



MSL SOLUTIONS

The increasingly vital role of the medical science liaison (MSL) in rapidly evolving times

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About Two Labs

Two Labs provides expert, integrated services that eliminate barriers to product launch and provide strategies for continued market viability.



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THE EVOLVING LANDSCAPE FOR MEDICAL AFFAIRS AND MEDICAL SCIENCE (MSLS)

Medical Science Liaisons (MSLs) are vital to the success of every company. They provide physicians and other healthcare providers with the information and data necessary to ensure that medicines are utilized effectively and safely, they serve as scientific peers and resources within the medical community, and they serve as scientific experts to internal colleagues at companies. Currently, MSL virtual interactions are prominent and provide customer insights that serve as the basis for many critical business decisions. This will not change, however, the way in which it is done may look significantly different and will require keen awareness of changing customer needs, preferences or interaction, and the new types of technologies to meet these new demands.

As leaders of MSL teams, we will be tasked to efficiently navigate and effectively deliver on promises while pivoting quickly and decisively in the coming yet undefined times.

Additionally, our work will be measured increasingly by our ability to:

Help customers reach their newly defined measures of success



Understand and swiftly solve customer problems, while learning and refining processes on the fly



Anticipate and provide feasible solutions for disruptions to clinical trials, product development, and patient services



Innovate, with flexibility always top of mind, while customers seek to grow their business and realize opportunities in the 2021 "new normal"

2020 has significantly changed every aspect of our lives globally, and one way or another, 2021-22 is likely to be when the world transitions to the next "normal." Layer into the already complex world of healthcare, additional political and financial uncertainties and it's clear what lies ahead is likely a bumpy road. Until we can settle into new norms and ways of working, living, and innovating, we all must stay nimble and ready to pivot on a moment's notice.

How biopharma collaborates with customers, defines high-service culture, and delivers, will without a doubt be redefined as we move forward.

Despite the unknown, as executives take stock of what has happened over the last 12 months, optimism remains and is growing. In a December 2020 survey of global executives, respondents' expectations are increasingly positive; 61% feel that global economic conditions will be better six months from now, up from 51% in mid-October.

Will your medical affairs, and specifically your MSL teams, be ready for this surge in growth, optimism, and opportunity?



WHAT ARE WE LEARNING IN THESE COVID-19 TIMES?

COVID-19 has pushed companies to adopt and adapt to largely virtual work environments. Each organization has responded differently to meet the needs of their customers as well as to ensure the safety and health of their talent. There is not a “one size fits all” approach by any means. In addition, the role and strategic intent of medical affairs, specifically the MSL, enjoys increased appreciation and visibility. Healthcare providers and academic leaders want to hear about the science of new products and are less inclined to respond to “sales calls” focused on approved medication and “on label” features and benefits. Today, service-centric organizations must lead with their knowledge of current and emerging science as well as value based-medicine as our customers become more sensitized to (and demand more) value-based outcomes as a marker for increased reimbursement.

Pharmaceuticals and biotech, combined with new emerging technology, are revolutionizing how we treat patients. New and innovative products are entering the market at record speed, making the landscape more and more complex for both physicians and patients. Despite their novel innovations and nimbleness, these organizations will continue to face the real dilemmas regarding a well thought out and strategic “Go to Market” medical affairs plan that will steward them through launch but also the continuum of the product lifecycle.

Due to the impact and learnings based on the advent of COVID-19, organizations are rethinking their strategic approach and reevaluating assets including the traditionally large investment in sales teams. Sales force size, reach and frequency, type of role (i.e., Account manager vs. traditional sales representative, etc.) are all on the table. Other considerations include:

- Successful facilitation of clinical trial enrollment including strategies to ensure acquisition of patients in competitive markets
- Identifying and retaining both clinical and business savvy medical personnel
- Securing outsourcing partner(s) that are the right fit to assist in launch strategy and execution
- Acquiring experienced talent into a well-structured infrastructure to manage launch activities while meeting accelerated timelines and milestones
- Deploying the right strategies and tactics to communicate the “right science” into the “right minds and hands” of top key opinion leaders (TLs) to ensure brand success



DEFINING VALUE IN A NEW ERA

As the new era unravels, MSLs will need to be proficient in not only the clinical science but also become experts in health economics and outcomes research more than ever. Key insights from MSLs will be invaluable as new studies are designed to answer specific questions about outcomes posed by leading physicians. Real-world evidence must be fully integrated with the medical strategy, and the MSL has the key insights to lead the organization through this process.

Tomorrow's value definitions will be broader than they are today. Healthcare leaders in various institutions will be required to generate real-world data (RWD) and real-world evidence (RWE) to support decision making for patient care and population and business management. There is no doubt that RWD and RWE have the potential to improve and accelerate the development and delivery of safe and cost-effective innovative medicines to patients, as well as influence the way we approach health and healthcare. Regulators are increasingly interested in and providing guidance on when and how RWD/RWE may be considered for regulatory decision making. The role of consumerism, pharmacy, and therapeutics committees (P&T), and broad dissemination of scientific information will increase and influence adoption of drug brands (or not). Legal and financial scrutiny will continue to be newsworthy and the call for increased transparency will get louder.

The questions to answer will be...

“Do we need to have a separate group or dedicated individuals solely focus on economics? Specialists? Or liberal artists?”



Again, there is not a “one size fits all” approach to this question. It will depend on the organization, its culture, market, and many other factors that will drive decision making.

TRENDS DRIVING INTEREST IN OUTSOURCING MEDICAL AFFAIRS

Pharmaceutical companies of all sizes, including start-ups, and biotech face many of the same issues as they move a product closer to commercialization. Limited resources, high-risk development environments, and accelerated launch demands are just a few of the hurdles that exist. Even if hurdles are overcome and the product is approved, successful commercialization is not guaranteed.

As we move into a new post COVID-19 vaccine era, MSLs will need to continue to be flexible as customers decide how they want their teams to interact with those outside their organizations. The landscape will be diverse and everchanging for quite some time. The new MSL will need to be flexible, technologically savvy, resilient, and possess a high level of scientific and business acumen. They will need to be well trained and able to be effective communicators in a world where face-to-face interactions may be the exception and not the rule.

Based on these trends, outsourcing of scientific personnel in a highly competitive market may make sense. This model allows for matching of the needs to workforce size, level of expertise, ability to effectively support often chaotic launch timelines and infrastructure developed and in place for absorption into the full-time company ranks if needed.

WHAT QUESTIONS SHOULD BE ASKED WHEN CHOOSING OUTSOURCED MSL ORGANIZATION?

Outsourcing, or partially outsourcing, MSLs is a critical business decision requiring the answer to several important questions prior to moving forward.

- Where are you in the product life cycle?
- How large of an audience are you intending to reach? Is it a small specialty or are you looking to reach primary care physicians?
- Is the audience hospital based or community based?
- Is the product "first to the market" requiring extensive education?
 - If this is a new treatment paradigm, it is imperative to have a significant educational program in place?
- What level of expertise do you require? PharmD, MD, PhD?
- How quickly do you need to have a team in place?

Once you have made the decision to outsource, choosing the right partner - one who understands your unique needs and embodies service-centered practices - is critical.



WHY PARTNER WITH MSL SOLUTIONS?

We are an experienced team of healthcare and business leaders with more than 25 years of experience providing medical and clinical affairs services to customers. We know what good looks like because we are thoughtful and listen to what our customers need. Many on our team have walked in your shoes and understand the complexity and expectations around what you are trying to achieve. Only after we have had time to meet and listen to our customers, understand their unique situations, and market position and culture do we begin to discuss solutions and execution plans.

At MSL Solutions, we build time into the process to understand our client's specific and unique challenges in addition to what circumstances surround their brand that must be overcome to reach success.

MSL Solutions has the ability to recruit and embed the "right" MSL Leader(s) that culturally fits with your established internal medical team(s). With our years of experience and network, we conduct this work quickly and efficiently, finding the best talent to meet your unique scientific needs. MSL Solutions will be responsible for the sourcing and screening of potential talent based on agreed upon criteria and requirements. We recommend that the internal team play a significant role in the interviewing process to ensure a well-rounded assessment and consideration of talent. Activities that this leader may participate in or lead include:

- Medical strategy and tactical planning
- Clinical study and enrollment support/planning
- Content development
- Commercial support
- MSL management/leadership
- Copy review
- FDA package/information development
- Publications
- KOL interactions and overall KOL management plan
- Congress surveillance
- Customer insight
- Medical information
- Pharmacovigilance

During these pandemic times, the hiring process and building of MSL teams continues and, in some cases, has accelerated. We believe that the "old" process(es) for identifying scientific talent needs to pivot and evolve to include screening and assessment for competencies that assure KOL engagement in a pre- and post-vaccine normal. For some time, face-to-face interactions may be limited highlighting the need for team members to embrace and show competency in the ability to navigate in this new virtual world with confidence and participate and drive engaging scientific discussion. We identify talent with the following enhanced skills that include:

- Collectively, we enjoy years of pharmaceutical experience and scientific publications
- Many team members have walked in your shoes
- Possess and established network and proprietary process to recruit and retain top talent
- Seek to understand before we provide tailored solutions
- We see what the future and potential of medical affairs leaders and MSL teams to bring science to the customer and are ahead of the curve in how we will manage this transformation

The partnership of **Envision** and **Two Labs** to form **MSL Solutions**, has deep knowledge and expertise in medical affairs and a proven track record that is extremely valuable for our current and future customers. We prioritize a service-centered offering. This partnership aligns with our core strategy on many fronts and can help provide our mutual customers with greater insight and success of their endeavors.

ABOUT THE AUTHOR

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During my more than 20-year career in healthcare, I've realized that no matter how effective the drug, how skilled the surgeon, or how compassionate the care, without the patient's and their family's understanding and commitment, outcomes will suffer. In this new era of outcomes-based healthcare, new therapies are becoming more complex, specialized and data-driven. Demonstrating real-world evidence of a brand's therapeutic success is dependent on identifying the right patients and sustaining their long-term adherence. As clinical experts working on the frontline, Medical Affairs professionals and Medical Science Liaisons (MSLs) greatly contribute to facilitating these positive patient outcomes. To be successful, a strong, diverse, and innovative Medical Affairs and MSL teams need to be reflected in your strategy.



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We'd love to speak to you about how Two Labs can support your commercialization process to achieve your launch goals!

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