Medical Writing

ALSO IN THIS ISSUE...

- Eutrophication of waterways: Can medical writers help?
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Volume 33 Number 4 | **December 2024**

EMWA 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

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THIS ISSUE **December 2024** | Volume 33 Number 4

Medical Writing Around the World

"Medical writing transcends borders, uniting professionals across geographies, demographics, languages, and cultures."

Guest Editors Asha Liju and Evguenia Alechine

Medical writing around the world

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Medical writing transcends borders, uniting professionals across geographies, demographics, languages, and cultures. This inherent global perspective has inspired the (above) theme for this issue.

While previous editions have explored medical writing in specific countries and regions, the COVID-19 pandemic has irreversibly reshaped the global landscape. Virtual meetings, remote work, and international collaboration are now commonplace, broadening opportunities for medical writers to connect and work together across continents. This issue aims to celebrate the worldwide medical writing community by integrating insights that reflect our collective resilience and adaptability.

We've curated articles that delve into topics ranging from cross-border collaboration and freelance medical writing to inclusive practices and language-specific challenges. Through these contributions, we aspire to strengthen the bonds within our community, fostering an environment where medical writers can thrive both individually and collectively on a global stage.

Our journey begins with an enlightening article by **Shruti Diggavi** and **Mati Kargren**, offering a multidisciplinary approach to fostering effective collaboration among medical writers. **Kelley Hill, Marissa Bernstein, Amber Reese**, and **Asha Liju** then introduce the innovative *"Follow the Sun"* model of medical writing, which capitalises on time zone differences to optimise team efficiency and workflow. To learn more about this topic, **Zsuzsa Csik** interviews **Julia Cooper**, a seasoned expert in global medical writing, who shares invaluable insights from her experiences leading international teams.

Professional development remains a cornerstone of our field, and **Michelle Guillemard's** contribution is a standout. She compiles an extensive list of training and growth opportunities tailored for medical writers worldwide. **Adriana Rocha**, in turn, examines the expanding freelance landscape, discussing the unique challenges and opportunities faced by independent medical writers across the globe.

Diversity, equity, inclusion, and belonging have become urgent global imperatives, and the medical writing field is no exception. **Jeanette M. Towles** explores this topic, offering strategies to promote these practices within medical communications. **Aurélie Gobet** complements this discussion by addressing the nuances of inclusive language, with a specific focus on French medical texts.

We also highlight the critical issue of representation – or lack thereof – of certain regions in health, science, and medicine. This disparity inevitably impacts medical writing. **Julie Chaccour** provides a compelling narrative on the barriers faced by young researchers from low- and middle-income countries, as they strive to contribute to equitable global health.

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Meanwhile, **Joana Fernandes** examines how the post-pandemic shift to remote working has transformed Portugal into a strategic hub for hiring medical writers, balancing cost efficiency with access to a skilled talent pool. **Syed Jaffar Abbas Zaidi** and **Faiza Khadim Arain** shift our focus to Pakistan, where they underscore the urgent need for enhanced copyediting standards to elevate the quality of the nation's medical literature.

Language diversity is an enduring aspect of global medical writing, and we celebrate this richness by inviting experts to share their experiences and challenges in working with different languages. **Etsuko Amano** (Japanese), **Stephanie Zhu** (Chinese), **Eugenia Radkova** (Russian), **Johanna Chester** (Italian), **Beatriz Viejo Belon, Valentina Luridiana Galati**, and **Rita Yanina Rasente** (Spanish from Spain and Latin America), **Ana Sofia Correia** (Portuguese), **Claire Harmer** (French), and **Sofia Urner** (German), generously contribute their knowledge, offering insights that will undoubtedly broaden our horizons.

As you navigate this issue, we hope that it serves as both a resource and an inspiration, enhancing your ability to collaborate effectively across cultures, languages, and disciplines. EMWA, as a truly international and multicultural community, stands as a testament to the power of global integration in medical writing. By deepening our understanding of the worldwide landscape, we equip ourselves to better address the challenges and seize the opportunities that lie ahead.

We sincerely hope you enjoy this edition as much as we enjoyed curating it. May it be a thought-provoking and enriching read, illuminating new perspectives and reaffirming the global nature of our profession.

With warm regards, **Asha & Evguenia**

Author information

Asha Liju, BVSc and AH, is a medical writing professional with over 17 years of industry experience. She is a Senior Manager at Parexel International. Her responsibilities include recruiting, onboarding, coaching/mentoring, professional development, driving process improvement initiatives, partnership setup and management, and client liaison. She is also an EMWA member.

Evguenia Alechine, PhD, EL, has been working in the medical writing and science communication field since 2016. Based in Buenos Aires, Argentina, she is an active EMWA member, co-editor of this journal, chair of the Getting into Medical Writing Group, and a workshop leader. She is passionate about communication, teaching, and career coaching as well as a strong advocate of the medical writing profession worldwide.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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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58th EMWA Conference

ONLINE AND IN REAL LIFE

Potsdam, Germany

Milan, Italy

Warsaw, Poland

Lisbon, Portugal

Warsaw, Poland | Lisbon, Portugal | Barcelona Spain | Thun,

Here is the conference by-the-numbers

556 delegates

35 EPDP workshops

150.25 hours of activities

1 Sustainability ESS

6 seminars

10 regional hubs

1 Freelance business forum

The 58th EMWA Conference, which included virtual events with in-person hubs, took place November 6–25. With online workshops, seminars, the Freelance Business Forum, and in-person hubs in 10 cities across the globe, the conference offered the best of both worlds!

Amsterdam, The Netherlands

Barcelona, Spain

Thun, Switzerland

London, UK

Switzerland | Amsterdam, The Netherlands | London, UK

From the Editor

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The global reach of medical writing

To date, I have visited 65 countries on 5 continents. One of the geeky things I do when travelling is walk into a drug store or pharmacy and browse the shelves. I find it fascinating, but also comforting, to see that healthcare products are generally the same. The names and the packaging may be different, but it feels great to see "familiar faces in foreign shores."

We are global

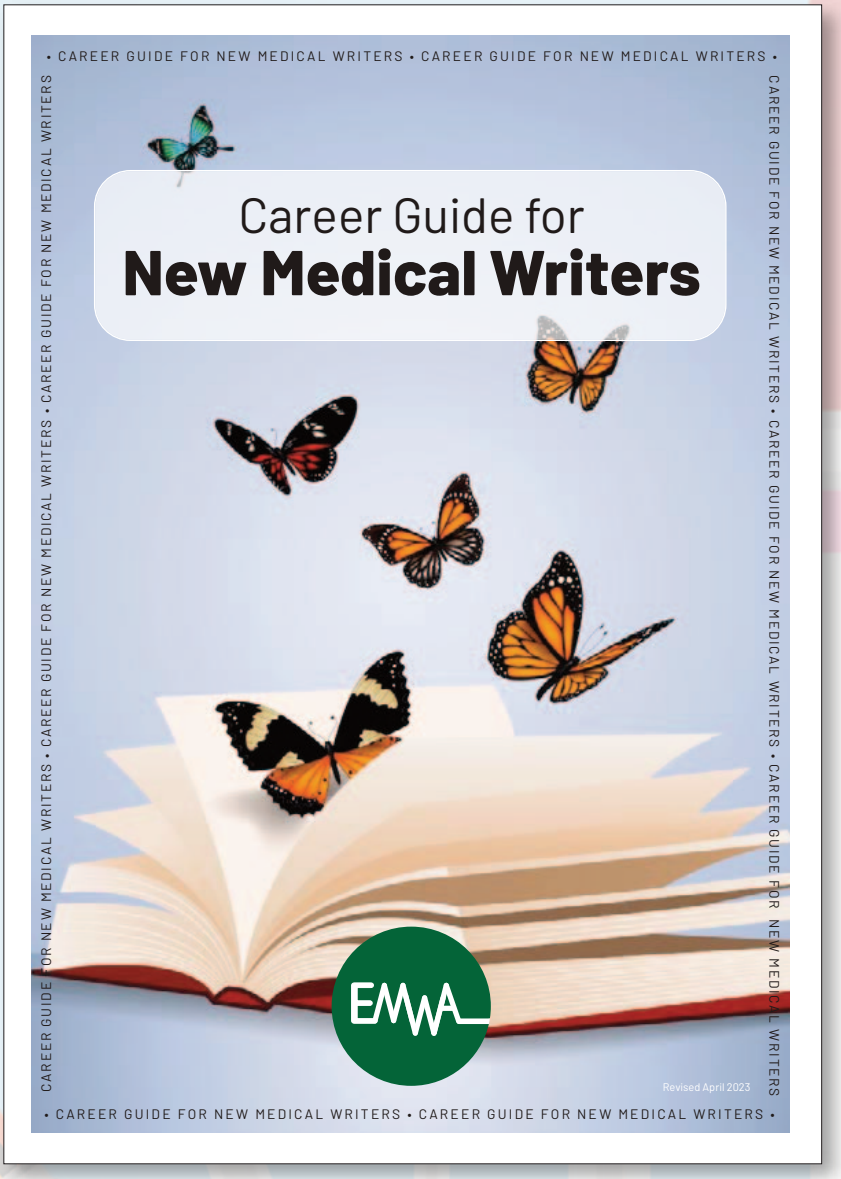
Medical writing as a profession has such a global reach – it doesn't matter who or where we are, the manuscripts we write are read across the world, and the drugs and therapies that we support for regulatory approvals benefit patients all over.

EMWA is more than just Europe. With more than 1500 members in 50 countries, we are truly a global community which covers all the continents, except Antartica. (If there are medical writers living there, please feel free to reach out!) Despite the geographic spread, digital solutions and virtual systems bring us together.

We are diverse

Medical writers come from diverse backgrounds. As scientists, healthcare professionals, linguists, and statisticians, somehow we all found our way into medical writing. Amidst these different baselines, we found common denominators – we love science, and we love to write and communicate.

This edition of *Medical Writing*, themed "Medical Writing Around the World", celebrates our globality and diversity. Kudos to guest editors Asha Liju and Evguenia Alechine for putting this all together. Enjoy this trip around the medical writing world, without leaving your sofa!



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.

President's Message

Medical writing: Diversity and inclusion across borders

Sarah Tilly
EMWA President 2024-25
president@emwa.org

doi: 10.56012/ahda7039

Dear EMWA Colleagues,

Many of our members were present at the Autumn virtual conference's opening session on Thursday November 7 as we witnessed medical writing around the world firsthand. We had local hubs across 10 countries with a rich agenda of local discussion, training, and networking. Our Spanish-speaking hubs, divided by an ocean yet united in language, even requested to join each other for the networking session! November 8 followed this theme and included two seminars on the essentials of medical translation – highlighting the need for scientific communication across the globe. Our conference also wrapped up with two appropriately themed educational workshops: inclusive language and cross-cultural communication.

As professionals we are well aware that medical writing is a crucial component of healthcare dissemination, from pharmaceuticals through medical devices and original laboratory research. Good communication serves as the bridge between complex scientific information and its intended audience, whether we are in academia writing about our own research or whether we are working for a global pharmaceutical company with a portfolio of products in clinical development.

In this issue entitled "Medical Writing Around the World", we take a wide-ranging tour around the challenges of working across the globe: team cohesion and understanding, managing time zones, discerning cultural norms, and customs regarding communication. But more importantly, we outline the numerous opportunities that arise for the medical writer to use their knowledge and the power of words to continue to effectively contribute critical written communication that leads to a better understanding and eventually to bringing healthcare innovations to patients. We look at the dynamics of leading a team of medical writers in a global setting, through to the inequalities in research still present today, how to advance diversity and inclusion in medical communities, and empower clinical research in low and middle-income countries.

Interestingly, I recently attended a scientific event on gender medicine: the differences between males and females in terms of disease symptoms, access to healthcare, time to diagnosis, and required treatment. Yet we still fill our Phase 1 studies with young healthy males, clinical studies further down the line often have a majority of male participants, analyses by gender are not commonplace, and final treatment regimens may not even be adapted to weight. If we still cannot manage gender equality in clinical research, we have a long way to go to ensuring ethical diversity and inclusion. As we become aware of medical writing around the world, let us not forget that we must also promote diverse and inclusive clinical research, as far as we can in our role.

While "globalisation" is often used as a pejorative term, we should remember that as medical writers our proficiency in language, coupled with our understanding of regulatory and healthcare systems, therapeutic areas, and patient populations, affords us a unique position to be a positive force in producing content that is true to science and research ethics, but for which the terminology, context, and implications are adapted to be culturally appropriate to each audience.

May EMWA continue to promote this healthy diversity and inclusion that we see in our profession and membership across the globe, which is (not by coincidence) part of our association's strategic plan through to 2027.

EMWA NEEDS YOU

EMWA is a member-run organisation

When you volunteer to assist EMWA in any capacity, you are furthering the development of our association.

You can choose how you want to get involved: in a very limited way or as part of a larger project. The choice is yours, and everyone shares the benefits.

EMWA members can volunteer in the following areas:

Conference
- Planning Committee
- Advertising

Finance

Journal
- Submitting articles

Website
- Contributions
- Web team

Freelance Business Group

Social Media Team

Training
- Leading workshops
- Professional development
- Webinar contributions
- Webinar team

Special Interest Groups
- Entrepreneurship
- Communicating with the Public
- Medical Communications
- Medical Devices
- Pharmacovigilance
- Regulatory Writing
- Sustainability
- Veterinary Medical Writing

Ambassador Programme

Getting Into Medical Writing Group

Executive Committee
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- Public Relations Chair
- Conference Chair
- Honorary Secretary
- Education Officer
- Treasurer
- EMWA Web Manager

WHY VOLUNTEER?
- Help promote the role of medical writers and strengthen our association
- Help to raise standards in our field
- Increase your visibility and communication opportunities within the medical writing community
- Add some prestige to your CV
- Improve your knowledge of medical writing and related topics

TO FIND OUT MORE

If you are a member of EMWA and eager to support ongoing initiatives, please contact info@emwa.org.

EMWA News

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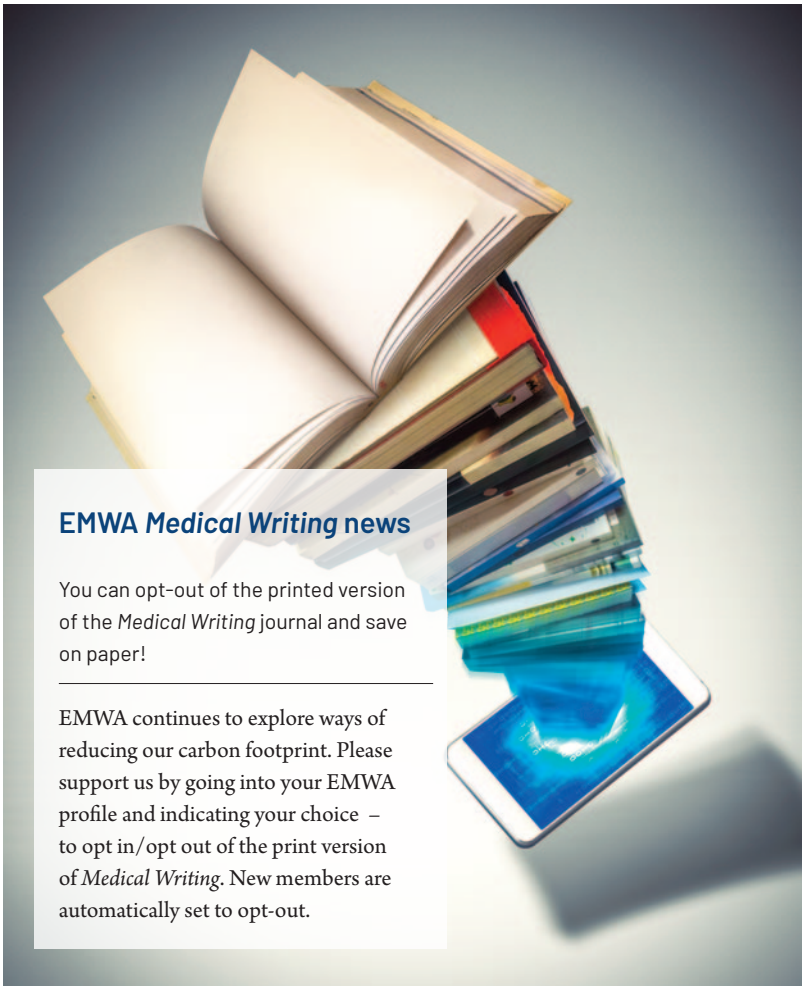
Ambassador Programme news

The EMWA Ambassador Programme is continuing its efforts to reach out to new audiences to promote medical writing. EMWA has supported the following events:

On October 8, 2024, **Martin Delahunty** gave a talk on "Careers in Medical Writing" and the benefits of joining EMWA at the University of Essex Employability for the Biosciences Workshop. The EMWA presentation was part of a formal assessed assignment where the 35 participating students had to consider the challenges and opportunities for a particular career pathway. This was the first time that students had a presentation on medical writing and medical communications. Only 3 of the 35 students had previously considered medical writing as a career pathway. Martin fielded questions on the different types of medical writing, possibilities for internships, and the differences between freelance employment and working for an agency. The students were especially interested in the results of the EMWA salary survey. Overall, the event went quite well as Martin did indeed succeed in kindling the interest of the students in a field that many had never heard of before.

If you are an experienced medical writer and 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).



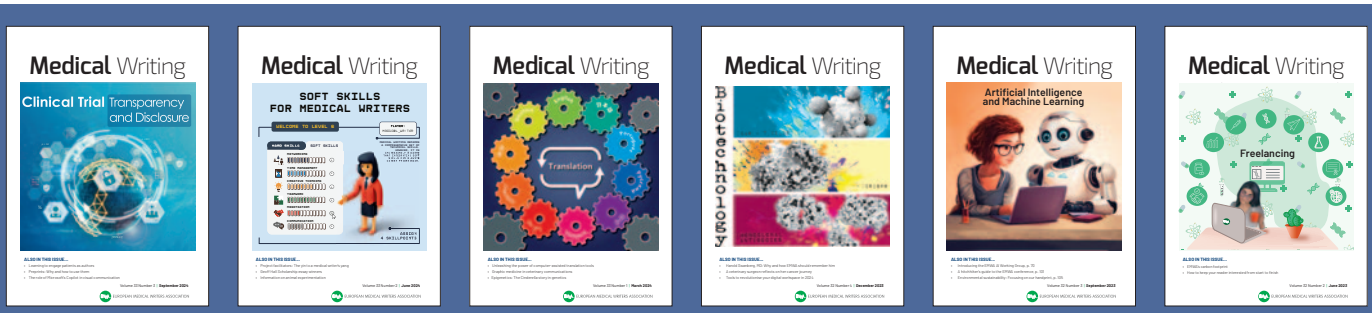
EMWA *Medical Writing* news

You can opt-out of the printed version of the *Medical Writing* journal and save on paper!

EMWA continues to explore ways of reducing our carbon footprint. Please support us by going into your EMWA profile and indicating your choice – to opt in/opt out of the print version of *Medical Writing*. New members are automatically set to opt-out.

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!

Freelance Business Group news

At the 58th EMWA virtual conference, we hosted the Freelance Business Forum, a free networking session with roundtable discussions on everything related to the freelance medical writer.

As freelancers working on our own, having a community is one of the most important parts of freelancing life, and this event is a great opportunity to meet and connect with other professionals.

If you want to know more about the Freelance Business Group, please check the dedicated LinkedIn group:
https://www.linkedin.com/groups/12769131/

CORE Reference

Check out the updated list of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), EMA (including Clinical Trials Regulation [CTR] and the Clinical Trials Information System [CTIS]), FDA and other regional guidances; best practice documents; and other tools and resources supporting clinical trial reporting; transparency and disclosure of clinical documents; real-world data and artificial intelligence/machine learning in the regulation of medicines.

The CORE Reference NewsSummary encompasses medicines, vaccines and devices; information is archived at:
https://www.core-reference.org/news-summaries/

Sign up for the bi-monthly email service:
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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 want to know more about the SIGs, please read this:
https://www.emwa.org/sigs/

webinar

EMWA Professional Development Committee webinar

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 with the opportunity for participant interaction. Webinar access is reserved for EMWA members only and requires registration.

For the planned or past webinars, please refer to this page: https://www.emwa.org/education/emwa-webinars-programme-2024/#webinars2023

Global and multidisciplinary perspectives on collaboration with medical writers

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Abstract
Medical writers, document quality reviewers, and document specialists work together to produce high-quality clinical and regulatory documents. Cross-functional collaboration with other functional leads like biostatisticians, medical monitors, and project leaders is also crucial for timely project delivery. We interviewed people in these roles who emphasised that clear communication, setting clear expectations, addressing challenges proactively, and leveraging digital tools are all needed for successful cross-functional and cross-regional collaboration. Understanding different perspectives and roles, practicing active listening, and being mindful of time zones and cultural differences are also important when working in multidisciplinary and global teams. Overall, effective collaboration leads to better outcomes and competitive advantage in medical writing.

Cross-functional and cross-regional collaborations bring together diverse skills and perspectives across multiple fields of expertise. They foster innovation, enhance problem-solving, and promote groups to work towards a common goal, leading to better outcomes and competitive advantage. In this article, we explore diverse outlooks from some of the most common roles who work with medical writers as well as medical writers themselves for a wholesome perspective on strong and sustainable collaborations.

Collaboration within the medical writing sphere
In this section, we provide insights into some of the different roles within medical writing, their main responsibilities, and how they collaborate with others. These roles may be termed differently and may have slightly varying responsibilities across organisations.

Medical writer
Medical writers develop a variety of regulatory documents throughout the lifecycle of a product (e.g., clinical study protocols [CSP], informed consent forms [ICF], and clinical study reports [CSR]), including after a product is on the market (e.g., post-marketing surveillance or safety aggregate reports). Besides the main responsibility of authoring, medical writers employ a variety of hard and soft skills, including project management, communication, collaboration, and time management.[1] Moreover, they possess an in-depth knowledge of medical concepts, therapeutic areas, industry best practices, and attention to detail, and ensure the accuracy of data and compliance with quality and regulatory requirements. Medical writers generally use a combination of collaborative authoring strategies during document development with internal and external cross-functional teams for inputs and review of clinical and regulatory deliverables.[2]

Document quality reviewer
Document quality reviewers primarily collaborate with and act as a strong support to medical writers towards ensuring first-time quality in each stage of clinical and regulatory document review. The main role of document quality reviewers is to facilitate the timely delivery of error-free, high-quality medical writing documents by identifying errors in grammar, style, syntax, and format according to applicable style guides and conventions. They also ensure the accuracy, logic, and overall flow of the clinical data and content presented. Performing a high-quality review necessitates knowledge of regulatory requirements and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP), as well as a deep understanding of the clinical research and drug development processes.

Document specialist
Document specialists work closely with medical writers to ensure that clinical and regulatory documents are ready for submission. The prime task of the document specialist is to guarantee consistent formatting and styles across templates. Moreover, they ensure that documents adhere to international regulatory document standards (e.g., ICH Electronic Common Technical Document [eCTD] specifications) and are easy to read and navigate. Document specialists assist in the accurate documentation of references and citations and may utilise reference management software to streamline the citation process. Normally, document specialists enable effective collaboration among cross-functional teams involved in compiling appendices/documents by coordinating timelines, milestones, and deliverables to ensure efficient workflows and timely completion of document-related tasks. They also ensure compliance with applicable client policies, company procedures for publication, and regulatory submission.

Mastering the art of internal collaboration
We reached out to our colleagues in different medical writing roles at Parexel about their take on internal and cross-functional collaboration, as well as collaboration across geographical borders and cultural barriers. Their unique answers and perspectives are presented in Box 1.

Communication is key
While document quality reviewers and document specialists primarily collaborate within the medical writing sphere, medical writers act as a bridge between the medical writing unit and

Figure 1. Common roles within the medical writing sphere and functional leads medical writers frequently collaborate with

other functional leads. (See Figure 1.) No matter the role, establishing transparent communication and addressing project risks up front are the keys to success. Furthermore, as our interviewees stressed, practicing active listening, clarifying uncertainties, and learning from one another are of the utmost importance to successfully managing your medical writing project.

Cooperation across a functional spectrum

Medical writers often need to cooperate with other functional leads such as biostatisticians, medical monitors, or project leaders (a.k.a clinical project managers). This cooperation can take place within the same company or, in the case of medical writers working at a contract research organisation, with the functional leads of the sponsor. In this section, we describe some of the most common cross-functional roles that medical writers interact with. These roles may be termed differently and may have slightly varying responsibilities across organisations.

Biostatistician

Biostatisticians play a significant role in all stages of clinical research, from designing robust studies, monitoring data integrity, and performing statistical analyses that are crucial for making informed decisions (e.g., about the effectiveness and safety profile of the study intervention) and advancing the field of clinical research.[3] One of their primary responsibilities is contributing to study design. Biostatisticians help determine appropriate sample sizes, develop randomisation techniques, and establish control groups, ensuring that the study will generate reliable and valid results. During a clinical study, biostatisticians monitor data management processes to ensure data integrity. They review data quality, identify anomalies, and address missing data issues. Additionally, they assist in detecting safety signals and evaluating the efficacy of the intervention. Biostatisticians are also responsible for selecting and performing statistical analyses to draw meaningful conclusions from the clinical study data. They utilise various statistical methods such as hypothesis testing, regression analysis, and survival analysis to analyse the data and determine the statistical significance of the study findings. This analysis helps make evidence-based decisions about the safety and effectiveness of the interventions being studied.

> Adopt an open mindset and try to learn from each other as much as possible.

Medical monitor

Medical monitors are responsible for ensuring participant safety and well-being throughout the duration of a clinical study.[4] Their primary role involves overseeing the proper implementation of the CSP and ensuring compliance with regulatory guidelines. Medical monitors closely monitor participants, evaluate adverse events, and recommend CSP modifications if necessary. With their extensive medical and therapeutic knowledge, medical monitors provide expertise in study design, patient eligibility, and risk management. They collaborate with various stakeholders, including investigators and project leaders, to ensure the smooth execution of clinical studies. Medical monitors also play a significant role in data review and analysis, ensuring data integrity and supporting the interpretation of study results. They actively contribute to the safety and success of clinical studies, bringing potential life-saving treatments to patients while adhering to ethical and regulatory standards.

Project leader

Project leaders are essential in clinical research as they oversee and manage all aspects of a clinical study.[5] Their primary responsibilities include coordinating and managing various stakeholders involved in the study (such as the study sponsor, investigator[s], internal team members, and external vendors) and ensuring adherence to CSP and regulatory guidelines. Project leaders play a crucial role in project planning, establishing timelines, and allocating resources. They are responsible for monitoring study progress, managing budgets, and addressing any

issues that may arise during the study.

Additionally, project leaders are responsible for maintaining quality standards, ensuring data accuracy, and upholding ethical considerations in clinical research.

Navigating success in global and cross-functional teams

We also reached out to collaborators from other functions at Parexel and sought their input on working with medical writers. Unique answers and perspectives from representatives in different roles outside of medical writing at Parexel are presented in Boxes 2 and 3.

Maximising synergy in global teams

In general, biostatisticians, medical monitors, and project leaders cooperate with medical writers during the development or review of the study synopsis, CSP, ICFs, CSR, or other clinical and regulatory deliverables. As mentioned by the interviewed functional leads, to increase project success, medical writers should go through therapeutic area training in advance (which is commonly conducted for product- and client-specific projects at contract research organisations), clarify the purpose of the deliverable, and ensure team members have the correct link to work on the latest draft of a document. Although time zone differences may pose challenges at times, global teams can also use them as an advantage during document review cycles when possible.

Box 1. Medical writing perspectives on successful cooperation

Question 1: When and with which roles do you normally collaborate?

Mary Burder, Principal Medical Writer, USA:
"Internal collaborations are with other medical writers on my team. External collaborations within the company are with clinical, safety, regulatory, clinical pharmacology, and statistical team leads."

Sneha Salgar, Principal Medical Writer, India:
"As a medical writer for pharmacovigilance authoring, I typically collaborate with safety experts, regulatory specialists, scientists, project leaders, and other medical writers and document quality reviewers."

Martina Grigat, Senior Medical Writer (currently a member of the document quality review group), Germany:
"For every quality check (QC) task, the main point of contact is the lead medical writer. If it is a collaborative QC (involving several medical writers), coordination between the quality reviewers is essential. Additionally, depending on the QC and its scope, I sometimes need to interact with drug safety physicians, medical monitors, and biostatisticians."

Pieter Visser, Lead Document Specialist, South Africa:
"As a document specialist team, we have a dynamic and adaptable collaboration with various roles throughout the document lifecycle. These include medical writers for ensuring proper formatting and the availability of internal and external links for document navigation; cross-functional teams from clinical operations, data management, biostatistics, pharmacokinetics, regulatory affairs, and safety/pharmacovigilance for review and input on appendices for various document types; project leads for project timelines and tracking; and sponsors of clinical studies and regulatory authorities for document formatting and submission requirements, respectively."

Question 2: What is your best tip for collaborating internally within medical writing and with external stakeholders/teams?

James Wolfe, Vice President of Medical Writing Services, France:
"In my experience with medical writers, most have been more introverted in their approach to leading their projects. Good medical writers need to marshal and guide their team of stakeholders. As everyone is different, it is essential to understand what is needed to develop writers to become good leaders."

Alexandra Wal, Medical Writer, Germany:
"Good and concise communication; emails should be as short as possible and clearly point out the most important aspects to consider without any room for mis-interpretation."

Karina Kordalewska, Associate Medical Writer, Poland:
"For internal collaborations, I recommend adopting an open mindset and trying to learn from each other as much as possible to gain a fresh perspective on writing and project handling styles."

Kavita Muchandi, Senior Principal Medical Writer, India:
"Setting clear expectations, monitoring, and patience are key to a successful collaboration. For example, if we need input from stake-holders, then the background, the parameters for which feedback is solicited, the timeline by which the feedback is required, and the format or collaborating platform, if applicable, need to be clearly communicated."

Christin Benjamin-Philander, Medical Writer, South Africa:
"Do not be afraid to ask as many follow-up questions as you need to get clarity on instructions or information. This approach prevents a lot of confusion during authoring."

Helen Wiggett, Senior Document Quality Reviewer, United Kingdom:
"Make use of available digital collaboration tools to make working collaboratively on a document easier and make sure you set up clear communication channels (e.g., Microsoft Teams) to ensure everyone is on the same page and kept informed throughout the process."

Pieter Visser, Lead Document Specialist, South Africa:
"My best tips for collaboration include practicing active listening and asking to clarify questions. Be mindful of language barriers and use clear, simple language to ensure everyone is on the same page."

Question 3: Any advice for working in cross-functional and cross-regional teams?

James Wolfe, Vice President of Medical Writing Services, France:
"The ability to understand writers across regions and functions is crucial as we expand our horizons. Never assume and break away from the 'group think' mentality; stop and reflect on someone else's approach, motivation, and probable next steps."

Ashwini Somayaji, Senior Principal Medical Writer, India:
"Be cognizant of time zones while setting up meetings, share an agenda ahead of time, and document the understanding and action items after calls. Follow through on the action items and involve subject matter experts where specific input is required."

Yogeeta Surinderkumar, Senior Document Quality Reviewer, India:
"I believe a 'Go the extra mile' mindset of setting clear expectations through transparent communication and proactively identifying and addressing potential challenges before they become significant issues helps deliver effectively as a team."

Beate Gerstbrein, Senior Principal Medical Writer, France:
"Peers from other functions may not be as tech-savvy as medical writers are with specific tools. Reviewers may require instructions on how to open a shared Word document so that the full Word functionalities are displayed and they are able to review and comment efficiently. Where needed, explain why shared documents should not be downloaded for offline review. Moreover, set up calendar placeholders for review periods, meetings, specific deadlines, and check up front for any potential time constraints from team members."

Pieter Visser, Lead Document Specialist, South Africa:
"To facilitate learning across regions and functions, organise cross-functional training sessions or workshops and create a mentorship program."

Box 2. Cross-functional insights on effective teamwork with medical writers

Question 1: When do you normally collaborate with medical writers?

Jagrutibahen Desai, Manager Biostatistics, India:
"Generally, I collaborate with medical writers at the time of project discussions, such as when developing the study synopsis, CSP, CSR, or reviewing CSR tables/figures/ listings. I also coordinate with medical writers at the time of internal or client partnership process revision."

Zuzana Traugottova, Medical Director, Czechia:
"The most usual occasions during which I collaborate with medical writers are the development and review of protocols, ICFs, CSRs, CSR addendums, and development safety update reports."

Marque Venter, Associate Director of Project Management, South Africa:
"I primarily work with medical writers to develop master or global ICFs and at the end of a study to compile CSR appendices."

Lucy Yim, Project Leader, Hong Kong:
"Normally, I collaborate with medical writers when an ICF needs to be drafted."

Question 2: What is your best tip for collaborating with medical writing colleagues?

Amy Pace, VP Biostatistics, USA, and Angela Hu, VP Biostatistics, Taiwan:
"Effective collaboration between biostatisticians and medical writers can enhance the quality of clinical documents and should be facilitated by:

- Clear communication when reviewing documents, i.e., employ a structured review process, use consistent terminology, and tag someone using the "@" sign when requesting specific input.
- Resolution meetings if documents in development need significant revision.
- Keeping the study team informed of any changes or new information, no matter how minor."

Marque Venter, Associate Director of Project Management, South Africa:
"My advice is to engage with the medical writers as soon as possible on project scope and expected timelines and provide as much detailed information about the project and CSP as possible. Ensure that requests from the medical writer are followed up on in a timely manner or establish a direct line of communication between the medical writer and other stakeholders to easily resolve more complex questions about the CSP, disease indication, or therapeutic area."

Lucy Yim, Project Leader, Hong Kong:
"My best tip is to provide the medical writer with all the study information and details they need."

Janos Antal, VP Global Head Neurology, Hungary:
"From my point of view, it is important for medical writing colleagues to go through therapeutic area training. Furthermore, email correspondences and track changes in documents may not always resolve an outstanding issue. Therefore, it is important to remain flexible and have the option for online discussions outside of regular team meetings."

Zuzana Traugottova, Medical Director, Czechia:
"For me, the most important aspect of cross-functional collaboration is the project kick-off meeting. Medical writers should clarify the purpose of a deliverable (e.g., the study drug, which study phase, study population, etc.) and the expected timelines."

Abbreviations: CSP, clinical study protocol; ICF, informed consent form; CSR, clinical study report.

Question 3: Any advice for working in cross-regional teams?

Denis Gungor, Associate Director of Biostatistics, Germany:
"Often, there is immense pressure at the end of clinical studies where we have no options to adjust timelines without impacting final delivery. From my experience, any neglected or uncommunicated detail comes back at a later time with a much bigger overhead and magnified impact. Hence, team members must stay in close touch to ensure project quality and timely delivery of clinical documents. Efficient communication without any gaps is of utmost importance when working in cross-regional teams."

Zuzana Traugottova, Medical Director, Czechia:
"Collaboration on a shared clinical document is crucial. Medical writers need to ensure team members have the correct link to work on the latest draft and that comments clearly demarcate the text they are referring to."

Marque Venter, Associate Director of Project Management, South Africa:
"When working in global teams, use time zone difference as an advantage during document review cycles when possible."

Lucy Yim, Project Leader, Hong Kong:
"Regarding collaboration across regions, respect time zone differences and set a reasonable timeline. To speed things up, call your colleague directly instead of emails."

Abbreviations: CSP, clinical study protocol; ICF, informed consent form; CSR, clinical study report.

Box 3. Practical tips on collaborating across roles and functions in international teams

Box 3a: Insights from medical writing peers

Document specialist
Practice active listening and clarify uncertainties up front. Be mindful of language barriers and use clear, simple language to ensure everyone is on the same page.

Document quality reviewer
Use digital tools to enhance collaborative document authoring and make sure you establish clear communication channels.

Medical writer
Know your remit and set clear expectations, anticipate risks, and prepare mitigation plans. Be mindful of time zones and cultural sensitivities for cross-regional collaborations.

Box 3b: Thoughts from frequent collaborators of medical writers

Biostatistician
Keep the study team informed of any changes or new information, no matter how minor.

Medical monitor
Medical writers should clarify the purpose of a deliverable (e.g., what the study drug is, which study phase, study population, etc.) and what the expected timelines are.

Project leader
When working in global teams, use time zone difference as an advantage during document review cycles when possible.

Conclusions

Based on the answers we received from internal medical writing colleagues as well as peers from other functions, successful collaboration requires a combination of supportive leadership, clear communication channels, shared goals, and cultural sensitivity. While challenges such as time zone differences and diverse work styles may arise, medical writers who foster a collaborative environment and maintain cooperative relationships are better positioned to succeed with projects requiring global teamwork. Ultimately, embracing cross-functional and cross-regional collaboration is not just a strategy but a necessity for long-term success in the medical writing field.

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"Follow the Sun" writing:
A hybrid operating model to optimise collaboration and efficiency

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Abstract

Time, quality, and accuracy are of the essence for expeditious global regulatory submissions. An around-the-clock, 24/7, global medical writing model has been developed that allows efficient development of high-quality documents with appreciable reduction in time to completion. Writers work across global time zones, relaying the work accomplished during their workday to the writer in the successive workday without interruption. This also enables "rolling" continuous quality control checks. Authors can focus on messaging and content with confidence as documents are developed. Best results are achieved by proactive alignment of content and messaging, strategic assignment of tasks to suitable talent, and fostering a culture of open communication founded on trust and mutual respect.

Medical writers are perpetually challenged to meet increasingly aggressive timelines for documents, whether they are stand-alone or part of a global regulatory submission. The 8-hour workday is often insufficient to meet the progress expected and this can be compounded by time limitations of working with subject matter experts who are in different time zones. Compressed timelines increase the potential for error, burden the team with unplanned extra review cycles, add stress for the writer(s), and can result in failure to meet corporate goals.

To address this challenge, we developed an operating model to optimise use of global resources and ensure continuous coverage around the clock: The "24/7 Follow the Sun" model. While 24-hour shift schedules have been successfully employed in other industries,[1] to our knowledge, they have not been used in the medical writing practice. Our Follow the Sun model was designed as a novel approach to ensure continuous authoring, collaboration across the globe, and maintenance of normality of the writing team's working hours. The goals of the model are to:

- Decrease the number of days needed to develop a document, resulting in reduced resourcing costs and reduced down-time due to non-working hours and holidays
- Optimise and improve document development efficiency by leveraging global talent across diverse geographical regions
- Provide professional growth opportunities and enhanced work-life balance for the writing team

This article describes the creation, use, and outcomes of the Follow the Sun model as experienced by a global medical writing team of writers, quality control (QC) reviewers, and document specialists (together called MWs). Our experience is with clinical Common Technical Document (CTD) modules for a regulatory submission. However, this model can be applied to other types of projects, collaborations, and document types, such as risk management plans or protocols, which are time sensitive and involve diverse teams of contributors and stakeholders.

Building the model

What does the model look like?

The Follow the Sun model leverages global team talent across various geographical locations to facilitate continuous progress on the project. When facing particularly aggressive timelines, medical writers (MW) located in overlapping time zones (e.g., EU between India and/or the

Figure 1. Benefits of the Follow the Sun Model

US) can play a critical role in ensuring the Follow-the-Sun model has optimal resource utilisation. Each team member completes an agreed-upon set of tasks during their workday, relaying work accomplished to the team members who will work during the next successive workday (Figure 2). This approach also makes continuous quality checks possible as the document is developed.

What is needed to enable the model?

Planning

To enable optimum outcomes, the project's scope should be set forth prior to its initiation, including goals, medical writing deliverables, expectations, activities, tasks, and timelines. A granular timeline should be developed by the MW team to provide a detailed outline and inventory of the MW tasks required for the project, which may comprise a single document or an interrelated set of documents. This is used by the MW team to track progress of specific tasks related to the writing portion of the project and "nests" within the overall project timeline.

Resourcing

The MW team selected for each project should be based on their experience relative to the tasks required for document development. Document development tasks include, but are not limited to: drafting content, creating in-text tables and figures, initiating review (peer review, subject matter expert review, or QC review), comment resolution, proof-reading and style guide checks, and formatting. Balancing skill sets relative to the timeline optimises work hours across time zones. Resourcing is scalable: depending on the status of the project, MW team members can be added or removed to ensure continuous support.

Choosing a strong leader is essential. The MW lead is responsible for coordinating all activities of the MW team. (In some cases, this role may be performed by a Project Manager. But for the purposes of this article, we will refer to the "MW lead"). The MW lead should have excellent

Location	Time zone	Hours (Beginning at midnight EDT)																								
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Central EU	GMT +02:00			•																						
East Coast US	GMT -04:00									•																
Bengaluru India	GMT +05:30																								•	
Sydney Australia	GMT +10:00																		•							

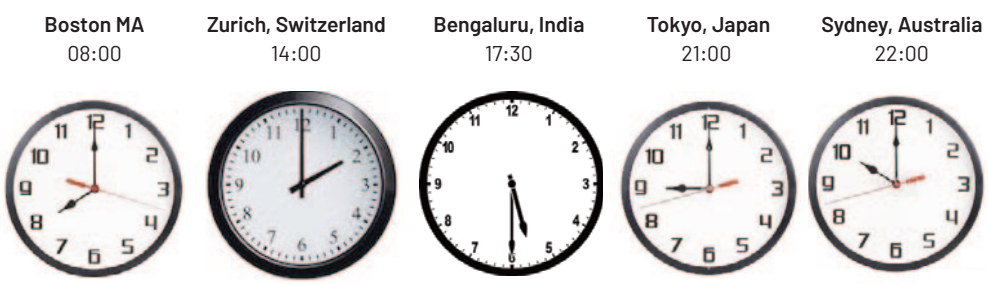

Figure 2. Workday overlap across time zones

NOTE: This example demonstrates workday overlap on a team with MW lead based on East Coast US.

diplomatic and communication skills, the ability to see the "big picture" and the finer details, and a broad understanding of the project content, strategic purpose of the document(s), and project deliverables. As the primary interface with the broader interdisciplinary project team, the MW lead should attend project team meetings, address, redirect, or delegate questions or concerns in the document that require team input, and manage the operational writing tasks. Ideally, the MW lead should be in the same time zone as the key project team members. It can also be valuable to have "local" MW sub-leads in each time zone who are empowered to address issues and questions that arise outside of the MW lead's time zone.

Tools

Web-based applications (e.g., Microsoft Teams, Vault RIM, SharePoint) provide a secure, shared workspace to store documents and work collaboratively and simultaneously. This centralised repository also serves as a hub for the document's current and previous versions, along with essential resources for its development, including reference materials, project timelines, team rosters, reviewer lists, and team calendars.

The tools used to draft the document must be accessible to all MWs, including templates and toolbars that adhere to conventions and provide consistent, predefined styles for formatting text, headings, tables, and references. Styles can be preset within MS Word or as an integrated custom toolbar (e.g., StartingPoint eCTD submission authoring suite). Use of a spreadsheet or Smartsheet to track document development plans, progress, and action items ensures each deliverable is accounted for.

Basics for good teamwork include being reliable and showing up when required, showing respect for others' work norms and cultures, responding promptly to questions or requests, and most importantly, being kind.

An important tool for document development is a conventions document (Table 1) that addresses project-specific considerations beyond those covered in a sponsor's style manual. Developing this tool prior to document authoring is beneficial for the team and reviewers, saving time early on and reducing the risk of impact from late-breaking changes. The larger project team can proactively identify and agree upon terminology (e.g., subject vs patient vs participant, trial vs study), content/structure of page headers and footers, standardised text (e.g, treatment regimen and formulation descriptions), and key message wording prior to initiation of writing. The conventions document can also be used to identify and avoid use of terminology that may introduce confusion when its content is translated into another language. The conventions document serves as a "living document," which can be further developed over time as a resource as the product/project matures.

Communication

Proactive communication and responsiveness are key to developing trust and collaborating successfully. The MW team should agree on the communication method that is quickest and easiest during document development. While email is a useful global tool, other instant messaging tools (e.g., Slack and MS Teams) and within-document communication using comment bubbles with "@" mentions for targeted feedback can be helpful. For the Follow-the- Sun model, we developed a colour-coded highlighting system to indicate development stages, quality control status, and areas requiring attention which facilitated MW communication (see Table 2).

A global MW team should be able to work together remotely almost always; this warrants good teamwork. Basics for good teamwork include being reliable and showing up when required, showing respect for others' work norms and cultures, responding promptly to questions or requests, and most importantly, being kind.[2] Expressing acknowledgement and appreciation is important for maintaining engagement.

Meetings for the MW team are vital for success.

- Timing: A day/time when all medical writers will be able to attend must be agreed upon; times should be rotated so that the inconvenience of early morning or late-night meetings is shared equally.

Table 1. Examples of terminology employed in conventions document

Correct	Incorrect	Notes
Adverse events were reported in x of y (x.x%) patients.	Overall, a low incidence of AEs was observed.	Given the limited follow-up in the Phase 2 studies at the initial submission, avoid use of words such as "low" when describing safety that may only be a feature of the limited exposure.
AEs of special interest	Targeted AEs	For consistency across the programme, as agreed with Global Safety.
AE that occurred during study drug administration is an *infusion-related reaction*	Infusion reaction	Unless specifically identified as an anaphylactic or immune related reaction, refer to the event as having occurred during drug administration.
drug 100 mg IV q8w	100 mg of drug administered intravenously every 8 weeks	<treatment> <dose mg> <route> <dose frequency>

Table 2. Example of colour-coding text for ease of communication

Example of colour code	What it indicates
Green = question for reviewer	Text has a question for the team to address
Blue = note for MW	Text has been updated and requires additional action by MW, such as: • Ready for Lead MW review • Pending question for Lead MW to address • MW note to self
Yellow = ready for QC	Text is ready for QC
Pink = QC completed	Text has been drafted and QCed
Grey = text is ready for team review	Text has been updated, reviewed by Lead MW, and QCed, and is ready for team review

Abbreviations: MW, medical writer; QC, quality control

- Frequency: A pre-scheduled meeting series provides a time when MWs can ask questions and provide updates; meetings can be cancelled if not needed. Meetings conducted regularly, sometimes daily, assess progress, encourage collaboration, identify action items, and address issues or problems. For less experienced writers, participating in such discussions and receiving real-time feedback from experienced writers offers a valuable growth opportunity: this enhances skills and helps build and retain talent. While complex high-level and high-visibility documents (e.g., Module 2 summaries, briefing books) are often assigned to senior writers, junior writers have much to gain by actively participating and contributing to their development.

Table 3. Benefits and challenges of the 24/7 Follow the Sun model

Benefits

- Reduces stress and burnout by working within "normal" work hours, and encourages best efforts for superior work
- Creates a sustainable work-life balance, supporting employee retention and job satisfaction
- Encourages talent engagement by offering opportunities for professional growth, international collaboration, and challenging projects with highly skilled and qualified writers as well as with other subject matter experts
- Collaborative efforts to solve problems and challenges
- The model is scalable, allowing for teams to be efficiently increased or shifted as work needs demand
- Writing team's project knowledge enables successful post-submission filing activities, e.g., agency responses

Challenges

- Building trust and rapport across cross-cultural teams during the initial phase of engagement requires mutual time and effort
- Addressing time zone differences, vacations, holidays, etc.
- Providing continuous open feedback, which requires time and effort
- Keeping central calendar current
- Cultural differences to request assistance or clarifications, or providing feedback
- Ensuring documents read as if written by a single writer ("one voice")
- Difficult for some writers to work in collaborative fashion, prefer to have ownership/control over document

- Agendas and minutes: A "standing" agenda for regular meetings will encourage MWs to be prepared to provide updates on their tasks. A tool such as OneNote can be used during the call to capture document status and decisions, creating an archive for reference and a place to record action items that require follow-up.

And finally, timely and open feedback is essential to prevent errors, improve productivity, ensure goals are clear, and boost the team's confidence. In some cultures, asking questions and providing critical observations are not encouraged, which can lead to misunderstanding as well as frustration, fear, and lack of self-worth. Everyone benefits when questions can be asked, differences can be resolved, and miscommunication minimised.

Using the model

With the elements for the model in place, the Follow-the-Sun model can be utilised for a single document (e.g., a clinical study report) or an interrelated set of documents (e.g., clinical overview, CTD Module 2 clinical summaries, risk management plan).

Project kick-off meeting for the MW team

This first meeting sets the tone and expectations for the project and aligns participants' understanding of the timeline, the deliverables, and the key stakeholders. The MW lead and, as appropriate, line function members, guide the presentations and discussion. Participants include all members of the global writing team, i.e., MWs, QC reviewers, and document specialists. A typical agenda includes, but is not limited to, the following:

- Background material to familiarise MWs with

the topic (training on disease or indication background, reference documents, source documents, journal articles, etc.); a clinical (or other) expert can be invited to present this information
- Confirm use of project tools and templates
- Identify and assign roles and responsibilities: MW lead, local sub-leads as appropriate, then by-writer responsibilities by subject or task
- Agree on writing best practices to be used: e.g., lean writing, conventions, template sentences for results, rolling QC and scope of QC (no formatting checks or no abbreviations checks), and standard email messaging to ensure the writing team has "one voice"

Ready, set, write!

The MW team now moves forward as one. They work rapidly and without pause across time zones in their assigned roles: writing, inserting tables and figures, performing rolling QC checks for accuracy and consistency, and applying formatting and other style needs. Tools such as the conventions document and use of the colour-coding system help the team to quickly understand what is needed and where, with consistent use of terminology. Writers add questions, assign tasks, and provide input to the other writing team members using pre-agreed communication methods. Optimum performance is achieved when responsibilities are very clear. Team members need to be willing to help each other as needed as project needs may shift over time.

Meetings, scheduled or ad hoc, allow rapid problem solving and can pivot resource allocation to solve unforeseen difficulties during document development (e.g., ad hoc analyses, changes in strategy, table re-run/updates, etc.).

When a draft is available, reviewers can focus on the content relevant to their expertise, confident that the MW team has worked to identify and correct in data and formatting, which saves reviewer time and energy. In addition, a section-by-section "rolling QC" saves valuable time near document completion, resulting in reduced time for final QC.

Project wrap-up

Once the project is complete and the deliverables have been transferred to the publishing team, all elements of document development should be archived in the appropriate repository. Some or all documents may be required to address subsequent regulatory needs, such as regulatory inspections or questions from health authorities, inform journal publications, or other documents for communication about the product or programme. The now-experienced global MW team is perfectly positioned for continued rapid responsiveness, saving time and resourcing energy when demands are received.

> Best results are achieved by proactive planning, alignment of content and messaging, strategic assignment of tasks to suitable talent, and fostering a culture of open communication founded on trust and mutual respect.

Finally, the global MW team should meet for an open discussion of plus/delta experiences and outcomes, summarised in a "lessons learned" format that can be applied to future projects (Table 3). Key metrics for performance should be summarised, and used as comparators with other projects to measure success or further needs for improvement. This is also a great time to have individuals and teams commended for the job well done and may even spark a virtual global celebration! Being a part of a successful team endeavour is invaluable for positive professional growth and sense of self-worth. This experience identifies and nurtures future leaders, and also encourages employee retention by fostering a sense of belonging and accomplishment.

Conclusions

The 24/7 Follow the Sun model, a strategic initiative to improve performance, was successfully piloted and subsequently implemented as a "business as usual" practice for individual documents and inter-related documents included in regulatory submissions. The model offers a sustainable, scalable solution to the ever-increasing need for faster development of high-quality documents. During the pilot phase of model implementation, time to write (draft to final) was appreciably reduced by working across time zones with informed, engaged MW team members.

Building and implementing this model requires commitment across the global MW team, their leaders, and key stakeholders. Benefits gained from use of the model can be significant; for success, considerations must be granted to address individual and team needs, at both personal and corporate levels.

It should be noted that this model predates the availability of ChatGPT or other generative artificial intelligence tools and could be modified to incorporate these and other technological advances as they become available. As the model

Lessons from the Follow the Sun pilot

Our initial Follow the Sun pilot was for a new biologics license application that included four Phase 1, two Phase 1b/2, and two Phase 3 clinical studies. The lessons we have learned and subsequent evolution are summarised in the table below.

How we started and what went wrong	How we corrected
Prepared minutes from MW meetings and circulated them by email. Required too much time.	Used OneNote online for live minute-taking during meetings.
Drove MW meetings using list of deliverables and asking each writer for status update. Required too much time.	Asked if anyone was not tracking to timeline; used meeting time to problem solve.
Used complex Excel spreadsheet tracker that included granular list of tasks with instructions and assignments for each time zone. Tracker was not maintained, and inaccurate information created confusion.	Relied on verbal communication at daily meetings, group IMs, OneNote, and most importantly, communication within the document itself using comment bubbles and colour-coding.

is revised, refined, and improved over time with the experience gleaned from early projects, benefits have included: significant reduction in time from data to final document, decreased external resource spend, enhanced collaboration among both writers and subject matter experts, reduced reviewer workload, and streamlined publishing.

Opportunities for global collaboration, professional growth, and better work-life balance offer increased job satisfaction and a greater sense of empowerment for writers across the globe, which subsequently encourages talent development and retention. Use of the Follow the Sun model has created a lasting alliance, with improved working relationships among MW teams across geographical regions, contributing to a long-standing, respectful, productive partnership. Best results are achieved by proactive planning, alignment of content and messaging, strategic assignment of tasks to suitable talent, and fostering a culture of open communication founded on trust and mutual respect.

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An interview with Julia Cooper: Insights and experiences from leading a global medical writing team

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Abstract

Julia Cooper, PhD, is the Corporate Vice President and Head of Medical Writing Services at Parexel. In this interview, she shares her insights on the different aspects of leading a global medical writing team and on how she and her team at Parexel approach training, quality control, conflict management, communication, and community-building. She also discusses overcoming challenges, building a united global team, and ensuring consistent, high-quality work throughout the world. (All sections in italics below are Julia Cooper's words).

Leading a global medical writing team is an inspiring and demanding role filled with challenges and rewards. In a conversation with Julia Cooper PhD, Corporate Vice President and head of Medical Writing Services at Parexel, we gain insights into this position's intricacies and the strategies that lead to success. (See Figure 1). Julia emphasises the role of shared values in forging a team, regardless of geographical separation. Creating a safe space for learning, utilising peer development programmes, fostering open communication, resolving conflicts, and nurturing a sense of community and belonging are crucial in cultivating a thriving working environment.

"We're one team, we're all trying to achieve the same objectives, so let's treat each other in the way that we would want to be treated ourselves. We can achieve our goals working with colleagues we enjoy spending time with."

From researcher to global leader

Julia chose to give me the short version of her career path. Walking me through the full version of how she attained a leading position at one of the major CROs might have taken up all our time.

Like many in the field, Julia did not plan to become a medical writer but started in academic research after graduating from university. However, she "always tries to be open to new avenues that she hadn't considered before," as she puts it. Soon, Julia discovered medical writing via a job advertisement and made her shift into the field. Later, she moved to Parexel as a Senior Medical Writer. A series of opportunities eventually led her to manage the European medical writing team, and a couple of years later she was invited to lead the global team.

Today, she manages nearly 300 employees within her direct team, and about 800 employees are involved with medical writing within the company.

Her exciting and dynamic career path aligns well with her personal interests. As she says, *"I love to travel, experience new cultures, meet new people during my travels and, above all, to experience the local food."*

Working in four different countries – Germany, UK, China, and Ireland – and getting involved in several professional organisations – including EMWA, AMWA, and the China Medical Writing Community – has allowed Julia to gain unique and broad perspectives on the role of the medical writer globally, her team's cultural differences and similarities, and much more.

Medical writing around the world

Over time, medical writing has evolved, and so has its perception – a process that spans the globe, independent of culture or location.

"I found that the biggest difference [in the perception of the medical writer] *is probably between teams who have worked with medical writers before and those who haven't... It was less based on cultural differences, more on the experience and understanding of what a medical writer can bring to the team."*

As clinical trials became more complex, the preparation of a protocol or a final study report, for example, often turned into a more challenging and intricate task. Simultaneously, timelines shortened, and the pressure grew. "*That has made the role of the medical writers increasingly multi-faceted,*" says Julia.

Expertise and efficiency are sought and appreciated in regulatory document preparation, so medical writers are now valued members of most teams who need to prepare these documents. Robust medical writer training includes a significant investment in acquiring the hard and soft skills needed to deliver high-quality documents, enabling the rest of the team to focus on their own competencies and contributions.

Expertise and efficiency are sought and appreciated in regulatory document preparation, so medical writers are now valued members of most teams who need to prepare these documents.

"They [the teams] *now understand what medical writers do. They view a writer as someone who is going to develop a quality clinical study report or the final deliverable per regulatory requirements. Because medical writers regularly prepare these documents, experienced writers know how to do this most efficiently."*

The skills and mindset of a medical writer who became a global leader

When I asked Julia about the skills she transferred from her role as a medical writer into her leadership career, she listed key competencies. Besides the evident writing skills, she highlighted organisation, project planning, building relationships, and communicating with people.

The principles used to manage a large regulatory document project can be extrapolated into different scenarios that leaders need to address, for example, when setting up a new

Figure 1. Five key points of Julia's insights of leading a global medical writing team

group utilising a global team or deploying a new technology.

"Being able to break goals down into smaller pieces and then map out the process, how you're going to get there, and what the timeline looks like… being able to negotiate with people and help them to reach a consensus… It's these organizational, communication, and listening skills that I learned as a medical writer that are equally necessary to succeed as a global leader."

Despite the many skills medical writers already possess when entering management and leadership roles, other skills need to be developed, according to Julia. A leader's responsibilities extend beyond the operational oversight of the project at hand. They need to look further and set the team up for future progress and success, ensuring the team evolves and adjusts to changes in the industry.

"At the individual level, it's helping people with development plans so that they continue to develop in their careers, and the team has a bench of evolving talent to meet current and future needs. For the wider team, I need to ensure we regularly evaluate our process and models to maintain high quality and maximum efficiency. To do this effectively, I need to regularly set aside time together with my leadership team to strategise and reevaluate our approach to operational processes, talent development, and technology. This is particularly important given the fast-paced evolution of AI and other technologies that are influencing our profession."

Uniting a team with members from all over the map

In addition to supporting individual and team progress, a leader must strive to establish a sense of community within the team. This is easier said than done, especially if the team is spread across different time zones.

At Parexel, leaders invest time and effort to create a community despite geographical dispersion of the team.

"Being united in the purpose of what we're doing and regularly communicating with the team on the value that medical writing brings, and how that helps to bring medicines to patients faster – that unites us as a community. Getting that message out – that what we're doing is really important and… to bring our team together regularly to talk about our goals, review our processes and learn from successes while recognizing when a team or a person has done something really well – is also an important way to unite the team and create community."

In a team, no one is alone

Julia underlines the importance of a team of people with different skills, from entry-level to experts. Everyone has an important part to play and some of the senior staff act as Julia's delegate when she is unavailable, or they help to share the leadership workload and perhaps learn a new skill. Whether a leader or an employee, accepting that you can't do everything by yourself is essential. This philosophy applies at all levels in the Parexel medical writing team.

"We try to make sure that people get to work with colleagues across regions and with various levels of expertise. While we have some teams dedicated to a particular client or a program, where possible, we make sure that people collaborate with their global colleagues. We encourage people to reach out… to ask for help, and it's almost unknown for those requests… to go unanswered. Somebody within the global team will pitch in... We have regular global and regional meetings, which are all done on Microsoft Teams. Where it's possible, we also encourage people to come into an office from time to time, but our locations are quite spread out these days, so that's not always feasible. To foster a sense of belonging, some of our managers will hold informal coffee chats on Microsoft Teams, where people can just dial in and talk about personal topics that we would have shared in the kitchen during the days when we were office-based."

Training and quality control globally

In addition to maintaining a positive team atmosphere, comprehensive training is also critical for a globally dispersed team. It keeps service quality and regulatory compliance consistently high across the whole team, no matter where the staff is based.

"In our team, everyone follows the same training and development programme, whether document-specific and other technical competencies or soft skills training. It's also important to apply the training in practical situations with the right level of support from a mentor or line manager. We also take advantage of shadowing opportunities – where an experienced writer will have a less experienced writer working under their guidance on the same program – and this tends to work quite well in medical writing."

Line managers are closely involved in individual training and supporting progress. They work with their team members to implement development plans that take into account the needs of the business and also map out a route to achieve personal career goals and aspirations.

As performance and quality must achieve the same high standards among team members in different regions, assessment of these aspects is harmonised across the team.

"We're trying to make sure that everybody has been given the same chances and that their performance is evaluated in the same way as closely as possible. A senior medical writer in Germany is evaluated on the same principles as a senior medical writer in India or the US, etc… we created skill standards by role to achieve this, which align with job descriptions. They include medical writer competencies tailored to the job title and experience level. Similar skill standards have also been established for supportive roles, e.g., document quality reviewers and document specialists. These are available to everyone in the team so that expectations are clear."

Managing conflicts in a global team

Despite promoting equality and a sense of belonging, issues and conflict occasionally arise in any team. However, Julia says that potential problems tend to be similar across teams, independent of location and background. As a leader, you need to listen, negotiate, communicate clearly, and put yourself in the others' shoes to understand where they are coming from. Establishing a safe environment at an early stage, to learn from mistakes and avoid blame, promotes transparency and learning across the team.

> I think that is really what it's about: understanding that there's much more that brings us together than differentiates us.

Should ethical issues arise, they are addressed with a similar approach: encouraging employees to speak up about their concerns and ensuring that they will be taken seriously. Surfacing a potential problem early on prevents a more serious one later.

"I haven't seen so many variations [of ethical issues and other problems] *across cultures. The most important thing here is to have an environment where anyone can speak up without retribution if they're not sure about something … working in a global company which has ethical standards and processes around ethics, it's clear what employees need to do if they are in any doubt about the situation. There are very clear processes and ways to communicate with company experts in these areas."*

A common goal outweighs difficulties

Ultimately, cultural differences and geographical locations influence teamwork and consistent quality only in a limited way.

"Most employees want a job that provides them with career perspectives, and a sense of meaningful work. They want to feel like they've done something that added value at the end of the day but also allows them to balance the job with their outside life, whatever that is, be it family, personal interests, or other commitments."

Our medical writing group understand that patients directly benefit from our work, and this unites the team across the globe. As Julia, an experienced cross-cultural leader of international teams, puts it:

"I think that is really what it's about: understanding that there's much more that brings us together than differentiates us and trying to make sure that everyone has comparable opportunities and are treated fairly."

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

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Interviewee information

Julia Cooper, PhD, is Corporate Vice President, Head of Global Medical Writing Services at Parexel, and leads a global team of around 270 staff. From 2013–2016, Julia was based in Parexel's Shanghai office, where she helped set up the China Medical Writers Community. She has held various roles on the EMWA Executive Committee, and currently chairs the AMWA Executives Advisory Council, and is joint interim Treasurer of EMWA. Julia is also a Nick Thompson Fellow.

Medical Writing in
JAPANESE

Writing medical documents in English while thinking in Japanese

Writing medical documents in English while thinking in Japanese is like trying to build a bridge between two islands with very different landscapes. It's a challenge that many Japanese medical writers face, and it's not just about knowing two languages – it's about navigating two different ways of thinking and expressing ideas.

Let's start with the basics: grammar. Japanese and English are like distant cousins in the language family – they have very different ways of structuring sentences. In Japanese, it's common to leave out the subject of a sentence because it's often understood from the context. For example, "食べた" (tabeta) could mean "I ate," "you ate," or "they ate," depending on the context. But in English, you need to spell everything out clearly. This means that when writing in English, Japanese speakers often have to add in details that they wouldn't normally think about in their native language.

Another puzzle is the order of words. In Japanese, the verb usually comes at the end of the sentence, while in English, it's usually near the beginning. For instance, "私は昨日病院に行きました" (Watashi wa kinou byouin ni ikimashita) literally translates to "I yesterday hospital to went, " but in English, we'd say "I went to the hospital yesterday." This difference can make it feel like you're constantly rearranging puzzle pieces in your head as you write. It's no wonder that sometimes the resulting English sentences can sound a bit odd or unclear to native speakers.

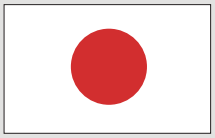
Medical terminology adds another layer of complexity. You might think that medical language would be the same everywhere, but that's not always the case. Some medical concepts that are common in Japanese might not have an exact match in English, or vice versa. For example, the Japanese term "冷え性" (hie-shou), which refers to a condition of poor circulation and sensitivity to cold, doesn't have a direct English equivalent. It's like trying to describe a unique Japanese dish to someone who has never seen it – you might know exactly what it is, but finding the right words in English can be a real challenge. This difference in medical terms isn't just about finding the right word; it's about making sure the core idea is understood correctly.

Writing in English while thinking in Japanese is not just about translating words; it's about translating entire thought processes. In medical writing, this challenge is even more critical. You can't just do a word-for-word translation because that often leads to confusing or even incorrect information. For instance, the Japanese phrase "お大事に" (odaiji ni), commonly said to someone who is ill, literally translates to "take care of the important thing, " but it's actually closer in meaning to "get well soon" in English. Instead, you need to understand the medical concept in Japanese, break it down to its core meaning, and then rebuild it using English words and structures.

This process of breaking down and rebuilding thoughts is a special skill that goes beyond just being good at both languages. It requires writers to think critically about how ideas are expressed in Japanese and English and find ways to bridge the gap between the two. They need to understand not just the words, but the cultural context behind medical terms and practices in both countries.

To get better at this challenging task, medical writers need to practice a lot and expose themselves to medical writing in both languages. Reading medical journals, reports, and books in English can help them get a feel for how ideas are expressed. Collaborating with native English speakers and other medical professionals can also be incredibly helpful. It allows writers to check if their English expressions accurately convey their original Japanese thoughts.

Writing medical documents in English while thinking in Japanese is a bit like being a translator, a medical expert, and a cultural ambassador all at once. It requires patience, practice, and a willingness to keep learning. This unique skill set not only facilitates effective communication but also bridges cultural and linguistic gaps in the global medical community.



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Training and development opportunities for medical writers from different regions across the world

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Abstract

In the dynamic and rapidly evolving field of medical writing, continuous learning and professional development are crucial for success. Medical writers play a vital role in translating complex scientific and medical information into clear, accurate, and engaging content for various audiences, including healthcare professionals, regulatory bodies, and the general public. To excel in this demanding profession, medical writers must stay updated with the latest advancements, writing techniques, and industry best practices. Fortunately, there are many training and development opportunities available worldwide tailored specifically for medical writers. This article delves into the various training possibilities available globally, from short courses to education programmes and from certification courses to workshops, conferences and online resources, providing a useful guide for medical writers eager to enhance their skills and advance their careers.

The field of medical writing demands a skilled workforce equipped with the latest knowledge and techniques. But you don't go to university and get a degree in medical writing. Many medical writers have transitioned to their field from other areas – from clinical medicine to general communications, marketing, and more. Medical writers enter the field with transferable skills that need to be refined to meet the specific requirements of the medical writing profession.

So how do experienced medical writers advance their skills and how do beginners transition to the field?

Over the past couple of decades, a diverse array of niche medical writing training and development opportunities has emerged globally. Many of these opportunities are available online, making it easy for medical writers, wherever they're located, to stay updated with their profession. This article provides a small sample of the broader range of training options available to medical writers. This list is not exhaustive and may not encompass all possibilities. The reader is encouraged to seek additional information and resources to gain a comprehensive understanding of the topic.

How to choose the right training and development opportunities

Before you explore training and development opportunities in medical writing, it's important to consider your goals and skill gaps.

- **Start with your career goal** – Where do you want to be in 6 or 12 months' time? Define your goal, then plan the necessary steps needed to achieve it.
- **Do you want to be a freelance writer or an employed writer?** – There are different options based on your objective, so decide whether you'll start a medical writing business or apply for permanent roles instead.
- **Identify your skill gaps** – Determine any missing skills based on your career goal. For instance, you might possess strong writing abilities but lack the knowledge to establish a freelance business. Alternatively, you may excel in academic writing but have no experience in consumer health writing. You could be new to artificial intelligence or need to enhance your freelance business skills.
- **Network with others who are where you want to be** – Connect with medical writers who are already succeeding in the industry for insights into their career paths and the steps they took.

Before you explore training and development opportunities in medical writing, it's important to consider your goals and skill gaps.

Once you have an idea of what you are hoping to achieve through training, in alignment with your goals, you can identify suitable training and development opportunities.

Formal education

Let's start at the beginning: university education. Many medical writers wonder if they need some type of degree to be a medical writer – and, if so, should it be a writing degree or a medical writing/scientific degree?

While not always a prerequisite, advanced degrees in scientific disciplines or health-related fields can provide a strong foundation for medical writers.

Certain types of scientific medical writing jobs require candidates to have advanced degrees, and this is always listed in the job descriptions. But is it worth doing a PhD to become a medical writer?

In some contexts, a PhD can be valuable for a career in medical writing, particularly if you aim to specialise in complex or research-intensive areas. It enhances credibility and expertise, but many successful medical writers worldwide have relevant experience, strong writing skills, and highly successful careers without a PhD.

While no universities offer specific degrees in medical writing (yet), many universities in regions such as North America, Europe, and Asia offer specialised programmes or post-graduate

courses in medical writing, biomedical communication, or science journalism. These courses can teach you valuable writing skills and industry best practices.

Professional certifications and associations

Participation in well-established medical writing associations enhances professional development.

Engaging with recognised associations ensures access to high-quality resources and a supportive network, thereby enhancing both learning experiences and professional growth.

Industry-recognised certifications, such as those offered by the American Medical Writers Association (AMWA) or the European Medical Writers Association (EMWA), validate expertise and enhance career prospects. Regardless of your career stage, certifications from reputable organisations look good on your CV and teach valuable skills. Here are some examples:

- **American Medical Writers Association (AMWA)** – AMWA offers the Medical Writer Certified credential and a variety of online and in-person courses, covering diverse aspects of medical writing.
- **European Medical Writers Association (EMWA)** – EMWA provides workshops, webinars, and the EMWA Professional Development Programme to support continuous learning.
- **Regulatory Affairs Professionals Society (RAPS)** – RAPS provides courses on regulatory medical writing as part of their professional development offerings.

Workshops, conferences, and webinars

Workshops, conferences, and webinars are critical for hands-on learning and networking. Attending relevant medical writing and industry events exposes you to new ideas from professionals working in the field. Workshops are excellent education tools, as they allow you to bounce ideas around with your medical writing peers and get feedback on your writing. Here are some options:

Workshops, conferences, and webinars are critical for hands-on learning and networking.

- **AMWA and EMWA conferences** – These events feature sessions on various aspects of medical writing, professional development workshops, and networking opportunities.
- **Drug Information Association (DIA) Conferences** – DIA conferences include sessions on regulatory writing and medical communications that cater to professionals in the pharmaceutical and biotechnology sectors.
- **Specialty conferences** – These include health topic conferences, health literacy-themed events, and SEO conferences.

Online medical writing courses

Online training provides the biggest and best opportunities for medical writing education worldwide.

The main benefit is that online courses are easy to access for anyone, anywhere. Medical writing courses cover various topics, including career development, skill enhancement, and freelance medical writing.

Through an online course, you can connect with niche experts around the world from the comfort of your own home, and online learning can be relatively cost effective. You can take courses as soon as you are ready and start upskilling today. You can also get individual feedback on your writing which is incredibly valuable for any writer.

It's important to be aware that online training catering to medical writers globally can sometimes be generic and can't always account for region-specific regulatory requirements.

While medical writing as a skillset is

essentially the same around the world, and many medical writers work for global clients, there are country-specific rules and regulations to be aware of for certain types of medical writing roles. For example, if you're working as a medical writer in Australia, you need to be familiar with the Therapeutic Goods Administration, which has specific regulations for marketing health products. These rules may differ from those in other countries. That's where taking a programme in your location from a local expert can be helpful.

If you're considering an online medical writing course, look for an option with a global base where you can connect with other students in your local area.

There are many excellent online courses available. However, some courses may lack substantial backing or credible experience, resulting in offerings that can sometimes provide less effective training and may not be a worthwhile investment.

Here are some reputable options:

- **Health Writer Hub**: Offers online courses in health writing and freelance writing (https://www.healthwriterhub.com/).
- **Emma Hitt:** Provides online courses in medical writing
- **Sarah Nelson:** Offers coaching for medical writers
- **CME Pro:** Specialises in continuing medical education resources
- **Medcomms Networking:** A platform for networking and resources in medical communications.

Online courses about related topics

In addition to online medical writing courses, online courses about more general topics can help medical writers upskill and stay updated with important industry topics.

Thinking about different areas, you can study topics in therapeutic areas or specific skills. For example:

- **Health topics, therapeutic areas, and medications** – If you have a special interest in a topic like neuroscience, taking a course can help you update your knowledge.
- **Health literacy and patient education** – If you are interested in learning more about behaviour change and health literacy, you can attend training seminars and follow new research in these areas.
- **General writing courses, including copywriting and technical writing** – Though these courses may not be aimed at medical writers specifically, they are excellent for writing skill development
- **Technical skills, such as SEO and AI** – Many clients and employers value medical writers with a broad range of expertise in new technologies. Certifications in these areas are a significant selling point.
- **Project management** – An essential skill for new and experienced medical writers alike
- **Freelance writing, including business management and marketing** – If you want to become a freelance medical writer, taking a course in business or marketing can help you stand out online and succeed.
- **Career and CV writing** – If you need assistance applying for roles or writing your CV, courses exist to help in these areas.

Other opportunities for medical writers worldwide

There are many options for medical writers to develop their skills aside from online and in-person learning. Here are some options to consider:

- **Mentorships** – Many experienced medical writers offer private mentorships for free or a small fee, and organisations like AMWA offer mentorship programmes connecting novice writers with experienced professionals.
- **On-the-job training** – Some agencies and medical companies offer mentorships and on-the-job training for entry-level medical writers; you can search for these opportunities on LinkedIn or a website such as Monster or Indeed.
- **Pitching and publishing** – Writing and submitting articles to journals, magazines, and websites helps you practice writing, gain recognition, and enhance your experience.
- **Volunteering** – Writing or editing for medical-related nonprofits and NGOs gives you practical experience and community service.
- **Peer-review opportunities** – Engaging in peer reviews for journals or conferences offers experience and skill development in scientific writing.
- **Region-specific opportunities and variations**

If you're considering an online medical writing course, look for an option with a global base where you can connect with other students in your local area.

While the core competencies for medical writers are universal, training opportunities vary across regions. For instance, the US emphasises practical, industry-focused training, while European programmes often incorporate a stronger academic foundation. Asia-Pacific countries are witnessing a surge in medical writing roles, leading to increased training initiatives.

North America

For medical writers in North America, the path to professional growth is paved with opportunities, from broad-based programmes to specialised certifications. Here are some of the prominent training and professional development courses available.

For early-career medical writers, the AMWA remains the core of the learning ecosystem. Its *Essential Skills* certificate programme provides a solid foundation covering the fundamentals of medical writing, while the new *Health Communication Curriculum* addresses principles of health communication, ethical considerations when creating health content, and more. AMWA's *Medical Writer Certified* (MWC) credential, available to professionals with at least two years of medical writing experience, has become a respected industry-standard credential. For established medical writers, advanced workshops at the annual conference and online courses focus on more specialised topics such as regulatory writing, freelance business building, and statistics.

University-based certificate programmes have gained popularity for those seeking structured learning pathways. The University of California San Diego Extension and the University of Chicago offer comprehensive medical writing certificates, blending online and in-person instruction to accommodate working professionals. These programmes are designed for professionals with advanced biomedical and life science degrees looking for careers outside academia and cover relevant topics such as writing to support regulatory documents, research grant proposals, and submissions to peer-reviewed journals, as well as ethical considerations in writing and editing. In 2024, the University of Chicago added a Professional Certificate in Healthcare Communication, which includes courses on medical copywriting, patient

education, and continuing education for health professionals.

Online platforms (e.g., Coursera and Udemy) have expanded access to both foundational courses (like *Understanding Medical Research: Your Facebook Friend is Wrong*, Yale University; and *Writing in the Sciences*, Stanford University) and specialist courses that allow writers to deepen their understanding of complex subjects, such as clinical trial design and pharmacology. Many foundational courses or coaching opportunities also now exist to help healthcare professionals, scientists, and science graduate students transition into freelance medical writing, such as *The 6-Week Course* offered by Emma Hitt Nichols or coaching with Prospology.

For medical writers seeking more specialised professional development options, the University of Washington offers *Specialization in Regulatory Medical Writing*, while the Regulatory Affairs Professionals Society and the Center for Professional Innovation and Education offer courses on how to write specific regulatory documents. Similarly, the *International Society for Medical Publication Professionals* develops courses on copyright and other topics for publication writers. In continuing medical education (CME), Write Medicine provides hands-on training in CME content development through courses and a membership. The Medical Copywriting Programme guides writers who are interested in pharmaceutical advertising and healthcare professional marketing.

Australia and New Zealand

Australia and New Zealand are two countries with relatively small populations but a large medical writing network! In Australia, medical writing training options include various resources and programmes. The best place to start is the Australasian Medical Writers Association who run an annual conference, host regular networking events, and share online training options for medical writers.

The Australian Writers' Centre offers online and in-person courses with a general focus but these are extremely useful for medical writers who want to hone their writing, editing, and journalism skills.

Some universities provide relevant postgraduate courses and units. The University of Sydney provides courses and units in medical writing as part of its postgraduate programmes. The University of Queensland offers relevant courses through its biomedical and health sciences programmes.

Online platforms such as Health Writer Hub and Coursera offer tailored courses accessible from Australia, covering health and medical writing.

Many foundational courses or coaching opportunities also now exist to help healthcare professionals, scientists, and science graduate students transition into freelance medical writing.

China

In China, there are no formal education programmes or degrees specifically for medical writing, whether at universities or non-profit medical writing related institutions.[1,2] Many writers rely on the hiring company's Standard Operating Procedures, Work Instructions, and/or document-specific templates (e.g., Clinical Trial Protocol and Reports) that conform to The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines. Additionally, writers also refer to past examples of relevant documents as "reference materials" to guide them as they begin their writing careers. Some companies offer on-the-job

shadowing and/or coaching programmes where junior medical writers are paired with more experienced senior writers.

In rare instances, medical writers are given the opportunity to participate in education programmes offered by AMWA, EMWA, and the International Society of Medical Publication Professionals (ISMPP), which are organisations that offer professional training for medical writers. In addition, the Chinese Medical Writers Community (CMWC) provides a platform for Chinese medical writers to meet and share knowledge through its annual conference. Furthermore, medical-related conferences in China, such as the Chinese Medical Affairs Conference and DIA, now include topics related to medical writing, providing writers with opportunities for exchange and discussion.

In China, medical writers face several challenges, including a lack of systematic and standardised training programmes, unclear career development paths, and challenges in cross-cultural communication.

Additionally, as the majority of the content in Clinical Trial Reports for the China Sub-population (subgroup analysis reports) is derived from global clinical trial reports, there is limited room for medical writers in China to grow. However, with an increasing number of local pharmaceutical companies in China aiming to, or already, registering their drugs globally and needing to write reports in English following ICH guidelines, the market presents both challenges and opportunities for medical writers' career development. Thus, there is a growing need for targeted training and development opportunities for medical writers in the region. Tailored training and development programmes, such as online courses offered by organisations like AMWA, EMWA, or ISMPP, with friendly time zones, can help medical writers in China and elsewhere in the APAC region acquire the necessary skills and knowledge to succeed in this rapidly evolving field.

> One of the best ways to find a suitable training and development opportunity is to ask around!

Moreover, with advancements in generative AI, medical writers can train themselves to become "prompt writers", specialising in creating instructions for generative AI to draft parts of Clinical Trial Reports and Clinical Trial Protocols. This allows medical writers to harness AI capabilities to expedite the document writing process while ensuring content accuracy and consistency. However, this also necessitates medical writers to continually upgrade their digital skills and AI application abilities to adapt to this evolving professional landscape.

Europe

In Europe and beyond, the EMWA Professional Development Programme (EPDP) provides training for medical writers through workshops and homework assignments. All workshops are approved by EMWA's Professional Development Committee (EPDC) and taught by leaders with hands-on expertise. These workshops are offered during the Spring (in-person) and Autumn (virtual) conferences every year.

There are about 120 different workshops in the EPDP programme at two levels of competency (foundation and advanced), covering subjects that span all areas of medical writing (regulatory writing, drug development, medical communications, and medical devices) as well as related topics such as statistics, health economics, soft skills, and cross-cultural communications. Workshop participants are eligible for EPDP credits and a certain number of credits qualifies for a Medical Writing Certificate.

In addition, the EPDC organises Expert Discussion Groups (EDGs) during Spring conferences and webinars all year round. EDGs are discussion groups designed more for expert writers and are focused on specific and advanced topics.

Peer recommendations

One of the best ways to find a suitable training and development opportunity is to ask around! We asked our LinkedIn networks about what had been instrumental in helping them succeed and here is a summary of the most popular responses:

1. **Seek reputable courses**: Look for courses from established institutions and professionals, or medical writing programmes from recognised schools. These often provide practical, high-quality training.
2. **Utilise free resources**: Take advantage of free courses and resources when available. For example, Stanford's "Writing in the Sciences" offers valuable insights and practice opportunities at no cost.
3. **Enhance your marketing skills**: Expand your knowledge on the business side of medical writing with resources from experts in marketing and copywriting.
4. **Seek guidance from experts**: Engage with mentors or advisors who specialise in areas relevant to your needs, such as those focusing on helping non-native English writers or scientific writing.
5. **Leverage podcasts and additional resources**: Listen to podcasts and use other educational materials to stay informed and

improve your skills. Resources on plain language and specific writing techniques can be particularly beneficial.

6. **Read influential books**: Enhance your understanding of medical writing by reading influential books, such as Trisha Greenhalgh's *How to Read a Paper*,[3] for deeper insights into research and writing.

Conclusion

Engaging in professional development opportunities is crucial for medical writers to maintain and enhance their skills, stay abreast of industry trends, and advance their careers. By defining career goals and then participating in certifications, courses, workshops, conferences, and other development activities, medical writers can achieve continuous growth and success in their profession.

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Disclaimers

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Disclosures and conflicts of interest

Michelle Guillemard is the founder of Health Writer Hub, an online health writing course provider. This affiliation is disclosed to provide context regarding the author's expertise and background. Alexandra Howson, PhD, CHCP, hosts the Write Medicine podcast and runs WriteCME Pro, a professional development membership for medical writers ready to specialise in CME. This affiliation provides context regarding the author's expertise and background. Ann Zhang, a medical writer at IQVIA, incorporated China-related content based on its topical relevance, without any external influences, affiliations, or undisclosed conflicts of interest.

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The worldwide landscape of freelance medical writing:
Exploring challenges and opportunities

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Abstract

The COVID-19 pandemic has had a significant impact on the pharmaceutical, biotechnology, and life sciences industries, ultimately affecting associated professionals such as freelance medical writers. Throughout this global event and its aftermath, the market has changed significantly, bringing with it new sets of challenges and opportunities.

In this article, we reflect on how the pandemic affected the industry and the current issues affecting freelance medical writers. We also explore freelancers' opinions on the subject, as provided to us through our webinar and an informal survey and provide possible strategies and approaches to tackle these challenging times.

Global landscape: 2020 to today

Industry had to adapt to the COVID-19 pandemic

The pharmaceutical, biotechnology, and life sciences industries were greatly impacted by the COVID-19 pandemic and needed to act fast so they could keep going. At the onset of the pandemic in March 2020,[1] there were two major industry priorities: (i) re-allocating resources towards COVID-19 research and development (vaccines) and product manufacturing (testing kits, protection equipment); and (ii) ensuring the workforce could still function under lockdown restrictions, meaning the workplace had to go virtual and people had to adjust to remote work.

This created a high demand in the industry for professionals who could both provide specialised medical writing support for COVID-19 projects and who had experience working remotely. Enter freelance medical writers.

> "The work just doesn't seem to be there anymore in the same way it was; previously, I was always busy and had to turn down work all the time without trying."

Specific challenges since 2023

By May 2023, COVID-19 was no longer considered a global health emergency.[2] Now that industry's needs have dwindled, so has the demand for COVID-19-related services, with most healthcare companies re-assessing their priorities and restructuring their business strategies. At first, this affected biotech companies focused almost exclusively on research and/or product development related to COVID-19, leading to mass layoffs.[3] Later, however, major pharmaceutical companies also announced restructuring and cost-cutting initiatives.[4]

Other factors contributed to a post-pandemic market downturn, such as worldwide geopolitical events and investor uncertainty in the face of instability. The original shift to COVID-19-related research delayed other clinical trials and drug approvals, setting the stage for slower industry growth in the long term.[5]

At the same time, technology companies rushed to keep up with the demands of the new virtual workplace and develop transformative digital technologies. The arrival of the artificial intelligence (AI) chatbot ChatGPT took the world by storm.[6] Since its release, the use of AI tools has been a point of contention among medical writing professionals, with some fearing these tools might replace them, while others are optimistic that they will aid and enrich their work.

What does this mean for freelance medical writers?

Since 2023, industry changes have greatly impacted professionals, and many freelance medical writers have seen significant changes in their own businesses. To form a clearer picture, Peter Llewellyn launched the #MedComms Freelancing Barometer in January 2024 to assess 2023's freelance activities. It received 550 global responses and highlighted clear issues in freelancing work, such as less demand for freelancers in the healthcare industry.[7]

We aimed to expand on this to understand what freelancers are facing in the 2024 market. In July 2024, Adriana Rocha and Eleanor Steele presented *The Worldwide Landscape of Freelance Medical Writing: Exploring Challenges and Opportunities*, a special webinar hosted by Peter Llewellyn[8] to explore the topic of this article. Later that month, we launched an informal survey to ask freelancers what challenges and opportunities they were experiencing in their current work.[9]

Here, we summarise the main opinions gathered from freelancers and, as always, we interpret their responses with caution.

Challenges

It's a mixed picture

In general, the responses received from the webinar and informal survey gave a mixed picture. Some freelancers reported no changes to their usual workload and were happy with how

the year was panning out, but one responder stated that "*There is a vague sense of uncertainty, which to some extent is part and parcel of freelancing.*" However, many indicated they had faced unusual challenges since 2022, which have continued going into 2024.

Fluctuations in workflow

Freelancers recognise that there are usually seasonal peaks and troughs in medical writing, but some indicated that the troughs were more exaggerated this year compared to previous years. Even busy freelancers, who still have a steady flow of work, indicated that they were turning down less work than in previous years, with one stating "*The market seems unpredictable.*" Experienced freelancers who have felt comfortable with years of stable and predictable workloads are now describing periods of feast-or-famine, with one responder stating, "*The work just doesn't seem to be there anymore in the same way it was; previously, I was always busy and had to turn down work all the time without trying.*"

Tackling budgets and negotiating contracts

In Peter Llewellyn's January 2024 MedComms barometer survey,[7] the data showed that despite maintaining their rates, nearly half of the freelancers stated their revenue at the end of 2023 was less than expected or predicted due to fewer projects. This trend seems to have continued into 2024, with responders to our survey and informal conversations with freelancers raising concerns regarding income stability. This brings up the big "B" – Budget! Budget is a recurring theme in the responses we've gathered. Several freelancers indicated that they have lost contracts because their service rates were too high despite maintaining the rates they've had for years and meeting all the client's requirements. What are the expectations of these clients who have a low budget but want an experienced freelance writer with a multitude of skills? Some responders described clients jeopardising the quality of their work by stripping back hours to meet tight budgets.

> "As my clients recently have tended to be research organisations and direct pharma companies, this has hugely enhanced my client interaction and project management skills compared with freelancing for MedComms agencies, where I often felt hidden from the end client."

Usual sources drying up

Some freelancers stated that they were experiencing fewer requests from contract research organisations (CROs), agencies, and their previous clients, which spans across both MedComms and regulatory work. There also seems to be a trend in agencies requesting freelancers to work in-house, which in most situations is impractical or not feasible. In addition, some people describe being engaged with recruiters and agreeing to projects but nothing materialising or, in the reverse scenario, the project expanding but the budget remaining the same. At the same time, some responders feel that there are more new freelancers in the field, creating even more competition. We currently don't have any quantifiable data on the current number of freelancers today versus a few years ago, but this is an opinion shared by many freelancers, with one stating "*There is definitely more work available than … when I started freelancing. However, there have been exponentially more freelancers since that time, and the increased competition makes it seem like there is less work available overall.*"

Networking and using professional platforms are usually effective sources for potential jobs, projects, or clients. However, many freelancers indicate that even the jobs and recruiters on LinkedIn have gone quiet, leaving freelancers at a loss as to where to search for new clients. More experienced freelancers, who for years relied on longtime clients and ex-colleagues from in-house positions, are now finding that these contacts are not able to provide work

opportunities anymore. This may be the result of agency mandates stating freelancers can no longer be used or their contacts no longer work at that agency due to business closures or restructuring – some freelancers have even found that their contacts had gone freelance themselves!

Upskilling and marketing

Upskilling oneself can be considered both a challenge and an opportunity for a freelancer. Clearly, the role of a medical writer has evolved over the years and, with further advancements in AI and online content optimisation, developing new skills can keep a freelancer ahead of competitors. But experienced freelancers, with years of stability and a constant workflow, are finding themselves in uncharted territory when it comes to developing new tech and business development skills. These freelancers have never had to market and sell themselves to clients and feel daunted, as before the client always came knocking. Some responders indicated that this is a major concern for them and that early-career freelancers skilled in these new technologies are offering lower rates and grabbing the opportunities.

> "I have seen a lot more opportunities for freelance work over the past month, so I hope that this trend continues. I used to be constantly busy, but the last 1.5 years have been much tougher."

A last point discussed was the shift in working patterns of freelancers, with some freelancers changing to in-house roles (employed) or hybrid roles (e.g., splitting their working time between an employed contract and freelance work). Various factors could be driving this, such as job security, income insecurity, or exhaustion, from repeatedly trying and failing to acquire and maintain clients. What we do know is that freelancers globally seem to be feeling a sense of uncertainty. So, how do we overcome these challenges? What opportunities and positives can we take from the current situation?

Opportunities

Use quiet times productively

Rather than viewing quieter times with anxiety, freelancers can use them as valuable opportunities for professional development. After all, fluctuations in workload are part of the medical writing industry. For example, the first quarter of each year is typically the quietest time in any MedComms agency and, therefore, also quiet for the freelancers who support them. One of the most effective ways to utilise these lulls is by factoring them into your plans and investing time, and potentially some budget, in training (see Table 1).

Freelancers could attend workshops, participate in webinars, or enrol in online courses relevant to medical writing or the broader pharmaceutical industry. By doing so, they can ensure their current skills remain sharp and up-to-date while also acquiring new competencies that can set them apart in a competitive market.

Pivot into new areas

Medical writing is evolving as a profession, and quiet periods present an ideal opportunity for freelancers to explore new avenues and expand their professional horizons. This might involve diversifying into different types of projects or exploring new therapy areas. Another strategic move could be to transition from working exclusively with MedComms agencies to directly engaging with biotech or pharmaceutical companies, a shift that can lead to more varied work and potentially higher rates. Indeed, one freelancer shared, "*I feel that clients are increasingly interested in working directly with freelancers, bypassing agencies*", while another said, "*As my clients recently have tended to be research organisations and direct pharma companies, this has hugely enhanced my client interaction and project management skills compared with freelancing for MedComms agencies, where I often felt hidden from the end client.*"

Developing new skills in visual communications and medical media content creation is another promising strategy. As healthcare communication becomes increasingly visual and interactive, writers who can combine solid scientific knowledge with multimedia skills are likely to be in high demand. The increasing focus on personalised medicine, partly driven by AI and big data, presents another opportunity. Apps that connect patients and their data to healthcare providers require medical writers to adapt complex medical information into lay language for patients. Additionally, the pandemic highlighted the need to combat medical and scientific misinformation, making medical journalism and fact-checking essential areas to explore, particularly in the context of AI-generated content.[4,5] By staying adaptable and open to new opportunities, freelancers can often maintain a steady stream of work and professional growth.

Table 1. Opportunities for freelancers during quiet periods

Use quiet times productively

- Don't panic during slow periods, especially Q1
- Ringfence time and budget for learning and development
- Keep current skills up to date and build new skills

Find sustainable, authentic marketing strategies

- Start by talking to people you know
- Regularly check in with previous clients/colleagues
- Mention additional services or capacity to existing clients
- Keep track of conversations and follow up regularly

Pivot into new areas

- Explore new types of projects
- Expand into broader therapy areas
- Consider working directly with biotech/pharma clients

Join a professional community

- Expand your network and connect with peers
- Access resources and support
- Discover new opportunities and clients

Abbreviation: Q1, first quarter of the fiscal or calendar year.

Find sustainable, authentic marketing strategies

Marketing your services as a freelance medical writer doesn't have to be intimidating or flashy. Often, the most effective marketing strategies are those that feel authentic and leverage existing relationships. A good starting point is to maintain regular contact with previous clients and ex-colleagues. This can be as simple as periodic check-ins to inquire about their current needs or to share updates about your services. One freelancer shared, "*Business development at all times will help you to manage during tough times. Do your best to be the top of the mind recall so that when the opportunity arises, you are the first on the [client's] list.*" When communicating with existing clients, always mention any additional services or increased capacity you might have available. New opportunities can also be found in unexpected places. Your broader social circle is likely to include people who work in related fields; you just may not realise it yet!

Keeping track of who you talk to and when you have those conversations is essential. This way, you can follow up regularly and maintain those relationships. Authentic, consistent communication can help you build a strong network and ensure a steady flow of work.

Support and networking communities

Joining professional communities can provide invaluable support and networking opportunities for freelance medical writers. These can range from large organisations, such as the European, American, and Australasian Medical Writers Associations, to smaller local organisations. Within EMWA, there is a dedicated Freelance Business Group that provides information for freelancers.[10]

Communities vary by geographical location – from Asia Pacific to South America – and by area of expertise, such as the MedComms Workbook[11] for MedComms freelancers and the Chartered Institute of Editing and Proofreading[12] for editors and proofreaders. You can find a more complete list of communities in last year's article on the need for community for freelance medical writers.[13]

Being part of such communities can offer support, advice, and networking opportunities, helping you to navigate the challenges of freelancing and find new opportunities.

Conclusion

Overall, there are reasons for optimism. Some freelancers agree that perhaps we are resurfacing from the dip, with one remarking, "*I have seen a lot more opportunities for freelance work over the past month, so I hope that this trend continues. I used to be constantly busy, but the last 1.5 years have been much tougher.*" By using quiet times productively, diversifying your work, employing sustainable marketing strategies, and engaging with professional communities, you can build a sustainable and rewarding freelance career in this dynamic field.

What's your opinion? What challenges and opportunities have you experienced as a freelance medical writer? You can continue the conversation at the dedicated EMWA Freelance Business Forum Online LinkedIn group,[10] come share your insights with other freelancers and let us navigate these issues together.

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Disclosures and conflicts of interest

Eleanor Steele works as the MedComms Mentor, providing professional training, mentoring, and consultancy to MedComms clients. Eleanor also manages the MedComms Workbook subscription service for MedComms freelancers. Adriana Rocha and Laura Kehoe declare no conflicts of interest.

Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

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Author information

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Eleanor Steele has worked in MedComms since 2004, first as a medical writer, then leading scientific teams in several different agencies. She is now a freelance consultant working as the MedComms Mentor to provide specialist training and mentoring to medical writers and consultancy to agencies around building, nurturing, and developing their medical writing teams. Since April 2024, she has also managed the MedComms Workbook subscription service for MedComms freelancers.

Laura A. Kehoe has been a freelance medical communications specialist for over 7 years and, prior to that, spent several years as an in-house journal editor. She has extensive experience in neuroscience, hepatology, psychiatry, mental health and, more recently, women's health and lifestyle medicine approaches for non-communicable diseases. She is also a lifestyle medicine health and fitness advisor and currently training as an integral coach.

Medical Writing in
CHINESE

Language-specific considerations for Chinese regulatory medical writers

Working as a medical writer in China (specifically, as a regulatory medical writer), we are expected to support regulatory submissions. Examples of these submissions include: clinical trial applications (CTA), investigational new drug (IND) applications, new drug applications (NDA), and biologics license applications (BLA). These are addressed to various major authorities (e.g., the US FDA and the EMA), while we must also priortise submissions for the China National Medical Products Administration (NMPA), where Chinese is the official language. As a result, Chinese medical writers face a unique set of challenges because we must be capable of producing regulatory documents in both Chinese and English with equal proficiency.

For global submissions, Chinese medical writers typically write regulatory documents directly in English, just as writers in other regions do. However, for regulatory submissions in China, the process can be more complex. When the project team includes non-Chinese members, writers often draft in English and then translate the final document to Chinese. Alternatively, writers may discuss study results and align content strategy in English, then draft documents in Chinese with China local teams directly.

As non-native English speakers, Chinese medical writers encounter several language-related challenges. Grammar and syntax pose typical difficulties. For instance, determining when to use articles like “the” can be challenging for junior writers, as Chinese lacks this grammatical feature. Similarly, errors in tense usage frequently occur due to the absence of specific tense distinctions in Chinese, in which time is often implied by context rather than explicitly stated through verb forms.

In terms of content and expression, there's a risk of directly translating Chinese language logic or fixed expressions that do not exist in English, which can lead to inaccuracies or ambiguities. For example, a statement in Chinese Clinical Study Reports is: “在治疗组A (treatment group A) 中 (in) 变量X (variable X) 的 (of) 下降 (decrease) 具有 (has) 统计学 (statistical) 意义 (meaning) 和 (and) 临床 (clinical) 意义 (meaning)”. A Chinese writer might translate the sentence from native language directly to English as "In treatment group A, decrease of variable X has statistical meaning and clinical meaning”. However, a better English expression would be: "In the treatment group A, the decrease in variable X was considered both statistically significant and clinically meaningful".

To enhance language skills, Chinese medical writers often use ongoing projects as opportunities for practice. We request support from native English speakers who act as document quality reviewers, using their insights to refine our language use. Additionally, medical writers also utilise technology tools such as Microsoft Word Editor, PerfectIT, or AI tools for language checks, leveraging these resources to improve the accuracy and fluency of writing.

Supporting simultaneous submissions for China’s NMPA alongside other major regulatory authorities presents additional challenges (i.e., China submissions for global trials where China joins at the same or later points in time). Chinese medical writers frequently serve as a bridge between local China teams and global project teams, facilitating clear and efficient bilingual communication. Additionally, writers must ensure consistency between Chinese and global submissions and guide the team to make informed decisions about the primary language for authoring China’s NMPA documents based on project specifics. If English is the primary language for authoring, writers should consider the language differences between Chinese and English, prepare the documents concisely for better translation efficiency, manage translation processes and timelines, and assist regulatory affairs teams in ensuring accurate Chinese translations and language consistency across documents.

In addition to improving English language skills, Chinese medical writers play an important role in harmonising regulatory submissions between China and other regions by continuously enhancing bilingual proficiency and cross-cultural communication skills.

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Global perspectives on EDIB:
Advancing equity, diversity, inclusion, and belonging in medical communications

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Abstract

The integration of equity, diversity, inclusion, and belonging (EDIB) principles within the field of medical communications is of paramount importance. EDIB principles, aligned with global guidelines on sustainability – encompassing labour practices, environmental stewardship, corporate social responsibility, and culture – are essential for enhancing the quality and reach of medical documentation. The adoption of EDIB practices has been found to positively impact medical research dissemination and public health outcomes by promoting diverse perspectives and inclusive knowledge transfer. These practices ensure that medical communications are more representative and impactful, reaching broader audiences and addressing diverse health needs.

The current state of EDIB in medical communications is characterised by varied perceptions and implementations across different regions. Challenges such as data privacy concerns, employment contract constraints, and disparities in educational requirements and job descriptions continue to hamper uniform EDIB adoption.

To enhance EDIB, several actionable strategies have been suggested. These include fostering collaborative approaches, implementing educational initiatives, and advocating for policy reforms. Such efforts are deemed essential for creating a more inclusive and diverse environment, benefiting both the industry and the communities it serves.

The potential benefits of a more equitable and inclusive global medical communications community are substantial. Looking ahead, the continuous evolution of EDIB practices will be crucial in addressing emerging challenges and leveraging new opportunities to foster inclusivity in medical communications.

Introduction

> *"If we are to achieve a richer culture, rich in contrasting values, we must recognize the whole gamut of human potentialities and so weave a less arbitrary social fabric, one in which each diverse human gift will find a fitting place."*[1]
>
> **Margaret Mead**

The above sentiment by renowned anthropologist Margaret Mead resonates deeply within the realm of medical communications and medical writing (herein referred to as medical communications), where the ability to convey complex information across diverse audiences is not just a nice-to-have skill but a necessity that is foundational to the core of the job function. Medical communicators, tasked with facilitating communication through various media and capturing the collective experiences of patients, are uniquely positioned to understand and implement the principles of equity, diversity, inclusion, and belonging (EDIB). These concepts are not merely buzzwords but essential components in enhancing the collective experience of individuals within any healthcare- or life science-related setting; as such, they require diversity leadership and action planning at both macro and micro levels. In the context of medical communications, EDIB principles serve as a bridge, connecting the intricate world of medical science with the diverse tapestry of human experiences, making medical communicators the ideal custodians of these vital concepts.

Definition of equity, diversity, inclusion, and belonging

To fully grasp the significance of EDIB in medical communications, it is crucial to understand each component of the term, as follows (Figure 1):[2]

- **Equity:** Fair treatment for all while actively working to identify and eliminate inequities and barriers
- **Diversity:** The full spectrum of human differences, including but not limited to:
  - Age
  - Ethnicity
  - Gender
  - Physical and mental ability
  - Race
  - Sexual orientation
  - Religion
  - Education level
  - Personality traits
- **Inclusion:** When each person is visible, heard, and considered within an organisation or community, going beyond mere representation
- **Belonging:** When all individuals are treated and feel like full members of the larger community, able to thrive in their environment

While diversity often focuses on proportionate representation across all dimensions of human difference, the combination of these four elements creates a comprehensive framework for fostering a truly inclusive and supportive environment in the field of medical communications and beyond.

EDIB's connections with sustainability guidelines and initiatives

EDIB principles align closely with global sustainability initiatives. The United Nations (UN) approach to sustainability has evolved from three pillars (economic development, social equity, and

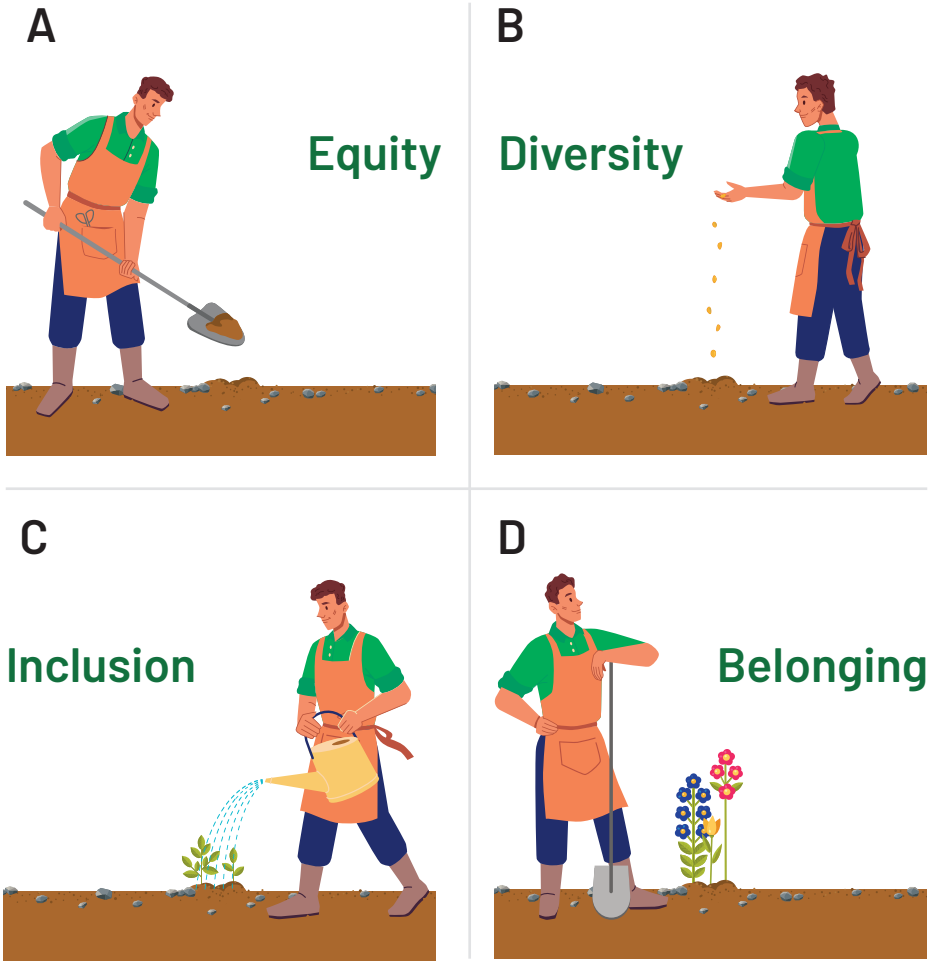

Figure 1. Comparison of EDIB concepts via a garden metaphor.
A. Equity: The soil (providing fair ground for growth);
B. Diversity: Various types of plants;
C. Inclusion: The act of planting and tending to all plants;
D. Belonging: The flourishing garden as a whole.

environmental protection) to include culture as a fourth pillar, reflecting the complexities of human society.[3,4] This four-pillar model resonates strongly with the EDIB framework.

The UN's Sustainable Development Goals (SDGs), adopted in 2015 and with planned implementation by 2030, operationalise this approach.[5] Health plays a central role, particularly in SDG 3: "Ensure healthy lives and promote well-being for all at all ages." This goal, supported by 13 specific targets, emphasises equity and focuses on meeting the needs of disinvested populations.

As medical communicators, we can advance these global health goals by integrating EDIB principles in our work. Externally, we can facilitate clear, accessible communication between healthcare providers and patients. This could involve: developing strategies to bridge gaps in understanding; enhancing informed consent processes; and creating materials that empower patients from all backgrounds to participate more fully in their healthcare decisions. Internally, we can foster EDIB within our professional community by amplifying diverse voices, advocating for equitable growth and leadership opportunities, and actively cultivating inclusive work environments where all medical communicators can thrive through targeted initiatives and policies (for example, by using bias-free language or by incorporating best practices for inclusive meetings).[6] By aligning our practices with these global objectives through thoughtful application of EDIB principles in every document we produce, every message we craft, and every professional interaction we engage in, we can reflect and reinforce the core values of health equity, cultural sensitivity, and inclusive communication in both our work products and our workplaces.

Current state of EDIB in medical communications: A global perspective

Regional variations in EDIB perceptions and implementations

The perception and implementation of EDIB principles vary across different global regions, reflecting diverse cultural, social, and economic contexts (Figure 2). In the European Union, for instance, there is a strong focus on gender equality in the workplace, with countries like Iceland implementing mandatory equal pay certification for companies.[7] The United Kingdom has taken a unique approach with the introduction of mandatory gender pay gap reporting for large companies, aiming to increase transparency and drive change.[8] In North America, Canada has been a leader in promoting multiculturalism, enshrining it in law, and implementing policies to support diverse communities.[9] The United States, meanwhile, had until recently placed a primary focus on racial equity, with many organisations implementing unconscious bias training and diverse hiring practices,[10] but with recent clapback against "woke" concepts in favour of merit-based ones, many companies have even chosen to curb their EDIB efforts altogether or remove the term "equity" from the construct due to the legal implications.[11] Japan has struggled with gender diversity in leadership roles, prompting the government to set targets for increasing the proportion of women in management positions.[12,13] South Africa's approach to diversity is deeply rooted in its post-apartheid history, with the Employment Equity Act mandating targets to redress past imbalances in race but also in gender and disability status.[14] In India, caste-based discrimination remains a significant challenge, leading to the implementation of reservation policies in education and public sector employment.[15] Meanwhile, in the Middle East, countries like the United Arab Emirates have

The perception and implementation of EDIB principles vary across different global regions, reflecting diverse cultural, social, and economic contexts.

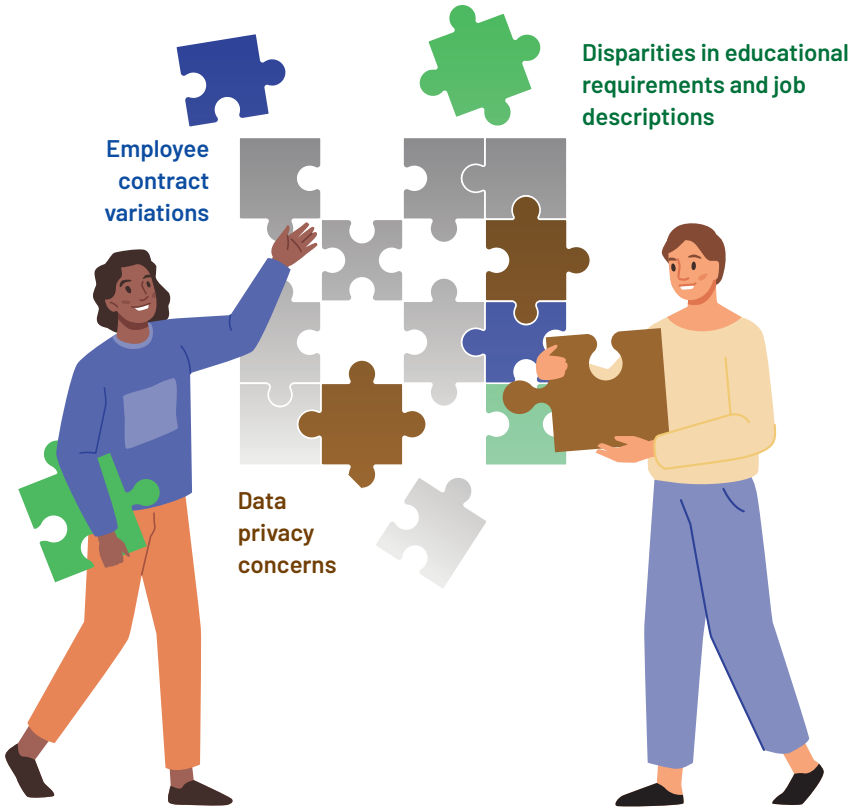

Figure 2. Puzzle pieces representing different major regional EDIB challenges (data privacy, employment contracts, and educational requirements), symbolising how different elements must come together to form a comprehensive global approach to EDIB, while also visualising the misalignments and gaps that exist.

been working to increase workforce participation of people with disabilities, introducing policies to support their employment and integration.[16] These regional variations highlight the importance of contextualising EDIB efforts to address specific local challenges and priorities.

While many countries have established clear EDIB goals and certification programmes, others have adopted a more flexible approach with less-defined endpoints. For instance, while the Netherlands has set goals around disability employment as part of their social initiatives, specific endpoints to measure these goals have not been established,[17] nor are there immediate plans for diverse business certifications.[18] Similarly, in Sweden, while there is a strong cultural emphasis on equality and inclusion, the approach to EDIB in the workplace is often less prescriptive. Swedish law prohibits discrimination, but many companies implement EDIB initiatives voluntarily without mandated quotas or certifications.[19] In Brazil, despite having laws against racial discrimination, the implementation and measurement of EDIB programmes in the private sector vary across organisations.[20] These examples illustrate that while there is growing global awareness of the importance of EDIB, the approaches to its application can differ substantially, with some countries opting for more flexible, culturally adapted strategies rather than strictly defined programmes or certifications.

Global challenges in EDIB adoption in medical communications

While the importance of EDIB in medical communications is apparent given its connections with overall global health initiatives, several challenges hinder its uniform adoption and implementation:

1. **Data privacy concerns across borders:** The medical communications field often deals with sensitive health information, making data privacy a critical concern. Different countries have varying regulations regarding data protection, which can complicate EDIB efforts. For instance, the European Union's General Data Protection Regulation (GDPR) imposes strict rules on data handling, including personal information related to diversity metrics.[21] In contrast, countries like the United States have a more sectoral (i.e., at the industry level) approach to data privacy.[22] These disparities can make it challenging for global medical communications teams to collect and analyse diversity data consistently, potentially hampering EDIB initiatives that rely on such information.
2. **Employment contract variations by country**: Employment contract variations by country pose significant challenges to implementing uniform EDIB policies in global medical communications teams. For instance, anti-discrimination clauses may vary widely; while the United Kingdom requires explicit protection against discrimination based on nine protected characteristics,[23] other countries may have more limited protections. Compensation structures can also differ, impacting pay equity efforts; for example, European countries prohibit asking about salary history,[24] while other countries do not. Flexible working arrangements, crucial for inclusivity, are legally mandated in some countries[25] but not others. Additionally, parental leave policies, which can significantly affect gender equity, vary greatly across nations.[26] These disparities can lead to inconsistencies in how medical writing organisations approach EDIB across their global operations, potentially resulting in uneven implementation of inclusive practices.
3. **International disparities in educational requirements and job descriptions:** The field of medical communications encompasses a wide range of roles, each with its own set of required qualifications. These requirements can vary substantially between countries, however, reflecting differences in educational systems and professional standards. For example, a survey among medical writers in India showed that over two-thirds were physicians and more than 90% had a life science background.[27] Conversely, in the United States and European Union, relevant degrees are described as ideal but not mandatory for medical communicators,[28,29] with need sometimes driven by specialty or specialisation,[28] and relevance is even extended to include language-related

degrees.[29] These disparities can inadvertently create barriers to entry for diverse candidates from different educational backgrounds or geographical regions, potentially limiting the global talent pool and hindering EDIB efforts in the profession. Furthermore, job descriptions and role expectations for medical communicators can differ across cultures and organisations. What constitutes an "entry-level" or "senior" position may vary, as can the specific tasks associated with medical communications roles.[30] These inconsistencies can make it challenging to implement standardised EDIB practices across international teams and may inadvertently perpetuate inequities in career progression and opportunities.

Addressing these challenges requires a nuanced, globally minded approach to EDIB in medical communications. It calls for careful navigation of international regulations, cultural sensitivities, and professional norms while striving to create a more inclusive and equitable field worldwide.

Benefits of a more equitable and inclusive global medical communications community

Embracing EDIB principles in the global medical communications community offers numerous advantages that extend far beyond the profession itself. Firstly, improved documentation quality across languages and cultures is a substantial benefit. When diverse perspectives are incorporated into the writing process, it leads to more comprehensive and culturally sensitive medical documents; this enhanced cultural competence results in clearer, more accessible information for patients and healthcare providers from various backgrounds.[31] Secondly, broader public health impacts in diverse global settings can be achieved through more inclusive medical communication. By ensuring that health information is tailored to and representative of diverse populations, we can improve health literacy, treatment adherence, and overall health outcomes across different communities.[32] Lastly, increased diversity among medical communicators and in the content they produce can help address historical biases in medical research and reporting. This can lead to more comprehensive coverage of health issues affecting minority populations, ultimately contributing to more equitable healthcare.[33–35] By fostering a more equitable and inclusive global medical communications community, we not only improve the quality and reach of health information but also contribute to advancing global health equity.

Strategies for enhancing EDIB in global medical communications

To advance EDIB in global medical communications, a multifaceted approach is essential. Fostering international collaborative approaches can be achieved through virtual teams and cross-border projects, which expose writers to diverse perspectives and working styles.[36] Implementing cross-cultural educational initiatives, such as cultural competency training and language exchange programmes, can enhance understanding and sensitivity among medical communicators.[37] Advocating for policy reforms on a global scale is crucial, with professional organisations playing a key role in coordinating leadership who can push for policy change across the industry.[38] Addressing region-specific EDIB challenges requires tailored strategies; for instance, in regions with limited access to medical education, mentorship programmes and targeted skill development initiatives can help diversify the talent pool. In this vein, the American Medical Writers Association (AMWA) is working on guidelines for an apprenticeship framework that will include job levelling recommendations as well as modular components for a suggested curriculum.[39] Also, AMWA has recently released an EDIB-related statement, emphasising its commitment to fostering a diverse, equitable, and inclusive environment within the medical communication profession.[40] Similarly, the European Medical Writers Association (EMWA) underlines their dedication to these principles in their code of behaviour.[41] The Drug Information Association (DIA) also demonstrates a commitment to EDIB through their dedicated initiatives and resources.[42] Finally, the potential for standardised global EDIB guidelines in medical communications is promising. While recognising regional differences, establishing a common framework for EDIB best practices can provide a roadmap for medical communications organisations worldwide. Such guidelines could cover areas such as inclusive language use, diverse representation in case studies, and equitable authorship practices. By implementing these strategies, the global medical communications community can work toward a more inclusive future, ultimately improving health outcomes for diverse populations worldwide.

> "Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."

Conclusion

The importance of EDIB in global medical communications cannot be overstated. As we have explored, EDIB principles are not merely idealistic concepts but essential components that enhance the quality, reach, and impact of medical information worldwide. From improving documentation quality across languages and cultures to broadening public health impacts in diverse global settings, the benefits of a more inclusive approach are clear and far-reaching.

As medical communicators, our pivotal position allows us to bridge the gap between complex medical information and diverse global audiences. By embracing EDIB principles, we can ensure that our work resonates with and benefits all communities, regardless of their background or geographical location. This is not just a professional responsibility but a moral imperative that aligns with the broader goals of global health equity.

The anthropologist Margaret Mead once said, "*Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has.*"[43] As a community of medical communicators, we embody this sentiment. While the challenges of implementing EDIB on a global scale are significant, they are not insurmountable. Through collaborative efforts, cross-cultural initiatives, and a commitment to continuous learning and improvement, we can drive meaningful change.

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Inclusive language in medical texts and medical translation in French

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Abstract

In French, the grammatical rule of the generic masculine, known as *neutral*, reveals a patriarchal worldview. This article looks at the consequences of this way of writing in medical texts and in medical translation. It also gives suggestions on how to write medical texts and translate in French in a more inclusive way.

Words matter, especially if you are a writer or a translator, or both.

You will find this article interesting if you speak some French, and even more interesting if you don't, because you will expand your horizons and learn something new.

The 1789 French "Déclaration des droits de l'homme et du citoyen" is a fundamental text of the French Revolution. It defines a series of individual and universal rights, as well as the conditions for their implementation. But how can those rights be universal, when "homme" means "man" and "citoyen" means "male citizen"?

With that in mind, Olympe de Gouges drafted the "Déclaration des droits de la femme et de la citoyenne" (Declaration of the rights of woman and of the [female] citizen)[1,2] in 1791. If this sounds odd, ask yourself why terms like "homme" or "citoyen" are supposed to represent all people.

My journey towards inclusive French

My name is Aurélie Gobet and I have been a medical translator for 13 years. I translate from German and English into French. I specialise in medical and pharmaceutical content, mostly translating clinical trial documents, drug leaflets, and medical marketing documents. I am an experienced translator and a feminist, and I have come to realise that I was conveying sexist bias when I wrote using the so-called *generic masculine* in French.

I also co-founded *Révolution Inclusive* with 11 other experienced translators. We offer training, rewriting and translation services in inclusive French. To date, we have run training sessions and workshops for translation students and a diverse group of people at translation and sustainable development events.

This article will explain my thinking on inclusive French and some of the specific challenges of inclusive language in medical texts in French.

Inclusive language: definition and purpose

Let us start with a definition of inclusive language: "The aim of employing inclusive language is to avoid the use of words, terms, expressions or grammatical structures that may, inadvertently or otherwise, be interpreted as in some way excluding individuals or groups of people."[3]

Inclusive language is a major tool to question what we have considered the norm until now (i.e. the cisgender, heterosexual, able-bodied, white male). It can no longer be the universal representation of humanity, which is much more diverse than that.

Language is also a way to represent people who are experiencing discrimination based on gender, age, race, health, and many other factors. Using inclusive language is a must to point out discrimination.

Inclusive language applies to everyone, especially people experiencing discrimination.

French grammar is sexist

In French grammar, the only agreement rule that is taught in school is "le masculin l'emporte sur le féminin" (the masculine form prevails over the feminine form).

It means that when you say "I can see a tree and 100 women. They are very far away.", "they" will be translated as "ils", which is the masculine plural pronoun that is supposed to be *neutral* in French.

However, studies show that our brains first imagine a group of men when we read or hear the pronoun "ils" in French, even though it is supposed to be neutral.[4] For example, if you say "un groupe de musiciens" (a group of musicians), people will imagine men.[5]

Inclusive language is important because we need to give more visibility in the French language to women and all people who are not cisgender men.

Challenges of binary gender distribution in medical French

Pregnancy and period in medical translations

Someone being pregnant or having a period might not identify as a woman. Someone having testicular cancer might not identify as a man. Gender is a very wide spectrum and is not binary. Sometimes it is related to what the genitalia look like, but sometimes it is not. Self-determination is key in the definition of gender.

So, be careful before you use the words "women" or "female participants" in the contraception part of a clinical trial document designed for participants. Not all women have ovaries (for example, trans women and women who had their ovaries resected don't) and not all people having ovaries are women (for example trans men). The same applies to menstruation.

A better way to handle it is simply to describe what you need to describe. It is very much down to earth. What do you really need to talk about? People? A specific part of their bodies (ovaries, uterus, testicles, breasts, etc.), a specific physiological process (period, menopause, etc.)?

Translation of "patients"

After I had training in inclusive French in 2021, I realised that translating the English word "patients" with the French word "patients" was incorrect.

As mentioned above, studies show that our brains first think of a group of men when we use words only in their plural masculine form in French (despite the fact that it is supposed to describe a mixed group of people).

We need to stop writing medical documents in the generic masculine in French. The less patients feel concerned by the terms we use, the less likely they are to feel concerned by clinical studies and treatments.

Male-centred clinical research

Clinical research has been male-centred for too long.

Can you imagine prescribing a drug for women that was mainly studied in men? It would be like considering that children are just tiny adults and that you can find the right treatment and dosage on a *pro rata* calculation.

Every person has a different physiology, and it is now obvious that your weight, height, and hormone levels have an influence on the way drugs work. Today, drug dosage is adapted to people who are younger, older, pregnant or who have renal or hepatic insufficiency. But why is it still male-centred?

Advice and resources

To write more inclusive medical content, you need to talk to the people directly concerned. I am one of those people, so for me it is really a matter of how I think of myself and how I talk about myself with other people.

Conclusion

Words matter. Words reflect our worldview. It is a fact that can no longer be ignored by writers and translators of highly gendered languages such as French. Not using the right terminology when referring to people means denying their existence in language and in our conception of the world.

There are many ways of using a more inclusive language. It all starts with coming to terms with a worldview that we may not be used to, as we come from a binary, patriarchal society. Change is happening right now in people's minds and in languages. Arbitrary grammar rules imposed by the ruling class will not prevent this change. It is the responsibility of writers, editors and translators to learn how to embrace this evolution and provide professional writing that truly reflects the world as it is.

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The author co-founded and is currently working for *Révolution Inclusive*, which offers fee-based services on inclusive French, such as training, content rewriting, and workshops.

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Resources on inclusive language

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Nations Unies. Orientations pour un langage inclusif en français. Available from: https://www.un.org/fr/gender-inclusive-language/guidelines.shtml (French version).

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Their commitment against sexism led them to co-create Révolution Inclusive in 2022 to fight discrimination in language and communication.

Breaking barriers:
Empowering researchers from low- and middle-income countries in global health communication

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Abstract
This feature explores the author´s experience in supporting researchers in low- and middle-income countries (LMICs). After years of honing her skills in both basic research and medical writing, Julie Chaccour transitioned into a position in research management, where she occasionally gets to apply her expertise to help address disparities in scientific authorship. The author describes an especially rewarding experience of facilitating a three-day workshop to a diverse team of social science researchers. Efforts like the one described highlight the importance of structured support for LMIC researchers in expanding their contributions to the scientific community.

My background

I began my career as a medical writer both because I wanted to blend my passions for research and literature and because medical writing offered flexibility when I needed it most. Looking to learn from the experiences of others, I joined EMWA in 2012 and quickly appreciated the close-knit community. At EMWA conferences, I observed that many people initially approach medical writing with a relatively narrow pharmaceutical or regulatory frame of mind. However, the field actually provides a broader range of opportunities, especially in academic medical writing, where I have developed my professional expertise. The need for trained medical writers is evident.

But could I carve a niche by transferring my knowledge of the pharmaceutical and medical device industry to a field as seemingly distant as global health? The challenges inherent in global health have motivated me since the beginning of my formative years. Global health is most commonly defined as "an area for study, research and practice that places a priority on improving health and achieving equity in health for all people worldwide".[1] Thus, my university studies were aimed at paving the way into vaccine development for underserved communities and neglected diseases. My actual work experience, however, opened my eyes to the many hurdles young researchers from low- and middle-income countries (LMICs) have to overcome on their way to "improving health and achieving equity in health for all people worldwide".

The scientific literature is heavily dominated by researchers based in the US, UK, and Europe, whereas the remaining 88% of the world's population produces less than 12% of the scientific literature.

Persistent disparities in authorship

Just as health disparities are rooted in fundamental social, political, and economic inequalities, so is the representation of LMIC authors in scientific communication. The scientific literature is heavily dominated by researchers based in the US, UK, and Europe, whereas the remaining 88% of the world's population produces less than 12% of the scientific literature.[2]

Now, even though LMIC authors are increasingly contributing to reporting the results of global health research, true representation, especially in leading authorship positions, remains inadequate,[3–5] which has important ramifications for the attention given to health issues in LMICs. There are many reasons for this disparity but one way we can address this as medical writers is to expand the skill set of young researchers to successfully take the initiative in publications.

I previously shared with EMWA some insights from a four-month stint in Mozambique in 2015,[6] which then led to a position as scientific coordinator of the Centro de Investigação em Saúde de Manhiça (also in Mozambique) 2017 through 2018. This role integrated many functions of institutional research support, one of which was identifying and ameliorating bottlenecks in the publication of research results. The training I had received from EMWA was instrumental in this endeavour.

Tailored writing support for global health researchers

During my two years in Mozambique, the Bill and Melinda Gates Foundation pledged financial support for a global programme aimed at identifying the real (not estimated) causes of mortality in children in LMICs. Called the Child Health and Mortality Prevention Surveillance, or CHAMPS, the programme generates data that are crucial for designing the right interventions to combat preventable deaths worldwide. To determine the causes of death, the programme uses an innovative, minimally invasive method instead of traditional autopsies.[7] Being of such delicate nature, the success of this programme hinges on the day-to-day labour of teams of sociologists and anthropologists who prepare its implementation in communities.

The coordinators of the initiative told me about the impressive data collection and

community engagement the global teams were accomplishing in the field but stressed that their teams would benefit from getting structured in-person training in communicating their work. We opted to leverage the global CHAMPS Network meeting in Addis Ababa, Ethiopia, to ensure maximum participation. A key challenge was that, while many participants had a humanities background, their target audience consisted primarily of scientists and healthcare professionals. Together, we identified the essentials to be covered in Addis Ababa in a short timeframe and tailored a three-day workshop to suit the different skill levels of participants from nine African and Asian LMIC countries.

While I am much more comfortable in the biomedical sciences where I do the large majority of my writing and editing, this particular workshop challenged me to do extensive background reading on conventions in the social sciences regarding study design, data analysis, and publication formats. On a side note, one of the perks of working in medical writing is that you never stop learning. Therefore, in addition to the usual elements of my workshops (structuring papers, writing abstracts, improving flow and style, overcoming writer's block, and understanding publication ethics), we covered how to formulate research questions and concrete objectives and how to develop concept notes for qualitative studies. I then worked individually with researchers on their manuscripts in progress, which was very appreciated, as their different levels required much different input. While some struggled to structure their introduction, more advanced researchers wanted feedback on the clarity of particular sections or input on the editing process.

This close collaboration also opened my eyes to the significance of their work; their insights and anecdotes left a lasting impression on me. We then made concrete plans for virtual follow-up meetings a month later to ensure accountability. Ideally, as the facilitator of such a workshop I would suggest accompanying researchers in the long term but unfortunately, only the largest and most affluent institutions can afford a fixed writing support position.

Conclusion

Overall, the experience has been immensely rewarding and relevant, and I am eager to engage in similar opportunities more frequently. Yet such research support is often not contemplated in the budget of global health projects. I firmly believe the LMIC researchers involved in these projects need the necessary support to give a voice to their research and challenge the authorship inequalities prevailing in international collaborations despite ongoing calls to decolonise global health. To all my fellow medical communicators, I invite you to consider the value and potential impact of transcending the traditional boundaries of the medical writing world.

Table 1. Challenges and rewards of working with authors from low- and middle-income countries

Challenges	Rewards
• It may be difficult to determine the "baseline" of the authors when designing a workshop. Often, LMIC authors do not enjoy formal scientific writing training in their university years.	• You benefit from a fresh and "unspoiled" audience that is motivated to absorb as much as possible and apply what they have learned.
• Opportunities are rare. The funding for formal training in scientific writing has to be identified and may come from limited project funds. However, "capacity building" has become a more frequent budget item, so there is hope.	• A wealth of data is collected as part of larger research projects in many LMIC countries but is yet to enter the public sphere. Enabling local researchers to publish them is an indirect contribution to the pathway to improving health in these countries.
• Some LMIC authors are non-native English speakers and workshops should keep this in mind.	• You get to see the impact of your work up close and celebrate the many wins of "your" authors on their way to becoming cited researchers.
	• You receive opportunities to broaden your personal horizon and learn about the amazing work done by skilled researchers from LMICs.

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Medical Writing in
RUSSIAN

From Russian to English and back again

Thanks to EMWA for raising this topic. Trying to capture the essence of medical writing in both Russian and English was a fascinating exercise for me. It wasn't easy, but the exploration of the issue itself proved very valuable.

On one hand, both languages share Indo-European roots, resulting in some similarities. This common ground makes understanding grammar and numerous concepts easier. Plus, the Latin origins of a vast number of many medical terms are a huge help when translating or writing medical texts.

Interestingly, in the field of clinical trials and drug registration there is still no universal translation for some terms in the Russian language and therefore even in Russian-language documents we use the English term, e.g. estimand (эстимана). What's more, some English abbreviations, such as GCP (Good Clinical Practice), GLP (Good Laboratory Practice), and GMP (Good Manufacturing Practice), are so ingrained in our daily work that they're simply used as is.

Nevertheless, the differences are striking. Russian texts are consistently longer and more verbose than English. The average English word has five letters, while a Russian word usually has six or seven. English has thousands of three-letter words, while Russian only has about 300. Translating from English to Russian tends to expand the original text by between 9% and 25%. This is because translating a single English word often requires two, three, or even more words in Russian to accurately convey the meaning, even if it sacrifices brevity.

The structure of Russian text is also different. It tends to be less personalised, with more passive constructions, additional information, clarifications, and variations in word order. This contrasts with the fixed word order and conciseness of English. It's no surprise that the English writing of Russian authors often has a recognisable Russian flavour – it's a natural consequence of the language's inherent structure. This adaptation can be a real challenge, especially when you're working on multiple documents in both languages simultaneously.

Another key difference lies in the style of the text. In Russian, the purpose of the writing heavily influences the approach. Official regulatory documents, scientific articles, and everyday conversations all have drastically different styles, unlike in English. This means that for things like research protocols, scientific articles, or even a brief advertising note about a clinical trial in Russian, the style, terminology, and phrasing will vary. You really need to tailor your writing to the specific purpose of the text. However, I've noticed a trend in recent years towards a simplification of Russian-language regulatory documents, largely due to the harmonisation of document structure and content with international English-language guidelines.

This exploration has given me a deeper appreciation for the unique challenges and rewards of working with both languages in the world of medical writing.

The Russian language is considered one of the richest and most full of nuance. For medical writers, this is a double-edged sword. On one hand, it's a treasure trove of creative possibilities, allowing us to choose just the right word to convey a precise meaning. But on the other hand, it can sometimes influence our English, giving it a specific flavor that might not always be readily understood. Luckily, the shared regulatory environment in drug development, along with common terminology, helps bridge the gap. It allows us to communicate effectively, both written and verbally, with colleagues and authorities worldwide.

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From Portugal to the world:
Leveraging remote medical writing for global impact

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Abstract

With the advent of the pandemic, global businesses in medical writing accelerated efforts to hire remote professionals across different countries. Portugal is a fruitful source of talent, yet it remains underrepresented in the medical writing industry. As a medical writer in Portugal, I highlight the practical advantages that make the country an attractive market for hiring remote medical writers and describe how adding Portuguese writers to international teams can offer a blend of talent, cost efficiency, and strategic advantages. While fully recognising that many countries are underrepresented in the medical writing world, I speak here of the benefits of my native country where I have settled my career.

The concept of working from home (WFH) has been around for decades, but it was the COVID-19 pandemic that expanded this practice to many industries. WFH was a necessity during the pandemic years and the multiple confinement periods became a driving force towards a more robust digitalisation and wider adoption of innovative tools for virtual collaboration. The sudden change in circumstances triggered a natural selection process that would, in many ways, test the adaptability of both companies and employees. Only those with the ability to quickly reorganise an office-based structure to a remote and online workforce would thrive. In the medical writing industry, many businesses decided to extend WFH, once an option for only a few, typically more experienced writers, to the entire workforce, regardless of their experience level. Several companies realised that they could not only effectively manage an online workforce but could also successfully hire new talent regardless of geographic location. And thus, the pandemic brought into play another concept that gained increased momentum during lockdown years: employees working remotely from a country different to the parent company location.

Remote medical writing fosters global businesses

Fast forward a few years, and the discussion around the appropriateness of remote work to each business is very much alive. Some executives argue that, in the absence of pandemic restrictions, it is time to return to the office,[1] whereas others believe that remote work is here to stay.[2] For the medical writing industry, perhaps the simplest, most influential argument in favour of remote working is that employees like it.[3,4] Greater flexibility, improved work-life balance, and access to global market networks and career growth opportunities are among the many reasons why working remotely has been embraced by so many writers.[3] Furthermore, working with people located in different countries has always been the norm for medical writers: meetings with international clients and project team stakeholders, mentoring less experienced writers or line management of writers working in offices in different countries, etc., are among the many daily activities that have been successfully managed online for a long time. Why not expand this to perform all medical writing activities remotely from a home office in a country of our choice?

Employers of medical writers across the globe are increasingly aware of the impactful advantages of remote work, not only in achieving and maintaining high employee satisfaction, but also in attracting and retaining new talent. Indeed, in post-pandemic years, remote work has become a driver for business health for multiple reasons. In an increasingly challenging workplace environment, the more adaptable the teams, the healthier the business. Diverse, cross-cultural teams, with members around the world, provide access to a range of skills and expertise, plus varied perspectives and ideas. Teams with different backgrounds are able to share multiple viewpoints, increasing the likelihood of finding innovative and effective solutions whilst adapting efficiently and better to changing market demands. It is now more common to see medical writing teams, both in contract research organisations (CROs) and pharmaceutical companies, distributed across different countries and regions – a much-needed mark of survival, progression, and growth after the hardship and constraints of the pandemic.

> "…a business in Portugal shares business hours with places as far east as Jakarta and Bangkok and as far west as Denver and Calgary, as well as the majority of the world's population in between."

Think globally, act locally

As mentioned above, remote medical writing teams now support global businesses, and many writers take advantage of remote work to improve their personal and professional lives. More and more, medical writing teams have people located across the globe, and many writers are working remotely from an increasing number of European countries. I choose to work from my home country, Portugal, for several reasons.

Portugal has a safe environment, pleasant weather, amazing food, vibrant cities, serene countryside, and beautiful coastal areas. I would think this country would have a more prominent presence in the medical writing industry, since there are good reasons why Portugal should be an emerging hub for medical writers. However, when it comes to global medical writing, Portugal, like other countries, is still enormously


Coimbra, Portugal

underrepresented. As a Portuguese writer, I have frequently pondered why.

I would say this might be mostly due to two significant reasons: Portuguese graduates may large be unaware of scientific careers outside of academic research, including medical writing; and, being a small country, Portugal often slips under the radar of hiring managers looking for scientific graduates with a talent for writing. As a result, I've made it a mission of mine to connect potential Portuguese medical writing candidates with those looking to hire new talent for this industry, through increased education and awareness of opportunities within the medical writing industry. This article is a step toward that mission.

Portugal as a hub for medical writers

As we know, English proficiency is a crucial factor in medical writing, not only because most documents are written in English, but also because most teams use it in their routine/daily interactions and communication. According to the worldwide ranking of countries and regions by English skills prepared by the EF English Proficiency Index in 2023, Portugal is ranked in the top 10 global countries with very high proficiency in English. Considering the European countries in the top 10, Portugal is supplanted only by Scandinavian countries (Figure 1).[5]

This makes sense. English has long been taught in Portuguese schools as the preferred foreign language; a growing number of children are now learning English from early preschool years. Furthermore, for historical and political reasons that I will not explore here, books, music and visual entertainment in their original English

Figure 1. Portugal ranks very highly in the Education First English Proficiency Index.[5]

forms, free of dubbing or translation, have always been available in Portugal. This permanent exposure to the English language is the reason why so many professionals present such a high proficiency level. However, English is not the only language the Portuguese are exposed to throughout their lives. Spanish, French, and Italian share a Latin core with Portuguese, which makes them easy to learn for a Portuguese. Indeed, many professionals invest in their multilingual skills, which can be of tremendous value to establish rapport with international stakeholders and work in projects for global companies. In addition, the cultural compatibility between Portugal and other European and Western countries can lead to smoother integration and collaboration within international teams.

Portugal produces a well-educated workforce. In the last decade, the number of doctorates in Portugal increased by 73%, a number that represents more than 43,000 PhD holders across different fields.[6] With such an abundant flow of talent, I'm confident that many graduates with PhDs in life sciences and similar fields would have the potential to become medical writers for the pharmaceutical and biotech industry CROs, and other entities.

Another advantage of hiring remotely from Portugal is its geographic location. Expat Empire, a consultancy business focused on helping people move abroad, says about Portugal:

> *Portugal's position on the western edge of Europe has several advantages when it comes to time. The Portuguese mainland and the island group of Madeira use the same time zone as the United Kingdom throughout the year, which is known as UTC+00:00 (Coordinated Universal Time). Meanwhile, the island group of the Azores is one hour behind at UTC-01:00. This means that a business in Portugal shares business hours with places as far east as Jakarta and Bangkok and as far west as Denver and Calgary, as well as the majority of the world's population in between.*[7]

This is extremely convenient when it comes to collaborating with American, European, and even Asian teams. Medical writers based in Portugal are thus very well placed for real-time communication, and can therefore facilitate overlapping working hours, which contributes to "around-the-clock" productivity (working in different time zones allows a continuous information workflow among writers and stakeholders) and project delivery. The country's strategic location within Europe also provides short travel distances to other key business hubs for occasional in-person meetings, if needed.

Hiring medical writers in Portugal can also be cost efficient. The cost of living in Portugal is relatively lower compared to other European countries. Companies can achieve significant cost savings without compromising on talent and expertise, while maintaining competitive salaries for high-quality work.

Conclusion

Hiring remotely in Portugal offers several compelling advantages for global companies, particularly in industries such as medical writing. However, there is still a long way to go to increase the awareness of medical writing as an exciting and challenging career for Portuguese graduates, while also bringing the attention of hiring managers to a country that promises a vast pool of highly educated and talented candidates. Once this gap is bridged, I see Portugal quickly becoming an emerging hub for remote medical writers in Europe.

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Medical Writing in
ITALIAN

Seeing the world through a different lens

Language influences the way we think, see and describe the world around us. Writing is a learned skill and education systems around the world emphasise different approaches to effective communication. As a native English medical writer living in Italy, my role is to assist clients in a change of perception and thought processes to an English-based model, asking non-native speakers to see the world through a different lens

It dawned on me one day whilst consulting with an Italian surgeon/attempted author of a rejected manuscript for a peer review journal, how difficult it is to express complex concepts in one's mother tongue, let alone in an acquired language. The text he had written didn't follow a logical flow, it was spoiled with numerous superlatives, facts were inconsistent, and the manuscript itself was unstructured. I struggled to get my head around the key messages and the surgical technique he was attempting to describe. In desperation, I turned to him and simply pleaded, "Tell me what you want to say in Italian."

I am an Australian and have lived in Italy for over 20 years. On the whole, Italians are gregarious, passionate, joyful, and enthusiastic orators. They can begin to tell stories from any point on a time continuum, jumping back and forth among events. The Italian education system encourages verbosity and creativity in style in all forms of texts; a stark contrast to the Anglo-Saxon education system, where succinct, logical essays are a must.

What the Italian surgeon went on to explain to me face-to-face, was far from what he had written on the page. Writing is a learned skill. Barriers to scientific publications among medical professionals are identified as (a) writing in general; (b) writing in English; (c) dealing with content structure and presentation; and (d) navigating in the author group.[1]

The Italian surgeon had noteworthy research to share with the international medical community, having led the first team in the world to treat ruptured abdominal aortic aneurysms with an endovascular approach. Together, we worked through the manuscript to respect the English scientific language structural guidelines and to ensure effective communication of the key messages. Today, this surgical approach is commonly adopted and saves lives, and the manuscript is still celebrated as a core reference. However, in rewriting the manuscript, the cultural nuances, some "colour", and a lot of passion were inevitably dulled in favour of clarity.

Language and culture are intrinsically linked. The renowned Danish linguist Otto Jespersen suggested that English is a "methodological, energetic, business-like and sober language, that does not care much for finery or elegance, but does care for logical consistency". He concluded: "As the language is, so also is the nation".[2] Language, therefore, inevitably influences the way we think and perceive the world around us.[2]

My role is to assist in that change of perception, to encourage a different thought process. The advent of large language models can help level that playing field, making English more accessible to all.[3] For researchers with a mother tongue other than English, effective communication requires them to see the world through a different lens.

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I would like to dedicate this article to my patient and intelligent clients, for having shared with me their experiences of changing perception.

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A case study from Pakistan: Improving medical publications in non-English speaking countries

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Abstract

Copyediting is crucial for enhancing the quality and credibility of medical manuscripts in Pakistan. Although English is an official language used in government and education, many researchers are not native speakers, leading to linguistic inaccuracies in publications that can cause misinterpretation and critical errors in medical understanding. Pakistan publishes approximately 70 to 90 medical journals, with about 86 recognised by the Higher Education Commission of Pakistan. However, these journals often face challenges such as inadequate peer-review processes, limited editorial oversight, and resource constraints, affecting their international recognition. Specialised copyeditors are seldom employed; editorial tasks are usually handled by board members who may lack proper training. Financial constraints hinder investment in professional editorial services and training. While there is a rise in freelance copyeditors offering cost-effective and scalable solutions, their expertise remains underutilised locally. Collaborating with these freelancers can help Pakistani medical journals meet global standards. Other strategies are also discussed to elevate the quality of medical publications in Pakistan.

The medical literature is essential for communicating research, discoveries, and innovative treatments. Specialised areas such as medicine require precise language and comprehensive editing to ensure clarity and accuracy. Globally, copyediting of medical manuscripts faces challenges such as language barriers, scarcity of expert editors, and the need for high publication standards. In Pakistan, these challenges are compounded by specific conditions in the medical publishing landscape, emphasising the fundamental need for clarity, precision, and detail in the publications. Copyeditors play an indispensable role in scientific and medical publications. They facilitate the conveyance of research outcomes in a manner that is both comprehensible and precise, thereby enhancing a journal's credibility and strengthening readers' trust.

Language challenges in Pakistan

English is one of Pakistan's official languages, and it is extensively used in government administration, legal proceedings, and higher education. Approximately 49%–58% of Pakistanis have some level of English proficiency, encompassing both native and second-language speakers.[1] However, achieving linguistic accuracy and clarity poses a challenge, increasing the risk of misinterpretation or miscommunication, which can lead to critical errors in medical understanding and application.

Scope of medical publishing in Pakistan

Pakistan publishes a significant number of journals across various academic fields, totalling approximately 2874 across all disciplines. There are approximately 70–90 medical journals, with approximately 86 recognised by the Higher Education Commission (HEC) of Pakistan.[2] Some of these journals are indexed in international databases, such as PubMed, Scopus, and Web of Science, enhancing their global visibility. Although many Pakistani medical journals are peer-reviewed and cover a wide range of specialties, their standards vary considerably.[3] Some meet international benchmarks, but others face challenges, such as inadequate peer-review processes, limited editorial oversight, and resource constraints.[4] Factors such as limited funding, lack of training in editorial practices, and language barriers contribute to these issues, affecting the credibility and international recognition of the published work.[3]

The English language is commonly used in scientific publications in Pakistan. However, this is not the first language used by many researchers. This can lead to difficulties in manuscript preparation and can increase the likelihood of grammatical errors. The scarcity of professional editorial services and developmental editing support further affects the quality and quantity of scholarly output. This context highlights the importance of enhancing editorial services to improve the quality and international standing of medical publications (Figure 1).

Current state of copyediting in Pakistan

Employing specialised copyeditors is uncommon in many developing countries, including Pakistan. Instead, these tasks are typically handled by editorial board members, who often lack specialised training in copyediting and proof reading. This deviation from global practices leads to a scarcity of formal structures and private companies dedicated to medical editing, making it challenging to uphold consistent standards and quality. Financial constraints limit investment in specialised software and training, which could enhance the quality of manuscripts. Moreover, the high costs associated with article processing charges for open access publications in international journals can be prohibitive for researchers.

The varied standards of medical journals in Pakistan affect the credibility and international recognition of published work.[3] This affects how the global medical community views the medical research emerging from Pakistan. Talented editors and researchers may seek opportunities abroad due to better professional prospects,

depriving the local scene of much-needed expertise. Limited access to advanced editing software and plagiarism detection tools further hinders the maintenance of the integrity and quality of medical literature. Sociocultural factors may influence research topics, affecting the diversity and relevance of the medical literature in a global context. Keeping pace with rapid advancements in medical science requires continuous updates to editorial practices, which may be challenging given the resource, training, and expertise limitations.

Challenges in publishing and English language editing

Scholars face growing pressure to publish their work in English,[5,6] as publications in English are generally considered more prestigious.[7] One significant issue that editorial board members face is English language editing and paraphrasing.[8] With English being a second language for many in Pakistan, ensuring linguistic precision in medical manuscripts becomes daunting.[9] These challenges can lead to misinterpretations or miscommunications, which could have grave implications in the medical field.[10] Editors of medical journals tend to focus more on scientific soundness than language quality.[5] Jawaid et al. analysed deficiencies in articles accepted for publication in the *Pakistan Journal of Medical Sciences* and found extensive grammar mistakes, inappropriate references, and unnecessary tables.[11] Aziz et al. examined English grammar issues in articles submitted to the *Annals of Abbasi Shaheed Hospital*. They identified errors such as the misuse of punctuation, incorrect tense and voice, and errors in article usage.[4]

Given the critical importance of avoiding grammatical errors, it is imperative for authors to thoroughly review their manuscripts.[14] Authors might benefit from specialised training in manuscript preparation before submission.[11] Currently, no journals in Pakistan provide specific developmental editing services to improve the writing prowess of their authors.[3,12–14] Developmental copyeditors play an important role in collaborating with authors, guiding them to refine their work by enhancing clarity, ensuring logical flow, and bolstering the overall relevance of their scientific manuscripts.[15] This specialised form of editing goes beyond simple corrections; it explores the content structure, argument presentation, and effective communication of ideas, ensuring that the final product is both scientifically robust and reader-friendly.[16]

The rise of freelance copyeditors

While the Western world has seen a rise in specialised editing companies catering to the medical community, Pakistan has relatively few such institutionalised structures.[17] Although some local freelancers and small companies offer medical editing services and international companies are accessible, these options may not be widely available or affordable for many authors in Pakistan.[18] This gap presents both a challenge and an opportunity.

Despite the absence of dedicated companies, there has been a notable increase in freelance copyeditors offering their services in Pakistan.[19,20] Freelancers have carved a niche on global platforms such as Fiverr and Upwork, becoming sought-after professionals because of their linguistic skills and domain expertise. However, their potential remains underutilised in the local medical publishing sector.

Collaborating with freelancers emerges as a cost-effective strategy that offers flexibility and scalability. Journals can commission freelancers on individual projects, allowing them to scale up operations during periods of increased manuscript submissions and reduce engagement during lulls. This approach bypasses the financial burden associated with consistent full-time employment. Freelancers' familiarity with international editing benchmarks ensures that Pakistani medical journals can align with global standards. Integrating freelance professionals with in-house editorial teams can promote a more diverse and formidable editorial collective equipped to manage a vast array of manuscripts.

The role of the Higher Education Commission of Pakistan

Pakistan's HEC is crucial for overseeing and improving the quality of higher education and research, including in medical education. The HEC ensures that academic and research outputs, particularly those of medical journals, adhere to international standards. This includes

Figure 1. Recommendations for enhancing the copyediting of medical manuscripts in Pakistan

accrediting journals based on their credibility and reliability, supporting them by funding research, and providing training for editors through capacity-building programmes.[21]

The HEC should promote the use of qualified English language teachers (ELTs) in medical journals to enhance the quality of articles through collaboration with scientific peers. Developing training programmes with international editing associations can improve the skills of local journal editors. Offering grants or financial incentives to journals committed to high-quality copyediting would encourage a general uplift in standards. Implementing mechanisms to periodically review the quality of copyediting and proofreading can maintain consistently high standards. Establishing partnerships with international editorial organisations would keep HEC updated with global best practices and innovations in medical editing.

Developing training programmes with international editing associations can improve the skills of local journal editors.

Recommendations for enhancing medical manuscripts

Editorial boards of universities and private medical journals in Pakistan are encouraged to collaborate with freelance copyeditors and ELTs to improve manuscript quality. This collaboration not only boosts the quality of the medical literature but also offers valuable employment opportunities to the freelance community. The recommendations include expanding editorial membership to encompass individuals with specialised copyediting and English language skills. Organising regular training sessions can enhance proficiency in English, paraphrasing, and technical editing among editorial staff members. Employing qualified ELTs is essential to ensure thorough editing to meet international standards. Establishing dedicated firms specialising in medical literature editing could elevate local journals by improving the quality of their publications. Connecting freelancers and publishers through dedicated platforms can ensure a steady supply of skilled professionals for editing tasks. Developing transparent standard operating procedures is crucial for maintaining consistency and quality in the manuscript submission, editing, and publication processes.

Financial constraints and professional associations

Both the European Medical Writers Association (EMWA) and the American Medical Writers Association (AMWA) are well-established associations that offer support, resources, and training to medical editors and copyeditors.[22,23] Membership benefits include free or reduced-price access

to tools, workshops, and networking opportunities that can significantly benefit professional career advancement. However, with annual membership fees of €130 for EMWA and $199 for AMWA, the cost of joining these global associations is prohibitive for many professionals in Pakistan. The high relative cost, when converted to local currency, often exceeds the financial capability of the average copyeditor. While these associations cater to a global audience, their fee structures do not account for the economic disparities among countries. Implementing a subsidised fee structure based on individual countries' economic conditions would make membership more accessible to professionals in lower-income nations. Making resources more accessible and affordable through local associations or restructured global membership is vital. Partnerships with international peers, including exchange programs and training, would further support skill development across diverse economic contexts.

Building awareness and local associations

Awareness campaigns should be initiated to highlight the importance of copyediting in medical literature. This can elevate the profession's stature and emphasise its significance. There is a pressing need to establish local copyediting and medical writing associations in Pakistan. This can provide affordable training, resources, and networking opportunities tailored to the Pakistani context. Implementing these recommendations will not only elevate the quality of medical manuscripts in Pakistan, but also position the nation as a credible and respected contributor to the global medical research community.

Medical journalism, copyediting, and English language teachers: A growing industry

The fields of medical journalism and copyediting in developing countries, including Pakistan, are undeniably on the rise. As more research emerges and global collaboration increases, there is a pressing need to ensure the quality of published works. This evolution offers a promising path for aspiring copyeditors and ELTs and reinforces the importance of their role in enhancing Pakistan's medical literature landscape. The insights gained by ELTs through collaboration with researchers regarding their research approach, execution, and writing could ease the editing workload. This allows these specialised editors focused on English instruction to perform their editing tasks more proficiently and effectively.[24] The expertise acquired through joint efforts could enhance the credibility of English teachers as intermediaries in scientific literacy and specialists in a field known as English for specific purposes (ESP).[25]

> There is a pressing need to establish local copyediting and medical writing associations in Pakistan.

Conclusion

The copyediting of medical manuscripts in Pakistan is currently in its early stages. Despite ongoing hurdles, a clear upward trajectory is discernible in this industry. The emphasis on quality and linguistic clarity in medical narratives is more pronounced than ever before. Copyediting is valuable for scientific fraternity for improving the quality of research reporting and expediting the publication process. With Pakistan steadily enlarging its research influence, involving specialised copyeditors is becoming increasingly essential to ensure that the nation's scholarly contributions are clearly articulated and accepted globally. Implementing these recommendations can substantially augment the stature of Pakistani medical manuscripts, cementing its role as a trustworthy and respected participant in international medical research.

Clear and concise language will help editors and reviewers concentrate on the paper's scientific content and thus smooth the peer review process. Therefore, integrating ELTs and freelance copyeditors into Pakistan's medical journal editorial services could be transformative. It will not only enhance the linguistic calibre of the output but also facilitate a level of excellence aligning with international benchmarks, consequently uplifting the global positioning of Pakistani medical research.

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.

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Don't miss!

The March 2025 edition

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 Editors: Sarah Milner and Heather Mason

Transparency through the lens of data protection and privacy: A clinical research organisation medical writing perspective

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Abstract

Medical writers maintain a fine balance between data transparency obligations and personal data protection in clinical reports. Hence, we must stay informed of data protection requirements outlined in the EU General Data Protection Regulation (GDPR) 2016/679 and their interaction with data transparency requirements of the EU Clinical Trials Regulation (EU-CTR) 536/2014 and EMA Policy 0070. Medical writers need to understand the core concept of personal data versus anonymised data and the differences between working for a data controller versus working for a data processor.

This article explores how a clinical research organisation, as the data processor, assists client companies, as the data controller, fulfil transparency obligations, illustrated by a successful collaboration model. We examine how medical writers contribute to an organisation's disclosure-readiness as well as promote the value of a disclosure-informed medical writer's upstream impact as clinical reports anonymisation specialists throughout the clinical trial lifecycle.

In the clinical research context, protecting the confidentiality of research subjects' identity has always been a fundamental ethical consideration, increasingly challenged by complexities in electronic data collection, storage, and the re-use of data from various sources, including the data transparency requirements of the EMA Policy on the publication of clinical data for medicinal products for human use (hereafter referred to as "EMA Policy 0070") and the EU Clinical Trials Regulation 536/2014 (EU-CTR). In this article, we explore the interplay between the EU GDPR 2016/679, Phase 1 of EMA Policy 0070, and the EU-CTR and how these now impact clinical research organisation (CRO) medical writers (MWs).

Basic GDPR terms

The EU GDPR applies to the processing of personal data[1] by data controllers and data processors:[2]

- Personal data means any information relating to an identified or identifiable natural person...
- The GDPR does not apply to the processing of fully anonymised data. According to GDPR Recital 26 "The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes".
- The GDPR mainly assigns the GDPR compliance accountability to the data controller – the natural or legal person, who, alone or jointly with others, determines the purposes and means of the processing of personal data.
- A data controller may employ the services of a data processor – a natural or legal person who processes personal data on behalf of the data controller and based on the data controller´s documented instructions.

> As data processors, medical writers play a key role in protecting data.

Interplay between EU-CTR and the GDPR on transparency

The EU-CTR requires information stored in the Clinical Trials Information System (CTIS) database to be publicly available but provides exceptions for such matters as the protection of personal data. To comply with EU-CTR transparency obligations, the reported and published data should be fully anonymised. The GDPR provides only a conceptual definition of anonymisation, necessitating the need for further guidance. As stated by the EMA's external guidance on the implementation of the EMA Policy 0070:

> *... there is a need for further guidance in order to ensure that Policy 0070 meets its objectives. For this purpose, EMA has prepared the following documents... External guidance on the anonymisation of clinical reports for the purpose of publication in accordance with EMA Policy 0070 (see Chapter 3).*[3]

So where do medical writers fit in?

Medical writers prepare most of the clinical reports that are required to be published under transparency regulations like EMA Policy 0070 and EU-CTR.

Some of the core attributes of MWs include data-centricity, time-bound efficiency, flexibility, and commitment to quality, all while striving for organisational simplicity. Therefore, it is not surprising that writers have evolved into the role of performing clinical reports anonymisation tasks as agreed between clients/sponsors as data controllers and CROs as data processors. Data privacy goes beyond Good Clinical Practice and ethical considerations in clinical research, and a MW's role in preserving it needs to be explored further. MWs have implemented some technical, organisational, and information technology

measures. As data processors, MWs play a key role in protecting data. Their expertise in anonymisation techniques and understanding of regulatory requirements make them essential contributors to maintaining privacy standards in clinical reports.[4]

The role of a data processing agreement between a CRO and sponsor

To understand how CROs may best collaborate with clients or sponsors while performing EMA Policy 0070/EU-CTR tasks, we need to first characterise a CRO's responsibilities regarding the anonymisation of clinical reports on behalf of the data controller:

- Only a data controller (the sponsor) decides how that anonymisation and data utility will play together.
- CROs act as data processor for the processing of study data but also for the anonymisation of clinical reports because the function of "anonymisation" of personal data in clinical reports is essentially the processing of personal data for the purpose of anonymising such data.
- Data processors do not make decisions on behalf of data controllers and are bound to follow the data controller's instructions. The CRO may make suggestions as to how the anonymisation of personal data could be made technically possible, but the decision for how personal data will be anonymised for protection must come from the sponsor as data controller.
- The GDPR requires that a data controller execute a data processing agreement with a data processor to govern the processing of personal data by the data processor on behalf of the data controller.[5]
- So how does this collaboration between data controller and data processor work? This article explores this from the medical writing perspective.

Box 1. Success factors in anonymisation projects

Medical Writer Expertise

- Familiarity with report structure and content
- Keen eye for analytical detail
- Technological agility, including familiarity with AI tools
- Extensive experience in anonymisation techniques and data protection requirements
- Established working relationship with long term clients

Clear Communication

- Set clear expectations: Clear scope, timelines, deliverables, and specific considerations
- Facilitate end-to-end collaboration
- Reduce risk of redaction proposal rejection
- Minimise delays and rework

Use of AI Tools

- Enable processing of large number of documents
- Streamline data handling
- Shorten timelines
- Improve accuracy

Lessons from CRO medical writers as anonymisation specialists

Even though a multifunctional team is likely to be involved in an EMA Policy 0070/EU-CTR task, MWs in their role as anonymisation specialists can add significant value. Success factors in anonymisation projects are presented in Box 1.

Project kick-off: Anonymisation projects may be initiated with a kick-off meeting to ensure a comprehensive understanding of client requirements thereby fostering trust with a well-trained and skilled team. Clear communication of expectations between the MWs (as anonymisation specialist) and clients is crucial, positioning the project for success before initiating the actual task. The key goals of the kick-off process are stakeholder orientation, and

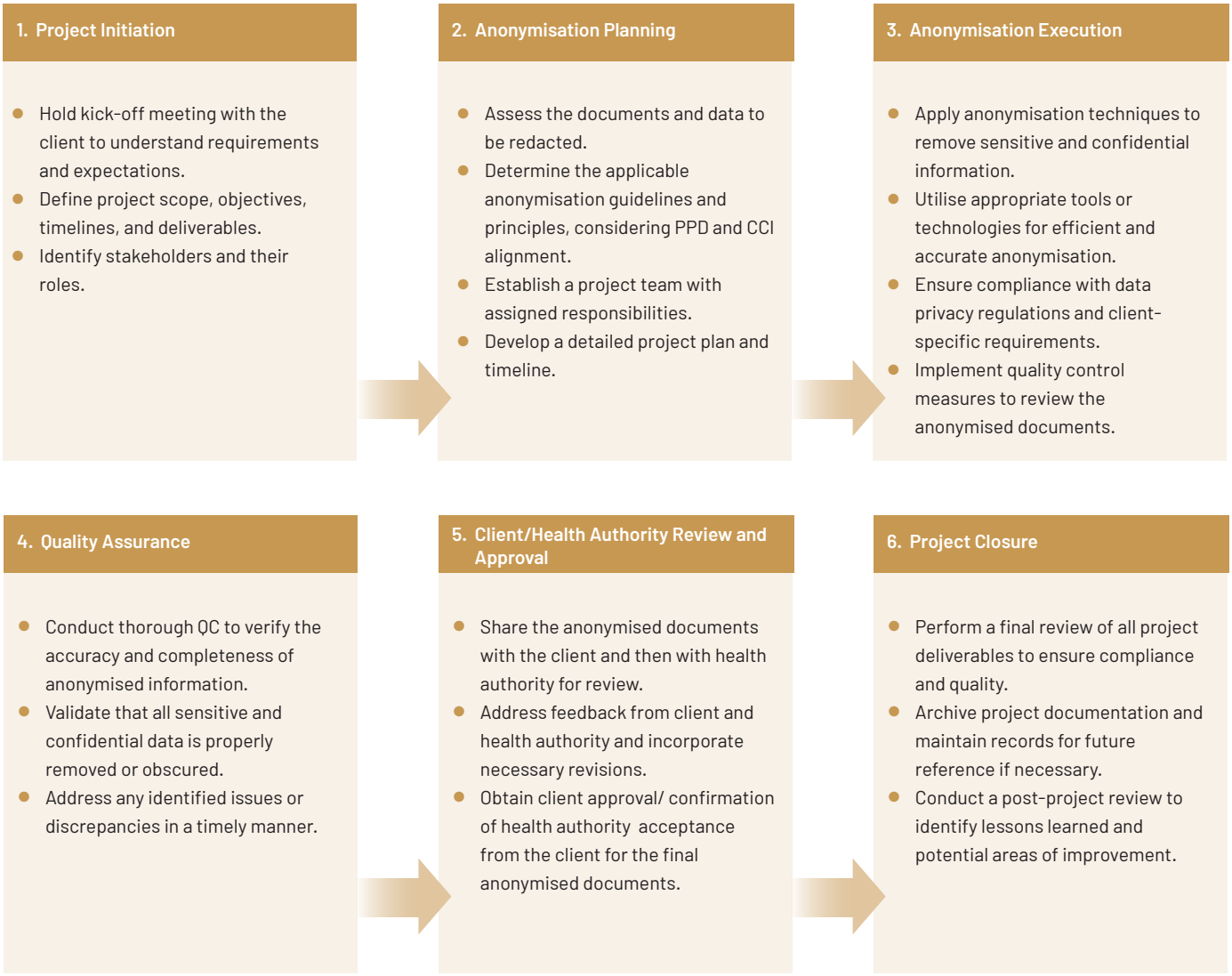

Figure 1. Schematic of the anonymisation process

Abbreviations: CCI, commercially confidential information; PPD, protected personal data; QC, quality control

project standardisation, and quality management.

Before commencing the anonymisation task, project-level guidelines to ascertain protected personal data (PPD) and commercially confidential information (CCI) in the clinical reports package should be agreed upon in writing. A schematic of the anonymisation process is shown in Figure 1.

Communication: Queries raised by a MW during the anonymisation process should be carefully handled by leveraging anonymisation-specific internal and external expertise, best practices, and lessons learned before generating queries to the client, and ensuring a thorough internal review. Clear and prompt communication is crucial, highlighting the importance of soft skills.

Document sharing: The clinical reports should be shared for client review via secure communication channels as agreed with the client.

Consultancy: MWs play a vital role in providing consultancy on the anonymisation process by leveraging their expertise in medical writing, regulatory guidelines, and clinical reports anonymisation.

Quality control: The QC process for anonymisation entails meticulously verifying the consistency and accuracy of anonymised information, ensuring that the final clinical reports' anonymised text is neither searchable nor editable, and conducting comprehensive checks on metadata, file properties, and overlays such as PPD and CCI for legibility and clarity. In the context of anonymised deliverables, artificial intelligence tools are increasingly employed by CROs to boost efficiency and meet tight deadlines, especially for critical tasks such as addressing EU-CTR requests for information. These tools enable MWs to produce high-quality clinical reports with reduced turnaround times. However, manual QC remains vital for logical consistency and accurate PPD and CCI identification and adding a human touch to anonymised clinical reports.

Documentation: Documentation of all these steps is an important aspect of medical writing. We need to document each step of the document cycle in a repository system for future reference

and audit readiness. These include approval emails, source documents, and other relevant conversations for future communication.

Conclusion

There needs to be a well-established collaboration between data controllers and data processors to succeed in delivering the strategic and time-sensitive tasks required for clinical report publication. The CRO MW upholds data protection regulations while striving for optimal data transparency and is pivotal in the implementation of robust anonymisation processes. They do this by leveraging artificial intelligence tools for efficiency and engaging cross-functional stakeholders to ensure a compliant and high-quality anonymisation package, as well as employing soft skills in stakeholder communication, such as ensuring leadership of the project, having the confidence to influence decision making, being well-organised and thinking ahead. Ultimately, this article emphasises the valuable role that MWs play in achieving transparency in clinical research and fostering a partnership with data controllers (clients or sponsors) to deliver high-quality anonymised documents.

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The authors declare no conflicts of interest.

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News from the EMA

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.

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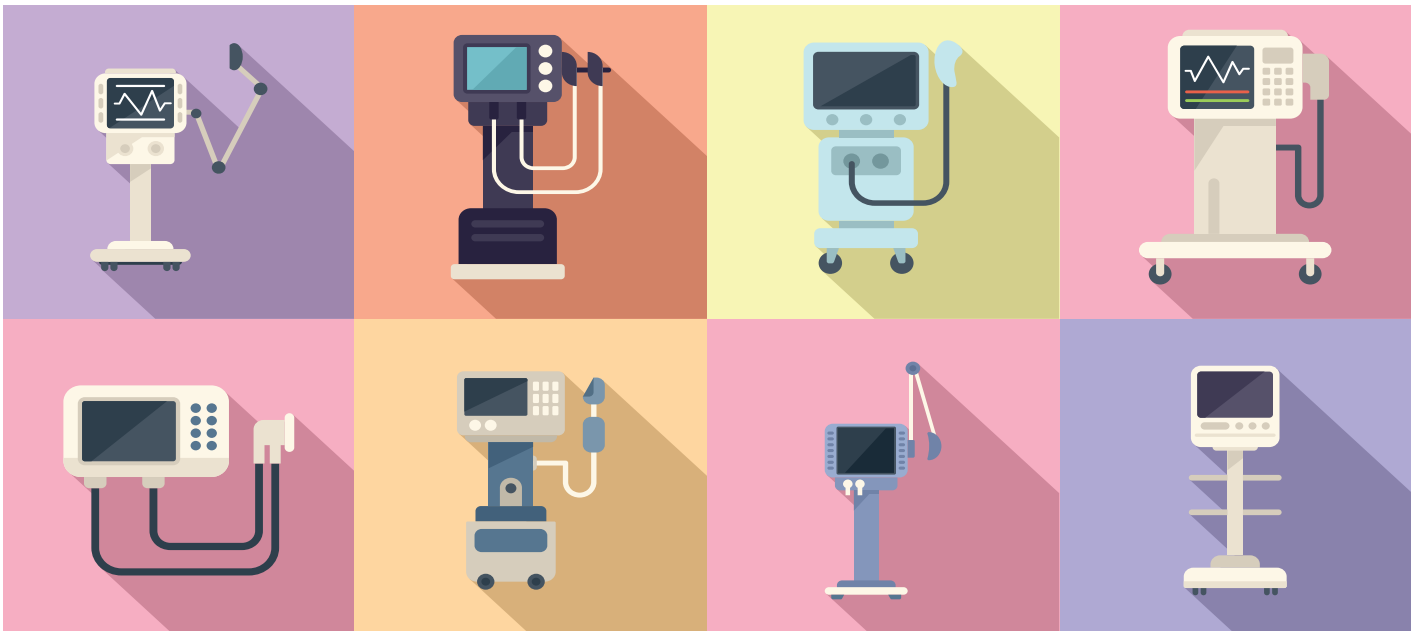

Photos: Freepik

New pilot programme to support orphan medical devices

August 2, 2024

EMA has launched a pilot programme for expert panels to support the development and assessment of orphan medical devices in the European Union (EU). The pilot programme offers free advice from the medical device expert panels to selected manufacturers and notified bodies on the orphan device status and the data needed for their clinical evaluation. While the pilot programme is currently scheduled to run until the end of 2025, the aim is to establish a long-term process for orphan device support.

Orphan devices are medical devices which are intended to be used for diseases or conditions affecting only a small number of individuals each year (not more than 12,000 individuals in the EU per year). Often, they are used to treat or diagnose rare diseases or conditions for which no or insufficient alternative diagnostic or therapeutic options exist, thereby fulfilling an unmet medical need.

Manufacturers can consult the expert panels at different stages of the development of the clinical strategy for their device, while notified bodies can request advice at specific moments of the ongoing conformity assessment of the device. As part of the pilot programme, EMA will prioritise certain types of orphan medical devices, such as devices for treating a medical condition that is life-threatening or that could cause permanent impairment of a body function, devices intended for children, and novel devices with potential major clinical benefit.

In June 2024, the European Commission announced new guidance on the clinical evaluation of orphan medical devices issued by the Medical Device Coordination Group, which is composed of representatives of all EU Member States.[1] This guidance provides the criteria to determine when a medical device should be regarded as an orphan device under the EU Medical Devices Regulation and aims to guide manufacturers and notified bodies when applying the clinical evidence requirements.

This pilot programme is part of EMA's regulatory support for the expert panels on medical devices, following the introduction of new legislation in the EU. Since March 1, 2022, the Agency supports the medical device expert panels that provide opinions and views to notified bodies on the scientific assessment of clinical and performance evaluations of certain high-risk medical devices and in vitro diagnostic medical devices.

Early advice to manufacturers, particularly to small and medium-sized enterprises, is a key tool to foster innovation and accessibility to safer and effective devices that address patients' needs. The orphan device pilot will run in parallel to the scientific advice pilot to manufacturers which already prioritised advice to manufacturers on the clinical development strategy and clinical investigations of devices addressing unmet needs.

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Photos: Freepik

ICH guideline E11A on pediatric extrapolation – Scientific guideline

August 27, 2024

The ICH E11A guideline provides recommendations for harmonised approaches for paediatric extrapolation to support the development and authorisation of paediatric medicines. It provides a framework for using extrapolation as a tool to support paediatric drug development that encompasses an iterative process for understanding the existing information available, the gaps in information needed to inform development, and ways to generate additional information when needed.

Pediatric extrapolation is defined in the ICH E11(R1) guideline as "an approach to providing evidence in support of effective and safe use of drugs in the pediatric population when it can be assumed that the course of the disease and the expected response to a medicinal product would be sufficiently similar in the pediatric [target] and reference (adult or other pediatric) population." The reference population can include other pediatric age subsets. Pediatric extrapolation can extend what is known about the reference population (e.g., pharmacokinetics (PK)/dosing, efficacy, and safety) to the target population based on an assessment of the relevant similarities of disease, drug pharmacology, and response to treatment between the two populations.

The ICH E11A on pediatric extrapolation guideline is to be read in conjunction with the ICH E11 guideline on clinical investigation of medicinal products in the paediatric population and the ICH E11(R1) addendum, both available on page ICH E11(R1) step 5 guideline on clinical investigation of medicinal products in the pediatric population – Scientific guideline. Furthermore, applicants wishing to follow an extrapolation approach are suggested to look also at EMA's Structured guidance on the use of extrapolation.

Harnessing AI in medicines regulation: use of large language models (LLMs)

September 5, 2024

EMA and the Heads of Medicines Agencies (HMA) have published high-level principles and recommendations for all staff across the European medicines regulatory network (EMRN) using large language models (LLMs) in their work.[1]

LLMs are a category of generative AI, whose applications can significantly support medicine regulators in their tasks and processes. Whether they are used to query the extensive documentation regulators routinely receive, to automate knowledge/data mining processes, or as virtual AI assistants in everyday administrative tasks – LLMs have enormous transformative potential.

However, LLMs also present challenges, e.g. variability in results, returning of irrelevant or inaccurate responses (so-called hallucinations), and potential data security risks. The purpose of the guiding principles is to build understanding of the capabilities and limitations of these applications among staff at regulatory agencies across the EU so that they can harness the potential of LLMs effectively and avoid pitfalls and risks.

The guiding principles cover various aspects of using LLMs, from ensuring safe input of data, to applying critical thinking and cross-checking outputs, to knowing whom to consult when concerns arise. Responsible use of LLMs requires familiarity with the tools. The importance of continuous learning is emphasised to keep pace with the fast-changing field.

Additionally, the principles encourage regulatory agencies to make efforts to support their staff in using LLMs. This includes defining governance on the use of LLMs, specifying permitted use cases, providing training and monitoring risks.

The guiding principles are one of the deliverables of the multiannual AI workplan to 2028 by EMA and the Heads of Medicines Agencies (HMA). This workplan guides EMA and the EMRN in their use of AI, maximising the benefits while managing the risks, and facilitating information sharing.

The guiding principles are a living document that will be regularly updated.

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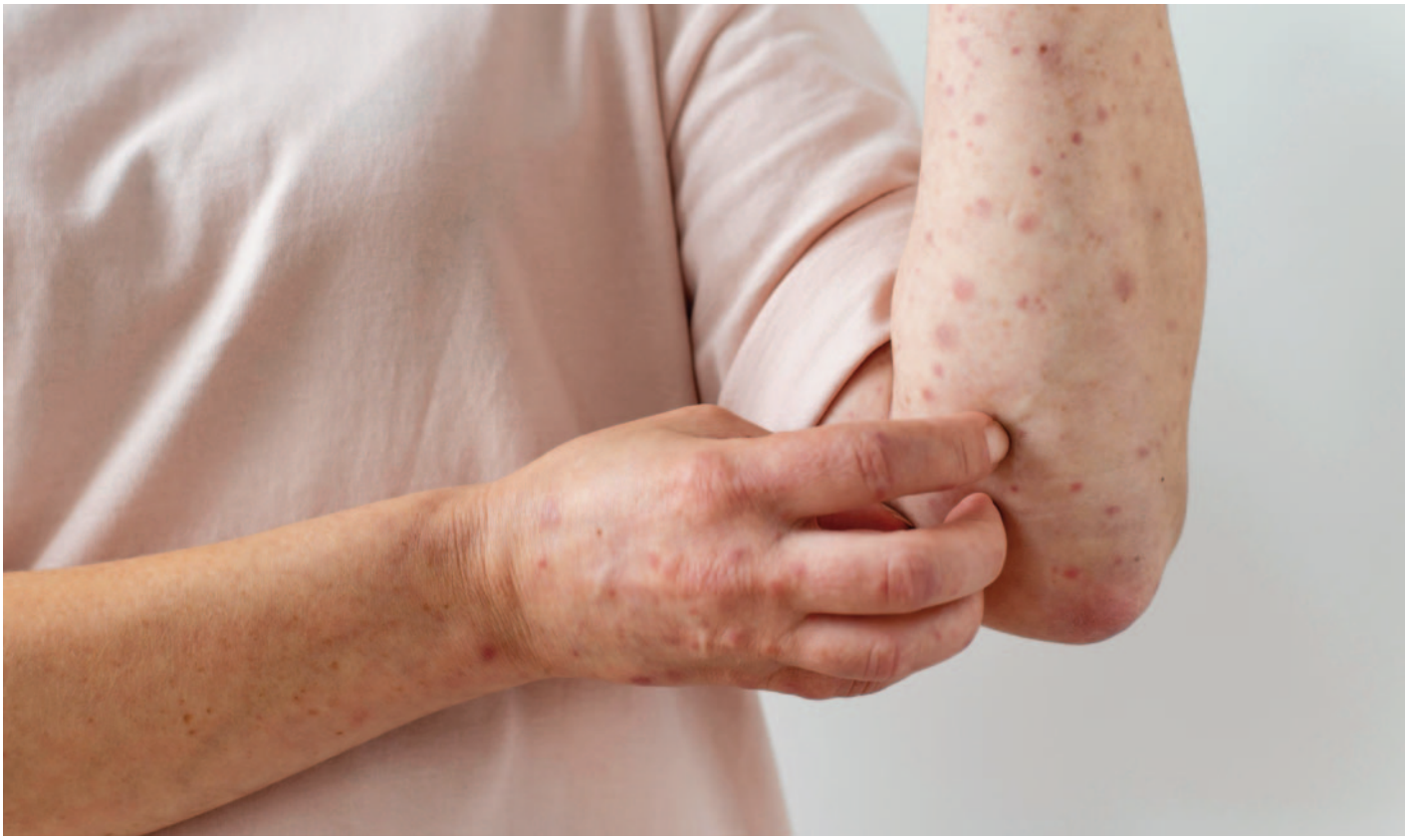
1. Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities. August 29, 2024. Available from: https://www.ema.europa.eu/en/documents/other/guiding-principles-use-large-language-models-regulatory-science-medicines-regulatory-activities_en.pdf



EMA recommends extending indication of mpox vaccine to adolescents

September 19, 2024

EMA has recommended extending the indication of the smallpox and mpox vaccine Imvanex to adolescents from 12 to 17 years of age.

Imvanex is already authorised in the EU to protect against smallpox, mpox, and the disease caused by the vaccinia virus in adults. It contains a live, highly weakened form of a virus called "modified vaccinia virus Ankara" (MVA-BN), which is related to the smallpox virus. EMA's human medicines committee (CHMP) based the recommendation to extend the use of Imvanex to adolescents on the interim results of a study that compared the vaccine's ability to generate an immune response (produce virus-specific antibodies) in 315 adolescents and in 211 adults.

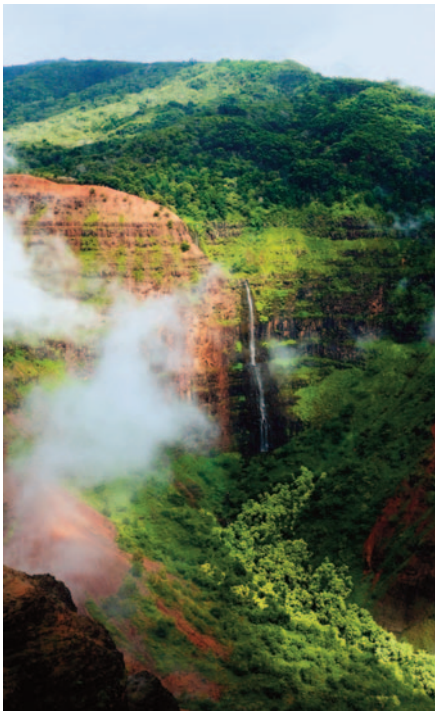
The immune response in adolescents was similar to adults. Therefore, it is inferred that the vaccine will provide similar protection in adolescents to that expected in adults. According to the submitted data, the safety profile of Imvanex in adolescents was comparable to that seen in adults and no additional risk has been identified. As part of its recommendation, EMA has requested the marketing authorisation holder to submit the final results of the study by May 30, 2025, to further characterise the information about safety in adolescents.

The Agency's assessment has important implications for the global response to the mpox outbreak in the Democratic Republic of the Congo (DRC) and other countries, which was declared a public health emergency of international concern (PHEIC) by the World Health Organization (WHO) on August 14, 2024. EMA is the regulatory agency of record for prequalification of this vaccine by WHO on September 13, 2024.

Mpox is a disease that is transmitted to people by animals, mainly rodents, but can also spread between people with direct contact. It is endemic in certain parts of Central and West Africa. The current surge in cases in the DRC and several neighbouring countries is driven by the mpox clade I strain that is known to cause a more severe form of mpox in humans than the mpox clade II strain that spread during the 2022/2023 PHEIC. Mpox can be fatal for people with weak immune systems.

Data indicate that Imvanex protects against both the clade I and clade II mpox strains.

In the EU, decisions on how vaccinations should be given are the prerogative of the expert bodies guiding vaccination campaigns in each Member State. The European Centre for Disease Prevention and Control (ECDC) published advice for public health authorities for mpox on their website.



Photos: Freepik

Don't miss!

The June 2025 edition

Communicating with the Public

When we communicate effectively with patients and the public, we empower them to make informed decisions about their health. This issue will cover the latest guidelines and standards to be considered when writing and designing information for patients and the public. 73It will also feature articles from thought leaders on plain language writing, inclusive communication, and patient involvement in research. With this issue, we hope to provide insights that will strengthen the role of medical writers as advocates for the patient voice, and as powerful and effective communicators of understandable science.

Guest Editors: Sampoorna Rappaz and Lisa Chamberlain James
The deadline for feature articles is March 1, 2025.

Photo: Freepik

Updated advice to minimise risks of interaction between weight loss medicine Mysimba and opioids

November 15, 2024

After re-examining its initial opinion, EMA recommends updating the advice aimed at minimising the risks of interaction between the weight loss medicine Mysimba (naltrexone/ bupropion) and opioid-containing medicines (including painkillers such as morphine and codeine, other opioids used during surgery and certain medicines for cough, cold, or diarrhoea).

Opioid medicines may not work effectively in patients taking Mysimba, because one of the active substances in Mysimba, naltrexone, blocks the effects of opioids. There is also a risk of rare but serious and potentially life-threatening reactions, such as seizures and serotonin syndrome (a potentially life-threatening condition that results from having too much serotonin in the body), in people taking Mysimba together with medicines for treating depression and opioids.

To minimise these risks, patients and healthcare professionals are reminded that Mysimba must not be used in people who are dependent on opioids, people receiving treatment with opioid agonists such as methadone or buprenorphine, and people going through acute opioid withdrawal.

Mysimba is a medicine used along with diet and exercise to help manage weight in adults who have obesity (have a body-mass index – BMI – of 30 or more) or who are overweight (have a BMI between 27 and 30) and have weight-related complications such as diabetes, abnormally high levels of fat in the blood, or high blood pressure. Mysimba was granted marketing authorisation on March 26, 2015.

People using Mysimba will be given a patient card to be carried with them at all times. The card will remind them to inform their doctor, in case of surgery, that they are using Mysimba. This is because Mysimba should be stopped for a minimum of three days before starting treatment with opioids, which are often used to prevent pain and discomfort during surgery and medical procedures.

The product information for Mysimba is being updated to reflect these changes.

Medical Writing in
SPANISH

Medical writing

Despite our diverse backgrounds and countries of origin – Beatriz is a Spanish molecular biologist, Yanina is an Argentinean biochemist, and Valentina is an Italian physicist – our professional journeys share some common points. We all started as scientists, spent several years in research, and then transitioned to the linguistic aspects of science: medical writing, translation, and proofreading. We also share the subjective side of our career change: after many years of reading and writing highly specialised English texts, we assumed that conveying the same content in Spanish would be straightforward. Instead, we discovered that this endeavour was far from easy: more often than not, we found ourselves at a loss for specialised Spanish words. We quickly understood that those years in research were both a gift and a curse, revealing a common struggle for medical writers who need to write in a language other than English.

One obvious challenge for medical writers and translators writing in Spanish is geographical diversity: Spanish is spoken in 21 countries[1] on three continents, each using a specific language variant with different words, phonetics, and even syntax. Many of these variants are strongly influenced by close contact with neighbouring Anglo-Saxon countries, which encourages the introduction of "false friends", such as *constipado* (which means "common cold") instead of *estreñimiento* for "constipation", or *injuria* (which means "offence") instead of *lesión* for "injury". The Anglo-Saxon influence is also a consequence of the fact that English is the lingua franca in the dissemination of science: although English is only the third most spoken language[2] in the world, with 330 million native speakers, after Mandarin Chinese (929 million) and Spanish (475 million), it accounts for 94% of articles in the scientific research database Web of Science, compared to only 1.3% for Spanish (2022 data).[3]

Thus, writing scientific content in Spanish almost

in Spanish

inevitably means translating from English. In most cases, this translation process is carried out by the individual scientist or linguist, leading to divergent and often questionable terminological choices. As a result, medical Spanish is much less standardised than its primary source, medical English. One way this manifests itself is through synonymy. Synonyms arise through a number of mechanisms: geographical variants (*útero/matriz* [uterus]); semantic calques (*fármaco/droga* [drug]); syntactic calques (*por VIH/VIH-asociado* or *HIV-asociado* [HIV-associated]); lexical loans, either crude (*derivación/bypass*) or adapted (*baipás* [bypass]); anglicised spellings (*glucemia/glicemia* [glycemia]); alternative etymologies (*nefropatía/enfermedad renal* [kidney disease]); or even simple misinterpretations of noun phrases (*valor de p/valor p* [p value]); to name but a few. When it comes to acronyms and abbreviations, duplication becomes a runaway process, as lexical variants of individual elements combine with syntactic alternatives to produce a plethora of translated terms: for example, "siRNA" (small interfering RNA) can become *ARNpi*, *ARNip*, *pARNi*, *siRNA*, *siARN*, *ARNsi* – and the list is not even complete!

Another essential aspect when adapting an English source text into Spanish (e.g., for an advertising campaign) is that Spanish requires more grammatical structures and elements than English to convey information effectively. This often results in sentences that are ~30% longer, as the following example illustrates: "Welcome to the EMWA Spring Conference!" (6 words, 38 characters) translates as "¡*Bienvenidos a la Conferencia de Primavera de la EMWA*!" (9 words, 54 characters). This means that when following the three principles of medical writing – clarity, rigour, and conciseness – Spanish-speaking medical writers must pay particular attention to the last principle.

Our role as medical writers or translators is crucial in adapting and bridging these linguistic gaps to ensure that scientific information is effectively communicated in Spanish. To help us in this endeavour, it is essential to make the most of resources such as Cosnautas, an extensive library of medical dictionaries specialised in biomedical sciences, as well as the specialised training opportunities offered by associations such as the Spanish Association of Medical Writers (AERTeM), the Latin-American Medical Writing Group (GLAMW), or the International Association of Translators and Writers in Medicine and Life Sciences (Tremédica). These resources are invaluable in equipping us for the challenges we face in our professional journey.

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Medical Devices

SECTION EDITOR

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Editorial

Establishing a solid state of the art under the Medical Device Regulation (MDR) is complex and requires both experience and expertise. As medical writers across Europe have successfully put into practice their knowledge and interpretation of the MDR, getting to know the experiences of other medical writers continues to provide new perspectives and insights. In this article, the author shares her tips and tricks for establishing an MDR-compliant state of the art in the hope to provide useful tools to other medical writers. **Payal**

Mastering the art of the state of the art (under EU MDR 2017/745)

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Abstract

Establishing the state-of-the-art (SOTA) represents a crucial aspect of a clinical evaluation under the European Medical Device Regulation (EU MDR) 2017/745. In this article, I share my experience of working on SOTA documents over the last four years. It first briefly recapitulates the SOTA requirements of the EU MDR (that are in fact almost non-existent) followed by the different steps required to conduct and document the literature search. Also included are some tips and tricks on structuring the SOTA. Finally, advantages and limitations of different scientific literature databases are provided.

Introduction

The state-of-the-art (SOTA) literature review represents a crucial aspect of a clinical evaluation required not only to obtain CE marking but also to maintain CE marking in accordance with the European Medical Device Regulation (EU MDR) 2017/745. According to the Oxford English Dictionary, SOTA can be both a noun and an adjective that means:

> "Belonging or relating to the latest or the most sophisticated stage of technical development, having or using the latest techniques and equipment".

Despite this simple definition, establishing an MDR-compliant SOTA is complex and requires a strict methodology including different stages (data identification, appraisal, analysis). Not to forget, this demands both time and experience.

I started to work as a freelance medical writer almost 4 years ago, after 8 years of working in academia. As a PhD student and/or postdoc, we routinely gather, analyse, and report scientific data on specific topics from the literature. And this is technically what is required to establish a SOTA. However, it took me a lot of practice (and a lot of phone calls with other medical writers specialised in the field) to master all the aspects of the methodology.

> The SOTA needs to cover two main topics: (1) the clinical background of the medical conditions targeted by the device under evaluation (DUE), and (2) the description of historical/alternative treatments and clinical evidence related to benchmark devices.

EU MDR requirements regarding the SOTA

In the EU MDR,[1] the term "state of the art" is mentioned several times, but no concrete description of how to establish a SOTA is provided. Instead, it only suggests that establishing the SOTA is to present the context of the medical condition that your device is targeting.

To gather more information on this (and on other clinical topics), the European Commission published guidelines called MEDDEV. Among them, there is the MEDDEV 2.7/1 revision 4 called "CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC". According to this guideline,

> "The current knowledge/state of the art therefore needs to be identified and defined, possibly also relevant benchmark devices and medical alternatives available to the target population."[2]

Therefore, the SOTA needs to cover two main topics: (1) the clinical background of the medical conditions targeted by the device under evaluation (DUE), and (2) the description of historical and/or alternative treatments and clinical evidence related to benchmark devices (Figure 1). To cover these topics, a documented literature review should be performed with pertinent literature selected that is then analysed, evaluated, and reported.

Apart from the SOTA, a third literature review is also required by EU MDR 2017/745 the purpose of which is to establish safety and performance profiles of the DUE. In other words, the main objective of the clinical evaluation is to evaluate the level of clinical evidence available for the DUE in the context of the SOTA.

The MEDDEV 2.7/1 revision 4[2] recommends the following three steps to conduct a literature review:

- Stage 1 – Identification of pertinent data
- Stage 2 – Appraisal of pertinent data
- Stage 3 – Analysis of pertinent data

It also recommends providing:

> "Brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/the state of

the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. Appraisal criteria used."

The international medical device regulators forum (IMDRF) is a voluntary group of medical device regulators from around the world, independent of the MDR, who also published a technical document regarding clinical evaluation in 2019 in which additional information on SOTA literature review can be found.[3]

Literature search strategy

Aim

Clinical background. The clinical background section aims to describe the natural course and consequences of the medical conditions concerned.[2] It is advisable to document the different clinical forms, stages, and severities of the conditions. Additionally, the frequency of the medical condition in the general population as well as in different subpopulations (age, gender, ethnicity, genetic predispositions, etc.) should also be described.

Alternative treatments and benchmarks devices. According to the MEDDEV 2.7/1 revision 4, this literature review should cover the following topics:[2]

- "Description of available therapeutic/management/diagnostic options, historical context and developments, summary of advantages and disadvantages of the different options, benefit/risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions and in relation to different target populations.
- Description of the benefits and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects and other risks (including the nature, severity, probability and duration of acceptable harm).
- Hazards due to substances and technologies that could be relevant to the device under evaluation. The mechanisms of harm, clinical aspects of minimisation, and management of side effects and other risks.
- Types of users. Diverging opinions of professionals as to the use of the different medical options. Unmet medical needs".

Type of references to search

Clinical background. The literature related to the clinical background of a medical condition can be vast. Also, the prevalence of a disease can significantly change with time. Therefore, it is important to target the literature search to latest studies to only reflect the current knowledge regarding the medical condition. Public health agencies (such as World Health Organization, European and American Centers for disease control and prevention, etc.) as well as medical societies or associations specialised in a medical field or condition (e.g., European Hematology Association, European Glaucoma Society, American Cancer Society, etc.) publish and update evidence-based guidelines on a regular basis. These guidelines or standards typically contain the latest knowledge related to medical conditions and represent the highest quality source of references.

Guidelines or standards typically contain the latest knowledge related to medical conditions and represent the highest quality source of references.

However, these guidelines neither exist for all medical conditions nor cover all aspects of the medical conditions. In such cases, other references such as review articles can be considered.

Alternative treatments and benchmark devices. In addition to the clinical background, guidelines published by public agencies and medical agencies/associations can also cover most of the topics required for this section of the SOTA. Clinical evidence of benchmark devices can be found in clinical studies, meta-analyses or systematic reviews if they are well-established

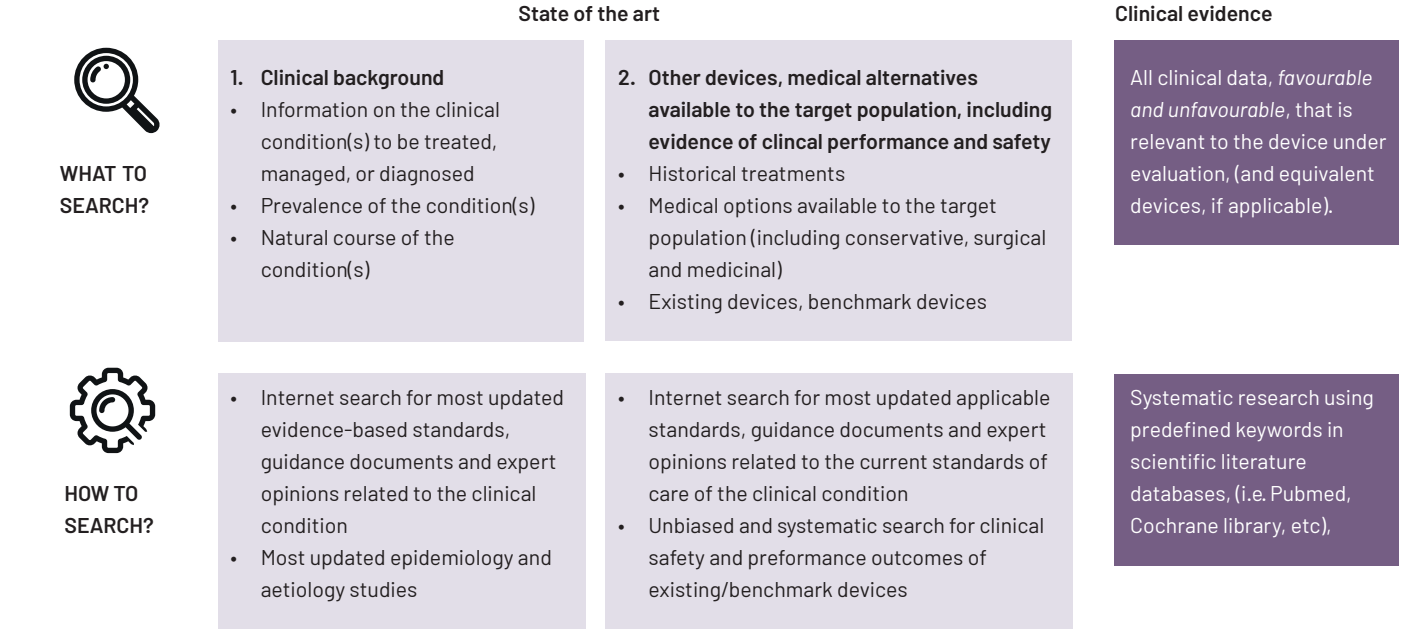

Figure 1. Literature search and review required for the clinical evaluation of medical devices under Regulation (EU) 2017/745

devices. The label, instructions for use and implant registries of benchmark devices (where available) should be also searched to establish their benefit/risk profiles.

Stage 1 – Identification of pertinent data

Guidelines and standards. Finding the latest evidence-based guidelines and/or standards is my very first step when I start to prepare a SOTA. Of course, the guidelines need to be up to date; I consider guidelines up to date when they have been published in the last 5 years. I make sure to use/cite only the latest version published by the agencies or societies/associations. To find them, I usually use search terms such as "diabetes AND (guidance OR guideline OR standard)". Alternatively, the websites of public agencies or medical societies/associations can be searched to find these guidelines. In some cases, the term "guideline", "guidance" or "standard" are used in the title of a document but are not officially written by medical entities. Therefore, as a quality control check, it is important to check the author's affiliation. To find pertinent review papers, the name of the condition can be used as a search term in scientific literature databases (e.g. PubMed). A selection criterion can also be added to only target "review papers". To find specific data on the prevalence of a medical condition or on the current standard of care, the search can be narrowed down by adding the term "prevalence" or "standard of care" in the search.

Review articles. If no guidelines exist regarding the clinical background or current alternative treatments, this can be found in review papers. To find them, I use straightforward search terms such as "[medical condition] AND "treatment" with a selection criteria for "review". However, it is important to make sure there is no bias in the review articles and this is why it is important to check author affiliations to detect potential conflicts of interest. It is crucial to not rely on a single review article since it may not cover all information. Instead, data from several review articles should be combined to describe the panel of existing alternative treatments as well as their benefit/risks profiles. To obtain more information about a specific alternative treatment, an additional literature search can be conducted using the name of the treatment. Clinicaltrial.gov also represents a useful tool to find any new clinical trials in a specific therapeutic area that use more recently developed devices.

Systematic literature review for benchmark devices. A systematic literature review should be conducted to gather all favourable and unfavourable clinical evidence related to the safety and performance of identified benchmark devices. The choice of search terms is key at this stage: they should be broad enough to capture all clinical evidence related to the benchmark device but not too generic resulting in unrelated hits. If a clinical study has been conducted and published on a medical device, the brand name of the device is most often mentioned in the abstract, but it is not always the case. For the search period, the date of commercialisation of the device can be used to make sure to gather all safety and performance outcomes reported in the literature. For the choice of the database, MEDLINE or Pubmed represents the main sources of literature. However, the MEDDEV 2.7/1 revision 4 guideline indicates that these databases may not cover all European journals. Therefore, other databases such as EMBASE/ Excerpta Medica or the Cochrane CENTRAL trials register should also be considered. A pre-screening should be conducted by reviewing all titles and abstracts of the results obtained after the search. At this stage, I exclude all results that do not refer to the benchmark device or that are not related to the safety or performance of the device. Then, the full document of the remaining results should be obtained for the appraisal phase. Finally, the label, instructions for use (IFU), or implant registries of the benchmark devices (where available) can be found directly on the website of the manufacturers or obtained by using internet searches.

> There is no "magic formula" to write a SOTA and since every medical device is different, the approach and methodology to establish the SOTA will vary.

Stage 2 – Appraisal of pertinent data

The methodology to appraise pertinent data described in the MEDDEV 2.7/1 revision 4 or in the IMRDF technical document mainly applies to clinical data of the DUEs, similar devices, and other devices. This system of appraisal is provided as guidance and can be adapted. As the clinical background is not used to assess the DUEs directly, it may not be extensively appraised. I include in the SOTA all guidelines published by public agencies and medical agencies/associations related to the medical condition since they represent the highest level of clinical evidence. For review articles and epidemiology studies, I try to detect any potential bias (e.g. subjective statements in favour of a treatment) and/or inadequate disclosure of information. It is also important to check the conflict of interests of the authors to ensure that an unbiased clinical background is presented.

Stage 3 – Analysis of pertinent data

Once sources of data have been identified and appraised, the last phase is to prepare a literature review of the SOTA. It is important to report all aspects of the clinical background described in all identified sources. I also try to add as much quantitative data as possible to provide an objective analysis. Moreover, the literature review of the available alternative and historic treatments should reflect all the aspects covered by the sources identified during the previous phases. It is essential to report a quantitative analysis of each clinical outcome reported for benchmark devices. Similar outcomes should be reported in the SOTA and in the section related to the clinical evidence of the DUE so that the safety and performance profiles of the latter can be assessed in the context of the clinical evidence of the benchmark devices. To report the clinical evidence related to benchmark devices, I typically prepare a table using the PICO classification criteria:

- Population(s)/disease(s) or condition(s)
- Intervention(s)
- Comparator group(s)/control(s)
- Outcome(s)/Endpoints(s)

In each column, I summarise only the main information (without overpopulating the table) and give a clear view of the clinical studies related to the benchmark device. It's important to detail all relevant outcomes/endpoints used in each study, and to provide the key results. Ideally, all results should be provided in the same units so they can be better compared between benchmark devices and most importantly with the DUEs. When a result with a different unit is provided, and when possible, I report the result as reported in the study and add a conversion to a more used unit. After the table, a conclusion containing the number and types of studies, as well as the key outcomes/endpoints should be presented. I also highlight in the conclusion the homogeneity among the studies, which helps draw scientifically sound conclusions.

Pros and cons of different databases for literature review

Choosing the right databases to conduct a literature review, including the ones required to establish the SOTA, can be tricky. In this section, I present the advantages and limitations of the

Table 1. Advantages and limitations of different scientific literature databases that can be used to conduct literature search under the EU MDR

Scientific literature database	Advantages	Limitations
Pubmed / MEDLINE	• Contains more than 37 million references • Multiple selection criteria to target the search • Provides options to export results as an Excel file (and other formats) • Search output compatible with reference managers such as EndNote • Free	• May not cover all European journals, especially the ones reporting user experience • Not all articles may have been indexed properly resulting in loss of evidence
Embase	• Contains over 29 million records from 8,500 journals (include MEDLINE database) • Multiple selection criteria to target the search	• Not free
Cochrane CENTRAL	• Contains only high-level-evidence articles including Cochrane systematic reviews, Cochrane protocols, clinical trials, clinical answers, and others • Free	• Limited to Cochrane publications
Google Scholar	• Covers more references than the other databases	• Search output cannot be properly documented • Not officially accepted by notified bodies as the primary database • Search output varies with every search • Not all references are peer-reviewed (trade/white papers, interviews, etc.)

four most commonly used databases in medical writing (Table 1).

In summary, no one database is better than the other, and no database should be used exclusively. Moreover, it is important to justify why the chosen database is the most appropriate choice for the given literature search.

Conclusion

There is no "magic formula" to write a SOTA and since every medical device is different, the approach and methodology to establish the SOTA will vary.

Nevertheless, some key points are common to every SOTA and include having an objective approach, adapting the literature search to the context (type of medical condition, quantity and type of data available, etc.), and justifying the methodology used (choice of database, quality control, inclusion/exclusion criteria, etc.). In-depth knowledge of the MEDDEV 2.7/1 revision 4 guideline is essential to understand all the aspects of the methodology needed to conduct and report a literature review under the EU MDR.

Acknowledgements

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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.

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Biotechnology

SECTION EDITOR

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Editorial

The World Health Organization (WHO) describes One Health as recognising "*that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent.*" Biotechnology has been used for decades to identify different issues. For example, biotechnology is used in GP clinic and veterinary practice tests to profile human and animal health.

One Health has been taught in veterinary schools for centuries. The WHO and other organisations have established global One Health activity. The health of the environment directly influences human and animal health. In an ideal world, everybody and everything would be in the finest picture of health, but that is not the case.

I learned about Rachel Carson's book called *Silent Spring* in the early noughties (c. 2000–2003). *Silent Spring* was published in 1962 and influenced the modern environmental movement. The Oscar-winning movie *Erin Brockovich*, based on the activism of a woman by the same name, was released in 2000.

Erin Brockovich helped build a case in 1993 concerning groundwater contamination that detrimentally affected the health of over 1000 people. The movie remains topical and related to my article below. Eutrophication (you-tro-fik-ay-shun) is one place where One Health issues meet. If you watch the movie, look at the ponds. The ponds are green, so are they eutrophic, or is something else going on?

To repeat, it is important to highlight that the health of the environment has an impact on the health of humans and animals. Because the environment's health directly affects human and animal health, medical writers intuitively know various documents that can raise awareness and help propel the environmental movement forward to improve global health.

Jen Bell

Eutrophication of fresh and marine waterways: Can medical writers, biotechnologists, and others help solve this problem?

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I was chatting with a few people recently when one of them mentioned how they went swimming in natural freshwater, and while they noticed a higher amount of blue-green algae in the water, they went swimming anyway. They said they felt "under the weather" as a result of their swim.[1] The conversations I had made me think of One Health and inspired me to write this article.

One Health concerns human, animal, and environmental health threat interfaces and I think algal blooms (indicating eutrophication) are a good example of where these health threat interfaces meet. Eutrophication can occur as a result of human activity, and it can occur naturally. So, more than identifying eutrophication alone is necessary to know if there is pollution from human activity in surrounding areas.

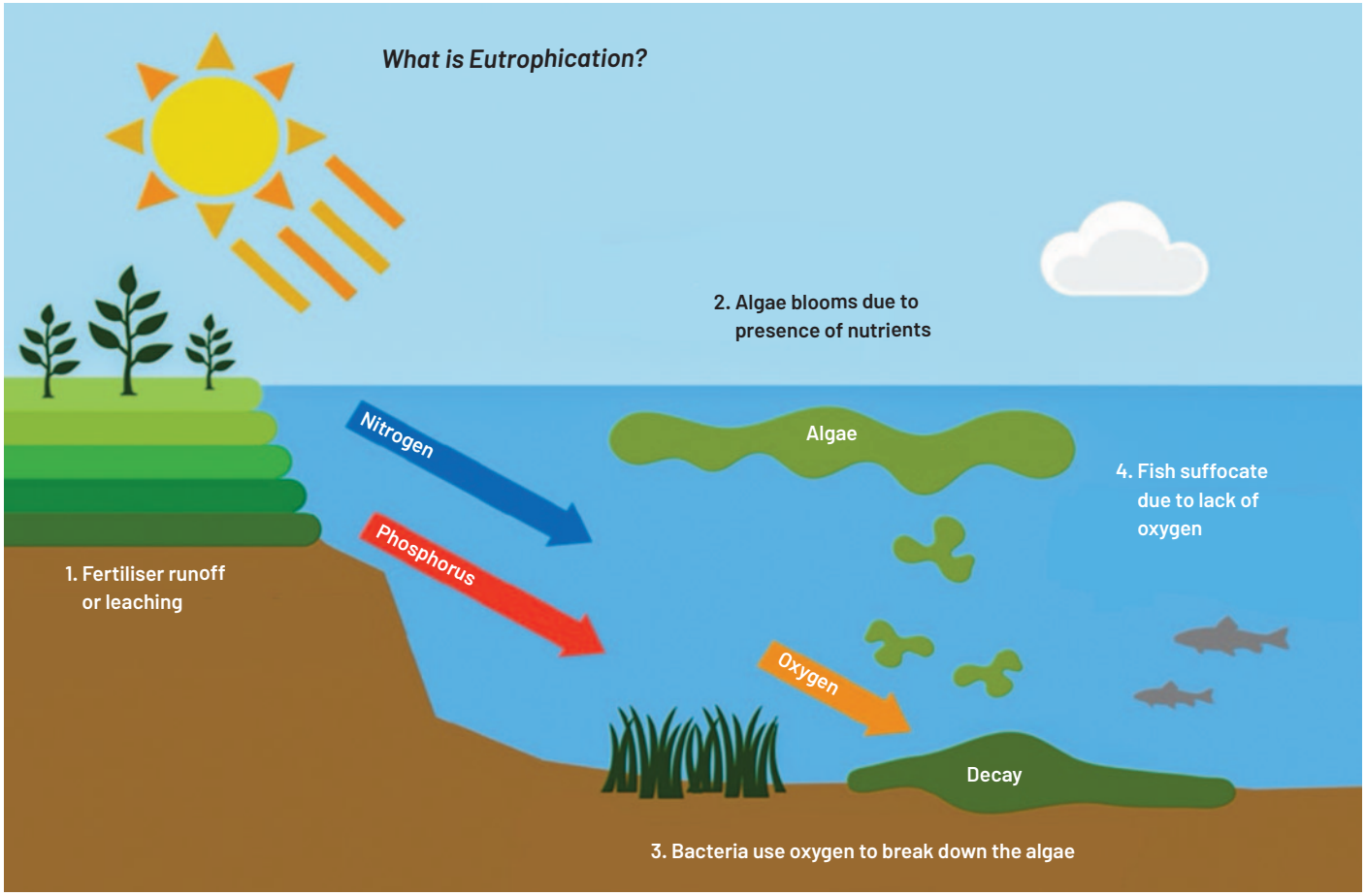
More than identifying eutrophication alone is needed to know if there is pollution from human activity in surrounding areas.

As medical writers, we can find many ways to do this type of research through our work.

Writing opportunities include:

- Environmental protection agency work
- Grant application work in agriculture, fisheries, food, or conservation
- Regulatory affairs work in agriculture, fisheries, food, or conservation

There are undoubtedly more writing opportunities for medical writers to pivot and transfer their skills.[2–4] One Health concerns human-animal-environment interface health threats, so it falls under the banner of medical writing.[5] As the Organisation for Economic Cooperation and Development's (OECD) Jim Philp wrote in his article for *Medical Writing* in 2023,[5] "*A clear role for medical writers will be to delineate change to regulatory systems necessitated by technologies …*" and this applies to most One Health issues. You need to roll your sleeves up and see what you can do to help.



iStock.com/Dimitrios Karamitros

Figure 1. A schematic image that helps understand what causes eutrophication.[9]

Why might blue-green algae make someone feel ill?

Returning to the topic of blue-green algae, they are also known as cyanobacteria – algae or bacteria, which? Cyanobacteria were once called blue-green algae by microbiologists; however, "blue-green algae" is the term probably more commonly used by non-microbiologists. Blue-green algae are photosynthetic microscopic organisms that are technically bacteria (cyanobacteria).[2]

Environmental protection agencies use biotechnology (molecular, biochemical, and analytical techniques) to identify the presence of cyanotoxins in waterways.[7] Cyanobacteria can produce cyanotoxins, which might cause liver, nervous system, gut, or skin reactions, and disturbances to any of these might make someone feel ill.[6–8] Please note that boiling water will not stop toxic poisoning, so don't boil "*polluted*" water thinking you can safely drink it.[6]

Boiling water will not stop toxic poisoning, so don't boil "*polluted*" water thinking you can safely drink it.

High proportions of blue-green algal blooms can signify eutrophication (Figure 1). Algal blooms occur when there are high amounts of nutrients in waterways. Eutrophication reduces sunlight penetration, so it decreases the rate of photosynthesis by submerged aquatic plants. The death and decomposition of algae lowers dissolved oxygen levels, which in turn causes the death of other aquatic species. As decomposition occurs, nutrients are released, which increase algal blooms and reduce sunlight penetration, so the cycle continues.

The human I spoke to put feeling ill down to swimming in blue-green algae in a freshwater environment, which likely contains animals like fish. Fish are a food source for humans and various animals, like other fish, birds, and mammals (humans are mammals and there is a discussion there for another time). Eutrophication often results in reduced oxygen in water, which might cause fish and other species to die. The chemicals that break down from dead fish and other species feed plants and microorganisms. Fish, birds, mammals, and plants inhabit the water, air, and land and end up as a food source for whatever eats them, so "*poisons*" biomagnify. Biomagnification is, "the *process by which a compound (such as a pollutant or pesticide) increases its concentration in the tissues of organisms as it travels up the food chain.*"[10] Everything is connected, and if one part of something is ill, another part is likely sick too.

It is important to know that only a few algal blooms result in toxins – all algal blooms do not produce toxins.[11]

Eutrophication causes are natural as well as from human activity, and biotechnology might help correct it

There are human causes and natural causes of eutrophication.[12] Human causes include agricultural runoff, industrial runoff, residential runoff, and recreational activities.[12] Natural causes include biogeochemical cycles, sedimentation dynamics, groundwater seepage, and

natural runoffs.[12]

Paul *et al.* (2022)[12] write in their review of literature that, "*At a global scale, recent biomanipulation research has a skewed distribution in Europe (41.10%), East Asia (32.88%), North America (10.96%), South Africa (4.11%), South America (2.74%), Middle East (1.37%), Oceania (1.37%), and non-specific regions (5.48%).*" They say they, "*revealed the comprehensiveness of eco-bioengineering methods and their strong ecological resilience to recurrence of eutrophication and fluctuating environmental flows in the future.*" They believe their review, "*reinforces the supremacy of eco-bioengineering methods as cost-effective green technologies providing sustainable solutions to restore the eutrophic waters at a global scale.*" Biomanipulation and bioengineering are forms of biotechnology.

Farmers are knowledgeable business owners who make a living from the environment

I am writing about farmers because they are One Health custodians who have not always realised it.[13–16] I also think governments have designated farmers as One Health custodians without necessarily realising it.

Some farmers learn their trade from the generations who passed it on, while others complete university degrees to set up their businesses. Farmers have a variety of backgrounds. To manage their businesses (and way of life), farmers know about the seasons, the land, animal and plant behaviour, regional agricultural laws and available funding, and various technological advances, for example, gene pool technology.[17] Undoubtedly, farmers know more about what they do than me.

To explain my gene pool example, a large gene pool has lots of diversity, and a small gene pool has less diversity. The greater the diversity, the better a gene pool can withstand environmental change. Farmers are required to follow gene pool/germinal product legislation because of the various technologies they use.[18] Gene pools relate to crops (plants), animals, and humans.[19] Gene pools do not necessarily concern genetically modified organisms (GMOs). Monitoring a gene pool helps prevent various conditions and diseases that can be inbred. Farming is more concerned with the genetic diversity of an animal or plant. However, the same applies to an ecosystem – the greater the genetic diversity (the more species), the better an ecosystem can withstand environmental change.[20]

In addition, some farmers might become involved in **ph**arming (note the "ph" in "pharming" instead of an "f"). Pharming concerns growing (often genetically engineered) crops and animals for pharmaceutical industry therapeutic products that treat various illnesses.[21–23] And many medical writers provide writing services to the pharmaceutical industry.

Figure 2. If I knew the river might be polluted, I might not have conducted my morning ablutions in it. I brushed my teeth in it. I was in secondary school and had yet to learn about waterway pollution.

Don't bite the hand that feeds.

Farmers and other food producers might hold keys that help solve eutrophication

Ways to divert algal blooms need to be realistic, and good people to speak to about this feasibility are farmers and other food producers. Farmers need to find a "*sweet spot*" of feasibility to earn enough to live and continue what they do. Without farmers, our supermarket shelves would be empty, and over the last few decades, the world has lost farmers because their way of life has become more difficult. A world without farmers would be horrible. Farmers made and continue to make a considerable contribution to building civilisations, and without them, I think civilisations will disappear. The Irish UNESCO World Heritage Site of Brú Na Bóinne (Brew Nah Boyn-ya.) identified that the first farmers settled in the Boyne Valley from about 4000 BC. Don't bite the hand that feeds.

At the same time, farmers are under lots of pressure because, as the European Commission points out,[24] "*World population growth, hunger, obesity and evolving consumer demands put pressure on agricultural production to improve food and nutrition security globally. Simultaneously, farming and food systems must be resilient against the challenges of finite resources, environmental degradation, climate change and the loss of biodiversity.*

Farmers are assigned so much with very little recognition or compensation for what they do. Ironically, farmers struggle to feed themselves and their families, never mind feeding the world.[25, 26] I don't blame farmers for disrupting urban centres of power to ensure they are heard and get their needs met. Farmers worldwide are in a similar situation and are supporting each other.[27–29] And while spraying manure and muck at government buildings shows distaste for the way governments treat farmers, spraying muck is a good symbol for various governments to realistically help farmers and others tackle causes of eutrophication and feed the world at the same time.

Eutrophication causes are not just from farming practices though. A significant factor of eutrophication is excessive nutrient loading. To repeat, human causes include agricultural runoff, aquaculture and concentrated feeding operations, industrial runoff, residential runoff, and recreational activities.[12,30,31] Natural causes include biogeochemical cycles, sedimentation dynamics, groundwater seepage, and natural runoffs.[12, 27, 28]

Final remarks

Regular people enjoy interacting with the environment without necessarily knowing what

dangers might lurk in it (Figure 2). Interacting with the environment is very normal and good for mental health, and in some cultures, it is part of their way of life. Governments protect all people and uphold human rights by protecting the environment. Farmers are good people to talk to about protecting the environment because they make a living from it, at least they try to. However, farmers are not the only people to talk to.

Farmers are invested in replenishing the environment so their land provides them a living year after year to be able to feed themselves, their families, and their communities – they are One Health custodians. Helping farmers improve their living standards will probably improve some environmental issues, including eutrophication. And reducing eutrophication will reduce the risks of people feeling ill after outdoor swimming – a popular practice that shouldn't end.[32]

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The author would like to thank her interlocutors (a big word I had to look up) for inspiring this article.

The author would also like to thank Colin Pillinger for giving a talk on his Mars experience.[33, 34] He was a man with a dairy farm who once worked for NASA and started a Mars lander project in a pub on the back of a beer mat. The lander got to Mars – it just didn't do what was expected of it when it got there.

Disclaimers

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

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Jen Bell went to agricultural college when she left school and continued her life science education a few years after that. She worked in pharmaceutical and medical device manufacturing and distribution quality management roles from 2010 to 2018. She is interested in One Health concerning threats in the animal-human-environment interface. Jen is passionate about the potential for biotechnology to improve lives. Today, she is a freelance biotechnology consultant and medical writer.

Medical Communications and Writing for Patients

Dear all,

I've been told that you know you're getting old when time speeds up. This year has been terrifying in that regard and I feel that January was a heartbeat ago!

Due to my clearly (rapidly!) advancing age, I have become more diligent about vaccinations for COVID and the flu. Therefore, I was fascinated by the retrospective article I'm delighted to share with you today from Yannick Borkens. Yannick explains that although effective vaccines were available in record time during the COVID pandemic, they were not universally accepted, leading to many unnecessary deaths. This unwillingness to be vaccinated led to some countries becoming creative about how to convince people to take the vaccines. Some of these creative ideas are mentioned in this article, and will certainly give you food for thought!

As 2024 draws to a close, I hope that it has been a good year for you all, and that you and your loved ones remain healthy and happy. Enjoy the upcoming Christmas break – may you dodge the snowballs, and may Santa be kind.

See you in 2025!

Bestest,
Lisa

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Encouraging vaccination through clever and abstruse incentives

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Abstract
The COVID-19 pandemic kept the world on tenterhooks for several years beginning in 2019. Well over 7 million people had died worldwide by 2023. Although the WHO ended the health emergency in 2023, the dangers of COVID-19 and future pandemics remain. Thanks to modern science, effective vaccines against COVID-19 were available and ready for use in record time. However, the willingness to vaccinate was limited. For this reason, some countries came up with various and sometimes abstruse ideas to increase the willingness of their population to be vaccinated during this difficult time and to get people excited about vaccination. Some of these ideas are presented in this article.

Introduction

In late 2019, a new, unknown form of pneumonia emerged in China. A novel coronavirus was quickly identified as the cause – 2019-nCov.[1] The origin of this coronavirus was, and still is, controversial. For example, the night markets of Wuhan, China, are seen as the source, where the virus is thought to have jumped from its animal host to humans.[2] Quickly, the new coronavirus, classified as SARS-CoV-2, spread across the planet. The COVID-19 pandemic has been called the worst environmental disaster of the 21st century.[3] More than 7 million people had died from COVID-19 worldwide by 2023. However, thanks to modern science, there was an early response to the threat. New vaccines against COVID-19 were developed in record time. These included, for the first time, so-called mRNA vaccines. But not everyone reacted positively to these developments. Many countries struggled with low vaccination uptake, especially at the beginning of the vaccination campaigns. To get people to vaccinate, different countries developed different strategies, mostly based on various premiums and gifts.

Vaccines against SARS-CoV-2

Many different vaccines against SARS-CoV-2 are now available. These are protein-, vector-, and mRNA-based. Especially the mRNA vaccines are interesting. After all, these are the first approvals of these vaccines ever. The two mRNA vaccines that are being used are Comirnaty® from BioNTech and Pfizer, as well as Spikevax® from Moderna. Both have similar mechanisms of action: During vaccination, the mRNA of a surface protein is introduced into the cell. In this way the mRNA is translated and the resulting protein, a spike protein, is presented to the immune system.[4] Figure 1 schematically shows the methodology behind mRNA vaccination. Besides these mRNA vaccines, the vaccine Vaxzevria® is probably the best known in my native Germany. Vaxzevria® is a vector vaccine consisting of "envelopes" of harmless adenoviruses. Vaxzevria®, also known as ChAdOx1, was developed by the Swedish company AstraZeneca and the British University of Oxford. However, due to various problems, for example IgG titers that were too low or also unexplained side effects, the vaccine was unable to hold its own against its mRNA competitors.[5,6]

Unfortunately, conspiracy theories and fake news become an elementary part of the pandemic. As an emotional topic, vaccination plays an important role in these conspiracy theories and medical as well as scientific fake news, especially about the mRNA vaccines, remains commonplace. For example, many people have been critical of the speed of development.[7] These

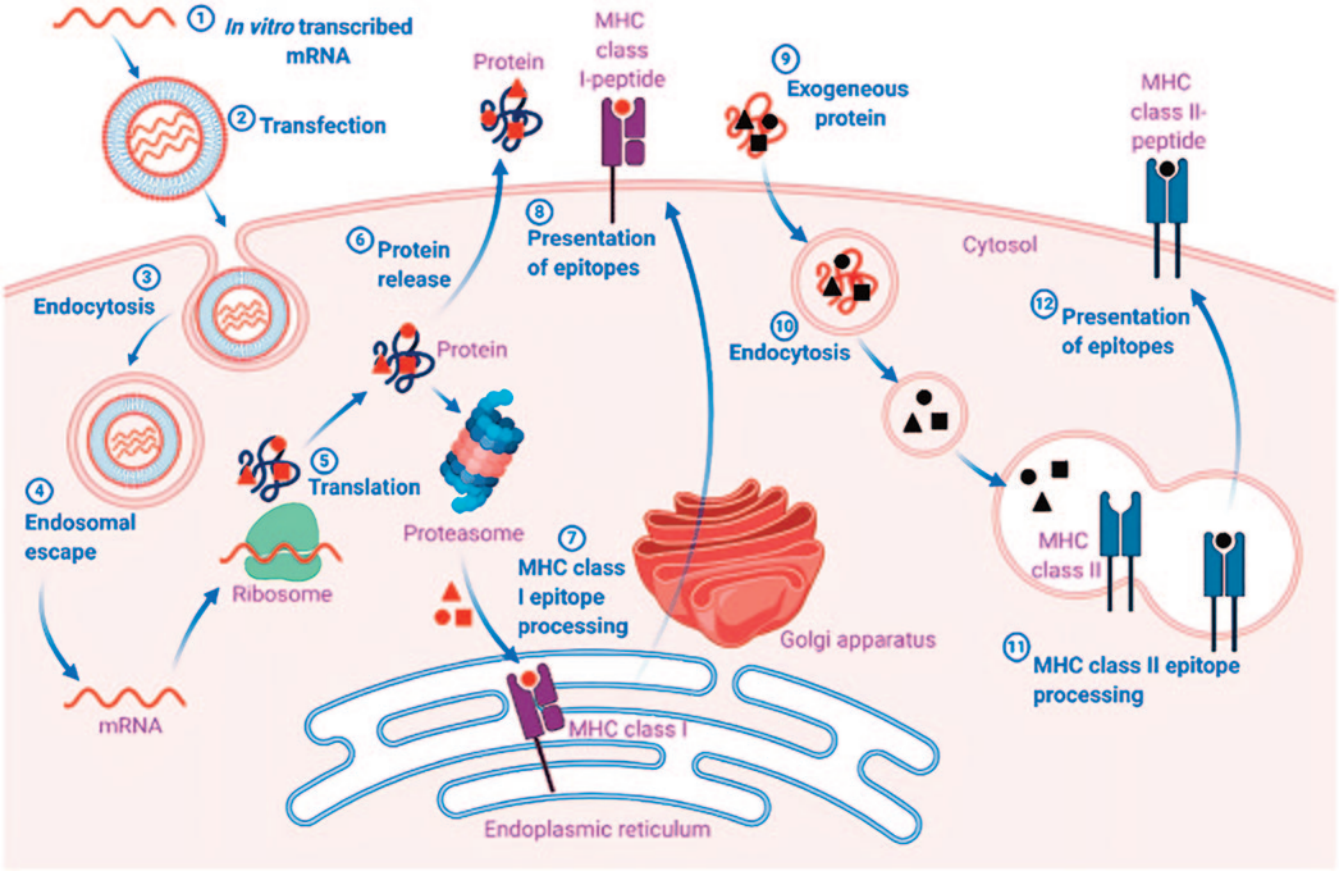

Figure 1. The schematic shows the principle of action of mRNA vaccines.

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conspiracy theories not only influenced vaccination readiness. The tone became harsher and well-known figures such as the Federal Health Minister of Germany Prof. Karl Lauterbach or Prof. Christian Drosten, Head of Virology at the Charité in Berlin, increasingly faced insults and threats. But also, physicians in private practice who offer COVID-19 vaccinations in their practices continue to be threatened by conspiracy theorists.[8]

At the beginning of the pandemic, this also affected the willingness of the population to be vaccinated against COVID-19. Experts were and still are certain that an end to any pandemic is only possible with good vaccination coverage and a high level of herd protection. COVID-19 is just one example. (The eradication of smallpox in the late 1970s can also be cited here.)[9] However, this rate was not reached by many countries for a long time with COVID-19. In some cases, it is still too low today. For this reason, some countries developed various measuresin the early stages of the pandemic to increase the vaccination rate within the population. These measures often included gifts, such as tickets to events, or simply money. Some authorities developed very abstruse ideas and incentives. Some of these abstruse ideas are described in this article. Readers will learn not only what the US did to increase its vaccination rate, but also about countries in which living animals were given as gifts for vaccination.

Table 1. Different vaccination rates of countries mentioned in this article. As of March 13, 2023.[15]

	First Vaccination		Fully Vaccinated	
Austria	7,143,825	(78%)	7,052,237.5	(77%)
Bangladesh	160,053,000	(93%)	144,564,000	(84%)
Germany	66,042,074.28	(78%)	64,348,687.76	(76%)
Indonesia	208,125,000	(75%)	177,600,000	(64%)
Thailand	58,794,000	(82%)	55,209,000	(77%)
United States of America	267,931,916	(80%)	227,742,128.6	(68%)
World	5,904,000,000	(72%)	5,494,000,000	(67%)

Vaccines incentives

Education, joints, and millions in profits in the US

If you followed the news in mid-2021, you got the impression that the US would be a leader in offering premiums for COVID-19 vaccination. In fact, the country developed several policies to increase vaccination readiness. For example, several states created a vaccination lottery in which people could participate. The prerequisite: vaccination against SARS-CoV-2. In Ohio in 2021, a woman won $1 million through the lottery. But money was not always raffled off. Many states, for example New York, also raffled off scholarships and thus entire courses of study at universities. (The US has relatively high tuition fees by comparison with other countries. Consequently, these measures were very popular).

Figure 2. In Neustadt am Rübenberge, Lower Saxony, vaccinations were advertised with free bratwursts.

Dominic Herbst, member of Bündnis 90/Die Grünen and mayor of the town, personally stood at the grill and handed the coveted food to those willing to be vaccinated. Photo: Moritz Frankenberg/dpa.

Other incentives, however, went in a completely different direction. For example, the state of Washington, where recreational use of marijuana has been legal since 2012, came up with the idea of rewarding people with joints in a programme called *Joints for Jabs*. All people who were vaccinated by July 12, 2021, and were over 21, were eligible. Before then, inoculated people in Washington were already allowed to help themselves to free drinks at brewpubs, wineries, and restaurants. The state of New Jersey also enticed people with free beer.

The US is also known for its sports culture. Major events such as the Super Bowl are not only relevant advertising platforms, but also enjoy great popularity outside the US. It is therefore not surprising that such events also played a major role in vaccination premiums. On the one hand, free tickets were raffled off. However, there were also offers directly at the stadiums. People who wanted to get vaccinated at the stadiums were allowed to attend the event for free. Among the providers were Major League Baseball, the National Basketball Association, the National Hockey League, and race car league NASCAR.

Bratwurst in Germany

In Germany, the *Impfbratwurst* (vaccination bratwurst) gained some notoriety, not least among contrarians and other opponents of vaccination. The latter continue to make fun of this measure on the internet. In fact, some German cities launched campaigns handing out free bratwurst to vaccinated people. Among the cities that distributed bratwursts were Dresden, Neustadt am Rübenberge, Wattenscheid, Augsburg, and Hannover. Originally, the idea came from the southern Thuringian town of Sonneberg. The Thuringian Bratwurst is considered a national dish and is also known beyond the state's borders. In some cases, customers were also served by prominent politicians, for example, in Neustadt am Rübenberge. Here, the mayor, Dominic Herbst, served customers personally (see Figure 2). But Germany did not only advertise with food.

As in the US, sporting events were used for inoculation. As the national sport, soccer played a crucial role here. The Hannoversche Sportverein von 1896 e.V., better known as Hannover 96, gave out 1000 free tickets to people who got vaccinated. The FC Carl Zeiss Jena also promoted vaccinations. In addition, vaccination buses and mobile teams were positioned at stadiums. One company in Jena had a different idea. To get its employees to vaccinate, it offered a vaccination bonus of up to 5,000 euros. The entrepreneur told the Kreiszeitung that the total cost (vaccination of all 550 employees) would amount to €2.7 million.

When looking at incentives in Germany, the impression is that culture and custom play an important role in many incentives. This was also evident in Bochum. There, vaccinations were held at the Christmas market in the winter of 2021. The rush was so great that not all those willing to be vaccinated could be accommodated. The Munich television station Pro Sieben considered another action. On November 24, 2021, a team vaccinated people as part of the programme *Zervakis & Opdenhövel. Live.* in front of the cameras. The action took place between 7 pm and 11 pm on the Pro-Sieben-Sat.1 premises in Unterföhring, in the district of Munich. Other incentives consisted, for example, of driving services with luxury cars that took people to get vaccinated. A hotel in Hamburg tried to increase the vaccination rate in this way.

Did the incentives work? As of April 8, 2023, 62.2% of the German population was fully vaccinated. On April 8, 2023, the *Bundesgesundheitsministerium* (German's Federal Ministry of Health) stopped recording vaccination rates. While the rate of the first vaccinated, i.e., those who received their first vaccination, was higher in the US, the rate of the fully vaccinated was higher in Germany as of DATE. This is only 67.2% in the US. Table 1 provides more information about different vaccination rates across countries.

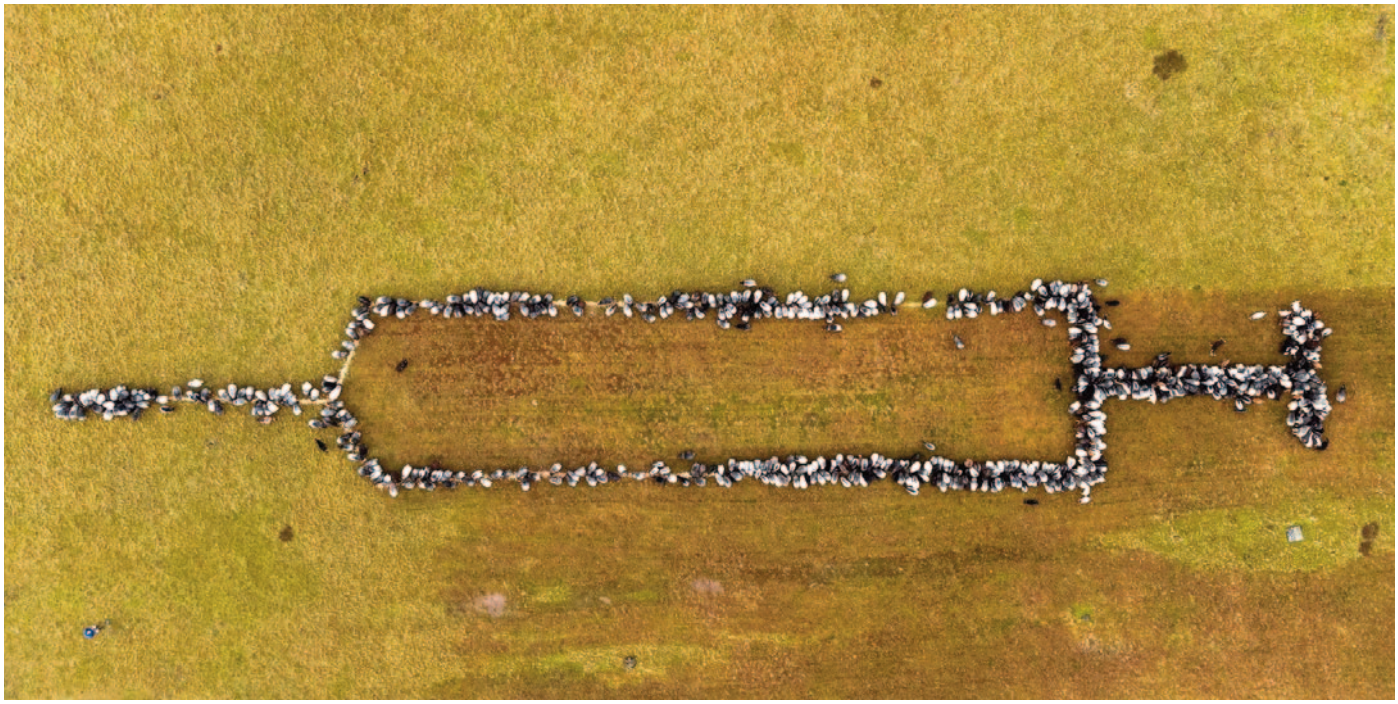

Figure 3. In Lower Saxony, shepherds arranged their sheep and goats into a giant syringe

Around 700 animals were involved in the action. Photo: Philipp Schulze/alliance/dpa.

Chickens, goats, and a cow – Where there are live animals for vaccination

In Lower Saxony, shepherds had a particularly funny idea. To promote vaccination, they had their sheep and goats form a giant syringe. About 700 animals were involved in the action. In the end, the syringe was 100 metres tall. The initiator of the action was the shepherd Hanspeter Etzold, who wanted to make his contribution to the fight against the pandemic in this way. The finished syringe is shown in Figure 3. In other countries, animals played an even more important role in increasing vaccination preparedness. While countries in the West advertised with cash incentives and the like, Asian countries distributed live animals. On Java, one of Indonesia's largest island with a population of 141 million, animals were given away to vaccinated people. Among other things, chickens and goats were raffled off. Thailand also used animals to promote vaccination. In the rural district of Mae Chaem, which is located in the west of Chiang Mai province (northwest Thailand), cows were often auctioned off in exchange for vaccination during the pandemic. Every week, a cow was raffled off among those who had been vaccinated. With a value of the equivalent of $261 ($1 equals about 34 Baht), this was a huge motivator. $261 is a lot of money in Thailand, especially during the pandemic, when tourism to Thailand was greatly reduced.

SEX SELLS – Even in a pandemic

The phrase "Sex Sells" originally comes from the advertising industry. The aim of this method is to achieve emotional arousal through sexual stimuli – for example, scantily clad women. As early as 1871, the Pearl Tobacco company advertised its goods with partially unclothed women. Even today, advertising with sexual stimuli plays an important role within the advertising industry. However, the general validity of the effectiveness of Sex Sells is empirically doubtful. Recent work in particular raises strong doubts.[10,11]

However, despite these doubts, some resorted to this concept regarding Covid inoculation. A brothel in Vienna made headlines in late 2021 when it set up a vaccination centre on its premises. Interested parties could not only get vaccinated there, but also received a brothel voucher for €40. Other brothels adopted the idea. In early 2022, for example, establishments on the famous Herbertstraße in Hamburg's Kiez district offered a so-called *Love Booster*. Almost 120 vaccine doses were successfully delivered in the process. The action in Hamburg is part of the *Sexy Aufstand Reeperbahn* art project. The aim of the project is to make the work as well as the hygiene standards of prostitutes and sex workers in Germany visible. Like other industries, brothels and independent sex workers suffered from economic losses, especially at the beginning of the pandemic. In the *Sexy Aufstand Reeperbahn* campaign, brothels collaborated with various artists, IG St. Pauli und Hafenmeile e.V., and the Corona Test Center on St. Pauli. Demonstrations by prostitutes and sex workers in Germany took place under the slogan #sexyaufstandreeprebahn. The protests were accompanied by various art actions and vaccination campaigns.

Countries outside of Europe also adopted this concept. One example was the largest brothel in Bangladesh, located in Daulatdia in the west of the country, employing 1900 prostitutes. The aim of the campaign was also to increase the vaccination rate among prostitutes, who were particularly at risk. (Bangladesh is one of the few Muslim countries where prostitution is legal.)

A slightly different (dis)incentive: paying for vaccination

Cash incentives have already been described in this article. However, there were also the considerations to make COVID-19 health measures (vaccinations and COVID-19 tests in particular) chargeable.

First, regarding tests, the idea was that people who had not been vaccinated against SARS-CoV-2 should pay for these tests independently and should not receive them for free (paid by the health authorities). For those who had been vaccinated, on the other hand, the tests should be free. These considerations were discussed by some authors in different publications. They

assumed that people would be more willing to receive a vaccination if that could save them from spending money for the tests. In this way, the authors of the associated studies hoped for an increased vaccination rate as well as an increased acceptance of vaccinations in general. However, it must be noted that the transfer of costs from the general public to the individual hits poorer people particularly hard. It can be assumed that such measures tend to reduce, rather than improve, acceptance of vaccinations among such people. Studies showed, that people with a higher income are more willing to pay for testing than those with lower incomes. Willing to pay is higher among men than women. The level of empathy also plays a role in the decision. Interestingly, willing to pay for tests is higher among people who show high levels of empathy than among people with lower levels.[12]

In addition to the idea of paid tests, there was, of course, the push to charge for vaccination itself. These included models where high-income individuals paid independently while low-income individuals got vaccinated for free. Willingness to pay for vaccine doses is closely related to income and education level. People with high income and high education level show higher willingness than people with lower income and educational level. Having already undergone COVID-19 infection also has an impact on willingness to pay.[13]

The general push to charge for vaccines received much criticism in the scientific community. Unlike the examples described in this paper, which were rewards, paid vaccinations and paid tests, functioned more as punishment. This decreased the willingness to vaccinate. For these reasons, paid-for vaccination services are counterproductive.

Conclusion

Medicine itself has always been an emotional topic. This, of course, also includes vaccinations. Even with the very first vaccination (invented for smallpox in 1796) there were opponents of it. The arguments of these first vaccination opponents were very similar to today´s arguments, for example, that having the disease provides more robust immunological protection. Vaccination opponents, as well as the general distrust of vaccinations, have become an increasing problem in our society. An important factor for successful vaccines, as well as vaccination campaigns, is trust. For this reason, vaccination incentives such as the one described in this article are also viewed critically by quite a few. The overarching discussion is not only about possible rewards for vaccination, but also about the introduction of compulsory vaccination or the return of certain freedoms such as restaurant or cinemas visits to vaccinated persons. It was precisely these so-called vaccination privileges and the discussion around them that played a role in the political discourse during the initial phase of the vaccination campaigns. Even if the topic in this article and the mentioned rewards amuse, the factor of loss of trust should not be disregarded. In the future, we should consider whether these rewards are the right form of incentive, or whether comprehensive education in the field of medicine and vaccines is not a better alternative. On the other hand, however, it is also questionable how far education goes and how receptive people are to it. The debate about vaccinations and vaccines will likely continue through coming pandemics.

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The author declares no conflicts of interest.

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Medical Writing in
PORTUGUESE

English to Portuguese translation: Know your audience!

Portuguese is a globally spoken language, serving as the official language in several countries including Portugal, Brazil, Angola, Mozambique, Cape Verde, Guinea-Bissau, São Tomé and Príncipe, and East Timor. This geographical spread emphasises the importance of Portuguese in disseminating medical information and the need for accurate, culturally sensitive translations. However, each Portuguese-speaking country has its own language variant with significant differences, making it crucial to identify the target audience's locale to ensure translations align with local practices.

Below are some examples of the many challenges I face when translating into Portuguese (Portugal variant):

Register and terminology: Translators must switch between formal and informal registers depending on the target audience, ensuring that materials like patient instructions are clear and clinical reports are precise. Classic examples of this can be found in the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of a medicinal product, where you have the exact same English term (e.g, "headache") in both documents, but different Portuguese equivalents (*cefaleia* in the SmPC and *dor de cabeça* in the PIL).

Gendered language: Portuguese, like many languages, assigns gender to nouns, pronouns, and adjectives, challenging translators to use inclusive language while maintaining grammatical correctness. Unfortunately, there are still no formal and generally accepted guidelines and recommendations for inclusive language which would help standardise practices for inclusive communication. Translators must balance grammatical correctness with inclusivity, often requiring creative solutions such as replacing gender-specific nouns with gender-neutral alternatives where possible, and rewriting sentences to avoid gendered language.

False cognates: Words that look similar in English and Portuguese but have different meanings require careful translation to avoid errors. For example: "infusion" (English for "administration method") vs. *infusão* (Portuguese for "tea/ herbal drink") – where the correct translation for "infusion" is *perfusão.*

Language-specific reference sources: Most online medical content is in Brazilian Portuguese, which can complicate the fact-checking process for other variants. Using the example of "infusion" above, while *infusão* is the correct term in Brazilian Portuguese, *perfusão* is the appropriate term in Portugal. Another example of this is "randomised," where the correct term in European Portuguese is *aleatorizado,* but Brazilian Portuguese remains closer to its English counterpart (*randomizado*).

Inconsistent terminology: Even authoritative sources in Portuguese can sometimes use inconsistent terminology. This can stem from excessive use of Anglicisms in the industry, misuse of terminology from other variants, evolving medical knowledge, differences between academic and clinical usage, and a lack of expert writing/translation professionals in content development. Translators must navigate these inconsistencies and often need to make judgment calls on which term to use based on the context and target audience.

Designation of health professions: Healthcare systems and professional titles vary, so translators need to find appropriate equivalents in Portuguese-speaking countries. For example, the role of "Nurse Practitioner" in English-speaking countries often includes responsibilities that are performed by doctors in Portuguese-speaking countries, and their level of autonomy and scope of practice can vary significantly.

Legal and regulatory requirements: While there are international regulations, each country has its own set of requirements and legislation governing clinical research and care provision. Translators must be familiar with both global guidelines and national regulations, ensuring translations comply with local standards.

The challenges I have shared here are to some extent, common to medical translation in general, regardless of the source and target languages. My hope is that it helps clarify why translation is never merely about transferring words from one language to another.

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Regulatory Matters

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Editorial

Gene therapy is a groundbreaking and fast-growing area in pharmaceutical advancement, providing promising treatments that potentially cure genetic disorders by directly altering the genes within a patient's cells. With increasing knowledge in the nature of genetic disorders and the help of advances in genetic engineering and biotechnology, gene therapy has evolved rapidly. Its path to clinical application is complex, often involving significant technical challenges and ethical considerations. Due to this complexity, regulatory guidance and frameworks are crucial in governing the design, testing, and application of gene therapy in human trials, ensuring that these therapies are safe and effective before making them available in the clinical setting.

In this article, by emphasising the rigorous regulatory frameworks that govern this area, Arunon Sivananthan offers an overview of the emergence of gene therapies, detailing the guidance provided by the US FDA and EMA and some stringent measures required to ensure the safety and efficacy of gene therapy products. I hope readers will gain value.

Zuo Yen Lee

Navigating the regulatory landscape of gene therapy

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Introduction

Gene therapy is at the forefront of the pharmaceutical industry, offering the potential to treat and even cure various genetic disorders. By modifying genes within a person's cells, gene therapy targets the underlying causes of disease by either replacing faulty genes, deactivating malfunctioning ones, or introducing new genes to fight illness. This groundbreaking approach promises to transform treatment for conditions once considered incurable.

The first gene therapy approved in Europe was Glybera (alipogene tiparvovec), approved by the European Commission in 2012 to treat lipoprotein lipase deficiency, a rare disorder causing pancreatitis and other complications due to impaired fat breakdown.[1,2] Despite its pioneering nature, Glybera was not approved in the US, highlighting the varied regulatory requirements across regions.[3,4]

Following Glybera, other gene therapies have gained regulatory approval. Examples include Kymriah (tisagenlecleucel) and Yescarta (axicabtagene ciloleucel), chimeric antigen receptor (CAR)-T cell therapies that were approved in 2017 for certain blood cancers.[1,2,5] These therapies demonstrate the growing scope of gene-editing technologies in medicine.

Regulatory frameworks are essential for safeguarding the safety and efficacy of gene therapies. Regulatory authorities like the US FDA and EMA rigorously assess the risks and benefits of these therapies.[6,7] This includes assessments of nonclinical testing in laboratories and animals, phased clinical trials to evaluate safety and efficacy in humans, and post-marketing surveillance to track long-term outcomes. These steps help protect patients from risks like unintended genetic changes or long-term adverse effects, ensuring gene therapies meet stringent quality and safety standards.[8]

Collaboration between regulatory authorities highlights the benefits of harmonised processes in speeding up approvals of new therapies while maintaining strict safety standards.

Collaboration between regulatory authorities highlights the benefits of harmonised processes in speeding up approvals of new therapies while maintaining strict safety standards.

Key aspects of this collaboration include:

- Parallel Scientific Advice programme from the US FDA and EMA, providing consistent guidance in new medicine development;[9]
- Coordinated approval timelines, reflecting joint efforts in review and approval of new medicine;[10]
- Joint inspections of manufacturing facilities to ensure compliance with both US and EU regulations;[10,11]
- Shared pharmacovigilance data for safety and efficacy monitoring across regions, for example for COVID-19 vaccines during the pandemic.[12]

As the landscape of gene-editing technologies continues to evolve, ongoing dialogue and cooperation between regulators, researchers, and industry stake- holders will be critical in overcoming challenges and unlocking the full potential of gene therapies for patients worldwide.

Overview of US FDA and EMA gene therapy guidance

US FDA gene therapy guidance

The US FDA's guidance on human gene therapy emphasises a structured approach to nonclinical testing, manufacturing, and clinical trial design.[13,14]

In terms of nonclinical recommendations, the US FDA stresses the importance of conducting robust studies to evaluate the safety and potential efficacy of gene therapies. These studies include both in vitro and in vivo experiments using appropriate models to assess biodistribution, persistence, and potential toxicity. Such research helps predict how the gene therapy product will behave in the human body and identify any safety concerns before clinical trials commence.

Regarding manufacturing recommendations, the US FDA underscores a thorough characterisation of the gene therapy product, including vector design, production, and purification processes. The US FDA provides specific requirements for the Chemistry, Manufacturing, and Control (CMC) sections in Investigational New Drug (IND) applications for gene therapies.[6] These requirements include detailed descriptions of the gene therapy product's composition, manufacturing process, quality control measures, and stability data. Manufacturers must demonstrate control over critical manufacturing steps to ensure the identity, quality, purity, and potency of the product throughout its shelf life. Also, manufacturers must demonstrate rigorous testing and documentation of raw materials and starting materials to prevent contamination and ensure consistency. Stringent control of materials is emphasised to safeguard the quality of the gene therapy product.

As for all clinical trials, a clinical trial design for gene therapies should include an appropriate patient population, well-evidenced treatment and dosing regime, appropriate safety and efficacy endpoints, as well as efficient on-trial and long-term safety monitoring.[14,15] Specifically, the unique challenges posed by rare diseases, such as small patient populations, require carefully designed clinical trials. The US FDA suggests using adaptive trial designs and incorporating natural history data to support efficacy assessments.[13] Adaptive trials allow for modifications based on interim data without compromising the trial's integrity, and clear criteria for patient selection and monitoring are crucial to accurately assess the therapy's safety and efficacy.

EMA gene therapy guidance

The EMA's quality guidelines outline detailed requirements for controlling the vector, transgene, and final product, focusing on ensuring the product is safe, effective, and reproducible, with consistent quality throughout its lifecycle.[7] The nonclinical guidelines, similar to those of the US FDA, require extensive studies to assess the safety and biodistribution of gene therapy products. These studies should be conducted in relevant animal models and include evaluations of genotoxicity, immunogenicity, and tumorigenicity to identify potential safety concerns before human trials. For clinical guidelines, the EMA recommends clinical trial designs that adequately demonstrate the efficacy and safety of gene therapy products. Innovative trial designs, patient registries, and real-world evidence are encouraged to support marketing authorisation applications, helping streamline the approval process while ensuring high standards of efficacy and safety.

Understanding where and how the gene therapy vector distributes throughout the body is crucial to ensure the therapy targets the intended tissues without affecting others.

To facilitate the development of innovative therapies, the EMA offers regulatory flexibility. This includes providing scientific advice, engaging in early dialogue with developers, and employing adaptive pathways to expedite the approval process while maintaining high standards of safety and efficacy.[7,16] The EMA advocates a risk-based approach for developing and evaluating advanced therapy medicinal products (ATMPs), including gene therapies.[17] This approach involves identifying and prioritising risks based on their potential impact on patient safety and product efficacy. By focusing on the most significant risks, developers can allocate resources more effectively to address them.

Interestingly, the EMA also released a guideline on environmental risk assessment (ERA) for ATMPs containing genetically modified organisms (GMOs). The ERA is a required component of the marketing authorisation application to evaluate the potential environmental impact of such medicinal products. This includes evaluating the likelihood of gene transfer to other organisms, the persistence of GMO in the environment, and any potential risks to human health and biodiversity.[18]

Expedited review and approval of promising therapies for unmet medical needs

Both the US FDA and EMA offer streamlined processes to fast-track the review and approval of gene therapies aimed at addressing unmet medical needs, allowing innovative treatments to reach patients sooner.[19,20]

The US FDA has several expedited programmes suited to gene therapies. The Regenerative Medicine Advanced Therapy designation, specifically designed for regenerative medicine therapies like gene therapies, provides intensive guidance, rolling reviews, and early US FDA engagement to discuss potential surrogate endpoints that could support accelerated approval. In addition, the US FDA's Breakthrough Therapy designation and Fast Track designation are applicable to gene therapies that demonstrate substantial improvement over existing treatments or address serious conditions with unmet medical needs.[19]

In tandem with these efforts, the EMA launched the PRIority MEdicines (PRIME) scheme, which supports the development of medicines for conditions with unmet medical needs, particularly where no alternative treatments are available or where the medicines offer significant benefits over existing therapies by offering early and enhanced scientific and regulatory support. Between 2016 and 2021, among the medicines approved under the PRIME scheme, seven were ATMPs, including CAR-T-cell therapies.[20]

Furthermore, the collaborative question-and-answer guidance document, issued by both the EMA and US FDA, underlines the joint consensus on crucial areas such as control strategy, process validation, stability, and Good Manufacturing Practice considerations in addressing the challenges of expedited medicine development under the PRIME and Breakthrough Therapies schemes.[21] This collaboration reflects the ongoing efforts of both regulatory authorities to maintain rigorous standards while facilitating the timely availability of life-saving therapies.

Measures for stricter gene therapy studies

Comprehensive nonclinical studies to address biodistribution and potential off-target effects

The primary challenge in nonclinical studies of gene therapy is ensuring that the therapy products are thoroughly assessed for their biodistribution and potential off-target effects. Understanding where and how the gene therapy vector distributes throughout the body is crucial to ensure the therapy targets the intended tissues without affecting others.[14,15,22]

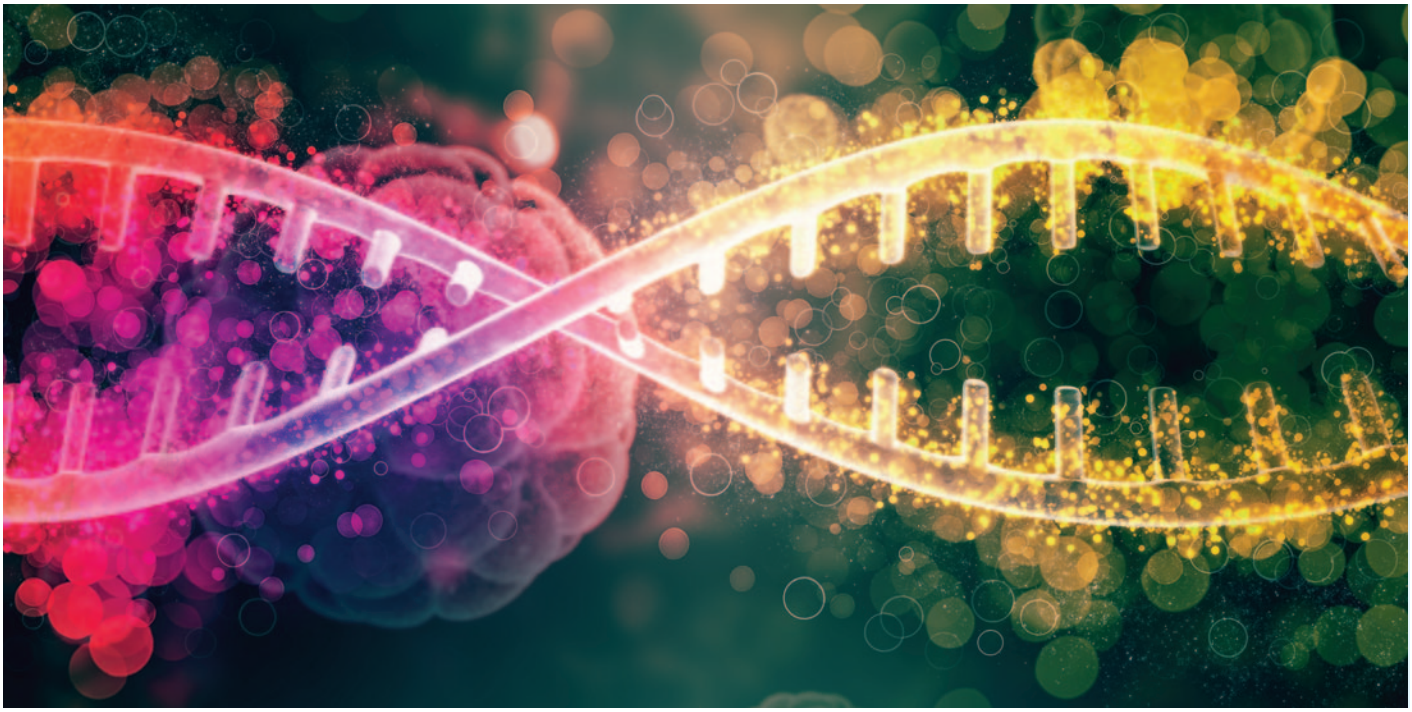

Photo: freepik

The US FDA recommends extensive biodistribution studies to map the distribution of gene therapy vectors across the body.[14,15] These studies are designed to identify both target and non-target tissues, assess potential off-target effects, and ensure that the therapy reaches the intended sites. Evaluations of potential off-target effects include the risk of insertional mutagenesis, particularly in gonadal tissues, to prevent germline integration. These assessments are crucial for predicting human responses and minimising unintended genetic modifications.

The EMA's guideline on the quality of gene therapy medicinal products outlines nonclinical biodistribution study requirements, emphasising the importance of understanding the distribution, persistence, and clearance of gene therapy products in both target and non-target tissues.[7,22] Like the US FDA, the EMA stresses the need to evaluate off-target effects and insertional mutagenesis risks, particularly in germline cells. Thorough testing ensures the safety of gene therapy vectors, addressing concerns about unintended genetic alterations.

Vector design and manufacturing controls to ensure product consistency and safety

Another significant challenge is ensuring product consistency and safety through robust vector design and manufacturing controls. Variability in vector design or production can lead to inconsistencies in therapy outcomes.[7,15]

The US FDA recommends designing vectors with high specificity and minimal off-target effects.[6,15] This involves using tissue-specific promoters and enhancers to ensure targeted gene expression. In addition, the US FDA outlines stringent manufacturing controls in the CMC section of IND applications. This includes detailed descriptions of the vector design, production process, purification methods, and quality control measures to ensure product consistency and safety.

Similarly, the EMA emphasises the importance of stringent quality control measures in the manufacturing process to ensure the purity, potency, and stability of gene therapy products.[7] The EMA also advises developers to use vectors with well-characterised safety profiles and employ advanced techniques to minimise the risk of off-target effects and insertional mutagenesis, thus ensuring that the gene therapy remains effective and safe throughout its lifecycle.

> Sponsors are required to prepare a long-term follow-up study protocol to monitor patients for delayed adverse effects.

Detailed requirements for clinical trial conduct

To ensure robust data collection and analysis, the US FDA requires comprehensive clinical trial protocols, particularly for gene therapy trials. These protocols must specify primary and secondary endpoints, detail patient selection criteria, and describe the trial design's ability to adequately address safety and efficacy questions.[14] The US FDA particularly underscores the importance of selecting clinically meaningful endpoints that focus on improving patients' reported outcomes.[14,23] For first-in-human trials of gene-editing products, the US FDA recommends enrolling patients who have no other feasible or warranted treatment options. These patients should also be at a less advanced or a moderate disease state due to the potential risks of the products in those with severe disease.

The protocols should also outline the methods for monitoring and reporting adverse events throughout the trial. A safety monitoring strategy should be defined. For example the trial should have an appropriate toxicity grading system and a toxicity management plan in place, especially for monitoring off-target editing and any side effects of on-target editing. Additionally, recognising the potential for delayed adverse effects induced by gene therapies, the US FDA recommends long-term follow-up (LTFU) studies of up to 15 years to monitor patients for delayed adverse effects.[14,15,23] Sponsors are required to prepare an LTFU study protocol that includes detailed elements such as visit schedules, sampling plans, monitoring tests, and maintenance of case histories. Moreover, sponsors must report serious adverse events and unexpected suspected adverse reactions, as well as submit periodic safety reports to the US FDA.[15,23]

The EMA also emphasises comprehensive

clinical trial protocols for gene therapy products, with a particular focus on patient follow-up and the monitoring of adverse effects with tailored approach considering the specific characteristics of the gene therapy products. For example, the EMA recommends LTFU for products involving viral vectors with a potential for chromosomal integration or latency at pre-treatment, 3-, 6-, and 12-months post-treatment for at least 5 years, followed by annual assessments until data do not indicate any risk to be followed. Recommendations are also provided for viral vectors without a potential for chromosomal integration or latency, plasmids, and non-viral vectors.[24]

Moreover, the EMA requires a detailed risk management plan to be submitted in a clinical trial application or a marketing authorisation application. This plan must encompass the pre-market and post-market surveillance strategies to ensure continuous monitoring of the product's long-term safety and efficacy. Any changes to the risk profile of the product, as observed during the clinical trial or post-marketing phase, should prompt a revision of the follow-up plan.[24,25]

Patients must fully understand the risks, benefits, and experimental nature of gene therapy trials, including available alternatives. Particularly, patients should be asked to provide informed consent to LTFU, which must describe the purpose of the follow-up, the expected duration, necessary assessments or procedures, and any adverse reactions that may be related to the gene therapy product under investigation.[14,15]

Conclusions

Navigating the regulatory landscape of gene therapy is a complex yet crucial endeavour for the safe and effective development of gene therapy products. The guidance provided by the US FDA and EMA are pivotal in ensuring that these innovative therapies meet the highest standards of safety and efficacy. By emphasising rigorous nonclinical studies, detailed clinical trial protocols, and long-term patient monitoring, these regulatory authorities address the scientific and ethical challenges associated with gene therapy. Their comprehensive oversight helps mitigate potential risks, such as off-target and delayed adverse effects, ensuring favourable benefit-risk profile of gene therapies in treating genetic diseases.

The US FDA and EMA are committed to fostering innovation in gene therapy while upholding stringent safety standards. Their collaborative efforts to harmonise regulatory requirements and streamline approval processes are crucial in facilitating development and ensuring patient access to cutting-edge treatments. As gene therapy rapidly evolves, regulatory frameworks must adapt accordingly to reflect new knowledge and technologies. This may involve integrating real-world evidence, leveraging advanced computational models for safety assessments, and fostering greater collaboration between regulators, researchers, and industry stakeholders. Future oversight may involve adopting more flexible and adaptive pathways to address the unique challenges presented by emerging gene-editing technologies. By remaining agile and forward-thinking, regulatory frameworks can continue to support the safe and timely development of innovative gene therapies.

Patients must fully understand the risks, benefits, and experimental nature of gene therapy trials, including available alternatives.

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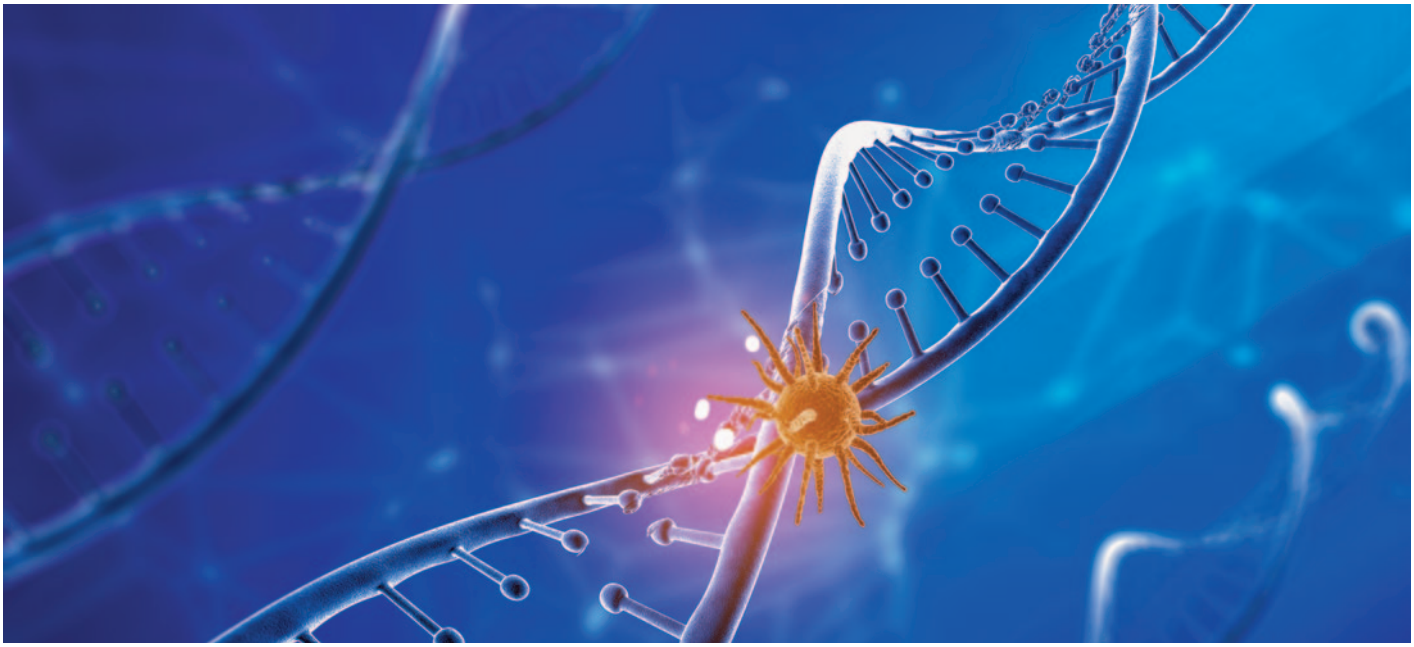

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Editorial

In the EMWA symposium held in May 2023, Sven Schirp, Global Head of Patient Safety (PS) Writing at Boehringer Ingelheim, gave an overview of the newly introduced requirement of the European public assessment reports risk management plan publication in the EU. For this article, I have asked him to share the experience gathered since then in his group (where I also work) and interviewed him, along with my colleagues Kerstin Prechtel, Principal Safety Writer, and Thomas Rohleder, Document Specialist.

Happy reading!

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Experience with risk management plan publication in European public assessment reports

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RMP publication in EPARs

Since October 20, 2023, for all centrally authorised products in the EU, the European Medicines Agency (EMA) has been publishing full risk management plans (RMPs) (initial evaluations and post-marketing updates) in European public assessment reports (EPARs). This process aims to further increase transparency of safety information for the public and replaces the publication of the RMP summary for the public (i.e. RMP Part VI).

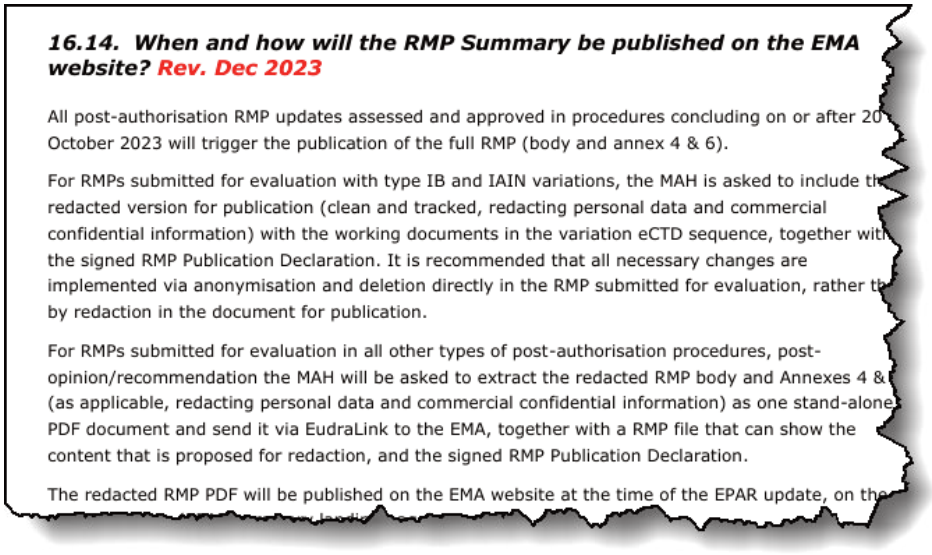
Published RMPs consist of the main body, annex 4 (specific adverse events follow-up questionnaires), and annex 6 (key messages of additional risk minimisation measures) in a single .pdf file. For the sake of publication, RMPs need to be reviewed to identify potential protected personal data (PPD) and commercially confidential information (CCI) for redaction. Marketing authorisation holders (MAH) submit their proposals for redaction of PPD and CCI. All changes are of editorial nature and are implemented in the RMP during the scientific review process preceding Opinion and adoption of the final RMP version. At the time of the EPAR update, the redacted RMP is published on the EMA website on the product's page (EPAR summary landing page). The published redacted RMP is referred to as "EPAR RMP" for the purpose of this article. Figure 1 provides the procedural advice related to RMP publication for products authorised via centralised authorisation procedure (CAP).[1]

How to address the EPAR RMP requirement – an example

The RMP publication process at the Patient Safety (PS) Writing group: An interview with Sven Schirp, Global Head of PS Writing at Boehringer Ingelheim,

Q: How did your group address the new requirement for EPAR RMPs?

Sven Schirp (SS): We had previous experience with third-party requests for RMPs, for which we used to review RMPs *ad hoc* (upon EMA request) and to create manually redacted RMP versions outside of our document management system (DMS). Since the new requirement applies to all initial evaluations and post-marketing updates of RMPs, we considered that a dedicated process covering all, from front-loading of activities up to creating redacted RMPs within the DMS, would increase our efficiency.



16.14. When and how will the RMP Summary be published on the EMA website? Rev. Dec 2023

All post-authorisation RMP updates assessed and approved in procedures concluding on or after 20 October 2023 will trigger the publication of the full RMP (body and annex 4 & 6).

For RMPs submitted for evaluation with type IB and IAIN variations, the MAH is asked to include th redacted version for publication (clean and tracked, redacting personal data and commercial confidential information) with the working documents in the variation eCTD sequence, together wit the signed RMP Publication Declaration. It is recommended that all necessary changes are implemented via anonymisation and deletion directly in the RMP submitted for evaluation, rather th by redaction in the document for publication.

For RMPs submitted for evaluation in all other types of post-authorisation procedures, post-opinion/recommendation the MAH will be asked to extract the redacted RMP body and Annexes 4 & (as applicable, redacting personal data and commercial confidential information) as one stand-alone PDF document and send it via EudraLink to the EMA, together with a RMP file that can show the content that is proposed for redaction, and the signed RMP Publication Declaration.

The redacted RMP PDF will be published on the EMA website at the time of the EPAR update, on th

Figure 1. Procedural advice related to RMP publication for centralised products[1]

Q: What does this process look like?

SS: At Boehringer Ingelheim, the PS Writing group has taken over the responsibility for redaction of RMPs.

- In general, for initial RMPs and RMP updates, the PS Writer front-loads activities related to the EPAR RMP requirement and advises the product team to prevent the inclusion of content that could potentially include PPD or CCI, to reduce redaction efforts at a later point in time. The RMP review should also cover the identification of PPD and CCI. This way, submitted RMPs are ideally already anonymised and there is no need to redact content later.
- At the point in time when the EMA requirement applies, the Global Regulatory Lead (GRL) requests the EPAR RMP. If there has not been a redaction-specific review during RMP preparation (which could be the case for existing RMPs with very tight timelines for the update), the PS Writer coordinates such a review within the provided timelines. Even if there is no need for content redaction, there may be standard items for redaction, e.g. post-marketing exposure by country in module SV (as this is considered CCI).
- Before redactions are applied, a copy of the submitted RMP (here referred to as pre-redacted EPAR RMP) is saved and stored in the DMS. In this pre-redacted EPAR RMP, the PS Writer includes proposals for redactions in red rectangles.
- The document specialist creates an EPAR RMP in the DMS based on the latest approved RMP according to EMA requirements of the EPAR publication. This EPAR RMP consists of main body, annex 4, and annex 6, and includes an adjusted table of contents and sequential page numbering. The redaction proposals from the pre-redacted EPAR RMP are implemented in the EPAR RMP.
- Both versions, the pre-redacted and the redacted EPAR RMP, are reviewed by the document specialist and the PS Writer, e-approved by the European Union Qualified Person for Pharmacovigilance (EU-QPPV), and submitted to EMA by the GRL.

Q: To what extent have the EPAR RMP requirement and the new process affected the workload in your group?

SS: Let me first explain how our group is structured. The safety writers take care of planning, coordination, and content-wise preparation of the pharmacovigilance documents. The technical finalisation and management of the documents in the DMS is done by our document specialists. For each CAP, initial or updated RMP being submitted to EMA, a redacted version needs to be prepared in addition. Thanks to the structure of the PS Writing group, the additional workload has been spread across two functions. Kerstin Prechtel and Thomas Rohleder can tell you more about their experience and perspective.

Content review of RMPs for EPAR publication: Interview with Kerstin Prechtel, Principal Safety Writer at Boehringer Ingelheim

Q: How are PPD and CCI identified in practice?

Kerstin Prechtel (KP): The EMA guidance[2] provides examples of PPD and CCI in RMPs, as well as rules for anonymisation. In general, the RMP is not expected to include either PPD (trial participant/patient level information) or CCI; however, for RMPs submitted before October 2023, redaction might be needed. The PS Writer reviews the RMP according to the guidance and marks any PPD and CCI for redaction. Particularly with regard to CCI, content review by specific functions may be needed, as the RMP might include detailed information on ongoing

clinical trials, unpublished data with an impact on future clinical development, manufacturing, or regulatory strategies. Therefore, the pre-reviewed draft is shared with the RMP authoring team, who has been trained about the EMA requirement by the PS Writing group.

Q: Who decides what should be redacted in case of doubt?

KP: The ultimate responsibility is with the lead PS physician. The PS Writer provides advice based on the guidance and the experience gathered with EMA. For example, once we received extensive proposals for redaction of clinical data from the medical colleagues and a reworded sentence to replace redacted information from the pharmacovigilance colleagues. However, we knew that EMA will not accept extensive blackening and revision of text and that all changes to the RMP should be of editorial nature only. After discussion with the lead PS physician, we made the final decision and communicated it to the team.

Q: Is Patent or Legal involved in the RMP review?

KP: We included Patent review in the first RMP reviews, when the teams needed to gather experience on potential CCI. Based on this experience, most information included in RMPs is either already shared via clinical documents under policy 70 or published. Therefore, the standard process does not require involving Patent or Legal in the review. We usually ask the authoring team if they deem their involvement necessary. In our experience, it does not make sense to routinely involve legal or patent functions in the review of the complete RMP. It makes more sense to ask them specific questions on selected sections or paragraphs, if required.

Technical preparation of EPAR RMPs – interview with Thomas Rohleder, Document Specialist

Q: Do you create an EPAR RMP even if there are no redaction proposals?

Thomas Rohleder (TR): According to our process, I do. The EPAR RMP is an EMA requirement and is submitted for publication regardless of whether it contains content redactions. The minimum extent of redactions concerns the "Confidential" or confidentiality statements in the headers/footers of the document. Since we create the EPAR RMP within our DMS, the confidentiality statements in the published output for submission, as well as selected appendices, are automatically removed. In addition, the table of content and page numbering are adapted to reflect inclusion of annex 4 and annex 6, only. This is the RMP that we submit for publication.

Q: What is the advantage of establishing this process and technical solution for EPAR RMPs versus preparing EPAR RMPs manually?

TR: We could prepare EPAR RMPs manually. However, in view of the high volume of RMP updates our company submits, the new process is more efficient and less error prone. The DMS generates an RMP output ready for publication, i.e. we do not have to spend time in removing the "Confidential" manually from all headers/footers and the appendices not intended for publication, or in adapting the table of content and page numbering.

Q: Would you say that the published output you create in the DMS is of higher quality compared with a manually prepared EPAR RMP?

TR: It is not only a matter of quality. Both solutions are valid and according to our experience, both seem to be accepted by EMA. However, the timelines for submission of EPAR RMPs can be short, and we usually finalise a high number of submission documents. With our process in the DMS, we save time and resources. Nevertheless, to keep flexibility, we can still prepare EPAR RMPs manually.

Q: Can the EPAR RMP be prepared in parallel with the actual RMP?

TR: This is technically not possible. The EPAR RMP is a new version of the latest approved RMP version in the DMS. Therefore, the EPAR RMP can only be created after e-approval and archiving of the submission RMP. We had to provide the EPAR RMP shortly after RMP submission in only a couple of instances. It was challenging, but it worked! Also in this case, having a process in the DMS helped us gain time.

Real-life and lessons learnt

Not only pharmaceutical companies, but also EMA are still learning and gathering experience with the EPAR RMP requirement. These are lessons learnt so far:

- Our DMS published output is well accepted by EMA, but in the past, we observed that also scanned versions of RMPs or RMPs with no bookmarks were published.
- We believe that the best approach is to create new RMPs and RMP updates in an anonymised way and front-load redaction review, to reduce efforts later, when time is tight.
- If in doubt when applying EMA guidance, common sense will help.
- Even though we have a process and a technical solution, we keep flexibility and would prepare an EPAR RMP manually, i.e. with no adapted table of content and page numbering, if needed.
- Our process efficiently addresses the EPAR RMP requirement, independently of the timelines, which may vary according to the regulatory procedure/ variation.
- EMA also seems to be still learning. In a recent procedure, we were asked to provide a redacted version plus a version that highlights the proposed redactions.

Disclaimers

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

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Medical Translation in
FRENCH

Du français à l'anglais:
Understanding your source

Medical translation requires total accuracy and precision. A translated medical document can be critical in determining the treatment or care a patient receives, as well as the information they have regarding their own health.

A translator must be well-versed in their area of expertise. They need to understand medical terminology in the source language (the language the text was originally written in), and accurately and succinctly render it in the target language (the language the text is being translated into). French is the main language I translate from, and it's not short of its challenges!

Syntactical and grammatical conventions vary hugely between French and English, and adapting to target conventions is essential. French tends to use more words to express a meaning than English, resulting in longer texts. If you have a 10-page French publication translation, for example, it may end up only being 8 pages in English. This is worth noting in terms of format and design, and important to flag to the client! Sentences are also generally much longer in French, and often need to be split up for clarity and readability in English.

For publications, where the source has (hopefully!) been edited and proofread, acronyms and abbreviations are normally spelled out on first use, so at least the translator knows what the short form refers to before rendering it in another language. For texts where these are rarely explained, such as medical reports, translators may need to do a bit of research to decipher these. Resources like Proz, Cosnautas, and the ITI Mednet forum are invaluable for researching tricky terms.

While some English acronyms and abbreviations resemble their French counterparts, making them easier to translate – e.g. *VIH* in French is simply reversed in English to become *HIV*; some require more in-depth knowledge. Examples commonly found in medical reports include *NFS* (*numération formule sanguine*), referring to a patient's complete blood count; and *EVA*, used to assess pain intensity, and known in English as VAS or the visual analogue scale.

It's not uncommon for translators to have to deal with concepts that simply don't exist in the target language. This is particularly true of healthcare schemes and systems which are often unique to an individual country or region. A French medical document might refer to someone's *carte vitale* (literally, *vital card*), for example. Depending on who the translation is for, you may need to add a translator's note to explain that this *carte* is a patient's state-issued, electronic health insurance card. An awareness of the source country and its corresponding medical system is particularly useful in instances like this!

In terms of best practices, having another medical translator review or proofread your work is essential. It's hard to spot small mistakes when you've been reading the same text for days … or weeks! The phrase "sleep on it" is just as true for translators as it is for writers; things often seem clearer in the morning when you can read a text with a fresh pair of eyes!

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Publications

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Editorial

In this instalment of Publications, Phil Leventhal, Danielle Drachmann, and Soren Skovlund discuss patient authorship, where people with lived experience in a specific disease or condition are listed as byline authors of peer-reviewed publications. Phil, Danielle, and Soren explain why patient authorship is important, how patient authors can meet the International Committee of Medical Journal Editors authorship criteria, and the potential barriers to patient authorship.

Maddy

Can patients and caregivers be authors of peer-reviewed publications?

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Increasingly, patients' and caregivers' experiences, needs, and desires are being considered in medical research and in the development and selection of treatments.[1] Patient engagement in research is a movement that promotes "the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, guided by patients' contributions as partners, recognising their specific experiences, values, and expertise."[2] In some cases, for example when the patient is a child, the caregiver may be better positioned to play this role, so, in this context, "patient" can also mean a caregiver, family member, or representative of a patient association.

Patient engagement can take many forms, including in the conception, planning, conduct, interpretation, or dissemination of research.[3-5] It can range from patients or caregivers serving as consultants to themselves driving research or its dissemination.[6,7] Underlying this is the understanding that people who have "lived experience" of a disease or condition can provide unique insight and perspective.[5,8,9] For example, patients and caregivers often have different priorities for treatment and different preferences for benefits and risks than clinicians, which can help in developing and selecting treatments.[3] Partnering with people who have lived experience, and especially patient organisations, can be particularly helpful when little information about an illness or disease is available, such as in rare diseases.[10,11]

Patient engagement is increasingly being recognised as essential and valuable,[8,12–14] and patient advocacy groups are actively seeking opportunities to partner in advancing research, developing new treatments, and driving policy.[11,15,16] Patient engagement has become a priority for the US FDA and other regulators, and the patient perspective is being increasingly considered in reimbursement decisions.[8,17,18]

Patient authorship

Patient authorship is a relatively new concept where people with lived experience of a specific disease or condition are listed as byline authors and sometimes even lead the development of peer-reviewed publications.[19] The concept of patient authorship has arisen because of the substantial contributions that patient partners are starting to make to medical research and its dissemination. The term "lived experience author" may actually be more precise than "patient author" because, in this context, "patient" can also include caregivers, family members, and representatives of patient or associations.

> The number of peer-reviewed publications with lived experience authors is low but is rapidly increasing.

Partnering with patient authors is being increasingly encouraged.[19,20] Patient authors can add value as authors by validating the need, relevance, and value of the research and by increasing the credibility of and trust in the results.[17]

The number of peer-reviewed publications with patient authors is low but rapidly increasing.[19,21,22] Despite this trend and calls to include people with lived experience as authors, there are some barriers to overcome. Practices for including patient authors remain heterogeneous, and clear standards are lacking. Further, the medical research community has expressed doubt that people with lived experience can or should be byline authors of peer-reviewed publications. A survey of 112 editors-in-chief published in 2021 found that nearly one-third considered patient authorship inappropriate, and about one in six thought that patients should have an academic affiliation.[3] Further, about one-third felt that the International Committee of Medical Journal Editors (ICMJE) authorship criteria should be revised to accommodate patient authors, although some of these editors stated that this was in the interest of protecting privacy or more clearly defining responsibilities.

What do guidelines say about patient authorship?

According to the ICMJE recommendations, which is the main ethical guideline for peer-reviewed medical publications, authorship should be based on the following four criteria:[23]

1. *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
2. *Drafting the work or reviewing it critically for important intellectual content; AND*
3. *Final approval of the version to be published; AND*
4. *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*

All four of these criteria can be met by people with lived experience, and, in contradiction to what some journal editors feel, academic credentials are not required.[24] As for the first ICMJE criterion, any author can make substantial contributions to a publication without being involved in all aspects of the research. For patients or caregivers, this could be by providing their unique perspective to interpret and communicate the results. Partnering with patients or caregivers is also encouraged for plain language summaries within publications as well as in stand-alone plain-language summaries of publications.[25] For the second ICMJE criterion, like other coauthors, patient partners do not need to write the manuscript but rather can contribute as critical reviewers of the content and writing, bringing their unique perspective. Finally, the last two of the four ICMJE authorship criteria can be met by any author and, for patient partners, only requires educating them about what the criteria imply and ensuring their agreement and compliance.

Beyond the ICMJE Recommendations, the 2022 update to the Good Publication Practice guidelines specifically validates the concept of patient authorship, stating:[26]

"Patients and patient advocates may be included in publication planning and development, including as authors or contributors to publications, as appropriate to the topic or therapeutic area."

The Guidance for Reporting Involvement of Patients and the Public, version 2 (GRIPP2) is currently the main guideline for patient engagement in research. It provides a detailed list of items to include in publications including patient or public involvement. However, it does not currently provide any guidance on authorship.

In sum, based on existing guidelines, people with lived experience can, and in many cases should, be included as authors of peer-reviewed publications.

Current issues to address

A main issue limiting patient authorship is a lack of clarity around how their role in preparing the publication should be indicated. Currently, there is no systematic way of doing this, making identifying publications with patients or caregivers authors time-consuming and inexact.[19,20,22,27] Using "patient author" or "patient/public author" as the affiliation has been proposed as a solution,[20,28] but patients and caregivers may not want personal information about themselves or their family members to be made public. Our own research has shown that, in articles on the experiences of people with rare diseases, 95% of patient authors list a patient advocacy group or association as the affiliation.[22] This may help keep their illness or condition confidential, while providing them with a respected affiliation. Similarly, authors who have both lived experience and an academic or professional affiliation may choose to make public only their affiliation. An alternative to tagging individual authors as having lived experience could be to simply indicate in a searchable field that people with lived experience participated as authors.

Based on existing guidelines, people with lived experience can, and in many cases should, be included as authors of peer-reviewed publications.

Education about patient authorship is another barrier limiting its adoption.[3,17,24,29] Patient and caregiver partners in research need to be made aware of and understand their responsibilities as byline authors of peer-reviewed publications. This will allow them to make decisions about whether they accept to participate as an author and how they want their contribution to be stated. Also, clinicians and other stakeholders need to be made aware that patients and caregivers can be authors and that they can provide added value to a publication. This can help them feel accepted as part of the authoring team and better navigate the team's dynamics. Fortunately, detailed guidance on how all of this can be accomplished is available in two recent publications.[17,24]

Conclusion

Patient authorship of peer-reviewed publications is a relatively new phenomenon that is part of the patient engagement movement. Partnering with patients, caregivers, and patient advocacy groups can provide added value to medical publications by enhancing their relevance and reach. As long as they meet authorship requirements, patients and caregivers should be able to be byline authors of publications. Continued work is needed to encourage this within the medical research community and find consensus on how to identify authors with lived experience in a way that respects their privacy.

Disclaimers

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

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Medical Writing in
GERMAN

German medical writing:
Navigating linguistic complexities

German is an official language in Germany, Austria, Switzerland, Luxembourg, Belgium, and Liechtenstein, and it represents the most widely spoken mother tongue in the European Union.[1] Medical writing in German presents unique challenges and opportunities compared to English, some of which are:

Lengthy compound words

German is known for its complex, compound nouns. In theory, the concept is logical: multiple nouns are combined into one descriptive word to convey complex ideas. In practice, however, these words can become very lengthy. An example is the commonly used word "Nahrungsmittelunverträglichkeit" (food intolerance), which can be broken down into its components: "Nahrung" (food), "Mittel" (product/stuff), and "Unverträglichkeit" (intolerance). While using long compound words is standard in scientific or administrative documents, their inclusion in concise documents such as brochures or advertorials aimed at the public can pose a challenge for medical writers.

Intricate sentence structure

German sentence structure is more flexible than English but also more complex. Creating subordinate clauses (sometimes multiple ones) is very common in German, and with their introduction, verb placement usually shifts to the end of the clause or sentence. This can lead to lengthy and intricate sentences. While such a complex structure allows for high precision and for packing extensive information into a single sentence, it can make it more difficult to follow the sentence and track the main action, especially for non-native speakers. Medical writers need to be particularly meticulous in maintaining logical flow and coherence. Translating such structures into English often demands restructuring to preserve the original meaning.

Formal vs. informal tone

Unlike English, German differentiates between formal and informal tones. The formal tone is generally used in professional settings, but pharmaceutical companies increasingly address patients with an informal tone to create a more personal connection. Informal language can engage patients more directly and appears more modern, whereas formal language can seem stiff and impersonal. However, some patients, particularly older people, may feel disrespected when addressed informally. Therefore, medical writers must carefully consider the appropriate tone for each document and the expected audience while also aligning with the company's preference.

Writing in English as a German medical writer

Writing in English can be a rewarding experience for a native German-speaking medical writer, as the language's more concise and direct sentence structure can make certain aspects of communication easier. Additionally, the lack of formal vs. informal distinction in English allows the writer to focus more on clarity and content without needing to consider the nuances of tone.

In summary, German medical writing involves navigating linguistic complexities that can impact clarity, tone, and coherence. Medical writers working in German must skillfully balance these elements to ensure the correctness and effectiveness of scientific or medical documents.

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The Crofter: Sustainable Communications

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Editorial

Greetings from the croft. When EMWA's Sustainability Special Interest Group recently calculated the carbon footprint of EMWA activities, we found that air travel to conferences was the major contributor to our annual greenhouse gas emissions.[1] Indeed, the carbon dioxide equivalent for flights was 125 times higher than for train travel. Many of us have probably weighed the benefits of train versus plane for short-haul travel, but Adam Jacobs has gone a step further by prioritising train travel for all his business trips. In this issue, he describes how he switched tracks to train travel, and provides some tips on how to get the most out of train-based voyaging.

We hope his article inspires other EMWA members to opt for low-carbon transport to conferences, and look forward to hearing about people's adventures! Sarah's pro-tip based on painful experience: double-check that you have indeed booked a seat or bed for overnight trains! Perching on a fold-out seat all night does not leave you as alert as you might like…

Finally, check out this issue's Biotechnology section on p.78 for a story on One Health, underscoring how sustainability touches all sectors of life and work.

Best,
Louisa and Sarah

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Saving the planet, one EMWA conference at a time

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I had been a frequent business traveller for some years until not so long ago. Most of my trips were by plane. I would typically fly to some destination or other most months.

Then COVID came along, and in March 2020, business travel suddenly stopped. It took a while to get going again, and my first international journey after that was to the EMWA conference in Berlin in May 2022. Having had that little break from travel was no bad thing, as it gave me the chance to pause and reflect on my travelling, and in particular, on the climate impact of air travel.

You would have to have been living under a rock to have missed some of the recent destructive and lethal extreme weather events, such as Storm Boris in Europe, Hurricanes Helene and Milton in the US, and Typhoon Yagi in south-east Asia. We've also seen extreme heat events in recent years, responsible for many deaths.[1,2]

And this is what we are experiencing in 2024, before we have even breached the target of limiting global warming to less than 1.5°C above pre-industrial global average temperatures. Given that current projections suggest we are likely to reach about 2.7°C by the end of this century,[3] the future looks frankly terrifying. It is becoming increasingly clear that governments will not save us from extreme weather events and temperatures incompatible with human survival in large parts of the world, and we must all take individual responsibility for our carbon emissions (as well, of course, as voting for politicians who seem likely to take climate change seriously).

> When I flew for business, I would often have to book several hours to unproductive "travel time" on my timesheet on the day of my flight. I haven't had to book any "travel time" hours on my recent train journeys.

So, I looked into getting from where I live in the south of England to Berlin (Germany) by train and found it was really not that hard. Because it was too far to travel from London (England) to Berlin in a day, I broke the journey with an overnight stop in Brussels (Belgium) each way (with the added bonus of having a nice meal with excellent beer). I have done almost all my business travel by train ever since.

Train versus plane – the environmental benefit

So, what is the environmental benefit of switching from flying to taking the train instead? It is hard to find completely reliable figures, and of course it depends on how eco-friendly the trains are (obviously, trains running on 100% renewable electricity are better than trains running on electricity generated by coal-fired power stations or diesel trains).

But according to the carbon calculator on ecopassenger.org,[4] a one-way trip from London to Berlin results in about 260 kg of CO_2 emissions by plane and 30 kg of CO_2 emissions by train. Quite a saving! Now, there was an additional carbon cost to my train travel as I needed an overnight stay in a hotel, and hotels are not generally carbon-zero affairs. However, since a typical overnight hotel stay in Belgium emits about 12 kg of CO_2,[5] the total was still way less than flying.

The joys of business train travel

One disadvantage of train travel is that it's slower than flying. Honestly though, I haven't found this to be a problem. Long-distance trains these days almost always have wifi, and I find it easy to get my laptop out and get some work done on a train in a way that I don't if I'm flying. So, in fact, there is probably less wasted time in a train journey than in a plane journey. When I flew for business, I would often have to book several hours to unproductive "travel time" on my timesheet on the day of my flight. I haven't had to book any "travel time" hours on my recent train journeys. And if I'm not travelling on company time, then it's very relaxing to watch the scenery go by while listening to podcasts and enjoying a glass of wine from the bar.

Since the EMWA conference in Berlin in 2022, I have been to the conferences in Riga (Latvia) in November 2022, Prague (Czech Republic) in 2023, and Valencia (Spain) in 2024. I will admit I flew to Riga. At the time, it was impossible to do the journey entirely by train as there were no cross-border trains between Poland and Lithuania. But the journeys to Prague and Valencia were both pleasant, with a single overnight stop each way. As a bonus, I got to stop in lovely Strasbourg (France) on the way to Prague and meet some local colleagues for dinner (who, being local, knew exactly where to go for excellent tarte flambée).

Business travel for my employer stopped dead in 2020, and only started again for me this year, but I have since been to Brussels, Paris (France), Lausanne (Switzerland), and Madrid (Spain) on company business. Journeys to Brussels and Paris were particularly easy, with a direct Eurostar from London. Lausanne and Madrid needed only one overnight stop. In fact, Lausanne could (at a pinch) be done without an overnight stop, but because of the timing of when I needed to be there it was easier for me to stop in Paris on the way (and who doesn't like an evening in Paris?) and in Geneva (Switzerland) on the way back. On my way back from Madrid I stopped in Montpellier in the south of France, which brought back happy memories of the 2001 EMWA conference there.

EMWA 2025 – to Riga by train?

I am currently considering whether I will make it to the 2025 EMWA conference in Riga by train. There are now Poland-Lithuania trains, so it would be possible. As far as I can tell, I would need three overnight stops, probably Brussels, Warsaw (Poland), and Vilnius (Lithuania). That makes it a long journey, but it would certainly be fun (I've never been to Vilnius before, and I'm told it's a lovely city). I haven't decided yet. If you see me at the Riga conference, ask me how I got there.

Adam kitted out for business travel and ready to hit the (rail)road

Train travel challenges and how to overcome them

A downside of train travel is that buying tickets can be quite complicated, and that it is often necessary to buy tickets from multiple operators. For example, for my trip to Valencia, I needed to buy a ticket from where I live to London with my local railway company, a ticket from London to Paris from Eurostar, a ticket from Paris to Girona, my overnight stop in Spain, from SNCF (France's national state-owned railway company), and a ticket from Girona to Valencia with Renfe (Spain's national state-owned railway company).

> Flying is a chore. Rail travel is an adventure.

It is possible to do all this in one transaction by using a travel agent or with a website such as the TheTrainLine.com, but it's important to realise that even though that may make the process easier, you may still end up with multiple tickets issued by different operators. This is fine if all the trains are on time, but you can be in trouble if you miss your connection. If you buy a ticket for connecting trains from a single operator, and miss your booked connection because the first train is late, you will usually be allowed to take a later connecting train. This won't necessarily be true if your connecting train is with a different operator and you have a non-flexible ticket.

I won't lie: this is a nuisance, and can be a problem for any cross-border rail journey. Co-ordination at the European level to give better

passenger rights in such circumstances would be very welcome. However, there are ways of mitigating the problem. If the journey needs an overnight stop, then one obvious strategy is to book the overnight stop at the same place where you change from one train operator to another. Allowing plenty of time for connections is another way of reducing the risk (perhaps you can plan to have a nice lunch at your connection location if your first train is on time?) Or you could book a flexible ticket for the latter part of your journey.

It is also possible to buy Interrail tickets, that is, a rail pass that allows European residents to ride trains throughout Europe with a pre-paid pass. This may even be a more cost-effective way to travel if you are going a long way. The system has changed quite a bit since I travelled by Interrail as a student back in the 1980s, and you can now buy tickets for periods shorter than one month. Interrail tickets are flexible, but this won't help you if your connecting train needs a compulsory seat reservation. I haven't yet tried this, so I can't tell you how well it works (but perhaps I'll buy an Interrail ticket to get to Riga next year).

Final thoughts

I am now a complete convert to train travel. Quite apart from the huge benefits in terms of my carbon footprint, an important reason why I'm sticking with it is because it's just so much more fun than flying. Flying is a chore. Rail travel is an adventure. I had got so used to airports and planes that I had forgotten what a complete pain they are, and I do not miss them now that I have discovered such a delightful alternative. Trains are so much more relaxing than planes, and you have nice views even on a cloudy day. Even though the journey sometimes takes longer (though it may not, given that train stations usually take you straight to the city centre), it can be more productive and pleasurable. Plus, if you do need an (overnight) stop it's a good opportunity to explore somewhere new or visit old favourites. It's hard to see the opportunity for a nice meal and a glass of wine in a city like Paris as a downside.

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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**

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.

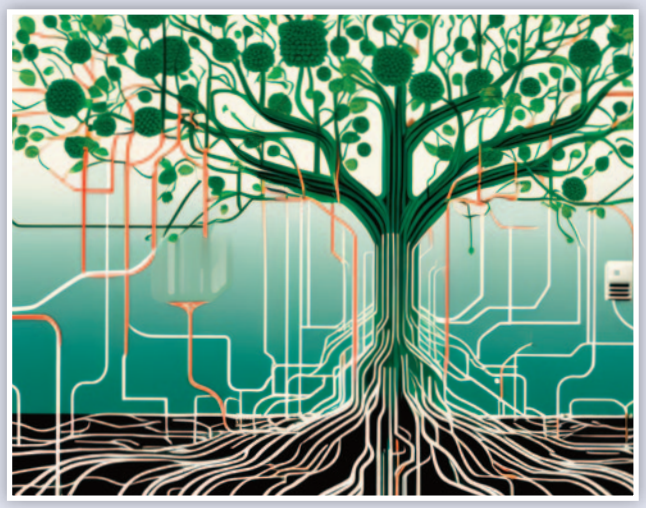
Guest Editor: Sarah Milner and Heather Mason
The deadline for feature articles has now passed.

June 2025:

Communicating with the Public

When we communicate effectively with patients and the public, we empower them to make informed decisions about their health. This issue will cover the latest guidelines and standards to be considered when writing and designing information for patients and the public. It will also feature articles from thought leaders on plain language writing, inclusive communication, and patient involvement in research. With this issue, we hope to provide insights that will strengthen the role of medical writers as advocates for the patient voice, and as powerful and effective communicators of understandable science.

Guest Editors: Sampoorna Rappaz and Lisa Chamberlain James
The deadline for feature articles is March 1, 2025.



September 2025:

Real World Data/Real World Evidence

Real-world data and real-world evidence have become integral to medical research and healthcare decision-making. Their value lies in providing insights into how healthcare treatments and interventions perform in everyday settings, which can differ significantly from controlled clinical trial environments. This issue of Medical Writing will include a broad range of articles on the issue theme covering critical aspects for medical writers working with these types of data.

Guest Editor: Maria Kołtowska-Häggström and Laura Collada Ali
The deadline for feature articles is June 1, 2025.

http://journal.emwa.org/