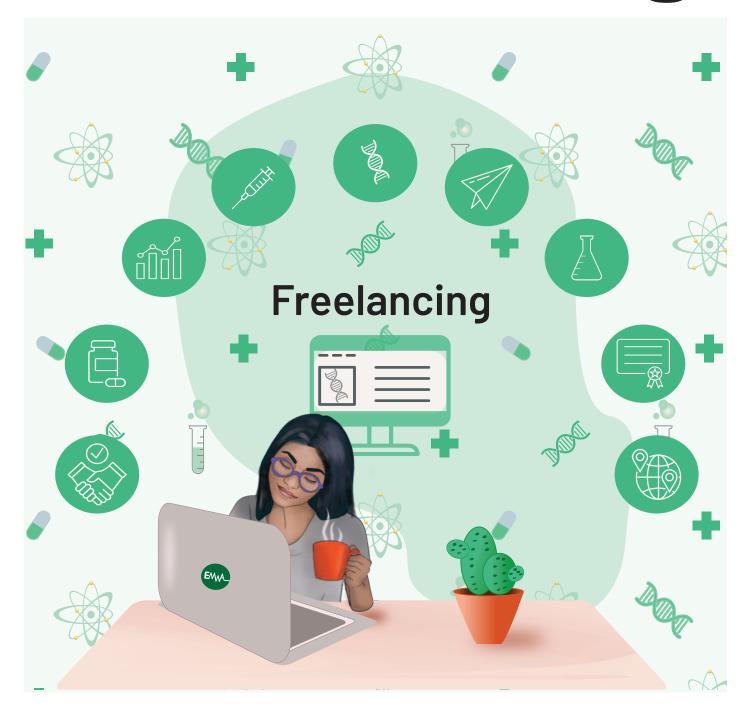
# Medical Writing



#### **ALSO IN THIS ISSUE...**

- EMWA's carbon footprint
- · How to keep your reader interested from start to finish





## Medical Writing



THIS ISSUE June 2023 | Volume 32 Number 2

## **Freelancing**

"Simply working for yourself isn't a magic formula to having rewarding projects and a perfect work-life balance, but creating a sustainable freelance career is possible."

Freelance Medical Writer Eleanor Steele, p. 30

Editorial: Freelancing Challenging but rewarding! Laura A. Kehoe, Satyen Shenoy	2	Jumping over and through obstacles: Navigating the freelance landscape Sara Ferrão, Fernando Oliveira	26	Seventh Freelance Business Survey: The freelance landscape 2018–2023 Johanna M. Chester, Shaniko Kaleci,	50
From the Editor Freelancing and carbon accounting Raquel Billiones  Outgoing President's Message Over the finish line!	5	How can coaching or mentoring help you craft a sustainable freelance career?  Eleanor Steele	30	Carbon footprint of EMWA activities: A first estimate Blanca Gomez-Escoda, Pavlína Cicková, Raquel Billiones	72
Satyen Shenoy  Incoming President's Message	6	The need for community: The importance of networking as a freelance medical writer	36	SPECIAL SECTION	
In with the new! Maria Kołtowska-Häggström	Ü	Peter Llewellyn  The work model of hybrid	42	Winners of the Geoffrey Hall Scholarship Essay Competition	82
55th EMWA Conference EMWA News	8	freelancing Kfir Lapid		Hanna Kurlanda-Witek, Sara Mostafa  REGULAR SECTIONS	
Somsuvro Basu		Books to support your medical writing journey	45	News from the EMA	80
Abstracts from the EMWA Spring Conference Poster Session	12	Trevor Stanbury  The freelance medical writer and	48	Medical Devices	92
FEATURE ARTICLES		the medical writing agency: A symbiotic relationship		Good Writing Practice	93
From academia to freelance medical writing: Navigating the transition	18	Namrata Singh, Shruti Shah  Charting your way to the top:	53	Veterinary Medical Writing  Lingua Franca and Beyond	10
Rebecca Tadokera  Soft skills needed for freelance	22	The 12 major milestones of freelance medical writing Sophie Ash		Regulatory Matters	104
medical writers  Allison DeMajistre	<i>44</i>	1		The Crofter	10'





## Freelancing: Challenging but rewarding!

eople often say they stumbled across medical writing as a career option, not really knowing what it entailed but having skills to be able to perform various medical writing tasks. The same can be true about freelancing. More often than not, people end up in a situation where freelancing becomes an option or a means to continue their career in medical writing.

Freelancing is becoming an increasingly popular option for medical writers and communicators, but it's not as straight-forward as finding a few clients and getting paid. There's so much more involved. Freelancers are business owners and to be successful, they need a plethora of skills; they need to be selfmotivated, driven and adaptable; and take the highs with the lows.

In this issue, we sought out experienced freelancers who have done just that transitioned from being medical writers to becoming business owners. They share their

#### **GUEST EDITORS**



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experiences and knowledge to offer our readers insight into becoming a freelancer, or for those who already are freelancers, tips on how to improve and boost business.

#### Towards entrepreneurship

We had the pleasure of working with many freelancers from around the world in this issue. We start in South Africa with Rebecca Tadokera, who discusses the transition from academia to freelance medical writing, and how to navigate the shift in career. We then

jump across the pond to America, where nurse-cum-medical writer Allison Demajistre explores the soft skills needed to get into freelancing.

Back in Europe, Portuguese-based freelancers Sara Ferrão and Fernando Oliveira compile a list of the obstacles that they jumped over and through to become freelancers. Hopping to the UK, a MedComms mentor herself, Eleanor Steele, gives an overview of coaching and mentoring for all levels of freelancing, and how it can benefit your career. Staying in the UK, Peter Llewellyn, the man who loves to get medical writers together, discusses the importance of networking by speaking with many of the local medical writers' groups in various

A growing trend among medical writers is that of hybrid freelancing, where they keep some freelance work but opt to have a percentage of fixed contract/employment



work as well. **Kfir Lapid,** based in Germany, explains the advantages of hybrid working from his and other hybrid workers' experiences.

Perusing in the Parisian cafés with a book in his hand, **Trevor Stanbury** gives the reader a review of the various books that could support their medical writing journey. We then head to the Netherlands where **Namrata Singh** and her colleague **Shruti Shah** give their insights into the symbiotic relationship between the medical writing agency and the freelancer.

Jumping back over the pond to Canada, **Sophie Ash** summarises her vision of the 12 major milestones in freelancing. The freelance features then conclude with an analysis of data gathered during the 6th and 7th Freelance Business Surveys conducted in 2018 and 2023, respectively, by **Johanna Chester, Shaniko Kaleci,** and **Laura A. Kehoe** of the Freelance Business Group subcommittee.

We would like to offer a huge thanks to all the contributing authors and the freelancers they reached out to for quotes and insights. It has been a pleasure to work with you all and we hope readers enjoy each article and are able to adopt some aspects to their own freelance work. Happy reading!

#### About the guest editors

Laura A. Kehoe has been a freelance medicalscientific writer and editor for over 6 years, based in Neuchatel, Switzerland. Since completing her PhD in Neuroscience, she has transitioned into the MedComms world, where she has worked in various medical disciplines from hepatology, psychiatry, and infectious diseases to orthopaedics and women's health. She is active in her voluntary work supporting other medical writers.



Satyen Shenoy is a medical writer based in Germany and a long-standing EMWA member. Following a long stint in basic and translational cancer research, he switched his career track to medical writing 13 years ago. He is currently working in the hybrid mode, half time as freelancer and half time as a clinical research associate with the Interdisciplinary Breast Centre at the Kliniken Essen Mitte.



#### 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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## From the Editor

### Freelancing and carbon accounting



Raquel Billiones Editor-in-Chief editor@emwa.org doi: 10.56012/mmik1527

There are regional and national differences with regard to fuel sources and energy policies. It is thus best to use a calculator that has been validated in your place of residence.

As part of EMWA's sustainability efforts, we have published a first estimate of EMWA's carbon footprint on p. 72. The authors of the paper also proactively disclosed their personal carbon

Finally, a huge thanks to Laura Kehoe and Satyen Shenoy for putting together this fantastic issue which is a great resource for the freelancing community!

n the world of carbon accounting, there is some good news, and some not-so-good

The good news is that the pharmaceutical industry has made strong commitments to decarbonisation.1

As pharma companies strive for carbon neutrality, carbon accounting is now part of dayto-day business; the carbon footprint for each process, each step, and each stakeholder is closely scrutinised. Freelance medical writers and communicators as business partners, vendors, and service providers within the healthcare industry will be part of this scrutiny.

Carbon footprint is a measure of greenhouse gas emissions produced by an organisation, activity, event, product, or individual in units of carbon dioxide (CO<sub>2</sub>).

The not-so-good news is that carbon footprinting is not yet fully standardised. The methodologies are still evolving, the calculations and metrics are not completely harmonised.<sup>3,4,5</sup>

The Greenhouse Gas (GHG) Protocol provides recommendations for carbon accounting for companies, organisations, cities, and countries.2 However, the GHG tools are not always easily "downsized" to small businesses and the self-employed.

There are many carbon footprint calculators available online, from the simple to the

sophisticated, from the expensive to the free. To navigate this ocean of carbon calculators, here are some suggested resources:

- The UK National Federation of Self Employed & Small Businesses Limited released the following blog in May 2023: https://www.fsb.org.uk/resources-page/ how-to-calculate-your-carbon-footprint-as-asmall-business.html
- The Carbon Trust launched the first ever carbon footprint label in 2007. Check out their recommendations for small and medium-sized enterprises: https://www.carbontrust.com/our-workand-impact/guides-reports-and-tools/smecarbon-footprint-calculator
- The National Association of Local Councils cites the following resource: An evaluation of online carbon calculators in the UK, by Amit Rastogi and Gareth Williams. https://www.nalc.gov.uk/library/ourwork/climate-change/3305-online-carboncalculators-in-uk-an-evaluation-report/file
- Greenly.earth reviewed 5 calculators and presents the pros and cons of each at https://greenly.earth/en-gb/blog/companyguide/5-best-carbon-footprint-calculators
- Also check our Paul Tisdale's tips for freelancers on p. 107.

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**Outgoing President's Message** 

Over the finish line



Satyen Shenoy EMWA President 2022-23 president@emwa.org

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ear EMWA Friends and Colleagues, A week or so after its conclusion, my brain is still flooded with kaleidoscopic memories of our recent spring conference. The phenomenal attendance, especially by the number of newcomers; the programme; the social events; the banquet; the conversations... and all of it amid the grandeur of good ole Prague. And to me, the remarkable success of #EMWA55 seems as the perfect culmination of my one-year service as the EMWA president.

It perhaps needs a mention, as often as possible, that the core strength of our association are its volunteers. At times, it is difficult to believe that an association such as ours with all it has to offer its membership is run entirely by volunteers. I've been an EMWA volunteer for eight years, starting off on the freelance business group and over time serving on the Expert Seminar Series committee, on the Ambassador Programme, as a workshop leader, and in other roles. I strongly

believe that volunteering my time for EMWA has been instrumental in my development as a medical writer. Serving EMWA has allowed me to develop my network, make friends and acquaintances involved with medical communications, learn from them, collaborate with them, and eventually build my freelance business. So, my advice, especially to freelancers, is to look for opportunities to volunteer.

"How does it feel to finish?", I was asked frequently in Prague. I'll admit, I have mixed feelings. The role of the president comes with a huge responsibility of overseeing the management of an almost 1500-member strong association that offers educational and other outreach programmes throughout the year and especially at biannual conferences. Of course, in this the president is well supported by members of the Executive Committee (EC) and our staff at Head Office; I can't thank enough EMWA colleagues who served on the EC with me as well

as our staff. This vast amount of background work, largely unseen by the membership, consumes a substantial amount of one's time and before one realises, the year is up. So, there is a palpable sense of relief and a feeling of satisfaction for having donated one's time and efforts in the top position in the association. And there's also a twinge of not having brought to life the initiatives I had hoped to start as the president. Perhaps this requires a different perspective: I don't need to be a president to bring in or share initiatives.

So, how does it really feel to finish? Well, most EMWA volunteers don't "retire", we merely exchange hats. And as I pass on the presidential headgear to Maria Koltowska-Häggström with my best wishes to her, I have tried on a few new ones including that of a joint guest editor of this issue themed on Freelancing. I am still very much an EMWA volunteer.

Happy reading!



## President's Message

#### In with the new!

#### Dear Friends, Colleagues, and EMWA Members

hen I joined EMWA in 2010, I never imagined that 13 years later I would attend the The 55th EMWA Conference as President and be part of the Executive Committee (EC), a body which for a few years I had watched timidly and ... with admiration. I still remember my first conference - it was Nice in Autumn 2010, and Laurence Auffret, the EMWA President then, was on the same flight going back home. We chatted and she told me a lot about EMWA and answered my never-ending questions, and I became more and more fascinated.

Yet, here I am - sitting in front of my computer writing my first President's message, having taken over the presidency from Satyen Shenoy at the May conference.

I would like to start by thanking people who made my EMWA journey possible:

• John Carpenter, who encouraged me to join EMWA and assured me that I would be able to pass all post-workshop assignments. Thank you, John, for your trust in me, your support of our Polish initiatives, and the wonderful time we spent all together in Warsaw. At the same time - congratulations on being conferred the Nick Thompson Fellowship - very well deserved!

- Laura Collada Ali, who introduced me to my first volunteering job - as LinkedIn Discussion Group Administrator. Thank you, Laura, for making me feel welcome during my first EMWA conferences
- Raquel Billiones, who brought me to the Expert Seminar Series (ESS) Organising Committee. Thank you, Raquel, for encouraging me to take another big step in my EMWA journey
- Sam Hamilton, who was brave enough to leave the leadership of the ESS Organising Committee in my hands. Thank you, Sam, for being such a wonderful teacher in ESS organisation
- Phil Leventhal, who accepted me as a section editor for Medical Writing and then offered me the opportunity to write an article and also to be a guest editor. Thank you, Phil, for making the writing side of myself come through.
- Barbara Grossman, who spent endless hours suggesting edits to my English and telling me over and over again that she "loves to read my writing". Thank you, Barbara, for your unwavering support and encouragement not only in my writing....

Maria Kołtowska-Häggström EMWA President 2023-24 president@emwa.org

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And thank you, to many others who make my interactions with EMWA a real pleasure.

As you know, the structure of EMWA EC is very smart: the President-Elect (previously Vice President) becomes the President after a one-year term. For me, the one-year run-up was very useful; I learned a bit how things work, familiarised myself with the EC and Head Office environment, and tried to understand the types of issues and matters that one needs to handle and resolve as President. I must say, it is not an easy task, and Satyen managed very well ...

Additionally, I took part in a number of activities, such as updating the EMWA policy on Promoting Products or Services in its Activities and Events, writing a recommendation for setting up a new Special Interest Group (SIG), and initiating transition from Regulatory Public Disclosure SIG to a general Regulatory SIG that will cover the whole spectrum of regulatory matters. However, my most important contribution, I would say, was restructuring the ESS Organising Committee and optimising the way it works. It was, of course, a team effort. This wouldn't have happened without the support and hard work of Tiziana von Bruchhausen, Bente Riis, and Eva-Maria Damsgaard Nielsen, with whom I worked closely when I led the ESS. We thoroughly reviewed the existing process, had a lively discussion, and finally came up with the proposal for a "two-chamber committee" consisting of an ESS Steering Committee and the ESS Session Organisers (see below).

The ESS Steering Committee is a fixed "core" committee that:

- Consists of permanent members
- Holds institutional memory of ESS processes, policies, and history
- Is responsible for reviewing all topic





EMWA's newly elected President Maria Kołtowska-Häggström, addresses the 55th EMWA Conference in Prague in May.

proposals, allocates them to an ESS session or sub-session, and finalises a proposal for EC endorsement

 Provides support for ESS planning throughout the year (i.e., for the Spring and Autumn conferences).

The ESS Session Organisers:

 Lead the organisation of an ESS session or sub-session

- Act as contacts for the ESS Steering Committee
- Report at regular ESS meetings (1–2 'ESS session organisers' per ESS session).

A SIG that organises an ESS session or subsession nominates a member to act as the ESS Session Organiser.

Tiziana, Bente, and Eva-Maria kindly agreed to serve on the ESS Steering Committee. I am

sure that they will continue to deliver more and more valuable and interesting sessions during our fantastic conferences that are always so well-organised by Slavka Baronikova and the Head Office Team. Talking about conferences, we must not forget the outstanding education programme carefully prepared by our Education Officers – Laura Collada Ali and Jules Kovacevic, and the entire EMWA Professional Development Committee (EPDC). Obviously, thank-you goes to all Workshop Leaders.

Finally, I would like to thank all members of the previous EC who welcomed me, patiently explained all routines, and made me feel at home. In particular, I would like to name those who left the EC:

- Satyen Shenoy, who during his presidency brought new initiatives that I am sure EMWA members will find beneficial and inspirational

   thank you, Satyen for your hard work and engagement.
- Sarah Choudhury, who is stepping down as Treasurer and whose tight and thoughtful steering of EMWA finance made the economic shape of our association very stable and sound. Thank you, Sarah, for your professionalism and care.
- Maria João Almeida, who has also decided to leave her position as Public Relations Officer.
   Maria made our voice heard and our messages read – thank you, Maria, for making EMWA visible in the public space.

My thanks also go to Lenka Roper, Emma Halloran, and Claire Whittingham at Head Office – your help cannot be overestimated.

At the same time, I would like to welcome the new members of the EC – Sarah Tilly as President-Elect, John Dixon as Treasurer, and Diana Ribeiro as Public Relations Officer. I look forward to working with you, together with the "old" EC members and with the entire EMWA community. I hope as a strong team with diverse skills and competencies, we will continue to grow the association for the benefit and the professional development of EMWA members.

## The 55th EMWA Conference:

## A success as always







he 55th EMWA Conference took place on May 9-13, 2023, in Prague. With more than 400 participants from across Europe and the world, it was a rousing success. Topics of workshops and presentations ranged from the latest in regulatory writing and medical communications, to artificial intelligence and freelancing. Sponsoring companies held court to talk about their operations and recruit promising talents. And a Career Guide for New Medical Writers (available at EMWA.org) was introduced to accompany the Getting into Medical Writing session.

Longtime conference-goers and first time attendees welcomed the opportunity for friendly conversation and to discuss the latest trends in the business of medical writing. Here are pictures and comments of attendees, who also enjoyed a variety of walking tours around Prague. Thanks to Medical Writing Co-Editor Evguenia Alechine for compiling these quotes, and to Philipp von Bruchhausen for collecting the pictures.

"Had inspiring discussions on the latest hot topics in the medical writing world, including the remarkable advancements in AI and its impact on our field."

Sofia Urner, new freelance medical writer







"As always, it was awesome to see old friends and colleagues and meet so many new people. I also feel privileged to be able to interact with regulators and industry experts."

Raquel Billiones, Editor-in-Chief, Medical Writing



"A melting pot of learning, networking, sharing and collaboration."

**Sarah Tilly**, EMWA Vice-President





"I left the EMWA conference with an abundance of information, a validation that this was an excellent career move, and some new laughter lines etched on my face."



## **EMWA News**















### Updates from the EMWA Journal Medical Writing

Several editorial board members have decided to step away from their roles this year. We want to thank them for all their contributions over the years. We are also happy to welcome our new team members:

- Sarah Milner joins us as Associate Editor
- Payal Bhatia is the new Section Editor of Medical Devices
- Ana Sofia Correia is the new Section Editor of Gained in Translation



EMWA webinars help members to develop skills and keep up-to-date with new or rapidly developing areas. Most of our webinars are live, online seminars allowing participants to ask questions. For live webinars, you only need to register - you will need your EMWA membership details.

Live webinars are recorded and uploaded to the Webinar Archive soon after the event. The Webinar Archive is only accessible to EMWA members: Webinar Archive

For information on upcoming webinars please go to: https://www.emwa.org/education/emwa-webinars-programme-2023/#webinars2023

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

### **EMWA Membership Hardship Fund**

Would you like to remain or become an EMWA member again but cannot because of financial difficulties and challenging times? If so, EMWA would like to provide some assistance.

To be considered, you must be an existing or past EMWA member. There is no limit to the number of applications. With support from the EMWA Executive Committee (EC), the Treasurer will review each application and judge them on a case-by-case basis. We ask you to tell us a little about yourself through these questions:

- What are your career aspirations? (300-word limit)
- What are your plans for any future EMWA involvement? (300-word limit)
- Why do you need this fee waiver? (300-word limit)
   In return, we ask you to make whatever monetary contribution you are able and the rest EMWA will cover. If you cannot make any contribution at all, EMWA will not discriminate

If you qualify, we will then review your case yearly. Hopefully, your situation will change; otherwise, we will consider supporting you through EMWA's hardship fund for a maximum of 3 consecutive years.

Details of anyone who qualifies will be kept strictly confidential by EMWA's Head Office.

This organisation's policy is to provide equal opportunities regardless of race, colour, religion, national origin, gender, sexual preference, age, or disability. EMWA, as a UN SDG partner organisation, aims to ensure inclusive and equitable quality education and promotes lifelong learning opportunities for all (UN SDG 4; https://sdgs.un.org/goals/goal4)

Please contact info@emwa.org and ec@emwa.org to apply.



EMWA volunteers help to further the development of your association.

You can get involved in a very limited way or become part of a larger project. The choice is yours, and everyone shares in the benefits.

- Help promote the role of medical writers and strengthen our association.
- Help to raise the standards of your field.
- Increase your visibility and communication opportunities with other medical writing members.
- Add some prestige to your CV while participating in exciting activities.
- Improve your knowledge of medical writing and related topics.

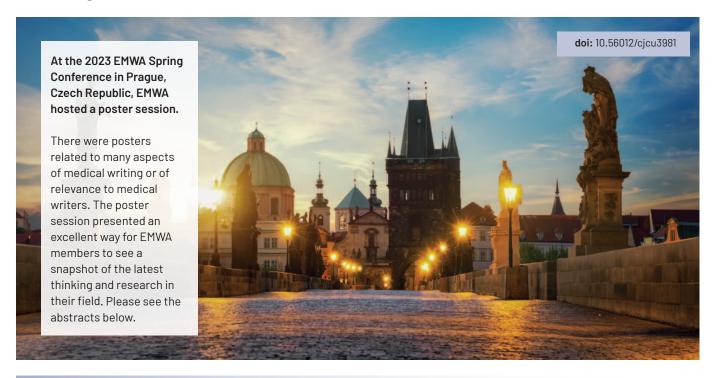
If you are a member of EMWA and eager to support ongoing initiatives, please check the following page: https://www.emwa.org/about-us/emwa-volunteers/Alternatively, contact the Public Relations officer (pr@emwa.org) to discuss other opportunities available.

## EMWA Podcasts to be launched soon EMWA will commence in 2023 with another outreach programme added to our menu - EMWA Podcasts. The EMWA Podcasts programme is designed for a broad range of individuals, from those who are yet to begin a career in medical writing to those interested in staying informed on cutting-edge topics in medical writing or regulatory affairs. With the goal of expanding the EMWA Podcasts programme, we are looking for volunteers to join the Podcasts team. If you are an EMWA member interested in joining the team, please email info@emwa.org.



# Abstracts from the EMWA Spring Conference Poster Session

## Prague May 2023



P1

What is career satisfaction to a regulatory medical writer? Medical writing field awareness and the way forward: An online survey

Sara Fernandes, Mauro Meloni, Robert Panek, Gregory Morehouse, Rona Grunspan Medical Writing, Quality & Editing and Clinical Trial Transparency, ICON plc

#### Introduction

People entering the medical writing field come from diverse backgrounds and many may not have considered the diversity of growth opportunities that existed when they began their careers. As the value of good medical writing has increased, we sought to understand the aspects of the job that medical writers (MWs) found rewarding and helped them shape the future of their writing profession.

#### **Methods**

An online survey was targeted to regulatory writers at different career levels to characterise job satisfaction. The survey aimed to understand if MWs had what they needed to be contented in their job, and which aspects were

important for professional development. Main areas of focus were: the relevance of technical versus non-technical skills, related training opportunities in career development, management efforts to keep MWs engaged, and satisfaction in being an important part of a team.

#### Results

Whether a MW sought to grow into a subject matter expert, or wished to evolve into a management role, the results show the key drivers for progression and momentum.

MWs surveyed expressed that opportunities to collaborate, being part of a solid team, and company culture were key motivators for career progression. A stimulating work/team environment, management support, development/

training opportunities, and salary and other benefits were of highest importance for job satisfaction. Training areas considered most valuable to a MWs career included interpreting and reporting data, clinical document writing, and technical writing.

#### **Conclusions**

The surveyed MWs showed a balance of needs and interests that include communication, collaboration, time management, critical thinking, conflict resolution, and leadership skills. Further work could examine the relationship between career phase and needs for satisfying career development, because job satisfaction may be perceived differently depending on the level of experience of the MW.

### **P2**

#### Blinded assessment of key publication content produced by ChatGPT from a sample poster

John Plant<sup>1</sup>, Jacqueline Janowich Wasserott<sup>2</sup>, Athanasia Benekou<sup>3</sup>, Phillip Leventhal<sup>4</sup>, Jonathan Pitt<sup>1</sup>

- 1 Evidera, Paris, France
- 2 Evidera, Brussels, Belgium
- 3 Evidera, Athens, Greece
- 4 Evidera, Lyon, France

#### Introduction

Written content produced by artificial intelligence (AI) could revolutionise the medical writing industry. ChatGPT, a chatbot for a new large language model AI, was publicly released for free beta testing in November 2022. This study examined ChatGPT's ability to generate key publication content from a poster.

#### Methods

ChatGPT generated the following content from a sample poster: target journal recommendation, manuscript title, abstract, keywords, and lay summary. Three blinded reviewers, all working in a publications team of a contract research organisation, were asked to rate the results with the instructions that they were assessing a job candidate. A 5-point scale from 1 (worst) to 5 (best) was used to rate the content generated as well as compliance with instructions, language accuracy, and language style. Reviewers also provided comments as free text and made an overall assessment (positive, neutral, negative).

#### Results

Median scores were 2.5 for target journal selection, 3.5 for title choice, 2 for the abstract, 4 for keyword selection, 3.75 for the lay summary, 4.5 for following instructions, 4 for

language accuracy, and 4 for language style. Reviewer comments highlighted flaws like awkward wording, questionable journal selection, and poor content and language in the lay summary and abstract, especially poor reporting of results. Overall ratings were neutral for one reviewer and negative for two.

#### **Conclusions**

ChatGPT performed poorly at producing most of the key publication content requested, although it performed well at following instructions and completing limited linguistic tasks that did not require an understanding of the content.



### Does publishing on MedRxiv affect a manuscript's outreach?

Pedro Caldas Custodio de Campos Silva\*†, Christian Matheou†, Alex Marshall, Shilpa Khobragade

- \* Corresponding author,
- † Joint first authors

Lumanity Communications, Surrey, UK

#### Introduction

The free online archive for medical and health research preprint manuscripts, medRxiv, allows authors to deposit unpublished research articles. Here, we explore whether depositing preprints on medRxiv impacts citations and alternative metric measures post-publication.

#### **Methods**

PubMed API was used to download article details from BMJ Open, which exclusively publishes medical research, from June 2018–September 2022. Downloaded articles were matched by their DOI to preprints from the medRxiv archive that were self-reported as published (n=308). A selection of BMJ Open

articles (n=1000) that did not match the medRxiv records were randomly selected to act as a control. Citations and Twitter shares were collected for both groups and compared by years since publication. Due to the non-normal distribution of the datasets, a Mann-Whitney U analysis was performed to test for significance between groups each year (p<0.05 taken as significant).

#### Results

One, two, and three years post-publication, articles with preprints had significantly higher citation counts than articles without preprints (p<0.00001, p<0.00001 and p<0.0001, respectively). In addition, Twitter shares were

significantly higher for articles with preprints one, two, and three years post-publication versus articles without preprints. A similar trend was seen when COVID-19 articles were removed, with the exception of year 3 for Twitter shares.

#### **Conclusions**

Articles posted as preprints on medRxiv are associated with significantly more citations and Twitter shares one, two, and three years after publication in BMJ Open than articles without medRxiv preprints. This preliminary analysis suggests there may be a benefit, in increased citation counts and Twitter shares, to prepublishing clinical research.



#### Challenges of mass balance studies (including absorption, distribution, metabolism, and elimination [ADME] and absolute bioavailability studies) in medical writing

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#### Introduction

Mass balance studies with (radio) labelled drugs are part of the clinical development programme of almost any new small molecule drug, to obtain information on the absorption, distribution, metabolism, and elimination (ADME) and absolute bioavailability of drugs in the human body. The aim of this review is to provide an overview of new developments and identify challenges of mass balance studies in medical writing (MW).

#### Methods

Standard and new designs for mass balance studies are collected from literature and combined experience available at ICON plc.

Rules and regulations that apply to studies with radiolabelled drugs, limitations in study design, and their impact on the MW processes are described. Challenges for MW are identified based on an informal survey on experiences and challenges with mass balance studies among ICON's early phase MWs.

#### Results

A variety of study designs is currently used for mass balance studies. Variation is found in labels used, amount of radioactivity administered, excreta collected, duration of studies, dosing sequences, and populations used. A clear description of the procedures followed, the objectives of the study design, and the results obtained is challenging for clinical documents including subject-facing documents.

#### **Conclusions**

Mass balance studies are an exciting type of studies with specific challenges for MW. New developments give rise to more opportunities to collect data in wider populations and with lower exposure to radioactive materials. Due to the increasing complexity of these studies, explaining the followed approach in a protocol, clinical study report, or subject-facing document requires more guidance for MW.

#### Evaluating the publication of randomised controlled trials in inflammatory bowel disease by trial outcome and journal attributes

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#### Introduction

Journal attributes by trial outcome were explored for published randomized controlled trials (RCTs) in inflammatory bowel disease (IBD) using machine learning (ML).

#### Methods

PubMed literature searches were conducted between 1/06/2015 and 24/08/2022 for RCTs that included the terms "Crohn disease", "ulcerative colitis" or "inflammatory bowel disease". Publications were screened using artificial intelligence to include primary analyses of phase 2-4 pharmaceutical interventional RCTs only. RCT interventions and outcomes were assessed using the ML

model Generative Pre-trained Transformer 3. Journal affiliation, impact factor (IF) and RCT phase were assessed manually.

#### Results

The search returned 1038 publications, of which 138 were RCTs for pharmaceutical interventions (in 35 unique journals). The majority of RCTs (83/138 [60.1%]) were published by society-affiliated journals (n=19). Overall, 30 RCTs reported negative results, of which most (22/30 [73.3%]) were published by society-affiliated journals, and nearly half (13/30 [43.3%]) by two journals (IF, 10.0 [n=7]; IF, 22.7 [n=6]). Most RCTs published in non-society-affiliated journals reported

positive results (45/55 [81.8%]; 13 journals); all except for one non-society-affiliated journal published a single negative RCT. Of the 30 negative RCT articles, 63.3% were open access; 14, 10 and 6 publications reported phase 2, 3 and 4 RCTs, respectively.

#### **Conclusions**

The results of this exploratory analysis suggest that society-affiliated IBD journals publish more RCTs, including negative RCTs, than non-society-affiliated/general medicine journals. This may have implications for choice of target journal for such data. As only IBD RCTs were assessed, the significance of these findings for other therapy areas is unknown.

### P6

#### The prevalence and incidence of sickle cell disorders in Germany

**Angela Anastasia Asante AAA**, University of Bremen, MnB Health Lab GmbH Potsdam, Germany

#### Introduction

Due to globalisation and migration, sickle cell disease (SCD) and Sickle Cell Trait (SCT) is spreading to demographic regions where it does not originate, for example; Europe, the Americas and others. This study sought to estimate the trend of sickle cell disorders in Germany, from year 2006 to 2016.

#### **Methods**

Analyses were made using claims data of statutory health insurance providers from the German Pharmacoepidemiological Research Database (GePaRD), which covers about 20% of Germany's general population. Statistical Analysis System (SAS) was the primary tool for data analysis.

#### Results

The year 2016 had the highest incidence rate and prevalence proportion of 3.60 and 27.17 per 100,000 persons respectively. The age cohort 30–39 almost consistently had the highest prevalence proportions annually, especially year 2016, which was 3.67 per 10,000 persons. This was significantly higher among males belonging to this age cohort, compared to their female counterparts.

#### **Conclusions**

About 20% to 40% of the population of some sickle cell endemic regions in West and Central Africa have Sickle Cell Trait. Until now, there are some modest increases in the prevalence of sickle cell in Germany, compared to the very

high prevalence in West and Central Africa. Recently, universal newborn screening for SCD has been introduced, which will help to identify SCD/SCT early on and increase awareness of the disease in the light of ongoing migration movements from endemic regions. This is one of the first studies on sickle cell in Germany using claims data. Results reveal dynamic epidemiologic developments, especially after year 2015.



Knowledge, awareness and practice in using digital enhancements in scientific publications: Survey from academicians, healthcare and industry professionals, and medical writers

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#### Introduction

Digital enhancements (DEs) attract more views, have strong social media presence and increase geographic reach of scientific publication. The current survey-based study assessed knowledge, awareness, and practice in incorporating DEs in scientific publications (DESPs).

#### **Methods**

A 20-question survey was circulated via e-mail and social media (LinkedIn and Whatsapp) to academicians, healthcare and industry professionals, and medical writers. Responses received from August 6, 2022, to September 16, 2022, were assessed using univariate analyses.

#### Results

In total, 256 responses were received (68 academicians, 73 clinicians, 41 industry professionals, 66 medical writers, 3 pharmacists, 5 did not specify). About 49% had >5 years of work experience. Most respondents (74%) agreed that DEs can help in better visualisation of presentation, improve publication reach and enhance reader engagement. While 59% of respondents were aware of different DESPs, only 40% of respondents used these; most used DE was infographics (51%). While 84% of respondents were interested in DESPs, 66.4% respondents considered inadequate budgets as a major constraint for developing DEs, followed by lack of knowledge in selecting the right DE (51.5%) and inadequate access to relevant tools and

platforms (36%). Most respondents suggested having discrete publication guidelines (74%) and clear company policies (85%) for using DESPs. The majority of respondents suggested having more awareness programmes (91%) and relevant trainings (90%). About 79% of respondents suggested involvement of publications-specific organisations (ISMPP, EMWA, AMWA, MAPS) in increasing DESPs usage.

#### **Conclusions**

Results suggest that while DESPs are slowly gaining popularity, increased awareness by publication-specific associations and training opportunities will encourage more authors to engage DESPs.



### P8

#### Good Publication Practice 2022: What is new from the medical writer's perspective?

**Surayya Taranum, Phillip Leventhal, Jonathan Pitt** Evidera-PPD, France

#### Introduction

The 2022 Good Publication Practice (GPP 2022) guidelines were published in September 2022. Here, we identified updates relevant to medical writers (MWs) producing publications.

#### **Methods**

GPP 2022 guidelines were compared to GPP3. Search terms including "medical writer", "writer", and "writing", were used to extract changes relevant to MWs.

#### Results

GPP 2022 has expanded the term "publications" to include plain language

summaries and enhanced content such as videos, audios, and infographics. Key updates relevant to MWs producing publications include: (a) a statement that MWs enhance the quality of publications; (b) authors must agree to work with a MW before the start of the project, provide direction and initial outline to the MW, and perform the final data check to ensure the quality and accuracy of the publication; (c) a MW may be listed as an author if they fulfil all the ICMJE criteria and is not disqualified from authorship by paid employment as a MW; (d) publications should include the MW's name, professional qualifications, affiliation, and funding source;

(e) MWs should not use their personal social media accounts to share information on company-sponsored research publications; (f) MWs should engage in formal training offered by relevant organisations (e.g., EMWA, AMWA, and ISMPP).

#### Conclusions

GPP 2022 provides important clarifications on the transparency, recognition, roles, and responsibilities of MWs. MWs should be aware of these updates and communicate them to their clients and collaborators.



## Language validation for patient documentation: Automated tools or layperson readability tests?

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#### Introduction

Within the MedTech industry, information written for patients was often developed without language validation. Introduction of the EU Medical Device Regulations (2017/745) emphasised a need for greater transparency. This requires manufacturers to provide clear and comprehendible documentation for users, the acceptability of which may be demonstrated through readability tests (RTs). Automated RT tools exist which use formulas that consider sentence length, word simplicity, etc. This validation study considers the performance of three different automated RTs, when compared against an assessment of readability and comprehension involving real lay people.

#### Methods

A RT was developed including success criteria: at least 90% of the questions should be correctly answered by 80% of lay people (with no prior knowledge of medical terminology). Three groups of laypersons (n=24; 24; 12) performed RTs on documents/sections that were also evaluated using automated tools (Readable; Grammarly; Microsoft Word). The results of each method were compared.

#### Results

While all automated RTs suggested "unacceptable" readability levels, results obtained directly with participants demonstrated that the documentation used was readable (success criteria met).

Additionally, participants' feedback suggested that, although some documents were too long, the level of detail, information, and organization were appropriate.

#### **Conclusions**

Medical writers' training and language validation enhance documents' readability. Although automated tools are a cheap and quick alternative to layperson RTs, overreliance on automated tools may provide misleading results. RTs performed on participants provide more relevant results to confirm the adequacy of the information provided. The effectiveness of combining automated and layperson RTs still requires further investigation.



## A case study of whether ChatGPT can produce abstracts that meet CONSORT for Abstracts requirements

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#### Introduction

Artificial intelligence tools, such as ChatGPT, have the potential to create documents that resemble human writing. However, whether ChatGPT can simulate high-quality scientific writing consistent with standard reporting guidelines is unknown. We thus assessed whether ChatGPT-produced abstracts could meet CONSORT for Abstracts reporting requirements.

#### Methods

A randomised controlled trial publication (N Engl J Med. 2020;383:2603–15) was selected based on its relatively short text, limited number of tables and figures, and widely understood topic (COVID-19). To fit within

the size limitation of its data entry field, ChatGPT was used to shorten each section of the text by two-thirds. These shortened sections were then combined and enriched with any CONSORT-related missing information and entered back into ChatGPT with the instructions to generate a CONSORT-compliant (a) structured abstract under 250 words and (b) title. The CONSORT for Abstracts checklist was used to assess the quality of the outputs. A qualitative evaluation was also conducted.

#### Results

The ChatGPT-generated abstract contained 277 words. Of the 17 items in the CONSORT for Abstracts checklist, 10 items (59%) were

reported, and 5 (35%) were not reported: participants, blinding, numbers randomised, numbers analysed, and trial registration. Two items were considered not applicable (12%). The abstract text did not always match the sections; it was repetitive and at times hard to comprehend.

#### Conclusions

ChatGPT did not comply with the CONSORT for Abstracts checklist and generated a poorly written abstract. Therefore, it cannot be considered effective at producing scientific abstracts of sufficient quality.



## A method of selecting appropriate Quality of Life Patient Reported Outcomes Measures in clinical trials

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#### Introduction

Quality of Life (QoL) Patient Reported Outcomes Measures (PROMs) has become popular to assess participants' perception of their own health and wellbeing. Selecting an appropriate measure is important for the reliability and validity of the overall self-perception and definition of participant and patient QoL.

#### **Methods**

The review was completed on peer-reviewed studies conducted between 2012 and 2023 using PRISMA methodology. An electronic search was completed on the following

databases: PubMed, Cochrane, and ClinicalTrials.gov. The questionnaires design and applicability were compared to best practice as per DeVellis and Thorpe (2021).

#### Results

The review identified five generic, validated QoL questionnaires: World Health Organization Quality of Life Assessment Instrument (WHOQOL), 36-item Short-Form Health Survey (SF-36), 12-item Short-Form Health Survey (SF-12) Nottingham Health Profile (NHP), and Euro-Quality of Life Questionnaire (EuroQoL, EQ-5D). SF-12 was found to be the most suitable, due to ease of

use, low participant burden, and ability to identify difference between quality of life domains.

#### **Conclusions**

Choosing an appropriate measure to assess QoL in clinical trials is complex. Factors that may affect the responses are complexity and timing of the questionnaire during the trial. Understanding how participants perceive their QoL may inform clinical "best" practices allowing them to be more patient-centric. A trial does not only consist of data collection in order to be published, it consists of processes to improve the participants' health.



## From academia to freelance medical writing: Navigating the transition

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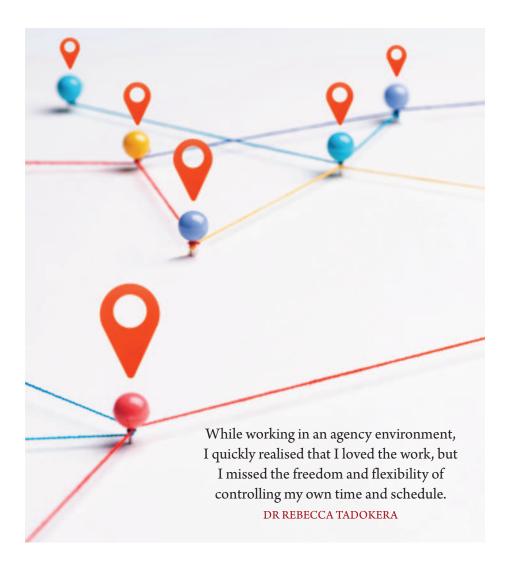
#### Abstract

Academics who have transitioned to medical communications (MedComms) find that there are many parallels between the two fields, leading to fulfilling and rewarding careers. Many of the skills honed in academia such as research, technical writing, and rigour are transferable to MedComms. Technical competence alone, however, is not enough. The transition from academia to freelance medical writing presents a unique set of challenges with a steep learning curve. In this article, four ex-academics share their transition journeys from academia to freelance medical writing, the challenges they encountered, and their learnings. Apart from the core business of writing, freelancers must wear many hats to be able to operate a successful business. Additional skills such as networking, marketing, and business management are a fundamental requirement for success as a freelancer. Equally important is skilfully defining your niche for services and positioning yourself as an expert to potential clients.

#### Introduction

ou are a medical writer? What exactly do you do? Do you write prescriptions for medical doctors? Are you a science journalist? These are the kind of questions I get whenever I meet people and tell them what I do. It gets more awkward when I tell them that I work freelance. Who are your clients? How do you find clients?

When you come to think that medical writing is still in its infancy in South Africa, all these



questions are understandable. But even in the western world, medical writing - of which MedComms is one type - is still an obscure profession, from an outsider's viewpoint. Once you are in the profession, that viewpoint quickly changes. Medical writing is an overwhelmingly vast profession. There are so many specialties and sub-specialties, that it is hard to make headway in the profession without an element of niching

Because medical writing is such a nonstandard career path, each person you meet has a unique transition story to tell, no matter which part of the world they come from. Despite the profession having been in existence for a while, not many institutions in the world offer formal

training or degrees in medical writing. Most medical writers I know profess to have "stumbled" across the career path. While the transition from academia is bold, many others have made the more daring leap from academia to freelance medical writing.

Working as a freelance medical writer presents various challenges and opportunities. For this article, I compiled the perspectives and transition journeys of four ex-academics from different parts of the world - myself included into the world of freelance medical writing. I hope that through sharing our stories, we encourage many others to see possibilities and take "the road less trodden" of becoming a freelance medical writer.

#### Q1. Can you share a bit of your transitioning story from academia to freelance medical writing and what led to that decision?

Rebecca Tadokera: Having committed over 12 years of my career to tuberculosis (TB) research, the decision to hang up my lab coat was both painful and challenging. Funding for TB research is notoriously difficult to win, especially in developing countries like South Africa where I am based. The arrival of the COVID-19 pandemic did not help matters. TB became one of the biggest casualties. Funding initially targeted for TB work was quickly diverted to COVID-19 research. This coincided with the time I was applying for funding to extend my soft-funded research fellowship on my path to becoming a principal investigator (PI). Eventually, I realised that I had two options: I either had to pivot to a new field of research that was better funded or start a new career altogether. I was frustrated with having to constantly fight for research funding, so I decided to leave academia completely.

My transition into MedComms has been twofold. First, I transitioned from academia to a MedComms agency environment, before transitioning to work freelance. Agency environments can be challenging for someone who is used to the flexibility and autonomy of working in academia. While working in an agency environment, I quickly realised that I loved the work, but I missed the freedom and flexibility of controlling my own time and schedule. Eventually, I decided to transition to work in the MedComms space as a freelancer.

Vicky Sherwood: I ventured into the world of MedComms more than 6 years ago, having left behind a PI position in cancer research. As an academic in the UK, I found myself working longer and harder for dwindling funding, pension

cuts, financial insecurity (with a mortgage, kids, and a car), an increased teaching workload, departmental micromanagement, and a salary that didn't keep up with the cost of living. All this led me to re-evaluate my academic career. With the economic uncertainty of Brexit looming at the time, I just couldn't see things getting any

better. Would I spend the next three decades of my working life worrying about finances and spending most of my weekends applying for funding?

To gain back control, I decided to explore my options outside of academia by networking and talking to folks who worked in the pharmaceutical industry. Fast-forward a year, and the networking efforts paid off. I'd discovered an area of the pharma industry that allowed me to incorporate all the things I loved most about being a scientist; scientific writing, medical education, and the potential for improving patients' lives - medical writing. I honed my medical writing skills at MedComms agencies first.

Morgana Moretti: Going back to the lab after maternity leave about four years ago, I realised I was unhappy doing academic research, especially the bench work. So, after having worked in neuroscience research for over 12 years, I started exploring other career options in industry. When the pandemic arrived and lab activities completely ceased, I explored some medical writing opportunities through freelance platforms. I figured it could be an excellent opportunity to use my science knowledge and skills outside the lab bench. I started freelancing part-time while still working in the lab in 2020 and since April 2022, I have been running my medical writing freelance business full-time.

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DR VICKY SHERWOOD

Arianna Ferrini: I started doing some freelance medical and scientific writing on the side during the COVID-19 pandemic. I think the pandemic gave me the space and time to stop and reflect on what I wanted to do "when I grew up" - something I had not done after I had completed my Ph.D. Writing and communicating science has always been a big passion of mine, so combining these two passions with my love for science and research was almost natural.

For 12 years, I was an academic researcher, and, despite the well-known challenges of this job, I loved it. However, after my PhD, I had lost some of my

motivation and started thinking about alternative careers. Leaving the lab was a very hard decision because I had always thought I would have gone for an academic career. But looking back now, more than two years later, I can honestly say it was one of the best decisions I ever made. Working as a freelance medical writer I can use my scientific expertise in a job where I feel valued for the work that I do and I have some flexibility, that, having a young family, is priceless.



Vicky Sherwood, PhD, is a freelance scientific writer, located in the UK, and the host of the careers blog Biomed Badass Blog.

Morgana Moretti, PhD, is a freelance medical writer and scientific consultant located in Santa Catarina, Brazil.

Arianna Ferrini, PhD, is a freelance medical writer and scientific consultant located in London, UK.



#### Q2. What were the biggest challenges in your transition, and how did you overcome them?

Rebecca Tadokera: I would say that the challenges have been different at each stage of the transition. Firstly, leaving academia is not something that academics discuss openly. Anyone who has tried to move out of academia will know that scarcity of information on alternative career options is one of the reasons why many PhDs do not even think about leaving academia. Yes, I had made the decision to leave. But now what? How, and where would I start?

My network consisted mainly of fellow academic researchers. I knew only a handful of people who had left academia after their PhDs. Networking, especially through LinkedIn, was a fundamental part of my transition into MedComms. The two entry-level roles I eventually interviewed for were through referrals from networks.

Another challenge stems from the obscurity of the MedComms field, making it difficult to break into. As a freelancer starting out, one of the biggest challenges I faced was in acquiring clients. You need credibility for people to trust you and hire you. Yet again, my networks have been my saving grace. Most of the freelance contracts I have won have been referrals through my networks. It is through my networks and mentors adopted along the way that I have consolidated my skills and expertise as a medical writer.

Vicky Sherwood: What else can I do? When I reached the point of asking myself this question as an academic, I had little knowledge of life outside of the academy. I'd spent 15 years building my academic career. Most of my contacts were academics, the majority of my work experience was

academic, and at the time, I wasn't sure if my skills were transferable to other types of employment. I had so much self-doubt and worried about how potential employers would view me.

I needed to find people who could help me answer some of these questions. LinkedIn was my solution for this. I focused on finding and connecting with pharma professionals with a similar educational background to myself, or who

had studied or worked at the same institutions. It was this approach that serendipitously led me to connect with medical writers and realise that this career would provide a fantastic opportunity for the future.

Medical writing is very different from academic writing. It was a steep learning curve - I needed to learn the processes, compliance and regulatory approval requirements, and client-facing skills, and I needed to learn fast! As an associate medical writer working in MedComms agencies, I was fortunate to have seasoned professionals and a supportive

team who were more than willing to answer my questions. This foundation accelerated my learning and prepared me for the world of freelance writing that was yet to come.

Morgana Moretti: My biggest challenges when transitioning from academia to medical writing were networking and marketing my services.

As an academic, I was used to focusing primarily on individual work and wasn't familiar with the processes and techniques involved in building a successful freelance business, including marketing strategies.

To overcome these challenges, I reached out to other medical writers and industry professionals to learn more about their experiences. This helped me develop a better understanding of the industry and

> to identify opportunities for building my network.

> I also started consuming marketing information and intentionally cultivating my brand. I initially used LinkedIn to strengthen my brand image, before creating a website showcasing my work and services.

> Arianna Ferrini: I think the transition needed the mindset shift to see myself as a business owner, on top of everything. As a freelancer, you get to wear many hats, so at the beginning, that was one of my main challenges. Investing in a business coach and taking time to reflect on how I wanted to build my business helped me overcome this challenge.

Adding to this was that as an academic, I thought I had to be "an expert" at everything. But that is impossible in medical writing, especially at the beginning. Eventually, realising that all those years of academic research gave me all the necessary tools to carry out excellent work even in areas where I would not consider myself an expert was an eye-opener.

I think the transition needed the mindset shift to see myself as a business owner, on top of everything. As a freelancer, you get to wear multiple hats, so at the beginning, that was one of my main challenges.

DR ARIANNA FERRINI

#### Q3. Which key transferable skills or qualities would you say have been critical to your success as a freelance medical writer?

Rebecca Tadokera: Success in freelancing requires so many different skills. Firstly, the technical skills of being able to research, write well, and follow guidelines, just like in academia, are a given. Agility, collaboration, networking, project management, and marketing are key skills that may not necessarily be transferable but are critical for freelancers. As a freelancer, you are not just a technical expert, but also a business owner. This means you have to wear multiple hats for your business to succeed.

Vicky Sherwood: The key to my freelancing career has been the contacts and knowledge

I built up during my time as a full-time employee in agencies and big pharma. The exposure to multiple project types during this time provided me with a foundation that I could draw upon to deliver highquality materials for my clients. Equally important is the network that I've built up during my time in agencies. These enabled me to find and work with high-paying clients in the sector, ensuring that I was never short of work as a freelancer.

Morgana Moretti: Technical skills are important, but I believe it's the soft skills that set the best freelance medical writer apart from the pack. Skills like organisation, adaptability, problemsolving, and time management help a project run smoothly and efficiently. These skills many acquired in academia - have been crucial to my success as a freelance medical writer.

Arianna Ferrini: The ability to be resourceful and manage time and projects have been critical for me as a freelancer. As part of my job, I do a lot of training on scientific writing and publishing, so I am often giving presentations. These are public speaking skills I honed during my time in academia. Equally important for one to succeed as a freelancer is the self-motivation and dedication required.

#### Q4. In your opinion, how important is it to have a niche as a medical writer and how does that compare with working in academia?

Rebecca Tadokera: As a new freelancer, it's tempting to think that casting your net wider means you are more likely to get clients. This was my thinking as well when I first started as a

freelancer. The problem with this strategy is that because you are working on so many different pieces, it can get very exhausting. It takes some time to come up to speed with a new area. And again, you become more of a generalist as you only scratch the surface and never really go deep into any particular subject, nor are you recognised as an expert. But then, having said that, sometimes trying out different projects is

good for gaining experience, especially when starting. Only then can you make an informed decision about what you like and would want to pursue more of.

When you think about it, freelance medical writing has parallels with academia. Academics tend to be hyper-focused in a specific niche area. This is the only way to gain recognition, authority, and credibility in the field. In medical writing though, there are different ways of specialising. While some will specialise based on the type of outputs, others will specialise by therapy area. Whichever way you do it, niching

Niching down is

important because

you can build

authority in your

industry and

speak directly to

your ideal client.

DR MORGANA

MORETTI

down is the one way to establish yourself as a freelance medical writer.

Personally, I have narrowed down to the two therapeutic areas that excite me the most: immunology and oncology. I have a preference for continuing educational material continue to do scientific publications and grant writing.

Vicky Sherwood: Employers

tend to like to tap into my cancer research knowledge and at times I've found myself pigeonholed into oncology writing positions. I enjoy oncology writing but sometimes I feel this can be to the detriment of gaining wider therapeutic area expertise. As a freelancer, I found it easier to gain exposure to more diverse therapeutic areas for projects. Agility is helpful as a freelancer. Being able to turn your hand to whatever projects come your way is useful to keep client options open and ensure a steady stream of work as a freelancer.

Morgana Moretti: Niching down is important because you can build authority in your industry and speak directly to your ideal client. In addition, you can focus on training opportunities related to your niche, which translates into significant value for clients. And when you are valuable to clients, you can keep a consistent flow of work coming. A niche in medical writing can be the subject matter you write about, the type of client you work with, or your writing style. This differs from academia, where a niche is usually a research topic or technique in which you choose to become a specialist.

Arianna Ferrini: I think it's important to have a niche and to know what kind of projects you prefer working on and what type of clients you would want to work with. Not so much in terms of therapeutic areas or deliverables. Actually, regarding those, I'd rather keep it varied so I don't get bored!

#### Conclusions

The career transition from academia to freelance medical writing provides fulfilment and flexibility for many ex-academics for whom technical competence, rigour, and scientific acumen have been honed over years of working in academia. Nonetheless, this transition also presents unique challenges, due to the differences between these two fields. Additional skills such as sales and marketing skills are also essential, which most academics do not necessarily acquire during their many years of academic research but are key to success for freelance medical writers.

The key to acquiring these skills is to be open to learning from others in the industry and learning by doing. Medical writers need to have both depth and breadth of expertise. Like in academia, establishing a niche as a freelancer helps you stand out from the crowd and position yourself as an expert. The benefits, of niching down, be it by therapeutic area, type of deliverable, or type of client, are evident in the success of freelance medical writers.

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#### Disclosures and conflicts of interest

The author declares no conflicts of interest.



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Some of her previous work in academia can be found in her Google Scholar profile at:

https://scholar.google.com/citations?user=33yBljYAAAAJ&hl=en

## Soft skills needed for freelance medical writers

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#### **Abstract**

Every professional needs to develop a set of hard skills and soft skills to grow and prosper in a designated field, and freelance medical writers are no exception. However, freelancing requires a unique combination of skills, given the independence and selfmotivation required for continued success not just as a writer but as an entrepreneur. These skills include client communication, networking, leadership, ingenuity, problem solving, time management, and finally, optimism and resilience. Freelancers must continually strive to perfect these soft skills if they want to remain at the top of their game, achieve their goals, and maintain personal growth and professional freedom. This article will discuss these soft skills and how to optimise them for your freelance career.

#### Introduction

uccessful freelance medical writers aren't simply a sum of their writing abilities, research techniques, and in-depth knowledge of science and medicine. These hard skills may help them break into the field, get a little work here and there, and survive just enough to keep their fledgling career afloat. However, it's not until they start to sharpen thier entrepreneurial soft skills that their medical writing business begins to grow and flourish, attracting high-paying clients that continually send them the work they love doing.

Unlike hard skills that require technical training and certificates, soft skills are more like personality traits you develop from experiences throughout your life. Not everyone is blessed with skills to create and manage a thriving business; most freelancers need to work hard to

attain and perfect those skills.

Think of how many medical writers you know who tried the freelancing gig and decided it wasn't right for them. They headed back to fulltime jobs, still as medical writers, but where their responsibility was writing, not running a business. They preferred working on their collaboration and teamwork skills as employees rather than working on all the skills it takes to keep a business running smoothly as entrepreneurs. Apart from teamwork and collaboration skills, entrepreneurial medical writers may also need many other soft skills, to grow and nurture a thriving business that continually brings them multiple referrals and glowing testimonials. In this article, I will give you my insights into the soft skills I believe are key to growing your business as a freelance medical writer.

#### Stellar client communication

It seems as though good communication would be an obvious skill for freelance writers to possess, since writing is communicating. While that's true, writing could be considered a hard skill, while strong communication with clients is a soft skill. This skill could be optimised in the following ways:

- Asking the right and precise questions and actively listening during the first meeting will give you information about what is expected, what is the timeline for deliverables, when they want updates, what are the quality standards, hard deadlines, etc.
- Defining everything upfront will help you create a professional, killer proposal, give you a clear direction on what to do and when to do it, and ultimately give your client the product they envisioned.
- Providing your clients with clarity and transparency throughout the project will keep them happy and ensure you're first on the list when the next project comes up.

#### Networking

Veteran freelancers will be the first to voice their opinion that developing networking skills is imperative when growing a business. This might make all you introverts cringe, but without a strong network and meaningful connections with other freelancers, you may find it difficult to grow your fledgling business.

Newer writers often think building connections with others in the medical writing business, particularly in their niche, is counterintuitive: Those other writers are competing for the same business, right? When you start freelancing, you'll soon discover there is enough business to go around, and the others in your network are happy to recommend you to the clients they are too busy to take on.

Building connections with other writers and potential clients takes practice and effort, but it becomes more manageable as your network grows. There are some proven strategies new freelance medical writers can implement to produce a strong and viable network. Here are a couple of strategies to get started:



- Informational interviews are a good way for new freelancers to meet those more seasoned in the medical writing business. Many people find it daunting to reach out to someone they don't know and ask for a video call, but the more calls you make, the easier it gets. You will discover that many other freelancers were in your position at one time and are happy to lend the same advice that helped them launch their businesses and find success in the profession they love.
- Another way to make essential connections and grow your networking skills is to join organisations like EMWA and the American Medical Writers Association (AMWA). Besides a long list of membership benefits, they also have local chapters and national networking events where you can make irreplaceable contacts; Peter Llewellyn presents an overview of such networking groups in his article in this issue on p. 36. Attending inperson events can be intimidating, but once

you get comfortable, you'll start looking forward to them rather than dreading them.

#### Leadership

Not everyone is a born leader, but it's a skill you can learn and develop as a freelancer.

A great leader possesses multiple hard and soft skills that take time and experience to perfect. Leadership skills include decisiveness and taking responsibility for the decisions you make. It also includes great communication and team-building skills. Clients will want to work with you when they know you can take command of a project from start to finish, and they won't have to worry about the quality of work or whether you will meet the deadline.

Being a leader also means you enjoy sharing your leadership experience to create other great freelancing leaders. The longer you are freelancing in the medical writing business with success, the more other writers will look to you for guidance. You could share this guidance by participating in mentoring programs, creating courses for new writers, presenting educational webinars, or speaking at networking events.

#### Ingenuity and problem-solving

Ingenuity is an extraordinary skill that requires you to be creative, imaginative, and innovative; it will help you find effective solutions to problems in your business, with your clients, and with your writing.

When you work in an office, there are coworkers to bounce ideas off and daily meetings to go over the expectations and details of projects. As a freelancer, you have to figure out a lot of the aspects of a project on your own. Yes, you want to keep the communication lines open with your client to ensure you're on the right track, but you can't call them every day with endless questions because you're not sure what you're doing. The reason they hired a freelancer was to simplify their job and not to have to give daily direction.



You will inevitably receive an offer to do a project that pays well that you've never done before. Rather than turning it down, get your problem-solving skills in gear and use ingenuity to figure out how to get it done. You know you can learn a new skill quickly, and if you have a great network to lean on, you can ask other freelancers for tips on how to do it. Great freelancers don't give up; they figure it out.

#### Time management

Of all the soft skills you possess and continue to work on, time management probably has the greatest impact on your income. After all, time is money.

You should be able to estimate how much time it will take to complete a project, to provide an accurate proposal to the client. You need to

stay on schedule and meet deadlines. If you take longer than expected, you'll lose money. Taking too much time with one project will also take you away from others, which could force you past deadlines. Either way, you risk losing income and future business.

Creating and following daily or weekly schedules can help solve some of your time management problems. Having a schedule can help you track how long certain projects take. You can also flag deadlines. That way, you don't

overlook a project due in two days, knowing you have four days' worth of work left to do on it.

Creating schedules also means you're able to set boundaries with clients. Remember, you became a freelancer so that you would be the boss. If your client starts demanding more of your time, you have to be able to say no, particularly when it cuts time short for your other projects and clients.

You also want to include time for yourself and your family in your daily and weekly schedules. Your business is essential but so is your personal and mental health. Time management is a skill that takes some practice, but once you have mastered it, your freelancing business will be much more enjoyable for you and your family. Also, your clients will find you a joy to work with.

#### Optimism and resilience

I thought it would be best to pair optimism with

resilience because you'll have difficulty building resilience without optimism when times get tough. When you're a freelance writer, you will inevitably face adversity or lulls in your business. Undoubtedly, it takes practice and freelancers need optimism to deal with adversity and resilience to remain optimistic when things aren't going well.

When you are an optimist, it means you can send 60 cold email pitches in three days and feel triumphant when only one of them replies with a Zoom invitation from the director of communications. Believing that one reply is better than none is genuine optimism.

Resilience comes into play when you get on the Zoom call with the Director of Communications only to hear your writing isn't what they're looking for right now. When you click

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"End Call" and close your laptop, the familiar feelings of failure will undoubtedly fill your head. Then comes the imposter syndrome to remind you that you don't have the skills to make a living as a writer, that you certainly aren't cut out to run your own business. Imposter syndrome likes to strike at your lowest and loneliest times, making resilience one of the most challenging soft skills to master. You can't become resilient without experiencing failure and you can't fight

imposter syndrome until you know what it is. As the old saying goes, "Keep your friends close and your enemies closer". Imposter syndrome is the enemy and when you know it well you can fight back hard. Instead of letting it fill your head after hearing your writing isn't quite what the company is looking for right now, you can click "End Call," close your laptop, drink a cup of tea, take a break, and start pitching again. Your resilience will kick the syndrome's butt, leaving it feeling like a failure and you the champion.

Freelancers must learn to develop optimism and resilience on their own. It's not like working as a writer in a large agency where you have coworkers to pick you up after a failure, dust you off, and tell you, "You got this. We know you'll get it right next time!" When you're a freelancer, you must pick yourself up, try again, and not give up. When you learn that the best part of failure is how much you will enjoy success when you find it, you've learned the irreplaceable skills of optimism and resilience.

#### Conclusion: Success with soft skills

Good writing, grammar, SEO practices, marketing, and accounting are important hard skills for freelance writers to master. However, refining your soft skills will take your business to the next level by helping you gain and retain clients, create a network of meaningful connections, achieve personal growth, and ultimately enjoy the freedom you deserve as a successful entrepreneur.

#### Acknowledgements

I would like to express special gratitude to Sophie Ash and Prospology for the support and knowledge her course provided me to grow and develop the hard and soft skills to grow and prosper as an entrepreneur. I'd also like to thank Laura Kehoe and her colleagues for the opportunity to write for Medical Writing's themed issue on freelancing.

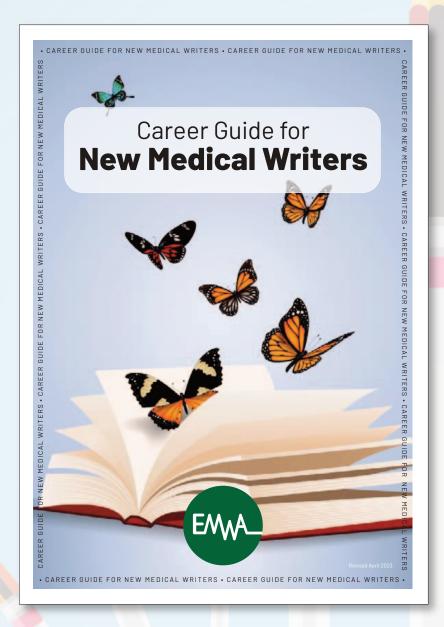
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The author declares no conflicts of interest.



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Career Guide for

## **New Medical Writers**



EMWA's Getting into Medical Writing group announces 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.



## Jumping over and through the obstacles: Navigating the freelance landscape

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#### **Abstract**

This article explores the major challenges and strategies for succeeding as a freelance medical writer. It covers several topics, including finding enough work, managing heavy workloads, ensuring document quality, and carving out time for professional development and financial management. Here, we provide some insights and practical advice to help freelance medical writers overcome these challenges, increase their productivity, and thrive in our profession.

#### Introduction

edical writers come from various backgrounds and our understanding of medical, scientific, and health terminology allow us to work in a wide variety of disciplines, documents, and materials. Roles and opportunities, whether freelance or employment, are evolving, and the demand for medical writers is constantly growing, mainly in pharmaceutical and healthcare communications industries.

Being a freelance medical writer has many positives and it can be extremely attractive due to the possibility of great work flexibility and independence. We can set our own work hours and location, often receiving a higher income compared to an employee, and we get to decide the type of clients to work for and the projects to take on.1 But is it all "fun and games"?

Freelancing generally implies working remotely from a home office, often alone, even before the Covid-19 pandemic. As a result, downsides related to potential mental health

issues due to isolation and lack of social interaction, or troubles in separating work and personal life, do not come as fresh news. Nowadays, with the rise of remote working,2 companies are better equipped and used to remote collaborators, which makes virtual meetings a lot more productive and, overall, a new natural way of working. Moreover, companies are realising the potential of using freelancers to get work done, and that full-time, in-house staff isn't always a requirement.

Therefore, apart from remote working and the recent pandemic, what are in fact the challenges faced by a freelance medical writer? Besides all the pros and cons, what are the day-to-day obstacles that are different in the lives of those who work with no permanent work attachment? Here we provide some food for thought.

## Uncertainty about having enough

Whether you are an experienced or a beginner freelancer, one must make peace with the ups and downs of client work, which means a varied income. We may be lucky enough to have clients on a retainer that help ensure a regular amount of monthly income, but this may come to an end or fall short of our income needs. At some point, the amount of work we get depends on how much work we do to get it.

Securing consistent work and interesting writing opportunities requires resilience and hard work. Developing our own marketing plan,

focused on our client's needs, and our thoughts on how our work can benefit them are key. Once we have identified our key competencies and established business goals, it becomes easier to market ourselves and attract the clients we want. Meanwhile, building a strong network through colleagues and professional associations like EMWA is

a great way to get ourselves well known in the field and for more clients to find us through referrals.3

## Having a lot more work than one can

On the flip side, and if we do things right, we may find ourselves in the exact opposite situation: having more work than we can handle.

One of the things that we need to learn is that sometimes we need to say "no" and take on some strategies to preserve our personal life and work balance, and consequently, keep our mental health intact.4

While this is a crucial aspect of freelancing, achieving it can be challenging. That's why we must consider several factors before making decisions. Distinguishing a good project opportunity from a bad one is an essential skill to acquire. In a good opportunity, the medical writer and the client should be aligned, with common expectations regarding each parties responsibilities. Generally, good opportunities pay well, but deadlines (especially the unreasonable ones) should be considered. Also, when deciding whether a project opportunity is good or bad, it is important to consider potential future referrals or projects that may arise from accepting a project, as well as the opportunity to gain experience in a specific topic.2

A strong network is again beneficial, not only for eventually getting references about a potential client (hence making the wisest decision) but also if referring or outsourcing to colleagues is the only way to help the client get the job done.

#### Improve/ensure document quality

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Quality is paramount in the world of medical writing, especially if we want to work on the best project opportunities. A common challenge faced by freelance medical writers is the need to balance multiple projects simultaneously. This can be overwhelming at times and result in a decreased focus on each individual project. As a result, the quality of the documents

produced may suffer. In addition, tight deadlines can create extra pressure to produce high-quality documents quickly, which can lead to mistakes and oversights. Despite these challenges, there are multiple strategies to improve the overall quality of the documents produced.

An effective way to improve document quality is to create a clear and detailed plan that outlines the specific requirements of each project. This can help to ensure that all necessary information is included and that the document is organised in a logical and easy-to-follow manner.

It is also important to make sure we are meeting our own and our client's quality standards. For instance, editing tools can help us identify grammar mistakes and save us a lot of time when proofreading documents. Most of them provide vocabulary solutions that can help clarify content and even reduce word count if needed.

Finally, a strong network of trustworthy fellow medical writers may also come in handy when it comes to proofreading and scrutinising documents. By collaborating with other professionals, we can leverage their expertise and ensure that the documents produced are of the highest possible quality.

#### Training and keeping up-to-date

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In freelance medical writing, staying up to date with the latest research and trends is critical for

success. All medical fields and our profession are constantly evolving, new discoveries are made every day, and it is up to us to reach out and obtain this knowledge.

To stay on top of one's game, we must be committed to ongoing professional development. This can include attending EMWA conferences, relevant

workshops and webinars, and training sessions. Many other professional organisations, found online, also offer certification programs that can help us progress in training, gain expertise, and stay up to date on best practices.

Another key aspect of staying up-to-date is reading relevant literature, guidelines, updates, and relevant standard operations procedures (SOP). We should make a habit of regularly reviewing academic journals and other publications to stay current on the latest research and trends in the field. It is crucial that we set aside dedicated time, such as 30 minutes per day or a morning each week, to fit reading into our tight schedules. Also, using technology to our advantage, such as listening to audiobooks or podcasts on relevant materials while commuting or doing other tasks, can be a smart approach.

#### Financial management

As freelance medical writers, we are responsible for managing our own finances, which can be a daunting task. This includes everything from setting rates and invoicing clients, to managing taxes and retirement planning.

One way to overcome this challenge is to



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educate ourselves on basic financial principles as well as to seek advice from fellow freelancers and professionals in the finance field. Since all

countries have different policies when it comes to setting up or being self-employed, understanding the rules in our own country is key to ensuring our freelance business runs smoothly. This can include hiring an accountant to help with taxes and budgeting. As freelance workers, we should also be diligent in tracking our expenses and income, so we can make informed decisions about pricing and invoicing.

Notably, one's experience will play an important role in finding strategies to quote for projects, and these are bound to evolve with your increased work experience. For example, lower prices and more time invested at the beginning of your career will eventually evolve to increasing or maintaining prices, but using less time to complete a project.

It is also wise to set aside funds for unexpected expenses and emergencies. This can involve establishing an emergency savings fund or subscribing to an insurance plan to protect us against unforeseen events such as illness or injury.

#### Lack of benefits

The lack of access to traditional employee benefits such as retirement plans, health/ professional insurance, paid time off, or sick leave can make it difficult for us to manage our personal and professional lives and can have a huge impact on our overall job satisfaction.

One way to address this challenge is to seek

out alternative benefits. For example, we can search for indemnity insurance plans provided by professional organisations, or eventually partner

> with other freelancers to create a shared retirement plan. Another option is to negotiate with clients for benefits such as paid time off or professional insurance. While this may not be possible in all cases, it is definitely worth exploring. Forward thinking and putting money aside so holiday time does not come as an additional stress because we are not getting paid can also be helpful, as well as asking other freelancers how

they deal with this situation.

Overall, while the lack of benefits is probably the most significant challenge one can face, careful planning, by considering all the expenses when quoting projects, and diligence can help us save up more money and enjoy a successful and fulfilling career as freelance medical writers.

Given the importance of this topic, in 2021, EMWA members were asked to participate in a salary and compensation survey. The results were published in 2022,5 aiming to provide some guidance on this matter for medical writers, both company employees and freelancers.

#### Final thoughts

Freelancing can be a profitable and rewarding way of working, but it doesn't come without its challenges. Here, we list just some of the challenges we have faced during our journey as freelance medical writers and that we work tirelessly to overcome. What about you? Don't let these challenges overwhelm you, speak to other freelancers who can offer advice. We would love

to hear from you about how you have tackled your own challenges. Please share your experience with us by reaching out to the email address provided at the beginning of this article

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The authors declare no conflicts of interest.

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

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Fernando Oliveira, PhD, is a freelance medical writer who holds a PhD in Bioengineering. With over 10 years of experience in academia as a researcher in medical biotechnology and infectious diseases, he started his journey into medical communications as a freelancer.

## **EMWA Future Conference** Virtual Conference

## November 9-16, 2023

The EMWA spring and autumn conferences provide a medium for networking, active discussions and extensive cost-effective professional training. It is also an opportunity to benefit from the experiences of other medical writers.

The venues, facilities, and training programmes are chosen to offer the best possible learning environment. In addition to the formal training sessions, a relaxed, friendly conference atmosphere provides for ideal networking opportunities and enables all those attending to meet medical writers and communicators at all stages in their careers.





# How can coaching or mentoring help you craft a sustainable freelance career?

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#### **Abstract**

Crafting a sustainable freelance MedComms career can be challenging. As freelancers, we need to understand our individual requirements to design and implement a freelance business that will work from a personal *and* a professional perspective. Support from a coach or mentor can help freelancers define these requirements and create a realistic plan to craft a business that will meet them.

#### Introduction

went freelance in 2018 because I had a young family and wanted to work in a flexible way. After 14 years in agencies, I'd had enough of the long hours, regular travel, and the feeling that no matter how hard I worked, there was always more to do. Freelance work would let

me set my own boundaries, pick and choose the projects that appealed, and I would never miss a school concert or sports day. Heaven!

In reality, this scenario doesn't happen unless you build it. Simply working for yourself isn't a magic formula to having rewarding projects and a perfect work-life balance, but creating a sustainable freelance career *is* possible. In this article, I will explore what a sustainable freelance career really is, some of the barriers that can make it hard to achieve, how coaching or mentoring could help you overcome them, and where to find appropriate support so that you can have the career that's right for you.

## What is a sustainable freelance career?

A career isn't a fixed thing – we evolve over time, and what suits, motivates, and challenges us will change with experience and different life stages. In Figure 1, I have outlined key elements of how I define a sustainable freelance career, but just like

careers themselves, there is no onesize-fits-all answer. Understanding what your ideal situation is, and proactively shaping how you're working to move towards that, is part of having a sustainable career. Another factor to consider is that we must sometimes move on from things that were right for us once, but now no longer work in the way they did before.

Julia Davies, qualified coach and freelance medical editor, highlighted to me the active "unlearning" process that can be a useful part of crafting a sustainable freelance career. "There is no single 'correct' way to do certain things – there's only the right way for *you*, and that can also change over time," she explained. "If you take agency life

and apply it to your new freelance life, this can lead to burnout, and an intensification of the issues you wanted to escape. It takes time and effort to consciously decide what sort of freelance business you want to have, and to implement that. It's not just a case of continuing the role you were doing in-house – as a freelancer you now run your own business."

There are a variety of other barriers that can prevent us creating a sustainable freelance career, and I have listed some examples of these in Figure 2. These are based on my own experience, plus my work with many freelancers, both as the person booking and briefing them within several agencies, and as a friend or professional mentor to others.<sup>2</sup> Again, these are merely examples of the barriers that freelancers may experience, rather than an exhaustive list.

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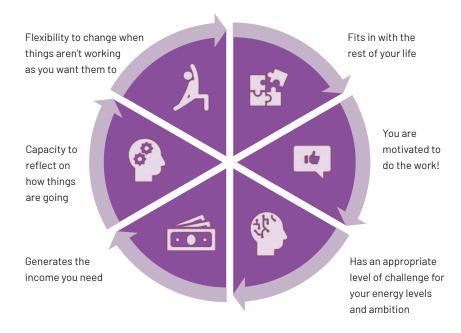


Figure 1. Potential elements of a sustainable freelance career



Figure 2. Potential barriers to a sustainable freelance career

#### Key questions for designing a sustainable freelance business

Taking the time to design the freelance business that suits you and your experience, skills, values, and requirements is daunting when you're caught in the hamster wheel of deadlines. However, it can be broken down into smaller questions, each of which could be considered separately, allowing you to gradually build up a picture of your current and ideal situations. Below, I suggest some questions you could use as a starting point for designing your sustainable freelance business.

If these questions bring up more questions or uncover deeper uncertainty that you are struggling to resolve, the book You Coach You by Helen Tupper and Sarah Ellis is full of insights and practical ideas to help you find your way.3 Helen and Sarah are co-founders of Amazing If, a company with a mission to make careers better for everyone, and presenters of the Squiggly

Careers podcast.<sup>4</sup> They champion the career "squiggles" that are part of modern working lives and, besides their books, their website offers a plethora of free resources.5

#### What can we do as individuals to create a sustainable freelance career?

#### Ask for feedback

As freelancers, we often don't get the same level of feedback as in-house team members. Providing detailed feedback to freelancers is often regarded as a poor use of time by agencies. But that doesn't mean that as freelancers we should stop hoping for feedback! Instead, we can make it easier for our clients to give quick and simple feedback.

In the Squiggly Careers podcast episode on "How to give and get fast and frequent feedback",6 Helen Tupper and Sarah Ellis provide multiple recommendations, including asking about one thing that was useful and one thing that was missing or asking how a similar project could be "even better if..." - two feedback frameworks that would enable clients to respond very quickly. Including simple questions like these when submitting work, or in a follow-up a few days later, won't guarantee you receive feedback, but would make it more likely that some clients will respond. Taking on board the insights you receive will help you focus time on aspects of your work where you may need to improve or find new processes, plus reinforce things that are working well.

#### Reflect on your work regularly

While clients may not always give us feedback, there are usually some lessons we can learn from any piece of work. Noting down things that went

#### Key questions to consider when designing a sustainable freelance business

#### Outside work, what other responsibilities or ambitions do you have?

- Do these currently get adequate time and focus in your life?
- How are these likely to change or develop over the next few years?

#### How much do you need to earn per month?

- Do you have a plan for ensuring you have this amount of work booked in each month, and a financial buffer for quiet months?
- If you have this amount booked, do you also have time for working on your business (e.g. finances, training, planning, networking, etc)?

#### In an ideal world, how would you structure your working days, weeks, and months?

- How do your current working patterns compare with this ideal?
- Are you able to proactively plan your time and stick to it, with a work-life balance you are happy with?

#### What kinds of project and/or therapy areas do you want to specialise in?

- If you're offered work in other project types or areas, how do you respond?
- Do you have a website or other method for sharing your specialities or preferences with prospective clients?

#### How do you want your business to develop over time?

Do you have a business development strategy, including training to develop your skills, and contacts to cultivate into potential new clients?

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well in a project, or what we particularly enjoyed, will help us use this knowledge in future work. Considering things that were more challenging makes it easier to come up with solutions or

alternative processes to try next time. If we leave it until we are doing a similar project again, we may have forgotten the insights that seem obvious immediately after finishing a piece of work. Thinking back over a project will also help us focus on the kind of work we want to do more of or the clients we want to collaborate with again.

If clients do give us feedback, we should obviously consider its implications for future work and potentially develop strategies to incorporate any learnings into our processes. We can also record

particularly good feedback into a Smile File compliments and appreciative comments can be so motivating on the days when everything seems to be going wrong.

It's also worth giving ourselves a pat on the back for a job well done when we've finished working on something, rather than instantly switching to the next item on the to-do list. Having a break, if only for a moment, helps us internalise the achievement. I've recently started a new notebook for recording what I've achieved in my business. Each month, I jot down key projects I've completed, hurdles I've overcome, and new clients I've started working with. If we don't memorialise these things, they can blur into one. Without the regular reflection of line manager one-to-ones or appraisals, we can feel like we're working all the time without really achieving anything!

#### Become part of a peer community

As a freelancer, one can feel very isolated. The confidentiality of pharma projects means we are trained from Day 1 that we shouldn't talk about

> our work outside of our teams and. as freelancers, we no longer have that team to help us let off steam. Cultivating a network of peers in the industry, both freelance and inhouse, can open up opportunities for peer mentoring and support. This could be as simple as keeping in touch with ex-colleagues, signing up for freelancer meet-ups (virtual or inperson), or contributing to LinkedIn groups. Peter Llewellyn explores this topic in more detail in another article in this edition on p. 36.

> If we talk about projects in a general way, redacting any client-

related content, we could hear about new trends or interesting opportunities, while also creating scope for acting as reciprocal peer mentors within our networks. An additional benefit of this is that it will almost certainly help you develop your skills and approaches too – explaining something to someone else is invaluable for making sure we really understand a concept.

#### How can coaching or mentoring help support a sustainable freelance career?

Often when we're struggling with something, there are two things that we really need:

- 1. The time to focus on the issue and find potential solutions
- 2. A sounding-board to talk through our ideas

This is where coaching or mentoring can be valuable. Paying for support means dedicating time to it, forcing us to take this commitment to ourselves and our business more seriously than if we were trying to fix things alone. It's the same rationale as paying a personal trainer even when we know we could create our own training plan. The ring-fenced time, and the professional we are working with, ensure we actually show up and do the work. And once we're there, other commitments and issues can fade into the background, making it much more likely that we will make progress on the specific challenges we need to overcome.

Furthermore, talking things through with someone who has experienced similar challenges or supported people in similar situations means we can learn from pooled experience rather than having to find our own way through every potential set-back.

#### Do you need a mentor or a coach?

While there is a lot of overlap, a mentor will usually have specific experience for you to draw upon, while a coach has more general training to help you reflect on your challenges and find your own way through. The lines between the two can be rather blurred, with mentors using elements of coaching in their practice, and vice versa.

#### Coaching

If you're struggling to define exactly what your challenge is, but you know something isn't working, it might be helpful to work with a coach. Charlotte Rooney, Burnout and Mindset Coach at A Half Managed Mind,7 explained to me that, "A coach is there to help you understand yourself better, working with you to define what you want, and how you can move towards getting it".

#### Typical challenges I support freelancers with as the MedComms Mentor

#### Skills gaps

- How to approach a particular type of project
- How to handle working with multiple freelance clients

#### Confidence gaps

- Approaching potential clients who are not current contacts
- Handling conversations around contracts or finances with clients

#### Career crossroads

- Designing and implementing a sustainable freelance business strategy that will fit their values and requirements
- Finding a permanent job that would actually suit them better than freelancing



A coach could also help you with challenges that aren't MedComms-specific, including burn-

out, issues around motivation, productivity, or work-life balance, and more general mindset or business challenges.

#### Mentoring

A mentor will usually have direct experience that's relevant to the challenges you are facing. They will use this experience to help you develop your skills, understand potential directions you could take, and highlight tools you could use to overcome those challenges. In the

chart on p. 70, I have outlined typical challenges that I support freelance clients with when working as the MedComms Mentor.

I work with clients to elucidate the possibilities open to them and use my experience to help them explore what will be the best fit for them. We then work together to build practical steps mapped out against a realistic timeframe to turn the possibilities into a solid reality.

#### Finding the right support

It is important to find a coach or mentor who you can open up to and explore potentially uncomfortable topics in a supported and respectful way. While coaching and mentoring is not a

regulated industry, most professionals will outline their credentials, ethos, and approach on

Whether

we are sole

traders or

operating as

directors of

our own little

company, we

are running

a freelance

business.

their websites. Many will offer a free consultation to let you get to know them and their methodology before making a decision. Use these resources to find someone you "click" with before you sign up for paid sessions.

But you don't necessarily need to pay someone! Mentors can be people you know, who are happy to have a coffee and chat to discuss how they've approached a challenge similar to something you're facing. If you're setting up an

informal mentoring relationship, resources from the Academy of Medical Sciences could be useful.<sup>8</sup> They have a series of tools covering mentoring topics such as types of mentoring relationships, helpful questions for mentors and mentees, and approaches for virtual versus inperson mentoring conversations.

Mentors can also be at a distance – people who you're not in regular contact with. When I was first promoted into a team leadership position, I would regularly ask myself, "What would Gary do?", when faced with tricky situations. He had been my line manager at a previous company and taught me so much that, even when we weren't working together

anymore, I could imagine how he would respond. This approach helped me sense-check my instincts before making decisions, giving me the confidence to do what was needed. Maybe you have someone from your past or among your current connections who you could think of as your "unofficial mentor", even if you aren't actually working with them on the things you're finding challenging.

#### Conclusion

Becoming a freelance writer or editor seems like a simple transition for someone with agency experience. It feels like a continuation of using the same skills but with greater control over how and when the work is done, and often a higher earning capacity. But that higher rate comes with strings attached that may appear innocuous until we find ourselves caught in them. No longer being an employee means we are responsible for everything - we must find our own work, manage our own projects, set our own rates, pay our own taxes, and send our own invoices. These considerations are new to many freelancers coming from an employment background and can seem like "additional" tasks that need to be slotted around the projects that "should" comprise our working time. In addition, training and professional development opportunities and benefits, like pensions and paid sick leave or holidays, disappear when we are forging our own business.





That is the crux of it - whether we are sole traders or operating as directors of our own little company, we are running a freelance business. But that's not how we usually describe ourselves or how we see our work. Without that entrepreneurial mindset, though, we will often find ourselves struggling to find time for the non-MedComms elements, unintentionally replicating the working practices we intended to leave behind and wondering why it all feels so challenging.

However, with the right support – whether that's from a professional coach or mentor, peers within the industry, or role models we don't know personally - we can overcome our individual challenges and have the confidence to create a sustainable freelance business that will become a long-term, fulfilling career.

#### **Acknowledgements**

The author would like to thank Julia Davies (qualified coach and freelance medical editor) and Charlotte Rooney (Burnout and Mindset Coach at A Half Managed Mind) for their insights during the drafting process and their review of the final manuscript.

#### **Disclaimers**

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

#### Disclosures and conflicts of interest

Eleanor Steele works as the MedComms Mentor, providing professional training, mentoring and consultancy to MedComms clients.

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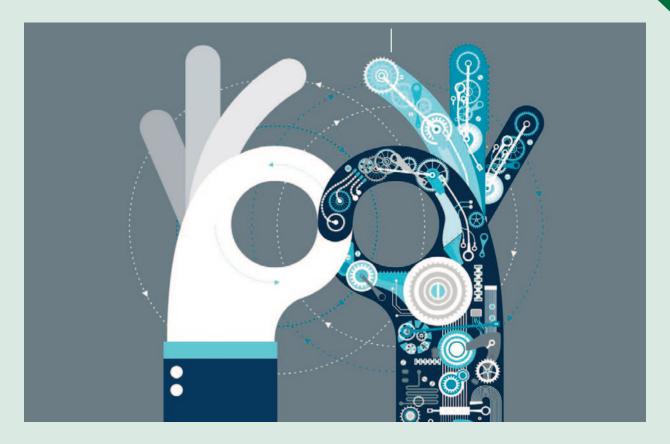
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#### **Author information**

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.

## The September 2023 edition



## **Automation/Software**

Streamlined complex medical report writing supported by artificial intelligence/machine learning is making its way into clinical regulatory writing. The medical writing automation's goal is to speed up and ease clinical development processes by reducing the time and cost involved in creating and keeping regulatory documents up to date. This issue will examine current issues, challenges, and opportunities towards human guided medical writing automation systems.

Guest Editors: Shiri Diskin and Daniela Kamir

# The need for community:

# The importance of networking as a freelance medical writer

#### Peter Llewellyn

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10.56012/etqg2327

#### Correspondence to:

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#### **Abstract**

Community and networking activity can really help when you are a freelancer.

Who do you turn to when it all gets too much? Can someone, anyone, who understands your challenges, offer a sympathetic ear and help to work out a solution?

Where do clients magically appear from? Are they all lovely to work with, let alone grateful? Do you understand the contracts they ask you to sign? Have you Professional Indemnity and other insurances (do you need them anyway)? What about taxes? Do you need an accountant? Who deals with invoices (in and out) and chases money when needed? Who helps when the laptop stops working, the software needs updating, or the client imposes their own IT systems on you? Remember that training your previous employer provided - how do you stay current now? So many practical questions. Read on for inspiration and support from across the global community of freelance medical writers.

#### Here's a short story...

ong, long ago, working life was much simpler, freelance medical writers were scarcer than they are today, and work assignments could have been agreed to during a quick phone call. Here in Oxfordshire, several local freelance writers and editors would meet occasionally for coffee, cake, and gossip. I doubt

they talked much about work. They were friends who had worked together and now simply stayed in touch. One day, however, someone mentioned how they were fed up chasing overdue payments from a particular client. It turned out, they all had the same problem with the same client. The next day, the company in question heard from all of them and promptly paid up, rather than risk losing their services forthwith!

I've often quoted that story to make a simple point. A freelance medical writer is running a business. To run a business successfully, you need to act like one. Invest in your business, in yourself.

As a freelancer,

you will

confidently wear

many hats, but

you will need

help, at least

sometimes.

As a freelancer, you will confidently wear many hats, but you will need help, at least sometimes. It helps to have someone on your side.

#### The benefits of networking...

I asked my new intern to imagine they are a freelance medical writer and to describe to other medical writers the benefits of networking. Here's what they wrote:

"As a freelance medical writer, networking can be a crucial aspect of your success in the field. There are several benefits to building and maintaining a strong network of contacts within the medical writing community:

- 1. Opportunities for collaboration: Networking can help you find potential collaborators and co-authors for future projects. Working with other writers can help you gain new perspectives and ideas, and can also help you build your portfolio and reputation.
- 2. Industry insights: By connecting with other medical writers, you can gain access to insider knowledge and information about the industry. You can learn about new trends and technologies and stay up-to-date with the latest standards and regulations.
- 3. Client acquisition: Building a strong network can also help you find new clients and

- opportunities for work. Your network can help you get your name out there and make new connections that can lead to new projects and income.
- 4. Professional development: Networking can also help you grow as a professional. By connecting with others in the field, you can learn new skills, gain new knowledge, and stay motivated and inspired.
- 5. Support system: Finally, having a network of contacts within the medical writing community can provide you with a supportive community. You can turn to

others for advice, feedback, and encouragement, and can build relationships that can last a lifetime.

In conclusion, networking can be an invaluable tool for freelance medical writers. By taking the time to build and maintain a strong network, you can take your career to the next level and enjoy all the benefits that come with being part of a supportive and dynamic

It helps to have someone on community." your side. I couldn't write it better myself. So, full marks to ChatGPT!

> It turns out the world is full of freelance medical writers. Many are happy to meet occasionally for coffee, cake, and gossip, maybe locally in-person or maybe online across time zones. And many happily support each other in an ever-more complicated business world.

> If I search for "freelance medical writer" on LinkedIn - always a great place to start looking for people - I find more than 100,000 names, obviously too many to make friends with all at once, but a useful reminder that there are plenty out there.

A sensible place to start, then, is by looking for the communities of most interest.



#### The more formal...

To state the obvious, the publisher of this journal, the European Medical Writers Association (EMWA), which currently boasts more than 1,000 members from 39 different countries (including 12 countries outside Europe), already provides a host of opportunities to build a relevant professional network. You can attend annual conferences and educational workshops and participate in a wealth of online activity. EMWA's Freelance Forum, chaired by Laura Kehoe, provides a perfect meeting point for anyone who freelances in and around medical writing.

Looking around, it's easy to find other large, international professional membership organisations, such as The American Medical Writers Association (AMWA), The Australasian Medical Writers Association (AMWA), The Chartered Institute of Editing and Proofreading (CIEP), and The International Society for Medical Publication Professionals (ISMPP) to name but a few. All welcome new members from anywhere and all offer a range of valuable opportunities to

learn, to meet, and to share experiences with other like-minded freelancers. To state another obvious point, though, they each have a different focus, whether that is their primary geographical scope or their specialist discipline, and will suit some individuals but not others.

Other much smaller groups also offer interesting paid-for networking opportunities for subscribers. My own MedComms Workbook for freelancers comes into that category.

Another is The Anthill, run by Abigale Miller in Canada. Abigale writes, "The core Anthill community is a paid membership format that includes access to our online community platform and regular events like work sprints, weekly planning calls, book clubs, study sessions, and more. Being in The Anthill provides some of the benefits of being in an office, especially having colleagues to chat with, learn from, and troubleshoot with. It's possible to make deep, trusting relationships with fellow writers who understand how medical writing works. We cater mostly to freelancers, but around 25% of our members are full-time employees who are either

thinking of moving to freelance or who want some more connection beyond their company."

#### The less formal...

What about simply sticking with the idea of informal coffee, cake, and gossip with likeminded folks?

Kathryn White has been a freelance medical writer for many years in the UK and early on saw the value in meeting with other freelancers. Kathryn began organising small, informal local meetings, sometimes inviting additional speakers to join them. Starting with known friends and over time attracting other participants as word spread, the group remained active during pandemic lockdowns and beyond. She writes, "My lovely group of fellow writers has helped me keep my sanity - knowing I'm not alone in the issues I face as a business owner and medical writer is a comfort. The feedback I often receive during or after our meet-ups or Zoom calls is: "Phew, it's good to know it's not just me!""

Over the years I've encouraged many freelancers to start their own local activities. Some kept going, many didn't! It takes perseverance and some luck along the way, but the rewards are there for everyone. Can you find a group that suits you? If not, how about starting something yourself?

For this article I sought - and found inspiration from across the international community of freelance medical writers.

Corinne Swainger organises an informal group in Northwest (NW) London. In practice, several members of the group travel into London to meet. That's maybe something to do with the fact that evening meetings are arranged every 3 to 4 months at different local/regional pubs and restaurants. They are convivial affairs. Corinne writes, "We all agree that we're more likely to mix personally and professionally as part of a small, 'in-person' group, versus a large in-person group, or an online group. At the NW London meetings, we usually have a good laugh and enjoy the chance to discuss issues that may concern some members."

In Yorkshire, Vicki Evans counts freelancers and employees amongst their group. Vicki writes, "The group is more than just work, not only have we developed friendships over the years, we also support each other with work, juggling family time, passing work between us and recommendations and basically, just being there for each other."

Of course, technology now means there are no borders. As an early adopter of Zoom, which proved transformative for my activities, I started arranging online video meetings of the New Zealand Medical Writers. I was in Oxford, late at night with a whiskey in hand, chatting to participants from across New Zealand and beyond, while they enjoyed morning coffees. Clearly, though, it was best organised locally. Amanda Xiaoqing Mao from Australia helped pick up the baton from me after a couple of years and the activity expanded within the region. She writes, "There is a gap in the MedComms community in the Asia Pacific region - on the one hand, to stay up to date with the latest trends, best practices, and global developments in the field; and on the other hand, to build

relationships, exchange ideas, and learn from one another. Asia Pacific (APAC) MedComms Network was established to fill the gap."

#### Across the community, approaches vary widely...

From the USA, Carla Eisenstein created The Coffee Chat Group as a social space for medical writers to connect with each other. She writes, "I make sure and meet everyone before they

join. I want the group to be a good mix of beginners, midcareer writers, and veteran writers. Freelancers and employees are welcome in the

After a conversation at an EMWA event in

2016, Carola Krause and Paul Wafula decided to expand informal networking activities among medical writers and communicators in the Berlin area in Germany. They write, "Initially, the objective of the Medical Writers' informal gathering, Berlin and Brandenburg Group was simple but effective; to create an opportunity to help and support each other in solving daily challenges affecting freelancers in their businesses, or even simply to just interact and get to know colleagues in our local areas."

The Scientific and Medical Writers Network (SMWN) organises face-to-face and online networking and skill-sharing events for science

These local and

international

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writers to talk,

share knowledge,

and gossip.

and medical writers in Benelux. Online events are also open to those outside Benelux. Cofounder Jackie Johnson writes, "The value of our network is in the members. We are a very closeknit group (considering we have over 100 members), and it's common to share jobs, best practices, tools, and tips within the group. The face-to-face events are a great way to engage with our local community, keep in touch, and supplement the bi-annual

EMWA events at a much lower cost."

The Swiss Medical Writers & Communicators group is a private LinkedIn group co-founded by Laura Kehoe and Raquel Billiones to bring together the many medical writers and

#### Groups to join

- The American Medical Writers Association (AMWA): https://www.amwa.org/
- The Anthill: https://the-anthill.mn.co/
- Asociación Española de Redactores de Textos Médicos (AERTeM): https://redactoresmedicos.es/
- Associação Portuguesa de Medical Writers (APMW): http://apmw.pt/ or https://www.linkedin.com/company/apmw.pt/
- The Australasian Medical Writers Association (AMWA): https://www.medicalwriters.org/
- Chartered Institute of Editing and Proofreading (CIEP): https://www.ciep.uk/
- The Coffee Chat Group: https://www.linkedin.com/groups/13912874/
- EMWA's Freelance Forum: https://www.emwa.org/freelance/
- Freelance medical writers based in UK & Ireland: https://www.linkedin.com/groups/12729342/
- Grupo Sudamericano de Medical Writing (GSMW): https://www.linkedin.com/groups/9176993/
- International Society for Medical Publication Professionals (ISMPP): https://www.ismpp.org/
- Medical Writer's Hub France: https://www.linkedin.com/groups/5173211/
- Medical Writers' informal gathering, Berlin and Brandenburg Group: https://www.linkedin.com/groups/8553972/
- Medical writing for beginners and beyond (free resources): https://www.linkedin.com/groups/9110350/
- Science and Medical Writers (SMWN): https://www.linkedin.com/groups/12126629/
- South African Medcomms Professionals Network: https://www.linkedin.com/groups/12703690/
- Swiss Medical Writers & Communicators: https://www.linkedin.com/groups/9071340/



communicators in Switzerland. They write, "The group currently has 73 members, [is] free to join, [and] members are either invited or request to join. Once a member, people are free to post questions or interesting items to others, and after two successful face-to-face meetings, we're trying to arrange more throughout Switzerland."

In South Africa, Rebecca Tadokera has been reaching out to other writers. "As a freelancer working in a place where medcomms is still very new, I had to rely heavily on my network. Most of what I know now I have learnt through my networks. The majority of my clients have been referrals through my networks, both national and international. I have seen first-hand the value of networking, that is why I am trying to build a community of freelancer medcomms professionals in South Africa."

#### A need for national activity...

Language is often a driving force for the development of national initiatives, but also the desire to champion local policies.

Amy Whereat writes that she "started the French medical writers' group as an informal social networking group among a group of English-speaking medical writers in France, who would meet regularly in Paris. The group soon gained attention from French-speaking writers and became the Medical Writer's Hub France. The hub united a heterogeneous group of freelance and pharma medical writers, medcomms writers, translators, and medical communication activists."

Interestingly, Amy goes on to explain, with Trevor Stanbury and Marie-Odile Faure, "we made the decision to develop a more formal Association, known as The French League of Writers (FLOW), in order to help make the medical writing profession become more visible, solve national problems as a group, and to support a growing list of local projects the group wants to achieve."

In Portugal, Maria Almeida has been involved in establishing the Associação Portuguesa de Medical Writers (APMW). It started as an informal meeting, but it was soon decided that something more formal would be useful. Face-to-face and online events are conducted in Portuguese. Maria writes, "this group is a way to help people come into the profession, for medical writers in Portugal to meet each other, and for everyone to learn more."

Evguenia Alechine started an informal Spanish-speaking medical writing group mainly for people in South/Latin America. Grupo Sudamericano de Medical Writing (GSMW) runs as a LinkedIn group. Evguenia writes, "The South/Latin American medical writing scene is completely different from those currently existing in North America or Europe. There is still not that much awareness about medical writing as a career opportunity in our countries, so our primary focus is to increase that awareness and offer both networking and training opportunities to group members."

The Asociación Española de Redactores de Textos Médicos (AERTeM) is a not-for-profit organisation initiated in 2005, and currently has a membership of 143 medical writers from Spanish-speaking countries, mainly Spain. Although the association is open to anyone, 70% of members are freelancers. Matias Rey writes, "Our association's raison d'être is to offer support to Spanish-speaking medical writers by actively working to stimulate the correct usage of Spanish in scientific publications, and to defend the dignity of this professional activity by

#### People to meet

- Evguenia Alechine: https://www.linkedin.com/in/evgueniaalechine/
- Maria Almeida: https://www.linkedin.com/in/maryjohn75/
- Raquel Billiones: https://www.linkedin.com/in/raquelbilliones/
- Laura C. Collada Ali: https://www.linkedin.com/in/laura-c-collada-ali-6a9a4625/
- Virginia Chachati: https://www.linkedin.com/in/virginiachachati/
- Johanna Chester: https://www.linkedin.com/in/johanna-chester-34a55b4a/
- Carla Eisentein: https://www.linkedin.com/in/carla-eisenstein/
- Vicki Evans: https://www.linkedin.com/in/vickievansfreelancer/
- Marie-Odile Faure: https://www.linkedin.com/in/marie-odile-faure-7b51336a/
- Rachel Hassan: https://www.linkedin.com/in/rachelhassan/
- Jackie Johnson: https://www.linkedin.com/in/johnsonjackie/
- Laura Kehoe: https://www.linkedin.com/in/laura-a-kehoe-phd-93893982/
- Carola Krause: https://www.linkedin.com/in/carola-krause-198344a5/
- Amanda Xiaoqing Mao: https://www.linkedin.com/in/amandamao/
- Abigale Miller: https://www.linkedin.com/in/abigalemiller/
- Matias Rey: https://www.linkedin.com/in/matias-rey-carrizo/
- Andrea Rossi: https://www.linkedin.com/in/andrea-rossi-ab95577/
- Trevor Stanbury: https://www.linkedin.com/in/trevor-stanbury-b95388100/
- Corinne Swainger: https://www.linkedin.com/in/corinneswainger/
- Rebecca Tadokera: https://www.linkedin.com/in/rebeccatadokeramedicalwriter/
- Mina Varsani: https://www.linkedin.com/in/minavarsani/
- Paul Wafula: https://www.linkedin.com/in/paul-wafula-phd-b301a15/
- Amy Whereat: https://www.linkedin.com/in/amy-whereat-3b7550a/
- Kathryn White: https://www.linkedin.com/in/kathrynewhite/





abolishing ghostwriting and fostering the public acknowledgement of medical writing professionals. The main strength of the AERTeM lies in the Executive Committee's (past and present) efforts to offer to our members an array of tools for them to become the medical writers they want to be."

Andrea Rossi, Laura C. Collada Ali, and Johanna Chester are creating a national network of medical writing professionals in Italy to reach out to aspiring and current medical writers, scientific communicators, university researchers, clinicians, and scientific journalists living and working in Italy or beyond. Various aspects of the medical writing profession, both from international and national perspectives, will be openly debated in Italian. They write, "A hardy and active network offers strength in numbers, and for common objectives, such as promoting the medical writing profession and ever improving the level of national recognition of medical writers' contribution to science, national initiatives in the local language, can and should be exploited."

EMWA is helping to start the Italian network activity and is interested in supporting more such national initiatives. Enquiries to Head Office are welcomed.

#### Something for everyone...

Despite all this activity, nothing ever quite suits everyone. Here are two more, very different, examples of newer groups.

After meeting at an in-person MedComms Networking event last year, Rachel Hassan and Mina Varsani set up a new dedicated LinkedIn group for freelance medical writers based in the

UK and Ireland. Rachel writes, "I think shared knowledge and community are so important in an industry like ours. I couldn't find any groups that were private and with only freelance medical writers. I decided to set one up." Mina agreed it would be useful to have a group more specifically tailored to their needs, and writes, "It's been so helpful having a group of friendly freelancers to ask questions or to share experiences with. It really

helps to break the isolation of freelancing." Virginia Chachati also started a LinkedIn

group, little more than a year ago, and it has already grown to more than 2,000 members, Medical writing for beginners and beyond (free resources). She writes, "I wanted to really celebrate the journey we take to become medical writers, and also work together to network, make valuable personal and human connections, improve how much we charge for medical writing services, discuss the best way to

produce medical writing content, and answer practical questions. I wanted to create a supportive and "safe" space for people to discuss their concerns without fear of being judged out in the open. And people could use the space to connect with others, find job opportunities, try out different paths in medical writing, and then pursue whatever suits them most - by making an informed decision!"

Conclusion...

My aim in this article was to highlight the benefits and opportunities out there for freelance medical writers to network. The medical writing community is expanding globally, as the profession is getting more and more established. These local and international networks and groups provide an essential platform for medical writers to talk, share knowledge, and gossip. There does seem to be something for everyone. But, if you're still not finding quite what you're looking for, then set something up yourself. Let me know and I'll happily help spread the word! Reach out on LinkedIn and let's help each other. It's good to talk.

#### Acknowledgements

There does seem

to be something

for everyone. But,

if you're still not

finding quite what

you're looking for,

then set

something up

yourself.

This article was written with a little input from ChatGPT as explained in the text. My thanks go to the many who have engaged in discussions on

> this topic. Kudos to the freelancers who have been quoted in the final text here, and my best wishes to them in their efforts to encourage networking amongst freelancers across our community. Why not reach out to them? They'd be happy to hear from you.

#### **Disclaimers**

The opinions expressed in this article are the author's own and

not necessarily shared by EMWA.

#### Disclosures and conflicts of interest

One of the MedComms Networking services run by the author is the MedComms Workbook, a paid-for subscription service for specialist MedComms freelancers, such as medical writers.

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# 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
- Editorial board

#### 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 Disclosure
- Sustainability
- Veterinary Medical Writing

#### **Ambassador programme**

# Getting Into Medical Writing Group

#### **Executive Committee**

- President
- Vice President
- Journal Editor
- Public Relations Chair
- Conference Chair
- Honorary Secretary
- Professional Development
   Programme Committee Chair
- Treasurer
- EMWA Web Manage

#### 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.

# The work model of hybrid freelancing

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#### **Abstract**

Must we choose between a path as a selfemployed, freelance medical writer, or as an in-house employee? It might come as a surprise that a medical writer can enjoy both worlds. If you dream of becoming a freelance medical writer but dread losing constant cash flow, or if you are a company employee who wants to use spare time to do what you enjoy most, you may consider combining parallel professional routes.

In this article, I address the previously unthinkable possibility of such a hybrid work

Five years ago, difficult circumstances led me to leave my academic career as a biology researcher. I turned to scientific writing and communication as a way to continue pursuing my love of science while also working flexibly. At first, I saw freelancing as a temporary solution for income until I found a "real job". Unlike many freelance medical writers that I met, I have never fully devoted myself to selfemployment. When I eventually landed a job, suddenly I realised I did not want to give up my business completely. Over a year later, I re-negotiated to work part-time to keep freelancing as a side activity. This feature discusses the possibility of hybrid freelancing, which allows for a balance of both employment and self-employment. Noteworthy, hybrid freelancing should not be confused with hybrid work, which refers to a combination of remote and in-office work.

#### Hybrid freelancing: A missing opportunity until recently

ccording to a 2015 survey by EMWA, 5.1% of freelance medical writers were also employees.1 However, the 2022 salary and compensation survey by EMWA did not report figures on hybrid freelancing.2 Other recent surveys of medical writers divided respondents into two distinct categories of employees and freelancers without explicitly addressing the hybrid freelancing model.<sup>3,4,5</sup> It is likely that the proportion of hybrid freelancers, who combine traditional employment with freelance work, has increased in recent years due to the growing popularity of remote work. The recent 2023 Freelance Business Survey did ask respondents this question and confirms this prediction, as outlined in the associated article in this Medical

Writing issue (p. TK); out of 194 respondents, 17% claimed to be hybrid freelancers. This general lack of recognition of hybrid freelancers is not unique to the medical writing profession. Many global online surveys of freelancers do not provide statistics on hybrid freelancers.

As an example of a survey that does, the online platform Freelancemap found that 6% of respondents in the DACH region (Germany, Austria, and Switzerland), who were mainly in the IT, finance, and industrial sectors, also considered themselves part-time or full-time employees.6 Official statistics on hybrid freelancers are difficult to obtain, as institutions such as the Organisation for Economic Cooperation and Development (OECD) typically make clear distinctions between selfemployment and traditional employment. It is hoped that the changing nature of work models will increase awareness of the complexities of employment status, including the hybrid freelancing model.

#### What are the "combined role" freelancers saving?

I asked current or former hybrid freelancers, all of whom are members of EMWA, why they chose this work model. These are their responses:

Laura A Kehoe: "I took on a hybrid position initially to explore more document types that I was less exposed to as a freelancer, with the aim of then taking that knowledge back into my freelance portfolio. It also gave me the reassurance of having a fixed salary per month."

Namrata Upadhyay: "I hadn't initially chosen a hybrid model; however, the circumstances (mainly COVID) ended up presenting this opportunity to me. I now choose nothing but a hybrid system and negotiate it as a must-have with all employers. Two main reasons. Firstly, the mindset that I approach my work (as an employee) has shifted. Since I have the security of my own freelance business, I bring a different level of discussion to the table at work, unafraid of judgement or so-called consequences, which is a welcome relief and great for one's mental health too. Secondly, if I face a challenge at work,

> I approach it as if I'm delivering the task to my client (rather than my employer). This allows me to approach challenges, again, with a unique mindset and has allowed me to excel significantly and be appreciated at work."

writing profession. Satyen Shenoy: "I wasn't actively seeking hybrid. I was freelancing full-time, until a great opportunity to work with clinical oncologists at a cancer hospital came up. This allows me to be involved in my passion for cancer research."

#### The pros and cons of hybrid freelancing

This general lack

of recognition of

hybrid freelancers

is not unique to

the medical

Self-marketing and income insecurity can be intimidating for an independent professional. Thus, maintaining a few loyal clients alongside the job can provide a sense of security and predictability in terms of income. As a freelancer, you have the freedom to choose your favourite projects, but as an employee, you are bound to your employer's demands and delegated duties. In addition, self-employed individuals are responsible for handling their own accounting, which is usually spared from employees. There have been many discussions about the pros and cons of being a freelancer versus an employee. I created a comparative table that compares employment to freelancing with another column on hybrid freelancing (Table 1). Freelancing generally offers more flexibility than traditional

Table 1. The pros and cons of hybrid freelancing

Feature	An employee	A freelancer	A hybrid freelancer
Independence	No (unless you lead the company)	Definitely	A combination
Social interactions	Working with colleagues, team spirit	Although clients may sometimes be viewed as colleagues, working alone can be isolating.	Solves the issue of loneliness associated with freelancing
Variety	Depends on your role and expertise area. Mostly limited to the company's product/service line.	A diverse range of work that you choose	A diverse range of work with the job component more predictable
Professional development	Depends on your role, employer, and development opportunities	Self-dependent.  No one else covers training and qualification costs.	Skills acquired through employment can enhance performance as a freelancer and vice versa.
Self-marketing and networking	Unnecessary	A must	To a lesser degree. This work model may be suitable for a small, loyal clientele.
Income level	Depends on your role, employer, and expertise area	Depends on your skills, clientele, and workload	It matters not when income from full-time employment is similar to that of freelancing
Income patterns	Fixed monthly income	Fluctuations in income	A steady salary could provide a cushion against fluctuations in freelancing income
Flexibility in working hours	Typically regular hours	Mostly flexible hours	Flexible when freelancing. It can be difficult to navigate between working hours as a freelancer and those devoted to the job.
Benefits	Pension scheme, vacation/sick days, eligibility for unemployment money, etc.	Lack of benefits	Benefits only apply to the job
Workload	Depends on the employer's demands, delegated duties, and your working habits.	Irregular work. Busy times and downtimes. It is sometimes hard to say no to a client.	Workload is a combination of both.  When the job becomes stressful, you may reduce your freelancing workload.
Work/life balance	Officially determined by contract. In reality, depends on your role and the employer.	A wide range – it is up to you to decide	A combination. When the job becomes stressful, you may reduce your freelancing workload to allow yourself more free time.
Commute	Commuting, to some extent, is required, unless the job is fully remote.	Typically no commute, except for meeting clients	Less commute
Accounting and insurances	No responsibility	Full responsibility. If desired, services can be outsourced	It can become more complicated when it comes to filing taxes
Privacy	No, when attending office	Yes	No, when attending office
Immigrants in Europe	Having a job contract can be beneficial in demonstrating integration and in the process of applying for a working permit or residence	Freelancing, especially when income is not high, can deter authorities.  More difficult to get a permit.	Solves this disadvantage associated with full-time freelancing





employment contracts. Hence, balancing parttime or full-time employment with freelancing is not easy. As a hybrid freelancer, it is helpful to maintain good relationships with both clients and colleagues and prioritise tasks based on their importance and urgency. Time management is key - you may choose to dedicate certain days or parts of the day to your freelance business and others to your job. Regardless of who assigns the task, it is essential to manage your time and

#### Conclusion

responsibilities effectively.

The COVID-19 pandemic has changed working habits considerably, as discussed in the September 2022 issue of Medical Writing entitled A Virtual Workforce. As remote work continues to gain acceptance, employees can allocate time to projects beyond their employment contracts. It is a unique opportunity for freelance medical writers who can opt for these hybrid positions and enjoy the best of both worlds. Yet, managing multiple clients and working with colleagues in parallel can be challenging; therefore, hybrid freelancing may not be a feasible option for everyone. It will be fascinating to observe how shifting work habits impact the development of hybrid working models in various professions in the coming years.

#### **Disclaimers**

The opinions expressed in this article are the author's own and not necessarily shared by his employers, Porous GmbH and Charité Universitätsmedizin Berlin, or EMWA.

#### Disclosures and conflicts of interest

The author declares no conflicts of interest.

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# Books to support your medical writing journey

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#### **Abstract**

On your journey as a medical writer, you will need many types of books: style guides, dictionaries, thesauruses, books about language and grammar, and books about how to be a medical writer. This article is not about these books – it is about the books that motivated me, helped me emotionally, and provided support when I felt like an imposter and was struggling. These books helped me, I hope they will help you too.

#### Introduction

didn't plan to be a medical writer. I was offered the job. I had been summoned to the director's office. It was a short meeting, he only had one question: Do you want to be a medical writer? I had written a few study protocols as project leader in oncology, and I was one of only two native English speakers in the company, although I knew little about medical writing. I was given a week or so to reflect. I already knew that I would say yes.

I scoured the internet for information about medical writing and I found EMWA. I also found books. This article is about the books I found and read over the following years, as I became a medical writer, and eventually opened my own company. This article is not about the numerous books on "How to become a medical writer" or the grammar and English language books that were required to convert myself into the medical writer I am today. This article is about the books that motivated me, helped me emotionally, and provided support when I felt like an imposter and was struggling. These books (summarised in Table 1) are like the friends I met at EMWA who helped me on the

way to becoming a medical writer: my fellow travellers.

#### So Good They Can't Ignore You:

## Why skills trump passion in the quest for work you love

Initially, I did not have a passion for medical writing. Steve Jobs during his commencement speech delivered at Stanford in June 2005 said, "You have to find what you love... [T]he only way to do great work is to love what you do."1 The so called "passion hypothesis" suggests that to do great work - and as an extension to be happy requires that you first find your passion and then you will love the work you do. Cal Newport, in his book So Good They Can't Ignore You, dispels this, and suggests that for most people, passion and love are side effects of developing skills and competences.1 The key is to develop the "Craft man's mindset". Do you want a passionate job? First, you need to focus on acquiring the skills required for the job and then passion will follow.

... for most people passion and love are side effects of developing skills and competences.<sup>1</sup>

#### Daring Greatly:

#### A call for courage

Medical writing is not an easy career. I think most writers, particularly early in their careers, suffer from imposter syndrome, a feeling that they lack the capacity to do the work, and a preoccupation that, eventually, everyone will find out that they are frauds. This is particularly problematic for medical writing, where a formal training system to validate the required competences is lacking. The sociologist, Brené Brown, in her book *Daring Greatly* explains the need to develop the courage to be vulnerable.2 She also deals with perfectionism and the feeling of never being enough. Medical writers produce original work that will be criticised, and we will fall short of expectations, but if we want to be successful, we need to be brave, vulnerable, and willing to embrace uncertainty. I have referred to only a few aspects that may be

applicable to medical writers, but this book is so much more: if you want a happier, more successful life, *Daring Greatly* provides key insights on what is required from a psychological perspective.

#### The Motivation Myth:

## How high achievers really set themselves up to win

For me, remaining motivated, especially as a freelancer, is a constant battle. A deep understanding of what motivates me is vital if my medical writing career and my company are to survive. Jeff Haden, in his book The Motivation Myth, indicates that motivation comes from success.3 Thus, to be motivated, you need to enjoy daily successes. Maybe you would enjoy writing 200 words or a 1-hour writing session instead of enjoying only completing the document. There are real rewards in observing daily progress towards a larger goal. Routine and planning are important. For goals that will take time to achieve, decide what needs to be done daily. The secret, then, is to focus and celebrate the daily achievements. If you accomplish these, you will eventually achieve your goal. This book is full of advice on how to increase motivation. The book even has sections on how to have your most productive day and week. This may be useful for medical writer with upcoming deadlines.

There are real rewards in observing daily progress towards a larger goal.<sup>3</sup>

#### Four Thousand Weeks:

#### Time and how to use it

Oliver Burkeman, in his book Four Thousand Weeks, explores how best to use and understand our limited time – the average life expectancy is about four thousand weeks. He challenges us to face and accept that our time is limited and that we are forced to choose what we want to do. He dispels the idea that we will find peace and calm when we are more productive. When we are more productive, we find more work. He also



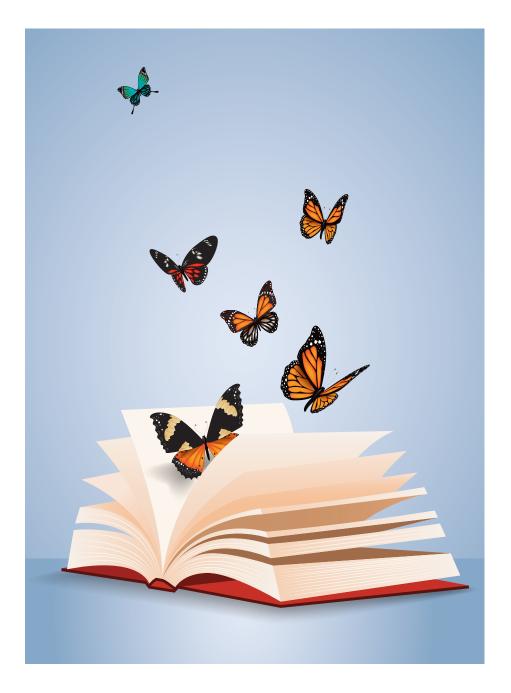


Table 1. Books to support your medical writing journey

Author	Book title
Brené Brown	Daring Greatly: How the courage to be vulnerable transforms the way we live, love, parent, and lead.
Oliver Burkeman	Four Thousand Weeks: Time and how to use it
Mihaly Csikszentmihalyi	Flow: The psychology of optimal experience
Jeff Haden	The Motivation Myth: How high achievers really set themselves up to win
Curtis Morley	The Entrepreneur's Paradox: How to overcome the 16 pitfalls along the startup journey
Cal Newport	Deep Work: Rules for focused success in a distracted world
Cal Newport	So Good They Can't Ignore You: Why skills trump passion in the quest for work you love

suggests that we become distracted because we feel emotionally uncomfortable about doing the things that are important. To overcome this feeling of discomfort, we find distractions. Oliver suggests working in blocks of time, developing patience, and learning to accept the uncomfortable feelings that arise when we care about our work. He also suggests doing activities that are intended mainly for enjoyment, like hiking and leisure reading. Everyone should read this book - it is well worth the time.

... we become distracted because we feel emotionally uncomfortable about doing the things that are important.4

#### Deep Work:

#### Rules for focused success in a distracted world

In his book *Deep Work*, Cal Newport postulates that the ability to focus or concentrate on a challenging cognitive task is valuable, rare, and meaningful.<sup>5</sup> He proposes that this "deep work" can best be performed in blocks of time without distraction. If you want to produce meaningful and valuable work, "deep work" is critical. Today, this is not the norm - work is frequently organised according to emails and meetings ("shallow work"), with the essential and deeper work done in the intervening timeslots. However, as a freelancer, and these days, with remote working, you can control, to some extent, when, where, and how you work. To state the obvious, to be a successful medical writer you must write. To write well, you must allocate time periods where you will not be disturbed. Cal suggests not only scheduling periods of "deep work" but also distraction periods, developing a deep work ritual, and implementing a daily shutdown.

#### Flow:

#### The psychology of optimal experience

Once you have a developed a "deep work" schedule, it may be worthwhile to further explore the benefits of states of deep focus. For this, I suggest the book Flow: The Psychology of Optimal Experience by Mihaly Csikszentmihalyi.6 In the "flow" state, a person is completely present and focused on a specific, doable task. This can be



observed when people sing, dance, and perform sports, but it can also be applied to work and other everyday activities.

#### The Entrepreneur's Paradox:

#### How to overcome the 16 pitfalls along the startup journey

So, if you are a medical writer, and you want to become an entrepreneur, beware! Curtis J. Morley in The Entrepreneur's Paradox: How to Avoid the 16 Pitfalls Along the Startup Journey notes that the qualities that made you good at your job are not sufficient for you to build a successful business.7 Indeed, you will need to plan, build a team, delegate writing, and train other writers. He also explains the importance of looking after yourself, as well as overcoming fears and moving forward despite the ever-present imposter syndrome. Networking with other entrepreneurs is also critical, as the African proverb states, "If you want to go fast, go alone. If you want to go far, go together." May I suggest that you attend an EMWA conference to network with other medical writers, so that you will travel far. The Entrepreneur's Paradox is not specifically written for medical writing companies, but it does provide important insight into the mindset required to build a successful business.

#### The journey continues...

To conclude, I would like to offer you not a book but a stanza of a poem written by C.P. Cavafy. This poem reminds me that life - and indeed medical writing – is a journey, so enjoy the ride. May your journey be filled with many books.8

Hope your road is a long one. May there be many summer mornings when, with what pleasure, what joy, you enter harbours you're seeing for the first time; may you stop at Phoenician trading stations to buy fine things, mother of pearl and coral, amber and ebony, sensual perfume of every kind as many sensual perfumes as you can; and may you visit many Egyptian cities to learn and go on learning from their scholars.

Extract from the poem Ithaka by C.P. Cavafy (translated by Edmund Keely)

#### Disclosures and conflicts of interest

The author declares no conflicts of interest.

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# The freelance medical writer and the medical writing agency:

# A symbiotic relationship

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#### Abstract

The medical writing industry is evolving. With a growing demand for competent and experienced medical writers in both the product industry (pharmaceutical, biotechnology-related, and medical technologyrelated) and service providers (clinical research organisations and medical writing agencies), there is an increased engagement with freelance medical writers. Freelance medical writers and medical writing agencies work in a symbiotic relationship. Here, we offer you the medical writing agency perspective by sharing some of the best practices and processes that are adopted by medical writing agencies to strengthen their engagement with freelance medical writers. We finish with some tips from the freelance medical writer's perspective about how to appropriately engage with an agency. It can work both ways, so getting the balance just right is key to a successful collaboration.

#### Introduction

ith expanding research and development activities in the healthcare sector globally, the medical writing industry is forecast to grow from \$3.58 billion in 2021 to \$8.39 billion by 2030.1 To meet these growing demands, competent and experienced medical writers are needed who can help the researchers to decipher their research findings to different stakeholders. While several pharmaceutical companies have their own medical writing departments, elsewhere about 70% of medical writing is outsourced to medical writing agencies and freelancers.2 While there exists very little information on how much medical writing work is outsourced to agencies or freelancers, a report by Kolabtree in March 2021 suggests that there was a 50% increase in the market demand for freelance medical writers during the COVID-19 pandemic.3 On one hand, this may be attributed to an increased requirement for medical documentation due to ramping up of research and development programmes in the industry. On the other hand, there was a major shrinking of larger companies in terms of manpower to reduce costs and therefore, involve freelancers for ad hoc projects. The exact number of freelance medical writers across the globe is not known. As the medical writing industry is still evolving, a need for external support is becoming a more common practice than an exception.

#### Freelance medical writer and medical writing agency: A symbiotic relationship

Freelance medical writers and medical writing agencies have a symbiotic relationship - agencies help these writers obtain adequate work and the freelancer executes the work with the muchneeded expertise and availability.



#### From a freelance medical writer to founder of a medical writing agency

My journey started as a freelance medical writer way back in 2008, when I was introduced to the field of medical writing. With very limited openings available at that time and most full-time roles only available as office-based jobs, it was a stroke of luck for me to get the opportunity to work as a freelance medical writer. It meant I could manage my family and be engaged professionally at the same time.

My experience and education from my time as a freelance medical writer have helped me to set up my own company, procure business, network with fellow professionals, and now, work with freelance medical writers. Freelance medical writers are referred to differently by different companies - consultant, part-time writer, self-employed medical writer, or medical writing specialist.

For most medical writing agencies, the freelancers are considered an extended resource pool who are engaged based on the following four Cs:

- 1. Capability: Agencies consider hiring freelance medical writers who are subject matter experts with decent relevant experience (at least 4–5 years of domain-specific writing experience) in medical writing. These consultants need little to no supervision with their work and can work independently. The recent 2021 EMWA survey suggested that about 70% of participating freelancers had more than 5 years of experience in the field of medical writing, and about half of them had project
- management experience as well.<sup>4</sup> The survey also suggested that the majority (86%) of the participating freelance medical writers had a degree in life sciences with about 73% having advanced degree (BBS, MD, PhD, PharmD, or equivalent).<sup>4</sup> There were more regulatory freelance medical writers (63%) than medical communication writers (26%).<sup>4</sup>
- 2. Capacity: Sometimes medical writing agencies receive work when their clients' entire team is occupied, and there is a stringent deadline. In such cases, as a relationship value to the client who is dependent solely on the agency for the work to be completed, the medical writing agency may recruit a freelance medical writer to help
- the internal writing team and support the project. A medical emergency in the internal writing team, a sudden exit or an unplanned absence of any writer are also some of the common reasons for medical writing agencies to engage a freelance medical writer.
- 3. Cost: One of the most important factors to consider while engaging with a freelance medical writer is the cost and profitability of the project along with client satisfaction. As per the 2021 EMWA salary survey results, the mean hourly rate for a freelance medical writer varies with experience from €90 (3–5 years of experience) to €110 (11–15 years of experience).4 For a freelance writer to be engaged, any medical writing agency should have a fair idea of the hourly rates from the specific country or region so that a fair market value can be considered. While considering the cost, it is also important to consider the detailed project scope, and any exceptions should be laid out at the beginning of the project itself and clearly communicated to all involved parties.
- 4. Conflict of interests: While engaging with a freelance medical writer, any conflict of interest between the freelancer and the agency should be discussed and made a part of the initial agreement. The working association should be transparent and honest  $\,$ for it to be beneficial. This is particularly important for part-time freelance medical writers. According to the seventh EMWA freelance business survey results of 2023, 79.3% of 194 freelance medical writers who participated in the survey were 100% freelancing and about 19.6% were hybrid working (freelancing and employed or contracted).5 Another important aspect to be considered here is all the ongoing agreements that the freelance medical writer may have with his/her other agencies/companies (Figure 1).

# Engaging freelance medical writers - Best practices for medical writing agencies

Many medical writing agencies working with pharmaceutical companies have their own well-documented internal policies and processes. Many agencies also have discrete policies and processes in place for outsourcing to freelance medical writers. However, these may differ from one agency to another depending on the nature of engagement; an agency may have different



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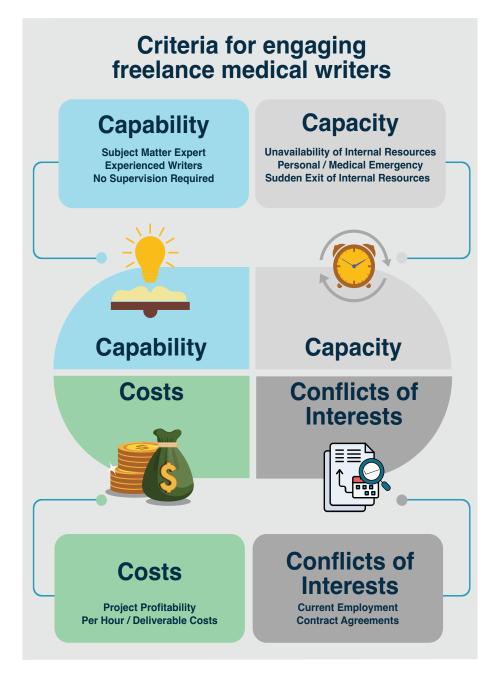


Figure 1. Medical writing agency's criteria for engaging freelance medical writers



processes involved for outsourcing to freelance medical writers on a retainership model versus those who are engaged on a per-project basis.

The following is a proposed general process that medical writing agencies may pursue when engaging with a freelance medical writer:

#### 1. Robust selection criteria and thorough background checks

Medical writing agencies usually begin by using one or more freelance networking websites or through social media platforms such as LinkedIn for posting their adverts. Selecting a freelance medical writer is not just based on their

Table 1. Best practices for a freelance medical writer to develop a successful working relationship with any medical writing agency

Best practice	Explanation
Appropriate project selection	Try to select projects based on your experience and interests.
Evaluate your capacity	Learn to say "no" when you are unsure if you can complete an assignment on time.
Manage your time effectively	Discipline yourself to be on top of the project, and ensure timely completion of deliverables.
Use clear and crisp communication	The success to any relationship is always clear and transparent communications.
Give yourself performance reviews	Ask clients for feedback, and take it constructively to improve your performance.
Ask when in doubt	Never assume anything, and if in doubt, reach out to relevant people for answers.
Own your work (that includes mistakes!)	Ensure you deliver the best quality deliverable, own your mistakes, and rectify them.



Photo: Freepik

experience and referrals, but medical writing agencies may also have assignments for testing technical and writing skills followed by a personal one-on-one interview. These assessments may be

paid assessments if the agency has plans to use the material developed by the freelance medical writer; in that case, these details are conveyed right in the beginning before sharing the assignment. Some medical writing agencies also ask the freelance medical writer to share samples of their work completed on previous projects to further qualify as a freelance medical writer for the job.

The next step involves a thorough background check (educational qualifications, past experiences along with relevant work samples, referrals for feedback on completed assignments in the past, current engagements, etc.) followed by a duly signed confidentiality agreement between the freelance medical writer and the agency. To maintain transpa-

rency at all levels, both expectations from the freelance medical writer and payment details (project-based or milestone-based) are charted right in the beginning and shared by the medical writing agency with the freelance medical writer.

The most important

The freelance medical writer may be assigned a unique identification code and all vital administrative details such as a bank account, tax information, and freelance medical writer's address for correspondence, along with an alternative contact number in case of emergency, are documented.

# 2. Onboarding of the freelance medical writer for the project

Once a freelance medical writer is selected for a project, it is also necessary for the agency to adequately introduce the writer to the technical team and the client team, if essential for the project. Ideally, the most acceptable way is to introduce the writer to the client early

during the project initiation call and gain the client's confidence and trust in the writer's ability. If this is not feasible for some reason, the freelance medical writer is adequately briefed on the project and provided access to all source materials (including call recordings, if any), so that there is complete knowledge transfer of all project-related information to the freelance medical writer. Medical writing agencies use several technology features to ensure client data security while sharing these materials with the freelance medical writer. Most agencies have dedicated interfaces like a project collaboration system with restricted access provided to the freelance medical writer. Keeping open communications, setting the right expectations, and considering the freelance medical writer as an extension of the in-house team are some of the key features that can lead to a successful freelance engagement.

Another important aspect is to provide timely feedback for the work commissioned by the freelancer. Freelancer feedback involves both quality of deliverables and the timeliness of delivery. Many medical writing agencies have a five-star rating system in place that helps them to reward the freelance medical writer with newer projects and appropriate incentives. Many medical writing agencies also invest in develop-

points for an agency to select the right freelance medical writer include capability and expertise of the freelance medical writer along with feedback or referral from independent sources that can validate the freelance medical writer's work. Both these points have equal weight and are considered of the utmost importance.

ing an online, advanced real-time dashboard complete with all the freelance medical writers' details, including experience, hourly rates, availability, feedback received etc., that can help them to decide and select the right freelancer for the job.

#### 3. Building relationships for continued collaborations

To ensure a medical writing agency secures and retains talented and competent writers, it is critical that the agency treats them well. Acknowledging the role of the freelance medical writer in the successful delivery of a project is as important as sharing client feedback. Some basic etiquette that every medical writing agency should follow while engaging with a trusted freelance medical writer include the following:

- a. Show respect and empathy for the freelance medical writer - check the freelancer's availability before assigning a project and appreciate that the freelancer may have to turn down a project if they have other commitments.
- b. Never delay payments to the freelance medical writer, or if a delay is likely, communicate it in advance and be transparent. Payments can be either per draft or per deliverable as agreed by both parties before initiation of the project.
- c. Keeping in touch with the freelance medical writer regularly - sending simple greetings, especially on holidays and their special days, can bring a smile to their face. Treating freelance medical writers as an extension of your internal team, and involving them in team gatherings and outings, may further strengthen the relationship between a medical writing agency and a freelance medical writer.

#### Tips for a successful freelance medical writing career

There are many benefits for a freelance medical writer to engage with medical writing and medical communication agencies; it can provide regular work, a reliable income, a means of being on a team, and a way to develop a work portfolio. Here, we provide some tips and ways to approach working with an agency from a freelancer's perspective (Table 1).

#### **Conclusions**

Working relationships between a freelance medical writer and medical writing agency are symbiotic. While a medical writing agency may engage a freelance medical writer due to capacity and capability constraints, a freelance medical writer can help complete the commissioned work with their expertise and experience in a timely manner. Medical writing agencies who outsource their work to freelance medical writers should have a robust policy and process in place to select the right freelance medical writer for each project. At the same time, medical writing agencies should also adopt best practices of empathy and active listening for the successful retention of their freelance medical writers.

#### **Disclaimers**

The opinions expressed in this article are the authors' own and not necessarily shared by their employees (as applicable) or EMWA.

#### Disclosures and conflicts of interest

Both authors are employed by Turacoz, a medical communication company.

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# Charting your way to the top:

# The 12 major milestones of freelance medical writing

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#### **Abstract**

As a freelance medical writer, it's tough to know how well you're doing - conventional career metrics don't apply and you don't have a boss keeping tabs on you. Yet, for your medical writing business to stand the test of time, with you at the helm, you need to be able to measure your success and know what's next in terms of personal and professional growth. The good news is that countless freelancers have gone before you, leaving a trail of breadcrumbs to help you find your way. Learn how to identify and interpret these breadcrumbs and use them to your advantage by following the guided trail of important milestones outlined in this article to help you take your business to the next level at a pace you feel comfortable with.

#### Introduction

mbarking on entrepreneurship for the first time is daunting – not only because it's likely your first time being self-employed and the steps to take may be murky, but also because there are no obvious measures of success that you can use to determine progress.

One way to assess your growth is to study the following twelve major milestones of freelance medical writing. These stages of growth have been identified and honed through years of hands-on research and personalised coaching to determine what makes one freelancer thrive and another return to full-time employment feeling defeated. As you explore each milestone, pay attention to those that resonate. See if you can

pinpoint how far you've come, as well as where you want to be. Not everyone reaches every stage and that's ok. But if you want to get "to the top" of the totem pole, tune in now.

## #1—Getting your first freelance medical writing client

The first major milestone you'll reach as a freelance medical writer is the day you can say "I have a client". Self-promotion doesn't always come naturally, and marketing efforts can seem like a waste of time. So, when things actually start to work out and you can legitimately call yourself a small business owner, it's a pretty big deal!

A clear sign that you've reached this milestone will be seeing a signed contract and/or scope of work from a client who wants to start a professional relationship with your company.

## #2-When your business becomes profitable

Not long after getting your first client, you'll have delivered one or two writing projects before reaching another important milestone: monetisation, followed by profitability. This is usually the point at which "I get paid to be a writer!" washes over you in a radiant wave of satisfaction.

At this stage, you'll likely be staring in disbelief at an email notification that says "Your invoice has been paid", or refreshing your digital bank statement, repeatedly, to see if the credit magically disappears.

## #3—Letting go of your full-time job to freelance

The next turning point in your entrepreneurial journey will likely be letting go of another job you've been hanging on to. When you first became a writer, you probably didn't expect your business to support you financially as well as it has. But when you notice your self-employed income exceeds your salary, it's time to quit the day job.

This typically looks like handing in your notice and telling everyone close to you – colleagues, friends, and family – the big (and scary) news.

## #4—Shifting from an employee to an entrepreneur mindset

After doing your own thing for some time, your perception of and approach to work will have begun to evolve – a shift from an "employee" to an "entrepreneur" mindset. Think of it as a change of paradigm or worldview in which you begin to realise you have all the power.

At this milestone, your behaviour will align more with that of a business owner than a writer. For example, you may take a spontaneous vacation, travel more "just because", reject unnecessary meeting requests, or increase your rate in line with the value you provide.

## #5—Being fully booked as a freelancer

The first time you have a full workload for a handful of clients, you know you've reached the next milestone in your business. Whether it happens expeditiously or takes its sweet time is up to you. But one thing's for sure: it brings a lot into question. At this stage, you're turning down work because your schedule is full and you're burning out, leaving you wondering "who has all the control?". (Hint: It's probably your clients).

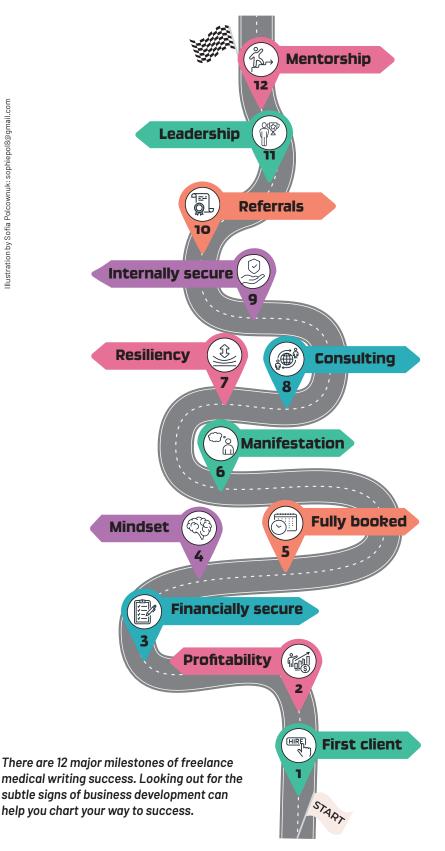
This looks like saying "no" to a new client or project that you'd usually take on but can't because you're unquestionably overloaded.

#### #6-Leaning 100% into your brand

As your business continues to evolve, you'll start wondering why you're doing so well. Which of your marketing efforts directly contribute to your success? Then, it hits you: it's your personal brand. You show up authentically and passionately in your business every day, which magnetises your ideal clients seemingly effortlessly.

A sign that you're at the manifestation stage is being able to clearly define your brand and make business decisions based on it. A great example is when pharmacist and new freelance medical writer Lindsay decided she's a specialist in novel drugs. Her messaging was instantly stronger and more original, and she became inundated with companies needing help bringing their products to market.





#### #7-Building resilience as a business owner

By the time you reach the seventh milestone of freelance medical writing, you no longer identify as being synonymous with your business. You can easily distinguish your business decisions from your own personal growth and self-worth. As a result, it's easier to stay grounded and recognise the need for investing in continued professional development, as well as ongoing self-care practices.

A classic indicator that you've crossed the resiliency milestone in your business is when a project proposal gets rejected and you don't feel anything. In other words, you continue on with your daily tasks and it doesn't have any sort of emotional impact on you. Then, it registers that it's been this way for a while and you hadn't even noticed.

#### #8-Realising you're a consultant now, too

As you and your business continue to evolve, you'll step into authority more than ever before. You'll question briefs because you'll know a better way for clients to achieve communication and sales objectives. You'll confidently make impromptu suggestions with little-to-no hesitation. Your business operations will flow with ease.

One moment to look out for when crossing this milestone is when a client asks you for content ideas or strategy input, instead of briefing you on what they want, and you take it in your stride.

#### #9-No longer being attracted to fulltime positions

The next crucial juncture as a freelance medical writer is when you commit to working only for yourself. While you let go of any "stable income" sources many moons ago, up until now, you couldn't escape the pull to snap up a 9-5 when a "perfect opportunity" presented itself. That ends now. You know, with every fibre of your being, that no full-time opportunity could ever give you the freedom and flexibility that freelancing does and that you can't put a price on that.

You're at this stage when you choose not to investigate a full-time role that you would have before. A listing pops up in your feed or inbox; you think "no thanks" and keep living your best

#### #10-When your reputation precedes you

Further in your evolutionary timeline, you feel at the top of your game. You're so focused on pleasing your clients, delivering great work, and making sure your business continues running smoothly that you haven't had to market your services for months. You're showing up every day, doing great work, and owning your greatness. You can't remember when you last felt the need to prove yourself professionally.

You know you've reached this milestone when you start getting referrals from strangers because your reputation precedes you. Companies just can't get enough of you!

#### #11-Being a leader in the field

As you continue to push boundaries in your business development, you'll find medical writing isn't the challenge it used to be. People will often approach you for advice on entering the field, and your brain will be primed for picking. Now a subject matter expert, you may decide to step up as a leader to support and educate others.

This looks slightly different for everyone, but it could be getting your first public speaking gig, developing your own training course, or becoming a coach or mentor in a specialty area.

#### #12-Building your own agency

At the height of your career, you're already a master of your craft; a trailblazer in your business; a true success story. As you perch on the medcomms equivalent of the Hollywood sign, admiring what you've built, there aren't too many places to go from here. You're facing burnout often, with far more incoming work than you can handle on your own. If slowing down isn't a desirable option for you, the only way forward is expansion.

This looks like hiring subcontractors and/or employees to support you in delivering medical writing projects so you can focus on marketing, sales, and client relationship management. It's not for everyone, but it will help you push through that glass ceiling you've been staring at for the past few months.

#### A tool for celebration and success

There's plenty of room to grow in freelance medical writing, so it helps to be able to take stock of where you are and determine where you're heading.

The next time you're feeling stuck or getting bored in your business, refer back to these twelve milestones and use them to inspire next steps. Or simply use them as a trigger to congratulate yourself on how far you've come!

There's no "end game" in entrepreneurship - it takes you wherever you choose to go. Some reach a comfortable stage, with a great work-life balance, where they happily remain until retirement. Others strive to reach as many milestones as possible before hanging up their hat.

One thing's for sure – you hold all the cards.

#### Disclaimers

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

Disclosures and conflicts of interest Sophie's company, Prospology, offers business and marketing coaching services to individuals who are new to freelance medical writing.



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# Seventh Freelance Business Survey:

# The freelance landscape 2018–2023

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#### **Abstract**

The freelance medical writing landscape has evolved in recent years, with more market demand for competent medical writers who can work on a project basis. In January 2023, the European Medical Writers Association's (EMWA) Freelance Business Group launched the 7th EMWA Freelance Business Survey (FBS), with the aim of analysing current trends in freelancing. Our analysis includes previously unpublished data from the 6th EMWA FBS to report changing behaviours in freelancing from 2018 to 2023. The 2023 FBS had a total of 223 respondents, more than in 2018 (n=142), most of whom were generally younger and less experienced (<5 years). Hourly rates charged were on average higher than those reported by respondents in 2018. Median hourly rates across all services provided was €82.2 and increased with years of experience. Networking and business advertising saw a decline in 2023, and word of mouth was considered the greatest influencer in gaining new business. Professional development efforts have taken a shift to personal research and online courses. Data presented here highlights the most current predominantly European trends in freelance medical writing.

#### Introduction

he freelance medical writing environment has been and still is an attractive employment opportunity for current and aspiring medical writers. Market demand for freelance medical writers reportedly increased by 50% during the COVID-19 pandemic and continues to grow, along with the global market for medical writing.1,2 The ways in which both medical experts and the public access medical and scientific information have changed with more information being available online, especially through social media channels. Consequently, pharmaceutical marketing strategies have been modified to embrace the opportunity to directly communicate with consumers. They have also responded to global political pressure and economic support, investing in research and development for innovation and clinical studies, all in an environment with an abundance of new regulations (especially in Europe).

Investigating, reporting, and communicating health information to both a broad nonprofessional/non-expert audience, as well as healthcare professionals, demands writers with the skills to interpret and communicate healthrelated knowledge in both plain and technical/ professional language.3

Understanding how and where freelance medical writers operate, what services they offer and how much freelancers charge for those services, and how ongoing education, workrelated stress, business issues, and personal growth are managed can provide a shared knowledge that can be translated into improved business performance. In 2003, EMWA launched its first Freelance Business Survey (FBS),4 which was followed by subsequent surveys in 2007,5 2010,6 2012,7 20158 and 2018. In January 2023, the 7th EMWA FBS was launched. This article analyses the results of the 2023 7th EMWA FBS and compares data of the 2018-2019 6th EMWA FBS (data was unpublished) to identify freelancing trends over the last 5 years.

#### **Methods**

#### Study design and procedure

In both 2018 and 2023, an online questionnaire was designed by the Freelance Business Group Committee members. EMWA distributed the survey details and access link to all its subscribers and announced the survey on its website and social media platforms. In addition, the authors posted the survey details to their professional networks via email or social media platforms. Email and social media posts clearly outlined the surveys' intention to collect pertinent information for an updated global view of freelance medical writing. The survey was open to all freelance medical writers and not restricted to EMWA members; the 2018 EMWA FBS was also sent to the American and Australian Medical Writing Associations for dissemination among their members.

A link to the online survey was included in all invitations. The survey was available online from January 13-31, 2023. The 6th EMWA FBS was open from December 19, 2018, to February 1, 2019. Voluntary participation in the current research was considered consent for research inclusion. Data was collected anonymously and treated according to the European Union's (EU) General Data Protection Regulations (GDPR 2016/679).

#### Surveys

Online surveys were developed in English and were distributed with the Survey Monkey platform in 2023, and Google forms in 2018, enabling secure and anonymous data collection (Survey Monkey, Google forms). In 2023, questions were developed based on the study conducted in 2018, and new questions were integrated based on COVID-19 post-pandemic work practice changes,9 work-life balance,10 and freelance medical writers' opinions and insights.

The surveys were designed to take less than 10 minutes to complete and were divided into six sections:

- 1. Demographics (2018 and 2023)
- 2. Work practices (2018 and 2023)
- 3. Pricing and payment practices (2018 and
- 4. Business practices (2018 and 2023)
- 5. Networking practices (2018 and 2023)
- 6. Wellbeing practices (2023 only)

There were 18 questions posed to the participants in 2018, which was increased to 35 in 2023. Most were developed with fixed



responses, but free-text and a mix of free-text/fixed responses were also employed. Fixed responses were devised according to common categories (such as age groups, employment type), Likert scales or all possible answers to a question the authors could think of, with a possible free-text option for "other" responses. Appendices 1 and 2 includes all the questions with the answer options for the online 2018 and 2023 surveys, respectively.

#### Data analysis

The responses were collected automatically and exported into a Microsoft Excel spreadsheet. Free-text responses (2023: questions 3, 8, 12, 13, 15, 30, 34, and 35) were retrospectively codified according to key themes. Some coded classifications were those with poor presentation (<5%), which were collected into larger groups for improved data interpretation, including age groups (<39, 40–49, 50–59,  $\geq$ 60) and hours in a typical working week (<20, 20–40, >40). In addition, respondents were also classified as medical writers working in medical communications (MedComms), regulatory, or hybrid fields based on the types of documents

delivered. As the age groups were different among the two surveys, percentage estimates based on percentage of answers in the 2018 age groups, were performed to enable comparisons. Average hourly rates were calculated for each respondent based on the mean of the hourly rates supplied per service type. Quantitative data analysis was performed with STATA" software version 17 (StataCorp LP, College Station, TX, USA). Frequencies were calculated considering all respondents (all omitted responses were noted), unless subgroups were considered, in which total n is specified. Mean and percentage frequency were used to express population characteristics. For quantitative variables, the Student's t-test (qualitative variables) and the Pearson Chi square test or the Fisher's test (in case of values <5 in the contingency) were employed. For quantitative variables, ANOVA one-way comparisons test was used to determine mean differences within groups. P<0.05 was considered statistically significant.

#### Results

#### Respondents' characteristics

Compared to the 2018 survey, there were more respondents who accessed and answered the 2023 survey (n=223 vs n=142). In both surveys, almost 80% of the total sample were female and almost 80% were under 50 years old (2018, 59.8% and 2023, 62.3%). Less than 5 years of experience as a freelance medical writer was reported by 45.3% (2023 data only). Most respondents were from Europe (2018, 79.6% and 2023, 78.5%); around 30% were based in the United Kingdom in both 2018 and 2023. Compared to the 2018 data, the representation of German and French respondents fell in 2023, whilst the contribution from Italy and Portugal grew. Among the non-European nations, 2023 saw a dramatic increase in respondents based in India; the 2018 survey was sent to the American Medical Writers Association (AMWA) to be shared with their members, hence there was a greater representation from the United States in 2018 compared to 2023. In 2023, almost 67% described their occupational status as 100% (fulltime), up from 63.8% in 2018, and most work between 20 and 40 hours per week. In 2023, only

Table 1. Demographic and basic business characteristics and habits of medical writer respondents to the 2018 and 2023 Freelance Business Surveys

	20	023	20	018
	n =223	%	n=142	%
Gender				
Female	173	77.6	112	78.9
Male	45	20.2	29	20.4
Non binary	1	0.4	N/A	N/A
Prefer not to say	3	1.3	1	0.7
Age groups, <i>years</i>				
<39	68	30.5	31	21.8
40-49	71	31.8	54ª	38.0
50-59	57	25.6	25 <sup>a</sup>	17.6
≥60	24	10.8	23a	16.2
Prefer not to say	4	1.8	N/A	N/A
Freelancing experience, years				
<1	28	12.6	N/A	N/A
1–5	73	32.7	N/A	N/A
6–10	41	18.4	N/A	N/A
11–15	25	11.2	N/A	N/A
>15	29	13.0	N/A	N/A
No response	27	12.1	N/A	N/A
Base country				
European	175	78.5	113	79.6
United Kingdom	67	30.0	43	30.3
Germany	25	11.2	24	16.9
Italy	18	8.1	2	1.4
France	14	6.3	13	9.2
Portugal	12	5.4	3	2.1
Countries with <10 respondents	39	17.5	29	20.4
(n=14 for 2023. n=12 for 2018)	00	17.5	23	20.4
Non-European	46	20.6	28	19.7
India	25	11.3	3	2.1
United States of Americab	8	3.6	21	14.8
Countries with <10 respondents (n=10 in 2023, n=3 in 2018)	21		3	2.1
No response	2	0.9	1	0.7
Occupational status description	1/0	CC /	07	67.0
Freelance (100%)	148	66.4	97	63.8
Freelance (hybrid)	38	17.0	46	33.1
Other (unspecified)	8	3.6	N/A	N/A
No response	29	13.0	0	0.0
Typical working week, hours				
<20	54	24.2	N/A	N/A
20-40	117	52.5	N/A	N/A
>40	24	10.8	N/A	N/A
No response	28	12.6	N/A	N/A

<sup>&</sup>lt;sup>a</sup> Estimates based on a division of responses from other age groups. performed for comparative purposes. For complete base country information, please see Supplementary Table 1.

10.8% work over 40 hours a week, down from around 20% in 2018 (Table 1).

#### Services and documents delivered

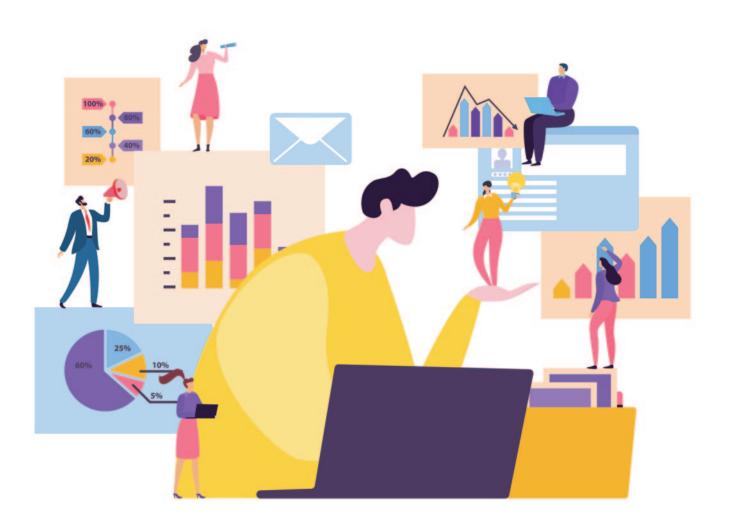
Writing services and proofreading and editing services were most commonly reported, constituting 68% and 20% of respondents' time, as revealed in the 2023 survey. Quality control saw a decrease in 2023 (45.5% in 2018 vs. 38.1% in 2023), and there was an increase in electronic publishing (7.0% in 2018 vs. 13.5% in 2023). In the 2023 survey, some respondents (16.6%) added in the free comment section under "Other", the additional services they provide, including strategy, quality and general management, marketing and sales, advisory and educational roles, graphic design, medical and social media monitoring, statistics, and volunteer work. In 2023, documents delivered by the respondents were mostly manuscripts for journals (58.3%); abstracts, posters, and slide kits for conferences (54.3%); and educational and training material (43.5%). Around a third of respondents deliver online articles and website content (33.6%) and regulatory documents (investigator brochures, study protocols and reports; 30.0%). Other documents include those outlined in Table 2 overleaf. Data could not be compared with 2018 data, as respondents could only "select 3" services in 2018, but could choose "all that apply" in 2023.

The ranges of responses for time estimates (2023 data only) and hourly rates were wide (Table 3). Writing a clinical study report was the most time-consuming type of service, requiring 111 hours ( $\pm 66.7$ ), followed by writing technical evaluations (71 hours,  $\pm 111.3$ ), then a standard scientific article (57 hours,  $\pm 36.8$ ).

The highest hourly rate applied by respondents was associated with consultancy (€109, ±67.6), followed by training (€100, ±75.4), regulatory writing (€95, ±59.4) and non-regulatory writing (€80, ±28.1). The lowest hourly rates were applied for translations (€65, ±27.3). Compared to the 2018 survey, average rates were slightly higher (between €2 and €10) for all service types, except for quality control.

The overall median hourly rate across all services provided was €82.2, which increased with years of experience, from €73 with <1 year of experience, €78 with 1–5 years of experience, €80 with 6-15 years, to €100 with >15 years of experience. A similar trend was seen across

b United States of America was included in the table as it had >10 respondents in 2018.



type of medical writer and years of experience (Table 4), p. 61.

According to the geographical location of the respondents (where >10 respondents were recorded), the highest average hourly rate was in France (€92.5), followed by Germany (€82.5), United Kingdom (€79.0), and Italy (€63.8). Portugal and India were highly represented, but many did not register hourly rates (33.3% and 72% respectively); rates were €57.9 and €23.0, respectively (data not shown).

#### **Business practices**

The average target

minimum

monthly earnings

reported in 2023 is

€5,608.40, derived

from a wide range

of responses

(€400–€30,000).

The average target minimum monthly earnings

reported in 2023 was €5,608.40. This value was derived from a wide range of responses (€400-€30,000). The main source of projects was from longstanding clients (40.8%) (Table 5), p. 62. In 2018, respondents were asked to select three of their main sources of projects, so a direct comparison of frequency cannot be made.

MedComms agencies and pharmaceutical companies were

the main clients in 2023 (43.5% and 31.8%) and 2018 (28.7% and 52.4%). Biotech/veterinary/

medical device companies, medical writing companies, contract research organisations (CRO) and academic institutions all made up between 14% and 20% of the main clients in 2023. Publishers and non-profit organisations were comparatively less represented in both 2023 and 2018.

Most estimates for client quotes (2023 data only) are created by rough calculations of the time to complete a project, multiplied by an hourly/daily/weekly/monthly rate (40.8%) or by quoting an hourly/daily/weekly/monthly rate and invoicing all hours worked at project completion (38.6%). Some respondents use personal pricing lists based on project/document

Continued on p. 62



Table 2. Services and documents delivered by freelance medical writer respondents

	20	23	20	)18
	n=223	%	n=142	%
Services provided <sup>a</sup>				
Writing	182	81.6	134	93.7
Proofreading and editing	114	51.1	102	71.3
Quality control	85	38.1	65	45.5
Consultancy work (e.g., training)	78	35.0	50	35.0
Translation	53	23.8	39	27.3
Electronic publishing	30	13.5	10	7.0
Other	37 <sup>b</sup>	16.6	31 <sup>c</sup>	21.7
No response	33	14.2	0	0.0

	Mean ±SD	Range	Mean ±SD	Range
Proportion of time dedicated to each service				
Writing	67.9 ±26.4	(5–100)	N/A	N/A
Proofreading and editing	19.8 ±19.4	(0–100)	N/A	N/A
Consultancy work (e.g., training)	17.9 ±18.1	(0-90)	N/A	N/A
Quality control	14.1 ±13.6	(08-0)	N/A	N/A
Translation	9.8 ±14.1	(0-50)	N/A	N/A
Electronic publishing	7.2 ±15.6	(0-80)	N/A	N/A
Other	22.2 ±23.8	(0-90)	N/A	N/A
No response	33	14.2%	N/A	N/A
	n=223	%	n=142	%
Delivered documents				
Manuscripts for journals	130	58.3	94	65.7
Abstracts, posters, slide kits for conferences	121	54.3	76	63.1
Educational and training material	97	43.5	80	55.9
(for patients and health professionals)	0,	10.0		00.0
Websites and online articles	75	33.6	41	28.7
Regulatory documents – investigator brochures, study protocols, and reports	67	30.0	124	86.7
Marketing materials	66	29.6	12	25.2
Conference proceedings	47	21.1	38	26.6
Regulatory documents – medical devices, biologics	41	18.4	53	37.1
Regulatory documents – summary documentation,		17.0	F1	75.0
CTD sections, SmPCs, product inserts	40	17.9	51	35.7
Market access / HEOR materials	23	10.3	N/A	N/A
SOPs and user manuals	20	9.0	27	18.9
Medical and scientific textbooks	17	7.6	20	14.0
Regulatory documents - other	15	6.7	29	20.3
Other	25 <sup>d</sup>	11.2	29e	20.3

a Data cannot be compared as respondents were asked to "select 3 options" in 2018 and "all that apply" in 2023

27

11.6

0.0

Abbreviations: CTD, common technical document; SmPCs, summary of product characteristics; HEOR, health economics and outcomes research; SOPs, standard operating procedures

No response

b Strategy, quality and general management, marketing and sales, advisory and educational roles, graphic design, medical and social media monitoring, statistics and volunteer work

<sup>&</sup>lt;sup>C</sup> Strategy, quality, project and general management, marketing and sales, advisory and educational roles, graphic design, medical and social media monitoring, statistics, clinical development consulting, indexing, coaching and mentorship, data checking epidemiologic research, event organisation and client liaison health technology assessment interpreting peer review, post-editing of machine translation publication planning, safety

d Advisory board documents, strategy documents, plain language material, event management, grant proposals, internal communications, regulatory defence and briefing, training material, social media, policy reports, digital assets, scientific platforms, ethics committee documents and theses

e Advisory board, health technology assessment submissions, research grant applications, translations, academic documents, consulting documents, clinical study reports, drug specification booklets, guidelines for professional organisations, global value dossiers, health economic dossiers, informed consent forms, internal reports, medical devices manuals, press releases, public databases e.g. Clinical Trials.gov, safety narratives, study guide apps, study reports (non-regulatory), reimbursement submissions, internal company documents, agenda developing for conferences and meetings

Table 3. Time and price estimates according to documents and services provided

	20	23 201		18
	Median ±SD	Range	Median ±SD	Range
Time estimates for service types, hours				
Writing a clinical study report / other regulatory documents (n=43)	111.5 ±66.7	6-280	N/A	N/A
Writing technical evaluations (n=3)	71.1 ±111.3	5-200	N/A	N/A
Writing a standard scientific article (n=78)	57 ±36.8	6-200	N/A	N/A
Writing patient material (n=32)	17.2 ±16.8	2-60	N/A	N/A
Translate a standard scientific article (n=16)	15.9 ±12.5	5-48	N/A	N/A
Edit a standard scientific article (n=59)	15.0 ±14.3	3-70	N/A	N/A
Writing a medical blog (n=27)	7.8 ±11.3	1-60	N/A	N/A
Writing content for a website (n=27)	11.2 ±12.8	1-60	N/A	N/A
No response (n %)	112	48.1	N/A	N/A
Hourly rates for service types (n for 2023; n for 2018), Euros				
Consultancy (n=57; n=67)	109 ±67.6	15-500	98 ±47.6	13-275
Training (n=39; n=44)	99.9 ±75.4	15-500	100.2 ±47.6	13-275
Writing: Regulatory (n=17; n=67)	95 ±59.4	17-500	88.0 ±32.1	13-190
Writing: Non-regulatory (n=120; n=109)	80.0 ±28.1	15-220	77.5 ±32.6	10-190
Editing (n=73; n=140)	69.9 ±25.1	20-120	44.7 ±28.6	10-180
Quality control (n=46; n=63)	69.8 ±26.8	20-160	72.7 ± 31.7	12-190
Proofreading (n=59; n=75)	65.7 ±25.9	10-120	61.6 ±29.0	10-180
Translation (n=27; n=44)	64.7 ±27.3	25-110	55.5 ±26.6	13-134
No response (n %)	70	30.0	10	7.0

Table 4. Level of experience and median hourly rates, assessed according to type of medical writer and provided

Level of experience												
	To	otal	<1	year	1-5	years	6-10	years	11–15	years	>15 y	years
All respondents, n %a	195	100.0	28	14.4	72	36.9	41	21.0	25	12.8	29	14.9
Hourly rates provided	149	76.4	15	7.7	58	29.7	37	19.0	20	10.3	19	9.7
No hourly rates provided	46	23.6	13	46.4	14	19.4	4	9.8	5	20.0	10	34.5
Median hourly rate, € range	82.2	17-500	73	17-165	78	17.5-500	80	45-150	80	50.8-140	100	65-250
Type of medical writer												
MedComms												
Respondents, n %	75	50.3	7	46.7	31	53.4	20	54.1	10	50.0	7	36.8
Median hourly rate, € range	77.0	17-250	73.0	17-165	77.0	25-500	77.0	50-130	72.8	50.8-85	115.0	65-250
Regulatory												
Respondents, n %	21	14.1	4	26.7	4	6.9	7	18.9	3	15.0	3	15.8
Median hourly rate, € range	100.0	17.5-206.7	75.0	43.3-120	74.7	17.5–160	100.0	70-150	105.0	100-110	124.0	105-206
Hybrid												
Respondents, n %	53	35.6	4	26.7	23	39.7	10	27.0	7	35.0	9	47.4
Median hourly rate, € range	83.8	18.6-167.5	67.5	23-78.3	80.0	18.6-125	83.8	45-110	107.5	65-140	100.0	70-167.

 $<sup>^{</sup>a}\ \ Number\ of\ respondents\ with\ details\ about\ the\ types\ of\ documents\ delivered\ (to\ be\ able\ to\ be\ categorised\ as\ a\ medical\ writer\ type\ [87.4\%])$ 



 $b\,$  For each type of service missing experience was registered for 7, 13, 8, 9, 2, 4, 6 and 3 respectively.

Table 5. Business practices: Source of projects and main clients

	20	23	20	18
	n=223	%	n=142	%
Major source of projects <sup>a</sup>	223		143	
Longstanding clients	91	40.8	120	83.9
Professional or social networking sites (e.g., LinkedIn)	24	10.8	47	32.9
Referrals from colleagues	15	6.7	62	43.4
Referrals from clients	16	7.2	56	39.2
Freelance listings (e.g., EMWA Freelance Directory)	5	2.2	31	21.7
Personal website	1	0.4	11	7.7
Other	3 <sup>b</sup>	1.2	10°	7.0
No response	68	30.5	0	0.0

#### Main clients

Main clients				
Medical communications agencies	97	43.5	75	28.7
Pharmaceutical companies	71	31.8	74	52.4
Biotech or veterinary or medical device companies	44	19.7	39	27.3
Medical writing companies	41	18.4	N/A	N/A
Contract research organisations	35	15.7	40	28.0
Academic institutions	32	14.3	39	27.3
Publishers, including health journalism	20	9.0	22	15.4
Non-profit organisations (e.g. NGOs)	18	8.1	11	7.7
Other	9d	4.0	29e	20.3
No response	66	29.6	0	0.0

- a Data cannot be compared as respondents in 2023 selected one response and in 2018 could select many.
- b Professional network
- c Translation agencies, direct prospecting, MedComms workbook, agencies, single client, personal networking
- d Hospitals, translation agencies, field research companies, individual scientist/clinician/statistician, consulting agencies, the food industry and in vitro diagnostics manufacturers
- e Hospitals, translation agencies, individual scientist/clinician/statistician, consulting agencies, healthcare systems, professional society, other freelancers, medical education companies, medical/scientific recruitment/resourcing companies, public relations companies

#### Continued from p. 59

type (17.0%) or client type/geographical location (9.4%). Client quotes for translations are created as a per-word/page fee (5.8%) (Table 6).

Of the respondents who provided information (n=144), half declared that they charge milestone payments, mainly in the form of interim payments (55.6%) and percentage of upfront payment (18.1%) or a combination of both (25.0%) in 2023. Compared to 2018 data, milestone payments were less frequently applied (2018, 66.9% vs. 2023, 30.9%).

Payment issues were less frequent in 2023 (45.7%) compared to those reported in 2018 (72.5%).

Of their earnings, most freelance medical writers declared fixed costs below 30% (46.2%),

with four European respondents (1.8%) declaring fixed costs of over 50% (2023 data only).

Most freelancers perform ongoing professional development through personal research (50.7%), which grew from only 18.9% in 2018. In 2018, the most common modality was through online workshops (57%) (Table 7 p. 64).

Most networking is performed online, via professional or social networks (41% and 66%) with conferences and meet-ups collectively also popular. Most advertised their business via social media or through websites in both 2023 and 2018. Professional directories and contact with prospective clients were less common in 2023 compared to 2018. Interestingly, in 2023, 14.3% of freelance medical writers declared that they did not engage in any networking, up from 4.2%

in 2018, and 22.0% did not advertise their business at all, up from 4.9% in 2018.

## What a freelance medical writer should know and use to be successful (2023 data only)

Beyond medical writing skills, respondents suggested that project management/delivery, work-life balance, and networking skills were those most essential for becoming a successful freelancer (79.4%, 62.8%, and 59.2%). Other skill sets included marketing (32.7%), statistics (27.4%), accounting (20.6%), and website design (5.8%), see Figure 1, p. 65.

The greatest influence on gaining new business was considered word of mouth of current or past clients (41.3%) with social media or LinkedIn considered less impactful (17.0%), see Figure 2. EMWA activities considered most helpful to freelancers included being associated with EMWA, networking opportunities and the *Medical Writing* journal (47.6%, 47.6%, 46.7%, respectively). Professional development workshops, webinars, and the Freelance Business Forum were also considered helpful (39.0%, 29.5%, and 28.6%), see Figure 3, p. 65.

Most networking is performed online, via professional or social networks... Most advertised their business via social media or through websites... Interestingly, in 2023, 14% of freelance medical writers declared that they did not engage in any networking, up from 4% in 2018, and 22% did not advertise their business at all, up from 5% in 2018.

 Data cannot be compared as the question was not obligatory in 2023 and was posed as a nonobligatory question of frequency

in 2018.

b Accept the offered rate
c Charge interest, small claims court
d Respondents came from Germany,
Netherlands, Italy, and Austria and
were all 100% freelancers and 3
worked primarily in management.

Table 6. Taxation and invoicing

	2023		2018	
	n = 223	%	n = 142	%
Calculation of estimates for client quotes?				
Estimate project time and multiply by an	91	40.8	N/A	N/A
hourly/daily/weekly/monthly rate				
Quote hourly/daily/weekly/monthly rate and at project	86	38.6	N/A	N/A
completion invoice all hours/days/weeks/months worked				
Personal pricing list based on document/project type	38	17.0	N/A	N/A
Personal pricing list based on client type/geographical location	21	9.4	N/A	N/A
Per-word/page fee (translations)	13	5.8	N/A	N/A
Other <sup>a</sup>	4	1.6	N/A	N/A
No response	65	27.9	N/A	N/A
Frequency of charging milestone payments <sup>b</sup>				
No	72	30.9	47	33.1
	72			66.9
Yes		30.9	95	
No response	89	38.2	0	0.0
Types of milestone payments applied (n=72)				
Interim payments	40	55.6	N/A	N/A
Percentage up front payment	13	18.1	N/A	N/A
A combination of the above	18	25.0	N/A	N/A
No response	1	1.4	N/A	N/A
10 100 100 100 100 100 100 100 100 100			1071	
Prior experience of payment issues				
No	45	20.2	39	27.5
Yes	102	45.7	103	72.5
No response	76	32.6	0	0.0
Modalities for payment retrievals ( <i>n</i> =102)				
Send emails and invoice reminders until payment received	88	86.3	N/A	N/A
Set up a call with the client to discuss how they might	10	0.0	N1/A	N1 / A
make an immediate payment	10	9.8	N/A	N/A
Pass onto a third-party collection agency	4	3.9	N/A	N/A
Other <sup>c</sup>	3	2.9	N/A	N/A
Percentage of monthly earnings destined to fixed costs				
>20%	30	13.5	N/A	N/A
20% - 30%	73	32.7	N/A	N/A
30% - 40%	25	11.2	N/A	N/A
40% - 50%	14	6.3	N/A	N/A
>50%	<b>4</b> d	1.8	N/A	N/A
No response	146	65.5	N/A	N/A

#### Work-life balance (2023 data only)

Almost half of the respondents declared they were working from home (48.9%), but nearly a third did not respond to this question, see Figure 4, p. 66. Work-related personal stress was common but mostly manageable, with 53.8% reporting feeling stress "sometimes" and 6.7%

"most times". Only 1.8% reported feeling stressed "always" and 6.3% never felt stressed. Stress among medical writers seems to be mostly triggered by workload and deadlines (71.8%) and trying to maintain a work-life balance, such as family responsibilities (57.7%). Finding new clients, finances, and holding onto or losing

clients were also reasons for stress (24.8%, 21.5% and 12.1%). Interestingly, COVID-related issues were not considered a common trigger for stress in 2023 (1.3%). Active attempts to reduce stress were reported by just over half of the respondents (54.7%). Most look to reduce stress through pastimes, such as physical activity (91.0%),

Table 7. Professional development, networking, and advertising

	20	)23	20	18
	n=223	%	n=142	%
Continuing professional development modalities				
Personal research (e.g. specialised journals, medical conferences, etc.)	113	50.7	27	18.9
Online workshops	58	26.0	82	57.3
EMWA workshops	54	24.2	72	50.3
Workshops conducted by other associations	53	23.8	68	47.6
EMWA webinars	49	22.0	N/A	N/A
Other	12a	5.3	30 <sup>b</sup>	22.4
No response	73	31.3	0	0.0
letworking with other medical writer modalities				
Online, via professional or social networks	91	40.8	94	65.7
EMWA conferences	49	22.0	67	46.9
Local meet-ups	43	19.3	46	32.2
I do not network with other medical writers	32	14.3	6	4.2
Conferences organised by other associations	27	12.1	46	32.2
Courses provided by companies, such as Management Forum	2	0.9	2	1.4
Other	3c	1.3	7d	4.9
No response	70	30.0	0	0.0
1odality of business advertising				
Social media (e.g. LinkedIn)	101	45.3	111	77.6
Website	68	30.5	82	57.3
I don't advertise my business	49	22.0	7	4.9
Professional directories	43	19.3	64	44.8
Contact with prospective clients	43	19.3	51	35.7
Medical associations or societies	12	5.4		
Print media	2	0.9	3	2.1
Other	3e	1.3	11f	7.7
No response	68	29.2	0	0.0

a Business and personal marketing, MedComms webinars, Clarity and Openness in Reporting (CORE) Reference newsletter, networking, on-site learning, client requested training, podcasts, The Organisation for Professionals in Regulatory Affairs (TOPRA), Regulatory Affairs Professionals Society (RAPS)

home-based activities (67.2%), social activities (51.6%), and mindfulness/meditation (32.8%). Respondents also suggested many other stressreducing activities, including travel, music, psychological assistance, pet therapy, reducing working hours, client selection, and simply saying "no" to clients.

#### Open-ended comments

Respondents made many requests, gave suggestions, and shared ideas for the EMWA Freelance Business Group. Some requested time and price guides to be made available for both freelance medical writers and their clients. Additional courses of "soft", marketing, and best practice skills were requested along with tips about how to identify new clients. More activities and training were requested at a local level or online, along with more networking opportunities and assistance with issues of "working from home". Some suggested the introduction of standardised skills, free education/reduced

Most look to reduce stress through pastimes, such as physical activity (91.0%), home-based activities (67.2%), social activities (51.6%), and mindfulness/meditation (32.8%)

 $<sup>^{</sup>m b}$  On the job training, client requested training, finding mentors, peer-to-peer learning, professional memberships, none

<sup>&</sup>lt;sup>c</sup> Phone/email

 $d\ Courses\ provided\ by\ companies\ such\ as\ Management\ Forum,\ AMWA\ ListServ,\ client\ network,\ Skype\ calls,\ Med\ Comms\ Networking$ 

<sup>&</sup>lt;sup>e</sup> Networking, marketing material send out

 $<sup>^{</sup>m f}$  Networking at conferences, recruitment agencies, longstanding relationship, word of mouth, develop articles on topics relevant to my experience

conference costs, a mentorship program, and the availability of testimonials. Finally, some respondents suggested allowing more time for the Freelance Business Group Forum at the conference.

#### Discussion

The survey's results highlight the changing landscape for freelance medical writing. There are many indicators to suggest that demand for freelancers has increased in recent years. More freelancers responded to the 2023 survey, most of whom were generally younger with relatively minimum experience (<5 years). There has been a great evolution of medical writing companies, similar to findings in the 2021 EMWA Salary Survey,11 and a relative fall in pharmaceutical companies as main clients. This is an indication of the trend by pharmaceutical companies to externalise medical writing activities through consulting companies.

Freelancers arguably seem passive in their business approach. There was also an astonishingly high proportion of medical writers who admitted to not engaging in any networking, up 3-fold compared to data acquired in 2018, or advertising their business, up more than 4-fold

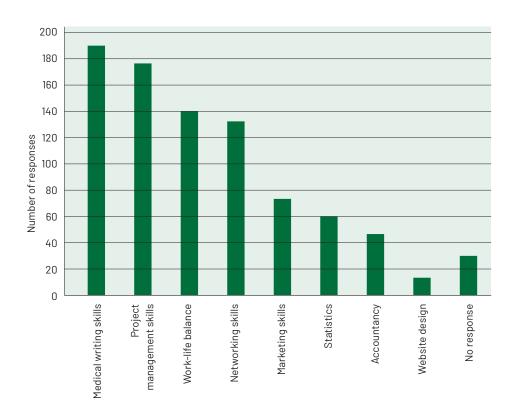


Figure 1. Skill sets considered important for becoming a successful freelancer

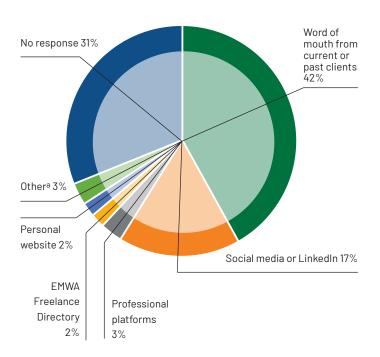


Figure 2. The greatest influence on gaining new business



Figure 3. EMWA activities most helpful to a freelancer



<sup>&</sup>lt;sup>a</sup> Recruitment agency, experience, EMWA conferences, networking, volunteer, professional network

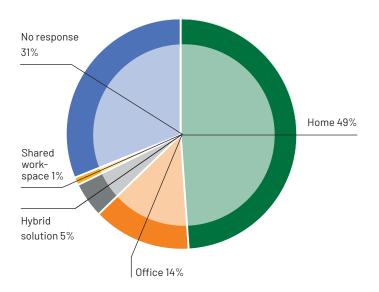


Figure 4. Work location

from 2018 data. The respondents also claimed that the greatest influence on gaining new business was word of mouth. The authors speculate that the common occurrence of long-term clients and the growing medical writing services market mean that freelancers do not need to network, advertise, or actively search for new clientele to acquire new business.

Freelancers also seem passive in their professional development. Professional development was mainly performed through personal research, e.g reading specialised journals or following medical conferences, whereas participation in workshops and courses and conferences (online and face-to-face) were less often reported.

Interestingly, a good work-life balance was rated as an important skill by almost two-thirds of the respondents. Stress levels, when present, seem well managed. Physical activity for stress reduction, which assists in improving mental health,12 may be a major reason for this effect of low stress levels, especially for a work style that is fundamentally computer based and isolating. 10,13

In line with increasing demand for freelancing services, the survey saw an increase in reported mean hourly rates. Reported rates are slightly higher than those reported in the subsection for freelancer responses in the 2021 EMWA salary survey; €82.2 (n=223) vs. €78 (n=103).11 This FBS also found an overall increase in rate per service with years of experience, a trend not seen in the 2021 salary survey. Importantly, this 2023 survey can be used as a guide for the time required by medical writers to deliver various services, and the relative prices, in terms of hourly rates, for the services provided.

#### Study limitations

With all survey-based studies, there are limitations. Despite this survey having the largest response rate compared to all previous EMWA FBS, geographic distribution and response rates were highly variable, with some countries, such as the UK, being over-represented whilst many countries missed participation. As a result, this could affect the overall findings and it prevented us from deciphering more associations on country-specific trends. Regression analysis was performed to identify trends across age, demographics, pricing, advertising, etc., however, due to some subsections having low responses, it was difficult to provide a clear conclusion (data not shown). This 7th FBS was structured on the previous 6th FBS but with additional questions, therefore, it was not possible to do a direct comparison on all questions and the proportion of respondents who completed both surveys is unknown. The distribution of the survey was mainly through the EMWA network and the authors' own networks, therefore, there could be selection bias in the study population. The classifications of the respondents according to medical writer type and the mean hourly rate were not direct questions and were assigned by the authors. The ranges of responses to hourly rates and salary expectations were wide, and some service estimates were provided from very few responses (data given in the tables). It is unsure if the larger monthly salary expectations were indicative of freelancers that potentially outsourced work or were running small businesses, and therefore, had higher incomes due to more workloads but also presumably higher outgoings (not asked in the survey) or due to the wide range of respondents' years of experience. Due to the variability in the hourly and monthly income and the relatively low number in some categories, data in this manuscript are provided as a guide only and should be interpreted with caution. Further, comparisons with the 2021 EMWA Salary Survey should be interpreted with caution as questions were not the same among the surveys.

Since analysing the results, some gaps in the knowledge remain. The survey did not ask about job satisfaction or the impact of the pandemic, which were covered in the 2021 salary survey.11 In addition, the question regarding years of experience did not differentiate between those as a medical writer and those as a freelancer, which could lead to some misinterpretation. Lastly, the type of medical writer was analysed through the type of services each respondent offered and not a clear question. These limitations will be considered in the 8th FBS.

#### Future challenges

Freelancing isn't without its challenges and to succeed, a freelancer must adapt with the working environment. We are in an era where European, country-specific, and product-specific regulations are constantly changing, and a freelancer must keep up with these working practices to be able to deliver to their clients the best quality documents. In addition, the emergence of more sophisticated artificial intelligence (AI) is also gaining pace and could both hinder and help a medical writer. The key is to have the correct training and professional development in AI to keep up to date with these growing trends.

#### **Conclusions**

This survey provides up to date information highlighting the evolving landscape of freelance medical writing. Excitingly, there are clearly opportunities for freelancers of all experience levels, both in the MedComms and regulatory fields, and for full-time and hybrid workers, regardless of geographical location. The data supports previous surveys, such as the recent EMWA salary survey, but in its novelty, offers indepth information about timing and pricing of projects, and allows insights into current trends

in advertising, networking, and gaining new business. Lastly, it is encouraging to see that freelance medical writers are not overly stressed by their situation and are adaptable to find ways to alleviate the work-related stress through various activities. Challenges and further changes are ahead but we are certain that the freelancers are prepared to take them on. The Freelance Business Group will continue to monitor freelance activity and plan to launch the survey on a 3-to-4-year basis and work alongside the EMWA salary and compensation survey team.

#### **Acknowledgements**

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#### **Disclaimers**

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

#### Data availability statement

Data and other supplemental information are available upon request. Please contact corresponding author.

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#### Appendix 1. EMWA's 2023 Freelance Business Survey

g.  $\geq$  70 years

h. Prefer not to say

# DEMOGRAPHICS 1. Gender a. Female c. Non-binary b. Male d. Prefer not to say 2. Age a. < 20 years e. 50-59 years b. 20-29 years f. 60-69 years

#### 3. Where are you based?

c. 30-39 years

d. 40-49 years

- a. In Europe; please specify country ...
- b. Outside Europe; please specify country ...

## 4. Was it straight forward to set yourself up as a freelancer in your country

- a. Yes (please go to q. 6)
- b. No

If no, could you please specify the issues you faced?

Please specify ...

#### **WORK PRACTICES**

- 5. How would you describe your occupational status?
- a. 100% freelance
- b. Hybrid freelance/contract/student
- c. Other
- 6. How many years of experience do you have as a freelancer?
- a. <1 year</li>b. 1-5 yearsd. 11-15 yearse. >15 years
- c. 6-10 years
- 7. How many hours per week do you typically work as a freelancer?
- a. 1–10 d. 31–40 b. 11–20 e. 41–50 c. 21–30 f. >50
- 8. Which of the following services do you provide and what proportion of your time (%) do you usually spend on each of them (select all that apply)?
- a. Writing
- b. Proofreading and editing
- c. Translation
- d. Quality control
- e. Electronic publishing
- f. Consultancy work (e.g., training)
- g. Other; please specify ...

- 9. What types of documents do you generally work on (select all that apply)?
- a. Manuscripts for journals
- Abstracts, posters, slide kits for conferences
- c. Marketing materials
- d. Market access / HEOR materials
- e. Conference proceedings
- f. Educational and training material (for patients and health professionals)
- g. Medical and scientific textbooks
- h. Regulatory documents investigator brochures, study protocols and reports
- Regulatory documents summary documentation, CTD sections, SmPCs, product packaging inserts
- Regulatory documents medical devices, biologics
- k. Regulatory documents other; please specify below
- I. SOPs and user manuals
- m. Websites and online articles
- n. Other; please specify ...
- Please select skill sets you think are important for becoming a successful freelancer (select all that apply).
- a. Project management/delivery
- b. Marketing skills
- c. Medical writing skills
- d. Website design
- e. Accountancy
- f. Networking skills
- g. Statistics
- h. Work-life balance
- i. Other; please specify ...

#### PRICING AND PAYMENT PRACTICES

- 11. How do you prepare your estimates for client quotes?
- I estimate the time the project requires and multiply by an hourly/daily/weekly/monthly rate
- I quote my hourly/daily/weekly/monthly rate and at project completion I invoice all hours/days/weeks/months worked
- c. I apply my personal pricing list based on document/project type
- d. I apply my personal pricing list based on client type/geographical location
- e. In the case of translations, I apply a perword/page fee
- f. Other; please specify ...

- 12. How long (in hours) do you typically work on the following types of services?
- a. Writing a standard scientific article
- b. Edit a standard scientific article
- c. Translate a standard scientific articled. Writing a CSR/other regulatory
- documents
- e. Writing technical evaluations
- f. Writing a medical blog
- g. Writing patient material
- h. Writing content for a website
- i. Other writing, please specify
- 13. In terms of an hourly rate (in €), what do you typically charge for the following types of services?
- a. Writing: Regulatory
- b. Writing: Non-regulatory
- c. Editing
- d. Proofreading
- e. Translation
- f. Quality control
- g. Consultancy
- h. Training
- 14. If you charge milestone payments which of the following do you use?
- a. Percentage upfront payment
- b. Interim payments
- c. Non-refundable deposit for bookings in the future
- d. A combination of the above
- e. Other; please specify ...
- f. I do not charge milestone payments
- 15. What is your target minimum monthly earnings?
- a. Please specify in Euros (€) ...
- 16. What percentage of your monthly earnings is destined to fixed costs of taxation/ insurance?
- a. >20% d. between 40-50%
- b. between 20–30% e. >50%
- c. between 30-40%
- 17. If you face payment issues, how do you retrieve your fee for work done?
- a. Send emails and invoice reminders until payment received
- b. Set up a call with the client to discuss how they might make an immediate payment
- c. Pass it onto a third party to collect on your behalf
- d. Other; please specify ...
- e. I have never faced any payment issues

#### **BUSINESS PRACTICES**

- 18. What is the major source of most of your projects (please select one)?
- Longstanding clients a.
- Referrals from colleagues b.
- Referrals from clients C.
- Professional or social networking sites (e.g., d. LinkedIn)
- Personal website e.
- Freelance listings (e.g., EMWA Freelance Directory)
- Other; please specify ... g.
- 19. Who are your main clients (select all that apply)?
- Pharmaceutical companies a.
- Biotech or veterinary or medical device h. companies
- Medical communications agencies C.
- d. Medical writing companies
- e. **CROs**
- Academic institutions f.
- Publishers, including health journalism a.
- Non-profit organisations (e.g., NGOs)
- Other; please specify ...
- 20. How do you advertise your business (select all that apply)?
- Website a.
- Social media (e.g., LinkedIn) b.
- Professional directories C.
- Medical associations or societies d.
- Print media e.
- Contact with prospective clients
- I don't advertise my business g.
- h. Other; please specify ...
- 21. In your opinion, what has the greatest influence on gaining new business (please select one)?
- Personal website a.
- Social media or LinkedIn b.
- Professional platforms C.
- Word of mouth from current or past clients d.
- **EMWA Freelance Directory** e.
- Other; please specify ... f.

#### **NETWORKING PRACTICES**

- 22. How do you continue your professional development (select all that apply)?
- EMWA workshops a.
- EMWA webinars h.
- Workshops conducted by other associations C.
- Online workshops d.
- Personal research (e.g., specialised journals, medical conferences etc.)
- Other; please specify ...

- 23. How do you network with other medical writers, freelance or not (select all that apply)?
- a. EMWA conferences
- Conferences organised by other associations
- Courses provided by companies, such as Management Forum
- Local meetups
- Online, via professional or social networks
- I do not network with other medical writers
- Other; please specify ...
- 24. Are you a member of any writers association?
- EMWA a.
- b. AMWA
- c. Australasian Medical Writers Association
- d.
- e. Other; please specify ...
- None of the above

#### If you are an EMWA member, please answer the following four questions:

- 25. How many years have you been an EMWA member?
- a. <1

c. 4-5

h. 1-3 d. >5

- 26. How often have you attended EMWA conferences in the past 3 years?
- a.

c. 5-6

b. 3-4 d. Not at all

- 27. Which of the following EMWA activities helps you the most as a freelancer (select all that apply)?
- Association with EMWA a.
- Professional development workshops b.
- Freelance Business Forum c.
- Networking opportunities d.
- Webinars e.
- Symposia f.
- Expert seminars g.
- h. Special interest groups
- i. Journal
- Other; please specify ... j.
- 28. Are you listed in EMWA's Freelance Directory?
- a. Yes
- b. No (please go to q. 28).

If yes, how would you respond to the statement -I have found the Freelance Directory to be a very useful tool for advertising and getting contacted by prospective clients.

- a. Strongly agree
- b. Somewhat agree
- Neither agree nor disagree c.
- Somewhat disagree

- 29. If you are not an EMWA member, do you plan to join EMWA in the future?
- a. Yes

b. No

- 30. Do you think EMWA should provide any additional activities to those already available? If yes, please specify
- Nο a.
- Yes; please specify ...

#### **WELLBEING PRACTICES**

#### 31. Where do you work?

- In my own office
- In a shared workspace b.
- Directly at the client location C.
- At home d.
- Hybrid solution (office/home) e.
- Other; please specify ...
- 32. Do you feel your work creates personal
- Never (please go to g. 34).
- Sometimes
- Most times
- d. Always
- 33. If so, what triggers your stress (select all that apply)?
- Workload and deadlines a.
- Finances b.
- COVID-related issues C.
- d. Holding onto or losing clients
- Finding new clients e.
- Work-life balance (e.g., family responsibilities)
- Other; please specify ...
- 34. Do you actively attempt to reduce work related stress?
- Yes a.
- b. No
- If so, which activities do you engage in (select all that apply)?
- a. Physical activity (e.g., group sports, yoga, Pilates, jogging, gym membership, walking, hiking, etc.)
- Mindfulness/MeditationSocial activities Activities within the home environment (e.g., cooking, gardening, etc.)
- Other; please specify ...
- 35. Finally, how do you feel in general about EMWA's outreach to freelance medical writers?

What suggestions or ideas do you wish to share with us to make it better?

Please specify ...

FINAL MESSAGE: Full results will be published on the EMWA website and in EMWA's journal Medical Writing.



#### Appendix 2. EMWA's 2018 Freelance Business Survey

#### DEMOGRAPHICS

### How would you describe your freelance work?

- a. Part-time
- b. Full time

#### 2. Are you an EMWA member?

- a. Yes
- o. No

If **no**, do you plan to join EMWA in the future?

- a. Yes
- b. No

#### 3. Where are you based?

- a. In Europe; please specify country ...
- b. Outside Europe; please specify country ...

#### **WORK PRACTICES**

## 4. How many hours per week do you typically work (as a freelancer)?

- a. 1-10
- d. 31-40
- b. 11-20
- e. 41-50
- c. 21-30
- f. >50

#### 5. Which of the following services do you provide and what proportion of your time do you usually spend on these (select all that apply)?

- a. Writing %
- b. Proofreading and editing \_\_\_\_%
- c. Translation %
- d. Quality control %
- e. Electronic publishing \_\_\_\_%
- f. Consultancy work (e.g. training) %
- g. Other %; Please specify ...

## 6. What types of documents do you generally work on (select all that apply)?

- a. Manuscripts for journals
- b. Abstracts, posters, slide kits for conferences
- c. Marketing materials
- d. Conference proceedings
- e. Educational and training material (for patients and health professionals)
- f. Medical and scientific textbooks
- g. Regulatory documents investigator brochures, study protocols and reports
- h. Regulatory documents summary documentation, CTD sections, SmPCs, product inserts
- Regulatory documents medical devices, biologics
- j. Regulatory documents other;please specify ...
- k. SOPs and user manuals
- I. Websites and online articles
- m. Other; please specify ...

#### 7. How do you typically charge for your services?

- a. Hourly
- d. Monthly
- b. Daily
- e. Per project
- c. Weekly
- f. Other; please specify ...

## 8. What hourly rate (in €) do you typically charge for the following types of service?

- a. Writing: Regulatory €
- b. Non-regulatory €
- c. Editing €
- d. Proofreading €
- e. Translation €
- f. Quality control €
- g. Consultancy €
- h. Training €

## 9. Do you typically charge milestone payments for long-term projects you undertake?

- a. Neve
- c. Most times
- b. Sometimes
- d. Always

#### 10. How often do you face payment issues (e.g. delay in payment) from a client?

- a. Never
- c. Most times
- b. Sometimes
- d. Always

#### **BUSINESS PRACTICES**

## 11. What is the major source of most of your projects?

- a. Longstanding customers
- b. Referrals from colleagues
- c. Referrals from customers
- d. Professional or social networking sites
- e. Personal website
- f. Freelance listings (e.g. EMWA Freelance Directory)
- g. Other; please specify ...

#### 12. Who are the majority of your clients?

- a. Pharmaceutical companies
- b. Biotech or veterinary or medical device companies
- c. Medical communications agencies
- d. Medical writing companies
- e. CROs
- f. Academic institutions
- g. Publishers, including health journalism
- h. Non-profit organisations (e.g. NGOs)
- i. Other; please specify ...

### 13. How do you advertise your business (select all that apply)?

- a. Website
- b. Social media (e.g. LinkedIn)
- c. Professional directories
- d. Print media
- e. Contact with prospective clients
- f. Other; please specify ...

# 14. Are you listed in EMWA's Freelance Directory (question only for EMWA members)?

- a. Yes
- b. No

If yes, how would you respond to the statement – I have found the Freelance Directory to be a

very useful tool for advertising and getting contacted by prospective clients.

- a. Strongly agree
- d. Somewhat disagree
- b. Somewhat agree
- e. Strongly disagree
- c. Neither agree nor disagree

If **no**, how would you respond to the statement – I will consider listing my business on the Freelance Directory if I have more information on how clients use it to get in touch with freelancers and any other benefits. Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

#### **NETWORK PRACTICES**

## 15. How do you continue your professional development (select all that apply)?

- a. EMWA workshops
- b. Workshops conducted by other associations
- c. Online workshops
- d. Other; please specify ...

#### 16. How do you network with other medical writers, freelance or not (select all that apply)?

- a. EMWA conferences
- b. Conferences organised by other associations
- c. Courses provided by companies such as Management Forum
- d. Local meet-ups
- e. Online, via professional or social networks
- f. Other; please specify ...

# 17. If you are an EMWA member, how often have you attended EMWA conferences in the past 3 years?

- a. 1-2
- c. 5-6
- b. 3-4
- d. Not at all

# 18. If you are an EMWA member, which of the following activities help you the most as a freelancer (select all that apply)?

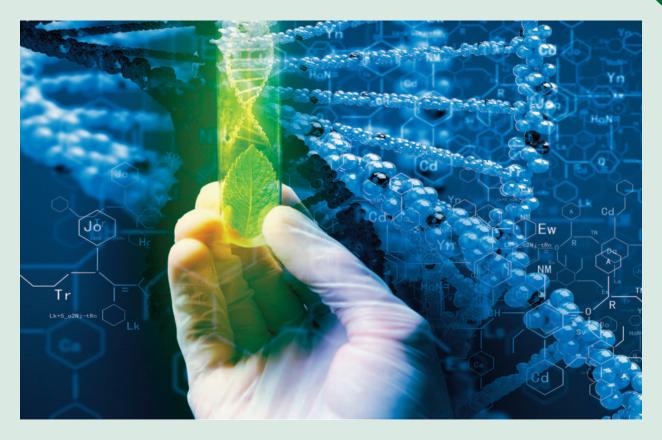
- a. Association with EMWA
- b. Professional development workshops
- c. Freelance Business Forum
- d. Networking opportunities
- e. Webinars
- f. Symposia
- g. Expert seminars
- h. Special interest groups
- i. Reading the journal
- j. Other; please specify ...

#### SUGGESTIONS

(Results will be used by the FBG subcommittee to bring new initiatives and benefits to EMWA members who are freelancers) How do you feel in general about EMWA's outreach for freelance medical writers? What suggestions or ideas do you wish to share with us to make it better?

# Oon it mice.

### The December 2023 edition



# **Biotechnology**

Biotechnology uses biological systems and living organisms in R&D and production processes.
Biotechnologies include biologic and biosimilar pharmaceuticals like monoclonal antibodies, vaccines and advanced therapy medicinal products, for example, gene and cell therapies and tissue engineered products. In addition, biotechnologies support the product lifecycle, for instance, in non-clinical work using in silico, in vitro, and animal testing methods. Also, support services personnel like those in biobanks and supply chains require an understanding of biotechnology. This issue focuses on the crucial role of writing and communications in biotechnology and product development.

Guest editor: Jennifer Bell

The deadline for feature articles is September 1, 2023.

# Carbon footprint of EMWA activities:

# A first estimate

Blanca Gomez-Escoda<sup>1</sup>, Pavlína Cicková<sup>2</sup>, Raquel Billiones<sup>3</sup>, supported by EMWA

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#### **Abstract**

The Sustainability Special Interest Group (SUS-SIG) of EMWA was established in 2020 to support the United Nations 2030 agenda for sustainable development from the perspective of a not-for-profit professional organisation for medical writers and communicators. One of the SUS-SIG's initiatives was to estimate EMWA's carbon footprint, which can serve as a baseline for future carbon reduction strategies. This article presents the first estimate of EMWA's annual greenhouse gas emissions, expressed as CO2 equivalent ( $CO_2E$ ).

#### Introduction

he United Nations 2030 agenda for sustainable development includes 17 sustainable development goals (SDG) described as transformative steps which are urgently needed to shift the world onto a sustainable and resilient path.1 SDG 13 in the 2030 agenda is to "take urgent action to combat climate change and its impacts". One of the targets of this SDG is to integrate such climate change actions into national policies, strategies, planning, and monitoring progress.

Greenhouse gas emissions (GHGEs; also

simply known as carbon emissions) are the main drivers of climate change. The primary greenhouse gas is carbon dioxide (CO2); others include methane, nitrous oxide, water vapour, and fluorinated gases.2

Legislations and policies in Europe that have aligned to the UN SDGs include the Directive 2014/95/EU (also called the EU Corporate Sustainability Reporting Directive) and the UK Climate Change Act 2008, which require large companies to report their GHGE targets and carbon accounting. Many companies, including major pharmaceutical companies, have set strong decarbonisation commitments as part of their environmental, social, and governance

The European Medical Writers Association (EMWA) is a not-for-profit organisation for medical writing and communications professi-

onals. While EMWA does not fall within the purview of the abovementioned legislations, many of its members are employees of or service providers for pharmaceutical and medical device companies that do. These companies - and thus, medical writers by association - are part of the broader healthcare industry, which is recognised as one of the major contributors to global emissions.4

The Sustainability Special Interest Group (SUS-SIG) of EMWA was established in 2020 to support the UN SDGs. One of the SIG's initiatives was to estimate the carbon footprint of

EMWA, thereby promoting sustainability awareness among its membership and beyond.

#### **Objectives**

This article reports a first estimate of EMWA's annual GHGE expressed as CO2 equivalents (CO<sub>2</sub>E). These baseline data aim to serve not only as basis for shaping EMWA's sustainability policy but also to pave the way for future research on measures for similar organisations and

#### Methods

The Sustainability

Special Interest

Group of EMWA

was established in

2020 to support

the UN sustain-

able development

goalss. One of the

special interest

group's initiatives

was to estimate the

carbon footprint

of EMWA.

#### **EMWA** activities

The core activities of EMWA were classified under three broad categories, with subactivities listed under each category (Figure 1):

- Operations and Membership Care, including head office (HO) activities, journal, website, and executive committee (EC) activities.
- Education, including conferences and webinars.
- Other initiatives related to collaborations within EMWA (i.e., through the SIGs), and with external organisations (e.g., Ambassador Programme).

The emissions associated with each activity were estimated and normalised as CO2E/year. Conversion factors used to convert GHGE into CO2E were based on published literature and

> other commonly used factors (Table 1).

> Calculations were based on retrospective data (where available) retrieved from EMWA HO records.

#### Computer use

The majority of EMWA activities involve computer work. Calculations of emissions associated with computer work were based on the methodology used in the article by Faber 2021.5 Emissions linked to computer use included energy use, the computer's life cycle emissions (accounting for different brands of laptops and the percentage of a laptop's useful

life spent participating in the activity), and data use. In addition, the use of an external monitor and a desk lamp was also included (see Table 1

Three types of computer-related emissions were considered:

- Emissions linked to standard day-to-day computer use and low volume data use (e.g., documents, emails, etc.).
- Emissions linked to computer work involving moderate volume data use, such as small-scale virtual team meetings.



Emissions due to large-scale events, such as virtual conference activities and webinars, intensive data use (i.e., streaming), and additional activities by event organisers.

#### Office space

Long-term EMWA office space use was mainly

linked to the EMWA HO operations. The energy consumption of HO (electricity, air conditioning, heating) could not be calculated directly because of the use of shared space and services. Instead, energy consumption was extrapolated from estimated energy consumption values per  $m^2$  of air-conditioned office space (Table 1). Each

full time employee was allocated 10 m<sup>2</sup> of office space, a recommended estimate from the Carbon Trust (Table 2).6

Temporary office space use included face-toface (F2F) conference venues and F2F meeting spaces of the EC outside of conferences. At the F2F conference, the same space was shared

Table 1. Conversion factors used to calculate greenhouse gas emissions

Activity	Conversion factor	Source
Standard computer worka	0.5 kg CO <sub>2</sub> E/hour	Adapted from Faber 2021 <sup>5</sup>
Computer work for virtual meetings <sup>b</sup>	1.2 kg CO <sub>2</sub> E/hour	Adapted from Faber 2021 <sup>5</sup>
Computer work for virtual conference and webinars <sup>c</sup>	1.3 kg CO <sub>2</sub> E/hour	Adapted from Faber 2021 <sup>5</sup>
Office/ conference room space usage	154.3 kg CO <sub>2</sub> E/m <sup>2</sup> /year	Lyle 2009 <sup>6</sup>
Air travel	250 kg CO <sub>2</sub> /passenger/hour	https://www.carbonindependent.org/22.html
Train travel	0.006 kg CO <sub>2</sub> E/km	https://ourworldindata.org/travel-carbon-footprint
EMWA website	0.00337 kg CO <sub>2</sub> E/visit	https://www.websitecarbon.com/
Paper printing (journal and handouts for workshops)	0.0043 kg CO2E/A4 page	Dias 2012 <sup>7</sup>
Postage of journal	0.025 kg CO <sub>2</sub> E/letter	https://www.theguardian.com/environment/green-living-
		blog/2009/nov/05/environmental-impact-mail
Hotel stays	11.5 kg CO <sub>2</sub> E/room night	https://www.hotelfootprints.org/
Standard lunches	1.88 kg CO <sub>2</sub> E/meal	Scarborough 2013 <sup>8</sup>
Vegetarian lunches	1.27 kg CO <sub>2</sub> E/meal	Scarborough 2013 <sup>8</sup>

Abbreviation: CO<sub>2</sub>E, carbon dioxide equivalent

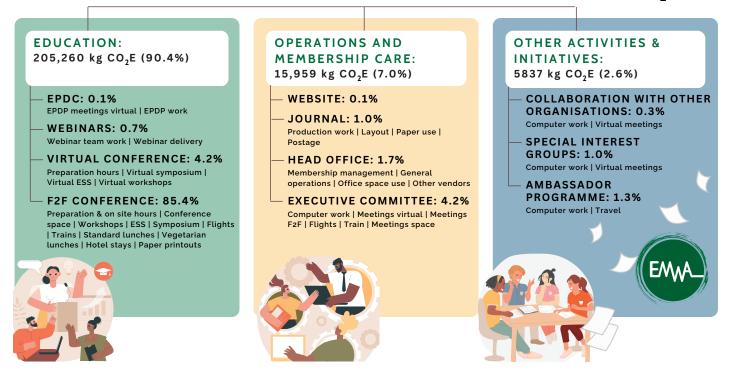
Computer work for virtual conference and webinars: laptop + monitor+ desk lamp+ high data volume (i.e., streaming) + server + website visits + organiser activities



<sup>&</sup>lt;sup>a</sup> Standard computer work: laptop + external monitor + desk lamp + low data volume + server

 $<sup>{}^</sup>b Computer work with online meetings: laptop + monitor + desk lamp + moderate data volume + server + website visits$ 

#### EMWA'S TOTAL CARBON EMISSIONS: 227 TONNES CO2E



#### EMWA'S TOTAL CARBON EMISSIONS PER CATEGORY

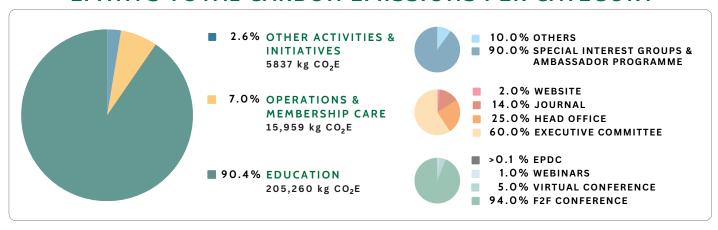


Figure 1. EMWA activities and corresponding greenhouse gas emissions expressed in carbon dioxide equivalents ( $CO_2E$ )

 $Top\ panel: Percentage\ of\ each\ category\ and\ subcategory\ was\ calculated\ with\ denominator\ representing\ EMWA's\ total\ annual\ carbon\ emissions.$ 

Bottom panel (left): Percentage of each category was calculated with denominator representing EMWA's total annual emission.

Bottom panel (right): Percentage of each category was calculated with denominator representing each category (Education, Operations and Membership Care, and Other Activities and Initiatives).

Abbreviations: CO<sub>2</sub>E, carbon dioxide equivalent; EPDC, EMWA Professional Development Programme Committee; ESS, Expert Seminar Series; F2F, face to face

Design@EMWA Creative Team: Pavlína Cicková

across the different events; hence calculations for workshops, symposium, expert seminar series (ESS) and similar events were aggregated (Table 2).

#### Paper use

Paper use was mainly due to the EMWA journal (*Medical Writing*) and workshop handouts at the F2F conference (Table 2). Calculating emissions due to paper consumption used conservative assumptions, including the life cycle of paper from the tree.<sup>7</sup>

#### **Events**

Calculations for large-scale EMWA events were based on data from conferences (F2F and virtual) and webinars. For F2F conference calculations, we used metrics from the Vienna Spring Conference 2019, the last in-person spring conference before the COVID-19 pandemic. In addition to space (as discussed above), computer use as part of the conference preparation, onsite operations, and delivery of the symposium, workshops, and the ESS was also considered. Other items included in the calculations were travel and overnight stays of delegates, conference lunches (with distinction made between standard and vegetarian meals) and the use of paper handouts (as discussed above; see Table 1 and Table 2).

The virtual conference calculations were based on data from the virtual May 2021 conference, with emissions mainly coming from

computer use. Data from these two conferences were deemed to be representative of EMWA's conference activities from 2023 onwards.

#### Assumptions and limitations

In cases where data were not available, assumptions and approximations were made based on existing metrics (Table 2). In all cases, assumptions made were those that tended to overestimate rather than underestimate emissions (i.e., when several conversion factors were available).

The following limitations of these estimates were taken into account:

• Estimates are based on assumptions and

- commonly used conversion factors (Table 1) and did not use the standardised scoping process per the Greenhouse Gas (GHG) Protocol.<sup>2</sup>
- EMWA HO operations were based on a shared services model, so direct energy use could not be obtained.
- Estimates were based only on data from two conferences, not on data collected from several conferences across many years. However, the 2019 Vienna conference was among the most well-attended (≈450 attendees). The May 2021 virtual conference attendance (≈300 attendees) was similar in size to previous autumn conferences.
- Emissions per unit of electricity were based on the US average,<sup>5</sup> whereas EMWA activities took place in Europe.
- No actual data were available for travel. Travel
  emissions were based on flights and longdistance train trips (assuming half of the
  delegates travelled by air, the other half by
  rail). The use of local public transport and
  private vehicles was not considered. EMWA
  conferences are normally held in major
  European cities with efficient public transport
  systems.

#### Results

These baseline

data aim to serve

not only as a basis

for shaping

**EMWA's** 

sustainability

policy but also to

pave the way for

future research

on measures

for similar

organisations

and activities.

#### Overall emissions

EMWA's total carbon emission per year was 227,056.47 kg (227 tonnes)  $\rm CO_2E$  (Figure 1). The bulk of EMWA's emissions come from Edu-

cation (205,260.49 kg  $CO_2E/year$ , 90.4% of total EMWA emissions). Operations and Membership Care and Other Initiatives accounted for 15,958.65 kg  $CO_2E/year$  (7%) and 5837.32 kg  $CO_2E/year$  (2.6%), respectively (Figure 1; Table 2).

#### Educational activities

Of all the educational activities (Figure 1, Table 2), the F2F conference was the main emission source (193,912.47 kg CO<sub>2</sub>E/year; 94% of education emissions; 85% of total emissions), followed by the virtual conference (9576.95 kg CO<sub>2</sub>E/year; 5% of education emissions; 4.22% of total emissions).

These two activities were large-scale events involving a large number of participants.

The major contributor to the high emissions

of the F2F conference was flights (168,750.00 kg CO<sub>2</sub>E, 87% of F2F conference emissions; 74% of total EMWA emissions), based on the assumption that half of the participants travelled to the conference by air (see Figure 2; Table 2). Other key contributors to the F2F conference emissions (Figure 2) were hotel stays (15,525 kg CO<sub>2</sub>E) and conference space (5400.50 kg CO<sub>2</sub>E). The main emission source for the virtual conference were virtual workshops (computer use with high data volume, 3783 kg CO<sub>2</sub>E), virtual symposium (026.4 CO<sub>2</sub>E), and Expert Seminar Series (ESS) (2017.6 CO<sub>2</sub>E).

#### Operations and membership care

Operations of the organisation and membership care accounted for 7% of total emissions. Activities of the EC (9601 kg CO<sub>2</sub>E/year, 4.23% of total EMWA emissions), and HO (3925.3 kg CO<sub>2</sub>E/year, 1.73% of total EMWA emissions), were the main contributors (Figure 1; Table 2).

Journal and website accounted for <1% of total emissions each (Figure 1; Table 2). Based on the conversion factor used by Dias  $(2010)^7$  for paper, one printed copy of the EMWA journal (excluding emissions linked to transport) produced approximately 300 g of CO<sub>2</sub>E. Total emissions of the journal paper copies printed and delivered per issue (4 issues per year) amounted to 2172.80 kg CO<sub>2</sub>E/year (including computer work of production and lay out).

A total of 77,000 visits to the EMWA website in 2021 accounted for 259.49 kg  $CO_2E$  for that year, based on website analysis metrics (see Table 1; Table 2).

#### Other initiatives

Other initiatives that include activities of the SIGs, the Ambassador Programme, and collaborations outside of EMWA accounted for 2.6% (5837.32 kg CO<sub>2</sub>E/year) of the organisation's total emissions (Figure 1; Table 2).

#### Discussion

EMWA's total GHGE are approximately 227 tonnes of CO<sub>2</sub>E/year. Based on the average of 1400 members annually, this breaks down to approximately 162 kg CO<sub>2</sub>E per member per year.

Educational activities account for 90.4% of EMWA's emissions, with the F2F conference as the highest driver (85.4% of EMWA's total

Contuinued on page 79



**EMWA** activity

subactivity

#### Table 2. EMWA greenhouse gas emissions by activity: Assumptions, metrics, and estimates

Assumptions

PERATIONS AND MEMBERS	SHIP CARE		15,958.6
Head office			3925.
General operations by HO	Standard computer work <sup>a</sup>	276 hours/year	140.
Other vendors	Standard computer work <sup>a</sup>	352 hours/year	179.
Membership management by HO	Standard computer work <sup>a</sup>	1018 hours/year	519.
Office space use	10 m <sup>2</sup> /FTE	4 persons part time, equivalent to 2 FTEs = 20 m²/year	3086.
Executive Committee activities (	9 members)		9601.
EC F2F meeting space (outside of conferences)	10 m²/person	100 m <sup>2</sup> space, 2x a year = 0.55 m <sup>2</sup> /year	84.
EC virtual meetings	Computer work for small virtual meetings <sup>b</sup>	108 hours/year	129.
EC F2F meeting (outside of conference), computer use	Standard computer work <sup>a</sup>	256 hours/year	130.
EC work (excluding meetings)	Standard computer work <sup>a</sup>	432 hours/year	220.
EC travel to F2F meetings	50% by train: 500 km one way	3 persons, 2x year, round trip = 6000 km/year	36.
j	50% by air: 1.5-hour flight, one way (equivalent to London-Berlin)	6 persons, round trip, 2x a year = 36 hours/year	9000.
'			
EMWA website			259.
Website	-	77,000 page visits/year <sup>d</sup>	259
EMWA Journale			2172
Layout	Standard computer work <sup>a</sup>		
	Average 15 min/page. 120 single-sided pages/issue, 4 issues/year	120 hours/year	6
Postage journal	CO <sub>2</sub> emissions/letter – within the UK	5624 copies of journals posted/year	140
Production work	Standard computer work <sup>a</sup>	86 hours/month = 1032 hours/year	526
Paper use	Average of 1400 journals printed/issue Average of 60 A4 pages/issue, 4 issues/ year	336,000 pieces of A4 paper/year	1444
DUCATION			205,260.
Professional Development Progra	amme Committee		202
EPDC work (excluding meetings)		2 hours/month, 6 persons = 144 hours/year	73
EPDC meetings virtual	Computer use for small virtual meetings <sup>b</sup>	6 meetings/year, 3 hours, 6 persons = 108 hours/year	129
Webinars			1568
Webinar team work	Standard computer work <sup>a</sup>	3 hours/month, 3 persons = 108 hours/year	55
Webinar delivery	Computer use for webinars <sup>c</sup>	100 participants, 1 webinar/month = 1200 hours/year	1513
Virtual conference <sup>f</sup> (once a year)			9576
Preparation hours	Computer use for small virtual meetings <sup>b</sup>	626 hours/year	749
Virtual ESS	Computer use for virtual conferences <sup>c</sup>	8 hours, 200 participants = 1600 hours/year	2017
Virtual symposium	Computer use for virtual conferences <sup>c</sup>	8 hours, 300 participants = 2400 hours/year	3026
Virtual workshops	Computer use for virtual conferences <sup>c</sup>	30 workshops, 4 hours, 25 participants = 3000 hours/year	3783.

Metrics for calculations

**Estimated GHGE** 

in kg CO<sub>2</sub>E/year

EMWA activity subactivity	Assumptions	Metrics for calculations	Estimated GHGE in kg CO <sub>2</sub> E/year
Face-to-Face conference <sup>9</sup> (once	e a year)		193,912.47
Workshops + expert seminar series + symposium	Standard computer work <sup>a</sup>	60 events (workshops + ESS + symposium, other seminars), 3 hours/session = 180 hours/year	91.78
Paper printouts	A4 size	36,582 pages/year	157.30
Preparation + on site hours	Standard computer work <sup>1</sup>	479 hours/year	244.24
Lunches	Vegetarian	212 lunches/year	269.24
Lunches	Standard	1130 lunches/year	2124.40
Conference space	3200 m <sup>2</sup> used during 4 days of conference	4 days = 35 m <sup>2</sup> /year	5400.50
Hotel overnight stay	Average of 3 nights for 450 participants, average from very low to low-environmental impact hotels (Europe) <sup>h</sup>	1350 hotel stays/year	15,525.00
Travel to the venue	50% of participants travel by train (500 km one way)	225 participants, round trip = 225,000 km/year	1350.00
	50% of participants fly to the venue (1.5-hour flight, Berlin-London)	225 participants x 3h (round trip) = 675 hours/year	168,750.00

#### OTHER ACTIVITIES AND INITIATIVES: COOPERATION AND COLLABORATION

5837.32

Special Interest Groups			2230.08
Virtual meetings	Computer work for small virtual meetings <sup>b</sup> 7 EMWA members/SIG	10 SIGs, 1-hour meeting/month = 840 hours/year	1006.32
Computer work outside of meetings	Standard computer work <sup>a</sup> 5 EMWA members/SIG	10 SIGs , 4 hours/month = 2400 hours/year	1223.76

Ambassador Programme			3024.48
Ambassador programme work	Standard computer work <sup>a</sup>	4 persons, 2 hours, every 2 months = 48 hours/year	24.48
Ambassador programme travel	4 events, 1.5-hour flight one way	1 person, 3-hour flight (round trip) 3000.00	
	(equivalent to London-Berlin)	times per year = 12 hours/year	3000.00

Collaboration with other organisations		582.77	
Virtual meetings	Computer work for small virtual meetings <sup>b</sup> 3 EMWA members/project	5 projects, 1-hour meeting/month = 180 hours/year	215.64
Computer work	Standard computer work <sup>a</sup> 3 EMWA members/project	5 projects, 4 hours/month = 720 hours/year	367.13

Abbreviations: CO<sub>2</sub>E, carbon dioxide equivalent; EC, Executive Committee; EPDC, EMWA Professional Development Programme Committee; ESS, Expert Seminar Series; F2F, face to face; FTE, full time equivalent; GHGE, greenhouse gas emissions; HO, head office; SIG, special interest group All data from 2019, except where otherwise indicated. See Table 1 for conversion factors used in the calculations.

- ${}^{\rm a}\,S tandard\,computer\,work:\,laptop+external\,monitor+desk\,lamp+low\,data\,volume+server$
- $^{\rm b}$  Computer work with online meetings: laptop + monitor+ desk lamp+ moderate data volume + server + website visits
- $^{c}$  Computer work for virtual conference and webinars: laptop + monitor+ desk lamp+ high data volume (i.e., streaming) + server + website visits + organiser activities
- <sup>d</sup>Website visits from 2021
- $^{\rm e}$  Data from 2020 and 2021 (Issues from December 2020, March 2021, July 2021, and September 2021).
- $^{
  m f}$ Data from virtual EMWA conference May 2021. Calculations based on actual data provided by HO.
- <sup>g</sup> Data from F2F EMWA conference in Vienna in May 2019. Calculations based on actual data provided by HO.
- $^{\rm h}\, Based$  on environment impact ratings of European hotels https://www.hotelfootprints.org/



Figure 2. EMWA greenhouse gas emissions by activity: Assumptions, metrics, and estimates

Abbreviations: CO<sub>2</sub>E, carbon dioxide equivalent; ESS, Expert Seminar Series; F2F, face to face

Flights have been excluded from the stacked bars to ease visualisation of the other categories  $% \left\{ 1\right\} =\left\{ 1\right\} =\left\{$ 

Percentage of each category was calculated with denominator representing total carbon emissions of specific conference type.

<sup>\*</sup>The major contributors to the emissions are flights.

emissions). This is not surprising as this large-scale event fulfils one of EMWA's core missions – continuing education for its members. The 2019 F2F conference in Vienna (450 attendees) generated a mean of 431 kg  $\rm CO_2E$  per attendee. The specific activity with the highest environmental impact was air travel to the F2F conference, followed by hotel stays. Although we did not distinguish between the scopes of the emissions, it is clear that the bulk of EMWA's carbon footprint falls under Scope 3, i.e., indirect emissions that include transportation and distribution.<sup>2</sup>

The emissions of the F2F conference were about 20 times higher than the virtual conference in absolute value (Figure 2). However, when corrected for number of participants, the F2F conference emission was about 13 times higher compared with a virtual conference.

The UK National Institute for Health and Care Research recommends the use of virtual meetings as part of carbon reduction guidelines for clinical trials. The COVID-19 pandemic forced companies and organisations to adopt these practices. Several publications report on the significant reduction in emissions by shifting to virtual conferences. Our data on EMWA's emissions also reflect these findings.

However, F2F activities come with clear benefits and advantages that virtual events cannot fully provide. For all decarbonisation strategies, the balance between the need for direct human interactions and the minimisation of environmental impact needs to be considered.

To the best of our knowledge, no emissions data of organisations of comparable type and size to EMWA have been published to date. To compare with other activities in the healthcare industry, the multicentre international CRASH-2 trial with over 10,000 participants emitted approximately 108 tonnes a year (92 kg CO<sub>2</sub>E per participant). The pharmaceutical sector emits, on average, approximately 48.6 tonnes of CO<sub>2</sub>E per USD 1 million revenue per year. In 2019, each resident in Europe generated 6.8 tonnes of CO<sub>2</sub> on average.

In the last 2 years, EMWA has implemented measures to reduce the organisation's carbon footprint, directly and indirectly. Data from these measures have not been incorporated in the calculations reported here.

Direct measures already in place are:

- Ending paper handouts at F2F conferences
- Encouraging more sustainable forms of travel for EMWA volunteers (see current EMWA reimbursement policy)

F2F activities come

with clear benefits

and advantages that

virtual events

cannot fully

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and the

minimisation of

environmental

impact needs to

- Allowing for some sessions at the F2F conferences to be hybrid, enabling some speakers and registrants to participate online.
- Enabling a fully open access journal, with the option to forego receiving a printed copy of the EMWA journal. To date, 42 (3%) members have opted out of the paper copy.
- Engaging Medical Writing as one of over 200 journals to support the September 2021 global editorial.<sup>12,13</sup>
- Organising events that be considered. revolved around the theme of sustainability, including webinars and the first Expert Seminar Series on Sustainable Communications in 2022.
- Supporting initiatives such as Plant a Tree and Pens for Kids (see the EMWA SUS-SIG webpage for details).

#### Initiatives planned are:

- Fully virtual EMWA autumn conferences starting 2023.
- Upgrade of the EMWA website, which will enable more efficient computer use and data transfer
- Improved data collection (e.g., collecting information on travel mode to F2F conference; use of industry validated CO<sub>2</sub> calculators for future estimates).
- Screening of vendors and venues based on their CO<sub>2</sub> footprint.

#### **Conclusions**

SDG 13 in the 2030 UN Agenda is to "take urgent action to combat climate change and its impacts." EMWA as a professional organisation within the health sector, has the responsibility to seriously consider our environmental impact and

protect planetary health. This first estimate of approximately 227 tonnes of  $\rm CO_2E$  GHGE per year provides a baseline that EMWA can use to develop carbon reduction strategies toward carbon neutrality.

#### **Acknowledgements**

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#### **Disclaimers**

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

## Disclosures and conflicts of interest

The authors are employed in the pharmaceutical industry and active members of EMWA. The authors declare no conflicts of interest.

#### Data availability statement

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

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Raquel Billiones, PhD, Editor-in-Chief of Medical Writing, has been a regulatory medical writer for more than 15 years for pharma and medical devices. Her core competencies include development of regulatory documents, public disclosure, and data protection. As founding member of the Sustainability SIG, she strongly advocates for human and planetary health. Her personal carbon footprint (excluding work-related emissions) in the last 12 months was 10.09 tonnes CO<sub>2</sub>E, 60% of which were due to family-related intercontinental travel.14

# Oon in this ser



# **Translation**

Medical translation is a complex and demanding field requiring specialised knowledge, skills, and expertise. In this issue, we explore a range of topics, including the role of medical translation in clinical trials and regulatory affairs, the importance of terminology management, the use of technology and machine translation, ethical and legal considerations, the impact of cultural differences, quality assurance and risk management, and the emerging trends and challenges in the field. This issue provides valuable insights into medical translation and its contribution to enabling communication with different audiences from different backgrounds.

Guest editors: Ana Sofia Correia and Claire Harmer The deadline for feature articles is December 1, 2023.

# Winners of the **Geoff Hall Scholarship Essay Competition**

#### Dear All,

The Geoff Hall Scholarships (GHSs) are given in honour of a former President of EMWA. Geoff was a very special person, an extremely valued member of EMWA, and a very good friend to many EMWA members. He firmly believed that the future of EMWA lies in our new and potential members, and so it's a very fitting legacy that we have the Scholarship Awards in his memory. The Scholarships are awarded annually on the basis of an essay competition, and the title of this year's essay was "How to Keep Your Reader Interested From Start to Finish". The committee has the ability to award up to two scholarships each year. This year those scholarships were awarded to Hanna Kurlanda-Witek and Sara Mostafa.

#### FOR CORRESPONDENCE



Lisa Chamberlain James Lisa@trilogywriting.com

Hanna graduated from the University of Warsaw with a Master's in Environmental Science in 2008. She then completed her PhD in Geosciences at the University of Edinburgh in 2013. After working in an engineering consultancy in Warsaw for a few years, Hanna became a freelance science writer, writing about a wide range of topics, from radioactivity to viruses. Writing (as well as proofreading and translating from Polish to English) has always been a part of her professional life, but making it a full-time career became a life-changing experience.

Sara obtained her Bachelor's of Medicine and Surgery (MBBS) from the University of Khartoum, Sudan. She moved to the UK in 2018, and after a break in her clinical career, has recently embarked on her journey as a freelance medical writer.

Their winning essays are presented below, and we wish them the very best at the start of their very promising medical writing careers. For those of you inspired to pick up your laptop, this year's essay title is "Can Scientific Documents Be Easy to Read?".

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

> Bestest, Lisa

# How to keep your reader interested from start to finish

t is getting more and more difficult to catch a reader's attention and it is harder still to keep the reader engaged until the end of the text. Reading literacy rates are declining as screens replace print newspapers, magazines, and books, and this has an effect on how we read. As one study pointed out, "digital media stimulate superficial reading strategies, including scanning, skimming, and browsing, at the expense of more time-consuming strategies that allow for deeper comprehension."1

A quick web search brings forth a vast quantity of tips on how to get the skim-reading, multitasking reader to become "hooked" by your text in all of three seconds (the amount of seconds seems to decrease every few years). The tips that are featured the most could be

condensed to "write precious little" and "write the way you speak." But what if you write in a profession where the rules of online publishing don't necessarily apply? What if you can't "add spice", "explain the science so your grandmother can understand", or make it personal? Are medical writers (or writers of other highly-skilled professions) doomed to write reports and articles that no one wants to read?

In this essay, I will emphasise several points that I think are applicable to any writer who wants to keep their readers interested, whatever the topic.

Hanna Kurlanda-Witek

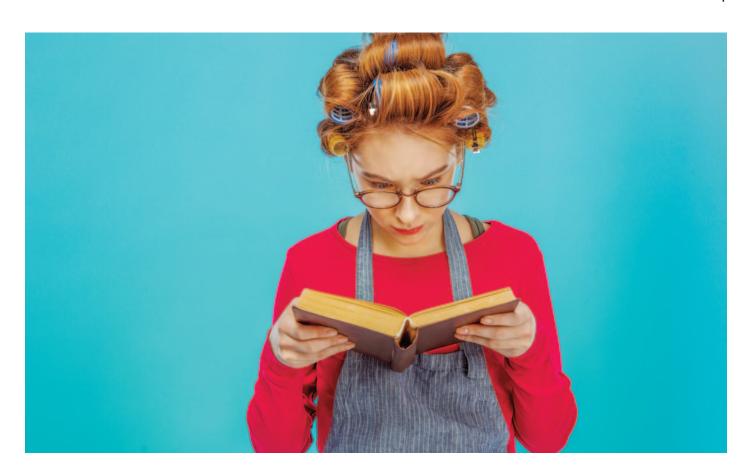
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doi: 10.56012/ylyf7647

#### Empathy at the core

When writing, it's easy to forget that we're not writing for ourselves. Writing is an art, even when it's meant to be purely informative, and like

artists, writers are often absorbed by what they are creating. But writing is also a form of communication; we write in order to help others understand this information. Empathy for the reader should be the underlying motive for writing in the first place. How will this



information help my reader? Could this sentence be broken into two shorter ones to make it clearer

for the reader? In fact, most advice for writers stems from one key point: keep the reader in mind as you write.

#### **Know your topic**

As most science and medical writers know, carrying out research on the chosen topic takes up more time than actually writing about it. This is not a waste of time. An incomplete report or poorly-researched article is obvious and is sure to

discourage a reader, even a non-expert in the field. Stating the facts doesn't have to be dull – including background information, eye-catching statistics, and a few intriguing facts will keep the narrative moving.

#### Trouble ahead for the reader

You've read so much about the topic, it's tempting to write about all that you've found out. The reader has to *know*. This is the trap that many writers fall into – overwriting. Trying to include every little detail inevitably leads to the dreaded "wall of text". It's likely that we've lost a reader at

this point. There has to be a balance between thorough explanation and brevity. The remedy

for long blocks of writing is to use visual cues that will catch the reader's attention, such as breaking up text using white space between paragraphs, using bullet points, or bold print.<sup>2</sup> Varying sentence length adds rhythm to a text, which also improves readability.

Another pitfall often associated with overwriting is the use of complex words (a term my thesaurus hints could be replaced with sesquipedalian). Of course, not much can be done about medical

terminology, but inserting a combination of long words in one sentence will make the reader lose focus. As cautioned in Strunk and White's *The Elements of Style*, "Do not be tempted by a twenty-dollar word when there is a ten-center handy, ready and able." <sup>3</sup>

#### **Accepting reality**

Empathy for the

reader should be

the underlying

motive for

writing in the

first place.

How will this

information help

my reader?

Writers spend many hours at the keyboard, working through draft after draft. There's a part of us that just wants to finish the task and move on to the next, yet I believe every writer wants their work to be read and appreciated. The knowledge

that someone will read our article or manuscript motivates us to make it as good as possible. However, we have to admit to ourselves that no matter how much we strive to make the content well-researched and readable, many people (even those who are interested!) simply won't read all of it. Most will skim it. Some will just read the first and last paragraphs. It is only rational to accept that this is the case and be grateful for any form of readership. Does this mean we shouldn't work as hard when we're writing? No. Even if only a few people read the whole text, these are your readers, and they deserve the best of your writing. Make sure they find what they are looking for.

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# How to keep your reader interested from start to finish

he year is 2022. Distractions, misconceptions and conspiracies abound. Having been tasked with creating something that, like cream poured into a bitter cup of coffee, rises to the top - I am anxious. I strive to be accurate, but that is not enough; I must also don my armour and prepare to battle for the reader's attention. Three ferocious adversaries hinder my path, each threatening to snatch the reader away. How, then, can I emerge triumphant?

#### Stage one

Before I enter the fray, I prepare for the first opponent: irrelevance. I remember the first time I learned that some people wrote for a living within the realm of medicine. After an investigation into what that entailed, I was charmed by one skill these people seemed to possess: the ability to break down complex concepts and reshape them to their liking. The core message would be the same, but the way it was conveyed would be adapted depending on the reader.

As with all things I find fascinating, I sought to learn how this was achieved. It turns out that the magic begins with audience analysis. 1 This close examination of the intended audience is the first step towards vanquishing irrelevance.

To do this effectively, Alley suggests we consider the following three questions:1

- 1. Who are they?
- 2. Why are they reading?
- 3. What do they already know?

The first and third questions are particularly important when addressing lay audiences. In this instance, level of health literacy and prior knowledge about the subject must shape the message, or we risk missing the mark.2

The second question helps us avoid a common pitfall in scientific writing: presenting a deluge of facts without highlighting (or even addressing, at times) what the reader truly wants

to know.1 Readers are interested in what they find valuable, and to provide true value, we must try to anticipate the questions that may arise in their mind and answer them.

#### Stage two

Readers are

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what they find

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that may arise in

their mind and

answer them.

When the reader's journey begins, a second rival, boredom, reveals itself. Now, my words are up against two enemies, and the delicate balance required to defeat them starts with the title.

The title is often the deciding factor for

whether the reader wishes to continue. The task lies in crafting a title that is attractive enough to spark interest, but still accurately represents what lies below it.3 The goal should not be to "entice as many people as possible to read [our] work,"1 for in doing so we attract a flock of fleeting readers, purely driven by fleeting curiosity. Since our desire is to keep readers interested, as well as to provide value, we should aim "to engage those people who want or need to read [our] work."1

Hartley<sup>3</sup> discussed the pressure writers sometimes feel to create catchy titles, at times compromising accuracy. He points out that "in the context of information retrieval", titles should also "be informative" in order to be found.

If the reader moves beyond the title, then we

know we have made a positive first impression. However, the reader has not yet trusted us with their time; they have merely given us a chance to demonstrate why they should. To quote Zinsser,4 "Readers want to know - very soon - what's in it for them."

That, then, is the job of the first paragraph or two: to show the reader what to expect. Again, this

part must be compelling enough to convince the reader to stay. This can be achieved by using interesting facts, anecdotes or thought-provoking questions.

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doi: 10.56012/bedp3270

#### Stage three

By the time the reader arrives at the heart of the document, irrelevance has been knocked down.

Boredom, on the other hand, proves relentless. Since this is usually a place densely packed with information, it is more likely for the reader's attention to wander. The aim at this stage is to maintain the "tension" that "pulls readers along without their noticing the tug."4

Say what needs to be said in its simplest form, without oversimplifying.1 Declutter, not just by removing unnecessary words, but also unnecessary jargon.5 Avoid falling for the trap of the passive voice, which masquerades as a more "scholarly" technique. Instead, propel the reader forward with action and verbs whilst giving them time to comprehend what they are reading.5

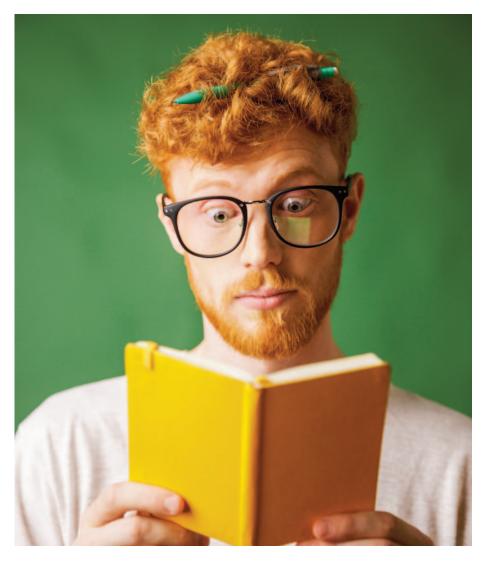
Writers can choose to breathe life into their writing here by incorporating elements of storytelling - although there are ethical considerations in science. If a story stirs up emotions in an individual, and those emotions, rather than critical thinking, drive their response, is that a form of manipulation? Katz<sup>6</sup> argues that in the presentation of scientific findings, maybe it is;

> that "Great storytellers embellish and conceal information to evoke a response in their audience."

> However, others argue that storytelling can be done with care and honesty7. Think of Pollock and Bono, and their vivid description of messages "buried under a desert of barren prose, revealed only to those willing to endure the tedious archaeological dig necessary to

excavate them."5 All too often, writers feel the need to dehumanise their writing, and in doing so, lose the connection to the reader.

By the time the reader arrives at the heart of the document, irrelevance has been knocked down.



#### Stage four

Towards the end of the reader's journey, two enemies lay amid the rubble, defeated. This is not yet time to celebrate, however – for another one lingers nearby. Disappointment soon rears its ugly head.

Having led the reader this far, the ending shouldn't feel like a regurgitation of what has already been told;4 that can resuscitate boredom and leave the reader feeling deflated. Instead, it is where we leave the reader with questions to ponder and next steps to take; where we leave a

seed that can grow into a meaningful discussion. It is where we hope that if the reader is disappointed, it is not because they regret having gone on this journey – but rather that they have arrived at its end.

If you are reading this sentence, then I have won the battle and coaxed you to complete this journey with me. Now is the time to celebrate.

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This is called the hash, pound, or number character. A hashtag is a keyword or set of keywords that is preceded by the # character. It is used in social media to create a thread of conversations around a specific theme or topic conveyed in short texts or microblogs. It is commonly used in Twitter, Instagram, YouTube, Pinterest, etc. A dictionary of most common hashtags can be found at https://www.hashtags.org/definition/~h/. For your info, EMWA is compiling a list of standarised hashtags for our social media use.

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

The two most important keys on your keyboard

# **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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Assessment of human dietary exposure to residues of veterinary medicines in the EU

January 19, 2023

MA and the European Food Safety Authority (EFSA) have published a joint report on the development of a harmonised approach to the assessment of dietary exposure of people to residues of veterinary medicines, feed additives, and pesticides in food of animal origin in the European Union (EU).

Veterinary medicines may leave residues in food derived from animal farming. Food can also contain residues of feed additives and pesticides to which animals have been exposed. In the EU, the presence of these residues is regulated to ensure the safety of consumers with legally binding maximum residue limits (MRLs) established. The establishment of MRLs relies on evaluations carried out by EFSA and EMA, which include an assessment of human dietary exposure performed by modelling the level of residues to which people may be exposed.

However, different approaches are used in the assessments depending on whether the residues originate from veterinary medicines, feed additives or pesticides. While the methodologies are based on common principles, differences in the scientific approaches and practices can result in different outcomes.

To advance harmonisation, the European Commission (EC) mandated EFSA and EMA in 2020 to develop a common approach to the assessments. The Agencies set up a joint working group, composed of specialists with relevant expertise. The working group developed a set of recommendations for each element of the exposure assessment, which were finalised after a public consultation that took place between June and September 2022. After that, the final report was adopted by EMA's Committee for Veterinary Medicinal Products (CVMP), endorsed by EFSA's Scientific Committee, and forwarded to the EC in December 2022.

The final report represents an important step towards harmonisation. If the recommendations are supported by the EC, their implementation in the different sectors will require a number of follow-up actions over the coming years. For veterinary medicines in particular, implementation of the recommendations will represent a very significant change to the way dietary exposure is assessed.

#### Mandatory use of CTIS from January 31, 2023, for all new clinical trial applications

January 31, 2023

n January 31, 2023, all initial clinical trial applications in the EU must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. This follows a one-year transition, during which sponsors could choose whether to apply for a new clinical trial in the EU/EEA in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on January 31, 2022.

In the past, sponsors had to submit clinical trial applications separately to national competent authorities (NCAs) and ethics committees in

each country to gain regulatory approval to run a clinical trial. Registration and the posting of results were also separate processes. With CTIS, sponsors can now apply for authorisations in up to 30 EU/EEA countries at the same time and with the same documentation. The system includes a public, searchable database for health-care professionals, patients, and other interested parties.

The CTR foresees a three-year transition period, from 2022 to 2025. The first milestone has been reached today; in the next two years, by January 31, 2025, all ongoing trials that were approved under the Clinical Trials Directive will be governed by the new Regulation and will have

to be transitioned to CTIS.

The application of the CTR strengthens Europe as an attractive location for clinical research. The new regulation streamlines the processes for the application and supervision of clinical trials, and their public registration: all clinical trial sponsors will now use the same system and follow the same procedures to apply for the authorisation of a clinical trial, no matter where they are located and which National Competent Authority (NCA) or national ethics committee they are dealing with.

The authorisation and oversight of clinical trials is the responsibility of EU/EEA Member States while the European Medicines Agency (EMA) is responsible for maintaining CTIS. The EC oversees the implementation of the Clinical Trials Regulation.





A new role for EMA in monitoring and mitigating critical medical device shortages during public health emergencies

February 06, 2023

s of February 2, 2023, EMA's additional responsibilities regarding the monitoring and mitigation of shortages of critical medical devices during public health emergencies will apply. The new provisions are the last remaining part to be implemented of Regulation (EU) 2022/123, that reinforces EMA's role in crisis management of critical medicinal products and medical devices during public health emergencies.

The Agency is now responsible for coordinating responses of EU/EEA countries to shortages of critical medicines and medical devices including in-vitro diagnostics during public health emergencies. The Medical Devices Shortages Steering Group (MDSSG) will be set up to coordinate urgent actions within the Union in relation to the management of supply and demand issues of critical medical devices and to make recommendations to relevant stakeholders, including the EC, Member States, and notified bodies.

Once established, the MDSSG will be responsible for adopting lists of medical devices which it considers to be critical for declared public health emergencies. These lists come with new reporting obligations for manufacturers of medical devices, authorised representatives and, if required, also for importers, distributors and notified bodies of those critical medical devices. Together with information from Member States this will enable accurate monitoring of the supply of and demand for these devices so that measures to prevent or mitigate potential and actual shortages can be taken swiftly and in a coordinated manner.

EMA will ensure that the MDSSG closely cooperates with the existing Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) established in March 2022 during public health emergencies.

The MDSSG will be supported by the Medical Device Shortages SPOC Working Party (MD-SPOC WP) comprised of Single Points of Contact (SPOCs) for shortages from National Competent Authorities for medical devices, as well as by a sub-network of SPOCs from manufacturers of medical devices, authorised representatives, importers, distributors, socalled Economic Operators (EO), and notified

The manufacturers, authorised representatives, importers, distributors of those critical medical devices included in any list of critical medical devices will need to register their single point of contact (EO-SPOC) through EMA's IRIS platform to facilitate rapid communication during a declared public health emergency. Relevant information, including supply and demand data, will be monitored via a reporting system.

Medical devices in the EU are regulated at national level, but EMA provides scientific opinions for certain categories of medical devices. The MDSSG will be composed of a representative of the Agency, a representative of the EC and one representative appointed by each Member State. The MDSSG will be cochaired by the Agency and by a representative of a Member State. A representative of the Agency's Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) may attend meetings of the MDSSG as observer.

#### Actions to support the development of medicines for children

February 06, 2023

egulators in the EU have taken several initiatives in the past four years to increase the efficiency of paediatric regulatory processes and boost the development of medicines for children. These achievements are highlighted in the closing report of the EMA and EC action plan on paediatrics.

Some of the key improvements brought by the paediatric action plan include:

- Strengthened focus on unmet medical needs: Over the last four years, EMA and relevant stakeholders systematically got together to better identify and raise awareness on the areas where medicines for children are particularly needed, with a goal to shift the research agenda to these areas. For example, multi-stakeholder strategy fora to discuss and agree the needs of children with cancer, and of children with inflammatory bowel disease have taken place. The learnings from these meetings involving clinicians, paediatric patients and their representatives, academia, regulators, HTAs bodies, and developers are being taken into account by EMA when discussing paediatric investigation plans (PIPs) for new medicines.
- Adapting regulatory processes to better support innovation: To facilitate the establishment of PIPs, regulatory processes have been adapted and processes overall simplified. A major outcome of this work is the launch of a pilot phase for a "stepwise PIP" agreement:

- under this framework, it will be possible in certain cases to agree on a partial development programme, conditional on the development of a full PIP once evidence becomes available over time. This will allow agreeing on PIPs for innovative medicines where crucial information needed to define certain parts of the plan is not yet available, while planning the conditions and milestones for companies to return to EMA's paediatric committee (PDCO) and discuss the uncertainties once more data are available. More information on this newly developed framework, launched today, is provided in the guidance for a stepwise PIP pilot.
- Increased alignment of data requirements between decision-makers: To facilitate the compatibility of paediatric requirements between regulators, EMA has strengthened its collaboration with international partners, and notably within its paediatric cluster with the US Food and Drug Administration (FDA) and other international regulators. Work was also carried out through the European network of paediatric research at EMA (Enpr-EMA) to align international requirements for paediatric clinical trials authorisation and standards.

In 2017, the EC published a 10-year report on the implementation of the Paediatric Regulation. This report showed an overall success of the Regulation with an increase in authorised

medicines for children, but also identified some challenges, noting in particular that certain therapeutic areas (e.g., oncology, neonatology) still lacked sufficient developments for children.

On the basis of this report, EMA together with the EC held a multi-stakeholder workshop in 2018 to identify ways to improve the implementation of the Paediatric Regulation. As a result of this workshop, the paediatric action plan was developed to provide some immediate solutions to these challenges under the current regulatory framework. This work will contribute to the application of the Paediatric Regulation, while the EC is currently finalising a proposal to revise the EU's pharmaceutical legislation, which will include a revision of the legislative framework applicable for medicines for children. The adoption of the proposal is expected next month.

The Paediatric Regulation came into force in the EU in 2007 to encourage manufacturers to research and develop medicines for children's specific therapeutic needs by using a system of rewards and obliging developers to specifically plan the development of their medicine for children (e.g., by integrating it into the development for adults) and submit a corresponding PIP. A PIP is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for paediatric patients. All applications for marketing authorisation for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver.





#### New features further strengthen Priority Medicines scheme (PRIME)

April 04, 2023

MA is introducing a number of new features to the PRIority MEdicines (PRIME) scheme to strengthen its support for the development of medicines in areas of unmet medical needs. The PRIME scheme enables earlier availability of life-changing medicines for patients. By the end of 2022, 26 medicines that benefited from PRIME support had received a positive recommendation for approval in the EU.

EMA published a report presenting results from the first five years of PRIME in March 2022. It looked at how the scheme helped developers prepare for marketing authorisation assessments. This report showed that the PRIME scheme has had a positive impact on the authorisation of new medicines that benefit patients with no current treatment options for their disease or offer a major therapeutic advantage over existing treatments. It also called for further enhancement, including increasing the flexibility of scientific advice provision, and helping applicants better prepare for the marketing authorisation assessment phase. The implementation of the new features follows from this review.

To optimise the early scientific and regulatory support provided to promising medicines, a roadmap for each PRIME development alongside a product development tracker will be established. Both tools will facilitate the continuous dialogue between regulators and developers as the progress of the development is continuously monitored and as critical aspects for further discussion can be identified throughout the development process.

Starting as a 12-month pilot until March 2024, expedited scientific advice can now be provided specifically for PRIME developments in case of issues with a specific development programme that has already received comprehensive initial advice. This agile setting for scientific advice will allow to address queries from PRIME applicants in a shorter timeframe.

The final new feature is represented by submission readiness meetings, which will be held approximately one year ahead of the submission of a marketing authorisation application with developers of PRIME medicines. The scope of these meetings is to discuss the status of the development including the implementation of previous regulatory advice, and the resulting data package intended to support the marketing authorisation application. Prospective applicants would also be expected to present mature plans for post-marketing evidence generation, as applicable.

All these initiatives aim to facilitate and accelerate the generation of robust and relevant evidence for the evaluation of a marketing authorisation application, which will give patients earlier access to transformative treatments that can make a real difference.



oto: Freepi

MA has opened a public consultation on a reflection paper¹ that discusses key concepts for single-arm clinical trials that are submitted as pivotal evidence in support of marketing authorisation applications for medicines in the European Union (EU). This is the first guidance document by an international medicine regulator articulating the considerations and challenges associated with this type of clinical trials. Stakeholders are invited to send their comments via an online form by midnight (CET) on September 30, 2023.

Randomised clinical trials (RCTs) in which a new treatment is compared against a placebo or an existing standard of care are widely considered as the gold standard for generating evidence needed by regulatory authorities to assess the efficacy and safety of a new medicine. In RCTs, patients are randomly assigned to either the active treatment or the control arm. Usually, large numbers of patients are included for these trials to generate robust data on the efficacy of a treatment.

In certain areas such as rare diseases,

including rare cancers, where target populations of new medicines are often very small, a proportion of marketing authorisation applications are submitted to EMA with clinical data from single-arm trials as pivotal evidence. Because there is no randomised comparator in a single-arm trial, all patients in the trial receive the experimental treatment and only the outcomes under the experimental treatment can be observed.

The reflection paper outlines considerations on single-arm trials that are submitted as pivotal evidence to demonstrate efficacy in a marketing authorisation application. It aims to stimulate the scientific discussion around key concepts and challenges associated with single-arm trials and to improve their design and conduct.

The reflection paper has been adopted by EMA's human medicines committee (CHMP) with contributions from the Committee for Advanced Therapies (CAT), the Methodology Working Party (MWP) and the Oncology Working Party (ONCWP).

Following the public consultation, comments from stakeholders will be analysed and considered in the final document that is planned to be published in 2024.

#### Reference

 EMA/CHMP/564424/2021. Reflection paper on establishing efficacy based on single arm trials submitted as pivotal evidence in a marketing authorisation. April 21, 2023.

#### Reducing risks to human and animal health from exposure to N-methyl pyrrolidone in veterinary medicines

April 14, 2023

n December 8, 2022, EMA's veterinary medicines committee, the CVMP, recommended new measures to reduce the risks from exposure to the excipient N-methyl pyrrolidone (NMP) for women who may handle NMP-containing veterinary medicines and animals that are given these medicines. The recommendations address inconsistencies in the product information of veterinary medicines containing NMP, which are marketed in many EU Member States.

NMP is an excipient used in some veterinary medicines that is classified as a

teratogen (a substance that can cause birth defects following exposure during pregnancy) in laboratory animals. There is therefore the possibility that NMP could cause birth defects in children of women who handle or come into contact with NMP-containing medicines during their pregnancy, and in the offspring of animals given these medicines.

More than 1,100 veterinary medicines containing the excipient NMP are available in the EU under various trade names and in different formulations, for use mainly in companion animals and large farm animals.

These medicines are available as injections, solutions for infusion, spot-on and pour-on products, shampoos, sheep dips, sprays and concentrates for oral solutions for use in the drinking water of animals, or solutions for fish treatment.

The review of veterinary medicines containing NMP is the first referral under Article 82 of Regulation (EU) 2019/6 which was introduced as part of the new EU veterinary medicinal products regulation. The CVMP recommendations were sent to the EC, which issued an EU-wide legally binding decision on March 28, 2023.

# **Medical Devices**



# Spotlight on similar devices under the **Medical Device Regulation**

#### Payal Bhatia

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doi: 10.56012/dlip9626

#### **Abstract**

This article evaluates the potential of similar devices in clinical documentations, such as clinical evaluation plans (CEPs), clinical evaluation reports (CERs), and post-market clinical follow-up evaluation (PMCF) documents, based on the Regulation (EU) 2017/745 (referred to as the medical device regulation [MDR] in this article) and relevant Medical Device Coordination Group (MDCG) documents. Beginning with the concept of similar devices, the article presents how to identify similar devices, use similar device data, and apply this knowledge to clinical documentations. A stepwise approach provided at the end of the article aims to assist manufacturers and medical writers in this process.

#### Understanding similar devices

ccording to the MDR,1 similar devices belong to the same generic device group, which is defined as "a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics". In simpler words, any device can serve as a similar device if it has a similar or the same intended purpose OR is based on a common technology without exhaustive demonstration of technical, biological, and clinical characteristics, which are obligatory to claim equivalence. Another key difference between a similar and an equivalent device is that manufacturers are not required to have "sufficient levels of access to the data relating to devices ..." for similar devices. As a result, claiming similarity will be more straightforward than claiming equivalence.

To give an example of an Ilizarov lower extremity ring external fixator, which is used to stabilise broken bones using rigid rods, pins, and connectors inserted through the skin into the bone, the abovementioned definition can be translated as:

- "same or similar intended purpose": various medical devices used for the fixation of a broken upper or lower leg

- "commonality of technology": any external fixator.

An important detail to mention is the use of OR (not AND) between the two elements of the MDR definition, making them theoretically mutually exclusive. How this will be used in practice, both during preparation of clinical documentations and their review, remains to be

#### Using similar device data Similar device data for legacy devices based on wellestablished technologies

According to MDCG 2020-6,2 "It is important to identify all available sources of clinical data from both the pre-market and post-market phases. This will include all of the clinical data which is generated and held by the manufacturer as well as clinical data for equivalent or similar devices."

Similar devices can provide "soft" data, which rank roughly similar in level of evidence to the

clinical evidence provided by the state of the art (SOTA) but lower to the clinical data coming from own and/or equivalent devices (see MDCG 2020-6 Appendix III). Nevertheless, manufacturers can use similar device data for setting benchmark values for evaluating clinical performance and safety of own devices. A CEP or PMCF plan would be great documents for this purpose. (See the September 2020 issue of Medical Writing for the article on new documents required by the medical device regulation, p. 24). According to MDCG 2020-6:

- "Data from similar devices may be used, for example, to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc."
- For well-established technologies the clinical evaluation can be based on data coming from similar devices, under the conditions detailed in paragraph 6.5 (e).
- Data from similar devices may be also important to establish whether the device under evaluation and similar devices belong to the group of devices considered as "well established technologies (WET)."

#### Similar device data for clinical evaluations not based on equivalence

Another key

difference

between a similar

and an equivalent

device is that

manufacturers are

not required to

have "sufficient

levels of access to

the data relating

to devices..." for

similar devices.

When clinical evaluations cannot be based on

equivalence, manufacturers can make use of similar device data in several ways. According to MDCG 2020-5,3 similar devices may be useful for the following:

- 1. "Ensuring that the risk management system is comprehensive by identifying relevant hazards and clinical risks.
- 2. Understanding the state of the art, the natural course of disease and alternative available treatment options.
- 3. Helping to define the scope of the clinical evaluation, by identifying any design features in similar devices that pose

special performance or safety concerns.

- 4. Provide input for clinical investigation design or post market clinical follow-up design, and the post-market surveillance system.
- 5. Identification of relevant and specified clinical



outcome parameters for the intended clinical benefits, based on the published clinical data pertaining to the similar device(s).

 To define minimum requirements for a quantified clinical benefit that is considered clinically relevant, and/or to identify acceptable occurrence rates of risks and adverse events."

In summary, similar device data can be beneficial for all types of clinical evaluations including those based on own, equivalent, or no clinical data. Additionally, similar device data can be used in both pre- and post-market stages of a clinical evaluation. Finally, similar device data could further support legacy devices based on WET.

## Presenting similar device data in clinical documentations

According to MDR Annex II 1.2(b), technical documentation shall include "an overview of identified similar devices available on the Union or international markets, where such devices exist". Similarly, the template provided in MDC 2020-13 (Clinical evaluation assessment report template, section J)<sup>4</sup> insists that notified bodies check for similar device data. Therefore,

manufacturers are expected to search for similar devices as well as identify and include them in their technical documentation where such devices exist. Where no such devices exist (in exceptional cases such as unique intended purpose and technology), manufacturers can state this clearly in the CER to manage reviewer

expectations upfront.

In summary,

similar device

data can be

beneficial for all

types of clinical

evaluations

including those

based on own,

equivalent, or no

clinical data.

Where similar devices exist, the following stepwise approach may be useful to identify and assess these devices and present them in clinical documentations. This follows the MEDDEV 2.7/1 revision 4 structure for CERs. Please note that this is not an exhaustive list; there are several approaches that can be used and are beyond the scope of this article.

#### Similar device identification and selection (stage 0, scoping)

a. **Identify:** As a manufacturer, the first step is to identify similar devices. It must be stressed that identifying similar devices can easily be the most challenging step of this process. Manufacturers will have to show that their selection is based on scientifically sound rationales such as market share of the devices,

quality and quantity of the available data, known safety and performance profiles of the devices, etc.

b. Justify: Once similar devices are selected, manufacturers will have to justify their choice and address the question of why five and not 20 devices are selected. This would include showing strict compliance to the MDR definition i.e., same or similar intended purpose or commonality of technology as well as the criteria mentioned in MDCG 2020-7 section E (product name, intended purpose, intended users, intended patient population, medical condition, and indication). This must be done at the level of the PMCF plan and should ideally be done at the level of the CEP or CER as well.

## 2. Similar device data identification (stage 1, identification of pertinent data)

Once similar devices are selected, all data available on these devices and / or known to the manufacturer must be searched for and discussed in clinical documentations.

Similar device data sources may include:

- a. Scientific literature including peer-reviewed scientific articles, Cochrane systematic reviews, etc.
- b. Post-market clinical follow-up studies
- c. Post-market surveillance data
- d. Registries and other real-world evidence





#### 3. Similar device data appraisal (stage 2, appraisal of pertinent data)

This could be optional. As for the clinical data, similar device data can also be appraised for suitability and contribution criteria.

#### 4. Similar device data analysis (stage 3, analysis of clinical data)

- a. Similar device data must be analysed at the level of the PMCF evaluation report (PMCFER) and ideally also in the CER. Within the PMCFER, manufacturers are encouraged to follow MDCG 2020-8 section D.5Within the CER, similar device data could be discussed separate from the SOTA or as part of the SOTA. Alternatively, similar device data can be discussed in an independent set of documentations with appropriate interfaces to the clinical documentations.
- b. The conclusions drawn from similar device data shall be used to update risk management and post-market surveillance activities including PMCF.

#### All this for what?

At a first glance, all this may seem a lot of work. And undoubtedly, it is. But I am sure the industry will agree this is for the betterment. Imagine how identifying the so called "class effect" earlier could have saved several thousands of patients from the complications of metal-on-metal hips? If similar device data would have been analysed, these patients would have had a far better and much safer experience. The goal of all this effort is clear: patient safety first!

#### Conclusion

As per the MDR, manufacturers are expected to identify similar devices and discuss similar device data in their clinical documentations, especially CERs and PMCFERs. The process of identifying and selecting similar devices, however, is not well defined and therefore gives manufacturers several possibilities of how it could be approached. Similar device data are expected to be used to provide threshold / benchmark values that can be used for evaluating clinical safety and performance profiles of devices under evaluation. These data will not only strengthen clinical conclusions but also allow manufacturers to make important decisions in both pre- and postmarket phases of their clinical evaluations. Additionally, all types of clinical evaluations (based on own, equivalent, or no clinical data) can benefit from similar devices. As with the whole clinical evaluation process, similar device data shall also be continuously and systematically updated.

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#### **Disclaimers**

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

Disclosures and conflicts of interest The author declares no conflicts of interest.

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Payal Bhatia, PhD is a medical and regulatory writer who has been working at Medical Minds in Switzerland for more than six years. She has gained expertise in writing clinical documentations for all classes of medical devices. She is also an active EMWA member and recently started serving as a section editor of the EMWA's Medical Writing iournal.

# **Good Writing Practice**

# Syntactic punctuation distraction

Comma: Over-usage

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#### Introduction

omma over-usage probably results from a tendency to pause and emphasise. However, such intuitive punctuation is counterproductive to the coordination of sentence core constituents, the intent of which is to cohere syntactic units of similar grammatical function, such as noun subjects Example (1) and verb predicates Examples (2 and 3).

#### Between noun subjects

#### Example 1

(Methods section)

The polyclonal goat antibody actin (#sc-161<u>5)</u>, and polyclonal rabbit antibody Sam (#sc-333) were purchased from Santa Cruz Biotechnology.

The polyclonal goat antibody actin (#sc-1615) and polyclonal rabbit antibody Sam (#sc-333) were purchased from Santa Cruz Biotechnology.

#### Notes

As a test of comma over-usage, if all the modifiers are eliminated from the sentence, most writers would not place a comma between actin and Sam in the skeleton sentence Actin and Sam were purchased.

#### Between parallel verbs

#### Example 2

(Methods section)

Fertilised hen eggs were routinely incubated, and staged.

Fertilised hen eggs were routinely incubated and staged.

#### Notes

There is no reason to pause, to segregate for emphasis, or to mark for sequentiality (readers know that the actions are sequential not simultaneous).

#### Between nonparallel verbs

#### Example 3

(Introduction section)

The Introduction section is no exception, and would be improved by the usage of subheadings.

#### Revision 1

The Introduction being no exception would be improved by the usage of subheadings.

#### Revision 2

The Introduction, being no exception, would be improved by the usage of subheadings.

#### **SECTION EDITORS**



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#### Revision 3

Being no exception, the Introduction would be improved by the usage of subheadings.

#### Notes

Is a comma necessary between coordinated verbs that are of a different type? Is (a linking verb) and would be improved (the passive voice of a transitive verb) are not parallel. Such non-parallelism and the over-used comma may cue that coordination may not be the most effective sentence pattern. The comma probably is a signal (maybe an apologetic one) by the author to acknowledge the non-parallelism and to de-

In Revision 1, the first verb phrase is no exception is syntactically reduced to the participial phrase being no exception. By default, the verb phrase would be improved is emphasised.

In Revision 2, comma segregation of "being no exception" causes its emphasis.

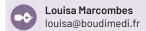
In Revision 3, transposition to the sentence orientation position followed by comma segregation provides context without the subject-toverb disruption in Revision 2.

#### **Tabular Summary**

Comma over-usage example	Revision	Action
Between coordinated noun subjects		
(1) Subject, and subject	Subject and subject	Comma deletion
Between coordinated verbs		
(2) Subject verb A, and parallel verb B	Subject verb A and parallel verb B	Comma deletion
(3) Subject verb A, and non-parallel verb B	(1) Subject participial phrase verb B	Verb A into participial phrase
	(2) Subject, participial phrase, verb B	Addition of commas
	(3) Participial phrase, subject verb B	Participial phrase translocation to sentence orientation
		position and comma segregation

# **Veterinary Medical** Writing

#### **SECTION EDITOR**



#### Editorial

Human medicine has recently seen a move away from the paternalistic patient-physician paradigm course to a collaborative one, where "shared decision-making" is a core principle. No longer a passive bystander, where their case management is dictated to them, patients are now encouraged to be proactive in their own clinical course, with the aim of improving patient outcomes. But does this approach work for veterinary patients? Clearly, not the veterinary patient themselves, but can vets use a shared decision-making approach with animal owners and hope for the same clinical benefits? Here, Henry Smith, the co-chair of the EMWA's Veterinary Special Interest Group (VetSIG), recounts a recent VetSIG meeting where these very questions were posed. Two veterinary academics, Dr Catarina Svensson and Dr Louise Corah, were invited to speak and drew on their own reseach in this field to help provide some answers. Meanwhile, in this edition of "From the Horse's Mouth", we report on some bad news for animal welfare but some good news for sustainability in veterinary practice.

Louisa

# A health decision shared can be a health problem solved: Time for veterinary medicine to embrace shared decision making?

#### **Henry Smith**

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doi: 10.56012/jxyr3177

hared medical decision making has been termed "the conversation that happens

between a patient and their healthcare professional to reach a healthcare choice together".1 This phrase wonderfully describes a hot topic in human medicine, but what happens when that conversation is with an owner and that healthcare choice is for an animal? Is there an ideal communication model when the patient can be anything from a surrogate family member to a cash cow? Or when some of the healthcare choices may be off the table due to an owner's individual financial, physical, or emotional circumstances? Last year, EMWA's veterinary medical writers addressed these and other questions about shared decision making in veterinary practice. To help us find answers, we turned to Dr Catarina

Svensson of the Swedish University of Agricultural Sciences and Dr Louise Corah, of the University of Nottingham, who research client communication in their respective fields of large and small animal medicine.

#### Two researchers speak

Dr Svensson

spent years

advising

farmers on

preventative

health

measures for

their livestock,

and became

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Catarina and Louise kindly agreed to speak at one of our quarterly meetings, and were then gracious enough to sit through two rounds of follow-up questions. Catarina is a Professor of

> Bovine Herd Health Management, with a long career in both academe and the dairy industry, and has a special interest in calf health. Her extensive list of publications has been further lengthened in recent years with groundbreaking reports on motivational interviewing by large-animal veterinarians. Louise lectures on veterinary communication and professional skills, and previously worked as a small animal veterinary surgeon (both first opinion and referral) before completing a PhD thesis titled "Defining the good consultation: What it is and how could we measure it?". Both Catarina and Louise have published and presented their research widely, but our discussion was mainly focussed

on two of their recent papers in the Veterinary Record: Catarina's evaluation of motivation interviewing training for cattle veterinarians,<sup>2</sup> and Louise's systematic review on measuring success for canine and feline consultations.3 Our two speakers have both taken very interesting - and different - paths into research on client communication.

Catarina spent years advising farmers on preventative health measures for their livestock, and became puzzled why some recommendations generally were followed and some were not. The latter often involved issues in her special area of calf health;4 for example, her recommendations on colostrum feeding often seemed difficult to get across to farmers. Partly inspired by a great quote from Dutch researcher Jolanda Jansen, "... hard-to-reach farmers lack motivation, not information",5 she came to see that motivating clients to make a change was the key to making things happen on the farm that could actually improve animal health. Searching for others with the same idea, she discovered psychologists and psychotherapists researching motivational interviewing to achieve behavioural change at the Karolinska Institutet in Stockholm. The next step was a research partnership on applying the motivational interviewing methodology for veterinarians in herd health practice.

For Louise, it was her clients - the pet owners she was discussing healthcare choices with - that set her onto the road to researching communi-



cation and decision making. She realised that successfully engaging with clients was one of the most satisfying parts of her job. This satisfaction could come in unexpected circumstances; for example, from being the nice vet on a horrible day who makes the experience of euthanasia a slightly less awful one for the unfortunate pet's owners. Talking to older members of the profession, Louise was struck by the fact that the long-term vets who most enjoyed relating to clients were often the ones who seemed to be most resistant to burnout. So, it was a logical step to join a group of researchers at the University of Nottingham, which was pioneering research on improving client communication. Her PhD followed, and that led to a lecturing job at Nottingham, where she is responsible for the communication skills part of the syllabus.

## What does all this mean for the animal?

Obviously, the patient in veterinary medicine can't "share" in the decision making in the way envisaged for human patients. Before reading anything about shared decision making, I had imagined philosophical debate about how to apply the human medical concept of patient autonomy to animals, but talking to Catarina and Louise made me realise things are more practical than that. Of course, as Catarina said, vets must become master interpreters of what animals are trying to tell us, through their signs and behaviour. As Louise commented, animal welfare is the "red line" for vets; upholding it is a

professional obligation of paramount importance. A veterinarian acts as the animal's advocate regardless of whether they implement shared decision making or not. Techniques such as shared decision making and motivational interviewing may make the veterinarian a more effective advocate for the animal, but the practical aim here is principally to improve communication with the client. Improved client communication may well improve things for the animal, as genuinely collaborative decision making is achieved but, as Louise pointed out, sometimes just maintaining animal welfare is the best outcome we can hope for.

#### Turning to the client

Our focus here then must be on the approach to the client. Interestingly, both Catarina and Louise, who had taken such different routes into the field, had many similar ideas (and often used similar terminology). Both started by stressing the need to recognize the autonomy of the client. A pet owner is not just a human who happens to be on the other end of a dog's lead. Dairy farmers are very much professionals with a full understanding of their livestock. As such, vets need to understand that clients are experts: experts on their animals, experts on their living and working environments, and experts on themselves (and the latter point is particularly important when clients will perform the treatment or preventative measure themselves, based on the vet's advice). In the decisionmaking conversation, veterinarians contribute their medical expertise and owners contribute their expertise on the individual animal, and on themselves.

So, for shared decision making with clients, can we just slip the human medical model "off the peg" and wrap it around the veterinary scenario? After all, the veterinarian-client relationship has sometimes been described as a close equivalent of the paediatrician-parent relationship in human medicine. Inevitably, there is some crossover between the two types of medicine. Both Louise and Catarina refer to the Calgary Cambridge model for structuring medical interviews in their published work, and this (human) doctor-patient communication model - with a few adaptations for the veterinary profession - is a fundamental part of Louise's classes on communication skills (a whole 71 points' worth of a framework!), and has been recognised by the National Unit for the Advancement of Veterinary Communication Skills (NUVACS) in the UK.6 It may be true that veterinary medicine tends to follow human medicine (with a time lag sometimes approaching 20 years, Louise humorously suggested), but there is a bigger picture to appreciate here.

If veterinary decision makers are taking their client communication models off any peg, then it is probably labelled "psychology" rather than "human medicine". Many of the motivational techniques Catarina evaluated were first developed to motivate recovering alcoholics and drug addicts to achieve behavioural change; indeed, the fellow authors of her papers on motivational interviewing include the eminent clinical psychologist and licensed psychotherapist Lars Forsberg, well known for his work on addiction and juvenile delinquency. Louise commented that her study of client psychology convinced her that the human might be the most fascinating animal she has encountered in her professional career.

Our discussion on veterinary shared decision making included an interesting insight into the human psyche, thanks to this quote from the psychologist Karl Rogers "People are most able to change when they feel free not to" (from his aptly titled book, *Becoming a Person*).8

What happens when all this psychology is put into action? Of course, we could only discuss theoretical cases, but Catarina and Louise provided us with some useful illustrations. Consider the case of a hypothetical diabetic cat with an arthritic owner; the vet and client may need to find other options if the owner can't administer the desired course of injections due to problems with her hands. In another scenario, consider what might happen when a vet instructs



a client to "... bring your cat back for some work on the teeth". There is a good chance that the recommended return visit will not happen. A better approach might be explaining the "why" and "how" for the dental procedure, and check whether the client has any concerns about the anaesthetic or any logistical problems with bringing the cat back in. As Louise mentioned, not every challenge is in the consulting room.

For a hypothetical scenario in herd health, rather than telling a farmer "You've just got to get your herd onto the rations I recommend if you want to get this incidence of displaced abomasum down", it would be better to say: "We seem to be up against a lot of displaced abomasum. I think the options are a, b, and c. What do you see the options as?". Catarina also mentioned a theoretical worst-case scenario, when a vet uncovers a violation of animal welfare law. In such situations, little is to be gained from saying "You are breaking the law! I demand that you desist now!". More could be achieved by saying "Did you know that this situation is actually against the law. Can I talk through the consequences of that with you now?". Catarina mentioned that if situations such as this developed in real life, and could not be fixed through conversations about potential consequences, the veterinarian might have to consider that the situation represented, in part, a failure in communication.

#### Does it actually work?

The success or otherwise of shared veterinary decision making is very hard to judge, and partly for a very gratifying reason. Both Catarina and Louise found that clients were highly satisfied with their veterinarians, irrespective of whether consultations involved a client-centred communication methodology or not. Louise could actually show empirically that veterinarians are a very trusted profession.<sup>7</sup> Client satisfaction is thus not necessarily the ideal outcome in evaluations of shared decision making. Catarina's research targeted the concept of "change talk". She found

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profession.

that, after consultations with veterinarians at least moderately skilled in motivational interviewing, farmers were 1.5 times more likely to talk about making changes. Of course, talking about a change is not the same as making it; however, intent can sometimes correlate well with

implementation. Catarina's preliminary findings are thus promising in terms of making improvements on the farm that could benefit animals. Louise highlighted the potential benefits of an effective shared decision in terms of adherence to treatment; clearly, an owner is more likely to stick with a treatment regimen they have been involved in selecting. Animals may not be formally sharing in decisions, as noted above, but they stand to benefit when communication methodologies are used effectively.

#### Should we shout the message from the rooftops?

In human medicine, shared decision making seems to have launched a whole wave of literature and other communicative materials (always a fascinating point for medical writers!). To cite just one example, a comprehensive array of patient-focused literature has been placed into the public domain by the Patient Empowerment Network, a non-profit-making organisation.9 Could veterinary shared decision making create a need for literature to prepare pet owners to

share in decisions, and for farmers to be participants in motivational interviews? Medical writers may be disappointed that this appears not to be the case.

Louise mentioned that, although several practices do produce such literature for clients, this is far from standard, and there be may less of a need for it now than when shared decision making emerged in human medicine. The Google Zero-Moment-of-Truth, which describes how the consumer decision-making process has been changed by access to digital media, is as likely to apply to clients' vet visits as to their selection of washing machines and foreign holidays.<sup>10</sup> Nowadays, people may expect to be included in shared decision making, and regard recognition of their autonomy as a default in any transaction. In Catarina's field, we should recognise that a message of "By the way, this consultation you are so generously paying for will be conducted according to this exciting new methodology from human psychology" may not always be received with unbridled enthusiasm by dairy farmers.

Should our efforts be focussed on preparing

the veterinary profession for this new age of more democratic communication? Both Louise and Catarina cautioned that time will be a severely limiting factor when trying to roll out attitudinal change to such a busy profession. Also, as Louise pointed out, there is something rather paternalistic about

telling people "It's now time you abandoned paternalism". Even if we can find a nonpaternalistic way to eradicate paternalism, now may not be the ideal time to embark on great changes in the veterinary profession, coming off the trials and tribulations of the COVID pandemic, which presented its own problems for vets and their clients and colleagues.

#### What's the way forward?

Even with the caveats mentioned above, clearly, discussions on shared veterinary decision making need to continue. It's time to take stock of where we are, and where we should be headed.

Recent generations of veterinary graduates have been trained on concepts like shared decision making and motivational interviewing, and may help to disseminate this new knowledge across the profession. Catarina commented that this is a good starting point, but it is just a starting point; motivational interviewing may require years of practice before it can be mastered, for

By contrast with their younger colleagues, the

majority of less recently graduated veterinarians probably received relatively little formal training on client communication methodologies, and paternalist communication may be a hard habit to kick once it has become ingrained. Louise took an assessment tool (the Option5 tool) from human medical scenarios, 11 to make a rough-andready assessment of how highly some vets scored as shared decision makers. The result - mean and median scores around 50% to 60% - probably tells us more about the difficulties of effectively "scoring" medical consultations than the true state of shared decision making in the veterinary profession. However, it does suggest that even some veterinarians with awareness of shared decision making may be closer to the paternalist end of the communication spectrum than they imagine. In other words, we need to do more work to get the message across, and go beyond the limited audiences that can be reached through research publications.

Medical writers can certainly help with this; indeed, I think we have made our own small

contribution by holding this conversation in our EMWA special interest group. Medical writers' core role is communication, and we are ideally placed to spread the message. As an aside, I came across one unconventional idea that might relate to medical writers' message-spreading abilities from the conversations with Catarina and Louise. Both of them use actors in their training sessions and classes, to play the

roles of clients opposite veterinarians and veterinary students. Medical writers are good communicators, so I thought: why shouldn't we take on the role of "medical actors"? It is an intriguing idea, albeit slightly impractical. Catarina described how her professional actors dropped into their roles as dairy farmers with minimal notice, leaving cattle veterinarians amazed at the realism of their portrayals. Maybe days of sitting in the office correcting obscure academic papers has not equipped me to portray herders of subarctic cattle very convincingly, but I think medical writers should keep an open mind on how we can to contribute to the debate.

#### Final thoughts from a medical writer

I was privileged to discuss shared decision making in such detail with Catarina and Louise, and other veterinary professionals in our special interest group. After these discussions, I tried to add a little context by investigating when and how shared decision making emerged in the human field. As far as I can tell, the concept largely dates back to the work of the bioethicist Robert Veatch, who in 1972 asked "What physician-patient roles foster the most ethical relationship?" <sup>12</sup> His work comes across as a philosophical and theoretical response to the question, which fitted well with the spirit of the times then. Now, times have changed, and I believe that the veterinary version of shared decision making is emerging in a more practical way. Both our speakers came to this area in search of practical solutions to practical problems.

Our discussions were focussed on the practical: What can the arthritic lady practically do for a diabetic cat? How can farmers practically be encouraged to optimise colustrum feeding? How can overworked and overstretched veterinarians practically be trained on a radical, new concept? How can we all practically get the message on shared decision making out to a wider audience?

There are challenges aplenty for the veterinary profession, and the medical writers (among others) who support them.

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My final thought was that we may be able the make these challenges seem simpler. Could the words "shared decision making", while being a useful umbrella term, add some rather daunting complexity? As Catarina pointed out, we are often dealing with situations where the vet is giving advice rather than taking decisions; as Louise pointed out many experienced, burnout-

resistant veterinarians have been practically implementing shared decision making for years without even realising there was such a theoretical concept. If we break down "shared decision making' to its most basic meaning, I think we could arrive at a much simpler definition. Is "shared decision making" just an elaborate way of saying "consultation"? After several hours of discussing this fascinating topic, I conclude that, as a medical writer, now is an exciting – and hopeful – time to be writing about veterinary medicine, and the efforts to enhance veterinary consultations for healthcare professionals, animals, and owners.

**Disclosures and conflicts of interest**The author declares no conflicts of interest.

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### From the Horse's Mouth

The quarterly pick of the news from the veterinary world

n May 25, 2023, the government of the United Kingdom abandoned plans to implement the Kept Animals Bill, a cornerstone piece of legislation that was intended to have wide-reaching implications for animal welfare, it was reported by the Royal Society for the Protection of Animals (RSPCA). To the dismay of animal welfare organisations and veterinary associations, the Bill has been scrapped after having been left in limbo by legislators for 550 days. The Kept Animals Bill had included legislation that protected a diverse number of species such as introducing restrictions on keeping primates as pets, banning the export of livestock, and banning the import of dogs with cropped ears. The provisions made in the bill had the potential to make a meaningful difference to the welfare of millions of animals in the UK. The government has instead indicated that it will pursue the policy commitments listed in the bill separately. However, no timeline has been provided for this. "We are facing the very real prospect of a dramatic downward spiral in animal welfare" Emma Slawinksi, director of policy at the RSPCA, has been quoted as saying.

he latest edition of Vetlit, the online veterinary journal resource, features a study recently published in the Journal of Small Animal Practice by R E del Solar Bravo et al. titled "Antibiotic therapy in dogs and cats in general practise in the United Kingdom before referral". This aim of this retrospective study was to characterise antibiotic prescribing behaviour by first opinion UK veterinarians and to compare this with contemporaneous UK antibiotic stewardship guidelines. The clinical records of 917 cat and dogs who were referred to the Internal Medicine and Oncology departments of two referral hospitals were reviewed. The study found that 486 (53.0%) of cases had been prescribed antibiotics for the condition they were eventually referred for. Bacterial culture and cytology support an

antibacterial prescription had been undertaken by the first opinion veterinarian in 8.8% and 1.8% of cases, respectively. Following diagnostic work-up at the referral centre, a bacterial aetiology was found or suspected in 17.9% of the cases that had received antibiotics. Overall, UK antibiotic stewardship guidelines were not followed in 344 of 486 (70.8%) cases who had received antiobiotics. The authors concluded that infrequent performance of microbial culture and cytology may be a contribution to overprescription of antibiotics in this patient population and that barriers to performing these tests in practice need to be removed, along with education initiatives to improve compliance with antibiotic stewardship guidelines and reduce antibiotic prescription rates.

he Royal College of Veterinary Surgeons in the UK launched their sustainability guidance document to help practices meet the requirement of the recently introduced practice sustainability standards it was reported in the *Veterinary Times* on April 6, 2023. The sustainability standards, to be incorporated as part of the existing practice standards quality assurance, the core standards which all practices are obliged to meet as directed by the code of conduct, were implemented from June 1, 2023. Alongside a written sustainability practice policy and responsible use of ectoparasiticides, veterinary practices in the UK will be provided with "how-to" guidance on compiling written sustainability practice policy and responsible use of ectoparasiticides, as well as an annual waste management survey, encouraging clients to return unused medications for safe disposal, and methods to reduce use of anaesthetic gases. The intention is also that these measures foster a sustainable approach by all members of the veterinary profession as they carry out their day-to-day professional activites.

# **Lingua Franca and Beyond**

#### Plagiarism: Is it a crime or just temptation?

How often when writing any text, you start by searching on the internet, using key words that are loosely linked to your vague idea of what to write and finally finding inspiration? Isn't it just one step to "borrowing" some words from what you found? Well, stop! If you do so, you will plagiarise, and act in an unethical and unfair way. But do you know what constitutes plagiarism and what does not? Andrew J. Davis explains in this article what plagiarism is, when a given text is considered plagiarised, and advises how to avoid plagiarism and, in particular, self-plagiarism. He also discusses the issue of acknowledgements and the complicated matter of copied images. It's

an interesting and relevant article for medical writers, and not only because of the main topic. I was fascinated to learn of the work of Elisabeth Bik: her outstanding skills for pattern recognition and her passion in tracing image manipulation in publications. I also learned an abbreviation which I did not know before – cf – confer meaning compare with...

Finally, when searching for inspiration ② I found that Andrew is a biologist with an interest in environmental sciences and sustainability so maybe a good start for cooperation with our Sustainability Special Interest Group (https://www.emwa.org/sigs/sustainability-sig/)?

#### **SECTION EDITOR**



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Something to consider?

Last, but definitely not least, I would like to thank Andrew for contributing to our section, and to invite all of you to learn more about plagiarism.

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If the text has an

overall identity of

>20% I warn the

authors. If the

identity is >70%

I reject the text on

the grounds of

plagiarism and

inform the authors

accordingly.

 https://en.wikipedia.org/wiki/ Elisabeth\_Bik. (Accessed 2023 April 8.)

# Plagiarism, lack of acknowledgement, and image fraud

#### Andrew J. Davis

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#### **Plagiarism**

lagiarism is the use of text written by other people but without indicating where the text comes from. This worries journals because they want to be sure of the link between the text of the work and the stated authors. As a consequence of this worry, many journals now automatically screen incoming manuscripts for evidence of plagiarism. The question is, though, how much reuse counts as plagiarism? There are some claims that journals have penalised authors for reusing very short pieces of text, or even for using organisational titles (e.g., World Health Organization). This is clearly ridiculous and should not happen. In such cases, authors are justified in protesting, and protesting strongly.

There are, however, several "official" definitions of how much reuse counts as

plagiarism. COPE (Committee on Publication Ethics<sup>1</sup>) gives one definition. And individual antiplagiarism applications (I use iThenticate) have their own recommendations. Taken together, these different definitions suggest that an overall identity of 15% or less is definitely not plagiarism and 25% or more definitely is. (And plagiarism of 15%–25% is an area where journal editors should exercise their discretion).

However, there is a problem with overall rates. This problem is that a text might have a low (<15%) overall rate of plagiarism but still have one or more paragraphs where the identity is much greater than 25% – even 100%

As a journal editor, I therefore use this procedure. If the text has an overall identity of >20% I warn the authors. If the identity is >70% I reject the text on the grounds of plagiarism and

inform the authors accordingly. Then, whatever the overall identity is, if any paragraph has identity >20% I warn the authors. Furthermore, if more than 20% of paragraphs have more than 20% similarity or any one paragraph identity >70%, I reject on the grounds of plagiarism.

So, how might authors respond to claims from journals that their papers are plagiarised?

The answer depends on how much of a stand the authors want to make. If the overall level of identity is really low and the authors want their manuscript to be accepted, then they might as well make adjustments to remove that low degree

> of plagiarism. The changes needed won't be very great. However, if they want to take a stand, they should point out (politely!) that their overall level of similarity is well below what COPE and major software packages define as plagiarism and so their manuscript should not be rejected on those grounds. If, in contrast, the level of identity is high, the authors will have to come up with a but innocent, convincing, reason, or else, considerably

rewrite their manuscript so that there can be no suspicion of plagiarism.

Whatever thresholds are adopted, the COPE guidelines on this are worth following.

I ought here to mention the phenomenon of

"text recycling". This differs from plagiarism only in that the text reused comes from other publications of the same author - it is, so to speak, self-plagiarism.<sup>2</sup> Authors often claim that they reuse their own text because, well, there's just no better way of writing what they want to say. This claim is made particularly for Introduction or Methods sections. (I find it difficult to accept it could ever apply to the Results or the Discussion. If your Results and Discussion can be expressed with reused text then is your manuscript really a new manuscript?) But reuse of text is not required in the Introduction or the Methods anyway because you can refer to your previous papers. If, for example, you're examining the same question, then you can write in the Introduction "The importance of this question is explained in detail in our previous paper (Yorick et al. 2021)," according to the normal rules of acknowledging ideas. And if the Methods are the same, you again cite your previous work. "We again analysed our samples with FT-MIR spectroscopy (cf Yorick et al. 2021)." There is thus no need to reuse blocks of text and risk raising suspicions of plagiarism.

#### Lack of acknowledgement

Reuse of ideas or content might be lack of acknowledgement, but it's not plagiarism.

If, without using the exact words of another author, someone uses their ideas or content they should acknowledge the other author. They do that either by citing their published work, other easily available sources (such as preprints), or a personal communication. If they don't acknowledge the other authors, and really did use their ideas, they are acting unethically.

It is extraordinarily difficult, however, to

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prove that someone is using your ideas or content. It is more than possible that different people independently have the same or similar ideas. For example, several people had evolutionary ideas before or contemporaneously with Charles Darwin. And Hooke, Schwann, and Schleiden all recognised the importance of cells. The idea or content has to be very special before you can prove that it's specifically taken from you.

In general, as an editor, I would want ideas and content that have already been published to be acknowledged, but thereafter things get very complicated. Whether the reuse of previously published ideas and content material is considered unethical depends



hoto: Unsplash Ning Wang

on who is reusing, how much they're reusing, why they're reusing, who holds the copyright of the reused material, whether "fair use" applies, the specific policies of the publisher that first published the material, and also the specific

policies of the publisher of the reused material. COPE says a great deal about these things but not in a single coherent place.

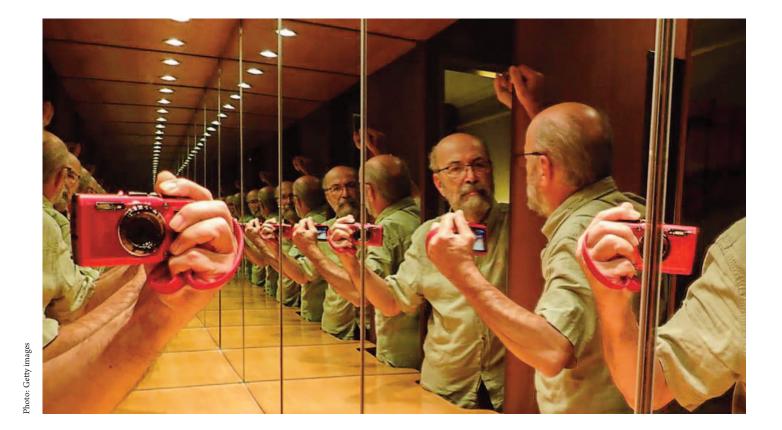
#### Copied images

Journals are not only worried about copied text but also about copied images. The reason for the worry is the same, journals want to be certain about the link between the creators of the material and the specified authors of a manuscript. Journals have a further worry about

images: this is that image reuse is very difficult to identify. Most known cases have only come to light because scientists have not been very clever and have, for example, used the same image in many different papers (in some cases more than

10 different papers!). And yet, image duplication is widespread.<sup>3</sup> Therefore, to detect this problem, journals are implementing checks of all images in manuscript submissions. These checks use humans, computers, or both, as covered in a recent *Nature* article<sup>4</sup> and elsewhere.<sup>5</sup> Some humans are very good at identifying copied images (e.g., Elizabeth Bik). And, although automated identification of copied images is in its infancy, and as yet, none of the available systems are 100% effective, they are quickly becoming more powerful.

But again, it's difficult to prove that an image is copied from a particular source unless there's something very characteristic about the image (such as a specific arrangement of points). For example, if I produce an image of the cell lineages in *C. elegans* then it's going to look similar to such an image produced by someone else. That is unavoidable because it's showing the same phenomenon. To prove that the image was copied, and copied from a specific source, it would be necessary to show that the suspect image was very closely similar to the model and also, the suspected author had, in fact, seen the



"Data is not copyrightable. Unless there is a creative element to data depiction that is being reproduced without alteration, fair use can be asserted, with attribution."

model. Neither of these are easy tasks.

The problem of duplicated images is complicated by the enormous differences in publisher policies. For example, Princeton University Press<sup>6</sup> says "Where a chart, graph, or table is being reproduced in a critical study of the work or to buttress an argument of the writer, no permission is needed. Data is not copyrightable. Unless there is a creative element to data depiction that is being reproduced without alteration, fair use can be asserted, with attribution." However, and in contrast, Oxford University Press<sup>7</sup> says "As a guide, you should always seek permission for: ...pictures (paintings, drawings, charts, engravings, photographs, cartoons, and so on); Figures and maps; Tables."

However, to help authors decide on best policy, there is a broad brush set of guidelines at the STM site.<sup>8</sup> (Learn more about STM at https://www.stm-assoc.org/about-stm/.) But finding guidelines for a particular case is very difficult indeed – there are just too many variables.

A wise course for authors, however, for text as

well as for images, is not to reuse any material without acknowledging its source and clearly attributing it to its original creators.

## Disclosures and conflicts of interest The author declares no conflicts of interest.

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Andrew Davis, PhD, has been a journal editor and reviewer for more than 30 years. He trained as a science text editor in the 1980s. Since then, he's been a science editor and translator with English Experience Language Services. From 1994 onwards he has taught scientific writing at Universities in Germany and Japan.

# **Regulatory Matters**

#### Editorial

More often than not, freelancing means juggling between running a business and writing. Training may not be at the top of the list for freelancers despite its importance in keeping oneself abreast of the changing regulations, new policies and guidelines, and for maintaining professional performance. In this issue, Kathryn White gives us a few tips on keeping up with training as a freelancer.

Zuo Yen Lee

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## Training: Lessons in self-leadership

#### Kathryn E. White

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raining courses – such an integral part of our working life as an employee. E-learning modules, standard operating procedures (SOP) updates and, if you're lucky, external workshops where you can escape the office for a day or two and enjoy a free coffee and possibly lunch. Every year, you probably review your training achievements with your manager to appraise your performance and identify any gaps in your experience.

Then, the twinkly promises of freelance life and freedom seduce you. Suddenly, your daily routine is finding clients and then holding on to them, completing projects on time while making sure invoices are issued, chasing payments to protect your cash flow, and ensuring you have more projects lined up. Training and continued professional development fade into the background.

#### Keeping up as a freelancer

As freelance medical writers, we are business owners. We have many hats to wear and several roles to juggle to keep our enterprise afloat. Yet, we owe it to our clients to keep abreast of the latest regulations, relevant guidelines, and recommendations. Where required, we need to

be aware of recent developments in our chosen therapeutic area(s). After all, we want to offer the best service for our clients, do we not? This also means we should improve our writing skills and knowledge, thereby ensuring we foster longevity in our business and client relationships.

Training becomes solely our responsibility when we are self-employed, so here are a few suggestions for maintaining professional development.

#### Make time for training

First and foremost, get into the habit of setting time aside for training, just as you would for other business management tasks. Allocate time, perhaps once a month, to review the areas relevant to your business.



#### Keep a training record

Set up a spreadsheet or equivalent to record the training you complete. Review it periodically or at least once a year so you can see where there are any gaps. Include the date the training took place, the name of the training company or trainer and their accreditations, and the topics covered. I also include whether the training took place online or face-to-face.

I have never been asked by my clients for this documentation, but some freelance colleagues have, so it pays to have this information readily available. One such colleague was made aware of the Italian Decree relating to Clinical Research Organisations. The decree defines the minimum requirement for personnel – including contractors – who perform clinical study activities involving data collection from at least one Italian site. The decree requires "a minimum of 30 hours of applicable training every calendar year".

It is a good business practice to ensure our training is recent, relevant, and recorded. Furthermore, this record acts as a great prompt for updating your curriculum vitae and summary of experience.

#### Informal and formal training

List the topics you need to be accustomed to, which will help you to create your training record. Include reading relevant guidelines and recommendations, such as the International Council for Harmonisation (ICH) guidelines, pharmacovigilance regulations, and legislation relating to medical devices, as well as reading clients' SOPs, and regularly checking for updates. All these activities are classed as training, so



document them. Sign up for content alerts from industry-related groups such as the Committee On Publication Ethics (COPE), Transcelerate Biopharma Inc, and therapy-related websites and journals – then information is automatically sent to you.

Become familiar with trusted sources of training and coaches. These include, of course, EMWA workshops and webinars, which offer formal training for which you receive a certificate of completion. Consider completing EMWA Professional Development Programme and earn foundation and advanced level certificates to add to your training portfolio. Peter Llewellyn of NetworkPharma runs the MedCommsNetworking.com community activity which includes excellent free webinars for everyone and face-to-face meetings around the UK. He invites speakers from a wide variety of companies relevant to medical communications. Online resources enable us to access training globally. For example, the American Medical Writers Association (AMWA) offers webinars and tutorials which can be purchased and downloaded without needing an AMWA membership.

It's very likely that as a freelance writer, you will work across many different therapeutic areas. Therefore, it is imperative that you familiarise yourself with each area you work in. Some clients will only award the work to writers with experience in a therapeutic area. Others will understand that we can read around the topic and gain sufficient understanding to enable us to produce good quality documents. Regulators provide helpful guidance on conducting clinical investigations in various diseases and conditions. For example, the EMA and US FDA have guidelines for conducting clinical studies in patients with respiratory diseases, diabetes, and oncology, to name a few. So, it is worthwhile reviewing the documents on their websites.

#### Training from clients

Some clients offer their contract medical writers training on in-house SOPs, relevant regulatory guidelines including Good Clinical Practice (GCP) updates, or on business-related information such as data integrity or business ethics, or on the use of in-house or external IT systems such as Datavision or Endnote. Remember to record this training. Clients may offer training in a particular therapeutic area though this is generally informal. They may provide basic background information with the primary purpose of putting their product into context. Information about a particular disease or condition and current therapeutic options can

usually be obtained from clinical documents such as the investigator brochure, protocol, and clinical study report, which may be provided – or requested – when you begin a project.

In the past, I have been asked by a client to produce regulatory documents I hadn't written before. I accepted the work but was transparent about my lack of experience. At the time, I was reviewing some contracts and increasing my fees because it had been a while since I'd done so. For this particular client, I kept my rate unchanged. I felt they were giving me a fantastic opportunity to learn on the job and provided an investment in my future. My strategy paid off and that same company remains a customer and pays me the same fee as others. So, be aware of less obvious training prospects.

#### Networking

Learn from your peers. Experienced writers have a wealth of knowledge so be brave and ask them questions. I've found medical writers to be a friendly bunch and happy to help. It goes without saying that EMWA conferences and workshops are excellent for picking up valuable tips from fellow writers as well as building up a network of fabulous colleagues!

## Don't forget to brush up on your writing skills

We are writers and communicators, so we want to continually improve our skills in this area. There are a wealth of online resources, books, and tutored courses which cover various aspects of writing. However, I believe the best way of refining our writing ability is by writing and reading widely. Where possible, ask a colleague to review your pieces of work occasionally or ask an experienced writer to become a mentor. Each time I have done this, I have learned something new

One of the most exciting aspects of freelancing is the breadth of topics we may cover compared to when we are employed. Furthermore, many of us write regulatory documents as well as create medical communications content. We cannot be experts in every area we work in unless we specialise. Yes, we can read around a subject, and we have the background training to comprehend scientific/medical information, but we often collaborate with more than one client at any one time. Therefore, we lack the expertise that in-house physicians and regulatory/clinical team members have for a product or project. I think it is important that our clients are aware of this, particularly if they have not worked with medical writers before. Otherwise, clients may think we can work in isolation with very little

background information. The EMWA guidelines which describe the role of medical writers in developing journal articles<sup>1</sup> provide an excellent reference to send to such clients. I feel it's important that they understand our responsibilities and what we bring to the project.

#### It's not just about medical writing

Before I made the leap into self-employment, I consulted with a wise former colleague of mine who had already set up her own business. She advised me not to go freelance unless I was willing to devote time to learning business management skills. Small businesses often fold within the first five years of setup because of burnout.2 It's critical that as a freelancer, you understand the different roles you play as the director/owner of your own business and that you set time aside to learn management skills, including self-leadership. You are no longer an employee – the success of your enterprise is now down to you. Often, our fears are about not finding sufficient clients - but what if you start acquiring too many? This can and does happen. So, you need to put processes and systems in place to avoid you, the solopreneur of your own destiny, from becoming the bottleneck of your own business. If you can afford to do so, I would

highly recommend investing time and money in having business coaching – someone to hold your hand, certainly in the early days of your business, to boost your confidence. For longevity, client relationships must be nurtured, and word-of-mouth is your best business card.<sup>3,4</sup>

#### And, finally...

As freelance medical writers, we must be self-motivated to keep abreast of our training – and be willing to invest time and money into our development. We owe it to our clients to brush up on our skills and knowledge so we can continue to create quality output.

#### Acknowledgements

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#### **Disclaimers**

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

#### Disclosures and conflicts of interest

The author declares no conflicts of interest.

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# **The Crofter: Sustainable Communications**

#### **SECTION EDITOR**



#### Editorial

Greetings from the croft. Recently, I felt at a loss when I read in the 2022 Lancet Countdown report that "the carbon intensity of the global energy system has decreased by less than 1% since the UNFCCC [UN Framework Convention on Climate Change] was established" over 30 years ago and how our health is "at the mercy of fossil fuels". Fortunately, the report also noted "emerging glimmers of hope", namely with regards to leadership in the health sector and individual engagement.1

I am thankful for Paul Tisdale's insightful contribution on why we should and how we can proactively integrate sustainability into our businesses. And I applaud Oxford Pharma-Genesis' example. I am also proud of EMWA's commitment to sustainability. Elsewhere in this issue (p. 72), Blanca Gomez-Escoda, Pavlína Cicková, and Raquel Billiones report the findings of their study to estimate EMWA's carbon footprint. Their findings serve as a baseline for EMWA's transition to carbon neutrality.

To me, there is no question that proactively responding to climate change will create wins all around - for our clients, our businesses, our planet, and all dimensions of our health. I'm looking forward to trying out some of the carbon calculators that exist and establishing a baseline for my freelance business and setting some goals. If anyone is interested in sharing their results and goals with me, please reach out.

Kimi

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## Rising to the challenge of sustainability in healthcare communications

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limate change is among the greatest global challenges facing humanity, and although progress on tackling the issue is slow, the pharmaceutical industry is taking it seriously. This article explores what pharmaceutical companies are doing to be more sustainable, how they are reducing carbon emissions, and what this means for the healthcare communications sector.

The climate impact of healthcare provision is significant, contributing approximately 5% of greenhouse gas emissions globally.1 The pharmaceutical industry is a major source of these emissions, both directly through the manufacturing and distribution of medicines and medical devices, but also indirectly as a consequence of the activities of its suppliers.2

The leadership of pharmaceutical companies

recognises the importance of moving in step with societal values and expectations on issues relating to corporate responsibility, and there is an appreciation of the need to act now to address climate change. There are also commercial drivers of change such as industry guidance and government legislation. Many governments have committed to reducing greenhouse gas emissions, and there are advantages for pharmaceutical companies in adopting sustainable working practices in advance of deadlines to maintain access to global markets.

In recent years pharmaceutical companies have set targets for reducing their greenhouse gas emissions. These targets are regularly reviewed and often become more ambitious over time. For example, Novo Nordisk has committed to "net zero emissions in operations and transport by 2030, with net zero emissions across the entire value chain by 2045, at the latest".5 To achieve these targets pharmaceutical companies are changing their business practices; examples include switching to renewable energy providers, optimising building design, reducing business travel, opting for lower carbon methods of transport for raw materials and goods, reducing waste, remote monitoring of patients in clinical trials, implementing vendor selection criteria, and offsetting carbon emissions.6 With regard to pharmaceutical companies' medical communications, innovation will be pivotal to reducing the environmental impact. Studies have shown that

#### Carbon neutral Vs. Net zero emissions

Carbon emissions only

Achieved when carbon emissions are balanced by carbon removals Targets all greehouse gas emissions (e.g., carbon dioxide, methane, nitrous oxide, fluorinated gases)

Aims to reduce greenhouse gas emissions to as close to zero as possible, offsetting only the remaining emissions





in-person congresses have a large carbon footprint, particularly when delegates fly longhaul.<sup>7</sup> Investment in digital infrastructure during the COVID-19 pandemic demonstrated that it's possible for medical congresses to adapt to a world where travel was not possible; however, the return to in-person meetings more recently has shown that there is still a strong desire for the networking and knowledge exchange opportunities associated with this format. In the future, it's possible that large international congresses may have regional, parallel sites where plenary sessions could be simultaneously streamed in the evening and morning across different time zones, meaning that delegates could attend a site closer to them, without the carbon footprint (and time/cost) of long-haul flights, while providing the opportunity for face-to-face interaction with their peers. This also presents opportunities to reach and engage new audiences, and to support greater inclusivity. Healthcare communications providers should think about ways to support clients' climate goals using technology and innovation, in which there has been huge investment in recent years.

#### **Emissions explained**

Scope 1

	Jources owned or controlled by
	a company (e.g., running boilers
	and manufacturing facilities).
Scope 2	Indirect emissions from energy
	suppliers on the company's
	behalf.
Scope 3	All other indirect emissions in
	the value chain produced by
	suppliers (e.g., raw materials,
	distribution, transport, and
	healthcare communications
	consultancies). These are often
	greater than the company's
	direct emissions.

The direct emissions from

sources owned or controlled by

# What it means for the healthcare communications sector

As a service industry, the healthcare communications sector must respond to the needs of its clients, both in terms of project delivery and business practices, and when it comes to sustainability there is an advantage to moving ahead of the wave of change, rather than reacting to it.

Sustainability matters to the healthcare communications sector for several reasons. From a commercial perspective, pharmaceutical companies are embedding sustainability requirements throughout their value chain, and recent guidance has indicated that alignment with their goals will be a standard consideration in sourcing decisions. In the past year several companies have clarified their position regarding the requirements for suppliers: for example, auditing and disclosing carbon emissions through sustainability monitoring platforms such as EcoVadis, and publicly committing to science-based targets (SBT; through the Science Based Targets initiative) for the reduction of emissions. In addition to alignment with client stipulations, there is policy pressure in the form of government legislation; for instance, ultra-low emissions zones and frequent flyer taxes, which may require changes in business practice. Finally, there is an ethical argument that being more sustainable is the right thing to do in terms of environmental stewardship for future

generations. This is potentially important for current and prospective employees, who may wish to see their employer as forward-thinking and having shared values. As is often the case when adapting to changes in the business environment, acting early may be more costeffective and less painful than making changes

#### Practical implementation of sustainability measures

There are challenges when it comes to cutting the carbon emissions of the healthcare communications sector. Generally speaking, providers

National Health

Service England

was the first

healthcare system

to embed net zero

emissions in

legislation, through

the Health and

Care Act 2022,

with a target date

to achieve this

by 2040.3,4

are small-to-medium sized enterprises or sole traders with lean operations, and low absolute emissions, most of which are required for essential operations.

Auditing a company's carbon footprint is an essential first step in benchmarking, monitoring, and reporting progress in reducing carbon emissions. This can be achieved through several different platforms, although some, such as EcoVadis, have started to gain industry-wide recognition, which is para-

mount for consultancies that have multiple

Pharmaceutical companies are offering support to suppliers to help to reduce their carbon footprint. The Energize programme was set up through a collaboration among industry-leading pharmaceutical companies to engage with suppliers and support the adoption of renewable energy and reduce carbon emissions in their supply chain through power purchase

agreements. Switching to a renewable energy supplier, with or without the help of client support, is one of the most effective ways of reducing the carbon footprint of a healthcare communications consultancy and should be a high priority.

Maintaining relationships with clients and companies is critical for business development in the healthcare communications sector, and despite the improvement in virtual meeting capabilities over the past decade, in-person interaction provides an opportunity for the more expansive and relaxed conversations on which relationships thrive. To reconcile the need for

increased sustainability with business development, healthcare communications professionals should first aim to reduce carbon emissions through choosing activities with a lower environmental impact (e.g., virtual healthcheck meetings with clients) and, when emissions are unavoidable, seek to maximise the "return on carbon" - potentially reducing future emissions. This can be achieved through planning trips to meet as many clients as possible in one journey, or connecting with clients at medical congresses rather than travelling to the client's

office where many people may not be present owing to homeworking. Opting for lower carbon modes of transport, such as trains, where working on-the-go is also easier and there are fewer lost working hours, is preferable. If flying is the most appropriate option, taking direct flights will further help in lowering emissions. At a company level, configuring teams to support clients on the same continent (e.g., US-based teams working with US client companies) would also help to

"Oxford PharmaGenesis aims to be an industry leader on sustainability: facilitating and educating others on the developments that are needed to combat climate change. The push towards greater sustainability is driven by the mission of the company and the values of its employees, not only in response to client direction. The company was recently re-evaluated by EcoVadis and awarded a Silver medal (top 25%) for sustainability performance, previously been awarded Bronze in 2021. We are in the process of committing to SBT and will be setting near-term targets this year. Oversight of progress towards these goals will be provided through our environmental management team. Oxford PharmaGenesis has sought to raise the profile of sustainability in the pharmaceutical industry through research, conducted in collaboration with Oxford University, evaluating the emission reduction targets of major pharmaceutical companies.6 The company is also a member of the Sustainable Medicines Partnership a not-for-profit collaboration that aims to make healthcare more equitable and sustainable."

#### Chris Winchester,

Chief Executive Officer, Oxford PharmaGenesis

reduce travel-based emissions. Carbon offsetting schemes are another way a company or individual can reduce the climate impact of business development activities associated with travel, but these should be seen as complementary to, rather than a replacement of, efforts to reduce primary

# **New Special Interest Groups**

Welcome to our new special interest groups!







carbon emissions.

Companies and individuals should consider the working environment of their offices. For some employees, working from home avoids the carbon emissions associated with travelling to the office, but for others there may be a benefit to working in a shared space, with face-to-face human interaction, where the heating, cooling, and lighting emissions are shared among multiple occupants. The mode of transport when travelling to and from the office can also have big impact on carbon emissions: walking and cycling produce zero emissions, and public transport is better than travelling by car. Where travelling by car is the only option, employees could set up carpooling schemes, or switch to electric vehicles. Often overlooked, the digital carbon footprint of companies (servers, websites, internet searches) represents a growing proportion of total emissions. Companies should engage with their suppliers to seek further information on low carbon digital solutions; for example, net zero data centres. Finally, although this article has focused on carbon emissions and travel, other actions such as reducing resource and water use, or recycling, all play a part in supporting the shared goals of sustainability.

#### A sustainable future

Many healthcare communications consultancies and individuals are at the start of their journey towards a more sustainable world; however, we owe it to future generations to move with purpose and direction in tackling climate change. If the healthcare communications sector takes the initiative in reducing its carbon footprint, and supporting our clients to meet their targets, it will benefit everyone.

#### Practical tips for freelancers

Calculate your carbon footprint. Start by measuring your current carbon emissions. A list of calculators can be found here at https://footprinthero.com/best-carbon-footprint-calculators.

**Set a goal.** Set an ambitious but realistic target for reducing carbon emissions over a specified timeline. For example, a reduction of 25% over the next 12 months, and once you hit that target revise it to go lower.

Take action. Consider how clients are reducing their carbon footprint and whether you can reflect this in your own business practices. This could be prioritising local or regional travel over long-haul flights. Think about how you heat your home office or shared workspace – turning down the thermostat 1– 2° can make a big difference. If you have a network of colleagues or acquaintances with similar ambitions to be more sustainable, you could set challenges for one another to meet your targets. Start small if that's easier but stay on the pathway to reducing carbon emissions.

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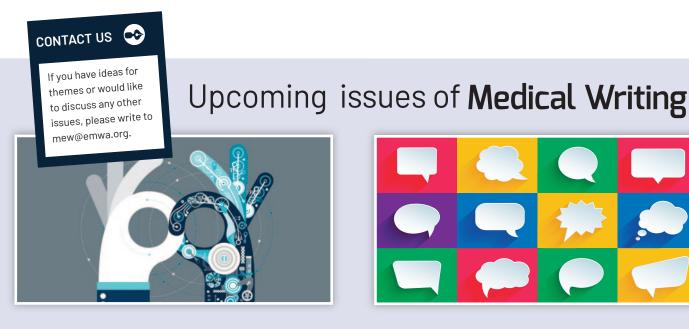
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#### September 2023: Automation/software

Streamlined complex medical report writing supported by artificial intelligence/machine learning is making its way into clinical regulatory writing. The medical writing automation's goal is to speed up and ease clinical development processes by reducing the time and cost involved in creating and keeping regulatory documents up to date. This issue will examine current issues, challenges, and opportunities towards human guided medical writing automation systems.

#### Guest Editors: Shiri Diskin and Daniela Kamir

The deadline for this feature has now passed.



#### December 2023: Biotechnology

Biotechnology uses biological systems and living organisms in R&D and production processes. Biotechnologies include biologic and biosimilar pharmaceuticals like monoclonal antibodies, vaccines and advanced therapy medicinal products, for example, gene and cell therapies and tissue engineered products. In addition, biotechnologies support the product lifecycle, for instance, in non-clinical work using in silico, in vitro, and animal testing methods. Also, support services personnel like those in biobanks and supply chains require an understanding of biotechnology. This issue focuses on the crucial role of writing and communications in biotechnology and product development.

#### **Guest Editors: Jennifer Bell**

The deadline for feature articles is September 1, 2023.



#### March 2024: Translation

Medical translation is a complex and demanding field requiring specialised knowledge, skills, and expertise. In this issue, we explore a range of topics, including the role of medical translation in clinical trials and regulatory affairs, the importance of terminology management, the use of technology and machine translation, ethical and legal considerations, the impact of cultural differences, quality assurance and risk management, and the emerging trends and challenges in the field.

#### Guest Editors: Ana Sofia Correia and Claire Harmer

The deadline for feature articles is December 1, 2023.



#### June 2024: Soft Skills for Medical Writers

Medical writing is a highly specialised field that requires a unique combination of technical knowledge, writing skills, and soft skills to produce high-quality work. While technical knowledge and writing skills are undoubtedly important, it is how one interacts with people that can truly set medical writers apart and enable them to succeed in their careers. This issue will focus on how soft skills are used within the different areas of the medical writing industry, and we hope it will provide valuable insights and inspiration for medical writers at all stages of their careers.

#### Guest Editors: Clare Chang and Nicole Bezuidenhout

The deadline for feature articles is March 1, 2024.

