



MEDICAL AFFAIRS: SHIFTING FOCUS TO DELIVER STRATEGIC VALUE

CONTENTS

Disruptive Market Forces Impacting The Global Pharmaceutical Industry.....	1
Strategic Value.....	1
Finding The Bandwidth and Budgets.....	2
Benefits of The Extended Medical Enterprise Model.....	4
Summary.....	5

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DISRUPTIVE MARKET FORCES IMPACTING THE GLOBAL PHARMACEUTICAL INDUSTRY

The global pharmaceutical industry is encountered with several concurrent disruptive macroeconomic shifts ... patent cliffs, declining revenues, health care reforms, and austerity programs aimed at reducing budget deficits. The consequent challenges are further compounded by factors such as stringent legal and regulatory barriers to entry, demanding payors, less accessible physicians, and a significant business focus toward emerging markets.

Confronted with the immediate need to address these challenges, medical affairs in pharma organizations is being called upon to deliver more strategic value throughout the product life cycle as opposed to being restricted to only an enabling function. These changes are compelling medical teams to be innovative and valuable partners not only to HCPs but also to internal stakeholders, even while the overall workload is increasing in an environment with significant limitations on headcount and budgets.

Whilst senior executives responsible for managing medical affairs grapple with the challenges of transitioning into delivering more strategic value, their teams—global, regional, and local—remain consumed by day-to-day operational and often tactical and non-strategic activities. Apart from changing mind-sets, equipping people with the right tools and training, overcoming these challenges necessitates investments and shifts to fundamentally new models and organizational structures.

This paper examines how medical affairs organizations are gearing up to deliver more strategic value and

implementing efficient and flexible operational models to provide sufficient bandwidth to the medical teams for delivering the necessary strategic outcomes.

STRATEGIC VALUE

Several large pharmaceutical organizations have recognized the need to move away from a siloed approach and are transforming their global brand/franchise teams to ensure that business strategy is a continuum that looks at all facets of the scientific, market, and competitive environment.



The Changing Landscape

Medical affairs operations are increasingly expected to deliver business outcomes rather than serve as an enabling function.

- Increased regulatory burden with the associated risks of noncompliance
- R&D productivity and payor/regulator demands for evidence to address unmet clinical needs
- Changing customer expectations and a surge in alternate channels of communication
- Geographical shift toward high-growth emerging markets

Medical affairs departments are being placed at the heart of the global product teams of the future due to their unique ability to bridge scientific research with the reality of clinical practice.

Consequently, there is a significant shift in expectations from medical affairs to deliver greater strategic value and help impact several key value drivers for the business such as engagement with customers on scientific/medical matters, strategy for medical evidence collection, patient education and adherence, case findings, formulary design, and economic value propositions for payors.

Besides the expectations to deliver strategic value, the operational responsibilities of medical affairs departments have expanded due to more stringent regulatory and compliance requirements.

It is imperative therefore that only limited internal staff focus on routine operational activities such as management of medical information for HCP inquiry responses. Time consuming activities such as handling and triaging inquiries, periodic updates of standard medical responses, development of custom responses, and associated literature search, etc are better outsourced to a strategic partner.

Early movers who are adopting this approach can see improvement in the strategic value that the in-house medical information services staff can deliver, for instance, by developing medical information-ondemand programs as a way to differentiate their overall value offering to health care

providers. Companies that are able to provide such innovations are likely to be viewed differently by their customers than traditional product-centric marketing organizations.

FINDING THE BANDWIDTH AND BUDGETS

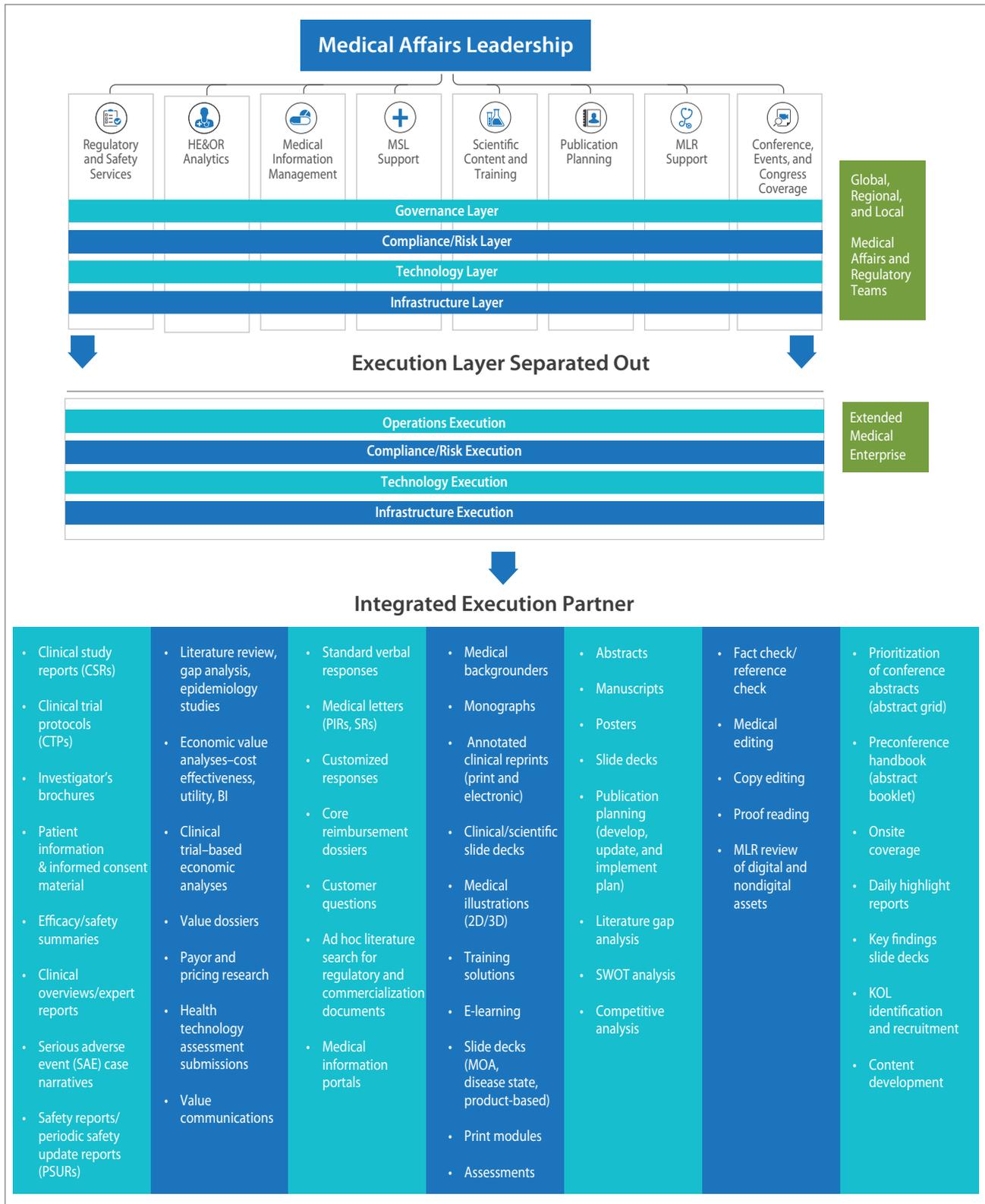
The leadership of medical affairs teams that we work with recognize that they need to implement operating models that not only meet the need to drive more strategic value but also ease out bandwidth constraints due to routine operational tasks.

One such operating model is the “Extended Medical Enterprise,” which consists of medical talent pools in a few low cost regions and hence provides the bandwidth for in-house resources to service key geographies globally and focus more on delivering strategic value. Our experience with global pharmaceutical companies that have been early adopters of this model confirms that such an approach can help position medical affairs teams more effectively for the future.

Traditional Versus Evolving Remit of Medical Affairs Departments	
Traditional Activities	Additional Responsibilities
Publications and Medical Communications	Field Medical Operations
Medical Meetings	Medical Communications
MSL Training	KOL Management
Medical Information Management	Multi-channel Customer Engagement
Medical Review of Promotional Materials	HE&OR Phase IV Investigations

Extended medical enterprise works by establishing a shared service to consolidate global medical operations, governance, compliance, and technology for various medical affairs functions.

One of the precursors to implementing this model is very strong centralization and/or close coordination between various global, regional, and local medical affairs teams.



The Extended Medical Enterprise Model

Multishored EME Implementation



Leveraging the EME Concept to Create Shared Services in Low-cost Destinations Across the World.

BENEFITS OF THE EXTENDED MEDICAL ENTERPRISE MODEL

- Creating strategic bandwidth for internal medical affairs teams by eliminating the pressures of day-to-day operational issues, which can be managed by the extended medical enterprise partner
- Standardizing and establishing global best practices as well as compliance norms by consolidating various functions to facilitate knowledge management and adherence to standardized guidelines
- Eliminating the need to develop competencies in every operating business unit in the company by centralizing this function under a shared umbrella
- Improving efficiencies due to economies of scale besides deploying tools and productivity mechanisms that ensure a continual process of refinement and productivity improvements
- Building operational medical capacity in low-cost regions with the savings reinvested in building more strategic and regulatory/market facing capabilities in global, regional, and local medical affairs teams
- Creating highly flexible capacities to manage workload peaks, specially around unexpected regulatory, medical, and customer triggers

SUMMARY

We believe that for medical affairs to keep pace with the changing requirements, the function has to transition into delivering more strategic value while dealing with the demands of day-to-day operations more effectively. Establishing a shared services infrastructure such as a multishored extended

medical enterprise provides a seamless extension of the medical affairs operation into a dedicated enterprise set up by a strategic partner. Such an approach could lead to the progressive enhancement of strategic capabilities within the internal medical affairs function, with more efficiency and standardization of routine operations.



