



# RE-THINKING MEDICAL AFFAIRS

Key Challenges for the Pharmaceutical Industry and a Framework for Success



## Part 2 of 4: Technical Success Requirements for Medical Affairs Excellence

July 2024

Share: [in](#) [✉](#)

CapSys Group's latest global research, *Re-thinking Medical Affairs*, uncovered that Medical Affairs functions in many pharmaceutical (pharma) and life sciences companies are still struggling to assume a leading role in shaping their organization's strategy definition and execution. Together with the industry leaders participating in the study, CapSys experts described the main shortcomings responsible for this situation and identified six success requirements to overcome them and achieve Medical Affairs excellence (see figure 1.). Four of these crucial success requirements are of a technical nature while two are organizational. This insight paper describes the four common technical deficiencies and the success factors associated with them.

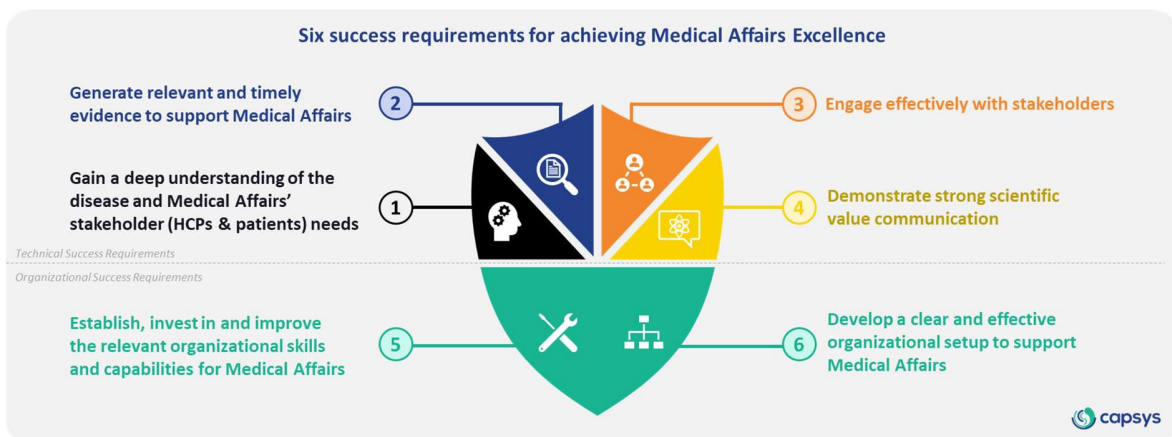


Figure 1: The six success requirements for achieving Medical Affairs Excellence. Success Factors 1 to 4 are the focus of this paper

## **Requirement for Success #1:**

### **A deep understanding of disease and stakeholder needs enhances medical affairs excellence**

For the first success requirement, Medical Affairs leaders and experts at CapSys observed that Medical Affairs in winning pharmaceutical and life sciences organizations tends to go beyond the science and strives for a deeper understanding of the disease and stakeholder needs. The primary purpose of the Medical Affairs function is to serve as an interface between the external medical and scientific community and the enterprise. Much like a cell membrane, Medical Affairs actively identifies and promotes the passage of vital material (knowledge and insights) into and out of the organizational 'cell'. Sourcing critical knowledge and insights from external stakeholders, articulating the implications for internal activities like evidence generation, and feeding new and relevant knowledge back to the external world is the core work of the Medical Affairs function.

Our research suggests this knowledge and insights loop is becoming increasingly critical. The speed, cost and complexity of innovation today are causing regulators, payers and healthcare providers to demand a more holistic, nuanced and objective knowledge package from

pharma companies – not only about new treatments, but also about unmet patient needs and burden of illness, emerging end-to-end treatment journeys and their costs and effectiveness, and ancillary healthcare system requirements to meet the needs of patients. Amongst the many pharma functions that interact with stakeholders, Medical Affairs is best positioned to lead and manage this overall knowledge and insights loop. Further, our research suggests that companies are holding Medical Affairs increasingly responsible for doing so.

Are today's Medical Affairs organizations prepared to deliver a robust knowledge and feedback loop? The short answer, based on what we've learned from our global panel, is "not really". Specifically, our research points to four weak links in the loop. The main themes in these weaknesses are an insufficient understanding of the disease and stakeholder landscape, too little strategic foresight and a suboptimal use of the information that already is available.

#### ***Four weak links in the knowledge and feedback loop***

- 1. Disease burden, true unmet needs, and the patient journey are often not understood well enough*
- 2. Regional or local stakeholder perspectives, needs, and challenges are poorly understood*
- 3. Clinical development plans do not anticipate the requirements of non-regulatory stakeholders at launch*
- 4. Medical Affairs' insights are insufficiently shared or inadequately integrated into business strategies*

So, how can these shortcomings be addressed? Insights from our *Re-thinking Medical Affairs* study show that successful industry leaders understand the disease and stakeholder

landscape better than their less successful competitors by consistently employing four important levers for success.



Figure 2: Imperatives for a deeper understanding of disease and stakeholder needs

## Requirement for Success #2:

### Generating the right evidence at the right time boosts Medical Affairs Excellence

Regarding the second success requirement, Medical Affairs leaders and experts at CapSys observed that the Medical Affairs function is under mounting pressure to demonstrate value in an increasingly demanding ecosystem. For optimal value to be created, evidence generation must be planned and conducted with the end goal of developing new treatments to meet the needs of patients. Ensuring patient access to treatments requires that the right evidence is generated at the right time to meet the various needs and requirements of stakeholders involved throughout the clinical development process.

The Medical Affairs function is essential to any pharma or life sciences organization but is often underutilized. Through its scientific knowledge and stakeholder networks, the Medical Affairs function has the potential to evolve to a more central role within the organization to facilitate

integrated evidence generation planning. Organizations that take advantage of this shift in the roles and responsibilities of Medical Affairs and reposition Medical Affairs to develop evidence generation strategies are on the path to Medical Affairs Excellence.

Creating winning evidence generation strategies inevitably involves making trade-off decisions between the various needs and requirements of external and internal stakeholders. Such trade-off discussions should take place early in the clinical development process and continue throughout the entire lifecycle of the asset. The development of scenarios with their corresponding migration strategies also needs to be considered in this manner, early and throughout clinical development. With its various stakeholder networks, Medical Affairs is well-positioned to play a role in facilitating internal communications and cross-functional

discussions to corroborate trade-offs. Further, with its breadth of scientific background, Medical Affairs can provide education and relevant insights to enable decision-making that achieves the best possible and robust evidence strategy.


In many organizations, however, evidence generation planning remains overwhelmingly challenging. CapSys' global study identified several frequent shortcomings in generating relevant and timely evidence that ultimately limit commercial success.

### **Shortcomings in generating relevant and timely evidence**

1. *Strategic and integrated cross-functional evidence generation planning to address multiple stakeholders' needs is sub-optimal*
2. *Clinical Development and Medical Affairs often have a poor relationship and misaligned goals*
3. *The ideation process for relevant multi-stakeholder evidence requirements beyond RCTs is initiated too late*
4. *Collaborative efforts to generate real-world evidence data are often ad-hoc rather than systematic*

Based on these shortcomings and observed best practice in the industry, life sciences specialists and CapSys experts identified five key levers of

success within the Medical Affairs Excellence Framework that Medical Affairs leaders should employ to better facilitate evidence generation.



**max**  
Medical Affairs Excellence

### **Five imperatives for generating relevant and timely evidence**

1. Implement a strategic, integrated and timely evidence generation approach latest from Ph2 onward
2. Ensure involving all key functions to address functional needs (ClinDev, Regulatory, MedAffairs, Market Access and Commercial)
3. Develop analytical and technical tools for insights and evidence generation
4. Ensure evidence generation investments yield data which is relevant to our key stakeholders
5. Increase collaboratives efforts and develop partnerships to generate relevant RWE data



Figure 3: Imperatives for generating relevant and timely evidence

### Requirement for Success #3:

#### Effective, personalized stakeholder engagement leverages Medical Affairs Excellence

For the third success requirement, CapSys experts and industry leaders contributing to the *Re-thinking Medical Affairs* study observed that Medical Affairs plays a vital role in helping organizations navigate stakeholder engagement and manage, or even deepen, quality stakeholder relationships. It does so by leveraging its therapeutic expertise and interactions with internal and external contacts and hence supports organizations deriving enhanced value from stakeholder engagement. The important role of the Medical Affairs function in stakeholder engagement becomes even more pronounced with the observable shift towards more complex and virtual stakeholder interactions.

Industry experts involved in the *Re-thinking Medical Affairs* study saw the need for Medical Affairs to assume even more responsibility and an even more active role in ensuring that patients receive the best possible care by providing relevant scientific or medical

information and ensuring medicines are used according to their intended purpose. To do this effectively, Medical Affairs must engage with key stakeholders throughout the healthcare ecosystem, intimately understand their needs, and build strong and lasting relationships. Organizations that successfully leverage their Medical Affairs teams in stakeholder engagement are better positioned to ensure that clinical development meets disease or patient needs and improves patient outcomes.

However, for many organizations, communicating effectively with stakeholders and being responsive to all their needs remains challenging. Medical Affairs leaders and experts at CapSys recognized several frequent shortcomings in stakeholder engagement that limit the value derived from stakeholder interactions and prevent Medical Affairs from playing an active role in shaping their organization's strategy.

#### **Shortcomings in stakeholder engagement**

1. *More effective relationship building with non-traditional Key Opinion Leaders (KOLs) and a broader set of Health Care Professionals (HCPs) is required*
2. *Building high-quality stakeholder relationships and gaining sufficient insights through virtual engagement is challenging*
3. *Collaborative efforts within the organization to enrich stakeholder engagement are limited*

Our study saw clear commonalities among those organizations who manage to address these challenges effectively. They all seem to attribute high value to four imperatives for effective and increasingly personalized stakeholder

engagement. These include a broadened stakeholder scope, an adequate engagement infrastructure, and intensive cross-functional collaboration.



Figure 4: imperatives for effective, personalized stakeholder engagement

### **Requirement for Success #4:**

#### **Strong scientific value communication is integral for Medical Affairs Excellence**

This brings us to the fourth technical success factor the global study identified: being able to communicate scientific value in a consistently strong and convincing way. Pharmaceutical and life sciences organizations are constantly challenged by stakeholders to generate robust and demonstratable evidence for their products to enable market access, reimbursement or utilization. A key to success in demonstrating that generated evidence meets the needs of the key stakeholders is through strong scientific value communication. This requires organizations to clearly communicate the evidence, identify stakeholders' unmet needs effectively, and demonstrate the true impact of the evidence on those needs.

Medical Affairs professionals are scientific experts in the disease area and treatments. They communicate directly with stakeholders such as regulators, prescribers, and patients. Medical Affairs is, therefore, well-placed to facilitate a two-way conversation between the organization and its stakeholders. Firstly, this ensures that relevant evidence can be communicated effectively to demonstrate the value to stakeholders and to improve clinical awareness. Secondly, effective stakeholder engagement by Medical Affairs can provide a valuable feedback

loop to the organization, enabling evolving stakeholder needs and healthcare outcomes to be considered for further evidence generation and the potential value of the product within the treatment paradigm to be strengthened.

None of what has been described above is new. What is still relatively new and a challenge to many Medical Affairs professionals, however, is that both directions of this two-way communication witness increasing demand from stakeholders to be digitalized to a certain extent. Medical Affairs communication is on an irreversible path towards omnichannel, and no-one is so far mastering effective omnichannel Medical Affairs communication to its full potential. Finding the right way for any individual organization will be a critical task involving both the risks of investing in unattractive offerings and the potential of differentiation as well as effectiveness and efficiency gains in delivering strong scientific value communication.

Regarding communication with stakeholders, Medical Affairs leaders and experts at CapSys recognized three frequent shortcomings that prevent the delivery of an impactful value narrative.

### **Shortcomings preventing delivery of an impactful value narrative**

1. Effectively orchestrating scientific value through omnichannel communication remains a challenge
2. Medical Affairs continues to struggle with digitalization, although this is slowly improving
3. Pharma investment in Medical Education platforms often yield sub-optimal traction due to preference for independent platforms

Considering these prevalent shortcomings and experiences provided by contributing industry experts, Capsys formulated five imperatives for strengthening scientific value communication.

They are centered around understanding what value is for individual stakeholders, effective use of omnichannel communication approaches and the use of cooperations with strategic partners.




#### **Five imperatives for strong scientific value communication**

1. Develop and defend a compelling, up-to-date, science-driven point of view of “best care” across the entire patient journey
2. Clarify the definition of value and consider the variations e.g., by stakeholder or country
3. Ensure our messages are compelling, targeted and aligned with our desired SoC
4. Measure effectiveness and impact of Med Affairs in achieving to “move the SoC needle”
5. Develop the right mindset and digital capabilities to effectively communicate the scientific evidence when and where our customers need it



Figure 5: Imperatives for strong scientific value communication

## **The Re-thinking Medical Affairs series of insights**

This is part two in a series of four insight articles based on CapSys' global *Re-thinking Medical Affairs* study and focused on Medical Affairs Excellence in pharma and life sciences. The first article of the series (part 1) gave an overview of the external trends influencing Medical Affairs

and the main challenges arising from them. Parts 2 and 3 provide key content and insights on the six success requirements for Medical Affairs Excellence. Part 4 provides a framework for a continuous improvement and self-assessment, the Medical Affairs Excellence Canvas

For these *Re-thinking Medical Affairs* series of articles and other upcoming industry insights please visit the Capsys group website under <https://capsysgroup.com/insights/>.

### About the *Re-thinking Medical Affairs* study

The insights for this study were collected through interviews with global and regional industry experts and key opinion leaders in Medical Affairs from large pharmaceutical and life sciences organizations. Contributors had broad therapeutic area expertise, were based in US and Europe and had both global and regional roles and responsibilities.

### Authors

If you want an in-depth discussion on the gathered insights or a conversation on the implications for your company, please get in touch with the authors Kenneth Weissmahr and Patrick E. Koller.



**Kenneth Weissmahr**  
Partner & Managing Director at CapSys Group  
in ✉ [kenneth.weissmahr@capsysgroup.com](mailto:kenneth.weissmahr@capsysgroup.com)



**Patrick E. Koller**  
Principal at CapSys Group  
in ✉ [patrick.koller@capsysgroup.com](mailto:patrick.koller@capsysgroup.com)

### About CapSys

CapSys provides top-tier management consulting support on strategy and execution topics. We are sector experts in Life Sciences and have a unique business model that provides flexibility and reduces risk for clients while maximizing impact.

At CapSys Group, we support our Life Sciences clients to overcome their most difficult growth challenges by:

- Providing strategic advice to unlock growth
- Embedding capabilities to sustain value-adding growth
- Enabling execution and change to activate growth