Maximizing the Value of Medical Affairs in TODAY'S CHANGING ENVIRONMENT

This is truly an exciting time for our colleagues in medical affairs. Following two to three years of shifts in responsibilities and funding for projects, it is now time to reassess the possibilities. The whole of medical affairs is positioned to become a designing factor in the future of compound development, scientific communications and improved patient care.

Running the Table

Increased numbers of Corporate Integrity Agreements, public scrutiny, and pharma's own thoughtful examination have led to a reorganization of how the science is communicated throughout the product lifecycle. It used to be that medical affairs sat at the commercial table as an eminent information source focused on assuring the integrity of data that would mostly be communicated through some commercially related effort.

The table now belongs to medical affairs. Commercial brand team members participate but are in no way expected or empowered to communicate the critical data elements that will genetically mark the future of a given compound. This responsibility is now firmly within the auspices of medical affairs. As a group, they are challenged to find ways to build science in a way that meets the clinical needs of the HCP and patient.

> Medical affairs is the great triangulator, bringing to together clinical development, publication planning, and commercialization.

This challenge requires medical affairs to identify the proper talent and build a structure that supports a synchronization of efforts among clinical development, medical affairs and data dissemination or publication functions. Medical affairs is well-suited to nurture the efforts of this triad because many in its ranks are scientists themselves and as professionals they have gravitated to a discipline that requires the ability to translate the science to clinical need. Medical affairs can oversee the product to maturity by providing the benefits of ongoing needs assessment, beginning with investigators and clinicians early in the lifecyle. It can facilitate the connection between internal and external stakeholders critical to needs based on clinical trial design and the promise of the compound.

Medical Affairs Based in Science

Indeed, medical affairs has all the tools to catapult the science backing up the compound into the limelight it deserves. Medical affairs is firmly rooted in scientific evidence and uniquely able to drive R&D efforts toward innovative solutions. They can help early-stage molecules evolve as more effective, clinically meaningful assets through thoughtful clinical trial design; label optimization; strategic, robust and timely dissemination of data; and early communication of essential supportive educational concepts for HCPs. Such activities also inform the economic and health outcome rationales critical to the compound's value story at time of commercialization.

Consider for a moment medical affairs as the great "triangulator."

Medical affairs has an opportunity to foresee the evidence needs of each product and proactively recommend appropriate studies early in the development process. They are able to bring together the power of clinical development to prove new and exciting compounds, the ability of publication management to disseminate "needs-based" data/information, and the commercial desire to best position the product for future sales potential.

If you look at it this way, it's easy to see how well-suited medical affairs is to be an innovative force in pharma.

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An Innovative Force

Medical affairs can ensure innovation by applying the following approaches.

Identify and follow a methodology for creating a clear and conistent platform. Medical affairs is in an ideal position to "triangulate" the science of the brand with the reality of the clinical marketplace and the development goals of the organization. They can facilitate and oversee the 360-degree development and coordination of scientific communications for the compound and the future brand. It makes sense that medical affairs should own and orchestrate the scientific platform development process.

Clients work to examine the compound data against the needs of the clinical marketplace to build a uniquely "ownable" scientific position for the compound. The platform must be articulated in language that is evocative and differentiating, as well as sustainable from development phase through point of commercialization. It is the single roadmap that clearly

demonstrates what the compound has to offer and how all involved in the development could and should articulate its scientific characteristics and benefits.

Bringing alignment among internal partners is crucial, assuring that the methodology is purposely pulled through. Alignment tasks include organization of the data, research, and input from all stakeholders. Failing to gain alignment will weaken the usefulness of the scientific platform. Agnostically aligning the parties accentuates ownership across all stakeholders and heightens the value of the resulting approach.

Medical affairs embodies the characteristics of the maestro and orchestra. In the end, success is about the efforts of real people with a deep passion for doing the right thing and advancing science to benefit patients.

Inform the science through real-world insights. Medical affairs is faced with opportunity to harness the power of insight and build strong alliances early in the compound development to support the evolution of appropriate data dissemination plans. Investigators and opinion leaders can be tapped for insights both in formal settings such as advisory boards, and in information one-on-one congress activities. As part of its remit, medical affairs will need to gain feedback from clinicians to nurture the development of the platform and core content. These efforts can also be enhanced to include key educators.

The ongoing discipline of interacting with investigators goes beyond gaining study data and becomes incredibly useful to identify potential issues with the utility of the compound. As the keeper of the scientific platform, medical affairs is the ideal group to monitor the clinical perceptions that result from the practical deployment of the clinical development plan and studies.

In the end, anything medical affairs can do to deliver a fully vetted scientific portfolio, including the potential clinical challenges, will be most appreciated by the commercial colleagues.

Venturing beyond the investigator to other opinion leaders has historically been part of the commercial responsibility. Now that there are more stringent rules about how opinion leaders may be engaged in premarket activities, medical affairs is poised to fill in the gap. Medical affairs organizes interactions that allow for information exchange among non-investigator opinion leaders about how to translate the science to clinical reality. Waiting until early commercialization to elucidate these challenges is dangerous and expensive.

So for example, imagine that you have a compound that will require a shift in dosing and administration that will run counter to the gold standard at the time of launch. Ignoring the potential impact of this and focusing only on "at all cost" protocol pull-through will result in a less than desirable outcome in practice. Understanding the perspective of the opinion leader practitioners in the context of the new dosing/administration approach and integrating that input with the experience of the investigators will enhance the development and early communication plan for the brand to be.

Find ways to give the science a voice. Assuming that language is the vessel for all understanding, creating a language that best communicates the compound's potential will make the difference between achieving improved patient outcomes and missing the clinical promise for the brand.

Medical affairs is well-equipped to manage the development and evolution of the compound's scientific and clinical language. They are able to connect the "nuts-and-bolts" of the clinical protocol with the trial expectations and employ a discipline that will distill the very best way for talking about the science and eventually the brand. The more explicit the language explaining the compound and how it works or its expected results in trial, the more deeply rooted the understanding of both external and internal stakeholders and eventually future HCPs and patients.

Whether an agent targets or selects can be vastly differentiating or confusing depending on the body of data available to support the claim and how the clinicians interpret the treatment landscape. Medical affairs can be responsible for achieving a precise lexical environment for the compound that can then be further developed by the brand marketers at commercialization.

Connect, connect, and reconnect. The scientific platform, lexical development and opinion leader insight-mining exercises described above are perfect ways for medical affairs to integrate the discipline of clinical development with data dissemination in publications and at congresses.

First, a main output of the scientific platform is a comprehensive library of scientific rationale, communication points and supporting evidence. This library is a strong framework and resource for publication managers developing and executing on a dissemination plan. Medical affairs can work closely with publication management to guide the use of appropriate data and assure consistency of language between the scientific platform and how the publications articulate the details of the science and the clinical promise. Without this guidance from medical affairs, data dissemination projects could become disjointed and create the very type of inconsistent communication that the platform and language analysis is built to avoid.

Talent for an Evolving Task

In the end, success is about the efforts of real people with a deep passion for doing the right thing and advancing science to benefit patients. Medical affairs embodies the characteristics of the maestro and orchestra. Achieving this balance is critical to maintaining order for the greater good, alignment for efficiency and creating a vision that is actionable. As you may be thinking, these traits are not conferred by an MD or PhD degree.

There is no arguing that the degree, training and experience are a minimum price for entry into this exciting new world. The distinguishing characteristics of scientific acumen, a collaborative nature, and the ability to apply innovative approaches and tools to create an "ownable" space for a given compound will bring order and vision to this new medical affairs universe. PV

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