

Medical Science Liaisons:

A key to driving patient access to new therapies

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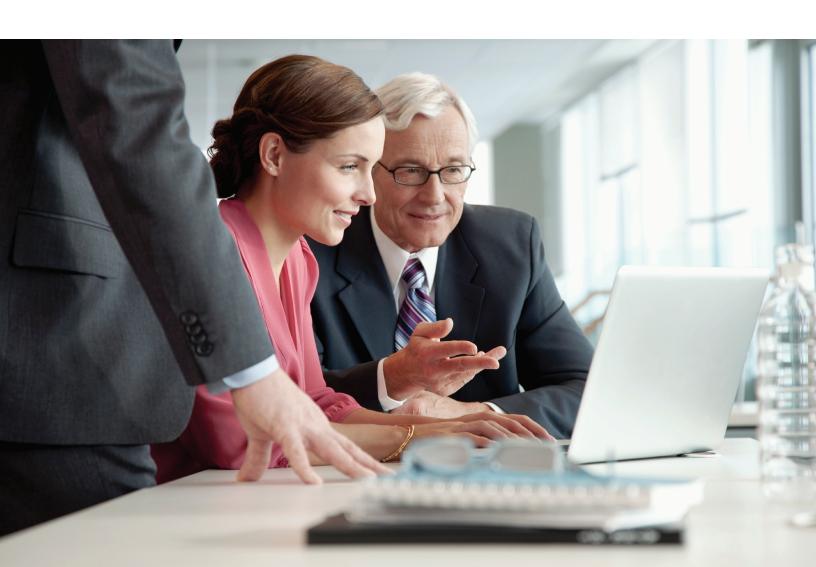


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Executive summary

Background: Factors behind the rise of MSLs in Europe and the U.S.

The growth in Medical Science Liaisons (MSLs) is being driven by the need to communicate increasingly complex scientific information associated with changing biopharma product portfolios and the development of personalized medicines with new modes of action, particularly for oncology and autoimmune disorders. As a key member of the Medical Affairs team – which acts as a scientific partner for healthcare stakeholders – MSLs provide a credible link to external stakeholders to act as a demand generator, helping bridge the communication between clinical development and commercial success. The key to productive MSL deployment is to ensure that the MSL team is engaging in legitimate medical projects and is able to execute these projects in a compliant way providing high quality support for all stakeholders.

Medical affairs teams must adapt to the complexity involved in building engagement across multiple stakeholders, whose demands are increasing. These include:

- Prescribers and healthcare providers requiring faster access to clear medical and scientific data to drive evidence-based decision-making and therapy choices, including knowledge of benefits – as well as risk of adverse events.
- Payer/health technology assessment (HTA) bodies demanding clinical trial evidence, health economic and outcomes research (HEOR) findings, comparative effectiveness research, and post-authorization, real-world and safety data to drive decision-making.
 This is resulting in the need for complex data analysis and the ability to interpret and communicate the associated medical and scientific outputs, ultimately generating higher hurdles for demonstrating product value.
- Regulatory authorities demanding adherence with all promotional codes of conduct and monitoring interactions between pharmaceutical companies and healthcare professionals to ensure transparency.
- **Patients** wanting empowerment in their healthcare and demanding access to medical information, participation in decision-making and choice of treatment options.

At the same time, there are increasing challenges in the form of:

- More specialized and complex product launches that are highly targeted, requiring education and translation of medical information into practical insights to support clinical decision-making.
- Wider healthcare professional engagement is often needed in addition to prescribing physicians, there may be a need to interact with pathologists and clinical geneticists regarding new biomarkers, for example.
- Restricted access to medicines, with austerity measures making it very challenging to convince stakeholders of a product's value, to enable patient access to expensive medicines.

Against this challenging backdrop, MSLs have a key role in demonstrating the value of customer-facing medical affairs support:

- **Engagement and insight:** Involvement of scientific opinion leaders in corporate medical activities.
- Positioning: MSL and external expert contribution to product strategy.
- Awareness and understanding: Reach of medical and scientific communication across
 the expert medical community.
- Patient access: Medical and scientific contribution to HTA process.
- Collaboration: Medical and scientific education for internal and external stakeholders.

What is an MSL?

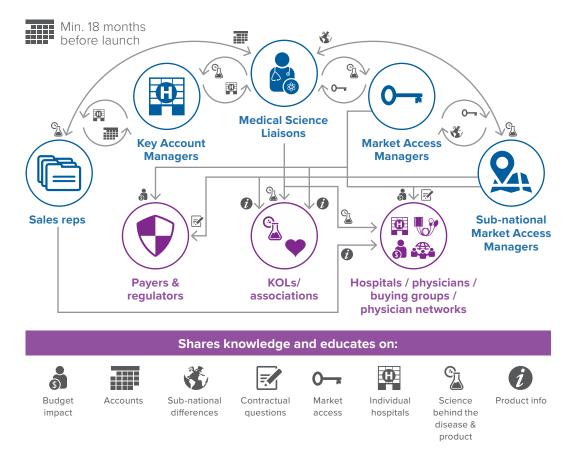
Medical Science Liaisons (MSLs) are therapeutic specialists with advanced scientific training. They are experts in communicating complex scientific and medical information to a variety of stakeholders. Their primary role is to build and foster strong relationships with key external experts in their shared therapeutic category. They provide a credible link to external stakeholders, helping bridge the communication between clinical development and commercial success. Additionally, MSLs are in a unique position to gather insights that inform business strategy in areas such as product development and market access. Demand for MSLs is strong and growing, globally driven by increasing stakeholder demands. As a result, deployment of MSLs has grown over recent years. In the U.S., almost all pharmaceutical companies deploy MSL teams and the number continues to rise across Europe (with over 50% having teams¹) as well as in the Asia Pacific region and Latin and South America.

In an environment that requires transparent and compliant communications, MSLs are positioned to generate and disseminate complex scientific information to both internal and external stakeholders. MSLs work throughout a product's lifecycle, acting as scientific communicators and resources within the medical community – as well as scientific experts to internal teams. In this way, they help patients gain access to appropriate medicines and help see that products are utilized effectively. Collaboration within the regulations and required Codes of Practice is key to success.



Medical Science Liaisons are in a unique position to gather insights that inform business strategy in areas such as product development and market access.

Figure 1: Helping to ensure information flow complies with local regulations



How MSLs differ from other team members

Important differences between MSLs and other members of the team include the following:

MSL:

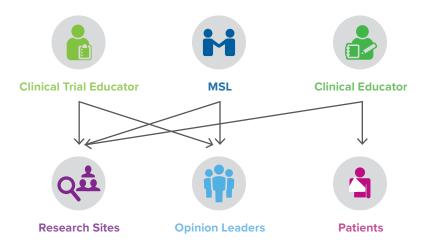
- Disseminates scientific data
- Delivers scientific presentations and education relating to the therapy area, mode of action and clinical evidence
- Develops medical plan and projects with Scientific Opinion Leaders (SOLs)
- Engages with external experts on the generation of scientific data, including investigator-initiated studies
- Scientific resource to internal stakeholders

Sales representative:

- Sells the product's benefits to encourage utilization of a brand.
- · Always limited to discussions within labeling.

Additional important roles closely linked to the MSL are beginning to be deployed globally and are best delivered through Medical Affairs (Figure 2). They do have distinct functions from MSLs but may have a shared professional background and will interact in the field.

Figure 2: Differentiation and interactions of Medical Affairs roles



Clinical Educator (CE):

- Provides comprehensive therapy education and/or product use training for healthcare professionals and patients.
- Assists providers and their staff to identify patients, improve service delivery and enhance patient adherence. This can help companies to overcome hurdles that may be slowing patient access and help meet the regulatory requirements of professional or patient education.

Clinical Trial Educator (CTE):

- Supports protocol and investigational product/device education to optimize appropriate subject accrual in clinical trials.
- Acts as a resource for educating referral networks to increase trial recruitment rates.

There is potential for CTEs to transition in a compliant way into MSL roles at the end of a clinical trial, thus retaining Key Opinion Leader (KOL) relationships and expertise with the product and therapeutic area – as well as connecting clinical and commercial best practices.

The MSL role throughout the product lifecycle

As part of a robust medical strategy that is aligned to broader business objectives, MSLs have a role at all stages of the product lifecycle:

- Early in development: Generating external expert interest in the science behind new molecules and their mode of action, and building awareness through tactical execution of medical strategy. MSLs may also have a role with the clinical development program through clinical trial site interactions.
- **Pre-launch:** Confirming that opinion leaders fully understand the science and drug; building awareness (through tactical execution of medical strategy); laying the foundation for market access and launch; and presenting data at scientific meetings. At this point, data gaps in the development program may be apparent and the implementation of the investigator-initiated study program may begin, with MSL involvement.
- **Launch:** Providing education on the clinical evidence and how to use the drug within clinical practice. The launch medical plan will be a key component of the overall commercial plan and support alignment of objectives, which supports the product's future commercial success.
- **Post-launch:** Answering prescriber questions will become an increasingly large part of the MSL role, along with continued medical education and implementation of publication- and investigator-initiated study plans. In many countries, the MSL role is reactive, responding to requests from KOLs to meet their educational needs. Another important MSL activity may be helping to determine the strategy and implement the operational plan for real-world data generation. This may involve assistance in establishing registries or more formal observational studies.

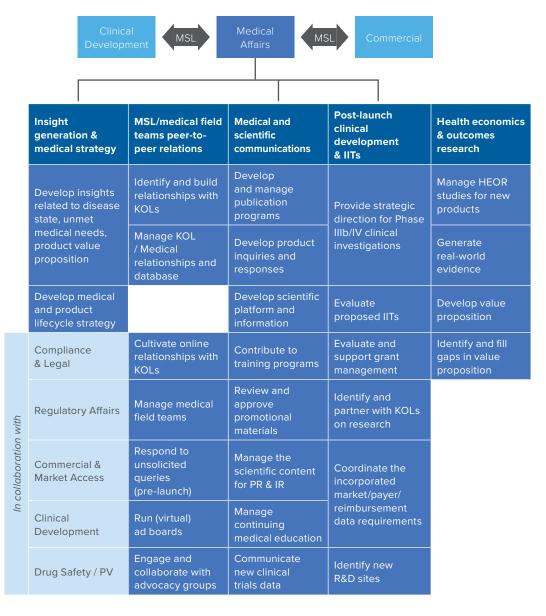
During all these phases, MSLs play an integral role in educating internal stakeholders to confirm they are up to date with latest clinical data; therapy and disease area knowledge; and aspects of the organization's medical strategy. The field medical affairs needs and skill-set varies throughout the compound lifecycle. Figure 3 illustrates these needs.



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Figure 3: MSL resources and teams to meet specific needs

Field-based Medical Affairs resources skill set



MA capability

Cross-functional collaboration

MSL deployment: Do's and don'ts

Due to a lack of global guidelines around the activities of an MSL, grey areas exist – some of which may lead to compliance concerns. MSLs must maintain a close collaborative relationship with the commercial organization. But there are some important considerations in ensuring appropriate separation between the commercial organization and Medical Affairs.

MSLs must never be seen to promote a product for off-label use – being part of Medical Affairs is not a protection!

What MSLs must do:

- Confirm that physicians report any adverse events, in line with local guidelines.
- Respond to medical information requests, according to the organizational policy.
- Avoid making commitments to investigators regarding funding.
- Respond appropriately to patient- or clinical trial protocol-specific questions.
- · Avoid answering off-label questions when participating in a promotional activity or event.

What MSLs can do:

In-field practices for an effective MSL – ensuring non-promotional, unbiased and broad scientific discussion with high credibility – are illustrated in *Figure 4*.

Figure 4: In-field practices for effective MSLs

Opinion leader engagement	 Involvement of experts in Medical Affairs projects Expert contribution to medical strategy Mapping of expertise
Scientific education	 Quality of scientific presentations and of responses to medical information needs Uptake of training opportunities
Data generation	 Quality and relevance of investigator-initiated research proposals Scientific support for company-sponsored research activities
Cross-functional team support	 Medical and scientific training for internal stakeholders Insight and contribution to development of medical strategy and tactical plan
Personal governance	Scientific knowledgeCompliance with regulations / Codes of Practice

Critical factors in deploying effective MSL teams

- Team design: Including an appropriate, compliant and results-driven reporting structure including clear project objectives, roles and accountabilities. The structure should also include methods for monitoring individual and team performance metrics and providing feedback.
- **Team profile:** Recruiting the right people based on a profile specific to the business and therapeutic area, with the goal of ensuring appropriate peer-to-peer interaction with KOLs. MSLs should possess excellent interpersonal and communication skills and also have a high level of scientific and business acumen. Typical qualifications for MSLs are seen in *Figure 5*.
- **Training:** A formal on-boarding program with a focus on live training, role-playing and prior at-home study of as much technical and scientific content as possible. Following initial training, consideration should be given to a program of MSL support to help ensure ongoing skills development.
- Medical Affairs resources: Tailored to the needs within the medical plan. It may be
 possible to repurpose existing clinical trial materials initially, but there is a need to
 refresh material with new clinical data.
- **Team management:** Based on principled project leadership and an effective communication system, designed to foster a unified team commitment and collaborative climate that results in superior performance.
- **Performance management:** Including clear and measurable individual and project metrics that can demonstrate value.
- Field-based Medical Affairs metrics: Field-based Medical Affairs (FBMA) metrics are
 required to demonstrate value in areas such as scientific engagement; generation and
 dissemination of data; and cross-functional team support. It is important to show return
 on investment for MSLs, but obviously the typical commercial success metrics including
 sales performance must not be used.

Figure 5: MSL qualifications²

Qualification	Global percentage
Pharm D	23%
Ph.D.	34%
MD/MBBS	11%
Master's degree	19%
Bachelor's degree	8%
Other degree	5%

Providing MSLs with tools to support effective engagement

Effective content tools are required to help MSLs drive clinical and scientific dialogue – these form the basis for effective engagement with healthcare professionals. The tools fall into four major categories.

The first is a **pre-deployment learning program** to support effective field interactions aligned to medical strategy. This program should provide comprehensive product and therapy area data that is accessible for ongoing reference. Such a program should use technology with a scenario-based solution that engages the learner and is easy to use, supports greater retention of information, and presents data in an appropriate and consistent manner.

The second is a **reference clinical compendium** which allows MSLs to access the latest data in an internal electronic format. Each section focuses on a key element of the critical data and may include clinical statements, copies of standard response letters, clinical data summaries and a list of regularly updated key references. This should be fully searchable and interactive, providing the references for approval of customer-facing material.

The third is a **master slide resource**, a slide kit for external use, supporting targeted discussions with external stakeholders during individual and group sessions. This may have a modular format, offering the flexibility to build custom presentations; illustrations and explanations of key scientific statements and supportive data; and a presentation builder as part of an electronic package.

The fourth is a **scientific engagement framework**, an internal tool which supports effective and tailored discussions with stakeholders.

A methodology and associated process for collecting insights gathered by the MSLs can help to guide future medical engagement activities and can be critical in informing future product strategy.

Advantages of partnering for Medical Affairs deployment

Biopharma companies can benefit from a partner's investment in MSL excellence programs, with access to high-quality, well-managed and scalable MSL teams as required.

Working with a partner on the deployment of Medical Affairs professionals offers several major advantages:

Strategic flexibility (over time)

- Deploy medical resources in a timely manner to meet specific needs.
- Manage the peaks and valleys associated with new product launches, competitive campaigns and impact of product patent expiry.
- · Focus on core portfolio and streamline resource allocation for launches and other major activities.
- Allow opportunities to consider ambitious and/or innovative strategies.
- Increase impact around product launch.
- Transition responsibilities from a clinical trial focus to KOL engagement/medical education prioritization.

Tactical flexibility (over execution)

- Deliver the precise level of resources based on the product lifecycle.
- Strengthen optimally skilled and trained Medical Affairs organization.
- · Adapt to changing market dynamics.
- · Support rapid decision-making and response to clinical (e.g. new data) or market (e.g. new competitor) developments.
- Provide Medical Affairs resources across geographies.

Compliance and risk management

• Support adherence to all legislation (Figure 1) and protect intellectual property. It is important that the different team members understand their roles and how they must operate in a collaborative way, with common objectives but appropriate separation.

CASE STUDY: DEPLOYMENT OF MSLs TO SUPPORT AN ONCOLOGY PRODUCT

Situation:

A U.S. biotechnology company wanted to develop an oncology presence and footprint in Europe. The company, with compounds in various phases of clinical research, focused on the development of personalized medicines coupled with companion diagnostics targeting specific sub-populations of cancer patients. To support its objectives, the company was looking to partner with an established outsourcing company that could provide a Medical Affairs infrastructure and resourcing across Europe.

Solution:

QuintilesIMS recruited and deployed a highly experienced oncology MSL team and International Medical Affairs Manager. Five MSLs were deployed across 12 countries: Germany, Austria, Switzerland, Spain, Portugal, France, the UK, Ireland, Norway, Denmark, Finland and Sweden.

Result:

The team focused on scientific and educational activities, providing valuable feedback to inform ongoing product development and commercialization strategies. The MSL team provided high-quality scientific engagement with healthcare professionals in key launch markets, making a valuable contribution to the HTA process. Previous team experience and QuintilesIMS's strategic clinical partnerships helped to gain access to key centers and external experts. The MSL team provided extensive feedback that was highly valued as strategic plans were evolving. Across all levels of the organization, the customer endorsed the excellence of the MSL team.

CASE STUDY: RAISING AWARENESS OF AN UNLICENSED INDICATION

Situation:

A European pharmaceutical company received positive data in an unlicensed indication, requiring additional scientific resources to address the interest from healthcare professionals prior to the granting of European Marketing Authorization.

Solution:

QuintilesIMS established a team of experienced MSLs and recent PhD graduates to deliver high quality scientific and medical education to the healthcare community. The team engaged with thought leaders, healthcare professionals and relevant decision makers in the scientific, provider and payer community in order to enhance product and disease knowledge.

The team:

- Developed and implemented strategic scientific communication plans in conjunction with the medical team
- · Engaged with healthcare professionals involved in the development of treatment protocols to make sure they had the most up-to-date and scientifically accurate data
- Identified and recruited regional participants for quality input and participation in therapeutic advisory boards and other medical projects
- Provided strategic insight to support planning for launch of the indication
- · Provided high-quality training for internal stakeholders

Result:

The customer's Medical Director expressed a high level of confidence in QuintilesIMS's understanding of the market and the company's ability to recruit, manage and develop high potential MSLs. His feedback was that the team did a great job and made remarkable progress towards the company objectives. He commended the collaborative approach of the QuintilesIMS team as they worked to execute the medical plan leading to the launch of the indication.

Why QuintilesIMS?

QuintilesIMS provides specialized Medical Affairs services to support our customers to gain and sustain optimal patient access to medicines and therapies. Since 2006, QuintilesIMS has been involved in more than 40 MSL projects and recruited in excess of 180 MSLs. This has included single country deployments, deployments across several countries within a region (e.g. to support EU launches) and within Latin America and Asia Pacific. These MSLs have worked across a wide variety of therapeutic areas including Oncology, Immunology, Respiratory, Inflammatory and Cardiovascular Disease, Psychiatry and Diabetes.

We offer a holistic approach to deploying the right Medical Affairs resources throughout the product lifecycle. Our commitment to operational excellence for our customers in all aspects of MSL deployment includes recruitment and training:

Recruitment of talented candidates

- Our extensive, global experience in recruiting MSLs means we understand how to attract the very best people.
- Our collaborative approach to staff selection is designed to help our customers identify candidates with the right skills.
- We work to understand your culture and values in order to find the right cultural fit for your organization.
- QuintilesIMS is seen as a great place to work, and that reputation attracts great staff.
- QuintilesIMS offers a rich internal network of professionals.
- QuintilesIMS, in collaboration with our customers, is able to offer continuity and career development.

Comprehensive training and development

- Access to the QuintilesIMS program of MSL training helps accelerate the impact of team deployment.
- Our comprehensive and scalable suite of training solutions supports development of specialized soft and technical skills for MSLs.
- We employ a collaborative approach to training and ongoing developmental support to continually improve your team.
- You will gain access to the QuintilesIMS Learning Management System to support ongoing learning and development.
- We are committed to a highly engaged, high-performing environment at QuintilesIMS to drive continued MSL growth and development.

Effective project management and leadership

- Strong oversight and governance infrastructure supports strict compliance to ethical, regulatory and quality standards.
- Collaborative development of quantitative and qualitative performance metrics mean that management is tailored to your unique business needs.
- Performance management and probationary structure are in place to drive performance improvement and promote compliant behavior.
- Resulting employee engagement and feedback on management effectiveness is significantly above IBM norms (and among the highest measures in QuintilesIMS).
- Independence of management is maintained between MSLs and the commercial group.

Figure 6: Why QuintilesIMS?

Differentiation to meet your medical needs



Conclusion

A well-implemented, scientific approach to medical advocacy benefits your entire business. With an important and increasing role in this area, MSLs can build engagement across multiple stakeholders – helping companies address constraints and challenges to gain and sustain optimal patient access to medicines – to bridge the gap between clinical development and commercial success.

References

- 1. Cutting Edge Information (September 2012). "Managing MSLs In A Global Medical Organization: Budget, Staffing And Compensation Benchmarks"
- 2. The Medical Science Liaison Society, The MSL KPI Disconnect: A Global Survey of MSL KPIs and Metrics. October 2015. Print. MSL Insights.

About the authors



Peter Rutherford, M.D., Ph.D. Vice President, Integrated Market Access, QuintilesIMS

Peter Rutherford is responsible for strategy and execution of Integrated Market Access and patient centric services within Europe and Emerging Markets for QuintilesIMS. Peter's background includes twenty-plus years of scientific experience gained from working across academia, industry, payers and providers. He is a highly experienced leader in the area of Medical Affairs and an established thought leader in relation to managing KOL relationships with regards to patient support programs. His broad geographic experience in leading Medical Affairs and Phase IV scientific communication has provided a deep understanding of the different stakeholder requirements, and the ability to collaborate effectively across the organization.

Most recently, Peter was Medical Director and EMEA Head of Medical Affairs for Baxter Healthcare, where he was responsible for Baxter's patient support services, leading physician relationships and advisory systems, investigator initiated research, Phase IV studies and medical communication and education. Prior to that he was with the North East Wales NHS Trust, where he was the Medical Director and responsible for patient pathway reorganization across the trust. He was also appointed to chair the NICE Guidelines Review Panel, a multi-disciplinary team tasked with reviewing evidence analysis, health economics and responding to stakeholders. Peter completed his medical training and Ph.D. at the University of Newcastle upon Tyne and Yale University School of Medicine. He is a Fellow and visiting Professor in Healthcare at Glyndwr University.



Nicola J. Smith Senior Director, Regional Head of Operations, Field Medical Affairs Projects, QuintilesIMS

Nicola is responsible for operational oversight of field Medical Affairs projects within Europe and Emerging Markets at QuintilesIMS. She has more than 20 years' experience in healthcare. After graduating from the University of St. Andrews, Nicola worked at a WHO-sponsored research unit at St. Vincent's Hospital, Sydney. She joined the pharmaceutical industry on return to the UK and has gained significant experience in operations and business development roles. Nicola became a member of the International Operations team at QuintilesIMS in 2010 with the responsibility for providing leadership on complex multi-country Medical Affairs projects for both biotech and pharma customers. She has been recognized on several occasions with accolades at major industry events.

