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Medical Affairs KPIs 2025:

DEMONSTRATING AND ENHANCING THE VALUE OF A MODERN MEDICAL AFFAIRS ORGANISATION

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MEDICAL AFFAIRS KPIs: A COMPLEX UNDERTAKING, BUT IMPORTANT TO GET RIGHT

Since the establishment of Medical Affairs as an independent function and throughout its evolution, Medical Affairs executives have often struggled to identify the best way to demonstrate the value that the group creates. Today, Medical Affairs rightfully holds a leading strategic role in our increasingly real world science and data-driven industry, critical for ensuring that external stakeholder needs are well understood within biopharmaceutical and medical device companies, and effectively met through evidence generation and scientific information exchange. Increased strategic importance has led to greater investment, and a concomitant senior management expectation of Medical Affairs to be able to demonstrate value at the corporate level. An increasingly complex portfolio of responsibilities also means that executives at all levels within the Medical Affairs function itself require improved tools to enable data-driven management of performance.

Due to these drivers, there is already an expectation in most organisations that Medical Affairs will maintain and report a dashboard of execution and impact 'key performance indicators' (KPIs). Levels of detail, sophistication and value of these dashboards vary. **Without insightful KPIs, it is impossible to effectively identify successes and to course-correct when efforts do not progress as planned.** Further, without an ability to recognise value, senior executives will question resource investments. This risks under-resourcing of critical capability areas such as insight management, real world evidence generation, digital engagement and patient centricity.

Medical Affairs is a complex discipline performed by a highly matrixed function; much of its value is not obviously quantifiable and so KPIs are not simple to define. **There are few industry-standard metrics that pertain to Medical Affairs**, although a small number are widely used such as those examining medical scientific liaison (MSL) activity. The remit and role of Medical Affairs also varies quite widely across industry, depending on company size, structure, strategy, product portfolio and historical events.

Structure and purpose of this paper

The purpose of this paper is to describe how effective Medical Affairs KPIs can be developed as straightforwardly as possible, and to present key elements that organisations should consider in their own KPI dashboards. The paper is broken into two main parts:

- The first section [A] outlines a framework for how a suite of Medical Affairs KPIs can be built from the ground up, for the benefit of recently established organisations and Medical Affairs leaders who are conducting a full re-design of their Medical Affairs KPIs. Having such a framework is important in establishing a clear pathway for KPI development and review, enabling efforts to be focused on the in-depth thinking required to develop a holistic and appropriate set of KPIs for an organisation.
- The second section [B] discusses specific capability areas in Medical Affairs where KPIs should be considered. This includes an outline of cutting-edge areas where the contributions of Medical Affairs are evolving, leading to an associated requirement for innovation in performance management.

Is the value of Medical Affairs uniquely hard to measure?

Medical Affairs has distinct accountabilities within a biopharmaceutical or medical device company that – at first glance – seem extremely hard to measure. For example, how does one build an indicator of scientific exchange leading to appropriate or optimal use of a medicine? Impact measures certainly should not refer to product sales, but may factor adherence and persistence, physician and patient understanding of the medicine's therapeutic profile, patterns of off-label use and a host of other variables that may not be fully under a company's control.

That said, these performance and value assessment challenges are not necessarily unique. In contrast to Medical Affairs, Development and Commercial functions both have long-established functional metrics that address quantitative targets or industrialised aspects of their key processes, and are recognised across industry. Nevertheless, even these metrics must be adapted to the modern healthcare environment:

- Clinical development metrics have traditionally focused on time and cost during phases of clinical development, but not on quality of the evidence produced. This approach might make sense if quality expectations were completely clear and consistent globally, e.g., to demonstrate the efficacy and safety of the medicine in a placebo- or single comparator-controlled trial and assure quality of the manufactured product. It is less fit for purpose in the modern environment where positive access and reimbursement decisions are often contingent on robust evidence of real world clinical and cost effectiveness. Further, product development can no longer be considered successful just because it achieves marketing authorisation in the USA. National and regional decision-makers across the globe have nuanced evidence requirements that a matrix of company functions must understand and address by working together in an integrated fashion.
- Commercial metrics historically simply focused on sales and profitability, using these lagging indicators as proxies to assess value to a company's customers. In today's more patient-centred healthcare model, it is increasingly important for long-term success to also gain more direct 'real world' feedback on patient and healthcare provider experience with a company's products and services in both clinical trial and naturalistic settings. This is just one area where it is vital for Development, Commercial and Medical Affairs functions to closely collaborate. Robust insights in these areas enable a company to optimise product use in the 'real world', and ensure it continues to develop offerings that sustainably meet customer needs in a highly competitive market environment. Importantly, this approach to assessment of value is far more in line with corporate mission statements, which invariably focus on improving human wellbeing, and never on revenue and profit motives.

SECTION A: HOW TO DESIGN EFFECTIVE MEDICAL AFFAIRS METRICS AND KPIs FOR AN ORGANISATION

The sequence of events to establish appropriate KPIs is summarised in **Figure 1** and described below.

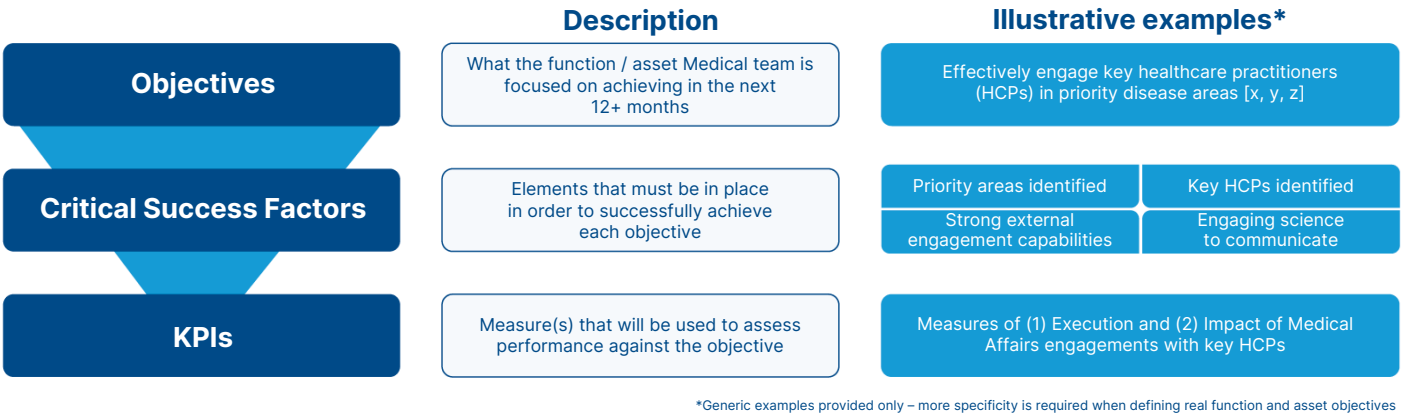

Figure 1. Descriptions and illustrative flow of objectives to KPIs

A1. Set appropriated objectives

Robust objectives are foundational to effective performance management. KPIs will be fruitless unless objectives are agreed and shared transparently, and no KPI should exist that cannot be explicitly tied to an objective. In mid- to large-scale organisations there are typically three key layers owned by a Medical Affairs department that are subject to some form of objective-setting **(see Figure 2 below)**:

1. **The overall Medical Affairs function** has objectives that reflect the function's role and areas for development. These will typically capture priorities over the coming 1–3 years and feature a mix of inward-looking elements (such as capability building and process improvement) and outward-looking elements (such as external engagement).
2. **Asset- or indication-specific teams** usually have a Medical Affairs plan from Phase II onwards, either as a standalone document or as part of an integrated Development, Launch or Brand Plan, as determined by life cycle stage. Led by a senior Medical Affairs executive, this plan will ideally provide a view of strategic objectives and expected tactics for the Medical team over the next 2–3 years, although many focus on the next financial year for budgeting reasons.
3. **Medical Affairs sub-functions** such as Medical Information, Publications and Field Medical will often have their own specific objectives, some of which may roll up into overall functional objectives, while others remain specific to the sub-function.

It is often stated that objectives should be SMART (specific, measurable, achievable, relevant and time bound)[1]. This is good guidance. It is even more important, however, that objectives drive performance in the organisation, while empowering staff at all levels and encouraging the right behaviours among teams.

[1] 'Agreed' and 'Realistic' are used interchangeably for 'A' and 'R'. No combination of words for the acronym 'SMART' is truly mutually exclusive.

MEDICAL AFFAIRS FUNCTION	
WHY	Assess and manage permformance of Medical Affairs function as a whole
WHAT	Mainly strategic – high level functional execution and impact
FOR WHOM	Shared within function and with leaders of key partner functions
OWNERSHIP	Head of Medical Affairs accountable

ASSET TEAM (MEDICAL)	
WHY	Assess and manage permformance of Medical components of asset team
WHAT	Usually a combination of strategic and tactical, factoring both execution and impact
FOR WHOM	Shared within asset team and with Medical Affairs leaders; may be shared with key partner functions
OWNERSHIP	Medical Affairs asset lead accountable

MEDICAL AFFAIRS SUB-FUNCTIONS	
WHY	Assess and manage permformance of Medical Affairs sub-function
WHAT	Execution of key sub-function deliverables, ideally including impact measures
FOR WHOM	Shared within sub-function and with Medical Affairs leaders; may be shared with key partner functions
OWNERSHIP	Head of sub-function accountable

Figure 2. The three key levels of Medical Affairs and characteristics of their associated KPIs

A2. Document the critical success factors for achieving your objectives

Critical success factors (CSFs) are elements that must be in place or put into action in order to enable the objectives to be achieved. Some may be possible to address quickly; others may require longer-term efforts. It is important to identify factors that are essential to the achievement of the objectives, and not try to list every possible contributing factor. CSFs may or may not include:

- Senior level sponsorship,
- Improved existing processes (potentially including automation and innovative sourcing strategies), or new customised processes if appropriate,
- Partnerships and relationships – internal or external to the company,
- Human resources including associated skills, knowledge and behaviours, and/or
- Productivity and enabling tools, including Information Technology.

Once the CSFs are clearly defined, the associated KPIs can be developed.

A3. Define the key performance indicators

KPIs provide an indication of whether CSFs and objectives have been met (lagging indicators), or whether they are likely to be met in future (leading indicators). Quantitative metrics are often hard to identify for Medical Affairs CSFs and objectives, therefore some KPIs will need to be qualitative, with the potential to assign a semi-quantitative scale and build a baseline to measure against where this is appropriate. At least some KPIs should have assigned targets, but there are often areas in Medical Affairs where targets may not drive the desired behaviours, so targets must be handled with care or even avoided in certain circumstances. Further information and definitions of commonly used terms in this area are provided in the Glossary at the end of this document.

For KPI design to be finalised and approved, KPI specifications should be completed that provide answers to the following questions:

- What management question will the KPI answer?
- What will the KPI measure specifically, and how does this answer the management question? What is the baseline, and what should the target be, if any?
- Who is accountable for each KPI and any associated narrative?
- Who or what provides the data?
- How often will the KPI be measured?
- How should the data be presented?
- How should the KPI results be communicated – by who, and to whom?
- How often should the KPI be reviewed?

Defining KPIs: beware the peril of unintended consequences!

Performance incentives and metrics can often lead to outcomes that are unintended and even opposite to the intended effect. This is also known as the 'cobra effect', based on an anecdote – albeit one that lacks historical evidence – that a bounty for every dead cobra in 19th century Delhi led to the breeding of large numbers of snakes. Even if the cobra example is in fact allegorical, similar and better documented historical events do exist[2].

To take an example relevant to Medical Affairs, the illustrative evidence generation KPI flow in **Figure 3** highlights that it is important to keep track of study timelines. However, if target timelines for study set up activities incentivise a rush to move to patient recruitment or data collection stages, then insufficient time may be allocated for feasibility assessment. This may ultimately result in downstream protocol deviations or even study failure, and longer timelines overall. This would be counterproductive to an overall objective of obtaining timely evidence to support market access.

OBJECTIVE	Ensure high quality and timely real world evidence is available for designated assets to support market access in the top 5 priority countries			
CRITICAL SUCCESS FACTORS	Evidence needs are identified	Studies are conducted efficiently	Studies achieve objectives	Data adds value to dossiers
KPIs	Key milestones e.g. • Priority country inputs obtained on schedule • Ev. gen. plan in place with gaps identified, on schedule	• Actual study milestones vs. schedule • Actual study costs vs. study budget	• Assessment of data generated vs. stated study objectives *(assessed with study in progress and on completion)*	• Evidence incorporated into dossiers • Evidence accepted in national & regional decision making • Market access achieved

Figure 3. Example flow of objective to KPI concepts related to evidence generation

[2] https://en.wikipedia.org/wiki/Great_Hanoi_Rat_Massacre

Summary principles for kpi development

KPIs should:

- Flow logically from objectives, with each objective supported by at least one KPI. For example, if there is a global objective to build specific capabilities then a capability-linked KPI should be defined.
- Enable management decision-making. If a measurement does not support management decisions it is not a KPI but a metric, and does not belong on a management dashboard.
- Be limited in number, based on their suitability for the required purpose:
  - Not all metrics should be KPIs - just because something can be measured (i.e. a 'metric'), doesn't mean it should be a KPI. The temptation to always incorporate quantifiable metrics into KPIs and dashboards should be resisted.
  - Top-level KPIs should focus on areas of highest impact requiring senior management level awareness and decision-making.
  - Sub-functions may have their own dashboards based on their objectives and activities, but these do not necessarily all need to roll up to the global / functional level. For example, the volume of promotional materials reviewed may not be of great interest to senior leaders, unless there is a specific concern on this topic (e.g. resource constraints for more strategic matters).
- Be understandable, possible to reference and visualise. Dashboard design is crucial here, ensuring ease of navigation while enabling users to drill into the detail where required.
- Be sensitive and specific to meaningful developments, reflecting positive and negative changes in performance in the areas that they examine.
- Be used in a transparent fashion, with appropriate context to explain results, and explanations to describe how indicators that are off-target or moving in the wrong direction will be brought back on track ('back to green', if traffic light indicators are being used).
- Be feasible to measure with available resources. It is important to know the constraints around internal staffing and budgets for external provider services.

SECTION B: SPECIFIC KPI DESIGN AREAS

Medical Affairs functions are typically responsible for a wide range of activities, so when identifying areas of focus for objectives and KPIs there is a large array of options to consider. Figure 4 summarises the main areas for consideration under four broad categories. It is important to consider which of these levers are expected to have the most impact on desired business outcomes. Hence global functional KPIs should typically focus on areas where Medical Affairs accountabilities deliver value to external stakeholders and/or to the broader organisation, as illustrated in **Figure 2.**

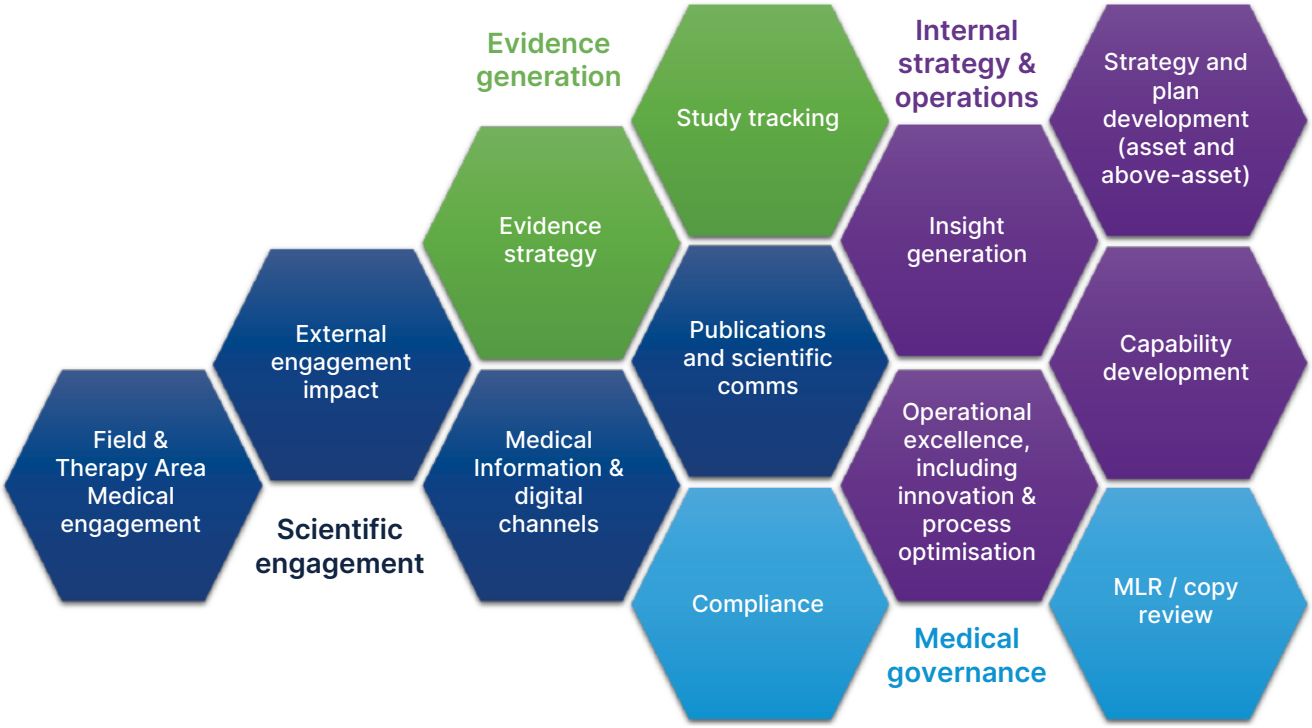

Figure 4. Topic areas for consideration in the design of Medical Affairs functional KPIs (not all areas will be a focus for KPIs in every organisation)

Some KPI areas are well-established, others are more novel or complex. Examples are given below; not every topic mentioned will be applicable to every organisation, depending on remit and objectives.

Well-established KPIs and metrics tend to ensure standard operations are executed within established parameters, and typically include items such as:

- **Field Medical execution:** Activity metrics include number of visits / meetings per MSL per month. Targets may vary by speciality and indication, in addition to geographic area covered. These metrics are not KPIs as they do not demonstrate productivity or impact without additional metrics and context.
- **Study tracking:** Milestone and cost tracking for evidence generation activities.
- **Publications execution:** Submission and acceptance of abstracts and manuscripts for target congresses and journals.
- **Strategy and planning:** This KPI may simply verify that each key asset at a certain life cycle stage has a Medical Affairs plan in place with clear objectives and tactics. More sophisticated approaches can look at tactic execution within the plans and track desired outcomes such as improved disease awareness among a set of HCPs, or whether specific evidence gaps have been addressed.

Evolving and emerging areas include:

- **Digital engagement:** 'Digital' is currently one of the most prominent areas for Medical Affairs management; it is attracting a great deal of resource investment targeted to both create a better user experience, and to capitalise on enhanced user analytics. Performance management in this area should focus on impactful engagement across multiple channels, ensuring these channels are delivering useful information in formats that external stakeholders want to use. This applies to traditional medical information and medical education for HCPs as well as more innovative interactive media such as apps supporting routine health, symptom management and treatment adherence. Industry surveys suggest many organisations are thinking about or seeking to pursue 'omnichannel' approaches. In the context of scientific content this means providing the user (often an HCP, but may include patients, payers or other stakeholders) a high quality and seamless customer experience across multiple communication channels. Performance management of all digital channels is therefore critical to effectively pursue an omnichannel approach tailored to the wants and needs of customers, targeting investment toward content and channels that are valuable and away from those that are not. There is a strong business case for doing this. For example, if KPIs demonstrate that half of globally-generated scientific content is not used in the countries, this is good evidence to support efforts at the global level to enhance and replicate the type of core content that does add value and drive engagement.
- **'Share of medical / scientific voice'** in the Medical Affairs context is a relatively novel medical / scientific impact metric of increasing industry interest. Enabled by rapidly advancing natural language processing and machine learning technologies, it is intended to show to what degree a company's science and medicines are discussed across multiple media channels in the context of the broader topic area. Ideally it should support assessment of the impact of events such as key congresses, product launches, the publication of new evidence, and so on. Unlike the other KPIs listed, establishment of a 'share of voice' indicator that is useful and relevant to Medical Affairs typically requires specific budget for specialised provider services, due to the nature of the technology and volume of data involved in deriving the indicator.

  There are multiple confounding factors to a share of voice indicator, such as competitor activity, other healthcare events (a global pandemic being just one example), and other social media noise. An explanatory narrative is therefore particularly important to give context to the information that share of voice readouts provide.
- **Change in patient management (**a.k.a. **impact on treatment decision-making)** leading to optimal patient access to a company's products and services is a primary aim of Medical Affairs' efforts, but is extremely hard to measure. In some ways it is linked to share of scientific voice, but is further downstream as it factors the impact of the communicated science on day-to-day clinical practice. It is influenced by multiple factors: efficacy of the company's products and services (and strength of evidence thereof); quality of communications; competitor products and science; and other decision drivers that influence prescribers, patients and caregivers. It might be tempting to look at prescription data, but this is a commercial metric and does not account for appropriate use of the products, which is an absolute requirement for any Medical Affairs activity. Companies typically employ carefully-worded survey-based methods when attempting to gather more insights on this crucial topic.

- **Insight generation and management:** Performance management in this area should focus on ensuring that insights on the needs of patients and their care networks are identified in a robust manner, and then used to inform strategy. This is not a matter of quantity but of quality, therefore KPIs in this area are likely to be qualitative, or at least not subject to numerical targets. **If information derived from an insights process does not inform strategic decision-making it is of no value, regardless of how many such 'insights' have been generated.**
- **Capability development:** Leading execution metrics for capabilities may focus on filling key new positions (such as insights leads, digital engagement leads, or enhanced global Medical Affairs asset lead roles), or upskilling existing individuals and teams through targeted training. Topics increasingly may include areas beyond Medical Affairs' traditional remit, such as engagement on, or definition and application of, Real World Evidence and Patient Reported Outcomes. They may also focus on the acquisition and leveraging of new technologies. Lagging outcomes measures should test whether these capabilities – once established – are delivering the desired impact against a prior baseline.

Regardless of whether an indicator is novel or well-established, its adoption should still follow the design principles described in Section A. It is also worth noting that there is no magic novel indicator that perfectly addresses any capability area – all have their limitations and should be managed with caution. As noted above, a share of voice indicator may offer fascinating observations and provoke useful hypotheses on the relative impact of a company's science, for example, but such an indicator will always be prone to confounding. The validity of any novel indicator should be enhanced by:

- Establishing a baseline where possible,
- Referring to as many relevant data sources as possible to enable the identification of 'noise' in specific sources,
- Considering multiple indicators to provide different angles (such as capturing external stakeholder feedback as well as internal perceptions on the quality of external engagements), and
- Including a commentary in the associated dashboard. This can be particularly useful to explain deviations from a baseline or target, and/or when known factors in the company or external environment have influenced the result of a particular KPI. For deviations beyond a target range, a correction plan may also be expected in this commentary.

Conclusion: Medical Affairs KPI dashboards drive functional performance while demonstrating value to the broader organisation

When building performance management infrastructure, it is important to recognise that a fully-fledged KPI dashboard cannot be created overnight. The thinking and internal engagement that goes into objectives and appropriate performance measures must be robust, to ensure that they are optimised to act as enablers of internal performance (including management decision-making) and can be transparently communicated to staff at all levels. The operations of the metrics themselves must also be well-defined and sustainable. These aspects should be iterated over months and years to improve the reliability and value of the KPIs to the organisation, and reflect shifting priorities.

Given all the above, the development of an optimal KPI dashboard is admittedly a challenging and resource-intensive task, but it is vital. Theoretically good strategies will fail without effective performance management that monitors and drives progress. Modern Medical Affairs functions hold critical strategic leadership and delivery accountabilities and must be able to justify the resource investments required to meet the high expectations of them. **A robust, user-focused and transparent KPI dashboard is, therefore, a crucial enabler of a Medical Affairs function's performance toward objectives**, as well as the most easily visible and important way to display Medical Affairs' value to the broader business.

Further reading:

Medical Affairs 2025, The Future of Medical Affairs (2018), Croft and McLoughlin

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