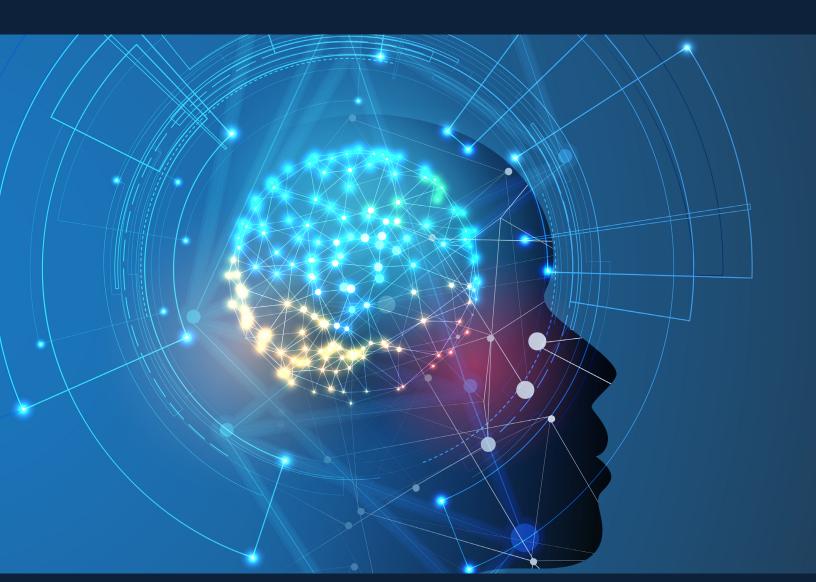# The evolving role of AI-powered solutions in Medical Affairs

A roundtable discussion in collaboration with members of the Medical Affairs Professional Society

**Artificial intelligence (AI) has been very much in the spotlight in recent months. It has garnered a great deal of media attention, and a diverse array of stakeholders ranging from health care industry leaders to mainstream consumers have been asking questions about the risks, benefits, and potential applications of this rapidly evolving technology. Medical Affairs Professional Society (MAPS) members are no exception. During the MAPS 2023 Global Annual Meeting and the MAPS 2023 EMEA Annual Meeting, there was a great deal of talk about AI.**

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To better understand MAPS members' perspectives on this topic, we recently convened a panel discussion on the future of data, AI, and analytics in Medical Affairs. Our panelists were six MAPS members with varying areas of interest and levels of expertise in artificial intelligence.

They were:

· **Caroline Blackie**, OD, Ph.D., Senior Medical Director, Johnson & Johnson

· **Jennifer Ghith**, MS, Senior Director, Omnichannel Strategy and Innovations Lead, Global Scientific Communications, Pfizer

· **Jumaah Goldberg**, DPT, Associate Vice President, Head of Neuroscience, U.S. Medical Affairs, Ipsen

· **Santosh Hariharan**, Ph.D., Associate Director Analytics – Medical Communications, Vertex

· **Elmira Lechat**, MD, MBA, Global Medical Director, Alexion

· **Joana Parreira**, MD, Senior Global Medical Director, Roche

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We invited these experts to discuss their views on the current state of AI adoption in the Medical Affairs function, as well as perceived barriers to its uptake. While there's great excitement about AI's potential to advance Medical Affairs' mission, improve insight management, and empower the function to become patient-representative (rather than patient-centric), individual organizations' readiness to implement new tools varies greatly. The technology's complexity – as well as the speed with which it's evolving – makes it time-consuming for Medical Affairs professionals to keep up with the latest developments and their potential applications to their functional areas. Many MAPS members have a pressing need to learn more about the available AI tools, how to validate their output, and how to best make use of them today and in the future.

# The current state of AI in Medical Affairs

As an umbrella concept, artificial intelligence – a field in which computer systems can perform such tasks as reasoning, learning from experience, generalizing, or finding meaning that are usually associated with human cognitive abilities – is familiar. However, AI has multiple sub-fields, and each has different current and potential future applications for Medical Affairs.

**Predictive analytics** involves the application of algorithms such as regression analysis to predict future outcomes based on relationships among variables in historical data sets. Netflix's recommendation engine is one example of a predictive analytics model. In Medical Affairs, this type of AI has been employed for some time to drive statistical analyses.

**Natural language processing (NLP)** incorporates algorithms that can parse, analyze, and interpret human languages so that models can be trained on unstructured text-based data sets. Literature search tools, such as DimensionsAI (created by the makers of Altmetrics) and Huma.AI leverage NLP for scientific discovery and insight management. Many of these platforms rely on a common technology foundation, though the individual search tools are branded, and published paywalls often limit the number and depth of insights that can be obtained from each one.

**Generative AI** focuses on creating new content, such as text, images, or audio. This content closely resembles content created by humans. The field is relatively new for mainstream usage, and its effect is being felt across many disciplines. BioGPT and BioMED are generative AI tools specifically trained to answer medical questions. (ChatGPT is not intended for medical or clinical use.)



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The panelists agreed that levels of awareness about the AI technology landscape were high across most of their organizations, with one panelist reporting that their company had recently hired new leaders with expertise in data analytics to support cross-functional collaboration and bring in the right stakeholders to accelerate adoption of AI.

However, multiple participants also voiced apprehension, especially regarding AI's implications for risk management and regulatory compliance. Many legal gray areas surround the use of AI – who, for instance, owns the output of models trained on proprietary and/or confidential data sets that aren't available for public use?

Participants also felt challenged by this technology's lightning-fast evolution. It can be a struggle to adapt budgets, processes, compliance filters, and workflows to keep pace with change this rapid. Because of this, it's also difficult to understand where AI can be applied most fruitfully in Medical Affairs today. One panelist mentioned that these tools should be used for data analytics rather than content generation, since they were generally not mature enough for that purpose in this field, but another noted that "long term" could mean just three to four months when it was a discussion of AI.

Particularly promising use cases for AI in Medical Affairs are dashboards that can integrate evidence from multiple unstructured and structured data sets into a single view. This may prove especially valuable in leveraging real-world evidence (RWE) for clinical research. An AI tool able to integrate RWE with other data sources could help Medical Affairs professionals better understand the real impact of an intervention or therapeutic outside of a clinical trial setting. However, many of the available tools are overly complex. Panelists mentioned the significant benefit to having multiple data sources feed a single, central dashboard, rather than relying on multiple niche tools. Most companies today use custom dashboards developed in-house for very specific use cases, which means these tools are seldom generalizable for other purposes or data sets.

# Challenges and barriers to AI's adoption

Because this technology is so new and fast-changing, regulators are also challenged to keep pace with the evolution of AI and its applications. Panelists noted that adequate regulations were not yet in place to handle many issues related to this technology's commercialization. Organizations will need to be prepared to discuss the models they use and describe how data are handled and outputs validated, which can be problematic since many may employ methods that are the intellectual property of the providing vendor. If a new software as a medical device that relies on AI is launched, the sponsor will likely have to reveal which data and validation techniques were used in its training. Not only will the sponsor need to provide this information to regulators, but reviewers will also need to be appropriately skilled and ready to have these conversations.

Panelists voiced data privacy concerns during the discussion, noting that Medical Affairs professionals should exercise caution when deciding which data can be entered into an open-source AI tool's prompt and which should be excluded.

Validation of the output of these tools will become increasingly critical as they're more widely adopted. This is especially true since ChatGPT has quickly become known for "hallucinating," or producing inaccurate results,

though this is in a lower-stakes setting. One panelist commented that if an AI literature search tool was used during the preparation of a manuscript, its authors should be expected to demonstrate that they had validated the results.

Lack of standardization is also a problem. At present, there is no standard for validating the outputs of these models in Medical Affairs. Lack of transparency and expertise in AI tool development makes it particularly difficult to implement standards in this area. One panelist felt that the major technology companies – such as Google, Amazon, and Microsoft – would likely create standards that will be broadly applied in the future.

Many participants also spoke about this technology's inherent complexity. Clinical data sets are by nature large and complex, and there's a great need for methods that can extract information from them that's both comprehensible and understandable for stakeholders. It's just as important to avoid data overload as it is to avoid overlooking important data, one panelist noted, and this balance is a delicate one. Another panelist remarked that it was key to ask what the real value of AI was to the patient, the physician, and the organization, rather than becoming distracted by the technology's novelty or the seemingly unlimited possibilities it offered.



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# Next steps

AI's future promise for Medical Affairs use cases is bright. At present, though, there's still a significant need for education in this area among Medical Affairs professionals, as well as standardization and regulation from the industry as a whole.

As regulatory authorities create more detailed guidance about the adoption and use of these technologies, the public's confidence in them may increase. The US Food and Drug Administration has taken an important first step by publishing an open call for comments on the use of AI in drug manufacturing. Such steps will help bridge communication gaps between groups that have not traditionally collaborated (such as clinicians and experts in AI). These collaborative relationships are much needed today.

Among MAPS members – and the Medical Affairs community as a whole – more education about these tools' capabilities (and the potential pitfalls of their adoption) will be critical. To learn about AI, Medical Affairs professionals will need to explore literature they may not normally look at (one panelist mentioned the AI Index Report, an interactive annual report put out by Stanford University), which is a challenge because busy Medical Affairs professionals often don't have time or expertise to do this work. But it is clear people need more guidance on how to locate high-quality, relevant information on AI tools.

# A call to action:
# MAPS member education initiatives

Panelists strongly recommended that MAPS develop a curriculum to educate members about AI. Such a curriculum should include inputs from technical experts as well as academic researchers. Perspectives from clinicians and end users of AI-powered tools in the Medical Affairs community should also be considered. This would be a solid step toward assembling the baseline knowledge and use cases that could be used to drive suggested approaches and guidelines in future courses.