ENVISION PHARMA GROUP

Bridging the gap: How medical affairs is reshaping the future of clinical and commercial success

Roundtable discussion summary | MAPS Americas – March 2024

MAPS Americas 2024 Puerto Rico MARCH 24-27

Contributors

- Javier Coindreau, Aurinia Pharmaceuticals
- Danie du Plessis, Kyowa Kirin
- Randi Kline, Teva Pharmaceuticals
- Sagar Shah, Pfizer
- Robin Winter-Sperry, Pfizer
- Eric Zhao, Black Diamond Therapeutics

Facilitators

- Angus Bromley and Dominic Marasco, Envision Pharma Group

Discussion summary

In March 2024, Envision Pharma Group held a Medical Affairs Professional Society (MAPS) Americas Roundtable where leaders engaged in direct discussions to recalibrate the role of science in commercialization strategies. They addressed the critical importance of integrating robust scientific understanding into the commercial journey, pinpointing the need for medical affairs to take the helm in defining and communicating the commercial value of healthcare innovations.

The increasing focus on specialized clinical value is compelling companies to meet evolving market needs in the commercialization process, including:

- **Communicating deep scientific value**: Articulating the complex science behind new therapies is now fundamental in demonstrating product worth to stakeholders
- **Early payer engagement**: Initiating dialogue with payers early is essential to shape the clinical narrative and communication strategy that resonates with payer requirements
- **Clinical trial design advisory**: Providing expert guidance on clinical trial design ensures products are well positioned to meet payer expectations right from the development stage
- **Bridging medical affairs and value access**: Acting as a strategic conduit between medical affairs and market access teams to streamline the journey from product development to patient delivery

In the context of an ever-greater emphasis on science within the realm of commercialization, medical affairs leaders are stepping up to assume new levels of responsibility. The roundtable served as a critical platform for leaders to engage through the lens of practical, on-the-ground experience – aimed at gaining a clear understanding of the collective viewpoint on the evolving role of medical affairs and fostering a productive exchange on current challenges and barriers.

Early involvement of medical affairs and standardization are advancing commercialization, but there's still room to grow

Medical affairs is stepping into the commercialization process earlier than ever, but standardization is lagging, signaling a clear need for progress. It is widely acknowledged that navigating the path to payer engagement demands decisive strategic support from medical affairs, alongside firm commitment and leadership. Practical application and astute resource management are non-negotiable, missteps here can lead to substantial setbacks, as evidenced by a significant delay due to a misjudged patient population in an early phase trial scoped by a contract research organization (CRO).

To that point, medical affairs is well positioned to support clinical trial site selection and capabilities assessment through their relationships with primary investigators, nurse practitioners, or allied healthcare professionals. These functions afford medical affairs a unique view into potential barriers and capabilities.

Collectively, the clinical trial process should be accomplished as a triad between medical affairs, clinical development, and the CRO to ensure appropriate swim lanes. This type of collaboration helps mitigate enrollment and milestone issues, resulting in a profound time-to-commercialization impact.

We have seen the immense benefits of forging a healthy partnership between medical affairs, value and access, and commercial functions early in phase 2. This collaboration is proving crucial, not just for successful commercialization but for advancing the overarching strategic approach, for example, in the implementation of a durable omnichannel strategy.

Smart organizations understand that failure to align with the medical affairs function can introduce huge risks, leading to invalidated trial designs, work delays, and financial implications – but agility is key. This may explain why small/emerging organizations appear to be adopting a medical affairs mindset more quickly.

A robust and well-coordinated understanding of the therapeutic domain and broader landscape can serve as the foundation for crafting a launch strategy. This entails creating a comprehensive product launch plan that integrates both commercial and medical perspectives, encompassing a wide array of tactics (including traditional commercial strategies) that set the stage for a successful launch.

Addressing the challenges and stiff-arming barriers

Despite its recognized value, integrating medical affairs into the commercialization process faces several barriers, including organizational silos, outdated perceptions of the role of medical affairs, the lack of free-flowing ideas, and resource constraints. Because budget allocations have not caught up with the demand placed on medical affairs teams, they are doing more with less.

Facing these limitations, medical affairs can turn to technology to drive efficiency and cut costs. The adoption of AI and digital tools allows for a strategic reduction in spending on areas like advisory boards and key opinion leader contracts, while also enhancing the caliber of insights collected, enabling a sharper focus on strategic decision-making.

As the healthcare landscape evolves, so does the need for adaptive change within organizations. Effective change management is critical, requiring strong leadership to marshal the necessary support and resources for what ultimately serves the best interest of patients. This is particularly true in larger, more complex organizational structures, where the need for a systematic approach to change is even more pressing. Also, compliance teams should engage as partners and seek to understand the broader view of the patient.

The call for medical affairs leaders to broaden their skillsets and capabilities to match the expanding scope of their roles, demands that they strip away older notions of sales and marketing accountability and embrace a shared expectation that includes strategic thinking, digital engagement, and evidence generation.

When medical affairs has a prominent seat at the table, patients benefit and organizations achieve better outcomes

Putting medical affairs at the forefront means organizations are better positioned to use resources for meaningful outcomes. Being effective in this area comes down to understanding business and science, in fact, the business **of** science. Speaking both languages credibly increases the value and impact of medical affairs inside as well as outside the organization. Furthermore, medical affairs professionals have the opportunity to inspire and engage cross-functional partners by effectively conveying the clinical applications of science, ultimately benefiting patients.

Medical affairs professionals often face the challenge of "staying in their lane," a notion that can lead to discomfort and demotivation. The resistance, influenced by the level of personal experience and organizational mindset toward functional roles, highlights the need for these cross-functional relationships and ensuring access to proper training. Medical affairs must embrace its leadership role in safeguarding patient outcomes, adhering to the ethos that the patient's welfare is non-negotiable.

Discussions indicate that in smaller or emerging organizations, a commercially astute Chief Medical Officer can significantly influence strategy. Such leaders are well-positioned to craft and execute launch strategies grounded in a thorough understanding of the therapeutic landscape, driving both the development and commercial tactics necessary for a successful product introduction.