Measuring performance of field-medical programmes: Medical science liaison metrics consensus

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Abstract

A Medical Science Liaison (MSL) Metrics Consensus initiative aims to identify field-medical activities throughout the pharmaceutical product lifecycle, and metrics associated with those activities. Since MSL programme deployment strategies may vary from company to company, pharmaceutical executives often use retrospective benchmarking studies to assist their field-medical teams in establishing programme metrics. This Medical Science Liaison Metrics Consensus initiative is the first of its kind to identify activities that are unique to field-based MSL team capabilities. Upon identification of unique contribution of MSL teams across the product lifecycle, metrics were identified and associated with MSL activities across the product lifecycle, with an emphasis on outcomes and compliance. Organisations may use the results of this Medical Science Liaison Metrics Consensus to proactively assess and design their MSL programmes' current valuation standards.

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INTRODUCTION

Medical science liaisons (MSLs) are catalysts of collaborative relationships and scientific knowledge exchange. These field-based medical professionals are therefore immersed in the generation of intangible value characterised by lengthy business cycles and vesting terms. Compared with Upjohn's original MSL programme four decades ago, today's MSL programmes have evolved through changing industry's hiring practices and organisational restructuring to address compliance concerns. Today's MSL programmes have become preferentially staffed with professionals with doctorate-level degrees and a specific therapeutic discipline. Reporting structure of MSL programmes have shifted from sales and marketing to medical affairs.

Industry's field-medical teams are facing the same challenges that knowledge workers in the fields of strategy and competitive intelligence have been facing: how do you measure the value of ideas and insights, and how do you subsequently track your team's unique contribution to an outcome that is remote from its multivariate points of origin? Today's medical science liaison programmes are still riddled with the same question: how do you measure the value of science-based collaboration, and how do these collaborative processes contribute to an organisation's bottom-line and competitive advantage?

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A survey conducted by Medical Science Liaison Institute of 19 MSL programmes in 2004 showed that MSL directors rarely used only qualitative or quantitative metrics to demonstrate value for their field-medical teams. Most MSL programmes used a combination of quantitative and qualitative metrics when communicating value to their internal stakeholders. This combination may be born of perceptual and practical considerations: MSLs often perceived strictly quantitative metrics as sales based and therefore inappropriate from a compliance standpoint; on the other hand, company executives often perceived strictly qualitative metrics as insufficient from a business justification standpoint.

Field-based medical teams are following the increased visibility of evidence-based medicine and are agreeing that outcomes-based metrics may be a more accurate and compliant reflection of the MSL programme's contribution to a pharmaceutical organisation. A follow-up survey of 17 pharmaceutical companies in 2005 by Medical Science Liaison Institute showed that more MSL programmes were incorporating outcomes as indicators of MSL performance and value. For example, in addition to tracking a quantitative metric such as number of interactions a liaison has engaged with a thought leader, companies may incorporate a qualitative metric such as the thought leaders' feedback on the quality of an interaction, and include an outcomes-based metric such as study publication that resulted from MSL-thought leader interactions. Outcomes-based metrics are perceived to add a compliance dimension to current MSL programme metrics because these may validate what an organisation claims to achieve through a field-medical presence.

Industry benchmarking surveys are useful but limited by its retrospective nature, small sample sizes, and source variability. Surveys may provide executives with a general overview of how industry MSL programmes demonstrate value and respond to a changing compliance climate. Standardisation in key activities of field-based medical programmes is, however, lacking, and even core activities like 'thought leader development' may vary from company to company.

MEDICAL SCIENCE LIAISON METRICS CONSENSUS

Earlier this year, Medical Science Liaison Institute invited more than 40 executives from over 20 pharmaceutical, biotechnology, device, and specialty pharmaceutical companies to participate in a Medical Science Liaison Program Metric Consensus initiative. Participants included vice presidents of medical affairs, MSL directors, MSL managers, and senior-level MSLs.

Through discussion groups, executives assessed metrics relevant to specific MSL activities at a particular phase of product development. Discussions focussed on MSLs' potential involvement throughout product development, from early development (preclinical and Phase I) to Phase II, Phase III, to product launch (Phase IV), and post-launch development. For each stage of product development, potential contribution of the MSL role and associated metrics were presented by an executive lead for that discussion group, followed by further open discussion as a collective whole.

Even as participants represented different companies of different sizes and as previously mentioned, field-medical deployment strategies may vary from company to company, a pattern soon emerged as to the key contributions of the field-medical role and measurements reflecting that contribution. In cases where challenges were presented in selecting appropriate metrics for long-term outcomes, surrogate metric markers of contribution were suggested.

MSL ACTIVITIES ACROSS PRODUCT DEVELOPMENT SPECTRUM

Involvement of field-medical teams in preclinical and Phase I product development drew the most debate. Concern rested in a business justification for investing in a field-medical team during such an early stage of product development.

Executives agreed that if a field-medical team already exists to support a marketed product, then MSLs may participate in preclinical development or Phase I activities as a special project in their portfolio of activities.

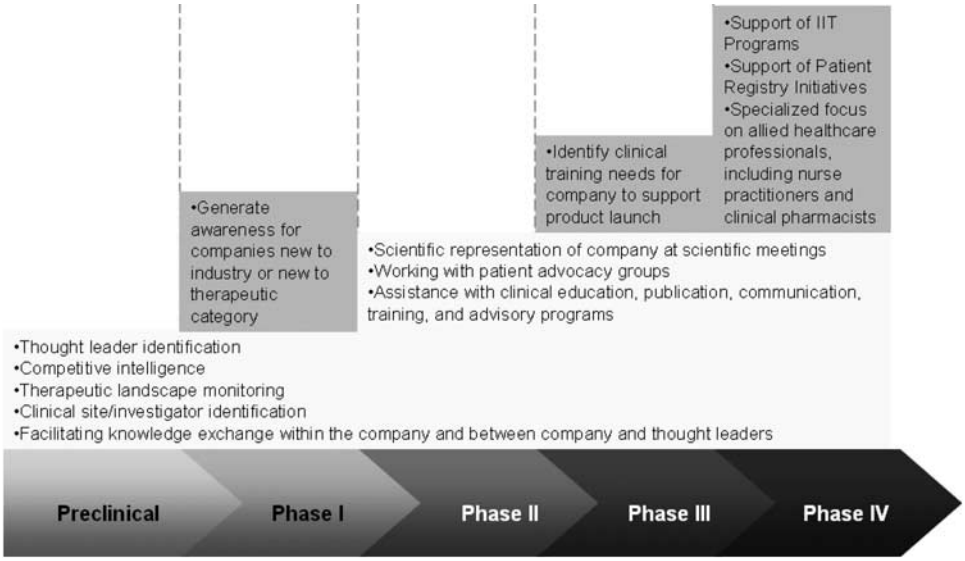

Figure 1: Contribution of field-based MSL programmes across the product development spectrum

On the other hand, if the company has no marketed products, many executives contend that installing a MSL programme is a tenuous business justification. Those who favoured field-medical presence during this stage of the product development viewed MSL programmes as a means to increase awareness of a company's entry into the pharmaceutical market or a new therapeutic category with thought leaders in that therapeutic category. Depending on resources allocated to MSL programmes at this stage, MSLs can pave the foundation for identifying therapeutic thought leaders for their companies and monitor the therapeutic landscape. For companies creating MSL programmes *de novo*, contract MSL teams may be a cost-effective option that allows companies to have field-based activities during early development while capping costs within a contractual period.

Companies deploying field-medical teams during Phase II and Phase III of clinical product development value their MSLs' contributions in profiling the therapeutic landscape, facilitating clinical research development, and establishing scientific representation on behalf of their companies (Figure 1).

Profiling the therapeutic landscape may include identification of thought leaders whose research and ideas have influenced treatment standards in a therapeutic area. Identifying thought leaders can include the identifying potential principal investigators (PIs), which naturally leads to the facilitation of clinical development during Phase II and Phase III. MSLs can collaborate with their companies' clinical research partners, including contract research organisations (CROs) to identify clinical trial sites that have the appropriate infrastructure to conduct clinical trials, as well as clinical investigators with a demonstrable track record of clinical study experience.

MSLs establish a scientific presence on behalf of their companies by interacting with therapeutic thought leaders and clinical investigators. Liaisons also act as field-based agents of their companies' medical function when participating in medical meetings, therapeutic advisory boards, disease state education initiatives, and select public initiatives that may involve patient advocacy groups and patient access programmes. Fertile scientific exchange facilitated by MSLs yields a wealth of therapeutic intelligence and competitive intelligence that enable pharmaceutical companies to make integrated and strategic decisions across multiple functions, including R&D, medical affairs, clinical operations, marketing, and managed markets. As product launch becomes imminent, MSLs help identify clinical training needs for their organisations and give advisory

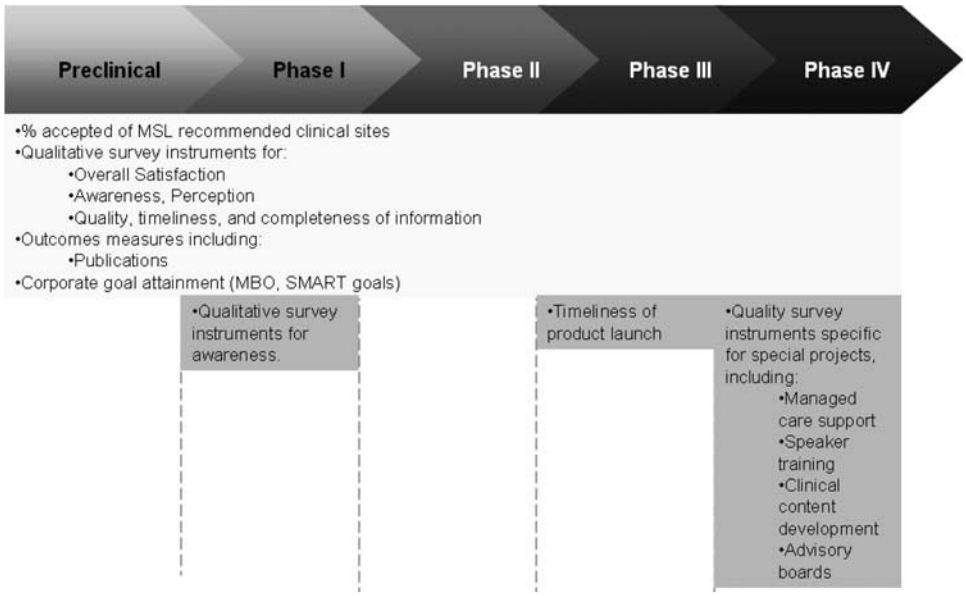

Figure 2: Metrics for field-based MSL programmes across the product development spectrum

input in clinical training content for sales teams.

Following product launch, MSL programmes continue activities relating to scientific exchange and competitive monitoring in their therapeutic category, as well as many of the MSL activities described during Phase II/III. MSLs can provide clinical expertise as part of managed care support or for clinical sales training within their companies. In the past few years, MSLs have emerged as primary facilitators of various aspects of their companies' investigator-initiated trial (IIT) programme.

Post-marketing surveillance is part of pharmaceutical companies' agreement with the FDA for a product approval, and MSL programmes have become involved in patient registry efforts to help improve outcomes measures for specific patient populations. Over time and as part of post-marketing surveillance, product safety data are gathered for reporting by pharmaceutical companies. Communication of product safety information occurs when physicians can report adverse events to pharmaceutical manufacturers and when pharmaceutical companies desire or be required to communicate product safety information to physicians. In case where safety concerns emerge and communication by pharmaceutical companies is required, field-based MSL programmes are a component in the widespread and rapid dissemination of important safety updates.

MSL METRICS ACROSS PRODUCT DEVELOPMENT SPECTRUM

A programme metric appropriate to MSL involvement in Phase I to Phase III of product development is a portfolio of clinical study site recommendations from the MSL team that is accepted by the organisation to participate in clinical development programmes (Figure 2). These clinical study sites should demonstrate an ability to meet clinical study milestones and staffed with qualified clinical research personnel. Whether clinical study sites recommended by the MSL team actually meet clinical milestones may become a constellation of associated programme metrics – for example, timeliness of clinical study activation, patient recruitment performance, and publication of study results.

Depending on disease state, and especially for rare diseases, there may be patient advocacy groups that are heavily involved in both the development of therapeutics as well as accessibility to therapeutics. Leadership within patient advocacy groups may proactively contact pharmaceutical companies;

this presents an opportunity for facilitation of information exchange by a field-medical team. Companies that dialogue with patient advocacy groups via MSLs may conduct surveys of the quality of this dialogue as a programme metric.

Since one of the MSLs' contributions during this stage of product development includes scientific exchange, the quality and outcome of this scientific exchange can be useful as a programme metric. A satisfaction survey of thought leaders who interact with the company's MSLs can provide information on the quality of scientific exchange from the company's MSLs. Parameters of such a satisfaction survey may include the completeness of response given by MSLs, timeliness of response, and thought leader's perception of the quality of interaction. The company's objectives in establishing such exchange, including increasing awareness of company presence within a therapeutic area, may also be developed into 'thought leader awareness' surveys.

As agents of scientific exchange, MSLs' facilitation of this exchange between companies and thought leaders may be translated into programme metrics. Tracking competitive information and scientific intelligence shared by MSLs to aid functional decision making by functions within the company can be a demonstration of value. In addition to field-based interactions between MSLs and thought leaders, MSLs may also facilitate knowledge exchange between thought leaders and functional leaders within their companies as part of continuing education or specific advisory needs for internal stakeholders. These are outcomes that companies can associate with MSL programme activities. Qualitative satisfaction measures can add another dimension to these outcome-based metrics.

For MSL programmes involved in IIT programmes, metrics generally focus on quality of submitted proposals and alignment of submitted proposals to a product development strategy. These metrics reflect the MSL teams' ability to recognise quality ideas and to understand the company's clinical strategy. Measuring the number of submitted IIT proposals can become problematic when ideas of IIT proposals are by definition originated from clinical investigators who may then contact MSLs. Measuring the number of submitted proposals may create a solicitous environment if MSLs feel pressured to fulfil a quota of submitted clinical proposals, and in a worse case scenario, prompt the 'seeding' of research ideas that are not originated from clinical investigators but from MSLs or companies themselves.

MSL teams have a portfolio of activities relating to the preparation of a potential product launch that continues after product launch. These activities may include monitoring the therapeutic landscape, responding to unsolicited requests for information from the medical community, clinically supporting managed care activities, participating in speaker training programmes, and facilitating the company's clinical study publication plans. The quality and quantity of portfolio activities can serve as metrics by describing effectiveness and productivity of the MSL team. Companies may, however, focus on only quantitative metrics, by 'counting activities' and installing arbitrary call quotas at the exclusion of associated outcomes, if outcomes take significant time to obtain.

A criticism of 'reach-and-frequency' metrics is these metrics are generally associated with field-sales activities, although field-sales activities are tied to short-term outcomes of market share change or sales goal attainment. A reach-and-frequency metric for field-medical activities are not readily tied to short-term outcomes to satisfactorily answer the question of MSL programme value, and may additionally confer a perception of the nature activities of the MSL team as analogous to field sales. When MSLs are given a role in field-based responses to unsolicited medical queries that can include unapproved (off-label) uses, forcing uniform call quotas on MSLs may encourage solicitous activities from MSLs who need to reach their call quotas.

Reach-and-frequency parameters should be individual to the MSL based on each MSL's clinical objectives and unique geographical profile, and used as individual performance indicators rather than as a reflection of the entire MSL programme value. In other words, based on the outcomes desired (the 'end') by the MSL programme, members of the MSL

team may gather executive input and jointly determine objectives that will include appropriate thought leader profiles and interaction frequencies ('means' to the end). To avoid misinterpretation or misuse of reach-and-frequency metrics in MSL programmes, many executives still manage by objectives ('MBO') and demonstrate the value of their MSL programmes with attainment of goals that are specific, measurable, attainable, relevant, and time bound ('SMART').

CONCLUSION

The rationale behind a Medical Science Liaison Program Metric Consensus initiative is to assess the unique contribution of field-based medical teams across a product lifecycle spectrum, and propose value indicators of MSL programme contribution. Rather than dictating metrics to MSL programmes, this information allows companies to assess the level of involvement of their field-based MSL programme across product development and review associate metrics that are perceived by industry executives as appropriate for and reflective of MSL programme contribution. Companies may then customise these MSL metrics recommendations for their own MSL programmes through input from internal stakeholders, including those from legal, compliance, regulatory, medical affairs, and commercial departments.

