SSI Strategy Whitepaper

Driving Therapeutic Impact: A Novel Model for Strategic Medical Affairs Integration

Written by:
Ramin Farhood, Len Walt, & Dani Thomas

SSI Strategy

Executive Summary

Early integration of Medical Affairs in drug development can significantly enhance the overall process, despite the tendency of biotech leaders to prioritize regulatory and clinical hurdles. A strategic model built on Scientific Communication, Key Opinion Leader Engagement, and Evidence Generation, supported by Operational Excellence, offers substantial benefits.

Implementing this approach from the outset can optimize clinical development timelines, improve regulatory readiness, and elevate the quality of evidence generated. Effective scientific communication aligns stakeholders, while early engagement with key opinion leaders provides crucial insights for trial optimization. A comprehensive evidence generation strategy addresses diverse stakeholder needs and potentially reduces development costs.

Companies adopting this integrated approach will be better positioned to transform scientific possibilities into real-world advancements, ultimately benefiting patients, healthcare providers, and other stakeholders. While implementing this vision requires investment, partnering with expert vendors can help mitigate risks and accelerate the development of a high-performing Medical Affairs function.

The high costs of drug development and the significant chance of failure means that Biotech leaders focus on attempting to successfully navigate regulatory and clinical development hurdles as a priority. Assimilating medical affairs into the organization during the early development phase is not a standard consideration. Realizing the comprehensive impact and value of medical affairs requires broadening traditional mindsets and integrating this function into the early stage of the drug development journey.

This paper outlines a strategic model for Medical Affairs, encompassing three core pillars—Scientific Communication, Key Opinion Leader Engagement, and Evidence Generation—all built upon a foundation of Operational Excellence. This integrated approach positions Medical Affairs as a catalyst for achieving timely and successful development milestones.

Scientific Communication: Forging Stakeholder Alignment

Effective scientific communication, anchored by proactively engaged medical affairs teams from the start of development, is essential for seamless dissemination of evidence-based scientific data that resonates with diverse external stakeholders. This strategic investment fosters credibility and cultivates a supportive environment for asset success.

The four core pillars of an effective scientific communication strategy are:

1. Scientific Platform and Lexicon: Standardize language, references, and narratives.
2. Medical Education and Information: Deliver high-quality, balanced education and evidence-based responses.
3. Publications: Enhance scientific credibility by sharing key data through peer-reviewed channels.
4. Congresses: Communicate scientific updates to key external stakeholders via impactful presentations and posters.

Early adoption of scientific communication strategies provides a competitive edge. It ensures consistency in scientific content and evidence-based positioning from the outset and elevates the organization's reputation as a trusted, reliable thought partner. Companies can optimize congress participation and visibility, and enhance their scientific credibility, with priority audiences while disseminating high-quality, accessible data through relevant publication channels. This coordinated approach provides a scientific foundation that facilitates productive partnerships.

Key Opinion Leader (KOL) Engagement: Catalyzing Study Optimization

Rather than treating KOL engagement as an afterthought, prioritize consulting scientific experts from the outset of clinical development. Building relationships with relevant KOLs early on provides invaluable insights throughout all trial phases, from refining protocols to optimizing study design and patient selection. Their real-world clinical perspectives and patient-centered insights are essential for generating meaningful data that addresses key unmet needs. The following list details specific opportunities where early KOL engagement can significantly benefit the development journey.

Several opportunities in the development journey can benefit from early KOL engagement.

1. **Deep Expertise and Guidance:** KOLs ensure the clinical development strategy is scientifically grounded and relevant, addressing unmet medical needs and aligning with current practices.
2. **Study Design and Trial Optimization:** Early KOL involvement ensures trials are methodologically sound,

scientifically rigorous, and optimized for efficiency and meaningful results.

3. **Scientific Advocacy and Regulatory Support:** KOLs enhance the credibility of new therapies, foster acceptance, and facilitate smoother interactions with regulatory agencies, potentially expediting approvals.
4. **Patient Recruitment and Engagement:** KOLs' networks and influence enhance patient recruitment and trust, while their insights ensure trials include relevant participants reflecting real-world conditions.
5. **Enhanced Competitive Edge:** Continuous KOL engagement builds trust and credibility, making the clinical program more attractive to investors, partners, and the medical community, thus providing a strategic edge in a crowded market.

Evidence Generation: Establishing value for the clinical and patient community.

Too many clients driven by a razor-sharp focus on hitting discrete regulatory and clinical milestones mistakenly rely solely on randomized controlled studies. This approach risks challenge from regulators who may be concerned about the validity of several aspects of the clinical program including the relevance of the patient population being studied, the validity of endpoints and most critically the correlation of the trial data into meaningful patient outcomes.

Medical affairs professionals are well versed in amalgamating organizational strategy, utilizing their scientific acumen, and deep understanding of the therapeutic landscape to contribute to the development of an integrated data strategy. This approach from the outset of development can help to address varied stakeholder requirements and can enhance the chance of success of the development program, shorten the development journey, and substantially reduce program costs.

There are several opportunities in the development journey that can benefit medical affairs input.

1. **Early drug development**

- Population/disease studies
  - Disease characterization, and identification of patient cohorts with highest unmet needs.
  - Identification of population cohort with greatest likelihood of treatment response.
  - Identification of clinical markers and biomarkers aiding targeted development programs.

2. **Regulatory Strategy**

- Protocol enhancement through real world evidence generation to validate the utility of the clinical trial program.
- Support the protocol and study rationale for the trial.
- Ensure that the patient cohort studied is representative of the population in need of treatment.

3. **Clinical Trial Execution**

- Support of site selection and the timely delivery of the study using data from health records, and registries.
- In rare diseases and diseases with a high unmet need, a comparator cohort to validate single arm trials.

Data from early evidence generation will contribute towards achieving timely and successful regulatory and development outcomes crucial to enhancing investor confidence and ultimately program success.

Organizational Excellence: Foundations for Strategic Impact

Developing robust organizational proficiency within medical affairs teams is essential for enabling strategic execution throughout the development lifecycle. An integrated operating model ensures alignment of activities, capabilities, and processes with program objectives and commercial readiness.

A core proficiency is maintaining a workforce with deep clinical experience across relevant therapeutic areas and disciplines. Personnel skilled in translating cutting-edge science into practical insights can meaningfully contribute beyond operational tasks. They provide valuable strategic perspective to optimize evidence generation plans and prioritize success metrics.

Equally vital is an established governance model that upholds objectivity, ethical conduct, and regulatory compliance across all engagements and initiatives. Defined decision-making procedures grounded in scientific rationale reinforce organizational integrity and stakeholder confidence by mitigating risks.

Having advanced data management infrastructure integrated across functions is also foundational. Seamless access to comprehensive, timely data empowers evidence-based decision-making to advance development goals. In parallel, refined operational processes drive study execution excellence through optimized quality, timelines, and resource utilization.

Cultivating these organizational proficiencies from early stages is crucial, as it establishes an environment conducive to strategic impact. Priorities should include:

1. Talent acquisition retaining proficient personnel aligned with pipeline priorities.
2. Continuous training promoting innovation and therapeutic expertise.
3. Implementing integrated data capabilities enabling proactive planning.
4. Refining processes in lockstep with corporate milestones.

Developing this cohesive organizational model amplifies the potential for medical affairs to substantively influence product success. Rather than being constrained to executional tactics, integrated proficiencies position these teams as authoritative strategic partners throughout the drug development continuum.

Conclusion

Drug development continues to be highly challenging and risky. Key aspects of early drug development, regulatory and clinical trial strategy are dependent upon medical affairs input. The fundamental pillars of medical affairs namely Scientific Communications, KOL Engagement, and Evidence Generation provide clinical advocacy, strategic insights, and supporting data to optimizing chances of success (see table 1). Early integration of this capability is imperative to attaining strict clinical development timelines, optimizing regulatory readiness, elevating evidence quality, and gaining a sustained competitive edge.

Companies that comprehensively cultivate these catalytic capabilities will be well-positioned to transform scientific possibilities into tangible real-world advances benefiting patients, providers, and stakeholders.

Medical Affairs Deliverables in Early Development

Scientific Communications	KOL Engagement	Evidence Generation

• Development of Scientific Communications Platform
• Development of Scientific Lexicon
• Publications Planning and Delivery
• Congress Planning and Execution
• Evolving Medical Information provision
	• KOL Mapping
	• KOL Engagement Plan
	• Scientific Exchange Meetings
	• Patient Advocacy Group Engagement
	• Insights Gathering
	• KOL Tracker
	• Engagement metrics
		• Landscape Mapping
		• Patient journey mapping
		• Evidence strategy and execution to strengthen clinical development plan
		  • Natural History
		  • Patient Registry
		  • Disease state

Operational Excellence		
Fit for purpose Medical Affairs Operating Processes Organizational design and timely support with key hires		

Table 1 provides a concise overview of the key deliverables within each Medical Affairs pillar and their contribution to optimizing drug development.

While achieving the vision outlined in this paper requires investment, the potential return on investment for early Medical Affairs integration is substantial. Partnering with expert vendors can mitigate risks and accelerate the development of a high-performing Medical Affairs function. By securing the right partner, companies can confidently navigate the complexities of drug development, achieve critical milestones, and maximize their chances of success.

About the authors

Ramin Farhood, MBA, PharmD

Ramin is Senior Vice President, Medical at SSI Strategy. He works with client executives and leaders to tackle the challenges of the Medical Office within small and mid-sized organizations. He is also adroit in championing USMA and GMA reengineering efforts for larger pharma client partners.

Len Walt, MD, MBA

Len Walt is Vice President, Medical at SSI Strategy. He has worked with many pharmaceutical and biotech clients on strategic issues related to their medical office functions, with a specific focus on gene therapies, rare diseases, and oncology

Dani Thomas, MD

Dani Thomas is Vice President, Medical at SSI Strategy. He is a registered physician from the UK with expertise in medical affairs leadership and multiple therapeutic areas from large biopharmaceutical organizations.

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