In Vivo
Pharma intelligence | informa

Moving Medical Affairs To The Pharma Forefront

In Vivo
Pharma intelligence | informa

Moving Medical Affairs To The Pharma Forefront

By Priya Chandran, Ethan Dabbs, Jennifer Fortune, Paul-Alexis Kebabtchieff and Hoan Ly

- The fast-evolving health care landscape is lifting the importance of medical affairs at biopharma companies, necessitating leaders to rethink the capabilities, talent, metrics, and focus they bring to their jobs.
- As a number of high-impact trends accelerate in the coming years, the opportunity for medical affairs functions to play a more active and influential role both internally and externally will increase.
- ***So what?*** In Vivo explores the overarching themes and questions from a roundtable discussion among senior medical affairs leaders from 14 top biopharma companies. The session was facilitated by The Boston Consulting Group and supported by surveys and interviews with larger groups of medical affairs leaders and professionals.

Medical affairs has the medical and scientific knowledge that pharma companies need as well as the direct relationships with health care practitioners (HCPs), key opinion leaders and other important stakeholders. But most medical affairs departments are challenged, both organizationally and from a capability perspective, to systematically take on expanded responsibilities in areas such as clinical trial design, patient recruitment, health economics and outcomes research (HEOR), and patient engagement. These responsibilities are particularly challenging as they require cooperation with an expanded set of stakeholders.

There was broad consensus among roundtable participants that the medical affairs function has evolved beyond its traditional role that primarily focused on engaging key opinion leaders to drive clinical practice and support patient safety. Survey data from The Boston Consulting Group (BCG) reveals that this evolution is still underway. Only 57% of survey respondents said their broader organizations fully understood the value proposition and potential of medical affairs today. There is also recognition of the function's current shortcomings. Respondents representing almost 60% of the companies surveyed said that the medical affairs functions of both their organizations and other major pharmaceutical companies were far from where they need to be in five years' time.

Roundtable members cited four principal areas in which medical affairs was making an increasing impact:

Contextualization of insights. As digitally generated data continues to play a larger role in all stages of the pharma value chain – from R&D to monitoring post-approval patient experience and outcomes – medical affairs is in a strong position to combine data with scientific and technical expertise to generate insights that inform key decision makers inside and outside the company to help shape the design and use of products for optimal outcomes. In this context, medical affairs also plays a critical role in understanding the diverse and evolving standards of care across markets and can help ensure that gaps in evidence are identified early and contextualized for specific ecosystems.

Informing and advancing clinical practice. Using company and industry data and personal judgment, medical affairs professionals are well positioned to interact with HCPs and help identify improvements in standards of care.

Advancing patient care and engagement. Pharma is fast becoming a more patient-centric industry. Medical affairs already engages with a wide variety of external stakeholders and can play a key role in coordinating the patient approach to better serve patient needs. This starts early in the development process in the design of more patient-centric trials and includes driving patient

engagement and experience post-launch to support better outcomes. As the pharma industry moves toward greater use of digital biomarkers, remote patient monitoring, and smart devices, among other advances, the ability to bridge the needs of patients, clinical trials, HCPs, and health systems will become crucial. (Doing so, however, requires clarity in understanding the direct responsibilities of medical affairs and other functions with respect to patient interaction.)

Building trust and credibility externally. Medical affairs can play a key role in engaging broad sets of external stakeholders to support initiatives that demonstrate the industry's commitment to better patient outcomes and enhanced clinical practice. These include disease level initiatives and patient and care-giver support as well as other initiatives that support broader access and appropriate use of medicines globally.

The roundtable participants were also highly aligned on the most important trends shaping this evolving role. There was overwhelming agreement that the confluence of more data and analytical advances and the need for better demonstration of value and improved affordability were driving changes in industry structure and the role of key influencers. Medical affairs has the opportunity to address the shift toward outcomes and value demonstration in two ways. It can act as a bridge between the R&D and commercial functions to ensure that the full organizational focus always centers on patient outcomes. And it can help meet rising demand for demonstration of outcomes by generating post-approval real-world evidence (RWE).

In addition, as patients play a more active role in determining treatment decisions and outcomes, and complexity in access and reimbursement increases, medical affairs should also lead the effort in communicating value to external stakeholders. Medical affairs needs to engage with payers, through health technology assessments and other vehicles, on the value of medicines. HCPs are demanding more specialized interactions (with medical science liaisons over sales reps, for example); medical affairs will play a more active role in shaping policy and prescribing behaviors. Medical affairs is also in an advantaged position act as the voice of the patient at a time when the reputation of, and trust in, the pharma industry is often called into question.

Organization And Resourcing

From their position as integrators, medical affairs leaders need to assess which areas they participate in, and which they should fully own or lead, in order to make explicit the value they bring to the table. These decisions will present some companies with organizational and resourcing questions.

While the organizational anchoring of medical affairs today skews towards R&D, it is clear from both the roundtable and survey results there is no "one size fits all" approach (*see Exhibit 1*).

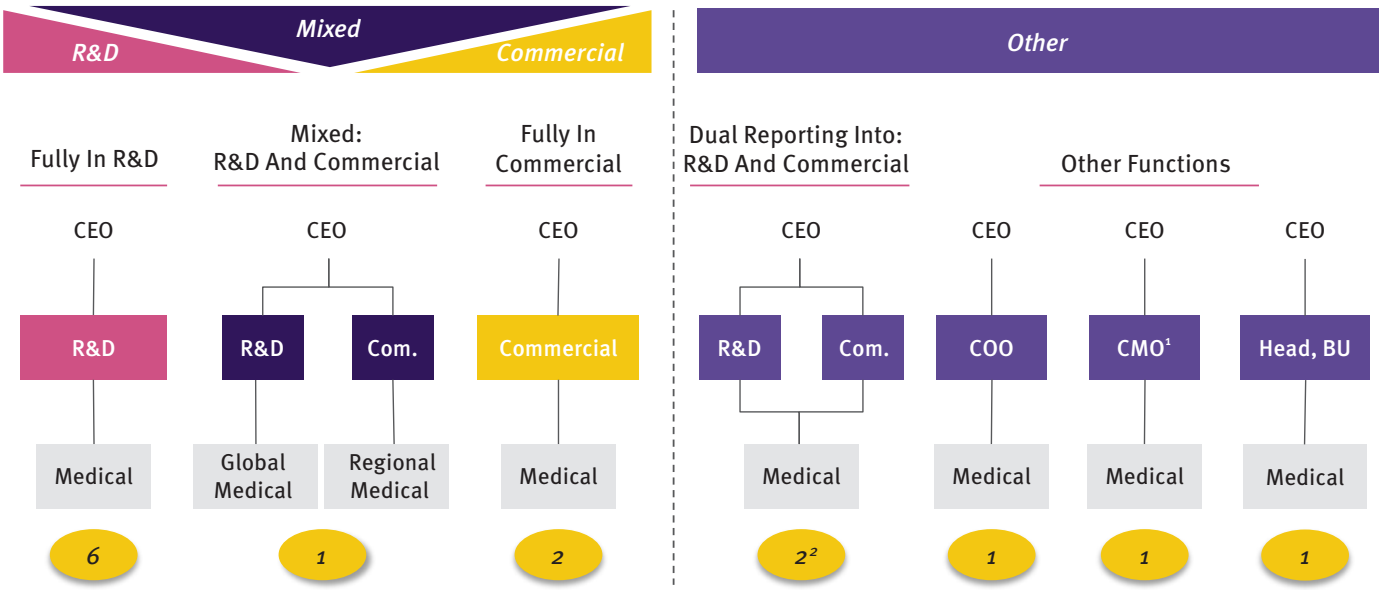
Indeed, roundtable participants offered arguments for the various options:

- anchoring medical affairs in the R&D organization, "Being close to R&D is critical... We can have a very deep understanding across the drug development process... we can provide input into clinical plan."
- anchoring in the commercial function, "Working within the business provides us to with the ability to coordinate faster in the field... we have the perspective of medical, HEOR and more traditional business [perspective] as well."
- and both, "We need to forge the relationship [between] R&D, medical affairs, [and] the business [to] bring and gather insights to develop drug[s] that will have an outcome that really matters and [will] get reimbursement."

Global, regional, and local roles were consistent across companies, with key global interactions (such as R&D and therapeutic area strategy) mostly owned by the global medical affairs function, while activities with a customer facing component (such as data generation and key opinion leader and payer engagement) are housed across all levels. Relatively few activities seem to be fully owned or driven at the regional level as many organizations have deliberately thinned out the regional layers.

Exhibit 1. No "One Size Fits All" Model For Medical Affairs Reporting And StructureSource: Boston Consulting Group

Reporting Of Medical Affairs Organizations



1. CMO = Chief Medical Officer; 2.Includes both direct and dotted line reporting
# of companies N = 14 companies

Source: Boston Consulting Group

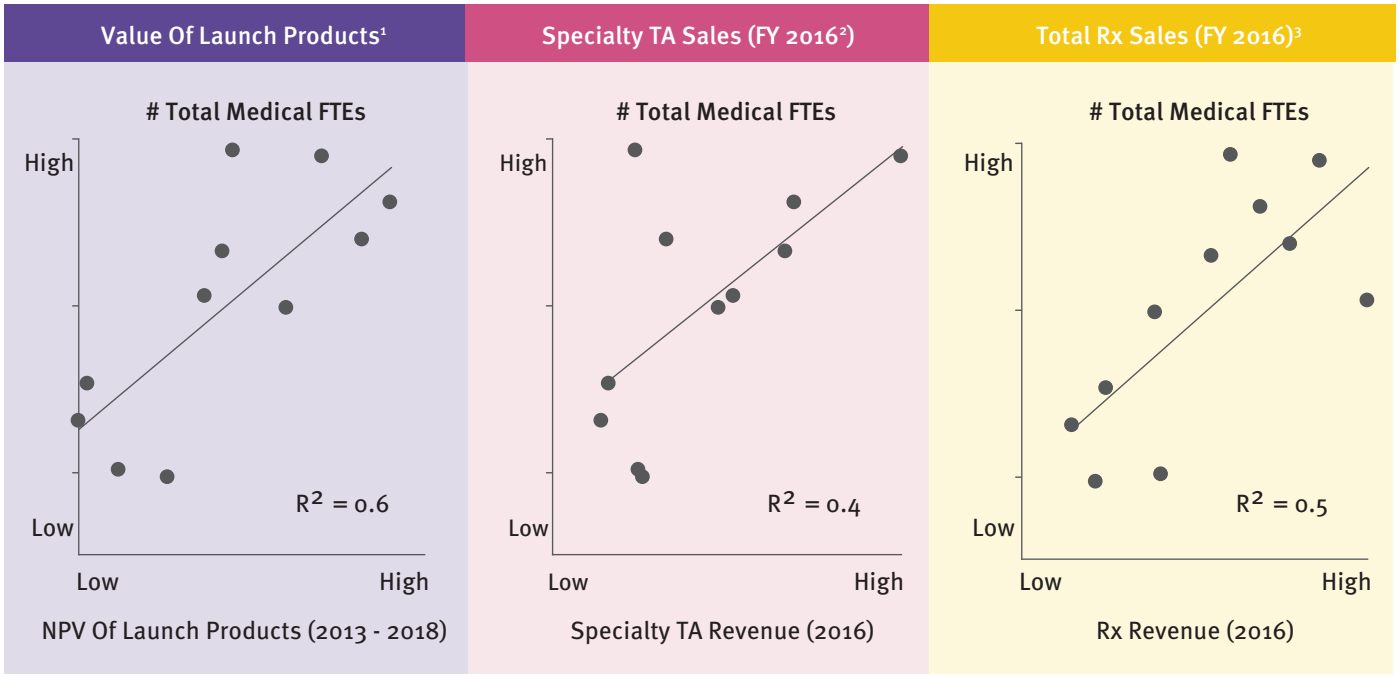
Organizational alignment typically trails the rising importance that medical affairs professionals put on emerging responsibilities such as patient and payer engagement. For some organizations these have become critical strategic priorities. There is rising recognition of the opportunity for medical affairs to advance these topics, but few organizations have given the function a clear mandate (either exclusively or in well-defined partnership with other functions). Medical affairs' involvement in areas such as driving diagnostics and engaging in real-world evidence also varies by company. This is also true for HEOR. In some organizations medical affairs controls HEOR, at least at the global level, while in others it has limited HEOR capabilities either at the global or field level. In most organizations the relationship between medical affairs and HEOR is still evolving.

Trends around medical affairs resourcing paint a varied picture. As can be expected, allocation of resources, in terms of both budget and FTEs, differs significantly along geographies and sub-functions (though a majority of FTEs were dedicated at the local level) as well as across companies. That said, medical affairs resourcing largely does correlate with the value of drugs and specialty revenue (*see Exhibit 2*). In the background of otherwise declining R&D and commercial budgets, resourcing for medical affairs has increased modestly – an average of about 5% – over the last few years, with the key stated barrier to greater resource allocation being clear articulation and demonstration of value.

The top priority for medical affairs functions in the near term is to build their capabilities to meet the evolving demands of their companies. There are three steps that medical affairs leaders should take to accelerate their impact and realize the full potential of the function:

1. Double down investments in skills and capabilities key to future leadership. Twocapabilities will substantially determine the extent to which medical affairs departments can meet evolving demands: digital en-

Exhibit 2. FTE Resourcing Correlates With Value Of Launch Products, Therapeutic Area Revenue And Total Sales



1. First launched (WW) between 2013 and 2018. 2. Specialty includes the following TAs: blood, cardiovascular, central nervous system, dermatology, endocrine, GI, urinary, musculoskeletal, immunomodulators, oncology, sensory organs, systemic anti-infectives. 3. Total sales include prescription (Rx) only. Correlation between specialty sales and FTEs does not take into account primary care mix. N = 11 companies.

Source: Boston Consulting Group

gagement and patient centricity. While companies have made significant investment in digital engagement in recent years, many need to do more. Companies need both data experts and medical scientists who together can vet the rising volume of available data to accurately gauge the value of medicines and support the generation of RWE to demonstrate treatment success and system impacts. Investments in digital engagement in customer-facing functions also need to continue.

Medical affairs must play a leadership role in driving a company's focus on patient centricity – approaching patients as engaged consumers of health care services rather than simple recipients of treatment – as patients' involvement in their own treatments continues to deepen and expand. This is an area that has been discussed for decades but has yet to be fully addressed by the industry. Patient centricity is no longer driven by patient engagement programs post-launch. It should start much earlier and include designing patient-centric clinical trials, understanding the varying needs of patient segments and differing patient journeys, the use of digital tools for monitoring, and collaborating with patients/former patients who have morphed into key influencers or key patient leaders.

2. Invest in talent and expand the scope of the possible. Developing broader medical affairs capabilities means gaining access to wider set of talent pools. Companies need to raise their recruiting and marketing game at colleges and universities to attract people with business acumen and digital skills as well as scientific knowledge. There is also a growing need for more diverse clinical roles, beyond MDs, including nurse practitioners, and other medical and clinical professionals, to address unmet patient needs and drive patient engagement. Even among MDs, the need for a greater diversification means medical affairs must source from beyond peer companies and adjacent functions to target high-quality post-residency fellowship programs and invest in developing professionals with evolving capabilities. In addition, more medical affairs professionals

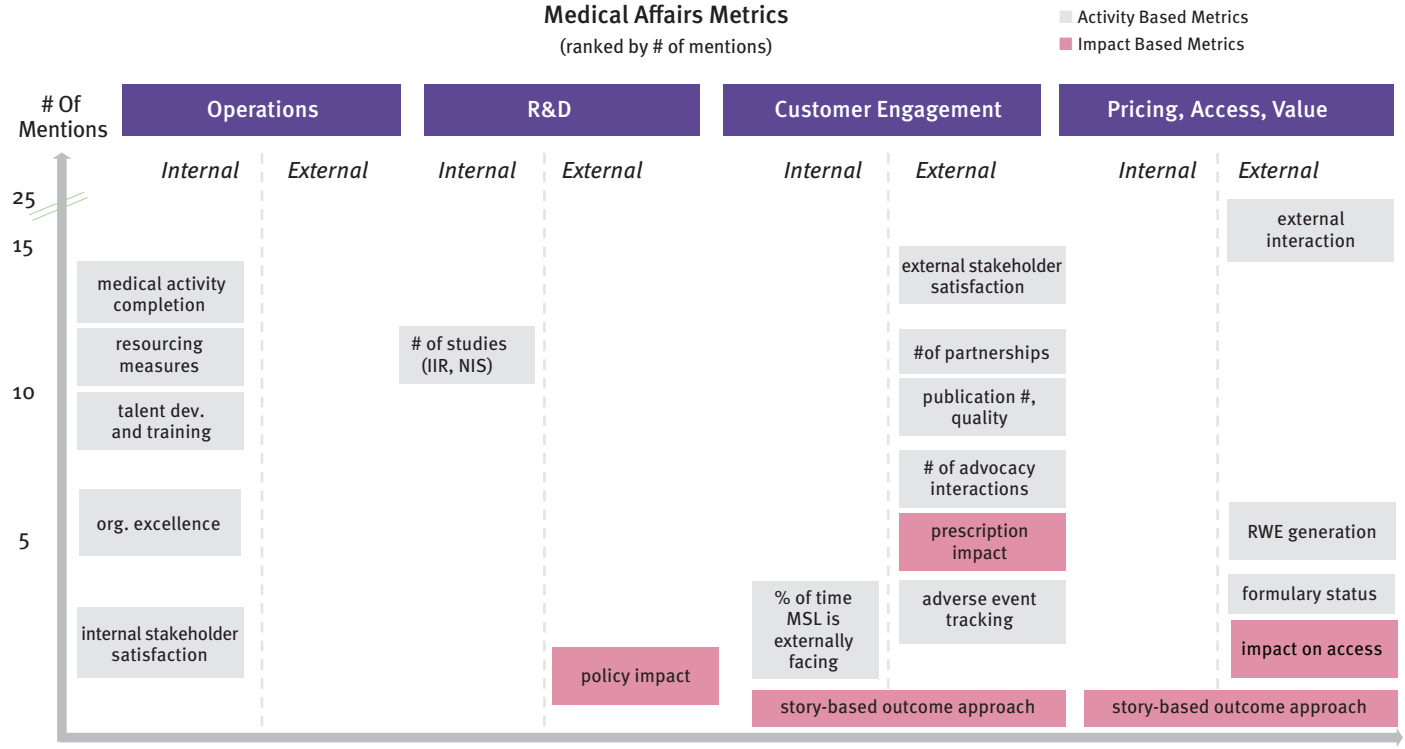
that combine clinical and data science expertise will be in great demand. Future skillsets must emphasize both strategic, digital and operational capabilities, balancing so-called "soft skills" such as communication and collaboration with technical and scientific expertise.

Developing the next generation of talent will also require changes in how companies manage their HR approaches, from recruiting through career path development. Medical affairs functions are faced with many hurdles in attracting talent, the foremost of which today revolves around expanding the talent pipeline to "get more MDs" into the profession." To meet these evolving needs and talent pools, companies must provide more adaptive and non-linear career paths. They will be required to flex their models and let their employees benefit from a richer set of experiences, even if these experiences are outside of medical affairs, especially such areas as patient access, key account management, development, and data science.

3. Develop the metrics that demonstrate value. Most organizations today still focus on metrics that track activities rather than impact.

As it seeks to expand its role and compete with other functions for resources and investment, there is an urgent need for medical affairs to demonstrate its value through more informative measurement of the results it achieves, while of course maintaining appropriate compliance guardrails. These metrics should include both internal and external components, with a focus on reflecting the value for customers, including HCPs and patients. Highlighting the outcomes that medical affairs has contributed to and driven, rather than the activities completed, should be a priority, and care needs to be given to include results that medical affairs has contributed to but does not fully own. Several proxy metrics exist that can compliantly measure medical affairs' contribution to such goals as market access achieved, inclusion in national guidelines and medical societies'

Exhibit 3. Impact-Based Metrics Are Rare Across The Industry



Source: Boston Consulting Group

recommendations, contributions to a company's own portfolio decisions and development of patient-reported outcomes. They can also help assess insights gathered by medical affairs on evolving issues such as site of care and patient needs. The value that medical affairs brings can be articulated in multiple approaches, including qualitative (value stories and narratives), and quantitative (inputs, outputs, and outcomes; *see Exhibit 3*).

The Task Ahead

In summary, there is a lot to do. The roundtable discussion indicates that medical affairs leaders are clear-eyed on the task ahead. They will need the engagement and support of their senior management colleagues in defining an expanded role that meets the needs of their companies and the changing marketplace. They will also need support in developing the capabilities necessary to take on new responsibilities. The pace of change in health care will not slow. The challenge for medical affairs to demonstrate its potential is urgent.

BCG Medical Affairs Roundtable Members:

- Heather Abourjaily, Senior Director, Global Head of Scientific Communications, Biogen
- Ajay Ahuja, Global Head of Medical Affairs, Allergan
- Niko Andre, Head Global Medical Affairs, Roche
- John Berg, Corporate VP, Corporate Medical Affairs, Celgene
- Priya Chandran, Senior Partner and Managing Director, The Boston Consulting Group
- Ethan Dabbs, Partner and Managing Director, The Boston Consulting Group
- Danie du Plessis, SVP Head Worldwide Medical Affairs, GlaxoSmithKline
- Fiona Dunbar, VP Global Medical Affairs, Janssen
- Sven Fraterman, Principal, The Boston Consulting Group
- Andrew Greenspan, VP Medical Affairs Immunology US, Janssen
- Judianne Hare, VP Medical Capabilities, Medical Affairs, Bristol-Myers Squibb
- Christophe Hotermans VP Global Therapeutic Areas, Biogen
- Michael Kavanaugh, Executive Director, Clinical Development and Medical Affairs Effectiveness and Scientific Communications, Boehringer Ingelheim
- Marcia Kayath, Head US Clinical Development and Medical Affairs Head, Novartis
- Paul-Alexis Kebabtchieff, Principal, The Boston Consulting Group
- Charlotte Kremer Executive VP Medical Affairs, Astellas
- Janet Loesberg Head of Intercon Medical, Bristol-Myers Squibb
- Michael Norton, VP US Medical Affairs, Abbvie
- Rory O'Connor, Chief Medical Officer Internal Medicine Medical Affairs, Pfizer
- Peter Piliero, Associate VP Global Medical Information Global Medical Affairs, Merck
- Maria Rivas, Senior VP Global Medical Affairs, Merck
- Jit Saini, Senior VP Global Chief of Staff, Head of the Strategy Realization Office; EMD Serono
- Thomas Seck, VP Clinical Development and Medical Affairs Primary Care, Boehringer Ingelheim
- Vaidyanathan Srikant, Partner and Managing Director, The Boston Consulting Group
- Stephanie Visioli, Head of Medical Affairs Operations & Compliance, Novartis

The opinions expressed in this article are solely those of the authors and do not represent the positions of the organizations they are a part of.