Profound Progress, Pragmatic Realities: A Critical Assessment of the McKinsey vision for Medical Affairs in 2025

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Introduction

The foundational vision for Medical Affairs in the modern pharmaceutical industry, as articulated in 2018, in the McKinsey landmark paper "A vision of Medical Affairs in 2025" *(1)* postulates that Medical Affairs will undergo a structural metamorphosis to emerge by 2025 as the third strategic pillar of the pharmaceutical enterprise, standing equal to research and development (R&D) and commercial operations.

This transition is necessitated by a shift in the healthcare landscape where science and data have become a primary currency to create value for HCPs and patients while simultaneously realising success for the company.

The 2018 mandate as suggested by McKinsey in their landmark paper describes this rise towards being the third strategic partner depending on four core deliverables to transform: (1) the innovation of evidence generation, (2) the acceleration of patient access, (3) the personalisation of medical engagement, and (4) the elevation of internal medical leadership.

As the year 2025 has concluded, evaluation of this vision and what has been achieved reveals a department in the midst of a sophisticated, albeit uneven, maturation *(2)*.

While the ambitious vision has been universally adopted and is being communicated widely, in reality, the actual status of Medical Affairs is best described as "accelerating or nascent and evolving" rather than fully complete. As a matter of fact, according to the ZS Medical Affairs Outlook Report 2025, approximately 71% *(3)* of organizations currently rate their maturity as strategic partner as "evolving," while a mere 13% claim "best-in-class" status, indicating that the journey to full fruition of the vision is not even near completion.

Despite the best intentions and urgency, it is clear that Medical Affairs has not yet fully transcended its traditional role as a support unit to become an equal strategic partner and proactive shaper of clinical value and adoption.

This paper aims to describe the current state of Medical Affairs for each of the four core deliverables as described by McKinsey in their vision paper for 2025.

The authors will share their personal opinions (not of any organisation or affiliation) and judgement on current progress. These infographics are AI generated but the text was very deliberately written by the authors personally to directly express their thinking.

Core deliverable 1: The Evolution of Evidence Generation

The first core deliverable of the McKinsey vision demands that Medical Affairs leads rapid-cycle, integrated, and comprehensive evidence generation. This requires a different way of working and use of new techniques and data sources, such as AI and patient owned big data, RWE, as well as a shift from functional silos toward a centralized view of data generation across the lifecycle.

The importance and status quo of Integrated Evidence Planning.

One mechanism for this change is the implementation of the Integrated Evidence Generation Plan (IEGP), which aims to identify and prioritize evidence gaps across the complete life cycle while developing cross-functional and cross country/regions study plans that align with organisational strategy.

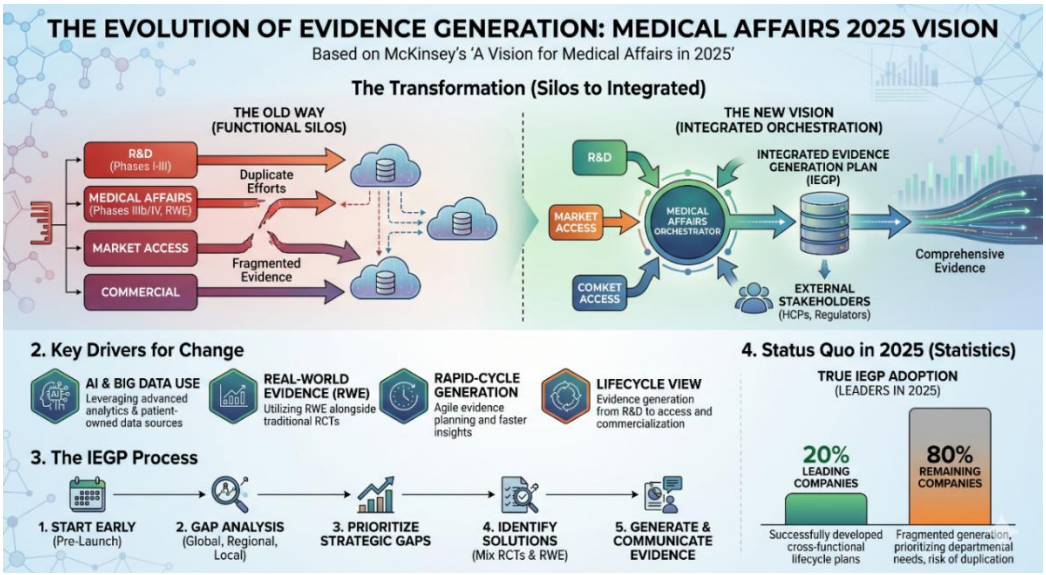
There are many stakeholders involved in evidence generation, and each has its own agenda and focus. For instance, phase I-III research requires strong R&D expertise, whereas phase IIIb/IV research and observational studies are often best undertaken by Medical Affairs. What is essential here is orchestration that transcends the different silos. As this orchestration requires a deep understanding of the patient journey and care reality and gaps, as well as expectations from both regulatory and pricing authorities worldwide, Medical Affairs is in a perfect position to orchestrate this integrated evidence planning from R&D to access and commercialization.

The IEGP process should start early, with a thorough gap analysis at country, regional and global level, followed by a prioritization of strategic gaps to be addressed by the right solutions, which can be a combination of RCT and RWE evidence generation, using both traditional and innovative methods.

By 2025, the adoption of IEGPs has become a hallmark of advanced medical organizations, yet widespread implementation remains a challenge. Only 20% of leading pharmaceutical companies have successfully developed a truly cross-functional, integrated evidence plan that spans the entire product lifecycle *(4)*. For the remaining 80%, evidence generation remains largely fragmented, with individual functions prioritizing studies that meet their specific departmental needs rather than the requirements of the broader organization and external stakeholders *(4)*. The implications of this fragmentation are significant. Without a unified evidence strategy, companies risk duplicating efforts and failing to provide a steady flow of evidence to support ongoing dialogues with regulators and healthcare providers (HCPs).

Real-World Evidence and Regulatory Integration

One of the most profound successes of the 2025 vision has been the elevation of RWE from a supplementary data source to a primary strategic asset. As predicted, regulators have demonstrated an unprecedented receptiveness to RWE, which is now regularly used for label expansions, safety monitoring (PASS/PAES), and drug utilization studies *(5)*. This process is governed by Regulatory Affairs and Market Access but Medical Affairs is a critical partner in study design and data generation, allowing for adoptive trial designs like digital twins, external control groups, and wearables for precision medicine and phase 3b/4 and RWE studies.



Core deliverable 2: Accelerating Treatment Access

The second core delivery of the McKinsey vision requires Medical Affairs to clearly articulate clinical and economic value to and accelerate access by being a central partner for Market Access and HEOR.

This partnership is important as these internal stakeholders are critical, with their expertise in economic value, HTA, pricing, reimbursement and HEOR, and activities essential for bringing new medicines to patients.

Medical expertise is essential in these activities, for instance during the creation of reimbursement dossiers and realistic HEOR models. Also, the set up and execution of HEOR studies can often not be done without the specific knowledge, skills and network that Medical Affairs brings.

In addition, it is one of the core responsibilities of Medical Affairs to try to accelerate access to treatments by articulating clinical value so that specific patient subpopulations receive therapies at the optimal stage of their disease.

Medical Affairs has the capabilities to not only improve individual patient outcomes but to make an impact at a healthcare system level.

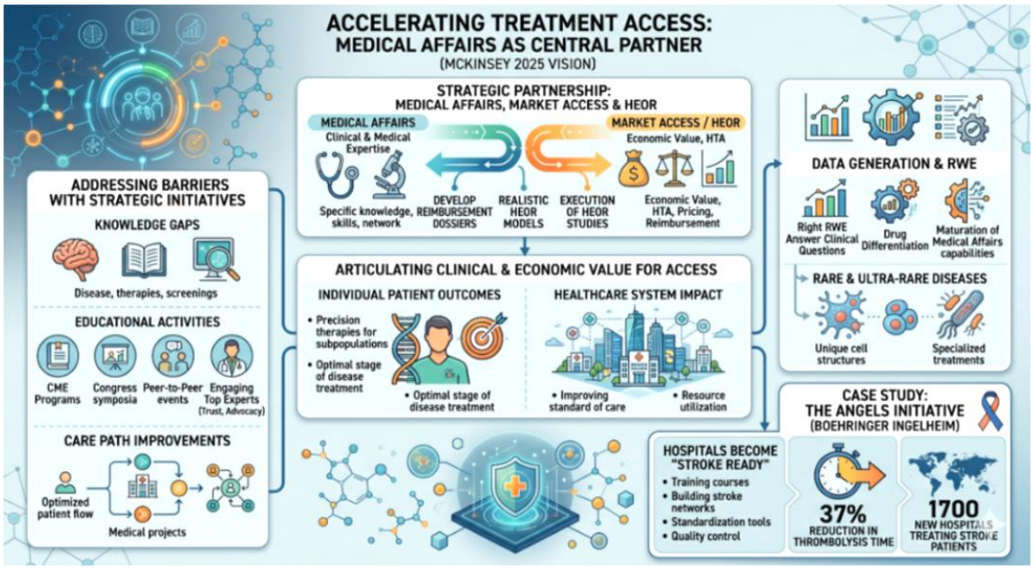
Medical Affairs with its deep understanding of the patient journey and care gaps is the perfect department to try to address existing barriers with different strategic initiatives and activities. Knowledge gaps around the disease, new therapeutic options or screenings can be solved perfectly with educational activities such as CME activities, educational activities at congresses and peer-to-peer events and by engaging the top experts building trust and partnership and advocacy.

Case Study: The Angels Initiative

AN EXCELLENT EXAMPLE OF MEDICAL AFFAIRS ADDRESSING EXISTING CARE BARRIERS IS THE ANGELS INITIATIVE FROM BOEHRINGER INGELHEIM TO SUPPORT HOSPITALS TO BECOME "STROKE READY" WITH TRAINING COURSES, BUILDING OF STROKE NETWORKS, STANDARDIZATION TOOLS, SHARING BEST PRACTICE, AND QUALITY CONTROL. IT RESULTED IN 1700 HOSPITALS THAT NOW TREAT STROKE PATIENTS THAT HAVE NEVER DONE SO BEFORE, DIRECTLY POSITIVELY IMPACTING PATIENTS LIVES

Moreover, Medical Affairs can facilitate improvements in care paths by executing medical projects and data generation.*(6),(7)*

Indeed, generating the right RWE at the right time to address unanswered clinical questions and to help in the differentiation of drugs is a core task of Medical Affairs which has matured significantly to achieve this goal. This is even more prominent in rare and ultra rare diseases where Medical Affairs plays a pivotal role in patient diagnosis and treatment.



Core deliverable 3: Personalizing Medical Engagement

The 2025 vision sought to upgrade decision-making by providing tailored information to HCPs, payers, policy makers and patients through a combination of personal and digital touchpoints (e.g. F2F interactions, congresses, peer-to-peer events, webinars and CME).

A critical evaluation of the 2025 engagement landscape reveals a significant "listening gap:" while 82% of life sciences executives are satisfied with their current engagement strategies, only 28% of HCPs believe these strategies effectively meet their needs *(8)*. This staggering disconnect suggests that many organisations are still practicing "fragmented tactics" rather than true omnichannel orchestration. In the view of customer centricity, multichannel communication really should be a cross-functionally orchestrated activity, with enough freedom for Medical Affairs to customize to their highly specialised and educated target group. This highly customized MSL communication with extremely knowledgeable external experts is obviously different from the high volume 'mass' communication by commercial departments.

Medical Affairs has been slow in the uptake of omnichannel or even multichannel communication due to a number of reasons.

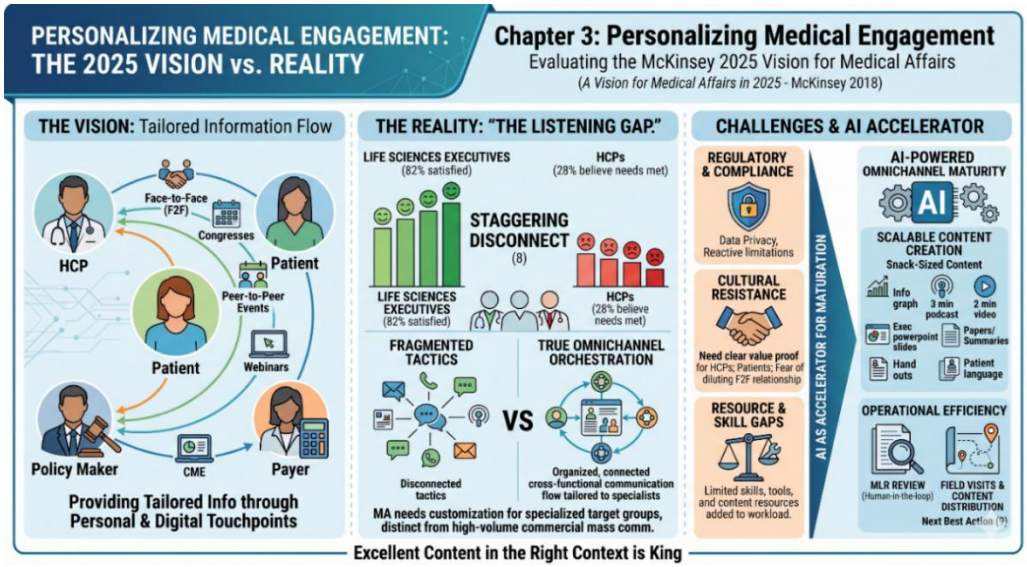
Firstly, in this highly regulated industry, data privacy and compliance hinder true omnichannel considerations at an individual level, on top of that, often communication and activities can only be reactive. True proactive omnichannel communication is very hard to achieve and an optimised multichannel communication may be more likely be the best-case scenario.

Secondly, Medical Affairs teams are not prone to embrace this type of communication if the value for the HCP, patients and themselves is not made abundantly clear to them. Historically, personal communication with HCPs has been the spearpoint of Medical Affairs and there is a fear digital channels will dilute this relationship instead of optimising it.

Thirdly, there are often not enough resources put behind the skills, tools and content needed to create a coherent multichannel strategy, as this has been added to an already substantial Medical Affairs workload.

The current strong rise of AI will be instrumental in the maturation process of omnichannel communication, due to the opportunity to create high quality content on large scale, as well as the ability to customise and define individual initiatives and communications. AI will be able to generate concise, targeted pieces of valuable information (e.g. info graph, 3 min podcast, 2 min video, executive power point slides, hand outs, papers, paper summaries, patient language) to cater to individual needs. In addition it can also help with medical and legal review with a human in the loop at the last step. This is often a bottleneck for new content. In addition AI (if given the access to the right data and databases e.g. CRM, publications, congress information, advisory board notes, content, strategy) can help planning field visits and individual content distribution over the right channel (e.g. next best action *(9)*. Excellent content, delivered within the right context, remains the critical determinant of impact.

The broader and emerging role of AI across Medical Affairs, including agentic AI, Generative Engine Optimisation and real-time knowledge tools, is explored in the section below.



Core deliverable 4: Stepping Up Internal Medical Leadership

The final area of the McKinsey vision demanded a radical transformation of medical leadership, positioning Medical Affairs as a strategic partner and the third strategic pillar.

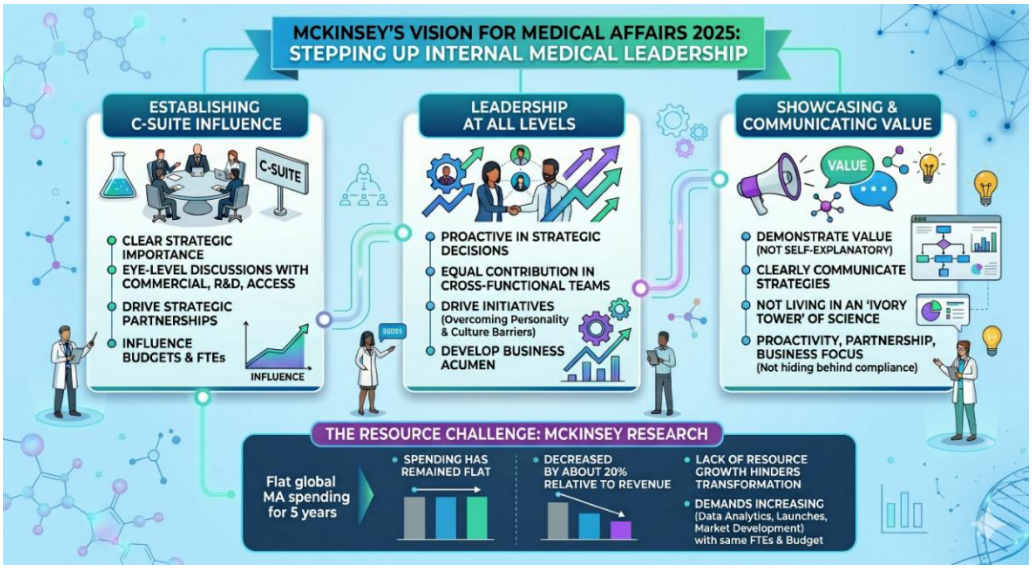
By 2025, the recognition of Medical Affairs as the vital third pillar is established within the industry's rhetoric, albeit not always in the reality. Ideally, Medical Affairs would have a place in the C-suite next to commercial, R&D, HR and Finance. This would clearly show the strategic importance and lead to discussions at eye level and as strategic partner.

Medical Affairs can only advance to being the third strategic partner if it shows leadership at all levels in the organisation, proactively taking part in strategic decisions, contributing to cross functional teams in an equal manner and communicating their own strategies and value and contribution to the brand strategy clearly.

This potentially also requires an effort of the whole Medical Affairs organisation at each level to communicate the value of medical to the cross functional partners, as it is clear this is not self-explanatory. Proactivity, business acumen, cross functional partnership are critical, as well as a willingness to move beyond a compliance-driven mindset and to take shared responsibility for the success of the broader team, rather than retreating into scientific isolation.

This also means stepping up and proactively driving initiatives, something that is sometimes hard as medical is not used to it and personalities (e.g. all coming with a very scientific background) may be different compared to commercial colleagues who are often more vocal and used to proactivity.

Another aspect is the topic of resources. Partly due to a lack of understanding of the value Medical Affairs creates it is often understaffed with limited budgets which also hinders the function to be a true partner at eye level. Medical Affairs is expected and well suited to deliver ever more on multiple fronts such as data analytics, launches and market development with a stagnant amount of people and resources. McKinsey states in their 2030 Medical Affairs vision paper “Transformations typically require tens of millions of dollars, but McKinsey research has shown that worldwide medical affairs spending has remained flat over the past five years and has decreased by about 20 percent relative to revenue.“ *(4)*. As long as this lack of growth in resources exists, it will be difficult for Medical Affairs to complete the transformation.



Considerations concerning other key areas of Medical Affairs

The Role of Artificial Intelligence

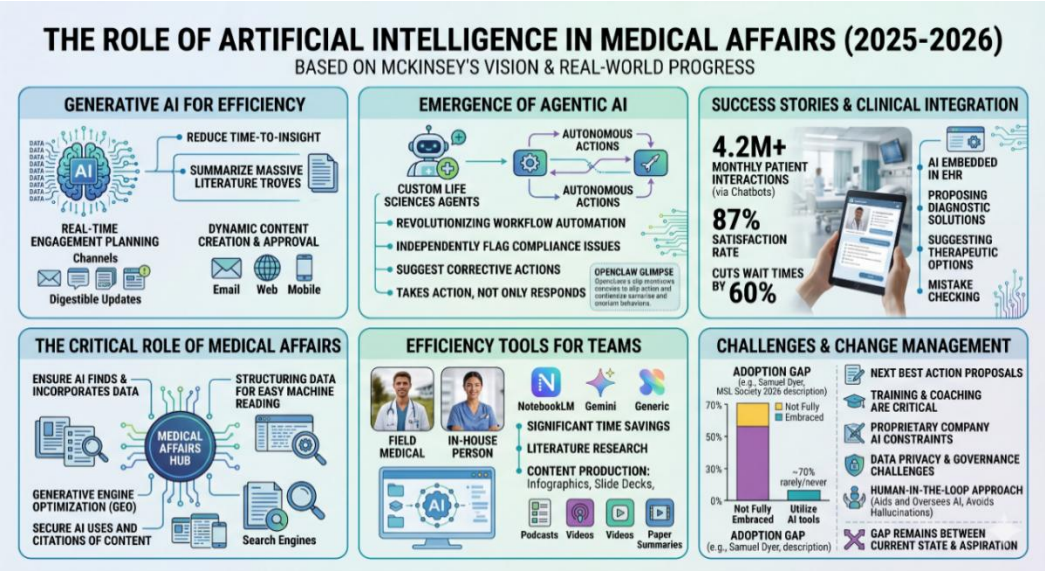
While AI is already reshaping how Medical Affairs personalises engagement today, the developments outlined in this section represent the near-future horizon: capabilities that are emerging now but have not yet been fully integrated into standard Medical Affairs practice.

By 2026, AI has become a critical piece of engagement efficiency. Generative AI is used to reduce time-to-insight, summarize massive literature troves, and enable real-time engagement planning and creation and approval of digestible content per channel per customer *(10)*. The emergence of "Agentic AI", custom-built agents designed for life sciences, is revolutionizing workflow automation by independently flagging compliance issues and suggesting corrective actions. Agentic AI will further revolutionize the way of working by taking action and not only respond to questions. Success stories include AI chatbots handling over 4.2 million patient interactions monthly with an 87% satisfaction rate, cutting patient wait times by 60% *(11)*. Additionally, AI will be embedded further into hospital and private practice platforms and processes including Electronic Health Reports (EHR) also checking for mistakes and proposing diagnostic and therapeutic solutions. This also means that Medical Affairs need to make sure that the AI and the algorithms find and incorporate the data from the distinct studies and companies. Medical needs to make sure that important data is ready for easy machine reading (GEO: Generative Engine Optimization) to ensure AI uses and cites or references the appropriate data, studies, content *(12)*.

For field and in house teams tools like NotebookLM and Gemini can save significant amounts of times for literature research and the production of content such as info graphs, slide decks, podcasts, videos, summaries of papers and so on.

This all requires a thorough change management to help the teams to embrace the digital transformation adapting and using the technology. At this point in time significant proportions of field medical are still not embracing the digital transformation fully as 2026 described by a paper

from Samuel Dyer from the MSL society. ~70% of MSLs + MSL Managers rarely or never utilize AI tools to prepare for KOL engagements *(13)*. In addition due to proprietary reasons only company approved AI can be used which often is not the latest version of AI giving suboptimal use of the new technology. Last but not least data privacy and governance are still a challenge. A human in the loop approach is considered good practice also due to the fact of potential hallucinations of AI. There is still a significant gap between where the teams are concerning digital transformation and the aspiration. Training and coaching in this area are critical.



Demonstrating Value, Impact Measurement and Performance Management.

The most significant change in 2025 is the shift toward measuring "Medical Impact" rather than just activity. Measuring Medical impact is instrumental in demonstrating value, providing strategic focus and managing performance. By truly measuring, showing and communicating Medical Affairs value the whole function elevates to a true strategic partner.

In order to measure impact, often a framework with three or four pillars is deployed, moving from activity metrics, via knowledge, beliefs and behaviour of physicians to true patient impact.Models of these are frameworks like the pillars of impact (Veeva) *(14)* or the patient outcome impact metrics of ZS *(15)*, which track shifts in knowledge, beliefs, care pathways behaviour change, and clinical outcomes.

Examples of activity metrics in the first pillar are number of MSL interactions. These pure quantitative metrics are standard and often used for performance management but cannot be used to show true value.

In a second pillar, Medical Affairs tries to measure HCP knowledge and beliefs (and potentially behaviour changes of physicians). These are indications of the effectiveness and quality of communication and the respective learnings. This could also apply to care pathways and protocols. HCP knowledge and beliefs are harder to measure, and different tools such as share of scientific voice, Altmetrics, market research or social media listening including sentiment can be

used. Changes in knowledge and beliefs may be a leading factor to true change of behaviour of physicians.

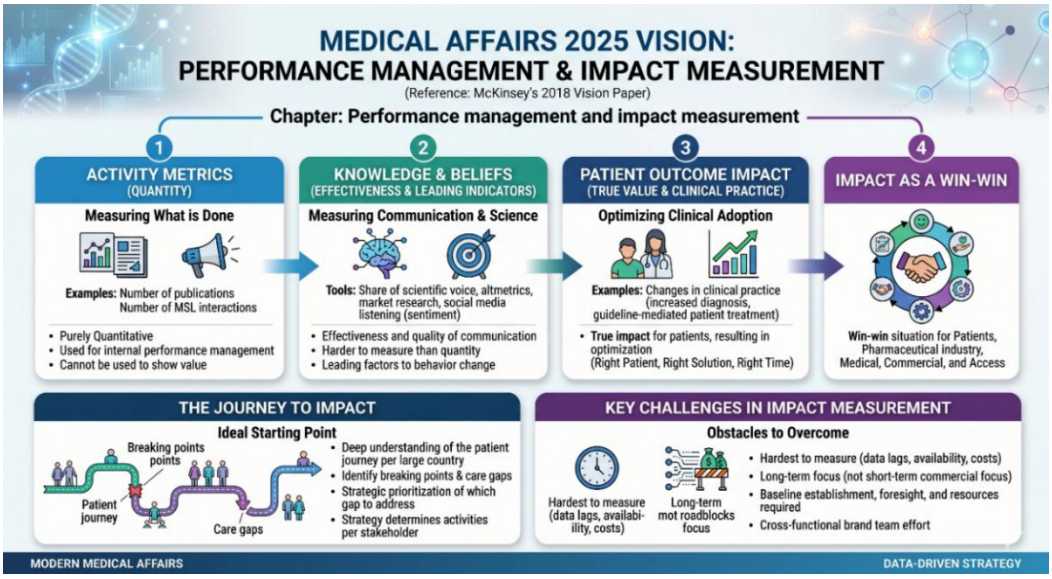
As a third pillar, the true impact for patients (often referred to as target patient outputs or outcomes) is sought. These changes in clinical practice (e.g. increased diagnosis of patients, faster referral or guideline mediated patient treatment) result in an optimisation of clinical adoption thus aligning precision therapies to suitable patients at the optimal stage of their disease progression.

This final level of impact is the hardest to measure, due to time lags to true impact, lack of data availability or costs of measurement. Another complicating factor is that such long-term outcomes are less visible in a company that focuses on short term outcomes such as patient use in the next quarter. Also, a baseline needs to be established first in order to show change, which requires foresight and resources. What is also important to recognize is that optimizing clinical adoption is obviously not only a Medical Affairs task but often a cross functional brand team effort.

Most companies are still in the early stages of developing robust impact measurement frameworks and there are no gold standards for true patient outcomes at this point in time. Also demonstrating Medical Affairs value depends not only on the right metrics, but also on savvy internal communication across all levels.

Ideally, this all begins with a deep understanding of the patient journey with the breaking points and care gaps. Strategic prioritization then occurs on which care gap to address and generating the strategy that determines the respective activities per key stakeholder.

It is a critical topic though since optimized clinical adoption stands to benefit patients, HCPs, and the pharmaceutical industry alike, aligning the interests of medical, commercial and access functions.



2025 Medical Affairs Core Deliverables - Status

1. Innovate Evidence Generation

By 2025, the adoption of IEGPs has become a hallmark of advanced medical organizations, yet widespread implementation and fragmentation remain a challenge. The importance of RWE is clear as it has successfully integrated into the regulatory and access landscape. However, true innovation in data generation, such as analysis of big data, real time evidence and AI led data generation by Medical Affairs has not yet been achieved.

2. Accelerate Access to Treatments

Medical Affairs with its deep understanding of the patient journey and clinical care gaps and its ability to translate science into value is the perfect department to improve patient access with different strategies and initiatives. Big steps have been made to address access gaps but still barriers exist. This is where smooth and strategic cross functional collaboration between functions (R&D, medical, market access, regulatory, commercial) will make the difference. Medical Affairs should take on a leading role in this.

3. Transform & Personalize Medical Engagement

Progress has been made concerning multichannel engagement and content but adoption of omnichannel concepts and AI is slow. A true understanding of HCPs and communication strategies is essential for Medical Affairs to make this impact, but this is also where it is currently still lacking.

4. Step Up Internal Medical Leadership

By 2025, the recognition of Medical Affairs as the vital third pillar is established within the industry's rhetoric, albeit not always in the reality. Medical Affairs is recognized as a critical function especially in a pre-launch phase and in rare diseases. However, the true value of medical affairs is not yet fully appreciated, due to several factors, including challenges in measuring true medical impact and insufficient internal communication of Medical Affairs value across all levels in the organisation.

In conclusion, it is clear the McKinsey vision of Medical Affairs as the third strategic pillar is not complete. Reality is that Medical Affairs potential is still inconsistently realised and too dependent on individual leadership rather than embedded organisational capability.

What has changed is the level of ambition and the quality of the conversation. Medical Affairs leaders speak the language of strategy, evidence, and cross-functional partnership far more fluently than they did in 2018. The C-suite increasingly agrees, at least in principle. But language and intent are not outcomes.

The arrival of AI is the most significant variable the 2018 vision did not anticipate to the extent it has happened. It has the potential to accelerate all four core deliverables simultaneously and to expose, more starkly than ever, the organisations that have built the strategic foundations from those that have not.

The third pillar is standing. It is not yet load-bearing.

In order for Medical Affairs to further transform and achieve optimal impact for patients and the company, additional resources, capability building and internal advocacy should be a priority and not an afterthought. This conversation needs to continue.

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Reinhard has more than 20 years of Medical Affairs experience in the pharmaceutical industry, holding country-level, regional and global roles. He has successfully covered all facets of Medical Affairs, including launch readiness, digital transformation, RWE generation, medical education, MSL excellence and medical strategy, and was responsible for leading Medical Affairs teams with direct accountability to senior management.

Reinhard has a broad knowledge of healthcare ecosystems and deep therapy area expertise spanning cardiology, neurology and immunology. Prior to his current role, and before moving into Medical Affairs, Reinhard gained experience in drug discovery and pre-clinical development in the pharmaceutical industry.

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Maaike is a Medical Affairs professional with over 25 years of pharmaceutical industry experience. Having switched from clinical practice to Medical Affairs in 2002, her career spans hands-on and senior leadership roles in Medical Affairs departments at both global and local levels, across multiple countries. She has gained experience in working with products across the life cycle, from rare disease to high-volume therapeutic areas, working with diverse internal and external stakeholders.

Since 2017, Maaike has specialised in training, consultancy and thought leadership for Medical Affairs, working with Medical Affairs teams and their leaders across the pharmaceutical and biotech industry. Maaike, who holds a Medical Degree from Utrecht University, is based in the Netherlands but works on a global scale.

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