



Medical affairs

Driving influence across the health care ecosystem

Introduction

Biopharmaceutical companies are aggressively pursuing strategies to remain competitive by developing and marketing innovative products. At the same time both the cost and practice of medicine are coming under increased scrutiny. With the needs of the health care system continuing to evolve, it has never been more important for companies to proactively demonstrate the impact of their treatments across a broader set of stakeholders.

Thriving in this changing environment will require more than the traditional commercial sales models, where health care providers increasingly restrict access to their physicians and payors rely more heavily on real world evidence and economic value when making formulary decisions. As a result, focused initiatives to demonstrate improved health outcomes, cost-effectiveness, and patient impact must become the priority. Delivering on these requirements demands that product development activities are driven by a deep understanding of the patient experience and that treatment value is communicated utilizing scientific and medical information in a manner that supports the incentives and needs of the various stakeholder groups.

As a result of these evolving dynamics, many Biopharmaceutical companies are now looking within their organizations to determine where the capabilities exist to understand the patient experience, access and influence a broad array of external health care stakeholders, and act as a liaison between the external medical community and the internal research organization. With its unique set of characteristics, Medical Affairs (MA) could be enabled to play this critical role. Many companies within the industry are already actively reorganizing their R&D groups to focus on core competencies and restructuring their commercial and sales forces in response to health reform and loss of exclusivity (LOE). The time is now right to invest in a MA organization that is capable of creating a strategic competitive advantage while safeguarding the public trust.

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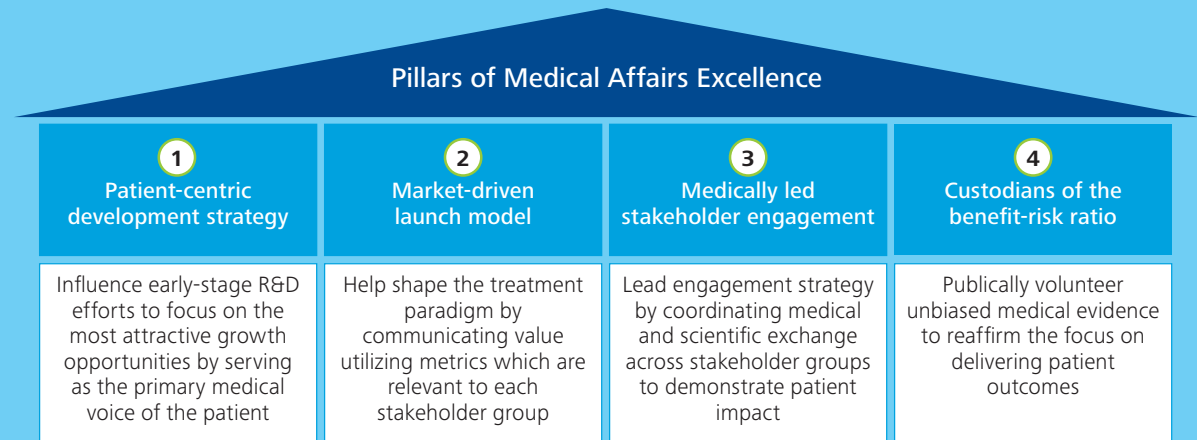


Instant Insights

Solving your most pressing business challenges starts with knowing the landscape. Instant Insights offers you a digest of vital knowledge and practical steps you can consider now.

Four-pillar framework

The four-pillar framework can guide the MA organizations to operate more effectively from early discovery to post-LOE management, and to deliver insights to a broadening group of stakeholders.



Our take

A strategic vision for the Medical Affairs organization

To help our clients provide clinical insights that drive innovation and demonstrate real world evidence of improved outcomes, we have developed a strategic vision for MA based on four pillars of excellence. The four pillars can provide an organization with a framework to more effectively bridge the gap between internal R&D and the commercial organization, integrate market input into the science, and communicate medical insights and product knowledge across providers, payers, patients, and all the other stakeholders throughout the entire product life cycle.

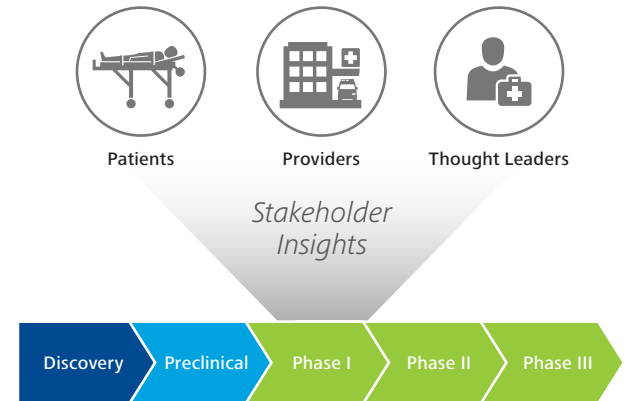
Patient-centric development strategy

Understanding the patient experience is the first critical step toward aligning R&D efforts to the patient's unmet clinical needs. Through a patient-centric development strategy, companies can focus on influencing early-stage R&D efforts by leveraging an integrated analysis of all data sources from which these requirements can be derived.

For example, medical inquiries can yield new indication targets; customer relationship management systems can contain opportunities for improved care management services; and electronic health data can unlock important new clinical endpoints. While the concept of patient-centricity is not new, leveraging MA to collect and channel this information back to the R&D organization is a next logical step in turning patient data into actionable insights.

There are three key components for enabling MA to uncover these clinical insights and ultimately infuse them into the discovery process:

1. Capture and integrate strategic information from across the broader set of health care stakeholders to understand patients' needs
2. Advance the enabling technologies (CRM software, social media, mobile apps, etc.) to capture insights directly from customers
3. Interact with R&D leadership as partners to define research objectives and study endpoints that will affect patient outcome



A patient-centric development strategy creates a pipeline of high-quality clinical insights that are in-tune with the demands of an evolving health care ecosystem.

Market-driven launch model

In the value-based care era of risk-sharing and population-based health metrics, therapeutic value beyond safety and efficacy needs to be demonstrated across the entire product lifecycle.

There are several instances in the health care literature calling for MA to help enhance patient access; however this only represents one component of a market-driven model. Leveraging MA to generate evidence-based value indicators *and* to use that information to influence the overall treatment of patients will be a key differentiator for both biopharmaceutical companies and their products in this new value-based care marketplace.

The MA organization can effectively shape treatment protocols by focusing on the following activities:

- Coordinate comparative effectiveness research to establish a unique treatment profile that supports market access
- Utilize depth of clinical information and peer-level interactions with stakeholders to help establish diagnostic patterns and treatment paradigms
- Partner with health economics and outcomes research (HOER) groups to quantify a treatment's total benefit-risk ratio

A market-driven launch model can help fully differentiated product values be more clearly communicated to, and understood by, stakeholders prior to initial marketing.

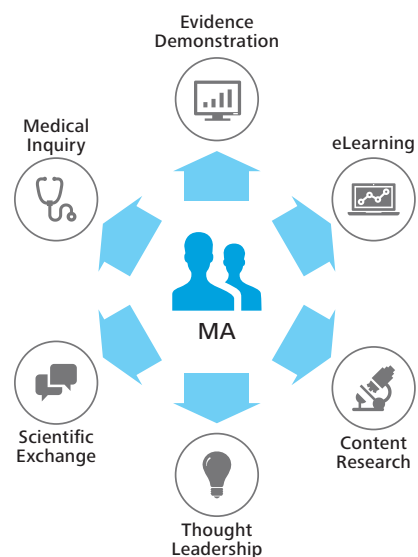
Medical led stakeholder engagement

Biopharmaceutical companies must be adept at utilizing the full spectrum of available methods and touch points to provide access to disease and treatment information and to promote research initiatives across the various stakeholder groups. With MA engaged to manage the coordination of medical and scientific exchange, helping to determine the most appropriate resources and content for a particular interaction, Biopharmaceutical companies will be better able to provide stakeholders with a unified experience and messaging that supports global strategic objectives.

Most MA groups already engage in peer-level conversations with key thought leaders and provider groups, disseminate educational information about a treatment or therapeutic area, and support investigator-led research initiatives. The challenge lies in presenting consistent, medically accurate messaging across a dynamic universe of stakeholders—particularly when these stakeholders are being engaged simultaneously by representatives from the R&D and commercial organizations as well.

By strategically positioning MA to administer a harmonized set of touch points through the structured deployment of key resources to each stakeholder, a company's ability to provide a coordinated experience could be increased greatly. By playing a more centralized role, MA can be empowered to:

- Coordinate activities among the broad range of customer-facing functions that exist within a company
- Anchor customer engagement around medical information and scientific exchange
- Reduce the potential for having multiple, misaligned groups of representatives that are providing intelligence within and across customer types



Medical led stakeholder engagement, under the direction of MA, can be a critical component of the prescription for the various marketing and promotional missteps that continue to plague the industry.

Custodians of the Benefit-Risk Ratio

In this new environment, public perception and patient trust are paramount; integrity and transparency are basic elements of a new Biopharmaceutical operating model. Companies can foster a reputation built on high levels of trust by publically volunteering unbiased, accurate, and complete medical evidence to reaffirm the focus on delivering patient outcomes. Positive perceptions of the company can be translated to its brands and can potentially become just as influential as the attributes of the product itself.

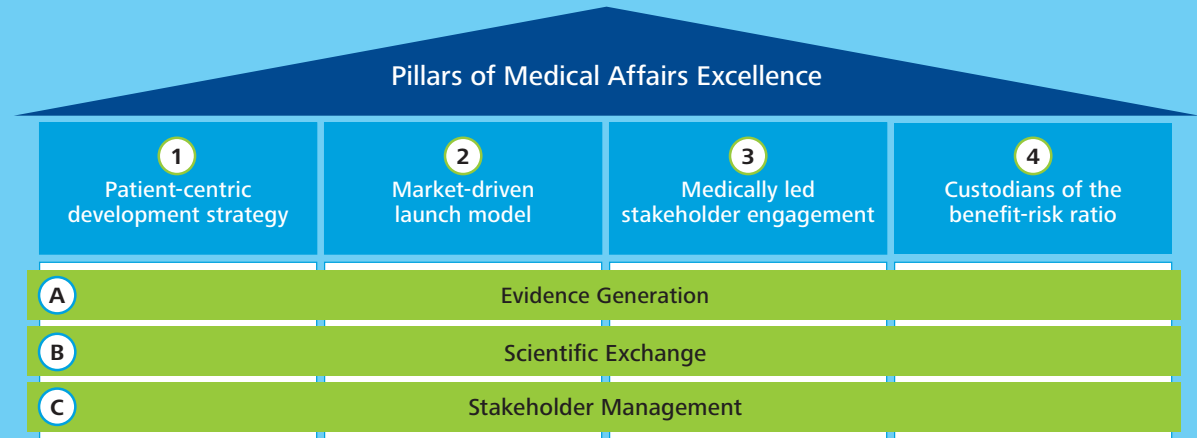
To more effectively manage the benefit-risk ratio of marketed treatments and enhance the company's public image, MA should be engaged in a lead role to help reinvent the way they define and implement their medical strategy, and:

- Shape corporate risk tolerance and compliance rather than be its recipient
- Shift the focus from thinking defensively about what MA can't do (e.g., use MSLS to promote off-label prescribing; offer excessive payments to physicians participating in observational studies, etc.) to acting proactively on the things that they can do (e.g., provide information on off-label use in response to documented, unsolicited requests from health care providers; sponsor investigator-initiated research, etc.)
- Communicate risks appropriately to help reduce their negative impact, enhance the company reputation, and avoid litigation

As custodians of the benefit-risk ratio, MA can work toward restoring the public perception that the focus of Biopharmaceutical companies is on driving health, and not profits.

The ABCs of MA Excellence

Implementing the four-pillar framework is a critical step toward operationalizing an optimized MA organization. Before these benefits can be achieved, Biopharmaceutical companies will need to focus on the development of a distinct set of core capabilities that are essential across each of the pillars:



A. Evidence Generation

"[S]uccessful drug development is taking the understanding of medicine's data-driven elements and combining these with the understanding of an individual patient, which gives you the best chance of getting the right answer for that specific patient."

—David Meeker, M.D, president and CEO, Genzyme Corporation

Evidence generation forms the foundation of a transformative MA organization. Biopharmaceutical companies must utilize advances in data capture and analytics capabilities to integrate information and derive insights on how to improve health outcomes. It will be critical to make available any data that supports the medical and economic impact of a treatment throughout the entire product lifecycle to impact development and commercialization activities as well as to help shape treatment paradigms and reimbursement algorithms.

B. Scientific Exchange

"The leaders of our industry have not spent enough time educating the public as to the value innovative medicines bring to society. There needs to be a much greater effort on the part of industry to educate."

—Ron Cohen, M.D, founder and CEO, Acorda Therapeutics

Scientific exchange requires a strategic shift in focus from marketing and selling treatments to understanding and solving the 'patient problem.' From an internal perspective, enabling scientific and medical discussions can help incorporate the patient-centric viewpoint into strategic R&D and commercial decisions. When directed externally, the exchange can act as a conduit to help integrate the efforts of industry, academia, and government agencies around meeting patient needs.

C. Stakeholder Management

"The future of this industry will no longer be about who has the biggest pocketbook or who has the most people. It will be about who can best manage that myriad of strategic and transactional partners."

—Courtney Billington, VP Global Janssen Supply Chain, Johnson & Johnson

Effective stakeholder management can allow a Biopharmaceutical company to 'drive' the relationships with key decision-makers and influencers. It starts with leveraging existing and emerging technology enablers to appropriately capture and synthesize insights from the different customers and then deploying these insights and knowledge to provide the most relevant and accurate information. The end goal is to cultivate the ability to anticipate the needs of each stakeholder group and to meet those needs with quantitative and qualitative intelligence in a manner that supports each party's objectives.

The Future of MA: Equal footing with R&D and Commercial

As MA organizations continue to mature and demonstrate the ability to influence health care decision making, the following trends could elevate MA to the same level as the R&D and Commercial groups and potentially enhance the delivery of valuable medicines to patients.

Commercial opportunities will be guided by substantiated unmet need

Understanding market and patient needs is about deciphering data collected through interactions with internal and external stakeholders and then translating those clinical insights into innovative therapies. To accomplish such a task, Biopharmaceutical companies must be able to interface with patients and patient groups, physicians and provider networks, insurers, and regulatory agencies in ways that enable the extraction of relevant information as well as leverage knowledge to influence the full product lifecycle.

Biopharmaceutical companies will serve as trustworthy care management partners

In this new data-driven ecosystem, evidence-based value indicators are becoming increasingly diverse, more measurable, and more easily accessible. As the industry races to catch up with advancements in social and mobile technologies, it is important to remember that regardless of how the regulatory and user communities respond to these new channels, Biopharmaceutical companies should communicate clinical and real-world results using clear and consistent language that is both medically accurate and tailored to a specific audience and medium.

The path forward: Critical next steps

As Biopharmaceutical companies begin the journey toward MA excellence, their paths will likely differ based on each's unique structure, organization, and maturity. However, several key steps will remain common:

#1: Articulate the future state of the MA organization

Think about the markets and consumers you serve. How will your MA organization inform its decision making? Influence the way patients are diagnosed and treated? Expand formulary access to your products? Become a trusted peer and partner?

#2: Evaluate the current-state against the future-state vision and the four pillars

How early is MA engaged in the development process? Are you producing the types of data and insights that can inform R&D and demonstrate treatment value? Are you providing the right mix of resources and information across stakeholder groups? Do you communicate your strategy in a way that builds trust or confirms bottom line thinking?

#3: Create a roadmap that spans the core capabilities and addresses the key challenges

How do you develop the talent and capabilities required to achieve the future state? Which systems and processes need to be augmented? How should you design decision rights and reporting relationships to allow MA to influence the R&D and Commercial organizations? How do you restructure the field medical teams to service such a wide array of key stakeholders?

The bottom line

With the Biopharmaceutical industry now under extreme pressure to deliver superior medical outcomes while simultaneously reigning in costs and reducing excessive spending, the time is right for Medical Affairs organizations to earn their place at the leadership table by creating opportunities to deliver new value for both patients and the health care ecosystem.

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