

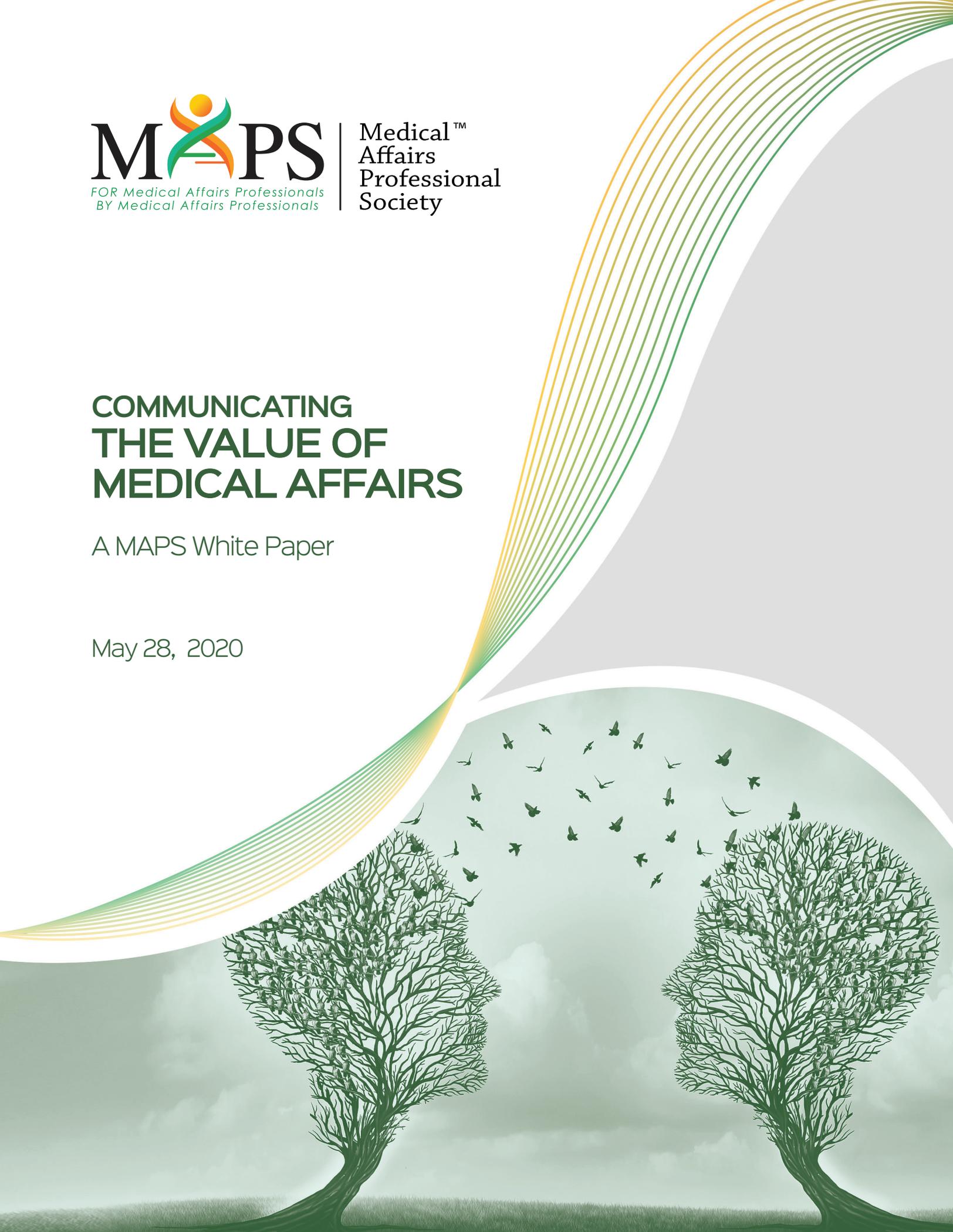


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COMMUNICATING THE VALUE OF MEDICAL AFFAIRS

A MAPS White Paper

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Communicating the Value of Medical Affairs

The pharmaceutical industry is at a pivot point where it needs to go beyond simply proving the effectiveness of the drugs it produces. The pharma company of the future will need to demonstrate its value to the overall healthcare system, particularly in terms of how its innovative products can improve patient outcomes.



Medical Affairs (MA) is the most powerful force in helping pharma achieve this. To thrive, pharma will need to harness the capabilities and deliverables of MA and embrace its clinical expertise and connectivity with healthcare providers (HCPs) and patients to keep up with an ever-evolving healthcare landscape.

MA's role in securing a bright future for pharma is undeniable, yet many before have struggled to bring forth concise and consistent descriptions that communicate the full range of benefits and expertise that MA brings to the table. As a result, the wider understanding of MA's role is not where it should be.

To that end, here we explore the role and value of MA, backed up with commentary from industry leaders, and define clear pillars of MA that communicate its true value. What's more, we propose a short elevator pitch that MA professionals can use to quickly yet succinctly describe the importance of MA for every successful pharma venture in the future.

A Changing Landscape

Previously, pharma companies were largely driven by their commercial departments, but as the industry evolved, there was growing concern that many of the facets of pharma—whether that involved drug development, evidence dissemination, medical education, research grants, and so on—were being disproportionately led and/or influenced by Commercial. In response, pharma began to compartmentalize its clinical development, commercial, and MA functions into more independent and comprehensive entities.

Today's pharma success is significantly different than the old salesforce-physician model, as it is now being driven by clinical outcome- and value-based evidence that is changing the face of the business. Increased demand for treatment protocols, guidelines, and medical governance all put pressure on the industry, urgently calling for both transparency and evidence of value. Pressures also come from new competitors, not least tech giants such as Amazon, who are already knocking on the door of the pharmacy world and may have their sights set on pharmaceutical development in the future.

All of this has placed a bright spotlight on the industry, making it clear that in order to thrive, pharma needs to deliver innovation that benefits society as a whole. Shifting its primary focus to patients will be absolutely key in achieving this, and emphasis should include the way in which pharma engages with society, how it safely introduces innovations into society in order to become partners to healthcare systems, and how it can become much more embedded in what patients really care about and need.

To do this, better communication and dissemination of information will be part-and-parcel of any sea change. The strength of new drug launches depends on the quality and delivery of accompanying evidence, so there is a need for strong links between clinical results and patient outcomes, as well as feedback on remaining unmet medical and patient needs—important at all stages of drug development.



The way in which data are handled is also changing. The MA of tomorrow needs to be a guru of Big Data, working more closely with Research and Development (R&D) and supporting science and data generation with more emphasis on real-world evidence (RWE) and digital health.

So the burning question is, can MA help solve some of the challenges faced by modern pharma? The answer is no: MA is *required* to address all of them.

Communicating the Value of MA

The medical and scientific know-how and established external credibility of MA are extremely effective forces that can be leveraged to place patient outcomes front and center. One could even go as far to say that MA is the common ground for the five “Ps” important in healthcare and pharmaceutical drug development and commercialization—Patients, Providers, Payers, Public, and Policymakers (Figure 1). It is the interface between internal R&D, commercial, clinical, and regulatory departments, and external entities such as HCPs, scientific experts, patients, caregivers, and payers/decision-makers—i.e. a huge variety of stakeholders, each with their own needs.

However, the strange irony of MA is that while it serves such a vital role in disseminating information to others, it often fails to effectively communicate the value and importance of its own function to its internal stakeholders.

The old view of MA—a “support” role that meets with HCPs, provides ad hoc medical information and education, and acts only when called upon to do so—may still be a prevailing sentiment in certain companies, and does no good in reflecting the reality of modern-day MA leadership.

That’s not to say the value of MA has gone unnoticed. In fact, the evolution of MA as an internal strategic partner—along with recognition of its contribution to the success of pharma companies—has increased in recent years; but still the communication of MA’s full potential tends to fall short.

“I think there is a huge gap in the understanding of what MA does,” says Ameet Nathwani, MD, former Chief Digital Officer, Chief Medical Officer, and Executive Vice President Medical at Sanofi S.A. (France). “R&D’s metrics are clear—the value of R&D is creating new innovative products that get to market with a good label—and the outputs of Commercial are usually measured by the sales and the revenue: again, a clear metric.”

MA interdigitates with almost all aspects of pharma, whether that is its early involvement in the R&D process, providing appropriate insights and inputs to help shape the development program, communicating the value of medicines to HCPs and payers to ensure they understand how to place it within their treatment paradigms, or bringing the voice of the patient to the table. As such, MA’s output is much more diffused, and particularly hard to quantify.

“There’s no single key performance indicator that can measure the value of MA, and therefore depending on who the leaders of companies are, and how mature those companies are, you will see MA viewed in a different light,” noted Dr. Nathwani.

“Every company organizes MA differently. If you look at R&D organizations, they’re largely the same, as is the case for commercial organizations. Yet MA organizations are massively diverse in terms of how they are set up, to whom they report, how they’re structured and what they focus on. That may be perceived a weakness from our side, and part of the reason why it is hard to get the message across about the value of MA. However, the deliverables of MA are more important than the organizational design.”

So, with these challenges in mind, what descriptions could the typical MA professional be armed with to quickly and directly communicate the value of MA to others?

The Elevator Pitch

MA professionals are externally-oriented medical and scientific leaders who represent the real-world clinical needs of patients, healthcare professionals, and other decision makers across internal scientific and commercial partners. Their forward-looking strategy across the product lifecycle and diverse functional groups act to advance patient care and ensure the well-being of patients. They do this by interpreting and contextualizing emerging data, generating real-world evidence, engaging in peer-to-peer scientific dialogue, identifying clinical practice insights, and educating healthcare providers and other decision makers on the safety and effectiveness of products.

The Foundation and Pillars of MA

The elevator pitch is a great starting point, but in order to dive deeper into communicating the value of MA, we believe there are foundational elements and several key pillars (Figure 2) that every MA department and professional should focus on.

Insights

MA has a key function in capturing high-quality external insights to drive and/or inform Medical strategy. Therefore, synthesizing and using external insights from sources such as advisory boards, Field Medical personnel interactions, Medical Information inquiries, scientific publications, and so on is enabled by the background, training, and deep-seated scientific expertise that MA professionals have of the therapeutic area and patient care.

MA has accountability for communicating scientific insights and integrating them into any product or portfolio assessment and/or strategic plan. These insights may be unmet medical needs, research and data gaps, competitive intelligence, current standards of care, epidemiology, patient journeys, treatment pathways, or patient outcome gaps. Insights may vary by region and/or country.

Evidence Generation

Continuous evidence generation which provides information on the safety and efficacy of medicines, as well as addressing data gaps, is an essential component of MA. Medical Affairs lifecycle strategies and plans should start well before first regulatory approval (even before proof-of-concept). Post-approval, there should be an active RWE generation strategy in place that incorporates company-sponsored and investigator-sponsored studies, research collaborations, and Big Data (including user-generated Big Data via media such as digital biomarkers). Evidence generation should be focused on value evidence that informs patients, providers, payers, the public, and policymakers, as well as the impact on patient outcomes. This element includes analysis of evidence generated outside the company.

Evidence Dissemination

Once evidence is generated, it should be communicated to internal and external stakeholders via appropriate channels including, but not limited to, scientific exchange, key opinion leader (KOL) engagement, medical information, publications, and continuing medical education.

While the ability to collect and disseminate information from a wide variety of sources is a mammoth task, it is MA's responsibility to integrate and synthesize the totality of data to inform the medical and scientific narrative and effectively communicate this information to HCPs and KOLs, payers, and policymakers so that they may make sense of a deluge of data and utilize it to inform patient care and improve patient outcomes. MA must also ensure emerging evidence is disseminated to internal scientific and commercial partners as this may impact their strategies and/or tactical plans.

Another aspect of evidence dissemination by MA is the development of patient solutions that can be utilized to optimize care. In many ways, MA should consider itself as the voice of the patient. As such, the

benefits and risks of any given treatment should be readily explored, and patient-reported outcomes should be harnessed to identify gaps in care, redefine outcomes, and work toward solutions. MA must also become comfortable with an omnichannel approach that can satisfy the need for timely medical information and variable communication needs of different stakeholders.

Governance and Compliance

Medical quality oversight is a core component of modern-day governance and compliance with a variety of guidelines, codes and regulations. MA also has an essential role in working with internal quality and compliance stakeholders to understand, establish and reinforce internal and external codes of conduct and promote transparency of practices in the regulation of company-wide activities. These activities include, amongst other things, review and approval of material used in Evidence Dissemination (promotional and non-promotional), independent medical education grants, and independent investigator-sponsored research. Core behavioral and leadership competencies for MA professionals must be established to ensure compliant activities especially as they relate to HCP engagement.

Medical Leadership

Development of MA asset strategy is a central thread of effective medical leadership, with MA being essential in informing company-wide scientific and commercialization strategies and cocreating brand strategies, all the while making sure MA exemplifies its leadership skills to maximize the chance of securing a seat at the table.

Tips for Success in the Future of MA

To unlock the true power of MA, its capability and value proposition must be fully embraced by the pharma industry. The silos that can form within these organizations lead to a broken chain of communication between MA, Commercial, and R&D, and important data do not make their way from department to department in time. In turn, an under-informed MA team is challenged to establish effective and valued peer-to-peer scientific relationships externally.

Therefore, MA must be included as an equal strategic partner, involved with all stages of the drug lifecycle, and have complete access to essential information from all parties involved.

Indeed, those working in MA should expect to be involved in the entire patient/product journey, utilizing all of the available tools necessary to gather insights from HCPs and patients and their experiences, and drive evidence generation via traditional phase IV clinical studies, Big Data, and RWE, as well as data gleaned from interactions with physicians, payers, patients, and caregivers.

What's more, the opportunity for MA to tap into a world of digital health information should not be

missed. In the digital era, patients are now able to track their own health and treatment successes, and are free to share that information on social media and online forums.

Ideally, all of the scientific and clinical results and information can be readily linked to patient outcomes, adding value at every stage of drug development and providing vital feedback on commercial and clinical/medical strategic priorities and patient needs early on.

“But how can we get this information to practitioners at the point of decision-making?” asks William Sigmund, MD, Executive Vice President and Chief Medical Officer at Becton, Dickinson and Company (USA), and head of the company’s MA organization. “We need new capabilities and digital solutions that can mirror how the digital world thinks, and how the digital world evolves—from Facebook to Instagram and beyond—while preventing misinformation.

“Practitioners of the future, everywhere in the world, are going to need more information that is truthful and not misleading, and having an MA group that has the capabilities to ensure appropriate data synthesis and dissemination and understand how information flows to the point of decision-making is going to be really important.”

“We invest heavily in creating platforms for data, analytics and RWE so that all of our teams can access data, differentiate it, and provide that value back to both the R&D and commercial teams,” noted Dr. Nathwani. “We train everyone on digital health, digital bootcamps, machine learning, AI (artificial intelligence), wearable technologies—we train them on the fundamentals of understanding RWE.

“That way, we are equipped to monitor the performance and the benefit of a product once it’s in market, but before there’s any RWE generated. We can use these insights to formulate new hypotheses and continuously update our understanding on what is a very dynamic patient journey.”

Of course, if MA is to live up to its potential, building and sustaining scientific relationships with a variety of stakeholders is essential. Not only does this benefit patients and HCPs, but increased engagement with these stakeholders helps pharma companies better focus their efforts on outcomes.

“MA has to be master of many things,” continued Dr. Nathwani. “It has to master the science and understand the reputation of treatments because, if it doesn’t do that, then it won’t be the voice of the patient, the physicians, and the healthcare practitioners that it is trying to assist.”

“But MA also then needs to understand healthcare systems. If we’re truly going to shift healthcare practice then we need to be a credible partner, one who understands the implications that particular healthcare systems face when assessing and/or adopting innovative new treatments.”

“If you have an effective MA organization in place that really understands the diseases, the medical

needs, the changes to the traditional landscape and the technological landscape, they can develop a very compelling lifecycle strategy and execute it quickly. That can provide a massive amount of value to both patients and the company.”

Dr. Sigmund added: “You have to understand what the unmet medical needs are—and MA really does. It’s our job to stay on top of what is happening in clinical practice, how physicians are now making decisions with regards to the medicines they use for patients, and what kind of fair, balanced and accurate information informs their decision-making.”

What’s clear is that pharma companies will need to fully embrace MA if they hope to thrive. With the clinical expertise, knowledge, and capabilities of MA professionals at their disposal, pharma leadership will put the patients’ needs first, continually informing clinical practice and delivering innovative products that improve patient outcomes.

Going forward, MA professionals should clearly articulate the value and key pillars of MA to their peers and then execute on their strategic plans.

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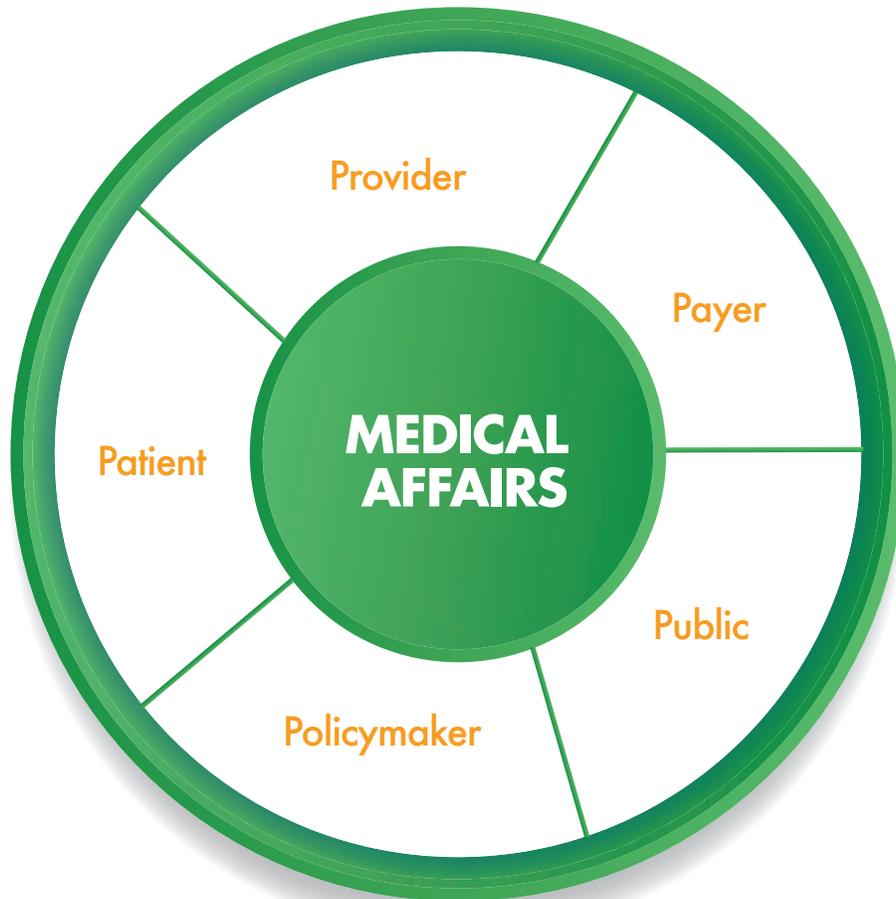


Figure 1.

Patient, Provider, Payer, Public, Policymaker: The five “Ps” of Medical Affairs (MA).

MA is the common ground for the five “Ps” important in healthcare and pharmaceutical drug development and commercialization—Patients, Providers, Payers, Public, and Policymakers. It is the interface between internal R&D, commercial, clinical, and regulatory departments, and external entities such as HCPs, scientific experts, patients, caregivers, and payers/decision-makers—i.e. a huge variety of stakeholders, each with their own needs.

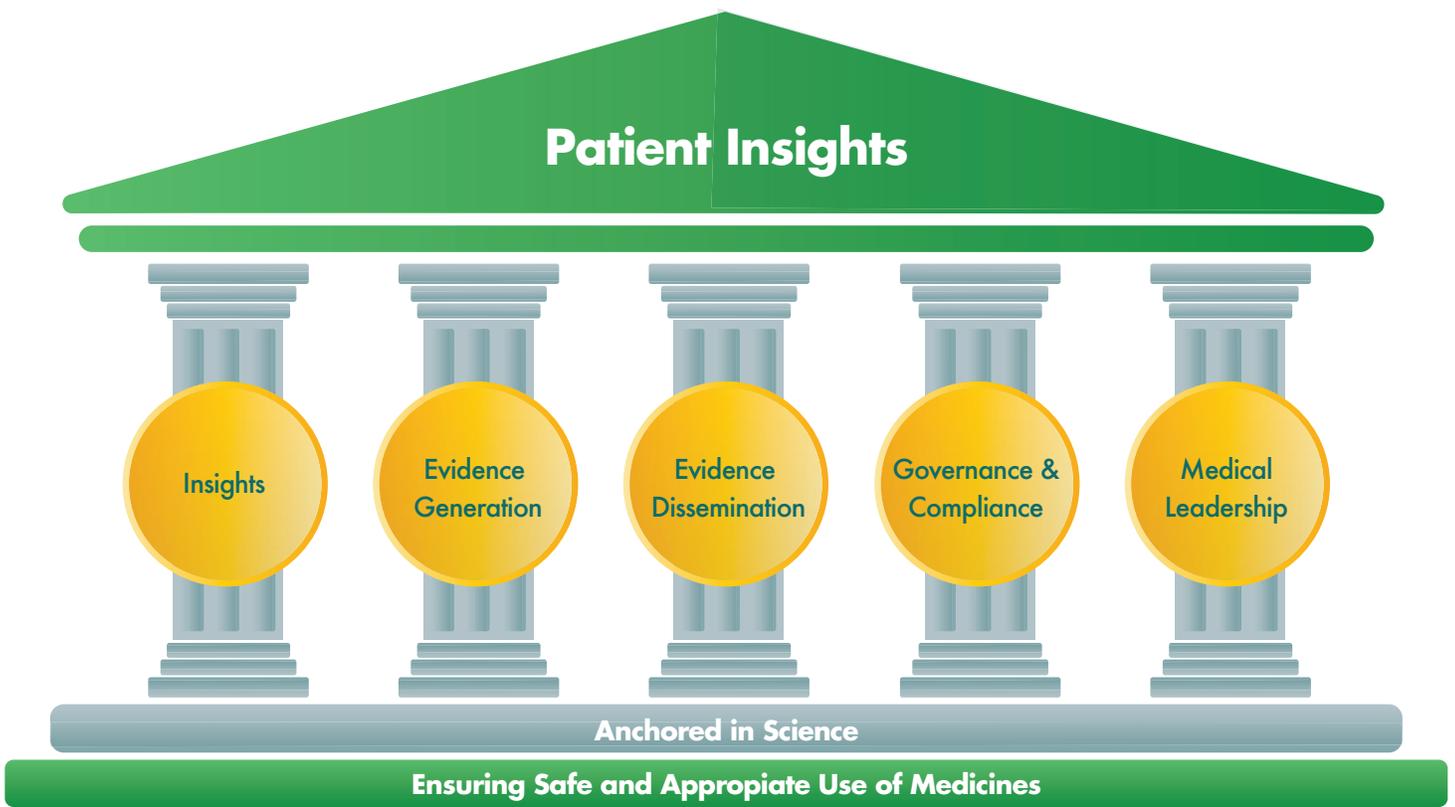


Figure 2. The Foundation and Pillars of MA

- Capture quality external insights that drive and/or inform Medical strategy
- Harness MA's background, training and deep understanding of science and patient care
- Collect and synthesize key insights:
 - Unmet medical needs
 - Research and data gaps
 - Patient journeys
 - Treatment pathways
 - Competitive insights
 - Current standard of care
 - Epidemiology
 - Patient outcome gaps
- Ongoing evidence generation that provides information on the safety and efficacy of medicines and that address data gaps and patient-reported outcomes
- Lifecycle strategies and plans starting well before regulatory approval
- Active post-approval strategies maximizing real-world evidence and Big Data (including digital data)
- Generation of value evidence that focuses on patient outcomes and informs patients, providers, payers, public, and policymakers
- Evidence made available to all parties via scientific exchange:
 - KOL engagement
 - Medical information
 - Publications
 - Medical education
- Synthetization of the totality of data to inform the medical and scientific narrative
- An omnichannel approach to provide timely information and satisfy the communication needs of different stakeholders
- Define and develop patient solutions
- Competency and behavioral frameworks
- Medical quality oversight:
 - Work with internal compliance stakeholders to establish and reinforce codes of conduct
 - Review and approval of externally facing information to ensure fair, balanced, accurate, understandable
 - science Review and approval of Medical grant applications
- Development of Medical asset strategy
- Inform company scientific and commercialization strategies
- Co-create brand strategy
- Exemplify leadership skills to maximize MA's seat at the table



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