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THE FUTURE OF MEDICAL AFFAIRS 2030

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INTRODUCTION

This paper synthesizes the views of senior global Medical Affairs leaders to provide a unified vision for the future of Medical Affairs. As such, this document represents the first consensus position by executives in Medical Affairs of our evolving roles, activities, and value in society, industry, teams and as individuals (detailing each in turn). By 2030, Medical Affairs will solidify its transition from executional to strategic, and the function will come to represent the voice of the patient within industry. We will not only disseminate evidence but also lead evidence generation activities that inform the real-world use of marketed and emerging treatments. Also in this time frame, we will solidify the role of Medical Affairs as industry's external earpiece, gleaning insights from our interactions with the health care ecosystem that drive understanding of patient, payer, and provider needs and opinions. Throughout this evolution, the true north of Medical Affairs remains the same: to ensure that our science and technologies benefit patients.

MEDICAL AFFAIRS VISION 2030

Medical Affairs will be a strategic leader at the center of clinical development and commercialization efforts, identifying and addressing unmet patient, payer, policymaker, and provider needs that advance clinical practice and improve patient outcomes.

MEDICAL AFFAIRS IN SOCIETY 2030

Major Change Points:



Medical Affairs will empower societal decision-making by communicating the value of emerging treatments



Medical Affairs will be at the center of societal issues such as access, health equity, outcomes, and patient-centricity



Medical Affairs will drive transformation of public sentiment regarding the biopharmaceutical and MedTech industries

In 2020, as the COVID-19 pandemic spread, health care professionals and others in the medical-scientific community turned to Medical Affairs for expert advice on issues ranging from treatment continuation for infected individuals, to the use of vaccines in vulnerable populations, to the difficult decision of whether to delay some types of care to reduce the risk of exposure. To address immediate needs, Medical Affairs was able to offer prepublication, preregistration scientific information to help health care professionals make appropriate decisions with their patients. In short, Medical Affairs demonstrated its value to society as the trusted scientific voice of industry. Now as we emerge from the pandemic, Medical Affairs has the opportunity to use its voice to benefit society in new ways.

One aspect of increasing importance to society is Medical Affairs' ability to address issues of value, taking into account clinical, humanistic, and economic factors to provide context for the appropriate use and reimbursement of emerging drugs, devices, and diagnostics. Medical Affairs is also positioned to include equity in industry's ability to deliver value to society, representing the voice of diverse patient communities in the development and delivery of and access to innovation.

Meanwhile, Medical Affairs is also positioned to help industry adapt to meet the needs of a changing society. For example, health care decision-making is shifting from a model driven by individual health care providers (HCPs) influenced by key opinion leaders (KOLs) to a model of decision-making shared with payers and patients. To benefit society, Medical Affairs must broaden the stakeholders with whom we engage to meet the data dissemination and scientific exchange needs of payers and patients in much the same way the function has traditionally met the needs of HCPs and KOLs. This may be challenging for the function.

By and large, we are scientific experts trained to communicate and collaborate with other scientific experts and HCPs; however, benefiting society in a health ecosystem saturated with misinformation will require Medical Affairs to speak a new language through new channels to outcompete misinformation with trusted science and counter misunderstanding with clear understandable information.

To benefit society, Medical Affairs must broaden the stakeholders with whom we engage to meet the data dissemination and scientific exchange needs of payers and patients in much the same way the function has traditionally met the needs of HCPs and KOLs.

In parallel, advances in the understanding of genetics and the practice of genomic medicine are accelerating the shift to personalized medicine. The resultant technologies will lead to more patient-specific transformative therapies and even to new classes of therapies. However, increasing treatment complexity will require more sophisticated scientific exchange. To ensure that society in fact benefits from personalized genomic medicine, Medical Affairs will need to develop and communicate a scientific narrative such that the value of the technology is understood and can be applied to the appropriate population or individual(s).

An additional area in which Medical Affairs will benefit society is in leading the transformation of societal opinion regarding the biopharmaceutical and MedTech industries. Due to issues such as opioid addiction and prescription drug pricing, society largely considers the pharmaceutical industry an antagonist rather than protagonist or partner in health care. For the benefit of society, this must change. By putting the patient at the center of drug/device development and by measuring industry success by patient benefit and outcomes, Medical Affairs has the opportunity to lead this change in opinion. The 2030 vision for Medical Affairs sees the function leading a new partnership between industry and society for the benefit of all.

The 2030 vision for Medical Affairs sees the function leading a new partnership between industry and society for the benefit of all.



MEDICAL AFFAIRS IN INDUSTRY 2030

Major Change Points:



Medical Affairs will own the scientific aspects of patient engagement



Medical Affairs will affirm its role as leader of the organization's scientific narrative



Medical Affairs' use of Real-World Evidence (RWE) will not only guide the use of emerging treatments but will inform regulatory decisions including label expansion



As a result of increasing strategic responsibilities, Medical Affairs will cede or streamline some of its existing operational responsibilities



There will be a significant expansion of the role of Medical Affairs in listening and responding to external stakeholders

The biopharmaceutical and MedTech industries have been traditionally dominated by two functions: Research & Development (R&D) and Commercial. R&D's primary responsibility is the discovery, development, and registration of innovative new drugs and medical devices, whereas Commercial markets and sells them. Approximately 30 years ago, driven largely by HCPs' need for scientific information and guidance surrounding the use of increasingly complex novel treatments coupled with new regulatory standards for pharma's interactions with external stakeholders, Medical Affairs emerged as the function scientifically supporting the post-registration period for new therapies. This early role of Medical Affairs was fairly straightforward: to provide expert, unbiased, accurate scientific information to inform HCP decision-making and thus benefit patients.

In the early 2000s, Medical Affairs expanded the ways it communicates scientific information and the external audiences it serves. The function developed capabilities in Medical Information (MI) to provide answers to unsolicited HCP questions; Publications teams within Medical Affairs managed the placement of studies and articles in scientific journals; and External Education teams developed programs for company-led education and oversaw funding for independent education events. During this time, Medical Affairs also took two very important steps to go beyond traditional communication tactics. First, Medical Affairs realized that in addition to speaking to the external scientific and health care communities, we are

uniquely placed to listen, moving from a monologue to a dialogue with HCPs. Second, Medical Affairs built Evidence Generation capabilities, allowing the function to generate novel data to address gaps through post- and increasingly pre-market studies.

This expansion of Medical Affairs capabilities has propelled the growth of the function from an almost purely executional communications role to a third strategic pillar within the organization, leading its own activities while collaborating as an equal partner with R&D and Commercial. Now, Medical Affairs is poised to undergo another dramatic evolution. Traditional capabilities are evolving, and new capabilities are emerging as we realize yesterday's vision and start to see new possibilities for the future. Following are areas of evolution, growth, and reprioritization that will help Medical Affairs grow to realize its potential and value within the industry.

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FOCUS AREAS OF INCREASING IMPORTANCE FOR MEDICAL AFFAIRS 2030

Data Dissemination/Communication

The future Medical Affairs organization will continue its traditional role in data dissemination/communication while adding significant new capabilities. One emerging need is communication surrounding the value and cost-effectiveness of therapies. Currently, value is managed and communicated by Health Economics & Outcomes Research (HEOR) and Market Access teams, with Market Access most often sitting within Commercial and HEOR acting as a parallel group sitting in Medical Affairs. (Though some organizations combine Market Access with HEOR in Commercial or place HEOR within Medical Affairs.) Regardless of the specific structure, Medical Affairs will be instrumental in owning or collaborating with cross-functional partners to provide scientific context for decision-makers including payers and policy makers. For many Medical Affairs organizations, this will require communicating a new kind of data (health economics) to a largely new audience (payers and policy makers) and as such can be seen as one of many examples of the broader challenge of communicating new things in new ways to new audiences.

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Another emerging challenge in data dissemination/communication is the dichotomy of integrating multiple sources of information into a coherent medical narrative and single scientific voice, and then being able to break this narrative apart to offer personalized medical engagement across multiple platforms to audiences with varying informational needs. For example, payers have different informational needs than HCPs do, and those needs are different than the needs of diverse patient groups and the needs of scientific leaders. And individuals in each of these audiences will prefer to acquire this understanding in different ways, creating the need for engagement plans that promote personalized communications that may be enabled by digital innovation. However, while the mechanics of data dissemination and medical communications in 2030 will be dramatically different than they are today, the goal will remain largely the same: to help external audiences understand the science of industry innovations so that treatments, diagnostics, and devices may be utilized appropriately to improve patient outcomes.

External Relationships

The role of Medical Affairs will continue to move from ensuring that “people know things” toward a model of long-term relationships and dialogue with external stakeholders. In addition to moving from a monologue to a dialogue, the initiation of external relationships will change from a model in which Medical Affairs reaches out to individuals and groups to offer scientific exchange to a model in which individuals and groups seek out relationships with Medical Affairs as a trustworthy, unbiased source of accurate and up-to-date scientific information. We see this especially from professional societies, patient advocacy organizations and, interestingly, in the form of symbiotic collaborations with industry companies with whom our organizations would traditionally compete. For example, the COVID-19 vaccine development experience shows that societal benefit was achieved by companies willing to collaborate on a solution. Medical Affairs will have an important role in identifying and forging those collaborative partnerships early on.

The COVID-19 vaccine development experience shows that societal benefit was achieved by companies willing to collaborate on a solution.

Strategic Insights

The realization that Medical Affairs can be an earpiece as well as a mouthpiece resulted in renaming our core communication as “scientific exchange” to better describe the two-way flow of knowledge passing out and in through Medical Affairs. Information passing out through Medical Affairs is usually called data dissemination or scientific/medical communications; information passing in through Medical Affairs is often referred to as insights. By and large, the industry now appreciates the role of Medical Affairs in gathering insights, and technological/digital systems are helping teams more successfully capture and analyze unstructured data to identify actionable insights. With insights unbound (or at least less bound) by the basic processes of capture/analysis, the future of insights is as expansive as our vision. That said, our current vision for the potential value of insights is limited. For example, many teams use insights exclusively to identify gaps. However, by 2030, Medical Affairs will need to envision and message the strategic importance of insights beyond gap analysis. This starts by asking the question, “What types of feedback and input from all sources beyond the organization’s walls could influence the strategy, actions, decisions, and goals of the organization?” In the future, insights will inform early development and strategic portfolio decisions, while novel, pragmatic insights from patient communities and RWE will change and improve the practice of medicine. By 2030, Medical Affairs insights will allow organizations to be more rapidly responsive to external conditions, sensing and adapting accordingly. The degree to which Medical Affairs achieves this goal and owns this activity will depend on our ability to envision and describe the value and impact of insights to the organization’s strategic priorities and to the practice of medicine that benefits patients and society.

[The future of insights is as expansive as our vision.]

Evidence Generation

In pharma, basic/translational science and clinical studies were once the exclusive domain of R&D (and academia), and a company’s post-approval scientific involvement with a new drug or device was aimed primarily at label expansion. However, the results of registrational trials often fail to inform real-world use of new therapeutics. Due to Medical Affairs’ role in providing context for the post-registrational use of emerging treatments, the function expanded its activities to include ownership of post-approval studies to generate safety and efficacy data in patient groups not addressed in registrational trials. From this starting point of peri- and post-approval studies, the role of Medical Affairs in evidence generation has expanded both earlier and later in the development life cycle. Early in the life cycle, this includes using insights to influence the design and end points for registrational trials, as well as input into the Integrated Evidence Generation Plan and ownership of studies surrounding registrational safety and efficacy data. Throughout the life cycle, including long after approval, Medical Affairs is leading the use of RWE to describe clinical effectiveness in real-world patient populations. In fact, as the use of new treatments is increasingly influenced by factors relating to health economics, Medical is making increasing use of RWE,

epidemiological data, analytics, and other non-traditional data/studies to provide context for the cost-effectiveness decisions of payers and policy makers. Meanwhile, HEOR activities that may be owned by or sit alongside Medical increasingly influence reimbursement, market access, treatment guidelines, and clinician uptake. By 2030, Medical Affairs must further drive innovative evidence generation strategies to speed the availability of high-quality data to improve clinical decision-making, increase access, and improve patient outcomes.

Medical Affairs is leading the use of Real-World Evidence to describe clinical effectiveness in real-world patient populations.

Patient Engagement

Industry has struggled to disentangle “patients” and “customers.” Even in Medical Affairs, we have sometimes referred to aspects of engagement and narrative as a “customer journey.” We see this choice in words as more than semantics; it is representative of the core goals of Medical Affairs and industry as a whole. Commercial is and should remain focused on engaging the “customer.” However, in the future, Medical Affairs must own the scientific aspects of “patient” engagement. This will require Medical Affairs organizations to transform patient engagement from a somewhat unidirectional approach, with a team assigned to inform patient communities of the organization’s actions and progress, to a model in which patients and patient communities work as essential partners with industry throughout the life cycle. For example, Medical Affairs will help the organization understand the natural history of a disease, the burden of disease, how/when a treatment can intervene to create outcomes that are meaningful to patients, and patients’ tolerance for benefit-risk profiles of drugs in different diseases—all while addressing issues of access, caregiving, and quality of life among many others. At the same time, Medical Affairs will ensure that patient insights are embedded in all data generation strategies and activities, and that patients have ready access to medical information that enables their active participation in making treatment choices. No matter how it is structured within the organization, patient engagement presents a significant challenge in a landscape of little precedent and significant regulatory oversight. However, it is a challenge Medical Affairs must address in order to reach the 2030 vision. Why do we develop treatments? For patients. For whom are treatments prescribed? Also patients. Medical Affairs teams with the passion and vision to conceptualize ways to involve and engage patients throughout the development life cycle will lead their organizations’ success while making a real difference in human lives.

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OPTIMIZED OR STREAMLINED MEDICAL AFFAIRS FOCUS AREAS 2030

Medical Information

The role of MI has been to provide trustworthy, well-researched answers to questions submitted primarily by HCPs. In the future, questions with known answers will need to be increasingly answered through artificial intelligence, chatbots, and other automated or semi-automated digital systems that allow for real-time information access. However, there will continue to be novel scientific questions with nuanced answers that will require customized content creation provided by MI experts. By 2030, MI will need to have robust analytical capabilities to identify information gaps and insights from inquiries that require additional Evidence Generation or Scientific Communication activities.

Compliance/Governance

Because Medical Affairs engages with HCPs who may prescribe or influence prescribing company therapeutics, compliance oversight of Medical Affairs has always been important to ensuring the integrity of these scientific exchange activities. That close relationship between the Compliance function and Medical Affairs often led Medical to take on compliance and/or governance responsibilities usually at the local country level. Compliance will continue to be essential for pharmaceutical and MedTech Medical Affairs professionals, but in the future, Medical Affairs should not have broad compliance-/governance-related responsibilities as this detracts from the scientific activities and expertise that Medical must deliver.

Operational Efficiency

With the expansion of Medical Affairs' responsibilities, we will need to better manage the diverse range of activities, teams, and people to ensure efficiency. With the maturation of Medical Affairs, global best practices for processes and structures are emerging, reducing the need for local/country organizations to create standard operating procedures (SOPs) and work instructions themselves. In some organizations, these SOPs/work instructions include frameworks for Medical decision-making and interactions, streamlining the ability to respond in real time at the micro and macro level.

MEDICAL AFFAIRS TEAMS 2030

Major Change Points:



Medical Affairs teams will further embrace digital transformation



Medical will engage much broader stakeholder groups including patient groups, academia, governments, and health economics bodies



Medical Affairs will need to dramatically evolve team capabilities to keep pace with new opportunities for them to lead

This paper has previously discussed how Medical Affairs structures must evolve to provide value for society and industry. Some of this change will happen at the organizational level or at the level of the function's own self-understanding; however, much of this change will be driven by capability-building at the level of Medical Affairs teams. This section provides an overview of the ways in which Medical Affairs teams must adapt to serve the needs of new audiences through the expansion of traditional capabilities.

AUDIENCES OF INCREASING IMPORTANCE

Expanded Definition of External Experts

Key audiences will continue to be HCPs and KOLs, but Medical Affairs is realizing that traditional definitions of HCPs and KOLs include many more roles than only physicians and scientific leaders. For example, HCPs include nurses, nurse practitioners, and physician assistants, and KOLs may include digital opinion leaders (DOLs) who have little or no scientific or medical training, but have the ability to disseminate “medical information” and shift opinion through digital platforms. Likewise, Medical Affairs is realizing that the role of nontraditional providers of patient education including peer navigators and other influential laypeople in a disease state. In MedTech, Medical Affairs must engage device/diagnostic decision-makers including lab directors, academic researchers beyond those publishing and presenting, and even nurses who make use of devices/diagnostics. Identifying HCPs and KOLs used to be accomplished by noting who is researching, publishing, and presenting; identifying HCPs, KOLs, and other external experts beyond the traditional definitions requires increasingly sophisticated digital tools to map networks of influence or collaboration and pinpoint individuals within these networks where Medical Affairs engagements may have the greatest impact.

Patients/Patient Associations

Regulatory and Compliance issues have generally limited direct communications between the pharmaceutical industry and patients. However, the move to “home care” and “near-patient care” will mean that patients themselves start to become important external audiences for some products/conditions in some countries. This is already true of patient associations and advocacy organizations, which seek to provide patients within their communities with the most accurate pipeline development, treatment, and disease-state information. While these associations are a bit like HCPs and scientific leaders in their role as gatekeepers of patient education, associations do not necessarily overlap with KOLs or HCPs. This means that associations are truly an emerging audience for many Medical Affairs organizations. In addition to providing patient education, these associations can also represent the “patient voice” back to the organization, providing input on, for example, meaningful end points, quality-of-life measures, and other aspects of study design beyond safety and efficacy. Thus, to realize the 2030 vision for the function, Medical Affairs teams will need to build the capability to engage and support patient associations in a compliant way in order to be truly patient-centric. Being patient-centric may require a dedicated role within Medical Affairs and/or new ways of working that span across cross-functional teams. By 2030, the specific structure to enable “patient-centricity” will need to be defined within organizations.

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Academia

Academia continues to set and/or influence treatment guidelines and, as such, is a top-level opportunity for Medical Affairs to affect sweeping change to benefit patients. Also, within academia (and similar to efforts to break down silos within industry), the model of individual institutions running individual studies and then protecting study results until published or presented is largely extinct. Now and into the future, academic institutions are collaborating in consortia that share data, procedures, molecules, and even patients (driven in large part by the sub-segmentation of diseases/conditions that makes clinical trial recruitment at any single institution impossible). Thus, identifying, building, and facilitating cross-academia collaborations to address unmet data and/or educational needs will be critical for Medical Affairs.

Health Economics Organizations

If academia and scientific societies define what should be done, payer and reimbursement agencies such as the National Institute for Health and Care Excellence (NICE) in the UK and the Institute for Clinical and Economic Review (ICER) in the United States increasingly define what is permitted to be done. As such, these bodies are an obviously important emerging audience for Medical Affairs. Achieving regulatory registration is necessary; however, the impact of a new treatment may not be achieved if HTAs and HEOR bodies consider the treatment to offer only incremental benefit at a high cost. To realize the 2030 vision, Medical Affairs teams will need to build capabilities in defining (through properly designed evidence generation) and communicating the clinical value, as opposed to only the efficacy, of industry innovations.

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Governments, Regulators, and Policy Makers

Just as Medical Science Liaisons meet the information needs of external stakeholders in the scientific community, industry is seeing the emergence of Health Policy Liaisons to ensure the availability of evidence for policy-based decision-makers. In different organizations, Health Policy Liaisons may sit within Medical Affairs, within HEOR or Market Access teams, or even within Government Affairs. Given the scientific nature of these discussions with policy makers, Medical Affairs should either take on this responsibility or work closely and collaboratively with Health Policy Liaisons to ensure that our clinical expertise is driving patient benefit.

Big Tech

Medical Affairs will need to be prepared to interact with so called “Big Tech” as either a partner or a competitor. For example, Medical Affairs will likely have to be prepared to make sense of and address meta-analyses based on big data that may conflict with their sponsored randomized clinical studies. And with Big Tech currently ahead of pharma in its ownership of and access to big data and the use of artificial intelligence and machine learning, collaboration with Big Tech presents significant opportunity for Medical Affairs teams.

Environment, Social, Governance (ESG)

Environmental, Social, and Governance (ESG) is a set of standards for how a company operates in regard to the planet and its people. As companies establish their ESG agendas, future Medical Affairs teams may need to support these efforts by communicating the impact of products on the environment and/or how they responsibly engage with external stakeholders. Currently, inequities in health systems create inequities in outcomes. The 2030 vision for Medical Affairs sees teams addressing the social determinants of health to broadly improve patient outcomes.

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EMERGING CAPABILITIES FOR MEDICAL AFFAIRS TEAMS

Digital and Analytics

For future Medical Affairs teams, “Digital” will mean more than the tools used to accomplish a task—it will be a philosophy or way of thinking that underlies all Medical Affairs actions and broadens our view of what is possible.

The COVID-19 pandemic accelerated the digital transformation of Medical Affairs. Not only did the impossibility of face-to-face interactions force teams to develop new capabilities for scientific exchange, but the inability to run traditional, in-person clinical trials prompted teams to adopt new methodologies and analytics tools to derive knowledge from new sources of data. Digital’s trajectory of increasing importance will put it at the forefront of analyzing external data to drive conclusions that inform clinical care. These digital and data analytic capabilities are not necessarily inherent to Medical Affairs. (As we have seen, scientific expertise does

not always come with the ability to share a screen during a call on a video-conferencing platform!) For future Medical Affairs teams, “Digital” will mean more than the tools used to accomplish a task—it will be a philosophy or way of thinking that underlies all Medical Affairs actions and broadens our view of what is possible. As such, the idea of Digital will need to be clearly defined and then embedded within Medical Affairs teams composed of non-scientific digital experts, while in some organizations designated Digital teams will support initiatives across the function.

Metrics and Key Performance Indicators (KPIs)

Defining the right metrics and KPIs to demonstrate how Medical's actions drive forward the organization's strategic priorities has been a longtime challenge for the function. Without an obvious success metric such as sales revenue or regulatory approvals, Medical Affairs has depended on measuring what we do (eg, number and frequency of MSL interactions or number of publications) rather than measuring impact. Future Medical Affairs teams will combine quantitative and qualitative metrics to measure and report not only what we do but also the impact to patients and the organization. However, the function's focus will need to remain on delivering value rather than becoming myopic in its desire to report on its value. In the 2030 vision, the value of Medical Affairs will be evident and obvious to internal and external stakeholders.

THE MEDICAL AFFAIRS INDIVIDUAL 2030

Major Change Points:



Medical Affairs' scientific experts will be augmented by individuals with competencies in business, digital, data, epidemiology, public health, HEOR, and more



Competencies such as emotional intelligence, learning agility, and leadership skills will be as essential as scientific acumen



Medical Affairs will need to invest significantly in training or hiring for new competencies

In the future, the “ticket for entry” to a career in Medical Affairs will continue to be strength in core foundational areas such as therapeutic area science and drug/device/diagnostic development, often demonstrated by a relevant terminal degree such as PhD, PharmD, or MD. But to achieve the Medical Affairs vision for 2030, clinical and scientific expertise will need to be augmented by business sense. Following are new and/or enhanced competencies and areas of expertise required by Medical Affairs professionals as the function moves toward the 2030 vision.

Digital/Technology

The health care ecosystem is seeing the maturation of its first generation of digital natives, with Medical Affairs stakeholders such as HCPs, KOLs, and other external experts becoming increasingly sophisticated in their use of digital platforms and technologies. Medical Affairs must keep pace. Some of these digital skills can be acquired through training. However, we expect that Medical Affairs will also need to hire its own digital natives who can lead digital centers of excellence to ensure that the function is ahead of the curve on priorities such as data analytics, digital and omni-channel communications, and insights analysis.

Data Analytics and Non-Traditional Studies

As we have seen throughout this paper, Medical Affairs will have an increasing role in evidence generation and data analysis. While these skills are largely scientific, they also require technical competencies different than those needed for traditional evidence generation studies. Many of these competencies have to do with being able to generate knowledge from large data sets, including those in public registries. As such, competencies may include RWE study design and analysis, biostatistics, database science, epidemiology, public health, and various subsets of computer science. With the US Food and Drug Administration

and other regulatory agencies seeking to define the criteria required for regulatory decisions based on RWE and the scientific and payer communities working to determine how to apply RWE to practice and reimbursement decisions, individual competencies in RWE and data science are increasingly essential. In 2016, an editorial in The New England Journal of Medicine characterized individuals involved in studying existing data as “research parasites.” However, as data lakes grow in size due to electronic health records, wearables, and even social media, research parasitism will become an increasingly important and efficient way to predict patient outcomes and provide context for health care decision-making with less need for slow and costly clinical trials. A strong governance structure around these types of data generation is—and will continue to be,—essential.

Access Acumen

In the future, the impact of new drugs, devices, and diagnostics will depend not only on safety and efficacy but also on access. Understanding and addressing national, regional, and local issues of pricing and reimbursement is the remit of Market Access teams, which often sit in the Commercial function. However, the activities of Market Access teams are increasingly influenced by context provided by Medical Affairs. For example, evidence generation (especially RWE) and insights may contribute to the understanding of disease natural history or burden of disease at global, regional, and local levels, and Medical Affairs’ contributions to deciding study end points may enrich understanding of quality-of-life impacts. Predicting the informational needs of Market Access teams and then delivering on these needs will require new individual competencies for Medical Affairs professionals, including understanding value and access paradigms, and the ability to translate data into clinical relevance to specific patient populations and the associated cost-effectiveness of such treatments.

In the future, the impact of new drugs, devices, and diagnostics will depend not only on safety and efficacy but also on access.

Cross-Functional Collaboration

Originally, Medical Affairs had a defined, almost “modular” role: The function engaged in peer-to-peer exchange with HCPs and KOLs to ensure the scientific understanding of emerging drugs, devices, and diagnostics. This role could be (and was) largely performed in a silo. However, as a strategic pillar of pharma organizations, Medical Affairs professionals now collaborate with cross-functional partners in interacting with a broader base of “customers.” With increasing responsibilities and deliverables, seamless collaboration and the associated competencies of communication, business acumen, and negotiation will become even more important.

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Leadership

Previously, Medical Affairs was led by other functions in the C-suite. Now in many organizations, the function sits in the C-suite. This is largely due to the success of the first generation of Medical Affairs leaders in demonstrating the value of the function to the organization. However, for Medical Affairs to achieve its ambitious 2030 vision, a second generation of leaders will need to emerge. While leadership competency may currently be a secondary skill that today's Medical Affairs professionals developed with training and experience, future Medical Affairs leaders will need to come to the table with primary leadership skills. We expect that future Medical Affairs leaders will be a mix of MDs, PharmDs, and PhDs, who will also have MBAs and other advanced business or public health degrees. These leaders will need to be adept at managing large teams as well as continuing to ensure that the voice of Medical Affairs is represented in their organization's strategic decisions.

Future Medical Affairs leaders will need to come to the table with primary leadership skills.

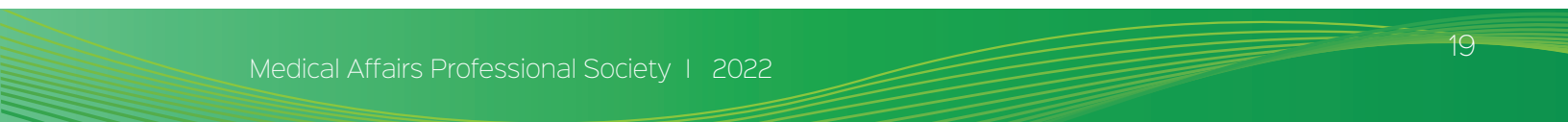
Communication Skills and Engagement

Medical Affairs has always required expertise in communication and scientific stakeholder engagement. To achieve success in 2030, individuals in Medical Affairs will need new competencies in these areas to engage in new data types with a broader group of stakeholders via diverse and personalized channels. For one example of many, Medical Affairs professionals including MSLs and others must not only learn to communicate study results but will need to also competently communicate RWE trial design and analytical methods. Likewise, MSLs and other individuals within Medical Affairs will require competency in incorporating digital solutions into their communications and engagement activities, including the seamless use of on-demand or "eMSLs." Finally, individuals in Medical Affairs will require competencies in communicating with non-scientific audiences, including patient groups, payers, and policy makers.



CONCLUSIONS

This paper provides a vision for the future of the Medical Affairs function in which the mission of Medical Affairs comes to represent the mission of industry as a whole: to benefit patients and society. That said, while this paper points the way, it is not a comprehensive road map of how to get there. Getting there will be a major activity of the Medical Affairs Professional Society's Focus Area Working Groups (FAWGs), which are teams composed of industry leaders in areas such as Insights, Evidence Generation, and Medical Communications. With collaboration from Medical Affairs leaders across organizations and powered by Medical Affairs professionals across focus areas and all levels of experience, the function will continue to progress toward a future in which Medical Affairs benefits industry and society while ensuring that patients become and remain the essential reason for everything we do.





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