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Optimizing Early-Stage Product Development:

Is It Ever "Too Early" for Medical Affairs Involvement in Strategic Planning?

ELEVATE
ARTICLE

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Introduction

In an evolving healthcare landscape, the role of Medical Affairs is gaining recognition earlier in the product life cycle. Traditionally, Medical Affairs has been involved from Phase 2 and beyond. However, the increasing complexity of healthcare—characterized by specialized care, novel therapies, and stringent regulatory requirements—drives the need for input from Medical Affairs during the early pre-launch phases (discovery, preclinical, and Phase 1).

This shift highlights the importance of Medical Affairs even at the proof-of-concept stage, ensuring that new therapies are developed with a comprehensive understanding of the regulatory and clinical environment.

Early engagement of Medical Affairs can significantly enhance the chances of product success. By providing valuable insights and identifying critical issues and gaps, Medical Affairs teams can support both short- and long-term strategic planning and help inform key decisions.

This early involvement enables teams to identify and address potential challenges sooner in the product life cycle, create more comprehensive evidence generation strategies that support product differentiation, and prepare better for the market launch of new products.

Additionally, it encourages collaboration between Medical Affairs and other departments, such as Clinical Development, Precision Medicine, and Commercial/Marketing.

What is driving the involvement of Medical Affairs at earlier phases of product development?

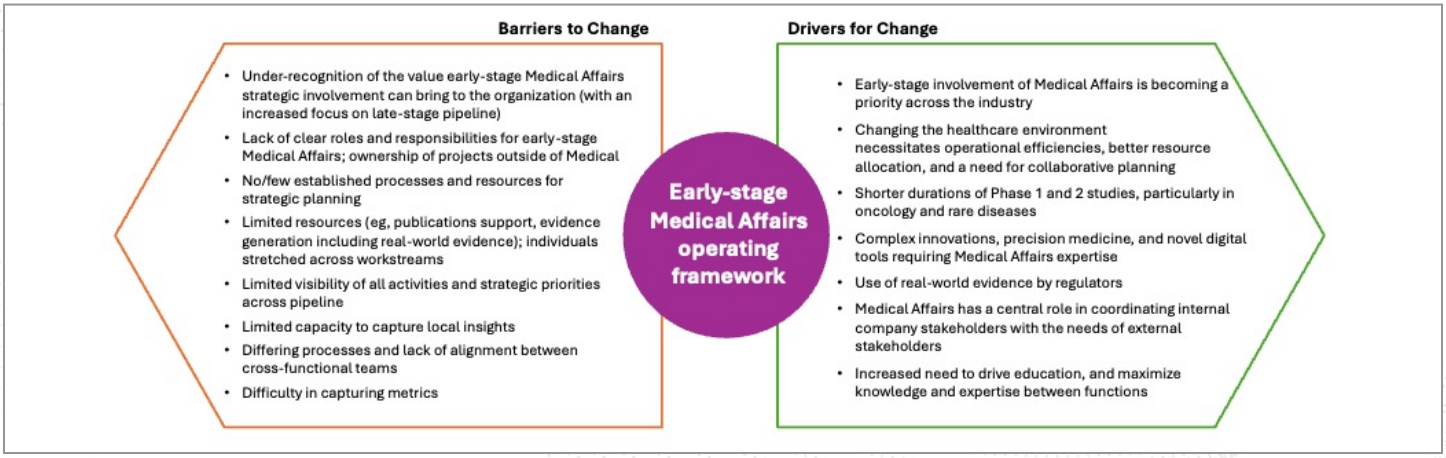
Medical Affairs operates at the intersection of science, healthcare, and business. Its effectiveness is shaped by a combination of barriers and drivers that influence its ability to bridge gaps between research, clinical practice, and patient needs while navigating challenges such as resource constraints, stakeholder demands, and evolving healthcare landscapes.

Several external factors encourage the early involvement of Medical Affairs in product development. These include heightened regulatory demands, an increased emphasis on health equity, the necessity for real-world evidence to support regulatory approvals, and the integration of digital health tools into clinical trials and treatment plans. Internal factors are also significant, with early strategic involvement, knowledge transfer within the organization, and cross-functional collaboration being crucial for success.

Medical Affairs should be actively involved in product development from an early stage, ideally starting several years before a product launch. This involvement allows the team to contribute to strategic planning and collaborate closely with other internal functions, such as Clinical Development. By providing valuable insights from healthcare providers and patients, Medical Affairs can help inform the design of clinical studies that produce robust and relevant evidence addressing patient needs.

However, the under-recognition of the value that Medical Affairs brings to the organization, along with internal resource constraints, lack of cross-functional alignment, and operational inefficiencies, can hinder this involvement.

Figure 1. *Factors influencing the decision to involve Medical Affairs at earlier stages of development.*



What are the benefits of involving Medical Affairs in earlier phases of development?

Medical Affairs teams are essential in shaping early development strategies to enhance the likelihood of future success. Their responsibilities are broad and can be categorized into four key areas: strategic alignment, future-proofing, relationship building, and external validation.

Strategic Alignment

Medical Affairs teams play a vital role in strategic alignment by creating and maintaining consensus on the long-term strategic focus for asset development. They prioritize unmet needs across potential applications and assist in developing the target product profile that guides clinical research efforts. Moreover, Medical Affairs offers valuable insights into current standards of care, product attributes, and the competitive landscape. This comprehensive understanding helps the team identify critical issues and gaps, supporting both short-term and long-term planning.

Future Proofing

To ensure future success, it is crucial to anticipate the competitive landscape at the time of launch. Medical Affairs should investigate expected changes in the healthcare environment, such as reimbursement pathways, technological advancements, and shifts in the standard of care, all of which can impact trial design. Additionally, they should identify potential patient populations across various regions that may benefit from the drug, gather expert opinions, and recognize any barriers to care. Specific activities and responsibilities may include the following:

- Identifying populations for whom an early-stage product may significantly improve outcomes over standard of care at the time of launch
- Mapping evolutions in clinical environment and likely competitive scenarios
- Building a robust understanding of the patient journey, key needs, and potential intervention points
- Validating novel biomarkers, endpoints, and comparators that may be required for future clinical studies
- Collaborating on evidence generation strategies, helping to identify evidence gaps to support approval, access, and future clinical uptake

In today's healthcare landscape, Medical Affairs teams play a vital role in meeting the increasing demand for early and comprehensive evidence for a wide range of external stakeholders. These stakeholders include policymakers, regulators, healthcare professionals, payers, and patients, all of whom require robust data to guide their decision-making processes.

Medical Affairs teams are strategically positioned to assess and prioritize the evidence needs of these diverse groups across different geographical regions, taking into account varying regulatory frameworks. By doing this, the team can determine the optimal timing for evidence generation throughout a product's life cycle, ensuring that essential information is available when and where it is most needed.

Relationship Building

Clinical development teams often form strong, lasting relationships with trial investigators. However, Medical Affairs can expand this network by identifying a wider range of external experts for future advisory roles and clinical trial investigator positions. This team plays a crucial role in managing relationships with key thought leaders and healthcare professionals from the beginning, fostering trusted connections that are vital for a product's success.

Medical Affairs teams leverage these relationships to gain insights into the perspectives of both healthcare providers and patients, evaluate disease awareness, and create educational materials. They also support the development of press releases, effectively translating complex scientific information for diverse audiences and communicating important evidence-based information to establish value.

Additionally, Field Medical is essential in building relationships with healthcare professionals, leading to collaborative opportunities in clinical trials and research programs. They also assist with patient recruitment and site initiation visits, as well as generating valuable insights.

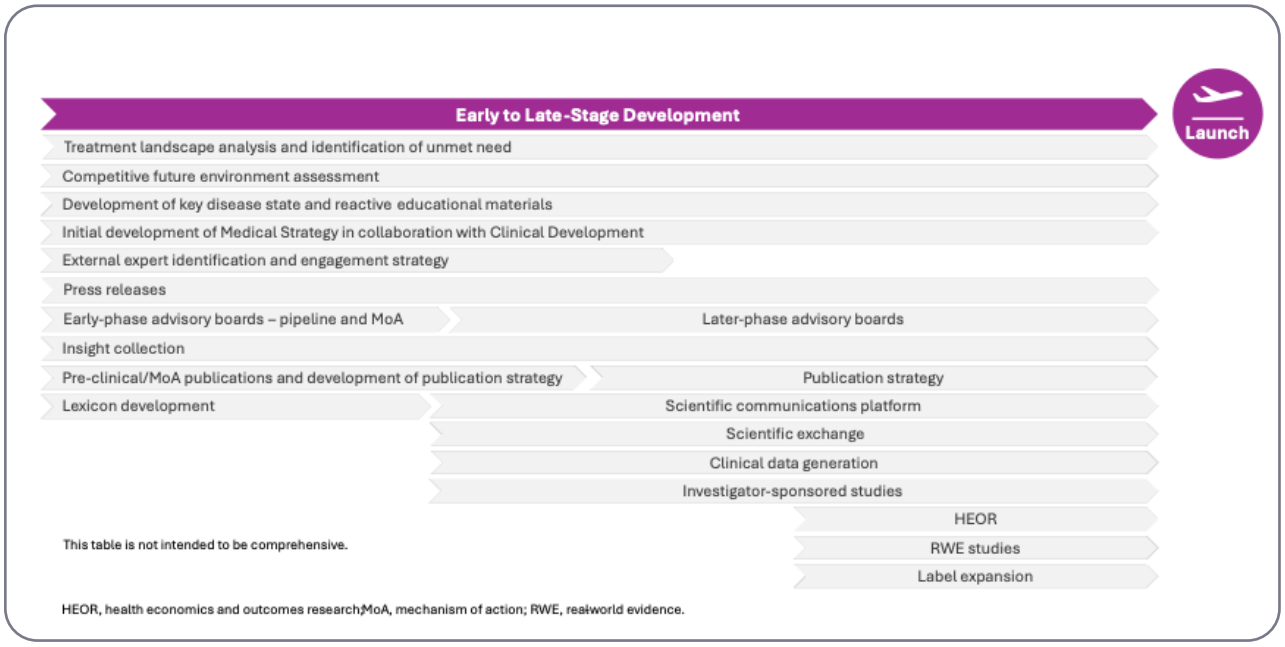
External Validation

Medical Affairs teams play a crucial role in gathering and sharing external perspectives and actionable insights across various functions to support evidence-based decision-making. They facilitate communication both internally and externally regarding portfolios, assets, and future plans. Additionally, the team assists in informing early-phase decision-making across functions by providing valuable insights and information:

- Informed business strategy
- Identification/validation of unmet needs
- Market understanding and guidelines positioning
- Optimization of product/trial design
- Evidence generation
- Increased external engagement
- Enhanced cross-functional collaboration

Despite progress, several barriers persist: insufficient company focus in the new therapy area, limited external expert relationships, absence of local and regional teams as well as medical science liaisons, low strategic importance, and inadequate funding.

Figure 2. *Medical Affairs activities that may be beneficial in earlier phases of development.*



*Medical Affairs teams play a **crucial** role in gathering and sharing external **perspectives** and **actionable insights** across various functions ...*

What factors might impact the decision to involve Medical Affairs at the different stages of product development?

There is no universal approach to determining the right time to involve Medical Affairs in product development.

The needs and strategies for product development can vary significantly based on factors such as the therapeutic area, the size of the company, the available budget, and the potential return on investment. Box 1 outlines important questions to consider when assessing the early involvement of Medical Affairs.

Box 1. *Considerations for early involvement of Medical Affairs*

- Is the company experienced in this therapeutic area? Do external expert relationships exist?
- Does the company have extensive knowledge of the treatment landscape and the competitive environment?
- Is additional work needed to assess future levels of unmet need and potential clinical trial comparators?
- What are the expectations for the product in development; is the product an additional treatment to existing treatments (me-too) or does it have the potential to be practice-changing?
- Are there Medical Affairs and Field Medical teams in place to support this product?
- What is the available level of investment?

Summary

Incorporating Medical Affairs early in the product development process allows companies to leverage their expertise to shape strategy, bridge the gap between clinical development and commercialization, support prescribers, and advocate for patients' health needs.

It's important to understand that involving Medical Affairs earlier should not follow a "one-size-fits-all" approach. Instead, a thoughtful strategy is advisable, ensuring the right level of investment and the flexibility to adapt as new clinical data become available.

In summary, engaging Medical Affairs in strategic planning from the very beginning is not a premature decision. It is a best practice that can significantly enhance the success of product launches and ensure long-term success.

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