

**RETURN**  
**ON SCIENCE**  
VOLUME 2

**Medical Science Liaisons**

**GLOBAL**  
**IMPACT**

**Defining and Measuring  
MSL Accountabilities**

**Clinical Trial Liaisons:  
A New Approach**

**Assessing Your Field-based  
Medical Program Through  
the Eyes of the Customer**



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# DEAR READER



The first volume of *Return on Science* focused on the emergence of the Medical Science Liaison (MSL) role as a valuable function within a pharmaceutical company for the proper and authoritative dissemination of clinically relevant information to the medical community. The role of the Contract Medical Organization (CMO) in meeting the needs of our industry by providing contract MSLs was also introduced and explored. SOS feels it is time to take another look at how the role of the MSL is evolving to face the challenges of a dynamic marketplace, and look closely at the needs of the key stakeholders in the industry and how they now view this function.

The focus of *Return on Science* Volume 2 is three-fold. The first is globalization of MSL activities. Products now require a greater worldwide harmonization and coordination of efforts towards advocacy development. Many important issues and potential pitfalls need to be considered when MSLs “go global.” I’m sure you will agree that this information is timely and relevant in today’s unified global marketplace.

The second discussion focuses on the trend towards the specialization of MSLs. *Return on Science* Volume 1 discussed how no two MSL programs are alike. This has now evolved, however, into some very specialized and highly defined roles for certain types of “MSLs.” We discuss the roles of the Clinical Trial Liaison (CTL) and Field-based Outcomes Research Manager (FORM), which are both advanced roles utilizing a specialized subset of skills derived from the traditional MSL role.

Finally, we focus on how best to analyze and clearly quantify the value and business contributions of the MSL role. Not an easy task and very different from company to company and from product to product. Two articles explore this issue. SOS understands the importance of cost-effective deployment of this valuable resource, and we believe these articles will provide significant information for executives making this key investment decision. We are especially pleased to present an article from our colleagues at Scientific Commercialization, the recognized leaders in MSL consulting services.

On behalf of SOS, I hope you find these articles informative and useful in your future business decisions. Feel free to contact any of us directly should you have any questions or comments.

Sincerely,

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## CONTENTS

### 4 A Global Opportunity

by Ian Bancroft

by Evan Demestihias, MD, RPh

### 8 Clinical Trial Liaisons

by Chuck Brauer

### 10 MSL Team Accountabilities

by Paul F. Souney, RPh, MS

by Daniel J. Cushing, PhD, FCP

by Daniel J. Leonard, MS

by Bill W. Massey, PhD

### 19 Through the Eyes of the Customer

by Beth A. Price

by Kyle Kennedy

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# Field-Based Medical Science Liaison Programs

## Introduction

While the global pharmaceutical market is dominated by the United States with a value of almost US\$ 250 billion in 2004, and the US is a core market for many pharmaceutical companies, it is the ex-US markets that account for more than half (54%) of the total in worldwide pharmaceutical sales and represent a significant future growth opportunity for the

industry (Figure 1).<sup>(1)</sup> Over the years, one of the biggest challenges for the US-based industry has been the increase in regulatory restrictions over the marketing of pharmaceuticals. One of the most successful responses to that challenge has been the investment by US companies in field-based medical support programs, which utilize the expertise of Medical Science Liaisons (MSLs) to interact with healthcare professionals, clinical investigators and key decision makers at a peer-to-peer level to ensure that both external customer needs and internal corporate objectives are effectively met. <sup>(2,3,4)</sup>

A successful MSL model has been developed and implemented within the US, and one might consider it a simple task to transplant the same model into the overseas market. However, it is critical that ex-US MSL programs are not over-engineered for the local international markets. Overseas markets may be easily confused or distracted by MSL programs if they are not implemented in a simple and clearly understandable fashion.

The goal of this article is to provide the reader with the key essentials to rolling out a successful international local market MSL program. In addition to reviewing the three core models for developing MSL programs overseas, the article also discusses key insights into program alignment and governance, appropriate clarification of the MSL role, issues concerning prelaunch MSL activities, and the effective deployment of MSLs in overseas markets.

## DEVELOPING AN EFFECTIVE MODEL FOR GLOBAL FIELD-BASED MSL PROGRAMS

The importance of global field-based MSL programs cannot be underestimated, as they provide a key mechanism to achieve corporate goals within local markets. Success ultimately depends on consistent application of initiatives across different settings, while allowing for inherent market differences and avoiding over-engineered implementation.

There are three widely-adopted and well-accepted models for development of global MSL programs (Figure 2). The first model is characterized by corporate funding and corporate direction, with central appointment of MSLs. Although this facilitates control and consistency across markets, it is often limited in that it garners affiliate objections, risks not meeting local market needs, and stalls due to lack of local cooperation.

Experience clearly demonstrates that the second model is the most effective method for establishing global field-based MSL programs. This model provides central funding for locally-driven programs and reflects corporate confidence in affiliate companies by allowing them to

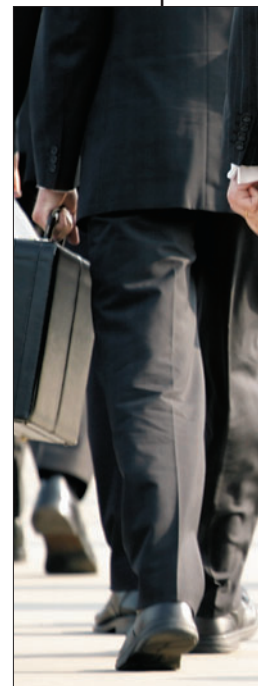


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# A GLOBAL OPPORTUNITY



take responsibility for the direction of their respective markets.

The third model allows individual countries complete autonomy over both the budget and direction of MSL programs and is possibly the most commonly adopted global MSL model. However, it is also the model largely responsible for why ex-US markets lag so notably behind the US in terms of MSL development; in general, local markets are unwilling to invest their limited budgets in pre-launch initiatives when there are seemingly more pressing concerns.

## THE IMPORTANCE OF ALIGNMENT

Choosing a valid model for MSL program development is only the first step in ensuring program success. Indeed, the key to implementing a corporate program and making it succeed at a local level is proper

Aligning globally developed strategies and local medical marketing tactics is key.

recognition and cooperation of both corporate and local stakeholders (Table 1). Key representatives include global and regional medical directors, who are likely to be responsible for managing the direction of the MSL program, and global and regional marketing leads who may administer the financial direction of the program. It is also essential to gain the support of, and effectively communicate with, the R&D, medical affairs, and marketing departments, the clinical research group, the medical communications department, as well as human resources and IT.

## DEFINING THE MSL ROLE

The role of the MSL is often confused with that of a medical advisor, particularly in the ex-US markets. However, these roles are almost polar opposites in terms of their approach to the communication of data in support of product introductions (Table 2). The MSL role is almost always external, with programs being deployed within the pre- and peri-launch periods of the drug. It is of considerable importance that MSLs are perceived by key opinion leaders (KOLs) as credible scientific contacts; therefore, their role should be data-based and non-promotional. Generally, MSLs have a medical or scientific background and are excellent communicators.<sup>(2)</sup> Holt and colleagues<sup>(4)</sup> described a unique global program of locally-based medical manager-consultants who were both highly clinically trained (MDs, or clinical PhDs or PharmDs) and had business training (MBA) or experience.

Specific tasks of global MSLs include KOL development activities, scientific support at congresses, competitive intelligence, reimbursement and formulary decision support, development of clinical practice guidelines, education and training.<sup>(2,3)</sup> Appropriate performance metrics should also be developed and used to measure the success of MSL-related activities.

**FIGURE 1 Value of the World's Pharma Market \$B's**

Worldwide Pharmaceutical Market 2000 - 2004					
REGION	VALUE '00 \$B	VALUE '01 \$B	VALUE '02 \$B	VALUE '03 \$B	VALUE '04 \$B
North America	157.3	183.8	205.5	229.1	247.7
Europe	85.0	91.2	103.0	133.4	156.6
Africa, Asia & Australia	93.2	88.6	92.2	105.4	118.4
Latin America	22.8	22.8	20.6	21.7	24.5
Total World Market (\$B)	358.3	386.4	421.2	489.6	545.2
Growth Over Previous Year		7.8%	9.0%	16.2%	11.4%

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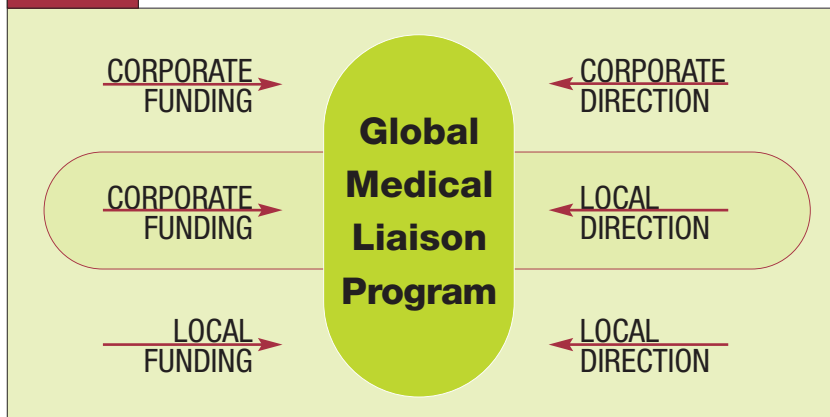


## A HUMAN RESOURCES PERSPECTIVE...

“Once a global opportunity is identified for rolling out an overseas MSL program, there are many factors to consider, not only from an operational standpoint, but also from a human resources perspective. Unlike the US, where many employment laws are similar across the states, each country/province overseas has their own set of rules and regulations. Some helpful hints that have proven resourceful during the planning and executing stages of an ex-US MSL program are:

- Research and review of local country laws, public policies, and trends that pertain to the employment process. This includes but is not limited to recruiting, paid time off, compensation, discipline, termination, & employment contracts.
- Understand the differences in health and welfare benefits offered and how they are sponsored.
- Review all protocols of employment with legal counsel from the country in question to ensure compliance and reduce liability.
- Time management is key. In addition to general content of what is needed, due to time zone differences and understanding cultures, things may take longer than accustomed to.”

**FIGURE 2 Global MSL Program Models**



### PRE-LAUNCH OPPORTUNITIES FOR GLOBAL MSL INITIATIVES

The pre-launch period is critical to ensuring the successful uptake of a drug in the market.<sup>(4)</sup> It is within this period that MSLs can develop important networks with KOLs and decision makers to ensure that the product lifecycle begins in the most favorable manner. One important objective is to raise company awareness, given that many top US pharmaceutical and biotechnology companies may not be as well known in other markets. In addition, it is important to increase disease state awareness among KOLs to ensure that there is understanding of the disease pathways that are being targeted. MSLs also play a role in clinical trial programs, particularly at a phase III level.

Although phase III trials may be administered centrally, local support from MSLs can aid patient recruitment and retention as well as data analysis. Furthermore, local MSL programs can focus on the development of publications based on local study sub-populations. Other pre-launch opportunities include facilitation of advisory boards and KOL education and development programs.

Contract field-based medical liaison teams can implement the consistent localization of global strategies.

### OVERSEEING THE GLOBAL MSL PROGRAM

A simple and consistent split between corporate and local markets is ideal when overseeing a global MSL program. Ideally, the global agenda and strategic goals of the program should be developed centrally to ensure a consistent direction across markets. Local countries should then be able to deploy MSLs to achieve these goals. This structure facilitates appropriate compliance with country-specific regulatory and promotional guidelines, customization of materials for market subtleties, administration to meet employment policies and integration with clinical, medical and marketing at a country level.

### GLOBAL MSL DEPLOYMENT

Global MSL deployment can involve contracted MSLs, internal MSLs or a mix of both. Outsourcing as a means of allowing companies to focus on their core competencies is becoming increasingly common across all business organizations, and the pharmaceutical industry is no exception.<sup>(5)</sup> In particular,

**TABLE 1** Key Corporate and Local Stakeholders for Development of a Global MSL Program

Global and regional medical directors
Global and regional marketing
R&D/medical/marketing interface
Clinical trial management
Medical communications
Human resources
Information Technology

programs ensures that best practices (largely learned from the US market) are shared to optimize program outcomes and maximize international effectiveness. Best practice includes: country key stakeholder alignment; integration with clinical, medical and marketing; and initiating KOL activities, including

**SUMMARY**

Field-based global MSL programs present a significant opportunity to achieve corporate goals at a local level by facilitating the development of strategic relationships with KOLs and decision makers. At present, ex-US markets lag behind the US with regard to MSL development and deployment, leaving those markets at risk of underutilizing an effective medical resource and thereby not realizing their full potential. Implementation of a simple and transferable model, which utilizes corporate support for local activities and is delivered in a consistent manner in accordance with best practices, will ensure that corporate goals are able to be met worldwide. Furthermore, exploiting the expertise of contract MSLs is an effective means of minimizing risk and allowing pharmaceutical companies to focus on their core competencies.

many companies choose to outsource at least part of their MSL programs to minimize risks and limit investment in recruiting, training and infrastructure, while exploiting the services of experts within this field.

Internationally, MSLs are generally deployed to support leading national academic centers and healthcare institutions in order to interface with KOLs in specific therapeutic areas.(2) Furthermore, relationships are often developed between MSLs and representatives in key government agencies, such as the United Kingdom National Institute for Clinical Excellence or the Canadian Office for Health Technology Assessment, which have a major impact on drug utilization in their respective countries.

In the US, MSL programs are generally initiated 12 to 18 months prior to the launch of a product, while in Europe, this may be as early as three years in advance of drug launch. Organizations that contract MSL programs can provide to the contracting pharmaceutical company the planning and logistic support necessary for that product launch.

**THE IMPORTANCE OF APPLYING BEST PRACTICE**

Global governance of the development and deployment of MSL

advisory boards, speaker training, workshops, formulary submissions and appropriate communication materials. The importance of MSL profiling and sourcing is also a key best practice learning, with effective MSLs often being people with medical or scientific experience augmented by broad experience within the pharmaceutical industry.

**TABLE 2** Roles of Global MSLs Compared With Medical Advisors

MEDICAL LIAISON	MEDICAL ADVISOR
<ul style="list-style-type: none"> <li>• Predominantly external</li> <li>• Focus on pre/peri-launch</li> <li>• Frequent KOL contacts</li> <li>• Non-promotional</li> <li>• Clinical trial input, with communication of pre-published studies to top KOLs</li> <li>• Generally medical/science background</li> </ul>	<ul style="list-style-type: none"> <li>• Release data via corporate</li> <li>• Predominantly internal</li> <li>• Focus through lifecycle</li> <li>• Infrequent KOL contacts</li> <li>• Legal responsibility/on-label</li> <li>• Clinical trial localization and responsibility for phase IIIB/IV trials</li> <li>• Generally medical background</li> <li>• Release data to sales and marketing</li> </ul>

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# CLINICAL TRIAL LIAISONS

## Applying Proven MSL Techniques to Connect Physicians with Study Opportunities

**D**eploying CTLs to help accelerate the successful completion of clinical trials is a relatively new concept. The basic principles of this approach have proven effective in other areas of pharmaceutical communications, such as Medical Science Liaison (MSL) programs. In fact, existing MSLs are frequently utilized to support patient recruitment initiatives (see adjoining column).

Physicians who see patients with non-responsive disease often seek additional treatment options. One such option may be participating in a clinical trial offering an alternative drug therapy that otherwise is not available. Surveys indicate physicians are willing to refer patients to studies if they are aware of them and have a basic understanding of the compound and study protocol. In fact, it's not uncommon for 60% of patients enrolled in trials to come from physician referrals.(1)

Certainly, traditional communications techniques such as advertising, direct mail, media relations, internet initiatives and physician dinner meetings are effective in delivering messages that create awareness of clinical trials and encourage physician referrals. However, in today's highly competitive drug development environment over 80% of all

trials are not completed on time.(2) These delays cost sponsor companies up to \$1.3 million a day in lost revenue.(3) There needs to be a more effective and expedient method of connecting physicians with appropriate studies.

An increasingly viable method for communicating with physicians is the deployment of an outsourced CTL team. The CTL who possess a minimum qualification of an RN or MS and expertise in the particular therapeutic area meets with referring physicians in close proximity of each site to review study parameters and the value of participating in a specific trial.



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**CTL**  
*Clinical Trial Liaisons*

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Clinical trials are becoming more difficult to establish and complete, particularly in such areas as oncology, HIV, or neurology, where recruitment and retention of patients can be challenging. Further, recent FDA decisions make it likely that clinical trials will come under increased scrutiny in the future. If so, the costs of these trials may increase exponentially.

A well-trained Clinical Trial Liaison (CTL), as a therapeutic specialist in a field-based position, can work closely with a sponsoring company's home office and Clinical Research Associates (CRAs) in presenting a unified message to primary investigative sites. While not removing the need or significance of the CRA, the educational background of these specialized individuals facilitates peer-to-peer relationships and offers opportunities that cannot be realized in a long-distance relationship. CTLs can provide education to staff members at the investigative sites, which is particularly important if the clinical trial is in a novel therapeutic area. Although many companies focus on specific therapeutic tracks, the CTL can also provide scientific support for other agents in the company's portfolio.

CTLs are uniquely positioned to provide a link between the sponsoring company and investigative sites. In one recent example, a company that had developed a therapeutic vaccine for treating advanced prostate cancer contacted SOS to provide a team of field-based clinicians to educate primary care urologists about this new product. Since the drug was in phase III trials at the time, the team's role expanded to include active recruitment for clinical trials at multiple locations across the country. These CTLs worked closely with CRAs at the company's home office on field-based administrative issues, and they acted as a source of scientific information. The CTLs became the primary point of contact for urologists making patient referrals to investigative sites. They also helped urologists establish and manage study inclusion criteria, trained provider's office staff on chart review, and worked with primary investigators on community outreach to generate awareness of the trial. In several cases CTLs were successful in identifying primary urology practices to be considered as expansion sites for the phase III trials, a role more typically seen with investigator-initiated studies.

The need to educate is as important as the need to recruit and retain patients in any drug trial, and CTLs have the ability to do both. Further, the incremental costs associated with CTLs can be offset by the increased value that they bring to the investigators in driving patient recruitment and retention.

## THE CTL PROCESS

The CTL follows a focused and logical process to interact with referring physicians and facilitate the enrollment of eligible patients (Figure 1).<sup>(1)</sup> The process includes:

- Developing a list of recognized physicians by disease state in each market
- Contacting physician offices to schedule appointments
- Meeting with the physicians to discuss the protocol, inclusion/exclusion criteria and share the support tools available to successfully enroll patients into the study (as appropriate, secondary staff including physician assistants, nurse practitioners and clinical coordinators are included in these meetings )
- Providing each medical practice visited with access to a secure, interactive internet site where slides, trial guidelines and clinically based resources can be accessed

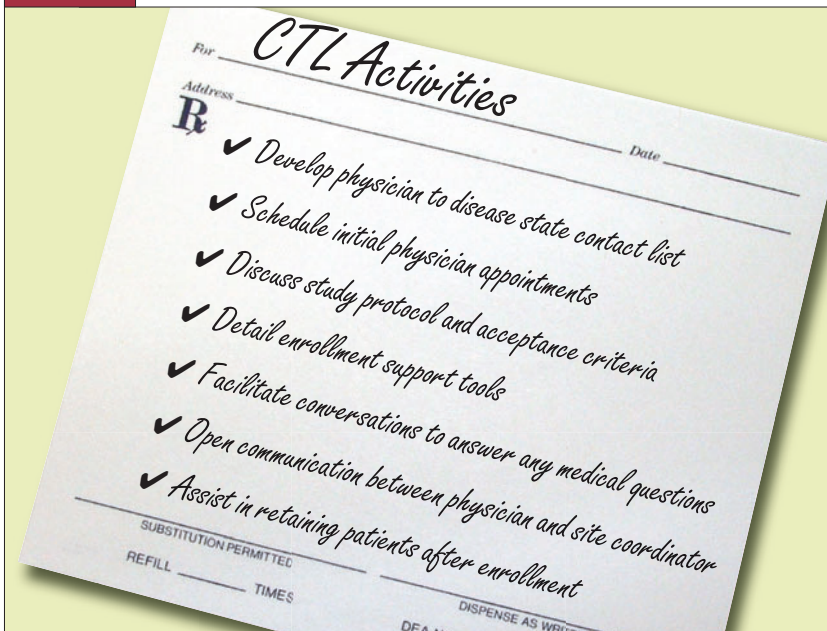
- Facilitating opportunities for physicians to interact online or on the telephone with healthcare professionals who will answer questions related to specific patients
- Opening communication channels between the referring physician and the primary investigator at the local site
- Coordinating activities with Clinical Research Associates to insure study goals are being met
- Assisting sites in retaining patients in studies after they have enrolled.

While the process and function described above provide a good framework for a viable program, it is advisable to customize the strategy and tactics for each program to insure that all opportunities are maximized and all potential obstacles are addressed.

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**FIGURE 1** The CTL Process





# An Approach to Defining and Measuring Field-Based

# MEDICAL SCIENCE LIAISON TEAM ACCOUNTABILITIES

## Introduction

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One of the persistent challenges for field-based medical programs (FBMP) across the pharmaceutical industry is the identification of transparent, relevant, and valid metrics that reflect the team's contribution to organizational business objectives and differentiate the FBMPs specific contribution from that of other customer-facing roles in achieving specific business outcomes. Efforts to define such metrics often produce a collection of activity measures without a clear link to expected outcomes (number of customer contacts, number of investigator sponsored studies submitted, number of presentations, etc.). Stakeholders criticize such efforts as irrelevant to understanding team performance and contributions to the business. FBMP members criticize these efforts as "micromanaging," "big brother" and /or ineffective for defining the value of the work that they do. However, all parties generally agree that specific measures reflective of accountability are essential.

Metrics are necessary tools for understanding performance progress to defined objectives. They may be useful in capturing credit for the team's contribution to business successes, evaluating gaps that may account for business shortfalls, and shaping appropriate corrective action plans or revised business strategy. Meaningful metrics inform teams as to where they are relative to defined objectives (on target, behind planned timeline, etc.). Metrics are also critical tools when competing with other functional areas for resources.





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Preparedness in defining the business case and the resource requirements proposed for the FBMP is strengthened by transparent, objective metrics that are easily understood by organizational leaders. Most functional areas have well-defined metrics directly linking performance to financials (i.e., sales). Organizational leaders often interrogate resource requests by asking, “How does return on this resource compare to that of a sales representative?” where ROI is well defined. In today’s environment, leaders are often asking what resources can supplant today’s sales paradigm and produce improved returns to the company and increase value in the medical community “under siege” by large numbers of sales representatives. In this environment, it is of little wonder why sales representatives are encountering decreasing access to and time with the customers they compete to see.

We believe well-defined metrics that appropriately and effectively measure business process outcomes, built around objective and easily defined deliverables or outcomes that are consistently collected and accurately describe a team’s contribution, are critical tools for successful FBMPs. The objective of this paper is to describe a process to generate FBMP objectives, identify and integrate appropriate

metrics, and discuss how a structured approach supports both leadership and team members (Figure 1).

**FACTORS THAT SHAPE THE FBMP OBJECTIVES/ ENVIRONMENTAL ANALYSIS**

Assessing the business environment is a critical step in objective planning. Four categories of information help to inform the process of team objective planning: FBMP capabilities and lifecycle positioning, internal stakeholder objectives, customer expectations, and market/competitor influences.

FBMP capabilities and lifecycle positioning frame the work on which the team will focus. Field-based Medical Science Liaisons (MSLs) have great success at gaining access to physicians that will not see a sales representative. The core activities of the FBMPs are geared towards achieving the “gold standard” peer-level relationship with key opinion leaders (KOLs) and decision makers. Core skills focus on delivering knowledge around complex scientific issues, clinical trial/research support, publication support, and presentation support. Typically FBMPs have a diverse mix of MSLs with basic science/research, clinical practice, and/or pharmaceutical industry experience. The most effective and

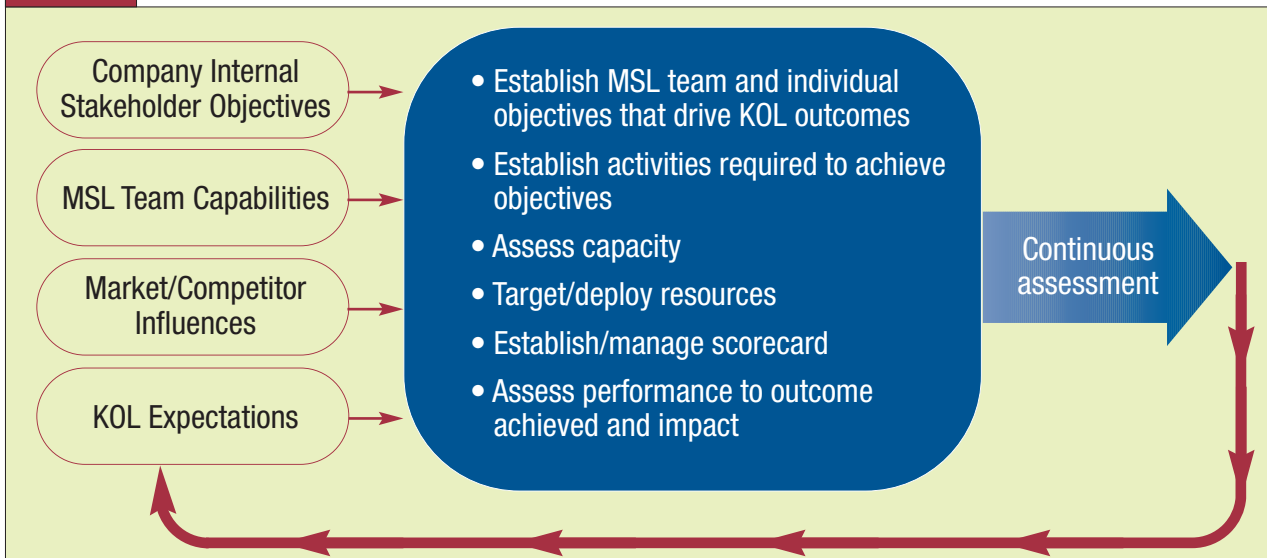
well-regarded FBMPs have acquired the competence to leverage these relationships to support customer needs related to the products, therapeutic areas and disease states that are corporate priorities. In addition to their activities with external customers, MSLs can provide value within the company supporting the development and registration process, training local sales representatives on disease state, therapeutic area and product knowledge, as well as engaging in the business and account planning processes. Keep in mind that individuals within the team may be at different levels of development for key competencies, and this variability may impact the teams overall approach and delegation of responsibilities.

Understanding of internal stakeholder objectives is fundamental to insuring that the work that the FBMP is contributing is aligned with organizational expectations. Organizations employ FBMPs because they anticipate that such teams will improve business performance; specific expectations may vary, usually related to life cycle position of products for which FBMP support has been recruited. Pre-launch expectations may include outcomes related to improving development performance (enrollment of





**FIGURE 1** FBMP Planning/Assessment Strategy



investigators, shortened time lines for patient recruitment, investigator performance to timelines/patient enrollment objectives, potential authors, consultants, etc.) or market preparation activities (education of KOLs and decision makers, product awareness, KOL relationship development, etc.). Generally, company expectations for pre-launch activities are primarily related to achieving more rapid approval, and quicker time to market. Support during launch and post-launch periods often are accompanied by expectations of more rapid brand uptake in the market and higher peak sales than expected with sales support alone. FBMP are expected to establish relationships with KOLs and leverage these relationships to align company needs with KOL skills/interests (authors, speakers, investigators, consultants); engagement early in a brand life cycle may ensure access from discovery throughout the brand’s commercial life, and subsequent transition to successor brands. Additionally, a frequent expectation is that the relationships and partnerships that FBMPs forge are expected to establish customer loyalty towards the pharmaceutical company and/or the related brand(s).

Customer expectations also influence FBMP planning. FBMP’s customer base includes KOLs and decision makers impacting drug therapy choices. It is necessary to understand organizational expectations regarding “who” the FBMP is accountable for engaging; some teams focus only on KOLs with national or international impact, while other teams may target regional and local opinion leaders. This mix may have a significant impact on the overall “expectations” of the FBMP’s customers. KOL

expectations and needs may vary on their scope of influence, but all customers targeted should value scientific exchange and the engagement of the FBMP. In all companies, MSLs are a relatively scarce resource, and this limited resource should focus on those customers that value the partnership. Such appreciation may have to be earned by the liaison and is not always immediately apparent. How much an MSL should invest is directly related to the potential magnitude of the asset the KOL may provide. A critical part of understanding customer needs and expectations is customer feedback. This can be gained by talking directly with the customer and/or formal surveys that request structured feedback. Needs should be assessed for the customer population as well as individual KOLs, and objectives established that address both. In formal customer surveys, KOLs report that they most value scientific discussions with individuals that are science/disease oriented (not product oriented), non-promotional, educators/providers of educational resources, provide new, unbiased scientific information (no “infomercials”), research oriented and can act as the KOL connection to the company.(1) These attributes may vary in importance to different KOL populations.

Plans for these customers need to reflect FBMP commitments to organizational objectives. Efforts with individual customers may need to be modified as organizational needs change. Each customer plan should define what you hope to achieve with each customer. Some customer targets may change during a planning cycle, the intensity of support to individuals may be



modified, and some may become “inactive” if their interests/skills are not currently needed.

A number of market/competitor issues have had significant influence on the current MSL role. The number of pharmaceutical companies utilizing FBMPs has exploded over the past few years. A primary driver for this is company efforts to gain meaningful time with key customers and other health care providers who influence selection of drug therapy. Traditional representatives struggle to secure time with many prescribers; typical call length reportedly is 2.4 minutes for “drop-ins” and 6.3 minutes with an appointment.<sup>(2)</sup> MSLs average 45 minutes or more per interaction with KOLs. This provides generous time for physician/healthcare professional education around targeted scientific issues, and provides an opportunity for broader scientific exchange. Improved understanding decreases the information gap and improves product market penetration. (Figure 2).<sup>(3)</sup>

Just as the market has become crowded for traditional sales

representatives, the increasing presence of FBMPs is increasing competition for customer time. As the number of MSLs increases, customers are “assessing” the value of these individuals to their practice, and are increasingly selective in defining value. This dynamic increases the importance of assessing FBMP performance from the customer’s perspective. Understanding the customer’s view of service quality, relationship quality, value of specific services, and attributes of a successful MSL is important to building and maintaining a successful team. KOLs have access to an increasing number of MSLs, and they will choose with whom they will engage based on the value they provide.

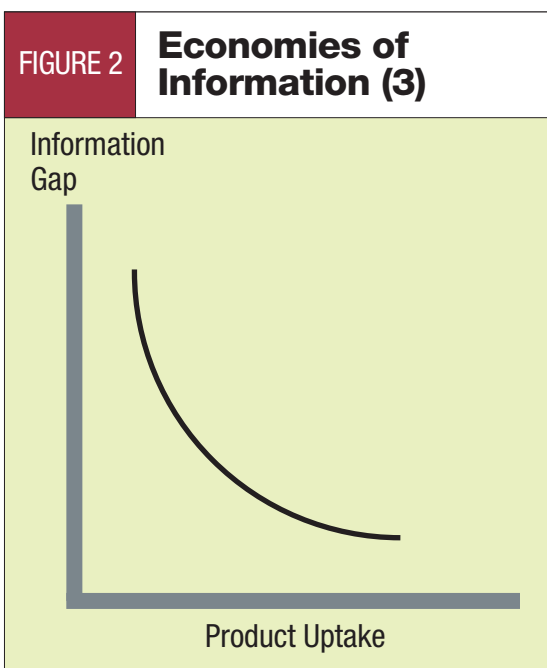
The presence of competitors/competitive brands introduces other factors that may impact FBMP planning. Assessing the scientific messaging of competitors may impact customer perspective regarding therapeutic issues. Understanding competitor activity is fundamental to maintaining an informed position with KOLs. They

hear from all players and expect that MSLs are at least aware of competitor activity, and expect that MSLs can communicate their company position as well as interrogate scientific integrity of related issues. It is also important to account for emerging issues and products in the competitor landscape: emerging science, clinical studies, future products/indications and emerging leaders (KOLs). Effective management of competitor intelligence

is a competency that may impact team accountabilities.

Significant regulatory challenges throughout the industry have impacted FBMP practice. Although it has been believed by some that FDA’s “safe harbor” clause provided for MSLs to proactively disseminate off-label information, this is clearly not the case. FDA representatives have commonly indicated that the agency does not authorize FBMPs to promote off-label information. The Office of the Inspector General (OIG) has noted in its 2005 work plan that it intends to scrutinize off-label promotion. Corporate compliance policies are more clearly addressing FBMP practices than policies of the past. Input from these sources has resulted in a more uniform interpretation that FBMP may respond to unsolicited requests for off-label information. Dissemination of information should adhere to scientific rigor, be unbiased, and not presented in a manner that misbrands a product. Two-way information exchange is permitted if it is bona-fide scientific information exchange, and fair balance is provided in each response to an unsolicited request. Although this guidance is not unique to MSLs, their competencies and accessibility by physicians and other healthcare professionals make them qualified resources for this responsibility. Compliance with these policies is an important accountability for FBMPs.

Other legal and ethical challenges have impacted industry reputations overall, and have also impacted business practices by FBMPs. Practices that empowered MSLs with relatively broad discretionary spending have been tightened up across the industry. Decisions regarding awarding research grants and educational spending, and other “unrestricted educational” awards are

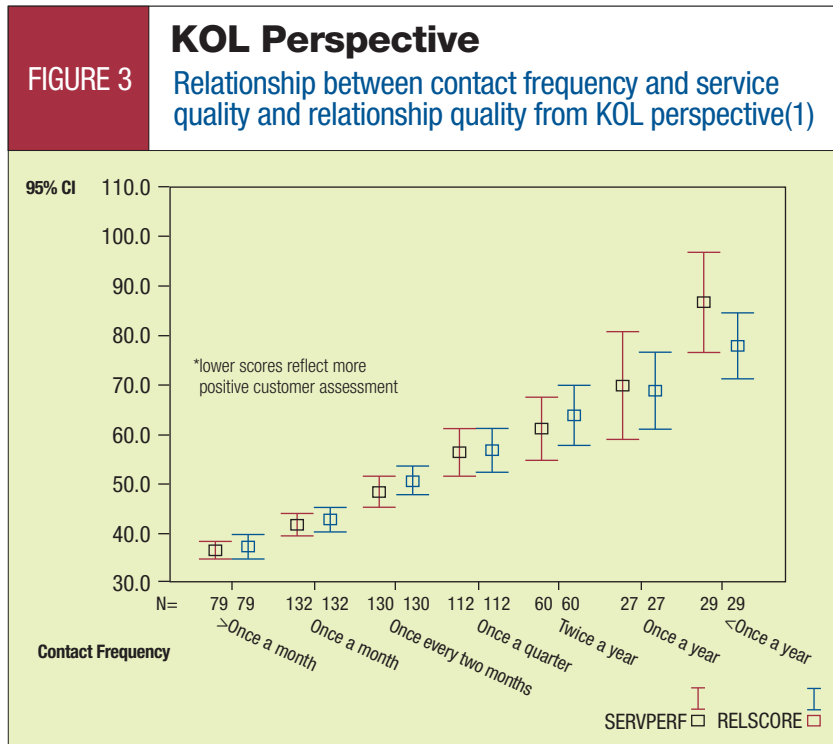




managed by more formal, rigorous review processes that minimize perceptions that such awards are issued to influence practitioner opinions. More objective assessments of “merit/quality” are being implemented. These practices minimize MSL involvement in shaping content of educational forums, as well as MSL influence on awarding research grants. Roles are focused on customer partnering that promotes high quality submissions and meets administrative requirements that might otherwise delay consideration. Guidance on such practices reflecting OIG and PhRMA Guidelines is part of most compliance policies.

Significant drug safety issues have also impacted industry reputations (Vioxx®, Bextra®, Tysabri®, etc). These issues have been confounded by failure to share results of research that clinicians perceive as early evidence of safety concerns, that may have influenced their decisions to prescribe these drugs, and possibly avoided adverse events that followed. While such recent high-profile events have shaken the public’s and medical community’s confidence in the pharmaceutical industry and the FDA (e.g., COX2 inhibitors and cardiovascular safety), FBMPs create an opportunity for reliable, credible, balanced sources of drug information. MSLs have demonstrated the ability to establish peer-level or colleague level relationships with KOLs and other practitioners. Scientific information exchange is core to creating these relationships. MSLs can provide information and educate practitioners about emerging issues, as well as provide customer feedback to appropriate company channels (concerns, research ideas, relevant clinical vignettes, etc.)

Finally, the public’s perception of drug costs and experience with



reimbursement issues has further fueled industry criticism. Effectively defining drug value based on scientific data and clinical outcomes can help provide perspective concerning relative value. Communicating clinical and pharmacoeconomic data may also help balance such concerns.

Globalization of pharmaceutical companies has introduced a new dimension to FBMPs. The success of FBMPs in the United States has led to implementation of similar programs globally that resemble the US model. As such globalization continues, opportunities to share resources, best practices and competitive intelligence between country-specific affiliate offices should be considered. Integration with global partners may create increased efficiencies such as better communication of investigator initiated trials occurring in ex-US markets, shared development of standard responses, and more coordinated customer management with international KOLs.

### ESTABLISH FBMP OBJECTIVES THAT DRIVE KOL OUTCOMES

Fundamental to planning is having a clear understanding of team strategy and how it supports organizational strategy. This helps provide a link that relates the team’s work to organizational business.

Once the environmental analysis has been completed, objective planning can proceed. Objective planning is the starting point for creating a business plan. Consider what needs to be accomplished by the team: who are the customers that need to be engaged, what outcomes need to be delivered, what needs to be done to achieve these outcomes, how will performance be measured, and what is the timeline for delivery. Since demand for FBMP services often exceeds capacity, an approach to prioritization may be required. All objectives should support the strategy.

Objectives are intended to enable control over your business plan, help motivate individuals and teams to reach a common goal, and provide an





agreed, consistent focus for all functions of an organization. The FBMP should build team objectives, which will help define individual MSL objectives, which will further determine individual KOL objectives.

One widely used approach is creating SMART (Specific, Measurable, Achievable, Relevant, Time-based) objectives.<sup>(4)</sup>

Specific means that an observable action, behavior or achievement is described which is linked to a rate, number, percentage or frequency. Is there a specific outcome, which is linked to a clear metric?

Measurable indicates that a method or procedure exists which allows the tracking and recording of the behavior or action upon which the objective is focused. Is there a reliable system in place to measure progress towards the desired outcome identified?

Achievable means that the defined objective is feasible. There is a likelihood of success, but this does not mean easy or simple. Objectives need to be a stretch and agreed upon by the parties involved. With a reasonable amount of effort and application can the objective be achieved?

Relevant requires that the goal or target being set with the individual is something upon which they can actually impact or change. The goal also needs to be important to the organization. Can the people with whom the objective is set make an impact on the situation? Do they have the necessary knowledge, authority, and skill?

Time-based simply requires that the objective have a start date (if it is ongoing) and/or a target completion date (if it is short term or project related). FBMP responsibilities have both strategic and tactical dimensions; time targets need to properly consider this perspective.

Most managers know what SMART means in relation to objective setting,

yet most remain challenged to comply with all these criteria. Keeping this scheme in mind, helps produce good, effective objectives.

Outcome measures frequently targeted by FBMPs include publications, presentations, investigations, and prescribing. Individual KOL objectives include assessment of KOLs current capability to achieve a specific outcome, identifying a plan (activities) that will improve the KOLs current performance level, defining the specific outcome (that contributes to individual MSL and team objectives) you hope to achieve in the defined time frame, and metric that addresses progress to goal.

### ESTABLISH ACTIVITIES REQUIRED TO ACHIEVE OBJECTIVES

An understanding of key productivity drivers and how they relate to the MSL is necessary to optimize performance. Outcomes are achieved by a combination of activities that lead to successful conclusion.

Scientific (knowledge) exchange is an interaction that focuses on two-way exchange of information on scientific issues. This activity fundamentally contributes to successful delivery of virtually all FBMP targeted outcomes. It is an activity consistently highly-valued by MSL customers. Relationship building relates to engaging the KOL and nurturing the relationship, with knowledge exchange not being the focus.

Leveraging KOL interests and professional needs is the basis for several activities, all of which may indirectly contribute to overall relationship quality. Meeting these needs requires partnering with the KOL to work toward solutions improving the KOLs disease management practices or drug therapy choices. Such activities might include patient education materials, drug

administration guidelines that may simplify or standardize therapy choices in their practice environment, or medical utilization evaluation tools. Coaching by MSLs may be a useful activity targeted toward improving KOL skills. Coaching may include improving speaker skills, explaining scientific issues related to speaker slides, grant writing, or skills related to improving investigator skills. MSLs may also engage in activities specifically intended to assess the capabilities of a practice site or practitioner for participation in company sponsored clinical trials or investigator initiated research.

A major opportunity for MSLs is recruiting KOL to participate in company sponsored events or activities as a speaker, author, investigator, or consultant. This activity leverages the MSL relationship with the KOL to align company needs with the KOL skills and interests.

Categorizing such activities provides a basis for tracking time dedicated to specific functions that may be important data for capacity planning.

### ASSESS CAPACITY

Creating a business plan always requires a review of the team's capacity to deliver on objectives. In order to determine the amount of time available for engaging in customer interactions, one must determine the number of days the MSL has available to meet with customers. The customer time must account for meeting planning, time with the customer and time required to accomplish work related to customer commitments.

Other MSL activities also need to be considered. Travel time is directly related to territory size and is the greatest determinant of the number of interactions that can be accomplished by a MSL. Additionally, time for knowledge acquisition/management,



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### MEASUREMENT TOOL TO CAPTURE CONTRIBUTIONS AND VALUE OF MEDICAL SCIENCE LIAISON TEAMS

Creating metrics for measuring what Medical Science Liaisons (MSLs) do is not as daunting a task as one might think. The more challenging aspects involve successfully setting achievable yet challenging goals, applying suitable resources, and importantly, utilizing the proper tool to measure performance. As the MSL team supports several stakeholders in the organization, including medical, marketing, sales, and regulatory, each group's input needs to be considered. Once goals are agreed upon, the MSL team needs to be evaluated for capacity and ability, and appropriate adjustments implemented. Finally, to measure success, today's software models offer myriad tools that can be customized to capture relevant activities, track against goals, assign weighting, create reports, and act as repositories for slides and other documents. Companies have successfully employed web-based relationship management databases for MSL teams that are customizable and user-friendly. This streamlines the process of measuring team progress, and has the flexibility to permit changes when outside influences alter the direction of the team. Periodic review of progress ensures proper alignment with company strategy and key messages. The effective MSL manager employs active communication to set goals, provides ongoing leadership to deploy an effective team, and utilizes the right tool to measure success.

project management (protocol review, headquarter projects, etc.), administrative activities (Customer Relationship Management data input, expenses, routing/scheduling, etc.). Other elements to consider are total number of workdays, professional and/or team/company meetings, vacation and holiday time.

Common distribution for FBMPs targets approximately 3 days for customer activities and 2 days for other business responsibilities for a five-day period. Annual calculations must consider available potential working days over the one-year period (often approximates 70% of MSL total time).

More detailed capacity planning can be accomplished with good data concerning time requirements related to key activities. For example, during the days identified, how many customer contacts can be accomplished? Further, utilization of customer surveys can generate data on quality of relationships and customer perceptions of service quality and relate such scores to number of customer contacts. This can provide objective insight into the level of work necessary to achieve the desired level of customer satisfaction (Figure 2).(1)

### TARGET/DEPLOY RESOURCES

Targeting specific KOLs is based on alignment of KOL interests and attributes with business needs. What does the FBMP/MSL need to deliver to meet objectives?

The MSL role should be centered on creating value for members of the medical community who influence other physicians and healthcare professionals. Potential targets include individuals with the attributes to contribute to priority outcomes (presentations, publications, investigators, formulary support, etc.) Although everyone in the medical community must keep informed on

the latest scientific advances, MSLs should target individuals who are receptive to scientific exchange and contribute attributes that are required to meet FBMP objectives.

Objective assessments are available to prioritize KOLs with multiple attributes, and assign specific weights to individual attributes to support the sponsor's customer management strategy to optimize desired outcomes.(5) Attribute weights may change depending on business priorities or product(s) position in lifecycle.

There are two common strategies for deployment of MSL resources. The most common approach is alignment with commercial regions. This approach aligns MSL support with commercial teams, providing scientific support for "on demand" customer support, sales training, and business planning. A second approach is based on workload and geographical dispersion of targeted KOLs. This approach optimizes coverage of geographic concentrations of KOLs. This approach is most often used when the MSL resource is limited. Decisions about deployment are driven by capacity, business priorities, and FBMP strategy.

### ESTABLISH/MANAGE SCORECARD

At its highest level, the balanced scorecard is a framework that helps translate strategy into operational objectives that drive behavior and performance. The scorecard asks you to think of your mission and strategy from four key perspectives:

- 1) How do customers see us? (Customer perspective)- the scorecard should incorporate specific measures of what customers receive in terms of time quality, performance, service and cost.
- 2) What internal processes must we excel at? (Internal perspective) Focus on core competencies, processes, decisions and actions that have the greatest impact on customer satisfaction.



3) How can we continue to improve and create value? (Innovation and learning perspective) Measures in this area indicate future and sustain success. They measure continual improvements to existing products and processes and introduction of new products or services.

4) How do we look to stakeholders? (Financial perspective) Indicate whether the three previous categories have been correctly identified and constructed.(6)

No single measure can provide a clear performance target or focus attention on the critical areas of FBMP business. The scorecard helps teams focus on measures that are most critical. When building a scorecard, tailor the measures to fit your company's/team's specific challenges. The scorecard can be viewed as a dashboard accessible to the team, stakeholders, and organizational leadership. It should focus on measures that define your progress to objectives, provide insight to the FBMPs contributions to the business, and reflect value of those contributions. The scorecard's overarching purpose should be to help the team evaluate the effectiveness of specific efforts, rather than gauge progress. The team must play a lead role in designing its own scorecard to optimize buy-in and ownership.

### ASSESS PERFORMANCE TO OUTCOMES/IMPACT

The evaluation phase examines metrics of different categories from a variety of sources. These sources include the FBMP scorecard reporting performance in defined areas, stakeholder reports related to areas of FBMP targeted work (investigator enrollment, research protocol submissions, speaker support, formulary status of supported brands, stakeholder satisfaction surveys, etc.), various forms of customer feedback, and commercial reports. This phase considers evaluating performance to planned objectives, but also begins to assess overall impact on organizational business objectives. Concepts here include FBMP impact on achieving registration benchmarks, product approval, and time to market. Commercial impact may also be considered. Although often the focus of spirited debate in the field-based medical community, FBMPs often contribute significantly to commercial success by adding value, which increases customer confidence and loyalty. Most teams are created to establish relationships with KOLs and drug therapy decision makers that influence quality of development deliverables, and drug therapy choices by KOL peers and institutional formularies. The MSL interaction

with KOLs shapes KOL opinions about scientific issues including drug therapy choices. This results in two levels of impact on product selection. First, direct impact reflects the decision of the MSL's targeted customer to prescribe specific product choices. Although this is not considered a primary reason to employ FBMPs, these customers often contribute significant prescription volume. More commonly, FBMPs are believed to target customers valued for their ability to influence prescribing of other practitioner groups. This is indirect effect; the MSL influences the KOL to influence drug therapy choices of others. The source of MSL influence is effective scientific exchange.

### SUMMARY AND CONCLUSIONS

Deployment of FBMPs by the pharmaceutical industry has increased substantially in the last five years. As pressures on the industry challenge profits, all organizational functions are challenged to improve measures of accountability and demonstrate the relative value of their functional contributions. Objective, transparent, valid metrics are critical to sound planning, execution and performance assessment.

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Research + Analysis + Value =  
Field-based  
Outcomes  
Research  
Managers

A man with short brown hair and glasses, wearing a dark suit, white shirt, and dark tie, is seen from the side, writing on a dark chalkboard. He is holding a white piece of chalk in his right hand. The chalkboard has the text "Research + Analysis + Value = Field-based Outcomes Research Managers" written on it in white chalk.

**Today's managed care environment** dictates that decision-makers analyze and incorporate cost-effectiveness into their product coverage process. The completion of critical outcomes research studies defining the "real-world" value of these products is essential for corporate success.

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# Assessing the Value of Field-Based Medical Programs

## THROUGH THE EYES OF THE CUSTOMER

### Introduction



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**F**ield-based medical program (FBMP) managers are often challenged to define the value of their programs' contributions to the company's business goals and to external customers. While all parties generally agree that measuring FBMP process outcomes are important, there is a lack of consensus on how best to capture the value of the varied functions these groups perform. Quantitative measures typically used to assess sales representative performance (i.e., number of physician contacts, number of presentations, etc.) overlook the value-added, qualitative aspect to FBMPs. By developing and periodically administering a well-constructed survey tool based on predefined objectives and outcomes, FBMP managers are able to monitor measures that are most critical, and gain the all-important internal stakeholder buy-in to continuing or expanding their programs.

The objective of this paper is to present a practical, hands-on approach to developing a survey tool that can be utilized to assess the value of a FBMP to both external and internal customers. Specifically, it will focus on how to create and disseminate the survey, and how to use the survey results to foster ongoing support from internal stakeholders. Details will be presented on the selection of an appropriate survey audience, positive aspects and potential pitfalls of surveying key opinion leaders (KOLs), critical ingredients of a successful survey, the development and evaluation process, assessing time and associated costs against the survey, and important feedback implementation strategies. In the end, the reader should have a greater appreciation for how to use the survey as an essential tool to assess the value of FBMP to their external customers and be able to utilize the results to communicate that value to internal stakeholders.(1)

### “VALUE” – HOW FBMP ARE PERCEIVED BY INTERNAL STAKEHOLDERS AND EXTERNAL CUSTOMERS

Understanding the definition of the word “value” is fundamental to insuring the proper utilization of the survey. As defined by Webster,(2) the word “value” may be viewed quantitatively, as in “a relative or assigned worth of importance, monetary or material worth, and equivalent worth in money, goods or services.” At the other end of the spectrum, “value” may reflect the softer or more qualitative definition, “to consider or view highly,” as in valuing one's opinion or views. So, why is this distinction important, and what does it have to do with surveying customers?



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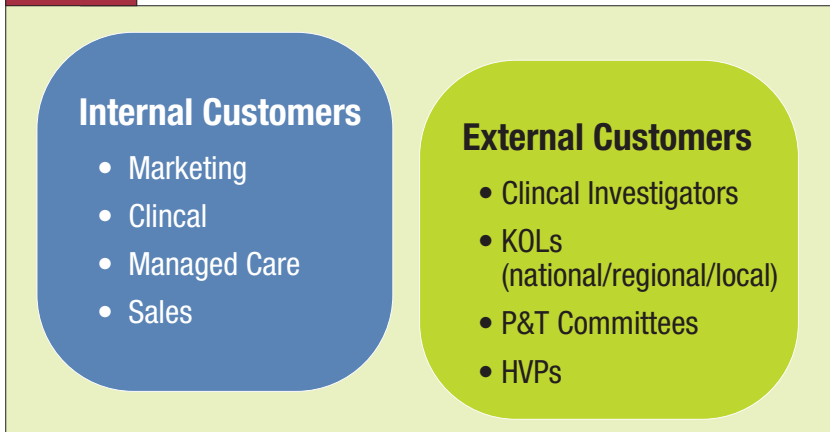
Value reflects a spectrum of quantitative and qualitative elements. When assessing customers' perceptions of the value of FBMPs, it is essential to incorporate a blend of both quantitative and qualitative measures into the survey. Similarly, when presenting the results on the value of a FBMP to internal stakeholders, be prepared to respond to the broad range of interests represented by

stakeholder groups. For example, upper management is likely to be concerned with value for dollars invested, and the return on their investment; marketing may want to know that the information conveyed and the relationships developed by the FBMP Medical Science Liaisons (MSLs) are building KOL interest in their brands; and regulatory may want to be assured that MSLs are acting

professionally and in line with regulations governing their conduct. By ensuring that the survey collects a range of quantitative and qualitative metrics, the results should effectively communicate the value that the FBMP brings to the business as a whole.

Understanding the value of the FBMP, or in other words, what the program is supposed to be recognized for, is critical to a successful survey. The first step is to determine who should participate in the survey. There are two broad groups of customers, internal stakeholders and external customers (see Figure 1). Some of the disciplines or functional areas that represent internal stakeholders include marketing, clinical research, managed care, sales, and regulatory. If the company has a separate pipeline or commercial development group, they might also be included. The obvious goal is to have as many groups as possible within the organization who recognize the value and utility of the FBMP, thus wanting this MSL group to support their business activities. Of note, Medical

**FIGURE 1 Who should you survey?**





Affairs is not included in the list of internal customers in Figure 1 because it is assumed that the FBMP are reporting into Medical Affairs, and are already endorsed by that group. It is recognized however, that the group may not be reporting into Medical Affairs, and if that is the case, Medical Affairs should be considered as an internal stakeholder.

In most instances, the principal external customer group would be the KOLs, including those with national, regional or local influence. Other external customers might include clinical investigators, depending on the activities provided by the FBMP. P&T Committee members might be considered, especially if the FBMP has a managed care or managed markets focus. High volume prescribers (HVPs), while potentially more of an interest to the commercial side of the business, may sit on the cusp of being a local thought leader because of their volume experience with a brand or brands. Whether or not they are a focus for the MSLs may depend on the company. In companies with a distinct separation between medical and commercial, often the MSL group might not know who the HVPs are. In smaller companies, or in rapidly changing disciplines like oncology, there may be significant overlap between those customers designated as KOLs and those, by virtue of their practice, designated as HVPs.

## POSITIVE ASPECTS AND POTENTIAL PITFALLS OF VALUE SURVEYS

It is important to review some of the positive and negative aspects of utilizing a survey before developing the tool and identifying external customer targets.

### Positive aspects

KOLs often represent the most important customer. As such, they are in the best position to provide invaluable feedback on how they value a FBMP. The survey results can assure that the team activities are in line with the external customers' expectations, that is, it can highlight the aspects of the program that are working well and meeting the customers' needs. Obviously, when designing the survey, KOL input should be included to allow measurement of their expectations against what the FBMP group is providing.

Survey results may provide feedback on a FBMP team's services compared with other FBMP teams. Often, this occurs without prompting when a KOL feels inclined to compare one group's activities with those of another company; they may refer to higher levels of resources from another company, or they may volunteer that one particular company is light-years ahead of its competitors. However, directly soliciting such input from all survey respondents might provide more robust information on what is going well and what might be done to improve the level of service.

The survey can be used, in conjunction with other performance indicators, to provide a measurement of MSL knowledge and expertise. While it would not be appropriate to use a general survey as the only assessment tool to evaluate an individual MSL's knowledge, it can serve an important role in determining whether or not the amount of technical and scientific training, and the overall conduct and professionalism is in line with the FBMP's goals.

Proper geographical deployment of the FBMP team is an ongoing challenge. As it relates to quantitative and qualitative metrics, deployment of MSLs is often based on proximity to the KOLs and their institutions. Ideally, face-to-face contact with a KOL four to six times a year is desirable, with additional contact by other means of communications. If the response from a KOL is, "Great resource, but I have only seen my MSL twice in the past year," this may be the trigger to critically evaluate the geographical deployment of the program. Is the location of this MSL hindering the

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## CUSTOMER SATISFACTION SURVEYS

### An Emerging Method For Measuring The Impact Of Medical Science Liaison Programs

Pharmaceutical companies have become quite adept in developing internal metrics to measure the various activities in which their Medical Science Liaison (MSL) teams engage. However, many manufacturers continue to search for additional and complementary means to ascertain the value of their teams. One such method gaining traction is the customer satisfaction - or Key Opinion Leader (KOL) - survey. One client recently requested that SOS design and initiate such a survey in order to solicit physician feedback on the value of its educational offerings as well as additional areas for service growth. To maximize participation, SOS created a concise, web-based questionnaire consisting of 13 multiple-choice questions. Invitations containing a secure link to the survey were e-mailed to KOLs with whom the MSLs had interacted a minimum of 3 times. A response rate of approximately 75% was attained by the end of the two week period during which the survey website was accessible for completion. Physician feedback demonstrated the value of their MSL relationships, and, importantly, that the team was serving a defined educational need.



frequency with which calls can be made? On the other hand, positive responses around geographical deployment could actually confirm that team members are aligned correctly.

Finally, a well-conducted survey can be a mechanism for fostering internal support and possibly expanding the team. Positive data from a KOL customer group can provide the impetus for the director to further champion the program within the organization. Disseminating positive results from satisfied external customers is likely to generate additional support from satisfied internal stakeholders. Even external comments like, “This group is great; they’re a wonderful resource but you know, we just need a little bit more, we just don’t see them that much – the four people you have covering the US is just not enough,” could go a long way to generating support for program expansion.

### **Potential pitfalls**

Alongside the positive aspects of surveying KOLs are the potential pitfalls. The challenge is learning how to turn the pitfall into a positive outcome for the

organization. The first issue is low survey response rates. Obviously, KOLs are busy individuals and may not feel that they have time to complete a survey. Critical thinking is paramount when deciding which KOLs to include on the survey list. For example, there may be a KOL with whom the MSL has built a great relationship, but knowing in advance that the KOL is too busy to complete the survey could prevent a wasted survey. The goal is to identify survey recipients most likely to return a completed survey.

In most instances, the organization will be best served by being open about the source of the survey. A blinded survey, with no company or MSL name mentioned, might cause confusion for a KOL. A greater response rate can be assured if the survey letter reflects the company’s commitment to the KOL and states the goals of the survey. A cover letter or email should state that the goal of the survey is to collect data that will allow the company to reinforce the services currently provided to the KOL, identify any limitations to those services, and improve or expand on those services

to better serve that KOL customer in the future. Specific reference to the name of the company, and possibly the name of the MSL, will ensure that the KOL’s comments are not misdirected.

The survey may identify shortfalls in program resources. As mentioned above, comparative comments about what one company does versus another, though initially perceived as a negative, can be used proactively to identify what might need to be improved or what resources are needed to make the improvements. Knowing that there are issues needing improvement actually helps the organization make positive changes, and once changes are made, can indicate to the KOL that the company values their comments.

Another pitfall is disgruntled respondents with comments such as, “You never provide any funding.” This is probably one of the most common responses in a FBMP survey. Despite the information and resources provided by MSLs, one of the most sought-after resources is funding for medical education or clinical research projects. When the inevitable company comparison

occurs, it may result in a negative response from the KOL merely due to the company's budget for this type of support. One response to this dilemma might be a proactive plan that outlines the type of educational grants or investigator-initiated studies that can be endorsed and supported, so that the MSL can maintain their credibility and confidently address those areas that can be supported.

There may be lack of clarity around the MSL role. The KOL may indicate that it is difficult to discern the purpose of the MSL among the myriad of other company representatives that call on the KOL. The company may have a medical representative, an education specialist, a specialty representative, and a managed markets specialist all calling on the same KOL. Some confusion on the part of the KOL is not surprising in this setting; however, more concerning is that the KOL might not actually be aware of the distinct service that the MSL can provide. Initially a pitfall, this might be turned into an opportunity for the MSL

to revisit the MSL's role, objectives and services offered.

The survey may be used by KOLs to directly compare individual MSLs. As mentioned above, there are other tools and mechanisms better suited to assess an individual MSL's performance. Survey results may inappropriately compare a good MSL and an exceptional MSL, with the KOL misinterpreting the exceptional performance as the standard. It will be important for the program director to be able to accurately interpret the results of the survey so that individual MSL development needs are not misrepresented.

Finally, the survey may have been employed during times of corporate financial scrutiny or bad press. It is said that timing is everything, and especially so with survey results. Again, interpretation of the survey will need to consider whether the responses reflect a functional issue of the FBMP and the MSL team or bad timing of the survey while a corporate issue is being debated.

## CRITICAL INGREDIENTS FOR A SUCCESSFUL SURVEY

How do you create a successful survey? Is there a recipe for success? The answer is yes, and some of the critical ingredients are outlined in Table 1. Some type of formal communication, such as a letter or an email, summarizing the survey is highly recommended. This accompanying letter provides a good opportunity to explain the objective of the survey or why the survey is being administered, who is endorsing the survey, i.e., the company name, the MSL name and/or the region, and provides clarification on how the responses will be utilized. Most physicians will appreciate their input being kept confidential, and knowing that their response will be used to improve the overall value of the program might increase response rates. Letters might also be sent via mail with email follow-up. Resources like [www.zoomerang.com](http://www.zoomerang.com) might be used to facilitate the implementation of the survey.

The survey should be concise and delivered in a user-friendly format, i.e., web-based, to facilitate response. Answers are provided with the click of a mouse instead of ensuring the survey is mailed back to the company. The survey should also be minimally time-invasive and easy to complete. Make the questions as simple and straight-forward as possible, using phrases that are easy to understand and response systems that facilitate responses, i.e., use check boxes or numbers entered onto a rating scale. Some open-ended questions are fine, but make it easy enough for the KOL to want to complete it. KOLs are under time constraints, so avoid twenty-minute surveys; it should not take more than 10 minutes to complete the survey. Again, if the survey is web-based, it shouldn't take much time.

A reasonable sample size is needed to make the survey results credible. One way to determine sample size is to note the total number of MSLs in the FBMP and the number of KOLs they are

<b>TABLE 1 Critical Ingredients for a Successful Survey</b>	
	<b>Accompanying letter/email summarizing:</b> <ul style="list-style-type: none"> <li>• Survey objective</li> <li>• Company name</li> <li>• MSL name and/or region</li> <li>• How responses will be used internally</li> </ul>
	<b>Concise, user-friendly medium – e.g., web-based</b>
	<b>Minimally time-invasive, easy to complete</b>
	<b>Reasonable sample size</b>
	<b>Balanced questions to yield hard data and company perceptions</b> <ul style="list-style-type: none"> <li>• Open- and closed-ended questions</li> <li>• Rating scales to facilitate response</li> </ul>
	<b>Target KOL/physicians with whom MSL has frequently interacted</b>
	<b>Content related to resource offerings</b>
	<b>Advanced senior management endorsement</b>
	<b>Unbiased mode of delivery, e.g., third party</b>



responsible for. For example, with a group of 10 MSLs who are responsible for 50 KOLs each, somewhere between 5-10 KOLs per MSL should be a sufficient sample size. The survey does not have to be sent to every KOL.

A balance between of quantitative and qualitative questions will yield hard data and an impression of how the company is perceived by KOLs. There should also be a mix of closed- and open-ended questions, taking into consideration the time required to complete a particular survey. The use of rating scales within questions can be used to facilitate responses to survey questions; for example, asking the KOL to indicate their response to a statement on a numerical scale of “strongly agree” to “strongly disagree.”

The survey should target the KOL/physician customer audience with whom the MSL has frequently interacted. Effective targeting is key to a successful survey. In order to collect useful data, target KOLs that have been seen at least two to three times by their MSL. The

The survey results can assure that the team activities are in line with the external customers’ expectations, that is, it can highlight the aspects of the program that are working well and meeting the customers’ needs.

MSLs themselves may be a good source for determining which KOLs to survey; the other option is to randomly select survey recipients from a list of KOLs that have met a specific call rate threshold. Random selection might eliminate bias, but it might also result in less qualitative information on the program. Also keep in mind that over time, re-surveying the KOL base is a useful method of determining the impact of services delivered. In this regard, the first survey conducted will represent the baseline upon which subsequent surveys will be compared.

Survey content should reflect the company’s resources. While it may seem obvious, ensure that the survey questions address the activities and resources that are actually being provided by the MSLs. That does not mean that open-ended

questions should not probe which services the KOLs might like to see provided, but avoid asking about things that have nothing to do with the group’s current or proposed activities.

Perhaps the most important step in the process is securing senior management endorsement of the survey prior to its distribution. The survey should be reviewed by some or all of the internal stakeholders. Prior endorsement of the survey instrument by internal stakeholders will ensure their buy-in when the results are disseminated, and avoid issues of omission after the fact.

Finally, deliver the survey via an unbiased mode of delivery. Third party involvement in survey delivery, i.e., “ABC Research is conducting this survey on behalf of XYZ Pharmaceuticals,” may offer an additional point of unbiased credibility in the eyes of the KOL survey recipient.

## SURVEY DEVELOPMENT AND ROLL-OUT - A STEPWISE APPROACH

**Step1** - The essential first step in developing a survey is to verify the FBMP objectives (see Table 2). This allows for confirmation of the group’s mission and recognition of what the group wants to be recognized for, i.e., the value associated with the group’s activities. Once the objectives are outlined, they should be reviewed by other internal stakeholders to confirm the intended value of the group from the perspective of the rest of the business. The crafting of the survey will be based on the group’s confirmed objectives.

**Step 2** – The intended audience should be identified along with a projected sample size. Again, the MSLs may

TABLE 2 Steps in Survey Development and Roll-out	
➤	1. Verify FBMP objectives
➤	2. Identify audience to be polled and determine sample size
➤	3. Develop survey format and identify medium
➤	4. Consider incentive
➤	5. Create survey content. Parameters may include: <ul style="list-style-type: none"> <li>• Knowledge</li> <li>• Credibility</li> <li>• Services provided</li> <li>• Services/resources compared to other MSL programs</li> <li>• Accessibility</li> <li>• Relevance of data to KOL’s practice</li> <li>• Expectations</li> </ul>
➤	6. Review research design and survey content with senior management prior to distribution
➤	7. Administer the survey
➤	8. Evaluate results and establish baseline for future surveys
➤	9. Disseminate to internal stakeholders ultimately demonstrating “value”

assist in developing this list, or a random KOL list could be generated. With a random list, ensure that MSLs have actually called on those KOLs on the list.

**Step 3** - Develop the survey format and identify the appropriate medium. Determine the types of questions that will be asked, i.e., will they be open- or closed-ended, or a mix of the two, check boxes, or with rating scales? Will it be web-based or mailed, and what will be the content of the introductory letter?

**Step 4** - Consider offering an incentive to encourage KOLs to complete the survey. Incentive options might include a cash payment or a gift certificate. Whichever incentive you choose, it must also comply with pharmaceutical industry codes of practice.

Regarding the time and associated costs for the first four steps in the process, plan for a maximum of two weeks. The costs associated with this phase are zero, unless an incentive is included for the survey recipient.

**Step 5** - Creating the actual survey content takes the most time because this is where the types of questions and the kind of information to be captured by the survey are determined. To that end, there are a number of parameters to consider, and they include.

- A) Knowledge of the MSL - how well-versed is the MSL on the therapeutic area, products, and competition? Does the MSL present information with fair balance, and what is the MSL's overall knowledge skill set?
- B) Accessibility - is the KOL easy to see? Does the KOL see the MSL in a timely manner; and is the MSL spending adequate time with the KOL?
- C) Credibility - is the MSL honest? Does the MSL have a command of the information being presented? Does the MSL provide balanced information? Does the MSL understand the whole marketplace?
- D) Relevance of data to the KOL's

practice - To be effective, MSLs must have mini-medical marketing plans for each KOL. When the MSL is face-to-face with the customer, is the MSL able to customize that data and information to meet the specific needs and requirements of that KOL? To assess the MSL's capabilities, try asking about the relevance of the data presented by the MSL to the KOL's knowledge and practice.

- E) Services provided - capture more specific information about services such as the appropriateness of slides, funding for medical education or investigator-initiated clinical studies, speaking opportunities for the KOL, overall competitive intelligence, or the provision of medical meeting reports. Also, pursue feedback on additional services that the KOL would like to see provided.
- F) Expectations - What are the KOL's expectations, and are they in line with what is actually being provided by the MSL?
- G) Services/resources compared to other MSL programs.

One suggestion on the survey content is to group similar questions into sections to make it easier for the KOL to maneuver through the questionnaire. For example, one group of questions might relate to MSL conduct, another might refer to professionalism, and another group of questions might explicitly inquire about knowledge. This will allow the KOL to better organize their thoughts as they progress through the survey, rather than having them struggle through what might appear to be a haphazard laundry list.

**Step 6** - Review the research design and survey content with senior management prior to its distribution to KOLs. Again, the purpose of this is to foster early buy-in by internal stakeholders. For example, looking at the total pie chart of MSL activities and their respec-







A well-conducted survey can be a mechanism for fostering internal support and possibly expanding the team.

tive internal stakeholders, one might find that the MSL activities dedicated to managed care/managed markets is only 10 percent of their time. It is unlikely that the survey content would focus in this area since the results would probably highlight this as a deficient area. However, by liaising with the internal managed care stakeholder, it is possible to identify a way to construct questions that will help to increase MSL resources in that area. Alternatively, wait until a business case to increase resources can be presented to the key internal stakeholder before addressing the topic with external customers.

The time associated with step 5, creating the survey content, would be a minimum of two weeks. Internal review of the research design, step 6, will likely require at least an additional week, and depending on the feedback, may require some time to incorporate the input into the revised survey. Again, costs associated with steps 5 and 6 would be zero.

**Step 7** - The time associated with administering the survey will be longer than previous steps, and is estimated to be about three weeks. The rate limiting factor will be the mode of delivery; a mail survey will take longer than a web-based survey. Ultimately, a combination of both methods may be necessary. Costs will again be dependent on the materials involved in creating the survey, the mode of delivery, and whether follow-up surveys are sent to improve response rates.

**Step 8** - Once the survey deadline has passed, use the returned surveys to collate the results, evaluate the data, and establish a baseline for the group. This

TABLE 3 Feedback Implementation Strategies	
	• Reinforce and/or deliver advanced MSL training curriculum
	• Clearly define and differentiate MSL role from other company representatives
	• Realign territories
	• Develop new company materials to provide enhanced value
	• Increase MSL budgets for funding, proposals, etc.
	• Expand FBMP team

can then be used as a comparator for all future surveys.

**Step 9** – The goal of conducting the survey is to be able to disseminate the results and ultimately to demonstrate the value of the FBMP to internal stakeholders. Again, with the right results, it will be easier to translate external customer satisfaction with the program into a satisfied group of internal stakeholders.

Evaluating the survey results and

base and established the need to deliver advanced training or reinforce core learnings for the FBMP group. If the survey results showed confusion among KOLs around the role of MSLs, it might be necessary to employ a program to clarify that role and to demonstrate the commitment that group has to its KOLs, as well as its role as an effective medical resource for KOLs. If there is an issue with proximity or frequency of visits,

Prior endorsement of the survey instrument by internal stakeholders will ensure their buy-in when the results are disseminated, and avoid issues of omission after the fact.

establishing the baseline, as well as disseminating the results could take another three weeks. In total, all nine steps of the process would take an estimated three months for completion.

**FEEDBACK IMPLEMENTATION STRATEGIES**

Once the results are disseminated, the process is still not finished. Based on the feedback from the KOLs, new or additional strategies may need to be implemented with the program (see Table 3). The results might have identified one or more deficiencies in the MSL knowledge

with MSLs not seeing KOLs often enough, or MSLs spending too much time on a plane, consider a realignment of MSL territories. The need to develop new company materials to provide enhanced value may have been identified. This is probably one of the most important areas, as it represents a means to differentiate the company’s FBMP from the competition. It may be as simple as developing new slide kits for KOLs, or providing more literature searches. Whatever it is, think about it as a means to enhance the company’s FBMP. One result that may consistently

appear is the need for increased MSL budgets to support KOL programs. If additional funding is possible, a well-conducted survey can provide the justification for such increased funding. If additional funding is not feasible, the survey results may indicate the need for a consistent message that MSLs might use to more confidently address the issue with KOLs. And finally, showing that there is considerable value in the FBMP, but not enough MSLs to support the customer base, the FBMP director would have the data to champion this concept to senior management in support of additional head count.

**CONCLUSION**

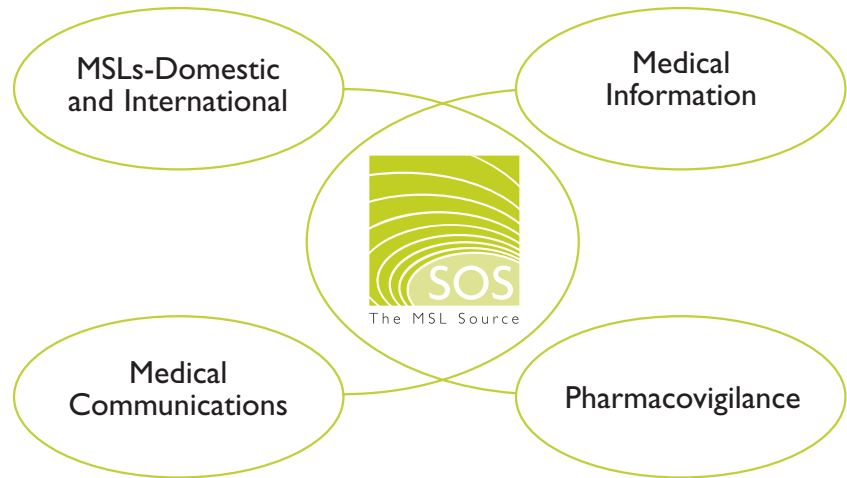
FBMP managers are often under pressure to show the value of the services provided by such teams. A well-constructed survey tool can provide the type of information internal stakeholders need to make financial decisions. When developing and implementing a survey to assess KOL perception of the value of a FBMP, the survey should be minimally time-invasive and easy to complete, it should be distributed to the right customers and convey a clear objective. The survey should be utilized to assess the value of the overall FBMP and not the value of an individual MSL. Survey content should encompass the specific activities and resources provided by the FBMP group, and senior management buy-in prior to survey distribution would be optimal. Administration by a third party such as a Contract Medical Organization, or via the web, lends credibility to the survey tool.

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## Company Description

SOS is a full-service, commercial-side medical affairs group, established in 1997 as the pharmaceutical industry's first Contract Medical Organization (CMO). SOS delivers comprehensive outsourcing of medical affairs activities, including global Medical Science Liaison (MSL) and medical communications services to pharmaceutical, biotechnology and medical device companies. We integrate these contracted medical affairs activities with our clients' core commercial and marketing objectives. The mission of SOS is to provide high-quality medical and professional affairs interaction to the medical community on behalf of our clients. We utilize the scientific knowledge and clinical experience of physicians, clinical pharmacists, nurses and other healthcare professionals to provide solutions for our clients.

## Markets Served

Pharmaceutical, Biopharmaceutical, Specialty and Medical Device

## Major Products

SOS is the preeminent provider of outsourced medical affairs services, and our contract global MSLs are widely viewed as the best in the business. We provide clients with flexible, turnkey MSL program support that leverages and accelerates each client's respective commercialization strategies. SOS allows you to tailor your MSL program to your corporate needs, from fully independent and traditionally outsourced programs, to programs that are integrated with existing internal MSL infrastructures. We pride ourselves on identifying and hiring the right kind of MSL candidate: a healthcare professional that possesses both clinical and business acumen that can seamlessly integrate into a company's culture. SOS is the premiere provider of turnkey MSL solutions. From recruitment and training of personnel, to the direct or indirect management of the program, we help you optimize your company's resources across all cycles of your products' development.

## Major Services

As a CMO, our only business focus is medical affairs outsourcing. Our core competencies include MSL services, medical communications, and drug safety support—critical activities normally associated with a commercial-side medical affairs department. This unique service model lets SOS provide clients with strategic, focused and flexible medical affairs solutions that best suit their immediate needs.





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