhijeet Kaveeshwar, and Susmita Sahu** bring emotional intelligence to the forefront. They discuss its impact on performance, such as communication and interpersonal skills, and the different ways to further develop one's emotional intelligence. **Asha Liju, Diana Daniel, and Grishma Kanchan** go one step further, highlighting the importance of emotional intelligence in an era of rapid advancement in AI. From communication to conflict management and critical thinking, these "3 C's" have an enormous influence on the success of a medical writer's work or career. The authors highlight the interplay among the 3 C's, emphasising emotional intelligence as a cornerstone for their successful application.

Speaking of big changes, the COVID-19 pandemic marked a significant period of mass migration from offline to online activities across various aspects of life and business. What was once a necessity is now a choice for many employees and employers. **Hanna Kurlanda-Witek** discusses the impact of remote working on soft skills development and work delivery and shares expert insights from four professionals in the industry on the topic. As a remote medical writer focused on developing patient information resources, **Catherine Richards Golini's** key stakeholders are patients and patient associations. Developing trust and rapport to discuss the personal experiences of diverse patient groups online can certainly come with its challenges. Catherine provides a unique understanding of the soft skills necessary to manage these sensitive conversations.

Medical writing is a dynamic field that may come with a lot of unpredictability. **Phani Ayalavajjala and Roy D'Souza** demonstrate this using three examples from the medical regulatory writing field. Their article sheds light on how resilience enables medical writers to overcome adversities and how to develop this key skill. **Jonathan Mackinnon, Anuradha Alahari, Leo Daffue, Wiebke Griemberg, Mati Kargren, Chris Matthews, Kavita Muchandi, and Gunnar Schilling** dive deeper into one of the most common and important regulatory documents



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Submissions:

For instructions to authors, go to the journal section of EMWA's website (www.journal.emwa.org). All manuscripts should be submitted to mew@emwa.org.

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written by medical writers: clinical study protocols. These documents provide guidelines on how a clinical study must be performed. Clinical studies may be performed globally or locally depending on the scope of the study. Additionally, the team members may come from different regions of the world. The authors provide an overview of how to work with multicultural teams and further zone in on regional differences when working on clinical study protocols.

Last but not least, climbing the career ladder is a journey of continuous growth, self-discovery, and strategic advancement, marked by both challenges and triumphs along the way. Having a mentor can make a world of difference to how quickly you ascend. The relationship between a mentor and a mentee is built on trust, respect, and a shared commitment to learning and

... Soft skills are indispensable for medical writers in this era, and even more important when considering career progression.

growth. It has significant potential to impact a mentee's personal and professional development, shaping their career trajectory and contributing to their success. **Nicola Haycock** provides an overview of this relationship in a medical writing environment, outlines the characteristics of a good mentor and mentee, and shows how each contributes to the mentoring process. Becoming a boss is a natural part of career progression, but becoming a good boss is about more than just balancing organisational goals, expectations from superiors,

and the widely different needs of individual team members. According to **Alexandra Hoegberg**, it's an intentional commitment that requires self-reflection, competence development, and an honest and regular assessment of your own and your team's progress. Alexandra shares insights into leading a creative team in a scientific environment with tips on how to make it work for you.

Overall, the take-home message is that soft skills are indispensable for medical writers in this era, and even more important when considering career progression. The articles collected here explore soft skills from different angles and corners of medical writing, from geographic area to seniority. We hope you will enjoy this issue and that some of these articles resonate with you in your everyday work.

Clare and Nicole

Author information

Clare Chang, PhD, has a background in molecular biology and started her medical writing journey immediately after her PhD. She started as a medical regulatory writer at a contract research organisation (CRO). She is currently an Associate Director Clinical Regulatory Writer at AstraZeneca, based in Sweden. She works mostly on submission documents for market authorisation of new indications or new drugs. She has been a proud EMWA member since 2017. She is also one of the section editors for the Regulatory Matters section of *Medical Writing*.



Nicole Bezuidenhout, PhD, is a Medical Writer at TFS HealthScience, a mid-sized global CRO, where she develops a wide range of scientific publications and clinical documents. Driven by a passion for accessible communication, and with expertise in digital marketing and sustainable development, she is also the Section Editor for the Digital Communication section of *Medical Writing* and Content Editor at Lightup Impact, an NGO focused on empowering nonprofits in East Africa. She has been a proud member of EMWA since 2020.



This is called the hash, pound, or number character. A hashtag is a keyword or set of keywords that is preceded by the # character. It is used in social media to create a thread of conversations around a specific theme or topic conveyed in short texts or microblogs. It is commonly used in Twitter, Instagram, YouTube, Pinterest, etc.

A dictionary of most common hashtags can be found at <https://www.hashtags.org/definition/~h/>.

For your info, EMWA is compiling a list of standardised hashtags for our social media use.



This is called the "at" sign or symbol. The @ sign is part of email addresses and social media user names ("handles"). Our EMWA handles are as follows: @Official_EMWA (Twitter), @EMWA (LinkedIn), and @europeanmedicalwritersassociation (Facebook)

The two most important keys on your keyboard

From the Editor

The skill of giving and receiving feedback



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Below is a joke I heard told in German, which I loosely translate and paraphrase here.

“When I was young, my teacher asked me what I would like to be when I grow up.

“I want to be a successful writer. I want to write texts that will affect people emotionally, move them to tears.

“Here I am, years hence and I believe I have achieved my childhood dream. My current job is writing error messages for Microsoft and SAP.”

Medical writing requires a wide array of scientific and technical skills, the so-called hard skills of our trade. This issue spotlights another set of skills that are often underestimated – the so-called “soft” skills. Of these, the art of giving and receiving feedback is key.

Life and science are all about feedback. For every action, there is a reaction. For each cause, there is an effect. Positive feedback loops reinforce or enhance whereas negative feedback loops counteract or balance.¹

Giving feedback respectfully

Providing feedback, whether as a document reviewer, manuscript editor, or error message copywriter, is an art that takes years to cultivate, let alone perfect. Wearing my editor and reviewer hat, I rely on four T’s to guide me:

Thank you. Start with thanking the author. Acknowledge the effort that went into the piece.

Time. Give yourself sufficient time to review. The author deserves no less than that. If you don’t have the time, then delegate to someone else.

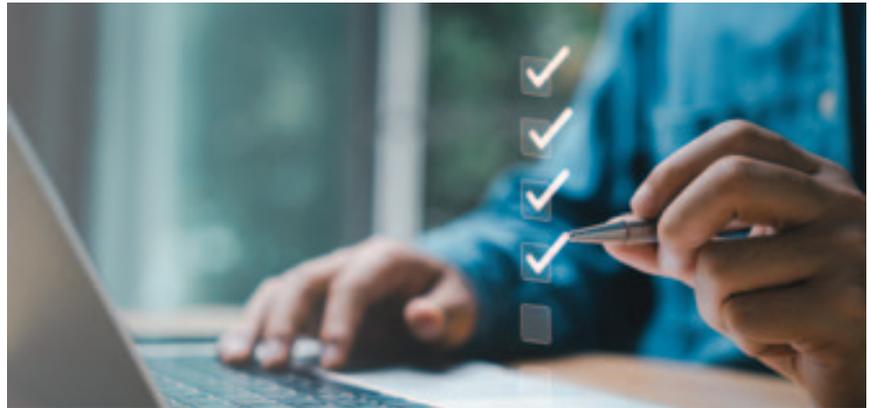
Give the writer a fair chance to revise or rewrite the piece. This means giving them ample time for revision.

Tone. The tone makes a world of difference when delivering unwelcome news. Give feedback, positive or negative, in a professional and kind manner.

Turning tables. Finally, ask yourself: How would you feel if the tables were turned?

Receiving feedback gracefully

There is no perfect document. All medical writers



have been, at one point, at the receiving end of the feedback loop. And it’s not always roses and rainbows. We dread the mark of the red pen – or in the digital age – the tracked changes, the comment bubbles, and the error messages.

Feedback to our written work comes from many different places, high and low, from our peers, the QC AI software, our line managers, the skip level and C-suite executives, journal peer reviewers, and the regulators.

Should these move us to tears? Give us sleepless nights? Exacerbate our hypertension and worsen our pre-existing heartburn?

When receiving feedback, I rely on four B’s to keep perspective.

Bask. Enjoy every positive feedback, celebrate every win, no matter how small.

Breathe. Not-so-good feedback? Breathe in and breathe out. Pause. Take a walk to clear the cobwebs. Look up and find the silver lining.

Bitter or better? Negative feedback can be a bitter pill to swallow. Or it can be the medicine to make you better. It’s your choice.

Plan B. So, it didn’t work this time. Now on to the back-up plan...

Lose what you don’t use

It’s the basics of evolutionary biology – what is not used is lost. For example, after having lived in Europe for more than 30 years, I have lost the

ability to cross the streets of Southeast Asia where there are no traffic lights.

As we move on our medical writing career journey, we should continue to practice and hone our soft skills, including giving and receiving feedback. We should do this regardless of where we are, at the entry level position or the upper echelons of management.

In a VUCA digital world where companies and jobs change on a daily basis, our soft skills are one of the few constants. These are the skill set that sets us apart from machines, the ones AI cannot replace.

Kudos to Clare Chang and Nicole Bezuidenhout for putting together this fantastic issue! And thank you to all our authors and

contributors, and our editorial team.

Finally, MEW would like to thank outgoing section editors Laura Kehoe, Claire Gudex, Phil Leventhal, and Kimi Uegaki and welcome Adriana Rocha, Maddy Dyer, Louisa Ludwig-Begall, and Sarah Kabani on board.

Positive feedback loops reinforce or enhance; negative feedback loops counteract or balance.

Reference

1. Palmer MA. Feedback loops and socio-environmental systems. National Socio-environmental Synthesis Center. 2022. [cited 2024 May 25]. Available from: <https://www.sesync.org/resources/feedback-loops-and-socio-environmental-systems>.

Outgoing President's Message

EMWA: An evolving organisation

Time flies – nothing new in that then! The year of my presidency is finished, so it is time to look back and summarise.

It was my first task as a president to introduce a 5-year strategic plan for 2023–2027, and together with the whole Executive Committee (EC) decide about implementation tactics for 2023–2024, the year of my presidency.

Before diving into what was done and what not, let's remind ourselves of the main elements of EMWA's strategy:

- Leverage the value of our profession
- Grow and strengthen the association
- Expand educational and networking opportunities
- Build and foster partnerships
- Mitigate medical mis/disinformation
- Facilitate responsible use of technology
- Continue and expand sustainability initiatives

Since it is impossible to take care of everything, the EC decided to focus on:

- Growing and strengthening the association
- Expanding educational and networking opportunities
- Building and fostering partnership
- Facilitating responsible use of technology.

We thought that this choice of priorities would result in leveraging the value of our profession. We deliberately left out mis/disinformation and sustainability from the list since both are supported by ongoing EMWA activities. For example, during the latest virtual conference in November 2023, Ivan Oransky, MD, co-founder of *Retraction Watch* and editor-in-chief of *Spectrum*, opened the conference with his very inspiring talk on publication retractions. It is notable that in 2000 only 40 papers were retracted from the scientific journals, whilst in 2022, it was more than 5000. These numbers are both good and bad news. On the one hand, they suggest much more efficient control over the quality of published data, but on the other they deliver a warning: Be cautious and critical while reading scientific publications, and this is not only in regard to predatory journals. Sustainability is nicely taken care of by the Sustainability Special Interest Group (SIG) led by Kimi Uegaki. The Sustainability SIG was established in 2020

to support the United Nations' 2030 agenda for sustainable development from the perspective of a not-for-profit professional organisation for medical writers and communicators. The group ran a project aiming at estimating EMWA's carbon footprint, and the results were published in *Medical Writing*, Vol. 32, Issue 2, as *Carbon footprint of EMWA activities: A first estimate* by Blanca Gomez-Escoda, Pavlína Cicková, and Raquel Billiones.

Now back to the priority list. A number of activities were undertaken to meet our goals, some of them linking different strategic initiatives. For example a newly established Regulatory SIG falls under "Grow and strengthen the association" as well as "Expand educational and networking opportunities", which was a continuation of the Regulatory Public Disclosure SIG. We on the Executive Committee felt that EMWA should have a SIG that covers a much broader scope of regulatory matters than just public disclosure. Therefore, a general regulatory SIG was created with Sarah Hopwood and Jules Kovacevic as co-chairs. The SIG meets regularly to discuss different topics of interest and has also created a LinkedIn group with the following subgroups:

- Transparency and disclosure led by Zuoyen Lee
- Clinical regulatory writing led by Sarah Hopwood
- Non-clinical writing led by Sally Hill

There are a few other subgroups in the pipeline such as orphan drug applications, advanced therapy medicinal products, and documentation for paediatric studies.

The other initiative that spans various strategic elements is the Artificial Intelligence (AI) Working Group run by Sarah Tilly. This group is distinct from SIGs but closely cooperates with all SIGs and consists of representatives from each of them. The AI Working Group is very active – preparing a mini symposium for the November conference and



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several on-line seminars, and the full day symposium on AI in medical writing that took place at the Spring conference in Valencia.

Speaking of education and networking we ought to include Local EMWA Groups (LEGs). This recent initiative addresses the need for local networking, discussions, information sharing,

and the dissemination of best practices in a given European country or geographic area – enabling communication in the mother tongue. LEGs should facilitate EMWA and its members to contribute to important country-specific conversations around medical writing. They are open to all EMWA members and constitute a platform to share country-specific expertise, discuss local needs and improve the attractiveness of EMWA to new medical writers. This year, two LEGs have been created – Italian and Polish.

There are other Regulatory SIG subgroups in the pipeline, such as orphan drug applications, advanced therapy medicinal products, and documentation for paediatric studies.

Finally to finish on the topic of education, we explored the feasibility of introducing formal education, i.e. getting a university degree in medical writing, though this did not prove to have merit. Having explored many options, we decided to focus on developing EMWA's Professional Development Programme not only in terms of the number of workshops offered and variety of topics they cover but also in terms of developing different formats of educational events. Here, I would like to mention Expert Discussion Groups (EDGs), an initiative that started in Spring 2023 during the conference in Prague. The concept was introduced by Jules Kovacevic, Laura Collada Ali, and the EPDP Team to involve experienced medical writers and



to create a platform for expert discussions on specific, advanced topics. Meetings of small groups (8–10 participants) are scheduled to last 1.5 to 2 hours, and the discussions are led by carefully chosen moderators. The participants need to be professional medical writers with ≥10 years experience and with a special interest and experience in the topic for discussion. The pilot EDG sessions that were launched during the conference in Prague were very much appreciated and well attended, so EDGs will continue during our spring conferences.

To strengthen EMWA as an organisation, we have completed a number of “house-keeping” tasks such as: fine-tuning our GDPR processes; introducing new email addresses for better and more specific internal communication; signing an agreement with a law firm to provide legal support at short notice; and also contracting a marketing and public affairs advisor. Finally, our contract with Moore Insight (our administrative and accountancy support provider) is to expire by the end of 2024, and therefore we have started a tendering process to select the optimal solution for EMWA to move forward and use members’ money in the most efficient way. In these and many other tasks John Dixon’s engagement and hard work cannot be overestimated.

Thinking about EMWA members we proposed a new position within the EC – membership manager, a person who will serve as a point of contact for members, facilitate communication and collaboration within EMWA, streamline volunteering applications by matching volunteers’ expertise with EMWA’s needs, and respond to members’ expectations and inquiries. The other initiative, prepared by John, is a new membership structure with different tiers of costs. Both proposals were passed at the Annual General Meeting at the conference in Valencia.

Another major undertaking, driven by Allison Kirsop, is to rebuild our website. The new design will be modern, easy to navigate, and will enable easy location of items of interest. The work started with thorough research to gain insights into membership needs.

Openness, collaboration, and partnership are highly valued by EMWA. This means not only individual members holding memberships in other organisations but also EMWA fostering

more formal cooperation and executing joint activities with other organisations. EMWA continues to develop projects with our old friends AMWA, ISMPP, and Open Pharma. Recently, EMWA supported AMWA in the development of a model apprenticeship framework. This project aimed to create a unified skill standard that describes capability expectations by job level for the development of medical writers. A new initiative is to start close collaboration with the European Association of Science Editors (EASE) and become mutual sister societies.

Last, but definitely not least, I would like to thank my friends from the Executive Committee without whom my year as EMWA president would have been much tougher and less enjoyable! I am convinced that we, as a team, have served EMWA members to the best of our ability and have done our best to uphold the values of the organisation. This fantastic group includes Sarah Tilly (president-elect), John Dixon (treasurer), Somsuvro Basu (honorary secretary), Raquel Billiones (editor-in-chief), Slávka Baronikova (conference director), Diana Ribeiro (PR officer), Jules Kovacevic (education officer), Laura Collada Ali (education officer), and Allison Kirsop (website manager) – thank you again! A particular thank-you goes to Allison who has decided to retire from her position as web manager. Allison will be replaced by Andrew Balkin – welcome, Andrew, to this very exciting time of the new website launch! I would like to

express my sincere appreciation to Slávka, who again volunteered to stay on as conference director to continue to organise our conferences.

At the same time I would like to recognise Emma Halloran, Lenka Roper, Claire Whittingham, and Lisa Wilson from Head Office whose hard work and support made our plans and ideas happen.

I feel very confident handing over the presidency to Sarah Tilly, whose contribution as a president-elect assures excellent

and very thoughtful leadership during her tenure. And with great pleasure, I welcome Martin Delahunty as a new president-elect and wish him and the entire Executive Committee under Sarah’s presidency a fruitful and enjoyable time.

I feel very confident handing over the presidency to Sarah Tilly, whose contribution as a president-elect assures excellent and very thoughtful leadership during her tenure.

President's Message

The road ahead

Welcome to the latest issue of *Medical Writing*. Following our record-breaking Spring conference in Valencia, Spain, which saw an unprecedented number of attendees, I am both humbled and excited to address you as the new President of EMWA.

The Valencia conference was a testament to the strength and dedication of our EMWA community. With just shy of 500 participants, the energy and enthusiasm were palpable, marking a significant milestone as our association looks to the future to develop, strengthen, and grow.

Our schedule at the conference was jam-packed. We had 49 face-to-face training workshops, four expert discussion groups, expert seminars in three key areas, a full day symposium, early morning, lunchtime, and evening short seminars, the Freelance Business Forum, and a full day of information, talks, and discussions on how to get into medical writing. I extend my heartfelt gratitude to all the workshop leaders, speakers, organisers, and attendees who contributed to making this event an outstanding success. The high turnout and the quality of interactions reaffirm our commitment to fostering a collaborative and supportive environment for medical writers across Europe and beyond.

No one attending the conference, whether in person or online, would have missed the overarching theme: artificial intelligence (AI) in medical writing. As a profession, we have come a long way in the past 12 months. We have moved beyond our initial fears to working out where we as individuals, companies, and EMWA members might fit into this new normal that is starting to emerge. It was stated that "AI will not take your job, but someone using AI will." I'm not sure it's so simple. Scientific rigour, critical analysis, a deep understanding of data, and the ability to target the right audience remain essential skills and no machine will replace the empathy and diplomacy required to communicate with cross-functional teams of individuals. We need to spot

EMWA would not be the association it is today without the dedication of hundreds of volunteers who provide training, engage on social media, support special interest groups and subcommittees, and promote the medical writing profession to students.

what AI tools do not uncover, and when they produce erroneous output and fabrications. It is therefore just as important that EMWA continues to develop educational activities in standard scientific, medical writing skills as well as supplementary activities as we learn the tools of the future.

Looking ahead, we are embarking upon an ambitious 5-year strategic plan aimed at strengthening our association and expanding our reach. One of the key initiatives is the launch of a new, user-friendly website. This platform will serve as a comprehensive resource for members, providing easy access to educational

materials, industry updates, and networking opportunities. It is designed to support our current members in their professional development and to facilitate greater engagement within our community, as well as promoting EMWA and our profession to future medical writers.

Additionally, the Executive Committee is soon to nominate the new Membership Officer. This position will be crucial in ensuring that we



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EMWA's Switzerland hub

continue to meet the evolving needs of our members and support our much-valued volunteers. EMWA would not be the association it is today without the dedication of hundreds of volunteers who provide training, engage on social media, support special interest groups (SIGS) and subcommittees, and promote the medical writing profession to students. The Membership Officer will focus on enhancing member engagement, addressing concerns, and fostering a welcoming environment for new and existing members alike. This initiative aligns with our commitment to value-driven membership and continuous improvement.

Naturally, our strategic plan also emphasises the importance of professional development and education. We will continue to expand our



workshop, webinar, and seminar programs, offering a wide range of topics that cater to the diverse interests and needs of our members. Furthermore, we are committed to supporting the growth of our SIGS, which provide valuable platforms for specialised knowledge exchange and collaboration as well as that of our local EMWA groups: country-based initiatives to facilitate local networking, discussions, information sharing and the dissemination of best practices in a given country or geographic area.

As we move forward, I encourage all members to take an active role in EMWA's initiatives. Your participation and feedback are invaluable as we strive to enhance our services and support the professional growth of our community, expanding our reach through digital platforms, and fostering an inclusive environment where every voice is heard and valued.

As we embark on this new chapter, I am reminded of the words of a former EMWA president, over 10 years ago: "The spirit of true sharing of experience and lasting friendship [is

Scientific rigour,
critical analysis, a
deep understanding
of data, and the
ability to target the
right audience
remain essential
skills [that] no
machine will
replace.

what defines EMWA]". This sentiment continues today. Let us uphold these values and work together to strengthen the association that we have grown to love and depend on.

Thank you for your continued commitment to EMWA. Together, we will build on our successes and achieve new milestones in the years to come.

Warm regards,

Sarah Tilly

President, European Medical Writers Association (EMWA)

Acknowledgement: The above was written with the assistance of ChatGPT, of course, never left alone but always with the EMWA President in the loop. Needless to say, ChatGPT was not able to output any of the more specific, personal messaging in this welcome message. I challenge you to try to guess what is ChatGPT-created and what is EMWA President-created!

EMWA News



Getting into Medical Writing Day in Valencia

Exciting news for all our new and aspiring medical writers!

During the 57th EMWA Conference, the Getting into Medical Writing group organised an entire day dedicated to everyone interested in medical writing, considering it as a career option, or taking their first steps in this career path.

This included the “Introduction to Medical

Writing” Seminar, CV and LinkedIn clinics, and ample networking opportunities.

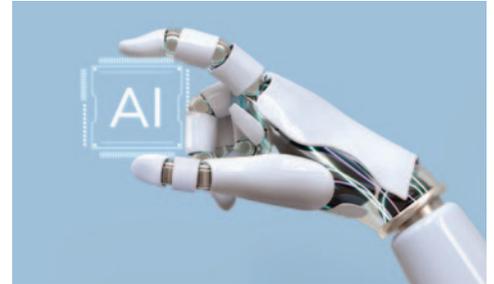
Please check out the **Career Guide for New Medical Writers** (<https://www.emwa.org/about-us/getting-into-medical-writing/career-guide-for-new-medical-writers/>).

SECTION EDITOR



Somsuvro Basu
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doi: 10.56012/Iggt7387



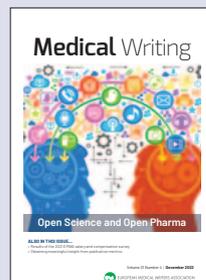
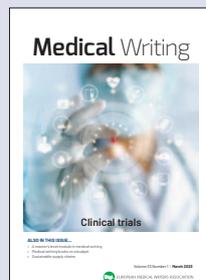
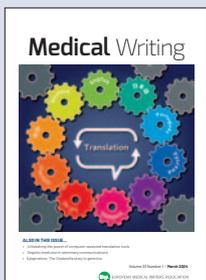
Symposium about artificial intelligence

The integration of artificial intelligence (AI) in medical writing is a transformative movement that is reshaping the landscape of our profession.

The AI symposium during the 57th EMWA Conference provided a 360° approach, from the technological perspectives of AI tool developers to ethical considerations, intellectual property, and copyright concerns that may arise whilst working with AI tools. Presentations covered various use-cases in regulatory documents and scientific publications, and ways in which information collected by AI tools is processed. Industry perspectives were shared about what is expected from a medical writing unit in these changing times and the new skills that medical writers will be expected to learn.

Did you know?

Existing EMWA members can receive a 10% discount off their next year’s subscription for referring a new member to EMWA. For more information, please contact Head Office at info@emwa.org



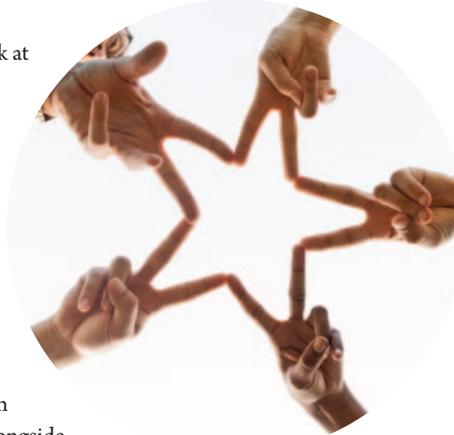
Check out the back issues of EMWA’s journal *Medical Writing*

at <https://journal.emwa.org/>

EMWA Ambassador Programme news

The EMWA Ambassador Programme continues reaching out to new audiences to promote medical writing and EMWA and has supported the events below.

On March 1, 2024, **Evguenia Alechine** (Chair of the Getting into Medical Writing initiative) delivered a talk at the University of Freiburg, Germany, during the Science Communication module of the International Master Program in Biomedical Sciences. The session was part of a week-long module introducing the students to medical writing and its career prospects. Evguenia discussed EMWA and its offerings and highlighted the Spring EMWA Conference in Valencia, Spain, that took place in May. Evguenia emphasised the opportunities that EMWA presents for newcomers. The students were intrigued by this novel career path, and they engaged in lively discussions about freelancing, part-time work alongside academic pursuits, the necessity of a PhD for medical writing, and international work opportunities. Overall, the session was well-received, and the students gained valuable insights into alternative career paths in biomedical sciences.



On May 8, 2024, **Abe Shevack** represented the Ambassador Programme at a “speed networking” session during the Getting into Medical Writing event at the 57th EMWA Conference in Valencia.

If you are an experienced medical writer and an EMWA volunteer and are interested in becoming an EMWA Ambassador, or if you know of any upcoming career events in your locality, please contact the EMWA Head Office (info@emwa.org) or Abe Shevack (aspscientist@gmail.com).

EMWA Webinars Programme

EMWA webinars help members to develop skills and keep up to date with new or rapidly developing areas.

Most of our webinars are live, online seminars allowing participants to ask questions. For live webinars, you only need to register – you will need your EMWA membership details.

Read about upcoming webinars at: <https://www.emwa.org/education/emwa-webinars-programme-2024/#webinars2023>



EMWA Special Interest Groups

EMWA membership allows you to participate in any **Special Interest Group (SIG) Meet and Share**, even if you are not an active member of that SIG.

These events are announced in the EMWA newsletter and in a separate mailing, closer to the event date. The Meet and Share sessions are great opportunities to learn more about a particular topic in an informal setting. Some sessions may be recorded, but many are not.

SIG members, on the other hand, participate in all SIG meetings (as their availability permits) and/or are more involved in the SIG activities, requiring an active role in providing more in-depth knowledge about what is going on in the SIG area.

If you are interested in knowing more about the SIGs, please read this: <https://www.emwa.org/sigs/>



Abstracts from the 57th EMWA Conference Poster Session

Valencia, Spain, May 2024

EMWA's spring conference in Valencia featured 18 posters on a wide variety of topics of interest to medical writers. Clinical trial regulations, plain language summaries, graphical abstracts, and document quality control are just a few of the subjects covered. Here, we present the list of titles and authors.

The full abstracts are available in a supplement published online-only with this article:

<https://doi.org/10.56012/zdtb3708>

Note, some poster submissions were not accepted for presentation at the conference, thus there are gaps in the poster-numbering sequence.

A graphic featuring the word 'VALENCIA' in large, 3D, golden letters. Below it, the text 'EMWA's 57th Conference' is written in a white, sans-serif font. The background is a photograph of the Valencia Convention Center at sunset, with its distinctive white, shell-like architecture and a large glass dome structure.

P1 The Impact of the EU Clinical Trials Regulation (CTR)

Irene Lako, Tasnim Uddin, Jelmer de Jong, Koen Janssen, Cor van der Heide, Noëlle Zweers, Rouyanne Ras, Alida Weeke-Klimp, Judith Hettinga
ICON plc

P2 Plain-language summaries of publications: Who, what, when, where, and why

Louisa F. Ludwig-Begall, Pablo Izquierdo, Rienne Schinner, Phil Leventhal
Evidera-PPD, a Thermo Fisher Company

P3 Medical Writers: A Pivotal Role in Leading Teams to Compliance with EU CTR Transparency Requirements

Montserrat Cuadrado Lafoz, Daniel Antoine
PPD Clinical Research Business of Thermo Fisher Scientific

P4 Working Across Therapeutic Areas – Boon or a Challenge for MWs?

Reema B Acharya, Anne Madalijns
Johnson & Johnson

P5 Turning waterfalls into swirls – can regulatory MW transform into agile MW?

Katharina Brauburger¹, Michael Breunig²

¹ Merck Healthcare KGaA

² BMW Group

P7 Growing Role of Regulatory Medical Writers in Driving and Optimising Submissions

Anne Madaliins, Reema Bardhan Acharya

Johnson & Johnson Innovative Medicine, Regulatory Medical Writing

P8 The trends of ChatGPT usage in medical writing: Results from a KAP

Sujatha Vijayakumar¹, Shital Sarah Ahaley¹, Ankita Pandey¹, Simran Kaur Juneja¹, Tanvi Suhane Gupta¹, Prakash Muthuperumal²

¹ Hashtag Medical Writing Solutions Private Limited, Chennai, India

² School of Public Health, SRM Institute of Science and Technology, Kattankulathur, Chengalpattu, India

P9 Analysis of adverse events in early phase trials. A medical writing perspective

Mădălina Nistor, Sara Fernandes, Mauro Meloni, Joanna Lesiak, Rona Grunspan

ICON plc

P10 Exploring the awareness and perceived utility of graphical abstracts in scientific publishing

Marta Mas¹, Catherine Heddle², Alina Gavrus Ion¹, Nicole Bezuidenhout³

TFS HealthScience, Department of Medical Writing

¹ Barcelona, Spain

² Solna, Sweden

³ New York, USA

P13 Preparation is Key to Success: Use of the Document Content and Messaging Summary (DCAMS) in Authoring Regulatory Submission Documents

Sarah Milner, Richard Grant, Laura Hunter, Jonathon Kaiser, Dara Goldberg-Spar

PTC Therapeutics, Inc.

P15 Maximising quality control review of regulatory documents

Patrick Barry, Kelly Danyow, Jamie Spagnuolo

Acumen Medical Communications

P16 An attempt to translate estimands into plain language

Ulrike Fischer, Kathi Künemann, Azuka Iwobi, Maarten van Dijk, Habib Esmaeili

P19 Plain language summaries created with Artificial intelligence – Can it save time or waste it?

Kathi Künemann, Seyma Öztürk, Sandra Martin

Staburo GmbH

P20 Videocast(s): Are they worth the effort as a digital enhancement?

Vandana Chaudhary

Medical affairs & Publications, Rhodocyon Health

P21 The Art and Science of Medical Writing amidst Technological Innovations

Vandana Chaudhary

Medical affairs & Publications, Rhodocyon Health

P22 Enhancing Patient-Centricity in Medical Writing: the Art and Science of Effective Plain Language Summaries

Sreeja Pillai, Sonica Batra

Indegene Ltd, Bangalore, India

P23 Quantifying sex bias in randomised clinical trials of major impact publications

Irene Mansilla, Alina Gavrus Ion, Anaïs Estrada Gelonch, Marta Mas

TFS HealthScience, Department of Medical Writing, Barcelona, Spain

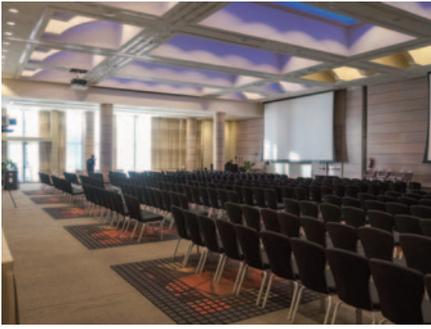
P25 Master Protocols: Implementing innovation in an evolving field

Petra Delgado Romero, Maria Wendt, Sabrina Stoehr

Global Medical Writing, Merck Healthcare KGaA, Darmstadt (Germany)

The full abstracts are available in a supplement published online with this article: <https://doi.org/10.56012/zdtb3708>





EMWA's 57th Conference

VALENCIA



The European Medical Writers Association (EMWA) 57th Conference May 7–11, in Valencia, Spain, was an illustrious gathering that brought together medical writers, editors, researchers, and professionals from across Europe and beyond. The conference served as a platform for exchanging knowledge, discussing the latest trends in medical writing, and fostering collaboration within the field. Participants immersed themselves in Valencia's rich heritage while engaging in stimulating discussions and workshops.

The theme was “Innovations in Medical Communication” with the focus being artificial intelligence (AI), and how medical writers can make the best use of it in their work. AI was the theme of a daylong symposium on May 9, as well as the Expert Seminar Series (ESS) on May 10. The “Getting into Medical Writing” all-day seminar drew 60 newbies considering the career path. Other topics on the agenda included regulatory writing, orphan drugs, and medical devices.

And BTW, in getting into the spirit of the conference, the italicised paragraph above was written by ChatGPT (with a human prompt and editing!)

Into the future we go, with EMWA by our side!

Thanks to EMWA volunteers who provided the photos (Raquel Billiones, Lisa Chamberlain James, Felix Schneider, and Alicia Waltman).





Outgoing President Maria Kołtowska-Hägström, new President Sarah Tilly, and President-Elect Martin Delahunty (2025-26)

Moving into medical writing from academia: A soft skills perspective

Vivek Ranjan

Regulatory Writer

Certara, Oxford, UK

doi: 10.56012/bsth1149

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Abstract

As I made the transition into medical writing and started learning the ropes, I realised first-hand that in addition to writing skills, soft skills are indispensable in becoming an effective medical writer. Not only are they vital in helping you enjoy your work, mastering the necessary soft skills will also help others enjoy working with you. In this article, I talk about six key soft skills that have played a crucial role in helping me make a smooth transition into the world of regulatory medical writing.

It has been nearly two years since I made the leap from academic research into full time regulatory medical writing. Changing careers was a daunting task at the time, especially since my work involved a very niche area inside academic research and I had no idea what else I could be doing given my extremely specific skill set. I had become aware that academia was not my cup of tea very early into my time as a researcher. I also knew that I wanted to continue contributing to science but was not too keen on doing this by spending endless hours at the bench conducting experiments. The obvious first step was to scour the internet for alternative careers for life science researchers. Upon narrowing down the choices available, a career in medical writing really appealed to me as it gave me the chance to remain within the confines of science while playing to my strengths as an avid science communicator and technical writer.

After I made the transition into medical writing and started learning the ropes of my role,

I quickly realised first-hand that in addition to writing skills, soft skills are indispensable in this line of work – so much more so than in academia. My time in research mostly involved working alone or in very small teams on projects for long durations of two to three years. Medical writing is much more dynamic in that you will most likely be working on multiple projects in parallel often involving vast and diverse teams with much shorter deadlines. This is when your soft skills truly come into play and can have a huge impact on how efficient and effective you are as a medical writer. Not only are they vital in helping you enjoy your work and deriving satisfaction from it, mastering the necessary soft skills can also play a critical role in helping others enjoy working with you. In this article, I talk about six key soft skills that were crucial in making a smooth transition from academia into the world of medical writing.

1. Communication

Communication is perhaps the cornerstone of medical writing. It encompasses every stage of your time as a medical writer – all the way from bagging your first medical writing role to your daily activities as a writer, as well as gaining experience and advancing your career. Medical writing is an umbrella term which brings together several different flavours of writing, such as medical communications, regulatory writing, medical publications, and medical journalism, etc. Communication skills played a significant role in helping me figure out the specific branch of medical writing I wanted to move into and even helped me land my first interview. This process involved an extensive amount of networking including: reaching out to writers working in each discipline of medical writing; setting up informational interviews; learning about the day-to-day work involved; getting an idea of the work culture and ethos; and understanding the challenges underlying each branch of medical writing. Attending an EMWA conference and networking in person helped me learn about several organisations that I would have never

come across on my own. It helped me glean what companies are looking for in potential employees; this in turn helped me tailor my résumé and writing samples to suit the roles I wanted.

Once I finally made my way into medical writing, I understood that both verbal and written communication skills were equally important. To start with, asking the right questions during your interactions with senior writers on the job can help you pick up things faster during your training period. As a medical writer, you also will be communicating with both colleagues and clients regularly. In addition to authoring, you will be writing emails, supporting other writers, attending and leading meetings, facilitating discussions among various team members, and ultimately driving documents through to approval. Communication plays a central role in all these activities and how effectively you communicate can directly impact

how productive and efficient you are as a writer.

2. Attention to detail

Attention to detail is a key component that companies look for in potential candidates during the recruitment process. This is because your day-to-day as a medical writer involves processing vast amounts of data and writing lengthy documents comprising several hundred pages. Most often,

these documents are prepared under tight timelines with a significant amount of back and forth among the various team members involved. The majority of these documents are critical in the drug development process and can play a decisive role in gaining approval for marketing authorisation from the regulatory authorities. They serve as a source of information for a diverse group of people including patients, clinicians, scientists, healthcare workers, ethics committees, and regulatory authorities. It is vital that the information presented in these documents is accurate and consistent. Documents also usually undergo a quality control stage during which they are checked thoroughly by other writers for errors. Medical writing companies can

Not only are they vital in helping you enjoy your work, mastering the necessary soft skills will also help others enjoy working with you.



assess your attention to detail in several ways. For instance, it could be as simple as the attention you pay to your emails when interacting with your potential employer during the recruitment stages. Writing assessments are also commonly used by most organisations during the initial stages where you could be provided with a variety of tasks including reading, writing, or editing depending on the company. These tasks will also need to be completed within a pre-specified time limit. Being pedantic and having gimlet eyes during these stages can actually give you an edge during the recruitment process and show you in a good light to your potential employer.

3. Adaptability

No two days in the life of a medical writer are the same. It is very likely that you will be juggling multiple projects on a daily basis, each requiring a different approach, style, and format. For example, a document written for investigators is a very different ball game from one that is aimed at patients. This diversity in the nature and scope of medical writing projects requires you to be versatile and adapt your writing style to suit your

purpose and target audience. Once you gain experience, you will also be working for several clients, which can add another layer of complexity to your projects. You might end up working on multiple client desktops with different document management systems, Sharepoints, email addresses, standard operating procedures, styles guides, etc., at the same time. Most regulatory and document guidelines are also constantly being updated and it is imperative that you keep abreast of these changes as a

medical writer. Working on the same type of document could give you completely different experiences based on the client you are working for, the project you are working on, or the team you are working with. During busy periods, you may not always have the choice to work on a project you prefer or a document you like. Being flexible and developing the ability to tackle any task or project that comes your way can help you gain experience quickly, especially during the initial stages of your career when the focus should be to learn as much as you

Attention to detail is a key component that companies look for in potential candidates during the recruitment process.

No two days in the life of a medical writer are the same.

can on the job. Learning to cope with the unpredictable nature of drug development as a whole and adapting yourself to each project depending on its scale and complexity, can help you progress quickly in your career.

4. Time management

As a medical writer you will need to dedicate chunks of your time to a range of activities including training, reading, responding to emails, entering timesheets, attending meetings, quality control, and project work. Bring proactive and planning can help you split your time effectively and can also have a direct influence on how smoothly your work days are. As a beginner, you are likely to spend most of your time training on various kinds of documents and reading numerous standard operating procedures. You may also be assigned work on specific sections of documents to give you a taste of what they entail and help you learn more without the added pressure of being responsible for the entire document. These experiences can help you get a rough gauge of the complexity of each section in the document and the approximate time required for the document as a whole. As you gain experience and begin to

lead projects, you will also be expected to plan and create timelines for the document development process upfront. A typical regulatory document will generally involve two to three drafts, two to three rounds of reviews, quality control, content endorsement, and approval. You will need to adhere to the timelines for each stage of the project unless there are unexpected changes including additional tasks requested by the client. One approach for tackling this would be to look at the big picture and then take a top-down approach to planning your work. For instance, you could prepare a list of the projects you are working on and then break them down by urgency and complexity. This can help you prioritise your projects and give you an idea of how many projects you can take on during a given period. Armed with this information, you can work out how to split your time between billable and non-billable activities and whether you might need to request additional resource to help you meet your project deadlines.

5. Team player

To be an effective team player is a must-have skill for almost every organisation in today's corporate world. As a medical writer, you may be assigned projects in which you are given all the information upfront and left entirely to your own devices to see it through. This kind of autonomy given during authoring could be the case with projects of a smaller scale involving documents with lower complexity. However, this is unlikely when authoring complex and high-level documents requiring input from a wide range of stakeholders. For instance, the preparation of decisive regulatory documents like a clinical study protocol, which essentially describes how a clinical trial will be conducted, or a clinical study report, which describes the data and outcomes of a clinical trial, will need input from multiple functional areas. These can include clinicians, biostatisticians, regulators, clinical associates, programmers, scientists, project managers, data managers, trial managers, and other medical writers. These documents necessitate a lot of back and forth during authoring and go through multiple rounds of drafts and reviews before they are approved. They

The sooner you learn to accept criticism positively and apply the feedback gained to your work, the quicker your learning curve is and the faster you can progress to leading your own projects.

also involve sifting through enormous amounts of data including tables, figures, and listings making it an onerous task to tackle alone. In addition, the authoring of such documents will often entail collaborative authoring, which involves the simultaneous input of multiple team members representing varying functions. Sometimes, there can be conflicting opinions and disagreements among the team; as a medical writer, you may find yourself leading comment resolution meetings to resolve these differences and find common ground, and ultimately drive the document development process through to approval within the given deadlines. To be an effective team player involves the mastery of a combination of other soft skills including active listening, communication, and conflict management. Although it may not be a straightforward

process, these are skills you can develop and hone over several years as you make your way from supporting senior colleagues with their projects to leading your own projects.

6. Accepting feedback

This is a skill you will become familiar with as soon as you break into medical writing and begin working on your very first document. As a beginner, your work will be vetted and checked for errors by senior writers and it is very likely that you will end up with a document riddled with track changes and comment bubbles giving you feedback. It can be a truly humbling experience for someone fresh out of academia,

even if you have several years of experience with scientific writing and have multiple publications to your name. The sooner you learn to accept criticism positively and apply the feedback gained to your work, the quicker your learning curve is and the faster you can progress to leading your own projects. In contrast to academia, you will also soon realise that as a medical writer you are not the owner of the document you author, and you may not necessarily have the final say on how it is written. Medical writers are service providers and how the document is written is ultimately up to the client. Although you may advise the client on the writing, it is important to understand that you are providing a service to that client. This may require you to accept major changes in your work if requested by the client – even if you think you have written everything perfectly. In these situations, it is imperative that you learn to swallow your pride and accept the feedback on the work even if you do not fully agree with it.

These are some of the key skills I continue to learn and hone as I take baby steps into the vast and complex world of regulatory writing within drug development. They have helped me gain much needed confidence, as someone with little to no experience in this domain, and have also helped me grow both professionally and personally.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by his employer or EMWA.

Disclosures and conflicts of interest

The author declares no conflicts of interest.



Author information

Vivek Ranjan, PhD, has been a regulatory writer at Certara since September 2022. He has a background in tissue engineering and biofabrication. Before taking the plunge into medical writing, he worked as a postdoctoral research fellow at the Center for Research in Transplantation and Translational Immunology in Nantes, France.



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Unlocking success as a book author: Navigating the essential soft skills of writing, gained through my PhD journey

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Abstract

This article explores the journey of transitioning from PhD to a book author, emphasising the importance of soft skills cultivated during academic pursuits. Drawing from personal experience, the author underscores the parallels between academia and authorship, highlighting skills such as effective communication, networking, resilience, and self-discipline. The ability to translate complex ideas, build relationships, persevere through challenges, and maintain a structured writing routine proves essential in navigating the publishing landscape. Practical strategies are offered to nurture these skills, including engaging in conversations, participating in authorial communities, embracing a growth mindset, and mastering self-discipline. Ultimately, the article illuminates how the journey from PhD to authorship is marked by growth, challenges, and the development of crucial soft skills, laying a foundation for success in the dynamic world of publishing.

Many PhDs nurture the aspiration of becoming published authors, often achieving this within academia through scientific publications. However, transitioning from scholarly writing to crafting books for a broader audience requires more than simply weaving together compelling sentences. As an author of numerous

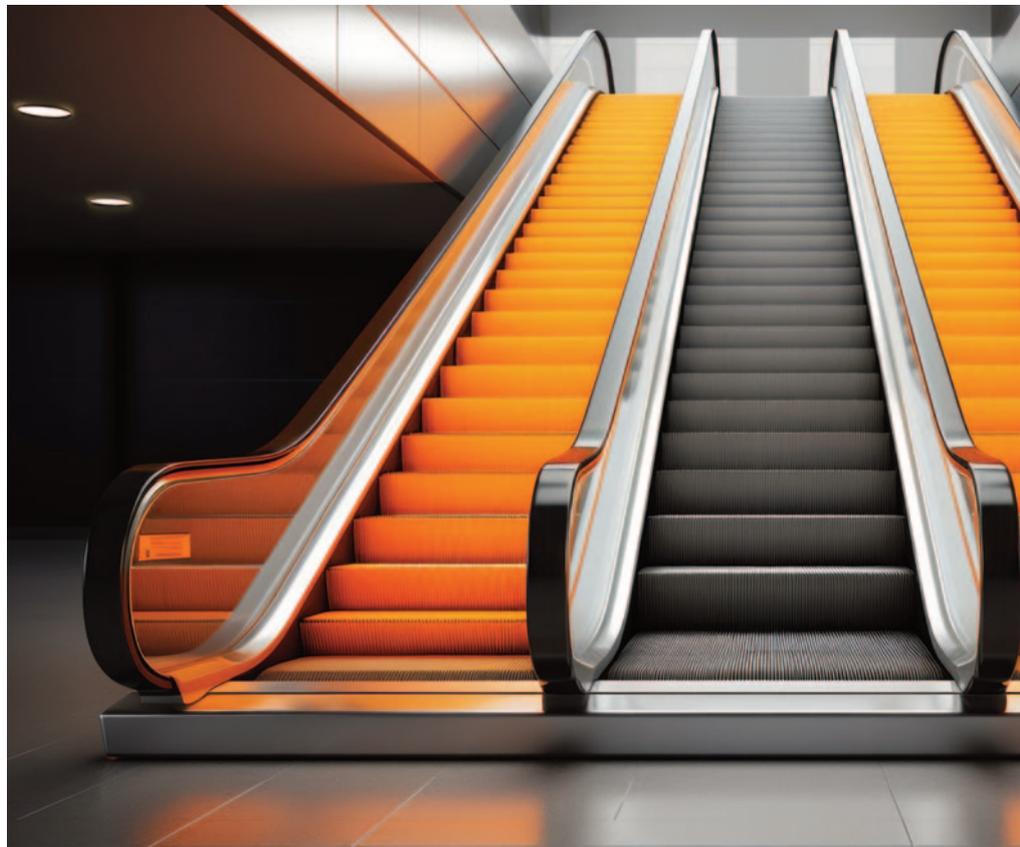
scientific and non-scientific books and articles, who has navigated the complexities of the publishing world, I can attest that many skills cultivated during one's PhD journey can be successfully applied.

My personal evolution into a writer was not solely driven by a love for language, but also by a desire to express myself in a different medium. The rigorous and occasionally stressful pursuit of a PhD unexpectedly provided an excellent platform for refining the essential skills for writers to achieve their objectives. Over years of research, analysis, and defending my dissertation before expert panels, I honed a set of soft skills that laid the groundwork for my writing career. In this article, I uncover the fundamental soft skills that empower PhDs to become aspiring authors.

The transformative journey:

From PhD to authorship

Pursuing a PhD equips you with the skills to engage with diverse audiences, whether it is presenting research or defending your thesis. You learn to translate complex ideas into a language that is understandable to both experts and laypeople. These communication soft skills extend beyond academia, becoming the cornerstone of connecting with readers through your writing, effectively conveying your message, and engaging your audience in a captivating narrative. This is a soft skill that we rarely develop during our academic journey, or without knowing, and proves to be instrumental when it is time to wrap up a publication, whether it is a short article or a book.



Academia thrives on collaboration. Building relationships with professors, fellow researchers, and conference attendees becomes second nature. Similarly, an author's world pulsates with connections – literary agents, editors, fellow authors, and readers. Networking is a valuable skill for writers, often overlooked in academia. A skilled networker understands the power of forging meaningful relationships, fostering a supportive community, and leveraging these connections to navigate the publishing landscape.^{1,2}

As we all know, research is riddled with roadblocks, failed experiments, and moments of self-doubt. Overcoming these hurdles with perseverance and a positive outlook instills resilience. This mental fortitude becomes your shield as an author, making you open to constructive criticism, rejection, and the inevitable periods of self-doubt. It fuels the determination to push through, refine your craft, and keep your writing dreams alive.

Completing a PhD demands tenacity. You manage deadlines, juggle responsibilities, and prioritise tasks – skills crucial for authors grappling with daily writing routines, meeting

publishing deadlines, and balancing writing with other obligations. Self-discipline becomes your internal motivator, driving you to dedicate consistent time and effort to nurture your manuscript and navigate the demanding world of publishing. Another driving force behind my decision to write two books in the PhD career advice field was witnessing my lab colleagues' lack of awareness about the diverse career paths available outside of academia. Assisting my peers and colleagues served as a significant motivator for me to embark on this journey. Therefore, my advice would be to choose a topic that you are truly passionate writing about.

In conclusion, three skills are crucial in transitioning from academia to authorship:

1. Effective communication skills are essential for successful publication, whether it's a short article or a book.
2. Collaboration is key in academia and writing, with networking playing a crucial role in forging connections and navigating the publishing landscape.
3. Resilience, developed through overcoming challenges with perseverance and a positive outlook, along with self-discipline and tenacity, are vital traits for authors to navigate the demanding world of publishing.

Cultivating authorial skills: practical strategies for success

So, as you can observe, a PhD journey extends beyond the realm of academia, not solely focused on publications and technical proficiency, but also equipped with soft skills essential for authorship. In the subsequent sections, I will delve into practical advice and exercises to nurture these skills in your writing journey.

- **Enhance your communication abilities:** Engage actively in conversations to grasp diverse viewpoints and refine your articulation through workshops or public speaking engagements. Seek feedback by sharing your work in writing groups or online forums and adapt your communication style to cater to different audiences. Consider starting a blog or writing articles to strengthen your ability to convey complex ideas clearly and engagingly.³
- **Develop networking proficiency:** Immerse yourself in the authorial community by attending industry events, conferences, and workshops, forging connections with fellow authors, editors, and agents. Participate in online forums related to your genre to

establish your presence and offer your expertise through guest posts or pro bono services. Remember, authentic connections and active listening are key to effective networking. From my personal experience, engaging with fellow authors who specialise in writing for particular journals within the career domain has significantly boosted my visibility and facilitated connections with editors. This networking effort has consistently led to opportunities to collaborate with new editors and secure additional commissioned work in the field of career development.¹

- **Foster resilience:** Embrace a growth mindset, taking on challenges as opportunities for growth. Celebrate your accomplishments, practice mindfulness techniques to manage stress, and surround yourself with a supportive network. Each morning, I use a gratitude journal to set a positive tone for the day ahead. This practice allows me to acknowledge and celebrate the aspects of my life that bring me joy, while also identifying areas for growth and improvement. Additionally, I prioritise daily meditation sessions, typically lasting at least 10 minutes. Engaging in breathing exercises during meditation helps me disconnect from the myriad tasks at hand and approach situations with a sense of calm and mindfulness.

Learning from feedback is crucial for enhancing writing skills and gracefully navigating setbacks. I actively seek and capitalise on feedback from others regarding my writing, internalising their input to present an improved version of myself in subsequent writing opportunities. This iterative process enables me to continuously refine my craft and adapt to new challenges with resilience and grace.

- **Master self-motivation:** Set achievable writing goals, break down tasks into manageable steps, and establish a dedicated writing routine. Make use of productivity tools like Asana and employ time management methods such as Toggl to maintain concentration and monitor your advancement. In the past, I experimented with a strategy akin to the Pomodoro technique, where I assembled a to-do list and a timer. The procedure involves setting the timer for 25 minutes and dedicating that time solely to a single task. Upon completion of the session, mark off one Pomodoro and jot down the tasks



accomplished. Subsequently, enjoy a brief 5-minute break. After completing four Pomodoros, take a longer, more rejuvenating break spanning 15 to 30 minutes. Remember, your writing journey is unique, so adapt these strategies to suit your needs. Cultivating these soft skills will not only improve your writing but also equip you with the resilience and adaptability needed to succeed in the dynamic world of publishing.⁴

Soft skills to thrive as an author

In traversing the intricate path from PhD scholar to accomplished author, one embarks on a journey rich with challenges, growth, and self-discovery.

Embarking on a journey of discovering confidence, navigating obstacles, and seizing opportunities requires a multifaceted approach. This encompassed various soft skills such as open-mindedness, curiosity, self-awareness, empathy, creativity, adaptability, and self-motivation.⁵ These attributes played pivotal roles in shaping my path through the challenges of academia and the intricacies of the publishing world.

- **Open-mindedness** was essential in embracing diverse perspectives and being receptive to new ideas. It enabled me to explore unconventional paths and consider alternative solutions to problems that arose during my PhD studies and while navigating the publishing landscape. Curiosity fuelled my desire for knowledge and pushed me to delve deeper into topics of interest, fostering continuous learning and growth.
- **Self-awareness** played a crucial role in understanding my strengths, weaknesses, and areas for improvement. By recognising my limitations, I could proactively seek opportunities for personal and professional development, honing my skills to overcome obstacles and excel in my endeavours.
- **Empathy** allowed me to connect with others on a deeper level, understanding their perspectives and fostering meaningful collaborations. This skill proved invaluable in both academia and publishing, where effective communication and interpersonal relationships are paramount.
- **Creativity** empowered me to think outside the box, generating innovative solutions and approaches to challenges encountered along the way. Whether it was devising experimental methodologies during my PhD

research or crafting engaging content for publication, creativity served as a driving force behind my success.

- **Adaptability** was essential in navigating the ever-changing landscapes of academia and publishing. Flexibility in adjusting to new circumstances, embracing change, and overcoming setbacks proved instrumental in seizing opportunities and staying resilient in the face of adversity.
- **Self-motivation** served as the underlying force propelling me forward, even in the face of daunting obstacles or setbacks. It fueled my determination to persist in the pursuit of my goals, driving me to continually strive for excellence and push beyond my comfort zone.

Thus, the transition from academia to authorship demands a mastery of technical prowess and the nuanced art of communication, networking, resilience, and self-discipline. As we reflect on the multifaceted nature of this transformation, it becomes evident that the foundation laid during the rigorous pursuit of a doctorate serves as a great start and fertile ground to build upon for cultivating the essential soft skills requisite for success in the literary realm. It is imperative to maximise the potential of your PhD journey. Based on my observations, many individuals tend to underestimate the value of the numerous opportunities available to establish a solid foundation (comprising both essential soft skills and technical expertise) to launch their careers on a promising trajectory, whether in industry or elsewhere.

Disclosures and conflicts of interest

Matteo Tardelli has authored two commercially available books on transitioning from a PhD to industry.

References

1. Streeter J. Networking in academia. *EMBO Rep.* 2014;15(11):1109–12. doi: 10.15252/embr.201439626
2. Tardelli M. Beyond academia: stories and strategies for PhDs making the leap to industry. 2023; ISBN13:979-8386861865.
3. Speakerhub. The significance of communication skills in writing. Medium 2023. Available from: <https://speakerhubhq.medium.com/the-significance-of-communication-skills-in-writing-b3e920fce47f>
4. Collins B. The Pomodoro Technique explained. *Forbes* 2020 Mar 3. Available from: <https://www.forbes.com/sites/bryancollinseurope/2020/03/03/the-pomodoro-technique/>
5. Stadlen E. How to get a book published outside academia. *IHE* 2022. Available from: <https://www.timeshighereducation.com/campus/how-get-book-published-outside-academia>



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Matteo Tardelli, PhD, is an experienced professional who transitioned from academia to various industries, including biotech and consulting, and now assists PhDs in similar career shifts. Published in *Nature* and *University Affairs*, he shares insights on post-PhD career success through talks at Ivy League institutions and conferences worldwide. As an author, Matteo's books *The Salmon Leap for PhDs* (2020) and *Beyond Academia* (2023) have sold over 4000 copies each on Amazon, with *Beyond Academia* receiving over 100 positive reviews. His *Beyond Academia* Newsletter features human stories on PhD careers.



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The hard truth about soft skills in medical writing

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Abstract

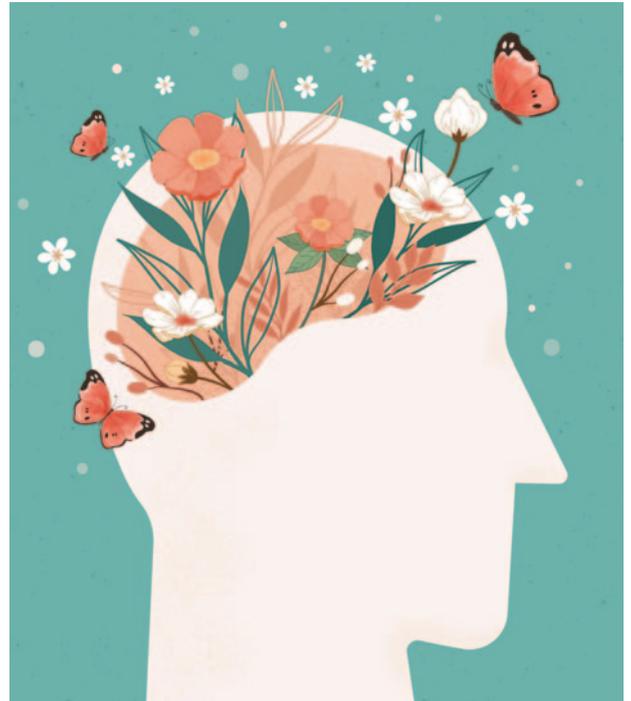
Historically, hard skills – such as technical, digital, or life sciences qualifications – have been seen as more valuable than soft skills in successful medical writing. However, hiring managers now recognise soft skills as one of the top educational needs in medical communications. Although the use of artificial intelligence (AI) is also emerging as a key medical communications tool, there are some things AI simply cannot do. That's where soft skills, like teamwork, adaptability, and leadership, come in. This article reviews the essential soft skills you now need as a professional medical writer, and how you can optimise them for your career.

Rebranding soft skills

Interpersonal, communicative, and “soft skills” are being rebranded as “power skills”, “durable skills”, and “essential skills” which are becoming increasingly valuable in the global and local medical communications industry.¹ In fact, a recent American Medical Writers Association (AMWA) survey reveals that soft skills are now among the top educational needs identified by hiring managers in medical communications.² Such soft skills include time management, critical thinking, working with a team, problem solving, adaptability, and leadership, as well as several other abilities.²

Since more medical companies have shifted to hybrid or remote work models, soft skills have become just as valuable as technical knowledge. For example, effectively communicating and collaborating with colleagues, KOLs, and clients

Interpersonal, communicative, and similar “soft skills” are being rebranded as “power skills”, “durable skills”, and “essential skills” in today's remote and hybrid work environments.



online, has become a top priority to succeed in a virtual world.

Unlike professional hard skills, soft skills, are not usually taught in medical communications. Soft skills tend to be human-centred traits that you develop from your own lifetime experiences. However, you can still learn and develop these capabilities to complement your hard skills. So, what key soft skills do you need to stand out as a medical writer in today's changing medical communications industry?

Human soft skills

According to a recent Forbes report, artificial intelligence (AI) is poised to “reinvent the entire communications industry”, and “pave the way for

better, more accessible human expression by eliminating monotonous tasks and expanding creative potential.” For example, these tools can help medical writers, researchers, editors, and content creators develop better ideas, formulate text and improve consistency, accuracy, and style.

Although the use of AI tools like ChatGPT-3 and Jasper AI are emerging as key tools for medical communication, you'll still need to branch out offline to update your essential soft skills.³ That's because there are some things AI simply cannot do (Table 1). In an increasingly AI and automation-driven workforce, durable soft skills remain a uniquely human strength, and hold significant value.

Time management

When you started your career as a medical writer, you probably didn't expect most of your time would be spent on management tasks that don't include any writing at all. However, it's estimated that medical writers spend 60% of their time on writing and 40% on project management.⁴

Also, according to a recent AMWA survey, time tracking is the biggest challenge for most medical writers.² Efficient time management is important for producing your high-quality documents on time. In addition, by optimising your time management skills, your clients and

Table 1. Essential soft skills for medical writers

1. Time management
2. Communication
3. Leadership
4. Adaptability
5. Problem solving/critical thinking
6. Innovation/creativity
7. Emotional intelligence
8. Collaboration/teamwork
9. Networking

colleagues are more likely to see you as an efficient, reliable resource. Here are a few tips to optimise your time management skills.

- **Set realistic timelines:** Have a practical idea of how long you'll need to complete each project. This should include your working time for research, planning, writing, and editing, post-review, client consultation and project administration. You can then confirm this time to your clients and set up your project schedule.
- **Set up and stick to a project schedule:** This allows you to prioritise your projects and set boundaries with your clients. For example, if you're working on various projects for one client, and an account manager starts demanding more of your time, then you should flag this up to your client's main account director, to determine which project takes precedence.
- **Be prepared to say "No":** Amazingly, some clients and colleagues expect medical writers to be "miracle workers" by producing an unrealistic amount of content in one day. If you experience this pressure, let your team members know as soon as possible what you can actually deliver, within certain timelines, based on your own professional and personal schedules.
- **Include personal time in your schedule:** As a fulltime or freelance medical writer, it's vital to set aside personal time for yourself, in your daily and weekly schedules, to maintain your physical and mental health.⁵ Building in this personal time will also help you to think creatively, manage your deadlines better, and edit your content with a fresh pair of eyes.

Communication

As a freelance or fulltime medical writer, providing clear, detailed communications is a critical soft skill for keeping your projects running smoothly. You can optimise this skill in the following ways:

- **Get a clear, written project brief** before you begin any work. Don't just rely on a verbal brief. Ask your client to provide answers to all your questions up front, regarding the project objectives, deliverables, timelines, deadlines, style, and content quality, to confirm your next steps.

- **Clarify any requested changes:** Ask your client to explain any unclear editorial changes they may request, so you can highlight any problems that these changes might cause. For example, some requested revisions may contradict the project brief and the style sheet or delay the content delivery.
- **Provide regular updates:** Keep your clients and colleagues regularly updated about your own progress, at each stage of the project. Ensure that you highlight any editorial issues that you or they need to deal with.

Leadership

As a vital soft skill, leadership in medical communications is not just for managers.² Revealing your leadership abilities shows clients that you can manage yourself and your workload. While your title may not be "Senior", "Lead" or "Principal" medical writer, you may still be given responsibility to manage the production of a new healthcare document – from start to finish. For example, these leadership skills include time management, problem solving, quality control, client/internal communications, and the mentoring of other writers. Although you may not consider yourself to be a born leader in medical communications, you can learn and develop these strengths over time.

Adaptability

In today's unpredictable biopharmaceutical healthcare communications landscape, adaptability is an essential soft skill that can allow you to stay ahead of the curve.⁶ This can be a valuable asset for you as a medical writer, if you're asked to meet the ever-changing demands of various projects, priorities, and clients – and still deliver quality output.⁶

Adaptability involves proactively leaving your comfort zone to learn new technologies, rather than waiting for them to be forced upon you. So as a medical writer, you could arrange to learn the basics of AI apps, like ChatGPT, and actively test this as part of your standard research and writing methods to see how it could expand your current abilities.

Problem solving

Recent results from a 2022 AMWA survey revealed that medical communicators need critical thinking as part of problem solving and

decision making – two other crucial soft skills.² Problem solving is a key way to identify and address complex challenges and opportunities in medical communications, where it is strongly tied to data analysis, creativity, and critical thinking.

For example, as a strategic medical writer, you'll need a critical eye to analyse challenging project briefs and to develop a plan to clearly present your content to specific industry audiences.

Emotional intelligence

Emotional intelligence – also known as emotional quotient (EQ) – is now recognised for its association to success in work and personal life, and overall well-being.⁷ As a human soft skill, EQ is your ability to understand and manage your own feelings, and empathise with others. Furthermore, professionals who control their emotions are able to take a step back, assess a situation and develop an effective plan of action. For example, in medical writing, EQ means taking criticism from reviewers on your latest draft, and calmly using this feedback to improve your next draft.

Innovation and creativity

In medical communications, creativity is typically linked with fields like art or design, but it is a broad term that involves several sub-skills, ranging from questioning to experimenting.

For medical writing, creativity also prompts you to focus on your other soft skills, such as critical thinking and problem solving. This helps you to develop unique, targeted solutions for new communications challenges you're faced with, as an independent consultant. Creativity also encourages you to collaborate with your colleagues to generate strategic ideas, concepts, and campaigns.

Collaboration and teamwork

Your ability to work well with a team is a vital soft skill, at all stages of your medical writing career. You'll need to work closely with various stakeholders, including account teams, creatives, clinical experts, and regulatory authorities. Having strong teamwork skills allows you to provide effective internal and external communications and deliver high-quality content to your team members.

As a vital soft skill,
leadership in
medical
communications
is not just for
managers.

Networking

By nature, you may be an introvert rather than extrovert, and are not keen on networking. However, as an important soft skill, networking is not just about meeting new people. It's also a chance to connect with colleagues, peers, and mentors that you know of, but haven't had the chance to personally interact with.

Expanding your medical communications network is critical at all your career stages. Although building connections with other professionals takes practice and effort, it becomes more manageable as your network grows. The following key actions can help you improve your networking skills:

- **Expand your connections:** Optimise your networking through the use of social media, virtual online meetings, and face-to-face conferences. Each of these sources can provide you with unique networking opportunities, and informal learning opportunities.
- **Join professional medical communications groups:** Another way to grow your networking skills is to join established medical communications organisations, such as the European Medical Writers Association (EMWA), the AMWA, and the global MedComms Networking community. In addition to membership benefits, these groups also offer you local chapters and national events where you can build valuable relationships, in person.

Conclusion: Refine your soft medical writing skills

Artificial intelligence is quickly emerging as a key "hard tool" in the healthcare communications industry, for efficient data research, analysis, and computation. However, durable, soft skills remain a uniquely human strength and hold significant value for medical writers and clients.

Formal training for medical writing rarely covers the development of soft skills. These soft skills tend to be personality traits that you develop from your own lifetime experiences. However, you can still learn and develop these capabilities to complement your hard skills. Refining your soft skills will help you build your medical writing career, create a network of meaningful connections, and achieve your personal growth.



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Soft skills tend to be personality traits that you develop from your own lifetime experiences.

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References

1. Runyon N. Why "power skills" is the new term for "soft skills" in the hybrid working world. Thomson Reuters. 2022 [cited 2024 March 29]. Available from: <https://www.thomsonreuters.com/en-us/posts/legal/power-skills-rebranding/>
2. American Medical Writers Association. Soft Skills. 2022 Insight Study [cited 2024 Mar 29]. Available from: https://info.amwa.org/medical-writing-a-professionals-guide-to-advancing-your-career#soft_skills
3. Parisis N. Medical writing in the era of artificial intelligence. *Med Writ*. 2019;28(4):4–9. Available from: <https://journal.emwa.org/artificial-intelligence-and-digital-health/medical-writing-in-the-era-of-artificial-intelligence/>
4. Shah H. Project management in medical writing. Poster. 2nd International Conference on Clinical Trials and Therapeutic Drug Monitoring. 2016 Aug 22–24, Philadelphia, USA. Available from: <https://www.longdom.org/proceedings/project-management-in-medical-writing-53909.html>
5. DeMajistre A. Soft skills needed for freelance medical writers. *Med Writ*. 2023;32(2):22–24. doi:10.56012/vxnk8628.
6. LinkedIn. 10 must-have medical writing skills. 2023 [cited 2024 March 29]. Available from: <https://www.linkedin.com/pulse/10-must-have-medical-writing-skills-emtex-life-science/>
7. Viezzer S. How Is emotional intelligence important in the workplace? *Simply Psychology*. 2023 [cited 2024 March 29]. Available from: <https://www.simplypsychology.org/emotional-intelligence-workplace.html>



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Unlocking the power of emotional intelligence in medical writers

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Abstract

Emotional intelligence (EI), the ability to recognise and understand emotions (one's own and those of other people), is a valuable attribute for medical writers (MWs). MWs play a pivotal role in communicating medical and scientific information to regulators, patients, caregivers, and healthcare professionals. EI helps MWs to understand the needs of the audience, develop effective communication skills, author impactful content, and collaborate efficiently with multiple stakeholders. It is thus essential for MWs to develop strong EI skills, i.e., be self-aware and self-motivated, be able to self-regulate, take ownership and responsibility for actions, be problem solvers, show empathy, foster healthy relationships, evaluate feedback positively, and implement balanced solutions. To enhance their EI, MWs can adopt EI-focussed training and development sessions at workplace, practice mindfulness daily, assess EI using multi-rater feedback scales, seek EI coaching, and set realistic goals.

Introduction

Emotional intelligence (EI) is the capability to identify and comprehend emotions (one's own and those of other people). The level of one's EI depends on how one treats oneself and others.¹ According to psychologists Peter Salovey and John Mayer, EI is a part of social intelligence. The term "EI" consists of two parts: emotions and intelligence.² Emotions relate to a person's feelings in relationships and intelligence refers to the ability to build inferences about something or about someone. EI also comprises four branches (see Table 1). EI empowers the mind, making us happy and content. Knowing the language of emotions helps us sustain strong personal and professional relationships.³

"Emotions drive people; people drive performance." This frequently quoted statement succinctly captures the effect that EI has on work. Daniel Goleman commented that 80% of our personal success can be attributed to our EI, and the remaining 20% to our intelligence quotient (IQ).⁴ Thus EI is a valuable attribute for medical writers (MW). (i.e., please just eliminate the part I have crossed out. It can significantly enhance their ability to communicate effectively, understand the needs of the audience, and

develop powerful leadership skills by working collaboratively.²

Characteristics of MWs with EI

Medical writing requires a fusion of scientific expertise and precise writing abilities, including creativity, adaptability, and meticulous attention to detail. MWs often work under tight deadlines, handle complex data analyses, adhere to diverse regulatory standards, and manage stakeholders' inputs. Having high EI can help MWs thrive in these challenging and dynamic situations. MWs with high EI are resilient, motivated, empathetic, social, emotionally aware, and have a strong ability to self-regulate with a clear and composed mindset. They are prepared to embrace failures or setbacks in pursuit of long-term success. These skills prove invaluable when dealing with demanding clients and stressful projects, allowing writers to effectively address challenges, leading to fewer conflicts, improved efficiency, and lower risk of burnout.⁵ The key components of EI skills in MWs are:

- **Self-motivation:** MWs with high EI are self-motivated and resilient. Self-motivation plays a key role in overcoming burnout, leading to enhanced efficiency and productivity.

Table 1. Four branches of emotional intelligence

| Branch of emotional intelligence | Definition |
|----------------------------------|--|
| Perceive emotions | The ability to recognise one's own emotions and the emotions of others based on verbal and non-verbal expressions |
| Express emotions | The ability to accurately convey or express an emotional state |
| Understand and analyse emotions | The ability to understand and process sequences of emotions, and the ability to transfer one emotion to another |
| Conscious regulation of emotions | The ability to regulate emotions (upregulating positive emotions and controlling negative ones) in self and others |

Abbreviations: EI: emotional intelligence

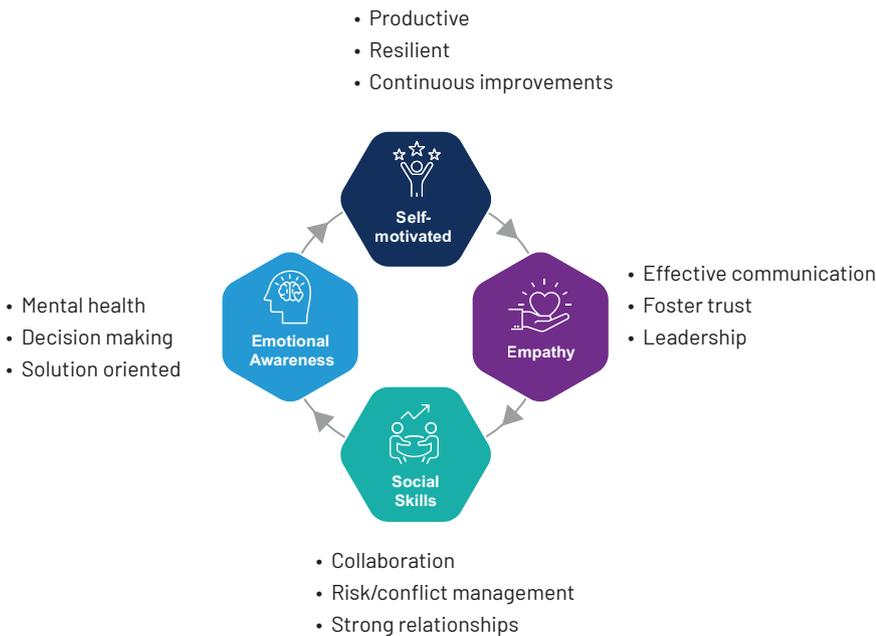


• **Empathy:** Being empathetic is crucial for MWs, both personally and professionally. The ability to perceive the sensory states of others enables MWs to establish emotionally favourable and adequate relationships with all stakeholders. Writers with EI understand what makes other people tick and hold profound respect for them. They are exquisitely

sensitive to the needs and perspectives of their readers. Rather than focusing on what they want to write, they figure out the best way to communicate what their audience wants to read. When MWs put themselves in the patient’s shoes, they can relate to the patient’s experiences and can adopt a more patient-centric approach to writing.

• **Social skills:** Medical writing requires a blend of interpersonal and social skills. It involves active listening and comprehending the clients’ expectations, managing fast-paced deliverables, navigating through project complexities and multiple revision cycles, collaborating with diverse teams, gracefully managing criticism at work, and ensuring that deadlines are met. Hence MWs, with their emotional understanding, can build meaningful relationships and affect positive outcomes.

• **Emotional awareness:** It indicates the extent to which MWs can understand themselves, recognise negative and positive feelings and emotions, and understand not only the cause of their occurrence but also the relationship between their own feelings and actions. MWs with high EI can keep themselves collected under stressful situations and wait for the right time and place to express their feelings appropriately.



Overall, MWs with high EI empathise with colleagues, clients, patients, friends, and family; identify the negative thoughts and emotions; express what they feel and, why they feel so; foster happy emotions; are open to creative thinking; focus on resolving conflicts through communication; and evaluate actions, behaviour, and relationships (Figure 1).

Figure 1. Leveraging emotional intelligence for success

Benefits of strong EI skills

EI can significantly impact the overall performance and productivity of MWs in the workplace. Strong EI skills contribute to improvements in numerous aspects, such as:

- **Technical skills:** MWs need to analyse extensive scientific information on different therapeutic areas and diseases. They are required to author correct scientific messages for diverse audiences, including patients. Increased awareness of the “emotional” needs of the audience helps MWs to develop varied content customised to the audience.
- **Teamwork:** Strong EI skills enhance communication, leading to effective collaboration with co-writers and different stakeholders in the projects. This boosts the morale of co-writers and helps in tapping the team’s professional capabilities.
- **Time management:** In the multifaceted domain of research, authoring documents is often the last task and writers are expected to deliver documents under compressed timelines. Collating inputs on content and getting the “buy-in” from all stakeholders can also be time-consuming. Thus, it is imperative to plan and define timelines. Managing one’s own time in a way that is considerate of others, avoiding procrastination, and embracing a daily routine also helps maintain a work-life balance.

- **Resilience:** Medical writing can be stressful, especially when dealing with multiple or varied clients, tight deadlines, and regulatory guidelines. High EI helps writers manage stress, respond well under pressure, and maintain focus. MWs with high EI take ownership and thrive in dynamic environments and circumstances.
- **Effective client relationships:** High EI helps MWs understand clients’ expectations and priorities, thus foster mutual trust and strong relationships.
- **Conflict management:** Difference in opinions and authoring styles are common during document development. Active listening, empathy, and negotiation skills help MWs drive open, constructive, and result-oriented discussions.
- **Handling feedback and improvement:** Writers with high EI confidently accept 360° feedback and maintain focus on solutions and improvements.
- **Continuous learning and growth:** MWs with high EI understand the ongoing self-improvement process, seek feedback, and continuously improve the skills needed to achieve personal and professional success.

Mindfulness is an inward-orienting, self-empowering practice that can improve writing engagement of MWs by reducing stress, enhancing creativity, and increasing focus.

Focussed approaches to enhance EI skills

A few strategies that MWs can incorporate in their daily routine to enhance EI skills are presented in Figure 2.

“Practicing mindfulness” as a path to EI

Mindfulness is an inward-orienting, self-empowering practice that can improve how MWs engage with the writing process by reducing stress, enhancing

creativity, and increasing focus. It is the practice of paying attention to the present moment with curiosity and openness. Proficient writing entails considering the point of view of the audience, not just that of the writer, and this requires mindfulness.⁶ An important starting point for MWs to develop EI through mindfulness is to simply learn to pause and evaluate what they have written, face their work in an honest and non-judgemental fashion by letting go of their attachments or biases, thus fostering a more productive writing process. Practicing mindful breathing techniques to reduce stress and enhance clarity promotes a more productive writing experience.

Using self or multi-rater feedback to build EI

Multi-rater feedback is a valuable tool for assessing EI in the workplace. Currently, several scales and tools to measure EI exist but many of these have not been empirically evaluated. O’Connor et al. (2019) provide an overview of the most credible measures, discussing their validity, reliability, and conceptual foundations. These assessments are instrumental in identifying areas for EI enhancement.⁷ These strategies, among others detailed in Table 2, are essential for MWs looking to improve their EI and, by extension, their professional capabilities and leadership skills.^{8,9}

Coaching for EI

In the quest for more efficient ways to ensure client success, EI is emerging as the new elixir for high performance while maintaining work-life balance. One-on-one coaching is a widely accepted approach to improve various aspects of EI. Progressive organisations emphasise the importance of EI training and use both external and internal coaching to boost employee performance.¹⁰ Coaching enables writers to



Figure 2. Implement a focussed approach to enhance your EI skills

Abbreviations: EI, emotional intelligence; SMART, specific, measurable, agreed or achievable, realistic or relevant, and time bound.

recognise EI's foundational elements, understand its role in personal development, identify effective tools for EI assessment, and employ proven techniques for EI improvement. This includes creating action plans to recognise stressors/triggers, establish positive behavioural patterns, and offer opportunities for practice. Moreover, coaching plays a crucial role in breaking cycles of unhealthy behaviour by fostering new perspectives for positive change, providing actionable strategies for immediate challenges, and encouraging accountability.

EI coaching empowers MWs to achieve their life goals by maintaining control over their emotions and promoting sustainable behavioural changes. Coaches guide MWs in making small, yet significant, adjustments that cultivate productive and positive relationships, enhancing overall performance. They encourage MWs to evaluate their EI levels and pursue individual coaching to advance their EI skills. The popular coaching models are the following:

- **"Goal Reality Options Will" (GROW) model:**¹⁰ Developed by coaching pioneer Sir John Whitmore, this model is akin to planning a journey. It employs a step-by-step approach to help individuals answer a pivotal question: "Where do you want to reach in life?"



- **Specific Measurable Agreed/Achievable Realistic/Relevant Time-bound (SMART) model:**¹² This model is traditionally used in business to emphasise tangible and measurable outcomes. It provides a structured method for setting and achieving goals.

Setting realistic goals

Today's environment of information overload and high work expectations makes it challenging for MWs to set clear professional goals. To assess their EI levels and identify areas of improvement, MWs can leverage the support of EI coaches.

Using models like GROW or SMART, MWs can define and achieve their professional aspirations within realistic timelines.

Conclusion

MWs possessing high EI are distinguished by their efficiency in communication, leadership, influence, and the ability to enact meaningful change. These individuals often become role models, inspiring colleagues, and contributing significantly to the enhancement of organisational culture. EI is clearly an important aspect of thriving in the workplace – it opens new

Table 2. Emotional intelligence measurement scales

| EI measurement scale | Characteristics |
|-----------------------|---|
| EQ-i 2.0 ⁸ | <ul style="list-style-type: none"> ● Self-rating assessment tool ● Reliable, valid, and widely used ● Administered by certified practitioner ● Tests 15 competencies grouped into five composites: self-perception, self-expression, interpersonal, decision making, and stress management |
| EQ 360 ⁹ | <ul style="list-style-type: none"> ● Multi-rater or 360° assessment ● Combines individual's perception of EI with the perceptions of managers, peers, and others for a complete evaluation ● Offers comprehensive assessment of feedback from multiple sources that provide valuable insight into one's personality and identify blind spots or areas for professional and personal growth |
| MSCEIT ⁹ | <p>Consists of 12 separate sub-tests that measure the following four branches of EI as per the Mayer-Salovey theory:</p> <ul style="list-style-type: none"> ● Perceiving emotions ● Facilitating thought ● Understanding emotions ● Managing emotions <p>It offers strategies for individuals to improve the way they communicate and connect to others.</p> |

Abbreviations: EI: emotional intelligence; EQ, emotional quotient; EQ-i, emotional quotient inventory; MSCEIT, Mayer-Salovey-Caruso Emotional intelligence Tests.

opportunities and lets MWs connect with others, fostering greater positivity and fulfilment. Leveraging EI, MWs can translate positive emotions into a more memorable experience for their clients and get loyalty as a result. Lastly, building EI skills is an ongoing journey. Thus, MWs are encouraged to consistently apply themselves in harnessing their inherent EI capabilities to achieve their professional objectives.

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References

1. Reshetnikov VA, Tvorogova ND, Hersonskiy II, et al. Leadership and emotional intelligence: Current trends in public health professionals training. *Front Public Health*. 2020;7:413. doi:10.3389/fpubh.2019.00413
2. Mayer JD, Salovey P, Caruso D. Models of emotional intelligence. In: Sternberg RJ, ed. *Handbook of Intelligence*. Cambridge University Press. 2000:396–420. doi:10.1017/CBO9780511807947.019
3. Chowdhury MR. How to improve emotional intelligence through training. *Positive Psychology*. 2020 [cited 2024 Feb 19]. Available from: <https://positivepsychology.com/emotional-intelligence-training/>
4. Goleman D. *Emotional intelligence*. 10th ed. New York: Bantam Dell; 1995.
5. Gray-Grant D. Why the best writers have the most emotional intelligence. 2017 [cited 2024 Feb 29]. Available from: <https://www.visualthesaurus.com/cm/2017/07/>
6. Parrish E. Why mindfulness is important for writers. 2024 [cited 2024 Feb 29]. Available from: <https://berriesandbarnacles.com/the-importance-of-mindfulness-in-writing/>
7. O'Connor PJ, Hill A, Kaya M, et al. The measurement of emotional intelligence: A critical review of the literature and recommendations for researchers and practitioners. *Front Psychol*. 2019;10:1116. doi: 10.3389/fpsyg.2019.01116
8. The Emotional Intelligence Training Company Inc. 2024 [cited 2024 Feb 29]. Available from: <https://www.eitrainingcompany.com/eq-i/>
9. Mayer JD, Salovey P, Caruso DR. *Mayer-Salovey-Caruso Emotional Intelligence Test (MSCEIT) user's manual*. Toronto: Multi-Health Systems; 2002.
10. Evercoach. The ultimate guide to emotional intelligence coaching. 2024 [cited 2024 Feb 29]. Available from: <https://www.evercoach.com/coaching-guides/emotional-intelligence-coaching/>
11. Leonard K, Watts R. The ultimate guide to S.M.A.R.T. Goals. 2022 [cited 2024 March 28]. Available from: <https://www.forbes.com/advisor/business/smart-goals/>



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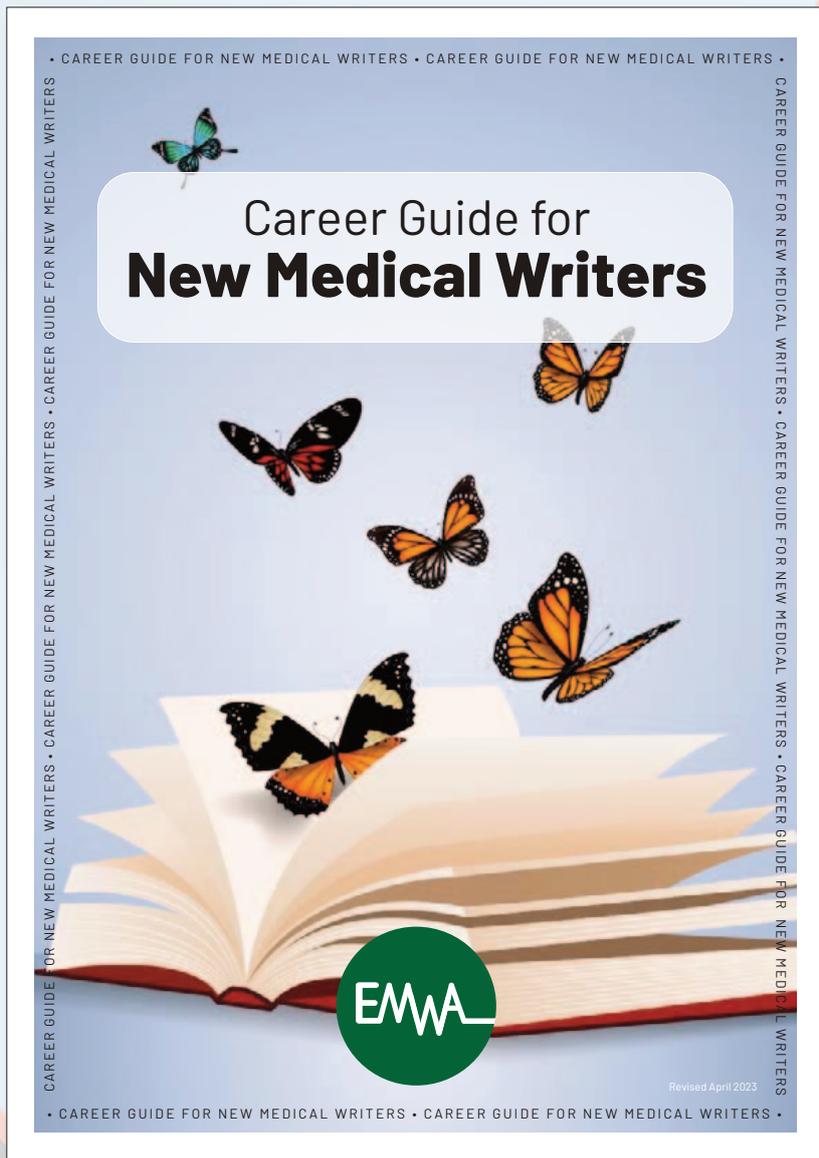
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Career Guide for New Medical Writers



EMWA's Getting into Medical Writing group has created an updated *Career Guide for New Medical Writers*, which is available on the EMWA website. If you're new to medical writing, it's a useful resource that will help you take your first steps on this rewarding career path. You can email us at gettingintoMW@emwa.org with comments.

The 3 C's of medical writing: Communication, conflict management, and critical thinking

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Abstract

Human-centred “soft” skills are becoming increasingly essential, especially in the current digital workspace. As medical writers navigate the intricate landscape of compliance and precision, they must fortify their soft skills with a foundation of emotional intelligence. In this article, we discuss the interplay of communication, conflict management, and critical thinking (the “3 C’s”) as the cornerstone to achieving success in medical writing.

For over a century, we have recognised that having well-developed soft and people skills account for most job success, whereas technical abilities and knowledge (hard skills) account for a minority.¹ More recent studies in 2015 and 2016 confirmed the importance of soft skills, with 93% of employees rating them as “very important” or “essential” and 97% considering them the key to business growth or success.^{2,3}

The rise of automation and artificial intelligence (AI) has further accelerated the demand for soft skills. According to a survey by the National Association of Colleges and Employers of 260 employers, communication is among the top three most sought-after skills.⁴ In another study by CPP Global, the publisher of the Myers-



Briggs Assessment, 85% of individual contributors and leaders reported experiencing inevitable conflict at work.⁵ Further, based on

McKinsey & Company briefing notes on AI, automation, and the future of work, critical thinking and complex information processing skills will grow in demand.⁶

In this article, we delve into the significance of the “3 C’s” of communication, conflict management, and critical thinking, and how these intertwine and mutually contribute to helping medical writers succeed (Figure 1).



Figure 1. The 3 C's

The 3 C's – communication, conflict management, and critical thinking

The significance of effective communication in medical writing

We medical writers often take on dual roles of project manager and writer; therefore, communication is a vital component of our responsibilities. This entails collaborating with cross-functional team members, participating in meetings and scientific discussions, providing

feedback and guidance to other team members, responding to queries and clarifications, analysing data, presenting key findings, and more. A LinkedIn article reported that 97% of employees feel that effective communication affects their task efficiency.⁷

Mastering effective communication empowers medical writers to efficiently collaborate and coordinate, successfully manage projects and stakeholders, objectively resolve conflicts, and adapt to dynamic requirements with ease. Effective communication is thoughtful, well-constructed, error-free, logical, complete, and consistent so that the audience receives the intended message. In challenging situations and during difficult conversations, it is essential to maintain a delicate and critical balance of being assertive without resorting to passive aggression or succumbing to pressure. In achieving this balance, effective communication must be coupled with critical thinking and conflict management.

A LinkedIn article reported that 97% of employees feel that effective communication affects their task efficiency.

The importance of conflict management in medical writing

Medical writers often encounter conflicts in the workplace. The CPP global study reported that 85% of employees dealt with conflict at work to some degree and 29% dealt with it frequently or always.⁵ This conflict may be related to, for example, differing opinions, timelines, document strategy and messaging, or understanding of guidelines. When conflicts are not resolved, they can negatively affect morale and cause resentment, frustration, stress, and reduced productivity. Therefore, conflict management is an essential soft skill to develop.

The key to resolving conflicts lies in the power of effective communication and the application of unbiased critical thinking. While resolving conflicts, we need to put our personal differences and preferences aside to make decisions that are

ultimately in the best interest of the readers.

When managed effectively, constructive conflicts provide opportunities for growth and learning, facilitate collaboration among co-workers, help maintain morale, prevent disruptions in productivity, and provide an environment to stay focused and engaged at work.

The CPP global study reported that 85% of employees dealt with conflict at work to some degree and 29% dealt with it frequently or always.

The nuances of critical thinking in medical writing

In today's fast-paced, competitive world, critical thinking has become essential for success in any career, including medical writing. A survey conducted by Reboot reported that 95% of respondents believe that critical thinking skills are vital in today's world and 85% think that these skills are lacking in people.⁸

Medical writers with strong critical thinking skills are equipped to question assumptions, challenge existing ideas, explore alternative possibilities, and see the big picture. By utilising critical



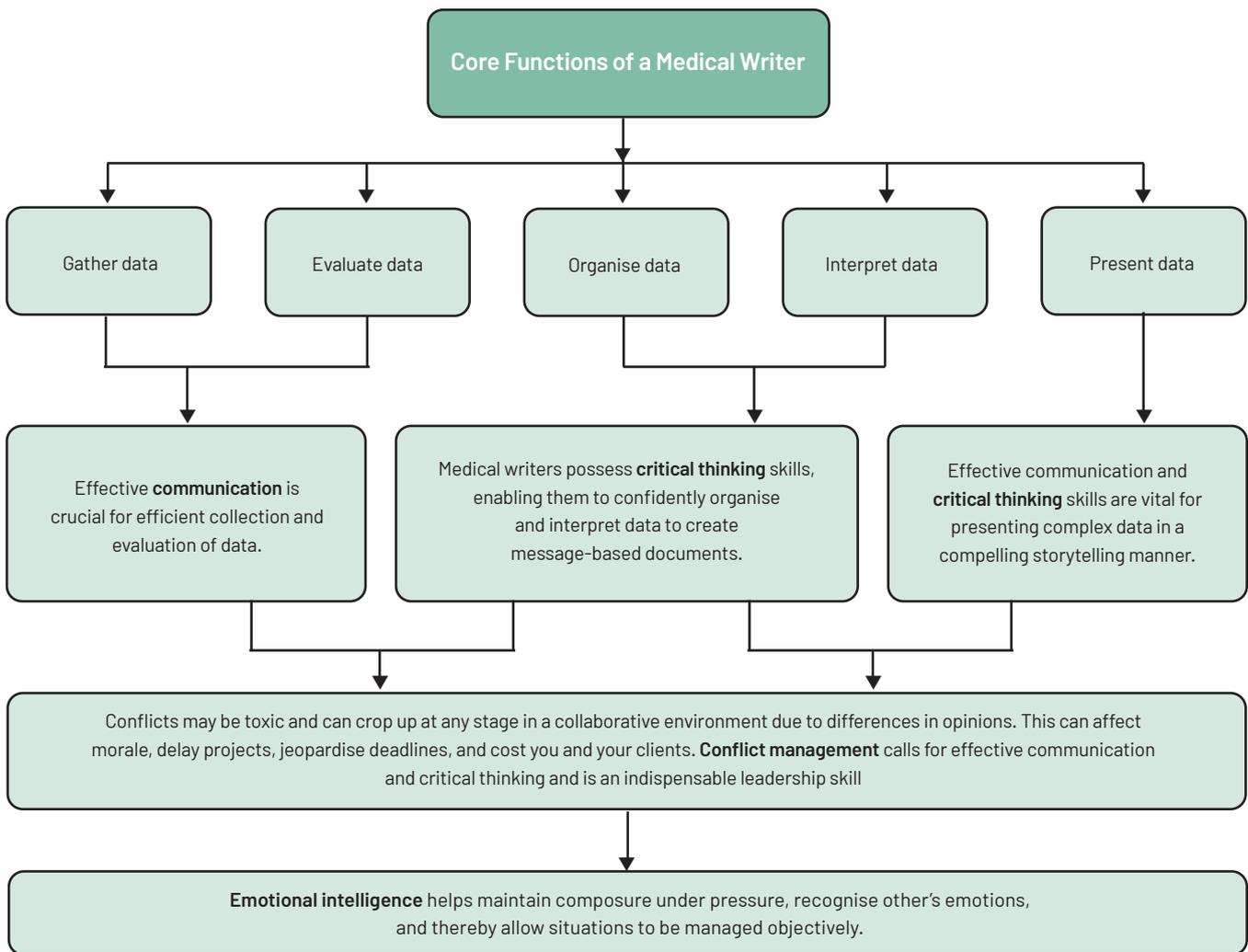


Figure 2. An example of applying the 3 C's

thinking, medical writers become empowered to arrive at innovative solutions and make well-grounded decisions. This is particularly crucial in the ever-evolving landscape and with the increasing complexity of scientific information, where medical writers must navigate challenges, maintain accuracy, and deliver high-quality documents.

Critical thinking is not innate, but it can be cultivated. Medical writers can nurture unbiased critical thinking skills through consistent practice, reflection, and exposure to diverse ideas and perspectives. Committing to continuous intellectual growth is essential for sharpening critical thinking abilities.⁹ By actively seeking out new knowledge, challenging assumptions, and engaging in critical analysis, medical writers can continuously refine and strengthen their critical thinking skills, leading to improved problem-

solving, more effective communication, and better decision-making.

The interplay of the 3 C's – a synergistic blend

The 3 C's are not standalone skills but rather are interdependent and complementary. Critical thinking enables clear communication, and effective communication is key to resolving conflicts. With strong critical thinking, medical writers can communicate their ideas effectively, provide constructive feedback, and take a systematic and analytical approach to conflict resolution. Communicating well in tough situations (even to say “no”) requires critically

A survey conducted by Reboot reported that 95% of respondents believe that critical thinking skills are vital in today's world and 85% think that these skills are lacking in people.

weighing implications and using sound logic to respond fairly and constructively.

While the interplay of the 3 C's is essential for successful outcomes, these should be fortified by a foundation of emotional intelligence. Emotional intelligence helps individuals understand and manage their own emotions and empathise and respond to the emotions of others. This awareness of emotions promotes open and honest discussion, forms the base for building professional trust, and augments the overall effectiveness of communication. Emotional intelligence also plays an important role in conflict management

by enhancing empathy, active listening, and the ability to see things from different perspectives. Further, it allows individuals to handle differences with sensitivity and to enable mutually favourable solutions. Emotional intelligence supplements critical thinking by providing awareness of how emotions influence decision-making. It is therefore the key to effective communication, conflict management, and critical thinking.

Medical writers apply the principles of the 3 C's consciously or unconsciously in their daily work (Figure 2). Therefore, honing these skills will not only help medical writers develop high-quality documents, but will also foster collaboration, engagement, and teamwork.

Concluding remarks

Regardless of whether you are a seasoned medical writer with years of experience or just embarking on this journey, honing the 3 C's of communication, critical thinking, and conflict management and fortifying these skills with emotional intelligence is not just an investment in your profession but also your personal growth and development. These skills can help us all become more insightful, empathetic, impactful, and simply better human beings.

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References

1. Mann CR. A Study of Engineering Education. Bulletin Number 11. The Carnegie Foundation for the Advancement of Teaching. Boston; The Merrymount Press; 1918.
2. Wonderlic. Hard facts about soft skills – An actionable review of employer perspectives, expectations and recommendations. 2016 [cited 2024 April 07]. Available from: <https://www.careereducationreview.net/2016/10/hard-facts-about-soft-skills/>
3. Kevin Murray & Co. Leadership Communication: Some hard facts about soft skills. 2015. Available from: <https://leadershipcommunication.co.uk/sharpen-soft-skills-will-make-inspiring-manager-boost-career/>.
4. Strauss V. The surprising thing Google learned about its employees – and what it means for today's students. The Washington Post. 2017 [cited 2024 April 07]. Available from: <https://www.washingtonpost.com/news/answer-sheet/wp/2017/12/20/the-surprising-thing-google-learned-about-its-employees-and-what-it-means-for-todays-students>.
5. Workplace conflict and how business can harness it to thrive. CPP Global Human Capital Report. 2008 [cited 2024 April 07]. Available from: <https://www.themyersbriggs.com/-/media/f39a8b7fb4fe4daface552d9f485c825.ashx>.
6. Manyika J, Sneider K. AI, automation, and the future of work: Ten things to solve for. McKinsey Global Institute executive briefing. 2018 [cited 2024 April 07]. Available from: <https://www.mckinsey.com/featured-insights/future-of-work/ai-automation-and-the-future-of-work-ten-things-to-solve-for>.
7. Statistics on why effective communication is important in the workplace. LinkedIn. 2020 [cited 2024 April 07]. Available from: <https://www.linkedin.com/pulse/statistics-why-effective-communication-important-/>
8. The state of critical thinking in 2020. The Reboot Foundation. Promoting and developing critical thinking tools and resources [cited 2024 April 07]. Available from: <https://reboot-foundation.org/the-state-of-critical-thinking-2020/>.
9. Alison. Critical thinking skills: why you need them and how to hone them. LinkedIn. 2023 [cited 2024 April 07]. Available from: <https://www.linkedin.com/pulse/critical-thinking-skills-why-you-need-them-how-hone-alison-learning/>.



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The soft skills gap for remote workers: Different perspectives

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Abstract

The COVID-19 pandemic has transformed the way we work, with many companies opting for fully remote or hybrid roles on a permanent basis. While remote working has many advantages, there are some soft skills that may deteriorate when working from home long-term. This article focuses on which soft skills are essential for medical writers and offers advice on how these soft skills can be improved. Four professionals from the medical writing industry contributed their insights on this topic: a freelance medical copywriter, a principal medical writer, and two mentors for medical writers.

Soft skills (also known as transferable skills, meta-skills, or generic skills) have always been an essential part of the work landscape. These are personal attributes that can make a job candidate stand out between two equally qualified candidates.¹ The COVID-19 pandemic has fundamentally shifted the way we work in a relatively short time, with many workers opting for full-time remote or hybrid roles.² But the advantages of remote work (no commute time, increased productivity, flexible working hours) have a downside: neglected soft skills, such as verbal and non-verbal communication, active listening, authenticity, and collaboration, among many others.

The phenomenon, often termed “the soft skills gap” or “soft skill decay,” is already the focus of social sciences departments and business schools around the world.^{3,4} The problems that

come from building and sustaining relationships in a dispersed workplace are leading to the surprising conclusion that soft skills may be even more important than hard skills.¹ As an example, a recent analysis of 12 million online job advertisements in Australia highlighted that advertisements for remote roles are more likely to mention interpersonal skills.⁵ The key findings of a report on educating the post-pandemic workforce stated that the top four soft skills that are currently in-demand are: problem-solving, time management, the ability to adapt to change, and leadership ability.² Some of these are similar or identical to key soft skills chosen by expert contributors to this article (*Figure 1*). Perfecting these skills in the home office may be challenging.

This article focuses on what soft skills mean to a freelance medical writer, a principal medical writer, and two mentors for medical writers, and how improving soft skills can make a difference in our work lives.

We all know there are many ways to communicate these days – email, video calls, WhatsApp, messaging apps – and each one demands a different blend of clarity and professionalism.



Figure 1. The key soft skills mentioned by this article's contributors



Freelance Medical Copywriter

Martyna Piotrowska

I think soft skill development is just as important as technical know-how. Sometimes soft skills may even be more so, especially when writing patient-facing materials. For example, there are certain tips on how to use inclusive language for patients, but in the end, we write for patients drawing from our own experience and instincts. In my view, the soft skills necessary to progress in your medical writing career are listening to others, being open to new ideas, and being flexible to change. If we want to work with others, we must rely on each other's experience and trust one another. Also, as we are facing the age of artificial intelligence (AI), adapting and learning new skills quickly will be crucial. Those of us with boundless curiosity will be the real winners.

In remote work, I have noticed it has become more difficult for me to speak to people over the phone or in person; I become irritated and just want to get back to my projects. On the other hand, working remotely means working online, and I honestly think I've progressed in skills such as time management and productivity (although I'm still working on it!).

As a freelancer, I think the hardest skill I've had to learn is managing my finances. This is a critical skill that causes a lot of stress, and unfortunately it is also a taboo topic, which makes it difficult to talk to someone who has more experience.

The soft skill I appreciate the most is the ability to focus completely on my work. I would find it really bothersome to be always available to colleagues while I'm working. I think it makes you lose focus and reduces productivity. When working on my own, I can decide my own priorities and devote myself to the task as long as I like, until I need a break.



Head of Medical Writing
Anonymous

Soft skills, such as communication, effective time management, teamwork, and flexibility, are essential for a medical writer. Authoring or maintaining various clinical, regulatory, and submission documents, e.g., clinical study protocols, clinical study reports, investigators’ brochures, and risk management plans, requires input from cross-functional teams (non-clinical, clinical, biostatistics, regulatory affairs, data management, etc.). It’s incredibly important to be able to communicate clearly and to formulate the right questions in order to receive the necessary input from other functional teams. Developing good working relationships with colleagues and wise time management are also essential.

For people who have just started their journey in medical writing and want to gain their first professional experience, working in the office is clearly beneficial, simply for better onboarding, mentoring, integration into the team, and learning about team dynamics.

The pandemic forced us to switch to home-based, remote working. This model has become very popular nowadays, with many medical writers currently preferring this option. Remote working provides more flexibility. Medical writers often emphasise that they can work more effectively from home, but they should try to keep a proper work-life balance. Indeed, remote working requires adaptation to technology-mediated communication, but does not negatively impact soft skills.

Before the pandemic, we were in the office every day. After over two years of remote working, we introduced a hybrid model, whereby the entire team comes into the office once a week. I think everybody benefits from this model. Although the team works remotely for the rest of the week, we have developed effective communication within the team, to keep a proper team dynamic – we have short briefing calls every morning, align on resources, etc. By using communication technology, we can interact successfully with each other, as well as with clients.



Medical Writing Mentor
Sarah Nelson
Green Pen Solutions

I believe soft skills are essential to succeed as a medical writer. This is why I included agency skills (which include soft skills) as one of my core 5 Pillars of Medical Writing (Figure 2).

Writers must become adept at managing the constant push/pull between producing high quality content and staying within budgeted hours; we are always working under time constraints. It is therefore essential to have good time management skills and techniques to ensure productivity. In this respect, working remotely can be advantageous, because writers can allocate “focus time” without the distractions of being in an office.

Another key soft skill is communication. Writers are good communicators, not only through our writing, but also in other forms of communications with team members and clients. We all know there are many ways to communicate these days – email, video calls, WhatsApp, messaging apps – and each one demands a different blend of clarity and professionalism.

I do not personally believe that remote working has robbed writers of soft skills. However, I am coming from the perspective of having worked in an agency for many years – I understand what’s going on in agency and client worlds, even though I am not physically there. It could be more challenging for junior writers who perhaps have only ever worked remotely and don’t understand the culture. As an example, I once mentored a junior agency writer who was in this situation and worked remotely. They did not understand the best way to work from home and would sit at their home desk for 8 hours a day, with no real breaks. There’s no way to remain productive for that long, and I am certain the senior management would not have expected this anyway. My mentoring helped the writer to adopt a better remote working approach and to set more realistic expectations.



Figure 2. The 5 pillars of medical writing

Courtesy of Sarah Nelson, PhD. © Green Pen Solutions, 2024.



MedComms Mentor
Eleanor Steele

Medical writers need a combination of soft skills beyond writing and scientific knowledge. Firstly, writers need to adopt a learning mindset; writing is a skill that must be honed over time, but medical writers also need to be open to new approaches for writing different types of content. This can be harder for remote workers who are less likely to be exposed to work by colleagues in other teams or work for other clients, than people who are in an office. This can lead to tunnel vision and makes it harder to spark connections or new ideas.

Also, as medical writers, it's important to develop a resilience to criticism. We often get feedback from a very broad range of stakeholders, and it isn't always polite! We have to detach ourselves from the way a comment is given to find the advice or learning point within it. I think this is harder for remote workers as feedback is more likely to be written, which can make it seem more blunt.

When working on our own, it is difficult to know when our work is good enough, and we can fall into the trap of striving for

perfection, which is rarely what the client is paying for. Sometimes we need a sounding-board to check whether our work is good enough, and it's harder to schedule a two-minute check in from home than when you're sitting next to someone you can ask.

My advice for remote workers:

- Think about all work and interactions as learning opportunities, not just tasks to tick off. Make notes at the end of a project about what worked well but also things you would do differently next time. Reflect on feedback and think about how it might apply to other projects or your writing in a broader sense.
- Make sure work doesn't take over your life! It can be harder to have boundaries between work and life if you work at home. Finding a way to separate your sense of worth from your work will help you take in feedback no matter how blunt it is. It also helps to have a work best friend who understands and who you can have a moan to when really annoying comments come along.
- Think about projects in terms of "must have" elements and "nice to have" elements. Do the "nice to have" elements if you have time and capacity but stick with "must have" if time is tight.

Upskilling soft skills for growth

Despite coming from different work backgrounds, all four contributors agree on the value of soft skills for remote medical writers. Unsurprisingly, communication – both verbal and non-verbal – is listed as a key soft skill, regardless of whether someone works in an office or remotely (Figure 1). A lack of communication skills, whether among team members or with clients, will inevitably lead to potentially serious setbacks. In remote work settings, when working via email or messenger apps, it is even preferable to *overcommunicate*, to ensure that communication is clear throughout the project.⁶

Time management and productivity were also indicated as essential in the medical writer's skillset by all of the contributors. Fortunately,

these are skills that can be perfected in the home office more easily than communication, especially with the consideration of setting work-life boundaries.

Interestingly, there is a shared view that junior medical writers benefit from working in an office by learning from more experienced team members, particularly if they have only started working during the pandemic and have never experienced an office-based role.

Not everyone wants to or can work in the office every day. For some, it is simply a matter of preference but, for others, with caregiver responsibilities or a disability, it is not, which

In remote work settings, when working via email or messenger apps, it is even preferable to *overcommunicate*.



makes remote medical writing all the more attractive. But great writing skills and medical knowledge are no longer enough to make employment a certainty (especially with AI getting better at these skills too). This is why it is increasingly important to note which soft skills

we may be deficient in and focus on how we can improve them, in the same way as we would approach long-neglected IT skills or a need to revise the principles of good clinical practice. An illustration of the enhanced status of soft skills is their renaming as "power skills" by the education technology company Udemy in 2022.⁷ Taking the time to perfect

these skills is sound advice for future-proofing a career in medical writing.



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References

1. Ferreira C, Robertson J, Pitt L. Business (un)usual: critical skills for the next normal. *Thunderbird Int Bus Rev.* 2023;65(1):39–47. doi:10.1002/tie.22276
2. Capranos D, Magda AJ. *Closing the skills gap 2023: Employer perspectives on educating the post-pandemic workforce.* Maitland (FL):Wiley Inc.; 2023.
3. Yang L, Holtz D, Jaffe S, et al. The effects of remote work on collaboration among information workers. *Nat Hum Behav.* 2022;6(1):43–54. doi:10.1038/s41562-021-01196-4
4. Melin JL, Correll SJ. Preventing soft skill decay among early-career women in STEM during COVID-19: Evidence from a longitudinal intervention. *Proc Natl Acad Sci USA.* 2022;119(32):e2123105119. doi: 10.1073/pnas.2123105119
5. Evans D, Mason C, Chen H, et al. Accelerated demand for interpersonal skills in the Australian post-pandemic labour market. *Nat Hum Behav.* 2024;8(1):32–42. doi: 10.1038/s41562-023-01788-2
6. Kuligowski K. Leadership tips for managing a (new) remote team. *Business.com.* 2023 [cited 2024 Feb 24]. Available from: <https://www.business.com/articles/leadership-tips-for-remote-teams/>
7. Runyon N. Why “power skills” is the new term for soft skills in the hybrid work world. *Thomson Reuters.* 2022 [cited 2024 Feb 24]. Available from: <https://www.thomsonreuters.com/en-us/posts/legal/power-skills-rebranding/>



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Connecting through screens: Navigating relationships with patients and advocacy groups in a digital world

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Abstract

As a Healthcare Publications Editor at Karger Publishers, I write, edit, and oversee the development of patient information resources in our *Fast Facts for Patients* series. Soft skills are vital in my role at Karger, where we are committed to collaborating with patients and patient groups for each information project. The challenge in my job lies in building and maintaining these relationships entirely online, as I work remotely.

I joined Karger in the spring of 2022 as a Healthcare Publications Editor. It was the job profile that attracted me, offering a healthy mix of the hard skills necessary for the role (developing, editing, and creating medical educational resources for a broad range of target audiences) and the soft skills of building and maintaining relationships with key opinion leader authors and other contributors. With my background in tertiary education and language teaching and a PhD investigating the lexical characteristics of patient information, the job seemed ideal. Karger is a Swiss company with teams in Basel, Switzerland; Freiburg, Germany; and across the UK. I live in southern Switzerland, at the opposite end of the country from Basel, and work entirely online.

Two years on, I'm still online and the job continues to suit me well. An increase in demand from sponsors has meant that I now dedicate most of my time to patient resources, while relationship building is done principally with

stakeholders who were not referred to in the original job description: patients and patient advocacy groups.

Online relationship building

Karger's *Fast Facts* series includes booklets, illustrated leaflets, and videos. Developing a booklet from start to finish takes around eight to ten months. Before writing begins, I will contact patient associations, set up meetings with them to discuss collaborating on the information project, and request their help in finding patients to take part in a focus group. The aim of the focus group is simple: to gain an insight into the experience of living with a disease and to understand what patients need from this information resource. Most patient associations have review boards, made up of people who have expressed their willingness to get involved in these kinds of projects and occasionally some patients in our focus groups know each other, having worked on similar projects previously. More often than not though, they do not know each other. If we are using a freelance medical writer for the booklet, they will also join the focus group. When patients agree to talk to us, they are also agreeing to review the booklet when it's written. Establishing this connection early on and having input into the content may well give the patients a greater sense of ownership and involvement in the booklet. I always have the impression that the patient reviews of the material are done with great care and consideration.

A new project means new relationships

Unlike most patient advocacy groups or associations, we don't focus on one medical area or condition, though a good many of our resources concern rare diseases where information can be scarce. That said, a recent project on urogenital

atrophy is an example of a surprisingly common condition that most people have never heard of. And because we write about many different diseases and conditions, we don't use a permanent board of patient reviewers or clinical advisors. Each new information project requires the building of new connections with patient groups and individual patients. This would be hard enough in the non-digital world, but relationship building from scratch can be challenging when done solely via Zoom.

When things don't go smoothly

Early last year, I worked with a patient advocacy group that seemed to view our collaboration as combat and as something that needed to be won at all costs. The project funder had introduced us to the group, but it nonetheless took a good many months and numerous meetings before they were ready to sign the agreement. I joined the project

at this point, anticipating smooth sailing, as is usually the case, but I was in for a shock. The first few meetings were entirely unproductive, the atmosphere tense and, at times, hostile. My attempts to present our working practices were shut down or dismissed as "not what we want". I left each meeting feeling demoralised. Two months passed, writing hadn't begun, and I was already behind schedule. What was going on?

A question of trust

For collaborations to work well, communication needs to be clear. Patient associations and patients need to understand what we are asking them to do, we need to

understand the extent of their involvement, and both parties need a record of what they have agreed to do. The essentials are put in black and white in the introductory email, with the details fleshed out in subsequent meetings. We finish with the signing of a simple agreement or in the case of patients, a consent document.

While it isn't appreciated or practised by everyone, chit-chat has a significant social function. It can break the ice, relax tension, improve emotion, and is critical in building, maintaining, and deepening relationships.

But, equally important for a successful relationship of any kind is trust. After reflecting on my meetings with the patient association described above, it became clear to me that this group didn't trust that we could deliver. Nor, as they let slip later, did they have much faith in the project sponsor. The association wanted the materials, but they had convinced themselves that what we would produce wouldn't be fit for purpose. At the next meeting, I enquired about previous experience with sponsor-funded healthcare resources. Sure enough, an unsatisfactory experience in the recent past with a different funder had left them feeling disrespected and misunderstood. This negative past experience was colouring our current interactions. Understanding what lay at the root of their negative attitude was the beginning of a far healthier working relationship.

Digitalisation and interpersonal interactions

Back in the day, if a healthcare information writer consulted with a patient association (and as surprising as it sounds, a good many didn't bother), they were likely to meet face-to-face, maybe over lunch, and small talk would have oiled the social wheels. In 2024, with back-to-back online meetings filling your day and leisurely lunches a dim and distant memory, keeping to schedule is paramount, leaving little time for small talk. My untrusting patient group and I had never engaged in small talk, and while

our meetings began on time, they also began on the defensive. I didn't know where these people were based, what their roles were, or what their relationship was to the health condition (it is quite common for some staff at patient advocacy groups to be patients). And they knew absolutely nothing about me. Needless to say, I began the following meeting by finding out a little more about the people in front of me.

While it isn't appreciated or practised by everyone (cultural differences seem to play a big part here), chit-chat has a significant social function. It can break the ice, relax tension, improve emotion, and is critical in building, maintaining, and deepening relationships. How colleagues choose to work is one thing, but without small talk, I suspect my collaborations, brief and intense as they are and conducted entirely online, would be markedly less successful.

Lessons learned

I now routinely begin my scheduled calls with a patient association at least five minutes ahead of schedule. When I'm meeting patients, I'll arrive 10 minutes early. Without fail, I'll be joined by someone immediately, often a person new to online focus groups and a little anxious. In these situations, small talk is magic, and we can begin

our meetings punctually – which in itself is another form of reassurance.

Establishing competence

Trust in the digital age is often established by reputation, online presence, and assurances in the form of reviews or accreditation. Being introduced by the sponsor of the project is also a great help as it can serve as a recommendation – though, as I had discovered, it isn't always guaranteed.

For patient healthcare resources, one form of accreditation is via the "PIF Tick" scheme. Run by the Patient Information Forum (PIF)¹ in the UK, the PIF Tick is confirmation that the recipient produces trusted healthcare information. Karger achieved accreditation for our *Fast Facts for Patients* in 2023. Fortunately, many UK-based patient associations have also been accredited by the PIF Tick, so no further explanation from me is needed. However, we often collaborate with patient associations from elsewhere in the world, in which case it falls to me to reassure them that we follow best practices in the production of healthcare resources, that our materials support health literacy, and that we know how to write patient-friendly plain language. And I am always ready to explain what this all means: surprising as it may seem, this knowledge is not universal,

Trust in the digital age is often established by reputation, online presence, and assurances in the form of reviews or accreditation.





even among patient resource producers and patient associations. My untrusting patient association knew they needed the materials written in patient-friendly language, but they were less confident about how to achieve this and had only a superficial understanding of readability and reading age. They were also unfamiliar with – and initially a little dismissive of – the PIF Tick, but a few links for further reading solved that problem.

Talking about what matters

While getting to know patients in our focus groups is the high point of each project for me, it is also moving and both emotionally and mentally tiring. I can only imagine how much more intense it can be for the participants.

Patient associations act as gatekeepers, and once the agreement has been signed and patients have been introduced to me, the hardest work has been done. Ahead of our focus group, patients will have signed a simple consent form, which makes clear not only what they are agreeing to do but also their rights to withdraw from the agreement ahead of publication. The patient has also indicated how they wish to receive their fee (at Karger, we compensate patients for their time) and have agreed or not for their names to be used in the booklet. I also send the

participants a list of possible questions and invite them to select a couple that they would like to speak on.

I firmly believe that people will talk about what matters to them when given the opportunity, and most meetings need no more than a couple of guiding questions before a natural conversation gets going, especially when small talk has kicked the whole thing off. Conducting focus groups as interviews seems to me to be contrary to the ethos of patient centricity.

Managing and listening

Other than showing support and asking follow-on questions, my role is to listen and manage the session. The hardest task is to make sure everyone gets a chance and that the naturally voluble don't prevent the less confident from speaking up. However, it is also the case that some people want to express themselves, and with this comes emotion. My years as a teacher help tremendously, though rarely did I witness the grief and sadness – and anger – that I sometimes do in patient focus groups. I once made the mistake of scheduling two patient focus groups in the same week – never again.

A humbling experience

It is a great privilege and very humbling to listen to people share their experiences of disease.

Some of the patients I have met have been very sick indeed, and I am in awe of the strength and the support they show each other. I am also struck by how very diverse their experiences of the same disease can be. I have no doubt that what they share with me changes the content of the resource, the way I write, and the tone I use. What motivates these patients to open up to a stranger online is the simple desire to improve the experience of sickness for other people. And as a healthcare content creator, it is my task to create a respectful, warm, and trusted environment so that these stories can be told.

Disclosures and conflicts of interest

The author is employed by Karger Publishers, which publishes the *Fast Facts for Patients* mentioned in this article.

Reference

1. Patient Information Forum. 2023 [cited 2023 Mar 21]. Available from: <https://pifonline.org.uk>



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Don't miss!

The September 2024 edition



Clinical trial transparency and disclosure

The clinical trial transparency and disclosure space continues to grow at pace. With the EU Clinical Trial Regulation being applicable since the 2022 launch of the Clinical Trials Information System comes increased requirements for public-facing documents. Provision of a summary of clinical trial results in lay language is also now mandatory in the EU. Challenges continue in balancing protection of personal data of trial participants with transparency, especially in the wake of the COVID-19 pandemic. All of these bring opportunities for medical writers to drive best practice in authoring clinical trial documents with disclosure in mind.

Guest Editors: Holly Hanson and Alison McIntosh
The deadline for feature articles has now passed.

Building resilience: Navigating challenges and thriving among the demands of regulatory writing

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Abstract

Regulatory writing is a demanding yet rewarding profession in which writers help pave the way for groundbreaking healthcare innovations that improve the lives of patients. However, as critical as our work is, regulatory writing is full of challenges that can feel insurmountable at times, even for the most experienced writers. Through real-life scenarios, we explore the transformative power of resilience, a trait critical in enabling regulatory writers to overcome adversity and obstacles we may face in our daily work. We look at strategies that can help regulatory writers cultivate resilience thus allowing us to thrive in the demands of regulatory writing.



Background

Picture this:

You are a dedicated regulatory writer, and as your day unfolds, your to-do list seems to expand endlessly. You are tasked with the intricate art of transforming complex scientific terminology into easily understandable prose, interpreting data accurately and transparently, and distilling it all into coherent key messages for your regulatory documents. Your responsibilities include meticulously navigating the ever-changing regulatory landscape and addressing a multitude of comments on your drafts – some helpful, others seemingly bewildering. On top of it all, you provide project management, clarify the roles and responsibilities in the document development process, and often unintentionally are a point of contact for your cross-functional team's general queries. All of this occurs while racing against the relentless ticking of the clock of your document deadline.

Does this scenario resonate with you? For those in the world of regulatory writing, this scenario is not hypothetical; it is a daily reality. We are the unsung heroes behind the scenes. We bridge complex data interpretation with compliance and global regulatory requirements, ensuring that every document meets stringent standards, paving the way for groundbreaking healthcare innovations to improve the lives of patients. But as indispensable as our work is, it comes with a set of challenges that can sometimes feel insurmountable. The journey of a regulatory writer is a constant push-and-pull between large volumes of data and tight schedules, demanding both technical precision and creative finesse. The question arises: “How do we not just survive but thrive in this demanding landscape?”

In this article, we will embark on a journey, exploring the vital role of resilience in the world of regulatory writing. We will delve into the common

obstacles regulatory writers face, examine the impact on our writing process and well-being, and equip ourselves with strategies to not only weather the storm, but emerge stronger and more resilient.

So, fellow regulatory writers, let's dive into the heart of the matter and discover how resilience can be our trusted companion on this challenging yet rewarding path.

Understanding the psychological journey through challenges faced by regulatory writers

When regulatory writers find themselves facing a barrage of challenges, they embark on a psychological journey that is all too human. This journey can be broken down into three distinct phases, each with its own emotional and cognitive characteristics.

Peaks of worry



Firstly, let's consider Kimberley, a junior regulatory writer who recently embarked on her career in the field. Kimberley finds herself in a challenging situation as she is tasked with creating her first comprehensive summary document. However, the reality of the job hits her hard when her document receives extensive feedback and revisions from various stakeholders, including senior experts in the field.

In this phase, Kimberley experiences what we commonly refer to as "peaks of worry." It is a situation that many of us in the regulatory writing profession can relate to. Initially, when confronted with a daunting challenge such as addressing numerous comments, some contradictory to each other and a number which provide no clear guidance on what changes should be made, individuals tend to reach these "peaks of worry." The mind races with anxiety, and it becomes tempting to either give in to the

overwhelming stress or to burden oneself with excessive worry when trying to progress the work to the next milestone. The weight of the situation can indeed feel insurmountable.

Philosophical contemplation



Meet John, an experienced regulatory writer, who planned a streamlined presentation of key data in his Clinical Overview for an upcoming submission. He convened a kick-off meeting where the team approved his proposal to refer to the pivotal Clinical Study Report (CSR) for additional data, emphasising the critical assessment of clinical data within his document. However, after the data readout, the team unexpectedly changed course, demanding inclusion of text, tables, and figures from the CSR in John's document, citing the need for their presence in the Clinical Overview. John now faces the challenge of persuading his team that his original presentation met regulatory requirements and effectively conveyed the necessary information. He warns that adding redundant data could dilute the document's key messages and potentially prompt requests for supplementary information.

In the face of these relentless challenges, John enters a phase we call "philosophical contemplation." This phase is not unique to John; it is part of the psychological journey many regulatory writers go through. During this period, John finds himself pondering what value he brings to a team who do not appear to take onboard his advice from years of experience in writing documents such as this.

Regulatory writers may often find themselves grappling with similar questions regarding the purpose and ultimate significance of their value and work in light of teams seemingly underestimating their advice.

Recovery and resilience



Lastly, let's turn our attention to Ananya, a seasoned veteran regulatory writer. One day, Ananya receives an urgent request to author a new business critical regulatory document with a tight deadline. To make matters more challenging, the strategy for the content has not been finalised and the team is spread thinly supporting other priority projects simultaneously, and thus are not yet engaged with Ananya. As the clock ticks, Ananya needs to get a draft written in time for the looming review, for which she expects to receive numerous revisions from the various stakeholders.

Ananya's predicament paints a vivid picture of the pressure regulatory writers often face. The sudden and unexpected request to produce a new unplanned document is a scenario that can disrupt even the most meticulously planned schedules. The lack of contribution from subject matter experts because they are spread too thinly across the various projects can add to the anxiety that regulatory writers feel when seeking to progress work to the next key milestone (such as getting a draft ready for an upcoming review).

Initially, when confronted with daunting challenges like no defined strategy, lack of team engagement, potentially complex content, and tight deadlines, it is easy for regulatory writers to become overwhelmed and to be unsure of how to move forward. However, after experiencing the initial "peaks of worry" and a short period of "philosophical contemplation", regulatory writers will enter the transformative phase of "recovery and resilience", the phase where the true essence of resilience shines through.

Resilience: a foundation for success

In the dynamic and demanding field of regulatory writing, success is not solely determined by one's technical prowess or knowledge of regulations.

While mastering the intricacies of the profession is undeniably essential, there is another crucial factor that sets exceptional regulatory writers apart – resilience.

What exactly does resilience mean in the context of regulatory writing?

At its core, resilience is the capacity to bounce back from adversity and adapt positively to challenging situations. In the world of regulatory writing, it is the unwavering resolve to maintain composure when faced with tight deadlines, complex content, managing team dynamics, evolving regulations, and the ever-present possibility of revisions, and many more scenarios that we as regulatory writers encounter daily. Resilience is an unseen force that manifests as the ability to remain focussed and steadfast amidst the storm of demands and uncertainties. It empowers writers to adapt swiftly to shifting requirements and situations while consistently delivering accurate and high-quality documents to their given deadline.

Practically, resilience equips regulatory writers such as Kimberley, John, and Ananya in the above scenarios, to approach difficulties with a problem-solving mindset. Rather than succumbing to worry or over-analysis, resilient writers compartmentalise tasks, leverage available resources, and engage in open communication with peers and stakeholders. They understand that they are not alone in their experiences and that collaboration can lead to innovative solutions.

Strategies to develop resilience in regulatory writing

Resilience is not an innate trait but a skill that can be nurtured through deliberate efforts. In the realm of regulatory writing, a profession characterised by high demands, uncompromising standards to meet stringent regulations, and substantial responsibilities, building resilience is not merely a choice; it is imperative. To assist empowering regulatory writers on their journey toward cultivating greater resilience, we offer a structured roadmap comprising practical steps and valuable resources.

Self-care practices

By nurturing your physical, emotional, and mental well-being, regulatory writers can cultivate resilience and fortify themselves against the rigors of the field, ensuring they remain adaptable, focussed, and capable of thriving amidst the challenges they face.



- **Setting boundaries and taking breaks:** Establish clear work boundaries and prioritise regular breaks away from your computer. When tackling tasks like addressing review comments, short breaks can help you refocus, provide clarity, and prevent misunderstandings. Learning to decline non-essential meetings/tasks also safeguards against burnout.
- **Digital detox:** Set aside dedicated time each day before bedtime to disconnect from electronic devices and screens. This break from technology can help reduce mental clutter and promote relaxation.
- **Mindfulness meditation:** Incorporate mindfulness meditation into your daily routine using apps like Headspace and Calm. These guided sessions can quiet a racing mind, reduce anxiety and rumination, and help you focus on the tasks ahead.
- **Gratitude practice:** Cultivate a sense of gratitude by taking time each day to acknowledge and appreciate the things you are thankful for. This practice can help shift your focus from challenges to positive aspects of your life, fostering resilience and a greater sense of well-being.

Mindset shift

In the fast-paced and demanding field of regulatory writing, the ability to embrace challenges is paramount to help regulatory writers grow and build resilience.

- **Prepare for the unexpected:** Instead of fixating on potential problems, create both a primary plan and backup plans. This approach ensures readiness to pivot if unforeseen challenges arise.
- **Break tasks down:** When faced with complex issues, divide them into smaller tasks for

easier resolution. This prevents procrastination and facilitates quicker problem-solving.

- **Embrace positivity:** Foster a constructive mindset by practicing positive self-talk and affirmations using tools like ThinkUp. This habit strengthens resilience and bolsters mental well-being.

Effective management techniques

By implementing targeted effective management strategies, regulatory writers can develop their resilience, optimise their performance, and thrive in the demanding and dynamic environment of regulatory writing.

- **Time management tools:** Utilise time management tools and techniques, such as the Pomodoro Technique or time tracking apps, to improve productivity and focus. These tools help you manage your time more effectively and avoid procrastination.
- **Time blocking:** Organise your workday into dedicated time blocks for different tasks, such as drafting, reviewing, and responding to comments. This helps prevent being overwhelmed and ensures focussed attention on each activity.
- **Priority setting:** Identify the most critical tasks and prioritise them based on deadlines and importance. Breaking down larger projects into smaller, manageable tasks can make them feel less daunting and more achievable. It is OK to say “no” to meetings/tasks that are non-essential and distract you from your priorities.
- **Task delegation:** Delegate non-essential tasks to team members or colleagues where possible to lighten your workload and free up time for high-priority responsibilities. Effective delegation requires trust and clear instructions.

- **Effective communication:** Maintain open and transparent communication with project teams and stakeholders to clarify expectations, address concerns, and prevent misunderstandings. Clear communication can reduce stress and improve collaboration.
- **Conflict resolution skills:** Approach conflicts with empathy and professionalism and actively listen to all views. This will help to understand the issue and may lead to a swifter resolution.

Learning from experiences, mistakes, and collaboration

By leveraging past encounters, refining approaches, and fostering collaborative endeavours, regulatory writers fortify their resilience, adaptability and problem-solving skills, essential elements in navigating the dynamic challenges of their profession.

- **Embrace lessons learned:** Utilise solutions that have proven effective in previous experiences, while remaining open to adapting and improving upon them for continuous enhancement.
- **Adaptability and continuous improvement:** Don't hesitate to modify strategies or solutions that did not yield optimal results previously, as resilience entails learning from mistakes and refining approaches.
- **Share best practices:** Facilitate knowledge sharing among team members by highlighting successful approaches and techniques, promoting a culture of continuous learning and improvement.
- **Cultivate transparency and collaboration:** Foster an environment of openness and teamwork within project teams, emphasising trust-building and effective communication.
- **Engage in collaborative problem-solving:** Actively involve your team members in problem-solving processes, leveraging diverse perspectives and expertise to find innovative solutions.

- **Understand team dynamics:** Draw upon past collaborations with team members to tailor your approach to future interactions, adapting to specific needs and preferences where possible.
- **Advocate for strategic content review:** Encourage reviewers to focus on strategic content evaluation rather than duplicating efforts on editorial aspects, fostering efficiency, effectiveness and improving the quality of the document. This will also reduce the "peaks of worry" that regulatory writers may experience when evaluating the (potentially numerous) review comments.

Continuous professional development, peer networking and mentorship

In the dynamic field of regulatory writing, where regulations and guidelines evolve, and expectations escalate, continuous professional development emerges as a vital tool for fostering resilience. By investing in ongoing learning and skill enhancement, regulatory writers bolster their capacity to thrive amidst uncertainty, ensuring they remain agile, competent, and resilient in the face of adversity.

- **Stay updated:** Continuous learning and staying informed about technology advancements (e.g., natural language generation [NLG], machine learning [ML], artificial intelligence [AI]) and guidelines are crucial for regulatory writers. Participate in webinars and workshops offered by professional organisations such as the EMWA to keep abreast of the latest developments in the field.
- **Online learning platforms:** Accessing courses on medical writing and related skills through platforms like LinkedIn Learning and Coursera can enhance your knowledge and expertise. These platforms offer a wide range of courses that you can complete at your own pace, allowing for continuous professional development.

- **Peer networks:** Engage with fellow regulatory writers externally through forums, discussion groups, and platforms like LinkedIn. Internally, collaborate with colleagues to exchange experiences and seek advice. It is essential to tap into the knowledge and experience of peers within or outside your organisation who have faced similar situations.
- **Mentorship programmes:** Seek mentorship opportunities within your organisation or industry to gain valuable insights from experienced professionals. Mentorship can provide guidance, support, and encouragement, helping you navigate challenges and develop professionally as a regulatory writer.

Conclusion

In conclusion, resilience is not a vague or intangible concept, it is the cornerstone of success in regulatory writing. While technical expertise is crucial, it is resilience that empowers writers to harness their skills effectively. By nurturing resilience, regulatory writers can not only survive but thrive in the ever-evolving world of regulatory documentation. It is a reminder that, in the face of overcoming what sometimes may feel like insurmountable obstacles or challenges, a resilient mindset is an opportunity for growth and the key to unlocking one's full potential and achieving lasting success in this demanding profession.

Disclaimers

The opinions expressed in this article are the authors' own and are not necessarily shared by their employers or EMWA.

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Managing protocol development with international teams:

Soft skill perspectives from a global team of protocol writers

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Abstract

Clinical trial protocol development forms part of the critical path for launching a trial, which means timelines are tight and progress must be fast and sustained throughout the protocol's development. In order to be successful, medical writers require well-developed soft skills to meet the needs of the trial team and to produce a high-quality protocol. We focus on five critical soft skills that are essential for medical writers working with international teams: critical thinking, leadership, communication, teamwork, and adaptability. Based on our experience as a global team of protocol subject matter experts from Asia-Pacific, Europe, India, South Africa, and the US, we also discuss soft skills that are important for working with team members across different regions.

Like many professions, it is important for medical writers to have both hard and soft skills to be successful.¹ There are too many soft skills that are integral to medical writing to cover in one article so we will focus on standout skills needed for protocol development. Notable skills that we consider fundamental for professional development as a medical writer (and therefore are not covered in more detail here) include *work ethic*, *creativity*, and *time management*. Certainly, having a reliable and disciplined work ethic is crucial. Similarly, creativity and time management are important and defining characteristics of medical writers, each applied in their own way to the document at hand.

For protocol development, we consider five soft skills (Figure 1) that stand out as critical to meet the needs of the trial team and to produce a high-quality protocol; we also recognise that soft skills are not one-size-fits-all and cultural elements must be considered when approaching a multinational trial team.

To set the scene, protocol development forms part of the critical path for launching a trial, which means timelines are tight and progress must be fast and sustained throughout the protocol's development. A further challenge for contract research organisation (CRO) medical writers is that there are often at least two teams involved – the “product team” (usually the client team representing the trial sponsor) and the “operational team” (internal CRO team comprised of various functional area members). Combined, this means that our starting point for protocol development is a document that needs fast development with a trial team that has not yet fully established collaborative bonds.

Skills across borders – which skills help to engage multicultural teams

Critical thinking

Critical thinking is a central tenet of medical writing; core critical thinking skills include interpretation, analysis, evaluation, inference, explanation, and self-regulation.² Like other document types, critical thinking for protocol development includes tangible skills such as analysing relationships between content and expressing information in a way that is understandable to a diverse audience of protocol readers. By contrast, intangible skills are related to people- and project-management and are important as medical writers need to constantly seek relevant and precise information at a time where details may be limited, as well as discuss and reach agreement on outstanding issues within the team.

How tangible and intangible skills come together will depend on the protocol setting. Where medical writers can particularly provide benefit is to critically interpret information in the context of the whole protocol and make sure that the team members agree. For example, imagine a scenario in which the trial objectives have changed and a team member has chosen to “copy-paste” legacy content from a prior protocol. Upon inspection, the legacy content is on the right subject but the reasoning behind it is in conflict with the current scope of the trial. In such circumstances, the medical writer must work with the relevant team members to understand what is needed and how they can harmonise the content to all team members' satisfaction. In order to achieve this, the writer needs to understand how the content is linked and who needs to be involved in reaching a consensus.

Leadership

In team-driven document development, leadership is a critical soft skill³ as it makes the difference between whether the team is steered towards completing the document on time vs. extended development time that absorbs significant effort from the team.

Leadership for a medical writer is a challenging skill as it requires the writer to establish a leadership role in an environment where there are already parallel formal leadership roles, such as project leaders or functional area leaders. For example, one common complication for protocols, in particular, is that document development often occurs in parallel to team formation, thus giving the medical writer two challenges in one – getting the team working together and developing the protocol. To overcome this, the medical writer must be able to coordinate input while simultaneously building trust with formal project leaders and key team members.

In our experience, leadership overlaps strongly with communication as initial engagement helps build trust in the team, confidence in approaching the task, and establishes communication lines. Once achieved, the medical writer needs to guide the team in identifying and



resolving obstacles so that progress momentum is maintained. Ultimately, these efforts coalesce into “managing expectations” – namely, if the reviewers are expecting a complete protocol at the first draft stage but are hesitant to provide

input or make decisions, the medical writer needs to communicate the risk of the team reviewing an incomplete protocol at Draft 1, thus risking additional review rounds and extending the development timelines.

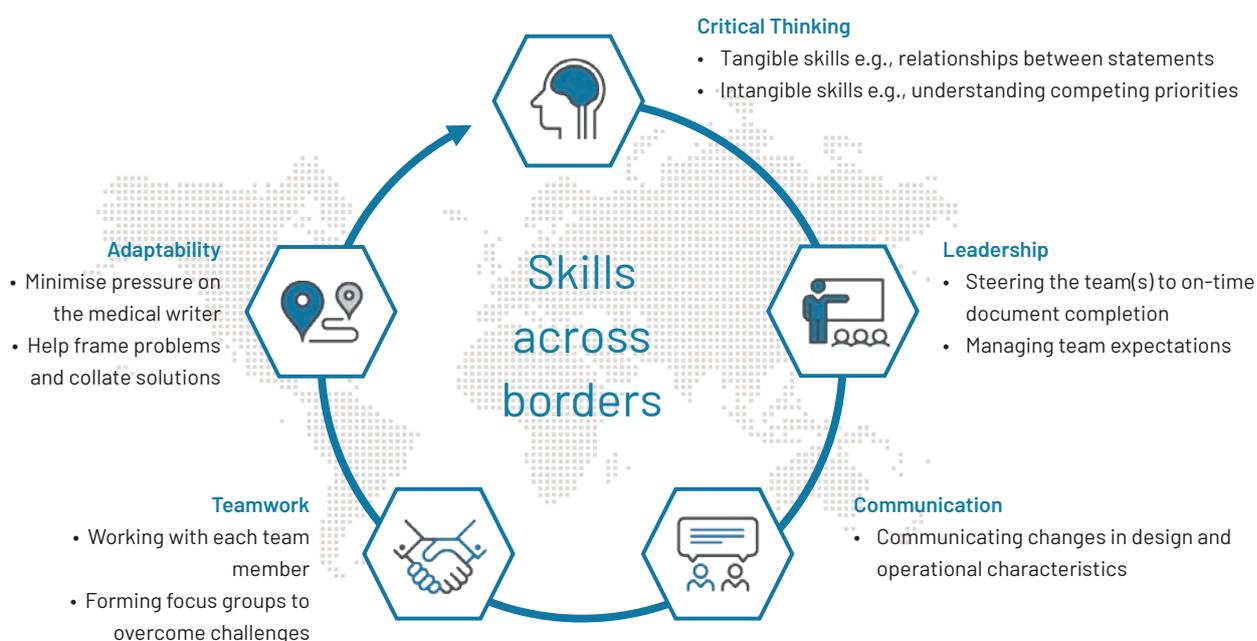


Figure 1: Essential soft skills for protocol development

Communication

Another hallmark of medical writing is strong communication skills,³ a competence that is often cited as critical for team satisfaction with the protocol development process. Building on the leadership soft skill above, managing expectations is a vital part of protocol development as the trial design matures and the team agrees on scientific and operating priorities. For example, it is not uncommon for teams to visit, and then revisit, key design and operational concepts. In extreme cases, entire designs can change during

the course of the protocol's development. Communicating these developments is key to avoiding misaligning expectations when it comes to the team's review. If done successfully, the medical writer can gain momentum with the team (e.g., flag in a timely manner that the draft cannot be completed without the required information, which will likely result in further downstream finalisation delays). If unsuccessful, the medical writer can damage their credibility in the eyes of the team members – further risking the timely completion of the protocol.

Teamwork

The number of team members required to be involved in protocol development continues to increase. New roles such as risk management, patient-reported outcome experts, patient representatives, diversity expertise, and data science join the well-established functional roles such as medical doctors, clinical operation leaders, biostatisticians, and data managers. Social interaction and awareness during development-related tasks such as demonstrating problem-solving or conflict resolution management in

Regional skills

Following our global skills above, some of the authors have provided perspectives on which skills they perceive as being important for the region they are based in. For those who are new to working with teams within these regions, taking note of some of these attributes may help you rapidly build trust and accelerate the start of your protocol development.

Asia-Pacific

Mati Kargren: Based on my experience working with clients in Asia-Pacific (APAC; e.g., Japan, mainland China, Hong Kong, Taiwan, Malaysia, or Singapore), *work ethic* is highly valued in the region. Asian colleagues and sponsors are particular about being on time. Optimally, when conducting a meeting with Asian colleagues or sponsors, you want to join the meeting a few minutes early to demonstrate that you are punctual and reliable. This is especially important when meeting sponsors for the first time, such as during a protocol kick off meeting.

On the contrary, even though you are expected to be punctual when interacting with Asian peers, you have to exert a greater degree of *flexibility* in terms of completing project work in the given timeframe. For example, when completing adjustments to country-level protocols (originating from global protocols), APAC clients more often than not expect you to put in extra hours to reach the deadline rather than extend the timelines.

Last but not least, clear *verbal and nonverbal communication*, and *cultural awareness* are important when facing APAC peers. Even though English is the modern-day lingua franca, not everyone has the same level of exposure or fluency in the language; accommodating for this through patience, repeating information to ensure correct understanding, and written

follow up can help ensure a productive working relationship.

Europe

Wiebke Griemberg: *Effective communication* plays an important role in Europe's diverse and multicultural work environment. Thinking ahead and understanding the needs of the team members, especially based on regional and cultural background, helps to drive good and effective communication. Not only in Europe, but generally in a global team setting, strong communication skills are particularly important to bridge cultural and language barriers.

However, the most significant soft skill is *adaptability*. Due to the diverse backgrounds in multicultural teams, adaptability is a great asset and enables you to navigate uncertainties, overcome setbacks, and effectively respond to evolving project requirements. Being open to new ideas and approaches, embracing change (e.g. from unexpected requests to timeline changes), recognising cultural awareness and sensitivities, or adjusting working styles to suit team members' needs all contribute to improved collaboration and engagement.

Gunnar Schilling: Working with a European client does not mean that all team members are located in Europe and even if they are from the same country, you can expect to encounter multicultural backgrounds from all over the

world. This European diversity has become more common over the past 25 years and at the same time has become less noticeable in the way we communicate, collaborate, and solve problems. In addition, there are certainly still country- and client-related differences in the way that people work and interact internally and with us as CRO medical writers, including the way they see us as an integral part of the team or more as contractors. It can be challenging to adapt our behaviour to the team's expectations right from the start of a protocol, but this is required if the protocol is to be completed successfully.

Anuradha Alahari: I agree that recognising cultural differences and *adapting* our working habits accordingly is important, especially in a service provider community like CROs. Medical writers should be cautious not to let the knowledge about a person's origin trigger stereotypical biases and prejudice. I try to avoid allowing my judgement to be clouded by such biases. To give an example of a cultural difference, after working in India and the US in academic fields, when I first started working in France as a medical writer, I used to be pleasantly surprised when people would thank me for what I considered was simply part of my job and sometimes just a minor task! Valuing each other's efforts and contributions helps team building.

relation to competing priorities or perspectives require strong teamwork skills.⁴ In our opinion, strong collaborative skills involve engaging each team member individually rather than coordinating activities through formal power structures led by project leaders. As team members work on multiple activities in parallel, it is often tempting to delay or attempt to defer decisions until a more opportune time – not necessarily considering the impact that this has on the overall protocol development timeline. Bringing together relevant team members

individually or in small focus groups to overcome challenges helps to make team work more dynamic and can further the protocol's development.

Adaptability

A key feature of protocol development is that it frequently brings unexpected challenges, thus requiring the medical writer to be adaptable to emerging situations.⁵ Being able to listen, understand issues, solve problems, and being resourceful when addressing challenges are ways the medical writer can demonstrate adaptability.

First and foremost, an adaptable mindset helps medical writers sustain a healthy working cadence, and secondly, helps diffuse the pressure and tension that can build up around project-related issues. For example, when a team gets stuck in decision loops with constant back-and-forth communication on outstanding items, trust in the team's perception of their ability to complete the task is eroded and introduces team fatigue. Medical writers who are confident in adapting to evolving situations can help teams stay on track by framing the challenge and collating solutions from collaborators.

Conclusions

In modern clinical trial protocol development, soft skills are an essential part of a medical writer's professional development. We consider *critical thinking*, *leadership*, *communication*, *teamwork*, and *adaptability* to be critical for modern protocol development. We also recognise that different regions have additional cultural values that enrich the collaborative task of protocol development. By highlighting some of the key skills we hope that this may help medical writers work with team members from the respective regions.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employer or EMWA.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

References

1. Lamri J, Lubart T. Reconciling hard skills and soft skills in a common framework: The generic skills component approach. *J Intell.* 2023;11(6):107. doi:10.3390/jintelligence11060107
2. Heard J, Scouler C, Duckworth D, et al. Critical thinking: Skill development framework. 2020 [cited 2024 Feb 23]. Australian Council for Educational Research. Available from: https://research.acer.edu.au/ar_misc/41
3. Oliver SK, Fergus CS, Skaff NK, et al. Strategies for effective collaborative manuscript development in interdisciplinary science teams. 2018. *Ecosphere* 9(4):e02206. doi:10.1002/ecs2.2206. Available from: <https://esajournals.onlinelibrary.wiley.com/doi/am-pdf/10.1002%2Fecs2.2206>

India

Kavita Muchandi: In my experience, *teamwork* and *adaptability* are two key soft skills in the context of authoring protocols for clients and teams in India. Protocol development timelines are generally short in this region, with the intent of speeding up the start of a trial. Many times, protocol development is expected to start based on available (and sometimes incomplete) sources, keeping placeholders for open items, and adjusting the content in light of new information or change in strategy. A medical writer's ability to collaborate with the team to obtain input and facilitate decision making to steer towards protocol timelines is important.

While *flexibility* is perceived as a positive attribute within the team, *problem-solving* helps medical writers to maintain composure under pressure. For medical writers from other regions who are to work with clients from India, cultural awareness is important. To avoid misunderstandings, it is advisable to summarise meeting decisions and action items in an email.

South Africa

Leo Daffue: South Africa has a rich history of multiculturalism, however, as a country we are not without challenges due to the many cultures, languages, and backgrounds of its citizens. South Africans as a whole need to be highly *adaptable* and *flexible*. There is rarely an answer of just "no", but rather one of "how we can make do with what we have at the moment" and then make a decision. We pride ourselves in the quality of our work, and to complete any task that is assigned. Using these traits can be extra beneficial in

almost any area of business, but especially when we are dealing with shifting timelines to name one example. As an extension of living in a multicultural country, South Africans are mostly sympathetic to how we interact with other cultures and people around the globe.

United States

Chris Matthews: US clients are typically native speakers of English, and misunderstandings, whether cultural or practical, are relatively uncommon when facing native English-speaking sponsors and colleagues. For protocol development, most communication is done via email, and US clients prefer emails that have an informal, friendly tone. For example, an email might start with "Hi" rather than an impersonal "Hello" or the very formal "Dear". For online meetings, chatting briefly with early attendees about personal topics (e.g. "How was your vacation?") or with the whole team (e.g. "Did everyone watch the Super Bowl?") demonstrates that you are interested in them, and fosters a sense of team togetherness. Whether in meetings or via email, it is important to pivot without too much delay to the outstanding issues in need of their help to be resolved.

A willingness to "go the extra mile" to complete drafts, including fulfilment of time-consuming last-minute requests, on time is expected among US clients. However, US clients recognise that you have obligations outside of work, and especially when unexpected and abstract issues arise close to a deadline, it is acceptable to let clients know that you may need more time to get them resolved.

- James TA. Teamwork as a core value in health care. 2021 [cited 2024 Feb 23]. Harvard Medical School. Available from: <https://postgraduateeducation.hms.harvard.edu/tr-ends-medicine/teamwork-core-value-health-care>
- Clevry. Adaptability soft skills: how to adapt to any situation at work. 2023 [cited 2024 Feb 23]. Available from: <https://www.clevry.com/en/blog/adaptability-soft-skills/>

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He works with clients across the globe and acts as medical writing subject matter expert for a partnership with a large multinational client.

Don't miss!

The December 2024 edition



Medical Writing Around the World

Medical writing transcends geography, demography, language, and culture. To date, EMWA has over 1400 members from 48 countries on 6 continents, and we want to celebrate the diversity and global presence of the medical writing community. In this issue, we will focus on medical writing activities around the world and will delve into topics like the benefits of having geographically diverse teams, translation and language-specific challenges, the landscape of global freelance medical writing, etc. We hope that these insights will assist the medical writing community in strengthening interactions and collaboration with teams and freelancers spread across the world.

Guest Editors: Asha Liju and Evguenia Alechine

The deadline for feature articles is September 1, 2024.

Mentors and mentees in medical writing: A very particular set of (soft) skills

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Abstract

Being a mentor or a mentee can be fulfilling and rewarding. In this article, we look at the role and relationship of mentors and mentees, and the importance of using soft skills within the mentor/mentee dynamic. Individually tailored and productive mentor and mentee sessions will furnish the mentee with enhanced soft skills to carry forward into their day-to-day work, which will, in turn, give rise to being a well-rounded and agile medical writer.

What is a mentor in the field of medical writing? We can consider them to be somebody specifically assigned on a one-to-one basis to guide and support a more junior writer. It is a role that goes beyond being somebody's "buddy" or person assigned to help with onboarding activities for somebody new to the role. The mentor would hold regular, pre-arranged meetings to talk through their mentee's work and activities, with the mentor providing guidance on the project work and more broadly on topics such as in-house company processes and how to handle meetings, communication, difficult situations, and tight timelines. Above and beyond this, the mentor will work holistically with their mentee, looking at their soft skills and how to enhance them via the mentoring process, to then apply them during their day-to-day work.

The mentor acts as a guide, rather than as an instructor or manager, encouraging open communication during the meetings between the mentor and mentee. A mentor needs strong soft skills because they need to listen actively and

understand the needs of their mentee, and adapt to these needs.

A mentee should feel comfortable in asking for any kind of support or guidance, irrespective of whether they think they should already know how to do it or are asking a "silly" question. Everybody has their skillset and knowledge, but nobody knows everything, so it's important for both the mentor and mentee to remember that.

Who can be a mentor?

Typically, a mentor would be in a senior role and have more work experience compared to their mentee. We might assume that a mentor would be from the same organisation as their mentee, but this doesn't have to be the case; it could be somebody in a writer's wider network – former colleagues, connections through the industry who know the role of a writer; even potentially somebody working in a different industry. Potential benefits of a mentor being outside the mentee's organization could be that the mentor has an outsider's view of the working environment of the mentee, which can reduce potential bias and provide a fresh perspective. Also, the mentee might feel more able, and comfortable with, opening up about any concerns or issues they may have, without feeling worried that their mentor may know of, or hold opinions about, anything (or anybody) raised. Particularly in the case of freelancers seeking a mentor, casting the net wide for potential matches would be key to finding a good candidate.

How to be a good mentor (and mentee)

The skillset of a mentor needs to be a combination of different abilities.

Apart from having a breadth of knowledge around what it is like to be a good medical writer, and how to do the job of writing a high-quality document (if indeed, the mentor is or has been a writer themselves), the softer skills are important too. A mentor needs to be

reliable – arranging, and sticking to a pattern of regular meetings, and, if taking away action items from those meetings, delivering them in a timely manner. The conversations with the mentee need to be pitched at the right level of formality – the meetings are not like those between a manager and their direct report, but not like a chat between two friends either. The mentee needs to be in a position where they find their mentor easy to talk to and approachable, without fear of saying the wrong thing, but still knowing that they will receive sound and useful guidance.

A good mentor should have the ability to truly interpret what the mentee is saying in order to identify their specific need(s). They should listen deeply – is the mentee in a situation where they have received negative feedback from a client on their document? The mentor needs to be able to get to the crux of the issue – the reasons for the client's feedback, the root cause, and what solutions are available for an improved next draft and restoration of the client's faith in the writer's capabilities.

Mentors need to carry a certain amount of confidence – with the mentee being less experienced and likely in a more junior role, they will consider their mentor to be somebody to look up to; someone who "knows their stuff". Subconsciously, the mentee may hold an expectation that their mentor is confident and self-assured enough to provide solid advice.

When a mentor speaks to their mentee with confidence, it instils encouragement and motivation within their mentee. This is another soft skill that arises from the mentor/ mentee relationship; that throughout the process, the mentee is learning the confidence and self-assurance to apply in their day-to-day role.

Remember though, that if you are mentoring somebody, don't only use examples from your personal experience and perspective to *tell* your mentee what to do. For one, your personal

The mentor will work holistically with their mentee, looking at their soft skills and how to enhance them.

The skillset of a mentor needs to be a combination of different abilities.



experience may not fit exactly with the guidance your mentee needs. Secondly, mentors should guide and encourage mentees to find *their own* path, rather than dictate what they think the next actions should be.

Mentoring (and being a mentee) has the potential to draw on so many soft skills – it should be a reciprocal relationship with both participants showing trust, respect, and willingness to listen and learn.

Resources

Mentors should direct mentees towards resources to help them with their work – information sources, software packages, etc. However, they should think more broadly too – what if a “resource” could be a person? A mentee could have a question or requirement which somebody other than their mentor is best suited to address. A good mentor provides the mentee with the ability and

confidence to reach out to others for further guidance. When a mentor and mentee work for the same organisation, it would serve the mentor well to have a good understanding of the resources available within the organisation – broadly, the expertise available across the different departments that the mentee might need to work with, company-wide information sources or platforms/applications, and whether company policy or guidelines exist to support their mentee’s need.

It should be a reciprocal relationship with both participants showing trust, respect, and willingness to listen and learn.

What about line managers and peers?

When might a line manager become involved, in addition to the support provided by a mentor? It is likely that a writer is in regular contact with

The mentee is learning the confidence and self-assurance to apply in their day-to-day role.

their line manager, but the function of a line manager is different from the support the mentee receives from their mentor. The mentee could arrive at a situation where discussions with their mentor are covering particularly difficult scenarios with a project or a client, in which case the mentee’s line manager is better-placed to give more structured and process-driven instructions on how to move forward.

When might mentorship assume a different form? So far, we’ve looked at a more senior writer being assigned the role of mentor, outside of the role of being somebody’s line manager, and unrelated to any one specific project or task. However, there may be an experienced writer leading a team of other writers in the production of a large document or set of documents for the same project or client. Here, the writer leading that work is also leading the writers who are supporting the delivery of the document(s), and the soft skills needed for mentorship as discussed



above also come into play. Beyond the fundamentals of leading a group of writers on a shared task (e.g., providing the templates, sources, timelines, etc.), the lead writer needs to consider that the team supporting the collective effort will likely vary in experience, be it in terms of years in the role, or whether or not the writers have experience in writing the document to which they are assigned. Further to that, the lead writer should remember that each individual writer has their own situation and personality traits – does the lead writer need to adapt to having writers spanning time zones? Do the writers prefer to receive continuous support and guidance, or do they prefer to take the instruction and work independently? The opportunity is there for the lead writer to draw on their own soft skills – being aware of others’ needs, listening and responding to their requirements as the work progresses, and adapting to changes in the team’s requirements when necessary. The more cognisant the lead writer is about the personality traits of the writers, the better. Some writers may be much more inclined than others to shoulder the burden of the work, while others assume a less involved approach. There could be writers in the team who are much more prone to feeling stressed under pressure than others – lead writers being in tune with these differences helps the work run more smoothly.

Well-rounded writers

With the passing of time, the relationship between the mentor and mentee should become solid and symbiotic, with both parties refining

their soft skills during the mentoring process.

The evolution of their soft skills will be transferable to the day-to-day work of the mentor *and* mentee, making each person better at what they do. A writer who has strong soft skills becomes well-rounded and better at working with others – clients, colleagues, and other professionals. The mentee (and mentor) will elucidate a stronger sense of self-awareness, and this will enhance many aspects of their work – if we understand ourselves, we understand others.

Perhaps you haven’t considered yourself to have been a mentor so far in your career, but if you have guided a team of writers in the authoring of a set of deliverables as described above, you may have acted in a similar way to a mentor. The skills you learned in that situation might have developed and refined your ability to become a mentor outside of leading a project.

Consider seeking opportunities to mentor somebody or become a mentee yourself – it will

benefit you by building on your soft skills and perspectives. Mentorship is a rewarding and fulfilling role that enhances your capabilities and will be an asset to a writer’s skillset. I recommend giving it a shot!

The relationship between the mentor and mentee should become solid and symbiotic.

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Disclaimers

The opinions expressed in this article are the author’s own and not necessarily shared by her employer or EMWA.

Disclosures and conflicts of interest

The author declares no conflicts of interest.



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A new EMWA section

The new specialised AI section in EMWA's journal *Medical Writing* aims to address the distinctive challenges and opportunities in the field of medical writing in the "AI century". This section seeks to empower both regulatory medical writing professionals and those in medical communications by aiding in the navigation of AI-based tools. It will explore regulatory frameworks, guidelines, and best practices, covering crucial topics such as risk assessment, validation, data privacy, and transparency.

Aligned with the objectives of the EMWA AI working group, integration of AI into the journal is intended to streamline the communication of accurate information about AI-driven healthcare technologies. Medical writers are encouraged to delve into discussions on AI applications, detailing their benefits, risks, and limitations to bridge knowledge gaps. Furthermore, inclusion of an AI section in EMWA is designed to promote collaboration and knowledge sharing among our readers.

Our dedicated AI section strives to equip medical writers with the knowledge and guidance necessary to responsibly navigate AI complexities, advancing the integration of AI into the medical writing field.

Artificial Intelligence

Please forward topic suggestions to Daniela Kamir at Daniela.kamir@bioforumgroup.com.

The balancing act: Leading creative teams for clear, accurate science communication

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Abstract

Leading a team is inherently complex, requiring managers to juggle diverse organisational goals, meet superiors' expectations, and cater to individual team member needs. The challenge intensifies when leading creative teams in a scientific environment. Here, bridging the apparent work-culture gap between scientific and communications disciplines is key. Leaders must ensure scientific accuracy while crafting communication that resonates with the target audience.

This article dives into the specific challenges faced by medical writers and other science communication teams: achieving clear, engaging communication without compromising scientific precision. It explores the complexities of leading such creative teams within a rigorous scientific environment. Effective leadership extends beyond mere results; it cultivates a team culture that both unleashes creative potential and prioritises meticulous fact-checking. The article presents strategies for fostering a high-performing team and addresses the perceived tension between scientific rigor and audience-friendly communication.

Introduction

Arguably, the best result in a professional setting emerges when the person doing the work can perform at the top of their ability. And since several brains contain more competence between them than one, a team of people have greater potential to achieve good results than a single person (if, that is, they can get along).

Effective leadership unlocks this potential. It empowers individuals to perform at their peak while fostering a collaborative spirit within the team. To maintain this high performance over time, a healthy team dynamic is essential, ensuring contentment and motivation among its members.

Achieving this requires fine-tuning one's leadership to each employee, in the current context, and as a part of the current team. This is a task that's daunting enough to any manager but doing it in a creative team while processing highly complex subject matters adds a few layers of considerations.

This article explores the intricacies of leadership within science communication teams. It argues that effective leadership is less about achieving results and more about *how* they are achieved, and emphasises fostering a team environment that enables creativity and high performance.

The myth of the good vs. the bad boss

Before delving into what it takes to be an efficient manager of a creative team in a science-focused workplace, let's first look at what can be said about good leadership in general.

While employees will be highly affected by the boss' leadership style, team managers themselves are generally assessed by their own superiors in the C-suite – i.e., the highest-ranking “chief” positions in a company – based primarily on results. Sadly, often too little attention is paid to how those results are achieved.

A team that enjoys a high degree of psychological safety, that has well functioning

work processes, where failure is accepted and success celebrated, will likely produce good results and be at the forefront of innovation.¹ But so may – at least for a period of time – a team led with an authoritarian leadership style, where individuals are more prone to experience burn-out. An annual review may show the same quality of result for these two teams. It can take years before signs of destructive leadership become apparent from the outside, when the number of sick days, staff turnover, incidents reported to HR, and so on, reach a level that can be considered statistically relevant.

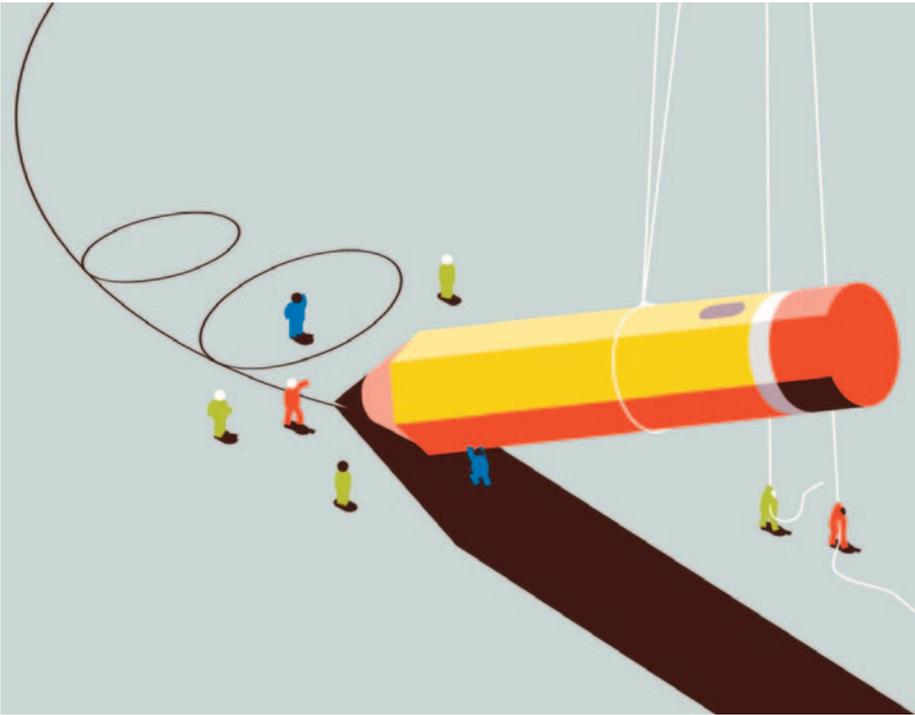
The C-suite would do well to keep a closer eye on the quality of the internal leadership, however. Bad management doesn't just sour the workday for employees, it has real and tangible repercussions for an organisation's bottom line, too. A UK study² done by the Chartered Management Institute and YouGov in late 2023 showed that managers have a deep impact on employee satisfaction, motivational levels, and likelihood of switching jobs. The study found that one in three people (both managers and workers) have left jobs because of a negative work culture. Among those respondents who reported that they had ineffective bosses, 50% planned to quit within the year.

On the other hand, soft, social skills work wonders. The consulting firm EY ran a survey on the correlation between authentic empathy and business success in the US. The results showed that 85–88% of the respondents felt that mutual empathy between business leaders and employees leads to increased efficiency, job satisfaction, creativity, idea sharing, and innovation.³

Conflating superficial traits with real leadership competence

Unfortunately, there are ample examples of ineffective bosses. Part of the explanation is that leading people is inherently difficult, and there is no such thing as a natural born leader.

Effective leadership is less about achieving results and more about *how* they are achieved.



Another factor to consider is the tendency for certain personality types to gravitate towards leadership roles, and many who seek power are not the most pleasant kind of leader to report to. For example, research published in *The Leadership Quarterly* shows a positive correlation between narcissistic tendencies and career advancement.⁴

And further, selection bias can play a role. Boards and hiring managers may prioritise stereotypical leadership traits such as confidence, charisma, certain physical traits, gender, and so on. Focusing too much on superficial attributes leads to overlooking qualified individuals with more quantifiable leadership strengths. Research⁵ by the psychologist and writer Dr Tomas Chamorro-Prezumic supports this notion, highlighting the importance of focusing on skills and experience over subjective characteristics.

It is, however, important to distinguish between ineffective management and malicious intent. Research shows that passive leadership, characterised by a lack of engagement and clear direction, can be more destructive than intentional manipulation. Most “bad managers” are just regular, well-meaning people who miss the mark because they lack the necessary skills or resources to fully support their teams. This often manifests as unclear roles in the team, muddled priorities, and vague instructions, ultimately

creating an environment of stress, conflict, and inefficiency in the team.⁶

Given the many various pressures leaders face – organisational goals, expectations from superiors, and the widely different needs of individual team members – perhaps it’s no wonder that most bosses will fall into passive leadership from time to time.

Becoming a better manager

The good news is that passive or otherwise destructive leadership doesn’t have to be the norm. People in leadership positions have every opportunity to set another standard, whether it is as a staff manager striving to be a better boss to their team, or as a C-suite executive taking care to hire managers based on real leadership skill rather than superficial attributes.

Becoming a good boss – or at least a better boss – is a commitment that requires self-reflection, competence development, and an honest and regular assessment of your own and your team’s progress. Below are some factors to take into consideration when you embark on this journey.

- **You’re probably not a good manager (yet).** The first step to recovery is to admit that you have a problem, as the old adage goes. In this context, it means acknowledging that you’re

unlikely as good a manager as you think you are. Throw out any false notion of what a “born leader” or a “good leader” is. You may have confidence for miles, but if you’re not able to listen to and understand your team members’ needs, you’re not there yet. You may be well liked, but if you can’t provide clear instructions and set expectations, you’re not there yet. Take stock of your strengths as a manager and be honest about your shortcomings. Your mission is now to start improving your leadership in the areas where you are most weak.

- **Focus on what your employees need.** Are you present enough where you’re needed? Consider if you’re giving your employees the tools and support they need to perform at the top of their ability. Maybe they need active coaching, or it can be a matter of setting the right priorities and clear goals to work towards. Pay extra attention when changes occur, for example new team members joining or new projects starting. These are the times when even high-performing employees, who have so far been working effectively on their own, may stumble and need help to find the new direction.
- **All good leaders are a work in progress.** You’ll never reach a point when you’re too competent, so make your own continued development a priority. If you have access to formal leadership training, make the most of the opportunity. Additionally, set time aside periodically to analyse your own and the team’s performance and progress. By gaining insights into what’s working well and what’s not, and what has improved, stagnated, or deteriorated, you’re able to course-correct and continue developing your own leadership as well as your team.

Leading creative teams in a scientific environment

While leadership in all forms is a balancing act between many demands, leading creative teams comes with its own particular prerequisites. The phrase “creative team” here refers to the many professions that meet and blend in the communications sphere, such as writers, designers, photographers, video- or audio producers, digital channel specialists, brand experts, marketers, and so on.

Winners of the Geoff Hall Scholarship Essay Competition

Dear all,

The Geoff Hall Scholarships (GHSs) are given in honour of a former President of EMWA. Geoff was a very special person, an extremely valued member of EMWA, and a very good friend to many EMWA members. He firmly believed that the future of EMWA lies in our new and potential members, and so it's a very fitting legacy that we have the Scholarship Awards in his memory. The scholarships are awarded annually on the basis of an essay competition, and the title of this year's essay was "Can scientific documents be easy to read?". The committee has the ability to award up to two scholarships each year. This year those scholarships were awarded to Louisa Ludwig-Begall and Florencia Garro.

Louisa Ludwig-Begall holds a PhD in Veterinary Sciences from the University of Liège, Belgium. To pursue her passion for crafting

FOR CORRESPONDENCE



Lisa Chamberlain James
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clear and compelling research stories, she joined Evidera as a publications writer in October 2023. Her first EMWA conference was the 2023 Spring Conference in Prague, and since then she has joined the Sustainability SIG.

Florencia Garro is a biomedical engineer focused on non-invasive brain-computer interfaces. She recently earned a PhD in Bioengineering from the Italian Institute of Technology, where she currently works on neuromechanical biomarkers for neurorehabilitation. Previously, she worked for 5 years as an R&D engineer in implantable medical device development, as well as a freelance technical consultant. One of her passions lies in blending

engineering and design with compelling storytelling and science communication. She is also a committed advocate for accessible science. She loves teaching, mentoring, and fostering open discussions. When not immersed in brain pursuits, she can usually be found running outdoors, immersed in indie rock beats, or lost in the world of Borges' stories.

Louisa's and Florencia's winning essays are presented below, and we wish them the very best at the start of their very promising medical writing careers. For those of you inspired to pick up your laptop, next year's essay title is "What value does medical writing bring to the study team?". (Next year's deadline for essays is September 30, 2024.)

I hope to read your essays soon, and stay safe all, until we see each other at the next EMWA conference.

Bestest,
Lisa

Can scientific documents be easy to read?

Introduction

*"There are thousands to tell you it cannot be done,
There are thousands to prophesy failure,
There are thousands to point out to you one by one,
The dangers that wait to assail you."*

– Edgar Albert Guest¹

An unfortunate (and unfortunately common) misconception is that scientific documents are perforce as dull as ditchwater and similarly impenetrable.

Scientific documents often report on dauntingly specialised topics, but these are not dull – they are scintillating science, transformative technology, and multifaceted, life-changing medicine! Such information should not be hard to access.² I posit that scientific documents not only *can* be easy to read but *must* be.

There are documents out there with muddied waters: wordy wells from which wisdom is but laboriously drawn and stilted streams that must be painstakingly panned in search of knowledge. There are, however, also crystal-clear scientific documents to delight wearied readers.

It comes down to this: scientific documents can be easy to read if a few simple rules are followed.

Rules for readability

Easy-peasy?

Easy may mean many things to many people. Equally, the term "scientific document" covers a multitude of scripts; a list of different document



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types transcends the bounds of this piece (for further details on medical document types please refer to EMWA's excellent *Career Guide for New Medical Writers*).³

Many people and many documents must be carefully paired. To do so, the writer must be fully aware of the audience's subject-specific literacy. For example, a research paper detailing the

intricacies of molecular norovirus evolution is probably easily understood by subject matter experts (molecular virologists), somewhat less by biomedical undergrads, and not at all by friends and family of the author(s) (I write from bitter experience).

An easy-to-read scientific document is tailor-made for its readership and avoids talking down to readers. A maxim to keep in mind here is Albert Einstein's "Everything should be made as simple as possible, but not simpler."⁴

Straightforward storytelling

Easy-to-read scientific documents stick to straightforward structures (think Introduction, Methods, Results, and Discussion for publications) and a clearly defined story. There are neither twists nor turns and certainly no red herrings hidden in murky depths.

A well-crafted document communicates its core message clearly and coherently at the outset. A highly effective and accessible way of presenting this message is to formulate it as a problem statement outlining the issue, its importance, and what the document does to address it; all subsequent sections of the text then bridge back to the problem statement.^{5,6}

The German figure of speech *ein roter Faden* likens a common theme running through something to a red thread. The term is thought to have originated with Johann Wolfgang von Goethe who described how ropes used by the British Navy were twined in such a way that a red

thread ran through all of them, rendering even the smallest piece of rope instantly recognisable as property of the British Crown.⁷

A problem statement twined through a scientific document like a red thread ties its different sections together. The core message resonates repeatedly with the reader and is thus more easily understood.

Sounding smart

An episode of the TV series *Friends* hilariously illustrates the dangers of overcomplicating things by trying to sound too smart. "They are humid, prepossessing *Homo Sapiens* with full-sized aortic pumps", writes character Joey of his friends Monica and Chandler. These two, however, are bewildered. The use of a thesaurus *on every word* of "They're warm, nice people with big hearts", has robbed the sentence of all meaning.

The case for using plain English is clear.^{8,9} To paraphrase (in somewhat of a comedown from the illustrious Einstein or Goethe) the fictional but wise Winnie-the-Pooh: "It is more fun to talk with someone who doesn't use long, difficult words but rather short, easy words like, 'What about lunch?'"¹⁰ It is also more fun and easier to read a scientific document following this dictum.

Simple simile

Metaphors, analogies, and similes can facilitate comprehension of complex subjects by providing familiar points of reference to readers. They have a long tradition in medical writing in particular¹¹

and can evoke graphic images with ease (think "strawberry tongue", "nutmeg liver", or "cauliflower ear"). Judiciously used (just don't go bananas!), such aids can enhance both the reliability and readability of scientific documents.

Short and sweet

Wordiness can pollute otherwise clear manuscripts;¹² long, meandering sentences can lose their befuddled (and often fuming) readers along the way. To all those verbose lovers of length: take the time to pick out pollutants and end those endless sentences! The brief is to be brief.

Easy on the eyes

Readability depends on more than pure content. While this may sometimes be outside an author's purview and reach into the realms of typesetting and design, the "look" of a scientific document can be immensely important to its comprehension.

Visually easy-to-access scientific documents are well-structured (using descriptive headings and distinct paragraphs) and make use of white space to offset large amounts of text. They are written in readable (in the most literal sense of the word!) fonts, text sizes, and colours (blue on green should never be seen!)¹³ and respect their readership's visual acuity. Wherever visual impairment may make a text *physically* difficult to read, modifiable electronic copies allowing text-to-speech conversion by screen readers are a great option.¹⁴ Comprehension of texts can be further enhanced by visual supports (e.g., graphical abstracts and illustrations, callout boxes, and colour coding). A text that is "easy on the eyes" enhances the flow and readability of the content.

Conclusion

Scientific articles that are easy to read and do not ask their readers to dredge the ditch for information are not impossible to craft. They can be (made to be) easy to read. To all those setting themselves this challenge:

*"Just start in to sing as you tackle the thing
That "cannot be done," and you'll do it."*¹

Disclaimers

The opinions expressed in this essay are the author's own and not necessarily shared by her employer.

Disclosures and conflicts of interest

The author declares no conflicts of interest.



References

1. Guest EA. It couldn't be done. Poetry Foundation. 1919 [cited 2023 July 20]. Available from: <https://www.poetryfoundation.org/poems/44314/it-couldnt-be-done>.
2. Bindé J, Sampson F, Demarais L, et al. Towards knowledge societies. UNESCO world report. United Nations educational, scientific and cultural organization; 2005 [cited 2023 July 17]. Available from: <https://medium.com/@arifwicaksanaa/pengertian-use-case-a7e576e1b6bf>
3. Singh N, Chang C, Chachati V, et al. Career guide for new medical writers. 2023 [cited 2023 July 17]. Available from: <https://www.emwa.org/media/4816/emwa-writing-guide-2023-high-res.pdf>
4. Calaprice A. The ultimate quotable Einstein. 4th ed. New Jersey: Princeton University Press; 2011. 475 p.
5. Hurley M. What's your problem? A practical approach to scientific document design. *Med Writ.* 2012;21(3):201–4.
6. Leventhal P. Manuscript writing – Using problem statements to organise and write a manuscript on original research. *Med Writ.* 2018;27(3):72.
7. von Goethe JW. Die Wahlverwandtschaften. 1st part, 2nd chapter. public dom. 2000 [cited 2023 July 17]. Available from: <https://www.gutenberg.org/ebooks/2403>
8. Reeves A. Time to make it shorter: plain English in our context. *Med Writ.* 2015;24(1):4–8.
9. Gilliver S. Plain language and readability. *Med Writ.* 2015;24(1):1–2. doi:10.1179/2047480614Z.000000000258.
10. Milne AA. The complete tales of Winnie-the-Pooh. 70th anniv. ed. New York: Dutton; 1999, p. 222
11. Bjork RE. When we dead awaken: reviving metaphor in medical writing. *J Adv Compos.* 1983;4:139–46.
12. Every B. Writing economically in medicine and science: tips for tackling wordiness. *Med Writ.* 2017;26(1):17–20.
13. Cutts M. Making leaflets clearer for patients. *Med Writ.* 2015;24(1):14–9. doi:10.1179/2047480614Z.000000000271
14. Clinical Trials Expert Group. Good lay summary practice. *EudraLex.* 2021; 10:1–85.

Can scientific documents be easy to read?

Reading a scientific document can feel like a treasure hunt: Precious knowledge is hidden within the article, waiting to be unraveled. However, its map (the text itself) may sometimes be quite confusing. Our brain won't invest excessive effort in deciphering it, at least not without some nudging. Even though it enjoys a good challenge, it is an efficient energy-saving machine.



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The perks of readability

Easy-to-read scientific articles tend to have a higher success rate, and, surprisingly, a higher chance of going viral.⁶ Yet readability goes beyond improving citation rates. It is a key weapon against two major enemies of science: misinformation and reproducibility issues.

The first comes in many flavours, particularly when laypeople turn to secondary sources because the original is too difficult to comprehend, potentially resulting in distortions or sensationalism. Most of us can relate to this to some degree.

But wait, how is readability related to the infamous reproducibility crisis?

Overall scientific literature is becoming more complex over time;⁷ if researchers struggle to understand a paper, it might hinder its reproducibility. This concern is not exclusive to humans: in programming-related areas,⁸ computers need machine-readable content to ensure replicable results.

Clear documents are deeply intertwined with the integrity and utility of research. Plus, they are good for our brains: they require minimal cognitive effort to be decoded.

Turning science into brain maps

Most writing guidelines oversimplify how the brain reads, focusing mostly on grammar, even though linguistic complexity alone has a minor effect on scientific impact.⁹

So, can scientific documents be more brain-friendly? They can if we turn them into brain maps.

While reading, our visual system connects the shape of letters with speech sounds.¹ However, it is significantly more efficient at building spatial blueprints – it is its primary job. We can exploit this feature by incorporating descriptive diagrams. They shouldn't be limited to the results section alone! The more we use to support an idea, the easier it becomes to grasp.

Let us first agree with our brains that reading is no simple feat. It is a relatively recent skill, so much so that it lacks a dedicated brain region, and evolution built it upon areas for visual processing.¹ Yes, our visual system has been literally recycled for reading.

It takes us years of practice to automatise the decoding of written material – although you might have forgotten those challenging childhood days. Still, one out of five adults in Europe has poor literacy, meaning that they struggle with basic text comprehension.²

Unfortunately, these numbers get worse for scientific manuscripts, the pinnacle of complex written information. Given that they are crucial for condensing and sharing our knowledge, shouldn't they be easy to read?

Mind my read-ability

Researchers have – obviously – come up with a term for how easy content is to read: readability. In a nutshell, high readability means that a text is clear, concise, and easy to understand, whereas low readability indicates the opposite.

Quantifying and researching this property, much as reading itself, can be challenging. While there are more than 200 traditional formulas, none of them is specifically designed for scientific documents.³ Most commonly used metrics (like the Flesch Reading-Ease score) are primarily based on simple features like sentence and word length,⁴ not even considering linguistic factors such as semantic relevance or text coherence.⁵

Besides, they do not account for the neurocognitive aspects of reading – our brains are still out of the loop.



Visuals are a powerful tool, especially when combined with text anchors: phrases, headlines, and symbols that act as reference points, creating a layout to spatially organise the flow of information. Yet, with great power comes great responsibility. For instance, it's easy to misuse color scales, leading to misinterpretation.¹⁰ The solution is to always use reliable scientific colour maps, such as those created by the researcher and designer Fabio Crameri.¹¹

Moreover, we can leverage another type of brain map, one we have employed since long before the invention of writing: stories. They glue every piece of information together, forming schemes that make it easier to recall and pass down. Today, we call this "Storytelling", the art of communicating events or ideas through engaging narratives.

Storytelling is great for readability because it harnesses the brain's natural affinity for stories. Just as we can effortlessly remember the particulars of a seven-book series such as Harry Potter, storytelling can convey complex data in a memorable manner. By converting scientific articles into compelling narratives, we transform the scientific journey into an enjoyable experience.

Readability awareness

A short note on the multilingual brain: While science is predominantly written in English, this is not the first language of many authors and readers. This is highly relevant because our brains are unconsciously drawn by the beauty of our

native languages to express ideas, which sometimes results in content that is complicated to read.

For instance, as a non-native English speaker, I often find myself crafting catchy sentences, only to realise that they fall flat or sound awkward – even if they are grammatically correct.

On the other hand, we should bear in mind that slang or "excessively English" nuances can be difficult to grasp. For example, phrasal verbs might be harder to understand because their concept (changing a verb's meaning by adding a particle) is not conceivable in many languages. In this case, we can enhance the text flow by simply using whole verbs when possible.

This "readability awareness" bridges language barriers, encouraging more accessible and inclusive manuscripts.

A journey for the reader's mind

In a world where knowledge is our ultimate treasure, we cannot afford unreadable maps.

Scientific documents can be easy to read if they speak plainly and effectively, acknowledging the diverse linguistic backgrounds of the audience. Let's move beyond grammar and readability formulas: by integrating graphic techniques and storytelling into our skill set, we can help readers navigate toward a better understanding.

It's all about drawing the right map in our readers' minds.

References

1. Dehaene S. Reading in the brain: The new science of how we read. Penguin, 2010.
2. PIAAC – Programme for International Assessment of Adult Competencies. Technical Report of the Survey of Adult Skills. 3rd Ed. 2019. Available from: https://www.oecd.org/skills/piaac/publications/PIAAC_Technical_Report_2019.pdf
3. Vergoulis T, Kanellos I, Tzerefos A, et al. A study on the readability of scientific publications. In: Digital Libraries for Open Knowledge, A. Doucet, A. Isaac, K. Golub, T. Aalberg, and A. Jatowt, eds., in Lecture Notes in Computer Science. Cham: Springer International Publishing, 2019, pp. 136–144. doi:10.1007/978-3-030-30760-8_12.
4. Benjamin RG. Reconstructing readability: recent developments and recommendations in the analysis of text difficulty. *Educ Psychol Rev.* 2012;24(1):63–88. doi:10.1007/s10648-011-9181-8
5. Scott A, Skalicky CK, Dasculu M. Moving beyond classic readability formulas: new methods and new models. *Journal of Research and Reading.* 2019;42(3–4):541–61. doi:10.1111/1467-9817.12283
6. Guerini M, Pepe A, Lepri B. Do linguistic style and readability of scientific abstracts affect their virality? *Proc Int AAAI Conf Web Soc Media.* 2012;6(1):475–8. doi:10.1609/icwsm.v6i1.14305
7. Plavén-Sigay P, Matheson GJ, Schiffler BC, et al. The readability of scientific texts is decreasing over time. *eLife.* 2017;6:e27725. doi:10.7554/eLife.27725
8. Akella AP, Koop D, Alhoori H. Laying foundations to quantify the "Effort of Reproducibility". ar Xiv, Aug, 2023. [cited 2023 Sep 21]. Available from: <http://arxiv.org/abs/2308.12580>
9. Lu C, Bu Y, Dong X, et al. Analyzing linguistic complexity and scientific impact. *J Informetrics.* 2019;13(3):817. doi:10.1016/j.joi.2019.07.004
10. Crameri F, Shephard GE, Heron PJ. The misuse of colour in science communication. *Nat Commun.* 2020; 11(1):5444. doi:10.1016/j.joi.2019.07.004.
11. Crameri F. Scientific colour maps. Zenodo; 2023. doi:10.5281/zenodo.1243862

News from the EMA

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The articles included in this section are a selection from the European Medicines Agency (EMA)'s News and Press Releases archive. More information can be found on the Agency's website: www.ema.europa.eu.



EMA to support establishment of the African Medicines Agency

January 26, 2024

EMA will harness its unique experience in coordinating intra-regional medicines regulation to support the strengthening of the African regulatory network.

EMA has received a grant of ten million euros from the European Commission to support regulatory systems at national and regional level in Africa, and in particular for the setting up of the African Medicines Agency (AMA), in collaboration with African, European, and international actors. The European Commission's Directorate-General for International Partnerships has signed an agreement with EMA marking the official launch of the project.

AMA will be a specialised agency of the African Union (AU) dedicated to improving equitable access to quality, safe, and effective medical products in Africa. To date, 27 countries have ratified the AMA treaty, and more AU members are expected to complete the process in the coming months. The creation of AMA is a

unique opportunity to facilitate the regulation and oversight of key medicines at continental level, promoting collaboration among African countries and regions.

Cooperation and collaboration are in the DNA of the European medicines regulatory network (EMRN). The EMRN is the cornerstone of EMA's work and success. The Agency operates at the heart of the network, coordinating and supporting interactions between over fifty national competent authorities for human and veterinary medicines. By sharing its unique expertise and regulatory model, the EMRN will share experience with AMA in pooling resources and coordinating work to regulate medicines efficiently and effectively, ensuring high-quality standards and use of the best available expertise, reducing administrative burden to allow medicines to reach patients faster and accelerating the exchange of information on critical issues such as medicines safety.

EMA has committed to mobilising experts to support AMA, its technical committees, and African regulators in the set-up of AMA's governance and scientific and administrative processes. EMA will also offer training to reinforce scientific and regulatory expertise in the evaluation and supervision of medicines together with experts from European Union (EU) Member States.

EMA's contribution is part of the 'Team Europe' initiative on manufacturing and access to vaccines, medicines, and health technologies in Africa (MAV+), launched by the Commission in May 2021. Under the EU's Global Gateway strategy, the initiative has mobilised so far 1.3 billion euros including around 135 million euros in grants for regulatory strengthening. Working together with EU Member States, African partners such as the African Union Development Agency (AUDA-NEPAD) and the World Health Organisation (WHO), the European Union will help to strengthen regulatory capacity in Africa with a comprehensive set of actions at continental, regional, and national levels.



New platform for collection of sales and use data of antimicrobials in animals

January 29, 2024

EMA has just launched the new Anti-microbial Sales and Use (ASU) Platform to support the collection of data by Member States on the sales and use of antimicrobials in animals. As of January 2024, all Member States in the EU and European Economic Area (EEA) must submit these data annually to the ASU Platform. This new obligation was introduced by the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) as one of the measures to fight antimicrobial resistance.

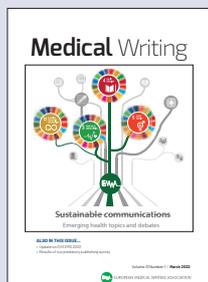
The collection of data on the sales and use of antimicrobials in animals has always been critical in the fight against antimicrobial resistance. The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project was in place between 2009 and 2023 as a

voluntary initiative by EMA and European countries to monitor the sales of veterinary antimicrobials in Europe. It served as a blueprint for the ASU Platform that supports and enhances the EU's actions to address antimicrobial resistance. It requires that all Member States submit data on sales of veterinary antimicrobials and use of antimicrobials in animals in a standardised format, enhancing the collection of data and their integration in a robust system.

The new IT system and web interface will not only streamline the submission of data for the Member States, but it will also strengthen the analysis and identification of trends in antimicrobial consumption across the EU/EEA. Access to reliable data provides invaluable insights

for participating countries on the impact of their measures to promote the prudent use of antimicrobials in animals and could help to identify potential actions at national and international levels to support an overall decrease of AMR.

EMA will publish annual reports showcasing the main results of the analysed data, with the first report expected in March 2025, after the first reporting cycle is concluded. It will also develop a public interactive database on a business intelligence interface, that will help to further disseminate the outcomes of the ASU Platform data analysis. A timeline for implementation and guidance to assist national competent authorities to implement the legislative requirements are available on EMA's website. The reporting of data on use in animal species will be implemented gradually.



Sustainable communications



Medical journalism



Medical decision making



Mentorship



Social media



Writing for patients

Check out the back issues of EMWA's journal *Medical Writing*

at <https://journal.emwa.org>

Launch of new HMA-EMA catalogues of real-world data sources and studies

February 15, 2024

EMA and the Heads of Medicines Agencies (HMA) have launched two public electronic catalogues: one for real-world data (RWD) sources and one for RWD studies.

The catalogues help medicines regulators, researchers, and pharmaceutical companies to identify the most suitable data sources to address specific research questions and support the assessment of study protocols and results. They aim to promote transparency, encourage the use of good practices, and build trust in research based on RWD. The initiative builds on more than 15 years of operation of the former databases, developed by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP):

- The catalogue for RWD sources enhances and replaces the ENCePP Resources Database, an EMA-coordinated index of resources of available research organisations, networks, and data sources in the fields of pharmacoepidemiology and pharmacovigilance within Europe.

- The catalogue for RWD studies expands and replaces the European Union electronic register of post-authorisation studies (EU PAS Register®).

As part of this initiative, the ENCePP website has been renewed. While some data sources and all centres and networks have migrated to the new catalogues replacing the ENCePP Resource Database, other content, such as ENCePP Guide on Methodological Standards in Pharmacoepidemiology and the ENCePP Code of Conduct, will remain available on the renewed ENCePP website.

The catalogues introduce various improvements to the previous ones. Using FAIR (Findable, Accessible, Interoperable, and Reusable) data principles, they use an agreed set of metadata to describe and connect data sources to studies. It is based on the list of metadata published by the HMA-EMA Big Data Steering Group in May 2022. A revised list will be

published soon. In addition, search on a wider set of metadata, enhanced view, export, and data submission functionalities have been implemented in the catalogues.

The publication of the RWD catalogues brings the EMRN closer to more data-driven regulation. Improving discoverability of data is one of the priorities set in the HMA-EMA joint Big Data Task Force final report (phase two), reflected in the European medicines agencies network strategy to 2025 and implemented through the joint HMA-EMA Big Data Steering Group workplan. Ultimately, these developments will help European patients receive better medicines faster and promote safe and effective use of the medicines on the market.

All European data holders, marketing authorisation holders, networks, researchers, and institutions who are interested in having their data used for medicines regulation or are obligated by policy on non-interventional post-authorisation safety studies (PASS), are encouraged to use these catalogues.

New recommendations to strengthen supply chains of critical medicines

April 23, 2024

EMA has published a number of recommendations to address vulnerabilities in the production and delivery of medicines included in the Union list of critical medicines and strengthen their supply chain (Reference Number: EMA/44164/2024).

These recommendations have been developed by EMA's Medicines Shortages Steering Group (MSSG) and will facilitate the availability and supply of critical human medicines for which vulnerabilities in the supply chain have been identified. Measures considered by the MSSG will be selected according to the risks posed to the supply chain and the type of medicine, and include:

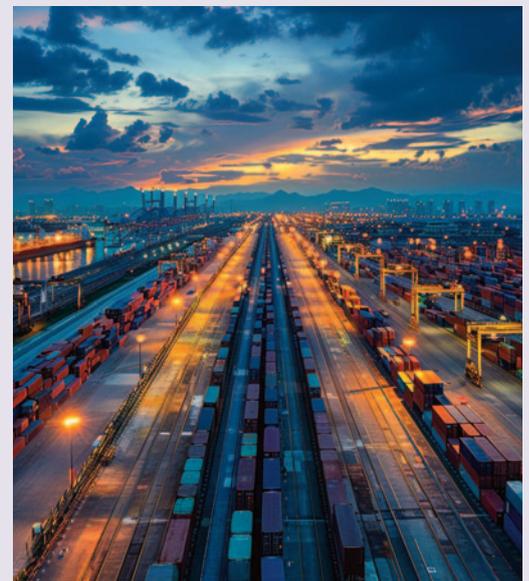
- Possible recommendations to marketing authorisation holders (MAHs) to increase manufacturing capacity and diversify the suppliers in the supply chain (for example through the addition of alternative manufacturing sites), and to monitor forecasts of supply and demand of medicines and available stocks in the entire supply chain.
- Recommendations to certain actors in the

supply chain, such as MAHs, and the European Commission to stockpile medicines to protect against fluctuations in demand or supply.

- The possibility to request a MAH to establish a shortage prevention plan for medicines in the Union list of critical medicines. EMA will publish guidance and templates for shortage prevention plans in June 2024.
- Provision of scientific and regulatory support to address vulnerabilities in the supply chain, including assistance to small and medium-sized enterprises.

Use of work-sharing procedures or other types of reliance on assessments conducted by another recognised authority, and accelerated timetables for required variations to address supply chain vulnerabilities of critical medicines.

The MSSG will work closely with the European Commission's Critical Medicines Alliance (CMA). The MSSG will develop regulatory and governmental policy recom-



mendations focused on short- to medium-term actions, while the CMA will focus on long-term measures in the field of industrial policy to address vulnerabilities in the supply chain of critical medicines.

In case of critical shortages of medicinal products included in the Union list, the MSSG Toolkit on recommendations on tackling shortages of medicinal products would apply.

New treatment for rare motor neurone disease recommended for approval

February 23, 2024

EMA has recommended granting a marketing authorisation in the EU for a new therapy for the treatment of adult patients with amyotrophic lateral sclerosis (ALS), a rare and often fatal disease that causes muscles to become weak and leads to paralysis. Qalsody (tofersen) is indicated for the treatment of adults with ALS, who have a mutation in the superoxide dismutase 1 (SOD1) gene.

In patients with ALS the nerve cells in the brain and spinal cord that control voluntary movement gradually deteriorate, causing increasing loss of muscle function and paralysis of voluntary muscles, including respiratory muscle, which ultimately leads to respiratory failure. ALS is a devastating disorder. The mean survival time with ALS is two to five years.

The exact causes of ALS are unknown but are believed to include genetic and environmental factors. In approximately 2% of people living with ALS, the condition is caused by a genetic mutation (change) that leads to the production of defective SOD1 enzymes, causing nerve cells to die.

Currently, there is only one treatment for ALS (riluzole) authorised in the EU. Patients are offered supportive treatment to relieve the symptoms of the disease, such as physical, occupational or speech therapy and breathing support. There is a large unmet medical need for effective therapies that preserve muscle function and prolong the life of patients with ALS.

Qalsody is an antisense oligonucleotide that binds to the mRNA of the SOD1 gene to reduce the production of SOD1 protein. By reducing the amount of defective SOD1 protein, this medicine

is expected to improve the symptoms of ALS.

The opinion by EMA's committee for human medicines (CHMP) is based on the totality of evidence, including the targeted way the drug works, effects observed in a SOD1 animal model, biomarkers, and clinical data.

Clinical data were obtained from a 28-week, randomised, double-blind, placebo-controlled clinical study in 108 patients aged 23 to 78 years with weakness attributable to ALS and a SOD1 gene mutation confirmed by a central laboratory. The study randomly assigned 108 patients in a 2:1 ratio to receive treatment intrathecally (through a spinal injection) with either Qalsody or placebo for 24 weeks. Plasma neurofilament light chain (NfL) was measured during the study as a marker of damage and deterioration of axons (thread-like structures attached to nerve cells that send out signals away from the cell). Reductions of approximately 60% in plasma NfL concentrations were observed in patients who received Qalsody compared to the placebo group, suggesting reduced neuronal injury. There was also a numerical improvement noted in the physical abilities of patients who received Qalsody compared to the study participants who received placebo, as measured by the standard rating scale known as "ALS Functional Ratings Scale-Revised" (ALSFRS-R).

The CHMP requested the applicant to submit data post-authorisation to further characterise the long-term efficacy and safety of Qalsody, on the basis of an open-label long-term extension study, collaboration with two disease registries, and an observational registry-based study.

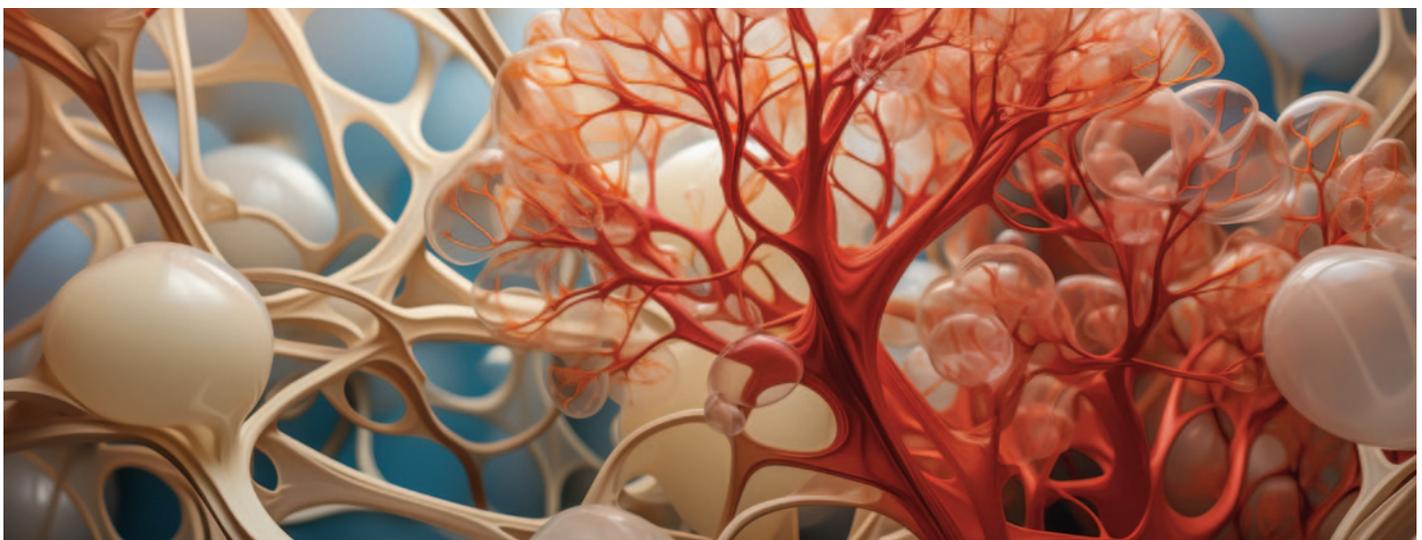
In addition, it will be investigated if the use of tofersen can delay or even prevent emergence of clinically manifested ALS in presymptomatic SOD1-ALS patients.

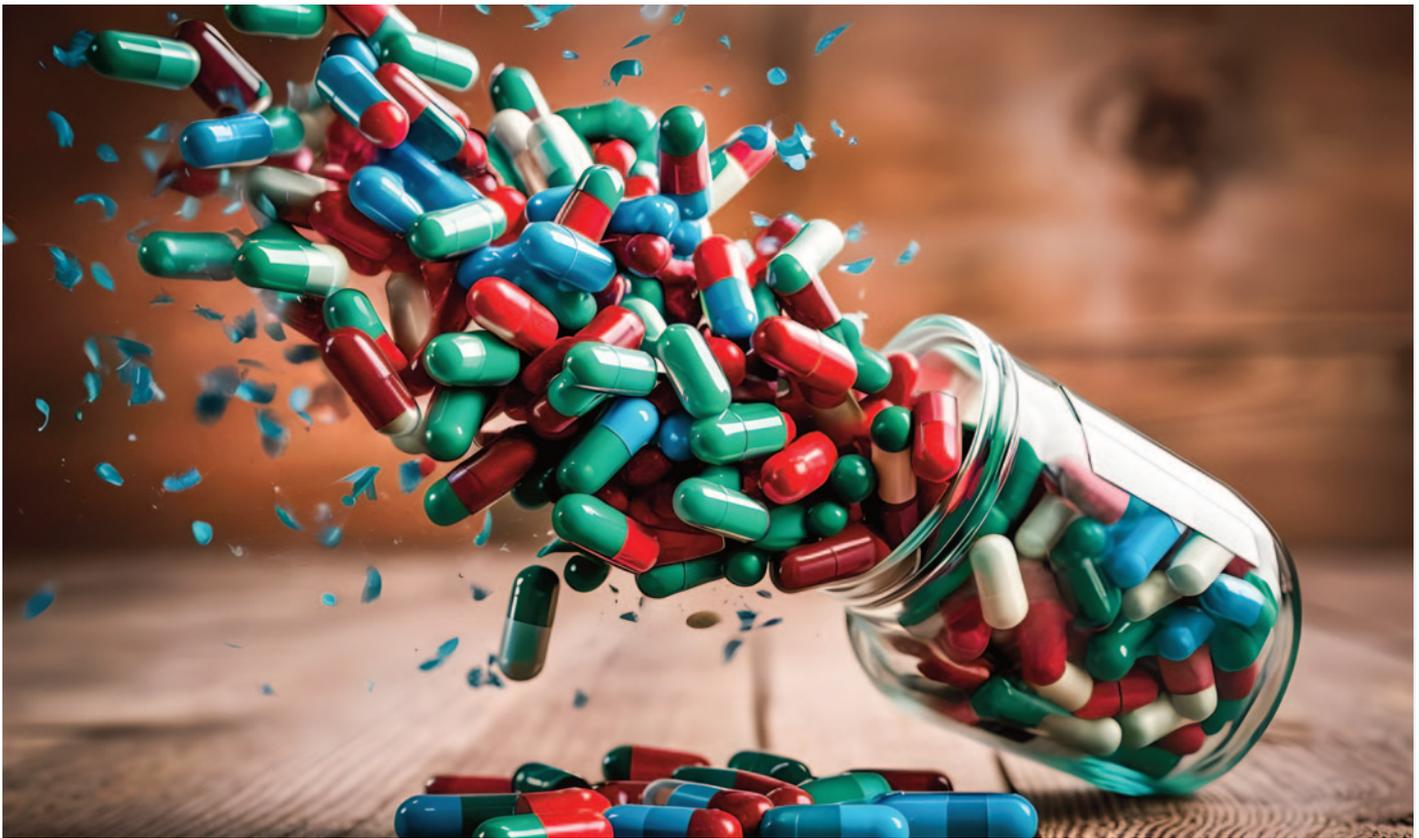
The most commonly reported side effects were pain, fatigue, pyrexia (fever), arthralgia (joint pain), myalgia (muscle pain), and increased levels of white blood cells and proteins in the cerebrospinal (brain and spinal cord) fluid.

The CHMP consulted patient representatives during the assessment of benefits and risks of Qalsody to ensure that patients' needs and their perspective are taken into account in the regulatory decision-making process.

The recommendation made by the CHMP is for a marketing authorisation under exceptional circumstances. This route of authorisation allows patients access to medicines for which comprehensive data cannot be obtained under normal conditions of use, either because there are only very few patients with the disease, the collection of complete information on the efficacy and safety of the medicine would be unethical, or there are gaps in the scientific knowledge. These medicines are subject to specific post-authorisation obligations and monitoring.

The opinion adopted by the CHMP is an intermediary step on Qalsody's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on the EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.





New antibiotic to fight infections caused by multidrug-resistant bacteria

March 22, 2024

EMA has recommended granting a marketing authorisation in the EU for Emblaveo (aztreonam-avibactam), indicated for the treatment of complicated intra-abdominal and urinary tract infections, hospital-acquired pneumonia, and infections caused by certain types of bacteria (aerobic Gram-negative) where treatment options are limited.

Infections due to Gram-negative bacteria that are resistant to many currently available antibiotics are a serious public health problem since patients have limited or sometimes no treatment options. Infections due to multidrug-resistant bacteria are estimated to cause 35,000 deaths in the EU every year.

Emblaveo will be available to be given by infusion into a vein. It is a fixed-dose combination of two active substances, aztreonam and avibactam.

- Aztreonam is already authorised for use in the EU on its own and avibactam is authorised for use in combination with another antibiotic (ceftazidime). Aztreonam is an antibiotic that belongs to the group “beta-lactams”. It works by attaching to proteins on the surface of the bacteria. This prevents the bacteria from building their cell walls, which kills them.

Aztreonam has been shown to be effective at treating a range of serious infections.

- Avibactam blocks the action of many of the bacterial enzymes called beta-lactamases. These enzymes enable bacteria to break down beta-lactam antibiotics, such as aztreonam, making them resistant to the antibiotic’s action. By blocking these enzymes, avibactam restores the activity of aztreonam against aztreonam-resistant bacteria.

EMA’s human medicines committee (CHMP) considered that the benefits of Emblaveo outweigh its risks for patients with infections caused by Gram-negative bacteria when they have few or no therapeutic options to fight the disease. Microbiology data indicate that aztreonam in combination with avibactam will be effective in infections caused by many multidrug-resistant aerobic Gram-negative pathogens and the combination could therefore address an unmet medical need.

Emblaveo was evaluated under EMA’s accelerated assessment mechanism because it is considered to be of major public health interest. EMA’s recommendation is based on the safety and efficacy data already available for each active

substance and the results of two phase III randomised studies submitted by the applicant. The studies were not designed to demonstrate efficacy but do provide safety and complementary data for the combination. This is in line with EMA’s guideline that allows for a flexible approach in the development of new antibiotics for human use targeting multidrug-resistant pathogens for which new treatments are needed.

The most frequent side effects in patients treated with Emblaveo were a decrease in the number of red blood cells, elevated levels of liver transaminase, and diarrhoea. This is in line with the documented safety information available for each individual substance.

The opinion adopted by the CHMP is an intermediary step on Emblaveo’s path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.



EU recommendations for 2024/2025 seasonal flu vaccine composition

March 26, 2024

Influenza viruses continuously change and evolve. The periodic replacement of the virus strains contained in influenza vaccines is therefore necessary to keep the vaccines effective. The recommendations for the influenza season 2024/2025 were endorsed by EMA's human medicines committee (CHMP) at its March 2024 meeting.

EMA has issued recommendations for the influenza virus strains that vaccine manufacturers should include in vaccines for the prevention of seasonal influenza from autumn 2024. Every year, EMA issues EU recommendations for the composition of seasonal influenza vaccines on the basis of observations by the WHO which are informed by regular monitoring activities on the prevalence and characteristics of different influenza viruses worldwide.

Based on this data EMA's Emergency Task Force (ETF) has issued a statement recommending a transition from quadrivalent to trivalent vaccines that do not include the B/Yamagata component. Currently, most authorised influenza vaccines are quadrivalent, which means that they are formulated to protect against the four main strains of influenza responsible for seasonal flu, A(H1N1)pdm09

and A(H3N2), B/Victoria and B/Yamagata. However, the B/Yamagata strain of the influenza B virus has not been detected in circulation since March 2020. This is thought to be due in part to the public health measures put in place to limit the spread of COVID-19 during the pandemic. Influenza B viruses are responsible for a quarter of annual influenza infections.

Given that the B-Yamagata virus strain no longer seems to pose a threat to public health, it is not necessary to include it in the formulation of influenza vaccines. The ETF recommends that this strain should ideally be removed from all live-attenuated vaccines from the 2024/2025 season. In the interest of guaranteeing vaccine supplies for the coming vaccination campaign, the transition to a trivalent composition for all other influenza vaccines should be completed for the 2025/2026 season.

Taking into account the statement from the ETF and the insights and recommendation from the WHO, the EMA's ad hoc Influenza Working Group, has issued the following strain recommendations for this year. Manufacturers of live-attenuated vaccines, or egg-based trivalent vaccines should include these three virus strains for the 2024/2025 season:

- A/Victoria/4897/2022 (H1N1)pdm09-like virus
- A/Thailand/8/2022 (H3N2)-like virus
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

Manufacturers of cell-based trivalent vaccines should include these three virus strains for the 2024/2025 season:

- A/Wisconsin/67/2022 (H1N1)pdm09-like virus
- A/Massachusetts/18/2022 (H3N2)-like virus
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus

Manufacturers of inactivated vaccines can consider producing a quadrivalent vaccine containing two influenza B virus strains for the 2024/2025 season. In that case a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus in addition to the strains mentioned above is considered appropriate.

The Agency recommends that marketing authorisation holders submit applications to change the composition of centrally authorised seasonal influenza vaccines by June 17, 2024.

Digital Communication

Editorial

Whether you're a social media newbie or a seasoned pro, navigating the ever-changing landscape of digital platforms can be challenging. Add to that a constant flow of new technologies, shifting user behaviours, and impacting global events, and it all becomes a bit too overwhelming to manage.

Social media is a powerful asset in our communicator's toolkits, enabling us to disseminate vital information, connect with audiences, and foster community engagement. As communicators in the health and medical

fields, it's crucial that we stay ahead of new developments that may affect our effective use of digital platforms. In this vast ocean of information, we must be proactive in seeking out best practices. But where to start?

Shannen Young is a social media strategy and digital communications expert – among her other impressive skills. In the article below, she doesn't just offer advice; she provides a roadmap to navigate the complexities of social media with ease. From foundational best practices to the latest and future developments in the digital realm, she delves into how these changes are

SECTION EDITOR



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reshaping our approach to communication.

I'm confident that her insights will equip you with the knowledge and strategies needed to thrive in this dynamic environment, ensuring we not only keep pace but lead the way in digital health communication.

Happy reading!

Nicole

Traversing the social media landscape: Digital health communications in 2024

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Abstract

Amidst a post-pandemic landscape marked by dis- and misinformation, new technologies, and platform shifts, health communications will need to be rightly balanced between convenience, quality, and trust to cut through the digital noise online. Navigating the dynamic social media terrain will require adherence to regulatory standards, while the adoption of new trends like artificial intelligence offers new approaches for content creation and audience insights. Medical communicators will need to harness the power of new technologies, employ content strategies tailored to audiences and platforms, and continue to measure social media metrics to stay ahead of the times and deliver effective and impactful campaigns.

In the minute it takes you to read the opening paragraph of this article, roughly four million posts are liked on Facebook, 694,000 reels are sent via Instagram DMs, and 360,000 tweets are shared to X (formerly known as Twitter).¹ From the early days of social networking websites like Myspace to instant messaging services like AOL, blogging, and Facebook, social media has grown to boast over five billion active users and permeate our daily lives as our primary source of social interaction, entertainment, and news.² With the average internet user spending two and a half hours daily on various platforms,² the social media landscape has become prime real estate for communicators, marketers, and technologists alike. In a dynamic and ever-evolving environment, social media is attuned to consumer behaviours and rapid technological developments that are reflected in audiences' desires for entertainment and to be entertained. Whether that be through authentic, personalised content, informative campaigns, or harnessing the power of artificial intelligence (AI), medical communicators need to adapt or risk falling by the wayside.

Navigating rocky terrain

A post-pandemic world

The exponential growth of social media and interconnectivity of the netizens of the world was a breeding ground for mis- and disinformation during the COVID-19 pandemic and resulting infodemic.³ Although the presence of mis- and disinformation online is not new and often a key component of destabilising campaigns by nefarious actors,⁴ we witnessed a fundamental shift away from trusting institutions and scientific experts and the

information they communicate during the COVID-19 pandemic.⁵ Despite a plethora of actors sharing inaccurate information and stoking an environment of scepticism "in the comments," health communicators have a unique opportunity to provide more accessible and targeted information online, improving the health literacy of audiences worldwide.

In addition to an, at times, belligerent environment online, the rise of new platforms and rebranding of old-timers pose new challenges for medical communicators and the organisations they represent. The upsurge of the video-focused TikTok and rebranding of Twitter to X sent ripples through the sea of social media apps, prompting the release of several competitors, including Bluesky,⁶ Mastodon,⁷ and Threads⁸ – Meta's rival to X – and a noticeable



Authors: Shannen Young, iStock, Adobe Firefly

shift to short-form video content on Facebook, Instagram, and YouTube in the form of stories and shorts, respectively.⁸ Influencers within the fields of science communication and medical communications are gaining traction on Instagram and TikTok, and to a lesser extent, YouTube, as the lay population becomes increasingly exposed to their content online through organic searches and algorithmic suggestions. LinkedIn continues to grow in popularity as the go-to platform for professionals, while user uptick on the X replacement platforms remains slow, a possible signal of user fatigue.

AI enters the chat

Since the release of OpenAI's ChatGPT in late 2022,⁹ generative AI has made waves across industries with social media being no exception. There is no shortage of third-party applications to generate social copy, edit, or proofread, and create graphic materials. While generative AI and AI assistants

are tools most medical communicators should have in their arsenal, it is important to keep the human component of communication at heart. Finding the right balance between convenience, quality, and trust is paramount.

When it comes to compliance and authenticity, placing human hands on the keyboard will help improve the chances that sensitive information and content resonates with target audiences and is interpreted as trustworthy.

Medical communicators can incorporate AI into their social media processes to assist with brainstorming content ideas, writing social copy based on prompts or existing posts, and suggesting appropriate images or videos to accompany posts.¹⁰ Major players in the social media and content creation field have incorporated AI assistants directly into their software, such as Adobe's Firefly,¹¹ Hootsuite's OwlyWriter AI,¹² and Canva's Magic Design.¹³ Being comfortable with the capabilities of AI is a strength and should not be a deterrence to streamlining social media workflows or redirecting human brainpower to more abstract concepts involved in strategizing. However, there are some social media tasks that should remain human, namely audience inter-

action, crafting content strategies, editing captions, ensuring graphic materials align to brand guidelines, and monitoring brand safety and compliance risks.⁶

Working in a regulated sector such as healthcare requires external communications to be consistent, evidence-based, transparent, and compliant with regulations throughout the product lifecycle. Following guidelines outlined by the EMA or FDA can help ensure that sensitive information is communicated to audiences practically, factors in the health literacy of target audiences, and follows the General Data Protection Regulation (GDPR) or Health Insurance Portability and Accountability Act (HIPAA) legislation. When it comes to compliance and authenticity, placing human hands on the keyboard will help improve the chances that sensitive information and content resonates with target audiences and is interpreted as trustworthy.

The social media promised land

Employing this interconnectivity and convergence of technologies on social media presents both risks and rewards and requires a certain subset of skills in digital health communications to deliver informative and authentic campaigns.



Authors: Shannen Young, iStock.

Figure 1. The roadmap to social media success

Abbreviations: KPI, key performance indicators.

Invest where your audience is

Before drafting text or visuals for social media channels, it is pertinent to have a concrete understanding of who this material is being created for. Health communications should connect with the social identity of audiences and convey actionable recommendations that align with existing cultural behaviours.⁵ By surveying existing platforms, communicators can create an audience persona that outlines the base age range, location, profession, and seniority level of followers and their possible interests. This helps target content, encode messaging, and determine if the audience

Before drafting text or visuals for social media channels, it is pertinent to have a concrete understanding of who this material is being created for.

demographic shifts over time. Analytics also provide insight into audience growth and which platforms and types of content appeal to followers. A drop in engagement or total follower count may indicate a negative return on investment on one platform – a social media audit can confirm suspicions.¹⁴ Keeping abreast of new platforms and content trends can help guide creative energy, digital marketing investments, A/B testing (comparing the performance of two variations of content), and future strategies. Increasing digital noise is just one of the many obstacles to connecting with audiences in the digital age of healthcare. By

investing in platforms, content, and campaigns that attract and retain audiences, medical communicators can set their social media processes on the trajectory to success.

Relevance is relevant

Target audiences want to feel the organisation they're engaging with is authentic and adheres to their stated causes and missions. They also want to feel the information or content they're interacting with is relevant to them and the platform they're using. Communicators can routinely inspect organisational brand identity across the social media realm to ensure consistency across platforms and adherence to institutional causes or missions. Likewise, the graphic identity should be complementary and relatively modern in appearance. Updating

banner and profile images and bios will help prevent social media profiles from becoming stale. Tailoring content to platform specifications and audience needs can help maximise potential engagement and reach. Table 1 provides some recommendations to consider when adapting social media content.

Success is in the eye of the beholder

Extracting meaningful insight from social media metrics can help guide future campaigns and strategies. There is no shortage of data that can be harvested on social platforms, with most offering native or external reporting for each post, follower trends, and ad campaigns. In a sea of likes, comments, reposts, and clicks, where is the best place to start?

Campaigns should be informed by overarching goals or objectives guiding the messaging of communications. Once defined, key performance indicators (KPIs) can be explicated and measured. The most common KPIs to track are:

- Impressions (the total number of times a post was seen in users' feeds)
- Engagements (the total number of likes, comments, or shares per post)
- Clicks (the total number of times users clicked on any element in a post with their mouse or digital finger)

Monitoring and measuring the performance of social media posts should be second nature to most communicators.

Content strategies should be informed by predefined goals and the KPIs that will be measured, and creative materials should be crafted with these in mind. Communicators should consider what type of content will prompt their audience to engage with a post, repost it to their networks, and take it home with them. Executing a content strategy can be made simpler using social media scheduling tools – such as Buffer,¹⁷ Hootsuite,¹⁸ or Later¹⁹ – or the native scheduling services found on most platforms, like Meta Business

Suite or Twitter Ads. Monitoring and measuring the performance of social media posts should be second nature to most communicators. Once analytics are performed, the results may be used to refine and adjust current strategies or creative materials. Should the goals, objectives, and KPIs be met, iterate posts and scale up for broader impact. The process can further be informed by lessons learnt from analytics, competitor surveying, and new social marketing techniques. A social listening service can take insights to the next level and there is no shortage of players on the market. These tools, such as BrandMentions,²⁰ Brandwatch,²¹ or Meltwater,²² allow users to gauge audience sentiment toward specific terms or phrases and opinions on current issues.²³ Tracking trending hashtags and adjacent topics can help campaigns reach more users and

tailor content to existing audiences. Real-time and historical data allow communicators to measure a brand's performance and reputation in online discussions. However, with changing privacy and data access regulations, the information these tools provide is subject to limitations. Ultimately, it is the story behind the content that will determine success.

What's on the horizon?

Medical communicators will continue to contend with the shifting sands of social media in the years to come. With nearly 49% of the world's population eligible to vote in the 2024 "super election year," mis- and disinformation is bound to be rampant.²⁴ Digital health messaging will need to cope with foreign interference online as actors potentially seek to take advantage of the legacy of institutional distrust from the COVID-19 pandemic and accompanying infodemic.

Regulatory hammers have recently come down on rapidly developing and deploying AI technologies, with the European Parliament adopting a landmark law cementing the rights and protections of humans in the face of accelerating AI.²⁵ Transparency is one of the concerns outlined in the act, which would see AI-generated content markedly labelled as such. Meta is already taking steps to identify AI content on Facebook, Instagram, and Threads.²⁶ In the face of deepfakes and deceptive images online, critical analysis and regulatory labelling will hopefully protect audiences from falling victim to deceit.

Table 1. Popular social media platforms and recommendations to tailor content

| Platform | Estimated number of users ^{a,b} | How to tailor content |
|---|--|--|
|  Facebook | 3.049 billion | <ul style="list-style-type: none"> ● Customise the action button on your profile to reflect your audience's needs^c ● Use language that invites comments or questions from your audience |
|  Instagram | 2 billion | <ul style="list-style-type: none"> ● Optimise visuals for posts, reels, and stories ● Optimise for mobile viewing ● Update the bio link to reflect a current campaign |
|  TikTok | 1.562 billion | <ul style="list-style-type: none"> ● Optimise videos for mobile viewing ● Keep social copy concise ● Trending topics and creative formats can change rapidly, adapt to the current trends |
|  LinkedIn | 1 billion | <ul style="list-style-type: none"> ● Write longer form social copy or short-form articles ● Invoke a professional tone in social copy ● Take advantage of the article, document, and poll functions when crafting posts |
|  X | 619 million | <ul style="list-style-type: none"> ● Keep social copy concise ● Choose hashtags strategically ● Evoke a light or humorous tone if it adheres to brand guidelines |

^a Meltwater. Global state of social media 2024.¹⁵

^b LinkedIn. About us: Statistics.¹⁶

^c The action button prompts users to take an action that is important to the page. See Facebook's help centre for more: <https://www.facebook.com/help/977869848936797>.

As technology advances and healthcare systems become more digitised, the number of people actively seeking health information online will continue to grow.²⁷ Digital health communications will need to adapt to the changing winds of social media to ensure uptick of key messaging and successful campaigns. Adhering to branding guidelines, tailoring content, and following a structured social media strategy are just some pointers to set medical communicators on a path forward.

Disclaimers

The opinions expressed in this article are those of the author alone and do not necessarily reflect the views of Uppsala Monitoring Centre (UMC).

References

1. Domo. Data never sleeps 11.0. 2023 [cited 2024 Mar 1]. Available from: <https://www.domo.com/learn/infographic/data-never-sleeps-11>.
2. Meltwater. 2024 Global Digital Report. 2024 [cited 2024 Mar 1]. Available from: <https://www.meltwater.com/en/global-digital-trends>.
3. Zielinski C. Infodemics and infodemiology: a short history, a long future. *Rev Panam Salud Publica*. 2021;45(40):e40. doi:10.26633/RPSP.2021.40.
4. Bradshaw S, Howard PN. The global organization of social media disinformation campaigns. *J Int Aff*. 2018;71(1.5): 23–32. Available from: <https://www.jstor.org/stable/26508115>.
5. Albarracin D, Oyserman D, Schwarz N. Health communication and behavioral change during the COVID-19 pandemic. *Perspect Psychol Sci*. 2024 Feb 6. Epub ahead of print. doi:10.1177/17456916231215272.
6. BlueSky Social. About BlueSky Social [cited 2024 Mar 28]. Available from: <https://bsky.social/about>.
7. Mastodon. Join Mastodon [cited 2024 Mar 28]. Available from: <https://joinmastodon.org/>.
8. Kelly S. Meta officially launches Twitter rival Threads. 30 million people have joined already. *CNN*. 2023 [cited 2024 Mar 3]. Available from: <https://edition.cnn.com/2023/07/05/tech/meta-twitter-threads-app-instagram/>.
9. Metz C. The new chatbots could change the world. Can you trust them? *The New York Times*. 2022 [cited 2024 Mar 1]. Available from: <https://www.nytimes.com/2022/12/10/technology/ai-chat-bot-chatgpt.html>.
10. Hootsuite. Social trends in healthcare 2024. 2023 [cited 2024 Mar 1]. Available from: <https://www.hootsuite.com/en-gb/research/healthcare-social-media-trends-report>.
11. Adobe. Adobe Firely [cited 2024 Mar 3]. Available from: <https://www.adobe.com/products/firefly.html>.
12. Hootsuite. OwlyWriter AI [cited 2024 Mar 3]. Available from: <https://www.hootsuite.com/platform/owly-writer-ai>.
13. Canva. Magic Design [cited 2024 Mar 3]. Available from: <https://www.canva.com/magic-design/>.
14. Martin M. How to run the easiest social media audit. Hootsuite. 2022 [cited 2024 Mar 4]. Available from: <https://blog.hootsuite.com/social-media-audit-template/>
15. Meltwater. Global state of social media 2024 [cited 2024 Mar 4]. Available from: <https://www.meltwater.com/en/state-of-social-media>.
16. LinkedIn. About us: Statistics. 2024 [cited 2024 Mar 4]. Available from: <https://news.linkedin.com/about-us#Statistics>.
17. Buffer [cited 2024 Mar 28]. Available from: <https://buffer.com/>.
18. Hootsuite [cited 2024 Mar 27]. Available from: <https://www.hootsuite.com/>.
19. Later [cited 2024 Mar 27]. Available from: <https://later.com/>.
20. Brandmentions [cited 2024 Mar 27]. Available from: <https://brandmentions.com/>.
21. Brandwatch [cited 2024 Mar 27]. Available from: <https://www.brandwatch.com/>.
22. Meltwater. Our technology [cited 2024 Mar 27]. Available from: <https://www.meltwater.com/en/our-technology>.
23. Sprout Social. Social media for healthcare: How to keep patients engaged in the digital age. 2023 [cited 2024 Mar 14]. Available from: <https://sproutsocial.com/insights/social-media-in-healthcare/>.
24. Ewe K. The ultimate election year: All the elections around the world in 2024. *Time Magazine* [cited 2024 Mar 4]. Available from: <https://time.com/6550920/world-elections-2024/>.
25. European Parliament. Artificial Intelligence Act: MEPs adopt landmark law. 2024 [cited 2024 Mar 14]. Available from: <https://www.europarl.europa.eu/news/en/press-room/20240308IPR19015/artificial-intelligence-act-meps-adopt-landmark-law/>.
26. Clegg N. Labeling AI-generated images on Facebook, Instagram, and Threads. Meta. 2024 [cited 2024 Mar 14]. Available from: <https://about.fb.com/news/2024/02/labeling-ai-generated-images-on-facebook-instagram-and-threads/>.
27. Eurostat. EU citizens: over half seek health information online. 2022 [cited 2024 Mar 14]. Available from: <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/edn-20220406-1>.



Author information

Shannen Young is a communicator by trade and a creative at heart. She enjoys crafting compelling social media campaigns using several mediums, whether that be graphic design, film, data visualisations, copywriting, and more. She is passionate about telling unique stories and turning complex ideas or methodologies into digestible and engaging content. Before joining Uppsala Monitoring Centre (UMC) in 2022, she performed various communications tasks at the Stockholm International Peace Research Institute (SIPRI). She holds a BA from Simon Fraser University (Canada) and an MA from Uppsala University (Sweden).

Veterinary Medical Writing

SECTION EDITOR



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Editorial

For this issue of Veterinary Medical Writing, Cemile Jakupoglu and Jennifer Freymann draw on their expertise in veterinary regulatory writing and put the spotlight on the las-interactive website. This online resource, developed from a platform initially conceived at the Philipps University of Marburg in Germany, is a rich database of information and training in the handling and regulations of animals used in clinical trials. Based firmly on the 3Rs principles

of replacement, reduction, and refinement, these educational resources ensure that anyone involved in the use of animals in clinical trials is kept up to date with the latest advances, which keep animal welfare at the core.

In this edition of From the Horses' Mouth, the keyword is "essential"; not only do we report, at last, on the publication of a global list of essential veterinary medications, but we are also invited to view veterinarians as essential workers, and we hope that is an idea that takes hold.

This edition is also my last one as the section editor. It has been a pleasure to be at the helm for the last three years, but the time has come to inject some fresh ideas and perspective, so I am delighted to hand the baton over to not one, but two, colleagues: Luiza Ventura and Jeff Blair, DVM. I know the section is in very safe hands and I am very excited to see what direction this team of veterinary medical writers takes it in.

Louisa

Spotlight on www.LAS-interactive.de: Information for animal experimentation and a useful resource for veterinary medical writers

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According to the EU Animal Protection Directive (Directive 2010/63/EU)¹, anyone who is involved in animal experimentation needs to be adequately trained. Depending on your role in animal experimentation (i.e., plan and design experiments, perform procedures, and look after and/or humanely dispatch animals), very specific competencies are needed. Online resources are valuable tools to cover the theoretical part of this training; one of them is the website www.las-interactive.de² (Figure 1). LAS-interactive.de combines two platforms: the fee-based training platform LAS campus and the freely accessible platform vtk online. The LAS campus is typically accessed by people who need to obtain proof of mandatory training before they can start working with laboratory animals, and they can get their certification via this platform.



Photo: tiburri (pixabay.com)

Here, we should mention that courses on animal welfare are also offered by other institutions such as FELASA (Federation of European Laboratory Animal Science Associations). In this article, we will focus on the vtk online ("Versuchstierkunde", German for "laboratory animal science [LAS]") platform, which is referred to as the LAS platform. After registration this platform can be

accessed without any fees.

Initially developed at the Philipps University of Marburg, Germany, and founded by DFG (Deutsche Forschungsgemeinschaft), the LAS platform provides in-depth information on different topics related to laboratory animal science in German, English, and French. We feel that the LAS platform can be a helpful source not

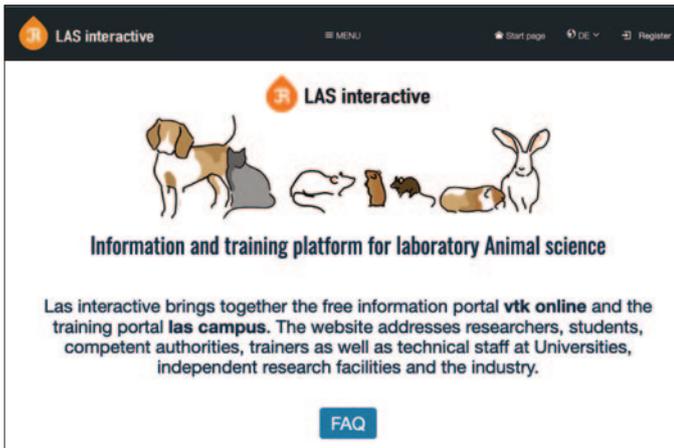


Figure 1. LAS logo including the most common animal species used in animal experimentation. April 1, 2024.

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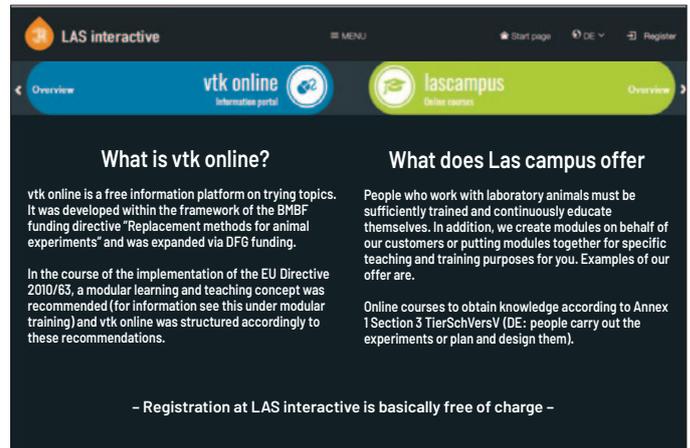


Figure 2. LAS interface with the free information platform vtk online and the fee-based training section "LAS campus". April 1, 2024.

Permission granted by Nicole Linklater, LAS interactive GmbH (personal communication).

only for researchers, students, competent authorities, and technical staff at universities, research facilities, or industry, but also for medical writers, particularly veterinary medical writers.

How to navigate the FREE LAS platform

In the following paragraphs, we will give you an insight into the information provided on the LAS platform. Once you have registered to LAS interactive and logged in, you are welcomed to the LAS interactive homepage.

Media centre

You can choose from numerous educational videos. For example: handling, blood sampling, or substance administration techniques; detailed information on the anatomy of different laboratory animal species in the image gallery; or learning about alternative methods (Figure 2). In the interactive content, you can find information on "who is permitted to work with laboratory animals" according to German and EU legislation.

Training modules

If you are looking for more intensive and detailed training, you can start any of the VTK training modules. Click on "overview" on the blue "VTK online Information portal". This currently offers access to self-learning content divided into core modules that include: national legislation; ethics; animal welfare and management (including pain recognition and euthanasia); function-specific modules (e.g., species-specific minimal invasive procedures); task-specific modules (e.g. anaesthesia, analgesia, and surgery), and additional

modules (e.g., introduction to genetically modified animals). (Figure 3).

You do not have to participate in studies involving animals to benefit from those modules, particularly if you are new to the area of laboratory animal sciences; these modules can be very helpful for your next writing job.

A laboratory animal compendium and speed learning opportunity

No registration is needed to use the LASed learning tool, a subproject of LAS³ or the speed learning⁴ section. The LASed learning tool is a great resource for key data of common laboratory species, and you will find data on: physiology (e.g., body weight, heart and respiration rate); blood parameters (e.g., blood volume, haematology and clinical chemistry); reproduction (e.g., litter size, weaning age, sexual maturity); breeding; as well as a legal requirement for animal husbandry can be compared for any species you are interested in. An example is shown in Figure 4. In the speed learning section,⁴ you can improve your knowledge of mouse histology in the form of interactive quizzes. Different anatomical areas as well as different magnifications are available, and the level of difficulty can be adjusted.

Knowledge improves animal welfare

Profound knowledge and skills are the basis for ensuring high-quality animal welfare, regardless

of the field of research. Through providing training materials and content, websites like LAS-interactive.de improve animal welfare and support the core ethical principle of animal use in biomedical trials. The concept of the 3Rs (**replacement** = methods that avoid or replace the use of animals; **reduction** = methods that minimise the number of animals used per experiment, **refinement** = methods that minimise suffering and improve animal welfare) was first

published by William Russel and Rex Burch back in 1959. It is embedded in EU Directive 2010/63 on the protection of animals used for scientific purposes.

Virtual education material cannot fully replace animals used in training. However, a video can be watched repeatedly until you feel comfortable starting practical training, while the animal in the video was just handled once. Furthermore, a student who has prepared well on the theoretical aspects is more likely to be confident during the practical training, reducing stress for the animals and improving experimental results.

Although we medical writers are typically not practically

involved, we are very likely to be the ones responsible for report writing or publication. A platform like LAS-interactive.de can be a very valuable source for us to improve our knowledge and, by extension, our work involving laboratory animal species, associated regulations, or

Virtual education material cannot fully replace animals used in training. However, a video can be watched repeatedly until you feel comfortable starting practical training.

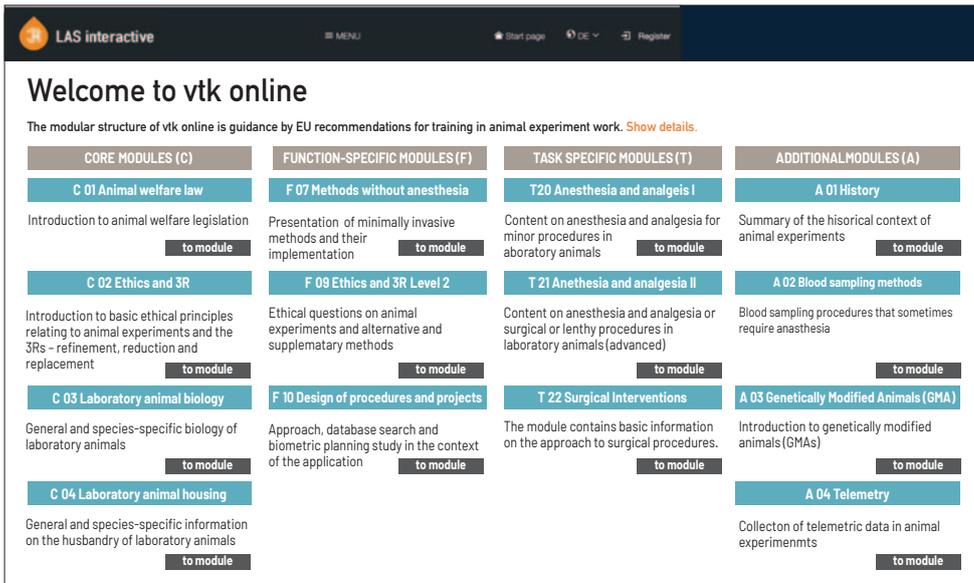


Figure 3. Excerpt of learning modules that are accessible for free, April 2024.

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different experimental procedures.

It is important to point out that other resources are available for medical writers, such as 3R SMART,⁵ an information and training platform for methods to replace and supplement animal experiments, which is aimed at a lay audience as well as scientists and technical personnel. This initiative is financed by the German Federal Ministry of Education and Research (BMBF) and developed in collaboration with the Foundation Veterinary University of Veterinary Medicine, Hanover, and the Philipps University of Marburg, both in Germany. Online resources from other countries were not in the scope of this article. Knowledge on laboratory animal science shall enable medical writers to improve their communication and cooperation with practical investigators with overall positive impact, especially on animal welfare.

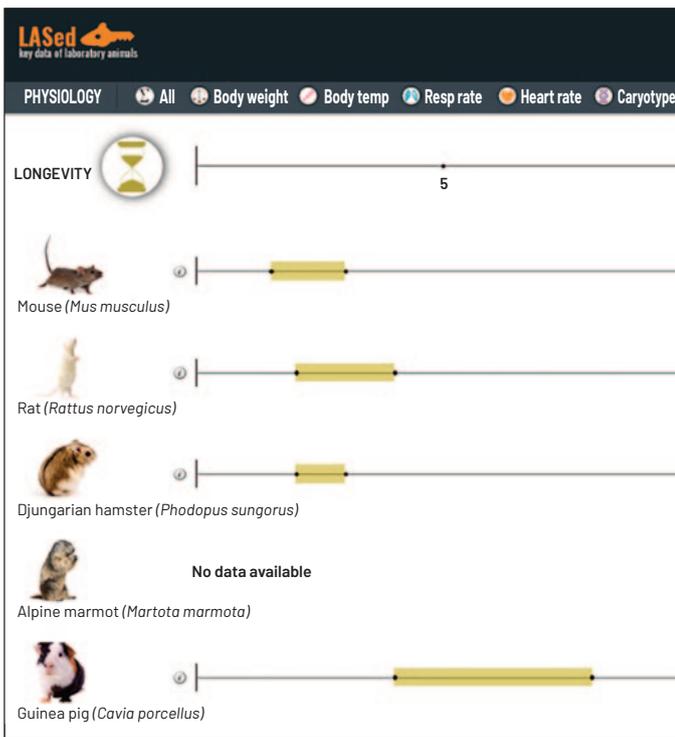


Figure 4. Longevity (in years) of mouse, rat, hamster, marmot, and guinea pig as an example of the data provided in the physiology section of LASed. April 1, 2024.

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References

1. Council of Europe. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. Off J Eur Union L. 2010;276:2. Available from: https://www.uhasselt.be/βmedia/iwnfbcx2/oj_l_2010_276_full_en_txt.pdf
2. LAS-interactive website [cited 2024 Jan 21]. Available from: <https://www.las-interactive.de/index.php?id=6005>
3. LASed learning tool, a subproject of LAS [cited 2024 Jan 21]. Available from: <https://www.las-interactive.de/bdt/index.html>
4. Speed learning tool, a subproject of LAS [cited 2024 Jan 21]. Available from <https://www.las-interactive.de/fileadmin/speedlearning/>
4. 3r SMART Platform [cited 2024 Jan 21]. Available from: <https://www.3r-smart.de/index.php?id=6881&L=2>

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From the Horse's Mouth

The quarterly pick of the news from the veterinary world

During the COVID-19 pandemic, veterinarians around the globe were working above and beyond to maintain animal health and welfare services during lockdown. In many jurisdictions, however, members of the veterinary profession (except those working in food production) were not designated as “essential workers”. This meant that they were denied certain protections, such as priority testing and early access to vaccines, that other frontline workers were granted. This was despite working with similar risks and under their usual statutory requirements to provide emergency care.

Perhaps, then, The World Veterinary Association's (WVA) latest theme to celebrate 2024 World Veterinary Day on April 27: “Veterinarians are essential health workers”, according to *The American Veterinary Association (AVMA) News* on March 11, 2024, will change society's perspective of the profession. This theme highlights the critical role veterinary professionals play in ensuring public health and safety as a tribute to their efforts in creating healthier communities and environments. According to the WVA, “Veterinarian's competencies must be regarded as an essential and integral part of health at large. The application of veterinary science contributes not only to animal health and well-being but also to humans' physical, mental, and social well-being.”

The World Veterinary Association (WVA) announced the first global list of essential veterinary medicines for food-producing animals on March 18, 2024. This initiative, part of a collaboration between the WVA and the animal welfare organisation Brook,

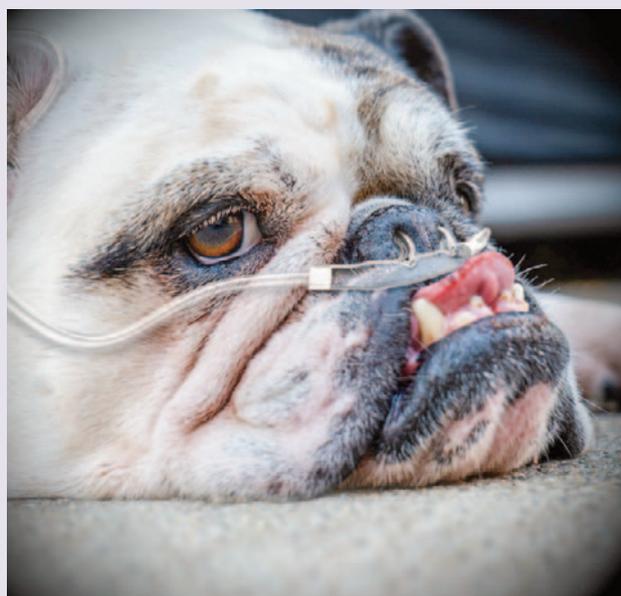
aims to standardise a catalogue of safe and effective medications and vaccines for veterinary use worldwide. Furthermore, it is a tool to combat the growing threat of antimicrobial resistance (AMR) and bolster efforts towards pandemic prevention.

Dr Olatunji Nasir, WVA's Pharmaceutical Stewardship Working Group Chair, stated, “As veterinarians, we are gatekeepers of the next pandemic because of the profound roles we play in the control of zoonoses; this is a responsibility that we share with authorities and agencies in our various jurisdictions. Together, we stamp our feet in the one-health

pathway.” A survey of veterinarians by the World Health Organization (WHO) reveals that 80% of respondents felt that difficulties in obtaining veterinary medicines limit veterinarians' capacity to manage animal health and welfare. The newly released list addresses this challenge, offering a blueprint from countries that will be able to tailor their essential medicines list based on prevalent diseases and pathogens in their respective regions. Such customisation will enhance zoonotic disease control and aid in preventing future pandemics. The list of essential veterinary medicines is now accessible on the WVA's website.

The Royal Society for the Protection of Animals (RSPCA) in the UK has launched a new campaign to raise public awareness about the welfare issues faced by brachycephalic dog breeds, the *Veterinary Times* reported on March 25, 2024. The hard-hitting “Born to Suffer” campaign, which features photos of prone bulldogs and pugs with nasal cannulae fitted for oxygen supplementation, is intended to persuade would-be brachycephalic dog owners to reconsider their choice of pet and, therefore, drive down the demand for dogs with this extreme morphology. Vanessa Howie, the RSPCA's head small animal veterinarian, has cited the “relentless exposure” of dogs with flattened faces being used in social media and marketing so that it has “normalised what is totally abnormal”.

In addition to raising awareness amongst the pet-owning public, the charity will also challenge policymakers to make commitments to introduce tougher legislation to help reduce the burden of health problems experienced by these breeds.



BORN TO SUFFER

Extreme breeding - I'm out!
Join us in shedding light on the plight of Pugs, French and English Bulldogs.



Permission to publish obtained (RSPCA)

Publications

SECTION EDITORS



Maddy Dyer
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ICMJE recommendations update: What's new?

Editorial

Dear readers,

I'm excited to start my new role as editor of this newly named section, Publications, formerly known as Manuscript Writing. EMWA Editor Emeritus Phil Leventhal has led the section for over a decade and written numerous informative, educational, and entertaining articles. Phil has passed the mantle onto me, and since publications are an important part of EMWA, I am pleased to take it.

As editor, I plan to share the interesting things I've learned about publication writing and strategy, which I hope you will find useful. Contributions to this section from other writers are also welcome. In this instalment, I discuss the latest updates from the International Committee of Medical Journal Editors.

Maddy Dyer

Maddy Dyer

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In January 2024, the International Committee of Medical Journal Editors (ICMJE) updated their "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals."¹ The updates relate to authorship, artificial intelligence (AI), environmental sustainability, funding, ethics, and referencing. The following italicised quotes are all taken from the ICMJE recommendations.

Why authorship matters

- "Editors should be aware of the practice of excluding local researchers from low-income and middle-income countries (LMICs) from authorship when data are from LMICs. Inclusion of local authors adds to fairness, context, and implications of the research. Lack of inclusion of local investigators as authors



should prompt questioning and may lead to rejection."¹

Before I read this, I hadn't heard of the practice of excluding local researchers. Conducting primary research in another country and publishing it without recognising local researchers and infrastructure is apparently known as "parachute", "parasitic", or "helicopter" research.²⁻⁴ It typically occurs in LMICs,^{3,5} defined as countries with a gross national income per capita of \$13,845 or less in 2022.⁶ For example, one review found that 20% of African COVID-19 publications had no African authors.⁷

Individuals who meet all four ICMJE criteria for authorship should be identified as authors.⁸ Excluding local researchers from authorship is unethical and unacceptable. Do medical writers also have a responsibility to question authors about this practice? Perhaps we could check if there is local representation on applicable manuscripts and ask authors whether local researchers have been given the opportunity to meet the ICMJE authorship criteria. We can remind authors that not including local researchers may cause the manuscript to be rejected. The focus should be on promoting

equity in research collaborations and avoiding "tokenism", defined as the practice of making perfunctory or symbolic efforts to engage communities.⁹⁻¹¹

How work conducted with the assistance of AI technology should be acknowledged

- "Use of AI for writing assistance should be reported in the acknowledgment section."¹
- "For example, if AI was used for writing assistance, describe this in the acknowledgment section. If AI was used for data collection, analysis, or figure generation, authors should describe this use in the methods."¹
- "Authors who used AI technology to conduct the study should describe its use in the methods section in sufficient detail to enable replication of the approach, including the tool used, version, and prompts where applicable."¹

The ICMJE doesn't clarify how AI for writing assistance should be reported in the acknowledgment section. Currently, the recommended description relates to how AI is used for study conduct rather than writing. Most publishers favour transparency. Check the publisher's AI

policy. For example, the AI policy of the *British Medical Journal* states that “transparent declaration includes a description of what AI technology was used (the name of the technology), why this AI technology was used (the reason for its use), and how the AI technology was used (what the task of the technology was). Consider including a summary of the input, output, and the way in which the AI output was reviewed on the part of the authors as supplementary files or additional information for the editor to review.”¹²

Use of AI in the review process

- “Editors should be aware that using AI technology in the processing of manuscripts may violate confidentiality.”¹
- “Instructions to reviewers should include guidance about AI use.”¹
- “Reviewers must request permission from the journal prior to using AI technology to facilitate their review.”¹

AI can help journal editors identify reviewers or perform initial quality control for submitted manuscripts.¹³ However, the value of AI in peer review is currently less clear.¹³ Peer review is intended to maintain scientific integrity.¹⁴ Peer reviewers must evaluate the quality, clarity, originality, and importance of manuscripts submitted for publication. I’m not aware of any journals that have gone as far as banning the use of AI tools for peer reviews of manuscripts. However, one research funder, the US National Institutes of Health, banned the use of AI tools for peer reviews of grant applications.¹⁵

This update left me with lots of unanswered questions.

1. Why might a peer reviewer use AI technology? They are invited to review a manuscript specifically for their expertise and opinion. Peer reviewing is voluntary, and individuals can decline invitations if they don’t have time. Perhaps AI tools could help peer reviewers to write more punctual, readable, and (in some cases!) respectful reviews.
2. Can we trust the quality of AI-facilitated reviews? We should be careful as using AI tools can lead to errors, biases, and breaches of confidentiality.¹⁶
3. In which circumstances might an editor grant permission to use an AI tool or not?
4. Would it also be important for editors to get permission from the authors of the manuscript?

Excluding local researchers from authorship is unethical and unacceptable.

Medical publishing and carbon emissions

- “Medical publishing contributes to carbon emissions that exacerbate climate change, which is an urgent threat to human well-being and planetary health. Editors, publishers, journal owners, and other stakeholders should work together to develop immediate strategies to reduce carbon emissions, with a goal toward achieving net zero carbon emissions.”¹

Improving environmental sustainability is an important goal, and we all have a role to play. However, the ICMJE doesn’t suggest how to achieve this. The obvious strategy that springs to mind is reducing journal printing and distribution. According to one estimate, printing 50,000 journal copies equals approximately 450 felled trees, 17.25t of CO₂ emissions during paper production, 6.560t of CO₂ emissions during print production, and 1.995t of CO₂ emissions during distribution if copies were mailed 500km by truck.¹⁷

To reduce waste, some publishers and journals have changed their models for print journals. For example, the Royal College of Psychiatrists and EMWA follow an “opt in” model; print copies are only sent to subscribers who want them.^{18,19} Some publishers have gone further by moving selected journals to online only.¹⁷

Acknowledgement of funding support

- “Disclosure of potential conflicts of interest is distinct and extends beyond direct support for this work. Within a manuscript, the funding statement should include only direct support of the work described. Support for an individual’s contribution for the work should be reported as such. General institutional support for an author’s time on the work should be distinguished from direct overall funding of the work. An appropriate funding statement might be: ‘This study was funded by A; Dr F’s time on the work was supported by B’.”¹
- “A medical journal should explicitly state its governance and relationship to a journal owner (e.g., a sponsoring society).”¹

These updates relate to transparency. The first point reminds us that funding and conflicts-of-interest statements are different. Within the funding statement, funding for the research (direct support) and funding for the researcher (indirect support) should be distinguished.

The second point is important because the publisher and sponsoring society of a journal can affect its reputation, and therefore an author’s decision to submit a manuscript to that journal.²⁰

Protection of research participants

- “All authors should seek approval to conduct research from an independent local, regional, or national review body (e.g., ethics committee, institutional review board) and be prepared to provide documentation when requested by editors.”¹

Which documents might be requested and when? Looking at publishers’ guidelines, the ICMJE may be referring to submitted ethics application forms, approval letters, and copies of informed consent forms.^{21,22} These documents might be requested if the editor suspects an ethical or legal issue with the research, or doubts the authenticity of the ethics approval statement in the submitted manuscript.^{21,22}

What can medical writers do to help? We can at least ensure that ethics approval and consent statements are complete. For example, reporting the name of the ethics committee, the date and reference number of the ethics approval, and the type of consent obtained from participants.

Reference citations

- “References should be made to published articles rather than to abstracts whenever possible.”¹

The final update probably isn’t news to most of us. Citing a published article is preferable to citing a conference abstract because the published article has been peer reviewed, includes more information, and reports final rather than preliminary results.²³

Conclusions

In summary, the key ICMJE updates relate to how AI tools are used and reported, why inclusive authorship matters, and why publishing should be more environmentally friendly. I welcome these updates, which aim to make publications more transparent, ethical, and sustainable.

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Disclosures and conflicts of interest

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References

- International Committee of Medical Journal Editors. Up-dated ICMJE recommendations (January 2024) [cited 2024 Mar 11]. Available from: https://www.icmje.org/news-and-editorials/updated_recommendations_jan_2024.html
- The Lancet Global Health. Closing the door on parachutes and parasites. *Lancet Glob Health*. 2018;6(6):e593. doi:10.1016/S2214-109X(18)30239-0
- Heinz E, Holt KE, Meehan CJ, et al. Addressing parachute research and removing barriers for LMIC researchers in *Microbial Genomics*. *Microb Genom*. 2021;7(10). doi:10.1099/mgen.0.000722
- Odeny B, Bosurgi R. Time to end parachute science. *PLoS Med*. 2022;19(9):e1004099. doi:10.1371/journal.pmed.1004099
- Morton B, Vercueil A, Masekela R, et al. Consensus statement on measures to promote equitable authorship in the publication of research from international partnerships. *Anaesthesia*. 2022;77(3):264–76. doi:10.1111/anae.15597
- The World Bank. World Bank Country and Lending Group [cited 2024 Mar 11]. Available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>
- Naidoo AV, Hodkinson P, Lai King L, et al. African authorship on African papers during the COVID-19 pandemic. *BMJ Glob Health*. 2021;6(3). doi:10.1136/bmjgh-2020-004612
- International Committee of Medical Journal Editors. Defining the role of authors and contributors [cited 2024 Mar 11]. Available from: <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>
- Tuyishime H, Hornstein P, Lasebikan N, et al. Authorship distribution and under-representation of sub-Saharan African authors in global oncology publications. *JCO Glob Oncol*. 2022;8:e2200020. doi:10.1200/GO.22.00020
- Miles S, Renedo A, Marston C. Reimagining authorship guidelines to promote equity in co-produced academic collaborations. *Glob Public Health*. 2022;17(10):2547–59. doi:10.1080/17441692.2021.1971277
- Hahn DL, Hoffmann AE, Felzien M, et al. Tokenism in patient engagement. *Fam Pract*. 2017;34(3):290–5. doi:10.1093/fampra/cmw097
- BMJ Author Hub. AI Use [cited 2024 Mar 14]. Available from: <https://authors.bmj.com/policies/ai-use/>
- Kousha K, Thelwall M. Artificial intelligence to support publishing and peer review: A summary and review. *Learn Publ*. 2023;37(1):4–12. doi:10.1002/leap.1570
- Wiley Author Services. What is peer review? [Cited 2024 Mar 14]. Available from: <https://authorservices.wiley.com/Reviewers/journal-reviewers/what-is-peer-review/index.html>
- Lauer M, Constant S, Wernimont A. Using AI in peer review is a breach of confidentiality [cited 2024 Mar 14]. Available from: <https://nexus.od.nih.gov/all/2023/06/23/using-ai-in-peer-review-is-a-breach-of-confidentiality/>
- Leung TI, de Azevedo Cardoso T, Mavragani A, et al. Best practices for using AI tools as an author, peer reviewer, or editor. *J Med Internet Res*. 2023;25:e51584. doi:10.2196/51584
- Cambridge University Press. Reducing print [cited 2024 Mar 16]. Available from: <https://www.cambridge.org/core/about/environment-and-sustainability/reducing-print>
- Royal College of Psychiatrists. A change to our print journals [cited 2024 Mar 16]. Available from; <https://www.rcpsych.ac.uk/about-us/publications-and-books/journals/opt-in-print>
- European Medical Writers Association. Medical Writing - March 2023 issue available now! [Cited 2024 Mar 16]. Available from: <https://www.emwa.org/news/medical-writing-march-2023-issue-available-now/>
- Suiter AM, Sarli CC. Selecting a journal for publication: criteria to consider. *Mo Med*. 2019;116(6):461–5.
- Sage Publications. Editor guidelines: Ethics approval and Informed consent statements. 2024 [cited 2024 Mar 16.] Available from: <https://us.sagepub.com/en-us/nam/editor-resources>
- Frontiers. Research ethics checks: Guidelines for editors and reviewers. 2024. [cited 2024 Mar 16]. Available from: https://www.frontiersin.org/files/pdf/Research%20ethics_guidelines%20for%20editors%20and%20reviewers.pdf
- U.S Department of Health & Human Services. Relying on an abstract or a preliminary or version of a paper while citing the published version [cited 2024 Mar 16]. Available from: <https://ori.hhs.gov/relying-abstract-or-preliminary-or-version-paper-while-citing-published-version>



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Editorial

In my first editorial as section editor for *Freelancing*, I'm delighted to have Laura Kehoe share her achievements as the previous section editor and chair of the Freelance Business Group (FBG).

During her tenure, Laura and the FBG team have made incredible strides in representing the

freelance community at EMWA, providing us all with the tools to grow, learn, and network. From the Freelance Business Forum to the Business Survey, passing along the Freelance Directory, all major activities are highlighted in this article that spans 6 years (!) of considerable challenges, such as going virtual during the COVID-19 pandemic.

Taking over Laura's functions in 2024, I hope I do a good job in my own way. I'm comforted to know the FBG team and other EMWA members will help me along the way and I wish Laura all the best in her future endeavours. Happy reading!

Adriana Rocha

Navigating my freelance journey while driving EMWA freelance activities

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I didn't plan to become a medical writer, but then again who does? It wasn't, at the time, a career on the list of things to do after a PhD. Shortly after completing my PhD, I got a job as an editorial coordinator for a high-impact journal in hepatology, learning all the intricacies of the publication world. It was in this role that I found EMWA and went to my first conference in Brussels (2016). I must admit, I felt a bit of imposter syndrome going to a medical writing conference when I was "just" editing. Oh, how I was wrong. I was amazed at the diversity of medical communicators at the conference and all the interactions I had gave me the realisation that there were multiple opportunities to be had.

A year later, I left my job and set myself up as a freelancer, not knowing what to expect and where this path would lead, but I was excited. I signed up to the next EMWA Conference (Cascais 2017) and the Freelance Business Forum (FBF). Shortly after registering, I received a message from Satyen Shenoy asking if I'd be interested in being a table leader for the forum. My initial thought was dread. How could I help others in freelancing; I've only just stepped into this field? Satyen reassured me that the event is very relaxed, and people want to simply share

ideas, ask questions, offer solutions, and help guide other freelancers. I decided to do it. And so, my freelance journey with EMWA had begun.

From table leader to FBG chair

Satyen quickly saw my enthusiasm and positive attitude towards freelancing and invited me to become a committee member of the Freelance Business Group (FBG) in 2018 at the Barcelona meeting. There, I met the other committee members; Allison Kirsop, Carola Krause, and George Xinarianos. Because of my background working in publications, I quickly took on the Out On Our Own (OOOO) section for the *Medical Writing (MEW)* journal, which led me to work with some amazing authors who were freelancers or business owners working with freelancers. Every story I have received over the years has been inspirational or educational and I hope this provoked a similar feeling in our readers.

I stepped into the FBG chair role when Satyen had a bigger item on his agenda – becoming EMWA vice president and then president. In the five years I've been the chair, I've had the pleasure to work and welcome several wonderful people to the FBG committee, such as Mariana Rickmann, Irene Farré, Diana Ribeiro, Sónia Costa, Beate Walter, Johanna Chester, and Adriana Rocha. Clearly, I'm a feminist!

Freelance achievements for EMWA

Over the years, we have launched several objectives and initiatives to improve freelance

activities, communications, and events for EMWA. Of course, since 2019 to today, we had a little hurdle to jump over in the form of COVID-19, which left all us volunteers stretched thin. Life as a mum, teacher, business owner, and volunteer became particularly challenging. During this turbulent time, our volunteer activities for the FBG waned slightly but we picked it up when things returned to "normal". Some of the things we've worked on are summarised below.

Freelance directory

When I first registered myself in the freelance directory, the information we could provide was very limited, making it difficult to be found by potential clients. The FBG committee, specifically Allison Kirsop, designed a more detailed profile option for the freelancers to fill in, giving them more opportunities to explain their expertise, academic and professional backgrounds, languages, etc. With the rise and success of professional platforms like LinkedIn, the freelance directory needs a revamp once again, specifically how it can be used by EMWA freelancers and clients searching for their ideal freelancer. Watch this space!

Virtual and face-to-face FBF

The FBG committee organises the FBF at every EMWA conference: an informal event where people can freely engage with one another, ask questions about freelance life, and network. The face-to-face FBFs are always a lively affair, with



many groups gathering around roundtables to discuss current freelance topics. The conversations often flow freely with the help of wine and beer served to the attendees! Table leaders are key for these roundtables to keep the topic on point and to give a summary of the discussions at the end of the forum.

With COVID-19 preventing us from meeting in person during 2020–22, we had to decide how to run the FBF online. This was going to be hard to achieve in a virtual setting, but we managed it. After initial presentations by myself and a guest speaker, we went into breakout rooms each with a different freelance topic or theme. We encouraged people to come off mute and interact. People were allowed to freely move from one breakout room to the next. It was so successful that we continue with this setup today in the virtual November conferences, giving freelancers that much-needed opportunity to talk and network with other freelancers.

The FBF is my personal highlight of the conferences due to the friendly and stimulating conversations I have every time. So, if you are a freelancer or interested in becoming one, then register for the next FBF, it's free for registered members. Equally, if you want to be a table leader and discuss a specific topic, then get in touch with the team at freelance@emwa.org.

Out On Our Own (now known as "Freelancing")

Since 2018, I have thoroughly enjoyed being the section editor of OOOO. As well as publishing personal journeys of other freelancers, I also aimed to find authors who could provide readers with practical and easy to access tips on being a freelancer. I hope I achieved that. In fact, over the last six years, we've had a total of 28 authors publish their experiences and guidance to inspire

and encourage other freelancers. I have been amazed at the generosity and enthusiasm of each author. Whether I reached out personally to them, or they approached me, every time the collaboration was fluid and productive. I thank each and every one.

Freelance Business Survey

Back in 2018, when I embarked on the FBF committee path, Satyen had just launched the Freelance Business Survey. Due to multiple reasons, we never got the results published. However, when Johanna Chester joined the committee at the end of 2022, she was as enthusiastic as me to run a new survey. We worked to create a more up-to-date survey addressing relevant issues on work-life balance and COVID-related questions and launched the survey in January 2023. With a quick turnaround, Johanna analysed the results and compared them to the 2018 data; we then wrote an article and published it in the Freelance issue of MEW in June 2023 as "The Seventh Freelance Business Survey: The freelance landscape 2018-2023". This survey offers insights into how freelancers are advertising their services, finding clients, pursuing their continued professional studies, hourly rates, their strategies to de-stress and handle the work-life conundrum, and so much more. Of course, data should be taken lightly, as demographics and individual responses create some diverse results. So, if you haven't already seen it, you can find it on the journal website in the June 2023 issue at <https://journal.emwa.org/freelancing/>.

Special Freelancing issue in MEW

With the editor-in-chief of MEW, Raquel Billones, and myself recognising that a special issue on freelancing was sorely needed, I teamed

up with Satyen again to guest edit one. Together, we approached various freelance medical communicators from around the world and invited them to share their expertise in feature articles. Again, I was amazed at the enthusiasm of each author we contacted. In total, we compiled an issue of nine feature articles plus the survey results. These ranged from soft skills needed as a freelancer, hybrid freelancing, mentoring and coaching, to book reviews that support people in their freelance journey. We hope that this issue offers some useful and essential tips for new and experienced freelancers. If you haven't read it, search the June 2023 issue of MEW.

LinkedIn Freelancing Group

For many years, EMWA members have been asking the FBF to create a special group where EMWA freelancers can ask each other questions or share information, and not just wait for the FBF each year. In May 2023, we decided to create a LinkedIn private group for any EMWA members interested in freelancing – known as the EMWA Freelance Business Forum online which can be found at <https://www.linkedin.com/groups/12769131/>. People are just discovering the group, but we already have 159 members. Our plan is to make this an active group, with regular posts and events if possible. So, if you haven't already joined, send a request to join and ideally include a little message with your EMWA member number to prove you're an EMWA member. And, if you're already a member, start sharing and chatting!

Future endeavours

The reason, which I've yet to explain, as to why I'm writing this summary article on the FBF achievements over the years is because I have handed the FBF chair baton over to another enthusiastic freelancer, Adriana Rocha, and I will gently step away from the committee in the coming months. It's time for a refresh, Adriana has her own ideas and initiatives she'd like to work on with the committee, and she will bring an exciting and fresh approach to EMWA and freelancing.

For me, my journey continues with new opportunities. I will continue to be involved with EMWA activities for years to come, but for now, I would like to thank everyone I worked with over these six years, thank EMWA and the EC for enduring me for so long, and to all the wonderful authors, committee members and table leaders who made my job a pleasure.

Happy freelancing!

Regulatory Matters

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Editorial

In the ever-evolving landscape of regulatory submissions, where deadlines loom large and the demand for precision is paramount, the role of a skilled project facilitator cannot be overstated. Their ability to navigate the complex web of requirements and streamline the submission process is not just beneficial but

often indispensable for medical writing teams operating under extreme time constraints.

A symbiotic partnership between the medical writing team and a project facilitator allows writers to focus on their core task – writing. In this issue of *Regulatory Matters*, Yoko Komatsuzaki and Julia Forjanic Klapproth shed

light on how project facilitators serve as central points of contact for the medical writing team and how they foster unity among team members, develop standard ways of working, and ensure project objectives, timelines, budgets, resourcing, and metrics are well-defined and adhered to.

Clare Chang

In regulatory submission writing, a project facilitator is the yin to a medical writer's yang

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Abstract

Authoring and reviewing complex, parallel regulatory submission documents under extremely condensed timelines demands significant effort from the medical writing team. However, a skilled project facilitator can alleviate some of this burden by offering support and assistance across the entire spectrum of regulatory submission writing activities. This symbiotic partnership not only reduces the overall workload for the medical writing team but also enables them to focus on their core writing tasks, ultimately enhancing the quality of their work and reducing stress. Additionally, it provides an avenue for the project facilitator to establish standard ways of working and best practices, which can further enhance efficiency and consistency across multiple submissions.

Regulatory submission writing is an enormous and costly endeavour that

begins during preclinical development and continues even after the product has been approved. Marketing applications encompass a series of documents that, combined, may exceed several thousand pages. These include clinical and non-clinical study reports, manufacturing information, and administrative reports.¹

These documents are subject to a stringent set of regulatory requirements and deadlines imposed by the health authorities to ensure the safety and efficacy of products under review. Whether the documents are produced internally or outsourced to a service provider, the medical writing team collaborates within a cross-functional framework and often interfaces with external stakeholders.

In this intricate landscape, project management permeates every facet of preparing a regulatory submission. Project managers are needed at each stage, from initial planning of the nonclinical and clinical development programs by coordinating the writing of the myriad of documents included in a submission, to supporting interactions with the health authorities, and

continuing throughout the lifecycle of the marketed product.

The project facilitator may serve as a central point of contact for logistical and overarching concerns among the medical writing team.

Today's demands on lead medical writers

The medical writing activities required to prepare these regulatory documents represent a microcosm of all these project management activities. Over the last 20 years, the role of a lead medical writer has become ever more complex, developing far beyond writing itself. For example, the following activities must be maintained in addition to drafting, reviewing, and revising the Module 2 summaries for a

regulatory submission:

- A project plan must be created and maintained to keep track of the numerous interdependencies.
- Writing resources must be juggled to handle additional writing activities (e.g., owing to the addition of new analyses, sometimes even new studies, and supporting reports).
- Subject matter experts must be corralled (in the face of many competing priorities) to agree on content.
- Messaging plans must be developed and kept up to date as new ideas arise.



A competent and seasoned project facilitator can make all the difference when it comes to the efficiency with which a regulatory submission is prepared and getting it done on schedule.

- Any quality control activities must be planned, performed, and implemented in the documents.

Monitoring these activities can consume a substantial portion of time, diverting the writer's attention from their core responsibility of producing high quality documents.

Project facilitator as a partner to the medical writing team

In this context, a new role has evolved to take some of these responsibilities of the medical writer facilitating their ability to concentrate on the writing itself – particularly in crunch periods when new data are arriving and the writer needs to be focused on having conversations with the subject matter experts to tease out the story to be told. We have termed this specific branch of project management, designed to support medical writers on these complex projects, project facilitators.

The project facilitator may serve as a central point of contact for logistical and overarching concerns among the medical writing team. While not directly involved in document authoring,

they actively participate in every phase of the project, including study start-up, authoring support, review monitoring, quality control, publishing, and project close-out coordination. This role extends beyond mere coordination. They are also valuable at fostering unity among team members by developing trust, flexibility, cooperation, and collaboration within the cross-functional team. They are partners with the lead medical writers, working in tandem to ensure nothing falls through the cracks.

To this end, project facilitators aid their team in ensuring that projects are well-defined with clear objectives, timelines, budgets, resourcing, and metrics. A competent and seasoned project facilitator can make all the difference when it comes to the efficiency with which a regulatory submission is prepared and getting it done on schedule. In addition to having a solid understanding of all standard operating procedures (SOPs), best practices, and work instructions, they must also possess leadership skills that influence the interactions between the cross-functional team. The role of a project facilitator demands a broad variety of skills, including building interpersonal relationships,

critical thinking, analytical abilities, budgeting, decision-making, and problem-solving. As Peter Reichert, a leader in the pharmaceutical field, explains, project facilitators can be likened to conductors leading an orchestra, where the project team are the musicians.² Just as conductors must be familiar with the entire musical score and anticipate challenging parts, project facilitators need to understand the project's entirety, recognise potential obstacles, and strategise ways to overcome these. Similar to how conductors may improvise or modify the performance, project facilitators may need to help the team see when to adapt and adjust the project as it proceeds.

In terms of facilitating communication across the project team, the project facilitator can assist in keeping team members connected. They are in regular communication with the medical writers working on the project and can see tasks where they need a helping hand, such as setting up meetings or reaching out to team members to get missing source material. They will participate in key meetings such as the kick-off meeting, which is a chance for the project facilitator to familiarise themselves with the team and determine pre-

ferred communication methods and frequency. They may also use this time to set goals and priorities, working closely with the project team early in planning to obtain their input on all major decisions. Through this process, they will get to know the team better and establish the standard ways of working. The project facilitator can make note of team dynamics, training or knowledge gaps, and even mentoring opportunities for team members new to a submission.

Cornerstones of the project facilitator role

As submission projects get into full swing, they require constant and effective collaboration between medical writers and a diverse, multi-disciplinary team comprising clinical, statistical, regulatory, safety, and other functional experts. Project facilitators play a crucial role in supporting the medical writing teams by focusing on the following six key activities.

1. Creating and maintaining project timelines

Helping a team stay focused on timelines ensures the project stays on course. The project facilitator diligently monitors the progress of the timeline throughout the authoring, review, and approval periods and, together with the medical writing team, flags up changes in scope that may result in timeline shifts. They will recognise deviations from the plan (when the rest of the team may be focused on other things) and act swiftly to develop contingency plans that bring the project back on track. They will organise meetings between the writers and the key stakeholders to renegotiate the timeline and make decisions in a timely manner. They are often tasked with providing the revised project timelines to the project team promptly.

2. Tracking project budget status

A review of milestones in parallel with the budget on a regular basis can illuminate areas of low or high efficiency. The project facilitator continually monitors the budget throughout the life of the project and assesses any impacts on the budget due to changes in scope, timelines, or resourcing. If the required resources will cost more than the anticipated amount, they will discuss with the relevant stakeholders and take appropriate action. This may involve developing a revised cost plan.

3. Monitoring changes in resources

Active engagement helps teams achieve maximum effectiveness. The project facilitator maintains a comprehensive resourcing plan throughout the duration of the project, detailing the roles and responsibilities of each team member. They proactively identify and help address any resourcing bottlenecks resulting from competing priorities, mediating discussions within the medical writing team to balance workloads and prevent burnout. If adjustments to resources are needed, they may assist the writers in organising a thorough handover to ensure a seamless transition. Considering that medical writers often exceed a 40-hour workweek while managing multiple documents simultaneously, the expertise of a skilled project facilitator is essential in effectively coordinating resources.

4. Facilitating cross-functional communication

Clear communication is imperative for teams to thrive. The project facilitator maintains several open lines of communication with the team, utilising formal check-in meetings and informal chats to ensure that all team

members are kept informed about project details such as timelines, budgets, resources, and pending deliverables. They aid in strategic planning by organising reviews and comment resolution meetings, clarifying the timing and roles for each team member. Recognising the time constraints faced by everyone, they ensure appropriate involvement of individuals in each step. Emphasising efficiency, they encourage teams to limit the number of reviewers per document and consolidate feedback into one set of comments per function. If necessary, the project facilitator can engage senior management to enforce these guidelines. As the project nears completion, they may assist in coordinating efforts with the quality control and publishing teams, confirming timelines, deadlines, and source document availability to alleviate the burden on the medical writer.

5. Optimising the delivery of necessary inputs and outputs

Medical writers must possess the ability to sort through vast amounts of data, extract information from various sources, reconcile differences of opinion, and deliver well-written documents. With a firm understanding of the interdependencies within a submission, the project facilitator can aid the medical writing team in obtaining all necessary inputs from the subject matter experts on an ongoing basis (e.g., literature, new analyses, and review comments). Additionally, they facilitate the timely delivery of drafts for review or approval and oversee progress to ensure adherence to deadlines. Weekly check-in meetings provide a platform for collaborative discussions among the team regarding these inputs and outputs.

New Special Interest Groups

Welcome to our new special interest groups!





Adding a project facilitator's skillset to medical writing activities can help teams achieve maximum effectiveness.

6. Assisting the medical writing team with risk management

A close examination of the issues and risk that impact productivity is the first step in troubleshooting and reaching resolutions. The project facilitator invests time in identifying and understanding risks to the successful completion of the project. By monitoring all changes as the project evolves and working closely with the medical writing team to understand their needs and ensure these are met, they proactively address resourcing constraints and bottleneck situations and any other concerns as they arise. Keeping the end in mind, namely, the timely submission to a health authority, any risks impacting this goal need to be identified and mitigated. Working with the medical writers and clinical and regulatory teams to address these situations, the project facilitators can help avoid or overcome these risks.

Another area the project facilitator can support the medical writers and project team with is the

coordination and running of a "lessons learned" meeting after a submission is complete. They can keep a running tab of issues that arise during the project and use these as a starting point for discussion during the meeting. As they were monitoring progress throughout the project, they are in a good position to recognise both efficient and problematic areas, and the project facilitator's perspective can help maintain balance in this conversation. Emphasising positive aspects boosts team morale and engagement. Striking a balance between addressing issues and acknowledging successes fosters a collaborative and motivated team.

Conclusion

The addition of a project facilitator's skillset to medical writing activities can help teams achieve maximum effectiveness. The project facilitator's ability to engage stakeholders early in the submission process, manage priorities, build consensus, and create an environment that embraces change has a profound impact on team effectiveness. As projects have grown more

complex, with more stakeholders involved, more regulations to consider, and a general push to have drugs reach the patient sooner, their contribution is a valuable addition to medical writing teams.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

References

1. Joubert S. FDA regulatory submissions: a primer. Northeastern University Graduate Programs. 2018 [cited 2024 Jan 26]. Available from: <https://graduate.northeastern.edu/resources/fda-regulatory-submissions-overview/>
2. Wilken K. The role of project managers in pharma. Parenteral Drug Association (PDA) Newsletter. 2019 [cited 2024 Jan 26]. Available from: <https://www.pda.org/pda-letter-portal/home/full-article/the-role-of-project-managers-in-pharma>

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The Crofter: Sustainable Communications

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Editorial

The Walrus and the Carpenter

Were walking close at hand;

They wept like anything to see

Such quantities of old debris:

"If this were only cleared away,"

They said, "it would be grand!"¹

Greetings from your new Crofter co-section editors! We have taken liberties with Lewis Carroll's humorous poem "*The Walrus and the Carpenter*". In the 1871 original, the poem's eponymous protagonists are disappointed with the "quantities of sand" at the seaside. Modern-

day beachgoers may nowadays weep to see plastic debris pebbling the shore. Indeed, EMWA member Catarina Leitão was so shocked by the amount of plastic waste she encountered on a Costa Rican beach holiday in 2015, that it sent her on an enduring journey of discovery and "down the rabbit hole" of sustainability.

In her article "How close are we to sustainability?," she tells of her involvement in non-governmental organisations focusing on environmental clean-ups and a circular economy and describes the challenges she unearthed in digging deeper. In her interview "Beautiful

Flower Breathes: beyond an environmental project" with Cátia Godinho, she presents the inspiring story of how the creation of an urban agroforest brought a community closer together and breathed a new spark into her writing.

Sarah and Louisa

Reference

1. Adapted from Carroll L. *The Walrus and the Carpenter*. Poetry Foundation. 1871 [cited 2024 March 16]. Available from: <https://www.poetryfoundation.org/poems/43914/the-walrus-and-the-carpenter-56d222cbc80a9>

How close are we to sustainability?

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Abstract

I have always loved nature. When I was a kid, I preferred watching wildlife documentaries to cartoons. Those documentaries taught me about the diversity of life and landscapes and the need to preserve and respect nature. Recycling, avoiding consumerism, and using public transport have always been some of my actions to protect the environment. However, in 2016, I felt the need to volunteer at non-governmental organisations (NGOs) dedicated to sustainability and to understand sustainability strategies being implemented at a macro level. I discovered how complex sustainability can be. Here, I share my discoveries.

Motivation for volunteering in non-governmental organisations

The call to get actively involved in sustainability projects resulted from a trip to Costa Rica in December 2015. There, I saw breathtaking landscapes and luxuriant nature, but also plastic waste on the beaches where there was greater tourist pressure. And it hit me that we, nature-loving tourists, were contributing to this plastic waste and the destruction of nature (we drank bottled water and stayed in newly-built tourist accommodations). I thought about the Portuguese beaches back at home, which – whilst not to the same extent – were also being colonised by plastic.

Back in Portugal, I started to work with Ocean Alive,¹ a non-governmental organisation (NGO) focused on changing behaviours and protecting the oceans and the seagrass meadows, which are home to many species and sequester large amounts of CO₂. As a volunteer, I was first involved in cleaning up the banks of the river Sado, and later in raising awareness of the negative impact of plastics on the ocean.

Months later, in an attempt to find out more about how society could move towards sustainability, I discovered the concept of circular economy and joined the Circular Economy Portugal Association,² where I volunteered at the Repair Café (a project to prevent electronic

waste)³ and in the Beautiful Flower Breathes project (a project to build an urban agroforest; please read my interview with its leader Cátia Godinho, below, to find out more).⁴

Circular Economy Portugal Association's founder Lindsey Wuisan, a Dutch expert in circular economy policies, passed on her knowledge and triggered my curiosity about strategies driving a possible transition towards sustainability. However, my research has led me to realise that many current solutions that alleviate certain issues, in turn, aggravate others.

Plastic versus biodegradable materials

My initial work as a medical writer involved covering medical congresses. Over the years, I saw the transition away from plastic cups, plates, cutlery, and bags towards paper or bamboo cups, plates, cutlery, and bags, in a bid to make these events more sustainable. I was curious to know more about the advantages of these changes, but my findings were unexpected.

Plastic, invented in the 19th century, has become a ubiquitous part of our everyday lives (in textiles, health appliances, electronic devices, construction, fishing, farming, packaging, etc.). In the 20th century, plastic bags replaced paper bags as a seemingly sustainable measure to reduce felling trees. However, over 99% of plastic is



Photo: Freepik

produced unsustainably from chemicals sourced from fossil fuels.

Nowadays, plastic bags are being increasingly replaced by paper (mainly), cotton, or hessian bags. In parallel, bamboo has become a popular alternative material for disposable plates and cutlery. However, large-scale production of these biodegradable materials often depends on monoculture, an intensive agriculture practice with negative environmental impact.⁵ Monoculture causes loss of biodiversity (only one species is planted and pesticides/chemicals are used extensively), soil erosion (all plants compete for the same soil resources and microorganisms that maintain soil fertility are killed by pesticides), and high-water consumption.

It seems to me that rather than replacing one resource with another, and continuing to produce and use disposable objects, the solution is to reuse durable products. This viewpoint is also being adopted by EMWA, which requested that the 2024 EMWA Spring Conference venue use crockery rather than disposable objects and suggested that participants bring a refillable cup or water bottle and their own paper and pens whenever possible.⁶ I hope that EMWA's example serves as inspiration and becomes a common practice at conferences globally.

Electronic devices and energy

To save paper, digital alternatives are increasingly used and e-billing, e.g., has become common.⁷ Nevertheless, computers, smartphones, data

storage in the cloud, and artificial intelligence (all crucial tools for our work as medical writers) consume energy. It is estimated that telecom networks are going to more than triple their energy consumption with Long-Term Evolution and fifth generation mobile networks.⁸

To reduce the digital carbon footprint, a global commitment is in place to transition from non-renewable to renewable energies, and to transition from fossil-fuelled to electric vehicles.

However, again there is no "easy fix" for sustainability, as renewable energies and electronic devices depend on raw materials obtained from mining activities, which have an effect on the environment. Moreover, the demand for lithium and cobalt (rare metals used in the batteries of many devices, including computers, solar panels, wind turbines, and electric vehicles) is growing rapidly: by 2030, the European Union is likely to need 18 times more lithium and five times more cobalt to cover the demands of electric vehicle batteries than in 2020.⁹ The rush for cobalt is intertwined with human rights violations and environmental destruction in the south-eastern Democratic Republic of the Congo (DRC) where 70–75% of global cobalt reserves are located.¹⁰ Siddharth Kara, the author of the book *Cobalt Red: How the Blood of the Congo Powers Our Lives*,¹⁰ has emphasised that global decarbonisation must not be achieved at the cost of violence against people and the environment in the DRC.

Is recycling the solution?

The United Nations recently noted that electronic waste (e-waste) has become the fastest growing domestic waste category in the world and poses a threat to health and the environment.¹¹ Considerable amounts of e-waste are shipped to low- and middle-income countries where workers dismantle electronic devices to extract valuable materials, exposing both themselves and the environment to toxic residues.¹¹ The Global E-waste Statistics Partnership stated that, in 2019, 53.6 million tonnes of e-waste were produced and only 17.4% were recycled.¹²

Recycling has been advertised as the primary solution to manage waste, but again, the reality is complex and not all materials are easy to recycle. Ongoing research is being developed to improve recycling of hard-to-recycle materials (including those – often plastic-coated – paper cups so beloved of conferences).¹³ However, most plastics remain impossible to recycle or degrade with successive rounds of recycling and thus cannot be perpetually recycled.¹⁴ I continue recycling plastics, but consider this only a short-term mitigation strategy.

Sustainable policies might be better channelled towards the other Rs of waste management – Refuse, Reduce, Reuse, Repair, Repurpose – rather than Recycle. Only this will reverse the events of Earth Overshoot Day, i.e., the date when the consumption of resources and generation of waste by humans exceeded nature's ability to absorb waste and generate new resources.¹⁵ Earth Overshoot Day was attained on August 2, 2023,¹⁶ and, although the trend has flattened in recent years, reaching an equilibrium between resource consumption and nature regeneration remains a distant goal.

How can we get closer to sustainability?

To me, it starts with the awareness that sustainability implies behavioural changes rather than changes in resource exploitation. We all have the power to make individual changes. However, sometimes our will is hampered by external constraints. For example, I have sometimes been unable to repair or upgrade electronic devices either because replacement parts were no longer produced or the device was designed to prevent upgrading. At other times, high cost and long repair delays (due to the lack of components in stock and a shortage of repair specialists) have led me to buy a new device. The good news is that policies are changing: in 2023, the European Commission introduced measures to make repairs easier and more attractive to consumers.¹⁷ A common charger for all mobile phones will be

introduced by the end of 2024 and one for laptops will follow in 2026.¹⁸

Overall, my volunteer work has led me to learn more about sustainability and to begin the journey of applying the “Refuse, Reduce, Reuse, Repair, and Repurpose” principles more often. I must confess that it has been a challenge to change certain ingrained behaviours. Making more sustainable choices in my personal and work life has been a slow process with setbacks, but it is very rewarding when I manage to integrate a new behaviour that brings me closer to sustainability.

Take-home messages

- Choose durable and reusable products over single-use and disposable products.
- Refuse, Reduce, Reuse, Repair, Repurpose, rather than Recycle.
- Change behaviour instead of resource exploitation.
- Choose an electronic device designed to be upgraded or repaired.
- Ensure that the replacement components of devices will continue to be produced and easy to obtain.
- Ensure that there are enough repair specialists to repair/upgrade the device you are considering purchasing and if it is economical to repair/upgrade the device.

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References

1. Ocean Alive. 2015 [cited 2024 March 16]. Available from: <https://www.ocean-alive.org/>
2. Circular Economy Portugal. 2022 [cited 2024 March 16]. Available from: <https://circulareconomy.pt/en/>
3. Circular Economy Portugal. Repair Café [cited 2024 March 16]. Available from: <https://circulareconomy.pt/en/projects/repair-cafe/>
4. Circular Economy Portugal. Bela Flor Respira [cited 2024 March 16]. Available from:

<https://circulareconomy.pt/projectos/bela-flor-respira/>

5. Horizon. The EU Research & Innovation Magazine. The rise and fall of monoculture farming. 2021 [cited 2024 March 16]. Available from: <https://projects.research-and-innovation.ec.europa.eu/en/horizon-magazine/rise-and-fall-monoculture-farming>
6. European Medical Writers Association. EMWA Spring 2024 57th Conference. 2024 [cited 2024 March 16]. Available from: <https://valencia.emwa.org/reducing-our-environmental-impact/>
7. Moodie A. Is digital really greener than paper? The Guardian. 2014 [cited 2024 March 16]. Available from: <https://www.theguardian.com/sustainable-business/digital-really-greener-paper-marketing>
8. Nastu J. Telecoms to triple electricity consumption, boosting growth of distributed energy generation. Environment + Energy Leader. 2021 [cited 2024 March 16]. Available from: <https://www.environmentenergyleader.com/2021/02/telecoms-to-triple-electricity-consumption-boosting-growth-of-distributed-energy-generation/>
9. European Commission. Critical raw materials resilience: Charting a path towards greater security and sustainability. 2020 [cited 2024 March 16]. Available from: <https://ec.europa.eu/docsroom/documents/42849>
10. Kara S. Cobalt red: How the blood of the Congo powers our lives. New York: St. Martin’s Press; 2023.
11. UN News. “Digital dumpsites” study highlights growing threat to children: UN health agency. 2021 [cited 2024 March 16]. Available from: <https://news.un.org/en/story/2021/06/1094052>
12. The Global E-waste Statistics Partnership. Surge in global e-waste, up 21 per cent in 5 years. 2020 [cited 2024 March 16]. Available from: <https://globalewaste.org/news/surge-global-waste/>
13. Doward J. Why Britain’s 2.5 billion paper coffee cups are an eco disaster. The Guardian. 2020 [cited 2024 March 16]. Available from: <https://www.theguardian.com/environment/2020/apr/26/why-britains-25-billion-paper-coffee-cups-are-an-eco-disaster>
14. Center for Climate Integrity. The fraud of plastic recycling. How Big Oil and the plastics industry deceived the public for decades and caused the plastic waste crisis. 2024 [cited 2024 March 16]. Available from: <https://climateintegrity.org/plastics-fraud>
15. Earth Overshoot Day. Past Earth Overshoot Days. 2023 [cited 2024 March 16]. Available from: <https://overshoot.footprintnetwork.org/newsroom/past-earth-overshoot-days/>
16. Earth Overshoot Day. This year’s Earth Overshoot Day lands on August 2: The trend is flattening but still far from reversing. 2023 [cited 2024 March 16]. Available from: <https://www.overshootday.org/newsroom/press-release-june-2023-english/>
17. European Commission. Right to repair: Commission introduces new consumer rights for easy and attractive repairs. 2023 [cited 2024 March 16]. Available from: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1794
18. News European Parliament. Long-awaited common charger for mobile devices will be a reality in 2024. 2022 [cited 2024 March 16]. Available from: <https://www.europarl.europa.eu/news/en/press-room/20220930IPR41928/long-awaited-common-charger-for-mobile-devices-will-be-a-reality-in-2024>



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Catarina Leitão, PhD, has been a medical writer at Evidenze since 2022. She is also a volunteer at the non-governmental organisations Ocean Alive and Circular Economy Portugal. Her volunteer work has included participating in plastic clean-up campaigns, repair cafés, and creating an urban agroforest. She is currently the Chair of the General Assembly Board of Circular Economy Portugal.

Beautiful Flower Breathes: Beyond an environmental project

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I have volunteered in different non-governmental organisations focused on sustainability and have been involved in many interesting projects, but *Beautiful Flower Breathes* has a special place in my heart. It taught me about syntropic agriculture, a technique that combines agriculture and reforestation, and showed me the social impact that the creation of an urban agroforest can have.

I volunteered during the project's first year (2018/2019). Five years later, in 2024, it is still going strong. Here, I share an interview with the person who conceptualised and implemented the project, Cátia Godinho. She explains how the concept was born and how it has evolved. I hope you enjoy this project as much as I do.

The interview

Catarina Leitão (CL): What is *Beautiful Flower Breathes* and how was it born?

Cátia Godinho (CG): *Beautiful Flower Breathes* is an environmental and social project to build and maintain an agroforest in the Lisbon neighbourhood *Beautiful Flower*. The project was born after I discovered the concept of syntropic agriculture, also named successional agroforestry, which combines forestry and agriculture.

Syntropic agriculture does not use chemicals or fertilisers. If well implemented, it can create a continuous photosynthetic matrix and produce large amounts of food in a small space without eroding the soil. I was mesmerised when I was introduced to this concept and wanted to test it in an urban context.

I pitched my idea to council members of Campolide Parish (a district in Lisbon) and they offered up a brackish piece of abandoned land in the neighbourhood *Beautiful Flower*. The land had been used as a dumpsite by locals and posed an interesting challenge: It needed to be cleaned up before it could be used. Our idea was to develop an urban agroforest on the land and organise workshops on syntropic agriculture and other sustainable land use, e.g., composting, permaculture, biodiversity, seed collection, and

conservation. In addition, we wanted to measure the amount of food that we could produce on this small piece of land.

Funding for the creation and maintenance of the agroforest was provided by the Municipality of Lisbon and the project was initiated in November 2018.

CL: What does syntropic agriculture mean and why were you so mesmerised by it?

CG: Syntropic agriculture integrates the forestry principle of species succession. It combines the planting of crops with that of trees and shrubs in a matrix that creates synergies between the different species. For example, sun-loving crops are initially planted alongside saplings but are later replaced by shade-adapted crops as the saplings grow into shade-providing trees. Since syntropy means the complexification of structure and concentration of energy (contrary to entropy, which is the simplification of structures and dissipation of

energy), the approach is called syntropic agriculture.

Syntropic agriculture was developed by Ernst Götsch,¹ a former Swiss geneticist who quit his job to test his hypothesis that it is better to cultivate species in favourable conditions than to create species for cultivation in poor conditions. Götsch states that forest mimicry can accelerate natural processes by capturing carbon, water, and nutrients, and creating balanced diversity. His proof of concept was the conversion of 500 hectares of eroded soil in Brazil into an agroforest in the early 1980s. To this day, this agroforest produces high quality cacao. By mimicking forest development and creating

By mimicking forest development and creating the ideal growth conditions for each plant, he created a diverse, productive, and sustainable farm.

the ideal growth conditions for each plant, he created a diverse, productive, and sustainable farm.

CL: How was the process of implementing the project?

CG: It took around 30 volunteers several weeks



to clear the land. We removed fences, furniture, toilets, carpets, and many other items. People from the neglected neighbourhood suddenly saw young outsiders improving their space. Many thanked us for what we were doing and welcomed our work. One lady was so happy we were cleaning up and improving her neighbourhood that she baked us several cakes. Meanwhile, her husband cheerfully played the accordion as we worked.

Other neighbourhood residents participated in their own way. People who were pleased with the changes took on the role of guardians, protecting the growing agroforest from further fly-tipping.

CL: What you have just described was the first year of the project. Nowadays, how is the involvement of the community in the project?

CG: As intended, community members, mainly retirees and students, are now actively involved and have claimed ownership of the project. Many of the younger participants have been involved with the project since its first year; as children, they played and helped on the land, absorbing vast amounts of knowledge along the way: nowadays, they can explain the importance of every plant and have become agroforest soil experts.

CL: Finally, what was the effect of this project on people's health?

CG: Our matrix of plants guarantees photosynthesis throughout the year and continuously sequesters CO₂. This reduces the city's carbon footprint and positively impacts its residents' health. But this project also had an extraordinary impact on community members' feelings of belonging. I think this mental health improvement may also have improved physical health: we helped combat loneliness.

One striking example of improved physical health is the story of a man who suffered from painful sciatica at the start of the project. Over time, as he found a purpose, company, and good food in the project, his pain lessened, and he confessed that our arrival was one of the happiest events in his life.

The local impact of this project on both mental and physical health was cross-generational. Many retirees abandoned their TVs to talk about agriculture and nature with their neighbours in the agroforest; many children followed their example and also engaged in "agrofitness" (physical activities such as hoeing and digging).

The project was especially valuable during the COVID-19 pandemic when many locals living off temporary jobs stopped receiving an income. In difficult times, they knew they could harvest vegetables from their neighbourhood agroforest.

I think this mental health improvement may also have improved physical health: we helped combat loneliness.

The impact of this project on me, a medical writer

I, Catarina Leitão, became involved in *Beautiful Flower Breathes* during a phase of intense work as a medical writer. To my surprise, every time I spent the weekend helping with the clean-up, I became re-energised and my mental fatigue disappeared. This allowed me to maintain my cognitive functioning and benefited my medical writing projects. Ever since, I have integrated nature into my daily routine: regular walks in the park help me to release stress and to maintain my mental health.

Scientific evidence shows that interaction with nature, including urban nature, has a positive impact on human health. Studies have shown that contact with a natural environment reduces stress,^{2,3} symptoms of depression,^{4,5} anxiety,⁴ and chronic pain,⁵ and improves mood,⁴ cognitive functions,⁶ creativity,⁷ and sleep quality.⁸

Thus, based on my experience and backed by scientific evidence, I recommend that you

volunteer in a similar project (and meet inspiring people like Cátia Godinho) or simply walk in nature. Experience the benefits interaction with nature has on mental health and creativity in medical writing!

References

1. Agenda Götsch [cited 2024 March 16]. Available from: <https://agendagotsch.com/en/ernst-gotsch/>
2. Van Den Berg AE, Custers MH. Gardening promotes neuroendocrine and affective restoration from stress. *J Health Psychol.* 2011;16(1):3-11. Available from: doi: 10.3390/ijerph10041250 PMID:20522508
3. Beil K, Hanes D. The influence of urban natural and built environments on physiological and psychological measures of stress – a pilot study. *Int J Environ Res Public Health.* 2013;10(4):1250–67. doi: 10.3390/ijerph10041250
4. Song C, Ikei H, Igarashi M, et al. Physiological and psychological effects of a walk in urban parks in fall. *Int J Environ Res Public Health.* 2015;12(11):14216–28. doi: 10.3390/ijerph121114216
5. Han JW, Choi H, Jeon Y-H, et al. The effects of forest therapy on coping with chronic widespread pain: physiological and psychological differences between participants in a forest therapy program and a control group. *Int J Environ Res and Public Health.* 2016;13(3):255. doi:10.3390/ijerph13030255
6. Mayer FS, Frantz CM, Bruehlman-Senecal E, et al. Why Is nature beneficial?: The role of connectedness to nature. *Environ Behav.* 2008;41(5):607–43. doi:10.1177/0013916508319745
7. Fredericks AD. How exposure to nature influences creativity. *Psychology Today.* 2022 [cited 2024 March 16]. Available from: <https://www.psychologytoday.com/intl/blog/creative-insights/202211/how-exposure-nature-influences-creativity>
8. Grigsby-Toussaint DS, Turi KN, Krupa M, et al. Sleep insufficiency and the natural environment: Results from the US Behavioral Risk Factor Surveillance System survey. *Prev Med.* 2015;78:78-84. doi:10.1016/j.jpmed.2015.07.011



Good Writing Practice

Methods of a journal article



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Introduction

The Methods section of a journal article is an experimental section along with the Results. It is analysed below in terms of 1. rhetorical intent, 2. thematic focus, 3. tense, 4. inclusion of materials, and 5. inclusion of data.

1. Rhetorical intent

The rhetorical intent of the Methods section is to convey an exactness and sufficient detail for evaluation and duplication of a study by another research expert. A researcher-author's attention to written detail is equated by a reviewer to the exactness with which the research was designed, performed, and interpreted. Not surprisingly, the amount of detail is often indicative of information unfamiliar to the author rather than to that of the expected reader(s). Thus, explanation is unnecessary for established methodology familiar to experts in the discipline.

The Methods section is ostensibly the easiest section to write, probably because the information is technical rather than conceptual, and the sequence is chronological (e.g., operational) rather than thematic. These characteristics may be the reasons many authors begin writing a journal article with this section. However, writing

this section could be premature if the data are inadequate to support publication.

2. Thematic focus

The sentences are not instructional (2nd person) but descriptive (3rd person, i.e., focused on "what" not "who"). Thus, sentences in a Methods section involve use of the passive voice.

Example 1

We isolated the protein...

Revision

The protein was isolated...

Example 2

Gel filtration chromatography was used to isolate the protein.

Revision

The protein was isolated by gel-filtration chromatography.

Notes

The revision to Example 1 is necessary to avoid the egotistic repetition in other sentences whose subjects could also be *we*. The revision to Example 2 is necessary to deemphasise *gel-filtration*.

3. Tense

The past tense is the least controversial tense usage for the Methods section in a journal article, which is justifiable as a retrospective in perspective. However, some information verb usage

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(and thus tense) can be avoided by using a list (see Example 4, below).

4. Inclusion of materials

Usually, non-multilevel materials are embedded (parenthesised) into the text of the Methods.

Example 3

The source of proteins A and B was serum of Sprague-Dawley rats (Jefferson Laboratories).

In contrast, multi-level information, that is, a grouping and subgrouping of many related details, contains too much information and is too distracting to be melded with descriptive methods. Consider a semi-table:

Example 4

Patients, individuals, experimental animals

- criteria for inclusion or exclusion
- characteristics

Questionnaire

- categories of questions

Data management

- statistical tests

Inclusion of data

Data may be included in the Methods section if it is intermediate data and not the focus of the journal article. Such intermediate data may include calculations. These are common in biostatistics journals where calculation functions as a prerequisite for application and subsequent statistical analysis, the purpose of which is to evidence a lack of bias in data collection. Such prerequisite data may even be expressed in tables. As an example, in survey studies involving completion of questionnaires, the number of completions and possible reasons for incompleteness may be stated as intermediate data.

Conclusion

Every section of the journal article has its unique difficulties. Attention to the above cited characteristics (1 to 5) may lessen difficulties in preparing the Methods section, thus ensuring success.

CONTACT US



If you have ideas for themes or would like to discuss any other issues, please write to mew@emwa.org.

Upcoming issues of **Medical Writing**



September 2024:

Clinical Trial Transparency & Disclosure

The clinical trial transparency and disclosure space continues to grow at pace. With the EU Clinical Trial Regulation being applicable since the 2022 launch of the Clinical Trials Information System comes increased requirements for public-facing documents. Provision of a summary of clinical trial results in lay language is also now mandatory in the EU. Challenges continue in balancing protection of personal data of trial participants with transparency, especially in the wake of the COVID-19 pandemic. All of these bring opportunities for medical writers to drive best practice in authoring clinical trial documents with disclosure in mind.

Guest Editors: Holly Hanson and Alison McIntosh

The deadline for feature articles has now passed.



December 2024:

Medical Writing Around the World

Medical writing transcends geography, demography, language, and culture. To date, EMWA has over 1400 members from 48 countries on 6 continents, and we want to celebrate the diversity and global presence of the medical writing community. In this issue, we will focus on medical writing activities around the world and will delve into topics like the benefits of having geographically diverse teams, translation and language-specific challenges, the landscape of global freelance medical writing, etc. We hope that these insights will assist the medical writing community in strengthening interactions and collaboration with teams and freelancers spread across the world.

Guest Editor: Asha Liju and Evguenia Alechine

The deadline for feature articles is September 1, 2024.



March 2025:

Rare Diseases

Although rare diseases are individually uncommon, there are more than 7000 rare ("orphan") diseases affecting around 300 million people globally. Rare diseases are incredibly diverse and often life-threatening. Long diagnostic delays, termed a diagnostic "odyssey", are common, and many have no effective treatments. Rare diseases offer unique challenges and opportunities that are not seen in other therapeutic areas. This issue of *Medical Writing* spotlights the evolving regulatory landscape, the nuances of unmet medical needs, the importance of the patient voice, and the key role of medical writers in the orphan disease space.

Guest Editor: Sarah Milner and Heather Mason

The deadline for feature articles is December 1, 2024.



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