



# 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.

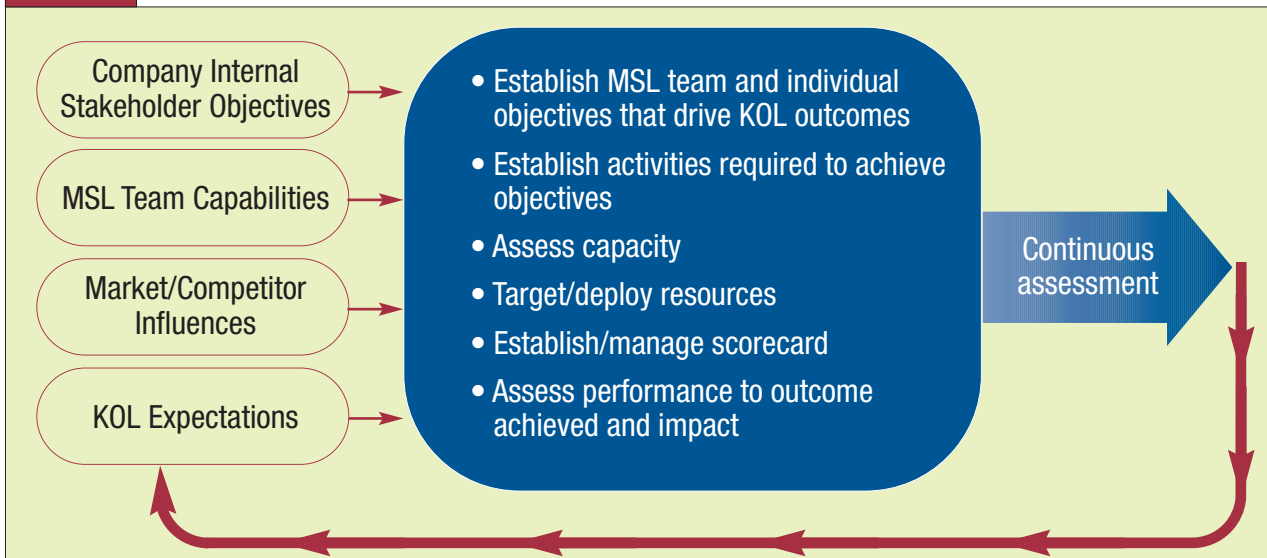
FBMP capabilities and lifecycle positioning frame the work on which the team will focus. Field-based Medical Science Liaisons (MSLs) have great success at gaining access to physicians that will not see a sales representative. The core activities of the FBMPs are geared towards achieving the “gold standard” 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.<sup>(1)</sup> 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.

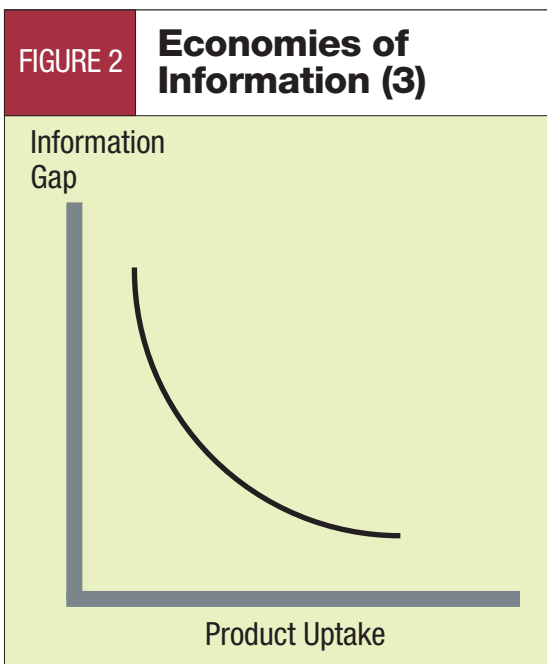
The presence of competitors/competitive brands introduces other factors that may impact FBMP planning. Assessing the scientific messaging of competitors may impact customer perspective regarding therapeutic issues. Understanding competitor activity is fundamental to maintaining an informed position with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

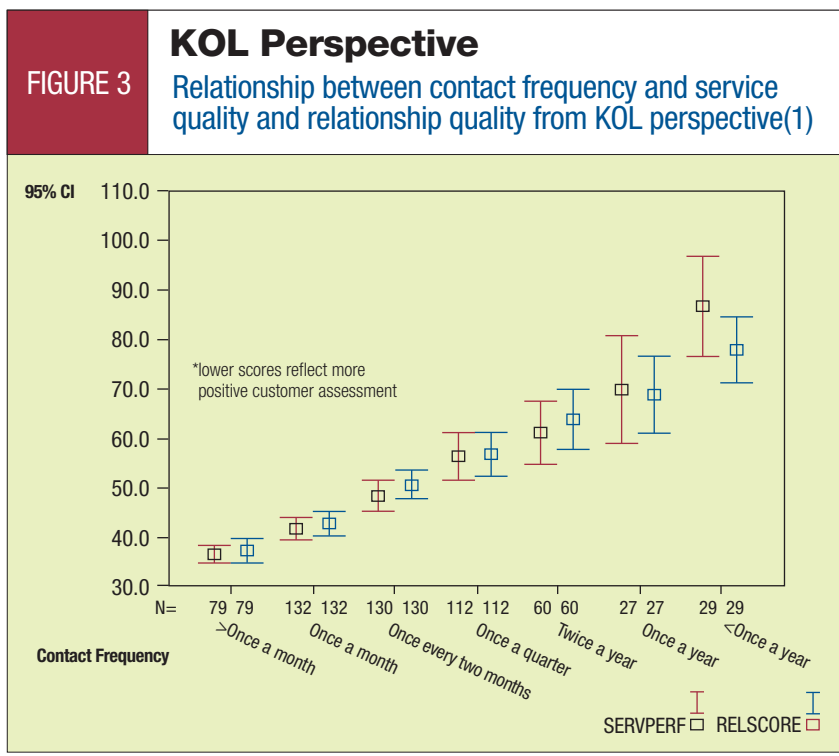




managed by more formal, rigorous review processes that minimize perceptions that such awards are issued to influence practitioner opinions. More objective assessments of “merit/quality” are being implemented. These practices minimize MSL involvement in shaping content of educational forums, as well as 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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