



Life Sciences Consulting and Outsourcing



Performance Management in Medical Affairs
Kinapse Consulting, 2011



As Medical Affairs evolves and takes a more prominent role in the development and commercialisation of medicines, it needs a more robust approach to performance management. However, Medical Affairs must first be defined in a way that is clear to all internal stakeholders. A definition of Medical Affairs accountabilities and deliverables which is supported by robust KPIs will help to align the Medical Affairs organisation, and importantly enhance cross-functional collaboration in the achievement of the goals of the business.

A methodical approach which focuses on first defining specific objectives and their associated critical success factors will then support the identification of meaningful KPIs. The KPIs should address not only the execution of key Medical Affairs activities, but also their impact.

1 The opportunity

In many companies, Medical Affairs has often been seen as a function whose primary remit is to provide internal support to the Commercial organisation. Traditionally, activities such as copy review, sales force training and issue management were the core activities. While these activities are still important, Medical Affairs is increasingly taking on a much broader remit in the development and commercialisation of drugs. Providing Development with insights on real world experience of a drug or disease, generation and dissemination of data, and partnering with Commercial and Market Access on strategic commercialisation issues are increasingly important elements of the role of Medical Affairs organisations. In addition, there is an increasing emphasis on external interactions; external stakeholders to Medical Affairs now go beyond patients and practitioners, with payors and policy makers also key stakeholders.

Despite this evolving role and the significant headcount and budgets allocated, many Medical Affairs organisations have still not addressed performance management adequately. It is not uncommon to see organisations where the development of key performance indicators (KPIs) in Medical Affairs is ineffective, thereby validating the arguments that Medical Affairs is 'different', hard to define, not possible to measure, and that implementing KPIs can even be detrimental. We argue, however, that Medical Affairs is different in some ways but not in others - it needs to be defined, and key activities and their impact need to be measured and managed. Importantly, if developed in a considered and holistic way, KPIs in Medical Affairs can provide a valuable platform for continuous improvement and capability development, as well as organisational alignment. If, however, the KPIs are developed in a way that assumes an entirely structured and quantifiable process akin to the development process then they will fail to capture the essential purpose and objectives of the Medical Affairs organisation.

2 Changing the mindset

There are many issues which typically compromise the ability of KPIs to drive the right decisions and encourage the desired behaviours in the organisation e.g. over-emphasis on quantitative measures where data is easily available, focus on execution of activities without measures of impact, lack of due recognition of external focus of Medical Affairs, over complexity of dashboards etc. While these are all important they can essentially be addressed through redesign of the KPIs and dashboards.

There may, however, be a more fundamental issue in that Medical Affairs organisations have often considered themselves to be 'different'. The traditional role of a physician in the pharma industry, and particularly the associated governance responsibilities, have contributed to Medical Affairs maintaining a degree of independence from other functions, and a reluctance to be influenced by targets or measures. In addition, lack of clear definition of Medical Affairs deliverables and accountabilities has meant that partner functions have not easily been able to define what it is they expect or need from Medical Affairs. This can cause frustration. If Medical Affairs is moving away from being a support function (as we believe it should) then it also needs to sign up to being measured and scrutinised in the same way as its partner functions.

In order to put an effective performance management system in place there needs to be an expectation that people within Medical Affairs will contribute to the development of KPIs and subsequently use them in a positive way. The perception of KPIs in the Medical Affairs organisation needs to change from one of control and measurement to one of empowerment and management. This last point is particularly relevant at a country level where the relationship between the KPIs, the broader organisational strategy and the day-to-day job does not always seem obvious.

Traditional focus	Proposed focus
Efficiency and costs	Broader Medical Affairs value proposition
Operational / internal focus	Impact / external focus
Short-term only	Short and long-term
Functional measures within Medical Affairs	Functional measures as well as interfaces with partner functions
Evaluation	Alignment, involvement and evaluation

Figure 1: Evolution of performance management in Medical Affairs organisations

3 The need to define Medical Affairs clearly

In recent years, there has been much debate regarding the ability to quantify the financial contribution of the Medical Affairs organisation. Several models have been proposed which are generally based on linking Medical Affairs activities to wider corporate goals e.g. increasing revenues, reducing costs, and minimising product and corporate risk.

Our hypothesis is that the need to put a financial value on Medical Affairs is largely driven by a frustration with the lack of understanding in many organisations as to what Medical Affairs actually does. A clear definition of the deliverables and accountabilities of the Medical Affairs organisation will clarify how partner functions can collaborate with Medical Affairs to achieve the goals of the business. However, one of the challenges in defining Medical Affairs in this way is that the function is not intuitively organised around processes other than its own internal planning for a product, which is inevitably a sub section of the wider development, launch preparation or lifecycle management. Medical Affairs therefore does not 'own' a process that supports a product in the same way that Development does before regulatory approval or that Commercial does after approval. Again, while Medical Affairs plays a key role in these processes, it is often not entirely clear to the organisation what that role is or how it is performed. We therefore recommend that when defining Medical Affairs, it is considered in terms of key business processes such as development, launch preparation and lifecycle management. In conjunction with supporting KPIs, this definition provides a more credible and realistic picture of the value of the Medical Affairs organisation without diminishing the importance of many of the activities around Medical governance and risk minimisation.

In our experience it is essential to clearly define Medical Affairs and to agree strategic goals and priorities for the Medical Affairs organisation before trying to define KPIs.

4 Assessing performance management capability in a Medical Affairs organisation

Most organisations aspire to establish a performance management approach which is based on KPIs that are useful to senior management in their decision making, enable partner functions to integrate Medical Affairs deliverables into their planning, and also allow the Medical Affairs organisation to collectively drive towards short, medium and long term goals. We propose four dimensions to consider as a Medical Affairs organisation assesses and improves its approach:

1. How well are KPIs aligned to achieving Medical Affairs and wider organisational objectives?
2. Is there an appropriate 'mix' of KPIs to answer the key business questions i.e. a mix of leading vs. lagging indicators, short term vs. long term indicators, qualitative vs. quantitative indicators?
3. Does the Medical Affairs organisation buy in to the KPIs, their purpose and their potential benefits?
4. Are the timely collection, processing and reporting of the necessary information feasible and practical?

Appendix 1 (page 7) provides more detail against these dimensions - the framework can be used to assess the current level of 'maturity' of performance management in a Medical Affairs organisation. It may also assist in defining and communicating the target end state within the organisation. The desired state will depend on a number of factors including the current performance management landscape, and the appetite for change. The goal should however be realistic and its achievement should deliver obvious benefits.

Regardless of level of maturity desired, in our experience there are a number of factors that are fundamental to the design of an effective performance management system:

- ▶ Start with the basic business questions that need to be answered...any discussion on what the KPIs are and how they are measured are unhelpful until the key business questions are agreed (e.g. how well do we bring medical affairs insights into the organisation, how well do we work with partner functions?)
- ▶ Make simplicity a key aspiration. The inevitable tension between keeping things simple and being comprehensive will again be resolved by considering the overall purpose i.e. what level of complexity and detail is required to drive decisions and/or influence events and behaviours in the organisation
- ▶ Consider how measuring, tracking and reporting any KPI will influence events in the organisation. If the KPI does not influence decisions or behaviours then don't bother measuring it.

5 Identifying key business questions and associated KPIs

In defining the key business questions for Medical Affairs, the first step is to map how the strategic goals of the organisation translate into actionable objectives (Figure 2). Although the task becomes more difficult as the level of detail increases, our approach is to identify a handful of objectives as specifically as possible, and then to identify and track the underlying critical success factors (CSFs). The CSFs are the things that will both enable and encourage people to work towards the objectives in an optimal way. In many cases, the discussion around operational elements will ultimately be extrapolated to include discussions around capabilities and tools that the organisation needs in order to sustain high performance – ‘organisational capital’. This longer term element should not be ignored.

Once the CSFs are agreed, associated KPIs are proposed. The KPIs need to provide an indication of whether those CSFs have been met and whether they will be met going forward.

More often than not, quantitative metrics will be hard to define for CSFs and some will need to be qualitative, based on a quantitative scale with a designated baseline. While there is a necessary upfront investment of time and effort in order to define qualitative metrics (e.g. around engagement with thought leaders or collection of Medical Affairs insights etc), this approach does push the organisation to identify and focus on factors which are likely to be the best surrogate indicators of future success.

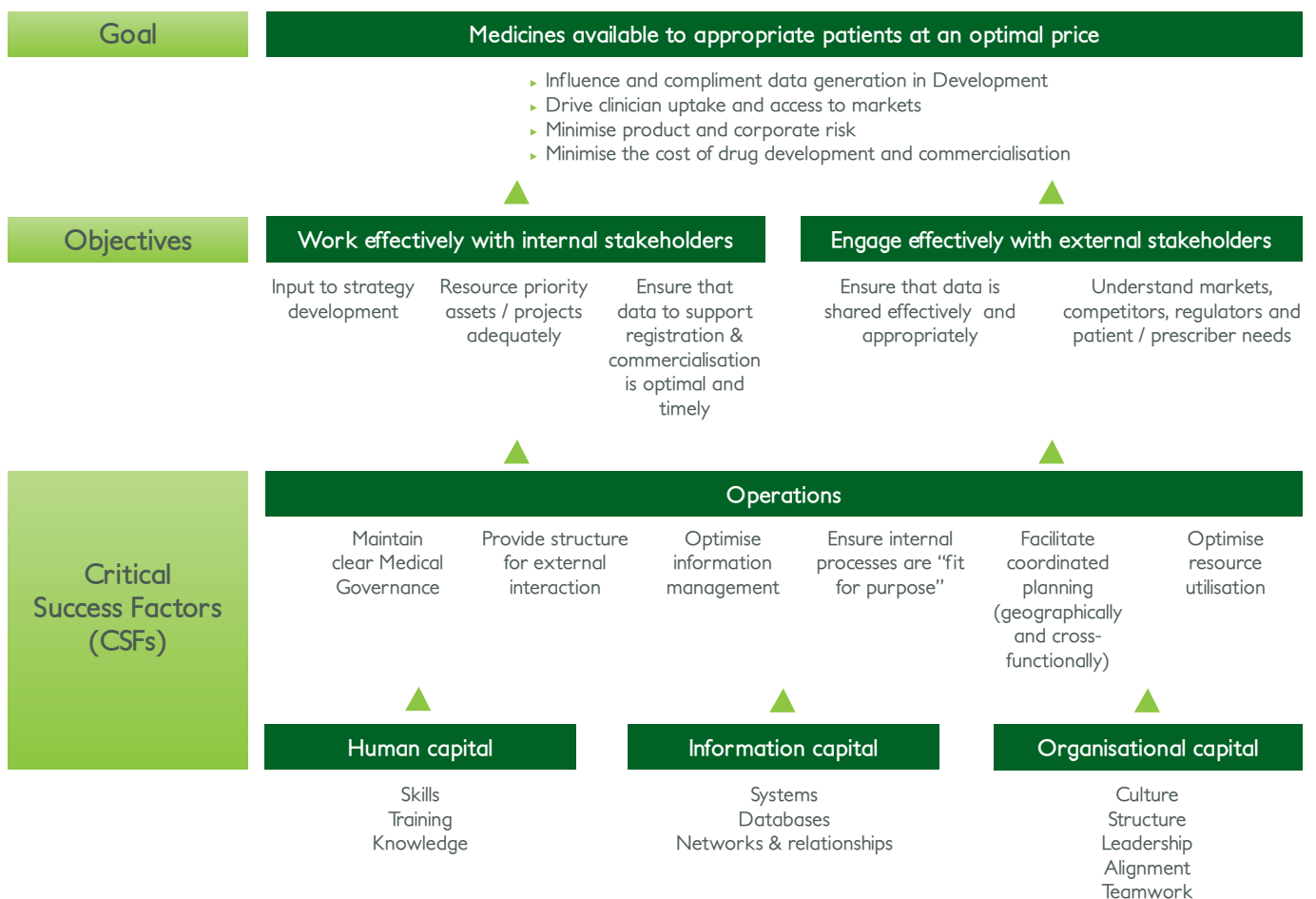


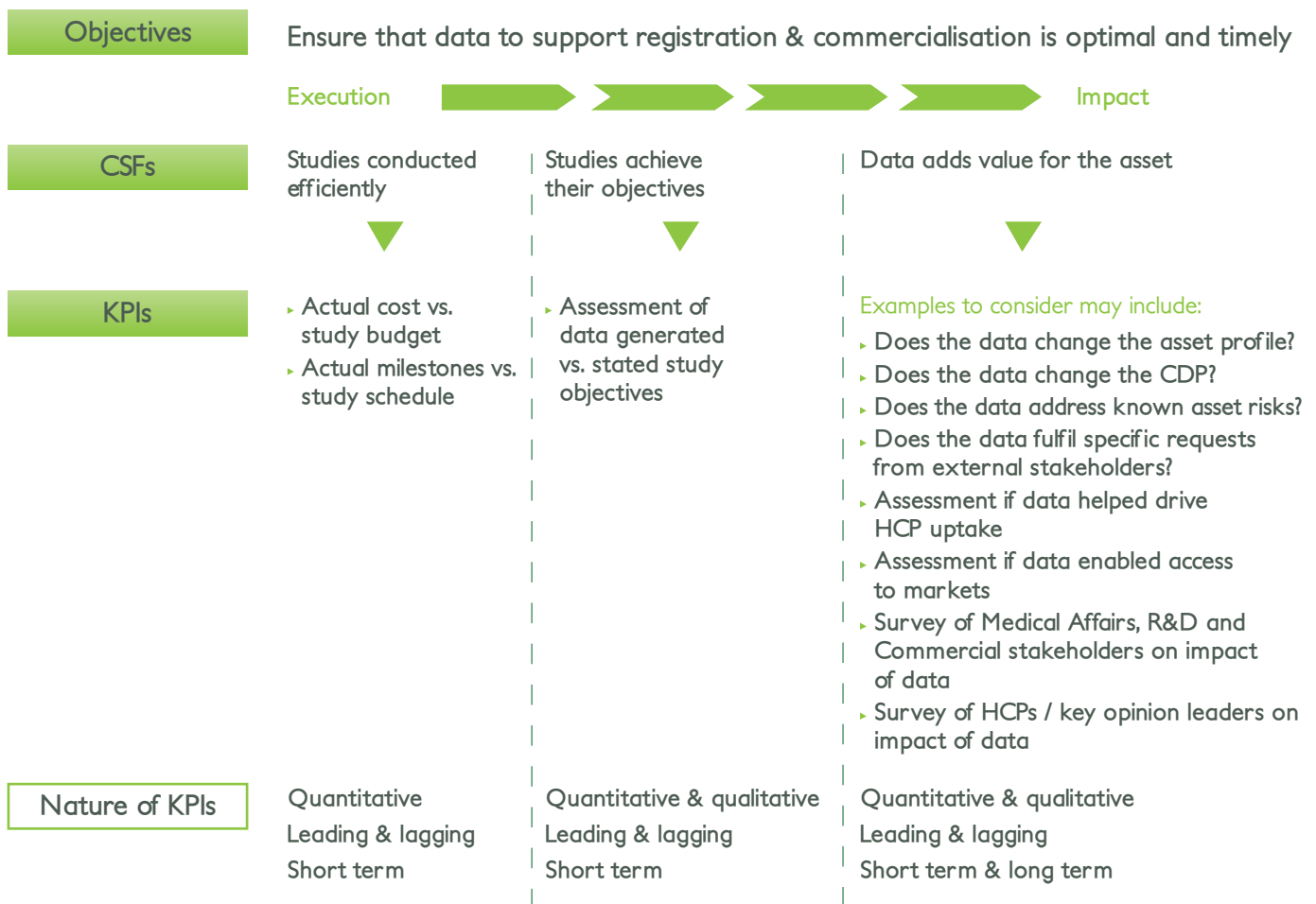
Figure 2: Illustrative strategy mapping in Medical Affairs

6 Developing KPIs to measure the impact of activities

While it is often easy to measure how well people have planned and executed activities, it is considerably harder to measure the impact of those activities. However, from a strategic perspective impact is a key priority. Again, our approach is to define exactly what the objective is, to identify CSFs around that, and then to define measures for those CSFs. Measures of impact are likely to be a combination of qualitative and quantitative elements, and often no one KPI will serve as an adequate indicator of impact. The risk therefore is that multiple KPIs emerge and the dashboard becomes too complex.

Example: A large proportion of Medical Affairs budget is allocated to Phase 3b / Phase 4 data generation studies. KPIs around planning and execution of studies are easily defined, but the impact of the activities is not often addressed by KPIs. How do we measure the benefit or impact of spending millions of dollars on data generation?

Some illustrative ideas are shown below. Organisations will differ, but the fact is that because the question is more complex, the KPIs will also be more complex





7 The need for hierarchy

In developing the KPI dashboard, it becomes obvious that not all KPIs are relevant to all stakeholders. Not only do we need to ensure that senior stakeholders see what is relevant to them and that this not diluted by potentially irrelevant detail, but we also need to ensure that all stakeholders see how the information that they receive (or provide) is aligned to the bigger picture i.e. how it ultimately contributes to tracking how well the organisation is doing in achieving its objectives. This alignment is best achieved by working top down from the key questions, using the same framework and approach at each level. This in effect creates a 'pyramid' which enables drill down from the higher levels, but avoids a situation where senior stakeholders simply see a consolidation of the regional dashboards. In most cases the different levels of stakeholder will be interested in different questions e.g. leadership teams are likely to want to focus on impact given that operations are generally running smoothly whereas country level Medical Affairs managers are likely to focus more on execution of major studies for example.

8 Standardisation of KPIs

In working with several global organisations, a question that comes up fairly early on is the issue of whether the KPIs should be the same across regions or business units. Our view is that KPIs should be standardised in situations where they will drive decisions across more than one part of the organisation or where comparability is necessary. For example, using standard KPIs to track resource allocation and budgetary performance enables the information to support resource allocation decisions across different parts of the organisation. Similarly, there needs to be comparability between products or brands i.e. how well is Medical Affairs supporting a product globally? This question invariably needs to address the execution and impact of a number of activities relating to the generation and subsequent dissemination of data, as well as specific interactions with relevant internal and external stakeholders. If KPIs around assets are comparable it makes for a more efficient process across different project teams, and it also helps with communications and sharing of best practice within Medical Affairs.

However, KPIs need to answer key business questions and different parts of the organisation will have different areas for improvement and different key business questions. Where KPIs are focused on a part of the organisation and its key business questions, a recognisable format helps, but standardisation is often counterproductive.

Conclusion

There is opportunity to improve performance management in Medical Affairs organisations in many companies. While the KPIs and dashboards can often be modified and improved, in many instances there is a need for a change in attitude towards performance management. Medical Affairs organisations need to hold themselves accountable in the same way as their partner functions; although in many instances this may first require clear definition of Medical Affairs deliverables and accountabilities in the context of the key business processes. If developed effectively, KPIs will then not only provide the obvious 'vertical' benefits of being able to report upwards and to drive performance, align and create buy-in within the Medical Affairs organisation, but also the 'horizontal' benefits of being able to communicate with partner functions so that those functions can more easily appreciate and extract the potential value that Medical Affairs increasingly offers in today's environment.

Appendix 1 - Maturity framework for performance management in the Medical Affairs organisation

	Level 1	Level 2	Level 3	Level 4
Alignment to strategy	<ul style="list-style-type: none"> ▶ Objectives and deliverables for the Medical Affairs organisation are not clearly defined and communicated ▶ Weak link between Medical Affairs KPIs and day to day operations 	<ul style="list-style-type: none"> ▶ Objectives for the Medical Affairs organisation defined but overly focused on change initiatives and short term issues ▶ Metrics around budget and resources feed into departmental metrics, but lack of obvious alignment of Medical Affairs objectives with corporate goals ▶ Global KPIs are a roll up of regional, regional a roll up of country 	<ul style="list-style-type: none"> ▶ Medical Affairs organisation identifies goals, clearly lays out objectives and strategy to attain them ▶ Clear alignment between local, regional and global KPIs in Medical Affairs; roll up of KPIs as well as specific KPIs in alignment with objectives at each level ▶ Alignment between strategy, objectives and operations is achieved at all levels 	<ul style="list-style-type: none"> ▶ Medical Affairs clearly articulates goals and lays out short, medium and long term objectives ▶ Clear understanding of how Medical Affairs contributes to wider business goals ▶ Alignment between local, regional and global KPIs, and cross functional alignment at all of these levels ▶ KPIs effectively link day to day operations with Medical Affairs and wider strategies
Operations	<ul style="list-style-type: none"> ▶ Unreliable or incomplete data ▶ Minimal tools and platforms to support information and knowledge sharing 	<ul style="list-style-type: none"> ▶ Quantitative data generally drawn from companywide IT systems ▶ Additional quantitative data captured in ad hoc spreadsheets owned by people in relevant areas ▶ Manual generation of reports is time consuming ▶ Delays in generating reports 	<ul style="list-style-type: none"> ▶ Complete quantitative data generated automatically ▶ Qualitative data collected through email or intranet surveys ▶ Reports generated automatically ▶ Reports comprehensive and available at end of month / quarter 	<ul style="list-style-type: none"> ▶ High quality quantitative data and qualitative survey data generated automatically and available as required ▶ Reports generated automatically and available at appropriate levels of detail for different stakeholders
KPI mix	<ul style="list-style-type: none"> ▶ Balance of KPIs largely driven by availability of data ▶ Performance measurement within Medical Affairs limited to tracking of execution of internal activities e.g. conduct of sponsored studies ▶ KPIs purely quantitative and retrospective 	<ul style="list-style-type: none"> ▶ KPIs address broader range of activities - may include issues such as external interactions ▶ No measures of quality of activities or their impact ▶ KPIs primarily quantitative and retrospective 	<ul style="list-style-type: none"> ▶ KPIs also aim to address quality and impact of activities ▶ Surveys used to generate qualitative KPIs around specific issues ▶ Leading indicators enable proactive management towards goals 	<ul style="list-style-type: none"> ▶ Balance of KPIs driven by key business questions ▶ Quantitative KPIs complimented by qualitative KPIs which are quantified against designated baselines ▶ Combination of qualitative as well as quantitative KPIs support management of all important aspects of Medical Affairs ▶ Leading indicators allow proactive management ▶ KPIs acknowledge sustainability and trends e.g. KPIs around capability development
Culture	<ul style="list-style-type: none"> ▶ Resistance to KPIs on the grounds that Medical Affairs cannot be measured ▶ KPI generation laborious, and value of the process questionable ▶ KPIs generally created to report upwards to senior management on budget and resources ▶ PDPs largely subjective and don't link to KPIs 	<ul style="list-style-type: none"> ▶ KPIs regarded as a 'necessary evil' ▶ Drive to use KPIs to understand the business better, but largely in terms of budgetary forecasting ▶ Although data from many areas used to generate KPIs, line managers are seen as accountable and responsible for performance ▶ KPIs developed in a top down manner and often perceived as controlling 	<ul style="list-style-type: none"> ▶ KPIs valued and discussed in a way that drives decision making ▶ KPIs used to report upwards, as well as to communicate and plan with partner functions ▶ KPI reports communicated widely within Medical Affairs but primarily 'owned' by global and regional groups; less relevance to local Medical Affairs groups, particularly outside major markets 	<ul style="list-style-type: none"> ▶ KPIs generally expected to drive major decisions at all levels ▶ KPIs used to report upwards and to communicate with other functions, but also to align Medical Affairs organisation and ensure clarity on objectives at all levels ▶ Representatives from all levels involved in the development of the KPIs ▶ KPIs seen as empowering



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