

# Reimagining Medical Affairs: Creating Value as Stakeholders, Commercial Models, and Therapies Evolve



## Introduction

This white paper discusses the evolution of medical affairs from a nascent function aimed primarily at educating healthcare professionals on the science behind life sciences products, to an integrated business unit engaged in two-way relationship building with a growing number of stakeholders. As the sophistication of medical affairs grows, the department's foundation of business processes and technology solutions must also change – enabling medical affairs to meaningfully grow life sciences business. This paper outlines a path towards a medical affairs organization that delivers focused clinical, social, and economic value throughout the product lifecycle.

## The evolution of medical affairs to a core business function

It was nearly half a century ago, in 1967, that the Upjohn Co. coined the term “medical affairs.” Bridging the gap between the commercial and R&D arms of life sciences organizations, medical affairs is critical in the deployment of therapeutic interventions that improve patient outcomes and deliver health system efficiencies.

The importance of medical affairs has grown dramatically over the past several years, due in part to increasing restrictions on commercial contact with physicians including PHRMA guidelines, released in 2009, and the Sunshine Act, which took effect in 2013. In fact, just 47% of physicians in the U.S. are now accessible by pharma sales reps, and the numbers decline sharply when looking at the most specialized practices. Among oncologists and nephrologists, the most highly restricted specialties, only 27% and 19% of physicians are fully accessible to reps, respectively<sup>1</sup>. Areas like this, where acute clinical and academic knowledge is needed, are where medical affairs is ideally suited to deliver its expertise.

Another growth driver of medical affairs has been the patent expiry of many blockbuster primary care drugs, and the subsequent focus on more complex specialty drugs. For instance, last year 24% of new FDA approvals were for biologics, and the industry is expected to spend \$400B on specialty drugs by 2020<sup>2</sup>.

Meanwhile, more than 450 compounds to treat rare diseases are currently in development<sup>3</sup>. Life sciences companies have come to rely on medical affairs to offer increasing depth of knowledge on these specialty treatments to gain credibility with healthcare professionals.

But recent changes in the healthcare landscape require medical affairs to adopt an even more strategic position. No longer focused on solely providing clinical and communications support throughout the product lifecycle, medical affairs must now deliver powerful insights focused on true product differentiation. And as the number and type of stakeholders grows – with diverse players spanning from patient advocacy groups to financial decision-makers for large health systems – medical affairs must create new tailored messages and personalized relationships.

To respond to these changes, life sciences companies are increasing their medical affairs investments. For example, 60% of life sciences firms planned to increase their medical affairs budgets in 2015, with half of those surveyed expecting to grow budgets by 10% or more<sup>4</sup>. But companies need to be strategic about how they allocate resources to ensure the greatest return on investment.

## Navigating the new stakeholder network

While the remit of medical affairs has recently grown in both depth and breadth, the underlying business processes and technological tools have not kept up with new demands. The industry must recognize and address organizational roadblocks to successfully adapt to a changing medical model.

The shift towards specialty drugs demands the delivery of complex information on indications, dosing, adverse events, and other factors to guide decision-making and optimize patient outcomes. One challenge is that this content is often difficult to access and stored across a wide range of disconnected tools, creating fragmented and limited points of view. Additionally, these systems are not harmonized with the commercial and R&D functions in mind. By limiting accuracy, collaboration, and innovation, these silos create problems that can impact product messaging, marketplace position, or patient usage. Without a single source of truth for medical affairs content, messages may be inconsistent across channels or geographies. Additionally, teams may miss opportunities to reuse or repurpose content for emerging stakeholders.

A second challenge is accurately identifying and engaging the right stakeholders based on different needs throughout the lifecycle of the product. As the number of stakeholders and channels grow, there is increasing demand for content that is relevant to stakeholders' specific needs, delivered through the channels they prefer, and updated in real-time. Speedy, accurate responses to a growing number of medical information inquiries can deepen relationships, cement partnerships, and solidify credibility.

Finally, life sciences companies struggle to leverage the wealth of data collected from stakeholders to improve patient outcomes and product penetration in the marketplace. Current approaches for managing medical affairs content and stakeholder relationships often lack the robust data science needed to harness the potential of new sources of data – such as social media or genomics – and generate proprietary insights that can provide differentiation and competitive advantage.

Successful medical affairs organizations will apply metrics to both new and traditional data sources to demonstrate the organizational contribution of particular content and relationships. Insights derived from new data sources will become a key factor in determining future research areas, investment opportunities, and resource allocation. Current approaches impede medical teams' ability to access this information and align it with more traditional data sources, such as trial outcomes and patient registries. This can negatively impact how patient care is optimized and therapies are created, diminishing competitive advantage.

## Shifting to a new medical affairs paradigm

A mature medical affairs operation must move past simply educating stakeholders to becoming a strategic partner with a depth of knowledge – not only about a specific branded product – but also about an entire therapeutic area. Medical affairs also has a growing responsibility to help the commercial team maximize the product's reputation and reach in the marketplace. To deliver effectively on internal and external expectations, medical affairs must:

- Understand and engage the right mix of healthcare stakeholders, including payers (public and private), policymakers, physicians, academic institutions, and advocacy organizations.
- Develop the ability to leverage insights from multiple sources and use them to create future partnerships, recognize clinical markers, identify robust outcomes, and inform strategic intent.
- Deliver more focused clinical, social, and economic value throughout the lifecycle of any therapeutic intervention, leading to compound exclusivity, optimal labeling, market access and reimbursement, better lifecycle management, and other core objectives.

New approaches to managing medical affairs content should seek to simplify and unite every step of the process, including review, approval, storage, and multichannel distribution of content. Capabilities encompassing end-to-end processes should replace siloed, fragmented processes, in order to improve control of and visibility into content destined for physicians and other stakeholders. A single source of truth, accessed simultaneously by all team members and deployed across channels and regions, is needed to improve compliance and efficiency.

Another key to successfully adapting to a new model for medical affairs is properly identifying and engaging a broader group of stakeholders. The stakeholder landscape is no longer comprised mainly of healthcare professionals and key opinion leaders. Payers, policy makers, advocacy groups, and executives of large healthcare systems all now influence purchasing decisions.

A failure to properly educate these populations may result in under-prescription, over-prescription, or other misuse of life sciences products, which harms patient outcomes and the bottom line. As life sciences companies shift their model to focus on targeted products for a specific cohort of patients, it becomes more important than ever to listen, understand, and react to these new experts – including the patients themselves.

To ensure optimal access, pricing, and positioning for life sciences products, companies need software, data, and strategic services to engage the right stakeholders with relevant scientific information across all channels. These three steps will help life sciences companies advance the effectiveness of their medical affairs organization:

- A. Improve engagement** – Identify the right stakeholders. Align interactions to their preferred channels and the product's lifecycle.
- B. Measure progress** – Deploy real-time metrics to define targeted engagement plans and develop insight from interactions.
- C. Leverage data for better outcomes** – Apply stakeholder learnings throughout the business to drive scientific credibility, patient success, and improved product access.

## Conclusion

Going forward, recognizing and partnering with the right advocates will allow medical affairs to truly represent the voice of the customer in strategic development and commercial decisions. Efforts to transform medical affairs teams into strategic partners for physicians, nurses, patient groups, health plans, and hospital group administrators will fall short if not backed up by complementary business practices and technology tools. Success will depend on deploying new approaches to validate scientific needs and optimize future engagement, by understanding stakeholder behaviors across channels. New strategies must enable medical affairs to access accurate, up-to-date information globally, and deliver it via stakeholders' preferred channels to drive credibility and deepen relationships.

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### Sources

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<sup>2</sup> UnitedHealth Center for Health Reform and Modernization, "The Growth of Specialty Pharma". For more detail visit:

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<sup>3</sup> PHRMA, "Rare Diseases: A report on Orphan Drugs in the Pipeline". For more detail, visit:

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<sup>4</sup> Best Practices, LLC, "Medical Affairs Excellence: Budget Trends and Outsourcing". For more detail, visit:

<http://whybenchmarking.com/2014/04/01/medical-affairs-excellence-budget-trends-outsourcing/>

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