The Value and Strategic Implementation of Insights Management



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INTRODUCTION

The global pharmaceutical industry is undergoing significant transformation, from a previous focus on sales to become truly customer- and patient-centric. In parallel, both the availability of big data and the technologies needed to create meaning from these data are newly available to Medical Affairs teams. The result is the ability of the Medical Affairs function to help industry understand external healthcare challenges and opportunities via strategic insights capture and management – identifying areas of strategic importance for patient identification, diagnosis, treatment, management, and follow-up.

Through insights capture, analysis and communication, Medical Affairs professionals act as the adaptive mechanism within pharmaceutical and MedTech companies, bringing key data, facts and observations from the healthcare environment back to the organization to create or adjust strategic directions. This paper provides a foundational understanding of insights management, including the definition and value of insights, processes and technologies for insights management, and key challenges in implementation.

What is a Medical Affairs 'Insight'?

A Medical Affairs insight is based on relevant information collected by a Medical Affairs professional through a verbal or written exchange with an external stakeholder or through examination of disease community data, which, after analysis and validation, can drive planning, actions or decisions.

Insights Often:

- Originate from the external healthcare environment
- Are captured by in-field professionals such as Medical Science Liaisons and others
- Undergo analysis and validation
- Can in sum constitute a "call to action"
- Are relevant to strategic objectives
- Are 'aha' moments that connect external thoughts and behaviors (or lack thereof) to potential internal action

Insights May:

- Be expected or unexpected
- Identify presence or absence of expected thoughts and behaviors
- Confirm current tactics/practices or set new strategic directions



THE VALUE OF MEDICAL AFFAIRS INSIGHTS

Ultimately, the goal of the biopharmaceutical and MedTech industries is to support the evolution of clinical practice by introducing effective and tolerated therapies that address unmet needs, while ensuring these therapies reach the right patients at the right time. This requires behavior change from stakeholders in the healthcare ecosystem: An existing therapy is replaced with or augmented by a therapy with an improved risk/benefit profile or offers other benefits such as superior value, convenience, etc., often requiring new systems of diagnosis, treatment, and monitoring.

Medical Affairs insights can help identify the current state and pinpoint areas of knowledge, opinion or behavior change necessary for the successful launch and use of an emerging drug, diagnostic or device, accelerating the delivery of the right therapy to the right patient. For example, in the pre-launch period, insights may underlie strategic planning for evidence generation or external education, or may identify patient-centric endpoints to guide the design of registrational clinical trials. Post-launch, insights may signal change in knowledge, opinion, behavior, or action longitudinally in the disease community and healthcare ecosystem, confirming successful strategies or identifying gaps that indicate new or different strategies may be needed. Insights that identify unmet medical needs may point the direction for future life-cycle management opportunities.

As such, the value of Medical Affairs insights is not limited to Medical Affairs and rather can inform the execution of strategies by other industry pillars such as Research & Development and Commercial. Until an organization tests its strategies with members of the disease community, strategies are only hypotheses, requiring the validation of insights to know if the organization's innovation is relevant. Without Medical Affairs insights, the potential exists to not only miss targets, but to be unaware of having missed them.

Operational excellence in the insight management process – including collection, validation, analysis and internal communication of insights – demonstrates the need for Medical Affairs collaboration as a driver of company strategy. This is especially true because Medical Affairs is usually uniquely equipped within the organization with the scientific and clinical expertise required to contextualize the value of insights. Just as Epigenetics allows cells to adapt to their surroundings, Medical Affairs insights allow biopharmaceutical and MedTech companies to reach a higher level of understanding and thus adapt to their surroundings. Organizations in which Medical Affairs drives the collection, analysis, and communication of actionable insights will efficiently recognize threats and opportunities in the external healthcare ecosystem, optimizing the ability to respond and adapt appropriately.



What is the value of a Medical Affairs insight?

The value of a Medical Affairs insight is the ability to capture and respond to learnings based on data, facts, and observations from sources beyond the organization.

THE PROCESS OF INSIGHTS MANAGEMENT Strategy Step 1: Define Insights Strategy

Without a well-defined strategy, insights management can become tactical and focused solely on "counting interactions," which could be executed by a support function. For Medical Affairs to move from a support function to a strategic partner, a successful insights management framework may optimally start with Medical Affairs defining key insight topics (areas of special interest), with input from the cross-functional team. Inside these key insight topics (KITs) are key insight questions (KIQs) that become listening priorities. When identifying KITs and KIQs consider the following thesis that is embedded in any approach to bringing industry innovation to market, namely: 1) unmet needs exist; 2) the characteristics and attributes of a new therapy are better than the existing approaches (for the primary population or for subgroups); 3) the healthcare ecosystem will understand and agree with points one and two. Key insight topics and listening priorities can be designed to stress-test these theses.

Additionally, an effective insights management strategy requires a mechanism to listen for emergent learning beyond the thesis that may influence a product's ultimate success. Importantly (and often omitted in current insights management strategies), an internal and external insights communications strategy is crucial. Thus, the basic framework of the insights strategy includes three parts, with KITs, leading to KIQs, leading to communication strategies.

- With cross-functional partners including Commercial, R&D, and Market Access also gathering insights, it can be challenging to align on KITs and KIQs.
- Aligning insights strategy with organizational strategic priorities lays the groundwork for demonstrating the value of eventual insights.



Insights management process



Strategy Step 2: Formalize the Insights Process

It has become state of the art within business management to ensure proper strategic and tactical planning prior to execution. In the case of insights management, this includes defining the processes and technologies needed to gather, analyze, validate, communicate, and act on insights. No single solution is appropriate for all organizations – management of 90 insights in a small company may be as simple as starting with a shared spreadsheet where Medical Science Liaisons (MSLs) can note interesting information, followed by a monthly/quarterly meeting to review and take informed action; however the management of 90k insights in a large company requires increasingly sophisticated digital and technological systems paired with an internal process to discuss, identify, and implement actions based on insights. Thus, defining an insights process requires "right-sizing" technologies to meet the needs of the organization. Too much technology in a small organization runs the risk of implementing solutions that are more cumbersome than a human-centric approach; too little technology in a large company runs the risk of leaving humans with too little time for analysis and strategy.

Key Challenges and Opportunities:

- Ideally, building an insights management process for a new company or revising a process for an existing company is a cross-functional effort to identify gaps and opportunities.
- The tool available for insights registration, analysis, and validation must be chosen carefully with input from key stakeholders and end-users to ensure it is an easy-to-use solution that combines in-field dynamic activities with seamless upload for the next colleague in a company's insight management process.

Strategy Step 3: Identifying Sources of Insights

At this point in the planning process, the organization has a listening device and has identified KITs and KIQs. The next step therefore becomes deciding in what direction the organization should point this system. Certainly, the traditional insight sources of MSL engagements and advisory boards



will continue to be essential. However, beyond these sources lies a rich ecosystem of possible insight sources, each with its own best purpose (and insights management challenges). Literature surveillance may inform publications strategy; social listening may inform Medical Information strategy; payer insights may inform market access strategy; insights from patient communities may help to decide clinical trial endpoints and even future development; listening to investor communities may inform capital opportunities. Meanwhile, increasingly sophisticated tools (e.g., digital algorithms, big data, artificial intelligence, machine learning, etc.) are adding additional insight sources beyond the traditional 1:1 written or verbal exchanges, allowing precision targeting within mapped networks of healthcare professionals (HCPs), key external experts (KEEs), and, increasingly, digital opinion leaders (DOLs). Today we are seeing the realization of digital tools that output CVs for the top 200 KEEs in a disease community, identify the KEEs most able to shift opinion or influence treatment guidelines, and allow predictive network expansion to pinpoint key external experts beyond HCPs or those involved in treatment of co-morbidities related to the disease state.



Figure 1. Sources of Insights

- Representative and accurate sampling remains challenging due to issues including confirmation bias and dominant voices (digital and 1:1).
- Increasingly diverse sources of insights must be structured into a tangible narrative.



Implementation Step 1: Generating Insights

In order to achieve a well-functioning and effective insights management process, strategic priority awareness (e.g., awareness of KITs and KIQs even at the tactical level) is key for all involved. Ensuring this understanding requires training. Relevant to this step of generating insights, training can start by focusing on defining what is (and isn't) an insight – and what physical actions team members should take to generate and capture data they believe may form the basis of an insight. While insights may eventually be relevant only to certain teams or regions, the goals and processes of insight generation should be standardized across Medical Affairs (allowing 'apples-to-apples' comparisons within the data). Time and resources spent training team members on exactly what is and is not insights data worth collecting – along with how to capture this data – will guard against the danger of "garbage in, garbage out" that undercuts the ability to generate value from data.

Key Challenges and Opportunities:

- An organization may use different tools for gathering insights from diverse sources; however, if this is the case, an organization will require an interface that permits a view into all these inputs to facilitate translation and interpretation.
- Automating insights management remains a major opportunity for optimization.

Implementation Step 2: Filtering Actionable Insights

The ability to translate data into insights requires the ability to step back and analyze information to identify trends, gaps, and new information relevant to KITs, KIQs and emergent learning. Floating insights to the top of a data lake can be done quantitatively or qualitatively. Quantitatively, consider that a data point is just a data point until a certain number of data points all indicate similar knowledge/sentiment/understanding at which point these data may coalesce into an insight. This quantitative analysis of insights is likely actioned by digital or data analysis teams within Medical Affairs or by cross-functional support teams created for this purpose. Qualitative analysis of insights requires sophisticated understanding of the organization's science, the disease state and associated patient related burden of disease, and the healthcare ecosystem. For this reason, Medical

Think of insights management like mining for diamonds. Finding 'diamonds' can require sifting tons of 'coal.' In this analogy, it's tempting to throw away the coal. However, if Medical Affairs searches only for diamonds, it discards value. There is much to be learned from coal, especially in understanding which current actions are having their intended effect.





Affairs is uniquely positioned to perform qualitative analysis of insights. Think of these qualitative insights as potential outliers when presented without the appropriate context, but which through the lens of Medical Affairs can affirm or adjust strategic actions and directions.

Key Challenges and Opportunities:

- Data, facts, and observations must undergo validation and analysis in order to be transformed into "insights."
- The more team members understand and are aligned with the goals and processes of insights management, the cleaner and increasingly effective the process and outcomes of insights gathering will be.

Implementation Step 3: Archiving & Storing Insights

Some insights may suggest single, discreet actions; however, many insights are less a point in time than a trajectory, requiring longitudinal monitoring to provide value. Over time, if an organization loses the history of insights, it loses the ability to recognize trajectory. For example, volume of an occurrence or another measure of insights may be compared to historical or baseline measurements from previous quarters to identify trends. Alternatively, insights may require accumulation of data over time such that a given data point may not seem important until it is seen to repeat, at which point it rises to the level of an actionable insight. This requires careful storage and tagging of data within digital systems such that historical data can continue to be mined and connections within data can be identified through future analysis. In the context of global pharma, it may also prove important to ensure the system is able to archive and tag insights across borders and within larger regions. This may allow trend identification based on countries/ regions with comparable or divergent healthcare systems, and may explain varying medicine uptake/ utilization, as well as national/genetic drivers of disease and treatment outcomes.

- Early indications from preclinical and clinical development will need to be combined with category tags from disease state, class of medication, etc. to appropriately structure insights so that they continue to provide future value.
- As insights management processes inevitably evolve, it can be challenging to ensure compatibility with the ways data have been previously archived and organized.



Implementation Step 4: Communicating Insights

Insights require communication to achieve impact. Importantly, it is the actions and decisions that result from the communication of insights that demonstrate the strategic value of Medical Affairs. Effectively communicating insights internally requires a communications plan that delivers insights to key internal stakeholders based on their relevance to various teams/departments/functions and their weight. This requires Medical Affairs to understand the corporate strategy and to be expert in translating the value of insights into language that aligns with the strategic priorities of R&D, Commercial and senior leadership. In other words, Medical Affairs must communicate insights that support its own functional objectives and goals but also the objectives and goals of cross-functional partners (e.g., helping Commercial teams adjust a product's value proposition based on insights from social listening, or demonstrating new opportunities for drug/device development based on insights from a patient community). In addition, insights may identify knowledge and evidence gaps that provide opportunities for external communication in the forms of External Education, Medical Information, Data Generation Plans, Publications and more. Again, successful product launch requires behavior change; insights should help identify or qualify opportunities for external communications to make the case for desired and relevant changes.

Key Challenges and Opportunities:

Collaboration at many levels is key. For insights management to be embraced and resourced by senior leadership, the process must be efficient, valuable, and timely – and the communication of insights must align and support the corporate strategic priorities.





Implementation Step 5: Acting on Insights

Insights have the potential to confirm or adjust strategies and tactics. Ensuring an insight management process is in place streamlines the ability to act on insights and requires a communication plan to be successful. A predefined communication plan permits rapid and seamless distribution of actionable insights to key stakeholders. Importantly, some insights are most valuable only when acted on quickly, for example insights on patient safety which may require immediate AE/SAE reporting or competitive intelligence that informs near-term product strategy. This may mean instead of being an iterative process (say, insights-based actions are decided and updated in a quarterly meeting), actions must be evaluated dynamically and in as close as possible to real-time. From an operations perspective, this requires designing a process within the available software that can combine daily practice into strategic decisions such that after information undergoes analysis/discussion and is identified as an actionable insight, that realization is immediately followed by a process that can define the correct action. What is nice-to-have versus must-have? Which insights should result in immediate action, and which initiate longer-term projects and even strategy development/improvement of existing strategies? Just as an inefficiently communicated insight may dissipate into irrelevance, an insight that is identified as actionable but is not acted upon may soon be lost or forgotten. Once actions are taken based on insights, the value of these actions should be communicated back to those implementing insights management to demonstrate the power of their actions to close the loop and ensure continued enthusiasm and strategic knowledge on the importance of the infield work delivered within the Medical Affairs function. MSLs, Medical Information teams and others gathering and analyzing insights often have much more to do than only gather and analyze insights. Reporting back the impact of insights can help ensure that insights management remains a priority.

- Depending on the available IT-systems and business operation in place, it can take a fairly long time to receive and process insights, especially from the field. Streamlined insights analysis and thus streamlined operational processing is absolutely essential to allow efficient actions to occur.
- Measuring the impact of actions resulting from strategic insights remains challenging. Continued dependence on quantitative measures such as number of insights, number of interactions, number of KEEs, etc. presents an opportunity for future innovation.



CONCLUSIONS

Medical Affairs insights have the potential to drive the evolution of industry toward increased organizational efficiency and optimized patient benefit. To achieve this goal, industry must understand the meaning and impact of insights, and institutionalize the processes by which insights can inform the organization and influence strategic decisions. The purpose of this paper is to equip Medical Affairs decision makers with the context needed to plan their own processes and technologies. Given the powerful added value of robust insights management, Medical Affairs professionals should now consider this discipline an essential practice to further establish themselves as strategic leaders within their organizations as well as within the broader context of the health sciences and healthcare ecosystem.

