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Medical Writing



Artificial intelligence and digital health

Also in this issue...

- An introduction to medical affairs for medical writers
- A primer on anonymisation
- Sound, microphone, action: Podcasts for medical writers



EUROPEAN MEDICAL WRITERS ASSOCIATION



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Medical Writing

Artificial intelligence and digital health

Artificial intelligence (AI) and digital health are changing the way we live and work. They are already and increasingly present in medicine and are slowly permeating the medical writing industry. For many medical writers, this raises the question whether these new technologies will be friends or foes, whether they will make our work easier, or whether “we will be replaced by robots”.

In the context of this trending and somehow “alarming” discussion, I had the privilege to put together this issue on AI and digital health. I invited experts in the field to share their knowledge and educate us on these pressing topics. In this issue, you will find everything from the basic concepts, including AI, digital health, machine learning, Natural Language Processing, mHealth, and blockchain, to the different ways these concepts are being integrated into the daily work of medical writers.

Nikolaos Parisis discusses the critical role medical writers play in AI-driven healthcare industry, describes how AI can empower medical writers in various domains (regulatory, medical affairs, redaction, and publishing), and highlights the importance of staying up to date with the AI world. **Jackie Johnson and Sean Manion** take this to the next level, discussing the implications of blockchain in healthcare, research, and scientific publishing and highlighting blockchain-related projects that are relevant to medical writers. **Sonia Costa** integrates AI and machine learning, the fast-growing area of Natural Language Processing-based tools and discusses the impact of these technologies in medical writing; and she proposes that we medical

writers embrace this new friendship with AI. **Yan Zhou** also looks at things from a positive perspective: he offers a view of drug development and medical writing in the digital world and the possibilities for medical writers to explore wider career pathways. Continuing on this theme of the advantages of AI, **Kelly Goodwin Burri** explains how AI can be used to optimise searches and streamline the review process for systemic literature reviews of medical devices.

Finally, two articles address regulations and standards around AI and digital health. **Theresa Jeary, Karin Schulze, and David Restuccia** share what medical writers need to know about regulatory approval of mHealth and digital healthcare devices in the EU and globally, and **Katharina Klesper and Jürgen Zerth** discuss the impact of digitalisation within the healthcare sector and how good practice standards in medical writing may help to convey digital health contexts for a wide range of target groups.

In closing, I want to thank **Martin Delahunty**, director of Inspiring STEM Consulting, for sharing his expertise and knowledge that helped put together this issue. He also nicely set the stage for this issue with his article in our last issue: *Artificial intelligence – will we be replaced by robots?*¹

I hope you enjoy reading this issue as much as the whole editorial team enjoyed working on it. Together, we invite you to join us in this fourth industrial revolution.

In this issue, you will find everything from the basic concepts, including AI, digital health, machine learning, Natural Language Processing, mHealth, and blockchain, to the different ways these concepts are being integrated into the daily work of medical writers.



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References

1. Delahunty M. Artificial intelligence – will we be replaced by robots? *Med Writ.* 2019;28(3):20–1.

President's Message



Dear EMWA Members

The Malmö conference in November was a great success with thanks going to the workshop leaders as well as the organisers including Head Office – and YOU; it was very good to see so many of you there.

Preparations are now well under way for the next meeting, a landmark for EMWA – its 50th conference, which will be May 5–9, 2020 – and an amazing achievement, especially remembering the small beginnings: see <https://www.emwa.org/about-us/about-emwa/history-of-emwa-1992-2008/>.

If you have any photographs or memorabilia from previous conferences, please do scan and send them; next year, we'll be sharing some of the highlights over the last 28 years, from the first meeting in February 1992 to date.

Just a short message from me this time but a reminder: 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 offers of help are welcomed.

Wishing you a lovely Christmas, whatever you do and however you mark this time of year, and a happy, healthy and successful year ahead.

Barbara Grossman
president@emwa.org

EMWA News



Joint Position Statement on Predatory Publishing translated into Italian

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. The joint position statement complements several other sets of guidelines that have helped define the characteristics of a predatory journal.

By joining with AMWA and ISMPP in both developing and publicising the Joint Position Statement on predatory journals, EMWA is providing a valuable service to publication professionals around the world by enabling them to more easily read, understand, and apply

the principles of this JPS.

In order to raise awareness among non-English speakers about the responsibilities of medical writers and publication professionals concerning this significant issue, EMWA has initiated the translation of this statement into European languages. We are proud to announce the posting of the first JPS translation into Italian by Andrea Rossi and reviewed by Tiziana von Bruchhausen. The translation is available at: <https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/italiano/>.

We are currently looking for translators. If you would like to volunteer please contact Abe Shevack (asp scientist@gmail.com) or the EMWA Head Office (info@emwa.org).



Webinar on EMWA conferences now online for everyone

EMWA conferences offer a wide range of worthwhile activities to our members – both those new to the profession and experienced medical writers. On the one hand, the training workshops, seminars and sessions on medical

writing and current “hot topics”; on the other hand, networking and socialising opportunities with colleagues from all over Europe.

“Oh Vienna!” Impressions of first EMWA conference” is a video now online at

<https://youtu.be/iQywvmuyAgs>.

The video shows EMWA delegates as they share their impressions from the Spring 2019 conference in Vienna.

Report on the Freelancer Business Forum in Vienna is online

EMWA members should log in and go to the Freelance Resource Centre (<https://www.emwa.org/freelance/freelance-resource-centre-1/>) to read about changes to the committee, the invited speaker and the results of the eight lively table discussions.

Table discussion topics included:

1. Additional Training Required to Run a Freelance Business
2. Value in Attending EMWA Conferences and FBF Event
3. Working With Clients Outside Your Country/Continent
4. Price Wars: Competing with Non-European Writing Hubs
5. Personal Liability Insurance: Do You Really Need It?
6. Managing Downtime Between Projects
7. Developing and Delivering Writing in Newer and More Specialised Areas
8. Getting Started in Freelance Regulatory Writing



Medical writing in the era of artificial intelligence

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Abstract

The increasing amount of data available together with advances in computer science are converting computers from simple tools that execute commands into self-taught, self-correcting machines that make decisions. This is the beginning of the era of artificial intelligence (AI) that promises a revolution in the way we live and work. AI has entered apace the fields of healthcare and medicine and has started to affect the work of medical writers. A recent survey has revealed that 40% of scientists are still unfamiliar with the use of AI in healthcare with opinions ranging from panic to over-optimism. These are big challenges for all medical writers (MWs). This article discusses the critical role MWs play in an AI-driven healthcare, describes how AI can empower medical writers in various domains (regulatory, medical affairs, redaction, and publishing), and highlights the importance of staying up-to-date with the AI world.

Artificial intelligence

Artificial intelligence (AI), is a general term describing the computer systems that have the ability to model human intelligence and perform in a human-like fashion. Visual and speech recognition, language processing, and decision-making are some of the human tasks performed by AI thanks to algorithms. Machine learning, a sub-domain of AI, is the study of algorithms that can educate and improve themselves through analysing an input, usually a large amount of relevant data. Two key facts are the main drivers for the AI revolution: i. recent advances in computing architecture and in AI technologies

that provide the required computational power,¹ and ii. ability to accumulate large amounts of data (big data). Feed a huge list of chess games and the computer will learn chess by itself.² And that was in 1996, before the era of advanced machine-learning algorithms. Almost 20 years later, there were algorithms that played GO, a strategy game way more complex than chess.³ And just recently, AI outperformed poker professional players.⁴

The latter is considered a landmark in AI history, as it is the first time AI outperformed human reasoning and intelligence in a situation with multiple non-linear interactions and with incomplete information where game theory needs to be applied. What makes AI superior is its ability to collect data, analyse them, identify patterns, learn from it, and extract an output without any human intervention. It rapidly creates its own logic using artificial neural networks that resemble biological neural networks, offering increased performance, subjectivity, and automation.

AI has shown incredible potential in many domains, including healthcare and medicine,⁵ with concomitant changes to medical writers (MWs). Thus, in this article, we discuss the potential benefits of AI in the everyday life and work of medical writers and the reason why MWs should remain at the forefront of the AI revolution.

AI-driven healthcare

Medical diagnosis, digital health, and medical devices

As mentioned above, the accumulation of data is a huge driver for AI in any sector. Newly developed AI algorithms work well with medical images, including, but not limited to, biopsy images, magnetic resonance imaging, computed tomography, and electrocardiography (ECG).^{6,7} AI reduces errors and increases the sensitivity, specificity, and speed of diagnosis by identifying patterns not identifiable by the human eye.⁸ Besides, there has been an exponential growth in the amount of medical data that can be collected via wearable devices, mobile telephone

What makes AI superior is its ability to collect data, analyse them, identify patterns, learn from it, and extract an output without any human intervention.



applications (apps), and other interconnected medical devices (Internet of Medical Things – IoMT).⁹ It is impossible for a human to analyse this data. Personalised medicine can be exercised through continuous and remote monitoring in real time thus reducing site visits and providing an online support network with quality interactions by using, for example, chatbots and apps, that improve patient engagement, management, and adherence. In addition, patients and consumers are becoming more open to constant monitoring by AI-driven healthcare, from wearable devices to robot-assisted surgeries.¹⁰ However, healthcare professionals feel uncomfortable about relying on AI-powered softwares,¹¹ a gap that needs to be bridged.



Drug development

In clinical trials, success depends not only on the selection of the right patients, but also on the support they feel they receive throughout the trial. AI can help in many aspects of clinical trials,¹² including patient enrollment and management. AI tools can analyse electronic medical records and preclinical and clinical data and select a cohort of patients that would benefit from a given clinical trial. It can also help in creating the optimal trial design and protocol.¹³ Several biotechnology startups are being created and established companies are entering the AI field with the goal of increasing speed and efficiency of the drug development process. Machine-learning algorithms have been developed to help in several steps of the process, from drug design¹⁴ and Quantitative Structure-Activity Relationship (QSAR) modelling¹⁵ to toxicity assays and side-effect predictions.¹⁶ Sophisticated algorithms could analyse simulta-

neously a plethora of data, such as multi-omics datasets combined with preclinical and patient data, and make predictions.

While several such cases have shown the potential of AI,¹⁷ in saving time and money, most of these approaches are far from becoming the norm; therefore, we will not discuss them further in this article. But as the field advances rapidly, MWs should be prepared for the time when AI-based innovations knock on their door daily.

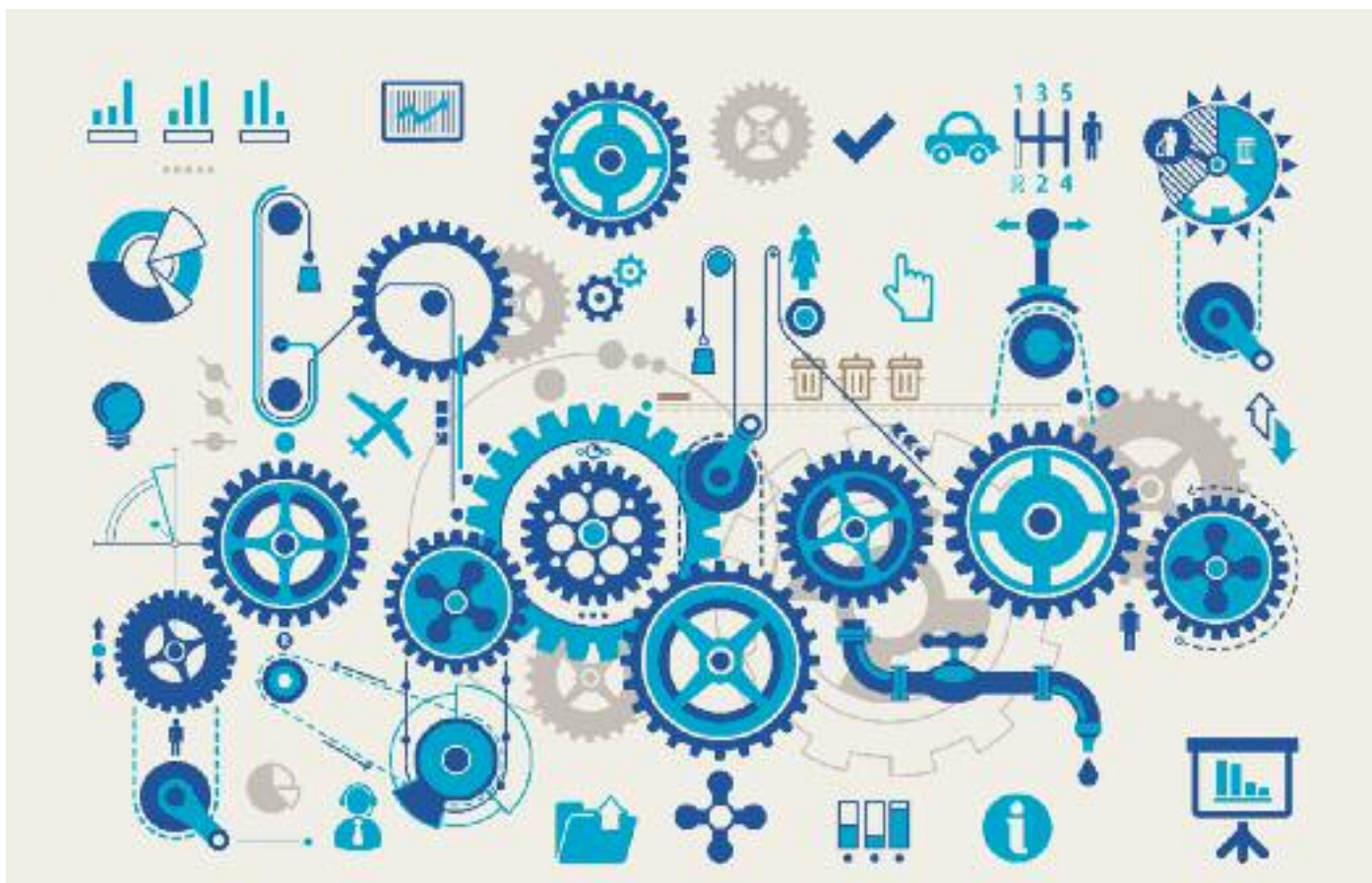
Scientific publishing and editing

More and more authors of scientific studies are becoming frustrated with the traditional peer review process highlighting, among

others, serious problems in fighting bias,¹⁸ slow speed,¹⁹ or lack of transparency.²⁰ AI tools can

A large portion of clinical protocols and clinical study reports can be automatically created by AI tools in a matter of hours, instead of weeks, so that the medical writer can focus on activities that require a higher level of scientific interpretation.

give a hand in most of the laborious processes of peer review. For example, AI-based programs can identify and control parallel communication strategies with reviewers until the required number of reviews has been reached.²¹ Plagiarism, bad reporting, and manipulated image detection tools are being tested by journals²² and, if used with caution, they can improve the publishing process. In a similar manner, editing can be automated with AI-based tools that can automatically control and amend documents to comply with required styles and formats.



Regulatory writing

Earlier we talked about machine-learning algorithms. At this point, it would be helpful to talk about natural language processing (NLP), the AI technology that helps computers understand the natural language of humans, beyond the ones and zeros. We come across NLP several times in our daily lives: Google Translate, Gmail autocomplete, text processors such as MS Word or Grammarly, personal assistants such as Siri, Alexa, etc. Interestingly, Yahoo! generates millions of automatic reports and match recaps to engage with its fantasy football fans in a personalised manner.²³ Writers and journalists have started to experiment with AI to help them generate original writing.²⁴

Along the same lines, MWs care about the readability of their writing, as this will dictate the reach, comprehension, and the impact of the written material. A good writer pays attention to the audience and knows how to adjust the text to its readers. Thus, the four major elements of

readability – content, style, format, and organisation – constitute the readability formulas that famous text processors, such as MS Word and Hemingway editor, use to score readability.^{25,26} However, these tools are based only on static metrics like number of words per sentence, syllables per word etc., and do not have the ability to understand complex grammar, context, or feelings expressed by the words. Thus, they cannot create original text. An AI tool based on NLP can use the same information as input, teach itself, and produce a variety of texts adapted to different audiences in a fraction of a time, such as nursing narratives,²⁷ or conversion of electronic health records into plain language.²⁸ Interestingly, this has worked in a variety of fields such as oncology,^{29,30} radiology,³¹ and others.³²

Similarly, NLP algorithms may soon help

MWs replace one of their most time-consuming, tedious tasks, offering at the same time, the highest degree of security: authoring structured

content. MWs retrieve information from various documents in order to, for example, transfer it to a different place in another document with minor modifications. A large portion of clinical protocols and clinical study reports can be automatically created by AI tools in a matter of hours, instead of weeks, so that the MW can focus on activities

that require a higher level of scientific interpretation.³³ Such tasks can be achieved with the highest transparency and security of personal data, as no human eye will have seen the confidential information. Achieving such a high level of productivity, confidentiality, and consistent compliance with regulations is the big promise of AI to regulatory writers.

While it seems very unlikely that AI will completely overtake the job of MWs, it is likely that MWs who embrace AI will overtake those who do not.

Table 1. Further reading on artificial intelligence in healthcare

Source	Description	link
The timeline of AI	Wikipedia page	https://en.wikipedia.org/wiki/Timeline_of_artificial_intelligence
The Medical Futurist	The latest news in medical innovation	https://medicalfuturist.com/
Forbes Magazine	AI And Healthcare: A Giant Opportunity	https://www.forbes.com/sites/insights-intelai/2019/02/11/ai-and-healthcare-a-giant-opportunity/#42f5a98d4c68
MIT Technology Review	the latest advances in machine learning, neural networks, and robots	https://www.technologyreview.com/artificial-intelligence/
Take Traction	14 AI & Machine Learning podcasts you should really be listening to	http://taketraction.com/blog/14-artificial-intelligence-and-machine-learning-podcasts/
Brain Inspired	A podcast where neuroscience and AI converge	https://braininspired.co/
AI weekly	A weekly collection of the best news and resources on Artificial Intelligence and Machine Learning	http://aiweekly.co/
Artificial Intelligence for Healthcare: Opportunities and Challenges	MOOC	https://www.classcentral.com/course/futurelearn-artificial-intelligence-for-healthcare-opportunities-and-challenges-13302

Abbreviations: AI, artificial intelligence; MIT, Massachusetts Institute of Technology; MOOC, massive open online course.

Medical affairs

In addition to data, text, and image analysis, AI algorithms can analyse networks.³⁴ AI tools can scan the vast medical literature and the scattered available networks of physicians and scientists to create a list of key opinion leaders as well as the best strategy to make contact. Deeper relationships can be formed, not by simple web searches, but from sophisticated expert information, trend identification, and sentiment analytics.³⁵ And this does not need to be repeated to remain up-to-date; it happens in real time. Similarly, AI tools can educate MWs and medical affair professionals with the essential information that will produce automatically by scanning the databases, gathering scientific insights, and producing summaries.³⁶

Collection and analysis of medical writing metrics

In order to stay on top of one’s work or business, MW managers need to be able to collect metrics,

As the impact of AI in healthcare grows, so does the hype. Medical writers, as the gatekeepers of accurate translation of medical breakthroughs, need to understand basic concepts of AI in order to avoid overly optimistic claims.

create graphs, analyse data, and make decisions in order to improve businesses. An AI-based system can automatically perform these tasks in real time and reduce the burden of performing them manually. Some metrics relevant to a medical writer’s job have been analysed by Haycock and Dawes, for example, basic document and client information, departmental head count, and skill sets, workload distribution, timelines, or budgets.³⁷ Besides, AI tools, as unbiased as they may be, can collect and analyse all types of metrics even those that, initially, may have seemed irrelevant by a human. And once analysed, graphs or narratives can be automatically created. Interestingly, those narratives can be created in a variety of ways, depending on who the target reader is. For example, a CEO may want to see different metrics than a line manager or a medical writer.

Why and how to stay up-to-date

As the impact of AI in healthcare grows, so does

the hype. Medical writers, as the gatekeepers of accurate translation of medical breakthroughs, need to understand basic concepts of AI in order to avoid overly optimistic claims.³⁸ In addition, it is becoming critical that MWs know how to communicate with AI-based systems in the era of profound transformation. AI is not magic and it is only as good as the quality of data used to train and test the model. Thus, AI requires strict regulations, appropriate datasets, and specific questions.

Table 1 contains a variety of sources through which anyone can introduce oneself to AI and stay up-to-date with current advances. Completing online courses, subscribing to newsletters, listening to podcasts or reading specialised blogs from experts can become a daily habit so that reporting of new AI-driven innovations becomes accurate.

Conclusion

Think of the numerous mundane tasks most MWs perform. While these tasks are considered a waste of talent and of scientific expertise of the medical writer, they are important and they need to be done. AI is becoming a useful tool in the hands of MWs by empowering them to

streamline such processes. While it seems very unlikely that AI will completely overtake the job of MWs, it is likely that MWs who embrace AI will overtake those who do not. But MWs should embrace it not only for their own benefit, but also for the benefit of society. As a strategic healthcare stakeholder, an AI-literate MW can separate science fiction from science and report future innovations in healthcare and medicine accurately.

Disclaimers

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

Conflicts of interest

The author declares no conflicts of interest and no affiliation whatsoever with the companies mentioned in the text.

References

- Hwang T. Computational power and the social impact of artificial intelligence. 2018 Mar 23 [cited 2019 Aug 12]; Available from: <https://arxiv.org/abs/1803.08971v1>.
- Deep Blue (chess computer). In: Wikipedia [Internet]. 2019 [cited 2019 Aug 12]. Available from: [https://en.wikipedia.org/w/index.php?title=Deep_Blue_\(chess_computer\)&oldid=909996580](https://en.wikipedia.org/w/index.php?title=Deep_Blue_(chess_computer)&oldid=909996580).
- Silver D, Schrittwieser J, Simonyan K, et al. Mastering the game of Go without human knowledge. *Nature*. 2017 18;550(7676):354–9.
- Brown N, Sandholm T. Superhuman AI for multiplayer poker. *Science*. 2019 Aug;365(6456):885–90.
- Hamet P, Tremblay J. Artificial intelligence in medicine. *Metabolism*. 2017 Apr;69S:S36–40.
- Pesapane F, Codari M, Sardanelli F. Artificial intelligence in medical imaging: threat or opportunity? Radiologists again at the forefront of innovation in medicine. *Eur Radiol Exp*. 2018 Oct 24;2(1):35.
- Attia ZI, Noseworthy PA, Lopez-Jimenez F, et al. An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction. *Lancet*. 2019;394(10201) 861–7.
- Brinker TJ, Hekler A, Enk AH, Berking C, Haferkamp S, Hauschild A, et al. Deep neural networks are superior to dermatologists in melanoma image classification. *Eur J Cancer Oxf Engl*. 1990. 2019 Aug 8;119:11–7.
- Qureshi F, Krishnan S. Wearable hardware design for the internet of medical things (IoMT). *Sensors*. 2018 Nov 7;18(11).
- Williams Brian. Enabling better healthcare with artificial intelligence [Internet]. Next In Tech. 2017 [cited 2019 Aug 14]. Available from: <https://usblogs.pwc.com/emerging-technology/ai-in-healthcare/>.
- AI use in healthcare increasing slowly worldwide [Internet]. Medscape. [cited 2019 Aug 14]. Available from: <http://www.medscape.com/viewarticle/912629>.
- de la Iglesia D, García-Remesal M, Anguita A, Muñoz-Mármol M, Kulikowski C, Maojo V. A machine learning approach to identify clinical trials involving nanodrugs and nanodevices from ClinicalTrials.gov. *PloS One*. 2014;9(10):e110331.
- Harrer S, Shah P, Antony B, Hu J. Artificial intelligence for clinical trial design. *Trends Pharmacol Sci*. 2019 Aug;40(8):577–91.
- Zhavoronkov A, Ivanenkov YA, Aliper A, et al. Deep learning enables rapid identification of potent DDR1 kinase inhibitors. *Nat Biotechnol*. 2019;37(9):1038–40.
- Martínez MJ, Razuc M, Ponzoni I. MoDeSuS: A machine learning tool for selection of molecular descriptors in QSAR studies applied to molecular informatics. *BioMed Res Int*. 2019;2019:2905203.
- Zhang H, Mao J, Qi H-Z, Ding L. In silico prediction of drug-induced developmental toxicity by using machine learning approaches. *Mol Divers*. 2019 Sep 5; <https://doi.org/10.1007/s11030-019-09991-y>.
- Lavecchia A. Deep learning in drug discovery: Opportunities, challenges and future prospects. *Drug Discov Today*. 2019 Aug;S1359-6446(19)30282-X.
- Fisher D, Parisi N. Social influence and peer review: Why traditional peer review is no longer adapted, and how it should evolve. *EMBO Rep*. 2015 Dec;16(12):1588–91.
- Nguyen VM, Haddaway NR, Gutowsky LFG, et al. How long is too long in contemporary peer review? Perspectives from authors publishing in conservation biology journals. *PloS One*. 2015;10(8):e0132557.
- Wicherts JM. Peer Review Quality and Transparency of the Peer-Review Process in Open Access and Subscription Journals. *PloS One*. 2016;11(1):e0147913.
- Mrowinski MJ, Fronczak P, Fronczak A, Ausloos M, Nedic O. Artificial intelligence in peer review: How can evolutionary computation support journal editors? *PloS One*. 2017;12(9):e0184711.
- SpotOn 2016 Report [Internet]. BMC Events. [cited 2019 Aug 13]. Available from: <http://events.biomedcentral.com/spoton-2016-report/>.
- Yahoo! Sports uses NLG to produce draft over 70 million reports and match recaps [Internet]. Automated Insights. [cited 2019 Aug 7]. Available from: <https://automatedinsights.com/customer-stories/yahoo/>.
- Samuel S. How I'm using AI to write my next novel [Internet]. Vox. 2019 [cited 2019 Sep 6]. Available from: <https://www.vox.com/future-perfect/2019/8/30/20840194/ai-art-fiction-writing-language-gpt-2>.
- DuBay WH. The Principles of Readability [Online]. [Internet]. 2004 [cited 2019 Aug 13]. Available from: <http://files.eric.ed.gov/fulltext/ED490073.pdf>.
- Dixon J. Readability tools: are they useful for medical writers? [video]. 2017 [cited 2019 Aug 13]. Available from: <https://thepublicationplan.com/2017/10/17/video-readability-tools-are-they-useful-for-medical-writers/>
- Min YH, Park H-A, Lee JY, et al. Automatic generation of nursing narratives from entity-attribute-value triplet for electronic nursing records system. *Stud Health Technol Inform*. 2014;201:452–60.
- Polepalli Ramesh B, Houston T, Brandt C, Fang H, Yu H. Improving patients' electronic health record comprehension



- with NoteAid. *Stud Health Technol Inform.* 2013;192:714–8.
29. Yim W-W, Yetisgen M, Harris WP, Kwan SW. Natural language processing in oncology: A review. *JAMA Oncol.* 2016 Jun 1;2(6):797–804.
 30. Savova GK, Danciu I, Alamudun F, et al. Use of natural language processing to extract clinical cancer phenotypes from electronic medical records. *Cancer Res.* 2019 Aug;canres.0579.2019.
 31. Pons E, Braun LMM, Hunink MGM, Kors JA. Natural language processing in radiology: A systematic review. *Radiology.* 2016 May;279(2):329–43.
 32. Kreimeyer K, Foster M, Pandey A, et al. Natural language processing systems for capturing and standardizing unstructured clinical information: A systematic review. *J Biomed Inform.* 2017;73:14–29.
 33. Virdee N. How AI tech is changing regulatory writing [Internet]. *Certara.* 2017 [cited 2019 Aug 5]. Available from: <https://www.certara.com/2017/04/21/how-ai-tech-is-changing-regulatory-writing/>.
 34. Pereda M, Estrada E. Machine learning analysis of complex networks in hyperspherical space. *ArXiv180405960 Phys [Internet].* 2018 Apr 16 [cited 2019 Aug 13]; Available from: <http://arxiv.org/abs/1804.05960>.
 35. Smith S. AI for Medical Affairs White Paper [Internet]. [cited 2019 Aug 8]. Available from: <https://www.sorcero.net/blog/ai-for-medical-affairs-white-paper>.
 36. Ganti L. How can AI technologies help streamline medical affairs processes? [Internet]. *Innoplexus.* 2019 [cited 2019 Aug 8]. Available from: <https://www.innoplexus.com/blog/how-can-ai-technologies-help-streamline-the-decision-making-process-for-medical-affairs/>.
 37. Haycock N, Dawes K. Collecting metrics in medical writing – the benefits to you and your business. *Med Writ.* 2019 Jun 1;28:85–7.
 38. England JR, Cheng PM. Artificial Intelligence for Medical Image Analysis: A Guide for Authors and Reviewers. *AJR Am J Roentgenol.* 2019 Mar;212(3):513–9.

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Blockchain in healthcare, research, and scientific publishing

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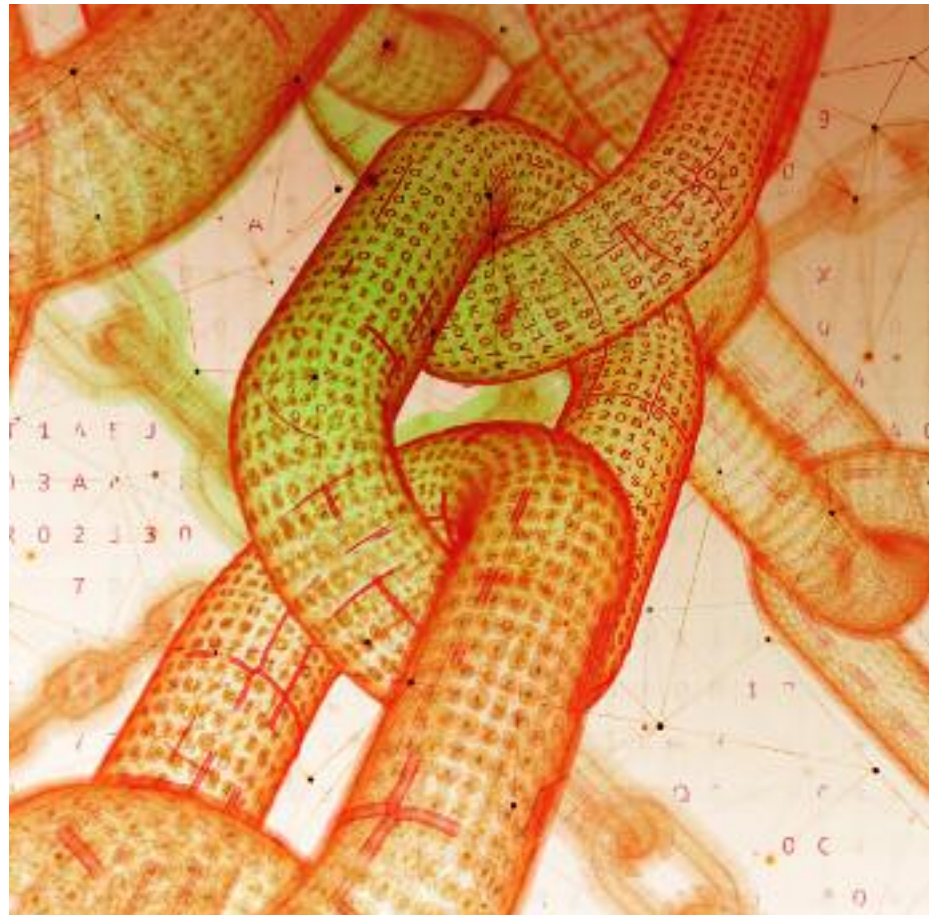
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Abstract

Data are being transmitted and stored on cloud-based networks, including clinical, research, and publishing data. These cloud-based systems often lack comprehensiveness, accessibility, interoperability, confidentiality, accountability, and flexibility, which can cause delays for medical treatments, slowed research projects, and general inefficiencies. The advent of blockchain-based technologies provides a reliable solution to ensure that data storage and access are standardised and transparent, independent of a trusted third party. It is not a new stand-alone system, but a layer of trust between the data and users that can integrate with other emerging technologies and optimise their impact. It is rapidly advancing in financial and supply chain industries and now being explored successfully in many applications across the healthcare industry. When applied in medical publishing, blockchain may serve to remedy data sharing and intellectual property issues that often confront medical writers, though implementing this new technology will have some hurdles. In this article, we highlight some selected blockchain-related projects relevant to medical writers.

Blockchain – The basics

Information and data are stored online by companies that guarantee trust and security (e.g. banks). This information can include email addresses, names, financial information, and more. Despite these companies doing everything they can to protect this data, nothing can be



definitively safe from hackers, mainly because the information is stored in one central place in the form of a computer. This data centralisation makes it easier to steal information – but blockchain works differently.

Blockchain technology is a way to record information (in “blocks”) onto many devices (forming a “chain”) all at once using the internet, and the type of information is not limited: blockchain can store money, data, music, agreements between individuals, and more. The anonymous individual or group known as Satoshi Nakamoto developed the Bitcoin blockchain in 2009 as a peer-to-peer electronic cash system¹ based on early work by Stuart Haber and Scott Stornetta.² Unlike a traditional cloud-based system, blockchain is a decentralised (i.e. no central point, making it more difficult to break into a single device and steal information), distributed ledger of digital transactions that

allows the exchange of data.

Through blockchain, data can be managed and organised in a new way: the data are open, permanent, verified and shared, and without the need of a central authority. Given that most industries could benefit from such a system, the application of blockchain technology is being explored for managing a variety of digital assets, such as medical records and research data, which touches the industries that are relevant to medical writers (i.e. publishing, healthcare, and research).

The parallels between blockchain technology and the core needs of the modern healthcare industries are apparent.^{3–5} For example, the ability of blockchain to create records of transactions that cannot be altered is valuable for healthcare supply chains. From the factory to a patient, information about drug shipments could be stored in the blockchain (i.e. temperature, price, dispensed to whom, etc), which would

Table 1. Selected blockchain projects in scientific publishing

Journal/organisation	Description
<i>Ledger</i> ⁷	The first journal focused exclusively on blockchain and the first to apply the technology to the publishing process. <i>Ledger</i> was recently awarded the University of Pittsburgh Cyber Accelerator Grant to help develop the journal and expand its capabilities.
<i>Blockchain in Healthcare Today</i> ⁸	The first journal focused on blockchain applications in health, including the health research that underlies the evidence base of medicine. The journal's publisher hosted an expansive conference at Columbia University last fall and made the content available in a special podcast issue. ⁹
<i>Journal of the British Blockchain Association</i> ¹⁰	The first blockchain journal aligned with a professional society, it is focused on bringing scientific rigour to blockchain across industries.
<i>Frontiers in Blockchain</i> ¹¹	The first legacy scientific publisher to devote a title to blockchain. Frontiers has started a new section, <i>Blockchain for Science</i> ¹² that specifically looks at applications across the science process.
Digital Science ¹³	Digital Science and their publishing associate Nature Publishing have teamed up with several other universities and publishers to apply blockchain technology to their publishing process.

improve safety (by allowing for more transparent documentation of each step of the drug development process) and minimise fraud. In a research setting, lab notebooks and records could be more easily and transparently managed (as the data would be accessible by everyone), and publishing processes could also be optimised.

There is no shortage of projects where blockchain could be implemented to increase efficiencies. In Estonia, for example, every citizen's health record is secured with blockchain technology, giving citizens control over their individual health records.⁶ Blockchain could also be used to support initiatives such as the UK's National Institute for Health and Care Excellence (NICE) and National Health Service digital frameworks for evaluation, both requiring a great deal of record keeping and data exchange. Other ideas for implementing blockchain include pharmaceutical supply chain, medical device cybersecurity, organ tracking in the transplant setting, medical claims and billing management, tracking of health wearables data, and improving public health data security.

Current blockchain projects

Scientific publishing

Communication is paramount for scientific

research, which depends on the exchange of ideas, hypotheses, data, results – and eventually – publications. Research data and discussions is often exchanged through a variety of mediums, across geographies, and between universities and private companies. As such, the scientific enterprise relies on researchers themselves to report on their successes and failures to preserve resources – though this is rarely what happens. Several journals have already started to pave the way for advances in blockchain, both as subject matter and internal tool, in an effort to eventually bridge these gaps (Table 1).

Professional societies and non-profits

Non-profit organisations play a critical role in science. Their movements can often be steady and deliberative, but the involvement of these established entities provides neutral standards (compared to universities and industry stakeholders), long-term vision, and commitment to projects. They can also serve as an industry consortium facilitator to promote collaboration. Some of these are listed in Table 2.

Table 2. Selected blockchain professional societies and non-profits

Organisation	Description
HIMSS Blockchain Task Force ¹⁴	The largest health informatics society has gone from just a panel on blockchain HIMSS2018 to a full day pre-conference symposium and multiple conference sessions in 2019 with more expected in 2020, including research. HIMSS and CRC Press released a text book in early 2019 on Blockchain in Healthcare that includes several chapters on research applications. ¹⁵
IEEE Blockchain for Clinical Trials ¹⁶	One of the largest professional societies in the world held two conferences on Blockchain for Clinical Trials in 2018 in the US and Europe. IEEE is developing standards for clinical trials alongside supply chain standards.
IEEE Standards Association ¹⁷	The standards arm of IEEE has launched a 2-year, open effort, 2418.6 – Standard for the Framework of Distributed Ledger Technology use in Healthcare and the Life and Social Sciences, including a subcommittee focused on research.
Blockchain in Healthcare Global ¹⁸	IEEE International Standards & Technical Organization – This 501(c)(6) trade association under the IEEE/ISTO umbrella includes a focus on health research.

Abbreviation: IEEE, The Institute of Electrical and Electronics Engineers; ISTO, Industry Standards and Technology Organization; HIMSS, Healthcare Information and Management Systems Society

Pharmaceutical industry and biotech

Not only are ten of the largest public companies in the world exploring blockchain,¹⁹ many biotech companies and pharmaceutical companies are too, though mostly behind closed doors – keeping business secrets heavily protected. Deloitte surveys have estimated that nearly 35% of life science companies had planned to deploy blockchain technologies in 2017, and 17% of respondents were already using blockchain (Table 3).²⁰

Why is blockchain difficult to implement?

As with many new technologies, particularly related to healthcare or research, blockchain-based advances have been enthusiastically promoted but have been difficult to realise. Evidence-based practice, patient safety, and legal compliance regulations do not encourage accelerated innovation. Another hurdle is the high energy consumption required for digitally signing a secure, permanent record. Additionally, data stored in public chains are not private, and patient data could be at a theoretical risk, although cloud-based storage also has these risks, albeit to a greater extent. Further, by virtue of the technology, data stored in the blockchain cannot be deleted, which could conflict with the EU General Data Protection Regulation,²³ whereby patients must be able to opt out of the storage and use of their data in some circumstances. However in many cases, the personal data itself is not stored on a blockchain, only an encrypted hash (or code) linked to that personal data, which mitigates GDPR-related concerns. Finally, companies, research groups, and publishers are known to be competitive rather than collaborative, which generally slows advancement and hinders implementation of new technologies like blockchain.

Implications of blockchain for medical writers

Medical writers often liaise with various stakeholders to complete a project: from statisticians to key opinion leaders, healthcare providers, and scientists. While working in these teams, writers need to gather feedback, and then merge these into one cohesive draft. By using blockchain, writers (and all other stakeholders) could have permissioned access to these data, drafts, and

publications in real-time, with time-stamping for contribution and a shared ledger of changes for all parties to see. Further, the systems used to develop publications can differ widely between clients. Maintaining an archive of these publications’ records can become a giant task in its own right. If the industries where medical writers are typically employed (healthcare, research, and publishing) started to use standardised, blockchain-based systems, these issues could be addressed. Further, successful discovery, design, and testing of applications can benefit from medical writers being engaged early in the process. This will enable potential solutions to improve current workflows rather than creating something entirely new that goes unused or forces uncomfortable change. As these new technologies are developed, it is up to medical writers (and all stakeholders) to maintain an accepting willingness to implement new ideas.

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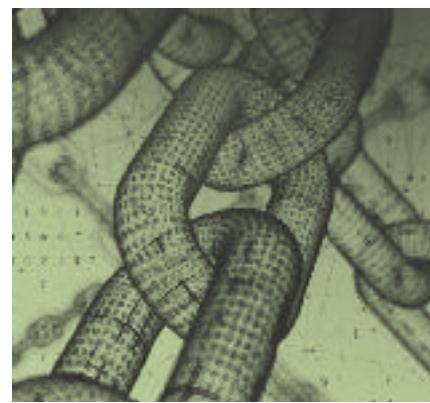
Conflicts of interest

JLJ serves as a review editor for *Blockchain for Science* and has received consulting fees from Novartis.

STM is the CEO of Science Distributed. He also serves without compensation on the board of Blockchain in Healthcare Global, as member and research subcommittee chair of the IEEE standards group 2418.6, as co-chief editor for *Blockchain for Science*, as review editor at *Ledger* and *Journal of the British Blockchain Association*, and on the HIMSS Blockchain Taskforce and HIMSS2020 Blockchain Symposium planning committee and chapter author of HIMSS series textbook.

Table 3. Selected blockchain projects in the scientific/pharmaceutical industry

Organisation	Description
Wolfram Alpha ²¹	One of the top names in research statistics has been exploring how to develop a framework that can be used for all of scientific research.
Science Distributed ²²	A small firm providing support to university and federal clients to identify use cases and design blockchain solutions at the network level for better health research.
Novartis ²³	One of many large pharmaceutical companies exploring a variety of ways to use the blockchain, including the IMI Blockchain Enabled Healthcare Program.
Chronicle, Inc & The MediLedger Project ²⁴	Pfizer, Genetech, McKesson Corporation, Amerisource Bergen Corporation, Premier Inc and other pharmaceutical giants have joined up to use blockchain for supply chain management.
Innovative Medicines Initiative (IMI) ²⁵	The IMI is a public-private partnership between the EU and the European pharmaceutical industry represented by The European Federation of Pharmaceutical Industries and Associations, a Brussels-based trade association. For the Blockchain Enabled Healthcare program, the IMI is earmarked up to €18 million, which was expected to last three years.



As these new technologies are developed, it is up to medical writers (and all stakeholders) to maintain an accepting willingness to implement new ideas.

References

1. Nakamoto S. Bitcoin: A Peer-to-Peer Electronic Cash System 2009 [Internet]. [cited 2019 Oct 30]. Available from: www.bitcoin.org.
2. Oberhaus D. The World's Oldest Blockchain Has Been Hiding in the New York Times Since 1995. Motherboard: Tech by Vice [Internet]. 2018. [cited 2019 Oct 30] Available from: https://www.vice.com/en_us/article/j5nzx4/what-was-the-first-blockchain.
3. Fan K, Wang S, Ren Y, Li H, Yang Y. MedBlock: Efficient and secure medical data sharing via blockchain. *J Med Syst*. 2018;42(8):136.
4. Li H, Zhu L, Shen M, Gao F, Tao X, Liu S. Blockchain-based data preservation system for medical data. *J Med Syst*. 2018;42(8):141.
5. Radanovic I, Likic R. Opportunities for use of blockchain technology in medicine. *Appl Health Econ Health Policy*. 2018;16(5):583–90.
6. Leeming G, Ainsworth J, Clifton DA. Blockchain in health care: hype, trust, and digital health. *Lancet*. 2019;393(10190):2476–7.
7. Ledger Journal. Pittsburgh, PA (USA): University of Pittsburgh. Vol 1, 2016–
8. Blockchain in Healthcare Today. Stamford, CT (USA): Partners in Digital Health. Vol 1, 2018–
9. Blockchain in Healthcare Today Podcasts [Internet]. [cited 2019 Oct 30] Available from: <https://blockchainhealthcareday.com/index.php/journal/issue/view/2>.
10. The British Blockchain Association London (UK): Kemp House. Vol 1, 2018–
11. Frontiers in Blockchain [Internet]. [cited 2019 Oct 30] Available from: <https://www.frontiersin.org/journals/blockchain#>.
12. Blockchain for Science [Internet]. [cited 2019 Oct 30] Available from: <https://www.frontiersin.org/journals/blockchain/sections/blockchain-for-science#>.
13. Digital Science [Internet]. [cited 2019 Oct 30] Available from: <https://www.digital-science.com/>.
14. HIMSS Blockchain in Healthcare [Internet]. [cited 2019 Oct 30] Available from: <https://www.himss.org/library/blockchain-healthcare>.
15. Dhillon V, Bass J, Hooper J, Metcalf D, Cahana A. Blockchain in Healthcare: Innovations that Empower Patients, Connect Professionals and Improve Care. 1st Edition ed: CRC Press Taylor and Francis Group; 2019 January 25, 2019.
16. IEEE Blockchain for clinical trials program [Internet]. [cited 2019 Oct 30] Available from: <https://blockchain.ieee.org/standards/clinicaltrials>.
17. IEEE Blockchain Standards [Internet]. [cited 2019 Oct 30] Available from: <https://blockchain.ieee.org/standards>.
18. Blockchain in Healthcare Global [Internet]. [cited 2019 Oct 30] Available from: https://ieee-isto.org/member_programs/blockchain-in-healthcare-global/.
19. Castillo Md. Forbes [Internet]. [cited 2019 Oct 30] Available from: <https://www.forbes.com/sites/michaeldelcastillo/2018/07/03/big-blockchain-the-50-largest-public-companies-exploring-blockchain/>.
20. Deloitte Survey: Building up Blockchain [Internet]. [cited 2019 Oct 30] Available from: [https://www2.deloitte.com/content/dam/Deloitte/si/](https://www2.deloitte.com/content/dam/Deloitte/si/Documents/about-deloitte/16%20US%20Innovation%20Blockchain%20Infographic_FINAL.pdf)
21. Wolfram Blockchain Labs [Internet]. [cited 2019 Oct 30] Available from: <https://www.wolframblockchainlabs.com/>.
22. Science Distributed [Internet]. [cited 2019 Oct 30] Available from: <https://sciencedistributed.com/>.
23. Morris N. Ledger Insights: Enterprise blockchain news [Internet]. [cited 2019 Oct 30] Available from: <https://www.ledgerinsights.com/novartis-pharma-blockchain/>.
24. The MediLedger Project [Internet]. [cited 2019 Oct 30] Available from: <https://www.mediledger.com/>.
25. IMI Blockchain Enabled Healthcare [Internet]. [cited 2019 Oct 30] Available from: <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/imi2-2018-15-02>.

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Embracing a new friendship: Artificial intelligence and medical writers

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Abstract

Artificial Intelligence (AI) and machine learning-driven software are evolving toward a technological advancement revolutionising the current global, social, and economic landscape. A major breakthrough in AI is the fast-growing natural language processing-based tools, where millions of euros are being invested in the development of software

packages that automatically, and accurately, generate text. The impact of this technology in medical writing is immense. Will we be out of a job in the near future? In an optimistic (and perhaps realistic) point of view, one can argue in favour of a friendly interaction between medical writers and machines, with major advantages for the craft of medical writing.

Times are exciting! The prospective applications of artificial intelligence (AI) and machine learning (ML) technology in the medical and healthcare industries are revolutionary. For many years, AI/ML-based tools have been successfully used in radiology to improve the diagnosis and earlier detection of diseases.¹ The AI boom, in the recent years, has generated a plethora of platforms and applications that translate to new regulatory frameworks (both in the USA and EU). Some AI/ML-based technologies are categorised as medical devices (referred to as “software as medical devices” [SaMD] and thus

are subject to strict evaluations to ensure patient safety.² Notably, AI has the potential to make inroads in a number of new avenues, from disease detection and improved diagnosis tools to the development of new (and personalised) therapeutics, and can therefore contribute to better clinical decision making.

AI redefines Pharma R&D

A growing number of the largest global pharma companies are investing millions of euros in acquiring or partnering with start-ups to develop and improve AI technology, with the goal of speeding up drug discovery. DeepMind Health (launched in 2016 by Google) and IBM Watson (particularly in the areas of health, drug discovery, and oncology) are pioneers in health-related AI applications and have already been transforming the long and costly process of bringing new therapeutics to the market.

AI-based tools are used to predict good candidates among thousands of small molecule compounds, through biomarker identification

and target discovery, increasing the numbers of potential drugs identified and shortening the period of pre-clinical study. Moreover, this technology is also being used to promote the discovery of new therapeutics for rare diseases (for more information, please refer to Bulgaru [2018]³ and Jiang [2019]⁴). Interestingly, AI is also redefining the clinical trial landscape, with repercussions for scientists, physicians, clinical personnel, patients, and medical writers.

Natural language processing: A major breakthrough in AI

One of the characteristics of AI/ML-based tools is the fact that this technology relies on structured data to learn and improve its performance. A major breakthrough in the AI field is the fast improvement of natural language processing (NLP)-based tools, driven by the investment of titans, such as Microsoft, Google, and Amazon, which already have several trendy smart speakers integrated in the daily lives of many people. NLP is a rapidly expanding area of research and development. A major advantage of this technology is its capability to extract information from unstructured data, such as narrative text documents, which are otherwise incomprehensible for computer programs.⁵ Consequently, a massive amount of information locked in scientific and healthcare text databases can be transformed into structured data, and this progress will undoubtedly redefine the medical and healthcare industries. AI-based writing assistance will be a reality, in the near future, within the reach of many of us, and will, inevitably, transform the medical writing field.

As NLP tools can read unstructured data, they can easily scan metadata, perform tailored literature searches, and accurately extract targeted information from vast unstructured databases. This is particularly important in an age where a growing number of scientific articles are available at PubMed and hundreds of clinical studies are accessible at ClinicalTrials.gov. This vast collection of data is of an immense value, however it is basically impossible for a human being to be up to date with the latest discoveries, and relate the information on a given study to other hundreds

of studies already published. Thus, the application of NLP technology in clinical study design and pharmacovigilance is revolutionary, because skilled medical writers will be able to gather and analyse a surplus of information in a fast yet accurate mode. Many pharma companies are already investing in NLP-tools to perform complex data analysis and interpretation, study design, and generation of an array of documentation for each step in clinical research. Text mining (using NLP) performs linguistic analysis to the lexical level and is able to extract detailed information, reveal patterns across millions of documents, and automatically summarise loads of information.⁵

NLP at the service of medical writers

Aside from forming a basis for improving AI technology, how can this technology be useful to medical writers? A tremendous practical aspect of NLP tools is their ability to assist the medical writer in detecting errors during the anonymisation of patients enrolled in clinical studies, particularly in international multicentre clinical trials involving thousands of patients. Policies implemented by the European General Data Protection Regulation impose strict guidelines to ensure the de-identification of patients enrolled in clinical trials by pharmaceutical companies. To adhere to these policies, identifiers (information that may allow the identification of a patient) have to be redacted, which is a tedious, time-consuming work especially as they involve large databases. While several methods are used for anonymisation, it was recently shown that de-identification of large datasets is easily reversed by AI-based tools, i.e., these tools are able to accurately trace individuals in anonymised databanks.⁶ A way to overcome a possible breach is to, ironically, use NLP-based technology to create robust anonymised documents. Moreover, the automation of standard documents decreases human errors and the need for clinical staff and medical writers to certify that information has been accurately entered in large patient databases.⁷ This favours a reduction of the early stages of clinical trials and also results in a better

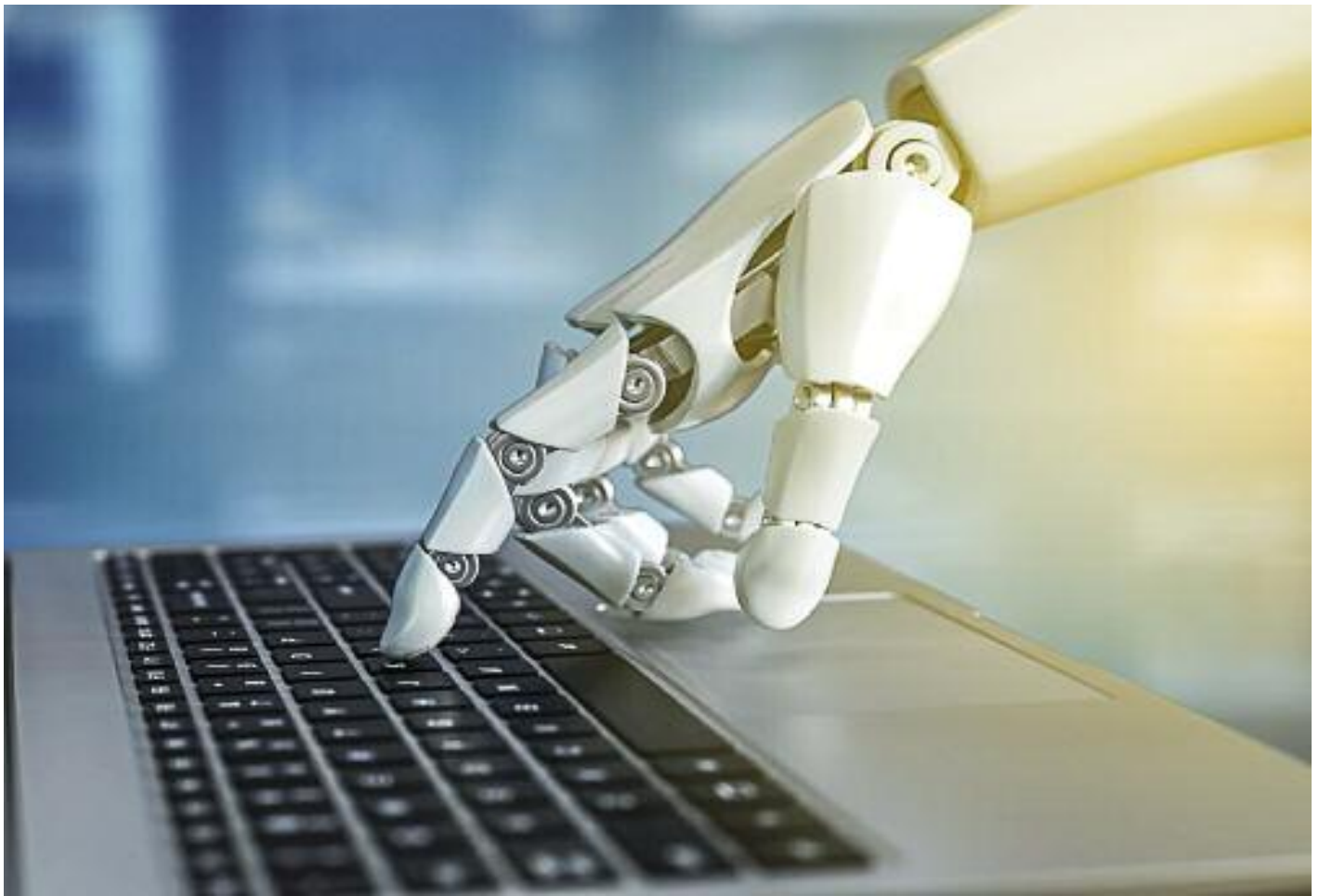
selection of patients taking part in a given study and promotes a high quality control of the entire process until the drug's market approval phase.

Interestingly, many content creators use AI writing assistant software that extracts information from the web and automatically produces a summarised text that is then edited by the content creator before publishing. The perspectives of the application of AI writing assistant software in clinical research are massive, especially if coupled with NLP translating tools to produce text documents disclosing complicated information to the general public. This is relevant to support medical writers in the production of documents complying with new strict European regulations, such as providing lay summaries (in each European language). Naturally, caution must be taken! Only specialised translators/writers should use this technology to generate documents. Pharmaceutical companies and medical writers are responsible for the accuracy of the information that is disclosed. The risk of emergent "fake health news" in wellness blogs and other social media should not be high, if the source information used by NLP-tools is correct. Nevertheless, policymakers need to take serious steps to protect the public from potential misinformation generated by a software (or its operator!) that is still in development.

Future challenges

In clinical research, the use of AI assistants specialised in regulatory writing is still at an early stage. Some biotech companies claim their software accurately produces 80% of a clinical study report, in less than 72 hours, still little official information on its efficacy is disclosed by medical writing departments of pharma (or CRO) companies.⁸ The improvement of AI-based tools for regulatory writing will inevitably redefine the role of medical writers. Medical writers will no longer be responsible for extracting information from different sources and for integrating it into a readable and comprehensible text document. AI-based tools can perform this task accurately in a short time, drastically reducing the load of preparation of documents. Unfortunately, due to strict confidentiality laws, scarce clinical data are available for use as sample data to develop and improve performance of NLP in the clinical field. Most available software uses historical data of clinical trials that pre-date the development of

AI-based writing assistance will be a reality, in the near future, within the reach of many of us, and will, inevitably, transform the medical writing field.



AI-based tools for optimal performance.

In addition, little to no data exchange among different players, from pharma to academia and biotech companies, limits further progress of AI in clinical research. Remarkably, this culture of confidentiality is already diminishing through collaborations among the different players and the creation of repositories and platforms for sharing databases (e.g., clinical narratives with de-identified data). Another key step is the adoption of universal electronic health records, which contain an extensive and valuable coverage of clinical data of patients over time. Also, an important step towards AI-driven innovation is the implementation of dissemination centres that share resources among research communities, such as the Health Natural Language Processing Center (<http://center.healthnlp.org>) and European Language Resources Association (<http://www.elra.info/en/>).⁹ Despite the current limitations of AI-driven technology, there is no doubt that clinical research is already being transformed with major benefits for the pharma industry and, ultimately, for the consumer.

Open-source AI software

For freelancers, open-source software is

A tremendous practical aspect of natural language processing tools is their ability to assist the medical writer in detecting errors during the anonymisation of patients enrolled in clinical studies, particularly in international multicentre clinical trials involving thousands of patients.

appealing, particularly if this technology is evolving as reported. If you have the chance to play around with this technology or if you are simply interested in getting familiar with what the future might look like, there are some options for user-friendly NLP-software. SemEHR, Apache cTAKES, GATE, and CLAMP, for example, are specialised in text analysis and extraction of target clinical information from electronic health records, unstructured clinical notes, and narrative patient reports. SemEHR also identifies contextualised mentions of biomedical concepts in

clinical records, being able to pull out the cohort of relevant patients. You might gain some interesting insights on the array of possibilities that publicly available clinical databases and open-source NLP-tools can offer.

Conclusion

In a nutshell, the prospects of AI in the medical and healthcare industries translate into a significant reduction of time and costs required for the development of new drugs, an increase of new potential treatment options for rare diseases, and the development of personalised diagnostics and tailored therapeutics to the individual patient. The impact of AI-driven technology in the field of medical writing is immense. Any true lifelong friendship is not for the faintest of hearts and AI will, definitely, challenge the rise of a new breed of medical writers. We move at a fast pace, towards a future in which a medical writer, as a specialised craftsman, will use AI-based tools in a complementary fashion to enhance the writing process of complex documents. In the long run, AI will lessen repetitive tasks (e.g., extracting information from source and preparing document drafts) and give the medical writer more opportunities to apply their know-how in

producing complex scientific work. Remarkably, medical writers can use NLP tools to scan metadata across different databases and identify meaningful key information, otherwise inaccessible through classic keyword search. This has the potential to unravel new therapeutics options and is a rewarding feature of the career of medical writing. The intersection between medical writer and AI will have major implications across medical and healthcare industries, resulting in higher chances of disclosure of information to a wider audience and a cost-effective drug development and, therefore, more innovative treatments. Times are, indeed, exciting!

Conflicts of interest

The author declares no conflicts of interest.

References

1. Pesapane F, Codari M, Sardanelli F. Artificial Intelligence in medical imaging: threat or opportunity? Radiologists again at the forefront of innovation in medicine. *Eur Radiol Exp.* 2018;2(1):35.
2. US FDA. Proposed Regulatory Framework for Modifications to Artificial Intelligence/ Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) – Discussion

Paper and Request for Feedback. [cited 2019 Aug 31]. Available from: <https://www.fda.gov/media/122535/download>.

3. Sennaar K. AI in pharma and biomedicine – analysis of the top 5 global drug companies. *Emerj.* 2019 [cited 2019 Aug 31]. Available from: <https://emerj.com/ai-sector-overviews/ai-in-pharma-and-biomedicine/>.
4. Bulgaru I. Pharma industry in the age of artificial intelligence: The future is bright. *Healthcare Weekly.* 2019 [cited 2019 Aug 31]. Available from: <https://healthcareweekly.com/artificial-intelligence-in-pharmacology/>.
5. Jiang F, Jiang Y, Zhi H, et al. Artificial intelligence in healthcare: past, present and future. *Stroke Vasc Neurol.* 2017;2(4):230–43.
6. Rocher L, Hendrickx J, de Montjoye Y. Estimating the success of re-identification in incomplete datasets using generative models. *Nat Commun.* 2019;10(1):3069.
7. Sennaar, K. AI and machine learning for clinical trials – Examining 3 current applications. *Emerj.* 2019 [cited 2019 Aug 29]. Available from <https://emerj.com/ai-sector-overviews/ai-machine-learning-clinical-trials-examining-x-current-applications>.

clinical-trials-examining-x-current-applications.

8. Fassbender M. Sanofi: NLP text mining and other AI tech to advance findings, improve data use. *Outsourcing – Phama.com.* 2019 [cited 2019 Aug 31]. Available from: <https://www.outsourcing-pharma.com/Article/2019/01/30/Sanofi-NLP-text-mining-and-other-AI-tech-to-advance-findings-improve-data-use>.
9. Velupillai S, Suominen H, Liakata M, et al. Using clinical natural language processing for health outcomes research: Overview and actionable suggestions for future advances. *J Biomed Inform.* 2018;88:11–9.

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Drug development and medical writing in the digital world

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Abstract:

Artificial intelligence and digital health open a new chapter in the pharmaceutical industry. The digital technologies improve work efficiency, lower research and development costs, optimise medical research processes, and increase R&D outputs. The digital revolution had a significant impact on almost every aspect of drug development from pre-clinical to clinical studies with digital endpoints and post-market surveillance of safety events, and even for medical education. In the area of medical writing, digital technologies led to the transparency of medical research and close scientific communications in the paperless systems and offered more possibilities for scientific collaborations between study sponsors and clinical practitioners. The writing styles and publishing media became more diverse along with the use of mobile health apps. In parallel, new technologies also offer wider career pathways; therefore, writing professionals with multiple skills are needed in the digital world.

Development of artificial intelligence and digital health

Together with gene engineering and nanotechnology, artificial intelligence (AI) is mentioned as one of three cutting-edge technologies of the 21st century.¹ AI is defined as an area of developing computer systems that are able to perform multiple tasks in scientific and business environments that normally would require

human intelligence.² As a milestone of the fourth industrial revolution (or technological revolution), AI and digital health (DH) have created a new era in drug development and the pharmaceutical industry. It has penetrated almost every aspect of drug discovery and development, ranging from target selection, hit identification, lead optimisation, preclinical studies, and clinical trials to pharmacovigilance and monitoring of treatment adherence.^{3,4}

In the past 40 years, China's industry outputs continuously increased. In 2000, the expenditure for the healthcare sector accounted for 4.6% of the total GDP and is estimated to increase to

8.5% in 2020. The healthcare investment in 2020 is estimated to be 22-fold higher than in 2000.⁵ In a business report by the Deloitte consulting firm, the expenses of a new drug from research & development (R&D) to market launch were \$1.19 billion in 2010 while the costs increased to \$2.17 billion in 2018. However, the return on investment was merely 3.2% of the total R&D costs.⁶ Therefore, given higher costs and relatively lower market outputs, optimisation of R&D processes, methods, and resource allocations are on the agenda of medical professionals, stakeholders, and investors. The concepts of AI and DH bring wider and more



innovative perspectives to medical specialists and business players on R&D of drugs that are leading to improving medical research processes and transforming business models.

Links between drug development, AI, and DH

In the digital world, drug development experienced earthshaking innovations. The categories of medical research became more heterogeneous. The digital progress brought more possibilities into medical research (e.g., real-world and health economics studies) and collaborations among study sponsors, clinical investigators, and database service providers. Clinical data collection can be easily realised via electronic health records (EHRs) and personal health records (PHRs). The changes were not

limited to the clinical phases of medical research. For instance, in the pre-clinical phase, a digital polymerase chain reaction method was developed to perform DNA sequencing and bone marrow sampling to evaluate disease progression and manage disease risks.⁷ In the clinical phase, digital study endpoints drive innovations and reduce costly late-stage drug development failures. The study design involvements with digital endpoints are evaluated by regulatory agencies [e.g., US FDA (United States, Food and Drug Administration)] as innovative practices. In a study that was conducted by Boehme et al.,⁸ smartphone apps were used to track

New technologies also offer wider career pathways; therefore, writing professionals with multiple skills are needed in the digital world.

mobility patterns and a MOBILISED-D algorithm was created to detect real-world walking speeds. Given that the parameter of gait speed is associated with patients' survival, a walking test, as a surrogate mobility test, was

designed to evaluate the patient survival status by measuring the number of steps over time.^{9,10} In addition to involving digital endpoints in clinical studies, the importance of remote monitoring (e.g., monitoring of adverse events) and digital patient management (e.g., medication guidance, treatment compliance, and medical educations) have already been recognised by the US FDA.

Except for medical research, in the digital design areas of pharmaceutical manufacturing, the technology of 3D printing, instead of tablet compression, is applied to 3D drug products to improve safety, efficacy, and accessibility to medicines.¹¹ The competitive advantages of 3D printing exist in complex and personalised products, and products made on demand. The US FDA approved the first digital drug (ReSETM) in 2018 for treating patients with substance use disorders.¹² In China, traditional medicines stepped into global markets via business models of telemedicines (i.e., purchasing medicines online).¹³ More and more local high-tech digital and IT companies initiated collaborations with the industry, universities, and institutes to explore interprofessional innovations.^{13,14} In a survey of local physician communities involving 7,395 questionnaires, approximately 94% of physicians showed interests in DH wearables.¹⁵

Medical writing in the digital world

In the area of medical writing, the digitalisation progresses seem to have slower paces. In China, since 2008, the digital electronic archive systems of regulatory documents are being implemented by several global pioneer pharmaceutical companies. Since 2013, paralleled editing software (e.g., PleaseReview) was recommended for reviewing and editing regulatory documents. In 2019, the local health authority promised to launch an electronic system of regulatory submission following global electronic clinical



technical document (eCTD) standards. With the implementation of these new systems, regulatory and R&D professionals will be responsible for drafting, editing, reviewing, finalising, and publishing regulatory documents. The finalised documents will be sent out for consolidations with eCTD standards. The steps are completed by official regulatory vendors, and the application dossiers (including all the regulatory-compliant documents) will be submitted to the regulatory authority for reviews and approvals.

The benefits of digitalised regulatory writing consist of regulatory information sharing, improving work efficiency, lowering regulatory submission budgets, and creating new employment opportunities. In the e-system, the draft and intermediate versions can be edited, and all the changes are traceable, in compliance with global archival requirements. On the other side, information security, intellectual properties of regulatory documents, and electronic system compatibility are potential risks of digital writing. These potential issues, as well as public availability of medical research information, access to confidential regulatory documents, and qualifications of the professionals who can access confidential regulatory documents, are the questions that still need to be discussed.

In the US, social media use among adults increased from 5% in 2005 to nearly 70% in 2016.¹⁶ In 2017, 32% of social media consumers already had at least one health app on their smartphone or tablet, a percentage that had doubled since 2013.¹³ According to a published business analysis report released in 2016,¹⁷ the

top 3 mobile health app categories with the greatest market potential were remote monitoring (32%), diagnostic apps (31%), and medical condition management (30%). The content on social media covers drug development, clinical trial recruitment, therapy administration, adherence, information sharing of side effects, and responses. Therefore, medical writers with these skills and knowledge are needed and will be required in the employment market. For example, a mobile app (SBIRT: screening, brief intervention, and referral to treatment),¹⁸ as a highly promoted approach to identifying and treating individuals at risk for alcohol or drug problems, was developed to offer information on medical knowledge and skills from a classroom setting to clinical practice. The app was designed to focus on addressing alcohol and drug uses, and commonly co-occurring issues such as depression and anxiety.

Digitalisation pushes medical writing scopes to become more diverse. Some medical writers may prefer working on regulatory documents that are more formal and need to be compliant with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines, while those who are interested in physician and patient education may prefer publishing in the area of medical education for lay audiences on social media or apps. For patient education materials on social media, medical writers need to master the skill of simplifying complex medical knowledge and medical education

information into plain language that is suitable for patients without medical expertise. In the area of remote monitoring, application of cloud-connected web portals and electronic mobile systems assist reviewing, reporting and analysing real-time patient data, observing drug-related problems during home visits, and communicating drug-related problems to general practitioners (GPs) and pharmacists.^{4,8,19} The content of public health awareness education is likely to be diverse since the audiences are not limited to patients, GPs, and pharmacists, but also to caregivers, babysitters, and patients' relatives with lower levels of literacy. Thus, simple, concise, and friendly information (i.e., what you see, is what you get) is important.

To be a qualified writer in the area of social health media, authors need to understand the users' reading habits and their psychological characteristics. Digital health media mainly focuses on the general public and those without formal medical education; therefore, the writing style should be adapted to the target audience. In some cases, even cartoons, videos, or interactive programs or games can be used to help deliver scientific knowledge more effectively. For instance, in the treatment of pain, epilepsy, stroke, dementia, and other chronic medical conditions, digital technologies are used to deliver music-

based interventions in combination with drug administration.²⁰ For example, in stroke treatments, a music-based video game (MusicGlove) received regulatory clearance by the US FDA following a pivotal clinical study. In developing such kinds of mobile health tools, knowledge of music therapy, composition skills, and script-writing ability would be advantageous strengths for job hunting and career developments. The career of DH writing may offer a new career pathway for those medical writing professionals who possess multiple talents and skills. The technologies of AI and DH add value and create more possibilities for medical writers (e.g., scientific scriptwriters in healthcare sectors of DH companies) and will be trends for writing professionals with diverse strengths and educational backgrounds.

In the digital era, scientific writing will be a core competency for a writing professional and multiple skills are encouraged in industry environments evolving at a fast pace.



Summary

We are in a transition period from traditional R&D business models to innovative ones. Application of AI and DH pushes the industrialisation of medical research more rapidly with higher efficiency. The career of medical writing thus become wider and more diverse due to technological progress. In the digital era, scientific writing will be a core competency for a writing professional and multiple skills are encouraged in industry environments evolving at a fast pace.

Conflicts of interests

The author declares no conflicts of interests.

References

1. Tianle Shen and Xiaolong Fu. Application and prospect of artificial intelligence in cancer diagnosis and treatment. *Chin J Oncol*. 2018;40(12):881-4.
2. National Academies of Sciences, Engineering, and Medicine et al. Proceedings of a workshop – in brief. Artificial intelligence and machine learning to accelerate translational research. 2018 Jul [cited 2019 Jun 29]. <https://www.nap.edu/read/25197/chapter/1#>.
3. Sellwood MA, Ahmed M, Segler MH, Brown N. Artificial intelligence in drug discovery. *Future Med Chem*. 2018 Sep;10(17):2025–8.
4. Liu JF, Lee JM, Strock E, Phillips R, et al. Technology applications: use of digital health technology to enable drug development. *JCO Clin Cancer Inform*. 2018 Dec;2(2):1–12.
5. Daemmerich A, Mohanty A. Healthcare reform in the United States and China: pharmaceutical market implications. *J Pharm Policy Pract*. 2014 Jul;7(1):9.
6. Deloitte: A new future for R&D? Measuring the return from pharmaceutical innovation 2017.
7. Lodrini M, Sprussel A, Astrahantseff K, et al. Using droplet digital PCR to analyze MYCN and ALK copy number in plasma from patients with neuroblastoma. *Oncotarget*. 2107;8(49):85234-51.
8. Boehme P, Hansen A, Roubenoff R, et al. How soon will digital endpoints become a cornerstone for future drug development? *Drug Discov Today*. 2019 Jan;24(1):16–9.



9. Cesari M, Kritchevsky SB, Penninx BW, et al. Prognostic value of usual gait speed in well-functioning older people – results from the Health, Ageing and Body Composition Study. *J Am Geriatr Soc*. 2005 Oct;53(10):1675–80.
10. Studenski S, Perera S, Patel K, et al. Gait speed and survival in older adults. *JAMA*. 2011 Jan;305(1):50–8.
11. Norman J, Madurawe RD, Moore CM, Khan MA, Khairuzzaman A. A new chapter in pharmaceutical manufacturing: 3D-printed drug products. *Adv Drug Deliv Rev*. 2017 Jan;108:39–50.
12. Pear Therapeutics: FDA launched a first digital treatment regimen that redefines medications. 2018 Jul [cited 2019 Jun 29]. http://www.sohu.com/a/241824883_133140.
13. www.360doc.com The importance of digital health in the healthcare sector of listed companies. 2017 Jan [cited 2019 Jul 3]. http://www.360doc.com/content/17/0104/13/36864145_619985235.shtml.
14. Baidu database. Weekly updates on the industry of biomedicine and digital health. 2019 Mar [cited 2019 Jul 3]. <https://wenku.baidu.com/view/6359d994b42acfc789eb172ded630b1c58e9b62.html>.
15. Sohu Healthcare. How do pharmaceutical companies to offer add-value services in addition to drugs? Perspectives from digital health. 2017 Mar [cited 2019 Jul 3]. http://www.sohu.com/a/128247051_456032.
16. Housman LT. "I'm Home (screen)!: social media in health care has arrived. *Clin Ther*. 2017 Nov;39(11):2189–95.
17. How to offer add-value services in pharmaceutical companies? Talking from digital health. 2017 Mar [cited 2019 Jun 29]. http://www.sohu.com/a/128247051_456032.
18. Satre DD, Ly K, Wamsley M, Curtis A, Satterfield J. A digital tool to promote alcohol and drug use screening, brief intervention, and referral to treatment skill translation: a mobile App development and randomized controlled trial protocol. *JMIR Res Protoc*. 2017 Apr;6(4):e55.
19. Dijkstra NE, Sino CG, Heerdink ER, Schuurmans MJ. Development of eHOME, a mobile instrument for reporting, monitoring, and consulting drug-related problems in home care: human-centered design study. *JMIR Human Factors*. 2018 Mar;5(1):e10.
20. Metcalf CS, Huntsman M, Garcia G, et al. Music-enhanced analgesia and antiseizure activities in animal models of pain and epilepsy: toward preclinical studies supporting development of digital therapeutics and their combinations with pharmaceutical drugs. *J Front Neurol*. 2019;10:277.

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Intelligent use of artificial intelligence for systematic reviews of medical devices

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Abstract

Systematic literature reviews are an essential component of the medical device clinical evaluation process. The EU Medical Device Regulation requirement for regularly updated systematic literature searches will increase the burden on the medical writer to maintain and update systematic reviews for many systems and devices. Specialists in systematic reviews are beginning to adopt artificial intelligence tools that aim to optimise searches and streamline the review process. As these tools mature, the medical device writer tasked with a systematic review may want to consider the potential benefits of integrating them into their established systematic review process.

Systematic reviews are the foundation for evidence-based medicine and clinical guidelines. They are also an essential component of the clinical evaluation of medical devices marketed in Europe. The EU Medical Device Regulation 2017/745 (MDR) prescribes a systematic scientific literature review as part of the clinical evaluation process to “identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence”.¹ The EU MDR also includes regular screening of the scientific literature as part of the general methods and procedures for post-market clinical follow-up of marketed medical devices.

The systematic review process is time and resource intensive, requiring highly skilled

reviewers to complete a series of very specialised manual and repetitive tasks. Add to that the reality of a vast and continuously expanding body of medical literature on which a review is based and, in some cases, the entire process takes so long to complete that a review may already be outdated by the time it is published. Various groups, including Cochrane, the recognised expert source on systematic reviews, acknowledge that it is not possible to keep all systematic reviews up-to-date and have developed guidance on when an update is appropriate.^{2,3} However, for the medical device industry, the EU MDR dictates the frequency of these updates (e.g., annually for the highest risk Class III devices) as part of the ongoing clinical evaluation process. Device manufacturers understandably should have an interest in the development and implementation of new technologies to make the systematic review task faster and more efficient.

Artificial intelligence (AI) experts have realised the inherent challenges of the conventional systematic review process and are championing AI technology as the key to managing the flood of scientific literature.⁴ AI has become prominent in the healthcare field, and there is now an emerging AI subspecialty

specifically focussed on how to improve systematic reviews. Machine learning and natural language processing are current applications of AI that hold promise for evidence-based medicine to generate, update, and maintain an up-to-date synthesis of clinical data in a given field. So how exactly can AI improve the systematic review process? What kind of AI tools should the medical device writer be aware of? And should we expect machine learning to eventually relieve us of this clinical evaluation task altogether?

The conventional approach to systematic reviews

Systematic literature reviews can be broken down into several discrete tasks:⁵

1. Protocol – definition of review question, search query, and selection criteria
2. Search – conduct searches in relevant databases
3. Screen – initial publication selection based on title and abstract review; final selection based on full-text articles
4. Extract – extraction of relevant data elements
5. Appraise – critical appraisal of full-text articles, including bias risk assessment

Table 1. AI terminology relevant for systematic literature reviews

Term	Definition
Machine learning	An application of AI that enables computer systems to learn and improve from experience (typically from large amounts of training data) without being explicitly programmed
Natural language processing	A component of AI that applies computational techniques to analyse human language as it is spoken or written
Text classification	Automated categorisation of documents into groups of interest
Data extraction	The task of identifying key data elements and information from texts (e.g., study population, outcomes)
Semi-automation	Using machine learning to increase the speed and efficiency of review tasks rather than to execute them autonomously
Human-in-the-loop	Workflows in which humans remain involved and are supported, rather than replaced, by AI (i.e., semi-automation)

Source: Adapted from Marshall and Wallace.⁶



6. Analyse – qualitative and quantitative data analysis, including meta-analysis, where appropriate

The conventional approach to systematic reviews requires highly skilled resources for what are mostly manual and repetitive tasks. Searches need to be set up and run in multiple databases. Screening and appraisal tasks are generally duplicated by two reviewers with disagreements resolved by a third reviewer. And depending on the number of relevant articles, data extraction is time-consuming and requires additional quality checks. While there are commercial packages available to aid a collaborative review process, many reviewers still rely on basic spreadsheets and reference manager software to track and document their reviews. For EU MDR compliant reviews, each review step also needs to be sufficiently documented so that they can be reproduced for future updates. For companies with many medical devices marketed in Europe, maintenance of reviews for each product to meet regulatory requirements becomes quickly untenable.

AI-supported systematic reviews approach

The steps to undertake an AI-assisted systematic are the same as for conventional reviews. The key difference between the two approaches is the extent to which individual steps in the process could be automated, or rather semi-automated

(see Table 1) using AI technology. Most of the labour-intensive review tasks – screening, data extraction, and to some extent critical appraisal – could be supported by AI-based tools. Table 2 provides some examples of AI-based tools already available that can be used to support distinct tasks of systematic reviews.

Most of these tools use AI to support just one discrete task in the overall review process, and most employ a “human-in-the-loop” workflow, in that they do not intend to replace human reviewers, but rather to make the reviewer more efficient.

Screening

The screening step of the review process is one of the most time-consuming, with much potential for optimisation through the use of AI. This is also an area where AI research efforts have been concentrated, with some tools mature enough to be implemented in your next systematic reviews. After removing duplicate publications from the search results, screeners may have to read several hundred abstracts and quickly and accurately determine if the abstract meets the inclusion requirements of the review. Machine learning tools used for the screening process are designed to learn from the decision of the human reviewer whether to include or exclude each reference reviewed. As the system learns,

references are continuously prioritised and sorted by their likelihood for inclusion. This can focus the screener on the records most likely to meet the inclusion criteria and potentially speed up the entire review process. The potential time savings that could be gained by priority ranking references using machine learning have been demonstrated in a user study of the screening tool RobotAnalyst.⁷

AI-based screening tools can also serve as a second screener. Another systematic review package familiar to some medical device writers is DistillerSR, a web-based reference screening, data extraction and reporting solution for systematic reviews.

Since 2018, DistillerSR has used AI-supported reference screening that uses machine learning and natural language processing. There are several other examples of AI tools that support the screening process using machine learning, including Rayyan and SWIFT-review (Table 2).

The conventional approach to systematic reviews requires highly skilled resources for what are mostly manual and repetitive tasks.

Data extraction

Data extraction is another systematic review task where AI applications are showing promise. The level of extraction provided by each tool can vary from identifying and highlighting sentences that are deemed most likely to contain relevant information to extraction of a specific data element. RobotReviewer is one example of such

Table 2. Examples of AI tools intended to support systematic review tasks

Systematic review task	AI-based functionality
Screening DistillerSR (https://www.evidencepartners.com/) Rayyan ⁸ (https://rayyan.qcri.org/) RobotAnalyst ⁶ (http://www.nactem.ac.uk/robotanalyst/) SWIFT-Review ⁹ (https://www.sciome.com/swift-review/)	Screening systems automatically sort a search retrieval by relevance (probability-based) determined using machine learning and text mining functionality. The relevancy predictions are continuously updated based on the reviewer’s prior selections. Some tools also utilise topic modelling where related abstracts are automatically grouped.
Date extraction ExaCT ¹⁰ (http://exactdemo.iit.nrc.ca/) RobotReviewer (https://www.robotreviewer.net)	These prototype systems automatically extract key data elements, such as PICO information and sample size, from unstructured written text. Automatically extracted content is presented through a web-based interface that assists the human reviewer in verifying and changing the extracted information for each data element.
Appraisal (risk of bias assessment) RobotReviewer ¹¹ (https://www.robotreviewer.net)	This tool attempts to detect risk of bias in randomised controlled trials using a machine learning algorithm; the human reviewer confirming the initial assessment of the tool (semi-automation). A free demo tool is available at https://robotreviewer.vortext.systems/ .

Abbreviations: PICO, population, intervention, comparator, outcome.
 This list is not intended to be exhaustive; see SR Toolbox¹² for more complete and up-to-date lists.

a tool that can extract text describing population, intervention, control, and outcomes – the so-called PICO elements. For a fun demonstration, take a PDF of your favourite randomised controlled trial publication and drag and drop the file into their demo tool available at <https://robotreviewer.vortext.systems/>. It will automatically highlight text throughout the document that describes each PICO element (Figure 1) and generates a report that summarises the study characteristics and main findings. One limitation of this tool is that it captures both intervention and control together under the single “intervention” label. A human reviewer is still needed to interpret the intervention under study and the control treatment.

In a systematic review of methods used for data extraction for systematic review, the authors found that many methods aimed to extract relatively straightforward data elements; the most frequently studied data elements were participant characteristics, interventions, and outcomes (as seen with the RobotReviewer example).¹³ Many other important data elements, such as duration of follow-up or incidence of adverse events for each participant group, have been studied to a lesser extent or not at all. Another limitation of the current AI tools is that most are limited to evaluation of randomised controlled trials. This is a barrier for adoption by the medical device writer as a substantial amount of the medical

device data used in clinical evaluations comes from observational studies. Some research groups have acknowledged this gap and are working to expand the body of AI research in this area.¹⁴

Critical appraisal

AI is also being used to appraise publications selected for full-text review, for example by assessing the risk of bias. One example system attempting this task is again RobotReviewer.^{14,15} The tool analyses the full text of a publication and identifies information about randomisation, allocation concealment, and blinding of participants and outcome assessment to generate a bias assessment report using the Cochrane risk of bias tool (Figure 2). In addition to the bias assessment report, the tool also automatically highlights text relevant to each potential source of bias (analogous to the highlighted PICO elements shown in Figure 1).

Adoption of AI tools by researchers and industry

AI tools for systematic review have not yet matured sufficiently to see widespread adoption by researchers or industry users. There are many

systematic review tools utilising machine learning as an underlying approach, in prototype or early development stage; 17 such tools in the field of healthcare were identified using the SR toolbox search tool.¹² Clear limitations to these systems at this stage include the limited types of data elements that can be extracted and the paucity of research into machine learning applied to observational studies or study designs other than RCTs.¹⁴ Some additional barriers to early adoption are scepticism about the reliability of AI-assisted reviews, a general distrust of handing over an assessment to a computer, or just the logistics of trying to integrate a new tool into an established process.¹⁶ While most of the example tools in Table 2 are either completely free or offer free versions, the cost of some commercial tools may be prohibitively expensive, especially for the freelance medical device writer.

A quick informal survey of members of EMWA’s medical device special interest group revealed that few had experience with AI-based tools. DistillerSR and Rayyan were mentioned, but not used regularly, and most

The full potential of AI-based tools to optimise systematic reviews has not yet been realised, but the field is developing rapidly. writers queried relied on spreadsheets and their preferred reference manager software to carry out reviews. Early adopters of AI-based review tools could

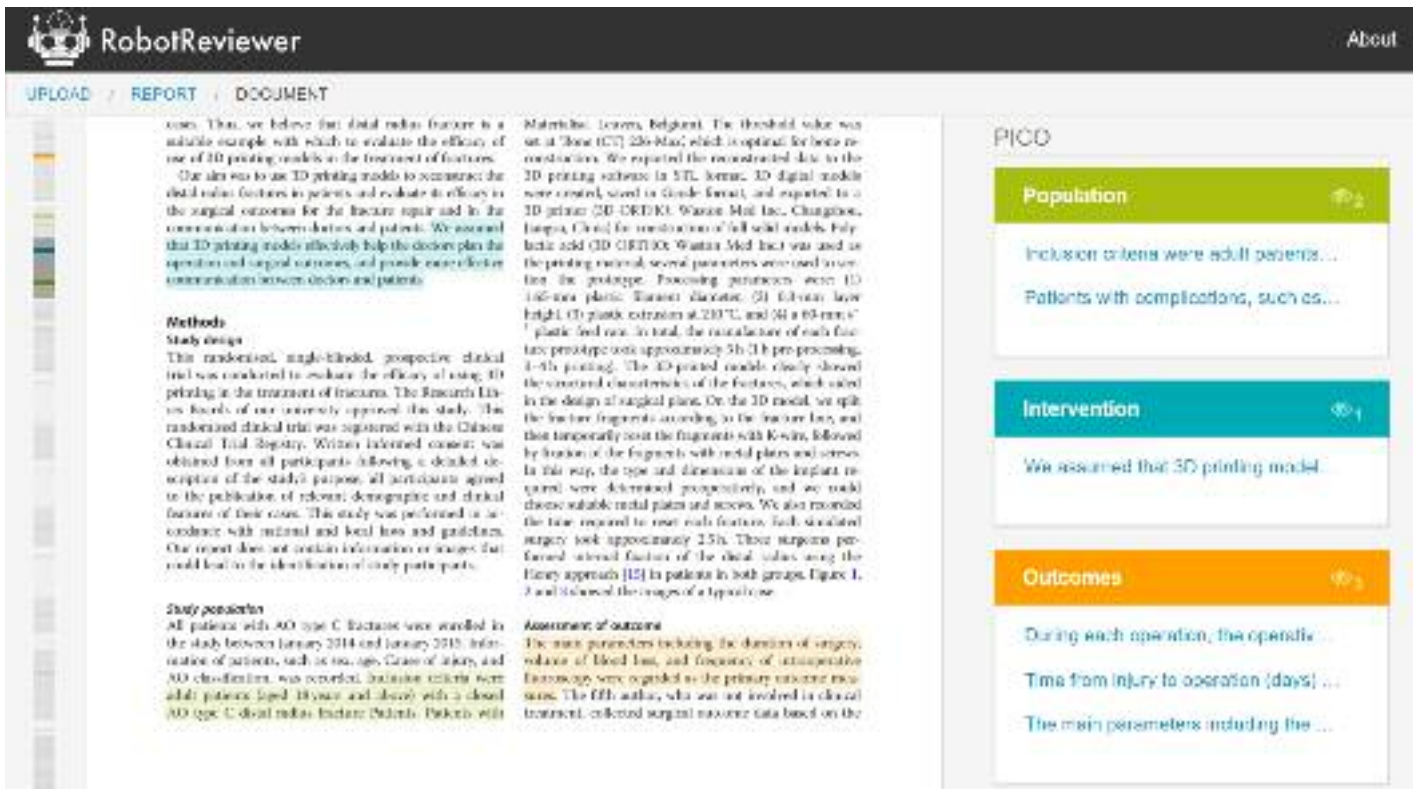


Figure 1. Web-interface of the RobotReviewer demo system showing automatically extracted information on study population, intervention, and outcomes from a PDF publication of a randomised controlled trial

potentially also contribute to their further development by providing data sets of screened and appraised literature that can be used to further train and refine these systems. But it remains to be seen if medical device writers will adopt these tools and be able to successfully integrate them into their review process.

What lies ahead

It seems clear that AI is not about to replace the human systematic reviewer. The full potential of

AI-based tools to optimise systematic reviews has not yet been realised, but the field is developing rapidly. If developers can address the limitations of the current tools, such as enabling screening of study designs other than RCTs and expanding the possibilities for data extraction, their appeal to the medical writer will grow. Companies and writers that are tasked with the creation and maintenance of clinical evaluation reports should evaluate the potential advantages of adopting some of these emerging tools into their clinical

evaluation processes. A validated, reliable, and easy-to-use tool that incorporates AI technology to support multiple steps of the systematic review process for multiple study designs is hopefully not too far away. Medical device writers should be on the lookout for such tools that could optimise the systematic review process as this exciting field continues to develop.

Trial	Design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of output assessment
Dishman RK, 2010	RCT	?	?	?	?
Fjeldsoe BS, 2010	RCT	+	?	?	?
Online R, 2008	RCT	?	?	?	?
Furber S, 2010	RCT	+	+	?	?

Figure 2. Example bias assessment table generated by RobotReviewer from full-text analysis of four RCTs

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Conflicts of interest

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References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. [cited 9 Sep 2019]. Available from: <https://eur-lex.europa.eu/eli/reg/2017/745/2017-05-05>.
2. Garner P, Hopewell S, Chandler J, MacLehose H, Schunemann HJ, Akl EA, et al. When and how to update systematic reviews: consensus and checklist. *BMJ (Clinical research ed)*. 2016;354:i3507.
3. Policy: Cochrane Review updates 2019 [cited 7 Sep 2019]. Available from: <https://documentation.cochrane.org/display/EPPR/Policy%3A+Cochrane+Review+updates>.
4. Extnance A. How AI technology can tame the scientific literature. *Nature*. 2018;561(7722):273–4.
5. Higgins JPT, Green S, editors. *Cochrane handbook for systematic reviews of interventions version 5.1.0* [updated March 2011]. The Cochrane Collaboration; 2011. Available from: <http://handbook.cochrane.org>.
6. Marshall IJ, Wallace BC. Toward systematic review automation: a practical guide to using machine learning tools in research synthesis. *Syst Rev*. 2019;8(1):163.
7. Przybyla P, Brockmeier AJ, Kontonatsios G, Le Pogam MA, McNaught J, von Elm E, et al. Prioritising references for systematic reviews with RobotAnalyst: A user study. *Res Synth Methods*. 2018;9(3):470–88.
8. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. *Syst Rev*. 2016;5(1):210.
9. Howard BE, Phillips J, Miller K, Tandon A, Mav D, Shah MR, et al. SWIFT-Review: a text-mining workbench for systematic review. *Syst Rev*. 2016;5(1):87.
10. Kiritchenko S, de Bruijn B, Carini S, Martin J, Sim I. ExaCT: automatic extraction of clinical trial characteristics from journal publications. *BMC Med Inform Decis Mak*. 2010;10:56.
11. Marshall IJ, Kuiper J, Wallace BC. RobotReviewer: evaluation of a system for automatically assessing bias in clinical trials. *J Am Med Inform Assoc*. 2016;23(1):193–201.
12. SR Tool Box. 2019 [cited 9 Sep 2019]. Available from: <http://systematicreviewtools.com/index.php>.
13. Jonnalagadda SR, Goyal P, Huffman MD. Automating data extraction in systematic reviews: a systematic review. *Syst Rev*. 2015;4:78.
14. Karystianis G, Thayer K, Wolfe M, Tsafnat G. Evaluation of a rule-based method for epidemiological document classification towards the automation of systematic reviews. *J Biomed Inform*. 2017;70:27–34.
15. Soboczenski F, Trikalinos TA, Kuiper J, Bias RG, Wallace BC, Marshall IJ. Machine learning to help researchers evaluate biases in clinical trials: a prospective, randomized user study. *BMC Med Inform Decis Mak*. 2019;19(1):96.
16. O'Connor AM, Tsafnat G, Thomas J, Glasziou P, Gilbert SB, Hutton B. A question of trust: can we build an evidence base to gain trust in systematic review automation technologies? *Syst Rev*. 2019;8(1):143.

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What medical writers need to know about regulatory approval of mobile health and digital healthcare devices

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Abstract

The rapid growth of mobile health (mHealth) led to the development of internationally harmonised guidance for software as a medical device (SaMD) by the International Medical Device Regulators Forum (IMDRF), covering definitions, risk classification, quality management, and clinical evaluation. The EU Medical Devices Regulation (MDR), applicable from May 26, 2020, onwards, specifically addresses SaMDs and adopted aspects of IMDRF guidance. In particular, Rule 11 of the MDR will have significant implications, as many products so far not classified as medical devices or as class I, may be considered class IIa, IIb, or III medical devices. The entry of technology firms into the medical device field will further drive mHealth and the incorporation of novel technologies into SaMD. This article aims to provide the relevant regulatory background information for medical writers who are requested to support the preparation of the regulatory and clinical documentation for SaMD required for MDR compliance.

The rise of digital healthcare, medical applications, and software as a medical device

The rise of mHealth applications

Digital healthcare (DH) or digital health and care, is defined by the European Commission as tools and services that use information and communication technologies to improve the prevention, diagnosis, treatment, monitoring, and management of health and lifestyle.¹ Central to DH are the three aspects of (1) the DH data input, (2) their subsequent analysis to provide robust and reliable health assessment outputs and (3) the ability for both the input and output information to be transferred between different hardware, often using wireless and mobile networks. The convergence of major technological advances over the last decades supporting

all these aspects, as well as societal changes, have led to the ongoing rise of DH aimed to improve access to and quality of healthcare, and increase the overall efficiency of the health sector. Crucial to this is the software that underpins the tools and services that analyse the data to support disease prevention, diagnosis, treatment, monitoring, and management decisions. Accordingly, ensuring the appropriate design and quality of medical software algorithms, as well as ongoing algorithm refinement, including artificial intelligence (AI) and machine learning (ML) software, is key in providing more informed healthcare decisions and improved patient care. Early DH focused on development of digitalised health information systems for patient data management and recording, with DH services like telecare, telehealth, and health analytics for data mining and analysis of health record data, which



were used by trained personnel. Although these products contained software, it was integrated in medical hardware, and thus covered by the applicable medical device regulatory framework. However, in the last decade, mHealth apps, stand-alone software which can be installed on personal mobile phones and tablets, became fully established in DH. From an initial 500 applications available in the first app marketplace in 2008, the field of mHealth expanded dramatically to approximately 150,000 mHealth apps available on the major app marketplaces in 2015,² which further doubled to over 300,000 mHealth apps in 2017.³ Unlike previous DH products, mHealth applications can be developed using platforms with relatively low costs and easily marketed in mobile applications marketplaces. Furthermore, mHealth applications were developed to be used by individuals without medical training, to generate and analyse data and even interconnect with unrestricted body sensors and monitoring devices or wearables.

Development of regulatory frameworks for software as medical devices

To address this rapidly expanding field, the US

FDA released a draft guidance on mHealth applications for public comment in 2011.⁴ Medical device regulatory authorities of Australia, Brazil, Canada, China, the EU, FDA, and Japan, as well as the WHO, established the International Medical Device Regulators Forum (IMDRF) with the aim to develop a harmonised approach to the regulation for medical devices, particularly stand-alone software. By the end of 2013, the first major mHealth directed regulatory document was released by the IMDRF Software As A Medical Device (SaMD) Working Group, entitled “Software as a Medical Device (SaMD): Key Definitions”.⁵ According to IMDRF’s definition, SaMD (1) must have a medical use of diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury as its intended purpose, (2) does not have to be part of medical hardware, (3) must be unable to drive medical hardware and (4) may be interfaced with, or a module of medical hardware. Subsequently the IMDRF released a guidance document for categorisation of SaMD into four risk groups (I-IV) in 2014,⁶ a guidance document on the quality management system (QMS) to be applied to SaMD based on the standards ISO

9001 and ISO 13845 in 2015, and a guidance document for clinical evaluation of SaMD in 2017,⁸ all of which were published at the time of the Medical Device Directive (MDD) in the EU. The new EU Medical Device Directive (MDR), will apply as of May 26, 2020, and in addressing SaMD it adopts aspects of the IMDRF approaches with regard to definitions, classification, implementation of lifecycle QMS, and clinical evaluation.⁹ This is highlighted in the recently published guidance on qualification and classification of software by the European Commission, which also introduced the term Medical Device Software (MDSW) instead of SaMD.¹⁰ The MDR will have significant implications for mHealth developers to ensure compliance with new requirements. Other global jurisdictions are in the process of adapting their legislation to include SaMD. The primary goals of this legislation are to balance patient safety with timely access to innovative mHealth products, while ensuring the continuous monitoring of the risk and performance profile of mHealth products, with focus on the MDR and personal data protection, including cybersecurity. The aim of this article is to provide an overview of current regulations and standards applicable to mHealth and SaMDs in the EU and US, which are important to know for medical writers who support the preparation of documentation required for regulatory compliance of mHealth products, with focus on the MDR (Table 1).

Application of the MDR to software and mHealth apps

The extent of required activities for regulatory compliance is based on the risk class of the SaMD. For the manufacturer, the first step in the conformity process for software and apps under the MDR regulation is an assessment of whether the product should be considered as a medical device according to the definitions (Table 2).⁹ If this is the case, the second step is to attribute the device to a risk class level based on the classification rules, which will then dictate the requirements for certification.⁹ These requirements include a declaration of conformity to the general safety and performance requirements (GSPR), technical documentation, verification, validation, pre-clinical and clinical evaluation, usability, risk management, medical device vigilance reporting, data integrity, information security and, should the conformity assessment

The primary goals of this legislation are to balance patient safety with timely access to innovative mHealth products, while ensuring the continuous monitoring of the risk and performance profile of mHealth products, with focus on the MDR and personal data protection, including ensuring cybersecurity.



Table 1. Overview of regulations and standards applicable to SaMD in the EU and the US

Regulation(s)	Jurisdiction (Regulator)	
	Europe (EU Commission)	US (FDA)
Regulation(s)	<ul style="list-style-type: none"> • EU MDR 2017/745 • Regulation (EU) 2016/679 (GDPR) 	<ul style="list-style-type: none"> • FDA 21CFR
Standard(s) cited	<ul style="list-style-type: none"> • ISO 13485 • IEC 62304 • IEC 60601 • IEC 82304-1 	<ul style="list-style-type: none"> • AAMI TIR 45:2012 • GAMP5 – SW Validation
Definitions	<ul style="list-style-type: none"> • EU MDR 2017/745 	<ul style="list-style-type: none"> • IMDRF/SaMD WG/N10: 2013
(Risk) classification	I, Im, IIa, IIb, III	I, II, III IMDRF/SaMD WG/N12:2014
Product approval	Im, IIa, IIb, III: EC certificate according to MDR issued by EU Notified Body	II, III: FDA approval via PMA or 510k
Certificate validity	Max. 5 years	–
Quality Management System and standards	<ul style="list-style-type: none"> • ISO 13485 • ISO14971 • EC 62304 	<ul style="list-style-type: none"> • FDA 21 CFR 820 (QSR) • FDA 21 CFR 810 & 830 • FDA 21 CFR 803 • FDA 21 CFR 806
Clinical Evaluation	<ul style="list-style-type: none"> • ISO 14155 – clinical investigations 	<ul style="list-style-type: none"> • IDE/IRB21 CFR Part 8 • 12, 50, 56, 54, and 820 • IMDRF/SaMD WG/N41:2017
Data protection	Regulation (EU) 2016/679 (GDPR)	<ul style="list-style-type: none"> • HIPAA • Federal trade commission health breach notification rule

Abbreviations: AAMI TIR = Association for the Advancement of Medical Instrumentation technical information report; CFR = Code of Federal Regulations; EC = European Commission; GAMP5 – SW = Good Automated Manufacturing Practices 5 - Software; GDPR = General Data Protection Regulation; HIPAA = Health Insurance Probability and Accountability Act; IDE: Investigational device exemption; IEC = International Electrotechnical Commission; IRB: Institutional review board; ISO = International Standards Organisation; MDR = Medical Device Regulation; PMA: premarket approval application; QSR = Quality Systems Regulation; SaMD WG: Software as a Medical Device Working Group

Note: Applicable regulations, guidance, and standards are subject to change and it is recommended to always check for current information.

route require it, the involvement of a Notified Body. The medical writer can play an important role in supporting the required documentation, in particular in assessing clinical evidence and the verification and validation of the software with a clinical association. Data sources for mHealth apps include descriptions on mobile market-places, in some cases with specific guidelines for medical apps related to privacy, claims, data, and methodology.¹¹ For SaMD defined in MDR, placement on the EU market is only allowed once it has been demonstrated that the GSPR are met and the product is CE-marked.

Definition of software as a medical device

The governing principle for establishing whether a software or apps is a medical device depends on its intended use (Table 3). If the intended use is for a medical purpose of diagnosis, prevention, monitoring, treatment, alleviation, as well as

specific prediction or prognosis of disease and injuries in humans, it is considered as a medical device, irrespective of the type of application. Further, the MDR defines software as an accessory to a medical device if it “enables” or can “assist the medical functionality”, which is broader than the corresponding definition in the MDD, that only includes software that “enables” the device as an accessory. In contrast, software and apps used for general lifestyle and well-being software are not considered as a medical device under the MDR, and thus not subject to MDR requirements. According to the MDD,¹² only stand-alone software is considered as a medical device; software embedded or in a medical device does not require certification separate to the device, in line with IMDRF definitions.⁵ However, the MDR is not limited only to stand-alone software and states that “devices that incorporate electronic programmable systems,

including software” or “devices that incorporate software” must address performance, quality, and risk management procedures.

Classification of software as a medical device

The MDR adopts a risk-based system for classification of stand-alone software from the MDD into four risk classes, considering the degree of invasiveness of the device and taking account the potential risks associated with the devices (Table 3).¹² In addition, the MDR includes a new rule specifically addressing the classification of software. Rule 11 assigns software that provides information to be used for making decisions for diagnosis or treatment to class IIa; however, if these decisions may cause death or an irreversible deterioration of health, or otherwise seriously deteriorate a person's state of health or a surgical intervention, it will be class III or IIb, respectively. Software intended to monitor physiological

Table 2. Definition of software as a medical device according to MDR 2017/745

Software defined as a medical device	Description	MDR ref.
Stand-alone software	<ul style="list-style-type: none"> • Software in its own right when specifically intended by the manufacturer to be used alone or in combination, for human beings for specific medical purposes including diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease or injury. • Software used with devices for the control or support of conception. 	Recital 19 & Art 2 (1)
Stand-alone software used as an accessory to a medical device	<ul style="list-style-type: none"> • Software is considered an accessory to a medical device when it is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s). 	Art 2 (2)
Software not defined as a medical device	Description	MDR ref.
Not a medical device	<ul style="list-style-type: none"> • Not intended to be used alone or in combination for a medical purpose. • Software for general purposes, for lifestyle and well-being purposes is not a medical device. 	Recital 19 Art 2 (1)
Embedded software in a medical device	<ul style="list-style-type: none"> • Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves. • Software that is intended to be used in combination with mobile computing platforms. 	Annex I Section 17.1-4
Additional considerations	Description	MDR ref.
Qualifiers	<ul style="list-style-type: none"> • Software shall also be deemed to be an active device. • The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device. 	Recital 19 Art 2 (4)

processes is assigned to class IIa, or class IIb, respectively, if it is used for monitoring of vital parameters, changes of which immediately endanger the patient. All other software not covered by these definitions falls into class I. Software which drives or influences the use of a device shall fall within the same class as the device. The SaMD risk classification has important implications for the manufacturer, as it dictates the conformity requirements. Depending on the manufacturer's decision, multiple conformity routes can be taken for class IIa, IIb, and III SaMDs, which involve assessment by a Notified Body.

Conformity requirements for software as a medical device

The GSPR of the MDR (paragraph 17.1) introduces a new requirement for ensuring software repeatability, reliability, and performance in line with its intended use and eliminating or reducing as far as possible the risks in the case of a single fault condition. This is coupled with the existing requirements as previously defined in the MDD for development and manufacturing to be in accordance with the state of the art, taking into

account the principles of development life cycle, risk management, including information security as well as verification and validation. These requirements are generally addressed by a QMS, thus the implementation of a suitable QMS is a prerequisite for compliance with MDR requirements. Accordingly, international standards like ISO 13485, ISO 14971, and IEC 62304, should be considered in the establishment of a QMS. Notably, the IEC 62304 standard is focused on risk management over the life cycle of the product and on its application to software regulation in the with US, and is closely intertwined with clinical evidence represented by data accumulated on safety and performance of the application through post-marketing monitoring.

Clinical evidence requirements for software as a medical device

The requirements regarding pre-clinical and clinical data for medical devices, including software, are set out in MDR Annex II. Documents outlining clinical data information on tests, generated data, and conclusions demonstrating pre-clinical safety of the software is required. Further, software verification and validation

should describe the software design and development process, provide evidence of the validation of the software, and should include testing performed both in-house and in a simulated or actual user environment prior to final release. Presentation of clinical evidence represents an important role for medical writers in supporting conformity assessments. This includes demonstration of a scientifically robust clinical association, validation of the software's ability to generate a clinically meaningful output measure, and critical verification that this output is accurate, reliable, and reproducible. The life cycle requirements set out in IEC 62304 highlight the importance of continuous monitoring, hazard identification and corrective actions as providing a source of clinically relevant evidence that intersects with post-marketing follow-up requirements described in Annex III of the MDR. IEC 62304 recognises the evolving nature of hardware platforms and associated software refinements to both maintain and improve software performance and resulting clinically meaningful measures. By recording, assessing, and integrating data from clinical use into the software algorithms, post-marketing clinical data integrates

into a total product lifecycle approach that is currently advocated by both the FDA and IMDRF.

Promise and challenges on the horizon

Compliance with new regulations

With the impending MDR application, differences in regulations and guidance between the EU, US, and the IMDRF will become more relevant, specifically those related to the broader definition of software as a medical device and risk classification. The MDR requires compliance of medical device manufacturers placing Class I, new, up-classified or modified products on the Market from May 2020, with only limited software-specific guidelines to support developers in their implementation. Because of the risk severity approach combined with the higher rule classification for combined software and medical hardware, many software products will be required to be reclassified into higher risk classes, which imposes more stringent regulatory requirements. In the context of mHealth, compliance to not only MDR but also to the recently enforced General Data Protection Regulation (GDPR) is highly relevant.¹³ The GDPR is applicable for companies throughout the world who are processing personal data of people living in the EU and by EU-based companies processing personal data irrespective of whom the personal data belongs to. Anonymi-

sation, when possible, or pseudonymisation of patient data, and its satisfactory encryption must be considered for MDR activities such as post-market surveillance, manipulation, transfer, storage, deletion of clinical data, safety and performance requirements, transparency, and traceability of medical devices. The GDPR imposes much stricter requirements, in terms of data protection, than those in the MDR or the software regulations of the US and IMDRF countries that focus primarily on cybersecurity protection. Compliance with the GDPR is particularly relevant for mHealth apps and will continue to be an important consideration in future software developments.

Artificial intelligence and machine learning-based software as medical devices

AI and ML technologies represent great promise for improving DH and mHealth applications; however, they also raise regulatory concerns, in particular related to their use in medical decision-making. While the MDR does not address AI/ML technologies, the FDA has recently proposed a regulatory framework for modifications of AI/ML-based SaMD for discussion.¹⁴ Importantly, the inherent nature of the constant adaptation of AI/ML software indicates that over time the certified software may become significantly different to when it was initially approved and therefore would warrant a new premarket

review to ensure maintained performance and safety. The proposed regulatory framework aims to overcome this issue with a total lifecycle approach, including a closer interaction with developers, identification of pre-determined change types that would be acceptable and periodic update reports on such changes. The FDA has already approved marketing of several AI-based medical devices since 2018.

Entry of technology companies into the medical device market

The entry of the major technology companies into the medical device field by investing in scientific knowledge and partnerships with established healthcare companies and academic labs has the potential to facilitate the integration of new technologies into the healthcare field. Examples of such collaborations, which also engage the user or patient in the development process include Google’s Project Baseline¹⁵ and Apple’s ResearchKit,¹⁶ or Apple’s CareKit,¹⁶ an open source framework to support the development of applications for medical care. Technology companies are also driving integration of mHealth-based apps with wearables, fitness bands, monitors, watches, and rings, to further increase the quantity and quality of available data, but which also raises challenges for MDR and GDPR compliance, as well as cybersecurity and patient’s rights.

Table 3. Classification of software as medical device according to MDR 2017/745

Class	Classification criteria	MDR ref. classification rules (Annex VIII)
Class I	• Considered under the MDR as a medical device but not under classification rules as IIa-III	Rule 11
Class IIa	• Informing on diagnostic/ therapeutic decisions, except those which are considered as class IIb and class III • Monitoring physiological processes	Rule 11 Rule 10
Class IIb	• Informing on diagnostic/ therapeutic decisions with impact that may cause serious deterioration of state of health or a surgical intervention • Directly influencing the performance of active therapeutic class IIb device • Monitoring of vital physiological parameters variation of which can cause immediate danger	Rule 9 Rule 10 Rule 11
Class III	• Informing on diagnostic/ therapeutic decisions with impact that may cause death or irreversible deterioration of state of health • For controlling, monitoring, or directly influencing the performance of active implantable devices • With an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as, are classified as class III	Rule 11 Rule 9 Rule 22
Not a medical device	• Not intended to be used alone or in combination for a specific medical purpose • Data storage or recording only	NA



Conclusions

While mHealth products and the pertaining software have great potential to improve healthcare, their performance according to the claims, and patient safety, need to be ensured. Therefore, international standards for SaMD have been developed by the IMDRF, and regulatory frameworks updated to include software-specific requirements. The MDR, which applies after May 2020 specifically addresses SaMD and will result in up-classification of many mHealth products, imposing more stringent regulatory requirements. Medical writers will play an important role supporting the preparation of regulatory documentation for SaMD required for certification according to MDR. The rapidly evolving technology, including the incorporation of AI/ML and the integration of SaMDs with sensors and monitors will require regular adaptation of regulations and guidance. Stakeholders, in particular SaMD developers, are encouraged to actively monitor development in this field to take necessary actions ensuring compliance with the applicable regulatory framework.

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Conflicts of interest

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References

1. eHealth: Digital health and care. 2019 [cited 2019 Sept 25]. Available from: https://ec.europa.eu/health/ehealth/overview_en.
2. IMS Institute for Healthcare Informatics.

3. Patient adoption of mHealth. Use, evidence and remaining barriers to mainstream acceptance. USA. 2015.
3. Research2Guidance. mHealth app economics 2017. Current status and future trends in mobile health. Berlin. 2017.
4. US Food & Drug Administration. Draft guidance for industry and Food and Drug Administration staff – mobile medical applications. Washington DC, 2011.
5. IMDRF Software as a Medical Device (SaMD) Working Group. Software as a medical device (SaMD): Key definitions. 2013.
6. IMDRF Software as a Medical Device (SaMD) Working Group. “Software as a medical device”: Possible framework for risk categorization and corresponding considerations. 2014.
7. IMDRF Software as a Medical Device (SaMD) Working Group. Software as a medical device (SaMD): Application of quality management system. 2015.
8. IMDRF Software as a Medical Device (SaMD) Working Group. Software as a medical device (SaMD): Clinical evaluation. 2017.
9. European Union, Regulation (EU) 2017/745 on Medical Devices. Official Journal of the European Union. 2017;L117.
10. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR. 2019. Medical Device Coordination Group (MDCG) as an author [cited 2019 Dec 6]. Available from: <https://ec.europa.eu/docsroom/documents/37581?locale=en>.
11. App Store Review Guidelines. 2019 [cited 2019 Sept 25]. Available from: <https://developer.apple.com/app-store/review/guidelines/>.

12. European Commission. Guidance document medical devices – scope, field of application, definition – qualification and classification of stand alone software – MEDDEV 2.1/6. 2016.
13. European Union, Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR). Official Journal of the European Union. 2016; L119: p. 1-88.
14. US Food & Drug Administration. Proposed regulatory framework for modifications to artificial intelligence/ machine learning (AI/ML)-based software as a medical device (SaMD) – discussion paper and request for feedback. Washington DC. 2019.
15. Project Baseline by verily. 2019 [cited 2019 Sept 25]. Available from: <https://www.projectbaseline.com/>.
16. ResearchKit and CareKit. 2019 [cited 2019 Sept 25]. Available from: <https://www.apple.com/lae/researchkit/>.

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Digitalisation in long-term care: An issue for medical writers?

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Abstract

Digitalisation within the healthcare sector, particularly in long-term care, comes with implementation problems. Accepting digitalisation in caregiving as patient and healthcare professional depends on the understanding of the scope and application area of digital supportive systems. Good practice standards in medical writing may help to convey digital health contexts for a wide range of target groups.

When looking at the progression of digitalisation in healthcare, there are vast differences in the social and health systems in terms of connectivity, internet service use and digital technology integration.¹ In the EU, the uptake of digital products and services is diverse with varying degrees of sophistication. Although the number of data-related technology users in the EU is growing rapidly, data use in healthcare still lags behind.²

Digitalised healthcare connects formal (professional) and informal (non-professional) caregivers via digital communication tools and platforms. These systems not only communicate health information but are also intended to improve social interaction via online assistance.³ However, the long-term care sector is a healthcare market where personal relationships between patients and physicians, nurses or caregivers are highly important. Any change process from these personal interactions towards

interaction and communication with digitalised tools is considered critically by all stakeholders. The perceived quality of the healthcare service is strongly linked to the quality of these relationships. Hence, implementation problems and other difficulties slow down the evolution of digitalised health.⁴

Healthcare is an information-driven sector where the choice of adequate communication channels and that of target-oriented content is highly important. However, there are barriers in developing suitable and sustainable “digital communications” in a comprehensive manner in Germany. An example of the current status of digitalisation in different branches for Germany is the D21-digital-index that also analysed acceptance and use of digital health applications (eHealth).⁵

Are medical devices more trusted than home digital assistance products?

A recent computer-based survey in Germany (N=2052, persons aged 14+) asked participants about their current use and perceptions of technologies such as “internet of things”, “artificial intelligence”, “algorithm”, and “bots”. About 20% of the sample considered the mentioned technologies as “rather positive”,

11% as “rather negative”, and 38% felt indifferent or neutral. In the sample, 27% did not know the meaning behind the technologies. The younger the respondents, the more they were open-minded towards new technologies; people with a low educational status were least open-minded.

Intelligent household appliances, even robots, were already used by 6% of the sample, where in comparison, digital health applications were used by 12% of respondents. People feel rather uncomfortable with digitalised assistance products at home but feel rather comfortable with medical devices that deliver medication to the body, supervise clinical parameters, and inform medical staff in case of emergencies

(Figure 1). Acceptance of robotics, however, seems to be limited.⁵

These results show that digitalised services are met with scepticism in a broad part of the German population – but there seems to be a higher degree of trust in digital health services. Personal interaction is the foundation of most forms of health care services where these relationships and interactions are based on information and mutual trust. Both seem to strongly influence the acceptance and usage of digitalised innovation in health care.⁶

Digitalised services are met with scepticism, but there seems to be a higher degree of trust in digital health services – maybe due to the importance of personal relationships and trust.

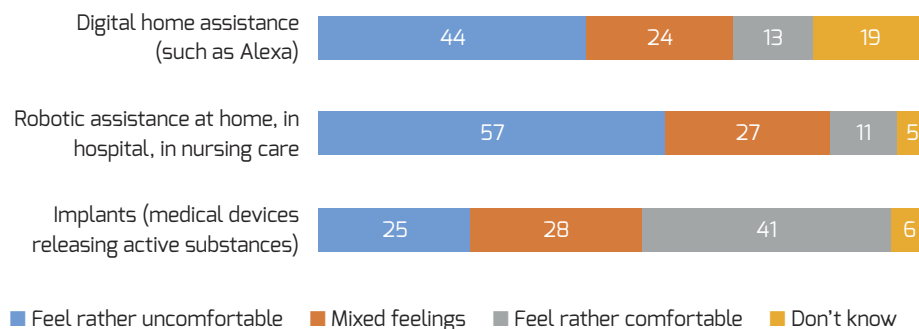


Figure 1. Perception of intelligent devices. Author figure based on data from Initiative D21 e.V., 2019



Higher degree of trust in robotics due to personal relationships in health care

Accepting robots in caregiving is dependant on users understanding their scope of activity and which services the robots will replace.⁷ Providing detailed information about the type of tasks robots are expected to accompany or substitute within long-term care is crucial to promote digital use. Consequently, there is a need for practical and understandable information about the role robots will play in specific caregiving scenarios. Equally so, it is important to understand caregiver beliefs about the impact robots will make, whether as a complement or substitute. A specific healthcare communications approach may help end-users' understanding of new digital technologies such as robots or new digital frameworks as well as to bridge from analogue healthcare relations. These guides may help healthcare professionals to communicate nursing care concepts and also inform patients

about how, and to what extent, digitalised tools and services can help in long-term care environments. Both nurses and informal caregivers could benefit from such support. The challenge will be to properly address health and digital literacy for the various different target groups.

Importance of (digital) health literacy

Health literacy is an individual's knowledge, motivation and ability to access, understand, appraise, and apply health information. Health literate people judge and decide on given options and alternatives in healthcare, disease prevention and health promotion to maintain or improve

quality of life.^{8,9} In a digital context, health literacy needs to be expanded to include digital literacy. This means users need to be able to use

There is a need to provide clearly understandable information about the role of robots in caregiving, and the concept of (digital) health literacy needs to be at the centre of good healthcare writing.

digital devices, and have appropriate cognitive, motor, sociological, and emotional skills.¹⁰ There is no common understanding of digital literacy so far.¹¹ One component, for example, is to understand how and where data are saved as well as how, to what extent and to which purposes, they are processed. Referring to care-related digital solutions, handling of someone's own care needs and potentials can be better matched if those involved are aware of potentials, risks, and pitfalls of emerging digital health care solutions.

It will be a necessity and challenge to address digital health literacy and develop best practices in healthcare communi-

cations. The role of good medical writing will need to convey digital health contexts for a wide range of target groups, their needs and demands.

Conflicts of interest

The authors declare no conflicts of interest.

References

1. European Commission. The Digital Economy and Society Index (DESI). 2019 [cited 2019 Sep 2]. Available from: <https://ec.europa.eu/digital-single-market/en/desi>.
2. European Commission. European Data Market study: Data related health tech growing fast. 2017. [cited 2019 Sep 2]. Available from: <https://ec.europa.eu/digital-single-market/en/news/european-data-market-study-data-related-health-tech-growing-fast>.
3. Kushniruk AW, Borycki EM (Vimarlund E, editor). Usability of Healthcare Information Technology: Barrier to the Exchange of Health Information in the Two-Sided E-Health Market? E-Health and Two-Sided Markets, Academic Press London; 2017. pp. 33–41.
4. Krick T, Huter K, Domhoff D, Schmidt A, Rothgang H, Wolf-Ostermann K. Digital technology and nursing care: a scoping review on acceptance, effectiveness and efficiency studies of informal and formal care technologies. *BMC Health Serv Res*. 2019;19:400.
5. Initiative D21 e.V. Initiative D21. D21-Digita-Index 2018/2019. 2019 [cited 2019 Sep 2]. Available from: https://initiated21.de/app/uploads/2019/01/d21_index2018_2019.pdf.
6. Shin D-H, Park YJ. Digital Policy, Regulation and Governance (2017) Understanding the Internet of Things ecosystem: multi-level analysis of users, society, and ecology. *Digital Policy. Regul Gov*. 2017;19(1):77–100.
7. Wirtz P, Patterson P, Kunz W, Gruber T, Nnat Lu V, Paluch S, Martins A. Brave new world: service robots in the frontline. *J Serv Manag*. 2018;29(5):907–931.
8. Sørensen K, Brand H. Health literacy lost in translations? Introducing the European Health Literacy Glossary. *Health Promot Int*. 2013;29(4):634–44.
9. Sørensen K, Van den Broucke S, Fullam J, et al.; (HLS-EU) Consortium Health Literacy Project European. Health literacy and public health: A systematic review and integration of definitions and models. *BMC Public Health*. 2012;12(1):80.
10. Eshet-Alkalai Y. Digital literacy: A conceptual framework for survival skills in the digital era. *J Educ Multimed Hypermedia*. 2004;13(1):93–106.
11. Samerski S, Müller H. Digitale Gesundheitskompetenz in Deutschland - gefordert, aber nicht gefördert? Ergebnisse der empirischen Studie TK-DiSK [ZEFQ]. *Z Evid Fortbild Qual Gesundhwes*. 2019 Aug;144-145:42–51.

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- Medical evidence generation – a 360-degree view
- Frontiers of research integrity: artificial intelligence
- Research integrity: publishers' perspective
- Medical communicators: what we can do

*[Reference](#)

Reality check on reproducibility. *Nature* 2016;533:437

We look forward to welcoming you to our EMWA Symposium!

6th EMWA Expert Seminar Series Wednesday 6th May and Friday 8th May 2020



EMWA invites everyone interested in the latest developments affecting the medical writing industry, including experienced medical writers, heads of medical writing departments and industry leaders, to our Expert Seminar Series (ESS).

The 2020 ESS will offer four separate sessions devoted to pharmacovigilance, medical devices, regulatory, and medical communication. All invited speakers are experts and specialists in their field, and will provide new and cutting-edge information.

Pharmacovigilance

After a brief overview of pharmacovigilance requirements and reporting in the field of human medicines, the session will dive into veterinary products and medical devices. Safety issues in the animal health industry will be discussed by a speaker from Cyton Biosciences (a service provider dedicated to European regulatory affairs and multi-disciplinary product development) and by a pharmacovigilance specialist from Boehringer Ingelheim Animal Health. For medical devices, the session will consider regulations and documents related to pre- and post-market safety reporting, and a speaker from Philips will go into more depth on risk management and the new edition of ISO 14971.

Medical Devices

The EU MDR 2017/745 comes into force in May 2020 and this new legislation is predicted to have a tremendous impact on the medical device industry, regulatory requirements, and documentation to support market access. The Medical Devices session will cover the following topics:

- MDR 2017/745 updates: requirements and documents
- Drug & device combination products under Article 117 of MDR 2017/745
- The new European Database on Medical Devices (EUDAMED) under the MDR
- Expert panel discussion

Regulatory

This ESS will provide an update on new important information in regulatory areas. There will be updates by regulatory agency representatives on marketing authorisation applications and advanced therapy medicinal products. We will also hear updates on biosimilars from speakers from the pharma industry, and experts from a statistical consultancy will discuss anonymisation at dataset level.

Medical Communication

Following a successful symposium on real world evidence (RWE) at the 48th EMWA conference in 2019, we are now pleased to present an ESS session on "The role of RWE in medical publishing", tailored for those who are – or wish to be – involved in RWE communication.

Presenters from the publishing industry and companies involved in analysing RWE will cover topics including: the role of medical writers in writing about RWE; reporting guidelines; data handling and identifying missing information.

We look forward to welcoming you to the ESS during the EMWA conference in Prague.

The ESS sessions will be held either side of the symposium day. We will be offering a 3-day registration package, designed for experienced medical writers and communicators, which will include attendance of all ESS sessions and the Symposium.

An introduction to medical affairs for medical writers

Ananya Malladi¹, Pavlina Cickova¹,
Robert Davies², Harry O'Connor¹,
Claire Hawksworth², and Steven Walker^{1,2}

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Abstract

The role of medical affairs in pharmaceutical and medical device companies is gaining prominence. Medical writers will increasingly find themselves supporting medical affairs activities or, indeed, transitioning to jobs within medical affairs departments. But, what does this field allied to medical communications involve? To learn more, the authors explored the literature and interviewed two senior medical affairs professionals from different industries. They discovered that medical affairs professionals have a strategic role, handle scientific dialogue, promote partnerships between stakeholders, and anticipate trends in the healthcare sector. While an MD or PhD is desirable for potential candidates, a scientific degree is acceptable. Working with medical affairs can be demanding, but there are attractions: good work-life balance and salary, diversity of activity, and opportunities to attend international conferences. Medical writers may be involved in publications, regulatory activities, research, meetings, and educational outputs. Medical affairs continues to evolve into a bridge between science and commerce which strives to be the 'honest broker'. It is increasingly becoming the face of the health industry and a strategic pillar within many companies.

Introduction

Medical affairs professionals (MAPs) within pharmaceutical or device companies have a unique and

evolving role.¹ They are increasingly regarded as the medical face of the organisation. Those of us outside of industry often have a limited understanding of their role and the potential career opportunities and sources of work medical affairs offers to medical writers. The present article provides an overview of medical affairs, focussing on current activities, entry requirements, career prospects, as well as some personal experiences. In preparing this information, we have explored selected literature, reviewed information provided on the Medical Affairs Professional Society website (<https://maps.within3.com/maps-community>), and interviewed two senior medical affairs professionals from very different organisations: Dr Leticia Orsatti MD, Global Medical Advisor at Boehringer Ingelheim GmbH and Jen Doyle, Vice President Medical Affairs, Medtronic LLC.

The evolving role of medical affairs

Individuals responsible for medical affairs are found across all pharmaceutical and medical device organisations. Most established companies will have a dedicated team. Medical affairs originally occupied a supporting role within the health industry. Over time, the role has evolved to become the third strategic pillar within many companies, alongside research and development and commercial/market access.

Leticia: The role of medical affairs has increased to match the evolving healthcare environment. Scientific dialogue has never been so important. Medical affairs is no longer seen solely as supporting or functioning as an approver, rather it has taken on a key strategic and leading role.

Jen: Over the years, the medical device market in the USA and Europe has drastically changed. When I began in the

industry 15 years ago, you could just sell the [surgical] product, without strong evidence of clinical benefit, direct to the surgeon. I personally feel medical devices require economic evidence, as well as clinical. Buyers are interested in how we can cost-effectively train hospital physicians. Medical device regulations have changed the regulatory landscape.

The importance of physician training and regulatory landscaping has significantly contributed to the importance of medical affairs in the past 10 years. I think medical affairs is a great place to be in and it's not going to go away anytime soon.

What do medical affairs departments look like?

There is no fixed medical affairs structure, function, or universal job description.² MAPs may come from a variety of backgrounds e.g. medicine, nursing, science, business, education, and marketing. Newer recruits may include data scientists, medical writers, and translators. Many will be office-based, with some working from home. Medical scientific liaison (MLS) staff are a group within medical affairs who are generally active across hospitals and primary care. They are therapeutic area experts trained to discuss treatment trends and scientific research.

While there will be working links to other specialist groups such as publications and legal affairs, the need to avoid conflicts of interest

means that there is generally a clear organisational separation between medical affairs and marketing.

What do medical affairs professionals do?

Responsibilities include understanding the constantly changing healthcare environment and providing strategy and leadership throughout the lifecycle of the company's products (Figure 1).³

Generally, MAPs support innovation, research, and data generation. They are the custodians of information relating the

Individuals responsible for medical affairs are found across all pharmaceutical and medical device organisations. Most established companies will have a dedicated team.

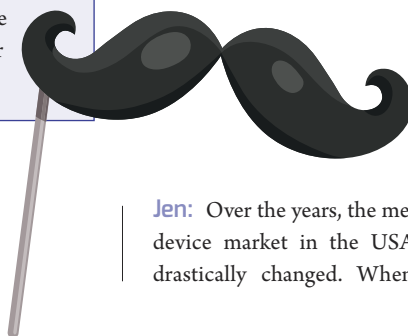




Figure 1. Some of the activities supported and led by medical affairs departments.

HCP = Health care provider, R & D = Research and development

company’s products and their application to relevant therapy areas. A core activity is to interact with healthcare professionals (HCPs), payers, service providers, universities, governmental departments and, increasingly, patients/patient organisations. MAPs are required to appreciate the needs of all these stakeholders and provide them with timely and balanced information.

Leticia: We can be involved at all phases of product development. Activities tend to be most intense during phases II and III. Medical affairs is responsible for the scientific strategy. To that end, we must generate unbiased medical evidence to educate the scientific community, train internal teams, understand key gaps that can be addressed with additional studies, engage with external experts to gather insights and feedback, and more.

Jen: Medical affairs has a seat at the table for all product development projects. We create what we call a ‘medical affairs strategy’, to comprehensively look at a product and to outline the clinical trial, reimbursement, physician training, and medical science strategy. Do we need a trial to register the product or for post-marketing and to drive adoption? What’s the reimbursement strategy? How will we train people on this? What are the preclinical test plans? This is just a very holistic approach to all the things that need to be done to support product development. There are many people on my team that work in this area and it is a big part of our job.

What does a typical day look like?

Leticia: My focus is usually on generating data of value to the scientific community, along with building medical events and training materials for our colleagues worldwide. I also lead activities such as advisory board meetings. These require a lot of work. I spend quite a lot of time travelling, in particular attending international congresses and meetings.

Jen: If I am not travelling then I am usually on the phone. Because my team is spread throughout the world, I try and visit them all regularly. Around 50% of my time is travelling. At other times, I am in meetings or on the phone. Some days I have meetings from early until late at night.

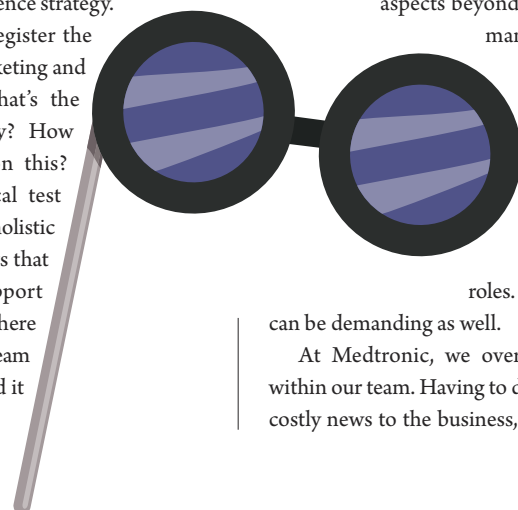
What are the challenges and pleasures of working in medical affairs?

Working in medical affairs is not an easy option. There will likely be lots of meetings, calls, and emails to contend with, as well as bureaucracy and pressure from line managers. On the plus side, being at the forefront of medical research and interacting with scientists and health care professionals is stimulating. For some, it is an escape from patients and the laboratory.

Leticia: I enjoy deep diving into our scientific data and responding to questions coming from the scientific community. I also enjoy interacting with global experts; it is such a great opportunity to learn. On the other hand, administrative tasks and managing lengthy processes can be challenging.

Jen: The pleasurable part is the variety. Clinical research is my first love, but I enjoy working on aspects beyond clinical trials. I like managing people. It brings me great pleasure to help develop the 100 staff that I’m responsible for and see them move into new roles. People management can be demanding as well.

At Medtronic, we oversee medical safety within our team. Having to deliver unpleasant or costly news to the business, even if it’s the right



thing to do, is challenging and requires a sensitive approach.

Does being a medical affairs professional damage your health?

Leticia: When I started, I was concerned about the workload. I was not used to the huge amount of emails received daily and the different definitions of urgency. It took me a while to learn how to prioritise, delegate, and say “No”. A good work-life balance is important. On the other hand, my work is rewarding, it gives pleasure and a sense of accomplishment.

Jen: When I am not travelling, I work from home most days. Medtronic is great about work-life balance and provides flexible working situations. My work-life balance varies from one week to the next, but I feel like I work hard when I’m supposed to be working hard. We have a good understanding of having personal time off.

What skills and qualifications are required?

Those that survive and prosper are typically clever, resilient networkers, often with foreign language skills, who are comfortable in an international environment. Valuable professional and personal skills include:

- The ability to successfully initiate and lead projects
- Effective communication with internal colleagues and external customers
- Business acumen and strategic vision
- Technical skill e.g. understanding compliance, medical and scientific expertise, and digital/analytical ability.

Most individuals working within medical affairs will have a higher degree. Medical doctors are much in demand, notably when project sign-off is required. Having a Master’s degree or doctorate will also serve you well, especially if you have clinical or research experience in areas relevant to the company’s activities.

Leticia: An effective MAP needs insight. They must understand and address the needs of all customers; prioritise patient safety and welfare; be innovative and curious; and grasp the basics of business. The

latter includes supporting company priorities and developing business acumen. Anticipating future needs and communicating well are successful MAP attributes.

Jen: It depends on the position. We have a need for medical doctors, but there are also roles for non-clinicians, as long as certain work is signed off by an experienced MD. Reviewing the literature, understanding the different disease states, and then translating that into a good strategy is generally the role of PhD graduates. But even with just a science degree (I have a Master’s degree in regulatory affairs) you can support a lot of the work that we are delivering to the business. Personally, I think a PhD is one of the most useful degrees in the field.

What are the typical salary range and opportunities for career development?

Leticia: Salary range is wide and depends on the role in the organisation. There are many opportunities for career development in medical affairs. It is important to grasp development opportunities and experience different positions.

Jen: There is a lot of variety, depending on the type of position and whether the employee has a higher qualification (e.g. a PhD). In the US, a team member without managerial responsibility might expect to earn \$90,000 to \$150,000. There are very good career tracks for individual contributors. At a managerial level, typical salaries range from \$130,000 up to around \$200,000 at director level, higher still if you are managing a large team of 20 or more people.

Where do medical writers fit in?

The role of medical writers within medical affairs generally depends on the different phases of product development. It may include producing familiar outputs such as study protocols, regulatory documents (e.g. clinical study and evaluation reports), and the full range of publications targeted at professionals and lay audiences.

Leticia: I work very closely with amazing

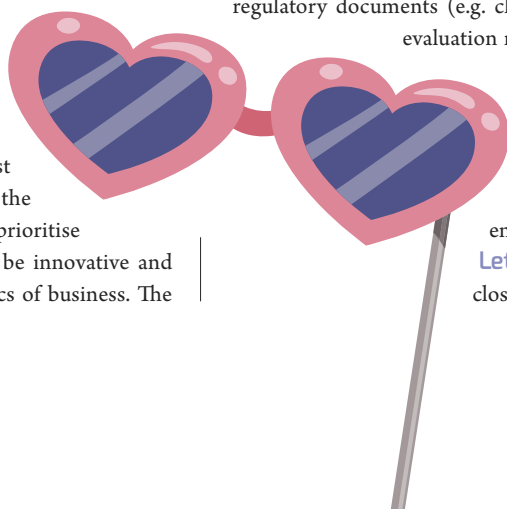
medical writers, and they assist our department with many activities: publications, abstract submissions, regulatory documents, scientific meetings, slides for training, etc. I probably interact with medical writers on a daily basis and acknowledge the great value they bring to our work.

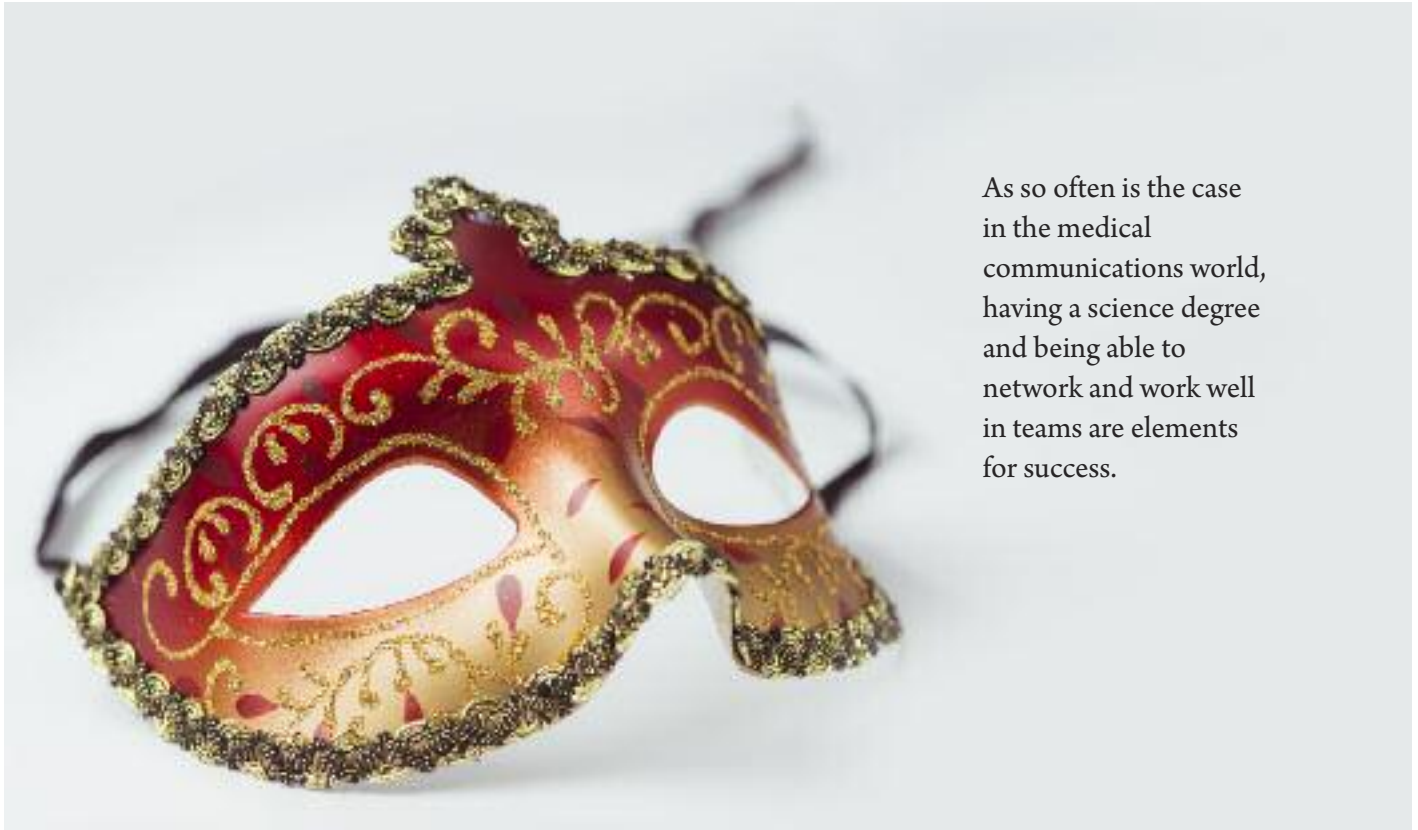
Jen: If you had asked me this question 10 years ago, I probably would have said ‘I have a bunch of people in my clinical team and they are pretty good writers’. About 8 years ago, we hired our first medical writer, despite the team being sceptical about having a dedicated writer. Now my team will not make a move without their medical writer. We have writers working on multiple clinical trials or scientific communication to reimbursement authorities etc. Having this exposure early on can benefit the publication strategy, and the medical writing team has proved to be a huge asset. The other part of medical writing is preparing the clinical evaluation report. It is becoming so critical that we now have 30 writers in the group helping with regulatory writing across Europe and China. We usually insource and occasionally outsource as well. Medical writing is vital for most of what we do.

Getting started in medical affairs: Personal experiences

Leticia: I am a paediatrician and was approached by a pharma company initially to work as a medical science liaison. What attracted me to this role was the opportunity to discuss familiar scientific data with my peers. The transition to other clinical areas such as cardiology and pulmonology, as well as new leadership roles as a medical advisor, went well but required training. I think the challenge of constantly learning and developing new skills is what keeps me motivated.

Jen: After finishing an undergraduate degree in biochemistry, I wanted to go to medical school. Instead, I got into manufacturing of medical devices and eventually moved into clinical research and from there into medical affairs. About 6 years ago, I took on an expanded role. This included clinical research and medical science, with responsibilities similar to those of a science liaison lead/medical director. Other areas I look after include healthcare economics, policy, and reimbursement, as well as healthcare provider training.





As so often is the case in the medical communications world, having a science degree and being able to network and work well in teams are elements for success.

Advice for new recruits to medical affairs

Leticia: Improve your scientific and communication skills and work on networking.

Jen: Don't underestimate the importance of networking. Build a network and get to know people. Many of us have multiple bosses that we need to work with. Flexibility and learning to manage by influence are vital.

The future of medical affairs

Leticia: I foresee medical affairs playing an increased and more relevant leadership role in our company.

Jen: One area that we are starting to become increasingly involved in is value-based healthcare projects. We are already starting to see some success and it is an interesting evolution beyond the traditional medical affairs work. It is about engaging better with customers, and that is exciting. We are setting up more of a governance around these projects and medical affairs, and I believe that is a future accomplishment for us.

Leticia: Medical affairs is here to stay. While relations and strategy will continue to be important, future activities will be driven by advanced analytics of patient data which go beyond a drug or device to include the whole therapeutic area. Successful companies will be

those that can demonstrate effectiveness, safety, and an enhanced value proposition. In the future, there will be increased reliance on real world data, patient-reported outcomes, electronic medical records, and artificial intelligence. Other trends are likely to be even greater regulation, increased transparency, and a push for industry to work in partnership with stakeholders to optimise care. Many consider the future to be 'digital'; others emphasise the importance of patient centricity during treatment and product development. Within an organisation, someone needs to be responsible for this public-facing role. Step forward medical affairs!

Conclusion

Medical affairs departments have been established across many pharmaceutical and medical device companies. They are increasingly seen as the face of the health industry and a valued, professional bridge between science and commercial interests. Working in

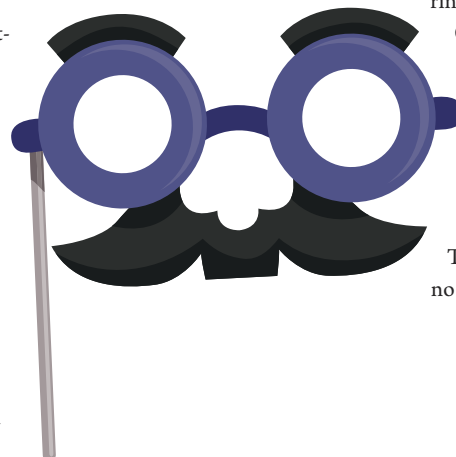
medical affairs appears an attractive option with a good salary and opportunities for career development. Depending on the organisation, there seems to be an increasing need for medical writers to work on a wide range of activities. As so often is the case in the medical communications world, having a science degree and being able to network and work well in teams are elements for success. Medical affairs is here to stay and being on board near the beginning of its evolution could be a good career move for many.

Acknowledgements

We are most grateful to Dr Leticia Orsatti MD, Global Medical Advisor at Boehringer Ingelheim International GmbH and Jen Doyle, Vice President Medical Affairs, Medtronic LLC for their contribution to this article.

Conflicts of interest

The authors declare they have no conflicts of interest.



References

1. Werling K, Carnell H, McCormick D. Focus on life science compliance: the evolution of medical affairs departments. 2011 November [cited 2019 Mar 15]. Available from: https://www.mcguirewoods.com/news-resources/publications/health_care/focus-life-science-compliance-nov-2011.pdf.
2. Carroll G, Yang T, Volini A, Xu A, Gazes S. Medical affairs: driving influence across health care ecosystem. Deloitte Development LLC 2015 [cited 2019 Sep 11]. Available from: <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-instant-insights-medical-affairs-031715.pdf>
3. Ismael A. Best practices for establishing and maintaining a medical affairs department. LinkedIn. 2015 September 8 [cited 2019 Mar 15]. Available from: <https://www.linkedin.com/pulse/best-practices-establishing-maintaining-medical-ahmed-e-ismael-md/>
4. Evers M, Ghatak A, Holt E, et al. A vision for medical affairs in 2025. McKinsey & Co. 2019 April [cited 2019 Jul 11]. Available from: <https://www.mckinsey.com/~/media/McKinsey/Industries/Pharmaceuticals%20and%20Medical%20Products/Our%20Insights/A%20vision%20for%20medical%20affairs%20in%202025/A-Vision-for-Medical-Affairs-in-2025.ashx>.

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A primer on anonymisation

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Abstract

Canadian and European regulators finalised guidelines that allow for sharing of clinical trial data. To maintain the utility of clinical information, risk-based anonymisation techniques are recommended. It behoves applicants to ensure organisational readiness to deliver anonymised dossiers. Key steps include understanding the regulatory requirements and anonymisation techniques, assessing internal competencies and/or commercially available software, and establishing infrastructure to deliver anonymised dossiers in a timely manner.

Anonymisation is defined as the process of turning data into a form that does not identify individuals and where identification is not likely to take place.^{1,2} Regulations, policies, and guidance have been promulgated in the EU to allow clinical-trial data (EU Regulation EU No. 536/2014) and dossier-level data (EMA Policy 0070) to be shared with the scientific community, participants, and the public.³ Recently, Health Canada finalised parallel guidance on the Public Release of Clinical Information for clinical trial and dossier-level data and expanded the scope of sharing to include not only drugs but also medical devices.⁴ In sharing clinical trial and dossier-level data, applicants have the challenge of protecting company confidential information (CCI) and safeguarding the privacy of personal private data (PPD) whilst retaining the utility of the data after it has been anonymised.

Regulators do not prescribe a specific anonymisation method, although several data transformation techniques can be used to

anonymise the direct identifiers (e.g. names, initials, signatures, job titles/positions, addresses, fax numbers, and email addresses),^{5,6} indirect identifiers (e.g., sex, age, dates, and socio-economic information),^{5,6} and CCI in clinical study documents and datasets. Anonymisation methods include redaction, pseudonymisation, randomisation, offsetting, and generalisation (Box 1).^{3,4}

Anonymisation methods

In its guidance, the EMA recognises that, in an initial phase, applicants will anonymise dossiers using the redaction method. Given that this method decreases data utility,⁶ the EMA recommends that other anonymisation techniques be used as soon as possible, whilst ensuring that data anonymisation is achieved.³ Health Canada's guidance recommends that anonymisation favour methods that retain analytical value (e.g. generalisation, randomisation, and offsetting) instead of redaction.⁴

Preparing an anonymised dossier is a labour-

intensive, iterative process for the applicant that is constricted by strict regulatory timelines. The main steps include:

- Applicant submission of a redaction proposal document package
- Consultation between the applicant and the regulatory agencies
- Submission of the final redacted document package
- Publication

Anonymisation reports

Both the EMA and Health Canada require that an anonymisation report be submitted with the anonymised submission in the proposal package. This anonymisation report contains the methods and justification for the processes used. The purpose of this report is to:

- demonstrate that changes included within the anonymised documents are adequate to protect study participants' privacy;
- provide the rationale for those changes; and
- demonstrate that after anonymisation, the

Preparing an anonymised dossier is a labour-intensive, iterative process for the applicant that is constricted by strict regulatory timelines.

Box 1. Redaction methods

Redaction: This involves removing or masking values. Redaction may best be applied to direct identifiers. When a directly identifying variable is critical to understanding the clinical information, other anonymisation methods should be selected. Redaction may be useful for documents such as protocols and statistical analysis plans.

Pseudonymisation: Personal information (e.g., subject identification number) is re-coded to disassociate the variable from the participant.

Randomisation: This involves making small changes to variables to reduce the possibility that the data are used to identify a participant.

Offsetting: This involves replacing numerical data by adding or subtracting a fixed quantity.

Generalisation: This technique uses re-categorisation within a range to enlarge the number of "like" individuals. Examples of generalisation techniques include:

- Aggregation: Replacing a value by a range, for example, replacing a trial participant's age by an age range (e.g. 56 replaced by 50–60).
- K-anonymity: Trial participant data are grouped with at least k other trial participants in that range, preventing the participant from being singled out and identified.⁷



participants in the study, and the number and distribution of study centres across countries.⁶ The acceptable maximum quantitative risk level for re-identification per the EMA and Health Canada is 9%,^{3,4} or qualitatively at a risk level of high, medium, or low based on the characteristics of the source data (e.g., disease prevalence, trial sample size, number of sites). The quantitative risk threshold of 9% is equivalent to a group size of 11. This means that a single participant, when grouped by similar variables, cannot be re-identified from 10 other participants ($k-1$) within the aggregated group. Health Canada also recommends that the applicants select a reference population for indirect variables to help estimate the risk of re-identification.

Software solutions for anonymisation

To complete these tasks efficiently over the breadth of a dossier, applicants require software solutions.

Redaction-only commercial software

Multiple software platforms enable manual redaction of PDF documents by users (Table 1). They often offer free trials. Below are desktop software options that are used by pharmaceutical companies for redaction or that are capable of handling the breadth of redaction required in dossiers. All of the software packages listed require licences for use.

Acrobat® Pro® DC (Adobe)

Adobe Acrobat® Pro® DC enables a user to redact PDF documents by using a redaction toolbar. Redaction is conducted in two steps. First, the text is selected and marked for redaction. The text will then appear within a red border. Second, the redactions are applied, which result in permanent removal of the redacted content including its metadata. Text, images, or multiple pages may be marked for redaction. A PDF marked for redaction may be downloaded and reviewed by another reviewer before a redaction is applied. The tool also includes a search feature where all text meeting the search requirements may be marked for redaction at once.

Objective Redact (Objective Corp.)

Objective Redact enables users to manually

risk of re-identification when released in the public domain is at an acceptable level and that the impact on data utility has been considered.

Regulators review the applicant’s stated rules and the anonymised clinical documents to assess whether the applicant has executed the planned

data transformations systematically and consistently.

The risk of re-identification takes into account the number of direct and indirect identifiers (“quasi-identifiers”), size and nature of the disease studied (e.g. rare or common disease, paediatric population), number of

Table 1: Commercial redaction software

Software	For further information
Adobe Acrobat Pro DC	https://acrobat.adobe.com/us/en/
Nitro Pro 10	https://www.gonitro.com/nps/pro/pdf-software
Objective Redact	https://www.objectiveredact.com/
PDFelement	https://pdf.wondershare.com/pdfelement.html
PDFzorro.com	https://PDFzorro.com
PDFescape	https://pdfescape.com
PDFfiller	https://.PDFfiller.com
PDF Studio Pro	https://www.qoppa.com/pdfstudioviewer/

redact PDF, Word, or Excel documents. Users can add annotations in comments indicating why the information was redacted, information that can be included in the anonymisation report. The program can search for phrases or structured data (e.g. birthdates or names). The software also removes any metadata or hidden code. Users can create an audit copy, which displays the redactions as translucent markings, allowing the underlying information to remain visible for review. A working copy can also be created that can be saved or emailed to reviewers. The working copy can then be opened within Objective Redact to complete the redaction process by accepting the redactions or can be further redacted and reviewed.

PleaseReview version 6.1 (Ideagen)

PleaseReview Version 6.1 enables multiple users to simultaneously and collaboratively redact PDF documents using pre-configured redaction categories (PPD-Policy 70 or CCI-Policy-70). Users have the option of further configuring appearance (font, font size, font colour, alignment), overlay text, and comment categories for PPD or CCI at a system-, workgroup-, or review-level. Redaction is conducted by selecting options from a dropdown menu. Users can apply redactions as a rectangle, highlighted text, or complete pages. Additionally, PDF document annotations (including redactions) can be imported into PleaseReview. The review owner may accept or reject redactions. Users can add justifications for redaction as comments when redacted. The information collected in the reconciliation report can serve as the basis for the justifications for de-identification of data reported to the EMA or Health Canada.

Automated software is recommended for handling anonymisation of dossiers, given their scope and complexity and the need to maintain data utility.

Commercial anonymisation software

Automated software is recommended for handling anonymisation of dossiers, given their scope and complexity and the need to maintain data utility. Applicants that need to anonymise a substantial number of clinical dossiers may opt to create and leverage in-house biostatistics and data management, who can customise SAS-based macros. This is a resource-intensive exercise and should be supported by a transparency team and governed by standard operating procedures. The process requires ongoing refinement to align with changing regulations and practices.⁸ Therefore, applicants who have either restricted in-house resources or who anticipate having only a few dossiers to be anonymised may opt to outsource the work. Alternatively, applicants may wish to develop in-house capabilities by partially outsourcing anonymisation services, for example using vendor-provided software platforms in-house with vendor support for consulting services. Several vendors provide anonymisation software and services tailored to comply with EMA’s Policy 0070 and Health Canada’s regulatory requirements. In general, software solutions are aligned with established anonymisation rules and standards (e.g., PhUSE^{1,2}) and are updated to comply with advances in data standards, artificial intelligence, and the evolving regulations. Given the wider scope of redacted submissions supported by these vendors and experience in redacting datasets for secondary use by researchers before these regulations were implemented, applicants can also leverage vendor expertise in relying on additional services provided. This may include:

- assisting with establishing standard operating procedures for anonymisation;

- providing software platforms and technical support and training;
- providing strategic recommendations for method selection of anonymisation and risk mitigation contingent on the population and dossier provided;
- reviewing and conducting quality control of the software-generated anonymised clinical reports and data;
- completing the anonymisation report and justification table (CCI); and
- assisting applicants in justifying the anonymisation method.

Vendor support may also extend beyond anonymisation and include protocol and results posting to registries, record maintenance, workflow planning, and writing of lay summaries.

In general, when approached by a client to anonymise a dossier, vendors first assign a project manager. Based on an analysis of the contents of the dossier, including the direct and indirect identifiers and CCI, they will recommend anonymisation rules for PPD and CCI based on the acceptable risk threshold for re-identification. Once they obtain client agreement on the risk threshold and methods used, they will generate the anonymised proposal package ensuring consistent replication of rules across data sets and documents. The package will then be reviewed by the client, and, once it has been agreed on, the vendor will finalise document proposal package. Vendors will also provide client support in responding to questions from health authorities and will prepare the final document package.

Key anonymisation software vendors are described below and listed in Table 2.

ARARA (Real Life Sciences)

ARARA is a software platform that enables automated anonymisation, quantitative risk, and data utility assessments of clinical documents

Table 2: Anonymisation software vendors

Platform	Company	For further information
ARARA	Real Life Sciences	https://rlsciences.com
Blur	d-Wise	https://cdn2.hubspot.net/hubfs/188561/Blur%20datasheet-2018.pdf
ClinGenuity	Certara	https://www.synchrogenix.com/technology/transparency-disclosure/
Eclipse	Privacy Analytics	https://privacy-analytics.com/software/privacy-analytics-eclipse/
Redact360	Kinapse	http://www.kinapse.com/redact360
Terminator	XOGENE	https://www.xogene.com/

and datasets. It is available as a desktop or cloud-hosted application. Sponsors can either outsource the anonymisation service or use the ARARA platform internally.

ARARA provides user options for de-identifying direct and indirect identifiers and CCI with user control over the automated modelling and anonymisation process. ARARA is pre-packaged with a range of anonymisation rules and templates that are preconfigured to meet the EMA and Health Canada’s 9% re-identification risk thresholds. The rules can be customised for different risk thresholds as needed for different populations. Ten different anonymisation models are also provided. Templates can be customised by data variable, model, or model thresholds and can be re-run in the user interface as needed, enabling users to rapidly test outputs and iterate through the process. The platform can process multiple datasets and clinical documents at once using the same anonymisation techniques. The platform provides reporting features including: risk and data utility visualisation dashboards, automated anonymisation reporting, traceability, and audit tracking tools.

Blur (d-Wise)

Blur is a software platform that supports automated data and clinical document anonymisation. Applicants may either outsource the anonymisation service or choose to use the Blur application internally. The Blur application provides menu-driven options for de-identification, risk reduction, and creation of auditable workflows and controls. The application enables users to apply different anonymisation techniques by data variables and allows viewers to compare the original source data and the data once it has been anonymised. The rule sets created within the data can then be applied consistently to documents using a template. D-Wise partners with ClaritiDox to deliver additional anonymisation services including advisory services,

assistance with process management, review of anonymised documents and datasets, writing of anonymisation reports, managing registry postings, and writing of lay summaries.

ClinGenuity (Certara)

Certara provides a complete redacted and anonymised Policy 0070 submission package applying its redaction management software, ClinGenuity. Certara has also developed advanced anonymisation solutions using quantitative risk assessment methodology using internal expertise and aligned with globally accepted regulations and industry standards. Certara provides an anonymised package and consulting services as a service model.

Eclipse (Privacy Analytics)


Privacy Analytics provides a complete anonymised Policy 0070/Health Canada submission package applying its risk-based de-identification software, Eclipse. The quantitative risk-based methodology is aligned with globally accepted regulations, standards, and guidelines for anonymisation. Privacy Analytics provides the anonymised package and consulting services as a service model.

Redact360 (Kinapse)

Redact360 service is Kinapse’s technology-enabled service for redaction and anonymisation of clinical data and documents. Kinapse provides a service comprising advisory and regulatory support for the method of anonymisation, programme management of the anonymisation process including providing the anonymised proposal and final packages, completion of the anonymisation report and justification tables, writing of clinical trial summaries, registry postings, and lay summaries. Although only Kinapse can use the technology-enabled platform to anonymise the clinical documents and datasets, the applicant may select amongst the suite of advisory and support services provided. Kinapse has established key performance indicators for their level services and incorporates them into their service-level agreements.

Terminator (XOGENE)

XOGENE provides a complete anonymised Policy 0070/Health Canada submission package, including the anonymisation report, justification table, and final anonymised datasets and documents. To perform the anonymisation, XOGENE applies the technology of its automated anonymisation and redaction platform (XOGENE Terminator) to PPD in datasets and clinical documents. To complete the package,



The regulatory landscape and technological advances to support disclosure and transparency requirements are evolving rapidly. Effective leveraging of internal and external resources is critical for compliance with regulatory requirements and timelines.



XOGENE also reviews clinical documents to identify CCI and reviews against regulatory and company policies. XOGENE can also support expedited (24- to 48-h) redaction for EMA Policy 0070 requests. Additional disclosure services provided by XOGENE include protocol and results postings to all registries, record maintenance on registry sites. XOGENE can also manage the writing of lay summaries, translation of lay summaries, site distribution, tracking, and oversight.

Applicant readiness for anonymisation

The regulatory landscape and technological advances to support disclosure and transparency requirements are evolving rapidly. Effective leveraging of internal and external resources is critical for compliance with regulatory requirements and timelines.

For initial marketing authorisation applications and line extension applications submitted to the EMA under the centralised procedure, the redaction proposal document package must be submitted between day 181 and day 220 of the procedure (≤ 30 days pre-opinion and ≤ 10 days post-opinion). A total of 84 calendar days are allocated from submission of the redaction proposal package to final publication. During the consultation process (total of 47 days) the EMA

will review the anonymisation report, justification table, and redaction proposal. The EMA can seek clarifications from the applicant, after which the applicant updates the justification table. As part of the EMA's review, a redaction conclusion notification is sent to the applicant and the applicant is expected to submit a redaction consultation agreement within 7 calendar days. Applicants then have 27 calendar days to prepare the final redacted proposal package. The final redacted version is published within 60 days of the commission decision on the approvability of the marketing authorisation application.³

For marketing authorisation applications submitted to Health Canada, applicants may request a process initiation meeting (PIM) between 120 calendar days before the final regulatory decision and 20 days after the final regulatory decision. Redaction proposal document packages must be submitted to Health Canada within 60 days after a positive decision. Health Canada reviews the proposal package (30 days) and provides rejected redactions to the applicant for revision. The process for revising and finalising any rejected redactions is allocated 25 days, comprising 15 days for applicant revision, 5 days for Health Canada reassessment, and 5 days for applicant submission of finalised documents. Health Canada will then publish the

data within 5 days, meeting the 120 day target from the initiation of the process. In the case of a negative opinion, the process may start 31 days after a negative decision. If a letter of intent for reconsideration is submitted, the process will start after the reconsideration process is complete (70 to 140 days), and the 120 day process for submitting the redaction proposal package will commence.⁴

These timelines may require applicants to prepare for the redaction in advance of a health authority decision. Therefore, it is incumbent on applicants to establish a company-wide readiness strategy towards engaging vendor services and global transparency. These steps may include:

- understanding and educating key stakeholders of the global transparency regulatory landscape and anonymisation methods;
- identifying members of a transparency committee;
- defining the scope of the transparency committee in a charter;
- establishing standards for the acceptable risk thresholds of re-identification for anonymised proposal packages submitted in the public domain;
- conducting a feasibility analysis and selecting an anonymisation framework (e.g. entirely managed internally, partial outsourcing, complete outsourcing);

- vetting and selecting an anonymisation vendor, software, and solution;
- establishing standard operating process and procedures for managing anonymisation requests including the process for managing requests, expectations of team members reviewing anonymised clinical documents and data sets, standard timelines for internal review, the process for adjudicating comments, and the point person to interact with the vendor providing services;
- completing vendor procurement steps to ensure immediate preparedness for dossier submission or upon a regulatory request;
- investigating information technology capabilities to support software platforms and compliant document and data transfer procedures;
- developing document and data checklists;
- ensuring accessibility of documents and data sets to ensure rapid transfer of clinical dossier components and data sets; and
- engaging in a continuous quality improvement process with the submission of each anonymised package.

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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

The author declares no conflicts of interest.

References

1. PhUSE. Protection of Personal Data in Clinical Documents – A Model Approach. Available from: <http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/02/Protection-of-Personal-Data-in-Clinical-Documents.pdf>.
2. PhUSE. De-identification and anonymization of individual patient data in clinical studies. A Model Approach. Available from: <http://www.transceleratebiopharmainc.com/wp-content/uploads/2015/04/TransCelerate-De-identification-and-Anonymization-of-Individual-Patient-Data-in-Clinical-Studies-V2.0.pdf>.
3. EMA. External Guidance on the Implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use. 2018 [cited 30 Oct 2019]. Available from: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-3.pdf.
4. Health Canada. Guidance Document on Public Release of Clinical Information. 2019 [cited 30 Oct 2019]. Available from <https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance/document.html>.
5. Hrynaszkiewicz I, Norton ML, Vickers AJ, Altman DG. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. *BMJ*. 2010;340:c181.
6. EMA. Data anonymization – A key enabler for clinical data sharing. Workshop report. 2017 [cited 30 Oct 2019]. Available from: https://www.ema.europa.eu/en/documents/report/report-data-anonymisation-key-enabler-clinical-data-sharing_en.pdf.
7. El Emam K, Dankar FK. Protecting privacy using k-anonymity. *J Am Med Inform Assoc*. 2008; -15(5):627–7.
8. Keerie C, Tuck C, Milne G, Eldridge S, Wright N, Lewis SC. Data sharing in clinical trials - practical guidance on anonymising trial datasets. *Trials*. 2018;19(1):25.

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Sound, microphone, action: Podcasts for medical writers

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Abstract

A podcast is a digital audio file that can be downloaded into your computer or mobile device. It is typically available as a series, and new episodes can be received automatically by subscribers. Podcasts are a source of education, inspiration, and entertainment. They are also a useful marketing tool for small business owners. This article provides a short history of podcasting, its uses, and its benefits for medical writers. It will also provide some selected sources, should you decide to give podcasts a go.

Digital audio files and internet made possible the production and distribution of the first podcasts. They were music or talk MP3 audio files that you could download into your computer and listen at your leisure. The downside was that portability was quite limited.

With the creation of RSS feeds, it became possible to receive files automatically with an aggregation software. For podcasts, this meant subscribing to a show feed and get regular updates on new episodes.

As mobile devices became ubiquitous and more powerful, podcasts started to grow too. Listening to them became more practical due to the emergence of mobile applications that could retrieve the podcasts' RSS feeds, download new episodes, and memorise where an episode is paused so that it can be resumed later.

In recent years, the number of podcasts has grown exponentially.¹ Today there are over 700,000 active podcasts.² This represents a sea of

opportunities for medical writers, both for learning and for increasing their visibility.

A podcast in every pocket

Back in 2000, not many people listened to podcasts. You needed a computer to download the MP3 file and had to transfer it to your player if you wanted to listen to it on the go. As smartphones became widespread and apps to retrieve and listen to podcasts appeared, the number of shows being produced surged.

What is the advantage of listening to podcasts? Why just listen when you can read a book or watch a video? For one thing, most podcast listeners do other things, like driving, house chores, or workout while listening. These activities usually are repetitive and automatic, so do not require full attention. That's why radios appeared in the first place, but radio has commercials, which cannot be avoided, so you cannot control what you listen to. Plus, most radios nowadays are music-based and lack in-depth information shows. They have a different model, too: a radio show is a one-to-many broadcast, where a single person talks to hundreds or even millions of people. Podcasts, in contrast, are one-to-one broadcasts. When you do listen to a podcast, you usually do it on your phone, using earphones – a much more personal experience. And while many podcasts now have ads, they are easy to skip.

What kind of podcasts are useful to medical writers?

If podcasts are a new but interesting idea to you, try listening to some on your mobile device. Go to your app store and search for "podcast player". Choose your preferred one and install it. Once inside the app, use the search box to look for your favourite shows. If you do not know any yet, Table 1 has some recommendations. You can also do a Google search using "podcast" + your preferred subjects and see what comes up.

Two blog posts offer some recommendations of useful podcasts to medical writers: "Podcasts for health writers", by Libby Evans from Health

Writer Hub and "10 excellent podcasts for the Medical Translator and Writer", by Oliver Thalmann from the Medical Translator website.^{3,4}

To my knowledge, there is only one podcast geared specifically towards medical writers, called "Medical Writers Speak", hosted by Emma Hitt Nichols, PhD. Unfortunately, it has not been updated since March 2019. Let's hope for a new season in the near future.

Podcasting opportunities for medical writers

News agencies, education, and entertainment



were the first industries that took advantage of podcasts to connect with listeners. Small business owners then began to see the potential of this channel for connecting with prospective clients and hopped into creating podcasts.

Creating a podcast show doesn't require fancy or expensive equipment – you might even already have all the equipment you need: a computer and a headset. The most important part is deciding on the content. Knowing what you want to say and to whom is what sets a useful podcast apart from a less interesting one.

Medical writers can assist in writing or assuring the quality of what goes into a health, medical, or scientific podcast. Every good podcast has some sort of script. If you work in a news agency that is planning to launch a podcast,

like the BBC Science in Action, you may be asked to write, edit, or fact-check the script for each episode. Script writing may also be offered by medical communications agencies and freelance medical writers.

If you are a freelancer or small business owner, creating a podcast can be a powerful marketing tool. In a world with a shortened attention span, having a distraction-free medium to reach your audience can give you a competitive edge. You can establish a connection with prospective clients, provide useful content, and increase your visibility in your area of expertise. Just keep in mind that just like all content creation, it will not give immediate results. To be successful, you have to be consistent, establish a relationship with your listeners, and provide useful content.

The future of podcasting in medical writing

Podcasting will continue to grow. Podcasts can reach a wide audience and are easy to listen to while doing other things. Medical writers can use podcasts to keep up to date in their preferred areas of expertise, learn new things, or take a break. Also, for freelance medical writers or business owners, podcasts can increase visibility in an area of expertise and are therefore a powerful marketing tool. Few podcasts are geared to medical writers, but where's a gap, there's opportunity!

Conflicts of interest

The author declares no conflicts of interest.



Table 1. List of useful podcasts for medical writers

Topic (in bold) Podcast title	Host(s)	Usual episode length (min)	Frequency (episodes/month)
Education			
Best Science Medicine	Dr James McCormack Dr Michael Allan	30	4
BMJ Best Practice	(several)	20	2
Emergency Medicine Cases	Dr Anton Helman	40–60	2–3
HelixTalk	Sean P Kane Khyati S Patel	40	1–2
Pediatric Emergency Playbook	Tim Horeczko	35	1
Real Life Pharmacology	Eric Christianson PharmD	10–15	4
The Curbsiders	Matthew Watto MD Stuart Brigham MD Paul Williams MD	60	6–7
News			
BBC Science in Action	Roland Pease	30	4
Health Report	Dr Norman Swan	30	4
Nature	Shamini Bundell Benjamin Thompson	25	6
Science Weekly	Ian Sample Hannah Devlin Nicola Davis	30	4
Writing and Freelancing			
High Income Business Writing	Ed Gandia	20–40	2
Hot Copy	Kate Toon Belinda Weaver	40	1–2
The Editing Podcast	Denise Cowle Louise Harnby	15–50	1–5
Unemployable	Brian Clark	30–60	5–7
Statistics			
More or Less	Tim Harford	10	4–6
Not So Standard Deviations	Roger Peng Hillary Parker	60	1–2
Stats + Stories	John Bailer Richard Campbell Rosemary Pennington	15–30	4–6
Entertainment			
Bedside Rounds	Adam Rodman MD	20–60	1
Hidden Brain	Shankar Vedantam	30–50	4
Sawbones	Dr Sydnee McElroy Justin McElroy	35–50	3–4
The Knowledge Project	Shane Parrish	50–120	1–3



References

1. Edison Research. The podcast consumer 2019. 2019. [cited 2019 Aug 29]. Available from: <https://www.edisonresearch.com/the-podcast-consumer-2019/>.
2. Podcast Insights. 2019 podcast stats & facts (new research from June 2019). 2019. [cited 2019 Aug 29]. Available from: <https://www.podcastinsights.com/podcast-statistics/>.
3. Health Writer Hub. Podcasts for health writers: Our top picks. 2019. [cited 2019 Aug 29]. Available from: <https://www.healthwriterhub.com/podcasts-for-health-writers/>.
4. Medical translator. 10 excellent podcasts for the medical translator and writer. 2019. [cited 2019 Aug 29]. Available from: <https://www.medicaltranslator.co.uk/en/10-excellent-medical-podcasts/>.

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Diana Ribeiro, MSc, is a pharmacist with more than 10 years of experience in the healthcare industry. Her love for communicating science resulted in the creation of Apothecary Medical Writing (<https://www.apothecarymw.com/>), where she provides writing services for biotechnology and pharmaceutical companies.

Regulatory Matters

Using technology to reduce the time it takes to generate patient narratives



Problem statement

Writing patient narratives using clinical study data is often a manual, tedious, and time-consuming task for medical writers and/or safety specialists. A narrative must be developed to describe each death, each other serious adverse event, and other significant adverse events experienced by a patient during a clinical study.¹ Narratives typically report summary information, including:

- Patient demographics, baseline characteristics, and medical history;
- Adverse events (AEs) and serious adverse events (SAEs); and
- Laboratory values.

These data are provided in statistical outputs (e.g., tables and listings), which typically are manually copied and pasted into the narratives. In addition, identification of which patients require a narrative can be challenging because the study team must manually review the outputs to determine which patients meet the predefined, study-specific criteria. Altogether, this results in additional costs, resources, and project time to develop the narratives and then verify their data via quality check (QC) review.

How technology can help

A software utility can be used to automatically generate patient narratives in Microsoft Word,

which supports the following:

- The ability to predefine the study-specific criteria (e.g., adverse event of special interest) that would determine which patients will require a narrative.
 - The author does not need to manually review adverse event listings to detect which patients will need a narrative.
- The ability to have predefined data points, such as baseline information, autopopulated into each patient's narrative "template" from the statistical outputs; the order and layout of data in the template can be predefined and configured on a per-study basis.
 - The author can focus on the descriptive text instead of having to manually copy/paste data from the outputs.
 - QC reviewers do not need to verify all data points in the narrative.

By using a narrative-generation utility, the following benefits may be realised:

- Significant time savings and improved quality.
 - Determination of which patients qualify for a narrative is automated based on configurable, study-specific criteria, rather than manual review of outputs, resulting in a list of patient narratives that ensures no qualifying patients are missed.
 - The author does not need to spend time

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manually searching the statistical outputs for the relevant data points and then copy/paste them into the narrative.

- QC review time is reduced because sections of the narrative are automatically populated from validated data, reducing human error.
- All narratives for a study can be automatically compiled into a single submission-ready document based on the list of patient narratives.
- Regeneration of narratives can be conducted for a study in a consistent manner.
 - For post–database lock updates, the utility can be re-run and the newly generated narratives easily compared to the original narratives, with any differences highlighted for the author to accept/reject, as needed.

Implementing a narrative-generation utility can result in significant time savings and improved quality. In addition, reducing the burden of manually generating narratives allows the authors and QC reviewers to focus their efforts on their areas of expertise, rather than mundane tasks, perhaps even resulting in a happier workplace environment!

Reference

1. ICH Harmonised Tripartite Guideline. Structure and Content of Clinical Study Reports E3. Current Step 4 version dated 30 November 1995 [cited 2019 Sep 23]. Available from: https://database.ich.org/sites/default/files/E3_Guideline.pdf

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News from the EMA

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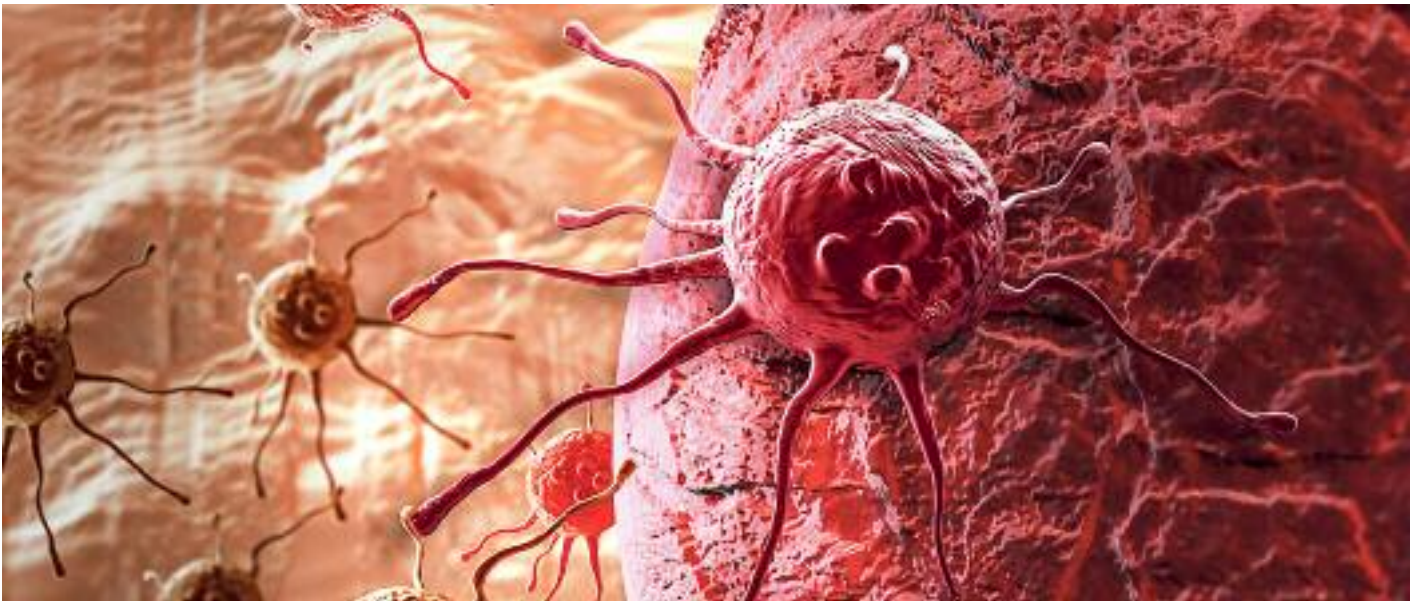


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The articles included in this section are a selection from the European Medicines Agency (EMA)'s News and Press Releases archive from July 2019 to September 2019. More information can be found on the Agency's website: www.ema.europa.eu.



First “histology-independent” treatment for solid tumours with a specific gene mutation

July 26, 2019 – European Medicines Agency (EMA)'s human medicines committee (CHMP) has recommended granting a marketing authorisation in the European Union (EU) for Vitrakvi (larotrectinib) for the treatment of adult and paediatric patients with solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion. Treatment with Vitrakvi is recommended for patients whose disease has spread or cannot be surgically removed, and who have no other satisfactory treatment options.

Vitrakvi is the first so-called “histology-independent” cancer treatment recommended for approval in the EU. This means that it can be used to treat non-haematological (i.e., that do not begin in the blood or bone marrow) tumours with this specific mutation, regardless of where in the body the tumour originated. Before patients can be started on the medicine, the presence of the mutation in the tumour should be confirmed by a validated test.

The active substance in Vitrakvi – larotrectinib – targets a very specific genomic alteration of a patient's tumour. This occurs when NTRK genes that encode specific proteins are abnor-

mally fused to a gene. This mutation, called NTRK gene fusion, leads to the development of proteins that can cause cancer cells to grow. Vitrakvi blocks the action of these proteins and in doing so inhibits the growth of the cancer. NTRK gene fusions can be observed very frequently in a certain number of rare cancer types that affect both adults and children. In addition, this gene fusion occurs rarely in some of the most common cancer types.

The efficacy and safety of Vitrakvi were studied in three single-arm trials (i.e., studies with no control group) that included a total of 102 adults and children with cancer that were evaluated. These patients had either already received standard therapy, or would have had to undergo disfiguring surgery, or were unlikely to respond to available therapies.

The share of patients who responded to treatment with Vitrakvi was 67%. Of those, the response lasted six months or longer in 88% and 12 months or longer in 75%. Tumour responses were seen both in rare tumour types such as infantile fibrosarcoma and salivary gland tumours, as well as in common diseases such as

lung and colon cancer. The most common side effects were tiredness, increased levels of liver enzymes, dizziness, constipation, nausea, anaemia (low red blood cell count), and vomiting.

The CHMP recommended a conditional approval for this medicine. This is one of the EU's regulatory mechanisms to facilitate early access to medicines that fulfil an unmet medical need. This approval type allows the Agency to recommend a medicine for marketing authorisation with less complete data than normally expected, where the benefit of a medicine's immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available.

The opinion adopted by the CHMP is an intermediary step on Vitrakvi's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once the 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.

Names of liposomal medicines to be changed to avoid medication errors

July 30, 2019, and September 26, 2019 – In July 2019, all marketing authorisation holders of medicines containing liposomal drug delivery systems were requested to submit to EU regulators a variation to change the names of these medicines as soon as possible before the end of September 2019. In September 2019, a clarification was added to indicate that the name variation should be done only if there is a high risk of medication errors which would raise concerns regarding the safe use of the medicinal product.

The initial recommendation was made jointly by EMA's CHMP and the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) at their July meetings and the clarification was adopted in the September meetings. The recommendation aims to make a clearer distinction between liposomal and non-liposomal formulations of the same active substance to avoid medication errors. Since the two formulations may have different biodistribution and release properties, medication errors can pose serious risks to the health of patients.

So far, there was no agreed approach to the naming of medicines containing liposomal or pegylated liposomal formulations. This recommendation is made to enable healthcare professionals and patients to better distinguish

them from conventional non-liposomal medicines. This is a particular concern when electronic prescribing and dispensing tools are used, as in the absence of a more descriptive term for the liposomal medicines, they can be mixed up with non-liposomal medicines.

Following a number of reports of serious medication errors, some leading to death, and after consultation with EMA's safety committee (PRAC), the CHMP and CMDh agreed on the following actions to reduce the risk of mix-up between these medicines:

- In section 1 of the summary of product characteristics (SmPC), the qualifier “liposomal” or “pegylated liposomal” should be added after the invented name and before the strength. This is in line with the standard practice for qualifiers.
- In those cases where a name change is considered necessary, applicants are requested to update the name throughout the product information, including all annexes.
- In those cases where a medicine is approved with an “international non-proprietary name (INN)+company or trademark” name, the qualifier “liposomal” or “pegylated liposomal” will be placed between the INN and the company name or trademark in section 1 of the SmPC.
- The currently existing European Directorate



for the Quality of Medicines standard term “dispersion”, which includes liposomes in its definition, should be used consistently throughout the product information.

- The CHMP and the CMDh have now clarified that for medicines administered topically or by other routes of administration, the qualifier “liposomal” or “pegylated liposomal” should only be added to the invented name in those cases when a clear risk of medication errors has been identified. Elements such as route of administration, medication error reporting, or long established use should be taken into consideration when assessing the need for the qualifier.

EMA/FDA analysis shows high degree of alignment in marketing application decisions between EU and US

August 16, 2019 – EMA and the US Food and Drug Administration (FDA) are aligned in more than 90% of marketing authorisation decisions for new medicines.

This is one of the findings of a joint EMA/FDA analysis comparing decisions on 107 new medicine applications at the two agencies between 2014 and 2016. The study also looked at applications for which the agencies had differing outcomes in terms of type of approval and indication. The most common reason for diverging decisions at the two agencies was differences in conclusions about efficacy. Differences in clinical data submitted in support of an application were the second most common root of divergent FDA and EMA decisions.

This is the first analysis by EMA and the FDA that compares the agencies' decisions related to

marketing authorisations.

Some differences were observed in the clinical data due to the difference in timing of submissions (more applications were submitted to the FDA before they were submitted to EMA). Compared to the FDA, EMA often reviewed applications including additional clinical trials or, particularly for oncology medicines, more mature data from the same clinical trial. In those instances, EMA was more likely than the FDA to grant standard approval, a broader indication, or use of a medicine as first-line therapy.

Over the past decade, EMA and the FDA have established joint working groups and several forums for information sharing and collaboration around many aspects of medicine development and regulation, including “clusters” on special topics and therapeutic areas, as well as parallel scientific advice and protocol assistance. These

groups bring together experts for example on plans for manufacturing or clinical site inspections, development of medicines for children, oncology products, biostatistics, rare diseases, and vaccines. While these groups are not forums for shared decision-making, the strong alignment in decisions on marketing authorisations suggests that they may be contributing to alignment on regulatory science.

Most of the information used for the study was sourced from EMA's publicly available European Public Assessment Reports and FDA reviews, which contain the agencies' rationale for their decisions on applications.

The article, entitled “A comparison of EMA and FDA decisions for new drug marketing applications 2014–2016: concordance, discordance and why”, is available through open access in *Clinical Pharmacology and Therapeutics*.

EMA's work on new veterinary regulation advances



September 23, 2019 – EMA has launched a new webpage that shows the progress made by the Agency in the implementation of the new Veterinary Medicines Regulation (Regulation (EU) 2019/6), which becomes applicable on January 28, 2022. On this webpage, stakeholders can find all relevant information regarding EMA's scientific and technical recommendations to the European Commission that will feed into delegated and implementing acts as part of the implementation of the legislation, as well as updates on other activities

such as the preparation for implementation progresses.

The new regulation contains new measures for increasing the availability of veterinary medicines and enhances EU action against antimicrobial resistance, a high priority for the Agency and the European medicines regulatory network. It also aims to reduce administrative burden and encourage medicine innovation and development.

As part of the implementation of the veterinary regulation, the Commission is now

preparing legislative acts, for which EMA provides scientific and technical recommendations when requested. Some of the topics covered by the Agency's recommendations are new requirements for the collection of data on the sales and use of antimicrobials in animals, which will complement the work already carried out by European Economic Area states and Switzerland to gather data on sales of antibiotics, or the development of a Union Product Database on veterinary medicines, which will provide information on all veterinary medicines that have been approved, and their availability in EU Member States.

Preparations are being carried out by experts from EMA and the EU Member States, in consultation with other EU bodies; where necessary. EMA's Committee for Medicinal Products for Veterinary Use (CVMP) adopts the Agency's scientific recommendations before EMA provides them to the European Commission. A number of recommendations were sent already to the Commission in August. The relevant documents on the progress of the work on this legislation will be published on the Agency's website as they become available.

Regulation (EU) 2019/6 repeals Directive 2001/82/EC and amends the provisions of Regulation (EU) 726/2004 relating to the authorisation and supervision of veterinary medicines, which currently governs the centralised marketing authorisation procedure for both human and veterinary medicines. The European Parliament and the European Council adopted Regulation (EU) 2019/6 in December 2018.

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Lingua Franca and Beyond

A real-life experience with predatory journals: Are we smart enough to avoid them?

I would like to start with “once upon a time, there was a medical writing agency...” but no, it is not a good start; unfortunately, it has all happened quite recently.

The story goes then: one of our clients suggested open-access journal X as a target for the article we edited for them. We checked the journal on the available predatory journal lists – it was not listed. We looked at its website that claimed a full peer-reviewed process; the publication fee was high but still somewhat reasonable, and the impact factor (IF) was between 0.5 and 1.0, so everything looked quite OK. Although the paper was decent, it was still far from rocket science so the proposed IF seemed OK. We formatted it for that journal and the author submitted it.

Already on the following day – surprise, surprise – the author received a message saying that the paper was accepted in Pre QC, and was asked for permission to publish; a publication fee was mentioned “while the paper is under review”. Initially, the author accepted the fee, and 1 day later received an invoice to be paid within 3 days! The message from the editorial office said that the article was “in the final stage of publication”(!). To make it crystal clear, the message sent the day before mentioned the ongoing review process, yet the day after the paper was in the final stage of publication with not a single reviewer’s comment – just like the best paper in the world, straight to publication.

This course of events alarmed us, and having researched more carefully, the answer was clear – it was a predatory journal, owned by one of those very aggressive “publishers”. Obviously, the IF claimed on their webpage was not found in the Journal Citation Report.

Immediately, we advised our client to withdraw the article because of misleading information about the IF. They followed our recommendation, and we anxiously awaited the journal’s response. We did not have to wait long. Less than 7 hours after our client had informed the editorial office about withdrawal of the paper, the “request” to pay the withdrawal fee of more than 1300 Euro arrived. We felt strongly that this money must not be paid but we needed support.

So, we turned for advice to EMWA, specifically to Barbara Grossman, the EMWA president. Her recommendation was clear: do not pay, *basta* [Italian: (it is) enough]. Thus, the argument with the journal went on – this time, the editorial office claimed that the IF was indeed below 0.5 (as a reminder, the one displayed on the website was much higher), but it would go up to above 2 by the end of the year. Our client still refused to pay the withdrawal fee. After awhile, the withdrawal fee was reduced considerably... The author still refuses to pay and the discussion is ongoing. The last “friendly reminder” was received a couple of days ago and concerned the reduced fee.

Needless to say, the whole episode was quite stressful, and it definitely was a bad experience. On the other hand, a bad experience usually turns into a very good lesson. Our learning started with re-reading the excellent AMWA – EMWA – ISMPP Joint Position Statement on Predatory Publishing.¹ We had definitely made the right decision: we were encouraged by the statement about difficulties in distinguishing “fake journals” from proper ones, and also reassured that our recommendation to withdraw the paper was ethically correct, even though business-wise it was risky. The list of characteristics of predatory journals and their publishers was also very helpful since we planned to introduce a standard operating procedure for journal verification. Particularly useful were the points about the appearance of a journal website, a journal’s financial policy, indexing in PubMed or the Directory of Open Access Journals, the large number of journals covering everything and anything in any scientific discipline, and also details relating to members of a journal’s editorial board. We have included similar points in our checklist. We also have added a point on publication history; often these journals have published very few articles, and this was the case for us too. To summarise, our lessons learnt were:

1. Predatory journals are not hypothetical creatures that may exist somewhere in the e-space but are rather a real risk and danger that one may encounter in daily life.
2. More stringent procedures are required to

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avoid unintentional submission to a predatory journal.

3. We were not smart enough in the past, but we hope to be smart enough in the future.

Now, an *offline* explanation to our readers:

You may wonder why I have written this article but avoided details of the journal and the publisher. Initially, I planned to disclose all these details, but I changed my mind after visiting the Stop Predatory Journals website. I was looking for the authors and owners of this website and eventually I read: *This site was built by an independent group which wishes to remain anonymous in order to avoid the harassment suffered by the creator/maintainer of ScholarlyOA.*² Being triggered by this disclaimer, I found an article explaining why Jeffrey Beall from the University of Colorado, Denver, decided to shut down his website,³ and I also looked at Scholarly OA.⁴ I have discovered a few other things that fall outside the scope of this article.

Lesson number 4: predatory journals are true predators.

References

1. AMWA – EMWA – ISMPP Joint Position Statement on Predatory Publishing, July 2019 [cited 2019 Sep 29]. Available from: <https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/>.
2. Stop Predatory Journals [cited 2019 Sep 29]. Available from: <https://predatoryjournals.com/about/>.
3. No More 'Beall's List' January 18, 2007 [cited 2019 Sep 29]. Available from: <https://www.insidehighered.com/news/2017/01/18/librarians-list-predatory-journals-reportedly-removed-due-threats-and-politics>.
4. Scholarly OA [cited 2019 Sep 29]. Available from: <https://scholarlyoa.com>.

In the Bookstores

How to read a paper – the basics of evidence-based medicine and health care (sixth edition)
Trisha Greenhalgh
Wiley Blackwell, 2019
ISBN 9781119484745,
paperback, 262 pages
£24.00

I must admit that it felt a little odd to be reading a book about “how to read a paper”, but this book is really about so much more than that. Its author, Dr Trisha Greenhalgh, is passionate

about evidence-based medicine, and this is a very hot topic right now in the era of increasingly “fake” news and predatory journalism. As a grumpy scientist who is increasingly irritated and dismayed by the rise and rise of utter nonsense presented (and accepted) as fact, I settled in for a good read.

It is astonishing that this book was first published 23 years ago, and yet we have not been able to eradicate poor science and sub-standard science reporting. However, as Dr Greenhalgh acknowledges, evidence-based medicine has both increased and decreased in popularity over the years. This edition is the fifth update to Dr Greenhalgh’s original book, and it includes more worked examples, updated references, improved graphics, and a very helpful questions section at the end of each chapter to help check understanding. This edition also contains a new chapter dealing with population genetics and “big data” so it is very current.

Dr Greenhalgh has a very easy, nicely flowing writing style, and punctuates what could be very dry text with lots of personal anecdotes. However, it’s worth pointing out that this book is aimed at medical students, not medical writers, and although there is a lot of overlap between the two, Dr Greenhalgh is a clinician and her aim with the book is to help other clinicians to assess the literature more critically to help them in their practice decisions. This means that the book is written from the clinician’s perspective and the anecdotes are from clinical practice. I found this a little irritating at times, but most of the time I enjoyed learning about “the other side”, and I’m sure it will help my appreciation of clinicians



when I next work with them in my project team.

The book is split into 17 very manageable chapters. The only time I have to read is while travelling, so it was great to have chapters that I could complete in quite short chunks rather than having to stop half way through and then try to re-trace my train of thought the next time I was on a train or plane. Chapter 1 starts with “Why read papers at all?” and then Dr Greenhalgh leads the reader

through the topic of evidence-based medicine very logically – with chapters covering how to search the literature effectively, how to approach a paper and assess it critically, and discussions of papers that report on very simple interventions, right through to detailed discussions about papers dealing with guidelines, systematic reviews, genetic and economic analyses, genetic association studies, and meta-analyses. Although I was already familiar with a lot of the material covered in the book, I found that I could easily skip over those sections to the more interesting or unusual sections that I had not encountered in this detail before. I actually believe that this was the intention, since the book provides very handy coloured “tabs” on the left- and right-hand sides of the pages to allow the reader to navigate between chapters very easily.

I was particularly interested in the chapter dealing with papers that describe evidence for patients and those looking at the patient’s perspective. This chapter describes the patient’s viewpoint, and deals with patient-reported outcomes research. Given the book’s target audience, there is naturally a section on shared decision making and option grids, but this was not laboured and was actually very well done. I have read many papers about decision aids and how best to produce them and use them to explain complex benefit-risk evaluations, and of course the book cannot cover everything, but it gave the top-line views of the topic. It was also

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really interesting to read the difficulties from the clinician’s point of view, and Dr Greenhalgh’s suggestions for how to present this information to patients and how to guide them through it.

This is quite a short book, but the chapters are very well referenced should the reader want or need more detail on any particular point, and they are punctuated with really useful lists of things to look for, or beware of, which I’ve bookmarked for myself for later! There are also lots of good tips and tricks for non-experts (one of the benefits of aiming a book at students), and I found the chapter on statistics to be particularly well written and explained.

The questions/exercises at the end of each chapter were also really helpful. Some were in the form of medical case studies, but they made sense in the context of that particular chapter, so were still helpful. Some chapters (e.g., “Assessing Methodological Quality”) also contained a summary at the end of the chapter and I found this very useful – both for future reference and as a check that I’d followed the main points correctly.

Overall, whilst I wouldn’t consider this a must-read text for medical writers, I am looking at my copy now and noting its plethora of sticky tabs on the side that I have used to mark pages for future reference. This book has something for medical writers of all levels and in all areas of industry, and it is also a very easy book to read – even if you don’t share the viewpoint of a clinician. Perhaps it’s not a bad thing for us all to have a bird’s eye view of how clinicians approach evidence-based medicine, and it’s certainly a timely reminder for us all to be on our guard and to think more carefully about how we read papers!

This book has something for medical writers of all levels and in all areas of industry, and it is also a very easy book to read – even if you don’t share the viewpoint of a clinician.

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Getting Your Foot in the Door



New to medical writing? Check out these links

“How did you get into the medical writing field?” is a question I often hear. This is a fairly easy question for me to answer. I saw a job advert back in 2005 in Germany, I applied for the position, I got the job, and I became a medical writer in 2006. I had a PhD degree in science, I had high English proficiency in a non-English speaking country, and I liked to write. I was at the right place at the right time with the right skills.

“How does one get into the medical writing field these days?” is a question far more difficult to answer. A lot of things have changed in the last 14 years. Online job applications, illustrated, even animated resumes, and web-based job interviews are just a few new-fangled job search and recruiting tools in a highly digitised world.

In this issue of *Medical Writing* on digital health, I'd like to share with you some digital resources that will hopefully answer this question:

1. The EMWA Career Guide 2016 edition (<https://www.emwa.org/training/a-career-in-medical-writing/>). This document is 3 years old so maybe it's time for an update. **If you are interested in collaborating with me on this project, please let me know.**
2. The Spring 2019 issue (Volume 28, Issue 1) of *Medical Writing* on Careers in Medical Writing (<https://journal.emwa.org/careers-in-medical-writing/>) presents a view of the medical writing career trajectory, from getting a foot in the door to retirement, and all that can happen in between. Just in case you missed this!
3. The MedComms Network “getting started” guides (<https://firstmedcommsjob.com/>) can be downloaded for free and provide lots of information on different types of communications jobs, including medical com-

munications, regulatory, and market access writing.

4. The Spring 2014 issue (Volume 29, Issue 1) of the *AMWA Journal* featured several articles for newbies to the field. The articles are 5 years old but still highly relevant. https://cdn.ymaws.com/www.amwa.org/resource/resmgr/journal/Issues/2014/2014v29n1_online.pdf.
5. The Cheeky Scientist Career platform (www.cheekyscientist.com) helps PhD graduates transition into industry careers. It is not specific for medical writing and communications but it has a very strong medical writing contingent (<https://cheekyscientist.com/mwo-learn-more/>). I was privileged to be invited to be part of a webcast panel earlier this year (thank you, Evguenia Alechine and Clare Chang!). Check out their list of alternative careers for PhD graduates (<https://cheekyscientist.com/top-10-list-of-alternative-careers-for-phd-science-graduates/>) and their industry transition ebooks. Not to mention the inspiring testimonials from members who succeeded in making the transition.
6. The Nature careers platform (<https://www.nature.com/careers>) features blogs and news items on careers for science graduates, again not specifically in the communications fields. But medical writing is definitely part of it. Check out Matt Edmonds' journey <http://blogs.nature.com/naturejobs/2017/11/03/an-evidence-based-career-change-my-move-into-medical-writing/>
7. Finally, don't forget about good old LinkedIn. Use the career advice and career interests options that are available even for a basic, free LinkedIn profile.

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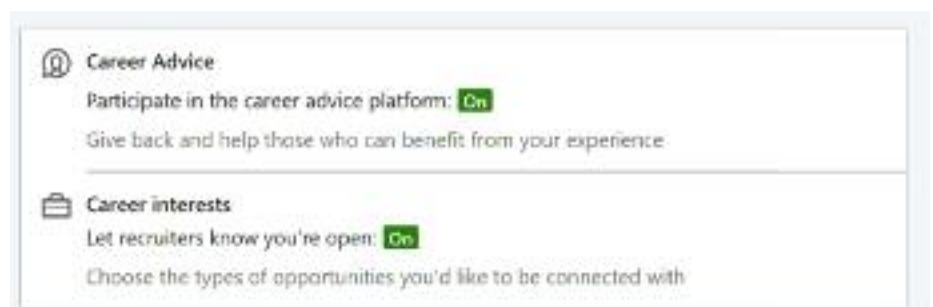


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I continue to collect links and other digital resources for Getting Your Foot in the Door so if you have anything to add to this list, please contact me.

Finally, I would like to congratulate three first-time attendees whom I met at the Spring Conference in Vienna in May. Great to hear that you have landed your first industry jobs! Please share with us your stories.





Editorial

Digital health is touching many aspects of the medical device world. Here Beatrix Doerr provides her perspective on the ways digital

health and artificial intelligence have touched the medical device world and have already changed the way healthcare is provided and experienced by both the patient and health care

professionals. In the era of digital health, I think we can all agree that these are exciting times for medical device development.

Kelly Goodwin Burri

Digital health and artificial intelligence in medical devices

When I was a veterinary medicine student around 25 years ago, I remember standing with my classmates in awe in front of a computer that showed us the four different heart chambers when clicking on the respective symbols. Such a simple programme would not even be interesting for a 3-year-old today. How I would have loved to have today's technology during my time as a student – it would have saved me from learning 2,000 pages of boring anatomy!

Technical advancements permeate every single aspect of our lives these days. Telemonitoring of pacemakers is routine, not to mention digital transfer of electrocardiograms (ECGs) or imaging data to experts. I remember well how I would spend hours trying to manually measure and interpret an ECG when I started to work as a veterinarian. Nowadays, you can simply send ECGs to an expert, which is much faster and certainly more accurate. And in the future, artificial intelligence will help us to interpret ECGs.¹

Another disease area where digital health and artificial intelligence is very helpful is diabetes mellitus. Not so long ago, patients with diabetes had to prick their finger twice a day to measure their blood sugar and needed to manually control their insulin dose, while today insulin pumps automatically measure blood sugar and administer insulin.² What an increase in quality of life! Not to mention the improvement in patients' health due to more accurate and reliable blood sugar control.

Other rapidly expanding areas are artificial intelligence for big data and novelties such as digital patient files owned by the patients. The search term "(artificial intelligence) AND (medical device)" deliver more than 7,000 hits on PubMed. And new initiatives are arising, such as a centre for artificial intelligence in medicine that has been founded as a cooperation of

universities with different stakeholders,³ or a new master's degree in "life science informatics."^{4,5}

Naturally, digital health also entails risks. As with any digital system, data can be hacked or devices even unduly influenced.⁶ Some digital health apps do not require a CE-certification as a medical device as they are not actually medical devices, e.g., your fitness tracker app. Other apps do require a CE-certification, e.g., when they are used to treat diabetes. However, some of the start-up companies are not aware of these regulations and might bring a non-CE-certified product on the market.

The new European Medical Device Regulation, MDR 2017/745,⁷ makes the following distinction:

It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of inter-connection between the software and a device.

There are efforts to control the potential negative effects of digital health and artificial intelligence and to set some compliance standards.^{8,9} This year, the first Cardiovascular Digital Summit has been organised by the European Society of Cardiology,¹⁰ and the British Standards Institution has published a White Paper on artificial intelligence that is worthwhile to read.⁹

These are just a few examples of this rapidly developing field. It is recognised that digitalisation has huge potential. A yearly increase in turnover of 16% is expected in Germany, and in

2028, nearly one-third of the revenue is expected from digital products. It is further expected that in the future most medical devices and services will have digital components.¹¹ We as medical writers and communicators can be glad to be a part of these interesting developments.

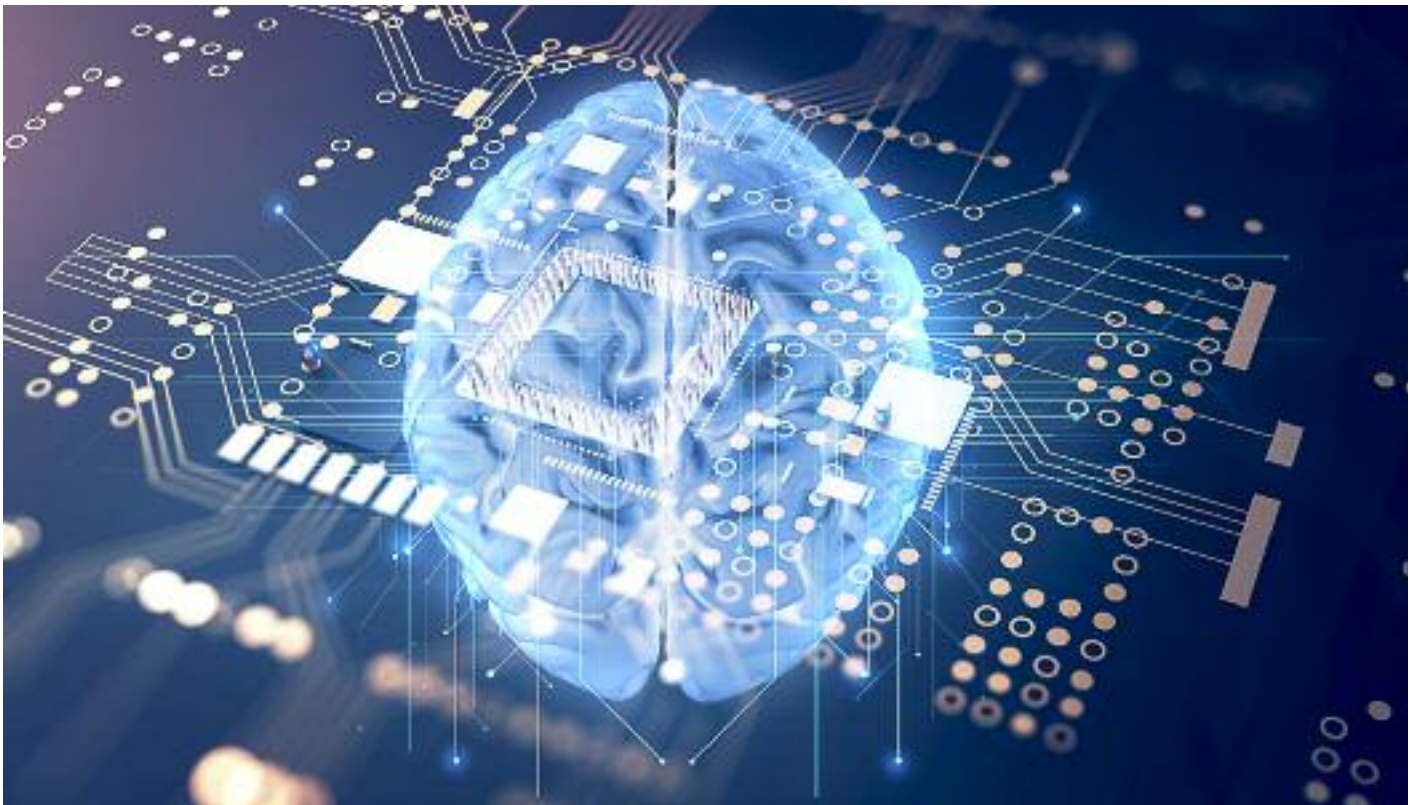
The ability of artificial intelligence to support humans to find information, to organise it, and to deliver it in a digestible format¹¹ will enable us to cope with the enormous amount of data out there in order to drive better decision making more quickly. Let's be curious of what the future will bring and be part of it!

Acknowledgements

The author thanks Kelly Goodwin Burri for her language editing.

References

1. Attia ZI, Noseworthy PA, Lopez-Jimenez F, et al. An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction. *Lancet*. 2019;394(10201): 861–7.
2. Diabetes Bros. Insulin Pump App [cited 2019 June 11]. Available from: <https://diabetesbros.com/insulin-pump-app/>.
3. KI-SIGS. Spaces für intelligente Gesundheitssysteme [cited 2019 August 12]. Available from: <https://ki-sigs.de>.
4. Life Science Informatics (Master of Science) [cited 2019 August 25]. Available from: <https://www.uni-bonn.de/studium/vor-dem-studium/faecher/life-science-informatics/life-science-informatics-master-of-science>.
5. Master Life Science Informatics [cited 2019 August 25]. Available from: <https://>



- www.th-deg.de/en/agw/courses/Isi-m-en.
6. The Guardian. Hacking risk leads to recall of 500,000 pacemakers due to patient death fears [cited 2019 June 11]. Available from: <http://bit.ly/2ZjZ50e>.
 7. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [cited 2019 June 12]. Available from: <https://Shrinx.it/tuit>.
 8. Bertelsmann Stiftung. Digital Patient [cited 2019 June 11]. Available from: <https://blog.der-digitale-patient.de/en/>.
 9. Bharath AA. BSI Medical device white paper. Recent advancements in AI – implications for medical device technology and certification [cited 2019 September 11]. Available from: <https://bit.ly/2IHmTNf>.
 10. European Society of Cardiology. ESC Digital Summit 2019 [cited 2019 June 11]. Available from: <http://bit.ly/2F2ganQ>.
 11. Medizintechnikbranche macht erstmals mehr als 30 Mrd. Euro Umsatz [cited 2019 June 14]. Available from: <https://www.devicemed.de/medizintechnikbranche-macht-erstmal-mehr-als-30-mrd-euro-umsatz-a-836700/>.

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Veterinary Medical Writing

SECTION EDITOR



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How to increase your *n*: Real-world data in veterinary medicine

Why re-invent the wheel? There are inventions and lessons learned that we can implement from human medicine.^{1,2} We herein report an easy option to acquire routinely collected data to foster research as already practiced in human medicine.^{3,4}

Our world is changing at fast pace – Research

Ten years ago, randomised controlled trials were regarded as the gold-standard and the term *real-world evidence* was rarely used. Since then, the demand for real-world evidence data, its acceptance, and amount has steadily increased. The old “hierarchy of evidence” is superseded as real-world evidence now complements randomised controlled trials that usually represent only a minority of real-life patients.^{5,6}

In humans, real-world data were traditionally created through observational registries. But with

increasing digitalisation, alternative data sources are now available, including electronic health records, pharmacy and health insurance databases, or even patient-powered research networks.^{3,7,8} By-products of the daily operations healthcare system such as electronic health records are relevant for many reasons, e.g., they avoid costly *de novo* data collection, provide statistical power through a large sample size, avoid study bias through inclusion and exclusion criteria, and can provide timely answers. Reporting guidelines for studies using routinely collected health data are summarised in the RECORD and RECORD PE statements.⁴

Our world is changing at a fast pace – Veterinary medicine

The world of veterinary medicine has changed as well. Twenty years ago, many veterinary practices

were still manually writing their records on paper cards, with a secretary manually typing the invoice weeks later. Nowadays, life without practice management software is unthinkable as it facilitates all aspects of the practice’s daily functions. Ever becoming more sophisticated, the software is also increasingly being used by universities and other large institutions to gather data for scientific purposes, providing statistical tools and a system environment comparable with traditional databases (access control, audit trail etc).

How to increase your “n”

While it is common practice to use practice management software for analysis of a practice’s own patients, a fairly new approach is to merge data from different practices or universities, allowing an easy solution for the increasing

demand for real-world data. Connecting data from several practices or universities quickly increases the sample size and hence provides a more robust scientific dataset that also allows for more sophisticated statistical analysis. Technically, this is fairly easy to do, depending on the practice management software in use. First, one needs to define the data to be extracted (e.g., species, breed, age, sex, disease, laboratory values). Thereafter, the participating veterinarians need to confirm their agreement to export their anonymised data by the simple click of a button. After being processed by the practice management software, the data are then exported to a CSV (comma-separated values) file, or if necessary, to other formats such as XML (extensible markup language).

Limitations include that data are restricted to that collected during the period of practice management software use, and that data may not always be complete. However, there is a fair amount of data collected in a standardised way that can be instantly accessed and analysed. If needed, additional questions could also be implemented and the practice management software could be used similarly to electronic case report forms; these cases would require manual data entry.

This new option is a cheap and convenient resource for a wealth of data and presents analysis potential for epidemiology, determination of risk factors, disease specific questions, etc.

There are 14 million cats and more than 9 million dogs in Germany alone;⁹ the electronic medical records of these are resources that should

While it is common practice to use practice management software for analysis of a practice's own patients, a fairly new approach is to merge data from different practices or universities, allowing an easy solution for the increasing demand for real-world data.

not be ignored or wasted, as they can foster the rapid advancement of research in veterinary medicine.

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Conflicts of Interest

Isabelle Wohllebe is an employee of GP Software GmbH, a company that provides the practice management software Vetera.

References

1. Oyama MA, Ellenberg SS, Shaw PA. Clinical Trials in Veterinary Medicine: A New Era Brings New Challenges. *J Vet Intern Med.* 2017;31):970–8.
2. Doerr B. Go, vets. *Go! Med Writ.* 2019;28:84–5
3. Mustapha JA, Katzen BT, Neville RF, Lookstein RA, Zeller T, Miller LE, et al.

- Determinants of Long-Term Outcomes and Costs in the Management of Critical Limb Ischemia: A Population-Based Cohort Study. *J Am Heart Assoc.* 2018;7:e009724. doi: 10.1161/JAHA.118.009724.
4. Langan SM, Schmidt SA, Wing K, Ehrenstein V, Nicholls SG, Filion KB, et al. The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE). *BMJ.* 2018;363:k3532. doi: 10.1136/bmj.k3532.
5. Evans K. Real Word Evidence: Can we Really Expect It to Have Much Influence? *Drugs-Real World Outcomes.* 2019;6:43–5.
6. Pragmatic and Observational Research. [cited 2019 Aug 04]. Available at: <https://www.dovepress.com/pragmatic-and-observational-research-journal>
7. Sources of real-world data. <https://rwe-navigator.eu/use-real-world-evidence/sources-of-real-world-data/>.
8. Real Word Evidence [cited 2019 Aug 04]. Available at: <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>.
9. Statistiken zu Haustieren in Deutschland [cited 2019 Aug 04]: Available from: <https://de.statista.com/themen/174/haustiere/>.

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Teaching Medical Writing



Bridging the gap: Academia to industry

SECTION EDITOR



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Editorial

The training of medical writers is not to be taken lightly and requires serious input from industry, established medical writers, and the academics making the transition. Following on from previous articles in *Medical Writing*, Sarah and Adrian Tilly use their experiences of providing a mentoring programme for people wishing to transition into regulatory medical writing to provide advice for both mentor and mentee alike.

Claire Gudex

We have recently met a number of academic professionals who want to transition into medical writing, leaving the pressures of the lab behind them and using their hard-earned skills in a different scientific environment. This is a trend that does not seem to be changing any time soon. Our conversations have revealed intelligent, astute professionals who possess all the attributes necessary to flourish as a medical writer. However, the majority struggle to gain the

experience required for a position in this field.

As industry guidelines and best practices are ever changing, the necessity of training medical writers is a given, and mentoring and continuing professional development are in vogue. Some groups and companies promote and practise this extremely well, and EMWA conferences are our port of call for the latest insights, teaching, and networking for medical writers. The question we might ask is, if we medical writers are so good at teaching and developing ourselves, why does there often remain a seemingly insurmountable chasm for highly qualified professionals wishing to enter the field?

Could it simply be that medical writing is now such a desirable career option that the number of applicants far outstrips the number of positions available? We are not sure this is the case, especially as an eye-watering percentage of jobs are apparently not listed on the usual job search engines or even on company websites.¹ So where are these jobs? They are found by doing your research, talking to the right people, and knowing the skills and attitudes required of a good medical writer.

Universities and other bodies offer training or

mentoring for people wishing to transition into medical writing,^{2,3} and many medical writers give their own free time to help others transition into the field. Whilst such mentoring is invaluable, we suggest that that we need to do more. While it helps to provide advice to the daily life of a medical writer, company profiles, and interview tips, this may not increase the likelihood of our mentee to be hired.

We suggest a two-fold solution. First (and there is already a definite move in this direction), companies need to be willing to take on new writers, invest in their training and development, and witness first-hand how rewarding and beneficial this can be. Second, those who mentor need to mentor a little deeper. A recent *Medical Writing* article urged the industry to provide more profound and long-sighted in-house mentoring.⁴ The same is true for those who mentor

people transitioning into medical writing. We need to help them gain appropriate experience so that they really have something to talk about during interviews. As a mentor, you might not think you have the time. You might not think you have the experience. But if you think laterally, there probably is

If we medical writers are so good at teaching and developing ourselves, why does there often remain a seemingly insurmountable chasm for highly qualified professionals wishing to enter the field?

some way that you can give your mentee greater exposure to what you do every day. For example, show them real clinical trial documents (of course without breaching confidentiality agreements)

or provide a formal review of their written work. It will require a little more of your time and energy, however. View these people not as a burden, but rather as part of the future of our industry – just a small investment of your energy pays off when you see someone else thrive.

Some people are already doing this, such as the Cheeky Scientist Association and the Health Writer Hub, and we are trying the same at Azur Health Science.

On the other side, for those of you looking to make the transition, please don't expect it to be

We [as mentors] need to help them gain appropriate experience so that they really have something to talk about during interviews.

handed to you on a plate. Yes, you have worked hard in your previous field, and yes, you might very well make an excellent medical writer, but there is definitely a new challenge ahead, and you

need to be willing and humble enough to face that and to take one step at a time. Network honestly, find a mentor, and give yourself the best chance possible to find and flourish in your first medical writing position.

References

1. Business Insider. At least 70% of jobs are not even listed — here's how to up your chances of getting a great new gig. 2017 [cited 2019 Sep 6]. Available from: [https://www.businessinsider.com/at-least-](https://www.businessinsider.com/at-least-70-of-jobs-are-not-even-listed-heres-how-to-up-your-chances-of-getting-a-great-new-gig-2017-4?IR=T)

70-of-jobs-are-not-even-listed-heres-how-to-up-your-chances-of-getting-a-great-new-gig-2017-4?IR=T.

2. Lee K. Mentoring tomorrow's medical writers. *Med Writ.* 2017;26(3):52-3.
3. Benau B and Urbine A. Educating the medical writer: A 5-year update. *Med Writ.* 2019;28(1):14-9.
4. Forjanic Klapproth J and Chamberlain James L. How to build a medical writer – new training for a new breed. *Med Writ.* 2019;28(1):96-8.

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A novel proposal for article discussion sections

We know that the discussion and conclusion sections of research articles are too often subjective, containing over-interpretation of data and spins (manipulation of language to mislead the reader).

To address this problem, the editors of *The British Journal of Anaesthesia* (BJA) developed an interesting publishing experiment: They invited a group of independent experts to write a *second* discussion section for a research article published in the same issue. The independent experts had not participated in the research and were only provided with the methods and results of the original paper.

As stated in a *Nature* note: “We’re all biased and this gives a second pair of eyes”.¹ Indeed, with similar data, authors can make inferences or tell different stories.

The BJA published several articles in connection with this experiment:

1. A randomised controlled trial with 13 American authors (anaesthetists, orthopaedists, geriatricians, statisticians);² patients were included in a Johns Hopkins Medical Center, Baltimore; this publication concerns a secondary endpoint of the study; the conclusion of the publication:

This study found that in elderly patients having hip fracture surgery with spinal anaesthesia supplemented with propofol sedation, heavier intraoperative sedation was not associated with significant differences in mortality or return to pre-fracture

ambulation up to 1 year after surgery.

2. The next article proposed a new discussion written by three experts: two anaesthetists, (one of whom was handling editor of the initial article), and a biostatistician.³ This article compares the two discussions (initial authors and external experts) and comments on the comparisons. The interpretation of the main result is the same. There are interesting comments explaining that the trial did not include enough patients to reach such a conclusion:

The major inferential difference between the Discussions is in relation to appropriateness of the sample size. In the Original Discussion the investigators opine that the study was large enough to detect a clinically meaningful reduction in mortality. In contrast, the Independent Discussant infers that the estimated mortality was too high and that the estimated decrease in mortality with the intervention was unrealistic; thus, with only 200 patients, the study was not sufficiently large to address the research question. There are also differences in emphasis in the Discussions regarding existing evidence and contextualization, and whether comorbidity should be a major issue for future research. In many other respects, there is inferential reproducibility between the Discussions.

3. Another article focuses on the reproducibility crisis in science and details the idea of

including a second discussion section for articles:⁴

Although replication of methods and results is necessary to demonstrate reproducibility, it is not sufficient. Also fundamental is consistent interpretation in the Discussion section. Current deficiencies in the Discussion sections of manuscripts might limit the inferential reproducibility of scientific research. Lack of contextualisation using systematic reviews, over-interpretation and misinterpretation of results, and insufficient acknowledgement of limitations are common problems in Discussion sections; these deficiencies can harm the translational process. Proposed solutions include eliminating or not reading Discussions, writing accompanying editorials, and post-publication review and comments; however, none of these solutions works very well. A second Discussion written by an independent author with appropriate expertise in research methodology is a new testable solution that could help probe inferential reproducibility, and address some deficiencies in primary Discussion sections.

4. The accompanying editorial discusses the feasibility of having two discussions for a paper.⁵ The idea is rather interesting. Who would accept an offer to spend time writing a discussion for a study that he or she has not done? The reviewers are best positioned for writing discussions. But the question is the incentive: Will they then

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become authors? Discussion sections are probably the weakest section of a paper, and they must be improved. Structuring the discussion, as proposed by the BJA, is part of the solution. Few journals have considered structuring the discussion with a standard format. The editorial notes that editorials can serve some of the function of a second discussion.

The BJA includes in its instructions to authors a list of elements that should be included in the discussion and notes the pattern it should follow: main finding, relationship of main finding to previous studies, additional (secondary) findings, relationship of additional (secondary) findings to previous studies, limitations, strengths, future directions, and conclusion.

References

1. Adam D. Reproducibility trial publishes two conclusions for one paper. *Nature*. 2019;570:16.
2. Sieber F, Neufeld KJ, Gottschalk A, et al. Depth of sedation as an interventional target to reduce postoperative delirium: mortality and functional outcomes of the Strategy to Reduce the Incidence of Postoperative Delirium in Elderly Patients randomised clinical trial. *Br J Anaesth*. 2019;122:480–9.
3. Vlisides PE, Ioannidis JPA, Avidan MS. Hypnotic depth and postoperative death: a Bayesian perspective and an independent discussion of a clinical trial. *Br J Anaesth*. 2019;122:421–7.
4. Avidan MS, Ioannidis JPA, Mashour GA. Independent discussion sections for improving inferential reproducibility in published research. *Br J Anaesth*. 2019;122:413–20.
5. Sneyd JR. Who watches the watchmen and the problem of recursive flea bites. *Br J Anaesth*. 2019;122:407–8.



Journals increase their requirements for the publication of randomised controlled trials

The requirements of editors and reviewers are increasing. Editors want to be sure that the authors are telling the truth about the observations.¹

What are these requirements? Some have become routine: Record the protocol, supplement data with all key trial data, include the completed CONSORT guideline flowchart and adhere to CONSORT guidelines, structure summaries with key points or highlights, sometimes add an abstract for the public and a sentence entitled “Conclusion and Relevance” at the end of the abstract. Other requirements appear, depending on the journal: No longer use *P* values for statistics and instead report the effect sizes with 95% confidence intervals (the 0.05 significance level represents a historical tradition rather than a rationally established cut point), report the number of secondary outcomes of the protocol and precisely how many are being reported in the manuscript, be explicit about the post hoc analysis, and provide a visual abstract (see for example <https://jamanetwork.com/journals/jama/article-abstract/2752470>).

These requirements, the objective of which is transparency and the fight against the crisis of reproducibility, could justify adopting the

registered reports (RR) model in medicine. The RR model (Figure 1) is defined by the Center for Open Science (<https://cos.io/rr/>) as “Peer review before results are known to align scientific values and practice”.

*Registered Reports is a publishing format used by over 200 journals that emphasizes the importance of the research question and the quality of methodology by conducting peer review prior to data collection. High quality protocols are then provisionally accepted for publication if the authors follow through with the registered methodology.*²

Among the journals that develop RRs in parallel with their other reviewed articles, there are some in medicine (*BMC Medicine*, *BMJ Open Science*, *Cancer Medicine*).

References

1. Bauchner H, Golub RM, Fontanarosa PB. Reporting and interpretation of randomized clinical trials. *JAMA*. 2019;322(8):732–5.
2. Center for Open Science [internet]. Registered reports. Cited 2019 Nov 27. Available at: <https://cos.io/rr/>.

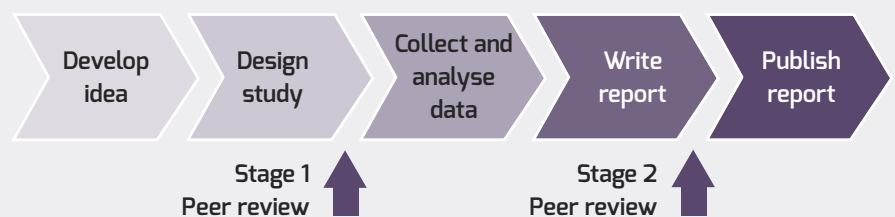


Figure 1. The registered reports model (with permission from the Center for Open Science <https://cos.io/rr/>)



Real-world data: A complement, not a replacement for randomised controlled trial data

New results were published in 2019 providing arguments for the debate on the generalisation of randomised controlled trials (RCTs). It is often discussed, or even admitted, that patients seen in clinical practice do not reflect those who have been included in RCTs.

Three articles, two of which are applied to the field of dialysis, deserve to be read.

These are studies with a lot of data, and these studies have been done well. Rather than detailing or interpreting the data, I am noting the key points of these articles:

1. In a meta-analysis, RCTs from Medline and Cochrane databases from January 2007 to December 2016 were included.¹ These are trials that included at least two sites and more than 100 American adult patients undergoing dialysis for end-stage kidney disease. The RCTs data were compared to the 2011 United States Renal Data System cohort with more than 500,000 patients. Based on median values, the typical study had 211 participants from 15 sites in a single country and a follow-up time from randomisation to final data collection of 7 months.

Question: How similar are dialysis-dependent patients recruited to large, multicenter randomized clinical trials compared with the general dialysis-dependent population?

Findings: In this meta-analysis of 189 trials including 80,104 participants, trial participants were significantly younger, more likely to be male, and less likely to have diabetes or diabetic nephropathy than patients in the US national registry. Moreover, the mortality rate of dialysis-dependent patients recruited to large, multicenter randomized trials was substantially lower than that of registry patients, both overall and when only studies recruiting participants from the United States were considered.

Meaning: These findings imply that caution should be exercised when generalizing results from clinical trials to the broader dialysis-dependent patient population.¹

The mortality risk was less than half that of the registry patients.

2. Another study, a survey, showed that patients undergoing dialysis often underestimate their

disease prognosis, both because of uncertainty as well as optimism.² Survey participants were approached between April 2015 and December 2018 from Seattle, Washington, and Nashville, Tennessee.

Question: What are the prognostic expectations of people undergoing dialysis, and how do these relate to their treatment goals and preferences?

Findings: In this cross-sectional survey study of 996 patients receiving maintenance dialysis at nonprofit facilities in 2 US metropolitan areas, most of the respondents were either

uncertain about prognosis or had a prognostic expectation of more than 10 years. In adjusted analyses, these groups were less likely than those with a prognostic expectation of fewer than 5 years to report having documented their treatment preferences and to value comfort over life extension, and more likely to want cardiopulmonary resuscitation and mechanical ventilation.

Meaning: Prognostic uncertainty and overly optimistic prognostic expectations among people undergoing dialysis may limit the benefit of advance care planning and contribute to intensive patterns of end-of-life care.²

The editorial accompanying these two papers calls for including older patients and those with serious comorbid illness in RCTs if we want evidence that can be used to inform decision-making for all patients.³

3. The objective of another study was to identify the number of trials published in seven high-impact journals in 2017 that could be feasibly replicated using observational data from insurance claims and/or electronic health records (EHRs).⁴ The seven journals were: *NEJM*, *Lancet*, *JAMA*, *The BMJ*, *Annals of Internal Medicine*, *JAMA Internal Medicine*, and *PLoS Medicine*. They included 220 US-based trials: 86 had an intervention that could be ascertained from insurance claims and/or EHR data. Among the 86 trials, 62 had an indication that could be ascertained, and 45 of the 62 at least 80% of

inclusion and exclusion criteria data that could be ascertained, while 33 of the 45 had at least one primary end point that could be determined.

Question: What percentage of clinical trials published in high-impact journals in 2017 generated evidence that could feasibly be replicated using observational methods and data sources?

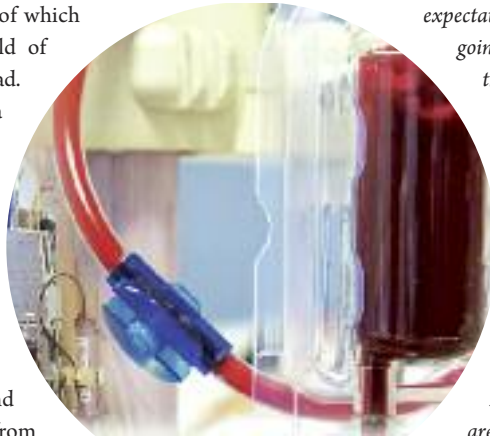
Findings: In this cross-sectional study of 220 clinical trials published in high-impact journals in 2017, only 15% could feasibly be replicated using currently available real-world data sources.

Meaning: This study suggests that, although the increasing use of real world evidence in medical research presents opportunities to supplement or even replace some clinical trials, observational methods are not likely to obviate the need for traditional clinical trials.⁴

This debate is complex, with disagreements among experts on the generalisation of RCTs. The societal demand to always analyse real-life data is understandable, but these data can rarely replace data from RCTs!

References

1. Smyth B, Haber A, Trongtrakul K, Hawley C, Perkovic V, Woodward M, et al. Representativeness of randomized clinical trial cohorts in end-stage kidney disease. A meta-analysis. *JAMA Intern Med*. 2019;179(10):1316–24.
2. O'Hare AM, Tamura MK, Lavalley DC, Vig EK, Taylor JS, Hall YN, et al. Assessment of self-reported prognostic expectations of people underlying dialysis. United States Renal Data System Study of Treatment Preferences (USTATE). *JAMA Intern Med*. 2019;179(10):1325–33.
3. Ross JS, Covinsky K. Clinical trial evidence for real world. *JAMA Intern Med*. 2019;179(10):1333–4.
4. Barlett VL, Dhruva SS, Shah ND, Ryan P, Ross JS. Feasibility of using real-world data to replicate clinical trial evidence. *JAMA Open*. 2019;2(10):e1912869.



Medical Communications and Writing for Patients

Editorial

Dear all,

As I'm sure you are aware, the field of medical writing for veterinary medicines is growing rapidly. If, like me, you know very little about this "new" field of writing, this issue's article from Cemile Jakupoglu and Sandra Götsch-Schmidt is an early Christmas present! Cemile and Sandra present "A short field guide to veterinary medical writing". Their excellent article explains, in easily digestible pieces, everything you need to know about veterinary medical writing as a profession, the different fields of this type of writing, how to get training in veterinary medical writing, and the upcoming trends in the area (please also be

sure to pay attention to the journal's regular section on Veterinary Medical Writing!)

Cemile Jakupoglu studied Veterinary Medicine at the University of Vienna and University of Munich. During her doctoral studies at the Helmholtz Zentrum in Munich she created genetically engineered mice to investigate the function of selenoproteins, and during her post-doctoral studies at the University of Bonn she used neural stem cell technology to investigate brain regionalisation. She worked as a Regulatory Affairs Manager for knoell Germany for 11 years, and since 2018 she has worked for Cyton AH Biosciences GmbH as Veterinary Regulatory Affairs Manager.

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veterinary surgeon before joining a pharmaceutical consultancy company in 2009. She now works as a regulatory and safety medical writer for human and veterinary medicines.

As 2019 draws to a close, I hope that it has been a good year for you all. Enjoy the upcoming Christmas break – may your socks stay snowball-proof and may Santa be kind.

See you in 2020!

Bestest,

Lisa

A short field guide to veterinary medical writing



Since autumn 2018 there has been growing interest in veterinary medical writing (VMW) within the European Medical Writers Association (EMWA). But how can VMW be defined? An online search performed on 17 May 2019 for the term "veterinary medical writing" retrieved the EMWA journal article on "Opportunities in veterinary writing" (Parry, 2014)¹ and the EMWA Webinar "Veterinary Medical Writing – same but different" (Götsch-Schmidt, 2018).² Other search results consisted mainly of consultancy businesses offering VMW services or medical writing education. In this article, we will use the term 'veterinary writing' to refer to writing for the veterinary profession and 'veterinary writers' to refer to writers who produce veterinary-related materials as proposed by Parry (2014).¹

VMW as a profession

Veterinary medical writers play a crucial role in the pharmaceutical industry, associated consulting companies, contract research organisations, academic research and education, and governmental agencies. Veterinary writers do not need a degree in veterinary medicine; however, it is an

advantage to have relevant educational background (such as biology or pharmacology that provides knowledge of mammalian physiology) as well as academic experience. Depending on the type of document to be written, biologists, chemists, other natural scientists and scientific translators have all found their niche in the veterinary writing field. On the other hand, veterinarians with scientific writing capabilities often find themselves employed within human healthcare sectors such as the pharmaceutical or medical device industries.

Fields of VMW

VMW is very diverse, even more so than medical writing in general. The reason for this is the number of species involved, stretching from A for “avian” to Z for “zoological” practice.

Veterinary writing comprises regulatory and non-regulatory, scientific and medical communication writing in different languages.¹ Veterinary regulatory and scientific research documents are normally composed in English. Other languages may be required for regulatory documents following national laws, like requests for animal testing; veterinarians hereby fulfil their role as custodians of animal welfare. Other areas where local languages are required include marketing communications, and study plans for non-English speaking assessors.

Veterinary regulatory writing aims to produce documents for the marketing authorisation of veterinary products, such as pharmaceuticals, vaccines, feed additives, or medicated feed; but it might also concern the evaluation of chemicals, biocides, or plant protection products. The latter overlaps with the typical work and writing areas for toxicologists.

Veterinary regulatory writing has to follow different laws and regulations, such as those of the European Medicines Agency (EMA) or the European Food Safety Authority to place a veterinary pharmaceutical product or feed additive on the market, respectively. In the case of toxicological laboratory animal studies ranging from acute toxicity to complex long-term carcinogenicity studies, OECD Test Guidelines³ must be followed. Accordingly, studies in animals can be conducted under different study standards. Academic research studies or early phase drug development studies might be conducted following Good Scientific Practice



As a result of the limited training possibilities for VMW, a new special interest group for veterinary medical writing, “vet SIG”, was launched at the EMWA conference in May 2019 in Vienna.

principles. Pivotal clinical trials in a specified animal species, the so-called target animal species, are usually conducted under Good Clinical Practice following VICH GL9.⁴ Toxicological studies or studies assessing drug residues in edible tissues might need to be conducted under Good Laboratory Practice.

VMW – same but different

The structure, content and terminology of medical writing used in the human healthcare sector can and should be broadly transferred to VMW. However, as presented in the EMWA webinar,² certain areas differ, like veterinary terminology (e.g., target animal species), routes of administration (e.g., intramammary), the assessment of residues in food producing animal species, and species specificity. Well-known examples of species specificity are permethrin toxicity in cats, occurring when products designated for dogs are improperly used in cats, and the fact that ruminants are generally not to be fasted. From a regulatory perspective, animal species can be categorised as “major” or “minor”. In the EU, major species include cattle, sheep, pigs, chickens, salmon, cats, and dogs. The EMA has implemented a policy to address the lack of veterinary medicines for treating minor animal species and uncommon diseases in major animal species – a similar system as the orphan designation.⁵

Another consideration in VMW is that it includes aspects of human and environmental safety. Integrating human, animal and environmental health, the concept of “One

World – One Health”⁶ guides the writing of submission dossiers for veterinary products. Residues in the environment and in edible tissues of food producing animal species, as well as antimicrobial resistance are evaluated for their potential impact on human safety. To address the human and environmental safety aspects, experts in ecotoxicology, analytical chemistry, and microbiology are needed.

Trends in VMW

As with human pharmaceuticals and medical devices, new rules, guidelines and regulations keep popping up in the veterinary field. In order to address different levels of public and animal health protection in the EU countries, the European Commission launched a revision of Directive 2001/82/EC in 2014 for a regulation on veterinary medicinal products. The main goals are to fight antimicrobial resistance, promote availability of veterinary medicinal products, and establish a modern, innovative, and fit-for-purpose legal framework. After 4 years of negotiations, on January 7, 2019, Regulation (EU) 2019/6 on Veterinary Medicinal Products was published.⁷ At the same time a new Regulation (EU) 2019/4⁸ on medicated feed came in force in January 2019, which repeals Directive 90/167/EEC. The new Veterinary Medicines Regulation, or simply VMR, will apply from January 28, 2022. Much work has already begun with writing the 28 delegated and implementing acts, and on reports from the Commission. The clock to January 2022 is ticking.

The newly adopted VMR requires the authorities to establish and maintain a Union Database of veterinary medicinal products, also referred to as the “product database”. At first the SPOR (Substance, Product, Organisation and Referential) task force⁹ was created for human areas only. However, various SPOR business cases were valid for both human and veterinary medicinal products, and it was decided that the task force membership would be spread amongst veterinary-specialised stakeholders.¹⁰ For medical writers, this means additional opportunities in the future to work as data managers.

Training in VMW

There is very little information or official training available for VMW, especially when compared to medical writing for human subjects. Basic

training in European veterinary regulatory affairs is offered at the Organisation for Professionals in Regulatory Affairs (TOPRA)¹¹ or by other commercial training organisations. We have been on the lookout for training opportunities in *regulatory* medical writing, but for the most part have had to teach ourselves or receive in-house training.

The situation is somewhat better regarding veterinary medical communication training. There is limited guidance available specifically for *publication* writing in veterinary medicine (e.g., Christopher and Young, 2011).¹² Although most of the information provided in this aforementioned booklet is of a very broad and basic nature, it offers some practical tips specifically for VMW. For example, use the term “clinical signs”, not “symptoms”. (Symptoms are sensations felt and reported by human patients.) A variety of courses in research writing and veterinary scientific writing are available, as detailed in the publication by Christopher and Young (2015).¹³

The International Association of Veterinary Editors (IAVE) lists reporting guidelines and resources of particular relevance to animal research and studies (e.g., REFLECT, CONSORT, ARRIVE, STARTD, and SAMPL).¹⁴ In 2014, the IAVE conducted a survey on the awareness, knowledge, policies and views of veterinary journal Editors-in-Chief on reporting guidelines for research publication. The reported outcome sounds somewhat sobering when the authors state that “... many [editors] appear to have little or no knowledge of reporting guidelines”.¹⁵

As a result of the limited training possibilities for VMW, a new special interest group for veterinary medical writing, “vet SIG”, was launched at the EMWA conference in May 2019 in Vienna. As part of the goals defined at the first vet SIG meeting in Vienna, we would like to raise awareness of veterinary medical writing. So, keep an eye out for the publication of more information on the EMWA homepage (and in the Veterinary Medical Writing section in this journal), and please get in touch to learn about how you can get involved.

Acknowledgements

Veterinary collaboration and enthusiasm following EMWA's announcement of the new vet SIG resulted in the writing of this article. We would like to thank all the people who inspired us. Special thanks go to Jessica Lin for providing English language editing and proofreading.

References

1. Parry NMA. Opportunities in veterinary writing. *Med Writ*. 2014;23;3:174–7.
2. Götsch-Schmidt S. EMWA Webinar held on 30th October 2018: Veterinary medical writing – same but different. Available at: <https://www.emwa.org/training/emwa-webinars-programme-archive/>.
3. OECD Test Guidelines for the Chemicals. Section 4: Health Effects. [cited 2019 May 31]. Available from: <http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>.
4. VICH GL9 Good clinical practices. CVMP/VICH/S95/1998; 2000 Jul 04 [cited 2019 May 31]. Available from: <https://www.ema.europa.eu/en/vich-gl9-good-clinical-practices>.
5. European Medicines Agency. Minor-use-minor-species (MUMS) / limited-market policy. [cited 2019 May 31]. Available from: <https://www.ema.europa.eu/en/minor-uses-minor-species-limited-markets>.
6. van Helden PD, van Helden LS, Hoal EG. One world, one health. Humans, animals and the environment are inextricably linked—a fact that needs to be remembered and exploited in our modern approach to health. *EMBO Rep*. 2013;14(6):497–501.
7. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance). 2019 Jan 01 [cited 2019 May 31]. Available from: <https://eur-lex.europa.eu/eli/reg/2019/6/oj>.
8. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (Text with EEA relevance). 2019 Jan 01 [cited 2019 May 31]. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R0004>.
9. European Medicines Agency. Substance, product, organisation and referential (SPOR) master data. [cited 2019 May 31]. Available from: <https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/substance-product-organisation-referential-spor-master-data>.
10. European Medicines Agency. Minutes of IDMP/SPOR Task Force meeting EMA/476463/2016. 2016 Jul 14 [cited 2019 May 31]. Available from: https://www.ema.europa.eu/en/documents/minutes/minutes-eu-idmp/spor-task-force-meeting_en.pdf
11. TOPRA – Organisation for Professionals in Regulatory Affairs. Essentials of European Veterinary Regulatory Affairs. Available from: <https://www.topra.org/>.
12. Christopher MM, Young KM. Writing for Publication in Veterinary Medicine. A Practical Guide for Researchers and Clinicians. Wiley-Blackwell; 2011. [cited 2019 May 20]. Available from: https://issuu.com/wiley_publishing/docs/vet_wfp_booklet_final?backgroundcolor=%2523222222.
13. Christopher MM, Young KM. Awareness of “Predatory” Open-Access Journals among Prospective Veterinary and Medical Authors Attending Scientific Writing Workshops. *Front Vet Sci*. 2015 Aug 13;2:22.
14. International Association of Veterinary Editors. Reporting guidelines. [cited 2019 May 22]. Available from: <http://www.veteditors.org/reporting-guidelines>.
15. Grindlay DJ, Dean RS, Christopher MM, Brennan ML. A survey of the awareness, knowledge, policies and views of veterinary journal Editors-in-Chief on reporting guidelines for publication of research. *BMC Vet Res*. 2014 Jan 10;10:10.

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Good Writing Practice

Syntactic number distraction

Redundancy: Unnecessary word repetition

Introduction

The repetition of a word becomes more distracting (i.e., redundant) in proportion to increased number. The word may be considered as individual (e.g., *the's* in a title) or as a constituent of a larger syntactic unit (a phrase or clause).

Experimental sections

Part 1 – Materials and Method section: Method

Example: Redundant “to”

Buccal and lingual full thickness flaps were reflected to gain access to the osteotomy site.

Revision

*Buccal and lingual full thickness flaps were reflected **to access** the osteotomy site.*

Notes

In *to gain access*, *access* is a nominalisation of the verb *to access*, thereby necessitating the usage of the perfunctory verbal *to gain*. In the Revision, the infinitive phrase *to gain access* is denominalised into *to access*, enabling the prepositional phrase *to the osteotomy site* to be syntactically reduced to the noun phrase *osteotomy site*.

Part 2 – Materials and Method section: Materials

Example: redundant “there were”

In group I, there were 17 men and 23 women, whereas in group II there were 19 men and 21 women.

Revision

*The gender distribution was similar between **group I** (17 men, 23 women) and **II** (19 men, 21 women).*

Notes

The constituents of an adverb clause of comparison repeat those in an independent clause. However, in most comparisons, it is possible to place the entities being compared at the end of the sentence with all other information preceding these compared entities – a

transposition that provides thematic focus and end-of-sentence emphasis. In the Revision, the number of men and women is subsumed under group number to show a hierarchy between primary and secondary (e.g., detail) information – such explicit hierarchical levels facilitate comprehension.

Contextual sections

Part 1 – Title of a journal article

Example: redundant “the”

The Molecular Basis of The Marginal Growth Zone in The Developing Liver: The Function of The Notch Pathway

Revision

Molecular Basis of Marginal Growth Zone in Developing Liver: Function of Notch Pathway

Notes

Descriptive titles, which convey the nature of the research rather the message (i.e., the principal results), primarily consist of nouns and prepositional phrases (not verbs or verbals). As result, such noun-rich titles seem to require the usage of articles, definite and indefinite. However, in practice such titles are usually free of definite articles – an article-minimised format considered a telegraphic style.

In the Example, if any of the constituents merit a definite article for emphasis it is *Notch Pathway*, because it is the focus of the research.

In contrast, the addition of a definite article before a less thematic constituent (e.g., *function*) would elicit usage of *the* before *notch pathway* and the other nouns. Thus, the addition of one *the* could have a ‘snow ball’ effect.

Part 2 – Introduction section: Research problem pertinent background

Example: redundant “a”

More than two million hospitalisations and nearly a half a million deaths are attributed to this infection annually.

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Revision 1

*More than two million hospitalisations and nearly **a** half million deaths are attributed to this infection annually.*

Revision 2

*More than two million hospitalisations and nearly half **a** million deaths are attributed to this infection annually.*

Notes

The indefinite article *a* can be redundant. Removal of either of the *a's* results in two revision options. Removal of both *a's* would result in an ungrammatical syntax. Expressions such as *half a million* usually replace *half of a million*, whereby the *a* substitutes for *of a*.

Part 3 – Introduction section: Research problem pertinent background

Example: redundant “to”

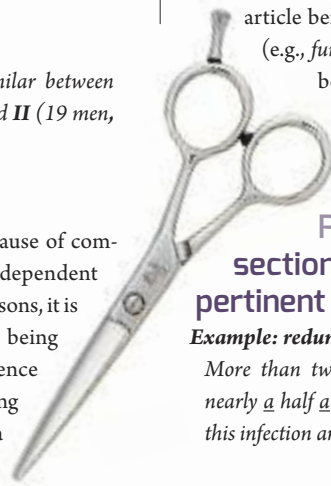
The non-elastic property of woven fabrics is applied to garments to achieve realistic visual effects.

Revision

***To** achieve realistic visual effects, the non-elastic property of woven fabrics is applied to garments.*

Notes

Repetition of *to* occurs when an adverbial *to*-containing prepositional phrase is contiguous to an adverbial infinitive phrase. In the Revision, the adverbial infinitive phrase is transposed to the sentence-start position, thereby distancing the *to's* from each other and minimising the redundant repetition.





Part 4 – Introduction section: Research problem pertinent background

Example: redundant “them”

Mature Mde’s interact with T-cells and activate them.

Revision

*Mature Mde’s interact **with and activate** T-cells.*

Notes

The Example consists of two transitive verbs (*interact with*, *activate*) each with a direct object (the noun *T-cells* and the pronoun *them*). The first verb is phrasal. Because the noun and pronoun are equivalent to *T-cells*, syntactic melding is possible by the coordinated verbs sharing the same direct object *T-cells*.

Part 5 – Introduction section: Research objective

Example: Redundant “and”

We exploited cone cell-specific expression of eGFP to compare the expression of >14,000 genes, consisting of signal transduction, cell cycle, transcription, growth factor, and cell surface proteins and receptors.

Revision

We exploited cone-cell-specific expression of eGFP

*to compare the expression of >14,000 genes, consisting of signal transduction, cell cycle, transcription, growth factor, **and cell surface constituents** (proteins, receptors).*

Notes

In the Revision, subsuming *proteins and receptors* under *cell surface constituents* enables elimination of the second *and*. An objection to subsuming is the usage of the superfluous subsuming word *constituents*. However, subsuming unequivocally denotes that *cell surface* modifies *receptors* as well as *proteins*.

Part 6 – Introduction section: Experimental approach

Example: Redundant object

To determine whether the function of Frizzled-1 is to induce mitosis or maintain it, Frizzled-1 will be characterized by recombination experiments on skin explant cultures.

Revision

*To determine whether the function of Frizzled-1 is **to induce** or maintain **mitosis**, Frizzled-1 will be characterized by recombination experiments on skin explant cultures.*

Notes

A progressive syntactic reduction of the co-

ordinated pairs provides insight that the coordinated pairs are infinitive phrases.

to induce mitosis or to maintain mitosis
to induce mitosis or to maintain it
to induce mitosis or maintain it
to induce or maintain mitosis

Summary

The rhetorical severity of repetition is a dissonance distraction. It is interesting that of the eight examples, six are distributed in the contextual sections; all of the examples of redundancy occur intra-sentence.

Several syntactic techniques are involved in eliminating redundant words, ranging from deletion of articles in a title to end-of-sentence comparison transformation in a complex sentence consisting of an independent and adverb clause. Perhaps the most interesting is the melding of contiguous infinitive phrases (or an infinitive and preposition phrase) to avoid the monotony of the infinitive marker *to* and the preposition *to*.

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Out on Our Own

Welcome readers,

This issue brings me pleasure and inspires me greatly, as I hope it does for our readers. Three freelancers-turned-entrepreneurs have taken the time and effort out of their very busy schedules to write in this edition of Out on Our Own about their very quick transition from being a sole freelancer to employing people and developing a business or two. Lesley Taylor decided after years in the industry as a senior medical writer she'd take a risk to go out on her own, and very shortly her ex-colleagues decided to join her to develop a business. Bruno Walter took a similar leap of faith,

leaving his job as a senior product manager for a medical device company to pursue his career as a medical writer. Very quickly, projects were flying in, and he had to expand his team to meet the demands. Lastly, Bilal Bham didn't necessarily think of becoming a businessman, but while freelancing, he enrolled in many business courses and is now the proud director of two businesses.

Becoming a freelancer, you're faced with an array of challenges but, as I can say from my experience and from hearing the stories of numerous others, the challenges are well worth it. Taking it that step further to develop a

successful business from your client base and employing others to take on the projects really requires courage and faith. These three entrepreneurs show us it can be done and done with a huge success. Of course, it isn't all plain sailing, and many skills need to be learnt along the way but working with a team that you have chosen, who follow your principles and passion for communicating science has to be a huge career and confidence boost. Well done to all of them and others out there who have taken this transition. I'm in awe!

Read their insightful journeys!

Laura A. Kehoe

Going it alone, but not for long!

My story as a medical writer began in late 2011. I had been a post-doctoral researcher at the University of Aberdeen studying cannabis-based compounds and their role in breast cancer when my husband, also a researcher at the time, was made redundant. We were expecting a baby imminently, so at 8 months pregnant we relocated to central Scotland for him to take up a new post which required country-wide travel. That was a re-voir to my career in academia.

Around 6 months after having my son, I received a message from a former connection in the cannabinoid field. She was working for GW Pharmaceuticals (GW); a company developing cannabis-based compounds for various indications. They were looking for a medical writer, and my former supervisor (thank you Prof. Ruth Ross) had put my name forward. Apparently, this was a perk of having written up my PhD thesis in 3 months! An interview with Heather (who became my boss) ensued, and I was offered the role.

Becoming a medical writer was a steep learning curve. It took me around 2 years to wrap my head around everything, especially all the terminology relating to clinical research. The patient element of drug development was so different from academia, and there was much to learn. Over the following 7 years at GW, I had the opportunity to

write a wide variety of regulatory writing and medical communications projects and was promoted to Senior Medical Writer after a few years. Latterly, I was the medical writing lead for GW's clinical pharmacology programme, which involved line managing staff, being part of the department's leadership team and overseeing medical writing activities for a large volume of trials.

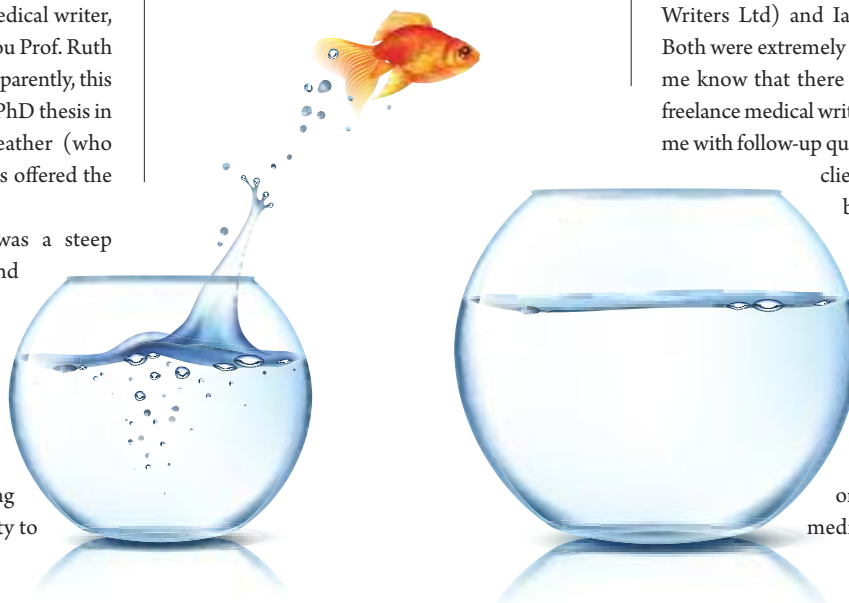
A career highlight was being involved in the successful NDA application for Epidiolex®. This was a huge achievement for the company and for our team, who had been actively involved in module writing and Advisory Committee

preparation. When things were stressful, I would joke with Heather that we should start our own medical writing company. We called the medical writing team 'the dream team', as we had such a good rapport and worked well together. My husband even joined as a medical writer a few years into my tenure!

Following FDA approval of Epidiolex®, the stars aligned, and in late 2018 I finally decided to try my hand at running my own business. Before I made the leap, my first port of call was to ask some fellow Scots what the market was like for freelancers. I used the EMWA Freelance Directory to search for local EMWA members and picked up the phone to Allison Kirsop (Scientific Writers Ltd) and Iain Colquhoun (Medeco). Both were extremely friendly and helpful and let me know that there was plenty of demand for freelance medical writers. They also gladly helped me with follow-up questions around dealing with

clients, billing, and bringing in business. Allison pointed me towards a series of books called *Freelance Medical Writing* by Emma Hitt-Nichols, which I duly purchased.

The book series was a great starting point. It gave a step-by-step guide on how to set up a freelance medical writing business,



including advice on choosing a name, building a website, bringing in customers, buying equipment, and much more. After devising numerous lists, I put the wheels in motion and started developing content for my website, had professional pictures taken, registered the company name, spoke to an accountant, had a logo designed, and did (or crossed out) the other 50 items on the list. The book gave me the confidence that everything would be okay. For that reason, I would recommend it to anyone considering taking the leap.

In early 2019, the stars aligned again. Not long after starting Alchemy Medical Writing Ltd, my former boss Heather, who had been the Head of Medical Writing at GW, approached me about working together. So less than 3 months after starting my new business, one director became two. Five months after that, two became three, when my former colleague and long-time friend Lauren Whyte also decided to join the business.

We are still in our first year of owning and operating a small medical writing firm. So far, it has been great. The highlights for me have been engaging with lots of new people (although it can be quite daunting speaking with CEOs, COOs, and other executives), learning new therapeutic areas, and diversifying the types of documents I get to work on. I can also be much more flexible around my young family, which is very important currently. The upside of having business partners is having people I can chat to, joke around with, bounce ideas off, and who are at the end of the phone if my attempts to beat a document into submission aren't going to plan.

The downside was the pressure to quickly build a client base so that there was enough regular work to keep us all busy, but that really didn't take long!

For anyone considering taking the leap into freelance writing, I would say buy yourself the book I recommended. If that makes you feel confident, then you are probably ready. And don't be afraid to team up with great people.

Lesley Taylor

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Out on my own, but never alone: From freelancer to managing director of a medical writing agency

This rainy Monday morning is a hectic one: The phone is ringing constantly; a rather pushy woman was just trying to persuade me to invest millions in her company; the mailbox is overflowing; the deadlines of two projects are breathing down my neck; the suspiciously friendly headhunter with the too-good-to-be-true candidate is calling for the third time; and then an employee's computer crashes. Terrific!

Six years ago, I could hardly have imagined this scenario. Six years ago, I quit my well-paid job as Senior Product Manager in the R&D department of a large medical device company to start my own business as a medical writer. I dreamed of more freedom, more independence, more self-determination. But the reality was different: Soon, I was struggling with accounting, legal, and administrative issues. I needed a company name, an office, a logo, accounting software, and all kinds of insurance.

So I started drinking my after-work beer with accountants, insurance consultants, graphic artists, lawyers, and IT specialists. I had expected a comfortable beginning, initially flirting with the idea of a part-time position alongside self-employment, but within two months of starting the company, the project requests literally overwhelmed me. My first Christmas holidays as a freelancer were not spent as a digital nomad on a beach in Bali, but brooding over clinical evaluation reports. Meanwhile, I could count on the assistance of my partner, who supported me from that point forward with administrative tasks. The company grew and grew, and suddenly I found myself in the unaccustomed role of boss. I had gradually morphed from my role as a sought-after specialist to an HR manager, project planner, and process optimiser.

Today I have four employees and am looking for a fifth; I am fully booked for months in advance and have to refuse orders; and yes, I work a lot and earn little because everything generated by the business is reinvested in the company and its employees. But if you want to be successful as an entrepreneur, long working hours and a modest lifestyle are part of the package.

What would I recommend to prospective

entrepreneurs? Persistence. Perseverance. Flexibility. And highly developed tolerance for frustration. Sometimes things don't work out as planned. And yet you have to go on, to dig in. You can't give up and need to maintain both a calm head and a healthy dose of confidence because in the end, things are never quite as dire as they seem.

You also need a lot of patience when you are looking for employees because finding the perfect match—on a professional and personal level—is incredibly challenging. Networking and self-marketing are also indispensable. You have to be prepared to talk about what you are doing with your company, whether at a children's birthday party or a meeting with an old schoolmate. Opportunities are lurking all around you. All you have to do is recognise and seize them.

And as hackneyed as it sounds, a good work-life balance is indispensable; otherwise, you'll burn out quickly. I now plan my holidays well in advance and then try to disengage myself to the extent that I can and delegate my responsibilities. And I've learned something else: Acknowledge and trust your gut feeling and try to work with clients and colleagues with whom things simply feel right.

Meanwhile, back in the office, the thunder and lightning continues: a customer wants to push the timeline forward by two weeks; the inbox informs me that it has reached its limit; the cleaning lady calls in sick; and then the tax auditor announces himself. Sighing, I accept that I can't go sailing next weekend after all. Admittedly, the work-life balance doesn't always work out. The 4-hour working week suggested by entrepreneur Tim Ferriss feels like a cruel hoax. And yet I love what I do because nothing beats the feeling of satisfaction that flows through you when you lock the office door on Friday evening and realise that in 6 years, you have built a successful company from scratch.

Bruno Walter

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Opportunities are lurking all around you. All you have to do is recognise and seize them.

From freelancer to director of two businesses

The first and only time I wrote for *Medical Writing* was back in early 2012, after having been freelance for about 6 months. One was an article titled “Networking Effectively”, and the other was an Out on Our Own article, because I had done well in my first few months! That desire to succeed, not go hungry, and pay the bills meant I quickly (had to!) learned to sell by phone, email, and LinkedIn AND to deliver quality on time!

Initially, I was quite happy being a freelancer, with no big dreams for growth. Like others, I have had my ups and downs and enjoyed not having much responsibility aside earning enough to live comfortably. I didn't think that this industry was where my fortune lay, so I got involved with another business, and I was very successful. I learned a lot about sales, marketing, and branding, and ended up going on a plethora of business courses through local business training schemes.

After this training and success, I set about rebranding my company name from, wait for it – Scripsi Scriptum Ltd – to Bham Pharma Ltd! I thought that having a Latin tongue-twister of a name would help people remember me, which they did, but telling them my email address over the phone became a mission! I chose BHAM because it is the acronym of our motto “Bringing Home A Modern Pharma”, (although Bham is

my surname, which I realised afterwards...). I also chose Bham because I wanted to build a remote-working business model, across all of my businesses, present and future!

Changing my offering across all digital media and having a bit of luck with clients looking for more than one writer was key to our growth. Including me, there are three medical writers, and we have a business development manager, so there are four in total as of November 1, 2019. The skills I picked up in my other business and from the trainings I attended have helped me immensely, from team building to time-management, to conflict resolution, to positioning and having a unique offering.

I believe that working remotely using all the digital tools available to us is both the present and the future for business. Office space is often an unnecessary overhead. I also believe in a fair work-life balance, meaning that my team do not have to waste time and money trying to get to and from work, and can contribute quality work to their job whilst taking care of their personal lives. I have parents on my team, and I don't believe it should be an either-or scenario of kids vs job. So far, it is working for us! I have a team that works hard, produces quality, and hits deadlines but still enjoys its personal time. I suppose one thing I should make clear is that

I am a leader and not manager and have a relaxed style of management. My attitude is simple: We set achievable deadlines, you hit the deadlines, no excuses. When working 8+ hour days as we do in our profession, not every hour is billable because of meetings, client calls, and other day-to-day activities, so providing the flexibility to staff whilst making sure clients know what to expect and when is a fine but achievable balance.

I am enjoying the challenge (and headaches!) of running a growing business. I am only getting started, and there's a long way to go, but I am on my way! I also have a fledgling digital media agency, Bham Digital Ltd, which offers compliant medical social media services, and I am using the same model as Bham Pharma for its growth. I am still growing, learning, and developing, but so are my businesses, and I don't want to stop at two, because I believe there are still many new and transformative business opportunities in the pharma, biotech, and medical device industries that can bring value to both clients and employees. Here's to having 2020 vision and beyond!

Bilal Bham

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“I believe that working remotely using all the digital tools available to us is both the present and the future for business. Office space is often an unnecessary overhead.”



Upcoming issues of **Medical Writing**



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



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.



September 2020: **European Union regulations**

This issue will focus on new EU regulations and their impact on medical writing. Key topics will include changes to centralised procedures, effects of Brexit on the EMA, and new regulations on medical devices, drug-device combinations, and veterinary medicines.

Guest Editor: Ana Madani

The deadline for feature articles is June 10, 2020.



December 2020: **Writing for patients**

This issue will feature articles from some of the key opinion leaders in the area of writing for patients. We will cover aspects such as the current state of information given to patients and how we can do this better, the role of the medical writer with patient associations, the patient voice in research publications and writing up patient-reported outcomes, writing for the internet, and how patient needs are being incorporated into traditional medical communications.

Guest Editor: Lisa Chamberlain James and Amy Whereat

The deadline for feature articles is September 8, 2020

CONTACT US



If you have ideas for themes or would like to discuss any other issues, please write to mew@emwa.org



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