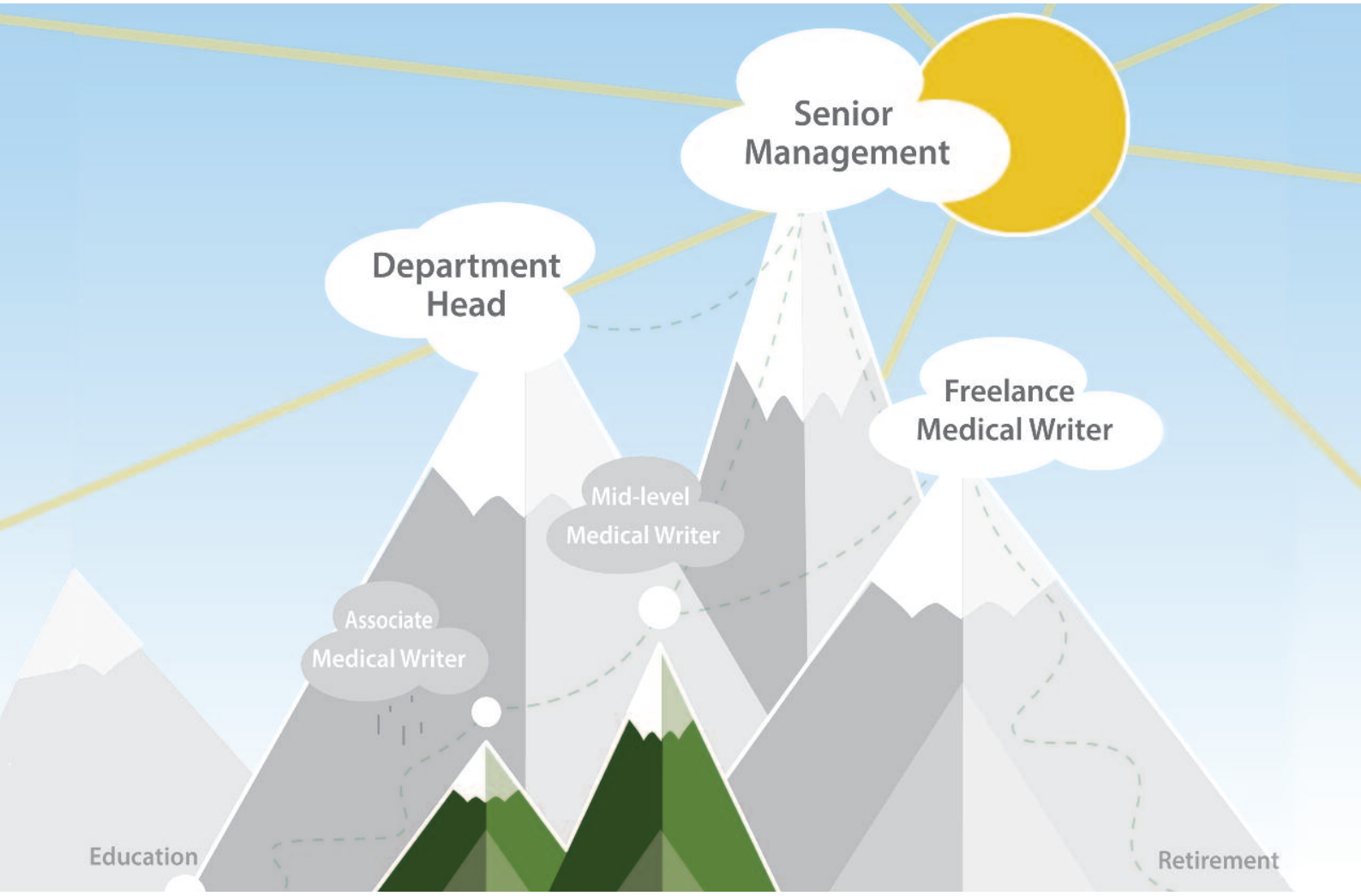
Volume 28 Number 1
March 2019

Medical Writing



Careers in medical writing

Also in this issue...

- Clinical trial disclosure landscape and awareness in Japan
- Biowaiver: The magic wand to reduce time and cost
- Benefits of using the EMWA Freelance Directory

EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

EUROPEAN MEDICAL WRITERS ASSOCIATION

Medical Writing is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers. Members of EMWA receive *Medical Writing* as part of their membership. For more information, contact mew@emwa.org.

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

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Medical Writing

Careers in medical writing

How did we get here?

Medical writers are a breed apart. Unlike many other professions we come from a diverse range of educational and often early professional backgrounds. Yet we find our way to medical writing – or perhaps medical writing finds its way to us – and most of us make a wonderful career of it.

Some of us become medical writers on purpose, such as those most recently joining our ranks from the online and on-site degree programmes in biomedical communications that are popping up around the world. Others become medical writers by accident. For example, reporting the results of our research is simply part of the job, then we discover we like the writing part more than the research. Or perhaps as an early-career writer we answered a help-wanted ad that landed us in a medical communications company having to come up to speed on science and medicine.

Breaking into medical writing isn't easy. Like many careers, we ironically need experience to get the first job but the first job to get that experience is elusive. Still, it is possible, as **Mary Gaskarth** explains – just look at how many medical writers there are! (More about that in a moment.)

No matter how we got here, there are a number of excellent certificate programmes available in which to immerse ourselves, hone our craft, explore new therapeutic areas and types of medical writing, and develop professionally throughout our careers. For many, professional certifications serve to underscore our capability and commitment to the profession, and such certifications may provide a valuable leg up for advancement. There's an excellent update on these programmes by **Danny Benau** in this issue.

Where are we?

Medical writers are everywhere. As the infographic by **Carola Krause** and **Brian Bass** on page 3 shows, worldwide there are approximately 1100 members of EMWA[1] and more than 4000 members of the American Medical Writers Association,[2] together spanning 58 distinct countries. It is estimated that 1250 (range 1000 to 1500) professional medical writers are based in India.[3] In addition, there are approximately 300 members of the Australasian Medical Writers Association,[4] and more than 1500 members of the International Society for Medical Publication Professionals (ISMPP).[5] But the medical writing universe is much larger than this.

Consider the number of medical writers who are members of the Drug Information Association, the Regulatory Affairs Professionals Society, and other professional associations for medical writers. Then add the medical writers who don't know they're medical writers. In our travels we've met many people doing the job of medical writing who don't think of themselves as medical writers. Maybe "medical writer" isn't what their company calls their position, or it's not the title on their business card. They may be a writer in a small biotech company, a health journalist, or working within the health system. We need to reach these individuals because their worlds touch ours and ours touches theirs.

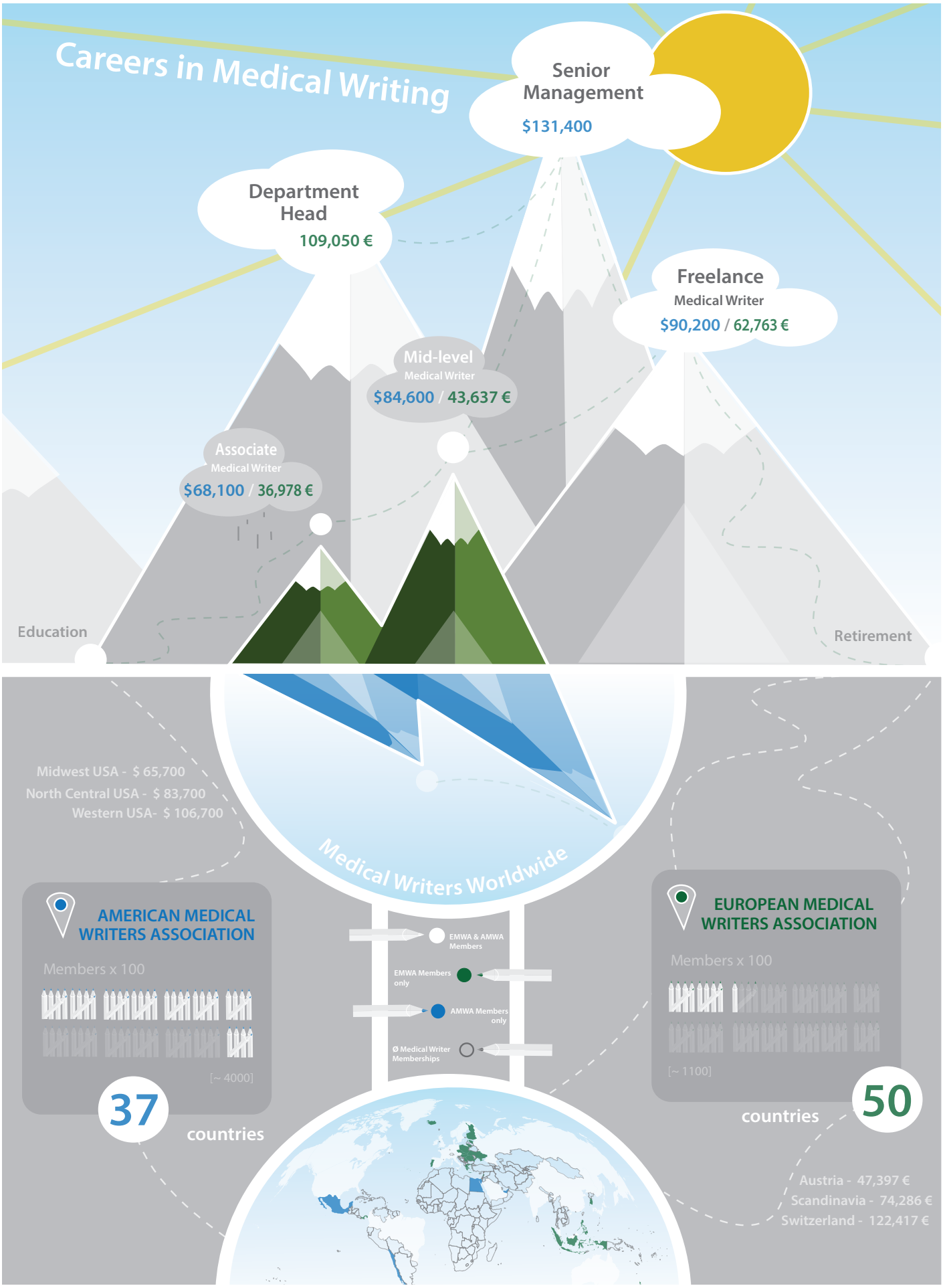
In our travels we've met many people doing the job of medical writing who don't think of themselves as medical writers. Maybe "medical writer" isn't what their company calls their position, or it's not the title on their business card.

Where are we headed?

Medical writers are going places. Just as the backgrounds that directed (or dragged) us here are diverse, so are the trajectories of our careers. The infographic depicts medical writers follow a path of success from associate to senior medical writer, perhaps advancing to department head and eventually into management.

Some medical writers forge their own path into freelancing at some point in their career, and as you'll read in the individual journeys highlighted throughout this issue, sometimes the employment and freelance paths switch back and forth several times. Some medical writers' journeys lead them into different types of medical writing – such as from pharmaceuticals to medical devices, and others to different parts of the world. Each of us plots our own unique course, and as you'll learn in this issue, we get around a lot!

Then there's retirement. Medical writing knows no age limit, for most of us we can work as long as we want. Perhaps we retire from the corporate life to start our freelance business and write merrily into the sunset. Perhaps we take the hard stop as an opportunity to launch an entirely new career, or to rediscover ourselves and our interests.



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About this issue of *Medical Writing*

It has been an honour for us to be invited to serve as guest editors of this special issue of *Medical Writing*. Being seasoned professionals, we looked at the paths our own careers have taken. We thought about our friends and fellow colleagues and the paths their medical writing careers have taken. We realised that medical writing isn't a destination but a journey, a journey that is different for each of us.

We devised this issue to take you briefly on many such journeys through the stories of those who have lived them. It is our hope that if you're just getting started, stories from experienced medical writers will inspire you and give you direction. If you're experienced, we hope the stories will motivate you to continue growing and evolving in new directions.

We begin at the beginning, starting with that initial step from academia to industry as experienced by **Evguenia Alechine**, **Som Basu**, and **Clare Chang**. **Matt Edmonds** made the leap into regulatory writing 18 months ago and is happy where he is. Similarly, **Clare Chang** and **Zuo Yen Lee** took the same step from bench to pen by moving back to their roots in Asia to get that first medical writing job. Throughout this issue you'll find stories on some of your colleagues' breakthrough moments when they got their foot in the door and landed their first medical writing job. It's truly inspiring and entertaining to read these different pathways.

Then comes the career transitions. Some writers change geographies, work environment and/or specialisation. **Clare Gurton** shares her journey from freelancing to employment; **Hye-Ryon Kim** opted to go the opposite

direction – from employment to being self-employed. For those who opt for employment, **Yan Zhou** gives the pros and cons of writing for a pharma company vs a CRO. **Laura Collada Ali** and **Monica Milani** write about how translation and writing cross paths to create opportunities. Two writers who started their careers in pharma, **Gillian Pritchard** and **Sarah Choudhury,** show how they leveraged their pharma-acquired skills to conquer the medical device industry. **Ansgar Dressler** shares his unique experience of shifting from numbers (statistics) to text generation (writing) – and staying there. Changing geographies can be scary yet exciting. Many of the articles already mentioned also deal with geographic shifts. **Szymon Brużewicz** took this shift even further by transferring a thriving freelance business from Europe to South Korea. Crossing the cultural divide was a journey in its own right.

There are some less known but none less interesting subspecialties of medical writing where people can take their career. **Nancy Linford** has carved out her niche in grant writing; **Ana Goios** has combined art and scientific writing in the field of medical illustrations.

The journey to management level is challenging yet rewarding. **Tania Dickson** and **Raquel Billiones** describe their rollercoaster rides to get there and become good managers. **Julia Cooper** and her colleagues at Parexel reveal the secret of their success in recruiting, training, and developing writers to become one of the biggest CRO medical writing teams today.

The topic of disclosure has gone global. The article on clinical trial disclosure in Japan by **Hiroko Ebina** and **Jocelyn Colquhoun** may not be career-related but nonetheless very important for our readers. And don't forget about our regular sections. A new section on veterinary medical writing is being launched in this issue!

Finally, in case you are wondering what medical writers do after retirement, throughout this issue you'll find stories on how your colleagues are moving into the golden years of their careers. Clearly, there is no end to the medical writing story except the ending you write for yourself.

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President's Message

Dear EMWA Members,

EMWA's spring conference will offer, once again, an impressive variety of workshops, expert seminar series (ESS), lectures, networking meetings, and a symposium on the important topic of the real-world evidence. Our members, whatever their degree of experience, will find excellent opportunities in Vienna to further develop their skills and knowledge. However, EMWA is far more than a pure training organisation: it is an invaluable platform to interact, share expertise, and inspire each other. Together, we can tailor EMWA to our need and shape our professional role through EMWA. Not only does our association benefit from members who are willing to share their expertise and support new ideas, but also supporting EMWA can bring in return benefits to the volunteers in terms of career and personal development. The EMWA Professional Development Programme (EPDP), ESS, webinars, journal, special interest groups (SIGs), working groups, ambassador programme, public relations: these are just a few examples of how giving back is always also an opportunity to grow!

At the very beginning of my career in medical writing, a colleague introduced to me EMWA and the EPDP opportunities. I remember how inspired I was from my first conference: the practical tips learnt at the workshops, the spirit of sharing experience and networking, the informal atmosphere, new friends … I came back with plenty of ideas for my everyday professional life, albeit my working field, pharmacovigilance (PV), was not yet a recognised medical writing area. EMWA gave me an excellent training in medical writing skills and motivated me to give back when I gained sufficient experience. I started offering PV writing trainings and liaised with other members to coordinate our efforts. Interacting with workshop participants of different degrees of expertise enriched me from a personal and a professional point of view. In my workshops, I aimed to raise awareness about the professional role of medical writers in PV. Shortly later, I was asked to organise together with another EMWA member the symposium on risk-benefit evaluation in 2015: this event brought us together with another colleague, who led the establishment of a PV SIG. Since then, this group has been making constant efforts to develop new workshops, offer updates, and enable discussions with regulators through ESS sessions. All of these activities have played a major role in strengthening the professional role of PV writers and the position of EMWA in public discussions. Whenever I contributed to enhance the PV offer for our members, I also benefited in return for my own growth. And on top of this, during the journey through various EMWA activities, I have found very good friends!

Interacting with workshop participants of different degrees of expertise enriched me from a personal and a professional point of view.

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EMWA is addressing other hot topics, such as regulatory public disclosure, medical devices, and predatory publishing, through dedicated SIGs and working groups. Recently, after the successful webinar on veterinary medical writing, things have started moving for this area. Our journal is launching a section dedicated to veterinary medical writing, which will enhance the visibility of this professional area and ease networking. At the same time and independently from this initiative, the Executive Committee invited a few veterinary writers we were aware of, to get together in Vienna and establish a SIG in veterinary medical writing. Further members learnt about this initiative by word of mouth and expressed their interest in contributing to the activities, regardless of their degree of experience. The number of people involved so far is still limited, but their potential is very high: this SIG will be an exciting opportunity to tailor EMWA to the need of our veterinary writing members and to help them shape their professional role.

See you in Vienna at another inspiring conference!

Tiziana von Bruchhausen
President@emwa.org

Getting Your Foot in the Door

How Sam Hamilton did it

I have always written. At primary school, I wrote imaginative stories, and delighted in my regular "10 out of 10" scores in English language, that had me reading my work aloud to my enraptured classmates. At secondary school, my writing became more formulaic to serve the needs of the "exam machine". As an undergraduate scientist, I enjoyed the discipline of melding theoretical arguments with crisply communicated evidence-based science. In my academic research associate days, I discovered that I wrote (for charities) and spoke well (on local radio) in communicating science and medicine to the public – something that I did just for fun. I was awarded a grant from the Committee on the Public Understanding of Science to develop my skills in this area. Then, having dismissed that crazy notion, I moved into the clinical trials industry.

Throughout my time as a clinical research associate, I wrote manuscripts for my company – just for fun and to keep my writing hand in. By now you may have guessed that this was all heading in one direction – but I didn't know that for quite a number of years. My "getting your foot in the door" moment came as a stressed international clinical project manager, pregnant with my first child, and generally too busy to think rationally. In a rare quiet moment, I realised I could not keep up the pace, and be a competent employee and sane parent. In that serendipitous moment, I finally realised that medical writing had been staring me in the face.[1] I talked to my manager, and with his blessing, I started working in my CRO's Medical Writing department for the wonderful Nicky Dodsworth.[2] I had finally come home – and the rest is history…

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EMWA Past President (2015-2016)
CORE Reference Project Chair

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EMWA News

Spring conference in Vienna

Last year, the November conference in Warsaw reached a record of attendees. Now, we are two months away from the annual spring conference in the beautiful city of Vienna, and we are beyond excited. This time, the 7th EMWA Symposium will focus on "Real-World Evidence: A Central Role for Medical Communicators", and there will be an offering of more than 50 workshops, including many on new topics. Check out the Vienna conference minisite (http://vienna.emwa.org) for detailed information.

Joint Position Statement on the Role of Professional Medical Writers

We also have some exciting news regarding the Joint Position Statement on the Role of Professional Medical Writers (JPS). Over the past several months, the JPS has received various organisational endorsements, has had related journal articles published about it, and has been translated into new languages. All this activity is a testament to the longevity and continued interest for the principles laid out in the JPS. Moreover, the recognition of the JPS has been underscored by endorsements and communications from organisations around the globe including:

- The Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network
- European Association of Science Editors (EASE)
- Australasian Medical Writers Association (AusMWA)
- Association of Regulatory and Clinical Scientists (ARCS Australia)
- The Council of Science Editors (CSE) and Board of Editors in the Life Sciences (BELS)

Clinical trial transparency and data disclosure

On another note, PhUSE has released a paper developed by industry experts with the goal of highlighting the evolving global landscape of clinical trial transparency and disclosure with special focus on individual study and submission-related requirements, which you can find on EMWA's website.

Additionally, three new resources on data sharing have recently been released:

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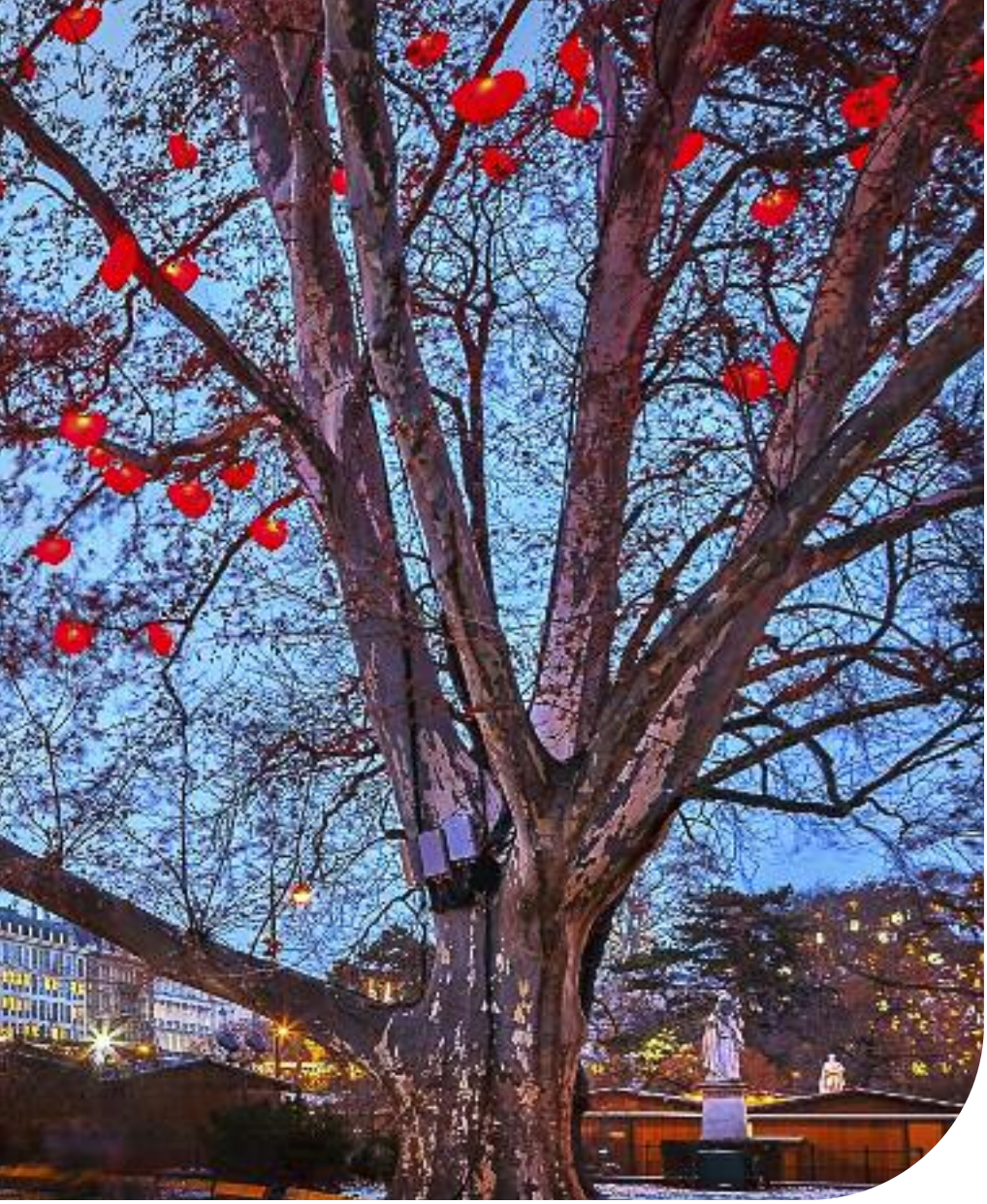

Veterinary medical writing

Since the last conference in Warsaw, there has been a rising interest in veterinary medical writing, which has led to the introduction of a new regular section in the journal and a Veterinary Medical Writing Special Interest Group.

Journal themes for 2019 and 2020

Finally, the following are the themes for journal issues planned for 2019, and we are already thinking about the topics for 2020. The editors are always looking for fresh ideas, so, please contact the journal office (MEW@emwa.org) if you think of a topic that should be covered.

- June 2019: Generics and Biosimilars
- September 2019: Trends in Medical Writing
- December 2019: Artificial Intelligence & Digital Health

Webinars in 2019

If you haven't checked them out yet, we have an amazing lineup of webinars for this year. Register on the website and don't miss them!

- **April:** "Checking House Styles: Customising PerfectIt for Advanced Users" by Daniel Heuman
- **June:** "Covering your first medical advisory board meeting: tips and tricks" by Laura Carolina Collada Ali
- **July:** "Nutrition basics" by Carolina Rojido
- August: "Writing your first white paper for the medical devices industry" by Laura Collada Ali
- **September:** "Pharmacovigilance writing: monitoring and enhancing patients' safety throughout the life-cycle medicinal products" by EMWA President Tiziana von Bruchhausen
- **October:** "Whole foods plant based (WFPB) science" by Carolina Rojido
- **December:** "Personal experience from transitioning from Pharma to Medical Devices" by Sarah Choudhury

Special Interest Groups

Regarding EMWA's Special Interest Groups (SIG), the new Medizinprodukte-Sicherheitsplanverordnung (MPSV) for Germany has been released end of November 2018.

Interested in volunteering for EMWA?

Keep in mind that EMWA is run by volunteer medical writers just like you. So, if you would like to contribute to any of our teams (congress planning, journal, website, social media team, conference advertisement, webinars team, internships project, workshop leaders, pharmacovigilance special interest groups, freelance business group, finance, etc.), don't hesitate and contact us (info@emwa.org)! We would love to hear from you.

Open Access Clinical Study Report (CSR) Template

In November 2018, TransCelerate Biopharma – an alliance among some of the world's prominent biopharmaceutical organisations - released a clinical study report (CSR) template.

TransCelerate's CSR template was developed using the two "well-known standards" – ICH E3 and CORE Reference (www.core-reference.org). The EMWA-AMWA CORE Reference development team was not involved in the TransCelerate CSR template development work.

Read our Press Release on TransCelerate's CSR template and use of CORE Reference in its development: https://www.core-reference.org/news-summaries/core-reference-statement-on-transcelerate-csr-template/

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How to get your first job as a medical writer

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Abstract
A successful medical writer needs to be an excellent time manager, communicator, and team player, and show great attention to detail and commercial awareness, in addition to possessing core writing skills and the ability to evaluate and contextualise data. Above all, there must be an enthusiasm to learn. Researching and networking within the medical communications industry will help build a picture of a medical writer's day-to-day activities. An online profile and error-free application closely tailored to the specific role and employer of interest, followed by illustrating relevant skills and potential with examples during interview, will supplement successful off- and on-site written tests and lead to the start of a career in medical writing.

I had barely even heard of medical writing as a career when I came across the advert for trainee medical writers in the back of *New Scientist* while writing my PhD nearly 18 years ago (job hunting in the olden days …). But I knew I had found my home in medical communications from the outset, for the same reasons that I still love it today: for the opportunity it affords to marry scientific interpretation with creativity and to communicate engaging truths in a fast-paced and exciting commercial environment, and because I get to work with a team of such bright, inspiring, and dedicated people. Do you want to know more?

How to find out more about medical writing and if it's the career for you

Although we market careers in medical communications more effectively these days, many people will still first hear about the career by word of mouth from ex-colleagues or university alumni who have gone on to become medical writers. It's a good idea to meet and talk with as many people as you can in the industry. This will help you build a picture of what a medical writing role is really like day-to-day. You might start by attending university careers events about "What to do with your further science degree" and alternative careers in biomedical science, but the internet is also a rich source of further information.

The European Medical Writers Association (EMWA; www.EMWA.org) is a network of professionals that represents, supports, and trains medical communicators in Europe. (This journal, *Medical Writing*, is the official journal of EMWA). The EMWA website, which houses a plethora of resources, is an excellent place to get a feel for what a career in medical writing encompasses. The organisation hosts bi-annual conferences for networking, discussion, and professional training, and via the website, you can access archived webinars, a job board, a reading list, and a comprehensive *Resources for Medical Writers* section. The EMWA also publishes *A Career Guide to Medical Writing*,[1] which includes a useful overview of the different types of medical writing.

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The American Medical Writers Association (AMWA; www.AMWA.org) is the equivalent organisation in the US, with a mission to promote excellence in medical communications and to provide educational resources in support of that goal. The services and resources offered are broadly similar to EMWA and the organisation curates a Medical Writer Certified (MWC©) credential in collaboration with the Medical Writing Certification Commission. On the AMWA website you will find a New Medical Writer Toolkit of resources specifically aimed at people looking to start a career in medical communications.

MedComms Networking, which is available at www.medcommsnetworking.com, serves a global community of medical communications specialists, and now hosts a sister website, www.FirstMedCommsJob.com. This new site serves as a one-stop shop for an array of services for those wanting to know more about medical communications careers, with a particular focus on the UK marketplace. You will find advice there about researching the market and tips for preparing your CV and cover letter. There are profiles of people in the business, including some medical writers who are 18 months into their first role. Resources include career guides for client services and account management roles, as well as medical writing roles, in addition to a map of agency office locations and access to virtual meetings on a range of topics in the website's archive. Importantly, you will also be able to find out about future live meetings organised by MedComms Networking. These regular events, which are free to attend and predominantly held at various locations across the UK, take the format of presentations on different aspects of medical writing careers, followed by the opportunity to ask questions of the large numbers of medical communications agencies in attendance. They are therefore an excellent opportunity to network directly within the industry and to learn more from the inside. Specialist recruitment and "Careers for scientists" websites may also be a useful source of information.

As you become more confident that a medical writing career could be for you, you might consider approaching companies for work experience. However, bear in mind that offering work experience is a significant investment for busy agencies; always be professional, appreciative, and mindful of confidentiality, and make the most of the opportunity to work amongst

Figure 1. Attributes of the ideal medical writer

medical writers and their wider account teams. July and August are peak work and holiday periods, so try to be flexible with your availability; requests for work experience in Quarter 1 may be easier to accommodate.

A PhD or not?

More than 75% of scientific team members at my company have a PhD, and medical writing certainly requires the scientific interpretation, critiquing, and contextualising skills honed during further degree study, but good medical writers also need skills beyond these, and I have many very successful medical communications colleagues who do not have a PhD. It is often less the *knowledge* that you gain from a PhD and more the *skills* developed, such as project management, problem solving, organisation, and the ability to communicate complex concepts, that are of interest to a potential medical communications employer. So, if you think you have the right combination of attributes, don't let the lack of a PhD put you off finding out more, and be ready to convince an interviewer that you have gained the relevant skills via a different route (for example, through undergraduate projects, hobbies, and outside interests, or contributions to magazines, blogs, or websites). And don't forget, there are career pathways in medical communications outside of medical writing itself

(for example, account manager or medical editor).

What makes a good medical writer?

Excellence in all types of written scientific communication is the hallmark of a good medical writer. Content must be accurate, clear, succinct, readable, appropriate for the objectives and audience, flow intuitively, and form an engaging narrative. The ability to interpret, evaluate, and contextualise data is critical, as is complete competence in grammar and spelling. These are the core writing skills, but in addition, and to be successful and fully rounded, writers need a number of additional attributes (Figure 1). They need to be very good at time management, able to work accurately at speed, juggle multiple projects at once, manage their own workload, and constantly reprioritise as circumstances change. Medical writers must have outstanding attention to detail, demonstrate commercial awareness, and have a team player mentality. They should be highly competent in all forms of communication and presentation (via email, on the telephone, and face to face), and they must have an enthusiasm to learn, work hard, and always strive for the best. Medical writing is a passion and career, not a 9-to-5 job.

Where to look for roles and how to make a successful application

What to look for

If you are seeking an entry-level position, this will usually be advertised as an *Associate Medical Writer* role. Companies seeking *Medical Writers* will invariably be looking for previous experience. Roles are advertised on company websites, on virtual job boards of organisations such as the International Society for Medical Publication Professionals (ISMPP; www.ISMPP.org), the EMWA, and MedComms Networking, as well as via recruiters and on LinkedIn.

Managing your online profile

Before initiating a formal application or approaching companies directly, ensure that you manage your digital footprint, and your online LinkedIn profile in particular. Think of yourself as a marketable commodity; consider how someone might feel viewing your profile for the first time and remember that first impressions count both digitally as well as face to face. Choose a professional and personable profile photograph, which doesn't show you in an environment that would allow a potential employer to pass judgement. Include appropriate and well-expressed content in the *Summary*, *Experience*, and *Education* sections of your profile. As a graduate, your *Summary* should briefly describe your background and future goals. Include relevant work experience or positions of responsibility in the *Experience* section. In the *Education* section, detail your degree, further degree(s), and information about large projects completed and your subjects of expertise. You can add personality to your profile by talking about your interests, hobbies, and any volunteering you do. This can help "bring your profile to life" for potential employers, who will be interested in finding employees who are a good fit with their organisation's values, in addition to people with the right skills set. Then you can get "LinkedIn active". Become confident using LinkedIn as a networking tool, follow industry leaders and, if appropriate, offer opinions and comments. Share content with peer groups on LinkedIn and start to make connections with people who may be able to help you break into the industry. Many recruitment agencies can provide further advice and resources on managing your online profile.

Your CV and cover letter

A few of the largest medical communications agencies have regular (annual or biannual) intakes of associate medical writers, but you could also start your job search by submitting a speculative CV and cover letter to companies that interest you. In a career with written communication excellence at its heart, your CV and cover letter are your first assessment and opportunity to show that you have the skills of a potential medical writer, and they should be tailored to the specific role and company you are applying to. They must be engaging, succinct, and intuitively presented. Detail your relevant experience (for example, academic papers you have authored, contributions to scientific blogs, examples of communicating science to different audiences) and explain why you have concluded that you have the desire and skills to train as a medical writer. Your CV and cover letter need to be grammatically correct and free of errors, so check them, get someone else to check them, and then check them again. With hundreds of applications crossing the desks of hiring managers each year, yours won't make the cut if it's not perfect.

The assessment process – what to expect and how to succeed

Figure 2 details a typical application and assessment pathway for an associate medical writer position.

Research the company

In order to tailor your application, you will need to thoroughly research the company to which you are applying. A company's website is a good place to start building a picture of the kinds of work that the company does, and what a job there might entail. With this information, you can make a compelling case for why you think you would like to work there. Google searches will help you find industry news, pharma websites, press releases, and awards news. It's a good idea

Figure 2. Associate medical writer: typical application pathway

to be familiar with hot topics in the broader healthcare environment. Recruitment sections are better on some company websites than others, but most websites will give names of people who work there, allowing you to research individuals further.

Assessment

For associate medical writer roles, if your initial application is of interest, the next phase is assessment, usually consisting of off-site test(s), on-site test(s), and interview(s). Successful applicants describe it as a rigorous process, but one that is realistic of the challenges you will face in the role, working accurately and to deadlines. Larger agencies employing groups of associate medical writers in regular intakes sometimes group the assessment activities in single-day events at assessment centres, where potential candidates are assessed both individually and in teams. Group exercises assess team-working and communication skills, and there are often opportunities to network with current medical writer employees as a part of the structured agenda.

Written tests

Written tests are set to uncover whether you have the basic writing and interpretation skills to succeed in a medical writing role, and marks will be assigned for accuracy, readability, inclusion of all the requested information, and appropriateness for the objectives and audience. You will also have the opportunity to demonstrate your knowledge of publication structure and what belongs where, as tests will often involve tasks such as writing a manuscript introduction based on an abstract, writing an abstract for a manuscript, or developing a set of PowerPoint slides. Always read the specific instructions provided carefully, but you will usually need to do some background research in addition to accurately representing the information provided to you. Completion of short error reading tests (spotting grammatical, spelling, and consistency errors in a paragraph of text) is frequently requested during on-site assessments, as accuracy and attention to detail are such critical skills for successful medical writing. If you already have medical writing experience, the written tests may also offer opportunities for you to demonstrate your knowledge of project and publication development processes.

Interviews

Once you have shown you can write, interviews are your opportunity to demonstrate your potential in all the other areas needed to be a successful medical writer, so be prepared to show your enthusiasm and communicate your skills, illustrating with examples as appropriate. Ask who will be interviewing you before the day, so you can research them ahead of time. "Why do you think you would make a successful medical writer?" is a typical opening question that you should be ready to answer. You may not have medical writing experience, but knowing the attributes sought will help you to draw relevant parallels with things you have done. Having researched the company to which you are applying, try to have a couple of questions ready to demonstrate your specific interest in working there. Pre-read Good Publication Practice 3,[2] the International Committee of Medical Journal Editors criteria for authorship,[3] and the Association of the British Pharmaceutical Industry guidelines[4] (or country equivalent). In addition, make sure you have a good overview and understanding of the pharmaceutical drug- and device-development process. The interview is also *your* chance to ask questions about the specific role for which you are applying and the company's culture, to see if this opportunity is that right fit for you. In particular, you may want to ask how training is coordinated, the types of work and therapy areas you may work on, the development opportunities and typical career pathways available, the office environment, and the style of senior management. Ask if you can speak with someone currently working in a medical writing role (if not present at your interview) to understand the 'day-to-day life' at that company.

Employment success

The ability to write clearly and accurately, a passion for science and communicating it, and an obvious enthusiasm to learn are absolute requirements for securing employment as a medical writer. The more of these ideal medical writer attributes you can demonstrate, the greater your chances of success. A good fit with the company's values and approach will also be at the top of a hiring manager's list of requirements. Medical writers have to follow a multitude of processes, procedures, and guidelines as part of their day-to-day work, but how to succeed at that can be taught, whereas most of the attributes sought are inherent. To succeed, more than anything else, you need to use every opportunity through the various parts of the assessment process to highlight your potential.

And finally – a view from the inside

In writing this article, I have spoken to many medical writers who joined the industry over the past 18 months. Here is a selection of their first impressions of the career.

- *"It's a fascinating job, which enables you to see so many perspectives on communicating the latest data."*
- *"I've been amazed at the diversity of work that medical writers can support and facilitate – I've learned so much in my first year – there's never a dull day as a medical writer."*
- *"I wish someone had told me earlier how interesting and varied it could be, as I would have got into this career sooner."*

My medical writing career satisfies my scientific mind in a commercial setting where what we do has a direct impact on improving patients' lives. I work with fascinating people, the pace of change is intellectually stimulating, and the challenges constantly evolve, such that no two days are ever the same.

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Acknowledgements

I would like to thank colleagues from CMC for their support with the development of this article: Hannah FitzGibbon, Phillip Hall, and Ray Magee for critical review of the manuscript; Ottilie Gildea for editing; and Hayley Smith for figure design. Thank you also to CMC's newest medical writing recruits for their contemporary insights into researching medical writing careers and the job application and assessment process.

Conflicts of interest

Mary Gaskarth is an employee of CMC AFFINITY, a division of McCann Health Medical Communications.

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Mary Gaskarth is Head of Scientific Services and a hiring manager at CMC AFFINITY. She began her career with Complete Medical Communications as a trainee medical writer in September 2001, following her PhD in cellular neuropathology at Imperial College London, London, UK. Mary is also an active member of ISMPP.

Donna Miceli's story

I was in my late '40s when I first began my career as a freelance medical writer. Back in 1962 when I graduated from college, with a dual degree in journalism and speech, becoming a medical writer was the farthest thing from my mind. In fact, I didn't know such a career existed – and perhaps it didn't at that time. Like so many in my generation, I got married soon after graduating and, before I knew it, I was the mother of four. Also, like many in my generation, I made the decision that, if I were going to have children, I was going to raise them myself. I managed to keep my writing skills sharp by volunteering to do publicity for community groups and, eventually, earning some money with a variety of freelance writing jobs, including writing copy for small advertising agencies.

When the company my husband worked for transferred us to Philadelphia, Pennsylvania (US), I had to leave my job as Assistant Director of Public Relations at a large hospital in Buffalo, New York. It had been my first full-time job in years, and I had loved it. My children were grown and I was at a loss for something to do until a former colleague told me about the American Medical Writers Association (AMWA). I immediately made plans to attend one of their annual conferences, became a member, and launched a new career. It turned out to be one of the best decisions I ever made. Thanks, in large part, to my association with AMWA, I enjoyed a successful career as a freelance medical writer, editor, and public relations consultant that lasted 27 years.

Now to the question at hand: What steps did I take to plan for retirement? The truth is none. I loved what I was doing, and I guess I thought I would just keep writing until no one wanted my services anymore – or my brain stopped functioning. I had the good fortune to be married to a man with a good job, with benefits, so I didn't have to worry about health insurance, mortgage payments, and all the other expenses of owning a home and educating children. His job also provided him with an excellent 401(k)-based retirement programme, including supplemental health insurance for both of us. I had also invested some of my earnings in an Individual Retirement Account.

In 2000, at age 62, my husband accepted a generous early retirement package and we moved to Florida. I had no intention of retiring. Fortunately, my husband supported my wish to keep working. Just 7 years later, he received a diagnosis of advanced non-Hodgkin's lymphoma. He died 9 months later, and my life changed forever.

I continued to work on existing projects, as much as I could, while my husband was going through treatment. My regular clients were wonderfully supportive during that period and after my husband's death. I eventually began accepting work again, but became a bit more selective about the projects I was willing to tackle, avoiding those with unusually tight deadlines. After 5 years of widowhood, I decided it was time to downsize, so I sold my four-bedroom home and moved to an apartment at a continuing care retirement community. Shortly after I made that decision, I decided it was probably time to retire. Surprisingly, the decision was easier than I anticipated.

So what am I doing now? I'm still writing! The community I live in publishes a beautiful quarterly magazine and I am one of the staff writers – as a volunteer, of course. I am also on the Board of Directors and several committees. In addition, I have been actively involved in starting a staff scholarship programme for our young employees. I continue to be active in AMWA and still attend the organisation's annual conferences. There *is* life after retirement.

Donna L. Miceli
Freelance medical writer for 27 years and past AMWA Executive Committee member

Life after Medical Writing

So what am I doing now? I'm still writing! The community I live in publishes a beautiful quarterly magazine and I am one of the staff writers – as a volunteer, of course.

Educating the medical writer: A 5-year update

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Abstract
This article is a 5-year follow-up to a 2013 publication: *On Educating the Medical Writer.* The current study was performed to examine the evolution of degree programme titles, certificate programmes, and the current trend toward so-called micro-credentials and nano-degrees. The return on educational investment is discussed.

Background
In 2013, Danny Benau (DB) published an overview of the educational and training opportunities for medical writers. The observations were based on 5-years' experience as Director of Biomedical Writing (BW) Programmes at the University of the Sciences (USciences).[1] Now, after the passage of another 5 years, the field of medical writing has changed and with it some changes in the education and training of its practitioners. Some reassessment may be in order. The results of the current project were produced by DB and Amy Urbine, a Master of Science (MS) candidate in BW who is conducting research on the job market for medical writers. In the prior paper, a distinction was made between education and training. Education was defined as being provided by an organisation accredited by a government-recognised agency with the goal of knowledge to be retained over the long term. Training may be provided by educational organisations, professional organisations, or commercial enterprises with the goal of *just-in-time* information for immediate use.[1]

The current education/training scene
A non-comprehensive list of degree-granting and certificate-granting organisations is displayed in Tables 1-5. The list is not comprehensive due to variations in search engine optimisation strategies used by the organisations. It should also be noted that the searcher's location can affect search results. When the search term *medical writing degree* was used with the search engine Google⟩, the only programmes in the first 50 hits awarding a graduate degree in medical writing that was not a certificate or track in a science writing degree programme

were at the USciences, the James Lind Institute, and the Medical University of Innsbruck.

The USciences MS degree is a traditional non-thesis MS. The programme at the James Lind Institute awards a Professional Diploma in Medical Writing (PDMW); the PDMW is similar to other diploma programmes of the Postgraduate Diploma (PGD) type. These postgraduate programmes are more common outside of the US; many are the equivalent of MS degrees while some are more like certificates. The medical writing programme at the Medical University of Innsbruck does not show when that programme will start again.

Of the search terms used for degree-granting programmes, the one with the most relevant hits among the first 50 was *healthcare communication degree*. The website mastersincommunication.com, owned by acgtMedia, LLC, lists over 65 US degree programmes in healthcare communication.[2]

Non-academic organisations closely tied to the medical writing field are listed in Table 6 along with certificate training and, where available, certification programmes that they offer. While few certificate programmes have significant entry prerequisites beyond holding a bachelor's degree, certification programmes may require experience in the field as well. While certificates show that the holder has participated in training, certification assesses the holder's grasp of training and competence gained through experience.

> The advantage of accredited degree programmes is that they are periodically assessed to maintain their accreditation. This becomes a measure of quality control and assurance in the knowledge passed to the students.

Trends

As mentioned in the 2013 paper,[1] the most common route into medical writing before the 1990s was through on-the-job training. The emergence of degree programmes in the field offered formalised experience with in-depth knowledge. The expense of academic degree programmes fostered the proliferation of certifi-cate programmes from academic institutions, professional organisations, and commercial enterprises. Even these have increased in cost over the years, and the current trend is toward even narrower-focused instruction that has been termed micro-credentialing or nanodegrees.[3] One such micro-credential is the digital badge. In a 2017 paper, Dyjur and Lindstrom reviewed the field of digital badges in higher education.[4] Basically, the badge is similar to a workshop certificate, but should be accompanied by assessment and may be part of a cumulative programme. In such a programme, the accrued badges may lead to a higher credential. The PGD programmes mentioned previously may work in such a fashion.

Table 1: Medical writing degree programmes

Organisation	Programme(s)	Comments
University of the Sciences	Master of Science in Biomedical Writing Certificate in Marketing Writing Certificate in Regulatory Writing	Online MS: 36 credits Certificate: 12 credits
Medical University of Innsbruck	M. Sc. Medical Writing	2 years, 94 credits, does not seem to be recruiting at this time
Johns Hopkins University	MA in Science Writing (MW is a track), Certificate in Science Writing	9 online courses, including a residency and thesis
University of Chicago Graham School	Medical Writing and Editing Certificate	Online 5 core courses 1 elective
Massachusetts Institute of Technology	Graduate Programme in Science Writing	1-year programme, 17 courses plus summer internship
James Lind Institute	Professional Diploma in Medical Writing	Online 14-module, 18 credits
University of Findlay	Medical Writing Certificate	3-credit course certificate in one of following: Fundamentals in Medical Writing, Clinical Trial Disclosure, Medical Writing of New Drug Applications Clinical Modules
Lenoir-Rhyne University	MS in writing with Graduate certificate in Narrative Healthcare	

Table 2: Medical writing education/training

Organisation	Programme(s)	Comments
UConn	Certificate in Health Professions Education	9 credits online
AMWA	Medical Writing Certification	
EMWA	Medical Writing workshops	
Bioscience writers	Workshops	

Table 3: Medical writing certificates

Organisation	Programme(s)	Comments
AMWA	Medical Writing Certificate	
Johns Hopkins	Health Communication Certificate	
USciences	Marketing or Regulatory Certificate	
CfPIE (Center for Professional Innovation and Education)	Certified Medical Writing Professional	
University of Findlay	Medical Writing Certificate	3-credit course certificate in one of following: Fundamentals in Medical Writing, Clinical Trial Disclosure, Medical Writing of New Drug Applications Clinical Modules

Return on education/training investment

Information gained from informal discussions with recruiters and hiring managers at lunches and breaks over many years of professional meetings suggests that the higher the level of programme validation, the more seriously the resulting credential is taken. The advantage of accredited degree programmes is that they are periodically assessed to maintain their accreditation. This becomes a measure of quality control and assurance in the knowledge passed to the students. A look at many recruiting sites will show that a degree will often be accepted as a substitute for a certain amount of experience. An example would be a job description requiring 5 years' experience with a bachelor's degree but only 3 years with a master's. Certification is direct evidence of knowledge acquisition and competence. Certificates and micro-credentials may vary in quality and acceptance.

One of the ironies of the proliferation of the *healthcare communicator* title has been the lack of correlation between the credential and job listings. The results of some preliminary online job searches have revealed that the *communicator* search term frequently becomes a qualification as part of a job description rather than a job title. A search on the term *medical writer* always results in that term being in the job title itself. The *communicator* term and the job title will likely converge over time, but for now the *medical writer* term seems to produce better results.

Acknowledgements

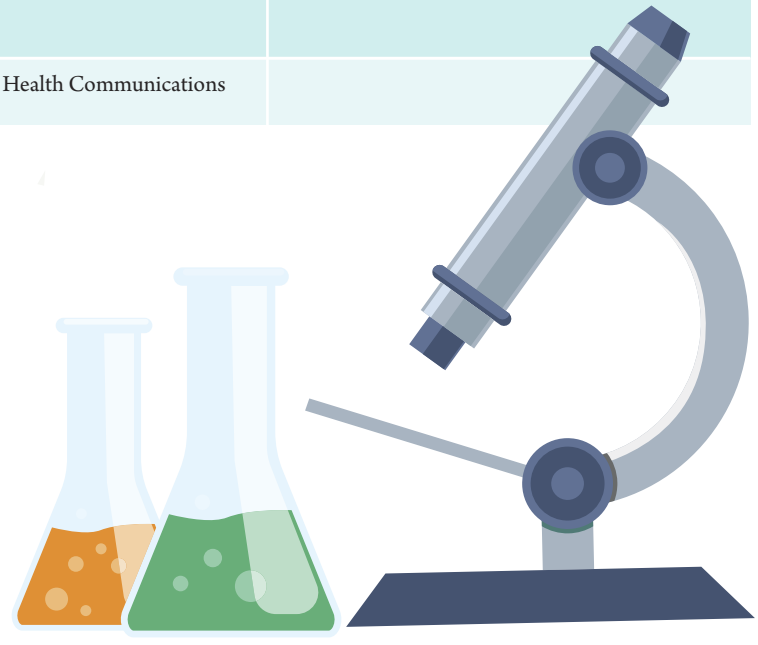
The authors would like to thank Brian Bass for his assistance in reviewing drafts of this article.

Table 4: Healthcare communication degrees

Organisation	Programme(s)	Comments
Boston University	Master of Science in Health Communication	40 credits
Northwestern University	Master of Science in Health Communication	
Bellevue University	Bachelor of Arts in Health Communication, Master of Science in Health Communication	127 credits
Tufts School of Medicine	Master of Science in Public Health in Health Education and Health Communication	
Johns Hopkins University	Certificate in Health Communication	
Columbia University	Master of Science in Health Communication	Open to students enrolled in select programmes
Illinois College of Liberal Arts & Sciences	Health Communications Concentration	
Harvard TH Chan School	Health Communication Online Master of Science	
University of Illinois Online	Public Health Communication and Marketing Master of Arts in Health and Risk Communication	
George Washington University	Master of Arts Health Communication	
Michigan State University	Master of Arts in Health Communication	
Gannon University	Master of Health Communication	
University of Minnesota	Master in Health Communication	
Chatham University	Health Communications Major	
University of Sydney		
Cornerstone University		

Table 5 : Healthcare communication certificate

Organisation	Programme(s)	Comments
Loyola University of Maryland	Healthcare Communications Certificate	
Tufts School of Medicine	Certificate in Digital Health Communication	
University of Wisconsin	Health Communication Professional Development Certificate	
Johns Hopkins	Health Communication Certificate	Must be enrolled in graduate or degree programme
Columbia University	Certificate in Health Communication	
Usciences	Certificate in Marketing, Certificate in Regulatory	
Boston University	Online Visual and Digital Health Communication Graduate Certificate	
Illinois College of Liberal Arts & Sciences	Health Communication Online Certificate	
University of Illinois	Health Communication Online Master of Science	
University of Kentucky	Health Communication Undergraduate Certificate	Must be accompanied by degree or seeking degree
George Washington University	Public Health Communication and Marketing Certificate	
University of South Carolina	Certificate of Graduate Study in Health Communication	
University of Utah	Interdisciplinary Certificate in Health Communication	
University of North Carolina	Interdisciplinary Certificate in Health Communication	
USC Annenberg	Post-Master's Certificate in Health Communication Management	
Stony Brook University	The Advanced Certificate in Health Communications	



Disclaimers

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

Conflicts of interest

Danny Benau is Director of Biomedical Writing Programmes at the University of the Sciences; this programme is mentioned in the article.

Amy Urbine is a student in the MS in Biomedical Writing Programme at the University of the Sciences; this programme is mentioned in the article.

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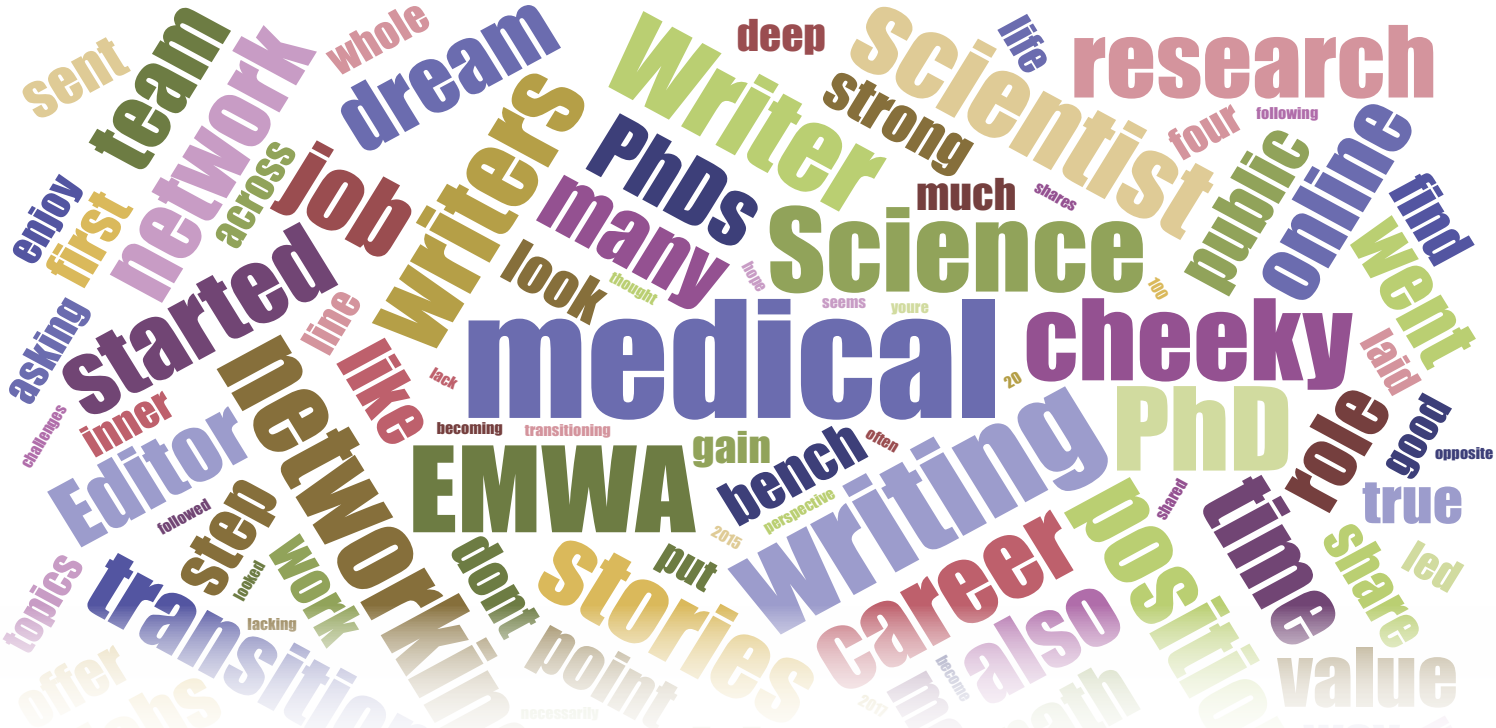
Amy Urbine is a student in the University of the Sciences MS in Biomedical Writing Programme and is working on her final capstone project of which this publication is a part.

Table 6. Certificates and certifications from relevant non-academic organisations[a]

Organisation	Certificate	Requirement	Certification	Prerequisites
AMWA	AMWA Essential Skills	8 credits via self-study work books, in person workshops	Medical Writing Certification, 125 question exam	Bachelor degree; at least 2 years medical writing experience
EMWA	EMWA Professional Development Programme	8 credits via workshops		
DIA	Certificates: Clinical Research, Clinical safety and Pharmacovigilance, project management, Regulatory Affairs	35 core units and 6 elective units, 16 core units and 16 elective units, 48 core units and 8 elective units, 28 core units and 16 elective units		
RAPS	Regulatory Affairs Certification: medical Devices, Pharmaceuticals or Dual, RAC Credential Exam	4 core classes, 9 electives	Regulatory Affairs Certificate, 100 Question Exam	Recommended for those in the regulatory field
ICMJE	None			
BELS			Board Certified Editor Exam	Bachelor degree; at least 2 years life sciences manuscript editor experience

AMWA: American Medical Writers Association; EMWA: European Medical Writers Association; DIA: Drug Information Association; RAPS: Regulatory Affairs Professionals Society; ICMJE: International Committee of Medical Journal Editors, BELS: Board of Editors in the Life Sciences.

[a] List is representative but may be not comprehensive



Cheeky medical writers: Transitioning from academia to medical writing

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Abstract

Many PhDs and postdocs in academia realise that they do not have such a strong passion for the bench, so some dream of becoming medical writers, but they often lack the information, training, connections, experience, and (most importantly) confidence to pursue their dream. In this article, we share our stories about transitioning from academia to medical writing. We hope that our stories inspire and encourage other academic scientists to become medical writers.

Many PhDs and postdocs come to the realisation that they no longer have a strong passion for the bench and may find medical writing an interesting career option. When viewed from the perspective of someone already working as a medical writer, the path from academia to medical writing may seem obvious, but it might not seem so natural when viewed from the perspective of someone still in academia because they lack the information, training, connections, and, most importantly, confidence to make the switch.

In this article, we share our stories about how we made the transition from academia to medical writing. Although we followed completely different paths, we shared some common challenges and supported each other along the way. We hope that our stories will inspire and encourage other PhDs to pursue a career in medical writing.

Evguenia Alechine, PhD, ELS

After I finished my PhD in biochemistry and applied for more than 30 postdoctoral positions without success, I went through a career crisis. I ultimately identified an interest in medical writing, thanks to deep inner work with a career coach. At that point, I also met EMWA member Jackie Johnson. My discussions with her laid the groundwork for a turning point in my career. Jackie helped me see my value as a PhD in the medical writing industry and inspired me to join professional associations such as EMWA and the Cheeky Scientist Association, a worldwide organisation that helps PhDs transition from academia to industry.

To get my career as a medical writer underway, I attended three EMWA conferences,

networked online and offline with both scientists and established medical writers, and joined the *Journal of Science, Humanities and Arts* as an Associate Editor. I also landed several freelance editing jobs (for international companies and clients), volunteered for EMWA's Public Relations team, became a Section Editor and, eventually, Co-editor of *Medical Writing*, and lead science communication workshops in academic institutions and healthcare organisations. It was a huge investment of time and resources, but it has paid off.

After the EMWA conference in Birmingham in 2017, I was contacted by one of my freelance clients (initially referred to by a colleague from the Cheeky Scientist Association), who offered me a full-time position as a science editor. My career growth within the company happened quickly, and I became the Chief Science Editor within a few months. I managed the content development project and a team of more than 30 writers and six to eight in-house editors. My daily job involved the whole editorial process of scientific content development, and I managed every step from researching the topics, assigning them to writers, reviewing the final articles, and managing the publication process and social media impact. It was a job that allowed me to be flexible in terms of working hours and location and was also in line with my belief in the importance of helping people through science and health knowledge. My success in this role was both the cause and consequence of a shift in mindset, from trying too hard to make a good impression and improving skills I was not "so good at" (and didn't enjoy) to leveraging my natural leadership skills.

Mine was quite an unconventional transition, but in the words of Joseph Campbell "If you can see your path laid out in front of you step by step, you know it's not your path."

After a few months on the job and feeling more comfortable in my role, I embarked on a worldwide voyage as a digital nomad, taking advantage of the job's flexibility to start a life adventure. Mine was quite an unconventional transition, but in the words of Joseph Campbell "If you can see your path laid out in front of you step by step, you know it's not your path."

My current role involves sharing the knowledge I learned along the way with other PhDs through career coaching, mentoring, and consulting, also by being the editor of the "My First Medical Writing" section and leading webinars for EMWA. I also continue to collaborate with the Cheeky Scientist Association and EMWA to encourage and help PhDs to transition from academia to medical writing. As a personal interest, I am using my scientific knowledge and critical thinking, medical writing capacities, and communication skills to help professionals in health optimisation and climate change create awareness and consciousness around these topics within the general population.

I truly enjoy being location-independent, wearing many hats, and working on multiple projects, from one-on-one career coaching to helping organise health optimisation conferences. My ultimate takeaway message would be "Don't look for your dream job, create it!"

Somsuvro (Som) Basu, PhD

It was late 2015, the first year of my postdoc. A terrible day in the lab, a critical experiment failed, and I received rejections to applications for three postdoctoral fellowships. This resulted in me asking Google "What are the alternative careers for postdocs?" Most of the answers directed me to research and development, which was not what I was hoping to find because I was starting to feel "allergic to pipettes." The fourth answer in the Google search was "Top 20 industry positions for PhDs", a career guide put together by the Cheeky Scientist Association. I then joined the association and found paths that I was unaware of before. Pens replaced pipettes, at least in the grey cells, and I realised that my true calling was science communications, editing, and medical writing.

Early 2017, I polished my LinkedIn profile and started networking. The networking tips I learned from the Cheeky Scientist Association helped me attract attention, gain confidence, and nurture relationships. My professional ties started to flourish. At that point, Evguenia and Jackie introduced me to EMWA. I promptly became a member and went to a couple of conferences, which moulded the core of my inner medical writer. At the first EMWA conference, I met my mentor Sarah Tilly of Azur Health Science. This alliance allowed me to achieve a comprehensive knowledge of medical writing and gave me a precious chance to experience first-hand a medical writing project. Furthermore, I was asked to write a full-length feature article for *Medical Writing*, an opportunity which helped me to gain a spot in the sphere of medical writing. My involvement in EMWA's Social Media team, a pivotal step on this journey, connected me to a broader population of medical writers.

I applied for eight positions: seven medical writing/science communication roles and one project manager role, all through networking. For six of the medical writing applications, I received rejections, but just at that time, I received a message from an ex-lab mate about an open position as a science communication officer. The ex-colleague was aware of my recent activities in the field through Facebook and LinkedIn, so I applied to the position, with the help of a strong referral from my PhD mentor. I went through a

few rounds of online interviews and, eventually, was invited for a site visit. I had individual meetings with two directors, three future office colleagues, and the public relations manager. The discussions revolved around science communications in general and involved specific questions to understand me as a person and a prospective team member. I impressed them with a set of plans describing envisioned sections of the research magazine and a plan for the initial months of the job. Six days after the interview, I received the email saying, "We are hiring you."

I consider it a dream position for a science communicator, with ample opportunities to learn and share exciting stories not only with other scientists but also the general public.

In my current role, I manage an in-house research magazine with the aim of showcasing the exciting research stories of the consortium and presenting current science trends and policies to a broad audience. The job requires close collaboration with scientists, the management team, the public relations team, graphic designers, and photographers. I consider it a dream position for a science communicator, with ample opportunities to learn and share exciting stories not only with other scientists but also the general public. Like Murial Rukeyser, I believe that "The universe is made of stories, not of atoms."

Clare Chang, PhD, sMBA

I was born in Taiwan and grew up in South Africa, so after receiving my bacherlor's degree, I went back to Taiwan for my MSc, after which I relocated to Denmark for my PhD. In my spare time, I wrote poems and journalled; to satisfy my interest in writing and to make some spending money, I started freelancing during my bachelor's studies, and the work grew steadily. As life would have it, halfway through my PhD, I realised that I did not want to be at the bench anymore, so I started to look for positions beyond the "research scientist" title and eventually came across medical writing.

After my PhD, in a desperate attempt to not remain at the bench – or at least in academia – I sent out more than 100 applications to all relevant industry positions, including research scientist, clinical research associate, medical writer, and regulatory affairs associate. Only three applications resulted in interviews, none of which resulted in jobs. I realised that sometimes if it's not right, then it's not right, and you should just let it go. The "ah-ha" moment was learning to chase as many leads as possible: Don't put all your eggs in one basket!

At that point, I joined the Cheeky Scientist Association, and after optimising my LinkedIn profile, résumé, and elevator pitch, I started getting more interviews and phone calls. Because I speak Chinese as a second language and I am a "third culture kid", and I wanted my daughter to be fully bilingual growing up, I decided to look for positions in Asia. At the same time, I focused my search on my passion: to work as a regulatory medical writer in a contract research organisation (CRO).

I spent 2 months powering through various online courses (including getting a Scientist

MBA), networking, setting up informational interviews, attending networking events, and sending online applications. During this time, I approached and started networking with other medical writers, including Evguenia and Jackie, who provided both references and resources. Networking also led me to EMWA – one informational interview led me to a mentor who encouraged me to both join EMWA and contribute as a writer. I started investigating Chinese CROs and came across dMed in Shanghai, whose company vision I liked. I sent them two applications – one for a medical writer and another for an associate medical writer position – but did not receive any responses.

Around this time, I also contacted a recruiter in Singapore for a position in the Asia-Pacific region. Although the position was already filled, about a month later, the same recruiter posted another opening for a company in Shanghai, and immediately asked for my résumé. In the initial phone screen, it was revealed – quite surprisingly – that the position was for dMed. The recruiters sent my profile to the company and started to schedule interviews. I had four interviews in 2 weeks – with the line manager, the Head of the Biostatistics Department, the Director of Human Resources, and the Head of Clinical Science. The interviewers went into detail about their passion, values, and the vision they had for the growing company. The whole process felt very natural, like a normal networking conversation. A couple weeks later, the recruiters came back with an offer.

> I realised that sometimes if it's not right, then it's not right, and you should just let it go.

During all this time, I was still networking. I attended an EMWA conference and met many writers there, including Jackie and Som. The EMWA conference opened up many opportunities: my mentor recommended me to join the editorial board of *Medical Writing* as an Associate Editor, and, while at the conference, I met four hiring managers who were interested in my profile, which led to further interviews. This coincided with two other interviews outside of EMWA, not to mention the offer from dMed. In the end, I decided to pursue the opportunity with dMed in Shanghai and turned down the other interviews. The story even had an unexpected twist: although I applied for a medical writer position, the offer I received ended up being for Associate Manager of Medical Writing.

Conclusion

Now you know our stories and you can easily see how the three of us supported and helped each other. Moreover, a long list of people and resources helped us successfully land our dream jobs and create the lifestyles we wanted.

Here we would like to share our "secrets" – the key takeaways that helped us identify our true calling and find our paths.

1. Network, network, network! Network with peers and potential colleagues, academics and business people, network online and offline, and network with authenticity.
2. Ask genuine questions about the jobs, roles, and companies you are interested in.
3. Revive old "dormant" connections – they can be valuable assets to your job search. Connect with as many people as you can and tell them about your goals. You never know who will give you your next referral.
4. Rome wasn't built in a day – the same applies to networking. It's never too soon to start!
5. Try to recognise the soft skills you learned, mostly unconsciously, during your PhD training, and leverage all your transferable skills.
6. Start your connections by adding value (e.g., acknowledging the achievements of other people, expressing interest in their experience, highlighting common interests, etc.) before asking for favours, and add as much value as you can. It always comes back when you least expect it!
7. Seek out a mentor: learn from someone who wants you to grow.
8. Know your value as a PhD!

To this day, we continue to help peers who are interested in medical writing by sharing our knowledge and connections and by inspiring others to the best of our abilities. We are only the "tip of the iceberg" of a vast network of professionals eager to make this world a better place – let's do it together!

Acknowledgements

The authors would like to thank all EMWA and Cheeky Scientist Association members who supported them in their career paths and especially Jackie Johnson for being their inspiration.

Disclaimers

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

Conflicts of interest

The authors are not employees of EMWA or the Cheeky Scientist Association and declare no conflicts of interest.

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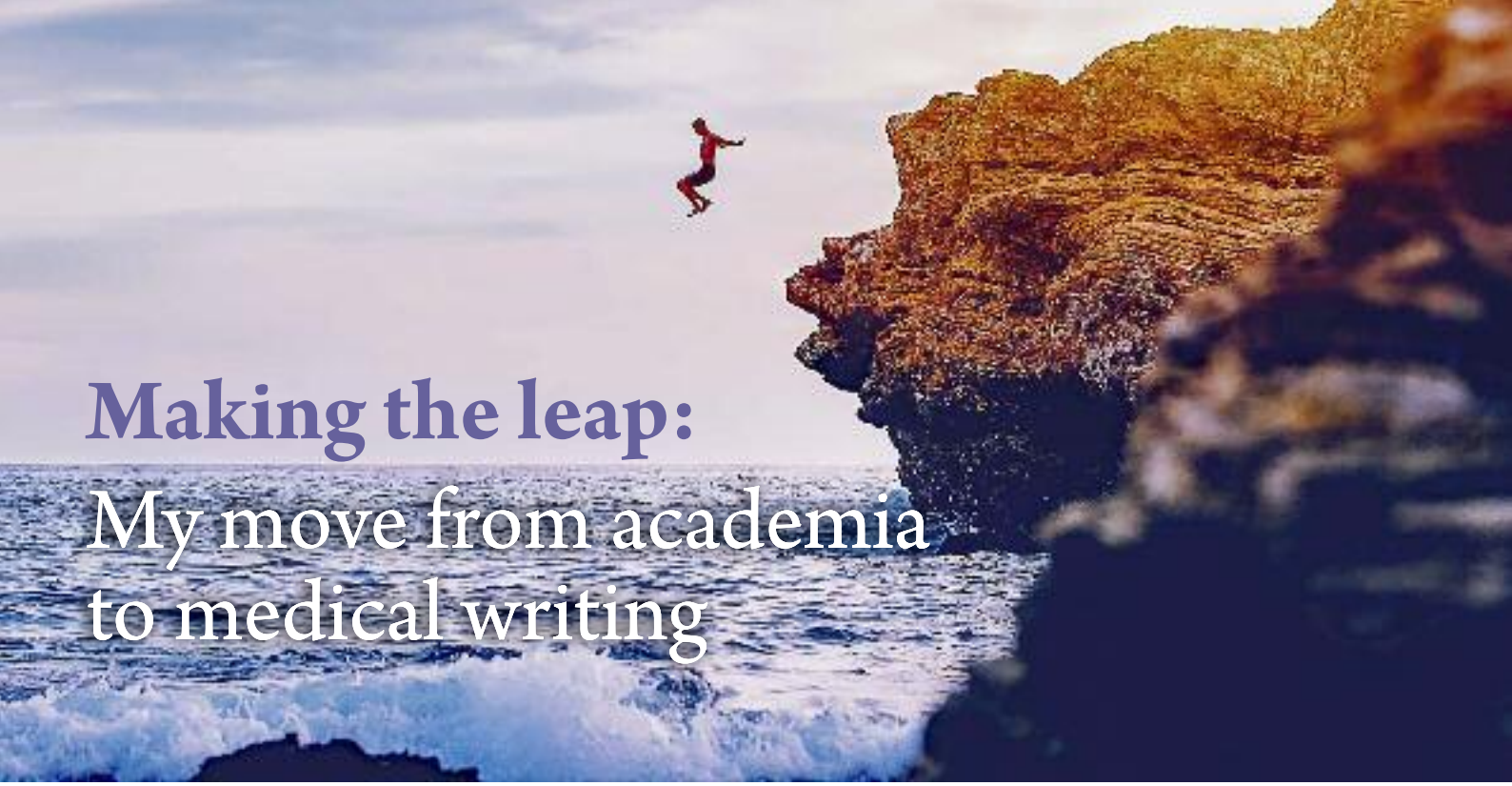

Making the leap:

My move from academia to medical writing

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Abstract

A complete re-evaluation of your career path can be a daunting task. By identifying your own key skills, a proactive approach can be taken. Talking to varied companies and people in the field and trying out different writing styles can help to find the best fit for those skills. This article presents a personal view of taking this approach to change profession from academic researcher to medical writer.

This article is adapted and updated from a post published on the Naturejobs blog in November 2017. The original blog post is available at https://go.nature.com/2CiGR5p.

Academic research just wasn't doing it for me anymore. The realisation came as a shock to me. Since my undergraduate days, I'd always assumed I would have a career in academia, with the goal of my own research group and a healthy flow of students to teach and mentor.

However, the rose-tinted glasses started to crack a little during my first post-doctoral position. I'd always known about the difficulties in making the breakthrough of getting your own funding, but the obstacles seemed to be getting higher. My PhD gave me solid but unexciting data, which was therefore difficult to publish. I found this position (surely not that unusual) was holding me back. The university offered plenty of additional activities I could perform to broaden my horizons and my CV, providing I did them in my free time. Yet the demands on that time would only get greater as I moved from one short-term contract to the next, with the prospect of hitting a pay ceiling for the foreseeable future.

Identifying strengths

On top of the uncertainty that short-term contracts provide, I also felt I had strong skills that weren't used or appreciated by my colleagues. I have always taken a meticulous approach to my work, sometimes bordering on an obsession with accuracy and precision. Away from the bench, I had sharp eyes for mistakes, inconsistencies, and dodgy conclusions, whether they were in our own documents or the wider literature. I enjoyed interacting with students, and I started to notice that they would choose to come to me for explanations of scientific or technical concepts. However, opportunities to get involved in academic teaching were frustratingly hard to find as a postdoc and would not be formally credited by the university.

> By identifying my key skills and taking a proactive approach in talking to different people and companies outside of academia, I found a career that suited me.

All of these concerns sat uneasily with me, but then I secured a position in a great lab at a different university for my second postdoc. This seemed the perfect outcome – I could continue to build my career in academia in a fresh environment with new opportunities.

A few months in, however, I was still uncomfortable. Things were done slightly differently at my new university, but I found all the same concerns niggling at the back of my mind. Now I found myself in the position of questioning whether the career I'd planned truly played to my personal strengths.

Finding a new direction in medical writing

Career advice for early career researchers at universities tends to focus almost exclusively on the academic route. However, I thought science writing could be the perfect fit for the skills I knew weren't being exploited in academia.

I started browsing job adverts and discovered not only that there were many companies looking for exactly the skills I had, but also that there were

many more different types of science writing jobs out there than I had realised. I entered diverse science writing competitions to see what style suited me best and found I enjoyed writing for audiences across the spectrum from lay to technical. When my entry to the Naturejobs blog #scidata16 competition[1] was selected as one of the winners, it gave me a confidence boost and re-affirmed that I was on the right track. The prize for this annual competition is the chance to work with an editor of a Springer Nature journal to report on the one-day Better Science through Better Data conference,[2] providing an invaluable insight into the world of science writing and publishing.

Making the leap

I had identified my strengths and the industry I wanted to move into, but how could I find a company that fitted my interests and personality? There are many places to turn for advice on getting into medical writing, including websites such as FirstMedCommsJob,[3] EMWA's Career Guide,[4] contacting companies directly, and careers events. The early career researchers group at the university institute where I worked held an event focusing on careers outside academia, and I made sure I took the time to talk to every writing company that exhibited. Among a number of medical writing firms was one that caught my eye: Insight Medical Writing. They specialised in regulatory writing, which was a new field to me. My interest was piqued, and I signed up for an open day at their office near Oxford, UK. After hearing about their work in more detail, I found it resonated with my personal interests and principles. When preparing regulatory documents all of the evidence must be systematically reported and discussed, unlike in medical communications where the focus is more on key aspects of the data. This perhaps reflects differences in the respective audiences. In order to decide whether to approve a new treatment, regulators must consider every piece of data produced during its development. Clinicians, on the other hand, will not have the time for this depth of analysis and will be most interested in how they can best improve the health of their patients.

I made it clear to Insight Medical Writing that I was interested, and, at the end of the normal recruitment process, I completed my career change. I was a medical writer!

Refining existing skills and gaining new ones

Now, after 18 months in the job, how do I feel the experience compares with my previous world in academia? It was immediately obvious that I was in an environment with like-minded people where the skills I had would be put to use. The biggest adjustment for me was the need to work with clients to deliver the document they require. In regulatory writing, we work on a diverse range of documents including new drug submissions, clinical study reports, pharmacovigilance documents, and literature reviews. I've learned a great deal from working collaboratively with colleagues in order to achieve a clear overview of complex data in these different contexts.

My scientific horizons have also been broadened by working on different drugs, diseases, or devices, depending on the client. This is a refreshing change from the often narrow vision of research projects. Indeed, from reading medical literature of varying quality and from different fields, I've appreciated the importance of presenting data and arguments with clarity, regardless of who the intended audience is.[5]

My first EMWA conference in Barcelona in May 2018 was a completely different experience from the academic conferences I was used to, with a greater focus on expanding skill sets and sharing expertise.

I was pleased to see that the skills I had originally identified are clearly valued across all types of medical writing.

Lessons learned

So what have I learned from my experience? I had a definite career plan, but as the academic environment changed, my plan no longer seemed so certain. By identifying my key skills and taking a proactive approach in talking to different people and companies outside of academia, I found a career that suited me. Taking opportunities to try out different writing styles increased my confidence and reinforced that I was choosing the right path. My previous ambitions were based on old information, and I had re-assessed them based on new data. After all, that's what any good scientist would do.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by Insight Medical Writing, Springer Nature, or EMWA.

Conflicts of interest

The author declares no conflicts of interest.

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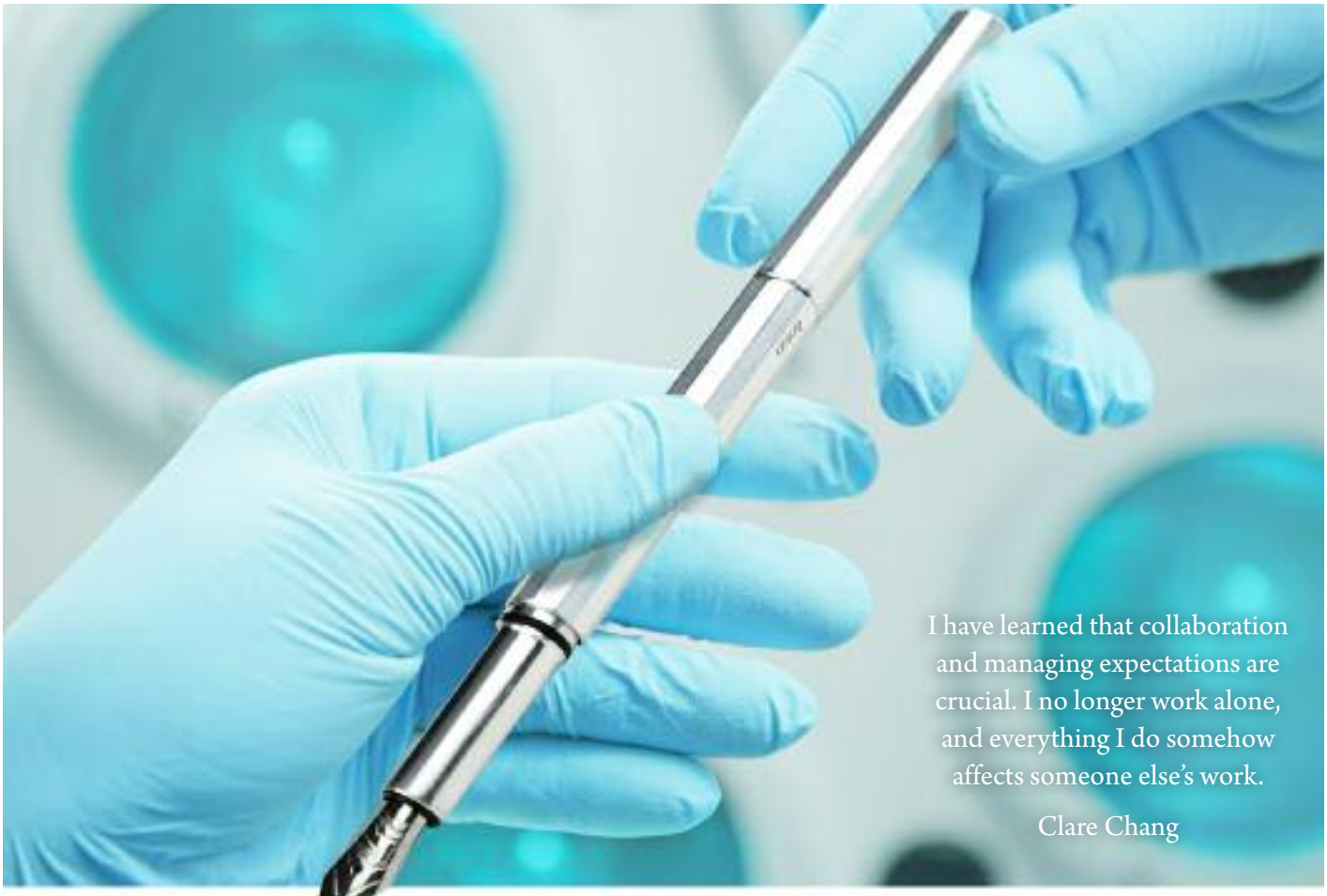

From bench to pen: Life as a new medical writer

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Abstract
In search of a career that would take advantage of their graduate-level skills, Clare Chang and Zuo Yen Lee found medical writing – a career path few PhD students consider. Within 6 months of graduating, with lots of effort and some luck, they found their first jobs. In this article, Clare talks about her first impressions 2 months into her new career, while Zuo Yen shares her insights from almost 2 years in regulatory medical writing. The two discuss the important similarities and differences with their academic work and how they have adapted to the challenges of their new careers.

Clare's journey has begun!
Clare's dream was to become a research scientist – to make remarkable and ground-breaking discoveries in the lab that would revolutionise medicine. However, as we grow, so do our dreams…so after almost 10 years of pipetting and cell culturing, she realised that it was time for a change from preclinical to clinical research. While exploring her options, she stumbled upon the words "medical writer", which led her on a journey into discovering medical regulatory writing as a career.[1,2]

My first impressions
My experience in becoming a medical writer was rather tumultuous. Not only was I starting a new job, I was starting a new way of life. After almost 10 years in academia, I changed tracks and started as a new medical writer in a contract research organisation (CRO). Less than 3 months


Clare Chang

ago, I was still soloing in the lab and enjoying the beautiful Danish midnight summer sun with the occasional stroll through the forest. Now, as a medical writer, the work is fast-paced, collaborative, and constantly changing, all in the large, fast-moving metropolis of Shanghai, a city that never sleeps.

My on-boarding was tumultuous because I had to tie up all the loose ends of my Danish adventure while completing all the administrative work that comes with changing countries, not to mention starting a new career path in a new country, culture, work environment, and language. Although everything was planned out, there was much that I could not foresee.

Fortunately, my company's Human Resources department helped me obtain my visa, find temporary housing, and receive the boxes containing my life from Denmark. Although I was stressed, they put me at ease by being extremely communicative and supportive. They set me up quickly with the essentials: a working computer, internet, and access to relevant information and resources. In the week leading up to my first day, I received my company email address and all IT-related materials.

Next came the actual job. My on-boarding meeting with my line manager was very comprehensive. She gave me an overview on the medical writing training materials and the company's standard operating procedures (SOPs), and she introduced me to two client-specific tasks. I had imagined that I would spend several weeks reading SOPs and watching how things worked instead of being thrown directly into the frontlines. The first few meetings with clients were quite nerve-wracking because everything was in another language, and I was unsure of the correct business etiquette. Overall, it was a fast-paced, well-planned, and a highly communicative on-boarding process. The company understood my situation and gave me sufficient and manageable work in those first weeks. My manager didn't want me to get bored reading SOPs, so she expected me to jump right in and learn on the job, which was a good approach for me.

Managing projects, time, sponsors, and expectations

During my first month, I was both pleasantly surprised and overwhelmed by the many differences between academia and medical writing in a CRO. I had used many of the skills previously, but applying them to clinical research is a little different. To begin with, as an academic scientist, I was the "subject matter expert" and led projects from start to finish, whereas regulatory writing requires me to find experts from the relevant departments to complete the written documents. Also, while manuscripts in academia are usually written by one person and completed in 6 months to 1 year, regulatory writing projects are collaborative and are completed in just a few months. For example, my first project was a protocol for a phase IV study, where I had to work with the necessary departments to address comments and incorporate changes. Overall, from the time I on-boarded, it took only 2.5 months for the protocol to be reviewed and submitted, even though I was juggling other projects at the same time. I learned that deadlines are much tighter and that reviewing and addressing comments often happen on the fly. Scheduled meetings also are more efficient – there is an agenda with pre-determined discussion points, and meetings end promptly – which is very different from the open-ended discussions and brainstorming sessions that occur in academia.

I have learned that collaboration and managing expectations are crucial. I no longer work alone, and everything I do somehow affects someone else's work. For example, if I write a patient informed consent form for a study, I need to communicate with people in clinical operations to make sure that what I am writing actually happens at the study site. When resolving an issue or addressing a comment, in some cases, we need to inform the sponsor so that we are on the same page and know what to expect and when. Furthermore, sometimes unexpected things happen and timelines and tasks can change, so I have had to learn to keep the people who need to know what is happening informed while not overloading them with emails and information.

Dealing with language differences

Even though I can speak and understand Mandarin Chinese, I have never been properly educated in the language because I did not attend a Chinese school – I learned Chinese from talking with my parents, family, and friends, watching Chinese TV, and reading the occasional book or article in Chinese. Now I am thrown into medical and regulatory jargon and concepts in both English and Chinese… as if the English learning curve were not steep enough! So, naturally, I was a bit nervous about working in Chinese. Despite not being completely confident with my Chinese, my line manager has not shied away from sending me projects that require Chinese proficiency, so I have had to learn quickly. Just recently, I had to align an English protocol of over 100 pages with its Chinese counterpart – all within a week. The first day, it took me 8 hours to align 5 pages, but by the end of the week I was getting though 20 to 30 pages a day. My colleagues also know that Chinese is not my strength and have been a great help, and, of course, I have helped them whenever they have needed assistance in English.

Building rapport with colleagues

During an interview, I was asked, "Do you think you can build rapport quickly and be persuasive? How do you do it?" The first thing that came to mind was people that exude confidence are the centre of any party. More recently, I have learned that building rapport requires building credibility, which in turn requires being confident enough to speak your mind, ask questions, and help people whenever possible. In addition, in China, sharing your non-work life, often through social media, is important for building rapport with colleagues. This has been an adjustment for me because I am used to keeping my personal and work lives separate, but on the positive side, sharing our personal lives helps us overcome the hierarchical structure that often comes from working in a company.

Further down the medical writing road: Zuo Yen's journey

After 6 years in academic research in Switzerland, biologist Zuo Yen decided to switch to medical writing and was reassured of her choice after attending EMWA's first Internship Forum in Munich.[3] The EMWA conference and the Internship Forum have provided Zuo Yen access to the medical writing industry and many experienced medical writers. Six months after the EMWA conference, she finally started her journey as a medical writer upon a referral to a company in Taiwan.[4] After almost 2 years, she has gained good understanding of a medical writer's life and the new challenges it presents to academic scientists.

Zuo Yen Lee

My experience adapting to the challenges of medical writing

Clare's experience of starting her new job remind me of my early days as a new medical writer. Like her, I needed to apply and adapt skills from my academic training, especially time and project management. Even after 2 years, I find myself constantly re-adapting these skills for every new project; each project has different timelines, expectations, and unforeseen glitches. I have learned that a good medical writer should be able to react promptly to whatever situation arises.

Perhaps one of the biggest of these challenges is meeting somewhat unrealistic timelines proposed by the sponsor. I need to first gauge my capacity and capability and then determine whether the sponsor's expectations are too ambitious and try to understand the reason behind the urgency. Finally, I have to work together with the team to come up with the best solution and determine whether additional communication and negotiation with the client or delegate are needed or whether the task can be delegated to a colleague. At times, it can be a challenge to find a balance between meeting the sponsor's expectations and delivering sufficient quality.

> In academia, I was trained to master a single subject in depth. Now, I need to prepare for a wide breadth of subjects.
>
> Zuo Yen Lee

I have also found that, as a medical writer, I need to remain flexible and open-minded and to constantly expand my knowledge across different therapeutic areas. In academia, I was trained to master a single subject in depth. Now, I need to prepare for a wide breadth of subjects. For example, I might be working on a new drug for lung cancer in the morning, another drug for hepatitis in the afternoon, and conducting a meeting towards the end of the day with a sponsor who has a new flu vaccine. Upon receiving a new project, I may need to read up on a topic that I do not know or catch up with new developments in a therapeutic area that I worked on a year ago. I often have to do this quickly and as I go, which can be a challenge.

A good medical writer is responsible for helping sponsors comply with the latest regulatory requirements. So, another challenge is that I have to remain up to date on the ever-changing regulatory landscape. For example, in light of the recent global trend in making clinical data available publicly, new policies have been introduced to strengthen the protection of personal data. In Europe, the EMA has implemented the Policy 0070[5] and the General Data Protection Regulation,[6] which strongly affect how we write our clinical reports for European sponsors. Just recently, I realised that the guideline on influenza vaccines released in 2016[7] replaced five other guidelines that I had been following religiously! I also need to be knowledgeable of regulatory requirements in Asia. For example, although clinical regulatory documents in China have largely followed the ICH guidelines since 2017, the National Medicinal Products Administration has retained some of their unique local requirements for submission, such as certain components in the appendices of a clinical study report.[8]

The bright side

Because each project is different and because I have to remain up to date with new knowledge and regulations, there's never a dull moment. Unexpected situations happen often, and I need to react quickly, but I always get the support I need from my colleagues. To produce a sound report, I have to collaborate with biostatisticians, medical experts, other more experienced writers, and the sponsor. I also often need the assistance of clinical research associates and, of course, the project manager, who helps liaise with the sponsor and negotiates reasonable timelines on my behalf. Not only do I work with internal departments, including data management, clinical operations, and business development, I also work with external collaborators, such as physicians, scientists, innovators, and sometimes even regulators. Working across these many functions and disciplines – and working in the "real" world–makes life as a medical writer in a CRO exciting, and even though I sit alone in front of a computer typing away on a document on my own, I do not feel lonely.

Conclusion

Few PhD students consider a career of medical writing. The term may sound too unfamiliar or even dry to people in the academic world. Some even consider it "leaving science". But switching to medical writing does not mean leaving science – it is a way to explore a new dimension of science. We medical writers are doing what we love …. and loving what we do! Admittedly, making the transition to industry can be intimidating to academic scientists. Finding where your interests and competencies lie will make the transition easier.

Disclaimers

The opinions expressed in this article are the authors' own.

Conflicts of interest

The authors declare no conflicts of interest.

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Clare Chang is a scientist at heart. Her thirst for knowledge has taken her on a journey from Africa to Asia and finally Europe where she graduated in 2018 with a PhD degree in Nanoscience from Aarhus University in Denmark. She started her position as Associate Manager in Medical Writing at dMed Biopharmaceuticals in August 2018.

Zuo Yen Lee graduated in 2016 with a PhD degree in biology from ETH Zurich. She has more than 8 years of combined experience in scientific research and the diagnostics industry. Since January 2017, she has been a Medical and Regulatory Writer at Clinipace Taiwan.

Getting Your Foot in the Door

How Jennifer Clemens did it

My career as an editor began in the mid 1990s for an environmental company. This opportunity was my first true "Getting My Foot in The Door" moment because I was persistent. I knew I wanted to apply my dual degree in English and Business Communications as an editor or a writer, but I had taken a job straight out of college purely to pay the bills and that was not in my field. After I had an interview for the editor position, I surreptitiously left my desk at lunchtime every Friday and used a payphone outside my office to call the person responsible for hiring. This was back in the days before cell phones, so I needed to resort to clandestine methods. I know that tactic of calling is not used as often today, and in fact, we often read "no calls, please" on job ads. However, my contact there had told me to "feel free to stay in touch", so I did! After a few weeks, I was hired, learned the Chicago Manual of Style, and created my first in-house style guide. I felt I had finally found my professional calling.

In the year 2000, I transitioned to scientific and medical editing for a medical communications (medcomm) agency where I learned American Medical Association style inside and out as their sole editor for numerous clients' manuscripts, posters, continuing medical education materials, and slide sets. It was then that I heard about BELS (Board of Editor in the Life Sciences) and earned my certification by studying for several months and then taking their international exam. My career since then has taken me in other exciting directions, such as Team Lead Editor for an online publisher and then to pharmaceutical companies, another medcomm agency where I specialised in digital content, and CROs where I learned about regulatory submissions. Now I'm happily placed at Merck and parlaying my experience as a subject matter expert into patient narratives and training new hires. None of this would have been possible had I not persisted with that awkward payphone call every Friday early in my career.

I surreptitiously left my desk at lunchtime every Friday and used a payphone outside my office to call the person responsible for hiring.

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The grass is always greener on the other side:
Freelance vs employed, experiences from a seasoned medical writer

Clare Gurton

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Abstract
This article is a short personal piece that attempts to explore the circumstances and triggers behind moving from employment to the freelance world and back again. It highlights some pitfalls and high points along the way and illustrates the pros and cons of each status.

I like proverbs, little common-sense truths … and this one sums up the freelancer versus employed dilemma better than most: Whether to remain freelancing, or conversely, remain employed, is a dilemma that will affect many of us during our medical writing career. It is a dilemma because each has its own pros and cons, and the pros tug at you from the other side almost all the time. Believe me, I have been doing this for over 30 years, and it doesn't change.

When you are working as a freelancer, you worry a great deal about the next project; you long for the assurance of a predictable income and regular time off. When you are employed, either in the agency or industry arena, it is hard not to feel tied and to long for the freedom of being your own boss. Of course, there are lots of other pros and cons and it seems that for almost every negative, there is a positive, and this almost equal balance makes the dilemma even worse (Figure 1).

Moving in either direction is not difficult in these days of internet, talent spotters, and the seeming insatiable appetite for good writers. LinkedIn is a great resource and a little time spent 'hunting' through contacts and networks is time well spent, even though it might feel like spying.

This is my potted story and within it I hope to illustrate some of the pitfalls and some of the golden moments; neither is better, they are just different. I cannot offer advice; *we* are all different. We have different needs, pressures, and pulls. Moving from employment to freelance and back again simply reflects the ebb

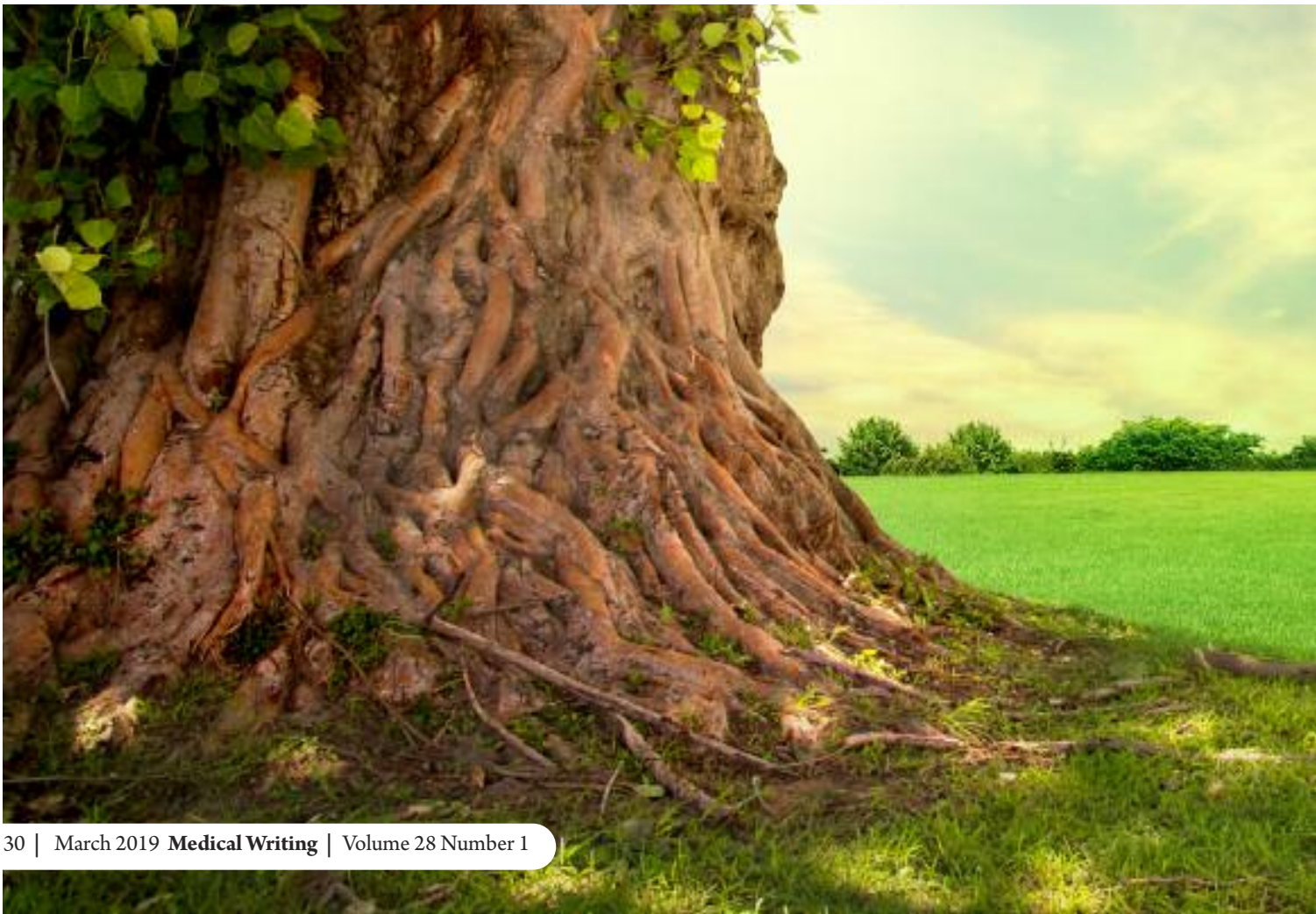
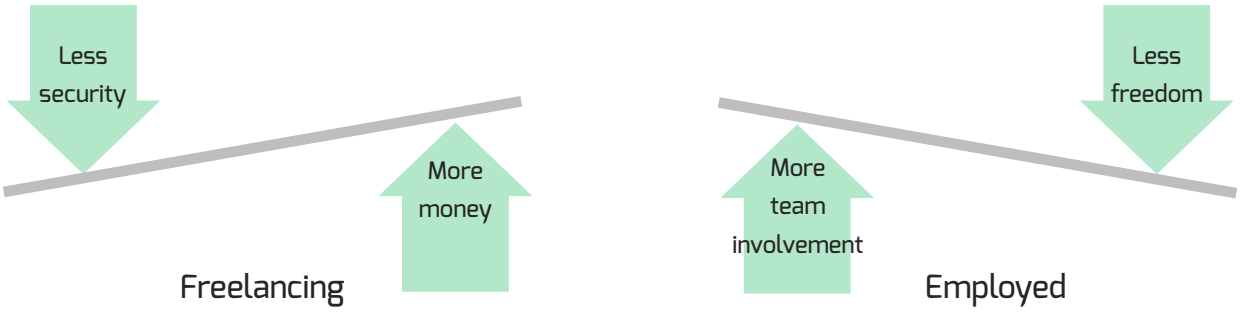


Figure 1: The freelance vs the employed seesaw



and flow of our lives at the time.

I first became a freelancer as a result of circumstance rather than design. I was working in a big pharma company which had just been taken over by an even bigger company, and re-location was on the agenda. This coupled with an attractive voluntary redundancy package made it a 'no-brainer' for me, particularly since I had promises of work from many colleagues. A year in, I was working from home, inundated with jobs, thoroughly enjoying my freedom, and earning what seemed to be a shed-load of money!

It is interesting to note that daily rates for freelancers have barely risen since then – 28 years ago! I think this has two drivers; there are many, many more of us around, and there is less money in the marketing and medical departments of big pharma today. So, we get comparatively poorer and, because of strong competition, there is an increasing pressure to excel.

The learning and challenge of freelancing

I continued happily as a freelancer for some years, expanding my network, building my reputation, and trying my hand at more and more types of writing. I worked on training programmes, product monographs, resource kits, public relations pieces, advocacy materials, abstracts, manuscripts, presentations, posters, etc. And I worked in many different therapeutic areas from

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vaccines to HIV, skin to respiratory disease, and medical devices to immunology. It was fun and challenging, and I was learning. (I have never worked in regulatory writing by the way – it is far too dry for me).

I think that it was this learning aspect of the work I most enjoyed – always a new challenge, and with it, the chance to hone my skills. I have always argued that medical writers wear many hats; one of the most important is the ability to learn a new therapeutic area very quickly and to be able to explain complex information in straightforward, accessible ways.

Learning and challenge was the upside. The downside was the comparative isolation; my friends and family, by and large, had no real idea of what I did. I was geographically isolated from any other medical writers and my clients, and there was no internet for skype calls. This meant that it was difficult to bounce ideas off other people and difficult to feel truly a 'part' of anything. Additionally, I lived alone and I worked too hard. I found it difficult to turn work down and was very poor at taking holidays and days off. This can be a real issue for a freelancer – I remember my first accountant warning me sternly; "you are your only asset" he said, "look after it".

Needs must ...

Well, I did look after my asset and I got pregnant! Not an accident, but something that would change everything. My partner and I decided to move from gentrified, manicured Kent to the windswept, wet coast of North Devon; we wanted gritty countryside and sea. We wanted our son to grow up in a village community.

We were miles from anywhere. Freelancing was no longer a choice, it was an essential – no agencies or pharma for miles and no internet yet either. Luckily, I had a network of clients and they remained loyal. And happily, after a year or so, I also managed to negotiate a freelance contract with a med comms agency that gave me regular work two days a week. This was on one drug in one therapeutic area and was the start of a more flexible approach to working within the agency world. The internet was starting to blossom and although we were still using dial-up, it was possible to to-and-fro with documents much more easily. I was in a very fortunate position; I had enough work to pay my way, a delightful new life in the country, and a young family to play with. And this is when the freelancer's world is just right.

Am I being left behind?

Some years later, when I was starting to do more writing again, I became increasingly aware that things within pharma and the agency world had moved on, leaving me behind. Processes had changed, regulations had tightened, and digital technology was racing ahead. I had been stuck with my head down one therapeutic-area hole, doing largely the same thing for some years and had had no exposure to the larger world around me.

As a freelancer, it is not always easy to keep abreast of changes and to understand some of the nuances of organisational reshuffles within the industry; often the demands of the current workload take all your time and putting aside for training is not the highest priority. I think it was my lack of experience with new software that became my biggest worry at this time and despite trying to do some online courses, I was conscious that my skills were diminishing.

As a result, I started to look around for opportunities for "remote" employment. Nowadays, this is much more common and working full- or part-time from home is offered by many employers. In those days, it was a leap of faith for any employer. But I was lucky and a client of mine with whom I had built up trust and reputation, agreed to take me on. I worked four days a week, from home, as a senior writer and then editorial director. I undertook to visit the offices once a month and, actually, this was a pleasure rather than a chore. It got me out and really helped build my relationship with others in the company. Remote working is fine, but I think you really do need to meet colleagues face to face on a regular basis to build up a positive and supportive relationship.

During my employment with this company, I built up business with an important US client, travelled to congresses and client meetings, learnt lots of new skills and felt happy and part of a team. It was a really good move for me at the time; it built up my knowledge and confidence and made me feel valued again.

The cycle begins anew ...

But the old proverb started to raise its head, and I started to feel constrained again. The more I thought about things, the more the worm of dissatisfaction wriggled. Alongside, things changed within the company and eventually, after nearly three years, I resigned and returned to the world of freelance.

I picked up with old clients, found some new ones, and started to network more. Peter Llewellyn had started up his MedComms Networking initiative and this was a great help for those of use divided by geography. It has gone from strength to strength, and I highly recommend being part of it.

Now, another eight years on, I am employed again – yes, the same old circle . . . I wanted more involvement, more client facing work, less last minute 'can you just' work. And I found a wonderful agency that took me on. They have a seriously flexible approach to working and a great spirit. I have been with the group for nearly four years now and have no intention of leaving. I have been through a couple of bad times recently and being part of the team and having some very kind and thoughtful colleagues has been a huge help and a wonderful support.

This is the strength of being employed – perhaps on balance for me, employment is the winner.

For now, at least . . .

Author information

Clare Gurton has more than 30 years of experience as a medical writer/communicator. She has worked within the pharma Industry and for many different medical communication agencies and as a freelancer.

Alistair Reeves' story

It was at the Galileo Museum after the Florence EMWA conference that we crossed a threshold with no return. We approached the counter to buy tickets, and the friendly signora there said: "I am wondering whether you qualify for the senior citizen's reduction or not". Even if others in similar situations had thought this, it was the first time someone had actually voiced the thought that we were grey and wrinkly enough to look like – don't use that word – pensioners. As it happened, we had to pay the full price because the threshold was 65 years and we were still a few years off.

I used to think I would never retire. That had something to do with being a freelance editor and trainer. You could pace your work. If you wanted, you could do nothing for a week and then do a 60-hour week or do more or less training. And I really enjoyed that flexibility for about 15 years. But I noticed one day that my patience at training events was getting rather thin. How many more times would I be asked if there is a comma before *and*? And I was a little sarcastic answering a participant on one occasion – taboo for a trainer.

I stopped training at commercial events fairly soon after that, but continued editing. Things were not quite the same. I had translated, corrected, edited and rewritten poorly put together scientific documents in English with alacrity for 40 years (a colleague once said that I was known for liking "rescue jobs"), but now it was rapidly becoming a chore and I needed a rest from giving back-to-back workshops for EMWA. I didn't spend much time analysing why, because there were loads of things we had put on hold for retirement. Now was the time to start. So I retired early almost 2 years ago, although I still do a couple of days a month for regular customers turned friends.

Two years on, I can say that I made the mistake of trying to do too many new things at once. I started learning the clarinet, and Italian, and also intended to brush up my Hebrew, French and Spanish, in addition to all the reading and DVDs that had piled up over the years. Sitting and reading during the day was still associated with a certain amount of guilt, because I could have been doing something "useful". I also envisaged us travelling a lot, doing weekly hikes and swimming every other day, and going to all sorts of interesting exhibitions, as well as getting on with overdue jobs around the house and garden. On top of that, music is our passion, and we scrambled to attend as many concerts as possible. We could never attend events during the week when working, and now we had all the time in the world. Oh yes – and I was going to prepare well-planned meals every day, and not just at the weekend.

Things have settled down a bit now. Those jobs around the house are finished. I am still learning the clarinet and I listen to French and Spanish audiobooks. I am catching up on reading (no guilt now) and go jogging and swimming. I cook a lot more, but we do eat out about twice a week. I run short seminars for EMWA. We still frequently go to concerts but don't overdo it, nor have we done as much travel as we thought – we did so much business travel that a few small trips and a "big" holiday once per year seem right at present. And now and again, I do absolutely nothing – which I can highly recommend!

Alistair Reeves
Medical writer (1977–2016),
EMWA Conference Director (2012–2014),
and workshop leader (1997–2016)

Life after Medical Writing

Things have settled down a bit now. Those jobs around the house are finished. I am still learning the clarinet and I listen to French and Spanish audiobooks. I am catching up on reading (no guilt now) and go jogging and swimming. I cook a lot more, but we do eat out about twice a week.

Pharmaceutical writer or CRO writer – choosing the right path

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Abstract
The career choice is an unavoidable topic for those scientific graduates or experienced professionals in the areas of medicines or the pharmaceutical industry. The career of medical writing offers a series of career possibilities for the individuals with degrees in sciences or experienced professionals in the areas of medicine or the pharmaceutical industry. This article offers insights on starting and developing a medical writing career from the perspective of a writer in China who has worked in both clinical research organisations (CROs) and pharmaceutical companies. The variety of business needs, the requirements of key stakeholders, and project goals in the pharmaceutical companies and CROs lead to differences in the work styles and paces, prospects for career development, and pathways that allow talents to flourish in the field of medical writing. Similarly, the various writing roles lead to more opportunities of career choices and transitions.

Background information
The area of medical writing is still an unknown area for many professionals who have a wealth of experiences in the pharmaceutical industry or clinical practice, even though China experienced important developments over the past 20 years in the area of medical writing. When you ask your medical peers to describe the position of medical writer, it has been my experience that medical writers are described as a group of people who are only familiar with copying and pasting data and text from others' works, correcting spelling errors, or drafting tables or figures without being proficient at writing original scientific papers or regulatory documents. As a scientific writing professional, I fully understand that what we can do is sometimes completely beyond people's expectations and imagination.

However, as medical writers, there is little doubt that we have opportunities in a burgeoning industry. The needs of the global medical writing market have shown continuous growth, and the writing business in 2008 doubled since 2003, reaching $694 million in 2018.[1] In a report that was published by the Nature Index 2015 – Asia-Pacific – Japan, South Korea, and Australia lead the way in the number of original scientific papers, followed by China, which has significantly more than that of India.[2] Although we have no published statistical data on the business market size of medical writing in China, the importance and weight of the career have already been fully endorsed by those peers with collaborative experiences.[3]

My writing journey
For me, being a scientific writer has proved to be an important career choice after graduating from medical school. Even after more than 10 years, I can still recall the images of being in the classroom of the annual meetings of EMWA and learning how to present data in a figure when I was just a junior medical writer. I feel fortunate to be able to do what I love. Work experiences in the pharmaceutical industry and clinical research organisations (CROs) have allowed me to understand the values and potential of the career. These developments have brought me lifelong growth and positive collaborations with peers and key opinion leaders in clinical practice. Here I would like to share some of my experiences and my understanding of the roles and responsibilities of writing professionals who work for the pharmaceutical companies or CROs. I hope that the information can be "road signs", particularly for those who are interested in exploring the areas that may once have seemed to be "scientific writing deserts".

With regard to the business needs and technical skills, potential options can include both pharmaceutical writers or CRO writers.[4] Medical writers in pharmaceutical companies offer technical supports on preparing regulatory or regulatory-related submission dossier documents and scientific publications. The pharmaceutical companies – as the research and financial sponsors – are responsible for developing product pipelines and are the purchasers of technical services. Therefore, in pharmaceutical companies, medical writers are responsible for monitoring project progression and quality of writing projects. Most writers in pharmaceutical companies have master's or doctoral degrees in a medical or biological field, and some have developed expertise in clinical practice or medical research before pursuing a professional role. In preparing manuscripts and regulatory documents, writers collaborate with physicians, researchers, statisticians, or other medical professionals from start to finish.

The responsibilities of the medical writers in pharmaceutical companies include writing documents while serving as project coordinators, process controllers, and decision makers on writing topics. As per the business needs of the writing projects, the writers need to be equipped with regulatory or publication knowledge. In the past 10 years, given the confines of budgets and changes in general in the structure of research organisations and the pharmaceutical industry, more and more pharmaceutical companies prefer to delegate some parts of research and development (R&D) works to third-party service providers.[5] The third-party service providers (CRO companies) employ professional scientific teams to work with the pharmaceutical companies on accomplishing regulatory, operational, and statistical goals, or on writing projects. For writers in a CRO, the job mainly focuses on drafting documents, coordinating review cycles, and working with the sponsor contacts to finalise and archive the documents.

Here readers who are new to this industry may wonder what the key differences are between the careers of medical writing in the pharmaceutical companies and the positions of the CRO companies. I would answer this question by first describing the relationships between the two types of organisations. When a pharmaceutical sponsor decides to outsource writing projects, they would first generally screen, evaluate, and recruit potential service providers.

After all the resource allocations are settled with a formal business contract between the pharmaceutical sponsor and the service provider(s), a writing project kick-off meeting would be held before the project is initiated. In the meeting, all the project procedures, timeline, stakeholders, and splits of responsibilities would be determined. Afterwards, the offsite medical writers would be responsible for drafting documents, coordinating their reviews, consolidating comments, and updating/finalising the documents. On the other side, the responsible project manager(s) or medical writer(s) from the pharmaceutical sponsor would serve as the contact for coordinating the external clinical investigators' review comments and those comments from the internal teams of the pharmaceutical sponsor. Once the paperwork is finished, the sponsor will electronically archive all the drafts and the final version of documents with traceable version numbers and dates.

The key differences in the career of medical writing are reflected in business and research needs, technical requirements, and career development. From the perspective of the pharmaceutical sponsors, they prefer cost-effective service providers who can offer high-quality writing, while CROs prefer to maximise revenues when they negotiate project fees with pharmaceutical companies. Within pharmaceutical companies, medical writers are expected to understand compound strategies, regulatory affairs or publications, be skilled in time or project management, and budget planning, etc., while CRO writers may need to be more detail-oriented and possess a higher level of writing skills. The CRO writers should be capable of performing multiple writing tasks within a short time; they should be able to learn new topics quickly by themselves and work efficiently with sufficient document quality under pressures from picky clients. Additionally, CRO writers need to have good emotional intelligence, be adept at building positive customer relationships with the pharmaceutical sponsors, and be able to negotiate project timelines and prices. The career development track in the pharmaceutical companies offers the prospect for junior medical writers to become technical experts/leads or performance managers/directors. Those who are not interested in the writing aspect after their initial experiences could have other opportunities to accept other positions (e.g., project manager, or regulatory affairs specialist). In CROs, there are similar writing career pathways as those of the pharmaceutical companies. The main difference is that CRO writers have a better chance at branching out into business development or taking on a consulting role if their talents lead them there.

> The needs of the global medical writing market have shown continuous growth, and the writing business in 2008 doubled since 2003, reaching $694 million in 2018.

Regarding career recommendations, I can offer some personal reflections to those newcomers in the field of writing with what I have experienced in over a decade. I advanced from a junior writing role in the pharmaceutical companies after I completed a clinical medicine degree and a master's degree in molecular pharmacology. At the beginning of my career, I focused on a single therapeutic area and was responsible for drafting documents of simple clinical study reports and scientific publications.

After 5 years, I became a writer in multiple therapeutic areas and found opportunities where I could be involved in those complex projects. After 9 years of deep involvement and being familiar with rapid work paces in the diverse therapeutic areas, I received a job offer from a prominent CRO. During the initial 6 months of my CRO journey, I was frustrated with the differences between the pharmaceutical companies and the service providers, due to rather accelerated work paces (even for an experienced writer), completely various business perspectives, and diverse client tastes. Therefore, in my point of view, I do not necessarily recommend that new writers initiate a writing career from a CRO since you may not have the opportunity to develop writing skills and gain a deep knowledge of compounds and diseases. Instead, you would move from one project (client) to another very quickly without adequately "digesting" what you learned. If you do have to begin your writing career from a CRO, you should take stock of your career progress at regular intervals to make sure that you are not burned out before you become a well-rounded writing professional.

At the beginning of a career, I suggest junior writers focus on understanding the industry, developing basic skills of writing, and increasing their knowledge of (pre-clinical or clinical) research and diseases, at the same time, working on building up long-term collaborative relationships with your colleagues, clients, or clinical investigators. The experiences would give you more confidence on the career track of medical writing and these valued relationships could bring in more businesses and potential clients, benefitting you down the line. If writing for pharmaceutical companies is your first job, I suggest that you place equal weight on increasing your knowledge as on developing your writing skills. Given that the pharmaceutical writers have opportunities to experience all facets of the R&D process, being versatile is important for your career development.

For instance, in pharmaceutical companies, you have the chance to be a part of planning scientific publications, interacting with colleagues from marketing and regulatory affairs departments, consulting on product launches and indication applications, or post-market product reimbursements. You can also participate in compound developments via writing projects in collaboration with third-party service providers. Working independently in the field of medical activities depends on how much you can invest in your career development and what your career expectations on your writing roles are in the coming 5 to 10 years.

Identifying clear career goals should be a priority for aspiring writers. With approachable career milestones in mind, junior writers are recommended to ask your managers or bosses for a reliable writing coach wherever you work, set a series of growth plans with your coach, and have a system of follow-up actions on your career progress. If your rate of growth exceeds your bosses' expectations, you will have more opportunities to be involved in complex projects with higher priorities. At that time, please stay focused, do not overestimate your capabilities, and remember to develop your career strengths, rather than trying to be a jack-of-all-trades. In addition to developing your writing ability, please join one or more writing communities or organisations to stay in touch with industry developments and network with your peers. The regular communications offer you more career possibilities and a sense of being part of a collaborative family.

"Rome wasn't built in a day." Through a medical writing career, you are developing as an assistant in medical research, as a leader in scientific communications, and as a valuable contributor to pharmaceutical businesses. In China, most writers prefer to develop their careers in pharmaceutical companies, rather than CROs because of the size and growth of the pharmaceutical company employment market. In recent years, the CRO industry has been growing substantially faster than global forecasts, but growth in R&D spending in the pharmaceutical industry has been especially strong, and is estimated to reach $39.3 billion in 2022.[6] Along with an increase in the R&D budgets, the employment market of the CRO industry will expand and a number of R&D positions will be available for scientific graduates or experienced professionals. The need for medical writers will increase along with the trends, which will also

result in more career opportunities in CRO companies.

As the industry evolves, the employment possibilities will continue to expand. As scientific graduates, junior writers, or senior professionals, we should seek to improve our individual capabilities, broaden career visions, and be prepared for any changes in the profession. As a 14-year practitioner, with similar goals as other medical writers, I am confident that the profession will become even better known and well-regarded and it will definitely have a bright future in the century filled with historic changes.

Conflicts of interest

The author declares no conflicts of interest.

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Author information

Yan Zhou, MD, MSc, PMP, ISMPP, has been a scientific writing professional since 2005, a witness to the expansion of medical writing in China during this time.

Getting Your Foot in the Door

How Janet Douglas did it

Before I got into medical writing, I worked as a veterinary surgeon in universities and referral institutions, did research (and hence wrote scientific papers), and wrote on veterinary topics for animal owners. But after finishing my PhD I was at a career crossroads. I loved to write and wanted to stay involved with science, but I didn't feel cut out for a future in research. This coincided with a move to a country where I couldn't practice veterinary medicine and the arrival of a baby, which made working part-time and freelance an attractive option.

Luckily for me, a veterinary colleague who had moved into the pharmaceutical industry needed a writer to prepare a series of manuscripts describing the primary clinical trials of a new veterinary product. I worked on these papers for almost a year, and realised that this blend of science and writing suited me well. Unsure where to find more writing work, it became apparent that the veterinary writing market was small but that medical writing was in demand.

Feeling wholly underqualified (because I am a vet, not a medic), I approached a medical communications company (medcomm) who evidently saw something they liked in my rather unusual background. Unwilling to commit to a full-time job, I held out for work-from-home – i.e., freelance work. As a trial, I wrote a review manuscript for them that evidently passed muster, and I subsequently worked for this company for many years.

Working for the medcomm, I quickly realised that you don't need to be a medic to do this job well – you just need to be able to figure out what you don't know, then go and find it out! I have been figuring out what I don't know, finding it out and writing it down for over 20 years now, and it has stood me in good stead as an interesting and flexible career.

As a trial, I wrote a review manuscript for them that evidently passed muster, and I subsequently worked for this company for many years.

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Abe Shevack's story

Life after Medical Writing

To retire or not to retire: that is the question.

My career in medical writing started relatively late. After working in basic research for many years in both academia and industry, I decided to change my career. I was introduced to medical writing in an unusual place. One evening, while exercising in the company gym, I overheard a conversation between two fellow employees. One of them was talking about being a medical writer. We spoke at length and afterward, I decided to apply for a position in the company and took a writing test. I was hired as a regulatory medical writer in the clinical development department. This started a career that has spanned more than 20 years where I have worked in a wide range of clinical indications. It was thrilling to have worked in so many areas and collaborating with all those interesting people. I have many wonderful memories such as the beer mug that I received from a German pharmaceutical company in appreciation for my helping with a submission.

Time flew by and I reached retirement age at Bayer in 2016. My colleagues organised a farewell party and laudatory words were spoken with toasts to my good health. Although I greatly appreciated this recognition, I still thought about having no plans for the future. Would I be happy just lazing on a hammock and catching up on my reading, watching movies that I missed, going to concerts, swimming at the local gym, and making entries in my long-neglected history of science blog? Or did I need something more?

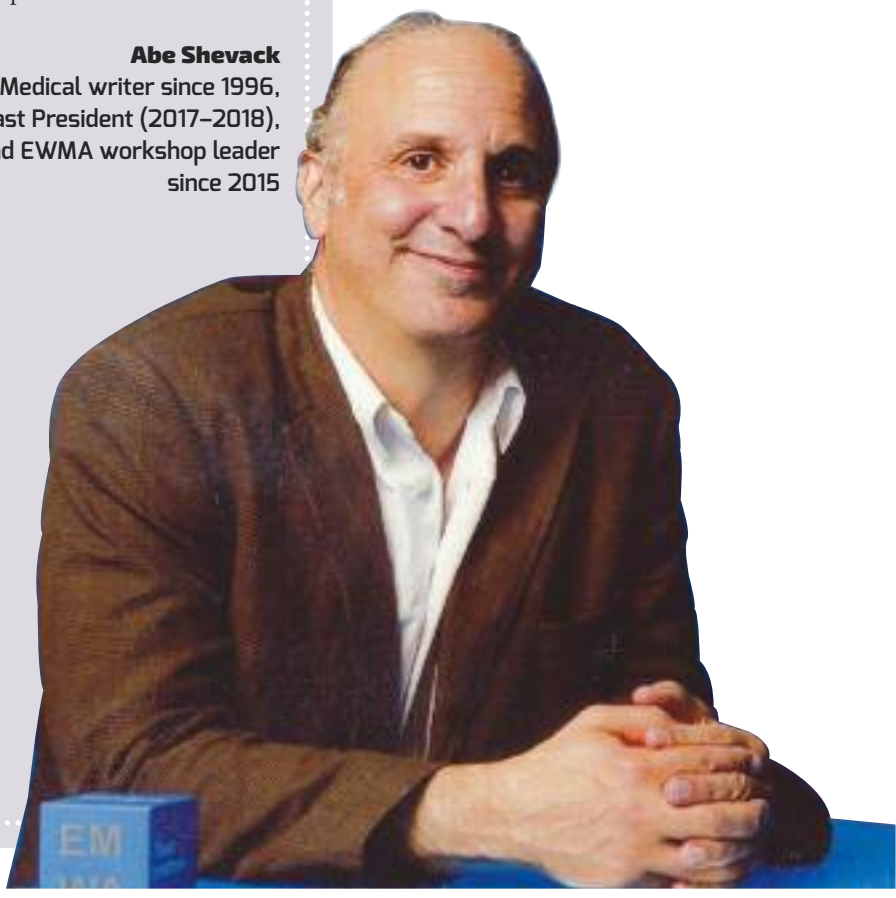
As it turns out, I have had no problem keeping busy due to my involvement with EMWA. I developed a workshop for the Brussels conference which I continue to enjoy presenting. And then to my surprise, I received a call later in 2016 from the EMWA executive committee (EC), asking if I would consider running for Vice-President (the prerequisite for becoming President in the following year). I felt very honoured by their trust and after due consideration I agreed. The two years of my tenure on the EC flew by and kept me amazingly busy. The experience was both enjoyable and challenging and I have grown to appreciate how well EMWA functions with the help of so many talented and committed people.

At around this time, I started my own medical writing consultancy and am in the fortunate position of being able to select short-term projects that I find interesting.

Whether or not to retire is a question we will all need to answer someday. Some may say that they would like to enjoy their leisure time and do all those things they weren't able to do during their professional lives. Others may feel the need to keep busy, perhaps taking on fewer responsibilities but remaining open to new challenges, while having free time to follow one's own interests. I believe everyone wants to feel useful, but ultimately it is up to each of us to make this important transition as we see fit.

Abe Shevack
Medical writer since 1996, EMWA Past President (2017–2018), and EWMA workshop leader since 2015

The experience was both enjoyable and challenging and I have grown to appreciate how well EMWA functions with the help of so many talented and committed people.



Career shift: Employment to freelancing

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Abstract
There are often social stereotypes and mental barriers associated with a decision to be a freelancer. For me, flexibility and autonomy are the main values for choosing the path of freelancing; however, high standards and work ethics must be maintained with discipline. One way of practising discipline in freelance work is to keep a double identity: as a boss and an employee.

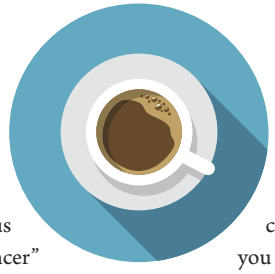
When the word *freelance* appeared in the 19th century, its usage was confined to describing mercenary soldiers.[1] Soldiers holding lances in the Middle Ages are now replaced by people carrying laptops in the contemporary era. We frequently hear the phrase "I am a freelancer" at social gatherings, which gives the impression that freelancers work less and enjoy their "free" time in exotic places. However, not many people are ready to jump at this immediately because oftentimes they would soon realise that they know nothing about life as a freelancer. During the decision-making process, the relaxed image of a freelancer is quickly obscured by fog. Here, I would like to discuss the mental barriers and inner battles when working towards becoming a freelancer.

Recently, I saw a friend who gave me a translated book about freelancing. The original book's title is *Free Agent Nation* by Daniel H. Pink.[2] I wondered why she chose that specific book, which was quite outdated since it was published in 2001. I then learnt that she left the consulting firm where she worked and started her own business as an independent policy consultant. Although the book was about the "new" era to be led by freelancers in the early 2000s, it can still serve as mental support for newcomers in the field now. Welcome, my friend!

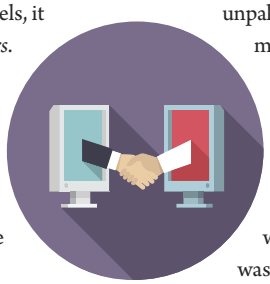
She said, "It is exciting to become a 'solopreneur' but I am also sceptical about my decision". Interestingly, she chose the term "solopreneur" instead of "freelancer", about which I will mention later. We discussed the reasons for her scepticism and concluded that it stems from the lack of social recognition for freelancers, rather than the typical reasons, such as uncertainty of failure or success. The lack of social recognition does not mean that people do not know the presence of freelancers; rather, it refers to the fact that most societies are not yet ready to accommodate the rapidly growing, diverse populations of freelancers.

Stereotypes
The superficial understanding about freelancers and their various social standings play as obstacles that contribute to many professionals' hesitance in their decision-making process.

In spite of the enormous growth in the number of freelancers, they are still classified as unconventional workers, strange geeks, or outsiders who cannot fit the traditional 9-to-5 jobs. As Daniel H. Pink pointed out, the freelancing sector has grown both in scale and



variety in the United States; the number of freelancers doubled within the last two decades and now it is estimated to be more than 50 million according to various sources.[3–5] Hence, the term "freelancer" is not alien to most. Moreover, similar terms have emerged, such as self-employed workers, contingent workers, independent professionals, independent contractors, digital nomads, on-demand workers, solopreneurs, micro-entrepreneurs, etc.[6,7] All these terms refer to people who do not belong to an organisation but work for themselves; however, they can be divided into many subcategories. Some people are forced to freelance temporarily until they get hired again by a company, some people represent their own business but work for one client for a permanent period, and some people voluntarily choose to be a service provider for many clients to do what they do best. The complexity of freelancers' jobs varies greatly, from micro tasks, such as filling out a survey on Amazon Mechanical Turk to comprehensive assignments like statistical analysis and developing a research protocol. Because of the wide spectrum of tasks and different freelance business models, it is difficult to define the term *freelancers*. Introducing oneself to others, especially those who do not share similar professional backgrounds, with a sentence "I am a freelancer" or "I am a freelancing medical writer" usually prompts for more explanations.



To some, the image of freelancing is rather distant from the image of serious professionals. As previously mentioned, people usually associate freelancers with someone living a relaxed lifestyle. As a freelancer, it's common to hear from acquaintances "why don't you come over my place to have a lunch as you have more time than me?" or "I envy you, you have a free soul to leave your job like that!" People also associate freelancers with the terms containing *free,* such as free folks or freeter, which does not convey the ideal image of an expert in any discipline. The fact that the term starts with *free* does not mean that freelancers are free from time pressure or professional responsibility. Hence, to overcome the stereotype surrounding the term, some freelancers, especially professionals who are used to have fancy titles on their business cards, choose different terms like solopreneur to emphasise their entrepreneurship and to impress others.

Considering all these mental barriers (and not only the real-life challenges to setting up a business), you may wonder why I chose the path of freelancing. For me, the main reason was the flexibility and autonomy I can have over my work, and I still believe these two elements are the crux to becoming a freelancer.

Life in an organisation

When I was working as a full-time medical writer in a pharmaceutical company, I had to deal with uncomfortable social norms imposed on all the employees: wearing business casual, trying not to fall asleep after lunch, participating in after-work gatherings, being exposed to unhealthy snacks delivered by colleagues who frequented a convenience store on the first floor of the building, etc. Initially, I tried to adhere to those annoyances as a trained docile lamb in a culture of collectivism, but soon I found my ways of dealing with unpalatable situations. For example, I wore modernised versions of the traditional Korean dress called Hanbok, the loose fit of which gave me more breathing space than the typical tight business casual. To survive sleepy afternoons, I left my desk with my laptop and pretended that I was having a meeting in the conference hall next to a breastfeeding room. Since all those who visited the breastfeeding room had quite regular schedules in expressing their milk in bottles, I was able to find some quiet time to refresh my mind for a fruitful afternoon. Sometimes I would call several female colleagues to join me in the main conference hall when it was empty, and we would dance salsa together. Besides, I did many things to make my office attractive to me, like installing a fish tank or growing herbs. I also formed a rock band with colleagues to avoid meaningless alcohol gatherings after work so that we could excuse ourselves for the band rehearsals. These anecdotal stories may sound like I did not enjoy my work. In truth, I liked my work very much and the company also appreciated my work (believe me, I always got the best score at the annual work performance evaluation). What I did not like was the work environment and the social norms that was expected to be followed by all employees. This realisation struck me after almost 6 years of adapting to life in the organisation. I concluded that I would be more productive in a flexible work environment, which meant my own office, and this inevitably led me to starting my own company.

Flexibility and autonomy

After registering my own company, I searched for a physical office. Yes, I was still a slave to a stereotype – a company should have an office. Luckily, I was given a nice office for free for a year by becoming a benefactor of a governmental project boosting intellectual businesses. But I visited the office less and less, and I worked at home more and more. I still maintain a physical office where I can work but I keep that place for registration purposes mostly. Instead, I have established my own home office separate from the space for personal activities. This way, I can use my time more efficiently by removing the commute time. I don't need to wear uncomfortable formal attire that hampers my work efficiency (the tightness of formal attire causes me migraines). I do not need an excuse to avoid alcohol gatherings, instead, I enjoy ballet classes at night. Unhealthy snacks from the convenience store are now replaced by fresh fruits or natto (fermented soybeans). When I get sleepy, I can have a cosy nap for half an hour without the stress of being found in an awkward place. Surprisingly, I now rarely feel sleepy in the afternoon. I guess it is a result of a healthier lifestyle, which became possible by investing time on physical activities like yoga and ballet, otherwise spent commuting and attending unwanted social gatherings. I can control my own schedule and work environment, which is hugely important to an unconventional creature like me. In addition to the improved work conditions, I also invest the extra time on creative activities like playing musical instruments, taking photographs, and dancing. The amount of work and my work performance are not hindered by these extra activities, rather they have boosted them. I greatly enjoy the flexibility and autonomy in my

work and these two pillars support my work efficiency. Many other freelancers also value these two factors the most, as indicated in Daniel H. Pink's book: 74% out of 1,143 survey respondents replied that independence and freedom were the main reasons for their choice to be free agents.[2]

Does my story look attractive to you, especially if you have ever considered becoming a freelance medical writer? If so, I would now like to introduce the challenges a freelance medical writer should overcome.

Challenges when you hire yourself

Your client makes a contract with your company where you are the business owner (let's say, the boss) and an employee at the same time. It may sound strange to newbies, but as a professional, you should keep the two identities without suffering from a *dissociative identity disorder*. Your identity as a boss should assign a reasonable amount of work to your employee, provide him or her with an agreeable salary and a welfare benefit plan, maintain a healthy financial status, and set up a system to guarantee the quality of work. Whereas your identity as an employee should do your best to accomplish each assignment with high standards, polish your skills, and raise an issue if a problem is detected in your company. Both identities must function well to maintain a successful freelance business. In a big organisation, a mess created by an unskilled employee or an unqualified boss may not be visible immediately; however, such a problem becomes obvious within a short time in a one-person company, and it may cause you to lose several clients.

In my opinion, the "boss" should outweigh the "employee" when maintaining your freelance business. That means, you should constantly audit your work, the work system, and the work ethics, analyse the problem and its cause and arrange preventive measures. If we take an example of workload, the "boss" should not take on too many projects and exceed the capability of the "employee". If a freelancer does not separate these two identities, the person usually takes all available assignments without questioning hard enough to make an objective decision. However, if your two identities are well-maintained, then your boss would push break at certain point or your employee might raise an issue, as either of them would eventually be overloaded to the point that work quality may be affected. This is especially the case when financial problems emerge; the desperate freelancer may accept work that is beyond his or her area or assignments that underpay. However, if you have a fair boss, you would not put your employee in such an unpleasant situation.

Keeping the boss and employee identities separate means having both an objective and a critical attitude to your business, so that you will not overexploit the flexibility and autonomy. For example, you could choose to start work whenever you want; however, your boss identity should not allow you to work between 2:00am to 9:00am because this would cause a problem when communicating with clients in the same time zone. Balancing this double identity in your business can help maintain high professional standards and strict work ethics.

You are not alone

A decision is always accompanied with an opportunity cost. We will never know what kind of journey is awaiting us until we hit the road. If you value flexibility and autonomy in your work and you have confidence in your skills as a professional, a new journey to settle down as a freelance medical writer will be enjoyable. Moreover, your journey would not be lonely as many other medical writers have already lit the light on the road you would take. Social stereotypes of freelancers are not applicable to freelance medical writers.

Conflicts of interest

The author declares no conflict of interest.

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Author information

Hye-Ryon Kim, DVM, started her career as a full-time medical writer in a major pharmaceutical company in South Korea in 2004. In 2010 she decided to change tracks and became a freelance medical writer. Her company, Medical Writing, provides regulatory writing services.

Medical writing and medical translation – two crossing paths

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Abstract
Transitioning from medical writing into medical translation and vice versa is one of the many opportunities professional writers and translators may encounter in their career path. In this article, we present two personal experiences in doing so. We also present some data retrieved from a short survey conducted among professionals working in both fields.

It is not rare to find medical writers who also do translations, and, likewise, medical translators who are also skilled writers. That is the case with the two of us: Laura C. Collada Ali is a medical translator as well as a writer, while Monica Milani is a medical writer who is branching into translations. We realised that we would be perfect real-life examples of this sort of career mingling and decided to share our experiences in the form of interviews with each other.

I also like very much working as a freelancer, as it allows me to be flexible with my schedule. I may go skiing for a couple of hours when the sun shines and then work late at night.

An interview with Laura C. Collada Ali

My job gives me the opportunity to learn new things every day.


Laura C. Collada Ali

What is your background, and how did you become interested in medical writing?
I've always loved languages. I love how each language is strictly linked to a particular culture, and I appreciate the beauty of their nuances. However, I don't have a favourite language. Therefore, I've ended up studying several! I graduated in Translation and Interpreting at the University of Alicante (Spain); being a Spanish native speaker, I learned English, French, Arabic, Italian, and Catalan. Translators use languages as their main working tool, yet they need to get familiar with the field they want to work in. For me, it was medicine.

In the years following graduation, I have attended many different workshops and seminars – on translation, writing, and medicine in general. My first professional assignment was at the European Organization for Research and Treatment of Cancer (EORTC), in Brussels. I was in charge of liaising with international experts involved in the revision process of clinical research protocols. I loved that role and learned so much; the languages I had studied were a great toolkit. After a couple of years, I ended up being the administrator of the Protocol Review Committee and of the New Drugs Development Committee and contributing to the collaborative protocol writing process. This is how "writing" started for me…

How did you get your first project in medical writing?
My first medical writing project consisted of preparing the reports of the EORTC Protocol Review Committee meetings. These meetings took place every 3 months and were aimed at reviewing and approving the development plans for new clinical trials in oncology. At the beginning, it was a rather challenging task as I needed to get acquainted with the oncology

field to properly understand and report the discussions. With time, I improved my confidence, felt at ease at writing these texts, and actually enjoyed a lot those high-level discussions. Over the years, I have covered many different types of scientific and board meetings as a medical writer.

Do you have any tips for medical translators who would like to branch into medical writing?

Always keep an eye on new regulations coming out at a worldwide level. When translating, it is often enough to know the regulations related to the source and target languages. However, when you switch into writing, you need to broaden your vision of the regulatory world.

Networking with medical writing colleagues and investing in professional medical writing training are extremely important. Thus, joining EMWA is a must!

What kind of documents do you translate or write?

I mostly translate regulatory documents and sporadically marketing material.

I write both regulatory and medical communication documents. It seems that writers eventually specialise either in one type of document or the other. I enjoy being challenged, so I do welcome opportunities to work on different documents. However, I might refuse to write documents on topics I'm not familiar with. When I don't have enough knowledge of the topic, I don't feel confident writing about it.

Has your work evolved over time and what are the causes of this evolution?

It has evolved a lot. I spent the first 10 years of my career working for non-profit research organisations. At that time, I did not know there was something called "medical writing".

When I decided to become a freelancer, I realised that what I had been doing in the non-profit setting was, indeed, medical writing! I immediately joined EMWA. As a freelancer, my portfolio of clients grew to also include pharma and medical device companies. Now I have a comprehensive understanding of different approaches to clinical trials, and I have become experienced in the preparation of different kinds of documents.

Do you think that formal training is necessary to become a medical translator?

The best translators I know of in the field of medicine do not have a university degree in translation. Translation university studies became a reality only in the '90s. Therefore, there is a generation of very experienced translators out there who do not have formal training and a degree in translation. That said, of course these professionals were passionate about languages and keen readers. I would say that reading in the target language about the field you are translating about is a must.

What do you like the most in your job?

My job gives me the opportunity to learn new things every day. Languages are my main working tool, and I very often need to do lots of research on the topic I'm writing or translating at the moment, which is something I really enjoy. I also like very much working as a freelancer, as it allows me to be flexible with my schedule. I may go skiing for a couple of hours when the sun shines and then work late at night.

What do you like to do in your free time?

I love reading and mountain sports, particularly, cross-country skiing and hiking.

An interview with Monica Milani

How did you become a medical writer and what is your background in the field?

I became a medical writer somewhat by chance. I didn't even know that this profession existed!

In my previous career, I was a researcher working in the immunology and oncology fields. While I liked my job at the time, what I enjoyed most was the communication of science. I found that more than generating data I liked presenting them – whether in manuscripts, posters, grant proposals, or so on. Driven by this interest, I started searching for jobs on the web using keywords such as "writer", "science", "communication" – that's when the medical writer profession popped up. Not only did I then realise that this profession existed, but that it was in high demand.

Career changes are always daunting. Though I had a background in science, I felt it wasn't enough and decided to get a degree in technical/scientific communication. In retrospect, I think the degree programme was useful, but not essential. More than anything else, it served to improve my confidence while exposing me to potential employers. Eventually, and with no small struggle, I landed the dream job – a junior position in a medical writing consultancy in the South of France. Voilà!

Why have you decided to also offer medical translation services?

After some years spent at a medical writing consultancy and a pharma company, I decided to transition into freelancing. This change prompted me to think about additional services I could offer to potential clients apart

Monica Milani

from medical writing. Since I speak three languages, translation naturally came to mind. I grew up in Italy, lived in the US for a decade, and I've now lived in France for more than 7 years. While I consider English as my "second native" language, I cannot say the same for French. Therefore, I am confident translating between Italian and English, and from French to English, but not vice versa. Perhaps that will come with time. Bottom line, I thought – why not take advantage of these skills and offer translation services as well? I don't think medical translations will be a big portion of my workload, but I would enjoy doing some occasionally.

What specific skills are needed to branch into medical translation?

Obviously, language skills are essential. I don't think it matters whether they were acquired at school or through life experience. Knowledge of technical terms is also essential.

Scientific texts have the value of being written in a relatively simple manner. The sentences are short and to the point. I believe this facilitates the work of a translator. I'm not saying that translating scientific texts is easy, but it's definitely easier than translating something literary. Overall, I think that if you master a set of languages, have a scientific background and enjoy the challenge of faithfully and accurately translating, you are set to go.

Would you focus on any specific type of document or would you rather adopt a client-oriented approach?

Right now, I take any opportunity within reason. I've just started as a freelancer, so I don't have the luxury of picking and choosing. I am flexible and happy to adapt to the client's needs. In the future, perhaps I'll find a niche and specialise in a few types of documents. For the moment, it is just too early to say.

What's your opinion of medical translators who branch into medical writing? Are they well-enough prepared? Would they be capable of working on any type of documents?

I think it is possible for medical translators to become medical writers if they have a scientific background by training or if they have worked long enough in the scientific/medical field. An analytical mind, attention to detail, and strong writing skills might be sufficient for transitioning into medical writing.

Once one understands the basics of scientific writing, they can write any kind of documents. I think this is especially true for regulatory documents, which are rigidly structured. It is less true for medical communication documents, which could be more challenging since they require a more creative or strategic approach.

What advice would you offer to someone seeking to include medical translation in their services?

I would say, if you feel secure in your language skills and enjoy translating, give it a try. A small dose of confidence doesn't hurt. We all go through some sort of "natural selection" for everything we do in life, including work. If medical translation is not your path, it will soon become evident.

So, besides writing and translating, what other things you enjoy in life?

I love to travel, hike, do yoga, read, cook, and take photos.

Results of a mini survey

The authors conducted a mini-survey to discover more about the interconnection between the medical writing and medical translation professions. The survey was aimed at medical writers who had branched into medical translation, as well as medical translators who had branched into medical writing, and it was distributed both through social media and to medical writing and translation associations across Europe. The purpose of the survey was to gain a general understanding of the responders' educational background, the time spent on their activities, and the motivation behind their desire to branch out. The data we are presenting come from a sample of 16 responders; thus, they may not be representative of a larger population.

Of the 16 respondents, the majority (n=10) were translators who had branched into medical writing. While adding medical writing to their repertoire of services, the majority of translators (8 of 10) are still spending at least half their time on medical translations. The same is true for medical writers: 5 out of 6 indicated that they spent at least 80% of their time on medical writing tasks. In this small survey, translators started offering medical writing services after an average of 10.2 years (ranging from 1 to 32 years) of experience in the translation field. Conversely, medical writers started offering translation services much earlier, on average within 2 years of staring their careers (ranging from 0 to 5 years).

Of the 10 medical translators, half have a university degree in the translation field; 2 have no formal training, 2 attended workshops, and 1 earned a certification at a translation institute. Importantly, 9 out of 10 have a scientific background. Of the 6 medical writers, the majority (n=4) have no training in translation, while they all have a scientific background.

Medical translators seem to branch into writing primarily due to personal interest, job opportunity, better pay, and job security. On the other hand, medical writers seem to branch into the medical translation field following a client's request or to increase their income.

Results of this survey also illustrated that translations are in demand for e-learning, audio-visual, marketing material, patents, drug leaflets, and declarations of conformity for medical devices, in addition to more traditional applications such as regulatory and medical communication documentation.

Conflicts of interest

The authors declare no conflicts of interest.

Author information

Monica Milani has been a medical writer since 2011 and has recently started her own company, Apropos Science. She has experience in a wide range of regulatory and medical communication documents covering various therapeutic areas.

Laura Carolina Collada Ali is a medical writer and translator with more than 15 years of experience in delivering multilingual authoring and translation services for leading independent research organisations, pharmaceutical and medical device companies.

Elise Langdon-Neuner's story

Life after Medical Writing

I miss nothing from my working life. I worked beyond retirement age and resigned when an organisational change in the company would have landed me with a new boss, someone I was not prepared to work with. To be able to walk away in these circumstances was good fortune. Rumours that a medical writer had time on her hands soon spread. I was asked to contribute to a book on medical writing, participate in a study on plagiarism … and to write this article about what happens when work stops.

Well, it didn't completely. Contacts at the Medical University in Vienna immediately approached me to edit their manuscripts. Ever since, I have had a regular contract with two departments. It's enough to provide a steady flow of work and supplement my pension. I can pamper myself with what otherwise would be guilty little treats.

Planning for retirement never entered my mind. Neither were there any dreams to be fulfilled when time allowed. My husband and I love travelling but had managed to squeeze in treks and expeditions to far flung places whilst working. These have continued. The difference is we are older – the downside of the utopia – and need to do more to keep fit. But if the forecast is good, there's the luxury of being able to spontaneously go off to the mountains and stay overnight at a hut. In the last 3 weeks alone, we have walked up eight mountains. To experience the sun rising and setting over the peaks and see the wildlife is pure joy. This year I have been able to photograph snow hens, wild turkey, marmots, chamois and ibex.

One change that is often absent from rosy-eyed retirement concepts is the constant presence of a partner who makes new demands on your time, for example, who might be prone to ask when lunch will be served. Some adjustments need to be worked out to give each other space, but with time this seems to have worked out well for us, meaning lunch is not always served on time and the realisation that when desperate one can get lunch for one's self has sunken in.

Learning has become more of a pleasure than ever since giving up work. Before, I learnt to pursue a career, which then involved continually gathering more knowledge. Now I am free to investigate whichever academic avenue I please – nature, geography, social history, photography – except everything as it always did invariably comes back to writing. What I learn I'm compelled to write. Currently, my main pursuit is family history, but there is a problem. I cannot forgive medical writing for its sameness – same words, same sentence structures – and the damage this has done to my writing style.

When I left home for university, I started a weekly exchange of letters with my father and certainly from his side, these letters were a poetic narrative of everyday life spiced with wit. The correspondence continued for over 30 years until he died. In the meantime, I had become a medical editor bent on no frills or thrills writing. All those years of editing and writing for clarity have wrought their revenge. Richard Smith, when he was editor of the *BMJ*, warned me as much. He told me academic writing would kill my creative writing. Thus, ironically, I am taking writing courses and reading books such as 500 words you should know to expand my vocabulary.

In sum, my retirement is happy and fulfilling. Crucial to this is the freedom to choose the challenges I set myself. My still-working colleagues can be encouraged in their own future enterprise because those I have known are not of the ilk that aggrandise or define themselves by work. Retirement holds no fears for medical writers, who have diverse interests to indulge in when the punishing pressure of deadlines is lifted.

Retirement holds no fears for medical writers, who have diverse interests to indulge in when the punishing pressure of deadlines is lifted.

Elise Langdon-Neuner
Editor-in-Chief, *The Write Stuff* (2003–2013), and medical writer (1997–2012)

Career opportunities in medical device writing: Employee and freelance perspectives

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Abstract

Many regulatory medical writers start their careers in pharma. Whilst many continue in pharma, some also work in medical devices and an increasing number are switching to medical device writing. This article explores how and why writers might move from pharma to medical devices, just write for medical devices, or work in both, and identifies the transferable skills from the perspective of two writers, one who is now employed by a medical device company and another who is freelance. With sound writing skills and broad experience, there is no reason why a writer cannot transition from pharma to medical device writing, work solely in medical devices, or even decide to work simultaneously in both fields.

Introduction

The introduction of MEDDEV 2.7/1 rev. 4 (2016)[1] on clinical evaluation followed by the Medical Devices Regulation (MDR 2017/745)[2] and In Vitro Diagnostic Medical Devices (IVDR 2017/746)[3] has increased the need for and awareness of regulatory medical writing by medical device and diagnostics companies. Consequently, writers with experience gained in the pharmaceutical industry are well-placed to either move to medical device companies or to take on medical device writing projects. In this article two medical writers share their experiences of medical device writing, one as an employee moving to a medical device company and the other as a freelance writer.

How we got to where we are now

The employee route

It was the Summer of 2017 and Sarah was thinking where to go next, having gone from clinical and regulatory to clinical, regulatory and pharmacovigilance, and then back to clinical and regulatory. With a background working in pharmaceutical industries and contract research organisations (CROs), there was experience as both the Sponsor and the Client. Sarah is a clinical writer first and foremost, and even as a line manager, still had a hand in writing to enable her to empathise, advise and mentor the individuals she looked after.

Moving into pharmacovigilance – a completely new area, was a steep learning curve working in a busy leading CRO, which culminated in presenting the EMWA Advanced Workshop on Development Safety Update Reports.

Employed roles have involved working either remotely with the option of working in an office, a combination of both, or being completely office based. However, due to the location, remote working was recently the only option for Sarah. Whilst for many freelancers, remote working is often the only and preferred way of working, Sarah started to miss the human face to face interactions and wanted to get back into science and writing. She was ready for a new challenge and a new working environment and leveraged her association with EMWA since 2006, MEW's journal articles, and her network of colleagues and friends to find out more about medical devices![4–8]

Look beyond the job title; one should also consider clinical scientist/clinical research scientist/clinical specialist roles. If one is interested in specialising in a particular indication the role provides wider scope in providing scientific input into all the steps involved in the preparation of a pre-clinical or clinical study, from planning and set up, interactions with key opinion leaders, surgeons and engineers, involvement in day to day study conduct, data cleaning activities, and production of the study report (amongst other things).[9]

The freelance route

Gillian became a regulatory writer in 2006 when she established Sylexis Limited. Previously she had worked for a pharmaceutical and medical devices consultancy, in clinical development for a global pharmaceutical company, in phase I-II clinical research for a CRO, and in academic clinical medicine. The practical experience of following a protocol, getting ethics approval, and obtaining informed consent, gave useful insight when writing clinical trial-related documents. Working in pharma enhances one's understanding of how medicines are developed, regulated and marketed; useful experience when writing study protocols and reports, clinical summaries and overviews.

Although Gillian's research experience was mostly pharmaceutical, there were opportunities to work with medical devices, e.g., an ambulatory blood pressure monitor and an investigational device for administering insulin. There were also opportunities to learn how medical devices were approved and regulated in the US and Europe and also to conduct phase III clinical trials of a pharmaceutical product delivered by a novel medical device. This pharma experience was then applied to medical device development at a time when ISO 14155 contained only guidance on trial conduct (good clinical practice) and the clinical investigation plan (protocol),[10,11] and when few medical device companies conducted clinical trials. Therefore, when Gillian established Sylexis, she simply continued working on pharmaceutical and medical device projects.

Whilst being freelance often means working from home and writing alone, this environment can be very appealing – no daily commute, few meetings to attend, no office politics, and the flexibility to fit around family or other commitments – but how does one keep up to date professionally and run a successful business? This is where EMWA has been invaluable. Gillian joined EMWA in 2007 and has learnt much from attending and leading workshops, the Freelance Business Forum, serving on the EMWA Executive Committee, and from friends and the wider EMWA community.

Look beyond the job title; one should also consider clinical scientist/ clinical research scientist/ clinical specialist roles.

Learning on the job and adapting existing skills are important. Working on a new type of document with a colleague or as part of a larger team, familiarising oneself with regulations, guidelines and new software programmes, and attending EMWA workshops are all ways of acquiring and honing new skills – whether employed or freelance! This is how Gillian learnt to write clinical overviews and summaries, and then clinical evaluation reports (CERs), and literature reviews. This experience was adapted with each iteration of MEDDEV 2.7/1 and continues with the introduction of the MDR and IVDR.

Employed vs freelance comparison

How does writing about medical devices compare when writing as an employee or freelance writer? Employed isn't necessarily better or worse than freelance status; it's a matter of personal preference, skills and circumstances. Table 1 gives a general comparison from the authors' perspective. Other writers' experiences may differ depending upon the size and nature of the company or the style of freelance work, i.e., several clients and projects or contracted to one client at a time.

What are the transferable skills?

As an employed writer

By a certain stage of career, one will have a sound background in clinical research, analysis and presentation of data, statistics, and writing various types of documents. Sarah found herself back in a laboratory again! Unlike the large global medical device companies, or even many pharmaceutical companies, the responsibility of producing and supporting a wide range of documents and other non-writing activities fell to her.

Therein lie exciting opportunities to transfer project management skills, and her previous clinical/regulatory/pharmacovigilance experience working as part of a multidisciplinary team, to mentor, advise, innovate, deliver, and still benefit from the variety of work. As a professional, don't be deflated by comments or direct feedback – it's part of the job. In smaller companies, there is the advantage of instant feedback and taking time to build and work on relationships.

Why medical devices?

Being in pharmacovigilance and still working in regulatory and clinical gave Sarah the appetite to move into a completely new area. A LinkedIn advertisement led Sarah to her current employer, CMR Surgical Ltd, in Cambridge, UK, developing a new robotic surgery system to improve access in minimal access surgery.[12–14] The idea of

working in a smaller company, working closely with the Directors, all renowned innovators in their field, to drive their vision forward, and to work in more technical environment appealed immensely to Sarah. The company was developing a prototype which gave opportunity for different areas of growth, especially one where a clinical and medical team was growing, and which Sarah would be part of.

The benefits offered by the company were generous and quite novel: generous non-contributory pension, life insurance (8x salary), bonus, childcare vouchers, and on a lighter note, as in Steven Walker's article in *Medical Writing*[4] free fruit!

Sarah now wanted to be part of one product development process. She relished the prospect of working on a prototype which was so close to achieving its regulatory goals – achieving a CE mark, and then a US 510K submission for FDA approval, which considered all the exciting challenges lying ahead from transition of MEDDEV to Medical Device Regulations. She likes the pace, (on most occasions!), being able to develop her own ideas, and freedom to pursue company funded professional development which is balanced with the business needs of a company.

Sarah used the June 2017 *Medical Writing* issue on medical devices to leverage her pharma experience and passion to move into medical devices. The transition point to medical devices was set at the 2018 EMWA Spring Conference in Barcelona where she attended the Medical Devices Symposium and participated in her first medical device related workshops on Literature Reviews and CERs, and presented her pharma workshop on DSURs for the last time.

Opportunities for development

Working with talented individuals and across many regions are just two things that Sarah likes about her new job. She plays a pivotal part in data collection and authoring the study plan/protocol. In this role, she has completed a surgical theatre access training course, trained in Good Laboratory Practice, refreshed training in Good Clinical Practice, and gained new skills writing for validation studies to show proof of concept in pre-clinical models and usability studies looking at the perspective of the user as well as the device.[13]

In addition, the company is looking at innovative approaches to surgical studies under the IDEAL collaboration, (Idea, Development, Exploration, Assessment, Long-term monitoring) framework for evaluating surgical innovation and robust data capture through a registry not only

Table 1. Medical device writing – employed vs freelance comparison

Work characteristics	Employed	Freelance
Product vs project	Involved in all aspects of a product development and throughout product life cycle, e.g., work with engineers in laboratory, post market surveillance. Opportunities to get back into the laboratory and do pre-clinical work.	Only involved with writing documents for a project e.g., CER.
Variety of work	Limited to the company's products and therapeutic areas.	Variety of products and therapeutic areas.
Employer and clients	Work for one company at a time.	May work for several companies/clients at the same time.
Remuneration	Regular salary and benefits, e.g., pension, health care, life insurance, discretionary bonuses, paid annual leave and sickness benefits that may offset a lower salary than in a pharma company, especially if moving to a small company.	May not have regular income or benefits. No paid annual leave.
Job location flexibility	Depends on employer and company culture.	Usually more flexibility of when, where and how to work.
Career development and training	Opportunities may, or may not be, supported by employer. May have access to in-house training. Opportunities to attend other conferences. Some employers will support EMWA membership and training.	Must pay for and organise one's own training and career development. EMWA is particularly useful.
Pharmaceutical projects	Move away from pharmaceuticals.	May continue working on both pharmaceutical and medical device projects.
Business activities	Will be involved in corporate activities, especially if working for a large company.	Must manage own freelance business as well as working on projects.
Transferable skills	Writing, IT, therapeutic area knowledge, scientific and regulatory expertise.	Writing, IT, therapeutic area knowledge, scientific and regulatory expertise.

promotes transparency but establishes comprehensive, long-term surgical data collection which can be used to improve patient safety.[12] Registry and real-world evidence/real-world data is a topical subject for medical writers, mandated by the FDA.

Writing for pharmaceuticals vs medical devices

Like pharmaceuticals, the medical device industry has its own regulatory systems which are just as demanding and scrutinising. The need for quality, peer reviewed, validated documents is pertinent to both industries following recent scandals.[15-17] Medical devices, however, have shorter product life cycles, going from development to market in three to seven years. Technological improvements are typically available within two years of a previous iteration, and whereas improvements in medicines might take 10-20 years. Many medical device documents follow similar structures to those required for pharma.[4] With this in mind, after three years in medical devices there's a good chance of seeing the device either get to market or stay on the market.

Writing for devices includes an assessment of device performance outcomes which are dependent on the experience of the operator and team, and setting, such as evaluating learning curves, quality variations, and alleviating equipoise problems. These are some of the interesting challenges to be considered for document writing for devices.

Sarah has produced slides for Investigator Meetings and might have the opportunity to attend one. In future, there will be opportunity to write Post Market Surveillance and Post Market Clinical Follow-up document which draw on safety narrative writing skills and DSURs.

As a freelance writer

The transferable skills for writing about medical devices as a freelancer are mostly the same as those for an employee writer, namely good writing and computer (IT) skills, sound regulatory document expertise, scientific/ medical knowledge, and the ability to adapt existing skills and knowledge to new situations.

Whereas an employed writer might be limited to a particular therapeutic area or type of medical device, a freelance writer might work across a range of therapy areas and types of device. This means being comfortable switching between different subjects; today an expert in spinal fixation devices, the next day discovering the nuances in different coating materials for drug-eluting coronary stents, and the following week writing about a glaucoma treatment. With each new project one has to 'get up to speed' and learn about the medical device and the disease being treated. This can be a useful exercise – particularly with the rigorous requirements of MEDDEV 2.7/1 and the MDR to present current knowledge and demonstrate that a device is state of the art.

Just as there is variety in therapeutic areas, there is also variety in the needs of clients.

- Large companies and CROs may simply need resource – they have document templates and standard operating procedures and will supply the literature search outputs, but they don't have enough writers in-house to write up literature reviews and CERs. This can be a great way to learn how to write such documents.
- Small companies, however, may not have either in-house writers or the expertise to conduct literature reviews or prepare CERs to the current MEDDEV 2.7/1 or MDR standards – they want an experienced writer who can help and advise them, conduct the literature searches and write the documents using their own templates and software e.g., EndNote for reference management. For these clients, prior medical device writing experience is essential.
- There is always more than one way of writing a document, and freelance writers see lots of variations. This is an opportunity to see what works well, what doesn't, and to adapt and develop document templates and writing styles. For example, provided the guideline or regulation is being followed, it may be a matter of company style or determined by the volume of literature whether the literature review is a separate document or a section of the CER, or whether the data extraction table is an appendix to the literature review or in the body of the report.

> By a certain stage of career, one will have a sound background in clinical research, analysis and presentation of data, statistics, and writing various types of documents.

> The development of technologies and an evolving regulatory environment mean that manufacturers will need knowledgeable writers.

So, whilst the transferable skills might be similar between writing about medical devices as an employee and freelance writer, the range of projects and level of expertise required may be different.

Next steps ...

Judge a man (woman) by his questions rather than by his answers: Before moving into medical devices – think about the type of role and department one is applying to; understand the job description, career development and promotion opportunities. What is the medical device's classification and is it marketed? This gives an idea of the development, strategic and regulatory plan for the device. Ask about the experiences and qualifications of the project teams. Often medical device companies can be small start-up companies – so websites such as Glassdoor can't help. One may delight in perhaps being the only, or the most experienced medical writer. Will one be mentored or be mentoring? Don't be put off. Use networks, e.g., EMWA, and faith in medical writing skills to confidently take on the challenge.

If part of a newly formed and growing clinical and medical team, ask about participating in laboratory-based studies, in addition to writing responsibilities. Would one be happy interacting with external consultants, surgeons, and clinical teams? Would one be comfortable working with cadavers, animal pre-clinical models, and brushing up on physics? Does the role involve preparing data in the format required for regulatory approval or scientific publications? Does the role require negotiating with and managing vendors and contractors? Does one have to travel and work offsite?

The development of technologies and an evolving regulatory environment mean that manufacturers will need knowledgeable writers. Could medical device writing be a career option worth considering?

Conclusions

In this article two medical writers, one employed and the other freelance, have explained how they came to write about medical devices, shared their experiences and highlighted the transferable skills between writing about pharmaceuticals and medical devices.

In conclusion,

- Writing about medical devices isn't so different from pharmaceuticals;
- Medical device writing opportunities exist for employed and freelance writers;
- The transferable skills are the same whether employed or freelance and are determined by previous career route and experience;
- With the freelancer route – opportunities to still work with pharmaceutical products;
- EMWA can help with writing for both medical devices and pharmaceuticals;
- Don't worry, we're all learning together! Employers will understand this.

Acknowledgements

Sarah Choudhury would like to thank Gillian Pritchard and Raquel Billiones for the opportunity to write for MEW, EMWA for providing her with insight for development areas for medical writers. She'd also like to thank the Chief Medical Officer, Medical Safety Officer, and Directors at CMR Surgical for supporting her work with EMWA.

Disclaimers

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

Conflicts of interest

Sarah declares no conflicts of interest. Gillian writes about medical devices for several clients.

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Author information

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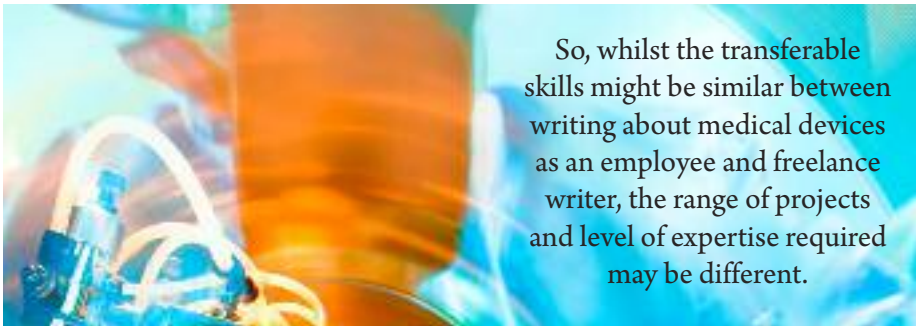

So, whilst the transferable skills might be similar between writing about medical devices as an employee and freelance writer, the range of projects and level of expertise required may be different.

How Ansgar Dressler did it

Getting Your Foot in the Door

Career transition: From statistics to medical writing

At the time I finished my studies and got my degree in statistics in 1997, I had never heard of medical writing, as is probably true for any student, even in the medical field. After my studies, I joined what was then Hoechst Marion Roussel (and later became Aventis, Sanofi-Aventis, and finally Sanofi) as a biostatistician. In the broad interdisciplinary field of clinical development, I closely collaborated with the data management, programming, and medical departments, and also with medical writing. Not only did I learn about the existence of medical writing and its role, but also did my first steps into the field of medical writing when I drafted the statistical analysis plan or the statistical methods section of a clinical study protocol. Although being used to and enjoying the core work of a statistician, i.e., applying appropriate statistical methods to analyse and summarise data, I also liked the aforementioned writing side of my work.

In the early years of my career as a statistician in the pharmaceutical industry, I was fortunate to get to know Julia Forjanic-Klapproth, Barry Drees, and Douglas Fiebig who all belonged to the medical writing department at that time, and who would found their own company, Trilogy Writing and Consulting GmbH, in 2002. Shortly before, in 2001, the entire development department of Sanofi-Aventis had been spun off and became the full-service clinical research organisation, Covidence (later renamed Accovion and then acquired by Clinipace), which gave me the opportunity to experience the whole spectrum of clinical development from the perspective of a service providing company.

When, for private reasons, I planned to leave the Frankfurt area and move to near Munich, and thus wanted to change my job, Julia, who I closely worked with basically in all projects during our first years in the pharmaceutical industry, offered me to join Trilogy as a medical writer. Of course, such a change in disciplines is a major step, especially since I liked the work as a statistician. But from my past experience I also knew that I would like the work as a medical writer, and given the other benefits, e.g., being an integral part of a small growing company and the possibility of working from home, I accepted the offer. Thus, after more than eight years in the pharmaceutical industry as a biostatistician I joined Trilogy in 2006 as a medical writer, and I have never regretted that step.

But what exactly changed? Aside from the obvious, that I moved from mostly dealing with numbers to mostly dealing with words, I find the work as a medical writer more diverse with regard to the different indications you work on and the different people and functions you work with. As a statistician I almost entirely worked in one indication (diabetes), and in fact became the statistics lead for diabetes within the company. I mainly interacted with the programming department. As a medical writer, however, I have worked in many different indications and not only interacted with many different departments, but also coordinated teams to get documents finalised on time. Even after more than 12 years as a medical writer, there are still new challenges and learning opportunities with every new project, e.g., a new indication, a new document type, or new team constellations with new responsibilities. I believe I would not have had such diversity of experience as a statistician, at least not in the position I had and not to this extent. And, of course, in my work as a medical writer I stay in touch with statistics, and my background in statistics often comes in handy when interpreting statistical outputs.

So, looking back at my career in the pharmaceutical industry, I have been happy with my decision to side step from biostatistics into medical writing, which I love to continue doing in the future.

Ansgar Dressler
Medical Writing Manager at Trilogy Writing & Consulting GmbH

Getting Your Foot in the Door

How Christine Møller did it

It was a unique combination of circumstances that led me to work in the editorial office of a medical journal, which was the reason I joined EMWA.

After meeting my husband-to-be, I arrived in Denmark intending to teach English, but was held back by my lack of recognised qualifications and by my inability to speak Danish. Needs must, however. So, instead of pursuing a full-time teaching career, I embarked on a succession of temporary positions.

I eventually gave up any hope of teaching and took a job at the British Council Library. When the library closed, the future looked bleak. As luck would have it, *Acta Pathologica et Microbiologica Scandinavica (APMIS)* was advertising for an editorial assistant. As one door closes another door opens.

I got the job at *APMIS* because I had worked for the British Council – even if I had only been stamping library books, showing people round the language section, and handing out pamphlets on life in the UK. Character references were written on official notepaper. All that evidently did the trick.

The tasks at *APMIS* initially included correspondence and registration of manuscripts. Later I also found myself doing language revision, editing texts, and making contact with the editorial board, authors, and reviewers.

The next step was when I attended a meeting in Tunbridge Wells organised by the *European Association of Science Editors*. On my return, I gave the Editor-in-Chief a glowing report of the communication workshop held by John Kirkman. A quick phone call resulted in John holding courses for us throughout Scandinavia. The goal was to encourage promising young researchers to submit their articles to *APMIS*. The groundwork had been laid for a career in medical writing.

Finally, one day everything came together: native English language, a British degree and teaching qualifications, employment as a liberal studies lecturer in the UK, teaching in Denmark, experience at the British Council Library, an understanding of what it takes to get a manuscript published, and inside knowledge of the workings of an editorial office. A former member of *APMIS*'s editorial board was instrumental in setting up the first medical writing courses at the Faculty of Health and Medical Sciences, Copenhagen University. This adventure was followed by many other courses, presentations, seminars, and workshops here and at other hospitals and research institutes, both in Denmark and abroad. Along the way, my firm Medical Manuscripts was established.

The rest, as they say, is history.

It was a unique combination of circumstances that led me to work in the editorial office of a medical journal, which was the reason I joined EMWA.

Christine Møller, BA, Dip Ed
Christine is Assistant Editor of *APMIS Journal of Pathology, Microbiology and Immunology*. She is also director of Medical Manuscripts and teaches courses in medical writing for PhD students and others interested in improving their language and communication skills.

Career shifts – surviving a change in geography: From Poland to South Korea

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Abstract
This article provides an insight from a medical writer who, for family reasons, moved his freelance business from Poland to South Korea. The article discusses cultural differences between South Korea and Western countries and gives practical tips for continuing a medical writing career and building business relationships in a completely different cultural and geographic environment.

Three years ago, in December 2015, I moved from Poland to South Korea. And no, this was not migration for business purposes but 100% for family reasons. Naturally, my freelance business migrated with me to South Korea. From both organisational and legal perspectives, this was a smooth transition, but I must admit this was mostly thanks to my wife, who literally grabbed my hand and walked me through all procedures necessary to register my own business in Korea. Although I still maintain a portfolio of my Polish clients, I obviously also have started positioning myself in the Korean medical writing market. Below, are some my thoughts about this process.

Korean *savoir vivre* in meeting a new client

Let's begin with a hint of *savoir vivre*. Probably all of you know that in Asian countries you hand out and receive a business card with both hands and with appropriate esteem, so consider this just as a reminder. If the person you are meeting has travelled to Western countries or done business

with people from Europe or the United States, you may shake hands, but I rarely encounter people with such experience. Do not try to establish physical contact, as it may only lead to confusion. In South Korea, a bow is a customary greeting. Depending on the interlocutor's position in a social hierarchy (more about this below), this term may refer to a simple head-nod or to a respectful "belly-button" bow. Thus, not infrequently, the person to whom you offer your hand to shake may not know how to behave. I still sometimes forget this and try to shake hands with my Korean acquaintances. Then, some of them hold my hand till the end of our conversation or shake it every second sentence. Ah, and forget about tapping your Korean client's back, even if you are close with this person!

The older you are, the more you know

When you meet someone new in Korea, be prepared that one of the first questions he or she will ask is, "How old are you?" (in Korean: *Myeot sarieyo?*). Yes, in Korea age is not a taboo, but an inevitable determinant of your social position. The fact that your Korean interlocutor is older or younger than you will affect the politeness level of your conversation; obviously, this refers primarily to conversations in Korean, but you should also remember about it when you talk in English to a Korean person who is older than you (or is just your prospective client, regardless of age). Koreans' respect for older persons is commendable, especially considering its scarcity in Western communities. However, in Korea, age is also considered a measure of one's experience. This view, however, is not necessarily good from a business perspective. For a Korean customer, the grey hair of a potential service provider means as much (or even more) than a dozen of professional certificates! A young person, although extremely experienced and qualified, may not easily gain trust from a Korean customer simply for being too young.

Hierarchy above all

Aside from age, professional or scientific titles can help gain trust from potential clients. An owner of a single-person company who proudly lists "CEO" or "President" on a business card will likely not impress anyone in South Korea. However, the situation changes dramatically if you are a PhD holder or even better, a professor! In South Korea, professors are considered as flawless as the Pope (or even better, considering that approximately half of South Koreans are atheists), and I would not want to be in the shoes of a person who dares to say otherwise.

Let me share an experience from our own working group. A year ago, one local clinical research organisation (CRO) asked my wife and me to edit and submit a manuscript prepared by a group of Korean researchers. The paper was written in amendable English, and we had to rewrite it nearly from scratch. Then we had to wait approximately 3 months for the authors' response and eventually received the same version of the manuscript as before. It turned out that the main author of the paper was a famous Korean professor and no one at the CRO was brave enough to inform him that his writing had been criticised and revised considerably. Instead, after a long debate, they decided to submit the unchanged manuscript to another, less demanding journal.

Size of company, size of respect

In South Korea, you can exist as a freelancer or one-person company, but this is not as simple and obvious as in some other places, such as the United States. Whether you have "CEO" on your business card or you introduce yourself as a freelancer, before you sign any contract with a Korean client, you should be prepared for a set of detailed questions. How many employees do you have? What is the organisational structure of your company? How big is your office and where is it located? What was your company's revenue in the recent years? But usually, it is not enough to answer the questions – they will likely ask you for relevant documents and perhaps also request an audit. So, you better think in advance about the way you are going to position yourself in the local market. This trust in large market players seems to be a feature of all companies from East Asia. During one conference, I met a medical writer from the United Kingdom, who for years has maintained his business in China. Among many other interesting things, he told me that a common practice among freelancers working in China is to hire a group of persons to accompany them during business meetings as employees of their 'big' company. After hearing that, I even considered assigning such a role to my father-in-law, a noble Korean gentleman with an extremely serious facial expression … Just joking, I would never do this to him!

Communication (not necessarily bidirectional) is a key

When we, Europeans or Americans, think about e-mail correspondence, we usually imagine a series of short, sometimes meaningless, messages:

- "I am sending you the file and will wait for your feedback. Regards!"
- Response (3 to 5 minutes later): "Thank you. I received your document. I will get back to you in x days/months. Best wishes!"
- Response (2 to 3 minutes later): "Thank you for your confirmation. I look forward to hearing from you. Cheers!"

Do not expect such "serial" correspondence when sending an e-mail to your Korean client. Typically, you send the document to your client and … nothing happens. Does it mean there has been a problem? Absolutely not! Unless you received an error message, your e-mail has been properly delivered to the recipients. If you are lucky enough, one of multiple persons carbon copied in the message might be on holiday, so at least you will receive an auto-responder. But aside from this, do not expect any confirmatory or thank you message. The main recipient will get back to you when he or she has something

If you are open to new experiences, habits, and culture, immigration to a new country can be a great adventure and a next step to self-fulfilment.

meaningful to write about, for example, 3 months later when the feedback for your work is ready. But be careful! This does not work the opposite way – if your client has a question to you, you should respond immediately. There is a clear-cut line between service providers and service recipients in South Korea and contrary to your expectations, no horizontal partner relationship exists between these two entities.

Welcome back to school!

From time to time, I deliver lectures for my Korean clients. In Poland, I would prepare 15 PowerPoint slides for a 45-minute lecture, if requested, accompanied by some more detailed training materials as hard copy. Communication during my lectures used to be primarily verbal and based on multiple interactions with the participants. I was even taught not to prepare too many slides overloaded with information and text as it is the best way to torture (or put to sleep) your audience. But things are different in South Korea – everything you talk about during your lecture should be on your slides, and nothing that is on the slides should be left untold. If your client is willing to pay you for a 45-minute lecture, this means that you should deliver the knowledge to your audience in no less than 45 minutes. Forget about using anecdotes to draw the attention of your listeners, questions to your audience, brainstorming, etc. Welcome back to elementary school (at least the one I remember from my childhood)! I can partially understand this attitude if a lecture is delivered in English; under such circumstances, the audience are more likely to follow the speaker if they can see the whole contents of the presentation on the screen. However, I participated in some lectures delivered by Koreans for Koreans and things looked exactly the same.

Accepting cultural differences

Reading this text, you may be surprised to hear that I have stayed in South Korea. I must admit that the beginning was sometimes difficult, but now, after 3 years, I have adjusted well to South Korea as a place to work and live. Different, yes, but when we enter a new environment, we should not expect that it will be exactly the same as the previous one, or that we immediately will be recognised as a foreign celebrity and everybody will adjust to our habits and expectations. This sounds quite obvious and logical, doesn't it? But based on the information from various internet forums and social media groups for expatriates working in Korea, I know that still many foreigners who arrive here make such false assumptions. As a result, although they have been working and living in Korea, not for three but for a dozen of years, they have become increasingly estranged, forming their own national ghettos instead of integrating in the local community. Meanwhile, a key to survive in a new geographic environment is understanding the term *cultural difference*. Unless you do your best to understand and accept cultural differences, you will end like those people mentioned above – frustrated while believing in your own superiority and suffering from lack of acceptance and understanding. However, if you are open to new experiences, habits, and culture, immigration to a new country can be a great adventure and a next step to self-fulfilment.

Conflicts of interest

The author declares no conflicts of interest.

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Grant writing and editing

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Abstract

Grant writing and editing is a medical writing subspecialty of growing importance. This article describes the roles available for medical writers who specialise in grant proposals. It also offers seven grant-writing tips. Finally, the article provides links to information about key European funding agencies.

Are you a medical writer who likes leading-edge research and development? Do you have technical knowledge across multiple disciplines? If so, a role as a grant writer and editor may be for you. As the pressures on scientists increase worldwide, there is a need for medical writers skilled in the art of technical persuasion. Because medical writers typically pair with subject matter experts and other stakeholders, the medical writer must combine the arts of writing and editing to produce a competitive grant proposal in a deadline-focused environment. Therefore, I will use the term *grant writing* to describe both grant writing and editing in this article. The advice here is primarily aimed at medical writers who are new to grant writing, though the tips may also be useful to seasoned professionals.

The need for grant writers is increasing in Europe

Researchers in academia and industry increasingly rely on grant funding to move their work forward. One indication of an increasing need for grant writers in Europe comes from a recent interim evaluation of the Horizon 2020 project. This EU-funded innovation-centred project, which intends to deliver nearly €80 billion in funding between 2014 and 2020, is the largest EU research and innovation funding effort to date.[1] The programme covers a wide range of scientific and societal projects and is divided into three "pillars": Excellent Science, Industrial Leadership, and Societal Challenges. Between 2014 and 2016, 115,235 proposals were submitted with a success rate of 12.6%. Of the proposals rated "high quality", only a quarter were funded. Because delivering high quality science is not enough to reach the funding threshold in this competitive environment, there is an opportunity for skilled grant writers to add value by pairing with grant stakeholders.

There are also indications that organisations are seeking funding in new ways. In the Horizon 2020 report, 54% of the successful proposals were from newcomers who did not take part in the previous EU funding effort, known as

Framework Programme 7. Notably, 73% of these newcomers were private for-profit companies. Thus, there could be a large number of European organisations that are new to grant proposal writing and could benefit from partnerships with experienced grant writers.

The role of a grant writer

Where can you work?

As with many medical writing subspecialties, grant writers might work on a freelance or part-time basis or be on the full-time staff. A grant writer might partner with educational organisations, research organisations, non-profit companies, government offices, and for-profit companies. Some organisations will hire a medical writer with a bachelor's degree, but many will seek writers with advanced degrees in science or medicine. There is no accreditation specifically for grant writing, but many clients appreciate the following credentials, which show a commitment to medical writing and cover aspects of the grant-writing process:

- **Editor in the Life Sciences (ELS)** from the Board of Editors in the Life Sciences
- **Medical Writer Certified (MWC)** from the Medical Writing Certification Commission in collaboration with the American Medical Writers Association
- **Certified Medical Publication Professional (CMPP)** from the International Society for Medical Publication Professionals.

Why do they need a grant writer?

Many scientists are trained grant writers and love the process of describing their new ideas. However, some love the science but not the writing. Some struggle to communicate in English. Some have training in medicine or other professional specialties but are new to research. Some scientists are just too busy and need professional support. Furthermore, sometimes a large team will need someone to bridge gaps in communication and create a unified "voice" for the proposal. This is especially true for infrastructure proposals. Also, sometimes an administrator will be tasked with moving a proposal forward but will not have the time or expertise to make it happen. You can step in as a trained medical writer to fill these gaps and stimulate a productive research environment.

What will you do?

Grant writing is a broad topic and working with a small company can be very different from working on a multi-centre proposal within a large organisation. Also, each funder has a different set of requirements. That said, there are some overall themes in the job responsibilities. Key characteristics of an excellent grant writer include flexibility in collaboration, keen technical intuition, and exceptional time management skills.

Reviewers want you to deliver the right information density in the clearest possible way. If you do this, you will have their attention.

The responsibilities of a grant writer often include the following:

- Edit and reorganise information provided by the scientific and medical specialists
- Ensure that all aspects of the proposal conform to the funder's specifications
- Consult on content strategy
- Write introductory sections and summaries
- Double-check the data for accuracy and consistency
- Prepare certain tables and figures.

The grant writer may also take on related roles, including the following:

- Identify new funding opportunities
- Educate stakeholders on funding criteria and best practices
- Manage milestones during grant development (especially for large grants with multiple stakeholders)
- Coordinate with administrative teams, including regulatory affairs, contract management, and finance
- Develop responses to reviewers
- Communicate with the funding agency.

A grant writer must also maintain strict ethical guidelines. For funding proposals, this includes presenting information fairly and accurately (not "overselling") and avoiding plagiarism. It is also best to avoid the controversial practice of reusing text directly from the manuscripts and grant proposals of the grant stakeholders.[2] The grant writer should also provide expertise but not take on the role of the technical expert, which is the responsibility of the grant stakeholders. In addition, it is important for grant writers to avoid taking projects on commission, in which payment depends on the success of the proposal. Upfront payment ensures that the writer does not have financial incentives to overstep ethical boundaries. When high ethical standards are maintained, the medical writer can be a valuable and well-respected part of a research project.

Grant writing tips

A grant writer's main responsibility is crafting winning proposals. Although advice on grant writing can be found in multiple books and articles, much of the available advice is aimed at principal investigators rather than at medical writers.[3] To try to add a fresh perspective, I have tailored the advice here to medical writers in the biomedical domain. The common feature among these tips is that they are intended to help you craft a positive emotional experience for the reviewer, which can give you an edge when competing against other high-quality proposals.

1. Visualise the reader.

Most grant review tasks are unpaid and do not replace the primary work duties of the reviewers. So, as you imagine the reader, think of the highly intelligent scientist who is short-tempered at 11 pm rather than the highly intelligent scientist who is fresh and ready to tackle the day. That said, reviewers do not want you to omit information in the name of easy reading. They are technical experts, after all. Reviewers want you to deliver the right information density in the clearest possible way. If you do this, you will have their attention.

2. Use technical terminology.

Striking a balance between technical terminology and clear communication is essential for the art of grant writing. The common wisdom in medical writing is to avoid jargon. However, for grant proposals, it is essential to include the right field-specific terminology. Reviewers want to know that the research proposal is from a knowledgeable team. Furthermore, technical terms are often the most precise terms. If you are writing about an unfamiliar subfield, be sure to read key articles and educate yourself on the common terminology.

3. Use a formula for success.

It is tempting to write creatively to avoid boring the reader. However, this is almost always the wrong choice for competitive writing. If a

reviewer cannot easily find the information to compare multiple proposals, the score of your proposal will suffer. As such, it is helpful to follow a formula that guides the reader from the big picture to the details. Therefore, the introductory section of the proposal should answer the following questions, in order:

- What is the overall problem and what is the magnitude of this problem?
- What solutions have been tried and why did they fail?
- What new information/technology/strategy will be used to overcome these roadblocks?
- What are the team's credentials for working on this problem?
- What specific problem will be solved by this proposal?

4. Show, don't tell.

This technique from creative writing can also be applied to proposal writing. A grant proposal needs to accomplish many goals with a limited word count, and the medical writer is often asked to shorten long proposals. You can reduce the word count by showing the team's competence rather than asserting it. Examples include the following:

- Cite the methods used in prior work. This demonstrates that the proposed methods meet the standards of peer review and can also demonstrate the publication record of the team.
- Use workflow diagrams instead of text descriptions for complicated research designs or infrastructure programmes.
- Show the use of analytical methods (including statistics) in the preliminary data figures rather than describing the detailed analysis methods for each experiment.

5. Degrade gracefully.

This term is borrowed from computer network design. You have no control over how a reviewer interacts with the document. Ideally, the reader will start at the beginning and read all the way through. However, this ideal scenario does not happen often. Maybe they will get distracted and need to come back and find their place. Maybe they will skim the proposal first then read it more thoroughly. Maybe they will read the first page of all the grants, give the proposals a preliminary ranking, and then return to read the proposals individually. Maybe they will print the proposal on their black-and-white printer and read it on the train. Maybe they will become intrigued by something you wrote and search the internet for more information. Will they accidentally miss a section? Will they be annoyed if they cannot find where they left off? Here are some simple ideas for helping the proposal deliver the maximum value even if the reader does not read it sequentially.

- **Use informative subheadings.** For instance, "Protein X is overexpressed in breast cancer cells" is more informative than "Results from breast cancer cells". These subheadings can help the reader quickly scan for the key points.
- **Use typography to highlight key phrases.** Highlighting figure callouts and a few key phrases can break up large blocks of text and orient the reader.
- **Be sure the figures stand alone.** Some reviewers prefer to evaluate the data before reading the text. Using figure titles, informative legends within charts, and clear statistical notation can help the reviewer understand the data at a glance.

6. Give the story a heartbeat.

It is easy for a grant proposal to be too technical or too emotional. Once again, it is important to find a middle ground. This is why, even though most traditional advice suggests giving your story a heart, I suggest giving the story a "heartbeat". Appeals to emotion are important because the reviewer needs to know why this project is going to make a broad impact. However, they should be limited and backed up with technical information. For instance, stating "Disease X causes the hospitalisation or death of 300,000 children each year in Europe" is much more convincing to a funding agency than stating "Disease X kills children" or describing the story of an individual child.

7. Consider the details.

Annoying the reader can doom even the most technically compelling grants. Therefore, it is essential for the proposal to look professional and be inviting to read. It is much better to let the document "breathe" by allowing space between lines and sections than to include every possible word. Here is a brief checklist to help you avoid pitfalls in document design:

- Is the proposal within the page limit/word limit?
- Are the fonts and font sizes acceptable?
- Are the margins correct?
- Are the heading styles consistent?

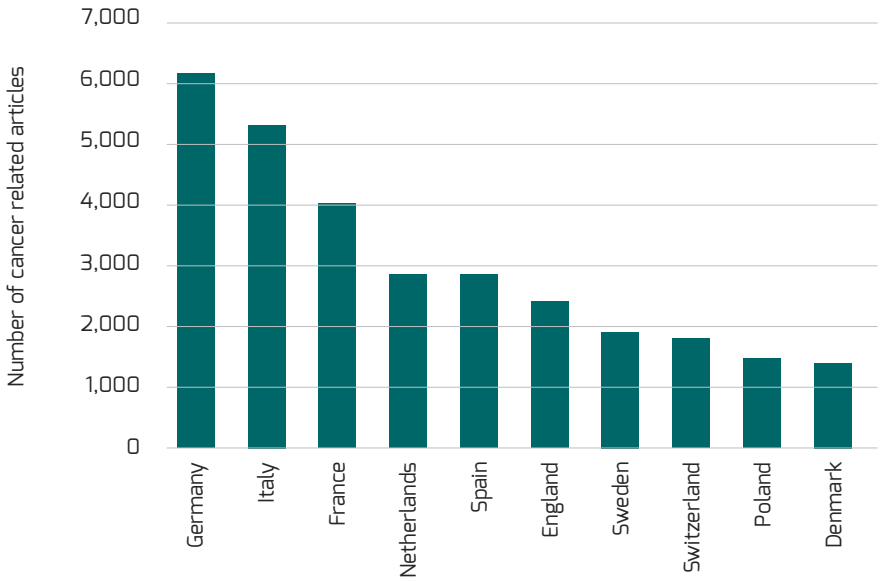

Figure 1. EU+associate countries with the largest number of cancer-related publications in the year 2017
This result is based on a bibliographic analysis of the Web of Science Core Collection (www.webofknowledge.com) Science Citation Index Expanded.

Table 1. Top funding organisations in EU+associate countries from a bibliographic analysis of cancer-related publications in the year 2017

Funding organisation	No of publications	URL
European Union	2098	https://europa.eu/youreurope/business/finance-funding/getting-funding/eu-funding-programmes/index_en.htm
German Research Foundation	1105	http://www.dfg.de/en/research_funding/index.html
Italian Association for Cancer Research	833	https://www.airc.it/english/what-we-do/how-we-support-research
Swedish Research Council	541	https://www.vr.se/english.html
Swedish Cancer Society	538	https://www.uicc.org/what-we-do/capacity-building/grants-and-fellowships
Cancer Research UK	446	https://www.cancerresearchuk.org/funding-for-researchers/our-funding-schemes
Carlos III Institute of Health (Spain)	353	http://www.eng.isciii.es/ISCIII/es/contenidos/fd-el-instituto/quienes-somos.shtml
Dutch Cancer Society	350	https://www.kwf.nl/english/Pages/Financing-research.aspx
Foundation for Science and Technology (Portugal)	336	https://www.fct.pt/apoios/
Swiss National Science Foundation	329	http://www.snf.ch/en/funding/Pages/default.aspx
Medical Research Council (UK)	258	https://mrc.ukri.org/funding/

- Are the figures legible at the current size?
- Are the figures legible for colour blind readers?
- Are the figures near the text that calls them?
- Have any editing marks and comments been removed?
- Are the references formatted correctly?

How do you find out more information?

To provide an overview of the major funding sources in Europe, I performed a bibliographic analysis using the Web of Science Core Collection (www.webofknowledge.com) Science Citation Index Expanded to find articles published in the year 2017 with the keyword "cancer". Cancer was chosen because it is an important global health problem and an active topic of research across Europe.[4] The article list was filtered to only include articles with at least one author from the 28 EU countries plus the 16 additional countries associated with Horizon 2020 (Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Macedonia, Moldova, Montenegro, Norway, Serbia, Switzerland, Tunisia, Turkey, and Ukraine). This set will be called the EU+associate countries. Figure 1 shows the 10 EU+associate countries with the largest number of publications in this filtered list of 28,944 articles. Of these articles, 20,099 contained information about funding sources. Table 1 shows the top funding agencies in EU+associate countries based on the number of publications, and it provides links to the agency funding websites. The EU was the primary funder, followed by national agencies. Other funders included for-profit companies, non-EU+associate country agencies such as the US National Institutes of Health, and many small funding organisations. This bibliographic approach could also be useful for evaluating candidate funding agencies in specialised subfields.

Author information

Nancy Linford, PhD, MWC, has been a medical writer since 2014. Before that, she was an academic scientist writing grants to fund her own research. She has worked on over 100 funding proposals, helping clients achieve millions of US dollars in funding.

Conflicts of interest

The author declares no conflicts of interest.

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1000 words in 1 picture: How I combine art and science in medical illustrations

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Abstract
Communication is as much verbal as it is visual. We tend to rely on technical texts for transmitting medical information, but sometimes an image may convey complex medical concepts in a simpler and shorter form. Medical illustration requires artistic skills and scientific knowledge, but the academic choices leading to this professional activity are limited. Here I describe how I gradually rediscovered my artistic side and welcomed it into my scientific background, exploring this exciting career path.

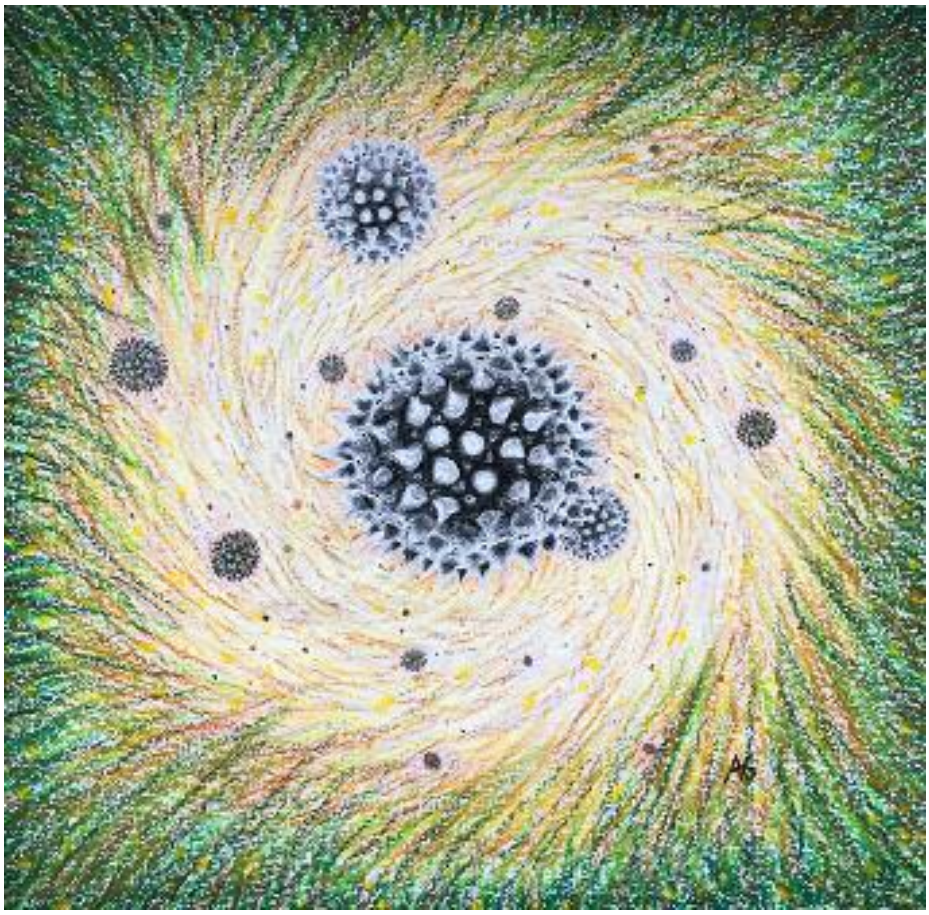

Figure 1. Hay Fever. Science-inspired painting. Mixed media.

When I was 15 years old, I had to decide which major field to study. I was generally a good student and had no major difficulties in any specific subject, although my favourite disciplines were arts and natural sciences. And, even though my arts teacher insisted that I should follow art, I easily opted for science. At that time, it was clear to me that I could make art a hobby.

I never had a scientific career path in mind. I took the biology course because I liked biology. I then took a research position in population genetics because I liked genetics. This position led me to apply for a PhD fellowship in the same topic even though a doctorate degree was not part of my plans. So, what does one do with a PhD in genetics? A postdoc, of course! And yet another one. During this time, I grew to like the topics I was researching. I particularly enjoyed working on forensic genetics and being involved in international societies. And although I never really enjoyed bench work, I liked analysing data and telling their stories. I liked writing and preparing posters and slides for presentations.

During all these years I never envisaged a possibility to professionally integrate art into my work. I was following a very typical scientific career path, which would lead me to a non-existing academic position at a university. In fact, the only two moments when I thought about this possibility were two intensive scientific illustration courses I took while still pursuing my biology degree. I also did not get to make art as a hobby as planned. During my PhD and postdoc years, my artistic side only rarely popped up when preparing slides or posters.

Academic career positions are scarce in Portugal, as generally in Europe, and after eight years of postdoc and having two children, I had to consider alternative career paths. I briefly tried working on genetic diagnostics until I decided that it was not making me happy or successful. I stopped for a year to try to find a job closer to home. During this year, I got more active online and maintained a blog about genetics for lay audiences. With more time on my hands, I began to draw and paint again and attended free workshops and other events on illustration. I did some science-inspired illustrations (Figure 1) and graphics explaining scientific concepts

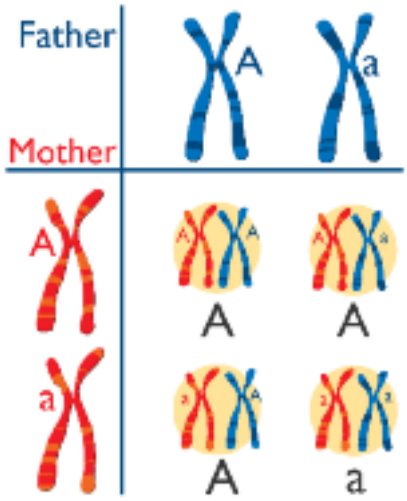

Figure 2. Graphic representation of dominant vs. recessive allele transmission. Digital illustration.

(Figure 2) for my blog and shared them on social networks. It was not until I accepted another research position in my hometown university that I got a request for illustration work.

My first true medical illustration project arrived through LinkedIn from a group of hospital clinicians leading an association for training in emergency medicine (POCUS Braga – AFEMED, Braga, Portugal). They had a set of slide deck presentations for workshops on point-of-care ultrasounds and needed a redesign including original illustrations. The first presentation was on deep vein thrombosis. My knowledge of thrombosis or ultrasounds was almost nil, so I did my homework. I learnt about these topics, did online searches, read books, examined pictures. I asked questions, and they gladly taught me how ultrasound can help diagnose deep vein thrombosis. I was even allowed to see one performed live, so I could understand how to distinguish arteries from veins in an ultrasound. I then created my illustrations using reference images, photos, ultrasound pictures, and my acquired knowledge. The result was a set of slides with a homogeneous design, handmade illustrations, and an overall clean look (Figure 3). This project was fun and allowed me to learn. It represented, for the first time, a possible alternative career doing what I love and using my scientific background.

As with medical writing, there is no academic degree specific to medical illustration. It requires skills from different fields. In fact, though divergent at first glance, these two activities have a lot in common, in particular, the main objective: to convey medical information in a clear (and appealing) way. Both require the ability to understand scientific concepts, an eye for detail, and communication skills. The main difference is the language: for writing, we need good English writing skills; for illustration, we need good drawing skills. They complement each other in transmitting information, and, sometimes, a picture may even be worth 1,000 words!

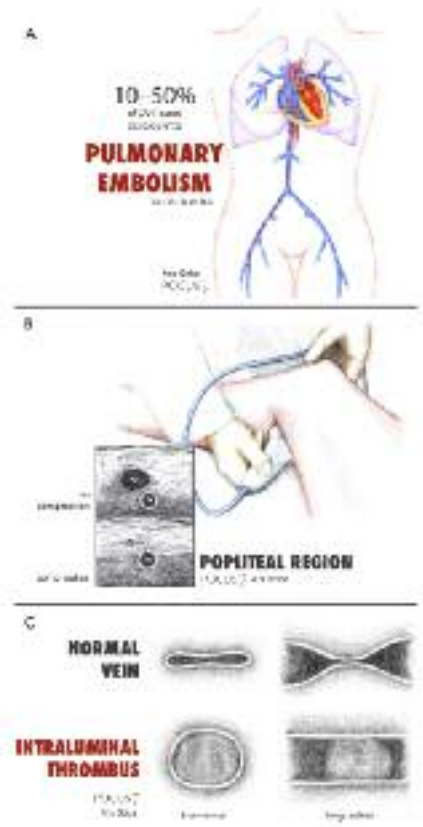

Figure 3. Deep vein thrombosis (DVT):
A. Consequence of DVT: pulmonary embolism.
B. Correct position to perform ultrasound for DVT diagnosis in the popliteal region and representation of ultrasound images.
C. Difference in ultrasound visualisation of normal vein and vein with intraluminal thrombosis. Medium: coloured pencils.

> I find myself using the same research strategies I used to write scientific papers.

My medical illustration work demands and reflects my scientific background. I also find myself using the same research strategies I used to write scientific papers. I look for reference images with the same critical view that I use to read scientific publications. I gather information from different sources and build the figures combining different references. When drawing, I try to achieve simple, yet scientifically correct images. Medical illustrations result from a scientific process. But for them to be visually appealing, I also search for literature and videos on design, illustration, drawing the human body and anatomy. And although some illustrations have limited artistic freedom, there is always room to input art into the process. Since I welcomed art back into my life, I began paying more attention to detail. I am more aware of light and shadows, alignments, and whitespace.

For the last year, I've been a researcher in a research institute connected to a medical school. I am helping develop a research line on population health. At the same time that I collaborate in projects on different health topics, I develop materials related to our new research line, which are used to summarise information or promote ongoing projects. These materials include graphical representations, slides, flyers, and texts. I also create medical illustrations for scientific papers, presentations, and posters. They may illustrate anatomic concepts, surgical procedures, or ultrasound interpretations. I have been able to network with different healthcare professionals and discover their communication needs. Through these experiences, I am finding that medical writing and illustration work synergistically in communicating healthcare messages. Luckily for me, they also work together to fulfil my needs for a career combining science and art.

Acknowledgements

I would like to thank Raquel Billiones for inviting me to share my work in this article and for editing the text. I also acknowledge AFEMED for the opportunity to illustrate the exciting project POCUS Braga.

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Ana Goios, PhD, has been a researcher at the Life and Health Sciences Research Institute for the past year. She also works as freelance medical writer and illustrator and embraces these activities in her research work, collaborating with other researchers, clinicians and institutions.

Medical writing at the management level – a rewarding career, but not for the faint-hearted

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Abstract
Discussion with writers from all walks of life and from across the globe has revealed that we have all come to our chosen career through different pathways. Furthermore, writer jobs are highly variable; two medical writers may have completely different roles and careers. Through a mixture of luck, both good and bad, I have taken the path of a medical writing manager. I have had the opportunity to work in pharmaceutical and device companies, one of the largest publishers in the world, several medical communications or medical education companies, as well as being a freelance writer. At every step along the way I have learnt so much, and can honestly say that each of these experiences has made me the manager that I am today. Herein, I describe parts of my journey, what I learnt, and what I believe are the attributes of a manager of medical writers.

My journey into medical writing

Starting out as a writer

Like most of us in our profession, I did not set out to become a medical writer. A year into my postdoctoral fellowship I came to the realisation that I could not stomach another 10 to 20 years of "paying my dues". So, I began to wonder, what do I do now? More importantly, after 9 years of university education, and almost 4 years as a postdoc, what was I qualified to do? Fortunately, I stumbled upon a website that would change my life and a medical writer was born …

My first suggestion to anyone out there considering a job as a medical writer – or any kind of job – is to never forget your network. In today's day and age, it's not *what* you know, but *who* you know. I landed my first job at one of the "Big Pharma" as a publications writer because my mother-in-law knew someone who happened to know a hiring manager. Do not assume your

network should be professional only – family, friends, or the butcher might know someone who could help get your foot into the right door.

Remember your network when searching for a job.

Pharma – a crash course in writing and an introduction to management

I loved my job in Big Pharma and I learnt so much from everyone around me. As a publications writer I worked directly with internal stakeholders such as statisticians, clinical monitors/directors, regulatory, legal, and marketing teams; and, external stakeholders such as steering committees and authors. I learnt about designing clinical trials, assessing the merits of investigator-initiated studies, and developing a publications strategy to meet regulatory and commercial needs. But perhaps most importantly, I learnt some of the skills needed to be a manager – both good and bad, and some that are better avoided.

I had a manager, but I also worked closely with other senior managers, giving me the opportunity to observe, learn, and experience. All the managers were smart, driven, and on top of their field, but each had a different style of managing their team. Some of the managers had a "directorial" style, which was like parents telling children what to do and admonishing them when they failed to live up to their expectations. In contrast, there were other managers who would set out the task, giving the employees a free hand to chart out their route. They would regularly meet with the employees to check on the progress and discuss the challenges and next steps. They would listen to the employees and ask them how they thought a given situation be handled and suggest a way for consideration by the employees. I learnt through these observations that it is important that managers connect with their employees, understand what may be challenging to the employees and help them meet the challenges by providing helpful advice and training if required. Managers should be facilitators for the employees to carry out their tasks and should not make the employees feel isolated or worst of all, below the mark.

Agency life – the grass might be greener on the other side?

A good manager will make you feel supported, empowered, and a valued member of the team.

My first job at an agency was the hardest year of my life. It was a small start-up and I gained my first taste of working for a cash-poor organisation. Like my role in pharma, I learnt a huge amount about medical writing. I also learnt about continuing medical education (CME), preparing commercial materials such as sales aids, booth materials, and product monographs, as well as, working in an agency setting. As exciting as this was, the workload was unbelievable, and my learning was "trial by fire".

Like all of us in the medical writing department, my manager was drowning in work. The managers were stretched so thin that they could not provide training or support, and most importantly were not able to provide a buffer between the "them" (clients and the account teams) and "us" (medical writers). Through this very stressful period, I learnt that a manager is responsible for the training of their staff, setting and reassessing their workload, and "protecting" them from clients and account teams. A manager may have to "stand-up" to the client or account team to ensure their team have the room to complete their work well. Lastly, I learnt that managers cannot be effective if they are carrying a full writing workload. Managing requires time and effort and needs to be recognised as a valuable task that delivers financial gains to the company.

Do not underestimate the value of a good manager.

Leaping into the unknown – managing a medical writing department and ultimately a medical education company

I joined the largest publisher of health science journals, another huge organisation with multiple divisions and levels of hierarchy. I started as a principal medical writer in a small "start-up" division and it soon became apparent that there was more work than a single writer could complete. There weren't resources to hire more staff, so we outsourced the work to freelancers. My role evolved to spending more time briefing freelance writers, reviewing their work, and reviewing their estimates against project revenues. As we moved solely into CME, an entirely grant-driven process, I learnt even more about pricing, estimating workload and resourcing, and identifying and delivering training to freelance writers.

About 4 years into my career at this organisation, I was asked to head-up the Office of CME. I jumped at the opportunity and spent the next 12 months leading a team of accomplished individuals to reorganise three separate divisions into a single business unit. What a learning experience! Who knew that there were so many financial and Human Resources hoops to jump through? I learnt about tax and capital expenditure and human resources implications. Most importantly I learnt how to diplomatically navigate a convoluted and hierarchical organisation. Additionally, I had the arduous task (along with my team) of educating and enforcing compliance with mandated guidelines across all divisions in a very large company with a global footprint. Sadly, the hardest managerial lesson I learnt was having to let staff go. Learning how to have a "tough" conversation is not easy for anyone, but it is an important skill that you unfortunately need to learn. Large organisations generally have a Human Resources manager who can (and should) be your key resource for learning these skills; while smaller organisations may want to consider Human Resources consultants for this role.

Change of pace

In 2010, I came to the realisation that although I loved my job and my career as a manager, it had come at a huge cost to my health and my family. I also missed my home and decided it was time to return to Australia. I freelanced for a bit before deciding to re-join agency life, at what was then, the premier medical communications company in, not only Australia, but also the Asia-Pacific region. I joined with some trepidation as this was a small, albeit well-established company and my previous experience with a small company had been less than pleasant. A few weeks after I joined, they merged with a large, global communications company, and the best of all worlds coalesced into one amazing organisation.

Tough conversations are part of being a good manager, but should not deter you from becoming a manager.

Although I originally joined as a medical writer and specifically informed the hiring manager that I did not want to be a line manager, 6 months after I joined, I was promoted to a manager. Unlike any other organisation that I had worked for, the first thing that happened was that I was sent on a 2-day leadership training course. How refreshing, the company wanted to ensure that I had the skills necessary to be a good manager (even though I had been a manager for some time). I have now been with this organisation for 5 years and I can say without a doubt that it is the best I have ever worked for. Although my job is no different from anywhere else I have worked, I feel very positive about my job and my career. It all comes down to my manager, their manager, and the senior management team. There is a culture of support and encouragement that permeates from the top down, and it is this culture that leads to an exceptionally high employee retention rate. Recent alignment across the company has ensured that all managers have received the same training and should all be managing in the same way. This organisation has recognised the value of good managers and has chosen to embrace this as company culture.

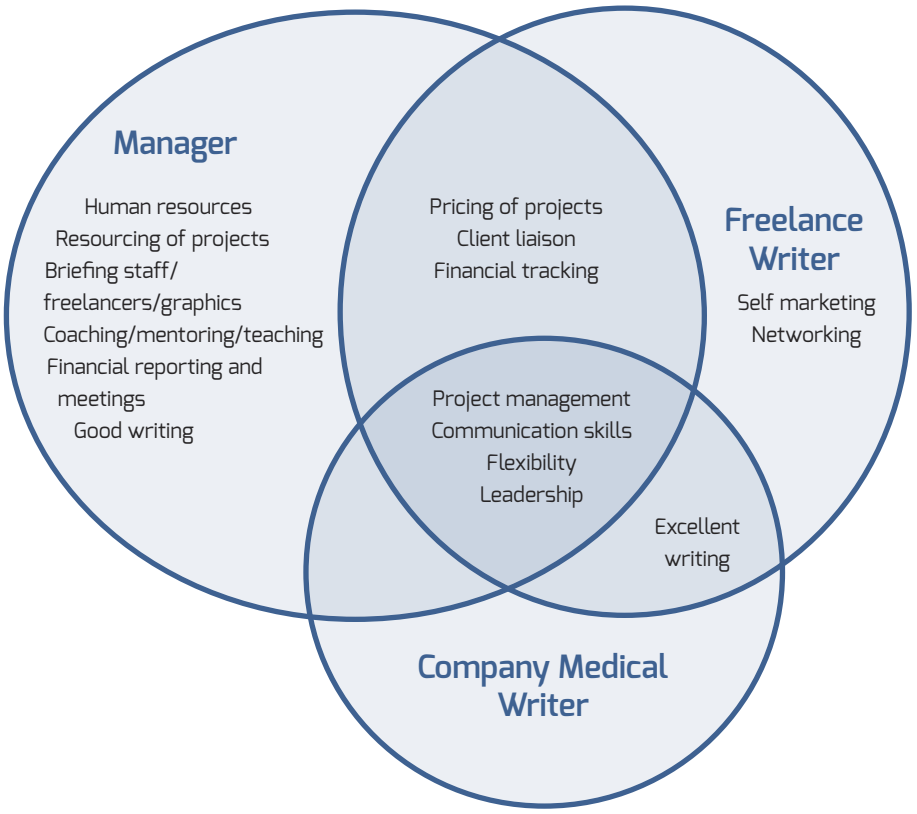

Figure 1. Shared and transferable tasks and skill of managers, freelance writers, and company writers

What does it take to become a good manager?

Like any skill, management can be learnt. As medical writers are adept at reading and assimilating information so that we can write about it. If one takes this approach to learning management skills, one can become a successful manager.

Throughout my career a lot of my management education came from watching and learning from others – both what to do and what not to do. For the most part that has worked; however, I have also attended no fewer than five different leadership training programmes. Some were useful, while others were not. The most recent training I received was one of the best. It made me realise that a manager's behaviour and style should be tailored to each individual staff member. I had to critically assess my personality as well the personalities of my staff in order provide them with the right type of management, relevant to that moment in their life. I am not going to get into "how" to manage, but I will say that there is value in attending the right management training programme and you may need to try several to find the right one for you. The ones I found most helpful involved "seeing" examples of the managerial behaviours and language that are appropriate to the situation.

> If you want to be a manager, start with identifying the training you need. If your organisation does not offer training, look to external organisations or companies.

What does a manager do and what skills do they need?

You may be asking yourself, how do I know if I am manager material? There's no single list outlining the skills or attributes of a good manager; however, I believe that there are skills that overlap or are transferable across individual writer types (Figure 1).

All writers and managers must have good project management and communication skills. The nature of our work also requires flexibility and an ability to quickly change direction, and we need to demonstrate leadership skills. I would also posit that freelance and company writers, if this is their chosen career, will be excellent writers, because anything less may lead to reduced business. But to be a manager, you do not have to be an excellent writer, you have to be able to recognise excellent writing.

> Leaders are people who create a vision of the future and who motivate and inspire others to engage with that vision in order to effectively deliver that vision.

Sometimes companies make the mistake of promoting their "excellent" writers into managerial roles, whereas other writers may be better suited or more interested in a managerial role. Management should not be viewed as a reward for good work, but instead an alternate career path. Freelancers and managers share the skills of pricing projects, client liaison, and financial tracking. That's not to say that company writers do not have these skills, but

depending on the size of the organisation, their exposure to these activities may be more limited. Lastly, there are many tasks and skills that fall to a manager. Some of these will have been learnt along the way as a writer, while others will require specific training. None of these are inherent qualities within a person and one should not assume that you cannot be a good manager just because you hate financial spreadsheets. You can learn to read them and understand what they mean. Managers are made, not born!

Conclusions

Management can be a very rewarding career for a medical writer. All it takes is a passion for seeing others succeed and grow into incredible people. Some days are hard and giving someone bad news about their performance is never easy, but if you are doing your job well, then the bad days are few and far between.

Acknowledgements

The author would like to thank all the managers, mentors, and Human Resources managers who have taught me what I know about leadership and management. You have made me a better manager.

Disclaimers

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

Conflicts of interest

The author declares no conflicts of interest.

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John Carpenter's story

Life after Medical Writing

Mark Twain once said that giving up smoking was easy – he'd done it dozens of times! I'm a bit like that as I've retired several times. The first time was in 1992, when I took early retirement from the University of Manchester. As a new pensioner, I went straight into a full-time job as a medical writer with a medical communications agency near Manchester. I stayed there happily until I was 'head-hunted' in 1999 and joined another medical communications agency just outside London. When this company reorganised in 2000, a number of us were made redundant – my second retirement. However, after a short pause, I was snapped up by an agency in central London. This odd post involved them paying me but not letting me do much. They too reorganised in 2001 and I was again in retirement. Then calls and e-mails started coming in from pharmaceutical companies and agencies asking me to give advice and help write documents. So I was now "unretired" – a freelance writer and medical communications consultant (grand title) with business cards and everything. I gradually began to switch my focus towards providing training, rather than doing the heavy lifting at the coal face of writing. As a founding member of EMWA, I had been running workshops at just about every conference forever. So I told everyone I intended to retire as an EMWA workshop leader when I turned 70 in 2013. But like Mark Twain's smoking, attending EMWA conferences and running workshops is a bit addictive, so I unretired again in 2013 and I'm still running EMWA workshops. And still doing training courses (mainly on medical/scientific writing) for groups outside EMWA. These help pay for my favourite toy (a sailplane) and holidays. I may well give it up again sometime. Who knows? But retire? I don't think I could.

John Carpenter
EMWA founder and EMWA workshop leader past, present, and future

Mark Twain once said that giving up smoking was easy – he'd done it dozens of times! I'm a bit like that as I've retired several times.

Thriving (and not just surviving) in a VUCA healthcare industry

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Abstract
VUCA stands for volatility, uncertainty, complexity, and ambiguity. The healthcare sector is considered a VUCA industry, constantly changing through rampant mergers and acquisitions, rapidly evolving regulations, and leading-edge innovations. So how does one build a career in this VUCA world? I share my career journey and the survival guide that helped me thrive and grow as a regulatory medical writer in the healthcare industry.

The VUCA healthcare industry

We are living in a VUCA (volatile, uncertain, complex, and ambiguous) world.[1] Volatility comes from constant and rapid change. Uncertainty comes with the unpredictable nature of modern life. Complexity is seen in the multiple interconnected confounding issues we are facing each day. And ambiguity is evident in today's mixed reality – a convergence of physical and virtual worlds.

The healthcare sector, especially, is a VUCA industry, being among the top industries most active in terms of mergers and acquisitions.[2] It is also one of the most highly regulated, the last 5 years having witnessed drastic regulatory changes, with more stringent requirements. Finally, it is also a hotbed of innovation, from clinicogenomics to surgical robotics, from advanced medicinal therapies to digital biomarkers.

In fact, the industry is witnessing seismic shifts as medicine gets more personalised, health data becomes highly valuable, and data sharing is made obligatory. Add to the mix the geo-political forces that could make the EMA relocate to Amsterdam or push clinical trial conduct towards China, and you have VUCAness probably at its ultimate.

So how does one cope, even thrive in such an environment?

In my 13+ years of experience as a regulatory medical writer, I have changed countries, shifted from an employee to a freelancer, then reverted back to being employed, and lived through four different mergers and acquisitions and six line managers within a single company. I took on challenges, grabbed opportunities, suffered setbacks – and bounced back. And through this rollercoaster ride, I slowly moved up the career ladder. Yet, never did I imagine that one day I would be leading a small medical writing team globally.

> VUCA stands for volatility, uncertainty, complexity, and ambiguity.

So please allow me to share my career journey (see sketch in Figure 1) and the survival guide that helped me advance my career in this environment.

1. Make it personal (even if it's virtual)

We frequently hear complaints that the virtual world is very impersonal and therefore does not foster team building, that one cannot build good working relationships with colleagues one only "e-meets" online.

I disagree. One can make things "personal" regardless of the physical distance. And distance shouldn't be used as an excuse for not building relationships and bridging gaps. In my previous contract research organisation (CRO) position, I was one of the very first Europeans to work on a US project back in 2012. In doing so, I inadvertently became a member of a global clinical team that met virtually on a weekly basis. It wasn't easy at the start. Technology was disruptive. Time differences were intrusive. But I then learned to appreciate the flexibility of being able to "meet" regularly without travelling. That virtual team was the big start

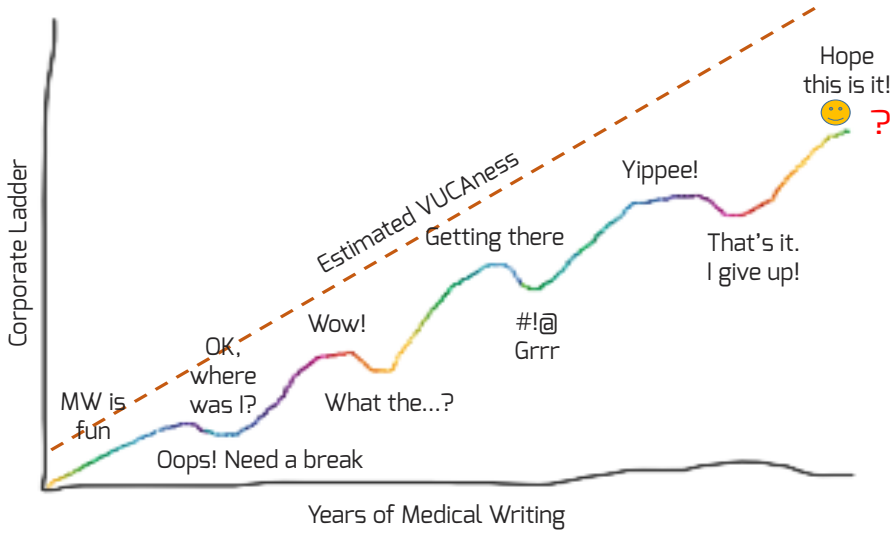

Figure 1. My career journey
The scales and data points are intentionally non-scientific.

for me. Many team members became good friends. I was already there before Webex and Skype became household names. Years later, when I changed companies, my virtual project manager in that team wrote "I will miss you. We may fill the slot but we can't replace you." We have never ever met in physical space.

2. Don't dwell in the past, look forward

Don't hark about what used to be. Look forward instead. Below are three statements I frequently hear that hold us back.

"The old system was better, faster." If this were the case, Apple wouldn't roll out new iPhone models each year to become the first trillion-dollar company. Upgrades and transitions are always a pain at the very beginning. It's like breaking in a new pair of shoes: you may experience initial discomfort, yes, but it is necessary unless you want to wear the same old pair in all the years to come.

"We've always done it this way." Maybe it's time to challenge the norm and think outside the box.

"It's a (regulatory) requirement." Regulations or guidelines? How many times do I have to remind people that ICH E3 is a guideline, not a straitjacket? And it's >20 years old."[4]

3. Foster the growth mindset

Stanford's Carol Dweck described two distinct mindsets – the fixed mindset and the growth mindset.[3] To thrive in a VUCA healthcare world, a growth mindset is needed. New regulations, new products, new paradigms, new technology – the growth mindset does not shy away from or get frustrated with these challenges.

I take the EMA Policy 0070 from my experience book. Following the 2014 EMWA symposium on public disclosure in Budapest, I had three choices:

1. bury my head in the sand and pretend it's not going to happen;
2. wait and see, then react, or
3. prepare for something that was inevitable.

I chose the third option and evaluated the risks for ongoing and upcoming projects. I did research, I discussed with colleagues, I strategised. And I spread the word within my company. The initial reaction among my work colleagues was scepticism: "The pharma industry will never allow this to happen."

But it did happen in October 2016 when EMA Policy 0070 version 1.0 was released. I was ready with a knowledge base, a plan, and an EMWA workshop. Overnight, I became the "disclosure expert" within my company.

4. Integrate, think "we", not "us" vs. "them"

Post-acquisition or post-merger, we tend to think in terms of "us" vs. "them". Those coming from a smaller company tend to view the bigger company as the aggressor. The sooner we switch our mindset to "we", the better. Forget about "legacy" projects. They are all OUR projects now.

Integration is about fitting in, not about giving in and compromising your values. You can integrate and still keep your principles intact. I found out over the years that the cultural divide is not just about geography, language, and ethnicity. Company culture counts a lot more, so if you make an effort at crossing that divide, you are already halfway there.

Meld personal goals with company goals. Believe in what you are doing and believe in the company you work for. If you don't, then you are in the wrong place, and an unhappy one at that. Aligning goals means working as a team even if the goalposts sometimes move.

I believe in what I do. My job is not just a source of income. It is part of who I am.

5. Welcome change, roll with the punches

Timelines shift, companies reorganise, products evolve, regulations change, and people come and go. And just when you think you have it figured out, the next big change happens.

Change is scary. But change is also necessary to correct mistakes and improve quality. In all this VUCAness, our jobs are changing around us. If we don't embrace change and change with our jobs, we will become irrelevant. As Charles Darwin highlighted over 100 years ago, "It is not the strongest of the species that survive, nor the most intelligent, but the ones most responsive to change."

So be agile and ready to change gears. Roll with the punches, then get up, roll up your sleeves, and get back to work. There are patients out there waiting for new treatments.

As a concrete example, with the new EU Medical Device Regulation (2017/745 MDR), we are witnessing a medical technology industry grappling with increased and rather unclear requirements. Many folks are crying "foul". At the 2018 EMWA symposium on medical devices, a wise colleague put all these in context with the statement: "It's all for patient safety." Another colleague of many years of experience remarked, "The MDR panic reminds me back when ICH E3 came into existence in the late 1990s. Everybody was worried and apprehensive." Today, the ICH E3 is so entrenched in the regulatory writer's psyche that one can't really imagine a world without it.

> "It is not the strongest of the species that survive, nor the most intelligent, but the ones most responsive to change."
>
> Charles Darwin

We can't go against the tide of regulatory changes. If we embrace it, we'll be happier for it.

6. Make technology your friend, make age an advantage

As artificial intelligence advances, we may fear for

our jobs. Will robots be writing our documents in the coming years? Maybe. Maybe not. But for now, I enjoy the free time I gain from using that robot lawn mower or that automated editing software. And in healthcare, like in many fields, I firmly believe that there is a need for human intervention and intelligence that no machine can truly provide.

The technological tools available for medical writers are staggering. We can't have them all, but I have chosen a core set of software I use to perform my work efficiently.

As parent to two teenagers, I am very aware of my limitations in adopting new technology. I have a lot to learn from the millennials. But I, too, have something they lack – the advantage of life and professional experience that age brings. I can use the technical savviness of the millennials in my group to complement my experience. Taken together, we make an awesome team.

> "The illiterate of the 21st century will not be those who cannot read or write, but those who cannot learn, unlearn, and relearn."
>
> Alvin Toeffler

7. Have a support group(s)

In the face of all this VUCAness, a support group is invaluable. This can be your family, your friends, or your colleagues. Do not underestimate the impact of a supportive spouse or partner in your life.

A kindred professional community is another great support. EMWA, AMWA, DIA, ISMPP – these are the circles where we share, discuss, learn, brainstorm, and come to grips with change. EMWA was the organisation that helped "make" me professionally, where I grew from a fledgling medical writer to a subject matter expert.

8. Take a (career) break when needed

This may sound counterintuitive, but there are situations wherein taking a break may actually be good for your career. When my family was young, I found the work-life balancing act quite exhausting. So I went for imbalance by design and worked freelance/part-time to focus on things that mattered the most at that time.[5,6] Years later, the scales were intentionally tipped to favour the career side. I could focus more on work, develop my skillset, and build up a career. Had I not stepped back from work at the right moment, I believe I would have burned out.

9. Manage with a heart, not with elbows

Never having gone through any formal management course, I was initially doubtful at how I would be at managing people or projects.

I never read the book *Nice Girls Don't Get the Corner Office*.[7] It's supposed to be a good read. But the title implies that in order to advance in your career, you have to elbow your way up and step on people's toes. I disagree. I learned that you don't need an MBA or a PMP after your name to be a good manager. What you need is good old common sense and human decency. Treat your direct reports the way you want your line manager to treat you. You don't need to forget your scruples to succeed.

10. Make mistakes, learn, unlearn, relearn, and forgive (yourself)

We are allowed to make mistakes. That's how we learn. Use each mistake for all it's worth – squeeze all the lessons you can get out of it. Traditionally, writers are the bastions of literacy. But as the futurist Alvin Toffler once stated "The illiterate of the 21st century will not be those who cannot read or write, but those who cannot learn, unlearn, and relearn."

So this VUCA world also needs us literary professionals not only to learn, but also unlearn and relearn.

Finally, also learn to forgive yourself. If you don't stop beating up yourself for each mistake, you'll never move on – or up.

The next adventure

When I started drafting this article, I didn't realise that the next opportunity was just around the corner. When this article gets published, I will have moved on to my next career adventure. I will have transitioned from a CRO to a big pharma, where I will be leading a small medical writing team in a therapeutic area I strongly believe in. At the time of writing, I am looking forward to the new challenges and exciting possibilities ahead. And my survival guide will surely come in handy.

Yes, it is a VUCA healthcare world out there. But it is also an industry of opportunities where one can be happy, grow, and thrive.

Acknowledgements

I would like to thank Laura B. Jaranilla for reviewing and editing this article. The article title was inspired by a presentation by Sarah Eckereder (https://www.bluedahliaconsulting.com).

Disclaimers

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

Conflicts of interest

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Elevate your medical writing team to success: Managing professional growth from internship to management

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Abstract

The opportunity for continual learning and development is one of the reasons many of us are attracted to, and remain in, the medical writing profession. A culture of learning is critical to instill ongoing development in any profession. For medical writers, it helps to maintain a broad perspective and adapt to the change that is a part of our industry. In this article, we describe our experiences in hiring, training, and developing medical writers at all levels, from internships through to mid-level career and into management.

A culture of learning is critical to a successful career in medical writing, and many medical writers cite the continual opportunities to expand their skills as one of the reasons they stay in the profession. The defined path for a learning culture (Figure 1) instills ongoing development and helps employees maintain a broad perspective and adapt to change. Line managers have the largest and most immediate influence and can leverage this by demonstrating a commitment to growth and encourage a safe environment for employees to ask questions and share ideas. Empowering employees and appointing stretch assignments expands their skillset and confidence. Support to achieve these goals creates trust within the organisation. In this article, we share our experience in hiring and onboarding, internship programmes, development of mid-level writers, and making the transition into medical writing management.

Laying the foundations: Recruitment and onboarding

To establish a culture that encourages employee growth, line managers need to make learning an expectation, not an option. This begins at the hiring stage, when candidates are evaluated not only for their knowledge, but for their initiative toward professional development. To handle the pressures of ever decreasing timelines and other project challenges, medical writers need to

Figure 1. Path of a learning culture

demonstrate resilience. Ideal candidates often describe their greatest challenges as their best learning experiences and have persevered and succeeded in times of change. Interviewers emphasise expectations for professional development, in addition to programmes and tools for support.

Capturing a new-hire's enthusiasm and engagement are key at the onboarding stage, so development tools and opportunities are introduced within the first weeks in the company. A new-hire mentor welcomes and assists employees in navigating department systems and processes. Writer skill standards, which were created to evaluate skill sets consistently within a job role and across levels (e.g., junior, senior, and principal writers), are introduced at this early stage. The DIA Medical Writing Competency Model (Clemow et al.,[1,2]) was used to develop these standards that also align to job descriptions, and designate expected competencies per level: writing, functional (project management), leadership (team management, process), and other (technical, editing and language). Previous professional experience is included as part of the evaluation. Skill standards are likewise used to determine and justify promotion readiness.

Internship programmes

The demand for medical writers continues to increase, and a well-run intern programme can ensure organisations have the means to develop a talent pipeline. Experiential learning, such as internship programmes, provides entry-level job aspirants with practical experience, priming them to efficiently and effectively enter the workforce. In combination with other training and support, the programme fulfils the "3Es of learning" – Experience, Exposure, and Education – as guidance to develop professional goals (Figure 2).

Carefully designed internship programmes benefit organisations in the following ways:

Efficient and cost-effective recruitment strategy:

- Performance of interns can be evaluated before offering permanent positions.
- Considerably less time to hire compared to experienced staff.

Faster growth and employee retention:

- With a defined learning programme, interns develop faster, with learning curves shorter than external entry-level hires who are immediately immersed in project work.
- Tailor-made programmes and incentives for interns lead to increased motivation and engagement, resulting in long-term retention.

Succession planning:

- With a faster learning curve, interns quickly take on straightforward writing tasks, which open capacity at higher levels, allowing senior writers to focus on advanced and complex work.
- Line managers and senior staff advance their career development with mentoring/coaching responsibility for interns.

Setting up an entry-level internship programme

A successful internship programme requires commitment from the employer to ensure interns attain a meaningful experience, benefitting all parties. A crucial first step is to clearly define the programme objectives, how the programme will benefit the organisation, and details on how to meet the desired outcomes.

The hiring process should be as rigorous as those employed for permanent hires, including interviews, administration of competency tests, behavioural interview techniques, and other recruitment strategies that will allow the organisation to target the right talent and "fit" within the department and company. A job description explicitly defining the desired academic qualifications as well as job roles, responsibilities, and expectations should be developed.

The curriculum should be targeted to connect people from different backgrounds and build a cohesive group. Interns hired out of universities will be unfamiliar with working in a corporate environment and with the basic principles of clinical research and medical writing; therefore, standardised structured training on these topics, including orientation to the organisational culture, should be provided. Practice exercises, job shadowing, and periodic assessments will measure progress. Trainers, coaches, mentors, and managers play important roles in orienting interns to the organisational culture, customising learning objectives, assigning job-shadowing exercises, and giving constructive performance feedback as well as eliciting feedback from interns.

An effective training strategy will entail:

- **Clarity of purpose** – Rationale for the course, target group, aims and objectives, desired learning outcomes, process plan, responsibilities, piloting and testing, and evaluation.
- **Defined lesson plans** – To assess knowledge gaps and define the training goals.
- **Adaptive and/or customised training** – Assign suitable trainers with different skillsets and expertise, relevant training materials (presentations and lesson plans), and carefully planned training logistics.
- **Consistency of approach** – All trainers follow the same principles, periodic status checks ensure progress stays on track, and full commitment is expected from all stakeholders.
- **Continuous feedback loop** – All (positive/negative) feedback from new hires is incorporated in real time to improve the curriculum and training methodology.

Structured, responsive, and flexible teaching

To expedite intern development, classroom training plays a role, alongside practical learning. Ensure each lesson has its own path with room for flexibility, and share with other trainers, mentors, or coaches to gain feedback. Use a lesson plan template or create your own. Putting the plan in writing allows you to spot flaws or omissions compared to the overall training strategy. Sharing these plans with others reveals how they can reinforce your lessons. Lesson plans may need to be altered when taking varied trainee development needs into account. Remain flexible in the event that a lesson deviates from a planned route; in fact, such instances are a form of feedback and signal a need for a plan to be updated. It also indicates that trainees are engaged.

Watch and listen to your trainees to identify

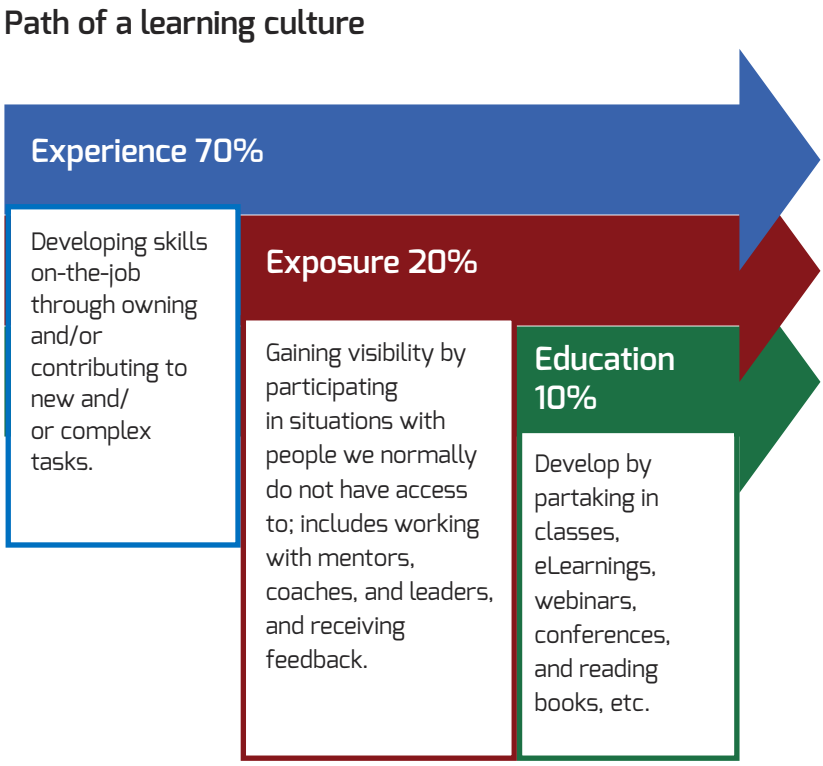

Figure 2. The 3Es of learning: experience, exposure, and education

what works for them. To start, ensure that each lesson is planned around the principle 'tell them what you are going to tell them, tell them, then tell them what you have told them'. When lessons have periods of interactivity mixed in with more traditional didactic blocks, a trainer can make the same point in different ways to reinforce the core objective, plus keep it fun and well-paced at the same time. In fact, fun can be a useful tool, not only to engage the trainees but also to keep them learning and foster team spirit. Consider starting each lesson with an activity or game that relates to a previous lesson: group trainees into teams and make such starting activities or games loosely competitive by keeping score. A prize for the winners at the end of the course is motivating.

Onboarding/offboarding interns

The decision to hire or release an individual at the end of the internship should be made following in-depth performance assessments; 360-degree feedback is particularly useful. Onboarding checklists ensure a consistent, targeted approach to integration and adaptation into the organisation. Interns transitioning into an entry-level writer position may be assessed for production-readiness before being allocated live project work. To keep them engaged with a steady and manageable workload, assign live work in an incremental manner and set clear expectations around the regular job duties.

Offboarding should be done in a carefully considered and sensitive manner. Give the interns open and direct feedback on their development and ask for their feedback on the programme; exit interviews should be conducted whenever possible. Interns should leave the organisation with a positive impression.

From entry-level to experienced writer

As described above, plenty of attention is devoted to employees at the beginning of their careers. However, it is important to pay attention to the majority of employees who are in mid-career; this is when job satisfaction often diminishes and engagement wanes. Feeling overlooked or forgotten can be the final push for individuals who feel they have given their best efforts to a company and now desire a change in roles or locations or need a new challenge to jumpstart motivation. Development plans, line manager support, and information sharing amongst the writing group maintain employee progression and momentum.

An individual development plan that outlines short- (1 year), mid- (2-4 years), and long-term (5+ years) development goals allows for transparent career path conversations with line managers. Using templates and a guide for self-assessment, preparation, and evaluation, the plan maintains a structured and consistent approach, while the development path itself can be flexible. The plan is owned and updated by the employee, who can make changes as needs and aspirations evolve, and new opportunities arise. The individual development plan can be reviewed regularly (i.e., quarterly, with an employee's line manager, who can identify opportunities for development goals).

For writers who want to remain in their current roles but acquire new skills, a writer mentoring programme can be useful as it focuses on targeted development (i.e., honing document development or project management skills). A mentor from another department or region may be identified to help a writer acquire skills that go beyond the writing role. As project management and leadership skills play a larger role for senior-level writers, soft skills training (i.e., managing challenging circumstances or teams, negotiating, influencing without formal authority, cross-cultural training) is offered and is available as needed. A forum for the global writing team to share expertise and discuss the lessons learned not only expands group knowledge but gives writers the opportunity to develop presentation skills and gain recognition as a subject matter expert. These activities instil confidence in writers to lead project teams, provide meaningful contributions to the writing team, cultivate autonomy and, importantly, maintain engagement.

Transition to management

Writer development plans address the transition of senior writers into operational leadership or management roles. Those who do not wish to become a manager may pursue a technical expert track, such as principal medical writer. For those who are willing to take the leap into management, the move from writer to manager can be a smooth transition with the right tools and support. Expectations may include a mixed bag of positives (new challenges, opportunities to make a meaningful difference, increased exposure)

and anxieties, centred around new people-management responsibilities, the perceived need to "know it all" to lead others, and managing former peers, to name a few.

Development tools similar to those for writers can be created for managers to facilitate the transition. Management aspirations are often identified at individual development plan discussions. An employee can evaluate his or her skill set against the job description and manager skill standards to identify competency gaps. Skills that make one a good medical writer are not necessarily the skills required at the managerial level; coaching skills, building a team culture, providing feedback, managing conflicts, and influencing others are key management competencies that may not have been essential in the past. The writer and line manager may discuss an action plan to close such gaps and determine a realistic timeline for the transition. A manager mentoring programme supports new or established managers on topics including delegation, giving feedback, managing across regions/cultures, and other leadership skills. Company-sponsored managerial effectiveness training educates novice managers on topics such as developing and managing a high-performing team, proactive problem solving, behavioural-based interviewing, and change management.

While these tools present management expectations, once in the role, new managers will undoubtedly experience a change from being experienced individual contributors having considerable control over their work, to delegating and managing others' work for which they have ultimate responsibility. Trust and relationship-building skills are essential for success. If managing former peers, an individual may soon find that not everyone is necessarily on his or her side. This shift in mindset may come as a surprise, and this is where a mentor or trusted adviser can help. An environment of open communication, where employees are encouraged to contact each other with questions or share lessons learned, further instils a learning culture. Managers can do the same, by sharing people management ideas or concerns (while maintaining employee confidentiality) and openly discussing leadership styles and techniques.

Concluding remarks

Targeted hiring, internship programmes, mid-career development plans, and tools to support the transition to management all foster the culture of continual learning that is essential to success in medical writing. Furthermore, the human element must reinforce the development philosophy. A reliable, supportive network within the department and company with transparency and open dialogue are essential. Line managers who develop trust and a strong working relationship with their writers are able to openly discuss the necessary skills and experience to progress to the next level and effectively plan for career progression. Development programmes should also incorporate the flexibility to allow individuals to explore new opportunities in a "forgiving" environment where mistakes can be made to broaden their knowledge base. In this type of environment, employees are encouraged to thrive and develop beyond their expectations.

Targeted hiring, internship programmes, mid-career development plans, and tools to support the transition to management all foster the culture of continual learning that is essential to success in medical writing.

Disclaimers

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

Conflicts of interest

The authors are employed by PAREXEL International Ltd.

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Clinical trial disclosure landscape and awareness in Japan

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Abstract
While disclosure of individual clinical study reports (CSRs) is becoming common globally, this is not yet the case in Japan, where the national health authority does not require CSRs to be made publicly available. As CSRs of Japanese studies might be used for marketing applications in other countries and regions, Japanese pharmaceutical companies that would like to expand their market internationally need to prepare CSRs that can be used for global applications and disclosure. In this article, we introduce the current situation in Japan regarding disclosure of clinical study data.

A snapshot of disclosure of individual clinical study results in Japan

In Japan, disclosure of individual CSRs is not required by the national health authority, the Pharmaceuticals and Medical Devices Agency (PMDA). However, individual study results are disclosed in other documents that the PMDA makes available. Other means by which study results are made publicly accessible in Japan include clinical trial registries, publications, and websites of pharmaceutical companies.

In Japan, disclosure of individual CSRs is not required by the national health authority, the Pharmaceuticals and Medical Devices Agency

Disclosure on the PMDA website

For a Japanese New Drug Application (NDA), Module 2 (including overviews and summaries) and a part of Module 1 of the Common Technical Document (CTD), as well as the PMDA's review reports, are disclosed on the PMDA website after approval (http://www.pmda.go.jp/PmdaSearch/iyakuSearch/, Japanese language only). As CSRs are located in CTD Module 5, they are not disclosed. The disclosure of documents related to NDAs in Japan is based on the Act on Access to Information Held by Administrative Organs (Act No. 42 of 1999).[1] Under this law, summaries of the PMDA's review tasks related to an NDA are disclosed to the public in order to demonstrate that the approval of the new drug was based on an appropriate evaluation of its effectiveness, safety, and quality of composition.[2]

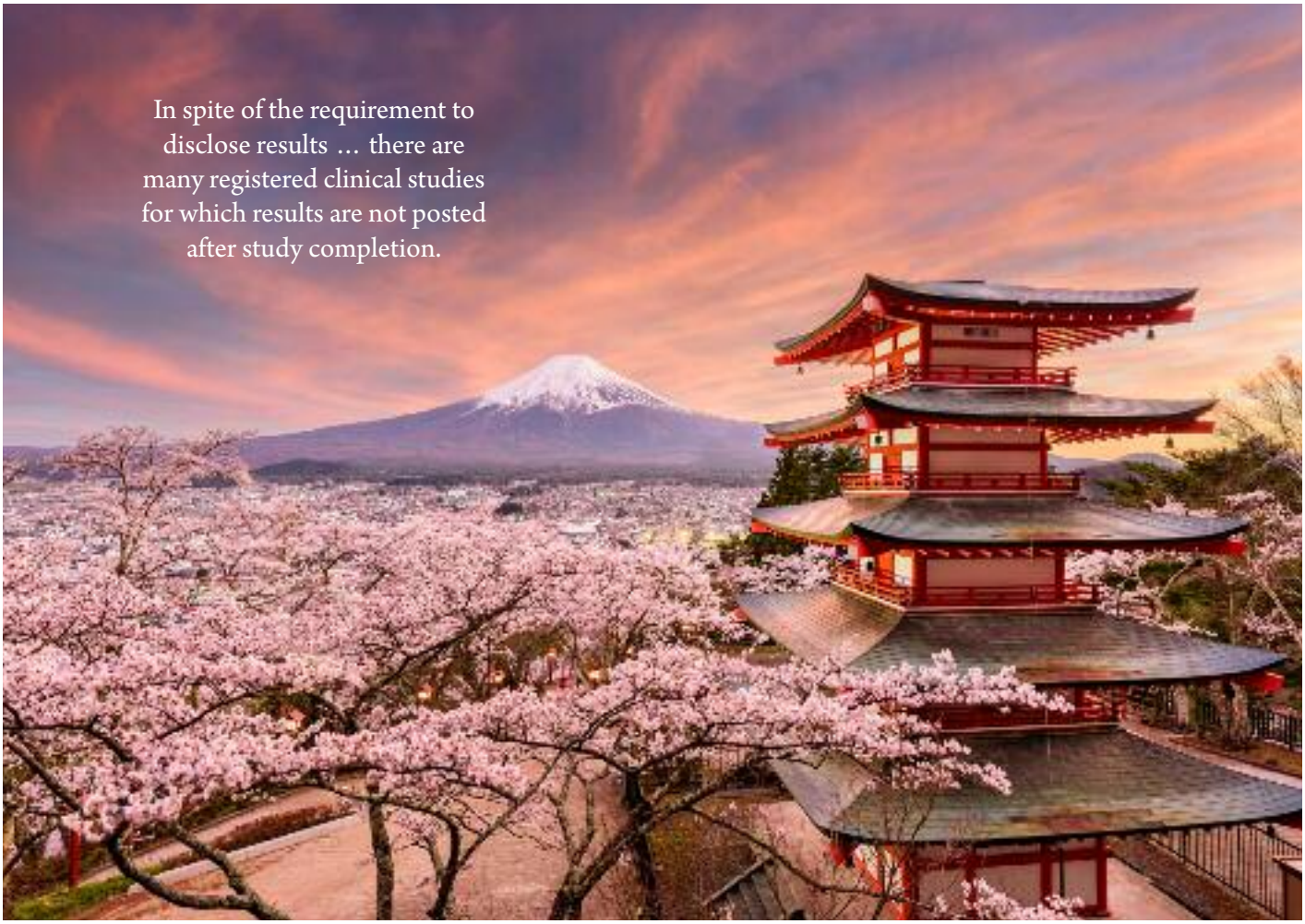
All the disclosed information is prepared in Japanese, with few exceptions. In the disclosed Module 2 of the CTD, the results of individual studies are available, in Japanese, in Modules 2.5 (Clinical Overview), 2.7.3 (Summary of Clinical Efficacy), and 2.7.4 (Summary of Clinical Safety). In addition, Module 2.7.6 (Synopses of Individual Studies) of Japanese NDAs includes more data than the standard ICH E3 synopsis in order to comply with the PMDA's preferences. For Supplemental New Drug Applications (sNDAs), which are filed to update parts of a prior application (e.g., to add a new indication), only the PMDA's review reports are disclosed. This means that the results of clinical studies that support approval of an sNDA are not disclosed, except as summarised in the PMDA's review reports.

Before disclosure on its website, the PMDA asks sponsors to prepare redacted/masked versions of CTD documents and the PMDA's review reports. Sponsors have to show which parts they would like to mask and the reasons (protected personal data or commercially confidential information [CCI]).[3] However, the PMDA may not accept all proposed masking, often disagreeing with the sponsor on what they consider to be CCI.

Disclosure in a clinical trial registry

After three clinical trial registries were jointly named the Japan Primary Registries Network (JPRN) in 2008, registration of clinical studies conducted in Japan increased sharply, with a more than five-fold increase in registrations per year by 2013.[4] This increase occurred after registration before study start became generally required by scientific journals as a prerequisite for publication of results. Another factor in this increase was the added requirement to register interventional trials after a 2008 update (enacted in 2009) of the ethical guidelines for clinical research in Japan by the Ministry of Health, Labour and Welfare.[5] These guidelines were superseded in 2014 by the Ethical Guidelines for Medical and Health Research Involving Human Subjects,[6] which require registration of interventional studies in one of three Japanese registries. Study registration information in Japanese and English is required; the latter may be in an English language registry. As more global and fewer local studies are run in Japan, the proportion of studies registered in ClinicalTrials. gov may increase.

For registered clinical studies, summary results are available in Japanese and English from JPRN registries: Japan Pharmaceutical Information Center Clinical Trial Information (JAPIC CTI, http://www.clinicaltrials.jp/user/ctrSearch_e.jsp), University Hospital Medical Information (UMIN, https://www.umin.ac.jp/ctr/), and Japan Medical Association Center for Clinical Trials (JMACCT, http://www.jmacct.med.or.jp/en/what-we-do/registry.html). English summaries of results may also be provided elsewhere (e.g., ClinicalTrials.gov). Limited data are generally disclosed in registries, including results for the primary endpoint and perhaps the main secondary endpoints. The format of disclosed results is as a brief synoptic summary in JAPIC CTI, the Japanese registry where most industry-sponsored studies are registered. When they are disclosed, study results on UMIN and JMACCT are most often provided as a link to a publication; alternatively, small text-box summaries without tables or figures are posted. In spite of the requirement to disclose results, as described above, there are many registered clinical studies for which results are not posted after study completion.[6]



Disclosure as a publication

Publication of clinical trial results as journal articles has become common globally. However, the publication rate is still low for registered studies.[7] This is also true in Japan. Of over 3,000 studies registered during the first 5 years in UMIN, results were published for only 10%.[8] In a survey of 179 lung cancer studies registered in UMIN, results for approximately half were published, and results were more likely to be published if positive.[9] Results of local studies in Japanese patients are sometimes published in Japanese language journals to inform local healthcare professionals of evidence relevant to the treatment of Japanese patients. The emerging trend towards inclusion of plain language summaries to accompany publications or abstracts to inform lay people has not yet caught on in Japan.

Principles for responsible clinical trial data sharing

Some large pharmaceutical companies have developed their own Japanese websites for posting their clinical study data. The disclosed documents are usually a "public disclosure synopsis" created for the general public, rather than a full CSR. Alternatively, links to clinical trial registration sites are provided. The documents posted on the company websites are usually in English.

In January 2018, member companies of the Japan Pharmaceutical Manufacturers Association (JPMA), which is a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), committed to clinical trial data sharing based on the "IFPMA Principles for Responsible Clinical Trial Data Sharing" (http://www.jpma.or.jp/about/basis/rinsyo/policy18.html). It is expected that this policy will promote data sharing by all companies. It includes the following five commitments:

1. Enhancing data sharing with researchers,
2. Enhancing public access to clinical study information (after approval of a medicine or a new indication),
3. Sharing results with patients who participate in clinical trials,
4. Certifying procedures for sharing clinical trial information, and
5. Reaffirming commitments to publish clinical trial results.

Many investigators, health care professionals, and patients who participate in clinical trials believe that sharing data from individual clinical trials might help inform other patients with the same diseases and those who treat them; however, in Japan, the study data are mainly used in NDA dossiers and not otherwise utilised. As Module 5 of the CTD is not disclosed, availability of detailed study information is

limited, especially in regard to study conduct, statistical analysis methods, and results of secondary or exploratory endpoints typically only described in CSRs. And yet this information could be helpful in guiding further research and in clinical practice.

Influence of the approach to CTD content on CSRs used for Japanese NDAs

The approach in Japan regarding CTD clinical content differs from that in other countries in that greater emphasis and focus is placed on the summarised data in Module 2 than on the CSRs. As a result, a more streamlined approach is taken in developing CSRs for NDAs in Japan, to allow deployment of more resources and effort for Module 2.

CTD preparation strategy: Robust Module 2 and concise CSRs

The CTD designates a common format for an NDA, with CSRs in Module 5; however, the way in which they should be written and the content that should be described depends on the country and/or region. As noted above, for Japanese NDAs CTD Module 2 must be prepared in Japanese, except for tables and figures, which may be prepared in English. The PMDA does not simply accept a direct translation of Module 2 documents prepared in English that were submitted to agencies in the US or EU (i.e., the FDA or EMA). As the PMDA seems to place emphasis on Module 2 in NDAs prepared using a Japanese language structure and logic, Module 2 is the established place in a Japanese NDA where claims are developed based on the risks and benefits of the drug. On the other hand, English is acceptable for Module 5. Therefore, most Japanese pharmaceutical companies that develop their product worldwide prepare CSRs in English in the same way as global companies do, even if the clinical studies are conducted only in Japan. Because of the emphasis on discussion of results in Module 2 of a Japanese NDA, the CSR for Japanese studies has become more concise, especially the discussion section, with a focus on quick and accurate preparation.

Presentation of individual clinical study results in Module 2

CTD Module 2.7.6 in Japan tends to be much more comprehensive than a standard ICH E3 CSR synopsis, often being 50 pages and sometimes more than 100 pages per study. In addition, an administrative notice, "Format for Preparing the Common Technical Document for Submission of New Drug Applications to Reduce Total Review Time", issued in 2011,[10] clarified that the safety data from individual clinical studies is to be presented in Modules 2.7.4 and 2.7.6. Therefore, there is a tendency to prepare the CSR synopsis in a way that facilitates efficient CTD preparation, for example by including enough information or data to meet the PMDA's requirements for Module 2.7.6, especially when CSRs are prepared in Japanese.

Importance of preparing a CSR to meet global requirements

Since there is no requirement to disclose CSRs in Japan, the interest of pharmaceutical companies is focused on preparing what is necessary or sufficient, and to reduce effort for CSR preparation. In global companies, local studies conducted only in Japan are becoming less common. In addition, because English is acceptable for CSRs in Module 5 of Japanese NDAs, pharmaceutical companies typically select English as the language for CSRs of Japanese clinical studies so as to avoid preparing CSRs in two languages should they be used for marketing applications in other countries or regions. As they are generally prepared in English, it would be productive if CSRs were written by native writers of English. Opportunities for Japanese writers to prepare CSRs have been decreasing, and writers seem to be less interested in CSRs and the changes in circumstances surrounding CSRs. However, Japanese pharmaceutical companies that would like to expand internationally need their writers to prepare CSRs that can be used for global applications and disclosure. CORE (Clarity and Openness in Reporting: E3-based) Reference (http://www.core-reference.org/)[11] is a useful tool that can be used by Japanese writers in preparing CSRs for global use; it provides timely information on the global environment surrounding CSR preparation, with consideration for disclosure after marketing approval. However, survey responses from 25 JPMA companies in 2016 showed that none were using CORE Reference and 72% were not at all familiar with it, although all expressed interest in learning about it.[12]

Conclusions

It seems certain that the number of CSRs for Japanese studies that are publicly disclosed is increasing, due to the fact that CSRs are often used for applications in multiple countries and regions. Other types of clinical study data disclosure, such as clinical trial registration websites and publications, are also currently promoted in Japan. However, the possibility remains that some clinical study data may remain undisclosed, perhaps in cases of clinical studies which were not used for an NDA and drugs for which marketing approval was not obtained or clinical development was terminated. We hope that disclosure of clinical trial data will be promoted in Japan, to fulfil an ethical commitment to patients and researchers and to promote advances in medical treatment.

Acknowledgements

The authors would like to thank Dr Linda Donnini (ProScribe Medical Affairs, Envision Pharma Group, Australia) for critical review and editing.

Disclaimers

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

Conflicts of interest

The authors are employed by ProScribe Medical Affairs, Envision Pharma Group, which provides medical writing services to client companies in Japan and other countries.

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News from the EMA

The articles included in this section are a selection from the European Medicines Agency (EMA)'s News and Press Releases archive from October 2018 to December 2018. More information can be found on the Agency's website: www.ema.europa.eu

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Restrictions on the use of fluoroquinolone and quinolone antibiotics recommended

October 5, 2018 and November 16, 2018 – Fluoroquinolones and quinolones are a class of broad-spectrum antibiotics that are active against bacteria of both Gram-negative and Gram-positive classes. EMA's Pharmacovigilance Risk Assessment Committee (PRAC) reviewed the disabling and potentially permanent side effects with these medicines given by mouth, injection or inhalation. and recommended restricting their use. The review incorporated the views of patients, healthcare professionals and academics presented at EMA's public hearing on fluoroquinolone and quinolone antibiotics in June 2018.

The serious side effects reported with fluoroquinolones and quinolones include inflamed or torn tendon, muscle pain or weakness, and joint pain or swelling; walking difficulty, feeling pins and needles, burning pain, tiredness, depression, problems with memory, sleeping, vision and hearing, and altered taste and smell. Tendon swelling and injury may occur within 2 days of starting treatment with a fluoroquinolone or may even occur several months after stopping treatment.

The PRAC review covered the following fluoroquinolone antibiotics: ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin and rufloxacin; and quinolone antibiotics: cinoxacin, nalidixic acid, pipemidic acid.

The PRAC recommended that some of the medicines, including all those that contain a quinolone antibiotic, should be removed from the market. This is because they are authorised only for infections that should no longer be treated with this class of antibiotics. EMA's human medicines committee (CHMP) has now endorsed the PRAC recommendations and concluded that the marketing authorisation of medicines containing flumequine or quinolones should be suspended.

Restrictions on the use of fluoroquinolone antibiotics will mean that they should not be used:

- to treat infections that might get better without treatment or are not severe (such as throat infections);
- to treat non-bacterial infections, e.g. non-bacterial (chronic) prostatitis;
- for preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
- to treat mild or moderate bacterial infections unless other antibacterial medicines commonly recommended for these infections cannot be used.

Importantly, fluoroquinolones should generally be avoided in patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic. They should be used with special caution in the elderly, patients with kidney disease and those who have had an organ transplantation because these patients are at a higher risk of tendon injury. Since the use of a corticosteroid with a fluoroquinolone also increases this risk, combined use of these medicines should be avoided.

The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU countries.

First treatment for rare inherited muscle contraction disorders

October 19, 2018 – EMA has recommended granting a marketing authorisation for Namuscla (mexiletine hydrochloride) for the treatment of adult patients with non-dystrophic myotonia, a group of inherited muscle disorders where muscles are slow to relax after contraction. These disorders are chronic life-long debilitating conditions characterised by pain, fatigue, and muscle stiffness, resulting in frequent falls and disability.

This is the first time that a treatment for certain forms of myotonic disorders could be authorised EU-wide. The active substance mexiletine has been approved for treatment of these disorders in France only since 2010. Non-dystrophic myotonia is caused by abnormalities in the ion channels, tiny pores in the muscle cells that control the passage of charged particles (ions) such as sodium or chloride and play a key role in the contraction and relaxation of muscles.

Mexiletine is a known antiarrhythmic medicine (used to restore normal heart rhythm), which was first authorised in Europe in the 1970s. It works by blocking ion channels for sodium ions in muscle cells. These sodium channels play a role in the contraction and relaxation of muscles and by blocking them, the medicine helps to reduce the rate of contractions as well as the stiffness that occurs when the contractions are prolonged.

The opinion from the Committee for Medicinal Products for Human Use (CHMP) is based on data from one phase 3 clinical trial in patients with non-dystrophic myotonia as well as data from the literature. These data show that treatment with mexiletine allows relieving stiffness in the muscles. The medicine's safety profile is well-established; the most common unfavourable effects with this medicine were gastrointestinal disorders, such as heartburn, nausea, vomiting, diarrhoea and abdominal pain. Another less frequently occurring side effect of mexiletine is that it can also trigger arrhythmia or aggravate an existing arrhythmia; the CHMP therefore agreed on specific measures to minimise this risk such as certain contraindications and cardiac monitoring.

Namuscla was designated as an orphan medicinal product in November 2014. As always at time of approval, EMA's Committee for Orphan Medicinal Products will review the orphan designation to determine whether the information available to date allows maintaining Namuscla's orphan status.

First vaccine for prevention of dengue

October 19, 2018 – EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended granting marketing authorisation for Dengvaxia, a live, attenuated dengue tetravalent vaccine, for the prevention of dengue caused by dengue virus serotypes 1, 2, 3 and 4 in people who are between 9 and 45 years old, live in an endemic area and already had a prior dengue virus infection.

Dengue is by far the most common mosquito-borne viral disease affecting people worldwide (mainly in tropical areas); tens of millions of cases occur each year resulting in approximately 20,000-25,000 deaths, mainly in children. Dengue is caused by a virus which is transmitted by *Aedes* mosquitoes, a type of mosquito that is widely spread in tropical and subtropical regions. Most people who contract the disease experience mild, influenza-like symptoms. However, around 2% of people affected will develop severe dengue, a potentially lethal complication that includes dengue haemorrhagic fever and/or dengue shock syndrome. Main risk factors for severe dengue include young age and chronic diseases. Secondary infection, in the form of two sequential infections by different serotypes, is also a risk factor for severe disease.

There are four types of dengue virus and people living in a dengue endemic area can have several dengue infections in their lifetime. No specific treatments for dengue exist and prevention is mainly limited to the environ-mental management of mosquitoes. There is currently no vaccine available for dengue in the EU.

The approved indication excludes the populations of the EU mainland and territories outside tropical areas since dengue is not endemic in these regions. However, a number of EU territories, mainly overseas, are situated in endemic areas, and these territories could benefit from this vaccine.

The benefits and safety of Dengvaxia have been evaluated in 31 clinical studies conducted mostly in dengue endemic areas (Latin America and Asia Pacific). Together, these trials included over 41,000 participants aged 9 months to 60 years receiving at least one dose of the vaccine. The overall available data demonstrate that for people between 9 and 45 years of age, the vaccine has positive effects in preventing symptomatic and severe dengue disease in people who have had previous dengue infection and live in endemic areas. In people who have never had dengue, there is an increased risk of clinically severe dengue disease leading to hospitalisation when vaccinees are subsequently infected with dengue virus. The CHMP therefore recommends limiting the use of the vaccine to individuals with prior dengue virus infection, for whom laboratory confirmation of the previous infection is available before vaccination. In addition, because there are no safety, immunogenicity or efficacy data to support vaccination of individuals living in non-endemic areas and travelling to endemic areas, vaccination of these individuals is not recommended.

A number of additional risk minimisation measures will be put in place, such as educational material for physicians and a guide for healthcare professionals. Use of the vaccine should be according to official recommendation from Member States.

CHMP recommends first oral-only treatment for sleeping sickness

November 11, 2018 – EMA's human medicines committee (CHMP) has adopted a positive opinion for Fexinidazole Winthrop (fexinidazole), the first oral-only medicine (tablets) for the treatment of human African trypanosomiasis (HAT), commonly known as sleeping sickness, due to *Trypanosoma brucei gambiense.*

HAT is a life-threatening, neglected tropical disease that is endemic in sub-Saharan Africa. There are two forms of sleeping sickness, depending on the parasite involved: *Trypanosoma brucei gambiense* or *Trypanosoma brucei rhodesiense.* The vast majority (98%) of reported cases are caused by *T. b. gambiense*. Most cases occur in the Democratic Republic of the Congo, with the remainder located in bordering central African countries.

HAT caused by *T. b. gambiense* is characterised by a more chronic disease evolution. Within a few weeks of infection, patients can experience bouts of fever, headaches, joint and muscle pains and itching. Over time the disease invades the central nervous system. Patients display neurological signs including mental confusion, slurred speech, seizures, difficulty in walking and talking and worsening sleep disturbances. If left untreated, the disease is usually fatal within a time span of two to three years.

Currently therapy is selected based on how much the central nervous system is affected. Treatments include intramuscular injections of pentamidine, which are painful and only adequate for the earlier stage of the disease. Other treatments are available, e.g., a combination of oral nifurtimox and intravenous infusion of eflornithine (NECT) as reference therapy when the disease has advanced and affects the central nervous system. However, all these treatments require a minimum health infrastructure and personnel, not readily available in some remote areas.

Fexinidazole Winthrop, as an exclusively oral treatment regimen for the disease, could potentially allow quicker and wider access to treatment because distribution and administration of tablets is easier. It was developed by the applicant in partnership with the Drugs for Neglected Diseases initiative, a non-profit drug research and development organisation based in Switzerland.

The benefits and safety of Fexinidazole Winthrop were evaluated in three clinical studies involving 749 patients across the different stages of the disease. The studies showed high cure rates in patients after ten days of treatment, especially in the earlier stage of the disease. However, for patients whose central nervous system is already severely affected, Fexinidazole should only be given under strict supervision in hospital when no other adequate treatment is available or tolerated. The most common side effects observed were vomiting, nausea, headache, insomnia, weakness, dizziness and tremor.

Because there were a small number of cases of late relapse in the studies, the CHMP recommends a follow-up monitoring of up to 24 months to ensure the surveillance of potential relapses. All eligible patients should receive Fexinidazole under supervision of trained healthcare staff to ensure full compliance.

Fexinidazole Winthrop was submitted to EMA under a regulatory procedure (Article 58) which allows the Agency to assess the quality, safety and efficacy of a medicine and give an opinion on its benefit-risk balance when used in low- and middle-income countries outside the EU. Medicines submitted under this programme are assessed by EMA in collaboration with the World Health Organization. They must meet the same standards as medicines intended for EU citizens. This is the tenth medicine recommended by EMA under Article 58.

The scientific opinion from the CHMP helps to support regulators in countries where regulatory capacity may be limited, by providing an expert evaluation of the medicine when used in local practice. National regulators can use the CHMP's scientific assessment to decide on the use of the medicine in their countries.

EMA gives guidance on safety monitoring of medicines used in children

November 30, 2018 – EMA has published the new good pharmacovigilance practice (GVP) chapter IV on specific considerations for the paediatric population. It offers a holistic view of paediatric pharmacovigilance and provides guidance on how to make best use of existing tools and processes to address the specific needs and challenges of safety monitoring of medicines used in children. In addition, it advises on how to adapt regulatory requirements to the paediatric population in the European Union.

The new GVP chapter covers approved medicines with a paediatric indication or with an ongoing paediatric development, but also medicines only approved for adults when they are used off-label to treat children, i.e., for a medical purpose not in accordance with the terms of the marketing authorisation.

A dedicated approach to pharmacovigilance in children is especially important given that paediatric clinical trials are often limited in size and duration, and adverse reactions in children

Revised guideline to assess risk of human medicines for the environment

November 30, 2018 – EMA has published a revision of its guideline on the environmental risk assessment (ERA) of human medicines for a 6-month public consultation. Stakeholders are invited to send their comments by June 30, 2019, to era_dg@ema.europa.eu using the template provided.

The presence of biologically-active pharmaceuticals in the environment is a growing concern, because some of these substances have shown direct effects on wildlife at or below the concentrations found in water and soil. For example, male fish exposed to the main ingredient in the contraceptive pill may become feminised and this can affect the capacity of the population to reproduce. Pharmaceuticals may also have indirect effects, e.g., a recent study shows that pharmaceutical compounds detected in surface waters can transfer from invertebrate larvae to the predators that feed on them.

Human medicines may enter the environment during their manufacture, use and disposal. The ERA is based on the use of the product and the physico-chemical, ecotoxicological and fate properties (degradation, persistence) of its active substance.

Environmental risk assessment of medicines ensures that the potential effects of pharmaceuticals on the environment are studied and that adequate precautions are taken in case specific risks are identified. Performing an ERA is mandatory for any pharmaceutical company submitting a marketing authorisation application for a medicine, regardless of the type of medicine. Appropriate details are included in the European Public Assessment Report of approved medicines, so that this information is available to the public.

The revision of EMA's guideline on ERA introduces a decision tree clarifying when ERA studies are required and provides more detailed technical guidance to applicants to increase the consistency of the assessments. One of the most notable changes introduced in the proposed revision is the introduction of the term 'endocrine active substances', to include all compounds that affect development or reproduction. Additionally, guidance is provided for the estimation of the exposure of predators to pharmaceuticals through the food chain ('secondary poisoning'), as well as directly through the environment. The revision also proposes to limit the use of a laboratory test method – the Organisation for Economic Co-operation and Development (OECD) 308 environmental fate test to certain categories of substances and this will reduce the burden of testing on applicants.

The revision of the ERA guideline is based on a concept paper issued in 2014 and the work of a group of experts led by the Safety Working Party of EMA's CHMP. It builds on the twelve years of experience gained since the original guideline was published and aims to facilitate the work for both applicants and regulators in the interest of environmental protection.

In the interest of animal welfare, the guideline encourages applicants to share data generated for the ERA, implementing the principles of 3Rs (Replacement, Reduction and Refinement) – in accordance with Directive 2010/63/EU to avoid unnecessary repetition of studies.

may substantially differ – in terms of frequency, nature, severity and presentation – from those occurring in adults.

The guidance focuses on aspects of pharmacovigilance of particular relevance to the use of medicines in children, such as off-label use and medication errors, and contains paediatric-specific guidance on all major pharmacovigilance tools and processes, including risk management plans, periodic safety update reports, post-authorisation safety studies, signal management and safety communication.

It also highlights the need to include comprehensive information in adverse drug reaction reports, such as the child's age, weight and height, as well as, the indication or intention of use of the medicine, including its strength, dose and pharmaceutical form. This is important for all actors involved in safety reporting of medicines in children, including pharmaceutical companies, sponsors of clinical studies and regulatory authorities, but also parents/carers, healthcare professionals, patient and healthcare professional organisations, and organisations of national healthcare systems.

The new GVP chapter was finalised after careful consideration of the extensive feedback received during a public consultation, and replaces EMA's human medicines committee's (CHMP) 2007 guideline on conduct of pharmacovigilance for medicines used by the paediatric population.

Data from patient registries to replace clinical trials in previously untreated haemophilia patients

November 30, 2018 – EMA has published revised guidelines on the tests and studies needed to support marketing authorisation applications for certain haemophilia medicines. The revised guideline for haemophilia medicines for factor VIII deficiency was published in July 2018 and the revised guideline addressing medicines for factor IX deficiency was published today.

The revision introduces an important change in relation to the investigation of recombinant and human plasma-derived factor VIII and factor IX haemophilia medicines in previously untreated patients: for this very small subset of haemophilia patient data should be collected from patient registries rather than from small clinical trials, that may not be fully representative of how the medicine is used day-to-day once it is on the market.

This new approach relies on data from registries as a source of high-quality, real-world data to support regulatory decision-making. It reflects that in this subset of patients, clinical data are difficult to obtain as the subset is highly selected and the numbers available for trials are very small.

The updated guidelines aim to optimise and facilitate the use of these registries and provide parameters for core data sets that should be collected. The new approach described in the haemophilia guidelines waiving the requirement for a clinical trial in previously untreated patients was discussed at an EMA workshop on haemophilia registries in July 2015. Following a public consultation in 2017, a second workshop on haemophilia registries was held on June 8, 2018, which aimed at defining the requirements for practical implementation using existing registries to support post-authorisation observational studies of haemophilia medicines. The workshop discussed recommendations on important aspects such as appropriate governance of registries, patient consent, data collection, data quality and data sharing, and interoperability between different registries.

More information on the practical implementation of the guideline is available in a questions-and-answers document. EMA's initiative on patient registries is supported by a task force comprising representatives from its scientific committees and working parties, representatives from the European Commission and experts from national competent authorities.

Regulatory Matters

Biowaiver: The magic wand to reduce time and cost

SECTION EDITOR

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The concept of a biowaiver is likened to the use of a magic wand to wave away the requirements for expensive *in vivo* testing. Biowaivers eliminate unnecessary human testing while providing a fast track for drug development. Cost savings from avoiding expensive clinical trials is possible with biowaivers, and this ideally would translate to more affordable medicines for patients worldwide to achieve universal accessibility to quality medicines.

The key for regulatory medical writers is to use the right "spell" in different situations to increase the chance of successful wand use, i.e., provide proper documentation to fulfil set requirements. Although biowaivers are more commonly applicable for generic drugs, they can also apply to new drugs or line extensions (e.g., new strength, new formulation) when certain criteria are met.

Some common biowaiver mechanisms include:

- Biowaiver for additional strength(s)
- Biowaiver for specific dosage forms
- Biopharmaceutics Classification System (BCS)–based biowaiver

Biowaiver for additional strength(s)

This type of biowaiver is applicable to all types of marketing authorisation applications (new medicinal products, generic products, hybrid, etc.). Bioequivalence (BE) testing is generally performed on the higher strength, while it is waived for the lower strength if the *in vitro* pharmacokinetics are proven to be equivalent. Pharmacokinetic linearity of the active substance is a prerequisite for the application of an additional strength biowaiver. The strength(s) to be chosen for the BE study are determined by critically reviewed data on pharmacokinetics linearity. Similarity of *in vitro* dissolution between additional strength(s) and the strength used for BE testing are demonstrated using the similarity factor (f_2) test or other justified methods.[1,2]

In general, all the strengths should have the same manufacturing process, same qualitative composition, and the same ratio between the amounts of each excipient to the amount of active substance(s) for all strengths. If there is deviation from the quantitatively proportional composition of the strengths, biowaivers may still be considered if certain conditions regarding the amount of active substance(s), core excipients, and fillers are met.[1,2]

Biowaiver for specific dosage forms

This type of biowaiver may apply to formulations such as aqueous oral solutions, parenteral solutions, locally acting, locally applied products (e.g., eye drops, nasal sprays, or cutaneous solutions), and gas for inhalation.[2] Certain pharmaceutical dosage forms are exempted from the provision of equivalence data due to their inherent characteristics. A prerequisite is that the test product should not contain a different salt (unless similar properties), ester, ether, isomer, mixture of isomers, complex, or derivative of an active substance than the reference medicinal product. In addition, the excipients should not influence the bioavailability of the active drug substance.[1]

BCS-based biowaiver

The application for a BCS-based biowaiver is restricted to highly soluble immediate-release (IR) solid oral dosage forms or suspensions with systemic action, i.e., either Class I or Class III (see Table 1).[1,3] Modified-release products are not accepted for BCS-based biowaivers. Pharmaceutical alternatives (e.g., tablet versus capsule) and fixed-dose combinations may be considered if all the drug substances are BCS Class I or Class III. Importantly, drug substance(s) should not have a narrow therapeutic index. *In vitro* dissolution testing is used in lieu of a surrogate test to evaluate the bioequivalence of a test and reference product.[1,3] *Table 1*

The BCS-based biowaiver criteria is judged based on solubility, permeability, dissolution, and

quantitative and qualitative composition of test product versus reference medicinal product. For the comparison of dissolution profiles, the similarity factor (f_2) is estimated. Two dissolution profiles are considered similar when the f_2 value is between 50 and 100. However, in the case of very rapid solubility (≤15 minutes) of both test and reference products, the dissolution profiles are considered similar and f_2 testing is unnecessary.[3]

In certain cases, BCS-based biowaiver might not be feasible due to product-specific characteristics despite the drug substance being BCS Class I or Class III; for example, the *in vitro* dissolution being less than 85% within 15 minutes (BCS Class III) or 30 minutes (BCS Class I), either for test or reference, or unacceptable differences in the excipient composition.[1,3]

For products with multiple strengths, the criteria for BCS-based biowaiver must be applied for each strength, i.e., dissolution profiles of test and reference product should be compared at each strength.[1,3]

It is interesting to note that the BCS classification of a drug substance may differ in different jurisdictions (EMA, USFDA, PMDA, etc.).[4,5] Provisional BCS classification may be searched via online databases such as that of the Drug Delivery Foundation,[6] while there is no official list for drugs with narrow therapeutic index. These aspects are reviewed by regulatory authorities on a case-by-case basis.

In conclusion, biowaivers are important mechanisms for new and generic drug development to bring essential medicines to those who need them most. It is important to be informed of the rationale for the choice of biowaiver and the necessary conditions to be fulfilled to provide effective documentation.

Table 1: Biopharmaceutics Classification System (BCS) Classes for Drug Substances

Class I **High solubility, high permeability** Compounds are well absorbed, and their absorption rate is usually higher than excretion rate **Examples:** Metoprolol, propranolol, captopril	**Class III** **High solubility, low permeability** Absorption is limited by the permeation rate, but the compound is solvated very rapidly **Examples:** Ranitidine, cimetidine, atenolol
Class II **Low solubility, high permeability** The bioavailability of the compounds is limited by their solvation rate **Examples:** Naproxen, diclofenac, carbamazepine	**Class IV** **Low solubility, low permeability** Usually not well absorbed over the intestinal mucosa, and a high variability is expected **Examples:** Furosemide, hydrochlorothiazide

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Gained in Translation

Editorial

It is my pleasure to introduce a new article in the Translation Section. Carolina Rojido, a medical doctor working as a freelance writer, explains how she first stepped into medical translation and what the challenges were. Enjoy the article!

Laura C. Collada Ali

SECTION EDITOR

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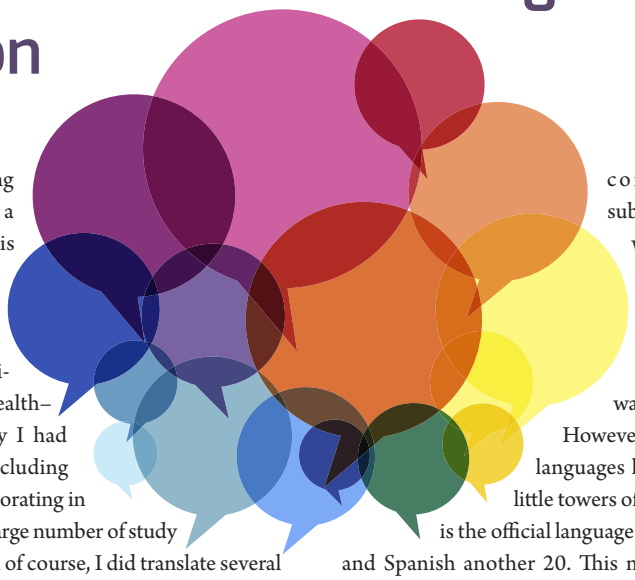
Career Shifts: My experience transitioning into medical translation



I think going from actual medical writing to translation or vice versa is not a one-way street but an avenue. On a personal level, I think that translating goes hand in hand with being bilingual, or trilingual as I am now with Spanish, English, and French, although my writing in French is not yet at a native level. Now that I am used to it, I really enjoy being able to easily use different languages as needed and to be able to translate into Spanish and English for my clients. For those who do not do this, they may wonder how to become comfortable shifting languages. When living in a foreign country, translating is really a part of daily life as immigrants may talk, read, and write at a minimum in their native tongue and in the language of the country in which they live. Here in Europe, it is quite common to shift among three or more languages when talking with a group of friends or colleagues. On the other hand, when living in one's native country, things are different. It is just a matter of immersing oneself in the non-native language by, for example, watching movies, reading books, or doing all the activities possible where you have to use these languages.

Anyway, the basis of achieving any of the above, regardless of where a person lives, is a mental openness and desire to learn and communicate with others.

My particular path into translation went like this: Once I graduated from medical school in Argentina, I left for the US where I studied and worked in medical research for 13 years. Some of my jobs were as a clinical trials coordinator, so I often found myself acting as an interpreter for patients coming to our research centre in Florida. Although I do not practice medicine, I really care to help and go above and beyond to make sure patients' needs are fulfilled. And for patients, being able to understand in their native language what is happening to them goes a long way in this respect. Later, as a project co-ordinator for a National Institutes of Health–sponsored study I had many duties, including writing or collaborating in the writing of a large number of study documents. And of course, I did translate several documents aimed at Spanish-speaking patients and caregivers. First, I was asked to proofread and edit an already-translated document. Of course, this was quite different from translating from scratch. This is the process I followed: I read the original and the translation; then I did it again making sure that there were no literal translations (word for word) where oblique ones (in which the structure or concept of the phrase cannot be literally translated) would be more appropriate; then I edited and proofread the translation, paying special attention to country-specific wording that may have been used unintentionally. I did translate other documents myself using literal and oblique translation techniques as well. I found that these techniques complement each other naturally and that with some practice they are used almost seamlessly.

The "country-specific wording" that I mentioned deserves a special mention. One thing is to translate into "official" Spanish or American or British English. For Spanish, the Royal Spanish Academy (RAE), as well as many other sources of linguistical information, comes in really handy as an official reference for the Spanish language. For English, one simply has to settle into either British or American English and their corresponding subtle differences, which the Cambridge Dictionary and word processing software help discern. However, both of these languages have their own little towers of Babel: English is the official language in 94 countries and Spanish another 20. This may have to be considered for the target audience of the source text, and – no doubt – has to be conveyed into the target text as well. What is the nationality of the target readers? What is their level of education? Is the target reader a patient? The answers to these questions easily determine the characteristics of the original text and help you to convey the message it contains with appropriate wording for the target readers.

Now that I am in Europe and I am officially a freelance medical writer, I am, of course, doing some translations and editing related documents. I have found that translation skills are a great complement to medical writing, especially because our trade frequently involves working with professionals from all nationalities. For freelancers in particular, this is especially useful as it serves to diversify the services we can provide.

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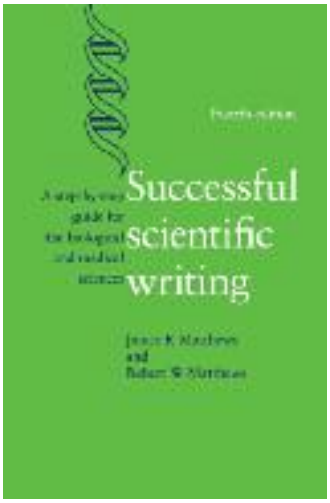
In the Bookstores

Successful Scientific Writing, fourth edition

James R. Matthews and Robert W. Matthews
Cambridge University Press, 2014
ISBN #: 9781107587915, paperback
23.72, 304 pages



They say, "Never judge a book by its cover". But I do. I pick it up, weigh it in my hands, examine it front and back; sometimes, I even smell it, searching for any hints that will help me divine its worth. From the exterior, *Successful Scientific Writing* by Janice R. Matthews and Robert W. Matthews exudes utility; it screams, "research". The cover is green, unadorned, and clean-lined. The high-quality spiral binding allows it to lay comfortably open on a desk, a lab bench, anywhere. This is a book that wants to be written in, to have its text highlighted, to have its pages dog-eared, to be used as any other common tool like a screwdriver or a pipette. Even the coffee stains on the upper right corner of my copy look perfectly at home.

Successful Scientific Writing begins with a preface outlining the changes since the last edition (this is, after all, the fourth edition). Since publication of the last edition (2008), the authors have doubled the amount of chapters, adding content about topics such as publication ethics and presentations. In the main part, *Successful Scientific Writing* mostly covers the *plat principal* of scientific writing, the peer-reviewed manuscript. The chapters start with planning and end with publication. Quotations from philosophers (Hippocrates and Kant), absurdists (Carroll), romantics (Tennyson), humourists (Vonnegut and Twain), and others intersperse the sections. Similar to other books of its kind, this book features cartoons and graphics to break up blocks of text and add flavour to what could otherwise be a plain read. There are also 30 writing exercises, along with an answer key, gathered in an appendix at the end.

The first four chapters of *Successful Scientific Writing* are devoted to pre-writing; that is, planning, literature searches, organising your thoughts, and journal selection. A short section on writer's block offers several different suggestions, citing other publications for further reading, instead of offering a simple one-size-fits-all solution. The next four chapters are on the general organisation of a peer-reviewed manuscript – IMRAD (Introduction, Methods, Results and Discussion). The authors also highlight parts on the periphery of a manuscript such as the title, keywords, abstract, tables, and figures.

About one-third of the way through, *Successful Scientific Writing* transitions from general information about writing manuscripts to the actual writing in the manuscript. The authors focus five chapters (about 80 pages) on the written communication of science. There is a chapter on reporting numbers and statistics followed by a chapter on revision, which offers practical advice such as removing multiple hedges, breaking up long sentences, and removing empty fillers. A chapter on style and syntax tackles proper tense, active/passive voice, modifiers, participles, and more. Matthews and Matthews also dedicate a chapter to word choice, discussing jargon and nominalisation, appealing for bias-free language, and providing a list of commonly confused words. A fifth chapter on writing covers capitalisation and punctuation specifically for scientific writing.

In the final third of the book, the authors address publication ethics (such as plagiarism, copyright, and fair use). A chapter on oral presentations offers advice about using visual aids from chalkboards to modern slideshows. The next chapter is about the oral presentation of slideshows and posters. *Successful Scientific Writing* ends with the final step in any author's journey: publication.

Overall, *Successful Scientific Writing* is a well-written guide for writing manuscripts that is an easy read thanks to the authors' clear style, many cartoons and timely quotations. Beginners will find the initial third of the book on arranging a manuscript useful, whereas both beginners and intermediate writers may find themselves returning to the sections on writing, revision, grammar, and syntax.

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Medical Devices

SECTION EDITOR

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Editorial

This issue is about careers in medical writing. Despite the recent scandal, the medical device sector is certainly a sweet spot to be in as there is an increasing need for medical writers due to the new European regulations. Sarah Choudhury and Gillian Pritchard have prepared the featured article "Career opportunities in medical device writing: Employee and freelance perspectives" that is available in this issue and is worthwhile reading (see page 46).

To prepare you for a career in the field, the Medical Device Special Interest Group (MD-SIG) has launched several workshops:

- Introduction to Medical Devices
- From Pharma to Medical Devices (new since November 2018)
- Literature Review for Medical Devices (new since May 2018)
- Writing Clinical Evaluation Reports for Medical Devices (an update according to MDR2017/745 and MEDDEV 2.7/1 Rev4 will be provided in May 2019)
- Writing Clinical Investigation Plans (alias Clinical Study Protocols) for Medical Devices (will likely start in November 2019).

In addition, several webinars on medical devices are available in the webinar archive and an Expert Seminar Series on medical devices is planned for May 2019 during the Spring Conference in Vienna.

For this issue on careers in medical writing, I am particularly happy that I was able to enlist Monica Meyer to review the medical device articles and provide practice-based input. Monica has more than 30 years of experience in the medical device industry, as Director Clinical Research Europe and as Director of a Global Medical Writing Team, an expertise that was particularly useful to the "Medical device files' article I wrote for this section.

In closing, if you have any comments or suggestions for the MD-SIG or would like to contribute an article to the Medical Device section, please contact me

Beatrix

The next medical device scandal: Medical device files – my personal view (Part 1)

During a visit to Greece more than 15 years ago when I was involved in an animal protection campaign, I met a journalist who was investigating prohibited fishing methods that local fishermen were using. When he was asked by the animal protection organisation if he could write about the ongoing spaying campaign, he responded with "… good news doesn't sell". I remember well how I thought this is quite sad as it leaves a falsely negative picture of the world. Moreover, positive news can also be important, such as in this case, where the intent was to increase public awareness of best practices to ensure a healthy and manageable dog population and provide information on adopting dogs from abroad.

Some years later, when I worked in clinical research, I was very concerned about an article in *Der Spiegel*, at this time a respectable German magazine that I trusted to contain reliable information. The journalist reported that people in Africa are abused as "guinea pigs" for clinical research as medical data are more easily retrieved in Africa than in Europe. This was only partly true. Certainly, it was less complicated to do research in Africa than in Europe, but what the journalist forgot to mention was that – to gain commercial approval in Europe or in the US – the research population has to be representative of the patient populations in Europe and the US. As there are known variations in substance metabolism between European Caucasians and Asians or Africans it is unlikely that a company would do a research study solely in Africa simply because it would be nearly impossible to get approval in Europe or in the US with this data alone.

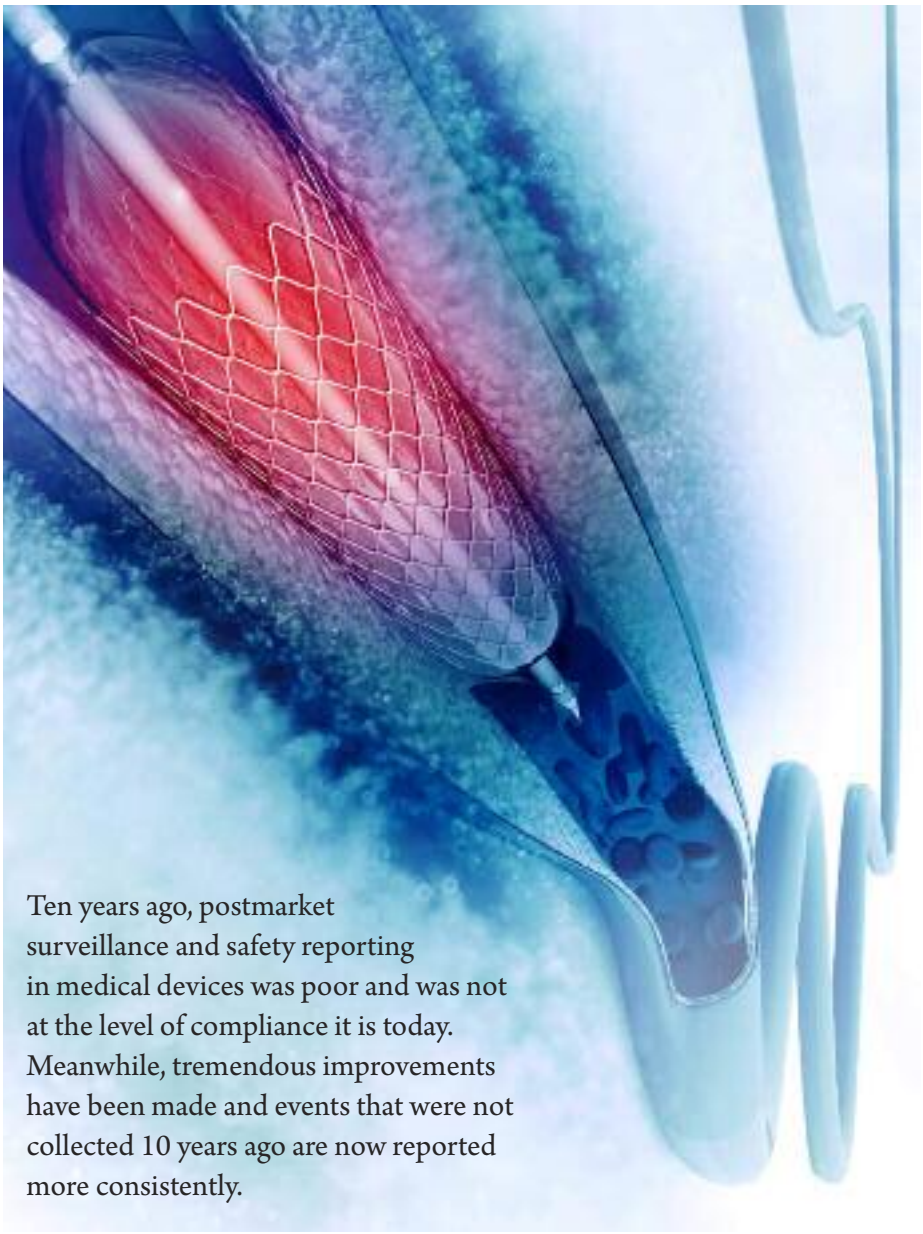
Shortly thereafter the next scandal was in the news – that coronary stents are worse than coronary bypass grafts as they lead to thrombosis and that they are used because "bad companies" and "bad physicians" are only interested in "making money" and not acting in the best interest of the patients. Well, again partly true. Indeed, first generation stents had elevated stent thrombosis rates, but at the time the article was published, third generation stents were already on the market that had overcome the elevated stent thrombosis issue.

Indeed, first generation stents had elevated stent thrombosis rates, but at the time the article was published, third generation stents were already on the market that had overcome the elevated stent thrombosis issue.

It made me wonder if journalists ever consider that they are jeopardising patient lives with such articles as patients may choose to refuse life-saving therapies based on biased information. Certainly, my trust in the media was shaken.

This form of reporting occurred even before online media became the major source of public information. Today journalists are under even greater pressure to attract readers and produce catchy headlines, so the situation has certainly become worse. I am not speaking about fake news or misinformation, but about a substantial bias in reporting.

Now to the latest scandal, the implant files.[1] One of the most respected German newspapers, *Süddeutsche Zeitung*, published a summary identifying "10 facts to know about the implant files",[2] which I would like to comment on. I am giving my personal view built on my experiences after nearly 15 years in the cardiovascular medical device sector, including more than 10 years in clinical research, several of them in leadership positions.



Ten years ago, postmarket surveillance and safety reporting in medical devices was poor and was not at the level of compliance it is today. Meanwhile, tremendous improvements have been made and events that were not collected 10 years ago are now reported more consistently.

Reported "Facts":

1. **The number of injuries and deaths in conjunction with medical devices is increasing.**

I can imagine that the reported numbers are increasing, but the numbers need to be seen in context. The increase is not necessarily due to more events, but these events are now more consistently reported. This has several reasons:

- Ten years ago, postmarket surveillance and safety reporting in medical devices was poor and was not at the level of compliance it is today. Meanwhile, tremendous improvements have been made and events that were not collected 10 years ago are now reported more consistently.
- The number of postmarket medical device clinical studies is increasing. The importance of collecting and reporting events to evaluate longer-term results and identify late events, their causes and device relationship is now key in maintaining commercial product availability. Potential incidents are thoroughly monitored and hence more events are reported.
- The definition of device relationship has slightly shifted: 10 years ago, events were mostly classified as "device-related: Yes/ Unknown/No". Only events with a reasonable likely device relationship were reported. Currently, there are five categories: "Not related/ Unlikely/ Possible/ Probable/ Causal relationship". According to German BfArM guidelines, events now have to be reported as device-related as soon as a relationship cannot be ruled out – a much more conservative approach that has increased the number of events.
- Ten years ago, only device-related events were commonly reported; now procedure-related events are also taken into consideration.
- There has also been an increase in the number of new medical devices used over the past 10 years as device-related therapies have been developed for patient populations where previously only medical therapy was possible. For instance, transcatheter heart valve therapy for severe aortic disease was initiated in elderly, high-risk patients with multiple comorbidities that prevented aortic valve surgery.

Therefore, the large increase in events is most likely due to new therapies, refined definitions, and more thorough reporting. It is anticipated that the numbers will increase even further as there will be more studies and postmarket surveillance will continue to improve.

The authors also mention that not all cases in which a medical device might have caused a life-threatening situation have been reported to the authorities. This is certainly true when it comes to cases outside of clinical studies. I can imagine that after a long working day, physicians would only report cases for which they believe there is an unexpected and likely relationship to the device. From personal experience, my dog suffered from auto-immune hemolytic anaemia that started 4 days after a vaccination. I am sure none of the treating veterinarians has taken the time to fill in a complaint form because the timely association was probably thought to be attributed to a random occurrence rather than to a causal relationship. However, since a relationship could not be ruled out, I completed and submitted a complaint form. This is something very important the journalists forgot to mention – that patients can complete such notifications themselves. I am not an expert here, but I think there are already attempts to allow simple notifications via social media in the pharmaceutical industry. Furthermore, in the new Medical Device Regulation (MDR), which will be fully applicable in 2020, devices will receive a unique device identifier. This will make such reporting even easier.

The authors also claim that there are no reliable facts on how many devices have been implanted. Well, according to MEDDEV 2.7/1 rev 4, the product clinical evaluation report must be regularly updated and submitted to the notified body, including information on "whether the device is currently on the market in Europe or in other countries, since when, number of

An article claimed that people in Africa are used as "guinea pigs" for research, but it would be nearly impossible to get regulatory approval in Europe or the US based on data solely from Africa.

devices placed on the market…" Furthermore, many countries have also established national registries to document the use of various medical devices.

2. Many implants are only tested in men.

I can only speak for the cardiovascular field, but I have never seen a study in which female gender was an exclusion criterion. I also doubt that such as study would receive approval from the ethic committees or competent authorities. Furthermore, it would not make sense to exclude one sex in disease states that affect both men and women, as rapid study enrolment is always desired. Even if impaired outcomes are encountered, e.g., in girls or women, a statistical subgroup analysis could be performed to account for it.

Notwithstanding the above comment, there are of course, diseases that are more prevalent in one sex, such as coronary artery disease.

3. There is no national certification for medical devices and implants in Europe.

This is correct. In fact, I think it is good that there is not a national, but a European certification programme (CE – an abbreviation of Conformité Européenne), as registering a device per country would be more complex and time consuming and companies might not seek approval in certain countries. In many countries, however, European CE certification does not guarantee access to new devices until reimbursement negotiations in the countries take place.

The authors further claim that there is no possibility for patients to see if a device is CE-certified or not. Actually, a medical device cannot be commercially distributed or sold in the European market if it is not CE-certified, which means all devices that patients receive are CE-certified. There are a few exceptions, though, such as devices in pre-market clinical studies or in cases of compassionate use. In these cases, the device must be labelled as an investigational device; patients must be adequately informed about the status of the device, and they must sign an informed consent form that also indicates that they are aware that the device is not CE-certified.

4. Private entities decide if a product may be implanted or not.

The authors state that, unlike the US with the FDA, private entities such as TÜV, BSI, or DEKRA ("notified bodies") may decide if a device receives certification or not. A manufacturer can change the notified body in case they are unsatisfied with the respective work. In the past 8 years, only 84 medical devices have been rejected.

Frankly speaking, I do not have the insights to judge the benefits of one system over the other. But clearly, although notified bodies are private entities, they cannot act in a legal vacuum. They are designated and supervised/audited by the national competent authority, which then reports CE approvals to the European Commission. For those who live in Germany: remember your car does not necessarily get the certification even though you pay "TÜV" or "DEKRA" for the inspection.

The low rejection rate of new devices compared to the approval rate might be due to the fact that most of the certifications are re-certifications. (Similar to cars, the certification for medical devices has to be regularly renewed, generally every 3 years). Furthermore, for novel devices, companies usually discuss with the notified bodies in advance as to what data the notified bodies want to see. If the device does not meet the pre-specified success criteria (commonly, a statistical-based sample size has to be calculated based on an expected endpoint), companies would rarely invest the time and money in a submission. And lastly, yes, in the past, approvals were easier. But this has changed

with revision 4 of MEDDEV 2.7/1 released in 2016 and approvals will become even more difficult in 2020, when the MDR is fully in force.

The new MDR also has more stringent requirements for notified bodies and hence the number of notified bodies has already been reduced and will probably be further reduced once the MDR is fully in force. Joint audits of the notified bodies with competent authorities are currently pending following submission of applications to meet the new directives.

5. The certification system is lax and prone to errors.

The authors report that an undercover investigation successfully attempted to get a hip implant device certified that was faulty and which was similar to a hip implant that had been retracted from the market.

When I read this, I suspected that this case occurred prior to the new regulations (revision 4 of MEDDEV 2.7/1). After searching the internet, I found that the respective publication is from 2012,[3] long before the new regulations. As stated earlier, it is true that some notified body certifications were too lax in the past, but this is exactly the reason why revision 4 and the new MDR were released that have significantly more stringent requirements.

Part 2 will be published in the next issue of *Medical Writing*.

Conflict of interest:

The author, Beatrix Doerr, acts as a medical writer and consultant in the medical device industry and owns shares from Edwards Lifesciences.

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November meeting of the MD-SIG

During the autumn conference in Warsaw, the MD-SIG met and the following items were discussed:

1. Next MD-SIG meetings

To allow everybody to join the MD-SIG meetings, these meetings will become regular parts of the conference programme.

2. Educational needs

We performed a gap analysis between the current educational content and the members' interest as assessed through the Spring 2018 Conference survey. It seems that we are on track:

- "More workshops on medical devices" – there has been a new workshop on medical devices during the 2018 autumn conference, at the spring conference in May, we will likely have a workshop on Clinical Evaluation Reports and one on literature review for medical devices, and another new workshop is planned for the Autumn Conference.
- "Medical device regulations in the EU and US" – this will be part of the Expert Seminar Series (ESS) at the spring conference this year.
- "Combined products" – this will be part of the ESS this year.
- "Clinical Evaluation Reports" – this workshop is currently updated and will be available at the spring conference this year.
- "Risk benefit analysis" – it is unclear if this suggestion refers to the part of the Clinical Evaluation Report or rather refers to risk management itself. But certainly, risk management is a topic of further interest.

In 2020, we also plan to start to offer trainings for the new in-vitro device regulation that will be fully in force in 2022.

3. Best practice

We discussed the following topics related to writing clinical evaluation reports (CER):

- Table of Contents: The structure provided in the MEDDEV guideline is somewhat inconvenient. Several members have worked with different tables of content, but all agreed that it is best to adhere to the MEDDEV's table of contents unless the sponsor has a different template.
- A tip from one member was to use the Clinical Evaluation Assessment Report (CEAR) checklist to verify that the CER contains all required information.
- There is a white paper that compares the Essential Requirements of MDD 93/42/EEC with the Safety and Performance Requirements of MDR 2017/745: Macomber L, et al. General Safety and Performance Requirements (Annex I) in the New Medical Device Regulation: Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive. Available at https://bit.ly/2AYmaeI.
- All members do two separate literature searches for the CER, one for state-of-the-art and guidelines, and one for the device in question.
- For weighing of literature, the Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence may be used, available at at https://www.cebm.net/ 2016/05/ocebm-levels-of-evidence/.

We are looking forward to seeing you at the next MD-SIG meeting in Vienna!

Journal Watch

Journal Watch is based on the French language blog, *Rédaction Médicale et Scientifique*, by Hervé Maisonneuve available at www.redactionmedicale.fr.

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Failure to disclose conflicts of interest: Research misconduct

There is a growing debate in journals and articles on financial and non-financial conflicts of interest (COIs). This debate exists in scientific journals and also in the mainstream media. I provide two examples: the *New York Times* (NYT) and *JAMA*.

In September 2018, the NYT published a long article on Dr José Baselga, the chief medical officer at Memorial Sloan Kettering Cancer Center, New York, accusing him of failing to disclose important ties to the topics of his research articles.[1] The NYT accused the editors of scientific journals of being lax because they did not control the COIs.

> *One of the world's top breast cancer doctors failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles in prestigious publications like* The New England Journal of Medicine *and* The Lancet.

Medical journals have said they don't routinely fact-check authors' disclosures. Dr Baselga sent corrections to the journals to declare his many conflicts; he resigned from his position. In December 2018, the NYT revealed further cases of non-reporting of COIs in the cancer field: [2]

> *Dr. Howard A. "Skip" Burris III, the president-elect of the American Society of Clinical Oncology, for instance, declared that he had no conflicts of interest in more than 50 journal articles in recent years, including in the prestigious New England Journal of Medicine. However, drug companies have paid his employer nearly $114,000 for consulting and speaking, and nearly $8 million for his research during the period for which disclosure was required.*

These articles forced the journal editors to react.

An editorial signed by the JAMA chief editor had the following conclusion:[3]

> *COIs are likely to become more challenging in the years to come. As more investigators and their institutions have and enter into financial relationships from which they benefit, it is critical that authors report COI information accurately, completely, and transparently so readers can evaluate whether the information in the article could be biased because of authors' potential COIs. Equally as important, if not more important, are the responsibilities of editors to ensure that published information is accurate and objective and to maintain the integrity of the scientific record. Ultimately, physicians, other health care professionals, and other readers must assess the information available to them, determine the value and importance of an article, and make decisions about its applicability to clinical care and contribution to health.*

In the same issue, a viewpoint proposed to redefine research misconduct:[4]

> *If leaders don't follow the rules, then we don't really have rules. It is time to strengthen institutional COI policies by considering the intentional or negligent failure to disclose significant financial relationships relevant to the conduct of research to be research misconduct.*

In December 2018, the ICMJE issued updated recommendations.[5] They added the failure to disclose COIs in the paragraph defining scientific misconduct (page 8, IIIB):

> *Scientific misconduct in research and non-research publications includes but is not necessarily limited to data fabrication; data falsification, including deceptive manipulation of images; purposeful failure to disclose conflicts of interest; and plagiarism.*

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Should journal editors consider potential harms of publishing certain research findings?

An article in the *Journal of Medical Ethics* addresses a general question in the context of biomedical journals: "Is there research that it is permissible to conduct but that ought not to be published?"[1] There is a concept referred to as *dual use research*. A simple example is in the field of terrorism. It is recognised that research whose results could provide ideas to terrorists cannot be published. If they are published, key points must be hidden, or only partially disclosed in order to avoid reproducibility. The *Journal of Medical Ethics* article describes two similar situations:

- A Danish team has shown that antibiotics reduce the symptoms of a widespread chronic disease. One reviewer noted that these data could change practices and contribute to an increase in antibiotic resistance, thus inadvertently resulting in deleterious health effects (the name of the disease is not given in the article).
- A *BMJ* article suggested that the adverse effects of statins were more important than the beneficial effects in patients at low and moderate risk of cardiovascular disease. The subject has launched a rather heated debate, particularly in the mainstream media. An estimate has been made: about 200,000 people would have stopped their treatment, and probably 2000 cardiovascular events would be observed in the future. Finally, *The BMJ* and authors withdrew statements suggesting that adverse events occur in 18% to 20% of patients.[2]

The main messages are:

1. The publication of Danish and British studies can cause significant harm to individuals.
2. Editors of medical journals have a moral responsibility for the potential adverse effects of publishing research.
3. The refusal to publish is not an adequate instrument to fulfil this moral responsibility.
4. Internationally recognised codes of ethics should provide a solid basis for assessing and mitigating the potential effects of the publication of medical research in general.

The article deals only with the publication of medical research, simply because it is a field of research that is already regulated by a number of international codes. However, the points raised certainly also apply to other areas of research.

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How to explain away negative tests: the Panellists' Playbook

The *BMJ* Christmas issue contains 25 articles, some of which are very humorous, others more serious.[1] One article in particular is worth remembering.[2] The second paragraph sets the scene:

> *When key opinion leaders are asked to comment on disappointing trial results in news reports or at conferences, we have observed that they seem curiously unable to recognise that the treatment doesn't work. They prefer to argue that the trial design was wrong, drawing from a set of stereotyped criticisms. Using cardiology as an example, we have systematically analysed the excuses they provide to compose the Panellists' Playbook, an anthropological classification that will be useful not only for readers but for key opinion leaders in need of inspiration (or backbone).*

This work is serious and is based on analysing *Medscape* and *MedPage Today* articles on the three largest cardiology congresses over 5 years. A trial was considered negative if the primary endpoint was not met. Of 321 trials in 15 congresses, 127 were negative, and the authors analysed 438 comments from opinion leaders. They listed 40 excuses classified into 17 themes. Frequent excuses: sample too small, other studies are needed, follow-up too short (Figure 1).

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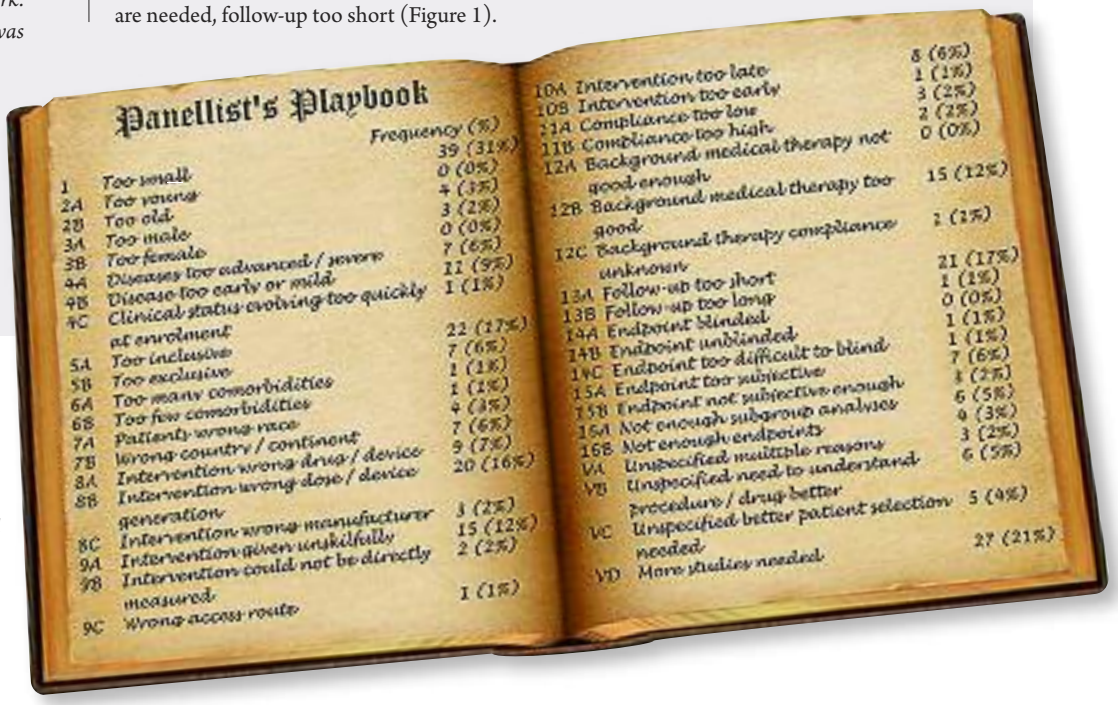

Figure 1. Panellists' Playbook. An efficient standardised framework for busy key opinion leaders asked to comment on trials with negative results. Reproduced from Key opinion leaders' guide to spinning a disappointing clinical trial result. Hartley A, et al. BMJ 2018;363:k5207.BMJ. with permission from BMJ Publishing Group Ltd.

Collaborating on multi-authored papers and resolving disputes

Every time I'm in discussion with researchers, the issue of teamwork – especially collaboration in writing – is a hot topic, even very hot. The most frequent practice is that of the first author to send a manuscript (without the order of authors) to his co-authors, with a vague request: What do you think? The troubles begin, and then the atomic war is triggered when trying to decide the order in which authors names should be listed. We do not have enough rules to decide the order of authors, or even to know which researchers can be authors. Existing rules (such as those of the International Committee of Medical Journal Editors ICMJE) are either not known to researchers or are ignored even when they are known. A new article suggests 10 rules for collaborating on multi-authored papers.[1]

1. Build your writing team wisely
2. If you take the lead, provide leadership
3. Create a data management plan
4. Jointly decide on authorship guidelines
5. Decide on a writing strategy
6. Choose digital tools to suit your needs
7. Set clear timelines and adhere to them
8. Be transparent throughout the process
9. Cultivate equity, diversity, and inclusion
10. Consider the ethical implications of your co-authorship

Interestingly, this paper includes a footnote regarding the order of authors. "MAF is the lead author. All authors contributed equally to this work. Besides for MAF, author order was computed randomly."

Another paper on authorship disputes concludes:

> Rather than viewing authorship disputes as rare events that must be handled on a case by case basis, researchers and journals should view the potential for disputes as predictable, preventable, and soluble. Independent bodies that can offer alternative dispute resolution services to scientific collaborators and/or journals could quickly help research communities, particularly their most vulnerable members.[2]

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Veterinary Medical Writing

SECTION EDITOR

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From vet to writer

I know all the stereotypes about vets. We work as clinicians as seen in All Creatures Great and Small and are intrinsically motivated to help every animal we cross. And yes, that is partly true. There are three major pillars in which vets can work. Most vet school students want to work with pets in a clinical setting after completing their studies, making this the most sought-after pillar and fulfilling the stereotype. In contrast, there is a large need for vets in the second pillar: working with food producing livestock or in abattoirs. In the big picture of general health this is much more important than performing neurosurgery on paraplegic dachshunds, even if it is less glamorous. The third pillar is lesser known: a scientific career. In itself another broad field, this may vary from working on the bench in a university or pharmaceutical company to supervising animal welfare in laboratories.

So what if none of that is for you?

Many vets do not find themselves drawn to work under any of the three main veterinary pillars. I am one of them. Having worked as a neurosurgeon on the beforementioned paraplegic dachshunds and completing a doctorate in neuroscience, it dawned on me that intrinsic motivation is key, in order to endure poor working conditions with long hours working and sub-par salary in vet clinics. Surgery was not a driving force for me, as wasn't scientific research. The mandatory three weeks working in an abattoir during vet school had ruled the public health pillar out as an option. With no intrinsic motivation for one of the three pillars in sight, I tried to find out what really interested me. To my surprise this turned out to be communication. Translating complex medical information into digestible pieces for worried pet owners and eager students kept me going during 90-hour workweeks. It makes sense as well; with extensive knowledge in all fields of medicine, vets have it easy to understand and relay medical information. If only there was a corresponding job…

Unploughed fields

It was only by chance that I met Lisa Würner of Trilogy Writing. She introduced medical writing as a fourth pillar of work to me and I was immediately hooked. I soon attended my first EMWA conference in rainy Brussels, found employment as a medcom medical writer at Edelman, and am now a medcom freelancer. More and more vets are now learning of medical writing and this is a great opportunity for EMWA to provide a home to these newcomers. If we spread the word that EMWA exists, this could be a good opportunity for established medical writers as well. Veterinary medicine is a relatively unploughed field for medical writers. Vet pharmaceutical companies and research facilities are just now learning that medical writing is "a thing", and with rising awareness, more employment opportunities will come, for rookies and professionals alike. Look out for this section in future issues of *Medical Writing*, if you are keen on exploring these new routes with us.

Translating complex medical information into digestible pieces for worried pet owners and eager students kept me going during 90-hour workweeks.

Good Writing Practice

Syntactic structure

Ellipsism: Noun Clause

Introduction

Ellipsis is the absence of a portion of a syntactic unit in a stylistic effort to be succinct. For example, the ellipsis of *that*, in a noun clause occurring frequently in research writing, often is only a minor distraction (e.g., *Smith hypothesised ^ protein A is insulin*), because the meaning is evident when the verb *is* is adjacent to the subject *protein*.

That initiating a noun clause is a complementiser (e.g., *Smith hypothesised **that** protein A is insulin*), and the noun clause functions as a complement. (A complement completes the meaning of a grammatical unit such as the direct object of a verb). However, there are instances whereby comprehension is impeded because of over-ellipsis (ellipsism).

The examples in this article are organised according to sections of a journal article (Experimental and Contextual) and their conceptual components.

Experimental section

Part 1 – Results section: data-based observation

Example: elliptical noun clause in an "it . . . that" pattern

It was shown by using fibroblast growth factors (FGFs) in explant cultures ^ the visceral endoderm could be induced to express the liver-specific genes albumin and α-fetoprotein.

Revision (de-ellipsism)

*It was shown by using fibroblast growth factors (FGFs) in explant cultures **that** the visceral endoderm could be induced to express the liver-specific genes albumin and α-fetoprotein.*

Notes

The *it . . . that* pattern is useful to delay placement of an extra-long noun clause from the subject position of a sentence. However, in the example, the *that* is missing, so the reader's expectation of the sentence pattern is not fulfilled.

In another type of pattern, such as *given that*, *that* is often ellipsed probably with just a momentary dissonance effect, because the reader automatically supplies the *that*. As evidence, *given* and *given that* are used interchangeably as a subordinating conjunction meaning *accepting that: A video sequence with better quality was transmitted by the VBR channel than by the CBR channel, given (that) the same average rates were used in both channels.*

Contextual sections

Part 1 – Introduction section: hypothesis

Example: elliptical noun clause in an "it . . . that" pattern

It is possible ^ the rate of bone resorption is significantly less for the indomethacin-treated rats.

Revision (thematisation)

The rate of bone resorption may be significantly less for the indomethacin-treated rats.

Notes

In the revision, in addition to replacement of the complementiser *that* (see Part 2) another revision option is indicated: thematisation. *It . . . that* sentences, while providing sentence variety and emphasising commentary (e.g., *possibility*), delay the thematic sentence subject and the main verb of the sentence.

Part 2 – Introduction section: hypothesis

Example: elliptical noun clause as a subject complement

One possibility is ^ a large proportion of the vitamin was bound to protein.

Revision (de-ellipsism)

*One possibility is **that** a large proportion of the vitamin was bound to protein.*

Notes

There is a subject-to-verb three-word gap in the noun clause, but the explicit logical relation between the subject *one possibility* and the subject complement *a large proportion* minimises the omission of *that* on immediate comprehension. The noun clause functioning as the subject complement (a renaming of the subject *possibility*) can be tested. That is, the subject complement and subject can be interchanged: *That a large proportion of the vitamin was bound to protein is one possibility*. Although useful as a test, placement of a noun clause into the subject position is an infrequent sentence pattern, probably because the overlong subject delays the main verb of the sentence.

Part 3 – Discussion section: hypothesis support

Example: elliptical noun clause object in a participial phrase

These investigations enabled concluding ^ the experimental conditions necessary to reduce the ejection force were fulfilled.

Revision (de-ellipsism)

*These investigations enabled concluding **that** the experimental conditions necessary to reduce the ejection force were fulfilled.*

Notes

In the example, there are six words between the subject of the noun clause *conditions* and the verb were *fulfilled* – a sufficient number to recognise that something interferes with the flow of the sentence pattern. In support, if the words *necessary to reduce the ejection force* are deleted between subject of the noun clause and its verb, the conceptual gap is minimised, and the necessity for *that* is reduced: *These investigations enabled concluding the experimental conditions were fulfilled.*

Summary

The distribution of *that* is extensive in journal articles appearing both in the Experimental (Results) and Contextual sections (Introduction, Discussion). Overall, ellipsis impedes immediate comprehension when the verb of the noun clause

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is too distant from the subject. Another consideration is nonthematic focus whereby the *it . . . that* in a sentence delays rather than places the noun in the subject position – a lack of thematisation.

The necessity for a *that* fronting a noun clause appears directly related to the distancing in the noun clause of the verb from the subject; that is, the greater the distance the more the necessity. However, to reflexively insert a *that* regardless of the distance is usually the selected option when the two possibilities are compared. Such routine insertion is limited, because an excess of intra-sentence *that's* are distracting, necessitating a selective insertion of *that* where it is most necessary.

Addendum

Another perspective for not using *that* (in all of the revisions above) is redundancy. Such over-usage of *that* may be analogous to over-usage of *the*. Even though grammatically correct, any over-usage, especially in the same sentence, can become distracting. Consequently, a hierarchy of specificity can be applied: eliminate the least specific usage.**

The redundancy of *that* is emphasised when the complementiser *that* occurs along with *that* as the relative pronoun (marked below to be deleted) in an adjective clause:

These would be the vitamins ~~that~~ you were taking at the time ~~that~~ you became pregnant not the vitamins ~~that~~ the doctor suggested that you take when you learn that** you are pregnant.*

The first complementiser *that** seems unnecessary because it is predundant to the second *that*, which seems necessary for emphasis.

*These would be the vitamins you were taking at the time you became pregnant not the vitamins the doctor suggested you take when you learn **that**** you are pregnant.*

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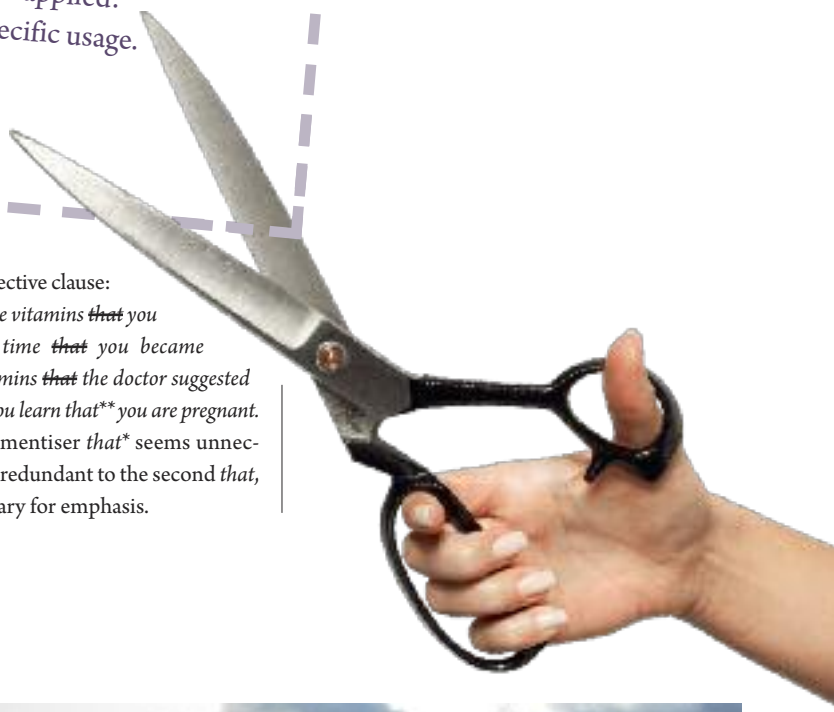
Even though grammatically correct, any over-usage, especially in the same sentence, can become distracting. Consequently, a hierarchy of specificity can be applied: eliminate the least specific usage.



Medical Communication

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Editorial

Dear all,

In this first issue of 2019, I present an article from Julia Forjanic Klapproth and myself on one of the latest "hot topics" – medical writing apprenticeships.

This topic is something that I know many experienced medical writers feel very strongly about, and it is a topic very close to Julia's and my hearts'. The ability to mentor and pass on knowledge and support to newer medical writers is one of the greatest things about EMWA and one of the things I personally value the most. However, most people need far more than mentoring and the excellent EMWA workshops to truly grow and develop the extensive skill set needed by a medical writer. Julia and I have spent many years training new (and experienced) medical writers, and we describe our thoughts and concept in this issue's article. As we explain, the model of apprenticeships is not new to many industries, and we have found that it works brilliantly for medical writing. Surely it should be far more widespread?

This issue's article is a heartfelt plea to the Industry to take the training of medical writers even more seriously than they do now. It can sometimes be difficult to build a business case for investment in training, and if you are pushing on a firmly closed door, I hope that this article will encourage and help you to open it … even if just a little.

Bestest,
Lisa

How to build a medical writer – new training for a new breed

Training medical writers has never been an easy task – there is a specific and demanding set of skills needed to tease out the crucial messages from data, manage stressed and pressured teams effectively, and keep up with the constant changes in the regulations and updates to templates. It is rare that an individual has all of these skills and most must be acquired and honed. There are many different suggestions and methods to train writers – all with varying degrees of success and aimed at slightly different outcomes. This article suggests a holistic approach of medical writing apprenticeships that the authors have been using for many years, based on the principle that medical writing is a craft not a defined check list, and the best way to learn any craft is from a skilled and experienced "master craftsperson".

Everyone involved in preparing regulatory documentation in the pharmaceutical industry is always on a desperate look out for excellent medical writers with years of experience writing the documents they need. But those mythical beasts are few and far between. The reason for this is that there is very little training provided across the industry to actually produce medical writers – let alone excellent ones.

In fact, although the discipline of medical writing is no longer new, the path to becoming a medical writer is often shrouded in mystery. The training that is available to anyone new to the profession varies considerably and very much depends on the institution hiring the new medical writer. Most medical writers learn the job by the "sink or swim" method: they are hired based on signs of potential and a basic skill set, given a set of journal Instructions to authors or the ICH regulations and some data, and told to "carry on". Or, they decide to become freelance medical writers – because they have a science degree and they know how Word works, so they just follow the regulations and try to figure it out. It is not surprising that so many documents are so poorly written with this as the status quo of becoming a medical writer.

Some companies offer some form of internal on the job training, which can be anything from being given the SOPs and internal company writing guidelines and told to ask if they have any questions, right through to specialised sequences of training carried out by both internal and external trainers. However it is done, and to whatever extent, two things are true: there are costs associated with training a new writer in terms of time and budget, and without training, both the writer's skill set and the end product suffer dramatically.

In fact, good medical writing is more than just a skill set, it is a *craft*, which means that it takes time to learn and hone. Medical writers must take material from various sources, of various quality, and mould that information into a succinct story. On its own, the ability to communicate ideas clearly is a craft unto itself. But in addition, medical writers must have the ability to work with many different contributors and accurately capture what all of those people envision is the right story to tell – often teasing out the key messages from tangential ideas to help keep the story focussed and meaningful. The combination of crafting thought into the written form and guiding teams through mountains of data and sometimes heated and politically charged discussions is a dual skill set that must be developed and refined to cultivate medical writers who are masters of their craft.

Most companies who recognise the importance of training their medical writers work with a mentoring concept, in which less experienced writers have a designated, more experienced writer they can turn to for help, support and guidance. Medical writers are well aware of mentoring – the Australasia Medical Writers Association has a formalised mentoring programme for medical writers[1] and some universities offer mentoring opportunities to students for medical writing.[2] Mentoring is traditionally defined as "a process in which a more skilled or more experienced person, serving as a role model, teaches, sponsors, encourages, counsels and befriends a less skilled or less experienced person for the purpose of

promoting the latter's professional and/or personal development".[3] Combined with other methods of teaching (e.g., workshops, conference attendance, training courses), the rewards of this form of teaching can be immense to both the company and the employee, and higher staff retention rates and job satisfaction scores are seen.[4] The concept is also embraced in the pharmaceutical industry, and 'mentoring ability' is often a requirement for more senior level writers.

However, mentoring usually takes the form of formalised meetings at regular intervals, with the mentor and mentee going about their daily lives with little interaction in the interim.[5] To truly learn the craft of medical writing, merely providing a mentor to guide and offer advice on occasion is rarely enough. As for any skilled craft, what is needed is a true apprenticeship. The Lombardo and Eichinger 70/20/10 Learning and Development model states that approximately "70% of knowledge or development comes from on-the-job experiences, tasks, and problem solving, 20% from feedback and from working around good or bad examples of the need, and about 10% from courses and reading".[6] Medical writing is no different and should be learned on the job and under the tutelage of a master craftsperson – someone who already has the knowledge and skills to not only explain what should be done, but to *show* the pupil how to do it. This incorporates the traditional methods of workshops and training courses, but with added, intensive, ongoing on-site training given on a one-to-one basis.

Apprenticeships require investment from all involved – from the company that must give the time to its employees to work together, and from the supervisor and apprentice, who must both invest time and energy in a learning experience that can last months or even years. Whilst this approach is well known and finely honed in other industries,[7] the idea of apprenticeships for medical writing is almost unheard of. Many articles have been written extolling the virtues of being able to learn under the guidance of a more experienced writer,[2,8,9] but true apprenticeships involve a level of on the job training and learning that goes far beyond traditional mentoring and are rare.

A medical writing apprenticeship hinges on working closely with medical writers who are very experienced and skilled in the area that the apprentice is trying to learn, and it moves far beyond traditional mentoring. Ideally an apprenticeship will last as long as it takes for a trainee writer to grow into their craft, culminating in their demonstrable ability to produce and manage complete documents on their own to everyone's satisfaction. This is a process that can take anywhere from 3 to 5 years, and varies with each writer. Everything the apprentice writes is reviewed and revised by an experienced writer, who then explains the rationale for the changes made. Working closely with several experienced writers on different projects has the added

advantage of sharing a broader knowledge and experience base with the apprentice. Shadowing the experienced writers as they work with authoring teams helps the apprentice learn what types of issues are worth fighting for and which ones can be accepted as is. They learn and understand what decisions they can make on their own and which ones they need to get team input on; what information they should spend time researching and what they should go back to their experts for. It is the balance of 'getting on with it' to pull the document together from what is available and knowing when to go back to a team to get further advice or trigger important team discussions that makes a good medical writer an added value to their teams. It is the knowledge transfer from the experienced writers to the apprentice on a day-to-day basis at all levels of the job that helps the apprentice to learn how to make the many decisions a medical writer is confronted with.

In addition to the day-to-day guidance provided by the supervisor, a true apprenticeship also involves regular course work over the duration of the apprenticeship programme to deepen the apprentice's theoretical knowledge and academic understanding of the area in which they are specialising. It is possible to meet this need in the context of medical writing by means of on site and online training courses available from organisations such as the European Medical Writers Association,[10] the American Medical Writers Association,[11] and the Australasian Medical Writers Association,[12] all of which offer certificates in many areas of medical writing. Other courses of varying length and cost are also available – including master's degree courses.[13] Unfortunately, these training options are used by many companies as the sole method of teaching their writers, without the essential day-to-day training that new writers need to then learn how to apply the theoretical tools they have learned. If the industry wants and expects to have medical writers who excel at their craft, then these two parts must go hand in hand.

It should also be noted that training is not just for new or inexperienced medical writers – writers of all levels and experiences can and should benefit from ongoing training. The field of medical writing is ever evolving and ever changing and so ongoing continuing professional development is crucial for anyone working as a medical writer, and the issues surrounding the best way to achieve this training applies to writers of every level.

With increasing legislation, decreasing timelines, and the new technological and artificial intelligence–based advances in medical writing, the demands on medical writers, and the requirements of their skill set are increasing exponentially. We truly are demanding a new breed of medical writers who must not only be expert writers, but robust enough to adapt on an ongoing basis to new regulations, an increasingly stressed pharmaceutical industry, and to having more and more responsibility placed on their time and skills. It is an exciting and thrilling time to be a medical writer – increasing demands bring with them increasing opportunities, but training for this "new world" cannot be done with training courses and mentorships alone.

Good medical writers are born…but excellent medical writers are created through apprenticeships.

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Regulatory Public Disclosure

Editorial

Regulatory public disclosure (RPD) is the subject of this regular MEW section, and EMWA's RPD Special Interest Group (SIG) – together, we help you develop your understanding and maintain your knowledge.

In the EMA region, we find ourselves in a lull with clinical data publication, ostensibly because EMA is focussing on their relocation from London to Amsterdam. By the end of October 2018, EMA had published all submitted clinical data, had cancelled new submissions due after August 1, 2018, and had suspended all new activities relating to the publication of clinical data. There is no timetable for the lifting of this suspension. EMA's web page "Support for industry on clinical data publication" (https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry-clinical-data-publication) is a valuable resource – check it regularly. In Q4 2018, I asked EMA if they could confirm if submissions made between Aug 2, 2018, and the (future) date of the lifting of the suspension - will or will not be subject to retrospective publication? EMA responded: "EMA is only processing applications adopted by CHMP up to the first quarter of 2017 and which were submitted to the Agency by July 31, 2018, (upon receipt of an Invitation letter). We cannot currently comment on how the process will be resumed and whether clinical data will be published retrospectively. EMA will contact concerned applicants/MAHs prior to the restart of clinical data publication, once its relocation to Amsterdam is completed. We appreciate any preparatory work done by companies regarding their upcoming CDP package submissions, however, and EMA is asking companies simply to pause any ongoing work until further notice."

When the suspension is lifted, Policy 0070 implementation guidance Version 1.4 dated October 15, 2018 (https://www.ema.europa.eu/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-3.pdf) will apply. As we need to be working towards this latest guidance, I summarise the changes from Version 1.3 below. I also spotlight EMA's first report on the Policy 0070 publication of clinical data, and in particular the commercially confidential information (CCI) redacted and the anonymisation techniques used. In doing so, I hope to help you carefully consider CCI presentations in your documents.

Our feature article this quarter, brought to us by Hiroko Ebina and Jocelyn Coquhoun of Envision Pharma Group, is a status update about the growing awareness of the clinical trial disclosure landscape in Japan (see page 74). The authors describe current disclosures and commitments to clinical trial data sharing in Japan, and explain the effect of the Common Technical Document on CSRs used for Japanese New Drug Applications. In short, understanding in Japan of the importance of preparing disclosure-ready CSRs to meet global requirements is growing.

The developers of CORE Reference are pleased that the developers of the TransCelerate clinical study report (CSR) template used CORE Reference and ICH E3 extensively during their template development process. Read the CORE Reference Press Release about this (https://www.core-reference.org/news-summaries/core-reference-statement-on-transcelerate-csr-template/), which includes links to all relevant materials.

In many ways, EMA's lull in clinical data publication allows time to reflect, fine-tune our disclosure processes, and consider what we would like to improve upon – in time for the lifting of the suspension.

Please continue to approach me with your articles and tips to optimise disclosure writing. I will continue to information share via this MEW regular section, through www.core-reference.org emails (sign up at: http://www.core-reference.org/subscribe), and through EMWA News Blasts.

Sam

SECTION EDITOR

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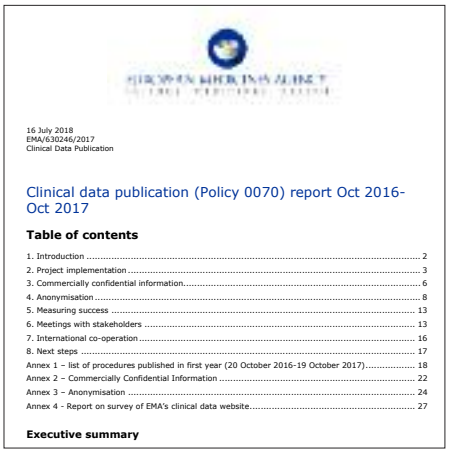
Commercially confidential information in clinical reports

EMA published their first report on the Policy 0070 publication of clinical data (July 16, 2018): https://www.ema.europa.eu/documents/report/clinical-data-publication-policy-0070-report-oct-2016-oct-2017_en.pdf. Over the period October 2016 to October 2017, EMA's report provides information on the total number of documents published, the amount of commercially confidential information (CCI) redacted and the anonymisation techniques used.

By gaining understanding about the types of information that might be accepted for redaction in clinical documents under the auspices of CCI, we can better judge the types of CCI that if included in our reports, might reasonably be expected to be accepted for redaction. Annex 2 of EMA's report reveals that a quarter of CCI proposals made by applicants were accepted by EMA, hence redaction of that information was allowed. All accepted CCI was related to pharmaceutical development; reasons for acceptance of CCI were broadly categorised as "Quality" (49 instances accepted) and "Clinical" (60 instances accepted). Detailed reasons for CCI acceptance within these two broad categories are illustrated in EMA's report (Figures 1 and 2).



16 July 2018
EMA/630246/2017
Clinical Data Publication

Clinical data publication (Policy 0070) report Oct 2016-Oct 2017

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Executive summary

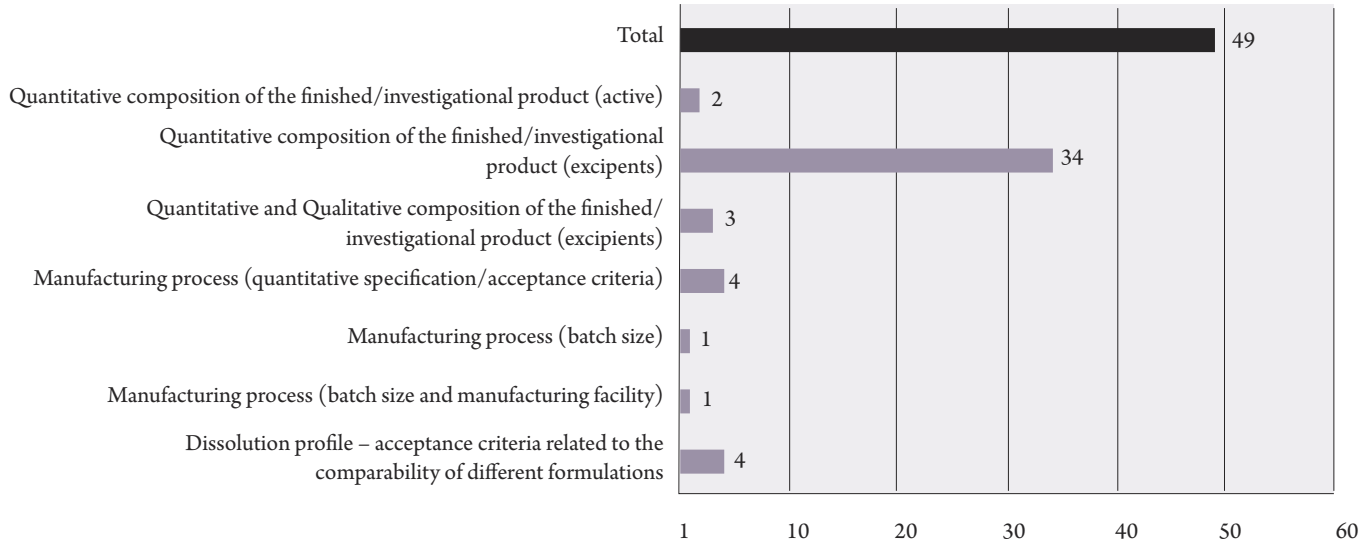

Figure 1. Quality CCI accepted – pharmaceutical development – detailed reasons

Source: European Medicines Agency. Clinical data publication (Policy 0070) report Oct 2016-Oct 2017. Annex 2, Figure 12
https://www.ema.europa.eu/documents/report/clinical-data-publication-policy-0070-report-oct-2016-oct-2017_en.pdf

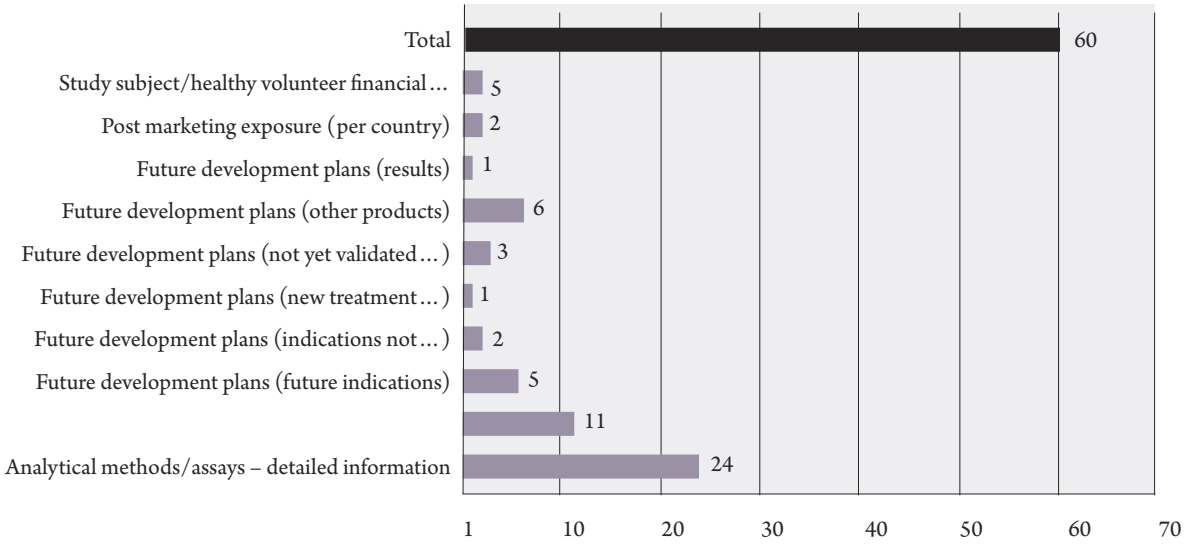

Figure 2. Clinical CCI accepted – detailed reasons

Source: European Medicines Agency Clinical data publication (Policy 0070) report Oct 2016 - Oct 2017. Annex 2, Figure 13
https://www.ema.europa.eu/documents/report/clinical-data-publication-policy-0070-report-oct-2016-oct-2017_en.pdf

CORE Reference

Read our Press Release on TransCelerate's CSR template and use of CORE Reference in its development: (https://www.core-reference.org/news-summaries/core-reference-statement-on- transcelerate-csr-template/)

CORE Reference (available for download from http://www.core-reference.org/core-reference/) identifies each point in an ICH E3-compliant CSR where anonymisation considerations should apply. Downloads stand at 17,000+ (March 2019).

CORE Reference has a News Summaries page: https://www.core-reference.org/news-summaries where relevant regulatory and disclosure news is posted periodically. Stay one step ahead and receive these updates in "real time" by signing up at: http://www.core-reference. org/subscribe.

Summary of Changes – EMA Policy 0070 Implementation Guidance Version 1.4

The following major changes to guidance are effective when clinical data publication by the EMA resumes:

1. Clarification has been provided on the publication of withdrawn applications in cases where the application has been re- submitted or has an agreed re-submission date
2. Clarification has been added on the publication of clinical studies where the main period/phase of a clinical study is still ongoing at the time of publication
3. Timetable of the main steps of the end-to-end process for the publication of clinical reports has been added
4. Wording has been added to reflect the review of the anonymisation report that takes place during the consultation phase
5. Wording has been added on the potential need to submit an updated anonymisation report and/or written responses to the comments transmitted by EMA on the anonymisation report before the submission of the Final Redacted Document package
6. Wording has been added flagging the availability of a checklist to assist applicants/ marketing authorisation holders with the preparation of the Final Redacted Document package
7. Template paragraphs and use instructions within the cover letter regarding studies already published previously under Policy 0070 have been included
8. In addition to the checklist for the Redaction Proposal Document package, a new checklist for the Final Redacted Document package has been added.

Several minor changes are also detailed. For EMA's complete Summary of Change document, see https://www.ema.europa.eu/documents/other/summary-changes-external-guidance-implementation-european-medicines-agency-policy-publication_en-2.pdf.

Status Updates – from Regulatory Regions

Europe

1. Clinical data disclosure is suspended until further notice from EMA. Check EMA's web page 'Support for industry on clinical data publication' (https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/ clinical-data-publication/support-industry-clinical-data-publication) regularly
2. On 04 Dec 2018, EMA published a 32-page data anonymisation workshop report (https://www.ema.europa.eu/documents/report/report-data-anonymisation-key-enabler-clinical-data-sharing_en.pdf) on the 30 Nov – 01 Dec 18 workshop "Data anonymisation – a key enabler for clinical data sharing" held jointly between EMA and the US-based Multi Regional Clinical Trials Center covering:

- The global landscape for clinical data sharing
- The foundations of data anonymisation
- The mechanics of anonymisation – meeting the challenge of different types of data
- Balancing access and data utility
- Future challenges for data anonymisation.

Canada

The Health Canada regulation on public access to clinical information on drugs and medical devices will finally be published on March 20, 2019. Press release: https://www.canada.ca/en/health-canada/news/2019/03/health-canada-finalizes-regulations-to-provide-public-access-to-clinical-information-on-drugs-and-medical-devices.html

– from the Journals

Hendrick Schmidt and Boehringer Ingelheim (BI) colleagues wrote a collaborative 'Corre-spondence' piece in the New England Journal of Medicine with the University of Basel. The article titled "An Industry Experience with Data Sharing" (https://www.nejm.org/ doi/full/10.1056/NEJMc1805610) describes BI's experience – as a member sponsor – in listing studies on https:// ClinicalStudyDataRequest.com

Resources

1. Visit the RPD SIG members' page: https://www.emwa.org/members/special-interest-groups/regulatory-public-disclosure-sig/ and the subpage for disclosure-related regulatory news updates: https://www.emwa.org/members/special-interest-groups/regulatory-public-disclosure-sig/regulatory-news-emwa-newsblast/.
2. "Anonymizing Health Data: Case Studies and Methods to Get You Started" by Khaled El Emam and Luk Arbuckle, ISBN number 978-1-449-36307-9, is available as an eBook. Précis: "Updated as of August 2014, this practical book will demonstrate proven methods for anonymizing health data to help your organization share meaningful datasets, without exposing patient identity. Leading experts Khaled El Emam and Luk Arbuckle walk you through a risk-based methodology, using case studies from their efforts to de-identify hundreds of datasets."
3. "Guide to the De-identification of Personal Health Information" by Khaled El Emam, ISBN number 978-1-4665-7906-4, is available as an eBook. Précis: "Offering compelling practical and legal reasons why de-identification should be one of the main approaches to protecting patients' privacy, the Guide to the De-Identification of Personal Health Information outlines a proven, risk-based methodology for the de-identification of sensitive health information. It situates and contextualizes this risk-based methodology and provides a general overview of its steps."

Out on Our Own

SECTION EDITORS

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Editorial

Welcome readers,

Advertising is key for any freelancer. In order to get clients, you need to get yourself known and ideally have a platform to display your services, previous work, and clients; the more platforms you have, the better. Of course, there are many routes you can go: LinkedIn, Twitter, a personal website, printing business cards, but EMWA offers another platform, the Freelance Directory. We would like to think all our readers are aware of this platform, but we feel that it may not be the case. The platform is open, so anyone, from the pharmaceutical industry, an academic, to a medcomms agency, can browse through the listed freelancers to try to find the one that matches their project needs. It's available on the freelance tab on the EMWA website. Upon arriving there, it is possible to search freelancers by country, skills and services, subjects, languages, etc. The advantage is that in your profile you can use specific keywords that summarise you and your work. The more you refine your profile, the better. We suggest giving as much specific detail as possible to make yourself unique. There are currently 71 members registered on the Freelance Directory. The Freelance Business Group subcommittee is in the midst of updating the page and making it more accessible. In this issue of *Out on Our Own*, three experienced freelancers who are listed in the directory give an account of what their experiences have been, address whether it is worth the registration fee, and detail how many potential clients have contacted them through the directory.

We believe the EMWA Freelance Directory gives you another means to advertise yourself. Some housekeeping, you must be an EMWA member to be listed, and it is not a free service. Read on to hear these freelancers' views and experiences, and if you have ideas or want more information then, get in contact. Happy advertising!

Laura A. Kehoe

Benefits and experience of using the EMWA Freelance Directory

"Put an emphasis on what makes you unique."

Surprisingly, many professionals still don't fully appreciate how professional associations can help them in their career path. They may view associations as training grounds in a given field and forget or disregard all the other opportunities these can offer.

Among the many tools EMWA is currently offering to be used as marketing opportunities, we have the Freelance Directory. In this listing, clients may find freelance medical writers, medical editors, and translators who are members of EMWA and have decided to advertise themselves using this marketing toolkit. Clients may use filters such as skill, therapeutic area, name, or country to find the most appropriate professional for their needs.

EMWA is a high-profile association, which means that EMWA members may also be considered as high-profile professionals. Being an EMWA member shows an understanding of the importance of professional continuing education, of being up to date with what is happening within the field, and of many other professional issues. This means that when a client is looking for someone in the EMWA Freelance Directory, he or she is looking for a qualified professional and perfectly knows that such know-how needs to be appropriately compensated.

EMWA is a high-profile association, which means that EMWA members may also be considered as high-profile professionals.

When I first decided I wanted to be listed in the Freelance Directory, I had two goals in mind. First, I felt very committed to the association and all the hard work it was doing at the time (and still does) to promote and advance our profiles, and thus, I thought that being present in that listing gave me a sort of "label" of which I was very proud. Second, I was in a situation in which I was not enjoying some of my clients anymore and wanted to be able to say goodbye to them. So, I needed to expand and improve my portfolio of clients.

I first subscribed to the listing in September 2014, and 3 months later I received a phone call from a client needing to find a medical writer to cover four scientific board meetings abroad during the next 2 years. The phone call started like this: "Hello, I'm Mr. X, I've found your details in the EMWA website and would like to talk to you about …". This turned out to be a very interesting and nice project and, eventually, I have worked on several other projects for this same client. The total annual Freelance Directory fee – which is €90 – paid for itself very easily, then!

Over the years, I have received an average of three new contacts annually thanks to the directory. Not all of them have turned into actual clients, but some of them have. For example, in 2017, I was contacted three times, which led to one very interesting 6-month project. Likewise, in 2018, three contacts turned into two actual projects.

Currently, I think I have reached my two objectives. You may ask, why do I renew my presence in the listing year after year? Well, I do think that my presence in the listing is an extremely useful online business card and even if very often I get new contacts thanks to word-of-mouth, I know that clients check both LinkedIn profiles and EMWA's website as well.

If you are wondering whether you should subscribe to the listing or not, my advice would be to give it a try and see what happens. Target your profile according to the number of freelancers listed in the directory in your own country and put an emphasis on what makes you unique. Hopefully, your experience will be similar to mine!

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"The Freelance Directory did indeed work in my favour"

In August 2016, I set out on a new career path as a freelance science and medical writer. My client base consisted of one regular source of work, and through actively sending emails to prospective clients, this number gradually increased over time. However, my methods of self-promotion were very time-consuming, and even though I found clients using the targeted email method, I began to wonder if there was a better way to get my name out there.

On joining EMWA as a member, I noted that this did not automatically allow me access to the EMWA Freelance Directory which was a source of advertising I considered might be useful. Setting up a profile required a fee of €90 in addition to the EMWA membership fee, and while I understood that my membership was essential to develop a network of contacts, I wondered whether there was any evidence of the Freelance Directory being worth the additional fee.

In November 2016, I set out to attend my first EMWA conference in Belgium and went there with the aim of speaking to other freelancers who might be able to advise on whether the Freelance Directory fee was a good investment or not. When you are starting, and don't have many clients, €90 can be hard to part with unless there's some form of guaranteed benefit and I was hesitant at spending money I didn't have. At the conference, I sought the advice of a few people, but unfortunately, most of the delegates I spoke with were either employed, or were not in the Freelance Directory, and I left the conference without the information I hoped to gain.

Fast forward to May 2018 and my new position on the Freelance Business Group subcommittee – this time I was sure I could find out what the benefits were. Alas, no, there was still nobody in my immediate network who could tell me if it was worth spending the additional €90 or not, and nobody who could advise me whether it was a good source for potential clients to find my services. It was then I decided to conduct a small experiment. My EMWA membership was due in 3 months, in July 2018, so I registered for the Freelance Directory for the remaining 3 months membership to test it out. If it didn't work out, I'd only paid for 3 months and not a full year. I parted with my pro-rata ~€30 and set up my profile. By the time July came around for my membership renewal, I was a bit disappointed not to have received any enquiries via the Freelance Directory. However, I decided to give it another chance – business was good, and I could now afford to lose the fee if it didn't work out. So, in July 2018 I renewed my EMWA membership and registered for the Freelance Directory for a full year.

This time things started to happen. In September I received a phone call from a client who had found my profile while searching through the Freelance Directory. He advised me that this was the first place medical communication companies are likely to use to source freelance medical writers and offered me a project, which I accepted. This project was exactly the type of work I was looking for, and since then we have developed a good working relationship, which has led to regular projects and a new established client. A month later, I received another call, this time from a different medical communications company, which resulted in another great project, an excellent experience, and another new client. A third phone call that same month led me to turn down work as I now had two new clients who could provide as much work as I could take on. In addition to my existing long-term clients, I am now extremely busy. I received all three phone calls after the clients sourced my details from the EMWA Freelance Directory, and none of these enquiries came through my website, LinkedIn profile, or any other form of self-promotion I used. I have had many emails and messages via LinkedIn, but these are mainly from recruitment agencies.

After 5 months of having my profile in the directory, finally, I had my answer – yes, the Freelance Directory did indeed work in my favour and is a valuable source of freelance writers for clients. Now that I think about it, even in those early days when I had limited earning potential, even one new project would have covered the €90 fee for the Freelance Directory. Not only that, it would have likely led to more projects and more clients. I can see this now, but when I was starting on my freelance career, I wasn't able to appreciate the bigger picture.

For anyone beginning a freelance career, who may also be hesitant about paying the Freelance Directory fee, let me assure you that I have had only a positive experience. My next task in 2019 is to improve my profile to include all the new work experiences I have had over the last 3 months and to fine-tune my details to make sure that I am found quickly when potential clients perform a search of the directory entries. In 2019, I am looking forward to developing long-term working relationships with my new clients, and I am hopeful that the Freelance Directory will help direct more new clients to my services. I've even joined the Australasian Medical Writers Association Freelance Directory to see if that bears any fruits, too. Let's see.

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"We should all be aware that as freelancers we can use each other to bring in work."

Having worked first in scientific research and then in education, about 10 years ago, I decided to set up as a freelance Dutch-to-English medical translator. My business soon expanded to include editing, writing, and training in scientific writing. While building up my business, I've always found my network – both local and online – to be a good source of work*, and when I joined EMWA in 2011 it was partly for access to the journal and partly to connect with like-minded professionals. Having not yet attended an EMWA conference, I do realise that I am missing out on meeting others face to face, but luckily the directory has indirectly put me in touch with other medical writers in my region. More on this below.

I've had my services listed in the Freelance Directory since 2017. In the 18 months since then, I've noticed that potential clients have only started to find me there in the last 6 months, which could be simply a coincidence or perhaps an indication of an increasing need for freelance medical writers. I have been pleasantly surprised by the diversity of emails I've received – both in terms of the type of client and the type of assignment – and I'm pleased not to have received too many messages from low-paying agencies or people looking for services that do not match the information provided in my listing.

Of the five clients that have contacted me through the directory, so far only one has resulted in a paid offer that I accepted – editing a grant proposal for a Danish university. However, this project easily covered my annual listing fee of €90, and the client has also passed on my details to other departments at the university – networking at work! The four other clients that have contacted me were as follows:

- A Swiss health communications company needed someone to write short congress reports. I couldn't take on the assignment as they caught me at a busy time, but they've kept my details on file for future reference.
- A Spanish editing company was looking to recruit more freelancers to edit scientific manuscripts written by non-native speakers of English. Since the hourly rate on offer was below what I normally charge I offered to share their request with other freelance medical writers and editors in my network.
- A Dutch clinical services company needed someone to write and revise clinical evaluation reports. As this is not something I have experience with, I again shared the information with others in my network.
- A UK-based non-native English-speaking researcher was looking for help writing up articles for publication based on chapters of his PhD thesis. We're still negotiating timeline and budget.

You may think it unnecessary to try and find another freelancer for new clients who contact me about assignments I cannot take on myself, but I think we should all be aware that as freelancers we can use each other to bring in work. My business would not be where it is today without referrals from within my network, and this is why I am keen to pass on potential work opportunities to others whenever I can. I've also found LinkedIn quite useful in this respect.

Given that EMWA has no members-only online forum or membership directory, the only way of finding other freelancers in EMWA is through the directory, so it's a shame that we're not all listed there. I think many of us do not realise that such a directory is just as important for being found by other freelancers as it is for being found by potential clients. Of course, when you're first starting out as a freelancer and still building your business, you have to decide which investments are going to bring in work, and I would imagine that joining professional associations such as EMWA, and attending conferences, workshops and other opportunities for networking and professional development take priority over paying for listing in the directory.

Having said that, some medical writers – both freelance and those working for companies – are managing to form their own networks. I recently joined a regional network of medical writers based in the Netherlands that is currently a Facebook group with more than 50 members. After a first informal meeting in June 2018, we held our first workshop in October and are getting together again in January 2019. For me, the connection came through my listing in the EMWA Freelance Directory, I connected on LinkedIn with Amsterdam-based freelancer Jackie Johnson who was also in the directory, and we met for coffee. Jackie is an active networker and is keen to help those new to EMWA or medical writing. In fact, many members of this local network are currently in academia and hoping to transition into medical writing, so it's an excellent opportunity for them to learn from others already working in the field. We share resources and job opportunities, and the discussions – both online and in person – have proved very supportive and inspiring.

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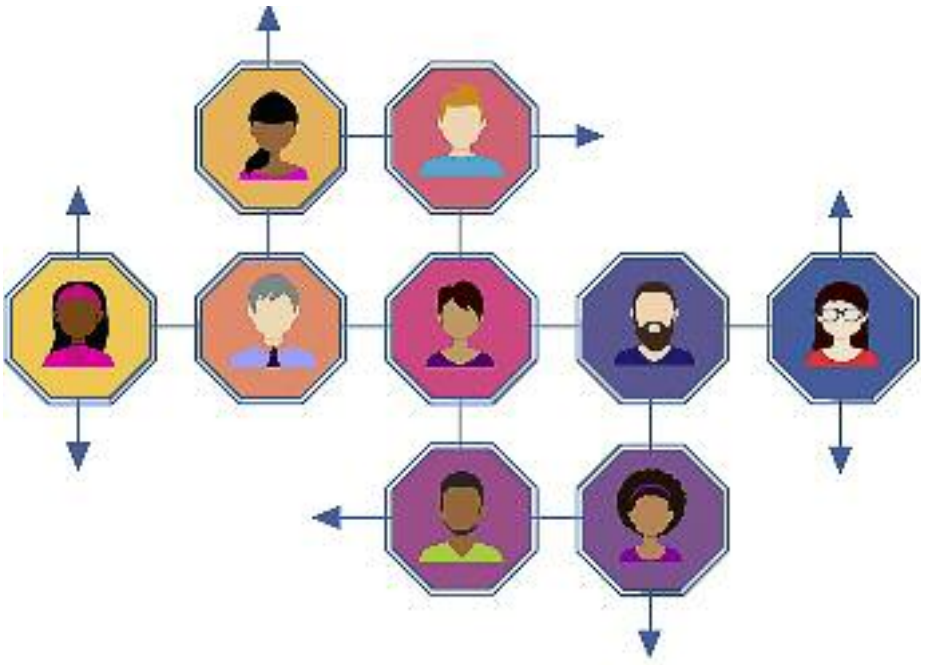

*See https://www.sense-online.nl/about/sense-publications/ esense/728-esense-40-2016/file for an article on networking that I wrote in 2016 for SENSE, the Society of English-language professionals in the Netherlands (found on pages 5-8 of the PDF).

Upcoming issues of **Medical Writing**

June 2019:

Generics and biosimilars

This issue will introduce readers to generics and biosimilars; provide and discuss their key legal and regulatory aspects in the US and Europe; and discuss their economics and how they affect pharmaceutical companies.

Guest Editor: Diana Radovan

The deadline for feature articles is March 10, 2019.

September 2019:

Trends in medical writing

The medical writing industry is growing and evolving at a fast pace, and we need to keep up with the trends. From public disclosure to global medical writing, find everything you need to know in this issue.

Guest Editor: Somsuvru Basu

The deadline for feature articles is June 10, 2019.

December 2019:

Artificial intelligence & digital health

Technological innovation is overtaking all industries, and medicine is no exception. Artificial intelligence, digital health, biohacking, and health optimisation are growing trends, and as medical writers, we must understand and communicate these advances.

Guest Editor: Evguenia Alechine

The deadline for feature articles is September 9, 2019.

CONTACT US

If you have ideas for themes or would like to discuss any other issues, please write to **mew@emwa.org.**

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