ELEVATE

The Broadening Role of Medical Affairs

Learnings from a MAPS 2022 Global Annual Meeting Panel

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INTRODUCTION

At the MAPS 2022 Global Annual Meeting, the Medical Strategy Focus Area Working Group (FAWG) presented the panel "the Broadening Role of Medical Affairs," which discussed, among other topics, how organizations have adapted to sweeping changes in Medical Affairs, the role of Medical Affairs in representing the patient voiced throughout the development lifecycle, and how to ensure Medical is represented in the organization's strategy. In Q&A format, this article summarizes key learning from the panel and audience discussion.

HOW HAS MEDICAL AFFAIRS ADAPTED TO THE CHANGE FROM THE OLD SALES FORCE–PHYSICIAN MODEL TO A MODEL OF RELATIVE INDEPENDENCE IN PROVIDING ACCURATE, NONBIASED SCIENTIFIC INFORMATION?

Previously, the organization's sales force and marketing functions communicated the company's scientific data and acted as the primary interaction point for opinion leaders. Increasing regulatory oversight forced organizations to distinguish promotional from scientific messaging, resulting in the Medical Affairs role transitioning from its position within Commercial to a new and independent function based on the dissemination of nonpromotional data. For many organizations, this transition wasn't smooth, resulting in a pause of Continuing Medical Education (CME) activities and delayed Investigator Sponsored Studies (ISSs), with, as one panelist stated, "all the grants sitting in marketing departments." Additionally, the realization that Medical Affairs could offer opinions that Commercial could not provided incentive to leverage Medical, requiring Medical to define and in some cases defend its identity as the voice of truth, ambassadors of patients in the industry, and the gatekeepers of accuracy in data. With increasing treatment complexity including entirely new classes of drugs (e.g., biologics for rheumatology), it became clear that Medical Affairs was also uniquely positioned to own interactions with scientific opinion leaders. In fact, one school of thought felt as if Medical Affairs could replace the salesforce as the main driver of discussions with the medical community and with external stakeholders in general. Instead, Medical now works in parallel with the salesforce in the field, each with its own scientific voice. The useful question is not whether Medical Affairs should replace the salesforce, but what is the right balance and how do we interact with and support each other in gathering insights, understanding the field, communicating in different ways, and the many other activities in which we intersect and overlap.

WHAT IS THE ROLE OF MEDICAL AFFAIRS IN PATIENT ENGAGEMENT?

A panelist shared the experience of monoclonal antibody development to treat patients with mild to moderate COVID-19. Development was streamlined but with the pandemic limiting access to health care professionals, ensuring patients received treatment was challenging. The challenge was compounded by the need to treat early in the progress of disease, by patients' intentional isolation from the healthcare system meant to slow the spread of the pandemic, and by physicians' reluctance to prescribe a drug under emergency authorization without data published through the traditional process of peer review. The result was that while the organization's treatment had the potential to benefit patients, many patients were unaware of its availability and even unaware of monoclonal antibodies as a class.

If the drug had earned FDA approval, direct-to-consumer marketing would have been the remit of Commercial. However, Medical Affairs was best positioned to communicate the possible benefits and risks of this class of emerging treatments. Working closely with regulatory and legal structures and collaboratively with FDA, the company's Medical Affairs organization took the unique approach of educating patients proactively about monoclonal antibodies as a class without specifically mentioning a particular product. . The group ran a commercial during the Oscars. "It was the first educational advertisement direct to consumer on monoclonal antibodies and how you should speak to your physician if you were recently diagnosed with COVID," the panelist said. "It will be interesting to see if Medical Affairs continues to take ownership of those interactions with the consumers and the patients moving forward."

This story illustrates the need for compliant patient engagement in some situations, and the creative solution some organizations are taking to reduce lack of scientific information as a barrier to appropriate use. "If you put the patient at the center of the universe of the healthcare ecosystem, you need to start engaging with the patient," said a panelist.

Panelists suggested partnering early with legal and compliance colleagues to collaborate on planning for patient engagement. "If you just come to the table with a plan, legal and compliance are going to say no, we can't do that," a panelist said. Instead, panelists suggest that by bringing engagement objectives to compliance and legal colleagues early in development, "much can be dealt with, even in our current restricted environment."

HOW HAS THIS EMERGING ROLE IMPACTED THE WAYS MEDICAL AFFAIRS GROUNDS DEVELOPMENT EFFORTS IN PATIENT MEDICAL BENEFIT?

Medical Affairs has the opportunity to influence trial design – even early trial design – by contributing patient-reported outcomes that seek to define not only quantity but quality of life. "Designing trials that measure what really matters to patients is so crucial," a panelist said. Especially in rare diseases there may be no defined, validated outcomes or clear understanding of disease natural history, meaning that clinical and scientific expertise may be less useful than the patient voice in defining meaningful trial endpoints. "Patients are sometimes more informed than some of the HCPs," a panelist said, "and not only are they more informed, they're more empowered through their affiliation with patient advocacy groups. So especially in rare disease,

patients are often our primary stakeholders and we work with them to really figure out where should we be directing our efforts." This reevaluation of what industry measures to determine the "benefit" of emerging treatments has created a shift in language from reporting "clinical outcomes" to working to identify "patient medical benefit." Medical Affairs is central to this effort.

In addition to endpoints, Medical Affairs owns data gap analysis, helping to decide what data the organization needs to make certain claims and how evidence can provide context for the value of a product. "They're going to face the incorporation of endpoints based on the patient experience in phase two and phase three programs, so understanding the patient experience is extremely valuable not only to put patients at the center of our universe, but also because it's essential for development," a panelist said. "It's a change in mindset. Instead of 'I'm going to design a clinical program only for submission and approval,' it's more about 'I'm going to design a clinical program for real-world patient benefit.'"

Much later, Medical Affairs continues to monitor and report on these outcomes important to patients through the use of Real World Evidence (RWE) and post-market studies. "And we continue to measure efficacy, certainly for assets that are developed in a rare or ultra-rare disease space, because even at approval there will be a paucity of data and you will need that longer term efficacy and safety data," a panelist said.

One way to conceptualize this shift is toward Medical Affairs' involvement in drug development is as a natural extension of the function's role in ensuring patient benefit of industry innovations. Traditionally, Medical Affairs sought to provide patient benefit by ensuring healthcare providers make appropriate product selections. Now the function is extending this philosophy to ensure industry develops products that will most benefit patients. "As drugs get more complex and more expensive, we have to make sure we're creating products that are going to help patients live a better life," a panelist said.

An Example of Including the Patient Voice in Drug Development
"We were in a room with patients when developing treatments against inhibitors in hemophilia. At the time, the accepted clinical trial endpoint was the circumference of bleed in joints. And one of the patients got up and said, 'Who cares? Who cares what's the circumference of that bleed? You know, you should be looking at Can I walk? Or am I in a wheelchair for the rest of my life?' From a patient-centricity point of view, we have a lot to learn from patients."

An Example of Failing to Include the Patient Voice in Drug Development
In our trials, we were highlighting key outcomes that we thought were relevant based on the disease state. While engaging patients after the study, we learned that there was not alignment and so we had to then really go back. Through a systematic literature review and burden of disease study, we started noticing some gaps – some of the key patient-reported outcomes were not in alignment with what we thought was important. So involving patients has to really occur on the front end.

HOW HAS INDUSTRY'S TRANSITION TO VALUE- BASED EVIDENCE MODELS AFFECTED MEDICAL AFFAIRS?

Increasing treatment complexity coupled with drugs targeting more defined patient populations can result in higher prices for emerging medications. "It behooves us to have the evidence to show why it's worth that," a panelist said. With Medical Affairs owning evidence generation outside the trials leading to regulatory approval, the function is becoming increasingly responsible for generating evidence that provides context for value decisions. Like involvement in drug development, involvement in value can be seen as an extension of Medical Affairs' traditional role in patient benefit: First, the function sought to ensure appropriate use; second, the function works to ensure appropriate development; and third, the function seeks to ensure appropriate access. And just as Medical Affairs can provide context for Market Access teams working with reimbursement agencies, patients can add their voice in support of increased access. "We find patients can be advocates for the organization when approaching payers, because the payers need to understand what is the patient benefit that they are paying for," a panelist said. Similar can be true of an organization's interactions with governments or regulators. "A patient can really be an advocate at your FDA meeting and at the advisory committee, or even when talking to governments," a panelist said.

HOW CAN MEDICAL AFFAIRS TO MAKE THE CASE FOR EARLY INVOLVEMENT?

When the majority of a drug's development path still lies ahead and there is "no income in sight," as one panelist said, it can be difficult to justify the resources needed for early Medical Affairs involvement. "It's up to us to continue building the case for more resources earlier in development," a panelist said. One way to accomplish this is to message the ability of Medical Affairs to avoid costly delays in the development program. Another idea contributed by panelists was the need for updated incentives for R&D: "If you changed R&D incentives from regulatory approval to what type of patient you can help afterwards, we'd have less resistance early involvement," a panelist said. Similar is true of evolving regulatory perspective: "Regulatory agencies need to start adopting the terminology of patient centricity because what they're looking for are clinical outcomes, but what the patient needs is oftentimes getting overlooked. Reform needs to happen internally and externally to make sure patients actually benefit," a panelist said.

HOW CAN MEDICAL AFFAIRS ENSURE THE ORGANIZATION IS RESPONDING TO THE EXTERNAL ENVIRONMENT?

Medical returns learnings to the organization from the external environment in the form of insights. "If you're frontline and you're hearing from the patient, and you're doing social listening, and you're hearing from the KOLs, then everything you're gathering as Medical Affairs professionals needs to be shared with both Commercial and R&D, and all the other functional areas in order to influence strategy," a panelist said.

For many organizations, it's not insights generation but insights management that is challenging. Mechanisms for sharing insights include collecting all insights in a searchable internal database (e.g., a Sharepoint site), analyzing insights and sharing via quarterly meetings/reports, or even weekly debriefs with important stakeholders.

"If you have 30-page report from the field, a 30-page report from every conference, who has time to read that? So stop the volume. Don't just share 100 insights but do the work and say, 'Hey, we believe these actions could result from these insights," a panelist said. If possible, include insight-driven actions in the annual planning cycle, which can formalize how important insights from the previous quarter can drive future strategic decisions. That said, the impact of insights may also be felt in real time. "If an insight confirms or highlights an obvious theme, don't wait until the end of the year to take action for the next year. Agile learning and agile adaptation of your strategies throughout the year can be as important as including insights in strategic planning," a panelist said.

When insights result in action, it can be important to message these results internally: "A really important part of insights is showing feedback to those MSLs and Medical people what happened with what they brought in. They need to be motivated to see what was turned into action. If you leave that part out, after a while they're going to lose interest."

WHAT IS THE ROLE OF MEDICAL AFFAIRS AS A BUSINESS LEADER WITHIN THE ORGANIZATION?

Medical Affairs professionals are generally medical and scientific experts and not trained business leaders. One challenge as the function continues to mature is bridging the gap between scientific/clinical expertise and business acumen. Panelists pointed out that while Commercial colleagues generally receive internal training in therapeutic area science, Medical Affairs professionals generally do not receive training in business functions. One remedy for many Medical Affairs professionals seeking leadership roles has been to pay out-of-pocket for MBA programs. However, panelists pointed out that yearly performance evaluations tend to include individual development planning, which may present opportunity for business training. Likewise, business training may be a negotiated addition to a hiring package when joining a new company. Informally, panelists mentioned the power of taking time to speak with commercial colleagues.

Business acumen can help to ensure Medical has a seat at the table for essential activities including brand planning. "When you have a Medical strategy versus a Commercial strategy, you end up in different places," Of course, co-development of the brand plan presents requires careful consideration to ensure the continued independence of Medical. However, panelists pointed out that Medical/Commercial collaboration at the strategic planning level can be accomplished compliantly, and it is at the executional, tactical level that separation occurs. "But without working strategically together from the get-go, I haven't seen a lot of successes," a panelist said.

CONCLUSIONS

From its genesis in data dissemination and HCP/KOL engagement, Medical Affairs has broadened its role into aspects of clinical trial design and business strategy. These activities allow Medical Affairs to infuse its focus on patient centricity into the organization's actions from the earliest phases of development through the period long after approval. By putting external insights and the patient voice at the center of the pharmaceutical and MedTech universe, Medical Affairs is playing an increasingly essential role in ensuring societal benefit from industry innovation.


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