The Value of Medical Affairs: Defining Strategic Metrics to Demonstrate Impact

Objectives
- Establish how to define, measure, and communicate the value of Medical Affairs to the broader organization and to external stakeholders through the annual medical planning process for the Medical Affairs team
- Discuss how to shift the value paradigm to both quantitative and qualitative measures of success for Medical Affairs
- Define how to link meaningful metrics in Medical Affairs to desired outcomes

Introduction
Medical Affairs (MA) teams oversee important internal and external activities that define clinical development, stakeholder relationships, scientific communications, and education in the pharmaceutical industry. As MA becomes an increasingly critical part of organizations and responsibilities continue to grow, MA teams are striving to develop new and relevant metrics that ensure the effectiveness and efficiency of their function. Additionally, communicating the value and importance of MA and other scientific (nonpromotional) resources to the broader pharmaceutical organization is critical as MA continues to grow. This starts with demonstrating the impact of MA through defining key metrics and assessments to ensure that multifaceted MA teams are meeting fundamental strategic objectives and delivering the most value to their organizations. Metrics should be meaningful, and can be either organizational to measure efficiency, or strategic to measure effectiveness and impact. By starting at the brand level, during the annual medical planning cycle, MA leaders can define and utilize the aforementioned strategic metrics as a critical starting point to define success. Monitoring these metrics can guide ongoing decision-making on how MA teams can appropriately support and provide value to the brand.

As the development of standardized metrics applicable to any MA team is complicated by the inherent uniqueness of this function across organizations, this white paper does not attempt to provide a prescriptive “one size fits all” solution. Rather, it suggests and describes a framework of key considerations and guiding principles for defining strategic metrics during the annual planning cycle and ongoing monitoring of outcomes.

Design MA Strategy
Define the strategy
To demonstrate MA value, a focused and prioritized medical plan must align and support the broader organizational strategic imperatives, and recognize the medical and scientific opportunities and challenges in the marketplace for both the brand and therapy area. Strategic medical objectives or outcomes of the medical plan should be influenced by, and aligned, to the met and unmet needs of the external stakeholders – healthcare professionals, patients, caregivers, regulatory decision makers, and payers – in the therapeutic space. Focused strategic medical objectives will maximize the overall medical value to the external stakeholders, while upholding the scientific integrity and respectability of the product and pharmaceutical organization that supports it.

Align internal MA stakeholders
The strategic focus should be clear because, as the multifaceted MA team grows to scientifically and clinically lead brands, the internal MA stakeholders and functional groups – including data generation and management, medical communications and education, health outcomes research, medical science liaisons, key opinion leader engagement, medical information, scientific publications, and others depending on the organizational structure – within MA need to work together toward these goals and maintain alignment to create strategic success. Each functional group will need to identify how they can partner and execute on the medical strategy to determine how they can contribute to outcomes. With collaborative leadership and effort, each group can define strategic medical activities aligning to strategic objectives that demonstrate beneficial impact and fulfill tactical need that is required for a comprehensive and valuable medical plan.

Define MA Metrics
Develop an approach to strategic metrics
Every MA team member should be working towards this common set of broad outcomes or strategic objectives; however, the methods by which these outcomes can be achieved and measured will differ by function/department. Therefore, a critical component of the MA approach to strategic metrics within the broader organization is to understand the key initiatives that each functional group will employ in their efforts to achieve the desired strategic outcome. Just as important is to understand where there may be areas of synchronicity and synergy that may increase efficiencies in pursuit of these outcomes across the MA functional groups (Figure 1).
Define strategic metrics

Types of metrics

Metrics can be broadly divided into two groups (Figure 2):

- **Goal-based metrics:** Metrics that are related to the activities/initiatives that need to take place to ultimately reach the desired outcome. Because these metrics are related to specific activities or initiatives, they are usually easier to build metrics around. Ideally, groups of goal-based metrics should be aligned to a given outcome-based metric. A sample metric is delivery of an advisory board program to gain critical insights in a specific timeframe.

- **Outcome-based metrics:** Metrics that measure whether the desired end outcome (strategic objective) has been achieved. These tend to be broad and, as a result, typically are more difficult to build metrics around. Often, many cross-functional stakeholders, even outside of the MA organization, contribute to these outcomes. A sample metric is shift in behavior by a healthcare professional.

While the outcome- and goal-based metrics are distinct, they are related. Therefore, it is critical to think about these two categories of metrics simultaneously. All metrics, whether outcome- or goal-oriented, must tie back to the objectives outlined in the medical plan, and it is critical to define those metrics prior to executing any tactical initiative. Only in this way can success be robustly measured and value demonstrated.

There are two further subcategories of metrics that need to be considered, and these may be applicable to either outcome- or goal-based metrics: specifically, quantitative vs qualitative metrics. Quantitative metrics, as the name suggests, are numerically measurable metrics, whereas qualitative metrics are more associated with changes in perceptions that cannot be numerically quantified. Outcome-based metrics are most often qualitative, while goal-based metrics are typically quantitative, but this is not a hard and fast rule. Examples of qualitative and quantitative metrics are provided below (Table 1).

An example of strategic metrics to illustrate all of these points is shown below, with outcome- vs goal-oriented metrics as well as qualitative vs quantitative metrics (Figure 3).

### Table 1. Example quantitative and qualitative metrics in MA

<table>
<thead>
<tr>
<th>QUALITATIVE METRIC</th>
<th>QUANTITATIVE METRIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal and external customer feedback (e.g., market research, surveys)</td>
<td>• Number and type of MSL activities and engagements</td>
</tr>
<tr>
<td>Insights captured from investigators, advisors, patients, and other external stakeholders that may inform medical strategy, clinical development, or other internal functions</td>
<td>• Number of accepted publications</td>
</tr>
<tr>
<td>Changes in formulary decisions or medical policy, or guidelines</td>
<td>• Number of symposia or educational opportunities supported</td>
</tr>
<tr>
<td>External recognition</td>
<td>• Number of formulary changes</td>
</tr>
<tr>
<td>- Credibility for scientific information in therapeutic areas</td>
<td>• Number of medical information requests</td>
</tr>
<tr>
<td>- News coverage</td>
<td>• Patient or investigator recruitment</td>
</tr>
<tr>
<td>- Social media coverage and/or reach</td>
<td>• Number of investigator-initiated trials</td>
</tr>
<tr>
<td>- What credible KOLs and HCPs in the field are saying at congresses and in publications</td>
<td>• Altmetrics (to measure publication impact)</td>
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<tr>
<td>- Sentiment analysis for altmetrics</td>
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<td>- Benchmarking to other companies</td>
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</tbody>
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HCP=healthcare professional; KOL=key opinion leader; MSL=medical science liaison.

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**Figure 3. Example of goal- and outcome-oriented metrics aligned with strategic objectives**

1. **Engage physicians who are concerned about safety**
   - **GOAL-BASED METRIC:** Identification of 15 KOLs per region who have expressed safety concerns about Drug X in next 3 months

2. **Determine the safety of Drug X in Y and Z populations**
   - **GOAL-BASED METRIC:** Completion of an assessment of latest clinical practice standards in RWE studies

3. **Educate HCPs on the benefit-risk profile of Drug X**
   - **GOAL-BASED METRIC:** Completion of 6 HCP educational events on the benefit-risk profile of Drug X in the next 12 months

**OUTCOME (Strategic Imperative)**

- Drug X is the foundation of therapy

**OUTCOME-BASED METRIC**

- Physician questionnaire to determine change in attitudes towards the place of Drug X in the treatment paradigm

**GOALS**

- Quantitative Metric
- Qualitative Metric

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HCP=healthcare professional; KOL=key opinion leader; RWE=real-world evidence.
Meaningful metrics

When defining the type of metric and how it should be measured to demonstrate MA value, it is important to identify what is meaningful. This can be dependent upon a variety of factors: the audience who evaluates the metrics, where a product is in its lifecycle, identified external stakeholders, organizational constraints, types of activities being executed as part of the medical plan, and others depending on the therapy area and the organization.

For example, one of the biggest drivers of what matters as it relates to demonstrating value is the audience who evaluates the metrics and outcomes, including internal stakeholders such as commercial, health economics and outcomes research (HEOR), regulatory, research & development (R&D) colleagues, as well as organizational and MA management. For each audience, you must ask, “what does this stakeholder value?” before you can ask the question, “how can that be measured?” These questions should also be considered when developing and communicating appropriate metrics to demonstrate the value of your strategic medical plan to the organization.

Ensure cross-functional internal alignment

Once you have defined your medical plan and appropriate and meaningful metrics in MA, it is important to gain organizational feedback outside of MA teams and agreement on the plan. Therefore, as you are finalizing your medical plans, provide an opportunity to collaborate with and gain alignment from other key internal stakeholders outside of MA (Figure 4). This is a critical step to ensure the entire organization has the same expectations of what the MA team will deliver. Ultimately, if the MA team delivers on the agreed medical plan (objectives and tactics), they have achieved their goals and delivered organizational value.

When gaining feedback and support from the cross-functional internal team, it is important to gain alignment on the current medical plan and defined metrics. Some important questions to be discussed include:

- Are all team members aligned with the current medical plan and defined metrics? Should anything be changed?
- How should the metrics be tracked and reported? How often should goals be reassessed for relevance to landscape changes (e.g., quarterly)?
- How should progress towards broader strategic objectives be assessed outside of the tactical measures? What can be measured from a cross-functional perspective? Multiple teams may contribute to these outcomes.

For every engagement with the cross-functional internal stakeholders, each member of the MA team needs to bring to the table thoughtful and purposeful ideas that are unique to the MA function, which will, in part, demonstrate the value MA can provide. Each engagement in the planning process is an opportunity for other stakeholders to understand the role of MA within the organization, including what its team members do and do not do. Key principles to keep in mind when you align on the medical plan and strategic metrics with cross-functional internal stakeholders include:

- Ensure the MA team provides cross-functional internal stakeholders with an idea of what tactics and metrics can be provided in the MA functional space, “what we CAN and SHOULD measure”
- Discuss what metrics the other groups are most interested in, and understand what each part of the organization expects or perceives as value from the MA team during that year and in the long-term for the brand
- Provide the opportunity for feedback on “what worked” and “what didn’t work” from the previous year(s)
- Clarify expectations and/or limitations; determine if “ideal” metrics are not achievable by a specific MA function or within the medical plan

While all cross-functional feedback on the medical plan and metrics should be considered, not all guidance may be adopted, as MA should be autonomous from the commercial organization.

The definitive goal of MA is to further the science and improve medical practice by informing on the benefit-risk profile of the treatments for the benefit of healthcare providers and patients; this should be shared with the extended cross-functional stakeholders. Ultimately, all strategic metrics should take this goal into account and provide an objective, commonly understood measure of achieving the medical vision and strategy for the brand.
Operationalize strategy and metrics

Once obtainable strategic metrics are determined, it is critical for the MA functional groups to align on how to execute the tactical plan, as well as track and assess the associated metrics. This ensures a level of accountability within each functional group and systematic assessment of whether the group is on track or requires adjustments in their plans. It is important to gain an understanding of what the baseline may be for many pertinent metrics, in particular those that are measuring a change in attitude or perception. This can include data or insights gathered through interactions with opinion leaders, survey of key opinion leaders (KOLs), podium/scientific publication messages, field medical assessments, social media listening, and other methods to ensure knowledge of the current state of the healthcare environment for the brand. This baseline will be compared over time as the metrics are assessed. Additionally, the metrics should be assessed at regular intervals (eg, quarterly) throughout the year. These regular assessments must use a streamlined process and method, so that the burden of tracking metrics does not become a barrier to their use.

Technological approaches may be of particular value for the streamlined tracking of metrics. For example, medical field teams may already use an integrated customer relationship management (CRM) system to collect and store specific metrics. One issue with that particular approach, however, is that all the functional groups need to track in the same system, and other functional groups, such as medical information or publications, may not be using the CRM system. MA dashboards are becoming increasingly common as they provide a single location to catalog planned tactics as well as identified metrics or applicable data for potential metrics analysis, including comparison to baseline assessments. Other more traditional methods of Word or Excel documents on shared team spaces are also being used. No matter what location and method of insight or data collection for metrics, it is critical that it is consistent across the functional groups, to quantify or qualify the success of current efforts and ensure the sustained relevance of the medical strategy and tactical approach.

Therefore, in order to appropriately track and assess metrics within your MA organization, you need to do the following:

1. Establish your baseline for the metric comparison
2. Determine process and timing for metric assessment
3. Identify a common tool for metric data collection and evaluation
4. Keep in constant communication with the functional groups to ensure accountability and proper adjustment to changes in medical plans
5. Develop an ongoing communication plan for cross-functional internal stakeholders to highlight achievements and accomplishments of the MA teams as well as key learnings from the metrics evaluation

Summary

Being a leader of the collaborative process with the extended internal teams (eg, commercial and R&D), ensures that MA is recognized as a critical function, always has a “seat at the leadership table,” and is seen as a robust and strategic organization within the company. Encouraging a cross-functional collaboration when designing the medical strategy and tactical plan, as well as defining and implementing metrics, will create alignment, which in turn will demonstrate the effectiveness of the MA team and organically show the value of MA. Additionally, assigning appropriate strategic metrics and periodic tracking will help the MA team deliver on the goals of the brand and provide opportunity for effective decision-making and potential optimization of the medical plan to deliver on or better meet the objectives. The medical plan and its metrics are dynamic and should be adjusted when needed throughout the year, but overall it is the roadmap to deliver new value to the science, patients, and the healthcare ecosystem within a therapeutic space. Thus, the appropriate execution of the strategic medical plan is one of the best measures of achievement by MA teams.

Key Takeaways

1) Use strategic metrics to show progress towards achieving the yearly medical plan and demonstrate the value that MA is bringing to the organization
2) Make certain that strategic metrics relate directly back to the specific strategic objectives
3) Ensure collaboration within the MA team; all functional groups need to provide input to achieve strategic objectives and maintain alignment on metrics to ensure measured success
4) Include strategic metrics that are outcome-based or goal-based, with both qualitative and quantitative measures
5) Consider the audience for the metrics and what they value
6) Ensure cross-functional internal stakeholder agreement on the metrics to maintain alignment on how to measure progress on the medical plan
7) When operationalizing metrics, consider baseline assessments, timing of updates, tools for metrics collection, and communication of progress and key learnings to the MA functional groups and cross-functional stakeholders

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About Envision
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Envision employs over 650 team members across 14 global offices, including 230 in-house medical writers and 120 technology specialists.

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