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Medical Writing



Trends in medical writing

Also in this issue...

- AMWA–EMWA–ISMPP Joint Position Statement on Predatory Publishing



EUROPEAN MEDICAL WRITERS ASSOCIATION



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WRITERS
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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.

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Medical Writing

Trends in medical writing

It is my privilege to present you the *Medical Writing* special issue garnering the current Trends in the Medical Writing sphere. With the perpetual amendments in the pharmaceutical industry and the ever-evolving approaches in operating and disseminating biomedical research, we are witnessing a matching progression in medical writing. Be it battling the rampant free-flowing medical misinformation in this post-truth world, or public disclosure of clinical trials, or the drifts in manoeuvring artificial intelligence and digital health, medical writers are prudently setting trends. We have assembled these anecdotes, in the form of thirteen feature articles, which are gaining attention by diversifying the already-colourful medical writing arena.

In the opening piece, **Raquel Billiones** discusses the latest development in biomedical exploration (biohacking, combination products, vaccine hesitancy, and many more aspects), which could eventually dictate the medical writers to modulate our stance. **Maria Carolina Rojido** enlightens us about lifestyle medicine: its importance in tackling non-communicable diseases, and the promising opportunities for the medical writers in this incubating field. **Martin Delahunty** walks us through the advancement in artificial intelligence-based tools fitted to support the scientific and medical publishing in his insightful account “Will we be replaced by robots?”

Content is king – we medical writers are aware of that. Nevertheless, a one-size-fits-all tactic will not help us achieve our goals. Then, how should we efficiently plan-develop-disseminate accurate and useful content for a diverse readership under different state of affairs? The following four articles unravel the solutions:

Science communication offers researchers with an invincible power of story-telling their discoveries to a broad array of population. **Melvin Sanicas** urges scientists to engage more with the public by protecting them from the malady of misinformation.

In this era of big data, keeping pace with the stockpiling scientific and medical data is a painstaking task. As a resolution, the content curators come into play, where they amass pertinent contents on a specific topic from a wide range of sources and serve it in a systematised fashion to respective clients. **Laura C. Collada Ali**, **Jackie L. Johnson**, and **Amy Whereat** shed light on the role of medical writers in content curation. Equipped with a blend of analytical and writing skills, medical writers could act as content curators

presenting trustworthy information to clinicians or patients. The trio expands the discussion by providing tailored strategies designed for specific audiences.

The American Medical Writers Association (AMWA), European Medical Writers Association (EMWA), and International Society for Medical Publication Professionals (ISMPP) have recently released a Joint Position Statement on Predatory Publishing,¹ educating us about this malign practice. We are republishing it in this issue. On a similar note, **Andrea Bucceri**, **Peter Hornung** and **Thomas M. Schindler** delve deeper into this topic making us aware of the severe consequences of publishing in these pseudo-journals. Moreover, they propose several recommendations to evade being knuckled down by the predatory publishers.

Taking the proceedings forward, **Diana Ribeiro** and **Mathew Wong** talk about the responsibility of medical writers in creating a precise content strategy to crack the vicious puzzle of medical misinformation in this age of “fake news” and “viral pseudoscience”.

As a successful trendsetter and inspiration for the freelance medical writers, **Brian Bass** highlights his precious experience about building medical writing business via the subcontracting/outsourcing path. He explains the pros and cons of the subcontracting practice, guidance that could be an asset for the future subcontractors.

In the next two articles, patients are at the cynosure. **Lisa Chamberlain James** and **Trishna Bharadia** cover the practical details of writing a lay summary, especially emphasising the challenges associated with the process and guidance for the medical writers to nurture the science-public alliance. **Vivien Fagan** shares her fascinating journey from regulatory writing to be in the field of clinical trial disclosure. She elucidates the actions she has taken along the transition, being under the umbrella of a clinical research organisation.

Be it battling the rampant free-flowing medical misinformation in this post-truth world, or public disclosure of clinical trials, or the drifts in manoeuvring artificial intelligence and digital health, medical writers are prudently setting trends.

It is challenging to stay abreast of the up-to-date regulatory practices in the dynamic setting of pharmacovigilance legislation. To make your job easy, **Sushma Materla** put forward a comprehensive approach to write a risk management plan. **Surayya Taranum** illuminates the latest trends in regulatory writing, guiding us around the developments in EU regulations for medical devices, data protection (General Data Protection Regulation and EMA policy 0070), and the influence of artificial intelligence in the global medical writing market. Finally, **Clare Chang** explains the transforming regulatory medical writing scene in China, particularly upon China's inclusion as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Moreover, she talks about the striking growth at the Chinese popular science writing turf – a steady stride boosting societal science awareness.

Before summing up, I would like to thank all authors for their esteemed contributions. I thoroughly enjoyed reading their edifying accounts. Big thanks go to Evguenia Alechine and Victoria White for their relentless help and support to put this issue together. I hope you find this issue of *Medical Writing* interesting and enlightening, inspiring the trend-setting medical writer within you!

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Corrections to articles published in June 2019 *Medical Writing*



Because of a production error that occurred after the authors' final review of the proofs, an incorrect symbol was displayed on p. 28 of the June 2019 issue of *Medical Writing* (Volume 28, Number 2), in the article titled "Statistical principles in biosimilar development".

The error was not present in the print version of the journal but was online for some time before being corrected.

The null hypothesis is stated correctly below, with the symbol before 1.25 correctly displayed as greater than or equal to.

$$H_0: \mu_T / \mu_R \leq 0.80 \text{ or } \mu_T / \mu_R \geq 1.25$$

$$H_1: 0.80 < \mu_T / \mu_R < 1.25$$

On p. 70, in the article titled "International Committee of Medical Journal Editors' requirements for sharing individual participant data from interventional clinical trials", the text incorrectly indicated that clinical trial sponsors must pay fees for participating in all data-sharing platforms discussed. The platform Project Data Sphere does not charge fees.

The corrected paragraph appears below and has been updated online.

Clinical trial sponsors pay a fee for participating in some of these platforms, which provide most of the services relevant to assessing and processing the data sharing requests for IPD. These platforms help clinical trial sponsors meet the ethical obligations for sharing of deidentified/ anonymised IPD. Some current data-sharing platforms include the ClinicalStudyDataRequest consortium,⁴¹ the YODA Project,⁴² Vivli,⁴³ Project Data Sphere (does not charge any fees),⁴⁴ and DataCelerate.⁴⁵ Furthermore, several other clinical data-sharing platforms concentrate their efforts at a national or institutional level (e.g., US National Institutes of Health), or at a disease-specific level (e.g., Alzheimer's Disease Neuroimaging Initiative).⁴⁶

**Save the date: EMWA
Conference in Sweden**

MALMÖ

November 7-9, 2019

<https://www.emwa.org/conferences/future-conferences/>

President's Message

Dear EMWA Members

I was asked if the time between conferences is a quiet time. Having been in post just over 2 months at the time of preparing this report, I can most definitely state – NO! New initiatives are regularly proposed and I am often reminded of how active our EMWA members are, with their great breadth of experience and knowledge, boundless energy, and enthusiasm!

To note just a few recent actions and initiatives:

- Members of the Ambassadors Group have attended several career events and participated in a video for medics considering a move to medical writing; check out the video, which you can access through *EMWA News* on the website.
- Also on the website, EMWA's *Resources for Medical Writers* are a considerable plus for its members. Have you seen the recent addition? Under *General* resources, the CCJ Checklist for authors writing scientific manuscripts provides lots of useful reminders.
- A Hebrew version of the Joint Position Statement (JPS) on the Role of Professional Medical Writers has been added to the collection of different language translations, bringing the total to 12. Perhaps you can add to this? We are looking for someone to translate the statement into Arabic; if you can help, please email me.
- A second JPS has just been finalised on the hot topic of predatory publishing, which was the subject of a very interesting session at the Vienna conference in May. EMWA representatives worked closely with the American Medical Writers Association and the International Society for Medical Publication Professionals to produce the JPS. Hopefully, it will also be translated into several languages, so helping to widen its impact.
- The CORE Reference development team has published *in Research Integrity and Peer Review: Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table*, available at <http://dx.doi.org/10.1186/s41073-019-0075-5>.
- Webinars are now an established part of the offering to EMWA members. Grab a mug of coffee (or your lunch depending on the time



zone!) and join in. With a wide variety of topics in both the current programme and in the library of past webinars, something is sure to be of interest. Many thanks to the Webinar Team, and thanks, of course, also to the presenters.

- Education Committee (EPDC) members have worked with EMWA Head Office to plan a diverse offering of workshops for the November conference in Malmö, Sweden. The EPDC also actively supports people developing new workshops. To help, they have developed a new workshop proposal form and timelines for developing a workshop, so that a potential workshop leader knows exactly what is needed and when! If you are considering giving a workshop, have a look at the website.
- Several new workshops will be run in Malmö including one in the increasingly important area of Medical Devices, which will complement the work of the Special Interest Group for Medical Devices (MD SIG). We now have five SIGs: Pharmacovigilance, Regulatory Public Disclosure, Medical Communication

and Veterinary Medical Writing (newly formed at the May conference), as well as the MD SIG; these greatly contribute to planning the Expert Seminar Series and Symposium held at each May conference.

- If you would like to be more involved with EMWA and can spare a little time, we are always looking for more volunteers. Keep an eye on *EMWA News* on the website and the monthly *Newsblast* email for updates and opportunities. All are welcomed.

I am looking forward to seeing many of you in Malmö at our 49th EMWA conference: November 7–9, 2019. Registration is open – go book! If you haven't yet made up your mind about coming, check out the August webinar, which can be accessed by both EMWA and non-EMWA members.

And if you cannot come to Malmö, remember to save the dates of our special 50th conference in Prague next year: May 5–9, 2020.

Barbara Grossman
president@emwa.org

EMWA News



AMWA-EMWA-ISMPP Joint Position Statement on Predatory Publishing released

On July 29, EMWA, together with the American Medical Writers Association (AMWA) and the International Society for Medical Publication Professionals (ISMPP), issued a joint position statement on the dangers of predatory publishing (see p. 34 of this issue). Predatory publishers and journals exist purely for profit. They undermine the

publishing process by failing to perform rigorous peer review and show little apparent regard for the ethical principles detailed in guidelines such as the International Committee of Medical Journal Editor Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. The

AMWA–EMWA–ISMPP position statement outlines the damage predatory journals do to authors and to the scientific community as a whole and provides practical tips for spotting such journals. It also underlines the responsibility we medical writers have for ensuring that the manuscripts we work on are not submitted to predatory journals.



New translations of the AMWA–EMWA–ISMPP Joint Position Statement on the Role of Professional Medical Writers

EMWA is also currently involved in translating another AMWA–EMWA–ISMPP joint position statement on the role of professional medical writers. Issued in 2017, this position statement sets out ethical standards for medical writers who help to develop scientific and medical publications. We are now spreading the word among non-native English speakers in Europe and

beyond. The position statement was recently translated into Hebrew by EMWA member Sharon Furman-Assaf. Originally published in English, the statement is now available from the EMWA website (<https://www.emwa.org/joint-position-statement>) in French, German, Italian, Spanish, Romanian, Portuguese, Hungarian, Ukrainian, Russian, Farsi, and Greek.

EMWA Ambassadors participate in webinar on careers in medical writing

As part of continuing efforts by the EMWA Ambassador's Programme to reach out to new audiences in order to promote medical writing and EMWA, John Dixon and Abe Shevack took part in a webinar organised by Medic Footprints, an organisation focussed on the various career opportunities available to medical doctors. The target audience was medics interested in exploring careers outside of medical practice. Abe spoke about what regulatory medical writers do and the documents they write to support clinical development in the pharmaceutical industry. John talked about transitioning from being a practising surgeon to med comms medical writing and about the spectrum of careers in this area. Another speaker, practising physician Vidhya Kumaranayakam, spoke about how she became, among many other things, a book author and publisher. At the start of the webinar, a short survey showed that most of the attendees knew almost nothing about medical writing. However, after the presentations and a subsequent Q&A session many of them indicated that they were interested in finding out more.

A recording of the webinar is available on YouTube:
<https://youtu.be/vSJSYWH-yOY>.



MedComm Special Interest Group gets down to business

As mentioned in the last issue of *Medical Writing*, the MedComm Special Interest Group (SIG) was established at the spring conference in Vienna to support publication activities of EMWA members. The first activity of MedComm SIG members was to participate in development and review of the joint position statement on predatory publishing. The MedComm SIG has also supported wide dissemination of the joint position statement. MedComm SIG committee member Andrea Bucceri has liaised with Taylor & Francis to enlarge statement advise to all librarians subscribing to *Current Medical Research & Opinion* (where the statement was first published) and through Taylor & Francis social media platforms. Other MedComm SIG members have shared the joint position statement through their private contacts. Other EMWA

members are encouraged to do the same.

We believe that sharing the joint position statement with academia is crucial, because the main victims of predatory journals are university researchers who must publish to develop their career or even keep their job but may not always be fully aware of predatory publishers' practices. The MedComm SIG is actively looking for the best way to share the joint position statement with academia and welcomes suggestions from EMWA members.

The joint position statement will be presented during a lunchtime symposium at the Malmö conference in November 2019 and information regarding its impact and, possibly, evolution will be shared at the Prague conference in May 2020. Stay tuned for further details!

**Andrea Rossi and
Slavka Baronikova**

Omic *in silico* and other trends in biomedical research: Impact on how and what we write

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Abstract

Medical writers and communicators write about biomedical research. It follows that the latest trends in this field translate to new trends in medical writing. This article provides a peek into the latest breakthroughs and developments in biomedical research that can impact what and how we write.

Introduction

As medical and scientific communicators, we write about breakthroughs and innovations in biomedical research. The latest trends in these fields translate to new trends in how we communicate. We have to continuously hone our skills, broaden our vocabulary, and expand our knowledge base. In this article, I share a collection of my favourite trends. Terms written in **bold italics** are defined in the glossary in Table 1.

The brave new world of omics

In the era of **omics** (genomics, transcriptomics, proteomics, metabolomics)¹ the term **biotechnology** seems inane and inadequate when applied to what is currently going on in biomedical research. Biology has come a long, long way since the start of the human genome project. Last year, an infant with a rare disease was admitted, diagnosed, treated, and discharged within 36 hours – after his whole genome was sequenced in record time of 19.5 hours.²

Let's take a look at some of the cutting-edge research coming out of the omic realm, topics that some of us may already be writing about.

Synthetic biology

Systems biology, move over to give space for **synthetic biology**.³ A recent feature in *The Economist* states “life runs not on software and hardware but in all-ware... [making] it highly resistant to human reprogramming.”⁴ But it can be hacked. By combining biology and engineering, synthetic biology enables us to hack, redesign, even create life. With the development of the **CRISPR/Cas9 technology**, gene editing has never been easier, cheaper, and faster.

Medicine is benefiting from synthetic biology, starting with finding cures for genetic diseases to regrowing or repairing damaged tissues and organs using 3D printers.

On an industrial scale, synthetic biology requires a high amount of resources that go beyond test tubes. This is where biology meets artificial intelligence. Biological experiments can now be automated, as gene editing becomes a digital rather than laboratory activity. This year, Swiss scientists created the first computer-generated genome of an organism,⁵ a bacterium created **in silico**.

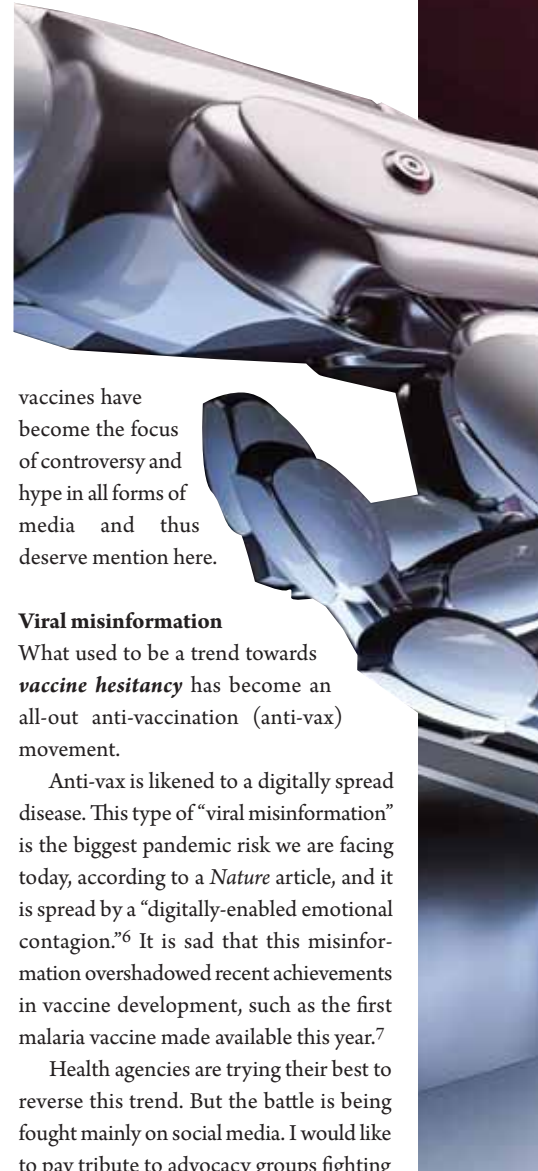
Do-it-yourself biology

Another side of the omics revolution is do-it-yourself biology (**DIYbio**).¹ The DIYbio movement literally originated like start up tech companies, in biological laboratories set up in garages and kitchens of biohackers and bio-innovators. Activities range from home micro-breweries to

“CRISPRing” marijuana, to culturing fluorescent bacteria for artistic purposes, to the more ominous threats of bioterrorism. Naturally, there are also concerns about the lack of checks and balances and ethical considerations.¹

Vaccines and viral misinformation

Vaccines are not new. Till a few years ago, it was such a low-profile therapeutic area as the burden of many infectious diseases have declined to the brink of eradication. In recent months however,



vaccines have become the focus of controversy and hype in all forms of media and thus deserve mention here.

Viral misinformation

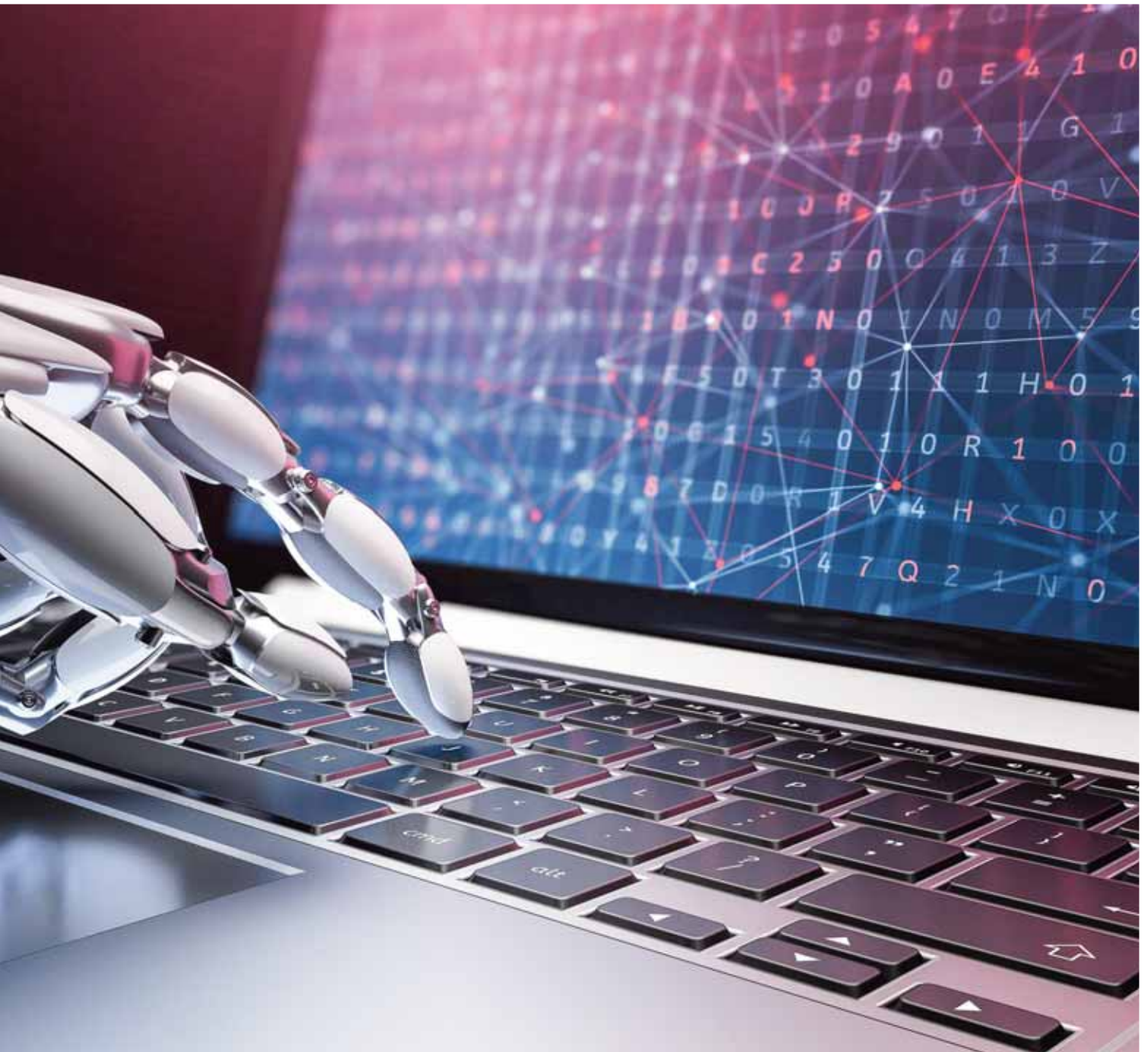
What used to be a trend towards **vaccine hesitancy** has become an all-out anti-vaccination (anti-vax) movement.

Anti-vax is likened to a digitally spread disease. This type of “viral misinformation” is the biggest pandemic risk we are facing today, according to a *Nature* article, and it is spread by a “digitally-enabled emotional contagion.”⁶ It is sad that this misinformation overshadowed recent achievements in vaccine development, such as the first malaria vaccine made available this year.⁷

Health agencies are trying their best to reverse this trend. But the battle is being fought mainly on social media. I would like to pay tribute to advocacy groups fighting the good fight, trying different public outreach strategies to counteract anti-vax thinking. Children's book writer Andrew Murray (“Buddy & Elvis”) uses cartoons and animations to increase awareness.⁸ One of his characters, my friend and colleague Melvin Sanicas, calls scientists to action in his article on p. 22.

Medical entomology

Because of the recent outbreaks of mosquito-borne diseases such as dengue, malaria, Zika, and chikungunya infections, the field of **medical entomology** has reemerged.⁹ Here, too, is synthetic biology active, with gene-editing techniques being explored to control, even wipe



out disease-carrying species of mosquito without harming the benign types.³

The recently released book *How Mosquitoes Changed Everything* by Brooke Jarvis describes how mosquito-borne diseases changed the course of human history.

Combination health products: ingestible and wearable devices

The delineation between drugs and medical devices are becoming blurred, again, as biology and technology merge to develop products that

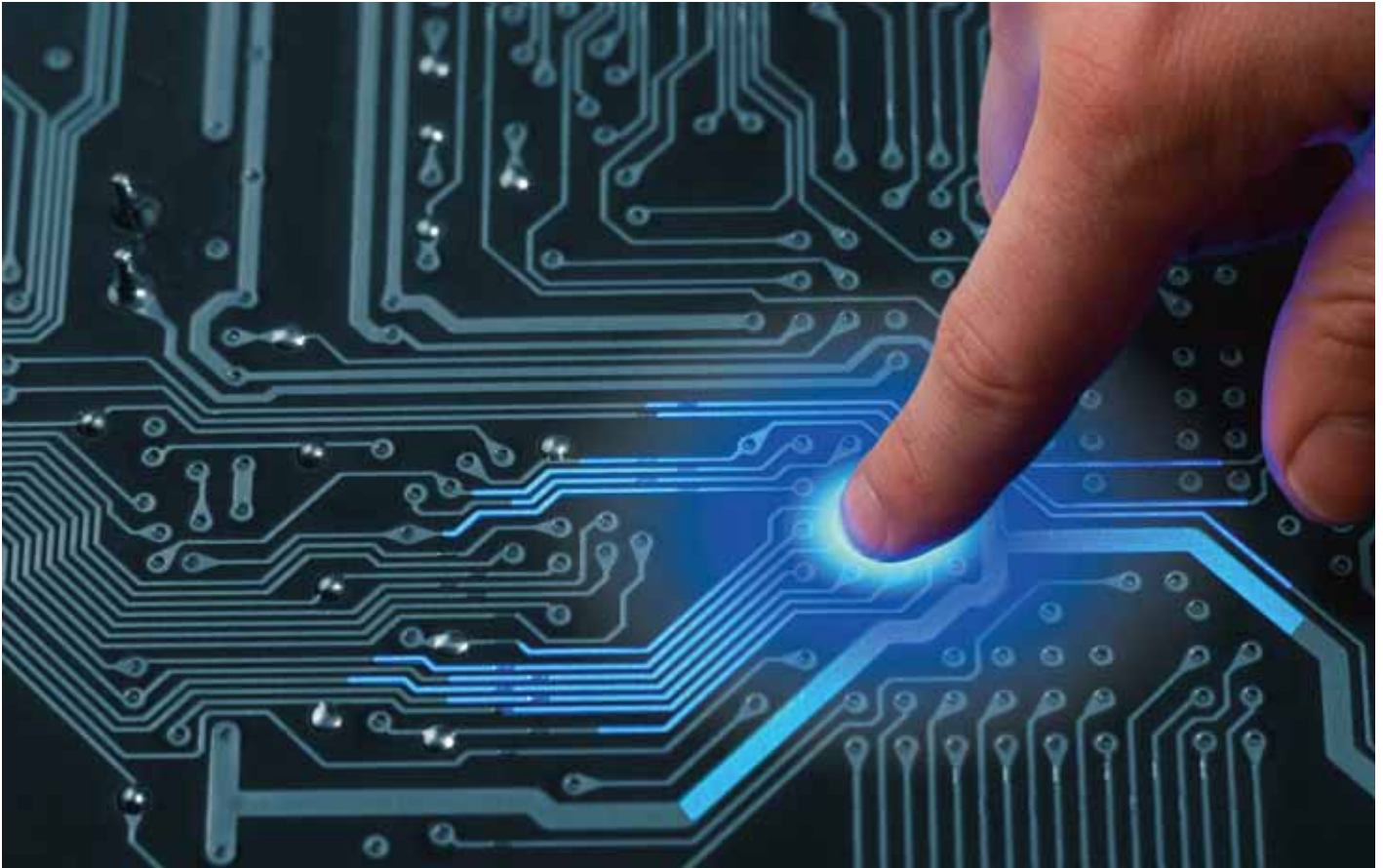
combine the best of both worlds. The EMA, which traditionally only deals with medicinal products, recently released a draft guideline on the quality requirements for drug-device combination products.¹⁰ The term **combination products** brings to mind pre-filled syringes and anti-histamine pens. But the trend is towards more complex and ingenious combinations and delivery systems, some examples of which are described below. We writers need to step away from our comfort zone to deal with new terminologies that may come from engineering, informatics, and material science.

A digital pill

This product comprises a pill with an embedded silicon chip, a wearable sensor, and an App. The chip, once in the stomach, is released and sends a signal captured by sensor and recorded in the App. This way, treatment adherence to the antipsychotic drug aripiprazole can be monitored. It was approved by the FDA in 2018.¹¹

Ingestible delivery system

Insulin without injections? This may become possible with a self-orienting mm scale applicator (SOMA) whose needle is made of insulin and its



“plunger” controlled by a sugar disc. This latest breakthrough in oral insulin replacement therapy for diabetes is currently in testing. Insulin is delivered by ingesting the SOMA, which then delivers insulin directly into the peritoneal wall.¹²

Wearable medications

The next generation of wearables might resemble a shirt rather than a watch. Swiss scientists are developing smart medical fibres and drug-releasing textiles. The technology has a wide range of potential applications, from wound care to glucose monitoring.¹³

Ethics and political correctness

Let’s have a look at trends in ethical questions and political correctness that can affect the way we write.

Political (over)correctness?

Gender parity and the “me too” movement were big topics in 2018 that have impacted our behaviours. It follows that sensitivity to these issues is also expected in scientific communication. Yet, we do not have clear guidelines on political correctness and cultural sensitivity.

A recent manuscript analysed long forgotten medical research projects that are suddenly rediscovered, like “sleeping beauties” awakened by a prince. The paper was rejected by a top US journal on the grounds of sexualisation by using a politically incorrect analogy. Alternative suggested terms are “hibernators” and “awakeners”.¹⁴ Do you agree?

Mind your sources

Even if you mind your metaphors, what about scientifically valid yet ethically questionable sources? During an operation, a surgeon had to refer to the *Pernkopf Topographic Anatomy of Man* to finish a rather tricky emergency procedure. Apparently, no other medical source, paper or digital, can match the accuracy and spectacularly detailed illustrations of human anatomy in this ≈80-year old volume. It was compiled in an Austrian medical school during the Nazi era, and was based largely on the bodies of the victims of those dark times.¹⁵ Is it ethically correct to use the material? Is it allowable to cite such materials in scientific papers? Does the end justify the means?

Watch your language

Though not necessarily unethical or politically incorrect, some terms we use in day-to-day clinical research may be inappropriate for use in medical publications. An ISMPP paper lists examples of common industry jargon that do not belong in a manuscript, mainly because they are too colloquial or even commercial. Two examples on the list that I have encountered frequently are “key opinion leader” (suggestive of influence and bias, use “external medical expert” or “subject matter expert” instead) and “key messages” (messaging is a commercial term, consider “scientific communication points” instead).¹⁶

The 11th edition of the *AMA Manual of Style* is planned for release this year and will include guidance on terminologies. Here are a few terms: use of “low income” instead of “poor”; addition of LGBTQ as an abbreviation; removal of “CD-ROM” and “fax” from the glossary, but inclusion of “cloud” and “IP address”. Furthermore, “sequence variation” and “allelic variant” are preferred over “mutation” and “polymorphism”, respectively, according to the recommendations of the Human Genome Variation Society.¹⁷

All things planetary

Ever heard of the term “*planetary medicine*” or “*planetary health*”?¹⁸ Previously viewed with scepticism, it is now scientifically recognised, even considered vogue. Check out the call for medical practitioners to act for planetary health and sustainable healthcare in the *Lancet*.¹⁹

In fact, with climate change coming to the forefront, several subdisciplines of planetary health have arisen, including planetary paediatrics,²⁰ planetary epidemiology,²¹ and planetary preventive medicine.²² Here too, synthetic biology is being harnessed to address environmental issues.³

What about digital health?

We cannot discuss healthcare trends without mentioning digital health and there is lots of ground to cover, including artificial intelligence and health data from “prewomb to tomb”.²⁴ As seen in the trends already discussed above, biology, healthcare, and technology are all interlinked.

I will not focus on this topic here but will instead let the next issues of *Medical Writing* – for December 2019 on digital health, followed by the issue on Data Economy in 2020 – do justice to these highly important trends. For now, check out and enjoy Eric Topol’s *Deep Medicine: How Artificial Can Make Medicine More Humane*.²⁴ It’s medical communication at its best.

Disclaimers

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

Conflicts of interest

Raquel Billiones is an employee of a pharmaceutical company.

Table 1. Glossary of terms

| Term | Definition |
|---|---|
| Omics | a neologism for the constellation of an organism’s “omic” information, which includes the genome itself (genomic), transcription products (transcriptomic), protein products (proteomic) and metabolic products (metabolomic). ¹ |
| Synthetic biology | an interdisciplinary branch of biology and engineering that combines various disciplines from within these domains, such as biotechnology, evolutionary biology, molecular biology, systems biology, biophysics, computer engineering, and genetic engineering. (Wikipedia) |
| CRISPR/Cas9 | stands for ‘Clustered Regularly Interspaced Short Palindromic Repeats’ and it is part of the defence mechanism found in the immune system of bacteria against viruses. After its discovery, it was used as part of the CRISPR/Cas9 genome editing technology, which allows scientists to edit, cut, or replace DNA at precise locations. This technology can be applied to permanently modify genes in living cells and organisms with the aim to correct mutations and treat disease. ¹ |
| <i>in silico</i> | an expression used to mean “performed on computer or via computer simulation”. The phrase was coined in 1989 as an allusion to the Latin phrases <i>in vivo</i> , <i>in vitro</i> , and <i>in situ</i> , which are commonly used in biology and refer to experiments done in living organisms, outside of living organisms, and where they are found in nature, respectively (Wikipedia). |
| DIYbio | Do-It-Yourself Biology, a citizen science driven movement that aims to find innovative solutions by studying life sciences related topics in non-traditional academic and industrial settings, namely in self-made laboratories (e.g. assembled in kitchens and garages) that are not ruled by the policies of a research or academic institution. ¹ |
| Vaccine hesitancy | refers to delay in acceptance or refusal of vaccines despite availability of vaccination services; currently a complex global problem that requires ongoing monitoring (WHO) |
| Drug-device combination products | therapeutic and diagnostic products that combine drugs, devices, and/or biological products (US FDA) |
| Medical entomology | also known as public health entomology, is focused upon insects and arthropods that affect human health as disease vectors (Wikipedia) |
| Planetary medicine or planetary health | body of research that investigates the links between Earth’s natural systems and human well-being, looking at how climate change and resource depletion cause problems like infectious disease and malnutrition. ¹⁶ not to be confused with the term “environmental medicine”, a field that is dealing with environmental excitants in the surroundings, and not recognised as a legitimate specialty but rather more of a quackery. ²³ |

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New recommendations released: **Good Practice for Conference Abstracts and Presentations**

Research that has been sponsored by pharmaceutical, medical device, and biotechnology companies is often presented at scientific and medical conferences. Although there is an industry standard to guide the development of full publications (Good Publication Practice for Industry Sponsored Research, GPP3),¹ this only touches on conference presentations. Until now, no specific guidelines or recommendations have been available to adequately describe best practice for conference presentations.

The Good Practice for Conference Abstracts and Presentations (GPCAP) recommendations² address the specific challenges of developing abstracts and presentations for academic conferences. The authors are all experienced publication professionals, having worked for either medical communications agencies or pharmaceutical companies, who have encountered the practical challenges associated with conference presentations. Having drafted an initial framework, the draft recommendations were published as a preprint at PeerJ³ for public review and comment to gain broader feedback, which enabled the authors to refine the recommendations

further, before submitting for publication.

The recommendations cover the following:

- authorship and contributorship
- transparency
- development, review, and approval of abstracts and presentations
- guidance on re-presentation of data (encore abstracts)
- copyright considerations
- appropriate citation of conference presentations

While developed with pharmaceutical industry sponsored research in mind, we believe that these recommendations are applicable to all research submitted to conferences, and we encourage readers from other fields to offer suggestions for further development via our website (<http://gpcap.org>).

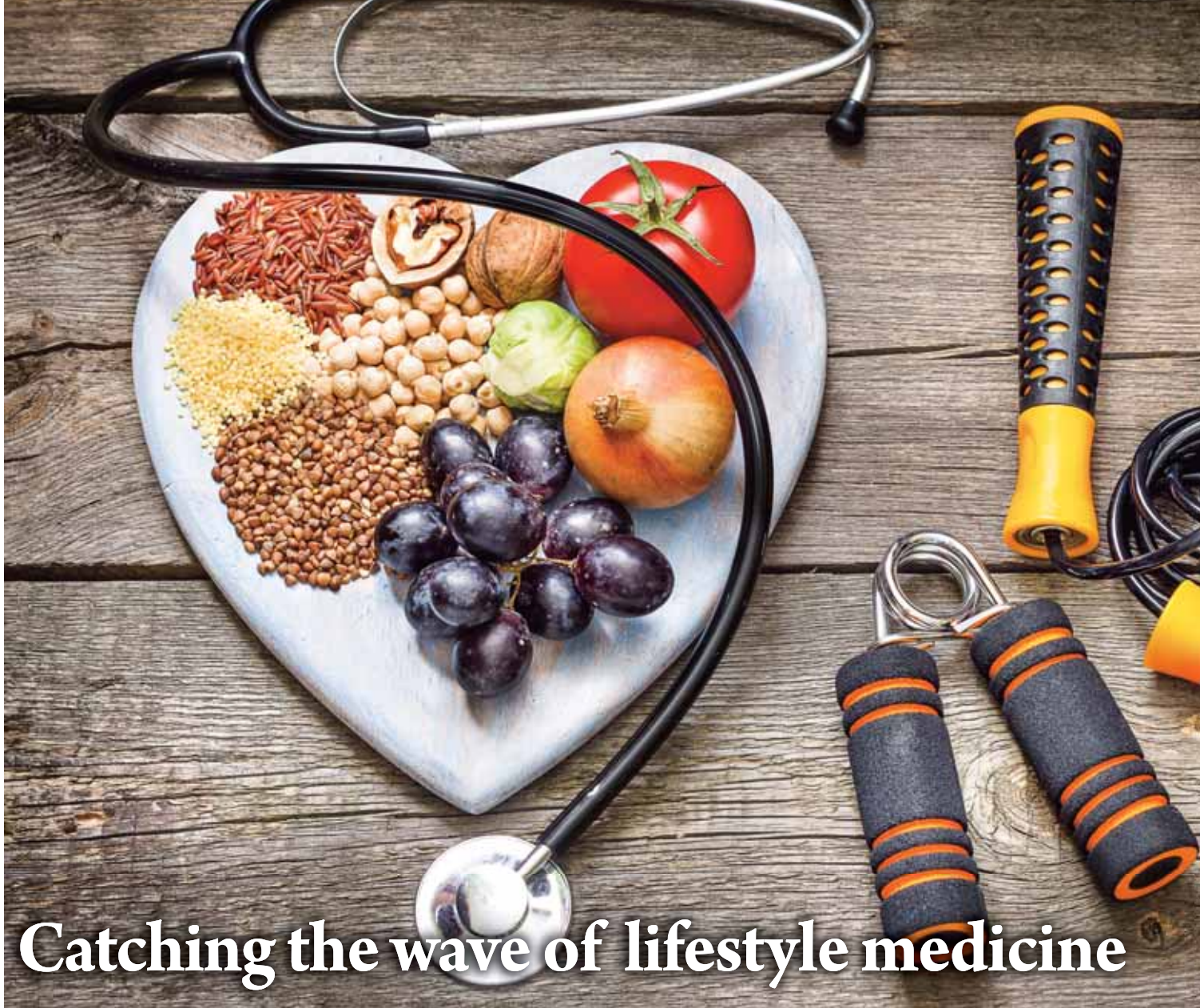
By following GPCAP recommendations, industry professionals, authors, and conference organisers will improve consistency, transparency, and integrity of publications submitted to conferences worldwide.

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Good Practice for Conference Abstracts and Presentations was developed by Cate Foster (MA, ISMPP CMPP™), Liz Wager (PhD), Jackie Marchington (PhD, ISMPP CMPP™), Mina Patel (PhD), Steve Banner (PhD, MA), Nina C Kennard (ISMPP CMPP™), and Rianne Stacey (PhD, ISMPP CMPP™).



Catching the wave of lifestyle medicine

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Abstract

Non-communicable diseases (degenerative chronic diseases) are wreaking havoc on human health, causing 70% of deaths worldwide, but lifestyle medicine is ready to tackle them by helping people change the habits behind them. A new medical specialty, lifestyle medicine can help relieve strained healthcare systems globally and is backed by a solid body of evidence. Moreover, there are

massive research, educational, and medical communication needs for all audiences, from laypersons to experts. Interested medical writers may have abundant opportunities to work on this rising medical specialty in the near future.

Fertile ground for a new trend

Modern medicine and the reductionist approach

Medicine is complex and is continuously evolving. Through history it has gone through several paradigms that have dominated the way healers thought about diseases and how to cure them. At present, modern medicine follows a mostly reductionist paradigm. This 'divide and conquer' approach, where processes are reduced into simpler units to understand them, has allowed for amazing advances in diagnosing, treating, and preventing diseases. It is possible to explore biological processes underlying a disease at the molecular level, but sometimes the

complex interactions between these processes result in effects different from those that might be expected. In other words, the whole is greater than the sum of its parts.¹

Non-communicable diseases (NCDs) are good examples of this. Together, they cause 86% of all deaths in Europe² and 70% globally.³ They include cardiovascular disease, chronic neurologic disorders (e.g., dementia), chronic respiratory diseases, diabetes, cancer, musculoskeletal diseases, and autoimmune disorders. Their prevalence and incidence are growing, and most are not curable or reversible by traditional means. These NCDs are the result of a combination of genetic, physiologic, environmental, and behavioural factors that are very often shared between them. Their aetiologies, pathophysiologies, and treatments are well known, but they are still the world's biggest killers. Why? It may be because, although we know them well, we do not understand them completely. We use reductionism to understand them since they are so complex, but we underestimate their root causes



and how they interact with each other. Also, although medicine offers fairly effective treatments for many of them, it does not properly address their risk factors: the reasons why people get these diseases in the first place are most often environmental and behavioural factors which affect physiological processes and gene expression, among other things.⁴ Studies showing dramatically increased rates of cardiovascular disease and cancers of people migrating from low-risk to high-risk countries have shown that environmental/behavioural factors are the primary determinants of chronic diseases, not genetic ones.⁵ And other studies, including twin studies, have shown that only 10 to 30% of chronic diseases are due to genetic factors.⁶

It is far easier for healthcare professionals to prescribe drugs or recommend surgery and for patients to accept these often expensive and risky treatments than to change lifelong habits reinforced by a consumerist society. This is not helped by the fact that we are cared for by physicians who do not fully understand nutrition

and are fed by companies that do not care about health. The problem starts in medical school, where education on nutrition, exercise, addictive substance avoidance, and other lifestyle interventions is notoriously deficient. As a consequence, physicians who recommend lifestyle changes as a first line of prevention and disease management may feel unprepared to provide counselling in behavioural changes.⁷ To make matters worse, the companies that sell animal products and ultra-processed foods (e.g. packaged baked foods, fizzy drinks, sugary cereals, ready meals, reconstituted meat products) are more interested in their profits than in the healthiness of their offerings.¹

Human lifestyle changes and diseases

Homo sapiens appeared about 315,000 years ago.⁸ In the last 10,000 years, our lifestyle habits have changed considerably. Our diet has seen some of the biggest changes. The advent of dairy products, refined plant derivatives (cereals, sugars, vegetable oils), fatty meats, and salt critically and fundamentally altered the glycaemic load, macronutrient content, fatty acid composition, micronutrient density, acid-base balance, sodium-potassium ratio, and fibre content of our diet.⁹ Moreover, recent studies have linked ultra-processed foods with weight gain and cancer.^{10,11} This shift, plus other changes like an increasingly sedentary lifestyle, chronically inadequate sleep, high stress, and use of addictive substances (tobacco, alcohol, other drugs), are very recent relative to our evolutionary history and underlie many of our degenerative chronic diseases. Such diseases are rarer in populations that have not much changed their traditional lifestyles. The most notable examples of these are the inhabitants of the ‘blue zones’: five places in the world that “not only have high concentrations of individuals over 100 years old, but also clusters of people who had grown old without health problems like heart disease, obesity, cancer, or diabetes.”¹²

In the last century, there have been gains in the fight against communicable diseases and child and maternal mortality, but they are still major problems in developing countries. At the same time, rates of NCDs increased by almost 30% between 2000 and 2015, causing more than

50% of the disease burden in lower-middle income countries and affecting more younger people than in wealthier countries.¹³ This negatively impacts the economies of lower-middle income countries. Meanwhile, NCDs cause 77% of the disease burden in Europe.² And although premature mortality from NCDs has decreased, there is a significant gap between life expectancy and healthy life expectancy (the number of years that a person is expected to live without an activity limitation or disability),¹⁴ with men spending a fifth of their life in poor health and women nearly a quarter.¹⁵

The above changes have all happened at an unprecedented pace that never seems to wane, as NCDs reach pandemic proportions and disproportionately affect disadvantaged populations that do not have proper access to treatment.¹³

The “new” trend of lifestyle medicine

What is it?

Lifestyle changes have been a part of healthcare recommendations for decades, but they have traditionally only been considered helpful measures and are often still considered optional. First mentioned as a medical discipline in 1999,¹⁶ lifestyle medicine is the logical response to our chronic disease pandemic. The Lifestyle Medicine Global Alliance (an organisation that unites national lifestyle medicine professional associations from around the world under a single banner) defines it as “the evidence-based medical specialty that uses lifestyle therapeutic approaches, such as a predominantly whole food plant-based diet, regular physical activity, adequate sleep, stress management, avoidance of risky substance use, and other non-drug modalities, to prevent, treat, and, oftentimes,

Non-communicable diseases (NCDs) are good examples of this. Together, they cause 86% of all deaths in Europe and 70% globally.

reverse non-communicable disease, sometimes referred to as degenerative chronic disease.”¹⁷ Lifestyle medicine uses a thoroughly holistic approach, where whole plant-based foods work synergistically and, together with exercise, stress reduction, sleep, harmful substance avoidance, and social support, help the whole person (body, mind, and microbiome). Prolonged healthy life expectancy allows individuals to be more productive in their professional and personal

lives. These changes can also help societies thrive by reducing their overall disease burden and healthcare costs. Last but not least, they are aligned with the changes humanity needs to implement for the sustainability of life on our planet, including our own as a species (Figure 1).¹⁸

Key elements?

Lifestyle medicine uses lifestyle interventions involving behavioural, environmental, medical and motivational principles to prevent, treat, and sometimes reverse NCDs that share risk factors and underlying mechanisms. It is complementary to traditional medicine, acting as an adjuvant to clinical and surgical interventions.¹⁹ It is low cost and causes few, if any, side effects.

The central element is a whole food plant-based diet that emphasises the consumption of minimally processed and nutrient-dense vegetables, fruits, whole grains, legumes, nuts, and seeds. It minimises or eliminates meat, poultry, fish, eggs, dairy products, and processed foods of animal (sausages and cured meats) or plant origin (refined grains, added refined sugars and oils,

artificial ingredients). It differs from veganism in its emphasis on whole foods; despite their deleterious health effects,^{10,11} highly processed plant foods are accepted in veganism. It also differs in that it encompasses a spectrum of eating patterns that are predominantly plant-based but that, like vegetarianism, may include some animal products. However, its therapeutic effects appear to be more significant the closer it is to 100% plant-based.^{20–23}

Together with other lifestyle interventions, this diet is anti-inflammatory, modifies gene expression, and changes our microbiome, thereby helping reverse the chemical processes behind NCDs.⁴

The growing body of evidence

The modern Western lifestyle is responsible for the global increase in NCD burden. Changing that lifestyle could help prevent, treat, and even reverse most NCDs: eliminating NCD risk factors can prevent 75% of heart disease, stroke, and type 2 diabetes and 40% of cancer.²⁴

The body of evidence supporting lifestyle interventions is growing. Research studies related

to lifestyle medicine have greatly increased in number in the last 30 years. In Clinicaltrials.gov, studies with the words lifestyle (factors, changes, interventions), plant-based (diet, dietary, or food), sleep, exercise (or physical activity), and stress management under the search field *Other Terms* increased on average 25-fold between 1990–1999 and 2000–2009 and 4-fold between 2000–2009 and 2010–2019 (Table 1). By comparison, oncology studies increased on average 8-fold between 1990–1999 and 2000–2009 and 2-fold between 2000–2009 and 2010–2019 (Figure 2).

In terms of individual studies, the Nurses’ Health Study (in which 75,521 women aged 38 to 63 years old were followed for 10 years) concluded that more than 80% of all heart disease and more than 91% of all diabetes in women could be eliminated if they were to adopt a cluster of positive practices (keeping a healthy body weight, regular physical activity, avoiding tobacco products, consuming more whole grains, fruit, and vegetables, and consuming no more than one alcoholic beverage per day).²⁵ The US Health Professionals Study²⁶ (in which 42,847 men aged

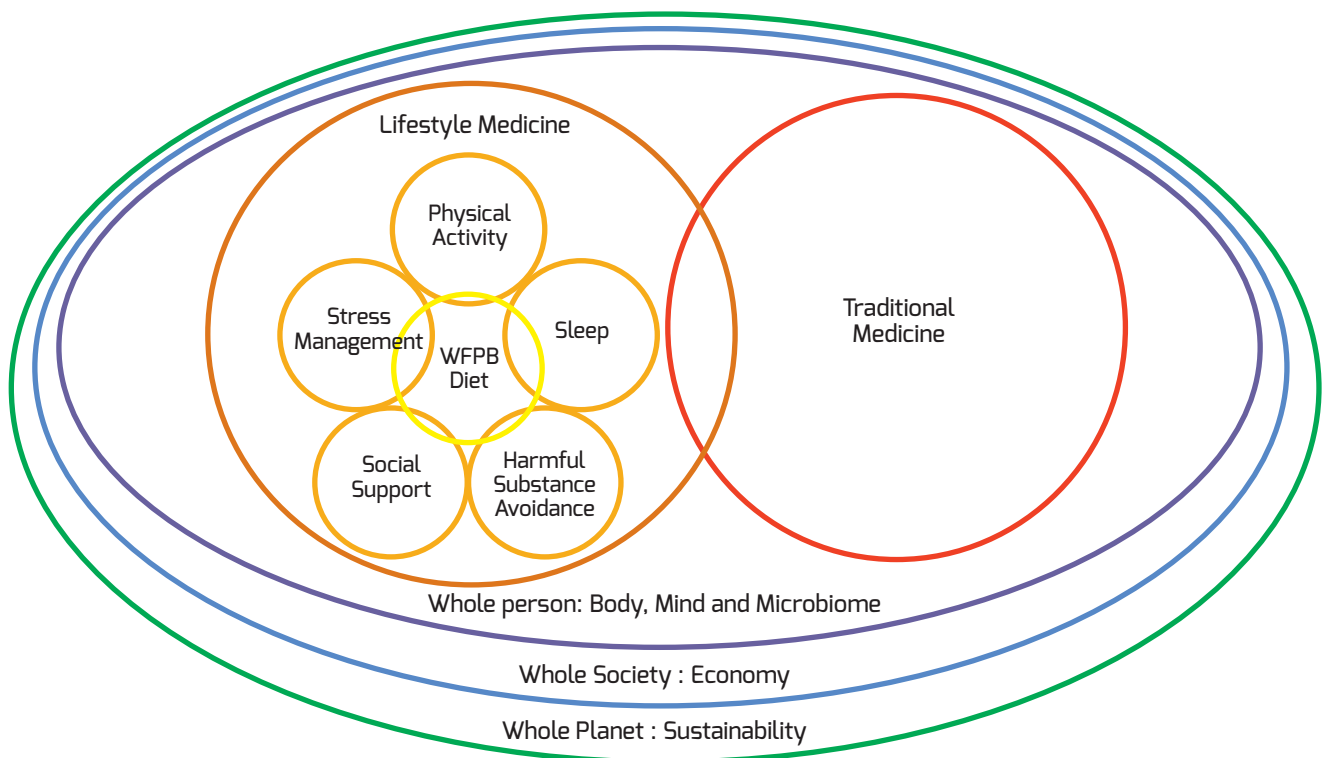


Figure 1. How lifestyle medicine works, according to the author

40 to 75 years old were followed up for 16 years) found similar results in men. Elsewhere, the American Institute for Cancer Research and the International Agency for Research on Cancer concluded that there is sufficient evidence to link

13 human malignancies to excess body fat.²⁷ Smaller studies have shown that a whole food plant-based diet can help treat and reverse cardiovascular disease and diabetes, and that it can help treat cancers.^{20,21,23,28,29,30}

In spite of these findings, the well-known statement “more research is needed” could not be more relevant than when it comes to studies looking at the effects of whole food plant-based nutrition. Most of the research has been done

Table 1. ClinicalTrials.gov search for studies related to lifestyle medicine with start dates from January 1, 1990, to June 25, 2019.

The keywords used under the search field “Other Terms” were:

| | |
|----|---|
| 1. | “lifestyle factors OR lifestyle changes OR lifestyle interventions” (plus the synonyms “interventional” and “procedures”) |
| 2. | “plant-based diet OR plant-based dietary OR plant-based food” |
| 3. | “sleep” |
| 4. | “exercise” (plus the synonym “physical activity”) |
| 5. | “stress management” |

| Search term(s) | January 1, 1990 – December 31, 1999 | January 1, 2000 – December 31, 2009 | Fold increase (2000–2009 vs. 1990–1999) | January 1, 2010 – June 25, 2019 | Fold increase (2010–2019 vs. 2000 – 2009) |
|--|-------------------------------------|-------------------------------------|---|---------------------------------|---|
| 1. Lifestyle (factors, changes, interventions) | 43 | 829 | 19 | 2849 | 3 |
| 2. Plant-based (diet, dietary, food) | 0 | 16 | 16 | 106 | 7 |
| 3. Sleep | 75 | 2702 | 36 | 8598 | 3 |
| 4. Exercise/physical activity | 172 | 4138 | 24 | 16,890 | 4 |
| 5. Stress management | 11 | 324 | 29 | 1172 | 4 |
| Sum (1 to 5) | 301 | 8009 | 27 | 29,615 | 4 |
| Average (1 to 5) | | | 25 | | 4 |
| Oncology (cancer, tumor, neoplasm) | 2725 | 21,923 | 8 | 42,536 | 2 |
| All studies registered | 6443 | 88,478 | 14 | 194,696 | 2 |

For comparison, “oncology” (plus the synonyms “neoplasm”, “cancer”, “tumor”, “malignancy”, “neoplasia”, “neoplastic syndrome”, “oncologic”, and “neoplastic disease”) was searched for under the search field “Conditions or disease”. Each set of keywords was searched three times for the periods January 1, 1990, to December 31, 1999; January 1, 2000, to December 31, 2009; and January 1, 2010, to June 25, 2019. All study types and results were included.

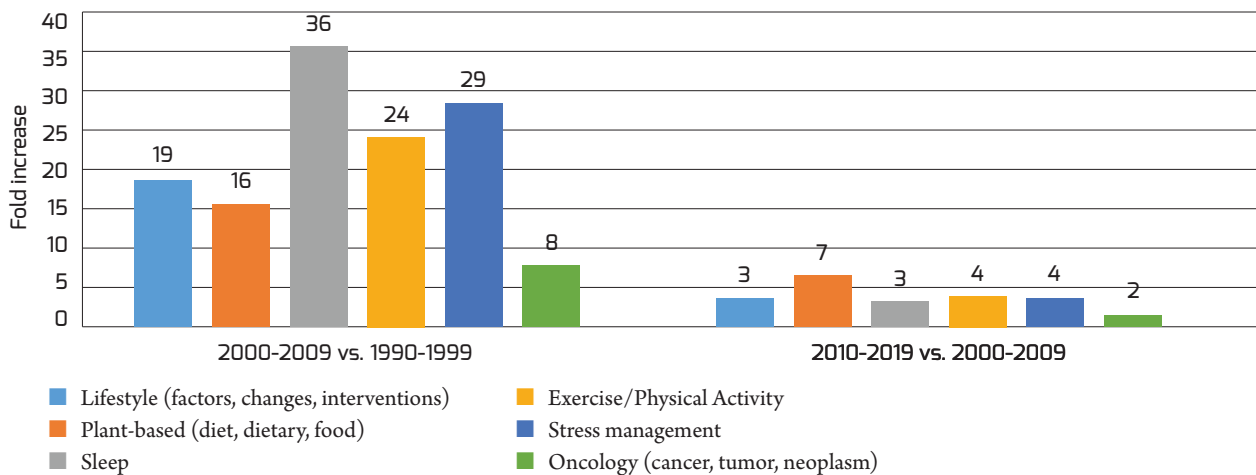


Figure 2. Fold increases in studies listed in ClinicalTrials.gov related to lifestyle medicine from 1990–1999 to 2000–2009 and from 2000–2009 to 2010–2019. Oncology studies are included for reference.

under the reductionist paradigm, looking at the effects of single foods or components. Fortunately, the effects of dietary and other lifestyle interventions are increasingly being studied, even in the context of randomised

studies, but much more research is still needed.

Where is it going?

Education and training

Many medical universities are starting to

incorporate more education on nutrition and lifestyle medicine, because their current curriculums are deficient in these aspects and medical students are demanding it. Harvard Medical School incorporated a Division of

Table 2. PubMed search for articles related to lifestyle medicine with publication dates from January 1, 1990, to June 25, 2019.

Titles were searched for the following keywords:

| | |
|----|---|
| 1. | “lifestyle interventions OR lifestyle factors OR lifestyle changes” |
| 2. | “plant-based diet OR plant-based dietary OR plant-based food” |
| 3. | “sleep” |
| 4. | “exercise OR physical activity” |
| 5. | “stress management” |
| 6. | “oncology OR cancer OR tumor OR neoplasm OR malignancy”. |

| Search term(s) | January 1, 1990 – December 31, 1999 | January 1, 2000 – December 31, 2009 | Fold increase (2000–2009 vs. 1990–1999) | January 1, 2010 – June 25, 2019 | Fold increase (2010–2019 vs. 2000–2009) |
|--|-------------------------------------|-------------------------------------|---|---------------------------------|---|
| 1. Lifestyle (factors, changes, interventions) | 213 | 1006 | 5 | 2382 | 2 |
| 2. Plant-based (diet, dietary, food) | 3 | 30 | 10 | 134 | 4 |
| 3. Sleep | 10,269 | 19,453 | 2 | 40,062 | 2 |
| 4. Exercise/physical activity | 18,261 | 31,310 | 2 | 64,917 | 2 |
| 5. Stress management | 285 | 526 | 2 | 917 | 2 |
| Sum (1 to 5) | 29,031 | 52,325 | 2 | 108,412 | 2 |
| Average (1 to 5) | | | 4 | | 3 |
| Oncology (cancer, tumor, neoplasm, malignancy) | 147,014 | 281,357 | 2 | 564,168 | 2 |

Each of these sets of keywords was searched three times, for the periods January 1, 1990, to December 31, 1999; January 1, 2000, to December 31, 2009; and January 1, 2010, to June 25, 2019, by adding the following to the search string: AND (“1990/01/01”[PDat] : “1999/12/31”[PDat]), AND (“2000/01/01”[PDat] : “2009/12/31”[PDat]), AND (“2010/01/01”[PDat] : “2019/06/25”[PDat]). No other filters were applied.

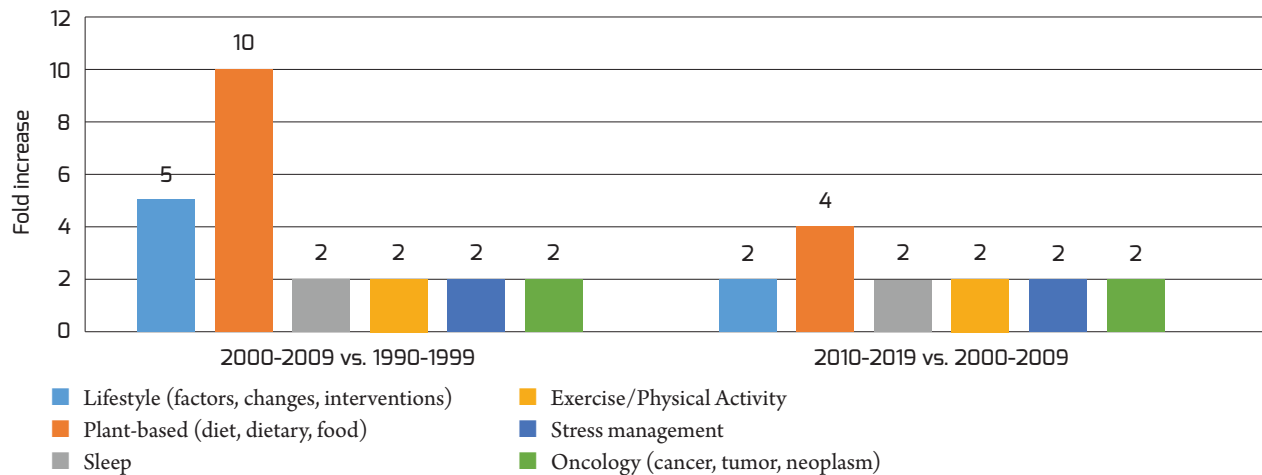


Figure 3. Fold increases in articles published in PubMed related to lifestyle medicine from 1990–1999 to 2000–2009 and from 2000–2009 to 2010–2019. Oncology studies are included for reference.

Nutrition in 1996,³¹ and a residence programme is currently being piloted in four American universities.³² In Europe, Cambridge University is creating a new curriculum on public health with a focus on nutrition, physical activity, and sleep,³³ and the UK University of Surrey offers a Masters in Nutritional Medicine.

Many medical organisations offer national and international board certification programmes. Several lifestyle medical associations are supporting licensed physicians wanting to train themselves on lifestyle medicine. The first was the American College of Lifestyle Medicine, which founded the Lifestyle Medicine Global Alliance in 2015 “in response to the need for lifestyle solutions in low- and middle-income countries and for coordination between lifestyle medical professional organisations around the world”. It includes organisations based in the United States, Australasia, the United Kingdom, Lithuania, Albania, Portugal, Iran, and Korea.¹⁷ Other lifestyle medicine associations and organisations include the European Lifestyle Medicine Organization, the Institute of Lifestyle Medicine, and the Plantrician Project.

Funding and policy changes

Calls for grants related to lifestyle medicine are abundant. The NIH’s National Center for Complementary and Integrative Health is requesting grant applications, as is the European Commission’s Steering Group on Health Promotion, Disease Prevention, and Management of NCDs.³⁴ The American College of Lifestyle Medicine and many other foundations (such as the Ardmore Institute of Health, the Weil Foundation, and the Osher Center for Integrative Medicine) and organisations (such as ProVeg, an international food awareness organisation that aims to improve human health, animal welfare, the environment, food justice, and public opinion on plant-based food) offer grants as well.

Policy changes are starting to take place, as hospitals and schools add more plant-based options and businesses (e.g. Nestlé, Danone, Unilever, Cargill) try to improve the quality and sustainability of their offerings.³⁵ Earlier this year, the Canadian government changed its dietary recommendations by eliminating the dairy section to simply encouraging people to consume 50% vegetables and fruit, 25% whole grains, and 25% protein foods (meats, dairy, beans, nuts, or seeds). That is, it is now

recommending a plant-based diet.³⁶

Following the lead of Kaiser Permanente, a large managed care organisation in the US that advises its physicians to recommend an active lifestyle and plant-based diet to their patients, lifestyle counselling is starting to be reimbursed in the US.³⁷

The evidence translates into...

Similar to the ClinicalTrials.gov study trends mentioned above, numbers of PubMed articles with the words lifestyle (factors, changes, and interventions), plant-based (diet, dietary, or food), sleep, exercise (or physical activity), and stress management in their titles have increased greatly. A simple search of the number of articles for the periods 1990–1999, 2000–2009, and from 2010 to June 25, 2019, shows the trend. Studies related to lifestyle topics increased on average fourfold between 1990–1999 and 2000–2009 and threefold between 2000–2009 and 2010–2019 (Table 2). By comparison, oncology studies increased on average twofold between 1990–1999 and 2000–2009 and between 2000–2009 and 2010–2019 (Figure 3).

The increased number of publications has translated into new and clearer guidelines and recommendations in terms of what measures should be put in effect (or not):

- The 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults recommends the plant-based DASH (Dietary Approaches to Stop Hypertension) diet as one of the basic steps to fight hypertension.³⁸
- The World Cancer Research Fund recommendations regarding lifestyle changes for preventing and surviving cancer include basic concepts underpinning whole food plant-based diets.^{39,40}
- The 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults includes plant-based diets in its recommended strategies to achieve caloric deficits.⁴¹
- Preventing Cancer, Cardiovascular Disease and Diabetes: A Common Agenda for the

American Cancer Society, the American Diabetes Association, and the American Heart Association emphasises the benefits of whole-grain foods, legumes, vegetables, and fruits and recommends limitations on red meat, full-fat dairy products, and items high in added sugars.⁴²

Moreover, lifestyle medicine is increasingly being addressed by major medical journals. *The Lancet* established the ‘Food in the Anthropocene’ commission, a scientific consensus of what constitutes a healthy and sustainable diet and the actions needed to support the accelerated transformation of our food system for the sake of our health and our planet,¹⁸ and launched *The Lancet Planetary Health* open access journal in April 2017. *BMJ Nutrition, Prevention and Health*, which launched in July 2018, publishes on the impact of nutrition and lifestyle factors on individual and population health. Other noteworthy journals dedicated to the subject are the *American Journal of Lifestyle Medicine* and the *International Journal of Disease Reversal and Prevention*. Congresses and conferences on lifestyle medicine and whole food plant-based nutrition are also increasing in number and attendance.

Relevance to medical writers

Even if lifestyle medicine were to become a global phenomenon, people would still get sick and need drugs or surgery for acute and chronic life-threatening conditions. However, the effectiveness of traditional medicines can be greatly increased if lifestyle changes are encouraged as a real part of prevention and treatment. Healthcare systems are collapsing under the weight of NCDs and developing countries’ economies are failing in part due to the double burden of diseases (communicable and non-communicable) and lack of resources they suffer.

The body of evidence behind lifestyle medicine is now so large that it comes down to honouring the Hippocratic oath and its most essential “First do no harm” concept. Many medical writers are healthcare professionals of some kind, and healthcare professionals have an ethical duty to inform their patients about the

Even if lifestyle medicine were to become a global phenomenon, people would still get sick and need drugs or surgery for acute and chronic life-threatening conditions.



lifestyle and dietary changes that can help them avoid suffering, disability, and early death. Some might say that medical writers are not qualified to give such advice. But we know smoking makes people sick, so all types of physicians have a duty to tell smokers to stop. If food can literally be the poison or the medicine people take every time they eat or drink, why not say so? Recommendations should not be watered down under the assumption that people will not change their habits. Other lifestyle changes are clearly very important, and depending on socioeconomic circumstances they may be harder or easier to implement. But one thing we are sure of: everybody eats and drinks many times a day, and most of us have at least some say over what we consume. We can be sure we'll all die someday, but what if we can stay healthy longer and die much later?

Medical writers should be aware of lifestyle medicine, as sooner or later they may be asked to work on documents related to it. The demand for regulatory documents will rise. But it is medical communications that will likely see the most activity, because of the huge need to fill knowledge gaps at all levels. Perhaps some medical writers will seek opportunities to write on this subject because they are interested in it for the benefit of their health or that of the environment. Some of those grants, studies, articles, books, websites, or conferences may come knocking on our doors sooner than expected. So, be ready!

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Conflicts of interest

The author declares no conflicts of interest.

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Artificial intelligence – will we be replaced by robots?

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Abstract

Advances in artificial intelligence (AI) increasingly dominate the news with billions of dollars in funding invested to combine AI with machine learning and data science across many disciplines, including medicine and healthcare. Within the context of scholarly scientific and academic publishing, AI is seen also as a potential means of bringing more

speed, efficiency, and effectiveness to current and increasingly challenged processes and systems as well as supporting open science principles.

We cannot fail to be impressed with the increasingly prevalent and dominant news on artificial intelligence (AI) advances. Whether it is the recent announcement by MIT,¹ one of the birthplaces of AI, that it has secured US\$1 billion in funding to create a new college that combines AI, machine learning, and data science with other academic disciplines. Or with Eric Topol, the renowned American cardiologist, geneticist, and healthcare visionary, whose latest book *Deep Medicine*² looks systematically at the role that AI is playing right now in US healthcare.

But there are health warnings. Although AI is already helping us diagnose cancer and under-

stand climate change, regulation and oversight are needed to stop the new technology being abused.³ Importantly, guidelines are being developed for the responsible design and implementation of AI systems.⁴

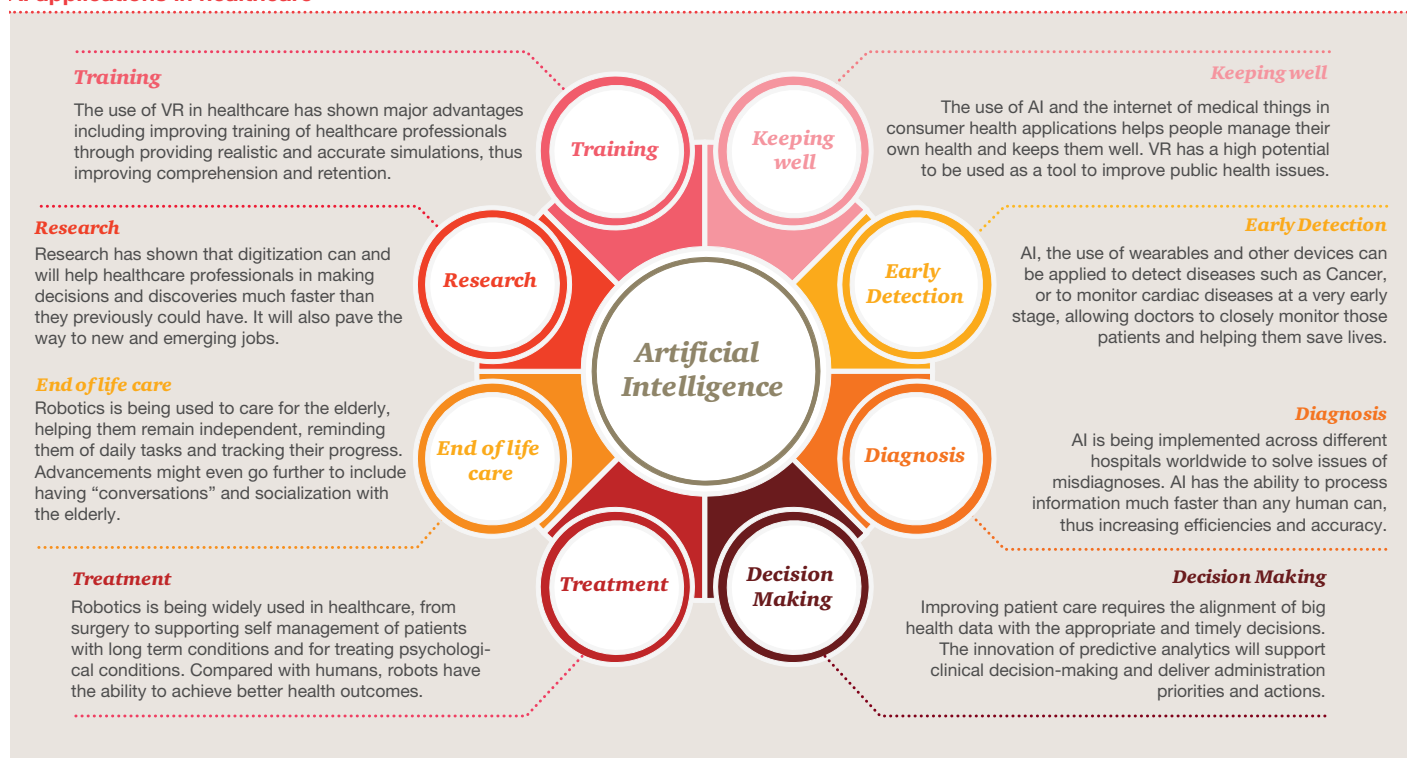
A recent *Science* article⁵ reflects on the practical hurdles and concerns when implementing AI in medicine and states that more collaboration is needed before involving patients.

The AI ecosystem

To begin, a common problem is that AI tends to be used interchangeably when actually describing one or a number of elements within the vast AI ecosystem, for example, machine learning or natural language processing. Figure 1 is therefore helpful in breaking down, mapping out, and communicating to a diverse audience, the many constituent parts.

Figure 1. AI applications in healthcare. Reprinted with permission from Mike Quindazzi, PWC.

AI applications in healthcare



AI and publishing

Within the context of scholarly scientific and academic publishing, AI is seen as a potential means of bringing more speed and efficiency to current processes and systems, as well as supporting open science principles.

In 2018, I gave a broad-ranging talk on various AI technologies at the European meeting of the International Society for Medical Publication Professionals – provocatively titled “Will we be replaced by robots?”.

But more recently, the experience of working with a number of clients and their journal editors brought me back to thinking again about AI’s potential real-world applications. Therefore, in my opinion, the most immediate and pressing problem that we could try to solve with AI is that of peer review.

Web of Science (Clarivate Analytics) reports that, since 2013, there has been a 2.6% annual growth in published articles and 6.1% in article submissions. Also, a recently published survey⁶ reports that, on average, an editor in 2017 needed to send out 2.4 peer review invitations to get one peer review report done, an increase from 1.9 invitations in 2013.

Consequently, the task of finding reviewers for an academic peer-reviewed scientific journal is projected to get much harder across all scientific disciplines. Peer review is a core critical function, therefore, to be sustainable and successful, journals must be capable of scaling with increased submissions and increased demands on the quality and nature of peer review.

This will demand significant advancements in automated technologies, including algorithms for assigning reviewers and improving reviewer experience and retention.

What we want of AI, therefore, is more operational speed and efficiency. AI is already beginning to hit the ground in these five areas:

- Identifying new peer reviewers with broader searches
- Fighting plagiarism with software that can identify components of whole sentences or paragraphs rather than verbatim text
- Discovering where authors fail to report key information that would affect accept or reject decisions
- Spotting statistical errors that generate false conclusions
- Detecting data fabrication

Real-world applications

When looking beyond the AI hyperbole to real-world applications, I was pleased to find one impressive example reported in the magazine *Communications of the ACM* (Association for Computing Machinery) that demonstrated how state-of-the-art tools from machine learning and AI are making inroads to automate and improve parts of the peer review process⁷. Allocating papers (or grant proposals) to reviewers is also an area in which much progress has been made.

These computational methods have been used to support other academic processes outside of peer review, including a personalised conference planner app for delegates, an organisational profiler, and a personalised course recommender for students based on their academic profile.

We hope that [the future directions for computational support], along with this article, stimulate our readers to think about ways in which the academic peer review process – this strange dance in which we all participate in one way or another – can be future-proofed in a sustainable and scalable way.⁷

– Simon Price and Peter Flach

This leaves me excited to see more applications of AI technologies to support the peer review process. With these applications, we may be able to move on from a process that has remained relatively unchanged since the first peer-reviewed publication *Medical Essays and Observations*⁸ published by the Royal Society of Edinburgh in 1731.

Further reading

Look out also for the forthcoming December 2019 issue of *Medical Writing* on the theme *Artificial intelligence and digital health*. This issue will show how technological innovation is overtaking all industries, and

medicine is no exception. AI and digital health are growing trends and, as medical writers, we must understand and communicate these advances.

Conflicts of interest

The author declares no conflicts of interest.

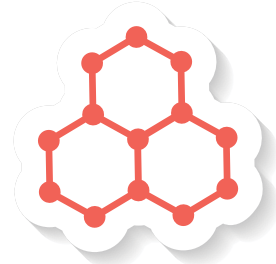
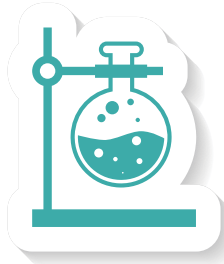
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Now more than ever, scientists must speak up for science

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Abstract

In this post-truth era we live in, the validity of facts from climate change and evolution to the shape of the earth and even vaccine safety is challenged by misinformation. As scientists, we should make greater efforts to engage with the public and to counter misinformation through publicising correct information on social media as well as through traditional publishing channels. We can all start with our friends, family, and colleagues. As scientists, we have a responsibility to speak knowledgeably on scientific issues that affect us all.

In the 21st century, “fake news”, “alternative facts,” and disputes over the validity of everything

from climate change and evolution to the shape of the earth and even vaccine safety demonstrated that what you believe depends a lot on the source of the information (or misinformation).

Thus, what does it really mean to be misinformed or uninformed about science? The word “misinformation” can be defined broadly as being information, which is incorrect, potentially by accident. Whereas, “disinformation” refers to a specific type of misinformation that is intentionally false. However, the distinctions between these terms – as well as terms like “rumour” or “fake news” – have not always been clear in research pertaining to these topics.

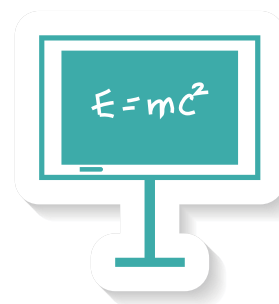
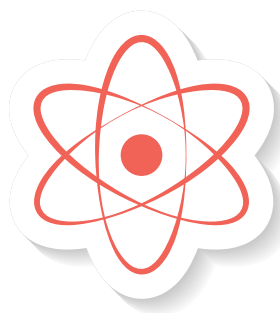
Moreover, a person who has been “misinformed” is often defined as someone believing in counterfactual claims while the “uninformed” is, simply not knowing. People can be both misinformed and uninformed simultaneously. For instance, they could be uninformed about how safety is a core element in all the phases of vaccine development while being misinformed about the facts of a specific vaccine-preventable disease

(i.e., “I had the flu shot, but I still had colds” – many viruses can cause colds and flu-like symptoms, not all colds and flu-like symptoms are caused by influenza/the flu). However, believing incorrect information about scientific topics (e.g., childhood vaccination) can have real-life consequences, especially if the person is also vocal and politically active.

Early this year, the World Health Organization (WHO) released a list of global health threats for 2019.¹ Unlike some of the health challenges on the list, at least one, vaccine hesitancy, is solvable. Despite WHO’s warnings, we are now seeing a return of vaccine-preventable diseases in many parts of the world, much of it because of mostly unopposed anti-vaccination groups, historical amnesia, widespread misinformation, and the rise of populist regimes spearheading the notion of “medical freedom” from vaccines.

So, what is behind the decline of trust in vaccines? There are well-funded and well-organised antivaccine groups in the United States and Europe with over 400 internet websites and

In this post-truth era we live in, the validity of facts from climate change and evolution to the shape of the earth and even vaccine safety is challenged by misinformation.





social media anti-vaccination groups injecting fear into parents about the dangers of vaccines and fake conspiracies about the vast cover-up by the governments. Social media also creates insular bubbles of information and online echo chambers where ideas and misinformation are easily reinforced because of the absence of diverse viewpoints. Rumours spread not only through social media and online networks but also via families and communities where the influence is much stronger, and we are paying the price in terms of global child health. The WHO reports more than 112,000 confirmed cases of measles worldwide, as of May 2019 – a 300% increase from the 28,124 cases this time in 2018.²

Therefore, to counter the populist rhetoric, we should emphasise how children have a fundamental right to be protected against deadly infections. This right trumps parental choice and “medical freedom.” Scientists and scientific associations should anticipate campaigns of misinformation and proactively create online strategies to counter them when (not if) they occur. We also need to become better at communicating scientific data – so we need to seek the assistance of social science and communications experts to know how the public values news headlines versus videos clips or tweets.

Scientists should be speaking up about all issues that affect our lives. Now more than ever, scientists should be constantly exposing misinformation, alternative facts, and pseudoscience. We may have separate roles in the organisations we work with or work for, but a scientist’s job is not only to analyse laboratory data, write manuscripts, prepare dossiers, or build a long list of peer citations. As men and women of science, our real job should be to make great discoveries and share them with the rest of the world.

With all its flaws, social media has some benefits too. It allows people from all over the world to engage, keep up with new findings, and find new collaborators. Through Twitter, for example, I have started to know fellow science advocates children’s author Andrew Murray from

the UK, virologist Dr Susan Nasif from Belgium, Clinical Pharmacist Dr Artyom Korenevsky from Canada, Law Professor Dorit Reiss, and Pediatrician-Scientist Professor Peter Hotez from the US to name a few. With our combined reach of over 100,000 followers from all over the world, we are debunking pseudoscience and misinformation, one tweet at a time.

Organisations that fund science or represent scientists are beginning to encourage greater public interaction and scientific publishers are seeing the value of scientific communication for the public.

The current climate change poses challenging times for science and the principles that guide all scientific endeavours. Science, medicine, and public health are at risk in today’s era of fake news and science denialism.³ We should speak up when robust scientific findings are being disregarded or treated as mere matters of faith. It does not have to be on social media. We can all start with our friends, family, and colleagues. As men and women of science, we have a responsibility to speak knowledgeably on scientific issues that affect us all.

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

Conflicts of interest

The author is employed by Takeda Pharmaceuticals International AG, a company developing vaccines that tackles problems in public health including dengue, norovirus, Zika, and chikungunya.

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When less is more: Medical writers as guardians of curated content

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Abstract

In this data-driven era, the type and format of publicly available medical and scientific information is significantly changing. Medical writers can serve as guardians of the information entering the public domain by ensuring accuracy and highlighting the most relevant studies for all stakeholders, from pharmaceutical clients to patients. Clinicians often seek information to stay current with new medical developments. New tools are available to present this information, and medical writers are working behind the scenes to make sure it is useful and accurate.

Houston, we have a problem: too much data here!

The quantity of medical and scientific information is constantly increasing: global scientific output doubles every 9 years.¹ It is becoming nearly impossible to keep up.

Importantly, clinicians are expected to stay up-to-date with the latest research outcomes; yet, the increasing amount of new data available makes it difficult. In this context, time-pressed clinicians need easily accessible, brief, and accurate information to allow informed clinical

decision-making.

Medical writers are often asked to curate content, which is defined as the process of gathering information relevant to a particular topic or area of interest. It sounds simple, but as Steve Jobs once said, “Simple can be harder than complex: You have to work hard to get your thinking clean to make it simple.”^{2,3}

Content solutions in the data-driven era

These needs are presently being addressed with the support of scientific content curators. A content curator collects, collates, and summarises the most relevant content published in scientific literature or at scientific congresses; the content curator then shares this information on specialised websites, in newsletters, etc. Table 1 lists some examples of content curators, though many others exist.

Content is usually referred to as being independent when it is not industry supported. Independent content clients are usually not-for-profit associations, organisations, or societies that are run by and for their members. Patient associations and scientific societies are typical examples. Sponsored content is provided with support from industry clients, who have an interest in providing information in therapeutic areas of interest to their end-users such as clinicians or the general public. Governmental bodies also curate scientific information – particularly regulatory drug updates – to inform clinicians about new products and treatment guidelines. Furthermore, pharmaceutical companies may hire individual medical communication agencies or freelance medical writers to curate content being presented live at scientific congresses. This gives companies the most up-to-date information, though these deliverables are rarely available in the public domain. This type of coverage and reporting is regulated under different laws in each country.

What is the role of medical writers?

Importantly, curators can ensure that the articles selected for publication are relevant and of high quality for the reader. Professional medical writers are increasingly in demand for content curation as they are well trained to understand the quality and relevance of the research. Those medical writers with scientific training and experience writing publications are well placed to ensure the information is critically analysed before reaching the reader. As well as solid writing and summarising skills, most experienced medical writers also have specialist medical knowledge, and a good understanding of best publishing practices and ethics. They also have a unique and personal understanding of the audience, since many medical writers were scientists or clinicians.

Different projects for medical writers

The deliverables for content curation can vary. Typically, the most important information needs to be identified and summarised in one or two key points. This can be quite a challenge! Writers may need to identify why this information is

Medical writers can now serve as guardians of the information entering the public domain: by ensuring accuracy and highlighting the most relevant studies for all stakeholders, from pharmaceutical clients to patients.

important, but also describe key study design elements, highlight the key results and their significance, and also note any study limitations. To ensure the content can be digested by time-pressed readers, some providers request that this be presented in no more than 200–300 words. Other providers ask for a journalistic style with the key information upfront and details following.

For medical congresses, clients may ask that the key findings be reported as a scientific press release (e.g. the style you can see at Univadis.com), a slide deck, a combination of the two, or something else entirely! Companies (and medical writers) are increasingly creative with how they present key findings to make the reading experience easier for their clients.

Scientific journals also have blog posts, which



are usually a lot easier to read than full articles. Medical writers may be responsible for summarising publications and delivering a brief text in the form of a blog post.

Communicating to the right audience

The needs of clinicians in practice are quite distinct from the needs of students, researchers, or the general public.⁴ Clinicians usually seek brief and accurate information for two reasons: to stay current with new developments in medicine relevant to their practice, or to find answers to patient-specific questions.⁵ With a full schedule, clinicians often have no time for reading new scientific literature. On the other hand, patients, students, and researchers may also want to know the latest developments. When summarising clinical research for patients, writers need to simplify the language and sentence structure so that articles are easy to read and understand, while key results are retained in context. So how do medical writers do this?

Medical writers can ask themselves the following questions to tailor texts to different audiences:

[For clinicians]

- Does this publication/abstract/poster/talk target the needs of clinicians? Did the researchers study outcomes that clinicians would be interested in?
- Where was the study performed, at which trial centres, and were there country- or ethnic-specific patient populations?
- How did the researchers interpret the results?
- Does the study answer the research question?
- Is the patient population in the study similar to the patient population that they treat?
- Is the intervention feasible for the population?
- Will the research finding have an impact on patient care?
- Does the study add new information to treatment algorithms?
- Does the study challenge current treatment guidance or present off-label use or both?
- Does the presentation describe novel endpoints that challenge current practice?⁶
- Were the research methods appropriate for the study question?
- Does the journal/congress/website present all the information accurately?

- Who funded the study? A pharmaceutical company or an independent group?

[For patients]

- Did the researchers study outcomes that patients would be interested in?
- Where was the study performed, at which trial centres, and were there country- or ethnic-specific patient populations?
- Does the study show a better quality of life for patients?
- Does the study suggest that patients can have more control over their own disease or condition?
- How did the researchers interpret the results?
- Who funded the study? A pharmaceutical company or an independent group?

A trend on the rise for medical writers

With the increasing demand for brief, summarised, up-to-date information, medical writers should be concentrating their efforts on providing comprehensive services for their audiences. Not only are dozens of articles curated

Table 1. Examples of clinical content curators

| Organisation or journal | Details | Frequency, format, and language |
|--|--|---|
| Independent curators | | |
| European Society of Medical Oncology | European professional organisation for medical oncology, comprising over 20,000 oncology professionals from over 150 countries | Online access and regular newsletters; publish approximately 4–7 unique articles per week Language: English |
| ESMO.org | ESMO is a non-profit publisher of oncology news that ensures clinicians are kept up-to-date with the latest developments affecting them and their daily practice. | |
| American Society of Clinical Oncology (ASCO) ASCO.org | ASCO Daily News provides scientific and educational summaries from oncology conferences and oncology news to ASCO members and oncology healthcare providers. Editorial content is designed to further the education and increase the quality of patient care. | ASCO Daily News is a print and online newspaper. Language: English |
| Local scientific societies | Some examples: seom.org | Publish weekly summaries of scientific literature and news in local languages |
| Private curators | | |
| Medscape | Medscape is the leading online global destination for physicians and healthcare professionals worldwide, offering: <ul style="list-style-type: none"> • the latest medical news and expert perspectives. • essential point-of-care drug and disease information. • relevant professional education and continuing medical education. • country-specific sites and free continuous medical education credits. | Publish daily summaries and online content Language: English |
| Univadis.com | A free, time-saving medical news and education platform for healthcare professionals. Executive summaries aim to keep clinicians up-to-date in just a few minutes each day. | Approximately 250 unique articles per week across all topics, written in English and translated into several languages or written in local languages Languages: Chinese, Dutch, English, German, French, Greek, Hungarian, Italian, Japanese, Portuguese, Romanian, Russian, Spanish |
| www.sciencedaily.com | ScienceDaily features breaking news about the latest discoveries in science, health, the environment, technology, and more – from leading universities, scientific journals, and research organisations. | Daily email digest Language: English |
| www.medpagetoday.com | MedPageToday is a trusted and reliable source for clinical and policy coverage that directly affects the lives and practices of health care professionals in the USA. Medical meeting coverage Free continuous medical education credits | Daily headlines Language: English |
| https://www.m3medical.com/ | M3 Medical is a new online medical community for healthcare professionals in Europe, Asia and the USA designed to enable members to interact with their peers, collaborate, and gain access to high quality and relevant information and knowledge to support their clinical practice and professional lives. Conference diary, conference coverage, blogs, and social networks | Daily email digest of healthcare and medical news on an American and European site in English, French, German, Italian, Spanish |

Continued opposite

| Government agencies | | |
|---|--|---|
| AIFA – Italian Regulatory Agency, AEMPS – Spanish Regulatory Agency. | Summaries of evidence-linked and validated drug updates, and practice guidelines | Monthly online updates Local languages: Italian; Spanish |
| National Health Service UK www.nhs.uk | An award-winning website for the general public in the UK, providing independent health news and information from recent scientific literature. Topics include common illnesses such as cancer, diabetes, neurology, and lifestyle issues. | Daily online update in English |
| Victoria state government Australia www2.health.vic.gov.au | An award-winning website for the general public in the UK, providing independent health news and information from recent scientific literature. Topics include common illnesses such as cancer, diabetes, neurology, and lifestyle issues. | Daily online update in English |
| INSERM médecine/sciences (m/s) www.medicinesciences.org | An international multidisciplinary publication focused on biology, medicine, and health research. m/s is a French scientific publication that started more than 30 years ago | Regular online updates, thematic issues, and special editions in French Language: English and French |

every week in English, they are also being translated or written directly in local languages. This implies new opportunities for medical writers and also for medical translators.

Conflicts of interest

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Predatory publishing – what medical communicators need to know

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Abstract

The rise of “predatory journals”, also known as pseudo-scientific journals, poses a risk to the integrity of science and therefore medical communicators need to know about their practices. Upon receipt of a publication fee, predatory journals publish manuscripts regardless of their scientific merit, very often without any peer review, and without providing editorial services. To maximise profit, such journals disregard all aspects of scientific integrity and foster the dissemination of bad and bogus science, lobby materials, and conspiracy theories. Publishing in predatory journals can have dire consequences for authors, their careers, and the reputation of their institutions. Medical communicators can help authors avoid falling prey to predatory publishers.

The problem of predatory journals

You may already have heard about “predatory journals”, also known as pseudo-scientific journals whose sole purpose it is to siphon off money from authors. These journals use the open access (OA) model to publish just about anything as long as the authors pay the required fee. The deal is: you pay the money, we publish without looking at the article too closely (if at all). The author gets a publication to add to the curriculum vitae and the publisher gets the money. Unlike genuine scientific journals, predatory journals shortcut the peer-review process entirely or substitute it for a superficial pseudo-review.

Medical communicators may be aware of predatory journals but may have thought of them as a peripheral phenomenon. This perception needs to change.

The number of predatory journals has risen dramatically in recent years and so has the number of articles published in them. Data from the Northern German Broadcasting Network suggest that, globally, some 400,000 scientists from all fields have published in such journals.¹ One company, OMICS, accused of platforming predatory and low-quality journals, prides itself on publishing over 700 journals generating tens of thousands of articles per year.^{2,3} The problem has become so big that the US Federal Trade Commission has recently obtained a ruling of \$50 million against OMICS for deceptive business practices.^{4,5}

Predatory publishers harm science and society as a whole. By publishing bad science and by making it available, they undermine trust in science and scientific progress. Their activities allow bogus work to be quoted and entered into the literature. Bad science as a starting point may lead other scientific investigations astray. Predatory journals take away money from taxpayers or grant-giving charities that was made available as part of research grants. Even worse, when uninformed patients in desperate situations get hold of unfounded, bogus research, they may

turn to ineffective and harmful treatments checklist.

The practices of predatory publishers undermine the credibility of science. This will directly affect medical communicators because they are part of the scientific endeavour. Medical communicators make science accessible. If sources are fouled with bogus science, the texts, documents, and summaries based on them will also be bogus and the work of medical communicators will be devalued.

Open access publishing and how the problem came about

OA publishing makes articles freely accessible online upon publication. Contrary to subscription-based publishers, whose published articles are only accessible after payment of a fee or via a subscription, OA publishers cover their publishing costs by charging authors a publication fee upon acceptance of a manuscript.⁶ Since it began in the early 2000s, OA publishing has grown to become a well-established publication model, and currently, many funding agencies and international organisations require that the data derived from the research they fund be published in an OA journal.⁷⁻¹⁰

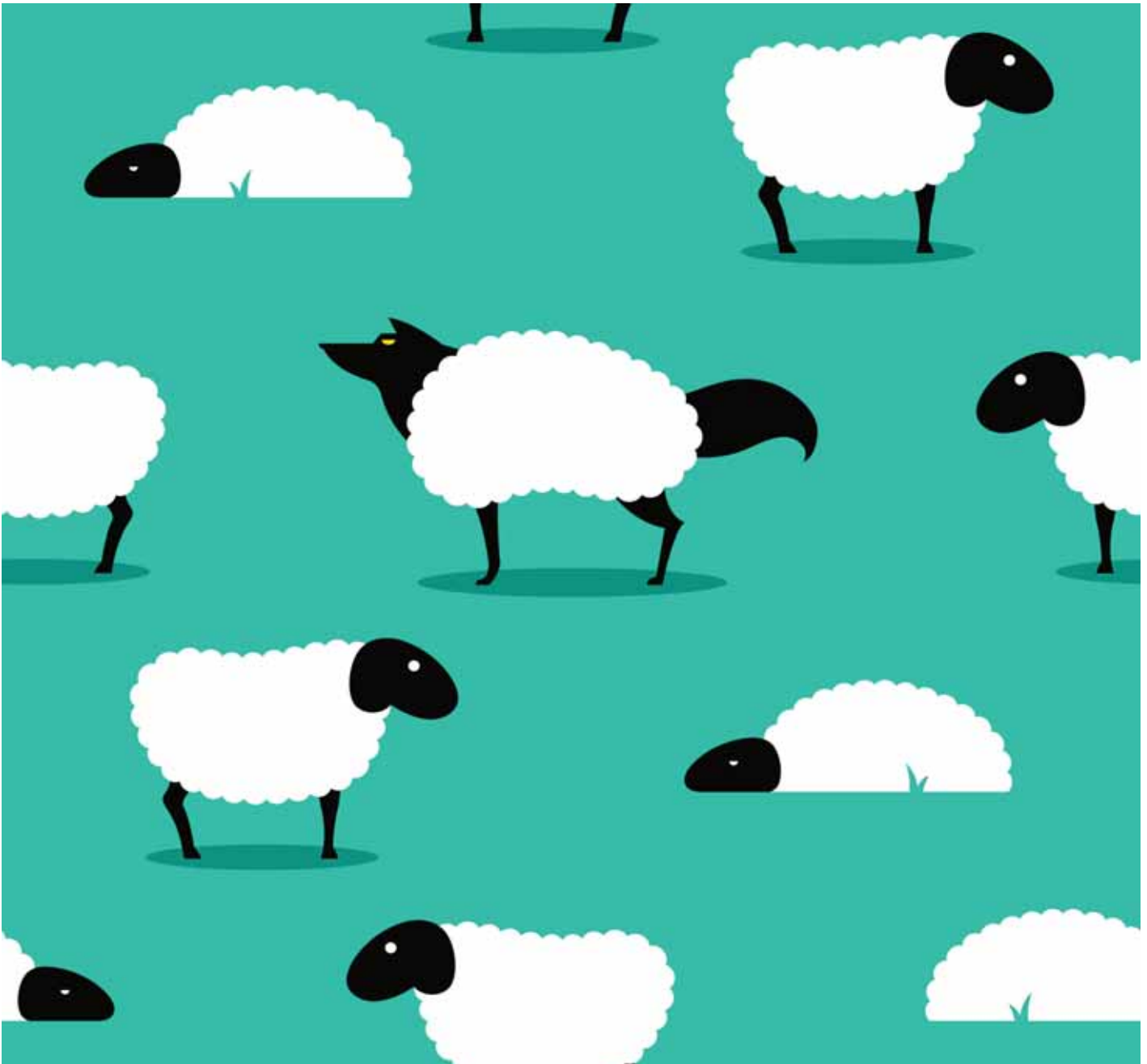
The success of OA publishing in science and medicine has opened the door for a new type of

Medical communicators may be aware of predatory journals but may have thought of them as a peripheral phenomenon. This perception needs to change.

fraud that exploits the need of authors to publish their results for career advancement and to obtain funding. These fraudulent publishers are now widely known as “predatory publishers” because of their aggressive and damaging tactics.¹¹ To maximise profit, they want to attract and publish as many manuscripts as possible. Articles are published without the usual standards and processes that genuine publishers adhere to.¹⁰⁻¹² Predatory

publishing is therefore best defined as the exploitation of the OA-publishing system for the sole purpose of making a profit, while neglecting key aspects of scientific rigour and publication ethics.

The number of predatory journals is rising.¹³



Those who publish their good research in predatory journals are unintentionally upgrading the bad and false science also published there.

Their fraudulent activities are fuelled by the need of researchers to publish results to advance their careers and increase their chances to obtain funding.^{11,14} In some countries, professional advancement in science and medicine is directly linked to the publication record through a point system.¹⁵ Many universities and research institutions require that PhD students publish their work in a journal – regardless of its quality – before awarding a degree.

To mislead authors, some predatory journals carry names that are similar or even identical to well-known established journals. This is a form of hijacking because these journals aim to divert submissions intended for genuine scientific journals. By misleading authors, they seek to get hold of scientifically sound content that they can then use to obscure the nature of their business.^{16,17}

The increasing number of predatory journals

has led to an increase in the number of articles published in these journals and, in turn, possibly even the citation of their articles in policy documents and medical guidelines. Because most predatory journals do not perform a proper peer review, they serve as a venue for badly conducted science. It is therefore not surprising that conspiracy theorists, such as anti-vaxxers and climate change deniers, use these outlets to publish.^{18,19} Some predatory publishers do

perform a pseudo peer-review process, after which they accept manuscripts regardless of the recommendations of the peer reviewers.^{20,21}

Although the traditional peer-review system has its flaws, it remains the best way to evaluate scientific content. It has served its purpose quite well since its systematic implementation in the 1970s. One possible way forward is implementing “open peer review”. This ensures full transparency to the reader as both the names and affiliations of the reviewers and their comments are available online.²²

The dangers of using predatory journals for authors and their institutions

The opportunity to publish anything in predatory journals is tempting for some researchers who want to publish irrelevant or inconclusive results for the sake of career advancement.¹³ However, this carries some long-term risks and authors should be aware of them.

Publications in predatory journals harm science and medicine. Without the scrutiny of a proper peer review, it is not possible to distinguish between good, mediocre, and bad science. Good science published in a predatory journal becomes contaminated and devalued. It loses its credibility because of the context in which it is placed. Question arise: Was the

article published in a predatory journal because it did not meet the standards of a genuine journal? Was the authors’ priority not scientific integrity but speed of publication?

Researchers who have submitted their work accidentally to a predatory journal may want to withdraw it upon realisation. This, however, is often not possible or only permitted after paying an additional fee. Scholars who publish their research in a predatory journal waste the time, effort, and money spent conducting it. Public money or third-party funds are wasted and are no longer available for genuine research. If scientists are aware of the predatory nature of a journal and nevertheless publish their work there, they may even be liable to prosecution. They are liable for using funds on dubious journals and by incurring expenses for travelling to scientifically worthless conferences offered by some predatory publishers. Research appearing in journals without scientific value ultimately becomes worthless to the authors and to the scientific community.

Authors cannot rely in any way on predatory publishers. Predatory journals are dishonest in regard to peer review, they hide the true costs, and they do not abide by rules and agreements. Authors who have submitted a manuscript to a

predatory journal but want to withdraw it later will often not succeed because the journal may want to upgrade its reputation by keeping it. Authors who are denied withdrawing their work have essentially lost the opportunity to publish in a genuine journal because this would constitute a second publication of the same content.

It is important for authors that their research is permanently available to the scientific community. With predatory publishers, however, permanent archiving and accessibility are not ensured. Should a dubious publisher go out of business, the articles published by them may no longer be available. In addition, there have been cases where articles were simply republished under different author names and with slightly different titles without consent of the initial authors. Predatory publishers do this to enlarge their article database.

Those who publish their good research in predatory journals are unintentionally upgrading the bad and false science also published there. Predatory publishers use the names of well-known scientists for their marketing purposes. By doing this, they appear genuine, which allows them to obscure their business model. When using predatory journals, serious scientists bring

Most predatory journals do not perform a proper peer review.

Table 1: Potential consequences of publishing in predatory journals for individual researchers

| |
|--|
| Researchers’ work appears in questionable environment. Their work is made available next to mediocre, bad, or even fake science articles. |
| The researcher’s name and affiliations may be used for advertising by the predatory publisher without their knowledge or consent. |
| The researcher’s name is permanently linked with the predatory publisher and its website, which may have negative consequences for their academic career. There is no assurance of permanent archiving, traceability, or accessibility of the article. |
| Papers are not included in reputable databases because some databases actively remove references to articles published in predatory journals. |
| Researchers cannot prevent their articles from being re-used by predatory publishers to enhance their database or for advertising. |
| Researchers may have to pay additional fees, particularly if they request withdrawal of the manuscript. |
| Public and third-party funds are wasted, resulting in potential liability. |
| Enforcing rights may be difficult because predatory publishers hide their location to avoid legal action. Even when their location is known, most predatory publishers fall under other jurisdictions than the authors’, complicating legal action. |

Table 2. Checklist for identifying predatory journals

| Item | Details |
|--|--|
| Overall | Look at the totality of the evidence; failure in complying with one item does not necessarily indicate a predatory journal. |
| Membership in a reputable publishing association | Absence of membership in reputable open access association such as the Open Access Scholarly Publishers Association (https://oaspa.org/), World Association of Medical Editors (http://www.wame.org), Committee on Publication Ethics (https://publicationethics.org/), and Directory of Open Access Journals (https://doaj.org/) is a sign of likely being a predatory journal. |
| Website design and use of English language | Spelling and grammar mistakes or poor web design are indicative of predatory journals. |
| Transparency about fees | Not clearly showing fees on the journal website is a sign of a likely predatory journal. |
| Editorial Board Members | Not being able to verify the identity the Editorial Board members with the information provided by the journal is a sign of a likely predatory journal. |
| Editorial office contact details | Not being able to verify a publisher's location, phone numbers, or email address is a sign of a predatory journal. |
| Scientific quality of articles | If the articles published by the journal are not well written, if you have not heard about the other authors that publish in the journal, and if you have never heard of the institutions mentioned, this could indicate a predatory journal. |
| Submission process | Providing only an email address as a method of submitting manuscripts is a sign of a likely predatory journal, as opposed to using a recognised submission system such as ScholarOne. |
| Digital Archiving | Not participating in a recognised digital archiving system, such as CLOCKSS (https://clockss.org/), is a sign of likely being a predatory journal. |
| Indexing | Not being included in a recognised index, such as PubMed Central is a sign of likely being a predatory journal (http://www.ncbi.nlm.nih.gov/nlmcatalog?term=journalspmc). |
| Journal Impact Factor | Not being able to verify that a claimed Impact Factor can be found in the Journal Citation Report website (https://clarivate.com/products/journal-citation-reports/) ²⁶ is a sign of likely being a predatory journal. |
| Adherence to ethical standards | Absence of policies dealing with the disclosure of conflicts of interest and absence of statements on copyright, intellectual property, or publishing licences are indicative of a predatory journal |

themselves down to the level of researchers of dubious reputation, wannabe scientists, conspiracy theorists, and lobbyists. For example, climate change sceptics are publishing papers rejected by serious journals in predatory journals.¹⁹ Unethical companies publish pseudo-studies in predatory journals to use the apparently genuine scientific reference to market their ineffective and potentially dangerous treatments. Anti-vaxxers spread their theses (“Vaccinations cause autism!”) in predatory journals.

Researchers risk their reputations and careers, as well as the reputation of their institutes when they publish in predatory journals, even when

they do not realise what they were doing. Researchers who did not know about the predatory nature of a journal, expose their ignorance and naivety. If they consciously use predatory journals, they might be accused of deliberate deception. Researchers should not count on the possibility that their publications in predatory journals will disappear from the internet at some point. Throughout their career, they will have the stigma of having used such an outlet; even years later, references to articles published in predatory journals can be found by commonly used search engines.

Should the growth of predatory journals

continue unabated, science may become viewed with suspicion. If the public, politicians, and the media can no longer tell good from bad science, its impact on society will be lost. This loss of trust in science may negatively influence funding decisions and the availability of an adequate research infrastructure.

How to avoid predatory journals

Although there is no golden rule for identifying a predatory journal, there are certain common characteristics.¹⁰⁻¹² One can avoid falling prey to predatory publishers by checking some free online checklists such as the Think.Check.

Submit checklist²³ and the Centre for Journalology at The Ottawa Hospital checklist.²⁴

Critical items are summarised in Table 2. Taken individually, the items listed do not necessarily prove that a journal is predatory. However, if several items do not apply, the likelihood of dealing with a predatory journal is high.

Because fraudulent publishers tend not to invest in website design or English language proofreading, their websites and emails often contain spelling mistakes, poor grammar, and poor design elements, such as low-resolution logos or images or overlapping text.

Names of editorial board members of predatory journals are sometimes entirely made up. They may also use names of genuine healthcare professionals without their knowledge or consent. Therefore, if the identity of the editorial board members cannot be verified, this may indicate the predatory nature of a journal.

Few genuine science publishers do not yet use a recognised submission system such as ScholarOne. Therefore, if a journal asks authors to send their manuscript simply to an email address, the alarm bells should start ringing.

Faking impact factors and indexing features is very common among predatory journals. Because of this, it is advisable to check their claims in the Journal Citation Report²⁶ and PubMed Central.

Lack of commitment to digitally archiving the published articles in a safe repository is also common among predatory publishers. A reputable journal will likely participate in a recognised digital archiving system, such as CLOCKSS (<https://clockss.org/>).

Finally, being a member of an international OA organisation such as the Open Access Scholarly Publishers Association (<https://oaspa.org/>) or the Committee on Publication Ethics (<https://publicationethics.org/>) is a good sign

Few genuine science publishers do not yet use a recognised submission system such as ScholarOne. Therefore, if a journal asks authors to send their manuscript simply to an email address, the alarm bells should start ringing.



that the journal is not predatory because the associations carefully scrutinise journals before admitting them as members.²⁵

Conclusion

Medical communicators need to know about all aspects of predatory publishing because it not only undermines the credibility of science but may also have serious consequences for authors, their careers, and their institutions. Medical communicators are often asked to support selecting an appropriate journal, therefore they are in a key position to help authors avoid falling prey to predatory publishers.

Disclaimers

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

Conflicts of interest

The authors declare no conflicts of interest.

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AMWA – EMWA – ISMPP Joint Position Statement on Predatory Publishing

American Medical Writers Association, European Medical Writers Association, and International Society for Medical Publication Professionals

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), and the International Society for Medical Publication Professionals (ISMPP) recognise the challenges to scientific publishing being posed by predatory journals and their publishers, which employ practices undermining the quality, integrity, and reliability of published scientific research. This joint position statement complements several other sets of guidelines that have helped define the characteristics of a predatory journal.¹⁻⁵

Predatory journals pose a serious threat both to researchers publishing the results of their work and to the peer-reviewed medical literature itself. These publications differ from legitimate open-access journals⁶ in that predatory journals subvert the peer-review publication system for the sole purpose of financial gain with little evident concern for ethical behaviour.⁷

Organisations such as the World Association of Medical Editors (WAME), the Committee on Publication Ethics (COPE), the International Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors (CSE) support good publication practices that are now widely recognised.^{6,8-10} Predatory journals do not adhere to these practices but instead exploit the Gold Open Access publishing model (for which authors pay a publication fee).¹¹ To generate revenue, these journals intentionally misrepresent practices of editorial and peer review, methods of journal operation, article process charging, dissemination, indexing, and archiving.¹

Harm to the scientific literature will be the ultimate result if predatory publishing proliferates. Legitimate research carried out with the best of intentions might be lost if it is not recorded, cited, or made accessible in the long term, and the scientific record is at risk of being corrupted.¹ But dangers to authors also exist in that their reputations can be damaged as a result of having their work published in predatory journals or being unknowingly “appointed” to their editorial boards. Furthermore, authors may find themselves trapped after they realise they have submitted an article to a predatory journal. There is a potential risk that some journals might not return submitted manuscripts or will publish a submitted paper even after an author has protested.

The large increase in scientific journals, including those that are predatory,¹² over the past 15 years can make the task of distinguishing predatory or “pseudo” journals difficult. However, online tools are available to help authors in this effort,^{1,8} and certain characteristics have been identified as being typical of predatory journals and their publishers:

- publishers or journals sending emails that aggressively solicit researchers
- a journal name that sounds somewhat familiar – but is actually a devious permutation of a legitimate journal name
- a website that appears unprofessional, with poor graphics, misused language, dead links, and aggressive advertising
- no street address or in-country telephone number noted on the journal or publisher’s website, or a fake address/phone number provided

- a lack of journal indexing in a recognised citation system such as PubMed¹³ or within a legitimate online directory such as the Directory of Open Access Journals (DOAJ)¹⁴
- promises of unrealistically quick peer review, or no information provided about a journal’s peer-review process
- article processing charges that are not transparent (and may be either very high or very low) or are payable on submission (that is, not dependent on the outcome of peer review)
- claims made of broad coverage across multiple specialties in medicine or across multiple subspecialties in a particular discipline
- a large stable of journals that have been started very recently and/or that contain no or few published articles, are inaccessible, or are of obviously poor quality
- an editorial board consisting of members from outside the specialty or outside the

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country in which the journal is published, or board members who are unknown to someone experienced in publishing in the field

- a submission system that is overly simple with few questions asked and no conflict-of-interest or authorship qualification information requested.

Authors should not purposely choose to submit manuscripts to predatory journals to augment their own record of publication, as has been seen more recently.^{15,16} The conscious and deliberate submission of manuscripts to predatory journals is not ethical. Medical writers and editors, as well as researchers, have a responsibility to evaluate the integrity, history, practices, and reputation of the journals to which their research is submitted.⁸ We encourage all authors to carry out due diligence by examining the reputation of the publications to which they submit, and send their work only to those journals that provide proper peer review and that genuinely seek to contribute to the scientific literature.

The scientific community must be made fully aware of the harm that publishing in predatory journals poses and understand how to avoid it. AMWA, EMWA, and ISMPP are committed to educating our members about predatory publishing and the responsibilities of medical writers and publication professionals in addressing this significant issue.

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How to combat medical misinformation with a sound content strategy

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Abstract

In our post-truth era of media and communications, implementing a sound content strategy can help your message reach the right individuals. It is time for experts and healthcare companies to lead the change as ethical and credible sources of knowledge. In this article, we provide insights about the importance of content strategy, and how collectively, we as medical writers must use our expertise to communicate complex concepts and motivate a change of opinion.

Are we doing enough to fight back against widespread medical misinformation?

We live in an age where people are influenced by purposeful misinformation, “alternate facts”, and influencers’ articles across all media and communications. This deluge of “fake news” has delegitimised content for the general population to the point of meaninglessness. We have witnessed the rise and persistence of misinformation by popular social media influencers and celebrities, supported by biased or misappropriated scientific research.

What is content?

Every piece of information and communication is content, and can span multiple forms of media from written articles, social posts, videos, podcasts, infographics, and more.

Using content for marketing purposes is a common practice among companies, telling stories to attract and retain customers. One of the earliest examples of content strategy was pioneered by Johnson & Johnson in 1888.¹ They published a manual that thoroughly explained how to prevent infections using antiseptic methods and provided information on their available products.² This example illustrates the three core principles of content strategy. Through the widespread use of the manual, they raised awareness of the problem, created a desire to address the problem, and more importantly, directed people towards their products as a solution.

Successful marketing campaigns are not limited to selling healthcare related products or devices. Many public health initiatives have their roots in marketing. This is exemplified with the current marketing efforts in support of mental health.³ For many years, society had the erroneous perception that mental health issues could just be “dealt with” or people can “get over it”. In 2001, the Mental Health Foundation sought to challenge those stigmas and launched its first Mental Health Awareness Week in the UK. Breakthroughs made by this marketing campaign includes the recognition and support of mental health in the workplace. The public awareness garnered through the long running campaign has led to a commitment of £2.3 billion a year for mental health services by 2023/24 from the NHS.³

Why does strategy matter?

Content strategy

A guiding definition of content strategy is the planning and management of all



forms of media and communications for a specific project or purpose. The project can span from a single journal article, product ad campaign, public relations for a company, or organisations for chronic disease. The current need for many healthcare companies and organisations, is to establish trust, build awareness, and provide a clear action for the consumer to take.

Having a sound strategy clears a path for your message.

Content strategy includes identification of the problem, defining the communication goals, identifying the audience you need to reach, and planning all of the communications required to achieve the objective. This may seem like a major oversimplification, but these are the core

principles to keep in mind as a medical writer.

The power of information

A medical, scientific, or clinical background and training is essential to content strategy and writing. Medical writers are in a unique position to understand the complexities of the problem at hand and strategise the types of content required to tackle the problem. Our core knowledge and innate ability to think critically are required





to clearly and accurately convey our message. The challenge is that we must hone our skills to tell a compelling story that resonates with our audience and gives them a reason to believe the science.

Some of us might wonder how can people believe things that were proven wrong by science so long ago, or how can certain bad advice be taken as ‘gospel truth’ when scientific research is at our fingertips. There is an abundance of scientific data in the literature, but these are hidden away from the typical lay-person with publisher paywalls and confusing jargon. For all good research out there, most people don’t see anything beyond bad science reporting in news headlines. Another challenge, no matter what our backgrounds are and how rational and logical we think ourselves, is that research shows that people make decisions primarily using emotions, and then use logic to back up those decisions,⁴ in what is referred to as confirmation bias. That is why it is important to emphasise that the role of the medical writer is to bring the crucial information out and make a meaningful connection with your intended audience.

Making a difference as a medical writer

The typical role of a medical writer may vary, but

We live in an age where people are influenced by purposeful misinformation, “alternate facts”, and influencers’ articles across all media and communications.

at its core, you are an educator to groups of potential decision-makers. The scale of decisions made by your audience is wide-ranging, which could include healthcare professionals like doctors, nurses, and scientists, or those outside of the clinical sector with industry business unit members, patient advocacy members, and the general public. Ultimately, you will be in charge of ensuring the message is clear and understood by each of these individuals. Your work informs everyone, whether it is an individual’s choice to get a vaccine, updating a hospital about the latest best clinical practices, helping venture capitalists invest in start-up healthcare companies, or brief legislative committees that are forming new public health policies.

The guiding principle is to never “dumb it down”. We aim to distil the core meaning of the principles of science to build trust and understanding. It remains crucial that you know your audience and can tailor your message to them, without distorting the facts. If you know your audience has a low degree of literacy or low technical fluency, don’t overcomplicate your message to reach them. No matter how technologically advanced media has become, building trust as a voice of knowledge remains a core tenant of medical writing.

With medical content strategy, we must also

remember to adhere to our ethical code and turn down or steer away from creating more misinformation. When it comes to content development, you may feel pressured to fabricate or exaggerate claims about the efficacy of certain products. Part of medical writing is to stand up for the scientific principles and not editorialise or stylise the data. This challenge has grown as you often must be prepared to fact-check sources and root out any potential agenda-driven biases that are inherent to the study design or source of funding. A good content strategy leverages your judgement on the validity of the scientific information and will screen out poor or deceitful sources.

Another key aspect of content strategy is for the most part, you are working on a two-way communication platform. Be mindful of what many of your audience members are saying and don’t hesitate to devise strategies that open direct engagement. You have the unique opportunity to understand at an individual level of needs and can help bridge any gaps in understanding. These can include accounting for having a respondent in social media posts, direct messages, and how to liaise with medical, legal, and regulatory personnel in the industry.

The future of content strategy in healthcare

People are weary of fake news and perhaps post-truth has its days numbered. There is a growing sentiment out there for the truth and fair representation of facts. We must always strive for

transparency and honesty when developing our content. Content strategy and medical writing are about meaningful, understandable, and compelling messages to inform and persuade the lay audiences.

Overall, it must be stated that: You are a champion of knowledge in the medical field, you can be an advocate for changing practices, and you are an educator of scientific and medical communications for many decision-makers.

Disclaimers

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

Conflicts of interest

The authors declare no conflicts of interest.

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Subcontracting: Not for the faint of heart

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Abstract

Subcontracting can be the answer to a successful freelancer's prayers, or the opportunity to work harder than you have ever worked before for less money than you made when you were a struggling newbie. The potential advantages of subcontracting are numerous, including being able to meet more of your clients' needs, expanding your reputation and your repertoire, reducing your personal writing workload, and making more money – even while you are sleeping. But the potential disadvantages of subcontracting are also numerous and very real. Subcontracting puts your reputation on the line and out of your hands and exponentially increases your risk for problems ranging from cash flow and liability exposure to conflicts of interest. Subcontracting is not a decision you make lightly, but neither was your decision to freelance. It might just be your opportunity to soar.

Any seasoned freelance medical writer will tell you that success has little to do with being a good writer. Being a good writer is fundamental to the task and therefore expected, assumed. Being good at what you do is your ticket to the dance; but once inside, there are a lot of people waiting to be invited out onto the dance floor. This is why I have long counselled people who are new to the field of medical communications to get in with a good company, develop your skills, and learn the industry from the inside out. Only then can you even begin to think about striking out on your

own. The reason is simple. When hiring a freelancer, clients cannot afford to make a bad choice.

Clients only call on freelancers when there's an emergency. They have a project, a deadline, and either no one on staff with the requisite qualifications, or no qualified person on staff who is available to do the job. They must turn to someone outside their company. They will call their familiar freelancers first – the people who have already proved themselves to be not only good writers but also good at getting things done and doing them right. If a client is calling you and they have never worked with you before, you can bet they are out of options. They are nervous. This is why I love being a freelancer. Whether it is a client I know or a client I have never worked with before, every time the phone rings is an opportunity for me to be a hero.

Nobody's born a freelance medical writer. Whatever our backgrounds, we make ourselves into good writers and then into good freelancers. We become popular with our clients, who put us on speed dial, recommend us to their colleagues, and take us with them on their career journeys to new positions, new companies, and new opportunities. We have more work than we know what to do with, but dare we turn anything away? And still, we see more opportunities...if only there were more than 24 hours in a day and seven days in a week! To paraphrase Tennyson, when work is consistently too busy, a freelancer's fancy lightly turns to thoughts of subcontracting.

Remember the fear and/or apprehension you felt when you decided to take the plunge into freelancing? Well, if quitting your staff position and launching a freelance business is like jumping out of a perfectly good airplane without a parachute, subcontracting is like building a new airplane for yourself while you are on the way down. It is not for the faint of heart and not a decision you make lightly.

Early in my professional writing career, freelancing was my side hustle. It enabled me to



make extra money and explore new types of writing. In 1989 I quit my perfectly good day job and started my freelance business. I began specialising exclusively in medical communi-

cations in 1994 and started subcontracting in 2003. In the 16 years I have been subcontracting I have seen a lot. If you think freelancing can be tough, subcontracting can be exponentially tougher. It can also be more rewarding – personally, professionally, and financially. I will share with you what I consider to be the main advantages and disadvantages of subcontracting.

If quitting your staff position and launching a freelance business is like jumping out of a perfectly good airplane without a parachute, subcontracting is like building a new airplane for yourself while you are on the way down.



The advantages of subcontracting

There are numerous advantages to subcontracting, and these are my top six:

1. Meet more clients' needs

As a freelancer, my first priority is to keep myself busy writing. Writing is what I love to do, and the projects I work on are fun and challenging. Subcontracting enables my freelance business to be a bigger solution for my clients than what I alone can do, whether because I am already committed or I lack the necessary expertise. When a client reaches out to me with an assignment, the first thing I do is assess whether I am the right person for the job and, if so, whether I have the bandwidth to take it on based

on the project schedule. If my answer to either question is no, I look to the freelancers on my team to see who has the right background and experience as well as the time to get involved. Thanks to subcontracting, my freelance business is able to say yes to many more projects, providing greater value to our clients and creating more great work opportunities for me and my team.

2. Expand your reputation and your repertoire

Our job as freelancers is to make our clients' lives easier. When clients can make a single call and get what they need, that is easy. By subcontracting, my freelance business has a reputation as a one-stop shop for all our clients' medical writing and editing needs. As a result, our clients typically reach out to us first because

we are likely to be the solution. If a project happens to be outside of our team's therapeutic areas of expertise, our clients will often offer the assignment to us anyway because they are confident in how we consistently deliver for them. In my experience, clients prefer to give a project to a freelancer they know despite it being in a therapeutic area they don't know, rather than give it to an unknown freelancer who says they know the therapeutic area. This gives us the opportunity to expand our repertoire, making our group all the more valuable to our clients.

3. Lighten your load

It is easy for successful freelancers to work themselves to the point of exhaustion. Face it, we love the challenge (and the money). But too much of a good thing can make us distracted, and



distraction can impede our performance and reduce the quality of our work. No matter how good we are, if important details start falling through the cracks, those cracks create openings for other freelancers to step in. (Remember what I wrote at the start of this article about there being a lot of people at the dance?) According to one MIT neuroscientist and expert on divided attention, multitasking is a myth.¹ Despite what we think, our brains have very limited bandwidth for processing new information. When we think we are multitasking, we are actually cognitively switching very quickly between tasks, which reduces efficiency and quality and increases the chance for errors. Subcontracting enables me to keep myself from becoming overloaded (well, usually), because I have other writers on my team whom I trust implicitly and with whom I can divide the workload to conquer it all.

4. Make more money

There's no disputing that freelancers love money. We work hard for it. And as successful freelancers know, you can earn much more money as a freelancer than anyone would ever pay you to work on staff. When you subcontract, you have more people working hard for it, which means you have more money coming in. The income from every project exceeds your out-of-pocket cost to the subcontractor, and that goes directly to your bottom line. How much excess? That is up to you, and up to what your market and your clients will bear. What helps determine what your clients and what your market will bear is the added value your company brings to the table compared to other freelancers. Value is intangible, but to your client it is palpable. When they get a level of quality, confidence, and efficiency from you and your subcontracting team that is greater than what they feel they get

from other freelancers, your company can command higher rates – but to a point, and this is where the difference between hourly and project pricing comes in. It is possible to build a subcontracting model based on hourly pricing. However, there is a finite amount clients are willing to pay per hour, so charging by the hour restricts you to charging for time, not for value. Value is how the subcontracting model works. Project pricing enables you to charge for the value of your service rather than for the time it takes to get something done. This, in turn, enables you to pay your freelancers well while still paying yourself. If you are not making money on the work your subcontractors are doing for you, what is the point?

5. Make money while you sleep

The worst thing about freelancing is that you don't make money when you are not working. Perhaps the best thing about subcontracting is that you can make money while you are sleeping, vacationing, caring for a sick child or an ageing parent, or struggling with a hurricane-induced power outage. I recently took a 3-week holiday, which is the longest time I have taken off in my entire career. When I go on holiday, I don't take any work with me. No email, no teleconferences, no computer. Nothing. I work hard, so I play hard. While I was away, the subcontractors on my team were continuing to work on their projects. New projects were coming in the door while others were being delivered. It's wonderful! I work with subcontractors across

Perhaps the best thing about subcontracting is that you can make money while you are sleeping, vacationing, caring for a sick child or an ageing parent, or struggling with a hurricane-induced power outage.

the US and around the world, and I have found that time zones also work to our advantage. As I am waking up in the eastern US, a writer on my team who resides in the UK already has 5 hours in on the day. As I am leaving my office at the end of the day, a writer on my team in California still has 3 hours to complete her assignment. When you subcontract, you can make money all the time.

6. Build your business into an asset

Freelancers are entrepreneurs. The ultimate goal of entrepreneurship is to build assets you can make money from for as long as you want, then cash out by selling the business and move on. Most freelance medical writers are what I call a "business of one". They are the business and the business is them. That can make the business difficult (but not impossible) to sell, because the buyer has to be willing to then become the business, too, and the clients have to be happy with the new owner/freelancer. Also, it takes money to buy a business. I doubt someone wanting to break into freelancing would be willing to risk the capital to "buy" another freelancer's clients, which is something a successful freelancer would never have to do anyway. A freelance medical writing business with both clients and subcontractors is bigger than the person who owns it, making it a more attractive asset for an investor who might or might not also be a medical writer. Eventually, selling the business could be an attractive option for you to transition into retirement or start a new venture.

The disadvantages of subcontracting

If subcontracting was easy, everyone would do it. It is not, and for a number of reasons. These are what I think are the top five disadvantages of subcontracting:

1. Work harder and earn less

Subcontracting involves a lot of work that has nothing to do with putting words on the page. Imagine this: you have six subcontractors, each of whom might be working with you on two assignments. Each of those 12 assignments began as opportunities, with phone calls or emails requiring your attention and follow up. Each project has to be estimated, which is a process on which I work very closely with the writer or editor who will be doing the work. After the estimate is submitted to the client there might be some negotiation, then finalisation, and invariably paperwork to review and sign. Multiply that by 12. When possible, I want to be on every call between the subcontractor and my client, so I know what is going on. Multiply that by 12.

My obligation is to the clients, to ensure they receive the value they expect from their investment in us, and to the subcontractors, to ensure they get whatever they need to do the job to the level of quality our clients expect, and to intercede if the project or the client goes off the rails. Multiply that by 12. While I prefer subcontractors to have direct lines of communication with the client (always copying me), I serve throughout the project as a sounding board for the subcontractor to bounce ideas, discuss their strategy and approach, review drafts, and run interference when necessary. Multiply that by 12.

Throughout the process I am fielding emails and phone calls related to each project. I am receiving progress invoices from the subcontractors and invoicing the clients, then receiving and processing payments and paying the subcontractors. Multiply all that by 12.

The bottom line is that when subcontracting, you can work harder than you have ever worked before and ultimately earn less for your time, effort, and value than before you started subcontracting. You have to be very careful about choosing the right subcontractors, choosing the right clients for whom you will let subcontractors work (and some clients want only you, not a subcontractor), marrying the right projects to the

right subcontractors, and managing the amount of time and effort you spend on these activities. And don't forget, while you are managing all the subcontractors, clients, and projects, you are also getting, estimating, writing, and managing your own projects!

A lot of what I described here may seem like project management, and a project manager would surely help. The challenge is deciding the point at which it makes financial sense to bring someone onto the team who costs money, but who does not generate money. However, the activities and responsibilities I have described are not all or only related to project management. Along the way I am making decisions and commitments only the business owner can make.

2. Risk your reputation

A key benchmark in the journey to becoming a successful freelancer is the point at which your reputation in the field brings you more work than your traditional marketing efforts. It takes a lot of time and effort to build a good reputation, and no time at all to destroy it. When you subcontract, you grant to every subcontractor the power to uphold or destroy your reputation. Make no mistake, this is not just a big thing, it's everything. I know many people who subcontract to new freelancers and novice medical writers. There's nothing wrong with that. In fact, I admire successful freelancers who not only mentor but actually make mentoring a part of their business model. A major benefit is that you can mould the subcontractors in your unique style and ways. A major drawback is that it's a lot of work to turn new writers into great writers and novice freelancers into great freelancers. As I alluded to in the last section, the more time you spend managing your subcontractors, the less money goes to your bottom line.

I feel a personal as well as a professional commitment to mentoring new and aspiring medical writers and freelancers, and I do it often. But when it comes to my business I want to hire only the most experienced and successful freelancers to work with me for the benefit of our clients. This is how I ensure our clients consistently get the very best work, which

When subcontracting, you can work harder than you have ever worked before and ultimately earn less for your time, effort, and value than before you started subcontracting.

supports our outstanding reputation as a business and our unique value as a business partner.

3. Risk your cash flow

From the client's perspective, a major advantage of hiring a freelance medical writing business that subcontracts is that they get access to a number of great writers and the

ability to accomplish a number of projects simultaneously, all through a single supplier. No multiple master service agreements or confidentiality/nondisclosure agreements, no multiple business entries for accounting. It may even be easier for them at tax time. The reason for this is that their business relationship is with you, not with the subcontractors. This means that the subcontractors' business relationships are with you, not with your clients. If a client becomes slow in paying, or worse yet tries to slip out without paying, that is not your subcontractor's problem. You owe the subcontractor's fee, and you owe them timely payment, regardless of what happens with your client. This can put quite a strain on cash flow if you don't stay on top of your accounts receivable and make sure your clients pay on time.

4. Risk your exposure

Freelancers are accustomed to signing confidentiality or nondisclosure agreements, ensuring any confidential information you receive in the course of doing business with your client will remain confidential. One could argue that as a business of one, you are in complete control and therefore there is little possibility of anything going wrong or of you doing anything unethical. But when you have subcontractors working with you, even though you presumably hire professionals who know better, your company's exposure to potential liability increases exponentially. As a freelance business, when you sign a contract you sign for your company. If you use subcontractors, your signature on the contract includes taking responsibility for your subcontractors. That is a lot of responsibility. At the start of any subcontracting relationship I ask the subcontractor to sign a nondisclosure agreement. It's a simple agreement I have prepared based on many examples I have seen



and read over the years. It is not restrictive of trade, and it does not include one of those nasty indemnification clauses. My business also carries general liability insurance and professional liability (errors and omissions) insurance. I did not bother with these when I was a business of one. The confidence I have in the professionalism and ethics of my team is now supported by the nondisclosure agreement I have with each subcontractor and the insurances my company carries. This gives our clients an added sense of confidence and comfort when I sign their contracts on our collective behalf.

5. Increase potential conflicts

Conflict of interest (COI) is a fact of life for freelancers. The longer you work the more therapeutic areas you work in; the more drugs, devices, or diagnostic tests you write about; the more clients and companies you work with; and the more likely you are to have to decline an opportunity due to COI. Now, multiply that risk by the number of subcontractors on your team. When you subcontract there is a much greater likelihood that COI situations will arise, and you need to know how to handle them. These are a few of the basic ethical principles to which all freelance medical writers should ascribe (this is certainly not a complete list):

- First and foremost, medical writers must always be acknowledged for their contribution to a manuscript.²⁻⁴
- Second, you should never work on competing products in the same therapeutic area at the same time.
- Third, if you work with medical communications companies, you should never help one client take business from another client.
- Fourth, if you work in promotional areas and also write continuing medical education, you must observe ethical washout periods.

The ethical situations described above are straightforward. But when you subcontract, ethical conundrums can arise. For example, is it unethical to have one subcontractor working on a project for a product that competes with another product on which you have a different subcontractor working on a project at the same time? Or, is it unethical to have one subcontractor writing a branded promotional PowerPoint presentation for a product at the same time another subcontractor is writing a continuing medical education piece for the same product? In my opinion, anything that even remotely gives the appearance of potential COI is something to avoid. This also builds trust with your clients. In my experience, when I turn down

an assignment due to COI, the client I am turning away typically respects and values my ethical position and comes back to me with other opportunities in the future knowing I will be the first to blow the whistle if a potential COI exists.

Tips to make subcontracting work for you

Just as freelancing is not right for everyone, neither is subcontracting. I thought about it for a long time before taking the plunge. I couldn't figure out how it could possibly work. If I was charging at the top of what a freelance could charge, how could I possibly hire subcontractors who were as good if not better than me, pay them just as well, and convince clients to pay even more so there was money in it for me? Then I remembered having a similar concern many years before when I was contemplating quitting my perfectly good job and starting a freelance business. Just as before, I couldn't let fear and uncertainty stand in my way. My subcontracting journey has not been easy, but it has been rewarding and fulfilling. I continue to learn new things each day.

I will leave you with these 10 subcontracting tips to help you get started.

10 Subcontracting Tips

1. First, be successful.

If you don't already have a thriving freelance business, don't start giving away your work to subcontractors. Your success comes first!

2. Always be transparent.

Clients need to know who is working on their projects, and not all clients want you to use subcontractors. In time, your clients will love your subcontractors so much they will request them by name!

3. Don't get in the way.

Let your subcontractors have a direct line of communication with your client, but make sure you are always in the loop so you can support the team and the process. You are the value added!

4. Stay on top of everything.

Your job is to make sure both your client and your subcontractor are getting what they need, and to keep things from getting out of hand. Projects move fast!

5. Estimate carefully.

When working with a subcontractor, you are estimating for two. Make sure there's money in the project for everyone!

6. Maintain your visibility.

This is your company, your clients, your team, and your reputation!

7. Know your limitations.

Subcontracting gives you more capability, but it does not make you invincible. Don't be afraid to say no!

8. Act like a business.

When you subcontract, clients expect you to act like a full-fledged business instead of a "business of one," because you are!

9. Be responsive.

The busier you get, the more vital it is that you respond quickly and thoughtfully to all emails and phone calls. Think you are busy now? Just wait!

10. Own every mistake.

Errors don't belong to the people on your team who make them, they belong to you. Learn from them fast!

BONUS TIP!

11. Be grateful.

Be the first to give credit to the people on your team for a great idea or a job well done. Without the orchestra, a conductor is just a person with a stick!

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Lay summaries and writing for patients: Where are we now and where are we going?

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Abstract

We examine the trend for increasing and more transparent patient information and ask how close we have come in the last few years to producing useful and meaningful information for patients. We also outline the challenges faced by medical writers and the pharmaceutical industry as a whole in trying to comply with recent European requirements for the creation of lay summaries of key regulatory submission documents. The risk management plan and the results section describe outcomes of clinical trials – and what this means for patients – who are the target audience that this monumental effort is intended to help.

“Patient-centricity” and “transparency” have been hot topics in the pharmaceutical industry for the past few years. They are not new, but they are increasingly important in the context of regulatory documentation. Their implementation has been supported by various official guidance documents and mandated by legislation, much to the delight of patient

advocacy groups and the public in general. Some information has always been available to patients, of course. Information about a medicine’s side effects and how to reduce any associated risks is given in the package leaflet that is supplied with the medicine, and so most patients are aware of this – even if its usefulness has been questioned regularly.^{1–3} Other patient-specific information is also available via the EMA website. The European Public Assessment Report summary explains how the EMA has assessed the benefits and risks of a medicine before allowing it to be used. However, the availability of this information is perhaps less well known to the general public, who are likely to be unfamiliar with the EMA website and may not instinctively know how to navigate it.

The most recent changes to the legislation in terms of information for patients and the lay audience (the introduction of the lay summary of the Risk Management Plan [RMP] and the lay summary of Clinical Trial Results [CTR]) have caused great discussion and concern in an industry very willing to provide information to patients but more experienced with producing complex scientific information for regulatory authorities. RMP summaries describe how the important risks of a medicine are being managed or will be managed, and the CTR lay summary explains the results of a clinical trial and what the sponsor believes they mean. However, these documents can be challenging to write, and however much they are needed, this effort is wasted if they do not reach or connect with their intended audience. Medical writers, who usually produce documentation for regulatory authorities, are highly trained in a specific writing style and tone, and the usual audience for their work consists of readers who have a very high level of health literacy and often a considerable knowledge of the specific disease or

therapy area. Writing instead for an audience of readers who may have a low level of health literacy and perhaps little or no disease and therapy area knowledge is a significant challenge.

This article looks at the challenges in writing the RMP and CTR lay summaries from the medical writing side and offers a viewpoint from the patient’s perspective.

Legislation and its challenges

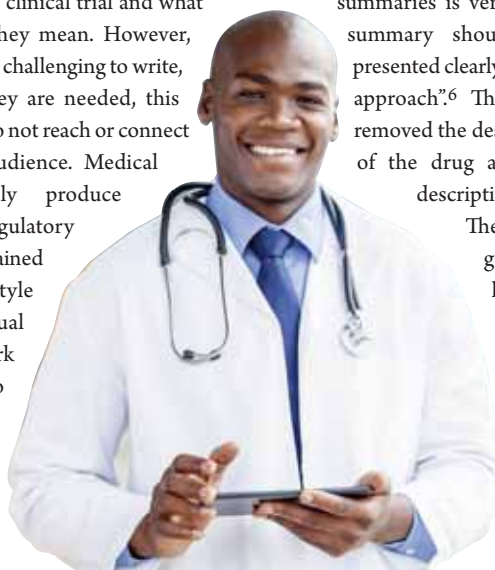
RMP (Rev 2) Section VI

In March 2014, the EMA began publishing lay summaries of RMPs for centrally authorised medicines to explain and make more transparent to the general public how the European regulatory authorities make decisions about the safety of medicines (the details of which have been discussed previously).^{4,5} This was intended to be a further step towards increased transparency and improved public access to information on medicines and was mandated by the European pharmacovigilance legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU).

In March 2017, the guidance on drafting risk management plans was revised to make significant changes to how lay summaries should be written, which is given in part VI of the RMP.

The guidance states that the audience for RMP summaries is very broad, and that the summary should be “written and presented clearly, using a plain-language approach”.⁶ The 2017 changes also removed the description of the efficacy of the drug and the epidemiology description.

The revised (revision 2) guidance states that the lay summary should contain information including safety concerns, risk minimisation measures, and pharmacovigilance activities. These sections would not pose any difficulty for





medical writers producing documentation for a regulatory authority. The problem, however, is conveying that information to a lay audience and particularly to those with difficulty reading. In the UK for example, 16% of adults (7.1 million people) are functionally illiterate. This means that they can understand short, straightforward texts on familiar topics, but have problems reading information from unfamiliar sources or on unfamiliar topics.⁷ Considering that the average reading age in the UK is 11 years,⁸ the challenge of explaining the risks and harms becomes apparent.

These discussions are also often supported by statistical information. Simply providing these numbers is not sufficient for the lay audience – an understanding of what the numbers *mean* must also be conveyed, so that the risks, benefits, and incidence/prevalence can be put into context. Additionally, the removal of the efficacy and epidemiology sections, although simplifying the lay summary for the medical writer to produce, makes it very difficult for the reader to understand the benefits of the drug and the impact of the disease in general.

Clinical Trial Regulation (CTR) EU 536/2014

In 2014, as part of its clinical trial transparency initiative, in the EU CTR 536/2014 (Article 37

EU CT Regulation), the EMA mandated that clinical trial sponsors produce a summary of the results of every clinical trial in plain language (language that is understandable to the lay audience) no later than 1 year after the end of the trial in the EU.⁹⁻¹² These CTR lay summaries will be made available in a new EU database once it becomes available.

This requirement had originally been planned to take effect in 2018, but the creation of the database and upload portal was delayed, and so it is likely that it will not be implemented before 2020. In the meantime, many pharmaceutical companies are making the documents available to the general public via their own company website (e.g., UCB¹³ and Boehringer Ingelheim).¹⁴

Despite the challenges involved in writing for a lay audience, the introduction of CTR EU No 536/2014 has been seen as a welcome opportunity for the pharmaceutical industry to deliver clinical study results to the general public – and especially to patients. A global survey in 2017 showed that 91% of the general public wants to receive a summary of a study after they had taken part,¹⁵ and so the information would appear to be wanted and needed by the general public. However, there is a danger that this opportunity will be wasted because writing for the lay audience is very challenging.

To address this, the EU provided further

guidance on the European Commission website in January 2017.¹⁶ This guidance gives example text and formatting, which, although not perfect, are certainly helpful. The updated guidance also suggests more lay-friendly headings and a question-and-answer format. It allows the medical writer to add subheadings and change the order of the headings, both of which can help readers more easily understand and navigate the document. Visuals and infographics are also mentioned in the guidance, but care should be taken with any graphics, since they do not always increase comprehension.¹⁷ However, they may make the CTR lay summary more user-friendly, and if used appropriately can be a powerful tool to help understanding.

Variable quality of existing patient information

Given the relative newness of CTR and RMP lay summaries and the lack of a general standard against which quality can be assessed, it is not surprising that the quality of current offerings varies considerably.

We conducted an online search for CTR lay summaries, which returned several pharmaceutical company web pages that contain lay summaries of trials that they have sponsored. Whilst some use graphics and tables to an extent, most still contain too much text; tools such as



bullet points and lists, which would make the document easier to read, are underused. One company's lay summaries contained only text and whilst the summaries were only about a page long, they were incredibly difficult to read and understand. In addition, even where companies used graphics, charts, and tables, sometimes they would have been better employed for different content within the document.

Generally, the content found in the summaries appeared to be relevant for a lay audience. However, it was difficult to assess whether all useful information from the original document was included. The best summaries answered the following questions for any potential patient reading the document:

- "Is this trial relevant to me?"
- "How would this intervention be administered and monitored?"
- "Can I fully assess the risks and benefits of this intervention?"
- "Will this intervention be available to me in the future and what will it mean for me?"
- "Where do I go for further information?"

Good examples of lay summaries also provide background information and explanation of the disease in question and the type of trial taking place. However, currently only some do this, possibly assuming that patients would already have basic knowledge in these areas.

What is clear is that that a systematic and comprehensive review of the current offerings is needed to fully gauge what is being done well and where improvements are required.

What do patients really want and need?

Putting aside legislative requirements, the quality of a lay summary can be benchmarked against whether it meets what a patient wants and needs. What industry and clinicians think a patient wants can be different from the reality, especially when it comes to patient input into their own healthcare.¹⁸ If lay summaries are to be fit for purpose, they need to be understandable, relevant, and accessible.

Understandability

It is important to avoid over-simplifying information to the point of losing the opportunity to educate patients or a lay audience about a particular disease area or intervention. These documents have the potential to be key decision-making tools – an informed patient often makes different choices about their healthcare.¹⁹ With an ever-increasing importance being placed on shared-decision making,²⁰ patients are increasingly looking towards lay summaries to help inform their healthcare journey. A lay summary that directs the reader towards a discussion with their clinician can support this. We need to find the middle ground between a lay summary being simplified so much that it loses its educational value and it not being simple enough for a patient to digest the information without the help of a qualified medical professional.

Another important aspect is for the lay summary to use words that are familiar to a lay audience. One such example is the use of brand names for medications. Some guidelines suggest

listing both generic and brand names where possible.²¹ If the brand name is not or cannot be used, providing signposts to where the reader can find that information is necessary. The same applies to explanations of medical terminology. Listing "high blood pressure" with "hypertension" in parenthesis would be a better way to describe this adverse event than simply listing hypertension on its own. It means that the document is still understandable but can also help to educate and improve health literacy.

As already discussed, the use of graphics can enhance a lay summary to a certain extent. It is also important to ascertain what are suitable data for translation into an infographic, chart, or table, and what formats are most likely to be understood by readers. In a user-testing study on CTR lay summaries, one participant asked why a certain bar chart was "upside down", demonstrating that some figure formats may be confusing to someone not used to them.²² Formatting of the lay summary is also important, with accessibility standards such as font size, colour, use of bullet points, and layout requiring some consideration to improve comprehension.

Relevance

As a decision-making and educational tool, the lay summary needs to be relevant. The content should be useful for the intended audience, not just what the sponsor wants to convey. For a patient who is considering a new intervention, the risk-benefit profile is likely to be a top concern. However, there are other factors that patients consider to be important and which the lay summary can and should include so that an



overall assessment can be made. These include who took part in the trial (to assess applicability to the reader); the mode of intervention (e.g., was the treatment administered orally, via IV infusion, via injection, etc.); the frequency of intervention, and any monitoring requirements. These can all have an impact on a patient's decision to pursue a certain intervention, whether that is within further clinical trial settings or once the drug is licensed and available.

Following on from this is the benefit of including an explanation of the stage in the development process the lay summary relates to. This could be a marker on a timeline or a "What does this mean for me?" section. It will help the reader to understand whether the intervention will be available imminently or not. The general public, and many patients, are unaware of the complexities and timelines of the drugs development process. Presenting them with a document that, for example, talks about a positive Phase 2 trial, could result in misguided belief that they will be able to go to their doctor and ask to be prescribed the drug.

Accessibility

Once published, lay summaries need to be accessible, i.e., they need to be easy to find and available to all. Open access sources are critical for this so that the lay reader is not blocked by a paywall. It is incredibly frustrating when a patient finds information, only to discover they are unable to access it. Some sponsors already use an open-access model and mandate that all affiliated research must be published in open access sources.^{23,24}

Finally, whilst there are already plans for a single upload portal for lay summaries, it is of the utmost importance that this is widely advertised to lay audiences generally and to patients specifically. This should be done via as many different channels as possible – via healthcare professionals, national healthcare systems (e.g., the NHS website), charities and patient associations, and the sponsors' own website. Participants in particular trials should also be informed of the availability of a lay summary of results. In addition, a single portal should not necessarily be the only place where lay summaries are published. If they are published in multiple locations, such as through the sponsor's website, via academic-sponsored sites, or through relevant research events, they are more likely to be seen. A discussion of the relative advantages and disadvantages of dissemination via different sources can be found in lay summary implementation guidelines published by TransCelerate Biopharma.²⁵

Involving patients in the production of lay summaries

There are many guidance documents for lay summaries that suggest the involvement of patients in their production. How this involvement would work, however, is not outlined as clearly, indicating that there is a need for best practice to be shared and a standard to be set. The Roadmap Initiative to Good Lay Summary Practices²⁶ could be a step towards this.

Not all patients are the same

Any type of engagement with patients necessitates the reminder that not all patients are the same. "Patients by experience" and "expert patients" are terms that are now widely used within healthcare settings. However, there is also the emergence of the so-called "pro-patient". These are patients who look at the overarching issues and systemic issues that cross over patient communities. They are often well-connected with various stakeholders and have a high level of health literacy, even outside of their own disease area. When involving patients in the development of lay summaries, we should bear in mind that each group of patients will be able to bring different value and expertise to the process and, therefore, may only be suitable for involvement at certain points.

Patients could potentially become involved by reviewing the lay summary for relevance of

content, and readability. A patient by experience could review a lay summary for readability and how well it might be understood by a lay audience, whereas expert and pro-patients would be more suitable to assess relevance of content. This is because those tasks would require a much higher level of health literacy and, potentially, the ability to understand the original clinical trial documentation from which the lay summary has been produced. It can also be beneficial to involve patients in developing lay summaries that do not cover their particular disease area. This is because patients may be in danger of becoming "too expert" or "too comfortable" in their own disease area to consider the document from a lay perspective.

User-testing for readability

There has been much discussion about whether readability tools are suitable for assessing health information. The Patient Information Forum points out that these tools only assess language and do not consider design, layout, structure, or the tone of information. In addition, different readability tools can often produce different reading levels and scores when applied to the same text.²⁷ Having end users assess the readability of a lay summary is not only an obvious choice but is also both feasible and can be highly successful, as evidenced by the Production of Lay Summaries for the Newcastle Cognitive Function after Stroke Cohort Study.²⁸

Initially, organisations may be put off from involving patients, due to cost and the possibility of having to train external collaborators. Training can be made easier with the use of available toolkits, such as the one co-produced by Envision Pharma, and multiple stakeholders.²⁹ It offers a template to provide patient reviewers with key information so that the lay summary can be put into context and the review process made easier. The cost of involving patients in the process should be offset against the added value that they will bring to producing a high quality, fit-for-purpose document. In the future, this cost needs to be considered as integral and necessary to the budget as the cost of involving a medical writer.

Lay summary development cannot progress without the involvement of the patient. As standard operating procedures for processing lay summaries are developed and templates for producing content are created, patients need to be constantly considered. Ultimately, patients will be the primary end user of this document

and involving them in the process will be key to it becoming less of a “box ticking” exercise and more of an exercise in producing good quality, relevant health information that can help people to make better decisions about their healthcare.

Conclusion

The latest regulations and the drive for transparency and patient engagement require us to present data and messages in a way that the lay audience can both understand and use. It is a huge challenge and requires a medical writing skill set different from that used to present data to regulatory authorities. Writing in lay language is far more than just translating clinical words into simpler ones, and it is crucial that we reach out to our audience, either through user testing or through engagement with patient advocacy groups, to allow us to understand what they really want and need.

What is clear is that this drive for clearer and better information for the lay audience is not decreasing but is most certainly gaining in momentum, and this is being acknowledged in the latest regulations and guidance. In a survey of adult internet users, 83% looked online for health information, and 60% said that it had an impact on their decisions or actions.^{30,31} This means that the quality of health information available to patients is a major concern and increasingly important. Medical writers are the gatekeepers for this information, and we should certainly welcome the trend for increased information to patients – as long as it is in a form that is helpful and fit for purpose.

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Conflicts of interest

The authors declare no conflicts of interest.

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Clinical trial disclosure:

Perspective from a medical writer for a contract research organisation

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Abstract

In this article, I summarise how, as a medical writer with over 20 years of experience in regulatory writing, all with a contract research organisation, I transitioned into the world of disclosure and how I now have my feet firmly in both camps: regulatory medical writing and clinical trial disclosure. I describe how disclosure captured my attention and the subsequent actions I have taken.

Background

Clinical trial transparency and clinical trial disclosure are terms that we are now all familiar with, and it is not just pharmaceutical companies that are under increasing pressure to make clinical trial data that has not traditionally been disclosed available to the public; any research group that registers a trial must comply with the same regulations.¹⁻⁴

As a medical writer working for a contract research organisation (CRO), these regulations have had a considerable but positive impact on my day-to-day activities. While our Global Regulatory Affairs group has been supporting our clients in their clinical transparency efforts since 2008 and the release of the Food and Drug Administration Amendments Act (FDAAA 801), requests to prepare clinical trial results

postings were intermittent and fluctuated in number. With the implementation of mandatory posting to the EMA's European Clinical Trials Database (EudraCT) of interventional clinical trials that ended on or after July 21, 2014, the impact was almost immediate: we saw a huge increase in the number of current and new clients reaching out to ask if we could support this activity.

The article is a summary of how, as a medical writer with over 20 years of experience, all with a CRO, I made the transition into the world of disclosure.

Clinical trial disclosure

EMWA played a big part in my leap into the world of disclosure, starting with the 2014 conference in Budapest, which attracted my attention with the 1-day symposium "Transparency of Clinical Trial Data – Where Does Medical Writing Fit In?". It was the start of a special relationship with a group of fellow EMWA members, some of whom I already knew through our years in the industry. I am talking about the Budapest Working Group (BWG) – the EMWA-AMWA developers of CORE (Clarity and Openness in Reporting: E3-based)



As a medical writer working for a contract research organisation, these regulations have had a considerable but positive impact on my day-to-day activities.

Reference (www.core-reference.org). I returned from Budapest a member of the BWG and full of ideas and insights for how our medical writing group could provide support in the area of transparency to our clients, old and new. Medical writers are ideally suited to working in results disclosure; we already have the skills that enable us to summarise clinical trial data and present the results to address the objectives of a particular study. In addition, we are renowned for our attention to detail. I know I am not the only medical writer who cannot help but “edit” everything I read, from newspaper articles to printed works of fiction!

I spent many hours getting up to speed on the regulations for the USA and EU/EEA. By the end of 2014, we had established a clinical trial disclosure group in the UK along with the role of

“disclosure specialist”. The sole purpose of this group was to perform disclosure activities, and the first two members of this group (including me) were medical writers by trade. We worked hard to learn the relevant regulations, taking advantage of all the training resources that are freely available through ClinicalTrials.gov and EudraCT.^{5,6}

We continued to grow our dedicated disclosure group by enticing other medical writers who were perhaps looking for diversity or even part-time work/reduced hours per week. Our aim was to engage a couple of candidates who could prepare the postings while supporting each other on their out-of-office days. Preparing a clinical trial results posting takes much less time than, for example, preparing a clinical study report (CSR), and this effort can be moulded to

suit part-time employees. This worked in our favour and over the past 4 years this group has grown.

We also invested in our own software solution to facilitate the creation, review, and upload of clinical trial results postings to EudraCT and ClinicalTrials.gov. This has proved fruitful for dual postings, where the clinical trial results are required to be posted to both EudraCT and ClinicalTrials.gov, as the software tool avoids the need for duplicate data entry. In addition, for EudraCT postings where the sponsor does not have a primary results user, the EMA can take up to 25 calendar days to process a EudraCT access request, and sometimes impending registry deadlines do not afford the luxury of time. Our software tool allows us to initiate the results posting and to download drafts for sponsor review. We can then upload the entry to EudraCT as an XML file⁷ when we get access.

Clinical trial results postings

Our daily tasks include the preparation of both EudraCT and ClinicalTrials.gov postings and, more recently, review of the study protocol, applicable protocol amendments, and the statistical analysis plan for any information requiring redaction before submission to ClinicalTrials.gov.³

As is typical in a CRO, levels of requests for our disclosure services can fluctuate. Following publication of the EU Trials Tracker⁸ (which lists, by sponsor, all interventional clinical trials in the EU Clinical Trials Register), we noticed a surge in requests from clients. Although not built or monitored by the EMA, the EMA have been using the tracker to reach out to sponsor companies directly, using the last known contact information from the EU Clinical Trials Register, to inform them that they either:

- a. Have results due, i.e., it has been more than 1 year since the “global end of trial date”; or
- b. Have inconsistent data, i.e., the sites where the trial was conducted have listed their status as “completed” but there is no accompanying “global end of trial date”; there is a “global end of trial date” but some sites are listed as “ongoing”; or the trial status is blank.



Where the EMA has been successful in reaching the appropriate sponsor contacts, there has been much surprise as to the number of sponsor studies currently without results in EudraCT.

The same group who put together the EU Trials Tracker (Evidence-Based Medicine Data Lab, University of Oxford) have also created the FDAAA Trials Tracker⁹ (which lists, by sponsor, all applicable clinical trials and probable clinical trials, where an applicable clinical trial is a trial that began after January 18, 2017, and a probable clinical trial is a trial that began before and ended after January 18, 2017). Note: the FDA itself is not publicly tracking compliance.

I predict that we will see the effect of these trackers for some time to come as increasing numbers of sponsor companies become aware of the trackers and can access them to see where they are non-compliant.

Clinical trial disclosure in a CRO

As is typical for a CRO, we are exposed to a wide variety of clinical trial results data, both in terms of phase and therapeutic area. No two studies are the same and, combined with the challenges of working in regulated databases with restrictions, character limits, and required verification steps, this means that preparation of clinical trial results postings is anything but routine. All this can keep even the most challenge-hungry individual satisfied.

This is a moving landscape and our group continually monitors industry and regulatory agency changes. We do this in several ways, including by signing up to notifications and blogs from the FDA (<https://www.clinicaltrials.gov/ct2/resources/rss>) and EMA (<https://eudract.ema.europa.eu/>), attending webinars hosted on their public sites, and using other online training resources provided by both agencies. We share lessons learned within our group and in the broader field of disclosure through forums such as the Drug Information Association (DIA).

Internally, our disclosure specialists have worked with our medical writers to make changes to the protocol and CSR templates to take account of data transparency. This not only helps our global medical writers ensure that they can provide sponsors with CSRs that

are disclosure-ready for any submission packages, but also ensures that – right from the outset with the protocol – medical writers are thinking about results disclosure.

For example:

- Both the protocol and CSR should contain only the necessary confidential information regarding the compound under investigation or the people involved in the trial (for example, avoid the inclusion of investigator or vendor names, centre IDs, subject-specific information, and proprietary information, where possible).
- Within the ClinicalTrials.gov Protocol Registration and Results System, there is a 600-character limit for the “official title” of the trial.
- Within EudraCT and ClinicalTrials.gov, there is a 255-character limit for an outcome measure title.
- Outcome measures should include the measure, units, and time points.

My role as head of clinical trial disclosure

To help me in my role leading this group, I am a member of DIA and associated medical writing and clinical trial transparency community groups. The BWG published CORE Reference in May 2016¹⁰ and we remain engaged in supporting the global medical writing community in fulfilment of reporting obligations that take full account of transparency and disclosure requirements.¹¹ I am an EMWA workshop leader on CORE Reference and was a panel member on this topic at the DIA 2017 Global Annual Meeting (Driving International Awareness and Use of Regulatory Writing Guidelines: Case Studies of the Clarity and Openness in Reporting:E3-based [CORE] Reference Guidelines).

Conclusion

I feel very lucky to have been able to play a pivotal role in the creation and subsequent growth of our in-house clinical trial disclosure group by engaging in activities such as hiring staff,

Clinical trial disclosure offers the opportunity to operate in an evolving environment and to become an expert in the evolving requirements and regulations. establishing processes and standard operating procedures, and developing job descriptions and job grades. As well as our disclosure specialists, we also have an additional

bank of medical writers trained in the preparation of clinical trial results postings. It is clear that medical writers have the skills required to competently complete the tabulated data postings in EudraCT and ClinicalTrials.gov: We have the ability to understand the design of a study and why it was performed; to understand what the objectives were and what the resulting endpoint results show; to extract the data that should be included; and to appropriately summarise text within the character limits set by the database.

Clinical trial disclosure offers the opportunity to operate in an evolving environment and to become an expert in the evolving requirements and regulations. You get to use your practical experience in working with clinical trial data to help your customers understand and meet their obligations.

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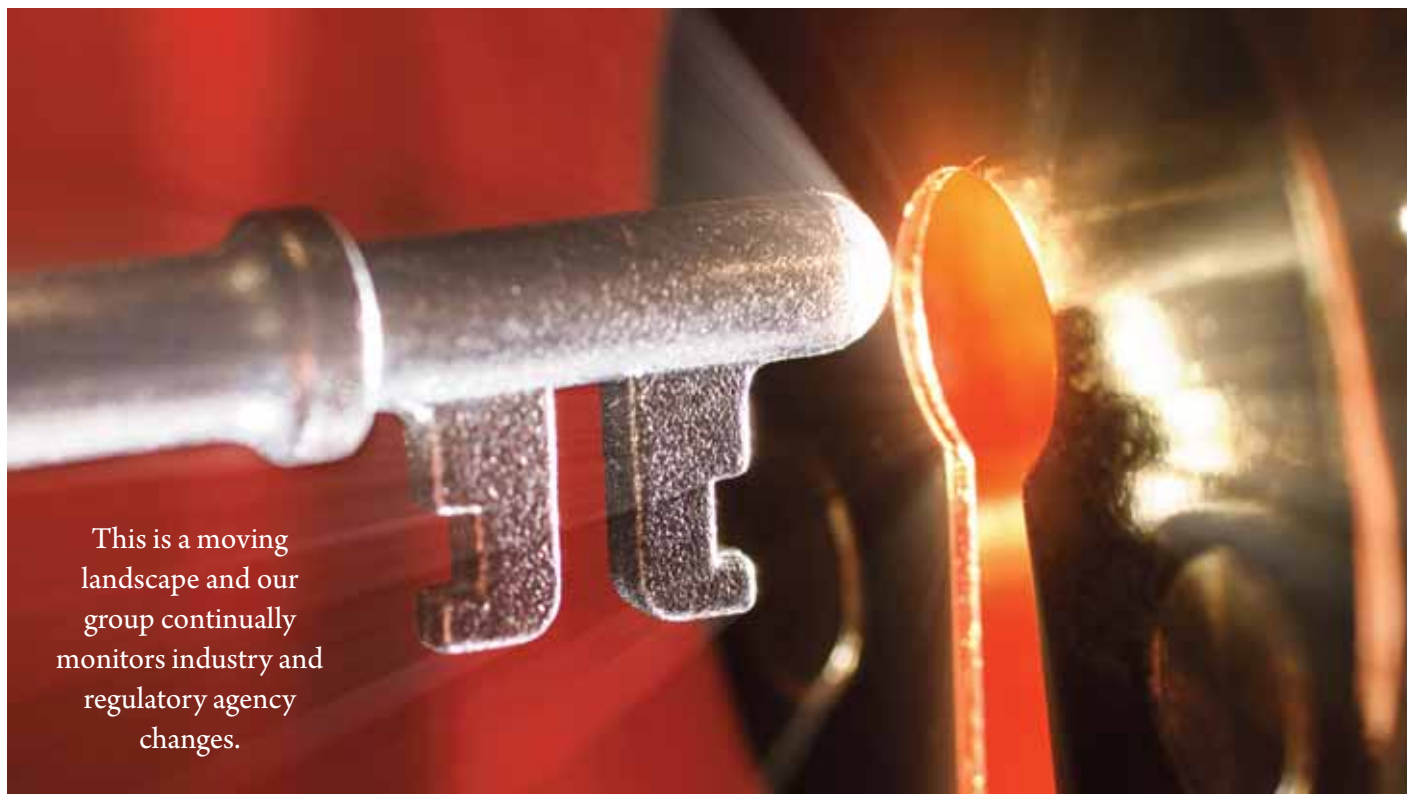
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Conflicts of interest

The author declares no conflicts of interest.

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This is a moving landscape and our group continually monitors industry and regulatory agency changes.

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The 360° approach to authoring risk management plans

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Abstract

Amidst the dynamic landscape of pharmacovigilance legislation, medical writers have been gaining increased visibility and importance beyond what had been their traditional role of coordinating and facilitating the development of risk management plans. Over the past couple of years, medical writers have been contributing extensively in driving the seamless integration of the recent Good Pharmacovigilance Practices guidance version 2.0 into companies' global pharmacovigilance systems, quality assurance systems, and relevant standard operating procedures. A comprehensive "360°" approach adapted by medical writers ensures efficient authoring of high-quality RMPs.

During the drug development process, the top priority at any stage for every stakeholder is patient safety. While there are numerous regulations by different health authorities (HAs), the Risk Management Plan (RMP) introduced by European Medicines Agency (EMA) in 2007 is considered to be one of the best examples of "good pharmacovigilance practices" (GVP) to ensure patients' safety. Since then, this pharmacovigilance (PV) system has mandated the development of an effective safety plan for every marketed product right from the first marketing authorisation application (MAA) to as long as it available in the market. An RMP has been demonstrated as one of the most effective PV tools and a key turning point for global PV regulatory practices. The GVP Module V switched the entire perspective of risk management approach from "spontaneous reactive" to "continuous proactive" in dealing with patients' safety.

Unlike other regulatory documents, the process of RMP development is unique and elaborate, and the medical writer (MW) plays a significant role in efficient authoring of RMP. This article highlights key approaches for authoring RMPs to help MWs to avoid errors or prevent unnecessary health

authority questions. This article is meant to serve an overview of the topic, designed to provide insights about a holistic, "360°" approach for RMP development rather than serving as detailed template training.

Essence of a risk management plan

Not just a regulatory document!

An RMP is a comprehensive document that details the safety profile of a product, a PV plan for collecting additional safety and efficacy data, and measures to mitigate safety concerns associated with the product's use.

The GVP Module V switched the entire perspective of risk management approach from "spontaneous reactive" to "continuous proactive" in dealing with patients' safety.

Additionally, it provides all the commitments of a marketing authorisation holder (MAH) on further plans to evaluate the effectiveness of risk-minimisation measures for managing patients' safety.¹

It forms a part of the Common Technical Document (CTD) Module 1.8.2. It is not just a regulatory document or a regular safety report but also a legally binding administrative document with monetary implications. Since 2014, the key RMP elements have become a part of the European public assessment report as a lay summary with transparency implications and a

big impact on the MAH's market position – legally, financially, and in terms of reputation.²

A global reference

EMA's RMP has been adapted worldwide and deemed a reference for other HAs of Rest of the World (ROW) countries (other than EMA or FDA) either to develop their own RMP guidance or to accept EMA's GVP guidelines. An RMP has been gaining increased importance for newer products especially those approved via regulatory procedures that enable earlier patient access (for example, conditional approval for orphan drugs) without compromising an efficient preliminary assessment of the product's safety. Nevertheless, such regulatory procedures often need more robust reviews by the HAs and a stringent risk management strategy with additional PV activities or risk-minimisation measures beyond those considered to be routine. This results in an increase in global cost of RMP implementation for the MAH.

Risk-based approach

A single product requires a single RMP regardless of the indications, formulations, or dosage forms, etc., unless otherwise justified by a scientific rationale and agreed with the HA. It is a living document that is updated continually throughout the lifecycle of a product in the market but, unlike other safety reports, not necessarily at regular intervals. The RMP submission requirements follow a "risk-based approach". The first RMP version starts with the first MAA and triggers for subsequent updates include any significant changes to the marketing authorisation, significant changes to the benefit-risk profile, the completion of important milestones for PV activities or risk-minimisation measures, or at the request of a HA when new information is available from the literature.

Trends in GVP Module V

Journey over a decade

The RMP guidance has been undergoing continuous transformation since its inception in 2007 and has taken a logical shape over the last 12 years in terms of data flow, consistency, and transparency in a submission-friendly modular format. Over time, the focus of an RMP has transitioned significantly from *drug* safety to *patient* safety. The evolution represents a paradigm shift from "safety" to "benefit-risk balance", and introduced the requirement to evaluate effectiveness of risk-minimisation mea-

asures. The concept of "additional monitoring" was introduced in 2013 for all new medicines approved after 2011 to reiterate the importance of reporting suspected adverse drug reactions by the physicians and patients.³

Two years of GVP 2.0: The impact and trade-off

It has been a couple of years since the industry experienced a major overhaul to the RMP template in parallel with the revised GVP guidance, version 2.0 in 2017. The extent of revisions was substantial but with a more risk-proportionate approach crucial to risk-benefit evaluation. With major revision to the definitions of identified and potential risks, MAHs are now clearer about categorising the risks while ensuring alignment with the adverse drug reactions defined in the product label. This led to re-evaluation of risk management strategies and development of more appropriate PV plans for each risk in the RMP. Because of these changes, MAHs required additional efforts and resources to submit all their revised RMPs within the regulatory deadline before Q2 2018. Moreover, this had a direct impact on the existing periodic benefit-risk evaluation reports (PBREs) for most of the marketed products. Nonetheless, the key focus is now streamlined to the information relevant to risk-benefit assessment. On the other hand, EMA has significantly eliminated redundant, non-value added requirements or integrated sections into more relevant RMP modules and removed duplication of information across other safety documents; for example, the section on post-marketing experience is now limited to exposure data rather than a duplication of overall periodic safety update report findings. Additionally, changes to the administrative sections and annexes have eased the job of an MW to a great extent, especially reducing the time required to ensure consistency across modules. However, the overall concept of mapping, which explains the similarity of specific sections between RMP modules with the other CTD modules and PBRE, remained the same in this revision.

The challenge for MAHs was not only to meet the regulatory deadline for submission of all revised RMPs but also to update their internal standard operating procedures and working guidance documents for regulatory compliance. Apart from these challenges, MAHs had to handle the administrative requirement of creating a "track change version" for existing RMPs and

since the new template had major changes, this posed an impossible task. However, this could be waived off for some of the RMP updates after HA agreement. Despite these challenges, collaboration amongst the project teams and constant HA interactions have been vital in dealing with the changes and in meeting the submission deadlines for RMP updates.

So far, most HAs of ROW countries with or without their own RMP requirements have been accepting RMP submissions in the older format, but it is anticipated that they will soon adopt this new RMP format. MAHs hope to implement a global risk management approach with minimal variations across countries to ensure efficient monitoring of patient safety.

Importance of medical writer's role

The template expert

Excelling in the art of RMP authoring is not as complex as it may seem, provided a logical and scientific approach is followed in applying the guidance in any scenario of an RMP development. Until the recent revision, MWs interpreted the GVP template to be too bureaucratic and a bit ambiguous especially when the rationale behind the requirements was either unclear or unexplained. One needs to be aware of the nuances of each RMP module and understand the interdependencies across the modules for optimal and chronological data flow between the modules. Stakeholders involved in developing regulatory guidance are aware that these are living documents, dependent on the dynamic regulatory landscape with the advent of wide range of new therapeutics. Hence, MWs should invest extra time in understanding the GVP guidance and template, religiously follow them, and learn to tackle the flaws on a case-by-case basis. Over time, MWs gain further knowledge and experience on the template requirements based on rapporteurs' comments, Pharmacovigilance Risk Assessment Committee's assessment reports, and health authority questions received at different time points after the CTD submission (e.g. Day 120, Day 180, etc).

The collaborator

As with the development of any other regulatory document, it is not the sole responsibility of an MW to develop an RMP. It requires a team of authors from various departments, not confined to safety, clinical, pre-clinical, epidemiology, regulatory, biostatistics, data management,

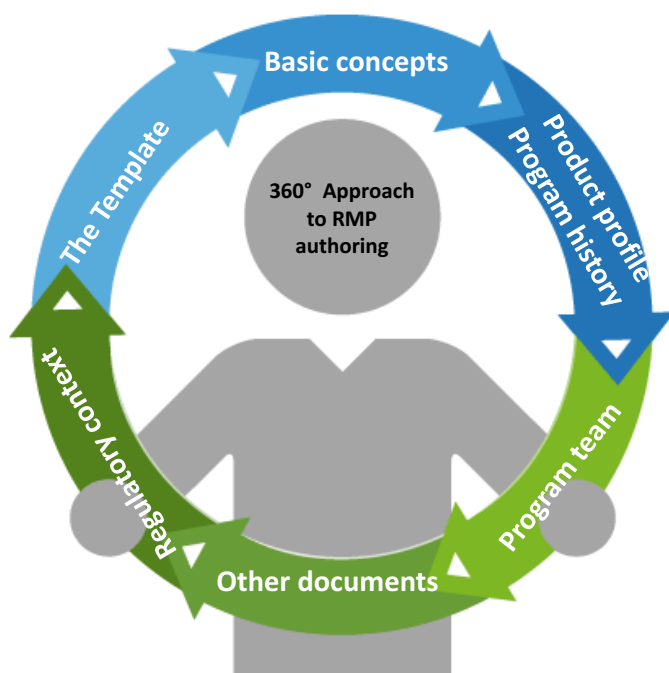


Figure 1. The 360° approach to authoring a Risk Management Plan.

pharmacokinetics, formulation development, etc. Based on the conventional organisational framework in the industry, the contributors are often dedicated to specific products but the MW may not be. An MW is deemed to be the template expert and a key driver of RMP development process since he or she gains a broader experience on RMP authoring for multiple products compared to any other RMP contributor in the project team. Therefore, an MW

should take the lead in guiding the team on RMP template requirements. Furthermore, an MW is a key collaborator in communicating with other regulatory MWs on the submission to ensure consistency of key messages in the RMP with various CTD documents (for example, Modules 2.7.4, 2.5).

Likewise, it is the team who has broader knowledge of a product's profile and its regulatory lifecycle rather than an MW. Therefore, an

MW should seek relevant contributions on the scientific aspects of the product from the team. Eventually, it is the team's responsibility to collaborate and integrate with each other to develop a high quality RMP with minimal or no health authority questions at least in terms of template compliance.

The 360° approach

An MW could adapt a holistic approach for seamless authoring of high quality RMPs and the concepts detailed below may provide a basic guidance on a 360° approach towards RMP authoring (Figure 1).

Basic concepts

Whilst authoring any document, an MW is expected to have sufficient knowledge on the disease or therapeutic areas pertaining to the product. Beyond this, extensive knowledge and understanding of PV domain is an additional prerequisite for authoring RMPs. Probably this is one of the reasons why RMP MWs are usually titled as "safety" MWs and not "regulatory" MWs. The GVP guidance covers all the possible definitions that are required in the context of an RMP, and an MW should understand their clear meaning and differences, if any. An MW should also be well aware of the different categories of PV activities and to which category the proposed activities belong to. Beyond the RMP guidance, an MW can also refer EMA's guidance on lay summaries, which can be applied to develop the RMP lay summary for European public assessment report.⁴

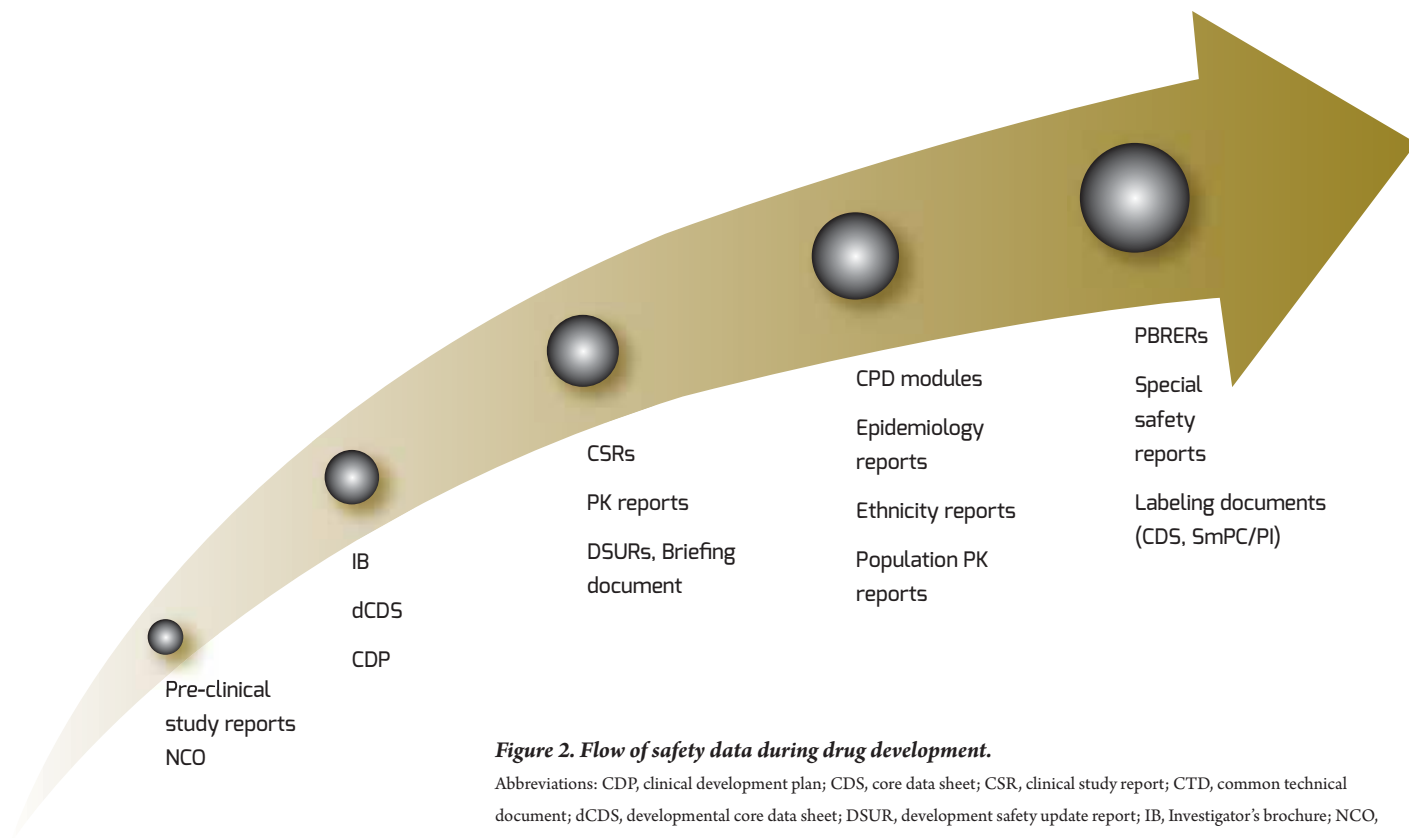


Figure 2. Flow of safety data during drug development.

Abbreviations: CDP, clinical development plan; CDS, core data sheet; CSR, clinical study report; CTD, common technical document; dCDS, developmental core data sheet; DSUR, development safety update report; IB, Investigator’s brochure; NCO, non-clinical overview; PBRER, periodic benefit-risk evaluation report; PI, prescribing information; PK, pharmacokinetics; SmPC, summary of product characteristics.

The template

The framework of an RMP template essentially follows a typical risk management cycle with three key elements:¹

1. What is known and unknown about the safety profile of the product?
2. Which activities are undertaken to collect additional data to fill the knowledge gap about the product’s profile?
3. What measures are implemented to mitigate the risks?

Information related to these three elements flow chronologically within the modular framework of the RMP template. Safety specification module of the RMP covers all the aspects required to define, categorise, and justify the safety concerns of a product; which includes epidemiology, pre-clinical and clinical data covering relevant safety, efficacy, and pharmacokinetics, limitations of the clinical programme, and post marketing data, where applicable. This comprehensive assessment is paramount to be able to strategise the remaining elements of an RMP, i.e., PV plan and risk-minimisation measures while justifying the proposed strategy. Where necessary, MAH may need to develop additional PV activities or risk-minimisation measures. Therefore, the MW

should be aware of the interdependencies between the modules and ensure consistency across them and also with other documents within the CTD or other safety reports within the regulatory procedure of the submission.

Product profile

Since an RMP covers key safety concerns of a product, an MW should understand its overall safety profile before beginning to draft an RMP. As a starting point, the class of the drug itself provides a clear picture of its pharmacological class effects to understand the preliminary safety profile of the product. Safety data start to be generated from the pre-clinical setting and as the molecule progresses in its lifecycle through the clinical development, more in-depth and reliable safety data become available for adequate safety assessment. So, the first comprehensive document to refer to would be an investigator’s brochure followed by the developmental core data sheet (dCDS) or the current approved label, if applicable. Understanding the chronological flow of safety data from one document to another and realising the differences in purpose behind each document within the clinical programme helps the MW to refer the right document for precise information needed for the RMP (Figure 2).

Programme history

As a single RMP exists for a single product, understanding the overall plan for the clinical development programme and leveraging prior submission experience eases the process of RMP authoring. For example, awareness of the history of approvals, indications, formulations, triggers for RMP updates, regulatory actions taken for safety reasons, Pharmacovigilance Risk Assessment Committee assessment reports, etc. This knowledge helps an MW to identify specific modules or sections of an RMP impacted and the extent of update required.

Regulatory context

The extent of an RMP update highly depends on the trigger for the update and the regulatory procedure it falls under (for example, Type I, Type II variations, renewals, article referrals etc.).⁵ So, awareness on the context of these regulatory procedures helps in understanding the scope of an RMP update. Further, it is necessary to understand the context of disease or therapeutic area of an RMP submission (e.g. paediatric indications, advanced therapy medicinal products, biosimilars, generics, associated medical devices). The template requirements depend primarily on the scope of the submission

and not all sections of the RMP might be applicable. Understanding the trigger helps in identifying sections or modules impacted during an RMP update (for example, reaching PV or risk-minimisation milestones, demotion or upgradation of a risk etc.). Fundamentally, the knowledge of current regulatory landscape helps in evaluating the impact on RMP updates.

Relevance of other documents

The modular format has an obligation to ensure

consistency with the source documents and other documents in the overall programme. This does not mean we have a compelling reason to literally ensure verbatim alignment but only ensure message-led alignment. The major documents within the clinical programme that could be referred as a source include CTD modules (2.7), investigator’s brochure, safety reports, labelling documents (CDS or summary of product characteristics), clinical study report, PBRRER, development safety update report etc.,

depending on the regulatory procedure. The GVP guidance provides a mapping between the RMP and CTD modules and with the PBRRER as a recommendation. Table 1 and Table 2

The programme team

RMP authoring is beyond collating content; it is a strategy in itself that is legally binding. Therefore, collaborating with the right stakeholders at the right time apart from regular project meetings is imperative in implementing the risk-manage-

Table 1. Mapping between RMP and eCTD modules

| RMP Module | eCTD |
|---|--|
| Part I Product(s) Overview | Module 2.3 Quality overall summary Module 3 Quality |
| Module SI Epidemiology of the indication(s) and target population(s) | Module 2.5 Clinical overview |
| Module SII Non-clinical part of the safety specification | Module 2.4 Non-clinical overview Module 2.6 Non-clinical written and tabulated summaries Module 4 Non-clinical study reports |
| Module SIII Clinical trial exposure | Module 2.7 Clinical summary Module 5 Clinical study reports |
| Module IV Populations not studied in clinical trials | Module 2.5 Clinical overview |
| Module SV Post-authorisation experience | Module 2.5 Clinical overview |
| Module SVI Additional EU requirements for the safety specification | Data not presented elsewhere in eCTD |
| Module SVII Identified and potential risks | Module 2.5 Clinical overview (including benefit-risk conclusion) Module 2.7 Clinical summary (SmPC) |
| Module SVIII Summary of safety concerns | Module 2.5 Clinical overview Module 2.7 Clinical summary |
| Part III Pharmacovigilance plan (including post-authorisation safety studies) | Module 2.5 Clinical overview Module 2.7 Clinical summary |
| Part IV Plans for post-authorisation efficacy studies | Module 2.5 Clinical overview Module 2.7 Clinical summary |
| Part V Risk-minimisation measures (including evaluation of the effectiveness of risk-minimisation activities) | Module 2.5 Clinical overview Module 2.7 Clinical summary |

Abbreviations: eCTD, electronic common technical document; RMP, risk management plan; SmPC, summary of product characteristics.

Source: Guideline on Good Pharmacovigilance practices (GVP), Module V –Risk management system, Revision 2, European Medicines Agency. March 28, 2017.

Table 2. Mapping between RMP and PSUR sections

| RMP section | PSUR section |
|---|--|
| Part II Module SIII Clinical trial exposure | Sub-section 5.1 Cumulative subject exposure in clinical trials |
| Part II Module SV Post-authorisation experience | Sub-section 5.2 Cumulative and interval patient exposure from marketing experience |
| Module SVII Identified and potential risks and Module SVIII Summary of the safety concerns | Sub-sections 16.1 Summaries of safety concerns and 16.2 Characterisation of risks |
| Part V Risk-minimisation measures (including evaluation of the effectiveness of risk-minimisation activities) | Sub-section 16.5 Effectiveness of risk-minimisation (if applicable) |

Abbreviations: PSUR, periodic safety update report; RMP, risk management plan.

Source: Guideline on Good Pharmacovigilance practices (GVP), Module V –Risk management system, Revision 2, European Medicines Agency. March 28, 2017.



RMP authoring is beyond collating content; it is a strategy in itself that is legally binding.

ment strategy. For example, consider the following opportunities to keep the RMP development process moving forward smoothly:

- Collaborate with statistician and statistical programmer during the planning phase to review the requirements for mock statistical outputs for each safety concern.
- Communicate regularly with the safety lead to get an update regarding any changes to the safety profile since he/she is the official responsible author of an RMP and answerable to the qualified person for pharmacovigilance.
- Collaborate with the regulatory affairs representative during the planning phase and after HA meetings or labelling review committee meetings to be sure you are aware of any changes to the scope of submission requirements.
- Gather relevant inputs/contributions from the epidemiologist and pre-clinical expert before data availability.

Similarly, the MW should provide review comments to the statistician and the programmer on the mock statistical outputs and identify any data discrepancies in draft statistical outputs to avoid major rework and potential delays in the submission timelines. Collating clinical inputs including administrative information on the PV milestones for clinical studies and the risk-benefit information before and during the content draft stage helps in avoiding last-minute follow-ups. Throughout the RMP development stages, an MW should ensure that inputs received from each contributor are compliant with the template requirements.

In conclusion, implementing a comprehensive approach eases the overall process of RMP

authoring within the constant, dynamic regulatory landscape of the GVP legislation. An MW acts as a “cog in the wheel” throughout the RMP development process and has been gaining increased importance not only as an active contributor but also as an expert and a collaborator in developing high quality RMPs.

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Disclaimers

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

Conflicts of interest

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Trends in regulatory writing:

A brief overview for aspiring medical writers

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Abstract

The EU regulatory system is undergoing a major overhaul. Several new pieces of legislation are now in place to enforce harmonisation and transparency in clinical trials while ensuring data security and individual privacy. New and aspiring medical writers need to be aware of trends in the regulatory landscape to adapt to new requirements in technical documentation. This article is an overview of the evolving trends in EU regulations for medical devices (Medical Device Regulation and In-Vitro Device Regulation) and data compliance (General Data Protection Regulation and EMA Policy 0070), and the impact of artificial intelligence (AI) on the global medical writing market.

Background

The European market comprises of 28 member states of the European Union (including the UK), the European Economic Area (Iceland, Liechtenstein, and Norway), Switzerland, and Turkey. As free movement of goods is a key strength of the European Single Market, there are critical regulations (as listed in the 2016 version of the Blue Guide on EU products) in place to ensure safety and quality of products.¹ Pharmaceutical and medical device regulations are important to ensure safety and efficacy of medicines, and protect public health. The EU has witnessed considerable overhaul of the



regulatory system for clinical trials and medical devices in the last few years to create a centralised and transparent procedure of assessment that can be implemented across member states. Biopharma and medical device companies are required to submit documents for approval of both new and existing products that are in line with regulations. The following sections discuss key regulations and trends that are of interest to medical writers.

New EU medical device regulations

The European medical devices market is the second largest in the world after the US, worth around \$115 billion in 2017, with nearly half a

million different types of medical devices made by more than 27,000 companies.² The Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC,³ the Medical Devices Directive (MDD) 93/42/EEC⁴ were introduced in 1992, and the In-Vitro Diagnostics Directive (IVDD) 98/79/EC⁵ was introduced in 1998 to ensure harmonised standards to compliance. These directives defined the “essential requirements”, which are standards met by the manufacturer for the design and production of the device, its risk assessment and product marketing to get the *Conformité Européenne* (CE) marking on the device. The MDDs defined three categories of devices based on risk assessment:

- Low-risk Class I devices for which the



manufacturer is allowed to affix the CE mark and register it with the national authority, which will check if the manufacturer has complied with all the requirements.

- High-risk Class II and III devices controlled through conformity assessment and market surveillance procedures by a Notified Body (NB, which is an accredited organisation that conducts conformity assessment of a medical device and issues the CE mark) and Competent Authority (CA, which is the government body in a member state responsible for transposing the MDD into national law, and for specifying the NBs in that member state).

The EU has witnessed considerable overhaul of the regulatory system for clinical trials and medical devices in the last few years, in order to create a centralised and transparent procedure of assessment that is valid throughout the EU.

Under the MDD, once a medical device receives its CE mark in one country, the manufacturer is free to market it to other countries within the EU. Thus, the MDDs supported the creation of a single market for medical devices in Europe. However, their interpretation and implementation was left to the discretion of national governments.

In 2010, a global scandal erupted over breast implants, when it was discovered that the French company *Poly Implant Prothèse* was using silicone to fill rupture-prone implant units.⁶ In 2012, the US FDA published a report on medical devices approved in Europe but not in the US due to safety concerns.⁷ Several other adverse events linked to medical devices were reported between 2015 and 2018 that exposed the need for a regulatory overhaul in the EU.

Medical Device Regulation and In-Vitro Device Regulation

New medical device regulations were introduced in May 2017 (to replace the MDDs)^{8,9} to overcome weaknesses that allow medical devices to stay on the market without sufficient clinical evidence of their safety and performance, and to ensure greater harmonisation in implementation across EU member countries.

First, the European MEDDEV 2.7.1 Rev. 4 guidance on clinical evaluation reports (CER) was published in June 2016 and was a critical component in submissions for product approvals. Next, to establish a more robust EU legislative framework to ensure patient health and safety, the European Parliament approved two key regulations on May 25, 2017:

- Medical Devices Regulation (MDR 2017/745)¹⁰
- In-vitro Device Regulation (IVDR 2017/746)¹¹

The MDR provides a 3-year transition period to May 26, 2020, and the IVDR a 5-year transition period to May 26, 2022. By these dates, certification of all new devices and recertification of existing devices must comply with these regulations. The regulations will take effect in every EU member state, and will not require any national legislation for implementation.

Impact of the EU MDR and IVDR

The MDR incorporates features from the MEDDEVs that will oversee a shift from a pre-approval method toward CE marking, to a product life-cycle approach to improve robustness, transparency, and traceability of the regulatory system. The regulation emphasises on responsibility for all actors in a product's life-cycle to establish high levels of product safety and performance. The regulatory transition will affect all stages of device development including production, distribution, and monitoring. Major changes include:

Reclassification of some medical devices

There are additional classification rules to consider when classifying a medical device, and some revisions to the existing rules. The term "medical device" is now expanded to include products meant for disease diagnosis, implanted cosmetic devices, and products that do not have a direct medical intent (e.g., sterilisation products, condoms, fillers). The changes in classification of medical devices may mean that many devices will be placed in a higher-risk class and subject to additional regulatory requirements. Another major amendment is the recognition of software that is used to diagnose or treat disease (both standalone and embedded in a device) as a medical device, and subject to conformity assessment based on its developmental cycle, risk management, and

validation. Devices that are introduced to or absorbed by the body are placed in a separate classification system. The key changes brought about in the IVDR include genetic testing, performance evaluation, reference laboratory testing and a new risk classification system for in-vitro devices (IVDs), and NB involvement in majority of IVD certifications.

Role of economic operators

The new regulation provides guidelines on the responsibilities of all economic operators (including manufacturers, distributors, suppliers, subcontractors, assemblers, and authorised representatives) in the supply chain for a medical device with regard to its technical documentation, labelling, complaint submissions, and post-marketing surveillance.

Changes to notified bodies

NBs will be subjected to greater scrutiny by CAs; strict designation requirements and evaluation of NBs to monitor and assess their capabilities may mean that a number of NBs may not be re-notified. Designated NBs will work closely with the European Commission to ensure that their clinical evaluation and post-market clinical follow-up plans are adequate before gaining certificates for certain classes of devices, and will be required to follow stricter procedures in conformity assessments of high-risk Class III medical devices.

Unique Device Identifiers (UDIs) and implant cards

Manufacturers are required to include UDI trackers along with the technical documentation for the device. The UDI is the key identifier of a medical device in the manufacturer's database and distribution chain, in the European Database on Medical Devices (EUDAMED), on certificates, and on the Declaration of Conformity. The UDI will be used in reporting serious incidents and safety correction actions, and in identifying counterfeit devices. Implant cards are required to carry information on the device lifetime and follow-up procedures for all implantable devices.

Clinical evidence

Under the EU's MDD 93/42/EEC, clinical

evaluation reports (CERs) and CE certifications were based on product equivalency. The new MDR requires technical documents relevant to each stage of the product cycle. In addition, the MDR requires all existing "legacy" medical devices to undergo conformity assessment according to the level of risk, even if previously approved under the MDD/AIMDD i.e., no "grandfathering" of devices will be considered. Stronger clinical data, including post-market safety and performance data are required for the certification and recertification of medical and in-vitro devices. There will be tighter regulations for compliance based purely on equivalence, requiring in-depth assessments and increased expectations of NBs, and rigorous technical documentation methods.

Post-marketing safety and surveillance

Unlike pharmaceutical drugs, the control point of medical devices is through post-marketing surveillance rather than pre-marketing tests. The EU, under the MDDs, relied on a decentralised approach where national regulators were responsible for collecting incident reports, and devices were reassessed if safety issues were raised. Under the MDR, it is no longer sufficient for manufacturers to review and analyse complaints registered on their databases. Companies are required to be proactive in gathering information about their devices. Technical documentation under the MDR now requires a post-market surveillance (PMS), post-market clinical follow-up plan (PMCF) and periodic safety update reports (PSUR) that address two main concerns:

- Is the device safe and does it perform its intended function?
- How can the device be improved?

The EUDAMED database

EUDAMED stores regulatory information from manufacturers and NBs and serves as an information exchange platform (a registry for manufacturers, medical devices, adverse incidents, authorized representatives, and Declarations of Conformity) between the European Commission and Competent Authorities of the member states. Under the MDR, it will also store information on post-

marketing safety and surveillance activities, PSURs, safety and clinical performance reports (SSCP), device registrations, NBs, certificates, serious incidents, clinical investigation data, and UDI Information.

Ultimately, the MDR aims to bring post-market surveillance of devices into a continuous product evaluation and improvement cycle that is linked to risk management information on the EUDAMED platform.

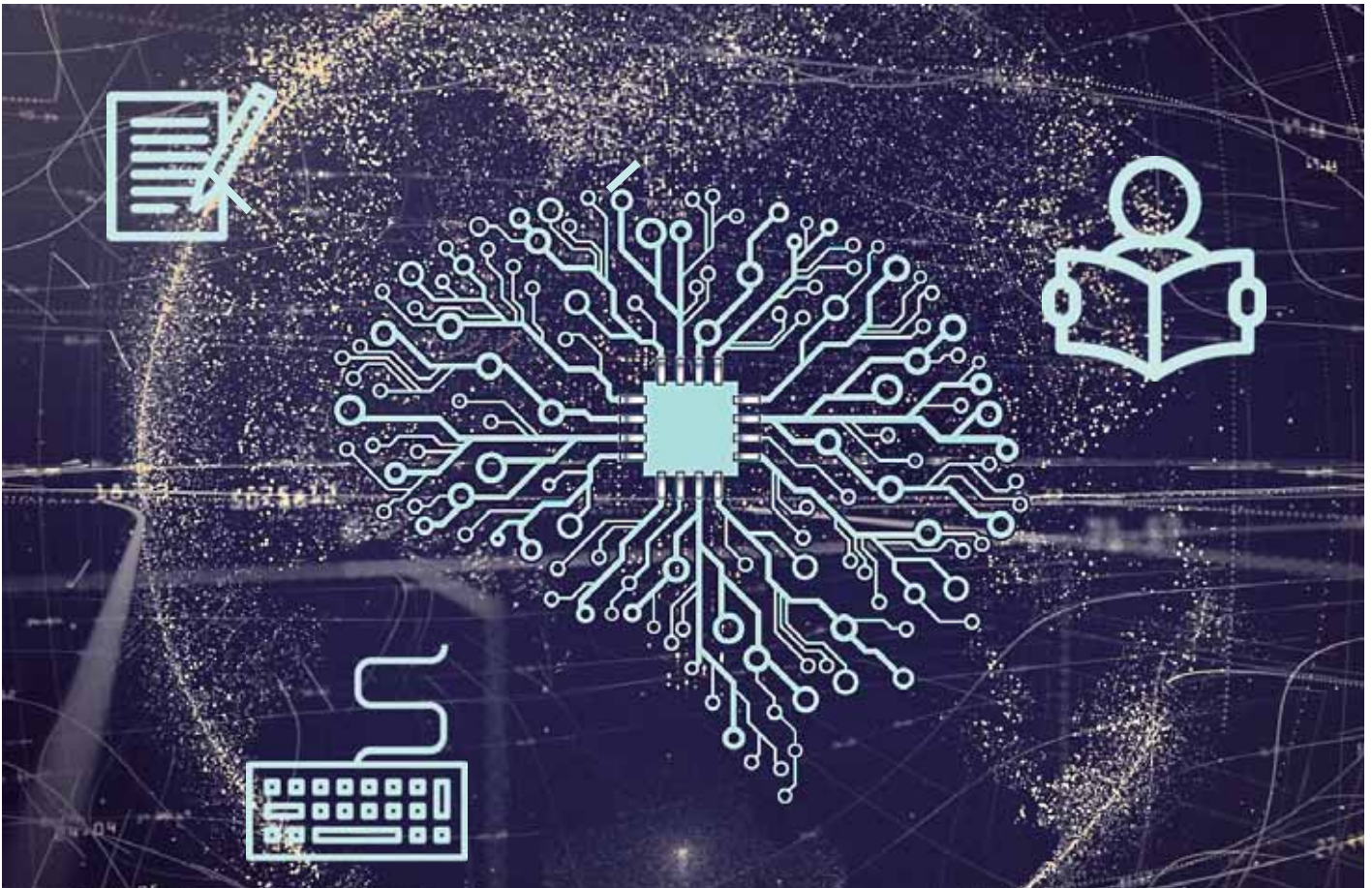
The challenges ahead

The MDR requires adherence to stricter regulations to ensure quality and safety of medical devices; it also requires all medical devices to conform to the regulation by May 26, 2020. While companies will have until May 26, 2022 before the IVDR takes effect, ensuring compliance under this regulation will be a bigger challenge; under the IVDR, nearly 85% of IVDs (an estimated 35,000 IVDs) will require clinical evidence for regulatory approval, compared to 7% under the IVDD.

The MDR/IVDR also requires all NBs functioning under the MDDs to apply for their NB designation, which must be approved before the NBs can proceed with conformity assessment procedures for devices. Due to stringent requirements for NB designation, the number of NBs could be much lower than before; the EC estimates designating 20 NBs by the end of 2019.¹² Brexit adds another layer of complexity as the UK NBs certify a substantial number of medical devices for the EU market; the EC states that in case of no-deal Brexit, all devices certified by UK NBs must comply with the EU import requirements.¹³ Further, as of July 2019, the EC has designated only two NBs for the MDR (BSI UK and TÜV SÜD)¹⁴ and none for the IVDR, which will increase the NB workload and add to the challenges that manufacturers will face in ensuring compliance.

Medical devices typically have short life-cycles (2–5 years), fast development timelines, and tough market competition. The rigorous requirements for certification under the MDR/IVDR, and the increased demand for clinical and safety data for medical devices are likely to delay their CE marking, and increase barriers to entry in the European market. Companies may have to review their portfolios to assess whether there will be sufficient return on investment for certain products to remain

Whether AI can be sophisticated enough to replace the medical writers remains to be seen.



viable. Upgrading and implementing a quality management system to encompass the entire life-cycle of a device can also require significant financial investment, which will have an impact on small and mid-sized companies. As a result, some estimates indicate that the number of certified devices entering the EU market could reduce by 30%, and that up to 50% of devices could die out.¹⁵

Traditionally, the EU was the first market to receive new medical technology, as the MDDs provided quicker channels to implementation for new medical devices than the FDA. One consequence of the MDR/IVDR would be that companies seek to develop and launch their products outside Europe at first, and enter the European market once they have gathered sufficient clinical and post-market surveillance data. Companies that relied on EU certification to market their products in other countries (e.g., Australia and the US) may re-evaluate their sales strategies and opt to obtain market clearance outside the EU.¹⁶ The US FDA has announced its strategic priorities during the 3-year MDR transition period to take steps to “reduce the time and cost of generating clinical evidence, typically the most expensive and lengthy regulatory

requirement for marketplace entry” while balancing pre-market and post-market data collection to make the system easier to navigate.¹⁵ Meanwhile, Latin American countries with faster marketing approval processes are also emerging as an attractive option for medical device companies.¹⁷

The months leading to May 27, 2020, when the MDR takes effect will present a lot of uncertainty and challenges for medical technology companies. At the same time, the increase in documentation required for medical device approval means that more medical writing opportunities will become available. Medical writers will be able participate in developing technical documentation for entire product life-cycles, and gain deeper insights into the fast-developing, innovative medical technology industry.

GDPR vs. EMA Policy 0070 – A balancing act

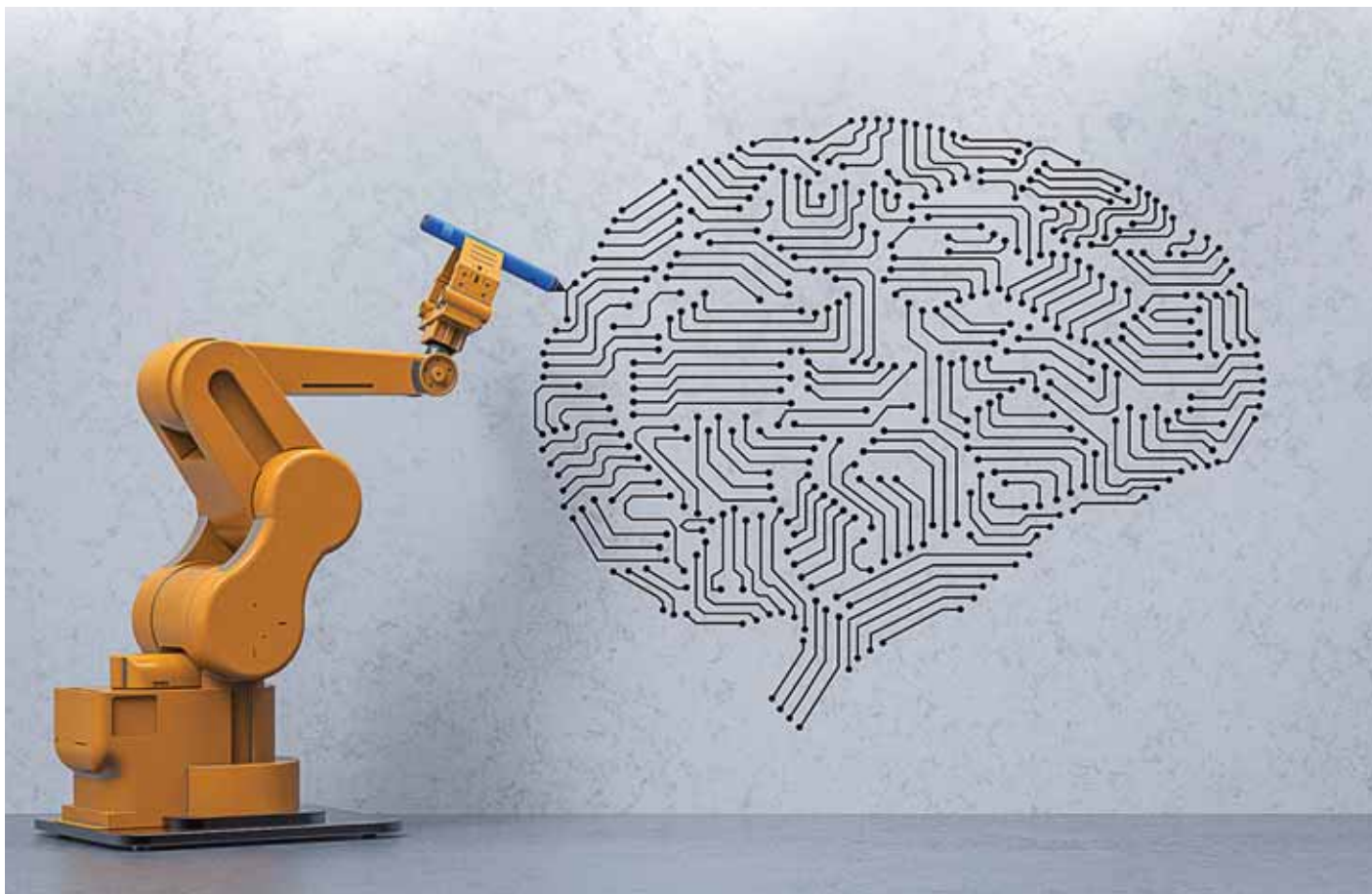
The EU General Data Protection Regulation (GDPR)¹⁸ is a set of compliance regulations that came in effect on May 25, 2018, to harmonise data protection and privacy of all EU citizens across all member states. According to the

GDPR, *personal data* are:

... any information relating to an identified or identifiable natural person (“data subject”); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person.

The GDPR applies to any organisation that handles data that comes from EU citizens, including companies based in the EU and those that collect (controllers) or process (processors) data from EU citizens. It is a complex regulation that identifies data as anything that can identify an individual directly or indirectly; non-compliance can result in significant financial penalties. The scope of GDPR in healthcare broadly encompasses these key takeaways:

- Strict definition of patient consent while acquiring personal data – organisations are expected to obtain explicit consent for the collection and storage of all personal data, and to be transparent about its intended use.



The EU Clinical Trial Regulation 546/2014 (which replaced the EU Clinical Trial Directive No. 2001/20/EC) aims to harmonise clinical trial submission and assessment across EU member states, and ensure highest standard of safety for trial participants and transparency of information sharing.

- Removal of patient data or the patient’s right to be forgotten – organisations can no longer hold personal data indefinitely and are required to delete all information permanently upon a patient’s request.
- Data protection – all organisations that collect and store patient data must take measures to ensure security, pseudonymisation, and data privacy to avoid compromising patient data. Risk assessment procedures must be in place to address any data breaches.

The EU Clinical Trial Regulation 546/2014 (which replaced the EU Clinical Trial Directive No. 2001/20/EC) aims to harmonise clinical trial submission and assessment across EU member states, ensure highest standard of safety

for trial participants, and transparency of information sharing.¹⁹ EMA Policy 0070 (released in March 2016) enables access to clinical trial documents by academics and researchers to enrich scientific expertise and innovation within the pharmaceutical industry.²⁰ Under EMA Policy 0070, companies are required to make GDPR-compliant public disclosure of selected clinical trial documents in a public portal. The policy is applicable to trials conducted within and outside the EU; including approved, disapproved, and withdrawn marketing authorisation applications.

The two legislations make it imperative for organizations to find the right way to balance data protection and privacy requirements with transparency and public disclosure. Anonymis-

ation of participants is essential to ensure privacy and prevent re-identification of patients in trial documents that are disclosed to the public. To ensure highest standard of data protection, clinical trial documents under EMA 0070 policy will be disclosed in two phases:

- Phase I concerns disclosure of common technical document (CTD) clinical overview (Module 2.5), clinical summaries (Module 2.7), Clinical Study Reports (CSR) and its appendices (including the protocol and its amendments, case report forms, and statistical analysis plans).
- Phase II will include the publication of anonymised individual patient data, and will be implemented after Phase I disclosures are complete.

This requires the practice of rigorous methodology and anonymisation techniques in preparing trial documents. Proactive anonymisation can be used by removing (e.g., patient name and geographic location) or replacing sensitive information (e.g., banding, where age is replaced by age range, or calendar dates by relative dates) to avoid redaction during public disclosure of documents. To ensure transparency during redaction, an anonymisation report that includes the methods of redaction and their impact on data quality is required.^{21,22} A risk assessment plan is also critical for mapping out the procedures to follow in case of a re-identification attack.

In addition to ensuring compliance in clinical trial documents, it is essential that information on all other platforms (e.g., journal publications, company websites, regulatory agency websites, congress abstracts and posters, patient organisation websites) is consistent with clinical trial data on public databases. Medical writers have a critical role in ensuring a balance between public disclosure of trial documents without compromising GDPR compliance, maintaining transparency, and gaining public trust.

Artificial intelligence and medical writing

The fast-evolving artificial intelligence (AI) technology has the potential to disrupt every stage of the \$63 billion clinical trials market, from drug design, patient recruitment and medication adherence, to gathering real-world evidence.^{23,24}

Some of the challenges that AI-enabled technology can be used to address include:

The challenge of real-world evidence

Traditional clinical trials are the gold standard for evaluating a drug's risk/benefit profile, but are not comprehensive enough to explain how the drug will perform in the 'real world' with a heterogeneous patient population. Real-world evidence (RWE) is information derived from real world data (RWD), or health data acquired outside of a clinical trial i.e., during clinical practice. The need for RWD exists because conventional approaches to drug development are time and cost-intensive (exceeding 8 years in development with costs of over \$2 billion), and come with no guarantee for success. Therefore, it is important to analyse and integrate RWE in healthcare to empower physicians, and provide

patient-focused treatments while reducing healthcare costs.

The second annual RWE Benchmarking Survey from Deloitte reports that 90% of pharmaceutical companies are building RWE analytic capabilities through the entire product cycle via investments, technology, and external collaborations.²⁵ RWE is useful both in improving clinical trial design and execution through upstream incorporation of RWE-driven expertise (e.g., use of synthetic control arm instead of an actual control arm), as well as monitoring post-launch safety of drugs.

The process of collecting and using RWE is not straightforward, and there is a dearth of standardised and reliable procedures that can be integrated in clinical studies. Typical sources of RWD include insurance claims, electronic health records (EHR), patient registries, patient-generated data (e.g., mobile and wearables, or "Internet of Things" devices), patient-reported outcomes, and social media insights. How useful data can be extracted from these diverse channels and analysed for clinical investigations in a GDPR-compliant manner remains a challenge.²⁶ Automation of data extraction, retention and expiry can help ease the burden of regulatory compliance while enabling companies to capture and evaluate valuable RWD.

Data mining in pharmacovigilance

The WHO defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem".²⁷ With the advent of digital media, the number of adverse events (AEs) reported has increased dramatically; in 2017, the FDA received reports of over 1.8 million AEs related to drug use, a 400% increase from the 363,171 reports it received in 2007.²⁸ To build robust drug safety surveillance systems, pharma companies are seeking to mine "big data" to identify AEs from other electronic data sources, including EHRs, medical literature, and social media.²⁹ The sheer volume of available data raises the cost of collecting, evaluating, processing, and reporting of AEs. Companies are increasingly turning to PV automation to streamline process steps, reduce time and labour costs, and speed information delivery while ensuring compliance. Examples include robotic automation of manual steps that do not require human intervention,

and AI-enabled approaches where the PV system can interpret and analyse the source documents, perform seriousness assessment and medical review on appropriate content.

Can AI-enabled technology replace medical writers?

Given the range of AI-enabled functions, there is now an increasing interest in its applications in regulatory documentation. The ultimate concern for medical writers is whether AI and machine learning can replace their role in preparing technical documents.

Following the EMA 0070 policy, there is interest in using AI applications in redacting sensitive information from clinical trial documents. While AI-enabled automation so far has not made major inroads into regulatory writing, technologies that enable automation of at least part of the regulatory document preparation are already available. For example, Synchrogenix has developed an innovative platform combining SaaS-based AI and natural-language processing technology that uses context-based understanding in automated authoring tasks.³⁰ The Synchrogenix AI tool is capable of taking information from previous study documents including CTDs, statistical analysis plans, tables, and figures, and placing them under the right sections of a CSR. Recent reports about the first AI-generated textbook using machine learning,³¹ automation of scientific writing and literature research through neural networks^{32,33} carry the promise of speeding up scientific and technical document preparation, and are likely to be widely used by medical writers in the future.

The sweeping regulatory changes in recent years are proving to be a rich opportunity for growth in medical writing. In fact, according to a report by Acumen Research and Consulting, from 2019–2026, the global medical writing market is expected to grow to US\$3.6 billion.³⁴ For PhDs seeking to transition outside academia, there has never been a more exciting time to be a medical writer!³⁵

Conflicts of interest

The author declares no conflicts of interest.

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The medical writing landscape in China

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Abstract

The Chinese medical regulatory writing and medical science writing landscapes are changing rapidly. Changes in regulatory reforms continue as China further strives to align its pharmaceutical industry with the world, which necessitates collaborative writers who are capable of keeping up with both changes in regulations and innovative medicine. Medical science writing is dependent on the adaptation of the material to suit Chinese media platforms. Despite the vast differences in regulatory writing and medical science writing, the essential skills are similar – understanding data and knowing one’s audience.

Introduction

Medical writing exists on a broad spectrum ranging from regulatory medical writing to medical science writing.¹ Therein, the corresponding drivers of trends in medical writing span from regulatory changes to new discoveries and cultural changes. Extensive reforms in regulations since China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as a new Regulatory Member have inevitably changed the clinical development landscape countrywide, and of course, everything related to document preparation for the regulatory medical writer.^{2,3} Contrastingly, medical science writing – the dissemination of scientific and medical information to the general public – is largely determined by the language and medium through which communication occurs and these revolve around culture and trends. This article explores the recent trends in medical regulatory writing and medical science writing, as well as the essential skills to becoming a successful medical writer in China.

Medical regulatory writing trends in China

Brief history of medical regulatory writing

Regulatory medical writing is a relatively new

profession that has emerged and taken off in China. According to Dr Ning Zheng (2018, personal interview with N. Zheng; un-referenced), Medical Writing Associate Director at *dMed Biopharmaceuticals* (a contract research organisation in China), China has been “repeating the history seen in Europe and the US, where clinical research physicians (CRPs) also prepared documents and medical writing was not a distinct profession”. It was considered strange that you needed someone to help you develop a document and it was also “difficult to persuade management as to why you needed a special writer”. Although it is true that CRPs can write, medical writers may express the idea more clearly. Amidst the work that many CRPs have (medical monitoring and communicating with principal investigators), they may not necessarily have sharpened and honed their writing skills. “As medical writers, we write every day, hence we have more experience, but we still need input from physicians because they have the therapeutic expertise”. Indeed, the medical regulatory writing profession has grown in China in recent times as more and more companies see the value in outsourcing work to medical writers or even having an in-house team.

Dr Nan Wang, Head of Global Medical Writing at *Bayer HealthCare (China/Finland)*



(2018, personal interview with N. Wang; un-referenced), added that as “regulatory requirements became tighter and with research and development on the rise in China” there came a “bidirectional need” for efficient clinical development: global pharma companies needed to start adhering to the more stringent regulations, meanwhile local companies wanted to go global. As such, “a strong market need for medical writers” has arisen; however, not only was there a “limited” supply of writers, everyone was also rather “inexperienced”. This is how the scattered regulatory medical writers of China came together in 2014 and formed a medical writing community. The group is active on *WeChat* and has become a platform for knowledge exchange. They also represent Chinese medical writers and help bridge Chinese medical writers with the world. At the time of writing, the community contains an avid group of 400-500 members.

Recent regulatory changes

Rapid changes in Chinese drug regulations call for changes in document development for a medical writer. In early 2018, the National Medicinal Products Administration (NMPA) implemented five secondary ICH guidelines (Notice No. 10 2018): M4, E2A, E2D, M1 and E2B (R3).⁴ E2A, E2D, and E2B (R3) define standards for safety reporting. For medical writing, the implementation of M4 is a big step

Being a compelling storyteller and engaging the audience on relevant platforms to pass on jargon-heavy and difficult concepts easily are critical.

because it calls for the use of Common Technical Document (CTD) modules for the submission of documents. This year, the NMPA has started to ask for public comments on electronic CTD implementation.⁵ All these guidelines call for more efficient document handling and transferability in documents across regions worldwide.

A major change in the procedures for investigational new drug (IND) applications /new drug applications (NDA) (Notice No. 50 2018) also came in 2018.⁶ This was followed by procedures on setting up a pre-IND meeting (Notice No. 74 2018).⁷ Briefly, the optimised IND and NDA approval times are now 60 and 150 working days, respectively. This allows companies to consider involving the Chinese market early on during pivotal developmental stages.

Further, a single IND approval is valid from Phase I through to III. To further close the gap, the Centre for Drug Evaluation released a List of Urgently Needed Overseas Drugs – drugs already approved in Japan, the EU, or the USA – to allow direct market application for said drugs as long as ethnic insensitivity can be demonstrated.^{8,9} These changes directly affect the overall timelines for document development with which medical writers are normally used to in China; the average waiting time for an IND application was 14 months between 2013-2015.¹⁰

Joining the ICH has led to a more stringent

regulatory environment, while opening doors for truly innovative new drug development and opportunities. Being able to comply with the ICH guidelines, while keeping up with the fast-changing landscape and retaining document quality, has become more important than ever.

Essential skills for the medical regulatory writer

Ning revealed that the title Medical Writer can be “misleading” because writing is a must – you need good grammar and the ability to express logically; however, other skills include “attention to detail” and the ability to “keep calm under stress” (2018, personal interview with N. Zheng; un-referenced). More importantly, project management plays a bigger part and is the more challenging aspect to medical writing. Some examples Ning mentioned include how to “manage reviewers especially when they do not follow your timeline”, how to “engage your project team” to complete tasks, how to rise above “cultural challenges” when working in international teams, and how to “manage stakeholders who are often of higher seniority than you”. These all boil down to effective communication and coordination.

Nan agrees and further explains that medical writing is a “cross-discipline job where you need to communicate effectively with others, while controlling, managing, and finding risks to complete a project” (2018, personal interview with N. Wang; un-referenced). Being a fast learner to grasp the crux of a project while not being the subject matter expert is very important. As Nan



recalled, “being able to design or contribute to the design of a protocol may not be that important for a writer; instead, the ability to ‘borrow’ another person’s knowledge to complete a project is more important. To me, this was a difficult thing to do in the beginning”. She reasoned that when you write a document, the document is not the limit. “Frequently, it encompasses an entire therapeutic area and learning is infinite. So, what is actually more important is the ability to use the right resources effectively in the limited time to complete a project”.

Science writing in China

Brief history of science writing

Science writing (also known as popular science in China) is the dissemination of scientific content to the general public. Science writing dates back to the late 1940s and was initiated by The Ministry of Culture, which stagnated during the Cultural Reform between the 1960s and 1970s.¹¹ After the 1970s, the Chinese government encouraged science associations to disseminate scientific findings to the general public so that they can benefit from it through lifestyle changes. With the advent of technology and as China started to open up, science writing took off since information was no longer propagated only by the government and professional associations. Over time, the public’s engagement has risen¹² – in the age of information, publishers, science communication agencies, and even the public have joined in.

Science writing, particularly with regard to medical content (medical science writing), in China is much like science writing in other parts of the world. Mingyue Jia, a medical writer at

Guokr (a science writing agency in China) (2018, personal interview with M. Jia; unreferenced), commented that the purpose of science writing is “to provide the public with general health-related and medical knowledge”, such as common diseases, remedies, how to overcome certain diseases, how to communicate with the doctor, and shed light on doctors’ perspectives. “It is a platform for communication”. Articles are varied and range from general information to cutting-edge research. Mingyue mentioned that many of the articles they worked on are sourced from overseas; these can be both journal publications as well as articles written by other science writing agencies. The key to science writing is the fine balance between “accuracy and attraction”. For Mingyue, analogies, adapting for cultural differences, and relevance are key to drawing their readers’ attention; this is the fun and artistic side of medical journalism. “Just laying out the hard facts and jargon will bore the reader”. She mentioned that one of the biggest differences in science writing between China and the US is that the US has a longer history and a more solid foundation. This can be attributed to the fact that high impact science journals are in English making it easier for science writers to “rewrite” the original source into an article that can be understood by a lay audience. In China, original materials in English have to be translated and cultural differences, habits, and relevance have to be considered. These are all key to public outreach, which, in modern times, revolve around social media.

Platforms for dissemination in China

In recent times, China has shifted from website-based dissemination to mobile-app based dissemination, thereby affecting lifestyle and habits. Contrastingly, most Western societies are used to accessing information via websites. The conundrum is that many businesses in China do not own or maintain a website; instead, they maintain businesses on mobile platforms (such as *WeChat*), and the contents of the mobile platform are only accessible on the phone and not through websites. Imagine a version of *Facebook* or *Twitter* where the posts you post and read are only available while using the cellphone app. Mobile-based platforms are the default in

China. You may find booking an appointment at a hospital difficult because the hospital may not necessarily have a website or that the website may be outdated. However, if you search for them using *WeChat*, the hospital may have a *WeChat* mini-programme through which you may find updated information, book an appointment, and find relevant reviews on different doctors.

Not only does success in getting information lie in navigating the different methods of social media use but so does success in informing.

A study showed that retweets on *Weibo* (a Chinese social media platform) were higher than retweets on *Twitter* by several orders of magnitude; therein, pictures, videos, and links accounted for a large percentage of the tweets.¹³ This is because trends in China are largely set by the public retweeting content while trends on *Twitter* are often attributed to

news sources or information from organisations that people follow. So, if you want to run a successful campaign in China, you need to consider the difference in practice.

While most of the world uses social media platforms such as *Facebook*, *Twitter*, *YouTube*, etc., China uses its own versions of social media platforms as a result of nationwide regulation of the internet (i.e. *The Great Firewall of China*). The most common are *Weixin* (or *WeChat*), *Sina Weibo*, and *Tencent QQ*. If we look at the figures, to quote Gary Liu (CEO of the *South China Morning Post*) from his *Ted Talk*,¹⁴ “By the end of 2017, the Chinese internet population had reached 772 million users. That’s larger than the populations of the United States, Russia, of Germany, of the United Kingdom, of France and Canada combined. Ninety-eight percent of them are active on mobile. Ninety-two percent of them use messaging apps. There are now 650 million digital news consumers, 580 million digital video consumers, and the country’s largest e-commerce platform, *Taobao*, now boasts 580 million monthly active users. It’s about 80 percent larger than Amazon”. This is a huge untapped market for non-Chinese companies! Beside the language barrier, which can be easily overcome by translators and interpreters, another challenge lies in navigating the Chinese internet, and this is crux to success in the Chinese market.

The common essential skill is to deliver the message most efficiently to very different target readers

Essential skills for medical science writing

For those interested in medical science writing, Mingyue mentioned that “good writing skills” are a must (2018, personal interview with M. Jia; unreferenced). Considering that some of the articles are published in English journals, good English skills are also a prerequisite. Although a medical background (for medical-related content) is preferable, those without a medical background must be able to grasp the concepts easily and possess good reasoning skills. Most of Mingyue’s colleagues have either a Bachelor’s or Master’s degree. Since medical science writing targets a wider audience, the ability to engage and connect the dots through wordsmithing, storytelling, and creative metaphors are essential. Finally, depending on the purpose, being able to use and navigate Chinese social media platforms is a bonus.

Conclusion

The medical writing landscape is changing rapidly in China. For regulatory writing, being able to keep up with the rapid changes in local regulations while working with the team to develop documents are essential. Luckily, a very active group of Chinese regulatory writers are there to support each other. For medical science writing, the government has passed the popularisation of science ball onto publishers and the public. Being a compelling storyteller and engaging the audience on relevant platforms to pass on jargon-heavy and difficult concepts easily are critical. The common essential skill is to deliver the message most efficiently to very different target readers – health authorities for regulatory writing and the public for medical science writing – even though the data behind could be the same.

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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 is employed by dMed Biopharmaceuticals but the views and opinions in this article are entirely her own.

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News from the EMA

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Re-analysis of data on use of breast cancer medicine Tyverb following treatment with trastuzumab

April 30, 2019 – European Medicines Agency (EMA) is updating the prescribing information for Tyverb (lapatinib) following detection of errors in results of a study involving post-menopausal women who had 'HR+/HER2+' breast cancer and whose disease had worsened despite previous treatment with trastuzumab. The results had indicated a benefit of Tyverb over trastuzumab when each medicine was used together with an aromatase inhibitor. While there are no new safety concerns with Tyverb, data on its benefit over trastuzumab in this patient population are currently being re-evaluated.

The detected errors were included in the prescribing information for Tyverb on July 30, 2018. However, these will now be removed while data are being re-analysed. In the meantime, the prescribing information will be amended to state, as before, that no data are available on the effectiveness of Tyverb compared with trastuzumab in this combination in patients

previously treated with trastuzumab.

In the light of this new information, doctors currently treating patients with Tyverb in combination with an aromatase inhibitor, whose disease had worsened despite previous treatment with trastuzumab, should decide whether to continue with the same therapy or consider an alternative treatment.

Tyverb is a cancer medicine used to treat patients with HER2+ breast cancer. This means that a specific protein called HER2 (also known as ErbB2) is present on the surface of the cancer cells. Tyverb is used in the following ways:

- in combination with capecitabine (another cancer medicine) when the cancer is advanced or metastatic and got worse following previous treatment including an anthracycline and a taxane (other types of cancer medicines) and following treatment of the patient's metastatic disease with trastuzumab (another cancer medicine). 'Advanced' means

that the cancer has started to spread locally and 'metastatic' means that the cancer has spread to other parts of the body;

- in combination with trastuzumab for metastatic cancer that does not respond to hormones (hormone receptor-negative disease), and which got worse when previously treated with a combination of trastuzumab and other cancer medicines (chemotherapy);
- in combination with an aromatase inhibitor (another type of cancer medicine) in women who have been through the menopause, when the cancer is metastatic and responds to hormones. This combination is used in women who do not currently need to receive chemotherapy to treat their cancer.

Tyverb was originally granted a conditional marketing authorisation valid throughout the EU in June 2008 and was switched to a full marketing authorisation on February 17, 2015.

Withdrawal of marketing authorisations for fenspiride medicines

May 24, 2019 – EMA's safety committee (PRAC) has recommended that the marketing authorisations for fenspiride medicines be revoked, so the medicines can no longer be marketed in the European Union (EU). This follows a review that has confirmed that these cough medicines could cause heart rhythm problems.

The PRAC considered all the available evidence in its review, including case reports and nonclinical studies (including hERG channel binding). This included cases of QT prolongation and torsades de pointes (abnormalities of the heart's electrical activity that may lead to heart rhythm disturbances) in patients using these medicines, results of laboratory studies, data from published literature and stakeholder input.

Heart rhythm problems can be serious and occur suddenly, and it is not feasible to identify in advance the patients who may be at risk of

these problems with fenspiride. In contrast, fenspiride medicines are used to treat non-serious cough. Therefore, the PRAC considered that these medicines should no longer be marketed.

Fenspiride medicines are available as syrup or tablets and used in adults and children from the age of 2 years to relieve coughs resulting from lung diseases. In the EU, fenspiride medicines are available under various brand names (Elofen, Epistat, Eurefin, Eurespal, Fenspogal, Fosidal, Kudorp, Pneumorel, Pulneo, Еуреспал and Сиреспн).

The review of fenspiride was initiated on February 14, 2019, at the request of France, under Article 107i of Directive 2001/83/EC. At that time, the PRAC recommended that supply of fenspiride medicines be suspended as a precautionary measure while the review was ongoing. Because fenspiride medicines are all licensed at national level, the PRAC recommen-

ation will now be sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) to make a decision about its implementation. The CMDh is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU, Iceland, Lichtenstein and Norway.



EMA facilitates early engagement with medicine developers to combat antimicrobial resistance

May 24, 2019 – EMA has opened up an early dialogue through its Innovation Task Force (ITF) to all medicine developers who work on therapeutic approaches for the treatment or prevention of bacterial and fungal infections. ITF is a forum for dialogue between regulators and developers of innovative emerging therapies, methods and technologies, in the early stages of research and development. ITF is usually reserved for innovative medicines. Given the growing threat to public health caused by antimicrobial resistance and the need for new treatments, EMA is inviting all developers working on medicines for the treatment or prevention of life-threatening microbial infections to enter into early dialogue with the Agency to help strengthen the drug development pipeline for new antimicrobials.

The emerging and steady increase of microbes that are resistant to antimicrobial treatments threatens the effective treatment of patients with infectious diseases. According to a World Health Organization (WHO) report, approximately 700,000 people die from drug resistant infections globally each year, a figure that could rise to 10 million deaths globally per year by 2050 under the most alarming scenario if no action is taken.

Without a sustained effort to contain antimicrobial resistance, common diseases are becoming untreatable and lifesaving medical procedures riskier to perform.

Stimulating the development of new medicines to treat resistant bacterial or fungal infections is one pillar in the fight against this threat, and a high priority for EMA and the European medicines regulatory network.

The ITF will facilitate an early interaction and broad-ranging discussion between innovators and regulatory authorities, which will help developers' orientation and subsequent use of formal regulatory tools such as EMA's scientific advice. The service is free of charge and any new medicinal product for the treatment of a life-threatening or debilitating fungal or bacterial infection would be considered for discussion in the ITF.

This platform for early dialogue will ultimately contribute to prioritising

and speeding up the development of antimicrobial medicines, which is in line with the European Parliament Resolution of 13 September 2018 on "A European One Health Action Plan against Antimicrobial Resistance".

Interested medicine developers are encouraged to complete the ITF briefing meeting request form and send it to itfsecretariat@ema.europa.eu to discuss their development plans for medicinal products addressing bacterial and fungal infections.



Strengthening engagement between EMA and general practitioners

June 6, 2019 – The EMA and the two major organisations representing general practitioners (GPs) and family physicians in Europe – the European Union of General Practitioners (UEMO) and the European section of the World Organization of Family Doctors (WONCA) – and the major organisation representing primary care professionals in Europe, the European

Forum for Primary Care (EFPC), have signed a joint statement committing to strengthening interaction between EMA and this important group of healthcare professionals.

While EMA benefits from an existing framework of interaction with healthcare professionals – including physicians, pharmacists and nurses – interactions with GPs and family physicians and

feedback from primary care to EMA are currently limited. Developing a strong working relationship with this very large group of physicians aims to:

- help EMA gain a better understanding of how medicines are being used in real life and the potential impact of specific regulatory actions on patient care;
- facilitate the incorporation of views and input from GPs and family physicians into the Agency's activities;
- raise awareness amongst GPs and family physicians of the role and activities of the EU medicines regulatory network.

The statement includes a concrete action plan to 2020 to guide EMA, UEMO, EFPC, and WONCA in their joint work. Specific areas of collaboration include involving GPs and family physicians in EMA evaluation activities, developing communication activities relevant to GPs and family physicians, as well as exploring options for further collaboration with existing research networks in primary care, with a focus on generating real-world evidence. The action plan also identifies opportunities for cooperation in regulatory science training.

The development of the joint statement follows a workshop which took place in 2016 with representatives of GPs and family physicians in order to explore new ways to engage with these providers of primary care in EU Member States and further involve them in EMA activities.

Progress will be monitored and discussed within the EMA GP/family physician expert group and reported to the EMA healthcare professionals' working party.



Bacterial lysate medicines for respiratory conditions to be used only for prevention of recurrent infections

June 28, 2019 – EMA is recommending that bacterial lysate medicines authorised for respiratory conditions should only be used for the prevention of recurrent respiratory infections, with the exception of pneumonia. This follows a review that concluded that there are no robust data showing that these medicines are effective at treating existing respiratory infections, or for the prevention of pneumonia, therefore they should not be used for these purposes.

In the review, EMA's human medicines committee (CHMP) considered the results of clinical studies, data on side effects reported with these medicines, and advice from an expert group on infectious diseases.

Although data are limited, the review found some evidence of effectiveness of these medicines in the prevention of recurrent respiratory tract infections and the safety profile is in line with what is expected for this type of product.

The CHMP therefore recommended that use of the medicines for prevention can continue, but the companies must provide further data on safety and effectiveness from new clinical studies by 2026.

Bacterial lysate medicines are made from bacterial cells that are broken down and are intended to stimulate the immune system to recognise and fight infections. These medicines are taken by mouth (as capsules, tablets,

New treatment for children with type 2 diabetes

June 28, 2019 – EMA's human medicines committee (CHMP) has recommended granting an extension of indication to Victoza (liraglutide) to include the treatment of children and adolescents aged 10 years or older with type 2 diabetes. This medicine is already approved for use together with diet and exercise in adults with type 2 diabetes, on its own or as an add-on to other diabetes medicines.

Type 2 diabetes is a chronic disease in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. It can lead to serious complications if a person does not receive treatment. According to the WHO, type 2 diabetes has increasingly been reported in children and adolescents recently, so much so that in some parts of the world type 2 diabetes has become the main type of diabetes in children.

The recommended treatment for paediatric type 2 diabetes is similar to that in adults, with emphasis on a step-wise approach starting with lifestyle modifications, particularly healthy eating and exercise, followed by the use of a single medical therapy and later by two therapies in combination. The aim is that the patient achieves and maintains low levels of glucose in the blood in order to prevent long-term complications.

Currently, the only two approved treatment options for paediatric type 2 diabetes patients in most countries are metformin and insulin. However, more than half of young patients do not achieve glycaemic control on metformin alone, even when combined with lifestyle interventions, and treatment with insulin has considerable side effects such as weight gain, or a high risk of

hypoglycaemia. Therefore, there is a medical need for alternative treatment options for children and adolescents with type 2 diabetes.

Victoza is the first non-insulin, besides metformin, to get a positive opinion for paediatric use for type 2 diabetes. The active substance in Victoza, liraglutide, is an 'incretin mimetic'. This means that it acts in the same way as incretins, a group of metabolic hormones that stimulate an increase of the amount of insulin released by the pancreas in response to food. This helps with the control of blood glucose levels. Liraglutide has been used in adults for approximately ten years, so there is an extensive amount of data available in particular with regards to safety.

The efficacy and safety of Victoza in children and adolescents was investigated in a placebo-controlled trial with 134 patients with type 2 diabetes aged 10–17 years. This study was carried out in accordance with a Paediatric Investigation Plan, which was agreed by the Agency's Paediatric Committee (PDCO).

The study compared patients in the liraglutide group with a placebo group over 26 weeks. Patients treated with Victoza, with or without insulin, experienced a clinically relevant reduction in the levels of glycated haemoglobin (HbA1c) that is measured via a blood test to evaluate average blood sugar levels in a patient over a period of weeks or months. A higher number of patients experienced hypoglycaemic episodes in the liraglutide group than in the placebo group irrespective of prior insulin use.



The results of the trial demonstrated that the safety profile of Victoza in this population is comparable to that in adults. The most common side effects were nausea, vomiting, diarrhoea, headache and abdominal pain.

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

granules/powder for making up an oral mixture or drops), dissolved under the tongue (as tablets), inhaled through the nose (as a liquid) or given by injection into a muscle or under the skin.

Bacterial lysate medicines are sold under several brand names including Broncho Munal, Broncho Vaxom, Buccalin, Immubron, Immucytal, Ismigen, Lantigen B, Luivac, Ommunal, Paspas, Pir-05, Polyvaccinum, Provax, Respivax and Ribomunyl.



Regulatory Matters

Trends in medical writing



Changes in the regulatory landscape and changes in our professional environment make this an exciting time to be part of the regulatory medical writing community. It is a time when new opportunities are presenting and when, like never before, the medical writing community has chosen to come together to conscientiously shape our professional landscape. As this happens, we recognise and value well-established approaches, reinforce innovations in practice, and secure the future for our profession.

The regulatory landscape

Medical writers have been adapting to changing regulatory directives for decades. This history of flexibility positions us well for the latest evolutions.

No place is more dynamic than China, where changing regulatory procedures, ICH adoption, and a potential marketplace of historic proportions make the clear, concise, and compliant communication of all aspects of drug development essential. Beginning with the clinical trial application, documentation increasingly plays a critical role in a shortened approval timeline. An example? In China today, if no comments have been received from regulatory authorities 60 working days after the written submission of a clinical trial application, that trial may move forward. With a plan to implement eCTD in 2020, review and approval of marketing applications will likely move more quickly as well.

In Europe, pending exit of the United Kingdom from the European Union, we anticipate continued changes with the European Medicines Agency (EMA) and the United Kingdom's

Medicines and Healthcare Products Regulatory Agency. From its new headquarters in Amsterdam, the EMA has maintained core public health work, as well as the evaluation and supervision of medicines. Some other activities, such as guidance development and transparency initiatives, have been temporarily scaled back.¹ Now is no time for health agencies and the pharmaceutical industry to let up on proactive measures such as allowing for preparation of slightly different sets of regulatory documents for the two agencies when they part ways.

The Food and Drug Administration (FDA) in the United States has launched a pilot programme exploring real-time data review for oncology marketing applications (called, of course, the Real-Time Oncology Review programme).² The FDA also newly sponsors participation in the written preparation of its Assessment Aids for marketing applications. The two programmes require new ways of working with data and information, and they provide a directional signal as to possible modifications to the review processes of the future.

Regulators also continue to emphasise the importance of meeting the needs of trial participants. We see moves towards more transparency for clinical documentation and more health literacy materials. These developments allow medical writers to expand our scope and skills, and they offer opportunities to explore how technology can support the development of regulatory deliverables. We see for informed consent, in particular, a need to re-evaluate the content and volume of information provided to

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trial participants in support of their critical decision-making process.

The professional landscape

Leaders in the American Medical Writers Association (AMWA) and the European Medical Writers Association (EMWA) work closely with medical writing industry executives to assess the state of the profession and to develop plans to ensure vibrant growth and development of our workforce. Activities kicked off at the AMWA annual conference in 2018 included systematic group conference calls, surveys of organisational members, and the development of new and innovative educational programmes. Our efforts aim to prepare the next generation of medical writers, develop leadership capabilities in these future standard-bearers, build partnerships in technological advances for regulatory communication, and quantify the value of medical writing to the drug-development industry.

We also sense within medical writing organisations an increase in adoption of competency guides such as the "Pharmaceutical Medical Writing Competency Model"^{3,4} in an effort to establish standard expectations for writing skillsets. This model, first published in 2011 and updated in 2017, helps establish hiring and performance evaluation criteria and also can be

aligned with a training plan for career development – all in support of medical writing. Another growing option for establishing credibility is the Medical Writer Certified (MWC®) credential, earned through an AMWA exam.⁵ The credential acknowledges core competencies in medical writing and a commitment to continued professional development.

Conclusion

Our trend line in medical writing points upward and outward. Today we can seize immediate opportunities to redefine our value and expand our scope of work in ways that highlight our scientific and clinical expertise, regulatory acumen, communication skills, and project management mastery. With the right vision and execution, this exciting – even exhilarating – time in our profession can turn out to be historically

important. We simply need to go after our medical writing goals with determination... and the right attitudes and right aptitudes.

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Medical Communications and Writing for Patients



SECTION EDITOR



Lisa Chamberlain James

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Editorial

Dear all,

The more eagle eyed among you will have noticed that we are changing the title of this section to “Medical Communications and Writing for Patients”. Not the shortest of titles, I know, but hopefully it is a more accurate reflection of the content that will be included in the section.

In this issue of the journal, I am delighted to

present a feature article I co-wrote with Trishna Bharadia (Lay summaries and writing for patients: Where are we now and where are we going? p. 46). Given the topic, we thought it best to present it as an open access feature article, rather than running it in our members-only section.

As a *The Spark Global* consultant, Trishna works with multiple stakeholders (including pharma, patient associations/charities, clinicians,

patients and the healthcare industry) in the UK and internationally, to bring the patient voice into the healthcare journey, addressing issues that affect both specific and cross-patient communities, as well as issues affecting the healthcare industry. She is very well connected, and her work has taken her to, or involved her with, organisations from the Netherlands, France, Austria, Portugal, the Czech Republic, Romania, Northern Ireland, Switzerland, Germany, Spain, England, Poland, and the USA, among others.

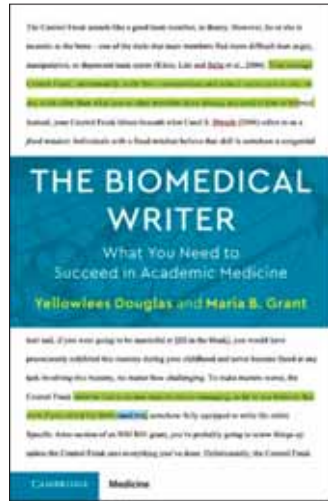
We both felt that the time was right to look at what has happened in the arena of writing for patients, and we offer suggestions for where the industry might be heading in this regard. I hope that you enjoy the article. As always, I would be delighted to hear any thoughts, suggestions, or proposals for articles.

Bestest,

Lisa

In the Bookstores

The Biomedical Writer
Yellowlees Douglas and
Maria B. Grant
Cambridge University
Press, 2018
ISBN-978-1-108-40139-5
Paperback
£22.99 206 pages



Yellowlees Douglas is a consultant on writing and organisations and an associate professor in the Center for Management Communication at the University of Florida, USA. Maria B Grant is a professor of ophthalmology at the University of Alabama, USA who has authored more than 200 peer-reviewed publications. The book is targeted at academic researchers rather than professional medical writers.

This small paperback consists of seven chapters each of which begins with a bullet point list of learning points and is interspersed with ‘Between the lines’ and ‘Snares to avoid’ information boxes – opportunities for a deep dive into some of the topics covered in the chapter. The first chapter (Writing: The most vital – and neglected – skill) serves as an introduction to the book and its authors.

Chapter 2 (Writing for your reader’s brain) is very different in style to anything I’ve read in other textbooks on medical writing. It takes an academic approach to how we read – from basic word recognition to recalling content – and provides tips on how to organise sentences and paragraphs to have the greatest impact. For me, this chapter underlined two important principles. The first is that papers must be readable to have impact – good research can be obscured by “clunky” writing. The second is that writers should always ask a copy editor to look at their work before submitting.

One of the learning points for Chapter 3 (Before you begin: getting to *So what?* and *Who cares?*) is to anticipate potential objections or rejections as you are writing. I think that this is good advice. To this end, the book’s authors remind writers to use appropriate guidelines (CONSORT, PRISMA, STROBE, STARD, and STREGA) to avoid compromising the reporting

of the study. They also suggest that researchers classify their study by its outcomes – i.e., as “incremental”, “first ever”, “incidental/dramatic”, or “a paradigm shift” (accepting that outcomes often straddle more than one category) before even writing an outline. They point out that this will also be useful in promoting the paper (e.g, through social media) post-publication. I found the “Progressing Your Career” section at the

end of Chapter 3 troubling, as it could be interpreted as encouraging writers to flout ICMJE and GPP3 recommendations. This section is ostensibly about mentorship, but in my opinion, readers could replace “mentor” with “sponsor”. In respect of review papers it says: “Usually, rather than write the manuscript themselves they enlist... someone they mentor to collaborate with them on the review.” For the word *collaborate* substitute *write*. And “Your mentor’s name may well get the paper published at a good journal.” This is the type of behaviour that the pharmaceutical industry has rightly been criticised for and which prompted the development of ICMJE and GPP3 guidelines. These authors acknowledge the perniciousness of these arrangements – in the process making a very valid observation about the way in which they affect women’s career progression – yet, disappointingly, encourage their readers to play the game rather than change the game.

Chapter 4 (Getting published: manuscripts, journals and submissions) is by far the longest chapter in the book (at 47 pages) and for me was the most important. The chapter has 10 sections. It starts with some great practical advice on targeting journals and familiarising yourself with their style and author guidelines. The authors make some important suggestions for ensuring that writers understand and properly convey the context of

The authors make some important suggestions for ensuring that writers understand and properly convey the context of their work through a thorough literature search.

SECTION EDITORS

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their work through a thorough literature search. They recommend the use of search algorithms in Google Scholar and PubMed to ensure that all of the background on the topic is captured and to highlight gaps in current knowledge and/or practice. The authors then take each section of the manuscript in turn and provide very detailed descriptions and advice on how they should (and should not) be constructed. The section on writing the introduction takes 15 pages, reflecting the importance the authors place on getting this right. The authors’ suggestions to create a basic outline that you can gradually expand, to use the introduction to highlight where the gaps in research are, to ensure that the methods section covers the Who, What, When, Where and How of the study, to stick to reporting data in the results section and keep commentary on those findings for the discussion all reinforced my beliefs about the most efficient way to write a manuscript. The authors make the very good point that this is what journal editors and reviewers are looking for – and deviating from that pattern is likely to result in manuscript revisions and publication delays.

Other high points of this chapter were the “Making discussions more accessible” section (which included the BMJ’s suggested structure for discussions) and an explanation of the terms *association*, *correlation*, and *causation*. There were some low points in the chapter for me, however. Some of the subsections were just too theoretical (in particular, the use of gambits in constructing the introduction). Some of the subtitles were just too contrived: titles such as “Manage the Scylla and Charybdis of discussions” and “Running the gatekeeper gauntlet when submitting” seemed to run counter to the advice in the chapter. Once again, the lack of encouragement to write collaboratively, with all

authors earning their place on the by-line, is disappointing. On the one hand, the authors are encouraging researchers to check and act on journal requirements, and on the other they say: "... you are writing the paper exclusively because the *invited* [my emphasis] senior author has delegated its writing to you" – behaviour that in most cases would prevent a journal publishing a paper. I also took issue with three of the otherwise excellent takeaways from this chapter: "consider publishing negative data" (many journals actively encourage this now in order to recognise the contribution made by patients taking part in the study); "filter the data you report in your results section to highlight only your most significant findings" and "highlight your most important finding in the opening paragraph of your discussion" (GPP3 encourages authors to be guided by the objectives/endpoints of the study, with the emphasis placed on the primary outcome).

Chapter 5 (Getting funded: applying for grants) will be of interest to EMWA members who work in this area, or who want to work in this area, but is outside my own experience. The authors reiterate their key messages for writing manuscripts: prepare well – ensure that you understand what type of funding is on offer and what it can be used for; anticipate the likely outcomes of your research and don't over- (or under-) sell it; understand the needs of your audience; clearly identify gaps in current knowledge and practice that the research will address; and prepare an initial outline of the application before starting to write. The authors encourage writers to think of their grant application as a business plan that leaves the reviewer with no unanswered questions and clearly demonstrates that you have considered all the problems that you might encounter and have

the tools to deal with them. The authors caution writers to expect to fail at their first attempt and provide strategies for responding constructively to criticism of the manuscript.

Chapter 6 (Collaborative writing: pass the baton) – which covers preparation of both grant applications and research papers – is very nicely done. It suggests the type of expertise that you need to have in your writing team to complete the paper and accurately describes the challenges of ensuring that everybody's views are considered, and a consensus arrived at before submission. I wasn't impressed by the authors' suggestion that all potential authors complete a light-hearted questionnaire to identify strengths and weaknesses as a writer, or their categorisation of different types of writer. The chapter does, however, include some pertinent advice on setting and enforcing deadlines and on different ways of communicating with the team during the writing process. I heartily endorse the authors' recommendation for face-to-face meetings whenever practicable (especially for discussing contentious or difficult matters). I found their comments about email exchanges interesting and enlightening. In this context, emails should be brief, have a clear subject, ideally state the main purpose in the opening sentence and certainly in the first paragraph, and seek to conclude a discussion not to start one. This chapter allays some of my concerns that the authors are sanctioning ghost writing and guest authorship, and I think that it is a shame that it was not placed earlier in the book.

Chapter 7 (Communicating with the public) deals with writing press releases and materials such as consent forms and lay summaries for the public to use. The preamble to the guidance on writing lay materials is very US-focused, but the step-by-step guidance itself is general enough to

be useful in any market. I very much liked the authors' practice exercises for writing press releases – gradually distilling down the key points of a research publication until the most significant and newsworthy findings remain. They list nine criteria by which the newsworthiness of research findings can be assessed: impact, significance, controversy, prominence, the unusual, timeliness, currency, usefulness, and educational value. If your findings encompass one or more of these, it should be possible to write a release that garners interest among the press. The authors remind readers to check with their publisher before issuing a press release and about the necessity to publicise the research and not any product that was used in the research. The 'Snares to avoid' section in this chapter concerns 'pay to play journals': it is clear from their description that the authors are referring to predatory journals here, and I think it is a shame that they didn't stick to this terminology. There are reputable journals that charge a fee for open access publishing and it would be a shame if researchers were discouraged from using them because of a misunderstanding. I also think that this section would have been better included in Chapter 4.

This book is not an easy read – you need to set time aside and study its contents. It is a book that some medcomms agencies may appreciate for its insight into how people take in and understand what they are reading, and how you can organise your writing to optimise the delivery of your messages. Aimed, as it is, primarily at academics, however, this book is not a general reference text for professional medical writers.

Reviewed by
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Save the date:
**EMWA Conference in
the Czech Republic**

PRAGUE

May 6 to 9, 2020

<https://www.emwa.org/conferences/future-conferences/>

Getting Your Foot in the Door

Editorial

The Vienna Conference is done and dusted. But the aftermath is so rewarding, as my knowledge has broadened and my network has widened. It was a joy to meet old colleagues but also get to know many people who are new to medical writing.

In this Getting Your Foot in the Door (GYFD) edition, I am especially happy to feature two testimonials from EMWA newbies. I want to thank Adriana for her constructive feedback and hope we can use her ideas for future EMWA events.

I met Sanjukta at an EMWA ambassador event in Munich in 2018 and was really pleased to her again on Vienna. I also want to congratulate her on getting her foot in the door – she recently started a regulatory affairs position.

See you in Malmö!

Raquel Billiones

SECTION EDITOR



Raquel Billiones

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Wanted: A “medical writing for dummies” manual

Vienna 2019 was my first EMWA conference. Coming from 8 years in academia and this event being my first experience into the medical writing field, what first struck me was the friendliness and genuine desire to network felt throughout the conference. Networking is taxing at the best of times, but here it was built in into the fabric of the profession. I was surprised to learn many of the attendees were freelancers; freelancing was a new reality that I had never thought of before. Talking with freelancers gave me a new perspective but the lack of guidance and mentoring starting out

a new career was a bit daunting and I needed to know more. I saw in the programme that there was a session entitled Getting into Medical Writing (GIMW) at the beginning of the conference and an Introduction to Medical Writing (Intro MW) at the end. I was confused by the similarity of the names but decided to attend both and learn as much as I could.

At GIMW, four medical writers of different backgrounds presented their personal experiences of how they became medical writers and what they currently specialised in. It was informative

but it also felt like unused potential. These people are experts at their particular fields, and while it is interesting to know their stories, we were there to know how to get started ourselves. I want to know what I require to become a medical writer, how to improve my skills continuously and become an experienced professional. Afterwards, there was an individual CV clinic with two experts which had to be arranged beforehand. Again, I felt there would have been more benefits from a short presentation on the subject instead.

On the very last day, there was the Intro MW session. Magali Le Goff presented a condensed picture of medical writing: what it is, what are the skills needed, and how to tailor your resume. I learned new things and consolidated my knowledge of others I had known before or learned throughout that week at the conference. However, it felt disjointed to have that session as

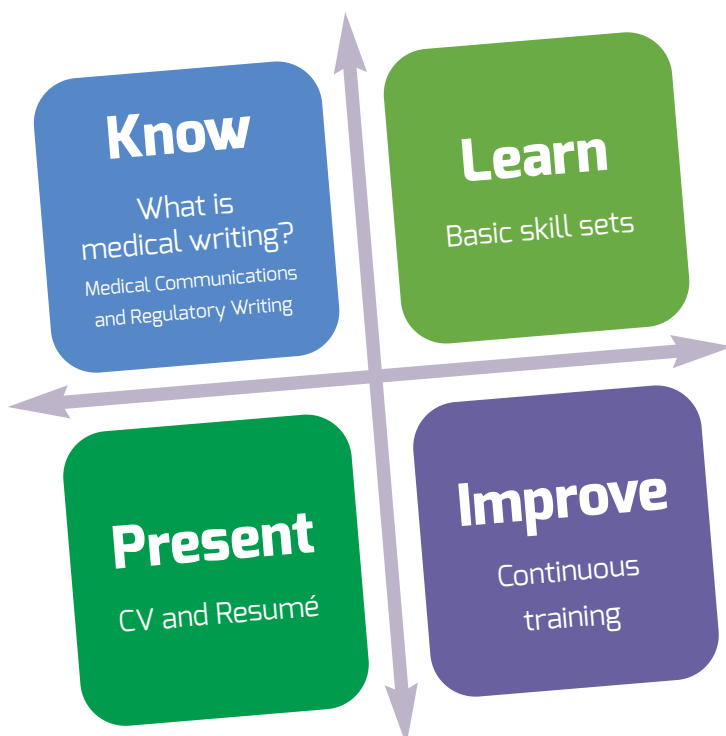


Figure 1. The medical writing for dummies method:

1. *Know*: know how medical writing is divided into medical communications and regulatory writing, what are the specifics to each field.
2. *Learn*: what do you need to learn to be a medical writer (text editing, language, relevant regulations and guidelines, etc.)?
3. *Present*: as an aspiring medical writer, how do you present yourself to potential clients or employers, what are the rules to a good CV?
4. *Improve*: as a medical writing professional, how do you improve your skills, learn new ones, share your knowledge?

the very last one of the conference, when it should have been the first.

Solely from my point of view as a newcomer wanting to learn more about medical writing, the Intro MW should have been the first event, followed by the tools and skill sets necessary to become a good professional. Within that scope, I would also like to know more how to get involved in EMWA. There were separate sessions such as the freelance business forum or the education committee, as well as other opportunities I heard from various people, but it would have been useful to have a centralised event where I can learn about volunteering, contributing to the official journal, creating a webinar, know about other (non-EMWA) online courses that helped other newcomers or even give a workshop. Finally, ending with a CV clinic presentation would complete the Medical Writing for Dummies Manual that would be invaluable for anyone entering the field (Figure 1).

I do understand the EMWA conference is a large event and that it is logistically challenging to schedule rooms and speakers. That being said, one constant reminder throughout the



conference was that EMWA was made by its members, for its members. And indeed, the potential is there, with talented speakers willing to volunteer their time and knowledge to teach others. A centralised medical writing for dummies committee would be able to structure

and present these sessions to better give a head start to its newest members.

Adriana Rocha
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How the EMWA community helped me shape my career

During the last years of my work as a senior postdoctoral researcher, I realised that much of my explorative self was somehow bound by a false sense of security and procrastination to try a career change. It took me time, but I started to slowly peep “out of the box” to find a way for reorientation. To start, I tried to take different types of courses ranging from project management, agile methods to social media and discovered a short one-day introductory course on medical writing at the Munich Biotech Cluster. Much to my surprise, this one-day course with Raquel Billiones and Abe Shevack, both senior members of EMWA, had actually laid the foundation of where I stand today. It was through this course that I came to know about EMWA.

This, in fact, was the source of light in the dark, seemingly never-ending tunnel. I enrolled myself for an extensive advanced training in Life Science Management at ATV Munich, to learn the fundamentals of clinical research and regulatory affairs. With the training, I found quite some overlap between my updated background and the professional profile of a

medical writer. I started to look for job opportunities in the field of medical writing and was invited to the next set of surprises. Every time I applied for a job, one aspect that overruled all other seemingly important attributes was the word *experience*. Was it not evident from the articles that I published that I could probably have some intellectual capacities? Sadly, the scientific articles that resulted from multi-institutional collaborations were reduced to just numbers. I was even advised to completely strike them off from my CV, leaving me no chance for a throwback. I gradually realised that I needed something more concrete and found the 48th EMWA conference at Vienna knocking at the door. I decided to attend the conference and enrolled for workshops that are part of the EMWA professional development programme. I must say, this has been an extremely fulfilling decision.

The friendly, open spirit for professional networking was what I found most interesting at the EMWA conference. Smiles from unknown members simply coming to share a word, technical suggestions, and above all, the feeling

of hope and positivity defined my days at the conference. Adding to this, the expert workshops in global regulatory documentation have been the most enlightening aspects of the conference. The depth of the technical input and high standard of the workshops were indeed noteworthy. Group discussions and laughing back at errors, but above all, learning and exploring a relatively new avenue has been more than exciting for me. With EMWA, I truly feel to be a member of a community of individuals who are trying to help each other and foster hope and success in an otherwise highly volatile and competitive field. Added to this, I realised that mentioning my participation at the conference on my CV kindled more positive responses from recruiters. As I write this article today, I feel more confident to find a new position in regulatory documentation, to be able to define my new professional identity, and above all “to strive, to seek, to find, and not to yield”.

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Veterinary Medical Writing

SECTION EDITOR



Karim Montasser

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Go, vets. Go!



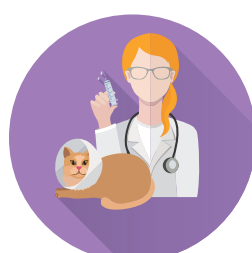
Like many medical writers, I started in another career first. For me, it was practising veterinary medicine in a clinic, then going into clinical research in humans, and then on to medical writing. Designing clinical trials, sample size calculations, and critically analysing literature became my passion along the way. But the more I learned, the more I realised that in veterinary medicine, we often base our treatment decisions on very limited information. Naturally, there is less money available for clinical studies in veterinary medicine compared to human medicine, so published studies often involve low subject numbers. Such small studies are

commonly not powered for clinical safety endpoints, are subject to bias, and could be seen as hypothesis-generating only.

Christmas and immunosuppressive medication

To give you a practical example: On Christmas Eve in 2017, our dog Estelle became ill and was diagnosed with autoimmune haemolytic anaemia. During my early years at the clinic, I treated this disease with dexamethasone and cyclosporine. Now, 20 years later, in a very modern and prestigious Munich clinic, our dog was initially treated with prednisolone, and – as this did not

bring the necessary treatment effect – with the very potent drug mycophenolate. Still, our dog deteriorated. A former colleague from my clinical days told me that I should not give up though; she had successfully treated dogs the clinic had given up on with azathioprine. So, which of the three therapies should be selected – the one I had good experience with in the past, the one my friend had good experience with, or the one the veterinary clinic was currently using? And soon the next question arose: Will our dog have a chance to survive at all? Despite all the supportive therapy, our dog was suffering tremendously, but on the other hand, she was only 6



years old, so we did not want to give up easily as long as there was a fair chance for survival.

What about evidence-based medicine?

I did what every medical writer would do – a literature search. But all I found were poor quality studies involving only a few dogs with insufficient length of follow-up (mostly only 30 days) and one meta-analysis about my dog's condition that included 380 dogs, though it did not refer to the different therapies.¹ My questions – which therapy is the best and what are the 1-year survival rates? – could not be answered from existing literature; it did not even give me a hint.

In Germany, veterinary medicine is one of the most demanding university degrees, and yet our treatment decisions are often based on personal experiences, beliefs, and limited data, rather than good quality evidence-based medicine. This should be unacceptable.

There are always options

In veterinary medicine, it would be utopian to ask for large-scale randomised controlled trials powered for clinical endpoints and registries with thousands of patients as it is done in human medicine; there would simply be no funding for it. Yet, as vets, we have learned to be creative and work with what we have. Indeed, there are several ways to improve research and the reliability of outcomes with little or no money, e.g.:

- Research Registration and Publication and Dissemination of Results as stated in the Declaration of Helsinki²
- Data sharing, as practised in human medicine^{3,4}
- Using data from practice management software. This option is already used for epizootic diseases, and there is one current pilot project with the University of Hannover (personal communication from VETERA).

But what was I to do as an individual that has been out of veterinary medicine for 20 years? I was thrilled when I learned about the webinar “Veterinary Medical Writing” by Sandra Goetsch-Schmidt and soon had the idea of

The more I learned, the more I realised that in veterinary medicine, we often base our treatment decisions on very limited information.

forming an EMWA veterinary medicine special interest group (vet-SIG). As is so often the case with good ideas – somebody else had it first. Sandra had gathered some people with interests for workshops and Tiziana von Bruchhausen, the EMWA president at that time, had the idea to form a vet-SIG group. Tiziana was instrumental in putting the strings together, and finally, the first vet-SIG meeting was held in May this year in Vienna.

This issue is about trends in medical writing – I truly believe veterinary medical writing can become a new trend. And with the vet-SIG group headed by Cemile Jakupoglu and Karim Montasser, EMWA can be spearheading the field. There are a myriad potential topics the group can cover, for example:

- Enhancing the awareness of veterinary medical writing
- Enhancing the training and hence quality in veterinary medical writing
- Fostering clinical research in veterinary medicine

In conclusion, the vet-SIG can help students get into medical writing, can help medical writers to become good “veterinary medical writers”, and can therefore help practising veterinarians make informed decisions, ultimately helping animals receive better treatment.

These are giant tasks – so no pressure, just a huge thank you to the group for their willingness to make a difference.

So, let's go vets!

Acknowledgement

I would like to thank Cemile Jakupoglu and Karim Montasser for their review and revision and Jessica Lin for her language editing.

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Beatrix Doerr

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The author with her dog Estelle, who had to be put to sleep 8 weeks after disease onset.



Medical Devices

SECTION EDITOR



Kelly Goodwin Burri

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Editorial

Medical devices should certainly be included on any list of trends in medical writing. That impression was only reinforced by the strong interest in device writing evident at this year's EMWA spring conference. The three medical device workshops on offer were fully booked and the expert seminar series was well-received. On a personal note, I was thrilled to see the growing opportunities for medical

device writing at EMWA. Starting out as a medical writer in 2004 the job fascinated me, but I had my doubts about whether it was a good fit for someone with an engineering and orthopaedic research background. Writing for pharma was clearly the training focus at my first EMWA conference back then, but in 2019, I am happy to say I have found my perfect medical writing niche!

In my first contribution as section editor

for Medical Devices, I would like to update you on the lively discussions that took place during the expert seminar series in Vienna. I also want to thank Beatrix Doerr for her many quality contributions as the previous section editor. I hope to continue her work with the same commitment to raising awareness about the exciting world of medical device writing.

Kelly Goodwin Burri

Expert Seminar Series: Updates from the medical device industry

The first expert seminar series on medical devices was offered following on the resounding success of the Medical Device Symposium held at the 2018 EMWA Conference in Barcelona. The session included three presentations from industry experts and concluded with a panel discussion.

Drug-device combination products: regulations and documentation

Mr Viky Verna (Vice-president, confinis ag, Switzerland, and formerly employed at the US Food and Drug Administration) kicked off the session with a presentation of the intricacies of regulations for drug-device combination products. The definition of combination products differs by regions but can be generally defined as a product consisting of two or more regulated products. Think of transdermal patches for drug delivery, inhalers, or pre-filled injection pens. In the United States these products follow a single regulatory pathway with specific requirements determined by the product's *primary mode of action* (PMOA). The PMOA is the most important therapeutic action of the product. In contrast combination products do not have their own separate regulatory pathway in Europe. Such products are regulated as either a device or medicinal product (drug) according to the *principle intended action* (similar to the PMOA) resulting in two main regulatory pathways:

- Medicinal products with a medical device component

- Medical devices incorporating an ancillary medicinal product.

In both cases, the combination products will need to comply with the European medical device regulation (MDR) or the in-vitro diagnostic regulation. This adds new requirements, including involvement of a notified body, for products that previously would have primarily followed the pharmaceutical approval route. The result is increased regulatory burden for both medicinal products and medical devices.

Innovation in combination products is occurring at a rapid pace. The evolving regulatory framework and expected industry growth present a unique opportunity for medical writers with an understanding of both the pharma and medical devices worlds. Watch this space as more regulations and guidance are expected to come.

Medical device approval in Europe, US and Japan: Similarities and differences

The second session of the morning featured Ms Myriam Stieler (Director Medical Affairs, BIOTRONIK AG, Switzerland) comparing the medical device approval processes in Europe, US, and Japan. The responsible parties providing approval in the three regions are the FDA (specifically the Center for Devices and Radiological Health) in the United States, the notified bodies in Europe, and registered certified bodies or the Pharmaceuticals and Medical Devices Agency in Japan. There are also some slight

differences in the risk-based classification of medical devices between the three regions. With the EU MDR implementation, approvals in Europe are expected to become more difficult. In contrast, the US and Japan are making efforts to harmonise their approaches that could potentially speed up the approval process in these regions. It was interesting to learn that for Japanese submissions there are no guidance documents available, and the process depends heavily on the individual reviewer assigned. It is essential to have local staff to support Japanese submissions. Ms Stieler also recommended to have consultations in parallel with the US and Japan whenever possible rather than expecting Japan to accept the position of US regulators. Overall the presentation provided useful insights for medical device writers supporting global submissions in these three regions.

Clinical evaluation, PMS/PMCF – Requirements for plans and reports requirements with impact on medical writing

Ms Susanne Gerbl-Rieger (Director Clinical Audit, TÜV SÜD, Germany) presented the perspective of a notified body in her talk on clinical evaluation and post-market surveillance activities of interest for medical writers. She began with an important disclaimer – expect many changes still to come. Many guidelines and common specifications are still being written, so this is a constantly evolving space. She strongly



recommended to read the MDR – all of it – and to keep monitoring for new developments as different aspects of the regulation are implemented. In particular, the common specifications for clinical investigations, clinical evaluation, and post-market clinical follow-up, when finalized, will provide more information and important guidance for medical writers. She stressed that quality counts, and there are many aspects for compliant medical writing. It will be essential for medical writers to be involved in the overall process of the clinical evaluation, and experienced medical writers can make an important contribution in the creation of key documents including the clinical evaluation plan (which includes a clinical development plan), clinical evaluation report, the summary of safety

and clinical performance, and the post-market clinical follow-up plans and reports. Ms Gerbl-Rieger also emphasised that manufacturers are not the only ones forced to adapt to the new regulations. Annex 7 of the MDR describes the specific responsibilities and requirements for the notified bodies under MDR, and the impact on notified bodies is significant. The increased resources needed to comply with MDR have resulted in an expansion of the resources at TÜV SÜD. They have almost doubled the size of their team to support the duties required under MDR.

Panel discussion

Beatrix Doerr and Art Gertel joined the speakers for the final expert panel discussion moderated by Racquel Billiones. A wide range of topics

were raised including the EUDAMED (the European Databank on Medical Devices), transparency issues for medical devices, and the use of registries to support post-market clinical follow-up requirements. EUDAMED will eventually serve as a repository for results of medical device studies, but it will take time until a large number of results are there. From an industry perspective, a consequence of MDR implementation could be a risk that small and innovative companies will not be able to afford to bring new products to the market. Overall the audience was very engaged, and the discussion continued well beyond the allotted time...only ending when we were finally asked to leave the room so that it would be ready for the next sessions.

Save the date:
**EMWA Conference in
the Czech Republic**

PRAGUE

May 5–9, 2020

<https://www.emwa.org/conferences/future-conferences/>

My First Medical Writing

Editorial

In this edition of My First Medical Writing, we welcome one of the first articles written by aspiring medical writer Mayya Sundukova. A physicist by training, Mayya pursued her PhD in neuroscience in SISSA, Italy, studying ion

channels, and then became postdoc at the European Molecular Biology Laboratory in Rome, Italy, to study pain mechanisms and develop tools for neuroscientists. Now, she is exploring several career opportunities in academia and industry and

developing her medical writing skills. It has been a pleasure working with her, seeing her grow day-by-day from constructive feedback, and now publishing her first article in *Medical Writing*.

Evguenia Alechine

Local photoablation of nerves to treat chronic pain

Chronic pain is bad, but no pain can be worse

Chronic pain has a devastating effect on those who suffer from it – almost 20% of adults in Europe.¹ Commonly used treatments block target molecules involved in the origin or maintenance of pain. Probably, there is no ideal molecule to block all types of pain. Nonsteroidal anti-inflammatory drugs, opioids, and antidepressants have limited success in many cases and cause serious side effects because of systemic delivery.² Also, from patients' and doctors' points of view, the adjustment of doses on an individual basis can be challenging.

However, no pain can be even worse. For example, patients with rare hereditary sensory and autonomic neuropathy type 5 (HSAN V) report insensitivity to pain and touch.^{3–5} Mutations in the neuronal growth factor (NGF) gene, which makes the resulting protein unable to function properly, are responsible for the lack of pain. NGF is essential for the development and survival of neurons that transmit pain, touch, and

temperature. Certain mutations in NGF lead to the absence of these neurons in affected patients. As they are unable to receive information about potentially damaging stimuli and dull pain, they suffer from repeated trauma to the joints, skin, and other tissues. Pain insensitivity disease is rare but very dangerous. On the bright side, understanding the role of mutations and characterisation of defective NGF has led to new ideas for treating chronic pain in other people. What if the source of pain could be eliminated locally at its origin – by “silencing” or ablating nerve endings in the skin?

Neuronal growth factor and potential analgesics

NGF has a prominent role in the onset and development of acute and chronic pain states as it binds to TrkA receptors. Apart from being important for nerve survival during development, in the adult nervous system TrkA receptors are expressed on sensory nerves that transmit pain and touch information.⁶ Volunteers

receiving NGF injections have reported enhanced responses to pain.⁷ A treatment based on blocking NGF with antibodies has provided pain relief in animal models and humans,⁸ but clinical studies were put on hold due to safety issues and side effects caused by systemic application.⁹

This article reviews a novel approach for pain treatment that was developed by my colleagues at European Molecular Biology Laboratory.¹⁰ Mutant NGF protein was used to stop pain at the periphery by locally photoablating pain-transmitting nerves with light-activated photosensitisers (Figure 1).

Light-activated therapy or photoablation for nerves in the skin

Light-activated therapy based on cell-targeted delivery of photosensitiser IRDye[®]700Dx (IR700) emerged in 2011 in cancer treatment and has been subject to clinical trials.^{11,12} The

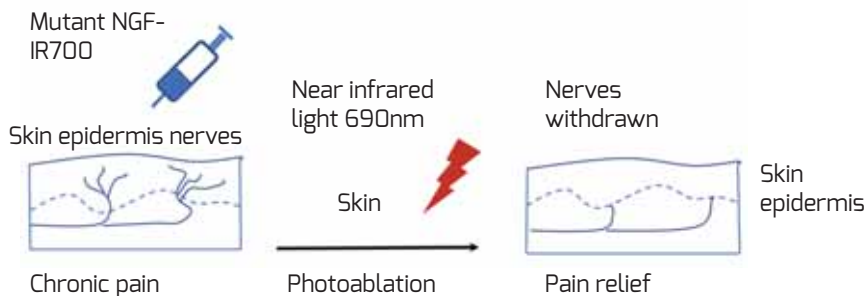


Figure 1.

Scheme for novel pain therapy. Mutant NGF protein was labelled with photosensitiser IR700 and injected into the skin of mice with chronic pain. Protein bound to pain-transmitting nerves, which express TrkA. Near-infrared light illumination activated the photosensitiser linked to the nerves and led to their photoablation. Nerves withdrew, stopping pain perception.

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approach relies on the targeted delivery of light-sensitive IR700 molecules to cells *in vivo*, thus sparing all off-target cells, and local near-infrared laser light application to activate the photosensitizer. Near-infrared light is harmless to living tissues and penetrates deeper than visible light, thereby allowing light to be applied to deeper layers of skin, muscles, or joints. Upon light activation, the photosensitizer IR700 releases reactive oxygen species, leading to cell death.

For pain treatment with light-activated therapy, knowledge about NGF mutations in patients with hereditary sensory and autonomic neuropathy came in handy. One particular mutation leads to a defective NGF protein that can bind the TrkA receptor but is unable to activate cell signalling, and therefore cannot evoke pain by itself.^{3,7} Engineered mutant NGF protein was labelled with IR700 and tested on cells *in vitro* and in mice *in vivo*.¹⁰ The mutant protein bound to TrkA-positive cells, and after exposure to near-infrared laser light, induced cell death within 1 day. Mutant NGF-IR700 was injected into the skin of mice and exposed to the light. Behavioural signs of pain were measured, such as paw withdrawal upon touching with special nylon fibres, a paint brush, or hot/cold stimuli.¹³ As expected, mice that received mutant NGF-IR700 and light showed no sensitivity to touch, due to specific local photoablation of pain-transmitting nerve endings in the skin.

Success of photoablation in preclinical pain models

Photoablation technology based on mutant NGF was successful in pain relief in preclinical models, where chronic pain arises from tissue injury.¹⁰ In different pain models, inactive bacteria were injected into the skin in a model of inflammation, a branch of sensory nerves that innervate the skin was cut in a nerve trauma model, and a toxic chemical was injected into the knee in a model of osteoarthritis and joint pain. After injury, mice would rapidly withdraw their paws when gently touched, showing behavioural signs of pain. Mutant NGF-IR700 was injected into the injury site and locally exposed to near-infrared light. After three consecutive days of treatment the mice were behaving normally without signs of pain, as before the injury. The effect lasted for at least 3 weeks. Authors counted the number of pain-transmitting nerves in skin sections from experimental and control mice. After the end of therapy, the nerves had withdrawn from the skin due to photoablation, blocking pain perception. However, 1 month after the end of the treatment, the nerves had grown back, and pain perception was recovered.

Perspectives

Results obtained in preclinical studies highlight the promise of photoablation therapy in humans. In the quest for more patient-friendly drug formulations (to replace injections), effective delivery of NGF-IR700 via a cream or micro-emulsion was established. Previously, a cream formulation containing a photosensitizer was used to treat a chronic skin itch condition in mice.¹⁵ Therefore, local non-invasive application and photoactivation of NGF-IR700 could provide a flexible option for personalised pain treatment based on the patient's sensations of pain and touch in the affected area, with minimal side effects.

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A proposal to define a new category of bad practice – The non-publication of clinical trial results

Poor research practices are usually classified as fraud (fabrication, falsification, and plagiarism) and questionable research practices. An editorial published in *Annals of Internal Medicine* accompanies a short paper describing the non-reporting of clinical trial results, based on 500 trials.¹ The survey concluded: “Large trials that are unreported for almost 4 or more years after completion are unlikely to be published later or to post results on ClinicalTrials.gov. The loss of evidence from these trials pertained to almost 90,000 participants.”² This is not the first publication to highlight the non-reporting of clinical trial results. The editorial develops the usual arguments, that non-reporting is contrary to the Helsinki Declaration, causes loss of public

trust, damages the quality of published research, etc. Volunteers who agree to participate in trials believe that their willingness to take risks will be useful for science. There is no justification for hiding trial results.

The editorial is clear and makes proposals to consider non-reporting as poor academic practice, with institutional responsibility:

Institutions should suspend investigators who do not report results within a year of finishing a trial, unless extenuating circumstances exist that impede reporting. These institutions also should consider lack of reporting in the academic promotion process. Funding agencies, such as the NIH, should withhold support from researchers who do not report results. Investigators who have completed clinical trials

*without reported results should be prohibited from applying for additional grants and current grants should be suspended. An even stronger incentive would be to hold institutions accountable for reporting results.*²

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Chinese authors overtake US researchers in research publications

The 2018 report of the International Association of Scientific, Technical and Medical Publishers shows that China was ahead of the United States in research publication output.¹ For 2.3 million English-language articles in peer-reviewed journals: *China has overtaken the US to become the pre-eminent producer of global*

research papers globally, with a share of about 19%, and on current trends its research spending will also exceed the US's by the early 2020s. The US accounts for 18% of global articles, while India has also seen rapid growth in recent years, and now produces 5% of global outputs, ahead of Germany, the UK and Japan, each on 4%.

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A preprint server for healthcare science: medRxiv

The first preprint server was developed by Cornell University in 1991 in physics: arXiv (<https://arxiv.org/>). The system, in which manuscripts are posted online after undergoing a minor period of moderation but before peer review by a journal, is a success. As of July 2019, arXiv has more than 1.5 million e-prints in the fields of physics, mathematics, computer science, quantitative biology, quantitative finance, statistics, electrical engineering and systems science, and economics. It was only later (2013) that a preprint server was created in biology/life sciences, and after a slow start, it is considered a success. BioRxiv (<https://www.biorxiv.org/>) is run by Cold Spring Harbor Laboratory (New

York). BioRxiv is expected to receive approximately 20,000 preprints per year. There are many preprint servers, for example those hosted by the Center of Open Science in Charlottesville, Virginia (<https://osf.io/preprints/>).

In medicine, projects have been announced since 2017, but many controversies exist. Some journal editors are opposed to the practice of submitting manuscripts before peer review. The creation of medRxiv was announced in June 2019, and it is possible to submit preprints at <https://www.medrxiv.org/>. MedRxiv is managed by three partners: Cold Spring Harbor Laboratory, the *BMJ*, and Yale University. A warning appears for each paper: "This article is a preprint

and has not been peer-reviewed. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice." Only research articles can be posted; case reports and opinion pieces will not be posted. A key screening question will be whether a preprint, if posted, has the potential to do harm to individual patients or the public. If in doubt, medRxiv will not post the preprint; the authors will be encouraged instead to publish only after peer review.

Will the presence of the *BMJ* in this project influence the behaviour of researchers and other medical journal editors?

Is the future of mega-journals as a major publishing platform threatened?

The arrival of mega-journals in the early 2000s has been acclaimed by the scientific community. These journals were open access and all research results became accessible. The model was to publish any research, provided that the methods were sound. The acceptance rate is around 60% to 70%. These mega-journals published all types of research and were not restricted to limited areas. An academic editor is appointed for each paper submitted and is responsible for the peer review process. Review notices are often posted online with the article. There is no large editorial board like the journals of learned societies. Some thought that 100 mega-journals would be enough to publish all the science. The economic model consists in charging authors publication fees when the article is accepted for publication, after peer review. The fee, known as an article processing charge, varies according to the journal, often in the range of \$1000 to \$4000.

The first mega-journal was *PLOS ONE*, created in 2006 by the Stanford University Library, and it published approximately 30,000



articles in the years 2013–2015. Competitors then appeared, including Springer's Scientific Reports. The annual number of articles published then declined slightly, as did the impact factor (from about 4 to 3).

Petr Heneberg analysed the bibliometric parameters of 11 megajournals and compared them with three control groups of gold open-access journals that do not satisfy the criteria for megajournals and that do not apply the concept of "sound science".¹

We show that nonselective megajournals have started to decline in all bibliometric parameters. These journals in particular have lost connection with the most advanced science as revealed by the decreasing citations to and from the top-tier journals. While some megajournals have underperformed on bibliometric parameters from the beginning of their existence, others experienced a short honeymoon period before declining. In contrast, major discipline-specific open-access journals remain competitive, and those published by less prominent publishers have even increased their performance. However, the discipline specific open-access journals also display decreasing citations to and from the top-tier journals.

The old model of learned society journals, of the prestigious journals of major publishers is not dead. The future of scientific journals still holds surprises for us.

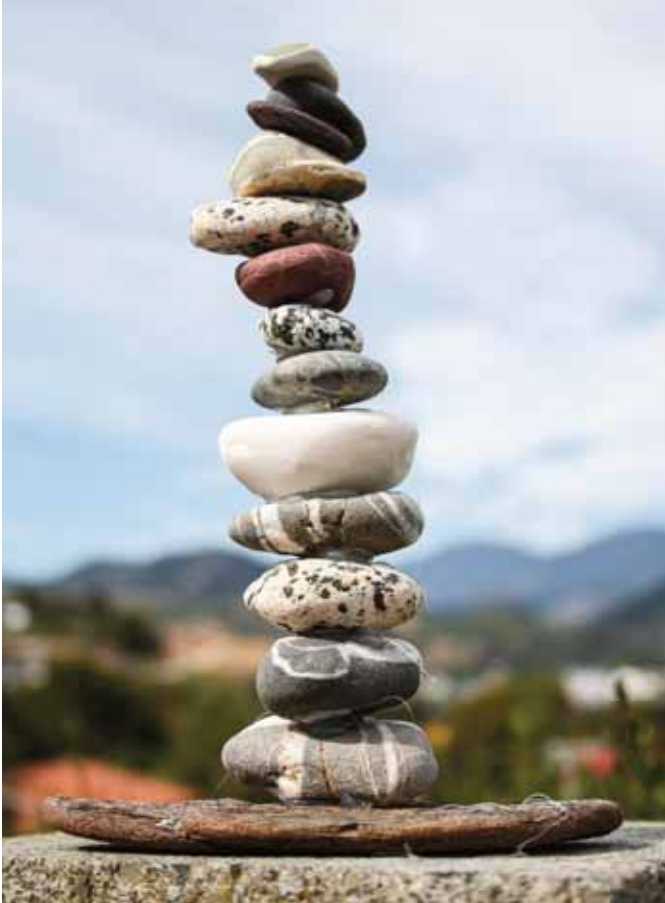
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Good Writing Practice

Syntactic number distraction

Circumlocution: Pre- or post-noun modification



Introduction

Excessive post-noun modification, usually as adjectival prepositional phrases, occurs frequently in research writing. Occurring less frequently, and less distracting, is excessive pre-noun adjectival modification (i.e., stacked modification). The post-noun adjectival modification often occurs after a noun functioning as an object of an adverbial prepositional phrase.

Experimental sections

Part 1 – Materials and methods section: Method

Example: excessive post-noun modification

Cells were washed twice with 1 x PBS and isolated by centrifugation for 6 minutes at 1600 rpm.

Revision

*Cells were washed twice with 1 x PBS and isolated by centrifugation (**6 min, 1600 rpm**).*

Notes

The tandem post-noun prepositional phrases are details of centrifugation. Such secondary level information can be demarcated from primary by using parenthesised noun phrases. Even the details of washing could also be so reduced to the noun phrase (*1 x PBS*).

In the Revision, *minutes* can be abbreviated to *min*, which lacks plurality and punctuation. Furthermore, deletion seems to prompt deletion; that is, with the deletion of the prepositions and abbreviation of the units, *isolated by centrifugation* seems a circumlocution of simply *centrifuged*. The verbs in the sentence are now parallel: *were washed ... and centrifuged*.

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Part 2 – Materials and methods section: Materials

Example: excessive post-noun modification

The sample from the University of North Carolina two-phase randomised clinical trial comprised preadolescent children with increased overjet (>7 mm), in mixed dentition, a year before peak pubertal growth, and without previous orthodontic treatment.

Revision

The sample was from the University of North Carolina two-phase randomised clinical trial. The inclusion criteria were (1) preadolescent children a year before peak pubertal growth, (2) increased overjet (>7 mm), (3) no previous orthodontic treatment.

Notes

In the Example, a series of four prepositional phrases conveying primary information is torturous to comprehend in contrast to a numerical listing of noun phrases in the Revision. The enumerated listing facilitates comprehension, a facilitation that is further enhanced by combining related criteria. Furthermore, such information insight enables in mixed dentition to be self-evident for children of that age.

Part 3 – Results section: Data-based observation

Example: unnecessary post-noun modification

Skeletal muscle hypertrophy was accompanied by an acceleration of protein synthesis and an increase of A1B uptake.

Revision 1

*Skeletal muscle hypertrophy was accompanied by **accelerated** protein synthesis and **increased** A1B uptake.*

Revision 2

*Skeletal muscle hypertrophy was accompanied by **increased** protein synthesis and A1B uptake.*

Notes

In the two sets of tandem prepositional phrases, not only do the nouns *acceleration* and *increase* add to noun density and abstraction, but their presence each necessitates a contiguous preposition: (*acceleration of; increase of*). Revision 1 involves syntactic reduction of a prepositional phrase into the adjectival past participles *accelerated* and *increased*. In Revision 2, with the deletion of the preposition and the article, the subtle distinction between *accelerated* and *increased* becomes unintended.

Part 4 – Results section: Data-based observation

Example: excessive pre-noun modification

Extremely low birth weight infants were the primary occupants of the neonatal critical care unit.

Revision

*Extremely **low-birth-weight** infants were the primary occupants of the neonatal critical care unit.*

Notes

Three coordinated adjectival pre-modifiers will be mildly distracting to an expert in the discipline, but more so for a non-expert. In the Revision, virtual unstacking is accomplished by hyphenation, which unites the three modifiers so that they function as one unit. *Low* is an adjective, but *birth* and *weight* are nouns functioning adjectivally. Thus, the three pre-modifiers are adjectival in function. The fourth modifier *extremely*, probably a cumulative modifier (i.e., modifies *low-birth-weight*), as most *-ly* adverbs, is usually not hyphenated.

Contextual sections

Part 1 – Introduction section: Research problem pertinent background

Example: excessive post-noun modification

The inter-compartment heterogeneity, such as posterior expression of Notch, Serrate, and Wnt 7a, and anterior expression of BMP-4 and Tenascin, results in an A-P asymmetry within the feather buds.

Revision

The following examples of inter-



*compartment heterogeneity result in an A-P symmetry within the feather buds: posterior expression (**Notch, Serrate, and Wnt7a**) and anterior expression (**BMP-4 and Tenascin**).*

Notes

The examples of posterior and anterior expression are secondary information, which can be syntactically reduced from prepositional phrases into parenthesised noun phrases.

Part 2 – Introduction section: Research problem pertinent background

Example: excessive post-noun modification

During tooth morphogenesis, Syndecan-1 expression is essential for the condensation of dental mesenchyme.

Revision 1

*During tooth morphogenesis, Syndecan-1 expression is essential for **dental mesenchyme condensation**.*

Notes

In the Example the two contiguous post-noun prepositional phrases can be syntactically melded. The Revision is accomplished by transposition of the object *dental mesenchyme* of the second prepositional phrase into a pre-noun modifier (*dental mesenchyme*) of the object of the first prepositional phrase. Thus, melding reduces the tandem prepositional phrases into one.

Part 3 – Introduction section: Research problem pertinent background

Example: excessive post-noun modification

Orthopaedic surgeons are setting arbitrary restrictions on the return to activities, with the intent of protecting the graft from injury.

Revision 1

*Orthopaedic surgeons are setting arbitrary restrictions on the return to activities **to protect** the graft from injury.*

Revision 2

***To protect** the graft from injury, orthopaedic surgeons are setting arbitrary restrictions on the return to activities.*

Notes

The tandem prepositional phrases *with the intent of protecting* is narrative and wordy. In Revision 1, the infinitive phrase *to protect* can be used to convey intent. Repetition of

the preposition *to* is redundant with the infinitive marker *to*, which is resolved by transposition of the infinitive phrase to the sentence start position.

Part 4 – Introduction section: Objective + experimental approach

Example: excessive pre-noun modification

Angiopoietin regulation of choroidal endothelial cell MM-P and MM-9 activities was investigated by gelatin zymography.

Revision

*Angiopoietin regulation of MM-P and MM-9 activities **in choroidal endothelial cells** was investigated by gelatin zymography.*

Notes

There are five pre-modifiers before *activities* that impede comprehension. Transposition of *choroidal endothelial cells* into a post-noun position separates the type of activities from their location and provides a balance between the number of pre- and post-modifiers, a balance that enhances comprehension.

Summary

The distribution of the two examples of excess pre-noun modifiers and the six examples of post-noun modifiers is equal between Experimental sections (Results) and Contextual sections (Introduction). The rhetorical severity of these examples is dissonance and possibly impeded comprehension. Revision of excess pre-modifiers can range from hyphenation (whereby the pre-noun modifiers are visually transformed into one unit) to transposition (whereby a pre-modifier is transposed to a post-modifier). In contrast, revision of post-modifiers involves a variety of syntactic options: melding of tandem appositives; parenthesis or listing (both of which involve syntactic reduction of a prepositional phrase into a noun phrase), or conversion into another syntactic unit (e.g., infinitive phrase).



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Regulatory Public Disclosure

Editorial

In the world of regulatory public disclosure (RPD) things rarely stay the same for long. This regular RPD section in *Medical Writing* and EMWA's RPD SIG help you keep up.

On June 26, 2019, the FDA concluded the recruitment phase of its clinical data summary pilot programme in which one sponsoring pharmaceutical company voluntarily participated. The FDA published a Federal Register notice (Docket No. FDA-2019-N-2012) seeking feedback on the pilot, the comment period for which closed on August 26, 2019. The FDA solicited feedback through a series of stakeholder questions designed to gather insight into potential benefits or risks, resource requirements, and challenges of the FDA publicly releasing a limited number of sections from certain CSRs at the time of marketing approval. The FDA also released a new integrated template that will be used to document the FDA's review of new drug applications and efficacy supplements. The same Federal Register notice sought public comment on the new integrated template. Art Gertel (CORE Reference Strategist) and I submitted our comments in July 2019. This important development is of interest to our professional community because this opens a potentially new and alternative pathway for public disclosure of clinical information to that of the publication of clinical study reports

(CSRs) and clinical summary documents that we have to date seen from the EMA and Health Canada. (See Status updates from regulatory regions box for links.)

EMA continues to hold clinical data publication activities. An EMA Management Board meeting is planned in October 2019 to review the situation, but as these activities are not listed as 2019 priorities, I expect that there will be little, if any, movement.

On a more positive note, EMA's improved methodology for the IT system – the Clinical Trials Information System (CTIS) – that will enable the EU's Clinical Trial Regulation to come into force, will hopefully lead to improved delivery. Member states and stakeholders (including business experts) are now directly engaged in the development of CTIS to ensure that their expectations are taken into account. This means that business expert representatives may continuously review, select, and verify CTIS functionalities (See Status updates from the regulatory regions box for links)

This issue's RPD feature article comes from Vivien Fagan. Viv tells us about her transition from the field of dedicated regulatory medical writing into the world of clinical trials disclosure within a global clinical research organisation environment and how she melds the two to ensure disclosure-readiness from the outset. Viv's article includes some great tips on gaining efficiencies from results reporting through to

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summary results posting (Clinical trial disclosure: Perspective from a medical writer for a contract research organisation, p. 52).

Clarity and Openness in Reporting: E3-based (CORE) Reference, developed by the Budapest Working Group (BWG), a partnership of AMWA and EMWA, is a user manual designed to help medical writers navigate relevant guidelines as they create clinical study report (CSR) content. CORE Reference was one of two principal sources used by TransCelerate BioPharma Inc., an alliance of biopharma companies, in the development of its CSR Template released in November 2018. A new CORE Reference open access article, was published in August 2019 in the BioMed Central journal, *Research Integrity and Peer Review*.

The publication is available at <https://doi.org/10.1186/s41073-019-0075-5>. Key resources from this publication are posted on the CORE Reference website and are directly accessible via the links in the box below. To whet your appetite, we also reproduce here, with permission, the abstract from the original *Research Integrity and Peer Review* article.

Kind regards, Sam



Abstract from:

Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table

Hamilton S, Bernstein AB, Blakey G, Fagan V, Farrow T, Jordan D, Seiler W, Gertel A. on behalf of the Budapest Working Group

Background

CORE (Clarity and Openness in Reporting: E3-based) Reference (released May 2016 by the European Medical Writers Association [EMWA] and the American Medical Writers Association [AMWA]) is a complete and authoritative open-access user's guide to support the authoring of clinical study reports (CSRs) for current industry-standard-design interventional studies. CORE Reference is a content guidance resource and is not a CSR template.

TransCelerate Biopharma Inc., an alliance of biopharmaceutical companies, released a CSR template in November 2018 and recognised CORE Reference as one of two principal sources used in its development.

Methods

The regulatory medical writing and statistical professionals who developed CORE Reference conducted a critical review of the TransCelerate CSR template. We summarise our major findings

and recommendations in this communication. We also re-examined and edited the Version 1 CORE Reference Terminology Table that we first published in 2016, and we present this as Version 2 in this communication.

Results

Our major critical review findings indicate that opportunities remain to refine the CSR template structure and instructional text, enhance content clarity, add web links to referenced guidance documents, improve transparency to support the broad readership of CSRs, and develop supporting resources.

The CORE Reference "Terminology Table" Version 2 includes estimand as a defined term and an adaptation of the original 'worked study example' to incorporate the recently evolved concept of "estimands".

Conclusions

As TransCelerate's CSR template represents an

important milestone in authoring CSRs, we offer CSR authors advice and recommendations on its use, similarities, and differences with CORE Reference and advise them to consider shared interpretations between the two.

Registration

CORE Reference is registered with the EQUATOR Network. The TransCelerate CSR template is not registered with any external organisation to the knowledge of the authors of this paper.

Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table: <http://dx.doi.org/10.1186/s41073-019-0075-5>

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Status updates – from regulatory regions

Europe

1. Priority goals for EMA in 2019 (https://www.ema.europa.eu/en/documents/work-programme/ema-activities-other-highest-priority-activities-category-1-activities-will-continue-2019-annex-1_en.pdf); EMA guideline development and clinical trial data publication on hold (<https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexite>).
2. CTIS project methodology updated in June 2019 to engage stakeholder input: <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation>.
3. EU guidance documents applying to clinical trials are described in the Clinical Trials Regulation (EU No. 536/2014). A draft Q&A document dated June 2019 has been released and submitted for discussion to the Expert Group on Clinical Trials. Some sections of the Q&A are incomplete and we can therefore expect this document to be updated. There is a

lot of information in the Q&A, as we might expect – do note Section 6 "Submission of Clinical Trial Results" (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation_5362014_qa_en.pdf).

4. Reporting of clinical trial results in EudraCT is the direct responsibility of sponsors. The EMA and the Heads of Medicines Agencies have issued a joint letter to remind sponsors of their responsibilities. They particularly mention underreporting by non-commercial sponsors and provide links to resources that all stakeholders may find useful in meeting their reporting obligations. This July 3, 2019, joint letter (https://www.ema.europa.eu/en/documents/other/joint-letter-european-commission-ema-hma-stakeholders-regarding-requirements-provide-results_en.pdf) and this press release (https://www.ema.europa.eu/en/news/call-all-sponsors-publish-clinical-trial-results-eu-database?mkt_tok=ey) are posted on the EMA's Clinical Trials in Human Medicines page

(<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials-human-medicines>).

United Kingdom

5. Further detailed guidance published Sept 2019 (<https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexite-deal>) includes a major update on all aspects of medicines and devices regulation in the UK in the event of a no-deal Brexit. See Section 3 "Clinical trials of Investigational Medicinal Products" for details relevant to the clinical trials community.
Register here to make MHRA submissions: https://www.gov.uk/guidance/making-submissions-to-the-mhra-in-a-no-deal-scenario?utm_source=8f1e190e-4364-43e3-b35a-4201a261b4c6&utm_medium=email&utm_campaign=govuk-notifications&utm_content=daily

United States

6. The FDA concluded the recruitment phase of its clinical data summary pilot programme (<https://www.fda.gov/drugs/development-approval-process-drugs/clinical-data-summary-pilot-program>) and published a Federal Register notice seeking feedback on the pilot and a new integrated template (<https://www.federalregister.gov/documents/2019/06/27/2019-13751/new-drugs-regulatory-program-modernization-improving-approval-package-documentation-and>). The applicable Docket No. FDA-2019-N-2012 for “New Drugs Regulatory Program Modernisation: Improving Approval Package Documentation and Communication”, including the background documents and comments received, is at: <https://www.regulations.gov>. Just insert the docket number into the search box and follow the prompts. Comments from Sam Hamilton and Art Gertel are also available at https://www.core-reference.org/media/1053/docket-fda-2019-n-2012_answers-to-fda-qs_sh-and-ag_150719.pdf.

Eastern Mediterranean

7. On July 25, 2019, the Lebanese Clinical Trials Registry (LBCTR) became a member of the Primary Registry Network of ICTRP.

LBCTR is also becoming a data provider and trials registered with LBCTR will be added to the ICTRP database. LBCTR was established by the Lebanese Ministry of Public Health with the support of the WHO Lebanon office and the WHO Eastern Mediterranean Regional Office (EMRO) IT team. This new registry will contribute to research transparency in the EMRO region and will ensure the registration of all clinical trials conducted in Lebanon (<https://www.who.int/ictrp/news/en/>).

... from the journals

8. Miller J, et al. Sharing of clinical trial data and results reporting practices among large pharmaceutical companies: cross sectional descriptive study and pilot of a tool to improve company practices. *BMJ* 2019; 366:l4127 (<http://dx.doi.org/10.1136/bmj.l4127>) shows that “...Despite noteworthy commitments by some companies to share participant level trial data and a willingness by others to improve their policies, many companies still have substantial room for improvement.”
9. Evuarherhe O, et al. Professional medical writing support and the quality, ethics and timeliness of clinical trial reporting: a systematic review. *Research Integrity and Peer Review* volume 4, Article number: 14

(2019) (<https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-019-0073-7>) describes the relationship between professional medical writing support for authoring CSRs, and the quality, ethics and timeliness of publications reporting clinical trials.

10. Clinical trial registry reporting: a transparent solution needed ([https://doi.org/10.1016/S1470-2045\(19\)30350-X](https://doi.org/10.1016/S1470-2045(19)30350-X)) is a *Lancet* editorial that highlights the shortfall in trial registry results reporting by universities in Europe. University triallists are encouraged to take the lead and make the necessary uploads, and it is suggested that clinical trial registries could send out automated email reminders.
11. Rocher L, et al. Estimating the success of re-identifications in incomplete datasets using generative models. *Nature Communications*, 2019; 10 (1) (<https://www.nature.com/articles/s41467-019-10933-3>) shows that allowing data to be used, to train artificial intelligence algorithms, for example is risk laden. This new research shows that once bought, the data can often be reverse engineered using machine learning to re-identify individuals, despite the anonymisation techniques.

CORE Reference

- Hamilton S, Bernstein AB, Blakey B, et al. Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table. *Research Integrity and Peer Review*. <https://doi.org/10.1186/s41073-019-0075-5>.
- 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 22,500+ (Sept 2019)
- CORE Reference News Summaries: <https://www.core-reference.org/news-summaries> and “real time” updates: <http://www.core-reference.org/subscribe>



Resources

1. The EMA's Scientific Advice Working Party released “Draft qualification opinion of clinically interpretable treatment effect measures based on recurrent event endpoints that allow for efficient statistical analyses” – which is relevant for development of estimands, i.e., clinically interpretable treatment effect measures (https://www.ema.europa.eu/en/documents/scientific-guideline/draft-qualification-opinion-clinically-interpretable-treatment-effect-measures-based-recurrent-event_en.pdf). Development of medicines is becoming increasingly estimand-based, and as we all try to better understand this developing field, I urge you share this opinion with your statistical colleagues. See Table 2 at <https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-019-0075-5/tables/2> for incorporation of estimand into the original CORE Reference Terminology Table worked example

2. The Center for Biomedical Research Transparency aims to increase transparency in biomedical research reporting. This *ISMPP Newsletter* reports the content that was presented in a free-to-attend meeting in the EU in May 2019 (<https://ismpp-newsletter.com/2019/06/18/introducing-cbmr-its-transparency-initiatives-and-ambassador-network/>). More of these meetings are planned for the EU and US. Although the topics of interest relate predominantly to publications transparency, (and less so to clinical data transparency in the clinical trials industry), free meetings like this where there is overlap of these areas may be of interest.
3. EMWA RPD SIG members' page: [https://www.emwa.org/members/special-interest-groups/regulatory-public-disclosure-sig/Subpage for disclosure-related regulatory news updates](https://www.emwa.org/members/special-interest-groups/regulatory-public-disclosure-sig/Subpage%20for%20disclosure-related%20regulatory%20news%20updates): <https://www.emwa.org/members/special-interest-groups/regulatory-public-disclosure-sig/regulatory-news-emwa-newsblast/>.



Laura A. Kehoe
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Out on Our Own

Welcome readers,

It is a pleasure for me to share an article in this issue from our previous Out on Our Own (OOOO) section editor, Satyen Shenoy. For those that don't know him, where have you been? Satyen, as he will describe, has been on the EMWA scene for many years. In Vienna, Satyen hung up his Freelance Business Group chairperson hat and placed it on my head. He went into a period of contemplation and asked to contribute to this OOOO issue. Over the years, one question kept cropping up and continues to, how to volunteer for EMWA? He summarises the volunteering opportunities throughout the EMWA organisation, this of

course is not limited to freelancers, but as he points out, many volunteers within the organisation are indeed freelancers. He offers a great overview of the structure of EMWA and how it is run and where volunteers are needed. Get involved!

Also in Vienna, I spoke to two enthusiastic attendees of the Freelance Business Forum, Diana Ribeiro and Matías Rey-Carrizo, who were experiencing it for the first time. When I approached them after the congress their enthusiasm was still high, and they both agreed to write articles on their personal journeys into freelancing. As I mention to many people, medical writing is not a degree that one can

complete and then step into the career path. We all have varied backgrounds and are from different countries, and often have fallen into medical writing. I love hearing the paths that other freelancers have taken and always along the way we have gained experiences that can be vital to share with others who are contemplating the freelance direction. Diana and Matías both offer us their journey and how they ended up in the Freelance Business Forum. Many thanks to all our authors for sharing their views and advice.

Happy reading!

Laura A. Kehoe

Growing as a freelancer through volunteering

In my three-and-a-half years as a volunteer for EMWA's Freelance Business Group (FBG), I have had the opportunity at our biannual conferences to meet and network with many EMWA members, most of them freelancers. What has encouraged me particularly has been the increasing number of new faces I see attending the Freelance Business Forum (FBF); this indicates that freelancing is fast becoming an attractive option for medical writers. One of the questions that I have received from freelancers over and over again, in person and by email is – "how can I volunteer for EMWA?" Now, since I pretty much serendipitously got involved with EMWA after being invited to help the FBG as a freelance advocate, I have often crafted an impromptu and patchy reply, not entirely to my satisfaction. So, in this article I would like to answer this question comprehensively and list different volunteering opportunities as a guide for those freelancers who are interested in volunteering for our organisation.

Executive Committee, subcommittees, and special interest groups

EMWA activities are exclusively managed by volunteers, of course, with an efficient administrative support from our office staff in Macclesfield, UK. Whether it be members

servicing on the Executive Committee (EC) or as table leaders at the FBF, we are all volunteers. Freelancers get involved by being EMWA Presidents (as with the current president, Barbara Grossman) and EC members, and also serve on various subcommittees and special interest groups (SIGs). The five volunteers on the FBG subcommittee are all freelancers. The point I

want to make is that freelancers are actively involved in the running of EMWA.

In recent years, numerous programmes such as the symposium and expert seminar series at the summer conferences have been initiated and these require assistance and inputs. In addition, various SIGs – medical communications, veterinary, medical devices, etc., have been launched, all of which requires active volunteers. So, how does one go about finding these opportunities to volunteer? Well, you could read about them on the EMWA website or in the monthly Newsblast in your email inbox or by checking EMWA's social media portals. You could also drop a line to our head office (info@emwa.org) and they will connect you with subcommittee/SIG chairs.

Workshop leaders

One of EMWA's most sought-after programmes is the EMWA Professional Development Programme (EPDP), which organises workshops at EMWA conferences. With over 120 different workshops that cover a range of subjects, the EPDP provides quality training to medical writers and helps them develop new skills. The EPDP is also a perfect opportunity for freelancers with a passion for teaching, such as myself, to volunteer as workshop leaders. The process is well-regulated, in that potential workshop leaders



Satyen Shenoy handing over the chairpersonship to Laura A. Kehoe at the Vienna EMWA congress.

need to send in a proposal to the EPD Committee (EPDC) for a workshop, which is then evaluated for suitability and other factors. Once approved and refined, the workshop is then offered at future conferences. It was a fabulous experience when an EMWA colleague and I underwent the process and developed a useful workshop which was first offered at the autumn conference last year in Warsaw. And from a personal viewpoint, it felt good to be able to share with the workshop attendees the knowledge I have gained in my career as a scientist and a medical writer. So, if you wish to design and present a workshop at EMWA conferences, do get in touch with the Chair of the EPDC, Marion Hodges.

EMWA Ambassador Programme

The EMWA Ambassador Programme is another recent initiative launched to raise general awareness of medical writing as a profession; as well as to introduce EMWA to those finishing their education, and looking for career options. Towards this, volunteers in the Ambassador Programme visit university career events, medical conferences, medical communication events, etc., and make presentations on medical writing on how a EMWA membership helps one develop as a medical writer. Since one of my goals as a freelance medical writer is to help develop the medical writing profession in Germany, I signed up as a volunteer at the last EMWA conference in Vienna. Besides joining the programme to canvas EMWA's outreach, there's another way of volunteering to help the programme. And that is through gathering information in your area on career events, job fairs, and passing on the information to the Chair of the Ambassador Programme, Abe Shevack. In addition, if you have contacts at universities and research institutes, it would be worthwhile exploring the possibility for the nearest volunteer with the programme to make a presentation to the post-graduate students at these places.

Future issues:

We are always looking for people to contribute to the future issues of the OOOO. Here, are a few themes that we'd like to address, so if you have something to say and want to contribute please get in touch.

1. From freelancer to business entrepreneur
2. Which path to take, MedComms or regulatory? How? And what's the difference?
3. "Experienced" vs "non-experienced" freelancers: stepping into freelancing too early?

If you have any additional topics that you'd like to see in our section, then we are always happy to hear.

Webinars programme

For the past couple of years EMWA's Webinar Programme has been hosting monthly webinars on a variety of topics relevant to the medical writing profession – from latest regulatory changes to improving writing skills. Besides being a good source of information and tips for EMWA members, this programme also allows presenters to share their particular expertise with their fellow medical writers. So, if you wish to present a webinar on a topic that you are proficient in then you could contact the volunteers, Laura Collada Ali or Carolina Rojido, who oversee the programme and discuss it with them.

Local networking

While EMWA conferences are a fantastic opportunity to expand one's networks and get to know other freelancers, it is not always practical for freelancers to attend all of these. To address this, freelancers around Europe have taken to local networking and organising informal get-togethers. While this is rather well-established in the UK, at present local networking is gaining ground in the Netherlands, France, and Germany. The advantages for participating in these are numerous. From getting a sense of camaraderie, to shooting the breeze with fellow professionals, to catching up on and discussing latest developments in our field; freelancers tend to benefit from such interactions. Such events are also useful for introducing non-members to EMWA and its activities. So how could you volunteer? Look for other medical writers in your area, get connected, and start forming a network. And yes, do talk about EMWA to non-members.

Writing for Medical Writing or the website

EMWA's journal, *Medical Writing*, has developed in leaps and bounds in the past few years with contemporary and relevant themes, feature articles that are open access, an extended content, and getting listed in indices such as Scopus, EBSCO, and Google Scholar. Besides this, it still continues to have the Out On Our Own

(OOOO) section which is dedicated to freelancing issues. Recently, a new online feature called "Web Editorial", which publishes opinion pieces on relevant topics, has also been added to the EMWA website. During my tenure as the editor of OOOO, I have had the privilege to bring to print a number of articles from freelancers offering tips and tricks, their opinions and perspectives on business management, etc. To give you an idea on how valuable these articles are, I would like to share an anecdote. When I decided to launch my freelance consultancy in Germany, I had no idea where to start. One of the senior EMWA members, whom I had met at a conference, advised me to look into the OOOO archives in the Freelance Resource Centre on the EMWA website. I did so and found two articles by another freelancer based in Germany who had gone through the hoops a few years earlier and I found these to be immensely informative. Since then, I have been actively requesting freelancers to volunteer to write articles for the OOOO. Your stories and experiences, your observations and pointers; these could be helpful to your fellow freelancers. And if you wish to share these with us then do contact the Editor-in-Chief of Medical Writing, Phil Leventhal, the Editor of OOOO, Laura A. Kehoe, or our Website Manager, Diarmuid De Faoite.

Conference participation

Since we freelancers are primarily business owners, network development is the key to our success. EMWA conferences are a great venue to engage in networking with other freelancers and non-freelancers, some of whom will also be volunteers. From these, you will get to hear about new initiatives and opportunities to help out, and you could volunteer your thoughts and ideas. It is a classic feed forward process where, with each conference you attend, your network grows and you will have more opportunities to share your opinions and perhaps even be invited to join a committee or propose a new workshop.

While I may have serendipitously been offered an opportunity to be an EMWA volunteer, it is an experience that does give me immense satisfaction. Like most wannabe volunteers, I too felt unsure at the start, wondering if I would ever be able to make time or contribute my best efforts for the FBG and EMWA as a whole. But with some fantastic support and encouragement, I did give my time and my best. At present, as a workshop leader and a volunteer on the ESS committee and the Ambassador Programme, I do feel like I have given something to an organisation that has given me so much, most important of which is an

identity as a professional medical writer.

In Vienna, I resigned from the FBG subcommittee to make way for another eager volunteer to join and have the opportunity to contribute. In Vienna, I also handed over the chairpersonship of the FBG to Laura A. Kehoe, a fellow EMWA member and a dear colleague

who I first met when she gamely volunteered to be a table leader at the FBF at the autumn conference in Cascais in 2017. I must add that it was her first FBF. And that is the best part about EMWA – new volunteers always step up to the plate, bringing with them fresh ideas and a desire to help our organisation grow. And grow we shall.

Happy volunteering!

Satyen Shenoy

Describe Scientific Writing & Communications

Getting into medical writing through the Freelance Business Forum

There is nothing like looking, if you want to find something. You certainly usually find something, if you look, but it is not always quite the something you were after.

J.R.R. Tolkien, *The Hobbit*

Not having the usual academia or industry background made me question if I could throw myself into the freelance medical writing world and be successful. Attending the Freelance Business Forum (FBF) in Vienna gave me confidence and a clearer vision for what I want my journey to be.

From over-the-counter to writing

My journey to become a medical writer is a recent one. For over 10 years I worked in healthcare, first as a pharmacy technician and later as a pharmacist. In both roles I kept longing for some other aspect of communication than the simple-yet-complicated interaction with patients at the pharmacy counter. Besides talking to people, I enjoyed writing information handouts and drug interaction reports for patients. I was also known for being always busy researching something and studying new (and old) medications. Over time, I realised that I would like to do more work in writing and communication, and less in retail pharmacy.

In early 2018, I connected with Maria João Almeida on LinkedIn. She is a Portuguese medical writer and a member of EMWA's Executive Committee. After answering my

questions (namely: what is a medical writer?), she directed me to the EMWA website. I looked around the website, searching for some kind of information that allowed me to feel comfortable in saying that I had the 'right' profile to be a medical writer.

I never found that magical piece of confirmation, but I did find a webinar open to non-members. There, Satyen Shenoy explained the benefits of EMWA for freelancers. That swayed me into becoming an EMWA member and gave me confidence to acknowledge that with enough planning and hard work I could build a new career as a freelance medical writer.

Next stop: Vienna, Freelance Business Forum

One thing that came up again and again in the OOOO articles of *Medical Writing* journal was the benefits of attending the FBF. Everyone wrote about how great it was to get to know fellow freelancers – it was like having a tribe inside the medical writing community. So, when I signed up to the Vienna conference, it was a no-brainer to sign up to the FBF too.

I was looking forward to attending the roundtable discussions, going from table to table like a bee in a meadow, hearing what everyone had to say.

In Vienna, after an opening speech by Satyen and a short presentation from a fellow experienced freelancer, the tables were set up. The table leaders moderated the discussion of their assigned table, giving prompts and keeping the conversation going. It was a happy affair, with

drinks and snacks, and I learned useful tips about medical writing and freelancing. I also discovered that medical writers are very resourceful: they can host a round table discussion without a table of any kind! There were not enough tables, and Carolina Rojido was left tableless for her discussion, but she did not let that get in her way. It's all about people, ideas, and having a great conversation, after all.

Sharing, learning, and having fun

Time flew during these discussions, and I am only sorry that I did not take part in more of them. I would also like the tables to have been a bit bigger. With so many of us attending the forum, there was a kind of a bullseye forming around each table, making the ones in the outer circles having to strain to hear the discussion and making it harder to participate in it.

The air was thrumming with energy. I talked with many like-minded people, all in great spirits, keen to support each other in their freelance journeys.

I even got to talk with Satyen, but before I could thank him for putting up the webinar that ultimately brought me to EMWA, pride got in the way. You know, I am from Cascais, where a previous EMWA conference was held and praised by Satyen in his opening speech. And this made my proud inner geek deliver a crash course on pronunciation ... Satyen was graceful enough to pronounce "kesh-kay-shh" to my satisfaction, but I am fully expecting some kind of revenge on an forthcoming event.

In the end, I left the FBF thankful for all the networking and learning. I would like it to be longer. I would like it to have more information. More discussion, more sharing.

In a nutshell, I want more FBF.

Diana Ribeiro

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Networking: The important part of the Freelance Business Forum

I would like to share with you my thoughts and impressions on the Freelance Business Forum (FBF), in case it may be of any interest to other freelance rookies. But first, please allow me to introduce a smidgen on myself. Like many medical writers, I did not know this profession even existed until shortly before falling head over heels into it. A former PhD colleague told me about medical writing, and although she was not very specific about what the job entailed – to describe it is even hard for some of us to this day – it still caught my attention.

After my post-doc, when the moment came to choose a new career path and after digging up some information on the field, I was completely resolved to become a medical/scientific writer. As some of you may know, a long academic background is not always the preferred choice for recruiters, but to make matters worse, my degree is in chemistry, far from the medicine, pharmacy, or biology usually required in many job advertisements. This meant I got the door slammed in my face on several occasions. However, after earning AMWA's Essential Skills Certificate, attending EMWA's internship forum in Barcelona, and getting tips and advice from well-seasoned medical writers, I was finally contacted by someone eager enough to place her trust in me for a job.

Fast forward one year and there I was, an

accomplished medical/scientific writer at my second EMWA Conference in Vienna on May 2019. I signed up for the FBF without knowing too much what to expect from it. I had read the experiences of Laura, Allison, and Sally (cf. OOOO Vol. 28 Num. 1) with the freelance directory, so my only expectation was to get more opinions on it from my colleagues.

The first thing that struck me at the FBF was the wine; after a whole day of workshops running on water, some fermented grape juice was most welcome! The most introvert among us, including me, were really grateful to have a socialisation enhancer. The event started with a nice talk by Joanne Hilton followed by an emotional farewell from the Freelance Business Group by Satyen Shenoy and a short speech by his successor Laura A. Kehoe. She then introduced the table leaders and their topics, and we were left to discuss and debate for quite some time.

I was particularly attracted to three topics: should we get training on day-to-day activities (e.g. accounting, IT); where and how to find new clients; and how to get your foot in the door with regulatory writing. The discussions were vivid, and everyone got his or her say in the matter. Once the time ran out, the table leaders summed up the collective conclusions and we all got some good picture of the addressed topic. In the end,

I went back home with some nice tips and a broader vision of subjects affecting medical writing I could not have thought of myself.

Notably, I managed to get some impressions from the attendees on the freelance directory, which eventually set my mind on signing up after the summer holidays. That is what to me was most important at the FBF; networking. Before joining EMWA I was not convinced by the power of connections, but how wrong was I! Although it is not immediate, I have seen word of mouth at work countless times, so given enough time it can really make wonders. Back to the FBF, I got in contact with some people with whom I am sure we will be able to establish lasting relations with, be it professional or not.

I would never have thought medical writers would give off that much advice to newcomers (who are potential competitors), but we stand where we are because Homo Sapiens is a gregarious species. Freelancers tend to work alone most of the time, so in the end, my personal view on the FBF – which could also be extended to EMWA – is that we are not alone but instead part of a vast family that believes in mutual aid to strive.

Matías Rey-Carrizo
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Upcoming issues of **Medical Writing**



December 2019:

Artificial intelligence & digital health

Technological innovation is overtaking all industries, and medicine is no exception. Artificial intelligence and digital health are growing trends. As medical writers, we must understand and communicate these advances and know how they will affect our profession.

Guest Editors: Evguenia Alechine and Martin Delahunty



March 2020:

Visual communications

Medical communications frequently include a visual component to aid in transmitting difficult concepts and articulating ideas. Graphics are crucial to translate the growing amounts of data available and to quickly communicate information in digital tools. Medical writers should understand how to visually engage the reader, either by preparing their own graphic material or collaborating with design or illustration professionals.

Guest Editor: Ana Goios

The deadline for feature articles is December 10, 2019.



June 2020:

The data economy

In an increasingly digitised world, data are economic assets that are becoming the lifeblood of the world economy. Medical writers need to know how the data economy affects the development of healthcare products and should understand which big data repositories are reliable, the specialised data analysis approaches needed, and the issues around big data protection.

Guest Editors: Raquel Billiones and Sam Hamilton

The deadline for feature articles is March 10, 2020.

CONTACT US



If you have ideas for themes or would like to discuss any other issues, please write to mew@emwa.org.



<http://journal.emwa.org/>