McKinsey&Company

Pharma Medical Affairs 2020 and beyond

Matthias Evers
Edd Fleming
Arnab Ghatak
Jan Hartmann
Arif Nathoo
Ron Piervincenzi
Lawrence Wai
Ann Westra

A rapidly changing world for Medical Affairs

Pharma's Medical Affairs faces growing internal and external challenges as well as new opportunities

In 2007, medical leaders from across the pharmaceutical industry assembled to develop a common understanding of a ten-year vision for Medical Affairs. With five years now past, it is hardly surprising that significant change has occurred in the world in which the pharmaceutical industry operates, especially given the remarkable economic environment and the continued acceleration of technological change.

While many of the trends predicted in 2007 will continue, the pace of change is expected to increase even more as we approach 2020. We believe that at least three new, stronger forces will emerge that will greatly alter the healthcare landscape:

1. **The definition of value will be much broader and will expand as the types of healthcare stakeholders who demand a demonstration of value increase. At the same time, there will be an increased focus on evidence and higher hurdles for proving product value.**

Given the industry's R&D productivity challenge and an overall risk-averse regulatory environment, maintaining a consistent focus on optimizing medical value across the product lifecycle has become critical to pharma's very survival. The definition of value, however, continues to evolve and expand across all major geographies.

In the United States, rising healthcare costs have forced employers and governments to rely even more on payors to control costs and influence individual healthcare decisions, and healthcare reform promises to intensify that trend. As fiscal landscape challenges linger, Europe faces similar pressures, with more countries taking on increasingly radical structural reforms that fundamentally reshape the structure, funding or organization of the healthcare system. As part of these reforms, there will be a massive explosion in the generation and usage of real-world data, particularly data measuring comparative effectiveness. Over time, this data will reach the critical mass necessary to become a critical factor in decision making.

2. **Interactions between pharmaceutical companies and various medical stakeholders will continue to evolve with the emergence of new decision makers and with greater public scrutiny of these relationships. The role of patients will also fundamentally change with the rise of consumerism in healthcare.**

As cost pressures continue to rise given ongoing healthcare reform, the decision-making power is gradually shifting from physicians to a new set of stakeholders who are driving containment of costs (for example, pharmacy and therapeutics (P&T) committee members at hospitals). Pharma's engagement with key opinion leaders (KOLs) and advisory boards will significantly transform under intense public scrutiny and demands for greater transparency through financial disclosures. KOLs will have to avoid even the misperception of being paid spokespeople for pharmaceutical companies.

Patients can be expected to take a greater role in their healthcare decisions as they actively seek medical information outside their physicians' offices. Presentation of scientific information to patients in a form they can readily understand will become more prevalent. The use of social media and innovative data collection will continue to expand as these become commonly used channels to hear the views of patients and physicians.

A Medical Affairs Primer

Medical Affairs organizations have emerged over the past half century in response to federal regulations around the separation of medical and commercial activities within drug companies. Many companies also chose to focus R&D resources on developing new products and moved post-launch activities, such as finding new indications for existing drugs, into the medical-affairs function.

Continued pressure from regulatory agencies and public sentiment have pushed more and more activities into Medical Affairs organizations.

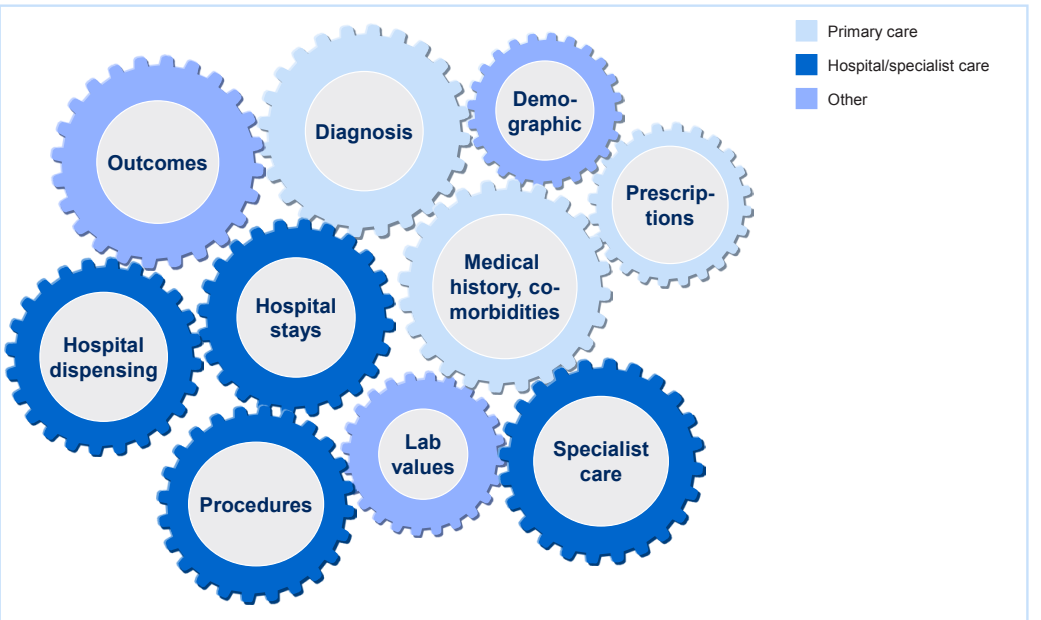
Today, these organizations commonly involve the following medical activities:

- **Medical field teams,** including medical-science liaisons and others who lead relationship management and communication of product information with health-care providers, payors, and other medically-focused customers (e.g., regulators, institutional leaders).
- **Post-launch clinical trials,** including the planning and execution of phase IIIb/IV company-sponsored interventional and observational studies and support of investigator-initiated studies.
- **Medical-information services,** including the medical staff sitting in centralized call centers to distribute medical information in response to drug-information inquiries.
- **Medical communications,** including the writing and support for peer-reviewed publications and other medical and scientific communications.
- **Medical education,** including the planning and grant support for medical education to healthcare providers and the training of internal teams (e.g., sales force).
- **Medical strategic activities,** including development and leadership of the medical-brand strategy for each product by medical directors and the collaboration with development, commercial, and others to shape the product's cross-functional life-cycle strategy and planning.
- **Health economics and outcomes-research (HEOR) activities,** including research and communications related to product value, (e.g., product value dossiers, patient-related outcomes, health technology assessments).

3. The proliferation of data and demands for transparency we see today will accelerate as we head towards 2020. The number and types of users of medical data and information will continue to expand rapidly.

In recent years, the channels of medical information available to different stakeholders have proliferated. Going forward, we foresee that the types of medical data that are relevant for a product will increase significantly. These will include new data – particularly real-world evidence and patient-generated data (e.g., genomic information), which in the past were often disconnected data points –that now need to be considered in the context of broader information sets (e.g., safety data) and have to be integrated to best leverage insights. (Figure 1)

Figure 1 – Future types of patient data



At the same time, widely publicized pharmaceutical company missteps have led to a greater demand for transparent data, policies and operations. Increased transparency will put additional compliance pressure on pharmaceutical companies, especially on Medical Affairs, given its responsibilities in data generation and dissemination. Companies are beginning to make detailed patient data that form the basis of trials of approved drugs and discontinued investigational ones accessible to researchers. However, greater transparency could also lead to potential misuse of the data as pharma will no longer maintain control of the data's interpretations in this environment. New forms of cooperation for data generation between pharma companies and other stakeholders (i.e., accountable care organizations (ACOs), integrated-delivery networks, payors) should be considered (for example, joint clinical trials with leading ACOs offering access to their information systems and to real-time data, prospective-outcomes research with payors in their patient population) .

A 2020 Vision for Medical Affairs

Accelerating the transformation and increasing the relevance of Medical Affairs

Given the significant changes in the healthcare landscape, this is an appropriate time to reassess and redefine the vision for Medical Affairs developed five years ago. Over the past 12 months, McKinsey & Company worked with Medical Affairs executives across the industry to produce this updated 2020 Vision for Medical Affairs. If achieved, the four aspirations below would enable the Medical-Affairs function to create significantly greater value for their companies, industry and society:

1. **Enhance patient access to and best use of optimal medical treatment** by clearly demonstrating value to practitioners and payors throughout the lifecycle of each product.

2. **Embrace patient-centric healthcare** by engaging and partnering with a broader range of healthcare stakeholders to more fully understand the different needs of patients and to be able to provide tangible value to patients.

3. **Facilitate coordination and integration of different medical data and types of knowledge** in the company and achieve external recognition for providing credible and unbiased medical information.

4. **Acquire and develop the talent** to cultivate and build a strong, multi-faceted Medical Affairs organization that encompasses the new set of competencies required to navigate the future healthcare landscape across the globe.

1. Enhance patient access to and best use of optimal medical treatment by clearly demonstrating value to practitioners and payors throughout the lifecycle of each product.

The healthcare system is increasingly resource-constrained, while at the same time treatment options are proliferating. Therefore access and treatment choices will ultimately require a solid understanding and convincing demonstration of medical and economic value. While enhancing patient access and ensuring the best use of optimal medical treatment have always been core to the mission of Medical Affairs, demonstrating value is increasingly important as a third strategy objective.

In order to fully demonstrate value, Medical Affairs must continuously upgrade its understanding of what value means from the perspectives of a broad spectrum of healthcare stakeholders—from patients to society to industry. For example, while patients focus on out-of-pocket costs, physicians focus on reimbursement, and payors/governments focus on cost to the health system. Enhancing medical value will require not only a deep comprehension of product characteristics but also a robust, market-informed view of both unmet medical needs and risk tolerance.

To that end, Medical Affairs has to become more proactive about bringing insights from a broader range of external medical decision-makers and influencers into early clinical development. Furthermore, it must also take a lead in demonstrating improved comparative efficacy and cost effectiveness to payors by employing the real-world evidence and data generated by others.

In order to understand and clearly demonstrate value Medical Affairs should do the following:

- Strengthen understanding of local medical practices and patient needs and derive relevant insights from it.
- Develop clear processes and systems to collect, collate and synthesize insights from different stakeholders and leverage these insights by collaborating with R&D and commercial functions.
- Relay insights for early life-cycle planning that arise from value discussions with commercial payors and hospital P&T committees.
- Utilize insights from physician interactions to ensure that brand strategy maximizes the medical benefits for patients and physicians.
- Conduct real-world-evidence analyses by mining large databases of payors and medical institutions for insights on how to improve treatments.
- Collaborate to ensure that cost-effectiveness and comparative efficacy data are available at launch to enable payors and physicians to choose wisely among competing products.

2. **Embrace patient-centric healthcare by engaging and partnering with a broader range of healthcare stakeholders to more fully understand the different needs of patients and to be able to provide tangible value to patients.**

With the rise of consumerism, patients are emerging as an important decision maker in healthcare. For example, due to the healthcare reform in the United States, patients now take a much more active role in healthcare decision making. The past few years have also witnessed a gradual shift in decision-making power away from physicians through an increasingly number of control mechanisms (e.g., treatment protocols, payor restrictions). A new array of stakeholders with rising influence have emerged, including P&T committee members at hospitals, medical officers at IDNs and large physician practices, physicians with online prominence and commercial payors. All of them play an expanding role in clinical decisions through their treatment guidelines, protocols and formulary listings.

Furthermore, the behavior and expectations of both patients and physicians over the next five to ten years will increasingly follow trends enabled by technology advances (e.g., usage of mobile devices, remote data access, availability of real-time information, acceptance of social media as a new medium for interaction).

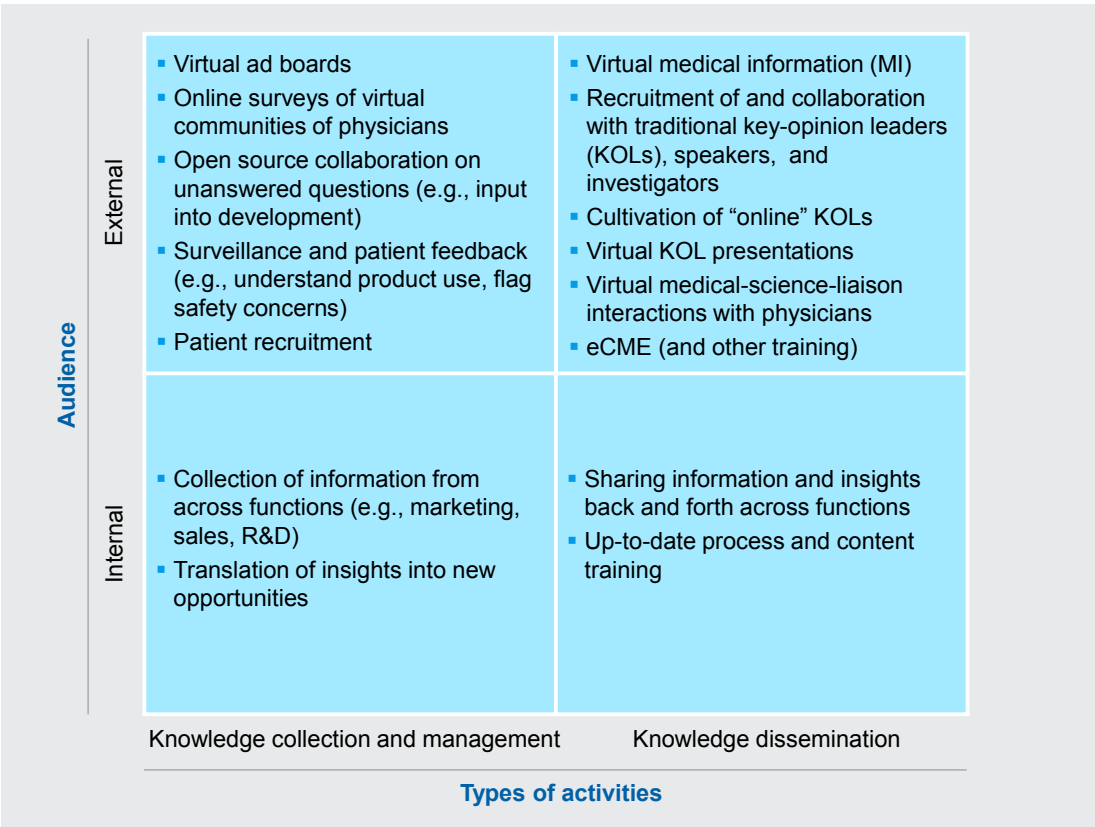
In the world of patient-centric healthcare, Medical Affairs must develop a deep understanding of patients' needs that encompasses the patient insights from different healthcare stakeholders. It first must identify and understand new medical influencers and then develop effective and innovative ways to interact and partner with them. This will require a more flexible engagement model that adapts to a changed communication landscape and captures opportunities utilizing multiple channels, including electronic and digital media (Figure 2). More sophisticated systems and tools will be needed to prioritize and track interactions while new policies and processes will be required to avoid even the appearance of a conflict of interest in medical interactions.

Moreover, as patients expect more information and two-way conversations, Medical Affairs has the opportunity to gain deeper insights into patients' needs through patient advocacy groups. The ability of Medical Affairs to take advantage of social media will further provide new insights into the patients' point of view.

Figure 2 – New media opportunities are relevant to Medical Affairs

In order to engage and partner with healthcare stakeholders to understand patients' needs, Medical Affairs should do the following:

- Maximize the medical benefits for customers by serving as the primary medical voice of the patient on all internal strategy discussions (for example, advocate for the patient-centric view as part of life-cycle management strategy).
- Embrace and experiment with new technologies in mobility and social media to be well positioned for the future.
- Drive engagement with a broader range of external stakeholders, including KOLs, emerging medical influencers, specialty physicians, payors and medically sophisticated patients.



- Make health outcomes the primary orientation of scientific engagement, strengthening the ability of medical systems to effectively manage the healthcare of entire populations.
- Demonstrate the clear value to patients of medical and scientific engagement with physicians, payors and other key stakeholders.
- Include patient advocacy groups as part of external medical-engagement plans to maximize patient insights.

3. **Facilitate coordination and integration of different medical data and types of knowledge in the company and achieve external recognition for providing credible and unbiased medical information.**

Medical information is increasingly complex and specialized, which makes it potentially highly valuable but often overwhelming to customers. Transforming this data into practical insights could drastically improve real-world medical decision making, providing value to physicians and patients. Unfortunately, public mistrust of pharmaceutical companies leads many to doubt pharma's ability to present unbiased medical information to customers. This challenge reflects not only the need for useful insights from a wide array of sources but also for unbiased and credible communication of these insights.

With unique access to a continuously updated understanding of the changing needs of physicians and patients, Medical Affairs can and should play a central role as the facilitator that brings the scientific voice to guide the design and execution of clinical studies. Moreover, as the facilitator, it is critical that Medical Affairs develop the one unified voice on the value proposition to patients, providers and payors.

At the same time, it is important for Medical Affairs to reestablish pharmaceuticals' integrity and credibility by communicating higher quality medical information that is of the highest relevance to customers. It should aspire to the greatest data transparency (e.g., providing access to patient-level clinical trial data) in order to gain recognition as an unbiased source of medical information.

Several steps are necessary for Medical Affairs to coordinate and integrate different medical data in a credible and unbiased fashion:

- Drive internal efficiency by integrating relevant medical insights into a central knowledge repository that includes internal medical data, publications and external knowledge from physicians and medical institutions.

- Increase accessibility to company-generated data for external evaluation and analysis—leading-edge companies have already made all of their trial data available online.

- Monitor and consider external patient data that may be directly posted and become accessible in public databases (for example, safety data).

- Leverage scientific and medical discussions to deepen Medical Affairs' focus on defining clinical treatment pathways.

- Drive rigorous standards of medical integrity, particularly in medical writing, communication of data and interactions with external healthcare providers.

4. **Acquire and develop the talent to cultivate and build a strong, multi-faceted Medical Affairs organization that encompasses the new set of competencies required to navigate the future healthcare landscape across the globe**

As medical roles and responsibilities have evolved to address a wider range of demands, traditional medical backgrounds and capabilities are essential but no longer sufficient for success in the new Medical Affairs organization. In addition, industry contraction and stricter codes of conduct with respect to interactions with KOLs and other physicians have increasingly restricted the traditional Medical Affairs liaison role.

The greater focus within pharma on risk management (e.g., adverse event reporting), the emergence of new types of data and the increasing sophistication of patients and other stakeholders present an even more challenges and opportunities to which Medical Affairs personnel must adapt. Success in the future will require strong relationships with a broader range of stakeholders such as patient and advocacy groups and payers.

The bar is high for Medical Affairs talent. They need to collaborate with R&D colleagues and deeply understand the science that underpins their work; they must understand the rules and regulations governing the industry almost as well as their compliance and legal department colleagues; and they should have the strategic thinking capabilities of their marketing counterparts as well as the customer-interaction skills of their colleagues in sales. The right talent is often scarce, especially at the local country level.

During the hiring phase, the key is to find candidates who surpass not only a minimum clinical and technical bar but who also have true talent "spikes"—people who may not possess all of the qualities required but who are distinctive in crucial areas that can provide a platform to more sustained success. Focus is needed to systematically build the required skills and capabilities in the Medical Affairs workforce so that they are in place to meet the growing expectations being placed upon them and their leaders.

In order to acquire and develop talent, Medical Affairs should take action on several fronts:

- Ensure that current leaders act as inspiring role models and serve as guides through formal mentorships, and that they are encouraged to provide the coaching that will get individuals, teams and the entire organization to perform at a higher level.

- Develop the skills and behaviors needed to enable Medical Affairs to meet the challenges of a changing healthcare landscape. These include strategic thinking, basic commercial skills, cross-functional collaboration, teamwork and scientific leadership. Only when mindsets shift from a technical focus to people skills—from leading projects to leading people—will truly capable leaders emerge.

- Focus on capability building, especially at the local country level, which may require a cross-industry approach or effort to ensure the availability of the right talent pool.

- Formally rotate leaders through countries, medical, and other functions and assign new talent to areas that build on their strengths; they should be comfortable at the start of their journey but have explicit career trajectories. Staff should be encouraged to take on 'safe' risks, lead regional or global initiatives or make planned lateral moves in commercial or R&D functions.

Conclusion

Much work will be required to realize this vision to create value for individual companies and the industry overall. At the heart of this effort, improved patient care and outcomes must be the central motivation of the Medical Affairs leaders. To do that effectively, Medical Affairs must become an equal to the R&D and commercial functions in advocating the patient-centric view. Deep patient insights have to come from engagements with emerging medical stakeholders and mining of new data, such as real-world evidence. Medical Affairs will also need to build new capabilities to leverage these insights.

Medical Affairs leaders will also need to balance enhancing their support for the commercial interests of their companies with maintaining appropriate external engagement and building public trust. Effective facilitation and communication of medical knowledge and innovative approaches to data dissemination will be a key to regaining this trust. These myriad challenges can only be met by upgrading human-resource capabilities and developing a deeper talent pipeline that extends into the upper echelons of the company.