### From the Editor

## The D's of robotics: Are we ready to delegate?



Raquel Billiones Editor-in-Chief editor@emwa.org 0000-0003-1975-8762

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What about medical writing? Are we ready to delegate our deliverable documents to a digital

Without actually realising it, I have been using digital tools over the years, with or without AI.

#### The dreary and the detection of errors

Early in my career, I manually created in-text tables and drafted hundreds of patient narratives. Let's face it, such tasks are dull and depressing. Nowadays, there are computer programmes that do these for us.

Manual data entry is not only **d**ull and **d**reary, it is also prone to error. Quality control of our documents - from data checks to readability metrics - is crucial. Detection of errors and mistakes is a very useful AI capability we should take advantage of.

These are just a few examples. Many articles in this issue tell us more about the uses of AI in medical writing, from systematic literature reviews to detecting plagiarism, to pharmacometrics and structured content authoring.

hen Shiri Diskin and Daniela Kamir suggested in 2021 to have a Medical Writing issue on automation in medical writing, little did I imagine how imperative this topic would be in 2023. I sincerely thank them for their avant-garde mindset and for producing this AI-some issue.

#### The dirty, the dangerous, and the dull

Robots were supposedly created to perform the 3D tasks - the dirty (e.g., declogging sewage systems), the dangerous (e.g., defusing bombs), and the dull (e.g., drudgery of repetitive assembly work). At least that's how it was for many years. More recently, robotics has been coupled with artificial intelligence (AI), and taking alliteration even further, more D's have been added to their tasks, including the dear (i.e., expensive) and the difficult.1 These last two are distressing to many - will we soon be demoted, and eventually displaced? Then there's an even darker side of AI featured in many a dystopic film, a digital demon we can't see that deceives, disrupts, and destroys.

It's not all debacles and

more human touch.2

doomsday. Present day robots have proven to be useful in other D's - think about domestic bots, drones used in disaster management, delivering relief goods to remote places. Devices help overcome disabilities and expedite diagnoses. Deep machine learning supposedly gives medicine ("Deep Medicine") a

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#### The dear and the difficult

So back to the question - if AI can do all that is dull, dear, and difficult, where does that leave us? Will robots finally overcome the triple constraints3 of "Cheap, Fast, and Good - Pick Any Two" and companies can have all three?

In medical writing, it should never be a pick of any two. "Good" has always been, and will always be, the standard; there is no trade-

off on quality. But leveraging AI, we can pair quality with speed. Think about it - we can develop good regulatory documents quicker and get treatments to patients faster. The first COVID-19 vaccines that got approved in record time surely had a little AI help. And they weren't cheap.

#### **Delegation and direction**

Clinical research requires skill sets that AI can never fully provide. In the standard project RACI (Responsible, Accountable, Consulted, Informed) matrix,<sup>4</sup> the "responsibility" and "accountability" remain in our hands. Because AI, like human intelligence, has limitations. We have heard about AI hallucinations, ethical considerations, and the lack of context and creativity. I still can't see an artificial system fully understanding the principles of Good Clinical Practice anytime soon.

Let's look beyond the document and focus on the goal. I never thought I'd be ready for a self-driving car, but there seems to be no stopping it. In the same way, we cannot do without AI in medical writing. We can delegate the driving, the autopiloting, but we determine the direction and the destination.

In fact, we are finding ways to co-exist with this new generation of AI-driven virtual robots. The articles in this edition attest to this. And, by the way, congratulations to the newly formed EMWA AI Working Group (p. 70).

#### **Disclosure**

No alliteration generator was used in writing this piece.

#### References

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## So back to the question – if AI can do all that is dull, dear, and difficult, where does that leave us?

#### Resources on AI regulations for health products

#### Regulatory resources:

- EMA. Reflection paper on the use of artificial intelligence in the lifecycle of medicines. July 2023.
  Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle\_en.pdf
- US FDA Draft Guidance for Industry and Staff. Marketing submission recommendations for a predetermined change control plan for artificial intelligence/machine learning (AI/ML) – enabled device software functions. April 2023.
- MHRA Guidance. Software and artificial intelligence (AI) as a medical device. Updated July 26, 2023. Available from: https://www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device

#### **Publications:**

- Hines PA, Herold R, Pinheiro L, et al. Artificial intelligence in European medicines regulation.
  Nat Rev Drug Discov. 2023;22(2):81–2. doi:10.1038/d41573-022-00190-3
- Fraser AG, Biasin E, Bijnens B, et al. Artificial intelligence in medical device software and high-risk medical devices - a review of definitions, expert recommendations and regulatory initiatives. Expert Rev Med Devices. 2023;20(6):467-91. doi:10.1080/17434440.2023.2184685

# Resources on guidelines for use of Al in writing manuscripts

Flanagin A, Kendall-Taylor J, Bibbins-Domingo K. Guidance for authors, peer reviewers, and editors on use of Al, language models, and chatbots. JAMA. July 2023. doi:10.1001/jama.2023.12500

Marušić A. JoGH policy on the use of artificial intelligence in scholarly manuscripts. J Glob Health 2023;13:01002. doi: 10.7189/jogh.13.01002

Zielinski C, Winker M, Aggarwal R, et al. Chatbots, ChatGPT, and scholarly manuscripts - WAME recommendations on ChatGPT and Chatbots in relation to scholarly publications. Afro-Egypt J Infect Endem Dis, 2023; 13(1): 75-79. doi: 10.21608/aeji.2023.282936

COPE position statement: Authorship and Al tools.

Available from:

https://publicationethics.org/copeposition-statements/ai-author

ICMJE defining the role of authors and contributors. Artificial intelligence (AI)-assisted technology. Available from:

https://www.icmje.org/recommendati ons/browse/roles-andresponsibilities/defining-the-role-ofauthors-and-contributors.html#four

The Lancet: Information for Authors. The use of AI and AI-assisted technologies in scientific writing. Available from: https://www.thelancet.com/pb/assets/raw/Lancet/authors/tln-info-for-authors-1686637133557.pdf

**NEJM Editorial Policies:** 

Use of Al-Assisted Technologies. Available from: https://www.nejm.org/aboutnejm/editorial-policiespolicies.

https://www.nejm.org/aboutnejm/editorial-policies

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