



Medical™
Affairs
Professional
Society

Vision for Generative Artificial Intelligence in Medical Affairs

By the Medical Affairs Professional Society (MAPS)

The following MAPS Partner Circle organizations contributed to this report:



Endorsed by members of the MAPS Executive Consortium:

Randy Brown, Global Lead | Respiratory Medicine, Immunology & Digital Health | Global Medical Affairs, **Teva**
Danie du Plessis, Executive Vice President Medical Affairs, **Kyowa Kirin**
Catrinel Galateanu, Head of Global Medical Affairs, **UCB**
Brad Glazer, Vice President, Worldwide Medical, **Baxter**
Jack Goodpasture, Medical Affairs & Transformation, **Lilly**
Andrew Greenspan, Chief Global Medical Affairs Officer, **Janssen**
Mandeep Kaur, Senior Vice President, Global Medical Affairs and Health Outcomes Research, **Horizon**
Deepak "Dee" Khuntia, SVP, Chief Medical Officer, **Varian**
Johnathan Lancaster, Senior Vice President & Head, Global Medical Affairs, **Regeneron**
Deborah Long, SVP, Global Medical Affairs, **Vertex**
Lobna Salem, Regional Chief Medical Officer Developed Markets and Japan, Australia, and New Zealand, **Viartis**
Kirk Shepard, CMO, SVP, Head of Global Medical Affairs OBG, **Eisai (former)**
William Sigmund, EVP and Chief Medical Officer, **Becton Dickinson**
Darryl Sleep, Senior Vice President, Global Medical and Chief Medical Officer, **Amgen**

Special thanks to **Matt Lewis**, Global Chief Artificial and Augmented Intelligence Officer, Inizio Medical and **Peter Piliero**, VP, Medical Affairs, Melinta Therapeutics.

**BROWSE OUR
PARTNERS' USE CASES**

INTRODUCTION

Human beings are the planet's most evolved cognitive entity. That is, we were until recently. The emergence of Generative Artificial Intelligence (Gen AI) platforms drives another coffin nail into human intellectual dominance, compounding earlier demonstrations of inferiority such as Garry Kasparov's loss in chess to the algorithm Deep Blue in 1997, IBM Watson's Jeopardy win against Ken Jennings in 2011, and the Stanford/Google collaboration that in 2012 led to the development of AI that could recognize cat photos. Today, Gen AI is unequivocally better than humans at a range of cognitive tasks, including its ability to spot patterns, make connections, and find meaning in vast amounts of structured and unstructured data.

The realization that machines accomplish certain cognitive tasks better than humans is nothing new (e.g., the Sumerian abacus appeared around 2500 BCE). However, all previous technologies have essentially been "tools," used by humans to make our jobs and our lives easier, or as a kind of cognitive prosthetic that allowed us to accomplish otherwise unachievable or inefficient tasks. Gen AI can be similarly used as a tool. But these technologies now have the potential to transcend the idea of a "tool" to provide not only execution of human-led or human-defined tasks but also the creation of new knowledge and new ways of making sense of the world around us.

Meanwhile, readers of this paper live in the real world in which we have a decision to make: Do we leverage Gen AI in its existing, imperfect form to provide value to our companies and eventually to patients, or do we watch other Medical Affairs teams and departments adopt Gen AI while we fall behind?

This paper provides a vision describing how Gen AI technologies will reshape the possibilities and practice of Medical Affairs related to the four functional pillars of Strategy & Leadership, Evidence & Insights Generation, Evidence & Insights Communication, and Engagement & Partnerships (figure 1). To create this vision, the MAPS organization leveraged the expertise of MAPS Partner Circle companies, many of which are at the forefront of developing AI solutions. We then solicited input from the MAPS Executive Consortium, which is composed of Medical Affairs leaders from across MAPS Industry Partnership Program companies. The result is a unified vision of the transformational use of Gen AI in Medical Affairs.

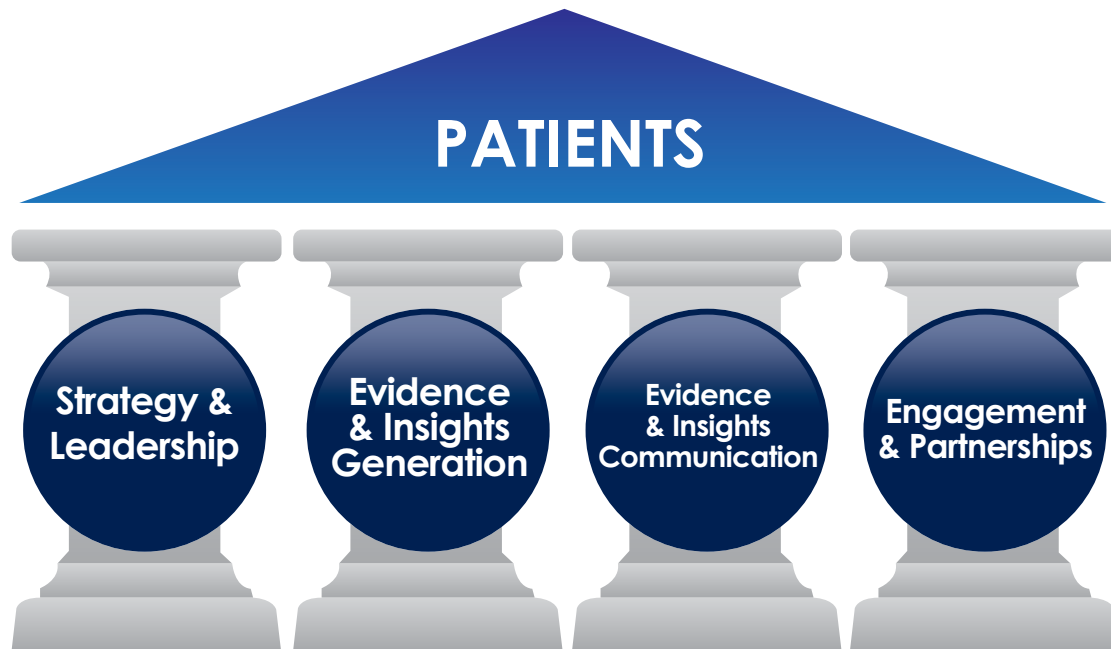


Figure 1. Pillars of Medical Affairs



Vision Statement: Strategy & Leadership

Gen AI lets us learn from the past and make predictions about the future – essential elements of creating a Medical Affairs strategy. However, due to the potential inaccuracy of AI-generated content, the best use of these technologies is to provide context and support for strategic decisions that continue to be made by humans.

Areas of Influence: Strategy & Leadership

Business Intelligence

Gen AI will change the basic paradigm of Business Intelligence (BI) from a model that requires knowledge of specialized BI platforms and programming expertise, to a model in which humans can conversationally generate data visualizations and analyze complex data sets. This query-and-response model of Gen AI platforms will not only be applicable to single data sources but will allow end users to easily combine data (especially unstructured data) from multiple channels into integrated views – replacing the expensive and inefficient data-level integration paradigms of the past.

Example Use Case:

Gen AI can be used as a digital colleague and data analyst in Business Intelligence related to congress planning, enabling the Medical Affairs professional to surface publications and attendees pre-congress, to interrogate content during congresses, and to unearth insights post-congress in a way that isn't possible today.

Decision Support

The spectrum of AI influence on decision-making can be conceptualized in three categories: 1) decision support, in which humans take into account AI insights while making decisions; 2) decision augmentation in which humans and AI models have equal input into decisions; and 3) decision automation, in which AI is empowered to make decisions and even act with some, little or no human oversight. Of course, different types of decisions will lend themselves more appropriately to each approach, with strategic decisions receiving the most human oversight, and some executional decisions or processes being managed by AI with more autonomy. Even when humans retain decision oversight, Gen AI will help human decision-makers better crystallize their understanding of information landscapes surrounding these decisions and enable faster decision-making.

Example Use Case:

Some Medical Affairs departments may allow significant autonomy of Gen AI models to suggest and even decide next best action for teams in subfunctions including Field Medical and Medical Information.

Predictive Analytics

Many of the data analysis and statistical modeling projects that currently require human expertise will be performed by AI (esp., leveraging machine learning and Natural Language Processing). From predicting drug response, to market trend forecasting, to the ability of models to test the outcomes of different decisions before implementing them, the use of AI and Gen AI will fundamentally transform the function and form of predictive analytics.

Example Use Case:

Gen AI will be used to predict both clinical trial outcomes and adverse events, allowing Medical Affairs teams to use Evidence Generation budgets more effectively, making human trials more likely to produce a positive outcome, and reducing the drug failure rate.

Efficiency

Gen AI will create process efficiencies that allow Medical Affairs departments to expand the scope of their activities. However, with the potential for efficiency comes the expectation for efficiency. With the adoption of Gen AI technologies, both internal and external stakeholders will come to expect information and insights more rapidly and with less investment. More rapid insights generation will also drive the ability and expectation to adapt strategies more quickly. The more rapid pace of insights generation and analysis will force businesses to adapt the way information flows through the company, providing pathways for near real-time actions based on insights created by Gen AI.

Example Use Case:

For one example of myriad ways in which the use of Gen AI will streamline existing processes, Gen AI can be used to survey the external scientific landscape to draft literature reviews. Identifying efficiencies will allow Medical Affairs leadership to strategically reprioritize resources.

Read the entire use case here.

“

The mindset is you have the data, you have the tool, you should churn the information.

—MAPS Gen AI roundtable participant

Impact Metrics

Medical Affairs has counted actions (engagements, publications, etc.) or used qualitative measures such as surveys to demonstrate impact internally. Gen AI will help Medical Affairs look beyond these “surrogate endpoints” to measure aspects that are more immediately relevant to the profession’s true north, namely improving clinical decisions to optimize patient outcomes.

Example Use Case:

Gen AI will allow Medical Affairs teams to more effectively and efficiently monitor changes in online conversations and claims databases describing customer behavior and/or opinion that can be linked to Medical Affairs actions.

Challenges: Strategy & Leadership

- **Strategy First:** With the emergence of any new technology, it is tempting to “grab at shiny things.” In other words, the danger exists to implement Gen AI solutions without connection to strategic purpose. Organizations must ensure that Gen AI answers a strategic need from a practical perspective and departments and teams must answer questions of data ingestion and data lakes before applying Gen AI to these data.
- **Change Management:** The opportunities for transformation afforded by Gen AI can seem overwhelming, driving the evolution of not only how Medical Affairs professionals accomplish their jobs, but the skills and training required to perform effectively. To realize the potential of Gen AI, leadership will need to develop guidance and governance and create a culture to address well-founded concerns while mitigating general nervousness that comes from incomplete understanding (while supporting competency development to augment understanding).
- **Cross-Functional Transformation:** Just as Medical Affairs will be transformed by the use of Gen AI, so too will the work of cross-functional partners such as R&D and Commercial. Awareness and understanding of these changes at the organizational level will ensure Medical Affairs continues to integrate effectively with cross-functional partners to provide value.
- **Integration with Human Systems:** It is essential to integrate Gen AI technologies with the human work processes. This requires a governance framework to define the ethics of AI use across applications and scenarios. Governance will also need to anticipate public policy and regulation and understand which individuals are accountable for oversight of AI systems, e.g., who are the responsible parties and what are the core practices for problem formulation, validation, and monitoring.

“

You can't just walk into any Medical Affairs organization and sprinkle Gen AI magic. There has to be a strategy-first approach.

—MAPS Gen AI roundtable participant



Vision Statement: Evidence & Insights Generation

Gen AI will allow Medical Affairs to streamline the scientific development process, using new sources of information to create new knowledge that positively impacts patients' lives. At the same time, AI will help Medical Affairs teams uncover insights from internal and external data to drive value for the organization.

Areas of Influence: Evidence & Insights Generation

Real World Evidence

The three basic challenges of Real-World Evidence (RWE) research are in defining study questions, identifying and gathering data, and synthesizing knowledge from these data. The second and third challenges are centrally relevant to Gen AI technologies and even the first may benefit from Gen AI acting as an innovation tool for human researchers in suggesting new and novel avenues to interrogate data. (Drawing new questions or new hypotheses from Gen AI will require sophisticated prompt engineering aimed at generating perspectives that haven't surfaced previously.) Additionally, Gen AI may be able to suggest new sources of RWE or amalgamate existing data sources into combined resources that can be used in new ways.

Example Use Case:

Gen AI could be used to identify topics of disagreement, or those that seem undecided, or unmet medical needs in scientific literature, online communities, social media, etc. These knowledge gaps may form questions or hypothesis for RWE or clinical studies.

“

Yes, the compute of Gen AI is more robust; yes, the models are more powerful; but if we aren't asking different/better questions, and solving for X in a different way, we aren't realizing the full value of this new innovation.

—MAPS Gen AI roundtable participant

Clinical Trials

Gen AI will help Medical Affairs teams (along with R&D and Clinical Development colleagues) more effectively discover and test new drugs, diagnostics and devices. In discovery, Gen AI can identify unmet needs as targets for development and may even suggest promising molecules or other therapeutic options from libraries, literature, etc. In planning for clinical research, Gen AI will help to predict (and even engage) patients most likely to benefit from trial participation, while also optimizing trial design to maximize the chance of success. Some trials may even be replaced by “virtual trials” based on AI models, though this application requires additional development and is likely to meet regulatory hurdles. Importantly, Gen AI will also help Medical Affairs teams to analyze study data to better understand subpopulation biomarkers and outcomes. In short, the opportunities of Gen AI will fundamentally change the way Medical Affairs departments and the biopharmaceutical/MedTech industries as a whole manage the science of discovery, development and commercialization.

Example Use Case:

Medical Affairs teams may use Gen AI technologies to identify the features of successful studies as a way to suggest promising designs for future studies. Similar use is possible with data: Medical Affairs may use Gen AI to identify what types of data led to trials or publications, and then use the results to narrow the search field of data likely to lead to future studies/publications/etc.

“

While guardrails will be necessary, Gen AI holds the promise of accelerating our ability as Medical Affairs professionals to serve patients through clinical evidence generation, scientific discovery to support lifecycle strategies and by identifying knowledge gaps where timely, relevant information can be delivered.

—MAPS Gen AI roundtable participant

Insights

Imagine a Venn diagram with circles representing all the possible transformational effects of Gen AI on Medical Affairs. These circles converge on Insights. One of the fundamental uses of Gen AI is to synthesize vast amounts of data into bullets, takeaways, trends, themes, talking points or highlights. At a basic level, these takeaways could be considered “insights.” It is worth noting, however, that Gen AI technologies may not have the contextual understanding to separate insights (which have actionable strategic purpose), from information or observations (which may be identified due to frequency but may not be relevant to the business). Human-reinforced learning throughout the lifecycle may be required to float true insights to the top. Likewise, prioritization algorithms will be needed to give weight to different data sources.

Example Use Case:

As MSLs enter notes from scientific conferences, conversations with KOLs and HCPs, or comments from various social media channels, AI-powered language models can be used to dissect the notes, extracting nuanced meanings, categorizing sentences into main points, and pinpointing vital topics, such as drugs and clinical studies. **Read the entire use case here.**

Patient Journey

Many real-world issues have the potential to undermine the appearance of efficacy or safety even for a promising treatment. Gen AI technologies can listen to diverse sources of data and online conversation to define how patients interact with the healthcare system in ways that affect outcomes.

Example Use Case:

Understanding patients' disease activity trajectories (patient journeys) is critical to evaluating safety, efficacy, and unmet need. Gen AI can be used to identify inflection points in these journeys – for example, identifying content in a medical note describing whether a patient's condition improved after starting a medication, or synthesizing insights from online conversations describing barriers to efficient diagnosis. **Read the entire use case here.**

Ability to Use New & “Messy” Data

The fields of epidemiology and Health Economics & Outcomes Research (HEOR) have long been able to point to social, economic and lifestyle differences that stratify health outcomes. Gen AI technologies will dramatically expand this capability, allowing Medical Affairs teams to integrate and incorporate data sources that were previously seen as too “messy” or expansive for use in publications or other scientifically rigorous content.

Example Use Case:

Medical Affairs teams will use Gen AI technologies to integrate data sources such as employment, education level or even measures related to health of the nation into traditional models of RWE studies.

Challenges: Evidence & Insights Generation

- **Validation:** Historically, drawing conclusions from data was difficult, time consuming, and expensive. Going forward, validating Gen AI assertions will replace these challenges. One roundtable participant points out that some Medical Affairs departments are creating “red teams” whose purpose is to take an adversarial role to AI assertions to challenge potential hallucinations.
- **Bias:** Real-World Data may be messy, contradictory, controversial, or open for interpretation by different audiences. Additionally, incorrect or biased data may be overrepresented in the sources that Gen AI references for knowledge creation. Unfortunately, the old adage applies: Garbage in, garbage out. In some cases, the solution may be human oversight of Gen AI output. In other cases, the answer may be adjustments to the algorithm that force AIs to either train on vetted data or give more weight to trustworthy sources.



Vision Statement: Evidence & Insights Communication

Gen AI is the engine that will allow Medical Affairs to deliver on the promise of personalized omnichannel engagement, transforming the way Medical Affairs participates in the exchange of knowledge with internal and external stakeholders. Across the spectrum of content creation, dissemination and impact measurement, Gen AI will ensure that industry knowledge reaches stakeholders to improve patient benefit.

Areas of Influence: Evidence & Insights Communication

Stakeholder Personalization

Gen AI will vastly increase the precision of stakeholder archetypes, which can be addressed with personalized content and journey mapping to facilitate customer experience through omnichannel engagement. More granular omnichannel journeys have the potential to create more personalized and thus more impactful interaction with our customers.

Example Use Case:

Many Medical Affairs teams are developing libraries of modular content that can be combined for use across geographies and stakeholder groups. Gen AI can be used to create sophisticated combinations from the “building blocks” of modular content that are personalized for stakeholder archetypes or even individual stakeholders – not necessarily editing or changing any approved content, but choosing and sequencing modular content for personalized use.

Content Creation

There is an important difference between Medical Affairs’ use of Gen AI and uses elsewhere in society: Medical Affairs cannot afford to be incorrect. In Medical Affairs content creation, Gen AI has transformational value in drafting content and in personalizing content for the needs/preferences of ever-more-targeted audiences, but it is difficult to imagine a future in which Medical Affairs teams allow customers to directly access AI-generated content which has had no human oversight.

Example Use Case:

Medical Affairs teams may train a Gen AI model on company data to draft Medical Information Standard Response Letters, after which scientifically trained human “editors” provide oversight before review and approval. **Read the entire use case here.**

Omnichannel Engagement

The previous two areas of influence speak to the power of Gen AI to drive omnichannel engagement. Content personalized to stakeholder archetypes along with sophisticated journey mapping exponentially increases the sequence of possible Medical Affairs touchpoints. Gen AI is uniquely capable of guiding Medical Affairs teams and their customers through this labyrinth. Meanwhile, Gen AI has the power to inform and validate segments and personas that will lead to better/more accurate customer journeys and content development.

Example Use Case:

Gen AI is uniquely equipped to identify the needs and preferences of visitors to a company's online platform, creating personalized paths through the company's omnichannel engagement framework.

Scientific Exchange

Gen AI can help Field Medical personnel establish thought leader networks and then equip MSLs for personalized scientific exchange – providing personalized content aligned with HCP needs and interests, and also pushing relevant content to MSLs at the appropriate time. Gen AI can also be used to determine next best action for Field Medical personnel and even to guide the company-wide customer journey.

Example Use Case:

Innovative Medical Affairs departments are using Gen AI to integrate the data of in-person engagements with self-service information portals such that an HCP searching for information within a portal will be offered additional relevant information and directed to an MSL as needed, and online information consumption preferences also influence MSL/HCP scientific exchange.

Patient Centric Communications

Medical Affairs has long been aware of a gap between the information we share with patients and the information they request. For example, due to compliance issues, Medical Affairs is unable to answer questions related to product and treatment access such as how to find a doctor for a rare disease, how patients can participate in clinical trials, or how to find financial support for treatment. With a more interactive form of communication through chatbots or other gen-AI interfaces, Medical Affairs may be able to close this gap, thus improving trust in our companies. In addition, just as Gen AI allows more personalized omnichannel communication with HCPs and KOLs, these technologies will allow more personalized patient communications, for example layering on targeted content for specific demographics within a clinical trial to drive engagement and retention.

Example Use Case:

Medical Affairs teams may use Gen AI to draft various versions of plain language summaries, adapting the content, format and style to meet the needs of patients seeking to directly access this information.

Challenges: Evidence & Insights Communication

- **Stakeholder Use of Gen AI:** With Gen AI, anyone can be a data analyst. This presents an existential challenge for Medical Affairs: If HCPs, scientific leaders and even patients can ask conversational questions of scientific literature and sophisticated data sets, and generate concise answers, what is the purpose of Field Medical and Medical Information teams? Moving forward, Medical Affairs will have to prove its ability to generate and contextualize knowledge beyond the dry and factual capabilities of Gen AI.
- **Small Data:** Medical Affairs content is often based on new and emerging understanding and/or data, presenting AIs with only a small pool of data to use as source material – and AIs specifically depend on big data to learn appropriate query responses.
- **Discovery:** If Gen AI is allowed to drive the scientific narrative (rather than Medical Affairs), there is the potential for external stakeholders to discover both information and misinformation that does not benefit patients or the company.
- **Empathy:** Because many Gen AI platforms are trained on human speech, they can be trained to mimic empathy when interacting with human customers. (Some studies suggest that AI empathy may have already surpassed that of human doctors.) However, empathy in evidence/insights communication may be seen as inauthentic.



Engagement & Partnerships

Vision Statement: Engagement & Partnerships

Gen AI technologies will help Medical Affairs teams magnify their value proposition to existing partners while discovering new value levers with traditional and innovative partnerships.

Areas of Influence: Engagement & Partnerships

Personalized Partner Content

Often, budget concerns force Medical Affairs departments to prioritize stakeholder groups, with partner organizations such as medical associations and patient advocacy groups sometimes treated as “edge” audiences in comparison with HCPs and scientific leaders. As previously described, Gen AI streamlines the ability to create personalized content and engagements, allowing Medical Affairs teams to be faster and more responsive in producing tailored content for specific partner audiences and thus widening Medical Affairs’ reach and value to these organizations.

Example Use Case:

Medical Affairs will use Gen AI to personalize content not only for patient associations, but for targeted patient populations within societies, and even for individual patient society events and initiatives.

Internal Partnerships

Just as Gen AI will help personalize content and engagements for external audiences, these technologies will allow Medical Affairs teams to give more attention to personalized content creation for internal use, including use in internal trainings. Similarly, the use of Gen AI to create insights and business intelligence from internal and external sources will further highlight the impact of Medical Affairs to leadership.

Example Use Case:

Medical Affairs will use Gen AI to create tailored education materials for personalized medical education within the company, adjusting format and complexity for relevant departments across Commercial, R&D and business leadership.

Medical Training

Innovative Medical Affairs teams are contributing to external trainings ranging from PharmD programs and fellowships to Continuing Medical Education (CME) events. Medical Affairs can help academia and HCPs/KOLs understand how their roles will change, and which skills will be desirable in the brave new world of Gen AI.

Example Use Case:

An External Education group (or mentorship group) within Medical Affairs may partner with PharmD, MD or PhD programs to identify additional non-traditional areas of training required for success and help students learn to navigate career paths in light of adjustments driven by adoption of Gen AI.

“

In general, our fellows will need to come into industry with a different skill set than before. Coming in empowered vs. intimidated and prepared to be flexible in the face of landscape changes due to Gen AI is going to be what sets the people that have a long career ahead apart.

—MAPS Gen AI roundtable participant

Research/Data Collaboration

Across clinical trials and RWE studies, the more data, the better the ability to draw conclusions. Only, there has historically been a tipping point at which the volume of data became so large as to become unwieldy and opaque – or large-scale data lakes were simply impossible to create due to the inability to standardize the features of data from different sources such that they could be combined and analyzed en masse. Gen AI specifically thrives in these ecosystems of massive and sometimes messy data; innovative companies have already realized the promise of big (and bigger) data and are creating frameworks for data sharing partnerships in which the benefits of big data combined with Gen AI outweigh any disadvantages of protecting intellectual property.

Example Use Case:

The Machine Learning Ledger Orchestration for Drug Discovery partnership is made up of 10 pharmaceutical companies sharing information about the targets and action of small molecule assets to aid the development of models that better predict the possible effectiveness of these molecules with diseases, conditions and patient populations. Medical Affairs departments within industry now have the opportunity to explore similar collaborations.

Identifying Avenues of Value

Gen AI will help Medical Affairs teams discover where within partner organizations their involvement can provide the most impact. In other words, Gen AI can look inside various processes, organizational structures, or “journeys” to find the gaps, steps, and inefficiencies where Medical Affairs teams can intervene with knowledge and engagements to help partner organizations address these challenges. Traditionally, Medical Affairs has provided individual HCPs and KOLs with information to help them make more informed clinical decisions; similar approach is relevant to organizations trying to understand how to best treat patients at a more macro scale, or to promoting patient outcomes and quality of life through system improvements.

Example Use Case:

Industry has struggled to discover levers of value within the individual complexities of Integrated Delivery Networks (IDNs). Gen AI will help Medical Affairs teams look within these networks to find gaps, inefficiencies and other challenges that could benefit from applications of industry expertise.

Challenges: Engagement & Partnerships

- Trust: Partners may be resistant to or require additional permissions/approvals to collaborate with Medical Affairs departments using Gen AI technologies.
- Reputation: Medical Affairs departments will need to be transparent in their use of Gen AI to ensure partner organizations are not surprised by content or engagements that are discovered to have been influenced by these technologies.
- Context: Establishing partnerships often involves sophisticated understanding of context. Gen AI may struggle to comprehend and accurately assess these complexities.

CONCLUSIONS

Generative AI technologies will transform not only how Medical Affairs accomplishes its current activities but fundamentally expands the function's possibilities. Some of these possibilities are known but untested; a few are being developed toward implementation; still others will emerge as end users experiment with the power and flexibility of these platforms. Due to the inability to predict all emerging uses, Medical Affairs departments and industry as a whole will need to remain engaged in monitoring for emergent applications of Gen AI – internally (across distributed organizations), from collaborating and competing organizations, and in society at large. The pace of Gen AI evolution also requires Medical Affairs leaders to ensure that implementation does not outpace governance, balancing efficiency/promise with a strategy-first approach that takes into account regulatory, compliance and legal concerns. Implemented as a reaction to a company's fear of missing out, Gen AI can be expensive, irrelevant and can expose the company to risk. Implemented from the perspective of company and Medical strategy, and with structures and processes in place to identify and mitigate current and future risks, Gen AI has the potential to help Medical Affairs generate and communicate industry science while reinforcing Medical Affairs as an essential partner and leading function in its mission to benefit patients.

Addendum: Additional Challenges

Accuracy Challenges with Gen AI

- **Accountability:** Accountability when implementing Gen AI requires humans in the loop. By placing responsibility on the human user, we ensure accuracy, ethical decision-making, legal compliance, bias mitigation, and public trust in AI technology.
- **Explainability:** Due to the “black box” nature of how AIs move from query to response, it can be difficult or impossible to explain how they arrive at their outputs and therefore assess the validity of the response.
- **Hallucination:** Gen AI is effectively a predictive technology, predicting a response that addresses a query (or other input). Sometimes these predictions are wrong, leading to a plausible answer that is nonetheless incorrect. Many have called these illusions of truth “hallucinations.” With limited visibility of citation/sources, identifying these hallucinations can be challenging.
- **Validation:** With Gen AI, generating the output is easy. It is much more difficult to decide how much to believe this output. In some cases, it may require as much human capital to validate AI responses as it would to leverage human expertise to create knowledge in the first place.
- **Bias:** If the data on which Gen AI was trained is biased, Gen AI outputs are also likely to be biased. These biases may arise from opinions expressed in online language or from data that is representative of only majority populations (among other sources).

Compliance Challenges with Gen AI

- **Data Privacy:** There are two major avenues of data privacy concerns in the context of Medical Affairs’ use of Gen AI. First is the danger that Gen AI technologies could expose company data or intellectual property; second is that Gen AI could expose patient or stakeholder information. These concerns will need to be addressed both from a mechanistic perspective to ensure the fact of data privacy and also from a messaging perspective to build trust in these platforms and in Medical Affairs departments using these platforms.

- Copyright: Gen AI synthesizes existing information – some of which may be copyrighted or otherwise proprietary. Copyright concerns may be especially pertinent to the use of Gen AI in generating visual content. Clear disclaimers should be used on all AI generated content to transparently disclose its use and anything that a company plans to copyright itself should be generated by a human.
- Regulatory Approval: The use of Generative AI in drug and device development may require regulatory approval, which can be a time-consuming and costly process.
- Confidentiality: Content fed into publicly available Gen AI will be used for generating results for all users as well as training the algorithm. It can't be deleted or retrieved easily. Companies can reduce or mask any confidential information before loading it into Gen AI. Additionally, companies can address confidentiality issues through enterprise GPT API license (or various other licenses with AI platforms). Clear data governance policies should be implemented prior to these being used by teams to ensure confidential material is safeguarded.

Writing support provided by Garth Sundem, Director of Communications & Marketing, MAPS, in accordance with GPP 2022 Guidelines.

Addendum: ChatGPT rewrites this white paper



Now you have the opportunity to adjudicate between this white paper generated by many humans brainstorming in a few different formats and ChatGPT, which subsequently mined the entirety of human knowledge to provide a response to the paper's central question. Following is the machine's response. We would love to hear your input at the MAPS LinkedIn page.

Query: How will generative artificial intelligence transform Medical Affairs?

ChatGPT

Generative artificial intelligence (AI) has the potential to significantly transform the field of Medical Affairs in several ways. Medical Affairs is a critical function within pharmaceutical and healthcare companies that focuses on bridging the gap between medical and scientific information and various stakeholders, including healthcare professionals, patients, regulatory authorities, and more. Here's how generative AI could impact Medical Affairs:

- 1. Scientific Content Generation:** Generative AI can assist in creating high-quality scientific content, such as research papers, presentations, and educational materials. This can streamline the process of communicating complex medical information to healthcare professionals and other stakeholders, ensuring accuracy and relevance.
- 2. Data Analysis and Insights:** Generative AI can process and analyze vast amounts of medical data, enabling Medical Affairs professionals to extract valuable insights. This can aid in identifying trends, patterns, and potential treatment approaches, leading to more informed decision-making.
- 3. Virtual Medical Advisors:** AI-powered virtual assistants can provide quick and accurate responses to medical queries from healthcare professionals. This enhances the support Medical Affairs teams can offer to HCPs, improving engagement and information dissemination.

4. Drug Development and Clinical Trials: Generative AI can optimize clinical trial design by simulating patient populations, predicting trial outcomes, and suggesting adjustments. This can accelerate the drug development process and increase the chances of successful trials.

5. Regulatory Compliance: AI can assist in ensuring that medical communications and materials adhere to regulatory guidelines and compliance standards. This reduces the risk of regulatory violations and ensures consistent messaging.

6. Patient Engagement and Education: Generative AI can create personalized patient education materials, including videos, pamphlets, and websites. This helps patients better understand their conditions and treatment options, improving adherence and outcomes.

7. KOL Identification and Engagement: AI can analyze digital footprints to identify Key Opinion Leaders (KOLs) in various medical fields. This aids in targeting the right experts for collaborations and engagement efforts.

8. Real-world Evidence Analysis: Generative AI can analyze real-world data to generate evidence on treatment outcomes, safety profiles, and patient demographics. This information is valuable for Medical Affairs teams when interacting with stakeholders.

9. Medical Training and Education: AI-powered simulations and virtual reality can enhance medical training for healthcare professionals. Medical Affairs can play a role in developing and delivering these educational tools.

10. Market Insights and Forecasting: AI can analyze market trends, competitor activities, and patient behavior to provide accurate forecasts. Medical Affairs teams can leverage these insights for strategic planning and decision-making.

11. Language Translation and Localization: For global companies, AI-powered translation tools can facilitate accurate communication of medical information across languages and cultures.

12. Automated Literature Review: AI can expedite the process of reviewing and summarizing relevant scientific literature, enabling Medical Affairs professionals to stay up-to-date with the latest research.

Despite these potential benefits, it's important to note that the integration of generative AI in Medical Affairs also raises ethical, regulatory, and privacy concerns. Striking the right balance between AI assistance and human expertise will be crucial to maximize the positive impact of AI in this field.

