

Medical Affairs **OUTSOURCING**

What are the top trends/reasons that have impacted the discipline of medical affairs and its function within the biopharmaceutical, medical device, and diagnostics industries and why is outsourcing of this function so desirable?

The medical affairs function is increasingly playing a more vital role within today's pharmaceutical, biotechnology, medical device, and diagnostic companies. Furthermore, the role of medical affairs activities are expanding both earlier and later across the lifecycle of a company's product. This expanded role is largely a result of practicing physician's desire to be and remain more clinically aware and educated about new treatment concepts and advances — on the cutting edge.

These areas are beyond and outside of the purview of the commercial teams' and sales representatives' ability and/or responsibility, which is leading to significant growth in company's field medical affairs organizations, i.e. medical science liaisons, nurse educators, and drug information call centers. Additional medical affairs growth areas include the health economics/outcomes research (HEOR) departments, medical communications (medical writing and publication planning), and clinical operations departments.

Specific Activities the Fully Engaged Medical Affairs Department Is Involved In

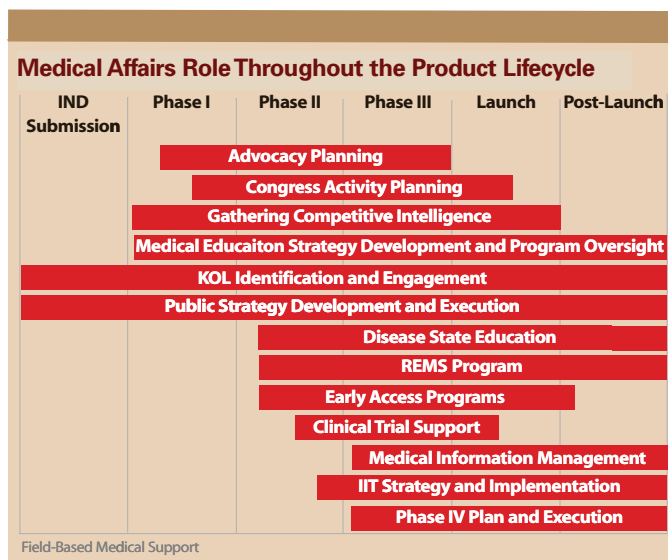
Field-based and in-house medical affairs constituents are able to engage in unbiased, peer-to-peer, scientifically focused discussions with a host of healthcare professionals. These audiences can range from top-tier academic thought leaders requiring high-level, scientific exchanges specific to their therapeutic areas of expertise, to payer audiences requiring budget impact and burden of illness economic modeling presentations that incorporate clinical outcomes and quality-of-life issues. As a result of various healthcare professional stakeholder demands for clinically based information, medical affairs departments have become involved in a greater number of critical initiatives that are essential to the successful com-

mercialization of a product. Examples are included on the chart below.

Regardless of the stakeholder, it is essential that all medical affairs representatives ensure their exchanges and dialogues with their healthcare professional audience are not promotional in nature but rather educating them on their request for information. As therapeutic areas continue to become more complex and physicians continue to demand higher level communications with company ambassadors, the medical affairs function and role will continue to expand. Additionally, as reimbursement policies continue to wield tremendous influence on prescribing behaviors, companies will need to prioritize and focus clinical discussions with payer audiences differentiating their products based on their unique attributes versus competitors.

Why Outsource This Function?

Despite the significant expansion and role that the medical affairs department plays in the implementation and execution of a company's clinical development, KOL development, scientific publications, and medical education activities, a top challenge remains insufficient resources, including budget and headcount. Historically, company medical affairs executives felt that based on the proprietary nature of the clinical information inherent to their company's pipeline candidates and marketed products and importantly, the respective scientific strategies in support of those candidates/products, coupled with the stringent requirement to abide by government and company specific regulations, all medical affairs personnel should be an internal asset. Recent trends and bench-



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marking studies conducted by a number of industry consulting firms have reported that this is no longer the case, especially in the area of field-based medical teams, medical information call center departments, and medical publications departments.

Medical affairs executives have come to recognize that they can maintain oversight of these critical functional activities using external specialized support while sustaining their ability to continuously be involved in other company activities that may require their active, day-to-day involvement. Similar to outsourcing models and structures within the contract sales and research arenas, medical affairs outsourced services afford companies with flexible and scalable solutions enabling them to utilize strategic management and resource components and critically, specialty degreed, healthcare personnel resources possessing both discipline-specific and therapeutic expertise. A major benefit cited by many medical affairs company executives is the ability to have these teams hired and trained very quickly with the option to modify the headcount across key initiatives and milestones (e.g. drug approvals or delays) based on marketplace and company changing dynamics.

It's clear that in order to play the central, vital role as an informational and educational resource, medical affairs departments must make use of all available resources and be flexible in approach; outsourcing is a very critical component in this regard. ^{PV}

The Medical Affairs Company (TMAC) provides the biopharmaceutical, medical device, and diagnostics industries with outsourced field-based medical (MSLs, NEs, CSs) and medical communications (medical information call center, pharmacovigilance and medical writing) services.

For more information, visit www.TheMedicalAffairsCompany.com



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