# Artificial Intelligence and Machine Learning

**W**e are in an era in which most people cannot imagine living without either computers or smartphones. We are well aware of how machine learning (ML) and artificial intelligence (AI) tools support our daily lives. And now, with their rapid development, medical writers can leverage these technologies to enhance productivity, quality, and innovation. The idea for a *Medical Writing* issue focusing on automation in medical writing arose about 2 years ago. This was quite a few months before ChatGPT became a household term, and the tool itself went swiftly into use with almost every copy-editing professional, every lawyer, and every person in any industry that uses text as their main tool of the trade. We were very interested in taking a snapshot of the landscape of tools that are currently available to medical writers and how they are being used.

**Anjana Bose**'s article explores the

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transformative impact of AI/ML applications in drug development and medical devices, highlighting the potential benefits of these technologies in areas such as clinical trials, post-marketing surveillance, and regulatory writing. The article also underscores the challenges of transparency, validation, and data privacy, emphasising the need for careful integration and collaboration between AI and human expertise to ensure responsible innovation in healthcare.

Within the narrower context of medical writing, AI and automation tools can be classified into two general categories: those that generate natural language text from data or other sources, and those that curate pre-made content from approved sources.

In this issue, we explore how various platforms can support the writing of MedComms and, employing tools in one or both of these categories.

**Azza Gramoun** provides an overview of AI tools that support the review, summarisation, and evaluation of clinical information to assess medical, useful for writers of clinical evaluation reports. **Katja Martin** highlights the growing impact of generative AI driven by large language models in the realm of medical writing, catering to the familiarity with AI of various user groups. Emphasising the need for comprehensive understanding, the article offers a balanced perspective that counters exaggerated AI expectations while exploring its benefits.

The article delves into specific AI applications, showcasing the potential of generative AI to enhance efficiency and quality in medical communication.

**Lucy Cobb** and **Nicola Haycock** describe their experiences with automation software in writing patient narratives for clinical study reports that require more than 100 narratives. The current tools do not use ML capabilities. What they do use is pre-programmed natural language text, into which specific data items are imported from the data set generated from electronic data capture (EDC) systems used in clinical studies. As we know from our own experience, the amount of work needed for a medical writer to edit and revise such a machine-generated narrative into coherent text with a clear story is quite substantial. Significant programming efforts are required to tailor the program to a specific product, study, and study population. Many times, specifically for medically complex cases, such machine-generated narratives need to be supplemented with information coming from sources external to the electronic data captures systems, such as the Council for International Organizations of Medical Sciences reporting forms. The option of having AI integrate information from both natural language sources and coded, cleaned, and meticulously queried databases is very exciting. We believe that it will not only reduce a lot of the grunt work required of medical writers, but will also make these narratives much more useful to the reviewers and any stakeholders who would like to use them as sources to identify potential problems with any product.

**Mati Kargren, John April, Gina Clark, Jonathan Mackinnon, Aliza Nathoo,** and **Elizabeth Theron** share their experience with structured content authoring for regulatory documents, specifically protocols. The article focuses on bulk text that must be reiterated across various submission documents or across protocols that serve different trials within the development program of a single product. These usually include background text such as description of the regulatory landscape, the development history of the product itself, information about the indication, and more. These texts can be authored and agreed upon once and then imported automatically into the various documents from the pre-approved source. As writers are involved in large submission projects with a significant number of documents containing repetitive text, it would be very interesting to see what the future holds for such amazing tools, especially with respect to the dynamics of updates. Will we be able to revise the text once and have a computer program import the revised text or the relevant revisions across the entire set of documents containing the same text? Most importantly, such tools will provide consistency across documents while also benefitting the process of submission preparation tremendously. Specific subject matter experts will be responsible for authoring and updating specific text paragraphs, and the required updates will be implemented in real time in all relevant documents. This will save others the need (or temptation) to re-review and revise these sections upon encountering them again in documents reviewed

later during the work, and would very effectively reduce the time and effort required to write these heavy submission documents.

As the use of AI authoring tools expands, **Natalie Bourré** has been exploring the topic of whether readers can correctly assess whether medical texts were written by humans or such AI tools. She reports on her experiment in which a range of respondents, including healthcare professionals, medical writers, and others, were presented with sample medical texts and asked to guess "who" wrote which prose. Our guest editors volunteered to be subjects in the research. You can read the intriguing research results in this issue.

AI and automation are not only changing the way medical writers work, but also the way they learn and grow. Medical writers need to keep up with the latest developments in these technologies and acquire new skills and competencies to use them effectively. Moreover, medical writers need to collaborate with other stakeholders, such as programmers, data managers, statisticians, reviewers, regulators, and patients, to ensure that the AI and automation tools serve the best interests of all parties involved. In the Digital Communication section, the article by **Sofie Bergstrand**, **Catherine Heddle**, **Montse Sabaté**, and **Marta Mas** discusses the integration of AI tools into medical writing processes, focusing on the potential benefits and challenges. Microsoft's AI tool, Microsoft 365 Copilot, is introduced, highlighting its potential to improve collaboration and productivity in medical writing.

> "The more that you read, the more things you will know. The more that you learn, the more places you'll go."
>
> DR SEUSS

Guest Editor **Daniela Kamir** interviewed **Uri Kartoun** about improving clinical risk assessment tools such as the MELD (Model for End-Stage Liver Disease) score. Assessing fairness by AI involves evaluating whether AI outcomes are unbiased across demographics, ensuring equitable decision-making and avoiding discrimination.

**Valérie Lannoy** looks at plagiarism's damaging impact on the biomedical academic publication domain. While AI offers hope in addressing this issue, a worrisome trend is emerging as new AI-based tools facilitate plagiarism. This article examines the historical context of plagiarism, particularly in the medical field, and explores the potential of AI to detect a unique form of plagiarism known as aigiarism. Additionally, the article emphasises the risks associated with AI-powered services that aid in paraphrasing copied content, and proposes potential solutions.

**Veerle Persy** examines the present applications, advantages, and limitations of AI in medical writing, and highlights the dynamic interplay between technological innovation and human expertise.

A collaborative article by **Viviana Moroso**, **Mats O. Magnusson**, and **E. Niclas Jonsson** presents their software-based solution to address the challenges of reporting complex pharmacometric analyses. By integrating various software tools, they are able to enhance efficiency, accuracy, and reliability in summarising and describing input and output data for drug development and regulatory assessment.

**Jamie Norman** and **Lisa Chamberlain James** discuss the current role of AI in medical writing and ask the question: AI for medical writers – friend or foe?

AI tools have their advantages and disadvantages. On one hand, AI and automation tools can reduce the amount of grunt work that medical writers face, such as writing repetitive text, formatting documents, checking references, and ensuring consistency. On the other hand, AI and automation tools can also introduce new challenges, such as ensuring the quality, accuracy, and reliability of machine-generated text, maintaining the human touch and creativity of the medical writing style, and dealing with ethical and legal issues related to health information privacy and intellectual property, among others. AI and automation are not threats to medical writing; they are opportunities for medical writing to evolve and improve. Medical writers who embrace these technologies with curiosity, creativity, and critical thinking will be able to harness their potential and create value for themselves and their clients.

Last, but not least, we are happy to introduce you to the members of the EMWA AI working group, **Sarah Tilly**, **Slavka Baronikova**, **Martin Delahunty**, **Namrata Singh**, and **Claire Harmer**, each of whom answers some questions about the working group itself and AI specifically.

We hope that you will enjoy reading the current issue on automation in medical writing as much as we enjoyed putting it together. Finally, be on the lookout for a dedicated AI/automation section in *Medical Writing* from December 2023 onward!

## About the guest editors

**Daniela Kamir,** PhD, has been a medical writer with the Bioforum Group, a global, data-focused, technology-driven clinical research organisation, since 2020. Daniela has an extensive international research background, with an emphasis on molecular biology and new technologies in the sciences and medicine. She is experienced in writing pre-approval regulatory documents and scientific writing.

**Shiri Diskin,** PhD, has been working as a medical writer since 2009. She founded the Medical Writing Department at Bioforum in 2018 and has been leading it ever since. Shiri manages large-scale writing projects in the pharmaceutical industry and is also a medical writing instructor.