

The present and the future: Strategic partnering to support MSLs

Dr Shambhu Bimal Mandal, Subject Matter Expert¹, Dr Abhishek Arvind Kurne²

Head -Medical Marketing, Tata Consultancy Services (TCS), India

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Business trends and the need for MSLs

A study published in 2012 analyzed more than three dozen drug and device companies' Medical Science Liaison (MSL) operations around the world. The study revealed that the top 20 pharmaceutical organizations invest between \$10 million and \$48 million to deploy MSLs in the US, Europe and Asia.¹

Field-based Medical Specialist (FBMS) teams are expanding worldwide as part of the industry's increased focus on global operations, particularly emerging markets. The introduction of the MSL function in these geographies is often challenging, as they face different regulations, compliance guidelines and limitations. According to a recent benchmark study, at the top 10 pharmaceutical companies in the U.S., the role of MSL has grown by an average of 76% since 2005.²

The concept of field-based medical support programs actually originated in 1967 at the Upjohn Company. With increasing sophistication of pharmaceutical drugs, more knowledgeable people were required to ease the exchange of scientific information and build a rapport with Key Opinion Leaders (KOLs). Initially, the MSLs were selected from experienced sales representatives who had strong scientific backgrounds with the aim of improving the perception of the company with KOLs, researchers and investigators.

With time, the original Upjohn model has evolved and transitioned to field medical based teams. The credit for this transition goes to E. R. Squibb (subsequently Bristol Myers Squibb). In this model, the field-based medical liaison team entirely consisted of doctoral trained health-care providers who interacted with the health-care community on a peer-to-peer basis. As a result of this peer based interaction, the clinically trained field medical personnel enhanced the relationship to focus on advancing standards of care and optimizing patient outcome, not product sales.³

Roles and responsibilities of MSLs in a life sciences organization

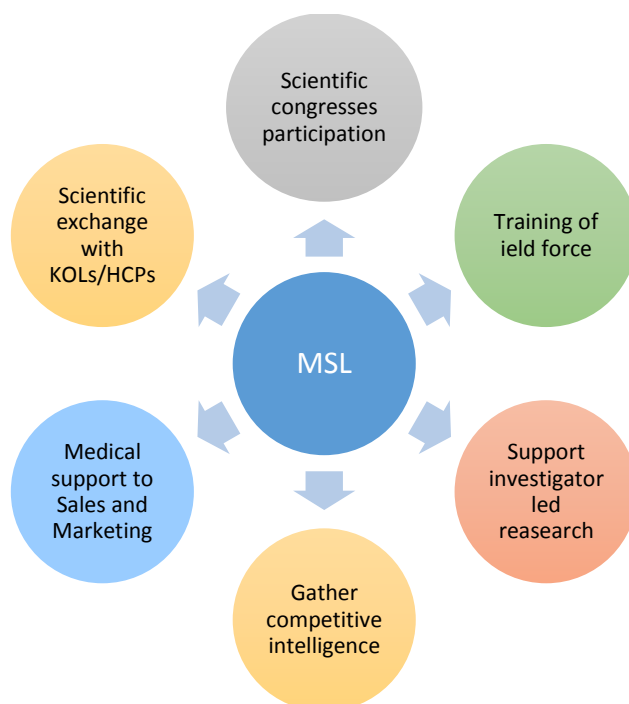
What is a MSL?

An MSL or FBMS is a healthcare professional who has a defined role within the life sciences industry, i.e. the pharmaceutical, biotechnology, medical device and the CROs. The MSL is a field based position whose objective is to cultivate collaborative relationships with the key opinion leaders (KOLs) and facilitate the communication and exchange of unbiased scientific information between the medical community and the organization. The major objective of the MSL is to establish professional relationships with the health-care community particularly KOLs and maintain peer to peer relationships with HCPs across hospitals, clinics and academic institutions.

The other key responsibilities of an MSL are:

- Medico-marketing support for product marketing and its implementation.
- Facilitate clinical research at the regional level by being the point of contact with clinical investigators, review and follow-up clinical activities.
- Support the Pharmacovigilance team by conducting training of doctors and field force.
- Prepare scientific presentations for internal and external meetings, gather competitive intelligence and provide input for product life cycle plans.
- Interact with regulatory and compliance agencies to ensure that all scientific activities and interactions are conducted within the regulatory guidance's.
- Attend medical conferences and also support advisory boards.
- Serve as scientific experts to internal colleagues at their organizations. ⁴

Core activities of an MSL



Key challenges pertaining to the role of MSLs

1. Training required for the MSLs

With the increasing number of fresh MSLs inducted every year, there is bound to be a talent crunch with these newly inducted MSLs as they are untrained manpower. The MSL needs to be provided training on the disease area, the therapy area that he needs to master, the products in his portfolio, and on the regulatory guidelines of the heavily regulated pharma market.

Also, continuous training of MSLs needs to be done on modules based on assessment for their growth into higher roles.

Understanding the roles and responsibilities of an MSL and how the training can be transferred to that role can prove to be an arduous task. There is always a knowledge gap between hiring a MSL and actively fulfilling the role of an MSL as every year fresh MSLs are inducted and they are not completely trained on the skill sets required to perform their day to day jobs.

It is therefore very important to identify which skills and knowledge can be applied to the role of a MSL and what other skills need to be developed through training.

Following set of questions can act as guide to design the training program:

- What do you want your MSLs to achieve?
- What is your MSLs expected performance?
- What is the level of information/knowledge needed for your MSLs to achieve your performance expectations?
- What skills do your MSLs apply on the field to achieve the performance objectives?

Secondly, the MSLs must clearly understand the objective of the training program. For example, the most important objective of the MSLs is to develop KOLs. What kind of training is required for the MSLs to achieve this objective to the best of their capability? To develop KOLs, the MSLs must be experts in their therapy area and only then will they be able to win the trust of the KOL or HCP.

For this, the MSLs needs to be trained on various topics others than the ones they are trained on during the onboarding process post hiring.

Training needs to be imparted on topics like the roles and responsibilities of an MSL, the SOPs involving Medical Affairs, the countries regulatory compliance involving the government drug policies, guidance's, responding to solicited/unsolicited on label /off label information queries, product licensing and so on.

The pharmaceutical industry is heavily regulated. The MSL must have a working understanding of the guidelines such as PhRMA, OIG, ACCME, HIPPA, Medicare and Internal legal and regulatory company guidelines.

2. KOL identification, selection and engagement during product lifecycle

The MSLs have an important role to play in product lifecycle management and to ensure that the products are utilized effectively.

The generic competitor products rapidly penetrate the market once the innovators drug patent expires because the life cycle of a pharmaceutical drug is very limited. A pharmaceutical company has to formulate a number of strategies to try to extend the life cycle of a drug, such as line extensions, reformulations, fixed dose combination products or switching to over-the-counter sales.

The MSLs obtain advice and feedback from KOLs about company products through peer-to-peer interactions and advisory boards at the regional level and provide it to the marketing and commercial teams. Important objective for an MSL is to identify KOLs and build relationships with them. KOLs are health-care practitioners who are considered experts in their respective fields for their speaking, publications, research, or influence. KOLs possess a unique reliability as their validity is often based on years of industry experience and medical affiliations. The MSLs need to develop and augment relationships with the KOLs within the health-care community and act as a medical junction for KOLs and external medical experts.

Decisions regarding the selection of KOLs as consultants should be made based on defined criteria such as:

- General medical expertise and reputation
- Knowledge and experience regarding a particular therapeutic area

The criteria for selecting consultants should be directly associated to the purpose and the persons responsible for selecting the consultants should have the necessary expertise to assess whether the particular healthcare professionals meet those criteria.⁵

Methods of identifying and selecting KOLs to suit the organizations strategy:

1. The Market

Firstly and most importantly, The MSLs need to consider the market. Are the MSLs trying to create a new market for their product or are they trying to enter an already established market?

MSLs should select KOLs in the new markets primarily based on their publication prolificness. New markets would not be citation rich, and therefore selecting KOLs who are supporting your product in acclaimed publications/journals would be very important. Publication count and journal impact factor are important metrics to help target KOLs in the new markets. Entering or expanding share in an established market is a more common activity for MSLs. Reaching out to the prestige leaders in the field would be an important activity for the MSLs. Prestige leaders are those who enjoy the esteem and respect of their peers.

2. KOL Alignment

The MSL should know how to align the KOLs based on the current stage of product lifecycle, stages of drug development, growth and market objectives. Based on this, The KOLs can be divided into two broad categories, the rising stars and the established leaders. In the pre-clinical drug development phase, the established KOLs would be able to help with their plethora of knowledge while the rising stars might be able to help with out of the box ideas.

At the late stage clinical trial phase, there might be a need to consider the engagement of established leaders and rising stars where the experienced leader can fulfil the role of a study chair

3. Engagement of KOLs

Once identification and selection of KOLs is done, the next activity is to engage these KOLs to build strategic lifetime relationships. The KOLs can be engaged for activities like participating and supporting advisory boards, participating in company sponsored research activities, delivering presentation/ speeches at scientific symposia's, developing scientific collaterals for publications, conducting CMEs for educating and training other HCPs.

The thought leader pool targeted by pharmaceutical companies is being redistributed largely due to recent regulations such as disclosing payments to HCPs. Thus, it becomes all the more important for MSLs to select KOLs and prioritize their time between meeting the important KOLs and the rest of the HCPs as it would not be possible for the MSL to meet, develop and engage all the HCPs. This could also be problematic as the MSL is not able to spend ample time visiting the HCPs who are not their KOLs. With decreasing access and decreased in-clinic time with HCPs and remote communications such as telephone and email discussions considered not ideal and less effective, MSLs need to find new creative ways to interact and communicate with HCPs.

3. HCP interaction and scientific content support

These days it has become increasingly important for HCPs to quickly access newly published clinical studies and data so their clinical assessments can evolve in real time. The HCPs put forth requests to the MSLs for various kind of scientific content. The most common requests are for clinical evidence, published clinical data, competitor information, updates on new data and off label discussions. The MSLs have thus become an important source for the HCPs to receive continuous updates about the recent updates and developments in their respective therapy areas.

The HCPs also require scientific content in the form of presentations to be used at scientific symposia's or CMEs for which the MSL prepare and provide the HCPs with relevant scientific presentations related to the therapy area or molecule. Thus it is important to recognize that MSLs are an important source of scientific content support for HCPs.

With the amount of time spent by the MSLs travelling on work, clinic appointments with HCPs and attending professional and scientific meetings, it becomes difficult for the MSLs to remain abreast with the

recent clinical developments as they are not able to devote ample time researching for scientific data to present to the HCPs. The paucity of time makes it all the more difficult for the MSL to devote enough time to prepare excellent scientific presentations required by the HCPs to present at a scientific congress.

4. Patient education, advocacy groups and MSL

As healthcare cost pressure continues to rise, patients and advocacy groups can be expected to play a greater and more important role in making healthcare decisions as they continuously seek medical information outside their HCPs' offices.

Thus, MSLs have the opportunity to obtain important insights into patients' needs and requirements through patient advocacy groups. The ability of MSLs to benefit from new platform such as social media will further equip the MSLs with new insights into the patients' point of view. Presentation of relevant scientific information by the MSLs to the patients and patient advocacy groups in a form they can easily understand becomes all the more necessary.

The MSLs must establish a deep understanding of patients' needs that envelops the patient insights from different healthcare stakeholders like HCPs and pharmacists. The MSLs must first identify medical influencers and then establish useful and innovative ways to interact and partner with them. This will require more engagement with patients and advocacy groups employing multiple channels, including social and digital media. The impact of social media and innovative data collection through social media will continue to expand as these become commonly used channels to hear the views of patients as well as the HCPs.

Cross functional collaboration with internal teams and synergizing with the medical affairs

Following are the most common functions which MSL collaborates with:

1. Sales and Marketing

The sales and marketing team are experts in business and the MSL can provide an invaluable clinical perspective to assist in the development of ethical and appropriate marketing plans. The MSL provide scientific support for assigned products; deliver scientific presentations; actively engage in relevant brand team meetings and helps to develop medical affairs strategies for assigned products. The MSLs also review and approve scientific promotional materials.

2. Medical Information Management

There is some overlap between the MSL and Medical Information functions and therefore strong interaction and communication between the two teams is a must. Both these functions provide input and feedback to the HCPs, patients, marketing and sales teams. Both the teams conduct literature searches and respond to queries with standard responses. Since the MSL is always on the move and he needs to keep up with the latest data and scientific information, his role becomes very challenging. Since the MSL travels extensively, he always has a scarcity of time and many times it gets difficult for the MSL to go through the queries from internal and external customers, conduct literature searches and prepare standard responses to these queries. Therefore the partnership of the MSL and Medical Information officer is important to ensure consistency and compliance in responding to the queries.

3. Medical communications and content writing

An MSL uses his medical writing skills in publications of local/regional clinical trials. The MSL also needs to assist the Medical Affairs team by providing quality scientific contents for clinical posters, abstracts, and presentation slides for internal and external meetings. Due to the MSLs hectic travel schedule and unavailability of time, he is unable to dedicate time for the search, collation and preparation of the scientific inputs.

4. Clinical research, Post Marketing studies and Pharmacovigilance support

In the field of Clinical Research, Post marketing Studies and Pharmacovigilance Support, the MSL:

- Facilitates investigator-initiated clinical research proposals from approval until completion, presentation, and publication.
- Visits clinical units and meets potential investigators and their teams so as to understand local issues that may promote or hinder success.
- Assists in the development, review and follow-up of clinical studies initiated within the relevant therapeutic area at the regional/local level.
- Leads local clinical projects to ensure that all clinical trials are conducted in compliance with the guidelines.⁶
- Assists in the development, review and follow-up of post marketing clinical activities such as registries, post marketing surveillance studies (phase IV) and epidemiological surveys at the regional/local level.
- Provides Pharmacovigilance support which includes training and medical assessment. The MSL supports the investigator by reviewing the reports of adverse events. He also help in dealing with customer enquiries on drug safety issues for assigned products.

MSL metrics, reports and insight mining

Measuring the metrics for MSLs will always involve a mix of quantitative and qualitative variables. One basic way to measure this is by tracking the number of MSL-KOL interactions and what came out of those interactions. All of this is very difficult to measure or track quantitatively. A quantitative variable may be the amount of face to face time an MSL spends with a HCP (i.e., 30 minutes every month). A qualitative measure might be the medical insights derived from those conversations, collected in a system that's easily accessible by other internal teams. Organizations can measure the value of MSLs by documenting their impact on the brand strategy execution.

The most common complaint that the MSLs have about the metrics system currently used is that it is quantitative rather than qualitative. The reason behind this is perhaps that quantitative metrics are generally much easier and faster to obtain and document, while the outcomes or qualitative measures are very hard to gather and take a good amount of time to gather.

Throughout the product life-cycle, key metrics from MSL activities may include outcome based measurements such as:

- scientific publications and qualitative survey for satisfaction indicators in thought leader interactions
- Company awareness and perception
- Quality/ timeliness/ completeness of disseminated information.

Clinical metrics may include percent of accepted clinical sites recommended by the MSLs.⁷

Qualitative metrics reporting

MSLs in most organizations are required to provide a weekly report based on their field activities and a comprehensive report at the end of the month. The comprehensive monthly report contains the details of all the activities done by the MSL such as, the number of KOLs or HCPs met in the entire month, the details of the interactions with HCPs and the medical insights received from them. The report also contains numbers and details of scientific presentations prepared, scientific articles provided to the HCP, medical queries responded by them, scientific sessions, conferences and symposia's attended specifics of discussions that took place at these scientific meetings.

Organizational value add through strategic partnering

1. MSL Training:

At present all MSLs are being trained by the Medical Affairs teams of the respective organizations. To reduce the burden of non-core activities from the Medical Affairs team, an organization can collaborate with partnering agencies which specialize in the training of MSLs. These agencies impart training to the MSLs either through live face to face sessions or through the electronic medium i.e via live webinars or audio-video (AV) modules.

2. Virtual MSL interactions with HCPs

Paucity of time and decreased access to KOLs due to schedule demands and overall availability have heightened the need for pharma companies to engage in alternative methods of communication between the MSLs and HCPs.

Biopharmaceutical companies have to recognize the value of implementing virtual communication technologies and use this technology with external stakeholders. These companies can partner with agencies where the agency will have MSLs based at remote locations and these remote based MSLs would have a virtual or web based interactive programs/discussions with the HCPs.

The MSLs can meet important KOLs face to face while interactions with rest of the HCPs can be through the virtual MSLs as the HCPs are comfortable using virtual technologies.

The pharma companies have to realize the value-added benefits including cost reductions, increased frequency of contact and ease in accommodating schedules with the virtual MSL model.

3. Scientific content support

MSLs now understand that to truly educate HCPs, supporting them with rich scientific content while they are researching new drugs is important to shift the HCPs on the product adoption curve. This is the point when HCPs are ready to engage with your brand. These can include internal presentations for their own department, presentations for HCPs and KOLs, and presentations at national meetings. But with the continuous travel and paucity of time this becomes a very tedious process.

The content partner can generate scientific inputs in the form of clinical posters for conferences, product monographs, product information to be uploaded into the digital and social media, scientific content for promotional inputs for the HCPs that would be used of marketing and sales team, training documents that will be used for training the sales and marketing teams as well as for training the MSLs and most importantly prepare presentations for the KOLs to be used at scientific symposia's.

4. Metrics and reporting

There are various reporting and analytics tools available for MSLs that serve as a platform to house all the information that has been entered/uploaded by the MSL. These tools act as a central repository and can be accessed by the MSLs and their managers whenever they want. This tool assembles real time metrics, dashboard outputs and prepares reports in a form that the managers can use to review MSL activity.

Life science companies can collaborate with a vendor that can generate and collate reports of MSLs based on geographies and therapy areas and generate report insights based on these reports.

5. Active online listening

Social and digital media has become very a critical source of information for the patients, patient advocacy groups, medical influencer, decision makers as well as the medical affairs team which also consist of the MSLs. The MSLs have to browse through the different social media channels to gain insights into the unfulfilled needs of the influencers, decision makers or patients which is an inconvenient task.

Tie up with active online listening experts to can help MSLs keep a track of medical influencers, decision makers and patient advocacy groups. They scan the virtual domain for any kind of query or discussion related to the product or therapy area and prepare reports based on active online listening and suggest the action that needs to be taken by the organization to fulfil the unmet needs of the concerned stakeholders. The agency can also prepare MSL specific territory based social media report. This in turn helps the organization build a rapport and relationship with the stakeholders and engage them proactively.

6. Medical Information support

MSL has to either search for literature and prepare a standard response to the query or forward the query to Medical Information Management (MIM) team. This takes a lot of coordination on the part of the MSL and is a time consuming process. This becomes even more critical if the MSL receives multiple queries form different KOLs. On top of that, the Medical information management team receives a lot of queries from various MSLs based out of various geographies which is a huge burden to keep track of and respond to.

To overcome this, MIM companies can be engaged and given the responsibility for responding to the queries put forth by the HCPs. For this, all the MSLs have to do is forward the query to the agency by uploading it onto a centralized system. The agency will prepare the standard response to the query by conducting the literature search based on evidence based medicine and abiding by the regulatory guidance's of that region. This standard response can be then sent to the concerned Medical affairs team or MSL for review and can then be sent to the HCP who sent the query. Such responses can be stored into the system and can be accessed by other MSLs and Medical affairs personnel if a similar query is received in the future.

MSL is a critical link between the medical product organization and its customers. Strategic partnerships with around MSL strategy can help to support business expansion and geographical coverage without losing the customer connect.

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