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A Critical Evaluation of Informed Consent in Clinical Research: Opportunities for Improvement

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Compliance Update: OIG Focus on Speaker Programs

The Emerging Need for Medical Affairs in Telemedicine

New Promotional Provisions Raise Questions in Hungary

Mentoring vs. Coaching for Field Medical

Is Your Product "Cost-Effective"?

The Journey Continues

Monthly Team Connection: Field Updates, Professional Development and Team Building in One Quick Tool

The Medical Plan: Demonstrating Stakeholder Influence With MSL Collected Real-World Clinical Insights

Scientific Share of Voice as KPI for Medical Activities – Key Success Factors

Is Artificial Intelligence (AI) The Key to Stronger Human Relationships for MSLs?

From Patient Care to Medical Science Liaison: One Physician Assistant's Journey

Promotability: How to Land Your Next Promotion

A Closer Look Into the MSL Career: Insights From MSLs Who Found Success in the Field

Best Practices: MSL and Commercial Partnership

The MSL as Agent of KOL Personalization

Accelerating Medical's Digital Awakening

Letter From the Editor

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Table of Contents

Letter From the Editor 1
Survey reveals salary levels for both Medical Science Liaisons and MSL management roles in the United States ... 2
The Journey Continues… 8
A Closer Look into the MSL Career: Insights from MSLs Who Found Success in the Field 10
Compliance Update: OIG Focus on Speaker Programs 16
Monthly Team Connection: Field Updates, Professional Development and Team Building in One Quick Tool 19
New Promotional Provisions Raise Questions in Hungary 23
Is Artificial Intelligence (AI) the Key to Stronger Human Relationships for MSLs? 27
MSLs in Latin America where the Pharmaceuticals Operations are Cluster MSLs 30
A Critical Evaluation of Informed Consent in Clinical Research: Opportunities for Improvement 31
Mentoring vs. Coaching for Field Medical 36
The Medical Plan: Demonstrating Stakeholder Influence with MSL collected Real-World Clinical Insights 39
How My Post-COVID Hobby Has Taught me About KOL Relationships 42
The Emerging Need for Medical Affairs in Telemedicine 44
Scientific Share of Voice as KPI for Medical Activities – Key Success Factors 47
3 Challenges Faced by Medical Affairs Teams and How to Overcome These Obstacles 49
Promotability: How to Land Your Next Promotion 52
From Patient Care to Medical Science Liaison: One Physician Assistant's Journey 54
The MSL as Agent of KOL Personalization 56
Accelerating Medical's Digital Awakening 60
Best Practices: MSL and Commercial Partnership 63
Is Your Product "Cost-Effective"? 64

Letter From the Editor

By karolina | March 2022

Dear MSL Journal Readers –

We are approaching Spring with new beginnings all around! While it may seem that the pandemic is beginning to abate, other worries replace this one; yet, our medical teams remain resilient, knowing patients are ever waiting for new treatments and better medical solutions.

This edition of The MSL Journal has a dearth of information to digest from multiple articles focusing on best practices, how to bring more value through field engagements and increased focus on gathering quality medical insights! I am incredibly impressed by how many fantastic articles we received to publish in this edition and thank our authors for their gracious investment in helping to develop medical affairs colleagues around the globe!

Medical Affairs has grown into its own strong sense of strategic value and more organizations are adding MSL teams as well as expanding teams, including creation of novel MSL roles and new Medical Affairs areas of focus! It is a hot market at present, with more open positions than people to fill them! This bodes well for those aspiring to enter their first MSL role! Stay focused on what you want to achieve, and you will do it! The 2021 MSL salary and compensation survey nods to the value of MSLs and MSL leadership with consistently top dollar salaries in these roles. Be sure to check out the full global survey results on the MSL Society website!

Technology, artificial intelligence, telemedicine and need for virtual engagement continue to be elevated in our content and I hope everyone will hone their tech savvy skills through these offerings! And, to round out this edition, the recent PhRMA Code updates are summarized to aid quick absorption of the key elements which went into effect January 1st.

MSLs are nimble, agile, flexible and adapt well to change; these capabilities fortify medical affairs colleagues in times of rapid change, as we all work to exceed expectations, find creative methods to define and demonstrate value while navigating a vastly different KOL landscape where hybrid meetings and virtual engagement have become the norm and KOLs have far less time to meet. It is incumbent on each of us to plan for success, prepare even better for each meeting and show up with a unique and memorable brand.

As we begin 2022, take stock of what you offer your internal and external stakeholders. It is my sincere wish that the culmination of all that each journal edition offers readers will impart wisdom, new ideas and positive energy as we lean into a new year and with hope that the world can find peace and strength in these times.

Wishing everyone good health and continued professional development,

Cherie Hyder

Editor:

Cherie Hyder, PharmD, MSL-BC

Cherie Hyder is Syndicated National MSL Director at Syneos Health. In her previous job at Biohaven Pharmaceuticals she supported a virtual launch of Nurtec ODT for acute migraine. She has been involved in drug development for more than 30 years, working at FDA in CDER and pharmaceutical companies including Pfizer, Lilly, Novartis, Solvay, and Avanir, among others. At University of Missouri, she received a Doctor of Pharmacy degree with the intention to devote her career to pharmaceutical research. She has multiple adjunct faculty appointments and enjoys teaching opportunities.

Survey reveals salary levels for both Medical Science Liaisons and MSL management roles in the United States

By Samuel Dyer, MD, PhD | March 2022

Introduction

Salary and compensation is clearly one of the most important factors in successfully recruiting and retaining the best MSL talent. It's crucial for companies to ensure the compensation they offer is competitive by benchmarking against others in their industry and region.

The MSL Society conducted the first-ever MSL salary survey in 2014. The 2021 survey includes 2,149 MSL professionals from 69

countries, making it the largest database of MSL salaries, and as a result, it is the most comprehensive and authoritative resource on global MSL salary and compensation levels.

Like previous years, the primary purpose of the survey was to gain insights into current global MSL salary and compensation levels across pharmaceutical, biotechnology, medical devices, and other healthcare companies that employ MSLs.

Individual country reports were created for all countries that received a sizeable number of responses. Based on the data gathered data, the 2021 Salary & Compensation Survey is available in 17 versions including the overall global results and 16 individual country reports: Australia, Brazil, Canada, Chile, Colombia, France, Germany, India, Italy, Mexico, Portugal, Russia, Spain, Turkey, U.K., and USA. However, this article will focus only on the U.S. results (all other reports and data is available on the MSL Society website).

Methods

The 2021 MSL Salary & Compensation online survey was open from August 24th to November 26th. The survey was only open to current MSLs (or equivalent title), MSL management, MSL operations, and executive management. Respondents were only allowed to participate one time and duplicate surveys from a single email address were not accepted. The survey results were not weighted. Partial responses that included salary data were included in this report as well, meaning that the N value in some tables will not add up to the total report N.

Respondents were invited to participate in the survey through a range of sources including:

- Announcements in the MSL Society LinkedIn group “Medical Science Liaison & Medical Affairs Networkers” as well as other LinkedIn groups
- The MSL Society newsletter
- Personal direct LinkedIn contacts

Results

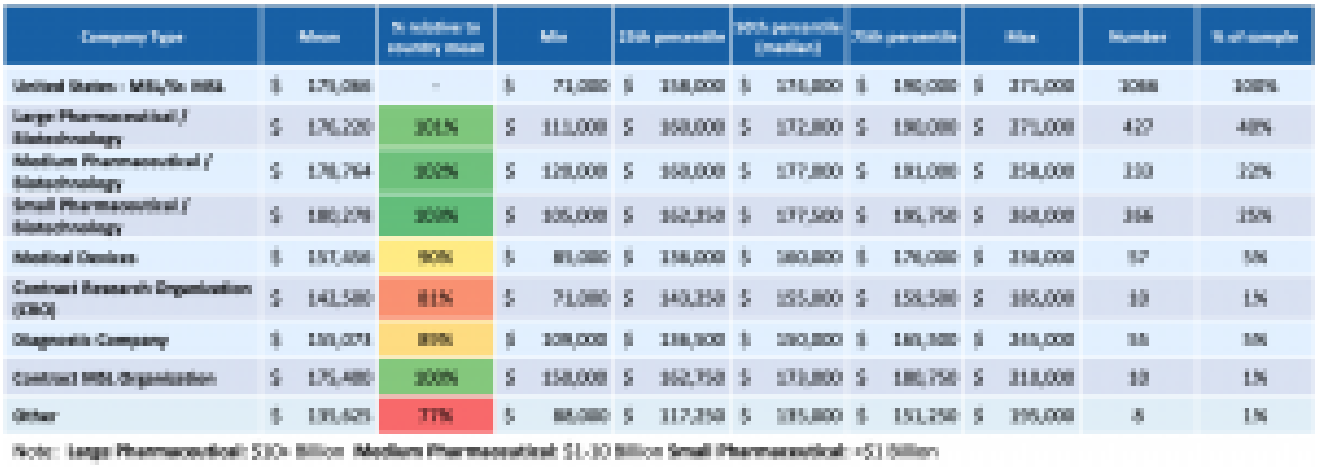
The U.S. data includes 1,355 current MSL professionals consisting of 1,066 Medical Science Liaisons (MSLs), 196 MSL Managers/Directors, 53 in Executive Management/Vice President of Medical Affairs, 16 in MSL Excellence/Operations, and 24 identifying as Others. When split by gender for all participants in the U.S., 41% of the respondents were male, 58% were female, and less than 1% identified themselves under the category “Other”. The U.S. data includes MSL professionals across all company types (i.e., pharmaceutical, biotechnology, clinical research organizations (CRO), diagnostic, and medical device) and educational backgrounds representing a wide range of years of experience. The salary calculations in each figure represent only base salary and do not include other compensation.

The survey also asked participants to identify their company type. Those in the pharmaceutical/biotechnology industry represented 85% of all U.S. participants in the survey, with 36%, 23%, 26% representing Large, Medium, and Small Pharmaceutical/Biotechnology companies respectively. Medical Device, CRO, Diagnostic companies, and “Other” comprised the remaining participants. However, it is expected that these company types will represent a much larger percentage in future studies due to the growth of the MSL role at these company types.

The type of company an MSL or MSL manager works for will be a contributing factor on their base salary and overall compensation. On average, MSLs can expect the highest salaries when working for a Large, Medium, or Small Pharmaceutical/Biotechnology company. For example, an MSL working at a Small Pharmaceutical/Biotechnology company can expect, on average, 15% higher salary than an MSL working at a Diagnostic company (see figure 1).

Figure 1

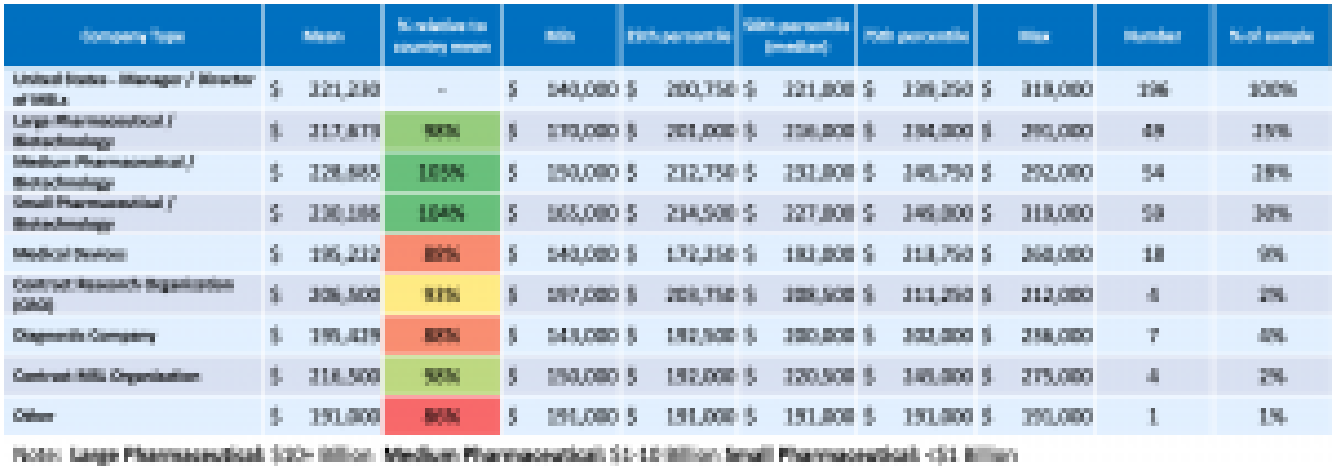
U.S. MSL/Sr. MSL Salary based on Company Type



Interestingly, Large, Medium, or Small Pharmaceutical/Biotechnology companies also pay higher salaries for MSL managers than other company types as well (see figure 2).

Figure 2

U.S. Manager/Director of MSLs Salary based on Company Type



As has been demonstrated in previous annual salary surveys, the years of experience has a substantial impact on the average base salary as well. While the overall average base salary for an MSL in the U.S. in 2021 is $175,066, there is a considerable range in salaries based on years of experience. For example a new MSL in the U.S. can expect, on average, a starting base salary of $157,482, while those with 11-15 years of experience can expect a base salary of $197,250 (see figure 3).

Figure 3

U.S. MSL/Sr. MSL Salary based on Years of Experience

Years of experience has a substantial impact on the average base salary for MSL managers as well. The overall average base salary for an MSL manager in the U.S. was $221,230 and in general as a manager gains more experience, they can expect increasingly larger base salaries (see figure 4).

Figure 4

U.S. Manager/Director of MSLs Salary based on Years of Experience

It's crucial for companies to ensure the compensation they offer is competitive and that their MSLs and managers are satisfied with their compensation to ensure retention. The survey revealed that the majority of both U.S. based MSLs (80%) and MSL managers (74%) are "Very Satisfied" or "Satisfied" with their pre-tax annual base salary (see figures 5 & 6).

Figure 5

U.S. MSLs: How satisfied are you with your pre-tax annual base salary?

Pre-tax Annual Base Salary	Percentage	Number
Very Satisfied	25%	255
Satisfied	55%	573
Dissatisfied	18%	183
Very Dissatisfied	2%	24

Figure 6

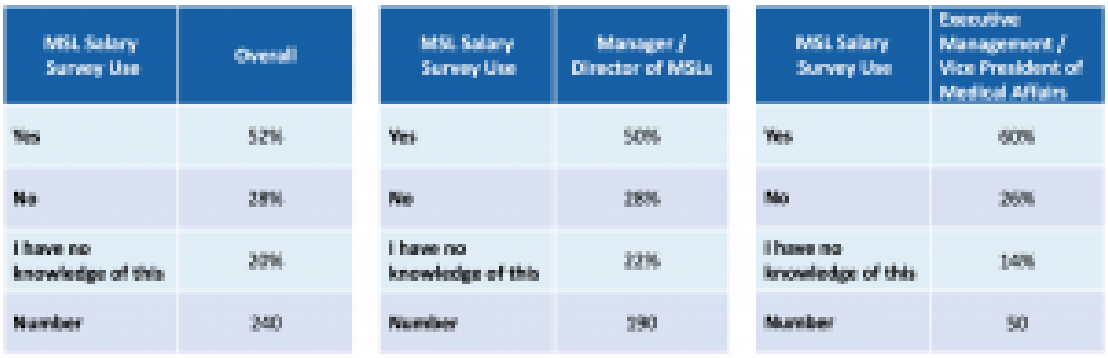
U.S. Manager/Director of MSLs: How satisfied are you with your pre-tax annual base salary?

Pre-tax Annual Base Salary	Percentage	Number
Very Satisfied	13%	26
Satisfied	61%	118
Dissatisfied	23%	45
Very Dissatisfied	3%	6

The importance of the annual survey conducted by the MSL Society is evident by the fact that 60% of U.S. based Executive Management/Vice President of Medical Affairs and 50% of U.S. based MSL Managers utilize the MSL Society's annual MSL Salary & Compensation Survey as part of their salary benchmark data (see figure 7).

Figure 7

U.S. Do you utilize the MSL Society's annual MSL Salary & Compensation Survey as part of your salary benchmark data?



MSL Salary Survey Use	Overall
Yes	52%
No	28%
I have no knowledge of this	20%
Number	240

MSL Salary Survey Use	Manager / Director of MSLs
Yes	50%
No	28%
I have no knowledge of this	22%
Number	190

MSL Salary Survey Use	Executive Management / Vice President of Medical Affairs
Yes	60%
No	26%
I have no knowledge of this	14%
Number	50

Conclusion

The results of the MSL Salary and Compensation Survey conducted by the MSL Society provide reliable insights into current MSL salary and compensation levels across pharmaceutical, biotechnology, medical devices, and other healthcare companies. Compensation for both MSLs and MSL managers are influenced by several factors including academic background (education), therapeutic area, years of experience, and company type. However, the factor that has the greatest impact on the base salary for MSLs and MSL managers is years of experience.

The 2021 survey conducted by the MSL Society is the largest and most robust database of MSL salaries in the world to date. As a result, it is the most comprehensive and reliable resource on both U.S. and global MSL salary and compensation levels. The use of this data each year assists MSL leaders, HR, and other decision makers make more informed decisions regarding salary and compensation levels.

References:

2021 MSL Salary and Compensation, USA Results, Medical Science Liaison Society, 2021.

Additional Resources

The full Global MSL Salary and Compensation Report and 16 individual country reports, which reveal details of these findings and other insights, are available for free for all members of the MSL Society under the resource section of the society website www.themsls.org.

Author:

Samuel Dyer, MD, PhD

Dr. Samuel Dyer is the CEO of the Medical Science Liaison Society and has over 25 years of international MSL experience. During his career, he has managed MSL teams and operations in over sixty countries across the United States, Canada, Europe, Africa, the Middle East, Australia, and New Zealand. He has facilitated the successful launch of pharmaceutical and medical device products for both Fortune 500 pharmaceutical companies and small biotechnology companies.

Dr. Dyer has coached, interviewed, and reviewed the CVs of countless aspiring MSLs. His insights and guidance have resulted in hundreds of aspiring MSLs successfully breaking into their first roles.

While leading the MSL Society, he has conducted MSL training programs for over 75 pharmaceutical, biotechnology, and medical device companies in more than 15 countries. Dr. Dyer has also written extensively on the Medical Science Liaison profession, including numerous published articles, benchmark studies, and reports. He has been the keynote speaker and moderated numerous international conferences on various MSL–related topics, including creating teams, management, MSL training, proper utilization of MSLs, global trends, and the KPIs and metrics used to measure MSL performance. Dr. Dyer has also served as a resource and consultant on several MSL–related projects for several organizations, including McKinsey & Company and Bain & Company.

Dr. Dyer has an MD from Washington University (Health & Science) School of Medicine, a PhD in Health Sciences from Touro University, a Master's degree in Tropical Biology (where he studied in the Amazon) from Southern Illinois University Edwardsville, and a Bachelor's degree in Biology from the University of the State of New York. Dr. Dyer also completed a certificate program for Executive Leadership and Strategy in Pharmaceuticals and Biotechnology at the Harvard Business School.

Dr. Dyer is the author of the multi-award-winning and Amazon #1 Best Seller, *The Medical Science Liaison Career Guide: How to Break into Your First Role* (https://amzn.to/4aoYcZp). The book is the first and only step-by-step guide on how to break into the MSL profession and it has received multiple prestigious awards, including:

- 2024 Winner of the American Legacy Book Awards in the Business: Careers category.
- 2024 "Gold Award" Winner – Literary Titan Book Awards in the Career category.
- 2023 "Best Book" Winner – Pinnacle Book Achievement Award in the Career Development category.

He is also the author of the *Medical Science Liaison Job Application Tracking & Interview Self-Evaluation Journal* (https://amzn.to/49n6MGR).

The Journey Continues…

By karolina | March 2022

Since embarking on my MSL career in 2019, I have chronicled much of my journey as an MSL in a variety of articles in this journal. As I reflected on my earlier writings, I realized that I have focused on what I have done but not what I plan to do. As I look with pride at what I have accomplished, I am excited about what I hope to accomplish in the future and how I plan to accomplish it.

I have strived to have a very methodical approach to my career. The onus is upon me to carve out a successful career that is personally and professionally satisfying. I feel each step that I have taken has prepared me for my current role. With careful planning, each step that I take will prepare me for the next phase of my career.

As much as I would like to take all the credit and say that my accomplishments have been achieved by my own wit and determination, I know that I would not be where I am without the honesty, encouragement, and support of those who see my potential and challenge me to continue to strive for more and achieve my goals. I also know that to attain the next step in my career I will continue to need guidance, truthfulness, and inspiration. One of my key advocates who is also an amazing mentor is Matthew John Rice, Global Learning Architect Director at MerckI. have learned a vast amount from his mentorship and friendship. With his guidance, I have sharpened my focus on what drives me and what is important to me. I have learned to course-correct myself when I start to veer off to a path that may hinder progress to my goals.

I started my MSL career at Alimera, a small pharmaceutical company, where I had the opportunity to work on a small, close-knit team led by Joan Hester, Senior Director of Medical Affairs. Joan, who is one of the key people in my career, continues to be a source of inspiration and sound advice even as I have moved to another opportunity. Working at a small pharmaceutical company afforded me the opportunity to gain broad experience in Medical Affairs from medical writing to training to interacting with leadership in addition to the typical functions of an MSL. Each opportunity trained my sights on what truly drives me as a professional. As much as I enjoyed the many experiences, I knew that to continue to grow I needed to find my next opportunity.

My journey in Medical Affairs continues with Regeneron where I have the good fortune to continue to work in the ophthalmology therapeutic area and be a part of a larger and more diverse team. With Regeneron, I not only learn from the different disciplines on my team, but I also learn from the years of varied experience among my colleagues. For me, the move to a larger pharmaceutical company means that the breadth of opportunity is different than that of a smaller company, but the depth of the opportunities is much more. I can refine those skills that will be key to my next career step by employing the vast resources available through a much larger Medical Affairs department. There is more opportunity to gain experience from others with similar interests and career objectives. I want to continue to understand the many facets of being a successful Medical Affairs professional and create a solid foundation for the next step in my career.

With patience and continued learning, I hope to pursue my next desired role in Medical Affairs. I have the career that I have because others have invested in me. I want to have the ability to invest in others and move into Medical Affairs training and development. I desire to be able to create, deliver, and facilitate role-specific and product training. Working with cross-functional partners to create learning opportunities and achieve objectives is exciting, thrilling, and daunting all at the same time. I know that when the right opportunity arrives I will be ready to fulfill the role with much zest, confidence, and knowledge.

To achieve the next step, I must not only continue to enhance my understanding of the Medical Affairs function, but I must continue to develop as a well-rounded professional. In addition to my mentors, I am working with Colleen Zimmerman, Certified Professional Coach, to develop my full potential. With Colleen’s coaching, I will focus on the possibilities, develop an action plan, and follow through to become the best candidate for my desired role.

I hope that in a future publication of this journal I will be writing to tell you how well I executed my plan, what I learned, what I would do differently, and how fulfilling my Medical Affairs Training role is. Until then, I plan to continue to learn as much as I can, maximize each opportunity given, and continue to draw on the wisdom and guidance of others.

Author:

Angela Valadez, PharmD, MBA

Angela Valadez is Senior Manager, Medical Affairs for Regeneron. Angela has a Doctor of Pharmacy degree from the University of Kansas and a Master of Business Administration from Baker University. With a passion for using evidence-based medicine to guide treatment decisions, Angela has worked with physicians throughout her pharmaceutical career to manage patient care and impact health outcomes. She was named a MSL Rookie of the Year Finalist in 2020 and was named MSL of the Year for Alimera Sciences in 2020.

A Closer Look into the MSL Career: Insights from MSLs Who Found Success in the Field

By Samuel Dyer, MD, PhD | March 2022

Breaking into the MSL role is a challenging yet fulfilling journey. As such, an MSL's unique place in the medical industry comes with a rich set of incomparable experiences and stories of personal growth. In this article, we look into the various insights of esteemed MSLs as they share with us their milestones, best practices, and challenges, and what career advice they would give for those in the MSL field.

1. What was your biggest challenge when trying to break into the MSL profession, and how did you overcome it?

Deepti Patel: My biggest challenge was building a network as physicians often do not invest in building a personalized brand and using networking platforms to connect. I initially focused my efforts on tailoring my LinkedIn profile to demonstrate that my skillset aligned with those necessary for the role. I joined Industry societies and groups, that organized or posted about courses and webinars, and through attending these I made meaningful connections with people in an authentic way.

Lille Tidwell, PhD: Establishing that my previous roles were directly related to a traditional MSL role. I had had job titles such as “Manager of Cell Science Education” or “Clinical Scientist” where I essentially did the same function as an MSL but some recruiters or companies wouldn’t see it that way initially.

Ruchit Parikh: Not having prior MSL/Industry experience. I interviewed for several MSL roles and received the same feedback, I did not have prior MSL/Industry experience for the position. So I asked hiring managers what I could do to obtain that experience and they advised me to start out by looking at Medical Information or Medical Communications roles within Biotech/Pharma. I was able to secure a Medical Communications Manager role where I created the materials that our field teams would use and this allowed me to interact with MSLs, understand the responsibilities, the tools they utilize, and how insights were reported back.

Daniel Kueh: Breaking the impostor syndrome. Developing confidence and natural intuition of the field and what the MSL profession is all about.

Rahul Bohra: Similar to how it is these days, the biggest challenge when I was trying to break in, was the lack of prior medical affairs (MA) experience. A big difference between then and now though was a dearth of guidance and resources specific to MA. There weren’t as many people working in medical affairs, and even fewer were open to providing guidance. Similarly, there were few open roles. The only, and valuable resource available to me, was Samuel’s book. Another major obstacle was the need for visa sponsorship. With these two blockers, I was not able to get much interest from the recruiters. My search from first knowing what medical affairs is and wanting to get in, to finally landing an offer, took almost two years. The major reason I was able to finally overcome the hurdles was my subject matter expertise matching the exact needs of the position that I had applied for. It took so long because the field of organ transplantation does not see much innovation compared to e.g. oncology.

Nabhan Islam: The biggest challenge for me was trying to secure callbacks from recruiters so I could even begin the interview process. I surmise this was because (1) I didn’t have any previous industry experience, and (2) my CV didn’t meet the expected industry standard. To address these issues, I joined the MSL Society, completed the live 3-day Communication & Presentation Skills Course for Aspiring MSLs, and attended the Annual Conference in Las Vegas, all in the same year. After completing these activities and reapplying with a much-revised CV, the number of callbacks increased dramatically and I was able to progress to the interview stage with multiple companies, eventually leading to my first MSL role.

Brian Berg: Understanding the terminology used in the field, and how to describe my skills/ experience in a way that would be familiar to and resonate with hiring managers. For me this was very important because I had experience working in industry as a pre-clinical scientist but never held the title of “Medical Science Liaison”. While I had developed many skills for KOL engagement through my work developing collaborative research projects, I didn’t have experience in medical affairs or formally being an MSL, but I knew this was a career path I wanted to pursue.

Kendra Pelz: My biggest challenge when trying to break into the MSL profession was getting a call back after applying. Since I have such a broad clinical background, I had to tailor my resume to meet the needs of the therapeutic area and highlight instances where I have been a conduit of information in that disease state. As a pharmacist, we have daily conversations with physicians, payers, and patients, so having a few stories that are transferable to the MSL role were invaluable to mention or include within my resume.

2. What resource in the MSL Society has been the most impactful in helping you break into the MSL Career and why?

Deepti Patel: I found the MSL guidelines resource helpful when I was researching what an MSL does, as it gave a great overview of the multi-faceted aspects of the role.

Lille Tidwell, PhD: The MSL Society Annual meeting. I had participated in a presentation skills workshop in 2015 where I met the MSLS leadership. I had access to the MSL salary survey as a member. I went to the annual meeting in 2019 where I met someone without any intention of outcome who was there just simply to attend the meeting. George was an experienced MSL in

the allergy space. I didn't have any experience in this field, but George was very willing to share with me his experience and the challenges faced in allergy. I sent him my resume, and within a month I received an invitation to interview and a job offer within 7 weeks of meeting George!

Ruchit Parikh: In addition to the book *How to Break into Your First Role* by Samuel Dyer, the webinars have been the most helpful.

Daniel Kueh: The workshop in Atlanta in 2016 on how to break into the role was immensely helpful. Listening and networking with MSLs and MSL directors helped address question #1

Rahul Bohra: Samuel's book, the online portal, salary surveys, and Samuel himself have been part of the journey thus far in Medical Affairs. Even today as a US medical director, I myself have referred to the step-by-step points of the process in the book as the base, on which I build the case for my candidacy. For my first MSL role, Samuel served as one of the experts to better describe the match between my credentials and requirements of the MSL job to the Department of Labor! I was one of the pilot participants in becoming a board-certified MSL (MSL-BC) by MSLS. I have been fortunate to mentor many aspiring MSLs to and in their first roles, and I always recommend the comprehensive resource that is the online portal and the book.

Nabhan Islam: The most impactful resource for me was the live 3-day Communication & Presentation Skills Course for Aspiring MSLs. As we all know, no one graduates from university with a degree in Medical Affairs. Completing the course provided multiple benefits that directly affected my applications and progression through the hiring process: (1) having an official MSL credential on my CV that was noticed by recruiters & hiring managers, (2) being able to correctly and articulately answer FAQs during the various interview stages, (3) learning to create a concise PowerPoint presentation for the in-person interview and present the data as an MSL, and (4) receiving direct and continuous feedback from Samuel and my fellow MSL Society colleagues to improve my CV.

Brian Berg: For me, it was attending the annual MSLS conference. This allowed me to more deeply understand the key skills required to be a successful MSL and how those skills are communicated and demonstrated. I updated my CV and was actually able to get the first position I applied for after attending the conference.

Kendra Pelz: Thank you to Samuel and the Society for the endless resources made for aspiring MSLs. I think the most impactful and tangible tool that the MSLS has provided is Samuel's book on how to break in. This was essential for my success in the aspiring stages. I used it as a training guide and blueprint to break in. I cannot recommend it enough to folks trying to land their first job or considering this career move.

3. What advice would you give to an aspiring MSL trying to break into the profession?

Deepti Patel: Don't be disheartened by rejections as this is an absolutely normal part of the process. Sometimes it isn't even about your capabilities. The manager may just have a very specific idea of the professional background/ experience that they want in an addition to their team. It is a tough role to break into, but perseverance and a genuine interest do pay off.

Lille Tidwell, PhD: Network, find a mentor, attend a workshop and the MSLS annual meeting!

Ruchit Parikh: Learn as much as you can about the role/ responsibilities either by connecting with MSLs on LinkedIn or meeting an MSL at an annual conference. Utilize the various resources provided by the MSL Society. Finally, don't give up, learn from each interview from each person you speak with, and keep trying.

Daniel Kueh: Learn from those who are already in the field. Network and build relationships. Think long-term and don't be so focused on getting their resumes out there.

Rahul Bohra: Have ambition, but be realistic and play to your strengths. For many, it does take time the first time around. Even if there is a minor inkling that there is something missing in your profile/personality, be it public speaking, interviewing or presentation skills, limitations in language/clarity of expression, etc. do not procrastinate. Start taking steps to address the shortcomings and audit yourself. While there are umpteen factors that decide which candidate gets the job, however, be accountable to yourself and analyze each missed opportunity to learn from it. Learn the karma principle, take ownership, but take care to be kind to yourself as well.

Nabhan Islam: I would recommend that you enroll in the MSL Society and (1) take advantage of all the offered resources (e.g., webinars), (2) complete either the live 3-day course or 12-hour eLearning course for Aspiring MSLs, and (3) attend the Annual Conference. This plan of action will provide a solid understanding of the MSL role, what to anticipate and how to prepare for each stage of the interview process, and opportunities to network and learn best practices from hiring managers and current MSLs.

Recruiters and hiring managers will notice the difference in caliber between you and other candidates who haven't made a similar effort, and that's how you get your foot in the door.

Brian Berg: Spend time reading about the role and understanding the skills needed to succeed. Evaluate your own skills, and where there are gaps seek out professional or on-the-job opportunities to help you develop/ refine those skills (which the MSLS has many resources for). Think about what is the most appealing aspect of being an MSL that drives you to become one, then as genuinely as possible convey that during your interviews. Also network, network, network! Connect with folks on LinkedIn currently in a role that you are very passionate about, then try to get a brief 30 min discussion with them. Learn about what they like about their job, what frustrates them, what do they think are the most important skills for that specific MSL role?

Kendra Pelz: The best advice I can give is to be prepared, take advantage of the call backs, and talk to other MSLs before these calls. I am so very thankful for my mentors who spent hours helping me prepare for the interviews. Listen to their advice, tell YOUR story, and follow directions.

4. What is your most significant achievement over the past year as an MSL?

Deepti Patel: I have only recently started as an MSL so I have to say it is becoming an MSL in the first place!

Lille Tidwell, PhD: This January I received an "exceeds expectations" performance review. For several years I had challenges in my position with a difficult employer, and it was rather frustrating as a professional. I felt like I would never succeed, and I even felt like I was being demeaned many times by certain employees. I am now with a company that values my contributions and sees my potential. I am part of the most fabulous MSL team and an amazing supervisor. We are truly a high-performing functioning team, and I am shining!

Ruchit Parikh: Having the opportunity to lead an advisory board specifically geared towards board-certified oncology pharmacists.

Daniel Kueh: Training new and existing MSLs on the disease state and associated investigational trials

Rahul Bohra: The past two years were quite interesting, and despite being an associate medical director, it came to be that I was a one-man medical team due to attrition and reorg. The national+regional MA and country responsibilities to global medical affairs lay with me. Many marketed products in multiple diseases and many pipeline products/diseases, working with all cross-functional colleagues on strategy and execution in a very challenging market for rare blood disorders. It was a tremendous growth opportunity, but very rigorous in nature, because missteps would mean patient lives being lost not only now, but in the future as well.

I grew up in the villages of northern India, where I witnessed my father (surgeon) serving rural communities tirelessly. I saw the difference he made, and the gratitude of the patients and their families. This has been my north star, and I am so very fortunate to have worked with a cross-functional team and leadership dedicated to the patients, such that despite the many difficult challenges, together we could actually realize "patients first". Without going into details, together we had a direct impact in saving many patient lives as well as their quality of lives, gained true partnerships and programs with experts and large institutions across the country, while working towards the long-term business goals, but always keeping the patients first.

Nabhan Islam: Over the last several months I've formulated the 2022 Medical Strategy Plan entirely from scratch in anticipation of approval & launch of our lead pipeline candidate in Canada, incorporating best practices from my previous MSL role and insights collected during 2021. This includes raising awareness and partnering with key stakeholders, conference attendance and sponsorship, Medical support for government & market access committees, creation and distribution of HCP educational materials, and procuring the Medical, Legal, & Regulatory approvals to support these activities. It's a lot of work, but it's very gratifying to create and implement a Medical Strategy Plan for an entire country that will result in our lead pipeline candidate being available to as many patients as possible.

Brian Berg: Leveraging several of my KOL relationships to bring several new clinical trial investigators on board, a couple of which will be their first time as clinical trial investigators. It's very rewarding to develop those KOLs to the point they can be recognized as true experts in an emerging area of medicine.

Kendra Pelz: I would say my most significant achievement over the past year as a MSL is the nomination for "Rookie of the Year". That entire process from reaching out for letters of support to answering the self-assessment questions was truly incredible. When I reflect on the application, it motivates me to continue to challenge myself, look for ways to improve, and make meaningful connections internally and externally.

5. What MSL Society member resource is the most valuable to you at the current point of your MSL career and why?

Deepti Patel: The recorded webinars and conference presentations are a really wonderful resource as you can access them at a time convenient for your busy schedule. Hearing from seasoned professionals discussing pertinent topics and giving advice on improving yourself as an MSL is invaluable.

Lille Tidwell, PhD: The Insight Gathering workshop

Ruchit Parikh: The webinars have been very valuable (when we went into lockdown) to understand how to effectively engage KOLs in a virtual environment. Also, the MSL Salary Survey has been very valuable to know where MSL salaries should be based on years of experience and therapeutic area.

Daniel Kueh: The educational resources and webinars by MSLs from other companies on best practices

Rahul Bohra: While I am no longer an MSL, the MSLS resources continue to be very useful, especially the meetings and the surveys. These tools give me access to the pulse of MA and where things are headed.

Nabhan Islam: Now that I'm about to start my 3rd year as an MSL, I'm still very much interested in professional development as well as extending myself to other avenues of Medical Affairs. To that end, I really look forward to each year's Annual Conference in Las Vegas. It's invaluable to hear and discuss what my colleagues are doing with their respective companies, what challenges and opportunities they've encountered, and what they see in the future for MSLs and Medical Affairs in general. I love the breadth of available workshops (although sometimes I wish I could be in two places at once) and especially the synergy that spontaneously develops as we bounce best practices off each other. The annual conference is also an amazing opportunity to network (it's where I met my current manager and national director), catch up with old friends, and blow off some steam, Vegas-style!

Brian Berg: Again, the MSLS Annual Conference continues to be the most valuable resource for me. I was able to gain so many great perspectives on the current and future state of the MSL role, gain very valuable career progression advice from recruiters, identify new technology applications for my company to consider, and was able to reconnect with one of my mentors from the mentoring program a couple years ago.

Kendra Pelz: The conference is essential for networking as a MSL. I learned so much, but found the most benefit from chatting with veterans and novice MSLs alike-So many fun people and so much to learn- especially as a new MSL.

About the author:

Samuel Dyer, MD, PhD

Dr. Samuel Dyer is the CEO of the Medical Science Liaison Society and has over 25 years of international MSL experience. During his career, he has managed MSL teams and operations in over sixty countries across the United States, Canada, Europe, Africa, the Middle East, Australia, and New Zealand. He has facilitated the successful launch of pharmaceutical and medical device products for both Fortune 500 pharmaceutical companies and small biotechnology companies.

Dr. Dyer has coached, interviewed, and reviewed the CVs of countless aspiring MSLs. His insights and guidance have resulted in hundreds of aspiring MSLs successfully breaking into their first roles.

While leading the MSL Society, he has conducted MSL training programs for over 75 pharmaceutical, biotechnology, and medical device companies in more than 15 countries. Dr. Dyer has also written extensively on the Medical Science Liaison profession, including numerous published articles, benchmark studies, and reports. He has been the keynote speaker and moderated numerous international conferences on various MSL–related topics, including creating teams, management, MSL training, proper utilization of MSLs, global trends, and the KPIs and metrics used to measure MSL performance. Dr. Dyer has also served as a resource and consultant on several MSL–related projects for several organizations, including McKinsey & Company and Bain & Company.

Dr. Dyer has an MD from Washington University (Health & Science) School of Medicine, a PhD in Health Sciences from Touro University, a Master's degree in Tropical Biology (where he studied in the Amazon) from Southern Illinois University Edwardsville, and a Bachelor's degree in Biology from the University of the State of New York. Dr. Dyer also completed a certificate program for Executive Leadership and Strategy in Pharmaceuticals and Biotechnology at the Harvard Business School.

Dr. Dyer is the author of the multi-award-winning and Amazon #1 Best Seller, *The Medical Science Liaison Career Guide: How to Break into Your First Role* (https://amzn.to/4aoYcZp). The book is the first and only step-by-step guide on how to break into the MSL profession and it has received multiple prestigious awards, including:

- 2024 Winner of the American Legacy Book Awards in the Business: Careers category.
- 2024 "Gold Award" Winner – Literary Titan Book Awards in the Career category.
- 2023 "Best Book" Winner – Pinnacle Book Achievement Award in the Career Development category.

He is also the author of the *Medical Science Liaison Job Application Tracking & Interview Self-Evaluation Journal* (https://amzn.to/49n6MGR).

Compliance Update: OIG Focus on Speaker Programs

By karolina | March 2022

Speaker programs undeniably represent the highest risk marketing practice in the industry, with a focus on paying HCPs who often prescribe a product to promote products to other clinicians. The US OIG (Office of Inspector General) has increased scrutiny of speaker programs in the recent few years, culminating in an SFA (Special Fraud Alert) released in November 2021, as well as prompting PhRMA (Pharmaceutical Research and Manufacturers of America) to update the PhRMA Code in August 2021 with an effective date of Jan 1, 2022. As we consider the impact of changes to speaker programs in the US, it's useful to consider the OIG's role which is their responsibility to ensure the fiscal integrity of federal healthcare programs such as Medicare and Medicaid. The OIG has the authority to exclude entities and people from participation in federal healthcare programs. Their exclusion authority serves as powerful leverage to impose significant compliance program requirements through CIAs (corporate integrity agreements).

In understanding the recent OIG sanctions, the SFA represents a means of notifying the industry that they are aware of certain abusive practices that they plan to pursue and prosecute and/or to bring civil and administrative actions, as appropriate. The OIG SFA focused on speaker programs identified a series of concerns from cases that the US DOJ (Department of Justice) has already prosecuted. The OIG views speaker programs that drug and device companies organize and pay for as having the intent to induce HCPs to prescribe or order products and is thereby highly critical of such programs. Their legal concerns stem from breaching the AKS (Anti-Kickback Statute) and at some times, the potential for violating the FCA (False Claims Act) based on past cases.

Speaker programs involve an HCP presentation to clinician attendees about a drug, device or product, or disease state on behalf of a company; HCP speakers receive compensation from the company, and HCP attendees often receive remuneration in the form of free meals, beverages, and other perks. OIG has made it clear that this type of arrangement, if not executed compliantly, implicates the AKS. The AKS defines remuneration broadly and can include anything of value where the offer, payment of receipt of items can be direct or indirect, overt or covert, and in cash or in kind. Information published by OIG notes that they do not seek to discourage meaningful HCP training and education. It appears their focus is on reining in speaker programs that are lavish or go beyond compliance boundaries. All parties involved in speaker programs including companies, speakers, and attendees will likely be subject to increased scrutiny going forward.

The updated PhRMA Code has taken effect on Jan 1, 2022, inspired by recent government enforcement activity and guidance on industry speaker programs. The PhRMA Code recognizes that company-sponsored speaker programs provide important substantive educational information about the benefits, risks, and appropriate uses of company medicines and diseases. They pivot from a position where speaker programs should present substantive education designed to address a bona fide educational need among attendees, considering recent updates for relevant scientific and medical information. Attendees of these programs must have a real need for the educational content provided at speaker programs.

Meals at speaker programs must be incidental to the educational information provided; this is to say that the education is center stage and the meal should not overtake the attendees' attention or focus. Incidental meals are provided at speaker programs as a business courtesy and must be modest in venue and food/beverage provided as judged by local standards. The venue or meal cannot be extravagant, the main attraction, or be perceived as such.

The updated PhRMA Code clarifies attendance at speaker programs, stating that repeat attendance at a speaker program on the same or substantially the same topic where a meal is provided to the attendee is generally not appropriate unless the attendee can be shown to have a bona fide need for the education presented. This is a tough hurdle to overcome if one would concede that the attendee had been educated in the initial speaker program of the same or substantially the same content. Companies will need to institute a system when HCPs register for a speaker program to avoid repeat attendees. The Code also notes that attendance at programs by a speaker as an attendee is not appropriate. Not surprising is the finding that spouses, family, friends, and other guests of a clinician attending a program are not appropriate unless they are HCPs for whom the educational information is appropriate.

Items that violate the AKS include:

- Little or no substantive information actually presented
- Alcohol is available (not viewed as allowing for an educational interaction; may be viewed as entertainment)
- Attendee meal exceeds modest value (concern is heightened by free alcohol)
- Program venue is not conducive to exchange of educational information (noise levels, entertainment, distractions, et al)
- Company sponsors a large number of programs on the same or substantially same topic, especially when there has been no recent change in relevant information
- Company commercial team influence speaker selection with a focus on past or anticipated revenue from prescriptions; use of a ROI analysis to identify participants

- Paying speakers above FMV (fair market value) or payment to speakers based on past or potential business they generate
- No new medical or scientific information; repeat HCP attendees to same or substantially same program or as a speaker attendee
- Attendees with no legitimate business reason to attend a speaker program; includes attendees who are medical professionals at speaker's own practice, staff of facilities where speaker is the medical director and individuals with no use for the educational information

The OIG has put companies and HCPs on notice regarding their concerns about speaker programs and they also lay out a framework for compliance for these types of programs. It is vital to assure compliance when planning programs in order to execute them properly and mitigate risks.

MSLs perform an essential role at speaker programs to assure speakers are trained and fully prepared to present on a company's product and disease state education. MSL activities at speaker programs, if permitted to attend per the company policies, must be independent of substantive commercial influence. The MSL role is focused on educating speakers and is not promotional in nature. MSLs may attend occasional speaker programs if company supports this; MSL attendance may attract off label requests and MSLs must exercise caution in this situation and follow their policy and procedures. There are times when MSLs may be allowed to present at a promotional speaker program in lieu of an HCP speaker. In these instances, with company leadership and legal approval and processes in place, MSLs would have to adhere to promotional standards at the event with no off label information and staying within the bounds of approved content in the presentation.

Some recommendations for MSL role in speaker training based on the OIG concerns about speaker programs:

- Define and establish clear guidelines as to how the MSL should provide speaker training support
- Document MSL speaker training and questions addressed with HCP
- Document off label requests and how the request was delivered
- Define and establish how MSLs should address off label questions
- Define and establish how MSL speaker training role is communicated to speakers

Some potential shifts may be on the horizon! Perhaps we will see fewer speaker programs, less speakers, less speaker training needs for MSLs. We may also see fewer HCPs agreeing to attend speaker programs, particularly live programs with a meal involved. Will alcohol be taken off the table for medical meetings or other HCP engagement beyond speaker programs if it is deemed not appropriate to facilitate HCP education? HCP consulting arrangements will undoubtedly be impacted as companies revisit FMV rates. Review of speakers who happen to be high prescribers may also identify risk. Perhaps there will be more demand for MSL or medical programs in light of the scrutiny on commercial speaker programs. There seems to be an emphasis on leading more virtual programs where no meal is involved to avoid this perception of remuneration. Commercial speaker programs may fade away as enforcement cases are elevated.

Company speaker programs provide important substantive educational information about the benefits, risks and appropriate uses of new medicines and updated information about disease states. PhRMA and FDA both support this effort and the need for HCP education. PhRMA also made updates to other sections of the Code pertaining to meals offered by company personnel during informational presentations, HCP consulting arrangements and company support for third party educational or professional meetings. OIG encourages companies to assess the need for speaker programs and consider the risks associated with paying remuneration, particularly since there are alternative means for conveying the information. HCPs and speakers are similarly encouraged to consider the risks of receiving remuneration for speaking and attending such events.

Stay tuned for more compliance updates!

Author:

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Cherie Hyder is Syndicated National MSL Director at Syneos Health. In her previous job at Biohaven Pharmaceuticals she supported a virtual launch of Nurtec ODT for acute migraine. She has been involved in drug development for more than 30 years, working at FDA in CDER and pharmaceutical companies including Pfizer, Lilly, Novartis, Solvay, and Avanir, among others. At University of Missouri, she received a Doctor of Pharmacy degree with the intention to devote her career to pharmaceutical research. She has multiple adjunct faculty appointments and enjoys teaching opportunities.

Monthly Team Connection: Field Updates, Professional Development and Team Building in One Quick Tool

By karolina | March 2022

Information sharing across an MSL team is vital to a team's success. However, communication barriers often inhibit field teams from sharing pertinent information in a format that is easily internalized by all team members. Traditional team communication barriers include a remote environment, large team size, prioritization of topics, and constantly changing medical strategy. The COVID-19 pandemic has accentuated communication challenges with added virtual barriers including "Zoom fatigue", computer distractions, and densely packed meeting schedules. Additionally, personality barriers influence effective communication as there are different ways individual MSLs learn and retain information, with multiple learning styles representation across a team. Therefore, the traditional Zoom meeting may not be ideal for information internalization for all team members due to the style and speed of delivered content. A format for readily and easily referenced information is warranted, highlighting key points to keep the MSL team on top of medical messages, best practices, and other important materials.

Our own practices have proven that an MSL team newsletter is a highly effective way to share information across a team. The newsletter allows sharing of key medical initiatives, with an added bonus of personal and professional development and team building. An effective format keeps all the content short, 1-2 pages are maximum, direct, similar to a resume, and is most effective when delivered on a time frame relevant to changing topics, such as monthly. The content should be visually easy to navigate, aesthetically pleasing, and displayed based on the most to least impactful topics (Figure 1). Hyperlinks embedded within the newsletter allow easy access to more detailed materials. Finally, the newsletter can be emailed to the team and stored in an accessible team portal to allow quick referencing.

When designing content, sections should be customized based on what the team finds most relevant and helpful, which allows personalization to the individual team's needs. There are three important themes included in the newsletter that can add value: medical strategy/field activity, professional development, and personal development/team building.

Figure 1. Sample Layout for Newsletter. Programs such as MS Publisher allow for easy manipulation of layout month to month to accommodate different sections. Blocks and headings make content easy to scan and navigate. A coordinated color scheme helps bring everythingtogether to make it reader friendlyand inviting. Remember to lead with the most important content.

- Medical Strategy/Field Activity
- A "**best practices**" section allows sharing of tips across an MSL team, or even from MSLs outside of the immediate team. It explains how best to handle typical processes, events, and planning. Examples include best practices for "getting follow-up meetings", "travel", or "territory management".
- A "**success story**" (or "non-success story") section allows for sharing of individual MSL stories to help other team members think outside of the box and learn new perspectives that worked or didn't work for certain situations. This information can also provide feedback or support for teammates.
- A "**powerful questions**" section provides two to three open-ended questions relevant to hot field topics that can help team members strike up conversations with KOLs. The questions should be constantly changing based on medical initiatives.
- A "**key medical strategy**" section should be a quick reminder of the medical organization's goals and initiatives in a simple bullet-pointed list supporting familiarization of these initiatives based on repeated reviewing.
- An "**insights**" section can focus on the team's goals when collecting insights or it can present key findings from the insights team. Either way – insights are the currency of the medical affairs team.
- A "**regional director (RD) corner**" section can focus on what the bosses want. It provides an easily accessible way for directors to share pertinent information.

- Professional Development
    - A "**team training**" section that provides a list with easily accessible hyperlinks to recent trainings is especially helpful when MSLs are not able to make or fully engage in a certain training session live.
    - A "**new publications**" section allows access to relevant publications in the therapeutic area for the MSL team to be aware of when engaging with KOLs, including any team journal club manuscripts

    - An “**emotional intelligence (EQ)**” section allows for soft skill development, which is key when interacting with KOLs. EQ topics can be shared via reading an article, listening to a podcast, or completing an online training course. This section can springboard to further individual development through material review via a quarterly team training session to recap the EQ topics.
    - An “**MSL goal of the month**” section can share an individual goal that a team member is actively working on this month/quarter. Goal sharing across the MSL team can align priorities and help understand needed areas of development.
- Personal Development/Team Building
    - An “**MSL/team member of the month**” section allows for team development, especially given the remote nature of the MSL role. This section would rotate through the MSL team and even include people that are in home office medical or others that interact with the MSL team regularly. This section is a way to find out more about personal lives, funny stories, best trips were taken, and bucket lists. It’s important to be creative with the questions that are asked to help team members connect.
    - A “**favorite ***” section would generate a list of favorite foods, vacations, or TV shows via a quick monthly poll to get the team engaged and learn more about each other.
    - A “**health and wellness**” section could share health tips, recipes, challenges on fitness, nutrition, and mental health. Everyone views these topics differently, so this section allows all to learn better balance from the viewpoints of others.

As described, the monthly newsletter can be easily assembled with minimal effort by a small group of MSLs leading but resulting in a huge team impact that saves time and effort for all members. With low individual time to review content, the ability to reference and drive key points is immense in helping the MSL team succeed. A key strength of this format is driven through personalization to the needs of each team, which will change over time as teams grow and contract and focuses differ. An annual review of included content can help ensure it is optimized to the evolving needs of the team leading to a continued impact. In conclusion, using a simple newsletter format with a variety of options can greatly improve the delivery of key material, better connect teams professionally and personally, and help each individual grow.

Authors:

Dalila Masic, PharmD

As a Chicago native, Dalila completed her PharmD at Midwestern University and her PGY1 and PGY2 residencies at Loyola University Medical Center. After completing post-graduate training, she stayed on at Loyola practicing as the Advanced Heart Failure/Heart Transplant clinical pharmacist. Given her passion for collaborative cardiology care and research, Dalila transitioned to a Cardiovascular MSL role at Sanofi in 2020. She enjoys cross-functional collaboration and generating innovative ideas to find solutions to problems.

Erin Reineke, PhD

Erin is currently a cardiovascular MSL for Sanofi. She has been in this current position for almost two years after spending time as a vaccines MSL for Syneos, supporting the GSK adult vaccines portfolio. A native of Pittsburgh, she earned her PhD. in Biochemistry in Cleveland, OH, and furthered her training at Baylor College of Medicine in Houston, TX. After training, she was an assistant professor and principal investigator at Houston Methodist Research Institute in Houston, TX investigating molecular control of cardiac stress responses. Her research career gave her molecular and clinical knowledge of many mechanisms underlying disease including inflammation, immunity, genetic control, and cellular signaling. She loves to use her expertise to make technical science understandable and available to everyone who can benefit. She is happy to apply these principles as an MSL to help more directly affect patient care. She will soon be moving to Northern California and is excited to embrace the California lifestyle to its fullest!

New Promotional Provisions Raise Questions in Hungary

By karolina | March 2022

On 28 June 2021, the Omnibus Act was published in the Official Gazette of Hungary, which amended the promotional provisions of the Medicines Thrift Act, on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products.

The provisions of the Omnibus Act concerning promotional activities entered into force on 29 June 2021 and immediately became the subject of an extensive discussion among market participants, legal representatives, and industry associations in Hungary.

The textual changes were not extensive and were only to clarify and solidify the known interpretation and market practice at the legislative level. However, the changes also led to broad uncertainty, therefore the Hungarian pharmaceutical authority, the National Institute of Pharmacy and Nutrition (the OGYÉI), decided to publish an (updated) interpretation of the new and newly modified provisions.

The amended definition of promotion and related market interpretations

The definition of promotion was also subject to a minor change which, despite its extent, resulted in several questions concerning the activities of Medical Science Liaisons (the MSLs).

The definition of promotion changed as follows (the relevant modifications are indicated in bold):

The definition of promotion
[Article 12 (1) of the Medicines Thrift Act]

Before 29 June 2021	After 29 June 2021
The promotion of medicinal products, mother's milk substitutes, mother's milk supplements, and dietary supplements for special medicinal purposes (in the application of this chapter, hereinafter referred to as "dietary supplements"), as well as medical aids (hereinafter referred to as "promotion"), means commercial practices concerning medicinal products, dietary supplements and medical aids, the composition, and efficacy of medicinal products and dietary supplements and the application of medicinal products, medical aids and dietary supplements applied for or against healthcare professionals authorized to prescribe, provide training on the use thereof, and distribute medicinal products, dietary supplements and medical aids.	*The promotion of medicinal products, publicly funded mother's milk substitutes, publicly funded mother's milk supplements, and publicly-funded dietary supplements for special medicinal purposes (in the application of this chapter hereinafter referred to as "dietary supplement"), as well as medical aids (hereinafter referred to as "promotion"), means **any** commercial practices concerning medicinal products, dietary supplements, and medical aids, **in particular** the composition and efficacy of the medicinal products and dietary supplements and the application of medicinal products, medical aids and dietary supplements applied for or against healthcare professionals entitled to prescribe, provide training on the use thereof, and distribute medicinal products, dietary supplements and medical aids.*

Under the new provision, any 'commercial practice' concerning a medicinal product, medical aid, milk substitute, and milk or dietary supplement (or their composition, efficacy, or application) that is aimed at healthcare professionals would be considered a promotion.

Intense interpretational discussions began immediately because those who took a conservative approach argued that the new wording could be interpreted in a way that the strict, highly regulated regime of promotion applied not only to external communications by promoter pharmaceutical companies, addressing healthcare professionals with a commercial intention, but to all, including non-sales related but purely professional internal communications and functions. Accordingly, they believed that the activities of professional employees not engaged in promotion or sales activities, such as MSLs, might also fall under the promotion regime. This interpretation could also entail that MSLs should, like a company's medical sales representatives, be registered with the OGYÉI in accordance with the provisions of the Medicines Thrift Act.

The OGYÉI's interpretation

The OGYÉI expressed its view on MSLs in its first promotional resolution published in 2020 where, based on the then-effective definition of promotion, it described the circumstances under which MSLs were not qualified as medical sales representatives.

According to point 4.1.9 of the first resolution:

"*The so-called Medical Science Liaison (hereinafter the MSL) does not qualify as a sales representative provided that the materials to be handed over by it as well as the method of handover is completely separable from the intent of fostering the sales of the product, i.e. it does not engage in commercial practices, not even indirectly. According to the OGYÉI, this can only be carried out lawfully if the claims contained in the materials to be shared in connection with the product are either in line with the accompanying documentation or are limited to the exchange of the most recent scientific information concerning products yet to be registered, pursuant to the criteria detailed in the previous point*."

As mentioned above, after the Act was adopted, questions were raised whether, in light of the changes, this interpretation was still applicable. Therefore, in September 2021 the OGYÉI provided a second interpretation on the new and newly modified

provisions of the Medicines Thrift Act, in which it reasoned that the previous wording of promotion held the same meaning as the amended one. However, the earlier text was grammatically imprecise, and this has now been corrected.

As for MSLs, the OGYÉI explicitly cited point 4.1.9 of the first resolution under which it confirmed that the earlier interpretation continues to be applicable to MSLs. Furthermore, it added that independent professional congresses and journals should be the primary venues for the dissemination of the latest scientific knowledge.

Conclusion

The OGYÉI's updated interpretation has dispelled doubts about the position of MSLs as it has been confirmed that an MSL should not be considered a medical sales representative, provided that they do not engage in any activities that would qualify in any way as a commercial practice.

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She advises major pharmaceutical, biotechnological and medical device manufacturers at national and European levels on the full range of issues from general pharma law to representing clients before the relevant authorities. Dóra is a leading eHealth expert; she has worked on a number of eHealth projects and currently advises telecommunications and healthcare companies on their projects.

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Miriam has been involved in various pharmaceutical matters mainly involving simple to complex regulatory issues. These issues concern over-the-counter medicines, prescription-only medicines, medical aids, cosmetics, medical devices, and food supplements. Miriam has extensive experience in providing legal advice on clinical trials, categorization of medical devices, and reimbursement of medical aids and medicinal products.

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Mercédesz specializes in advising life sciences companies on day-to-day regulatory and general commercial matters. Before focusing on the life sciences sector, she gained experience in a wide range of legal areas, having been involved in corporate matters, as well as financial transactions.

Is Artificial Intelligence (AI) the Key to Stronger Human Relationships for MSLs?

By Sorcero | March 2022

Medical Science Liaisons fuse research and value. They are not only scientific experts but true relationship experts.

MSLs are health care professional experts with deep knowledge. They develop peer relationships with cutting-edge scientific key opinion leaders (KOLs) in various fields of medicine. Knowledge and relationships enable MSLs to translate complex scientific information across various formats into new evidence or actionable insights. These insights transform patient care through Medical Affairs strategy.

Cultivating relationships with KOLs is an essential element of the MSL role. Relationships help MSLs understand and identify KOLs' specific needs and objectives. However, in today's environment, HCPs are relying more on data-driven decision-making. This makes the technical aspect of learning and teaching science through continuous scientific literature monitoring equally essential to the MSL function. As such, MSLs are finding new ways to combine the relationship-building and expertise of their ecosystem with the technical aspects of their role.

Through data gap analysis, in-depth competitive landscape reviews, new clinical studies, or even routine MSL journal clubs, Medical Affairs has been able to design new research. They have allowed more patients to receive new treatments and changed major medical guidelines. They've even directly impacted the course of an entire organization that extends beyond Medical Affairs.

This record of desired, repeated outcomes by MSLs explains why combining relationship building with technical expertise is becoming increasingly important. Yet, as volumes of research and publications across a wide variety of formats continue to increase exponentially, it is also extremely time-consuming.

A recent time and motion study at a top 10 pharmaceutical company showcases how this burden is reflected in the valuable MSL insights generation and analysis (Hill & Abadessa, 2021). A Medical Affairs executive from this organization demonstrated that the MSL insights monthly reporting alone took 185 hours to complete, which is more than the equivalent of one full-time employee annually (Hill & Abadessa, 2021).

From medical literature to articles, conferences, congresses, and even social media, there is now a full-time workload for teams to stay on top of the latest developments. The healthcare "datasphere" is predicted to almost double every two years, at 36% CAGR from 2018 to 2025. And these numbers have only increased since the pandemic (Rainsel et al., 2018).

This rapid surge of information not only impacts MSLs. It affects patients who are not trained to interpret readily accessible scientific data, as well as HCPs who are bombarded with irrelevant educational information in formats they do not prefer (Evers et al., 2018).

The exponential increase in exposure to scientific information may present a potential crisis, but it also creates an opportunity to redefine evidence-based medicine. It can improve the quality of healthcare at the clinical point of care, one better decision at a time.

Now, backed with more data, MSLs can support evidence-based decision-making by utilizing the most recent collections of data-driven research in support of their organizations' products. Through data, MSLs can quantify their impact, measure and track KOL influence, and capture key metrics including Scientific Share of Voice (SSoV).

Therefore, one question remains: How do MSL teams combine insight data generation and relationship cultivation in order to continue to improve patient outcomes?

Similar to other industry shifts, the answer lies in the appropriate implementation of new technology.

Technology that includes artificial intelligence (AI) and machine learning (ML) is lightening the burden of the manual process. It is augmenting human capacity and enabling new possibilities for MSLs.

Scientific literature monitoring is a key area that is moving beyond a strictly manual process. Through natural language processing (NLP) platforms, MSLs can absorb vast libraries of unstructured content and find the most meaningful analytics and takeaways. AI platforms enable data and insights to be collected from a larger variety of formats and sources than ever before. This includes spreadsheets, PowerPoint documents, social media posts, graphics, podcast audio recordings or transcripts, frequently asked questions (FAQ) databases, among others, which is extremely challenging to manage systematically without a single database.

Technology and AI can lead to less time spent gathering, sorting, and analyzing information, and more time focused on the human elements of the role. Designed for the specific needs of medical affairs, language intelligence empowers experts with immediate access to credible information from across various sources. With a single repository of tailored scientific literature that automatically refreshes at regular intervals, MSLs could rapidly filter through vast quantities of research and uncover accurate, relevant data.

MSLs are using this technology to filter and tag key passages and terms in order to uncover insights, metrics, and advanced analytics. They are customizing information to their therapeutic area or product landscape to allow monitoring of specific products, disease classes, and biomarkers according to KOLs' preferences. Data visualization dashboards are enabling MSLs to quickly identify patterns and trends from large datasets. When data is easier to reference, MSLs can save time and more easily demonstrate why information and products are valuable to KOLs. Data, when paired with an MSL's knowledge base, augments stakeholder expertise and improves patient care.

Fundamentally, when MSLs scale their capabilities through technology, they can more accurately uncover the insights that matter most to possibly generate a new clinical study, publication, or an entirely new Medical Affairs strategy. As a result of their firmer grasp of the most relevant literature, MSLs increase competence and become more differentiated and attractive as a resource to their KOLs. They can invest more time engaging in truly meaningful, high-value relationships.

Generating and communicating actionable insights, rather than meeting with KOLs alone, best communicates the value of MSLs today. Today's capabilities provide MSLs with the ability to access information anywhere in the world, in any format, wherever

they are. It can be overwhelming, but it can also be another component to the ways in which MSLs build relationships and accelerate the medical mission of improving and saving lives.

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Acronyms

MSL – Medical Science Liaison

KOL – Key Opinion Leader

HCP – Health Care Provider

AI – Artificial Intelligence

SSOV – Scientific Share of Voice

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Sorcero

Sorcero is on a mission to improve patient outcomes by empowering life sciences experts to dramatically increase productivity by 10X (1,000%), decrease literature monitoring time by 90%, and increase tracking of portfolio products by 30X (3,000%). Our unique Language Intelligence Platform enables medical affairs and regulatory affairs teams at 40% of the top 10 global life sciences organizations to explore vast libraries of unstructured medically relevant content, illuminating the most meaningful analytics and takeaways. Sorcero is privately held and headquartered in Washington, DC, and Cambridge, MA. For more information, visit www.Sorcero.com.

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MSLs in Latin America where the Pharmaceuticals Operations are Cluster MSLs

By karolina | March 2022

Since a few years ago, the presence of Medical Science Liaisons (MSLs), have been gaining strength within the pharmaceutical industry. The position has been assumed by healthcare professionals (nurses, chemists, biologists, biochemists, physicians, obstetricians) who reinforce their careers with postgraduate studies in the areas related to the position for example epidemiology and clinical research.

Regardless of the profession, the MSLs have reached an outstanding role because science is the backbone of the position and they work to find out the answers to the questions that come from physicians to provide them with the highest level of scientific evidence, also, MSLs promote clinical trials for new molecules, new indications, even post-marketing studies.

However, the MSL role, for some years, has been differentiated depending on the country where it takes place. For example, before we could state that the MSL role was similar in different countries, the fact is that the figure currently changed. In countries like the USA, Europe, and in some Latin American countries they still retain a pure scientific role, which does not exclude that the MSLs need to know and keep close the company indicators where they work.. Otherwise, In the last 5 years, the MSL role has changed remarkably.

When I talk about the change in the role I mean that some countries have added certain functions to the MSL role for several reasons that I would like to comment on very briefly below.

Countries that are part of a Cluster within the pharmaceutical company

Many times, management positions are far away and cannot have frequent contact with medical leaders, key opinion leaders, or stakeholders from other countries who could also respond, this has an impact on the local MSL having active participation in meetings and assuming functions that the medical manager should attend to, since the onset of the pandemic, the MSL has been involved in more activities like these. Some examples of these participations are meetings with payers, presentations to pharmacotherapy committees, meetings with presidents or boards of medical associations, foundations and patient associations, financials meetings, and meetings with cost control executives and healthcare technologies executives.

Likewise, the Cluster MSL takes some internal flow approvals responsibility in the company. These approvals include a review of materials for the salesforce, global material´s adaptations to local needs, material for external distribution review, among others; furthermore, in some cases, they review label´s updates, technical sheets, and other materials sent by regulatory affairs.

Other MSL Cluster responsibilities are the owners of the budget assigned to the therapeutic area of medical affairs, which means having contact with agencies and vendors to make an adequate and timely expense monitoring, and in some operations, the up or down budget deviations can be part of the KPIs

The MSL´s main function is not what we have described above, however that is what I am trying to convey in this article. MSLs in some Latin American countries play a hybrid MSL role, being responsible for scientific, access, regulatory, logistics issues, among others.

All this is a huge advantage for the MSL that performs the function because they are going beyond the scientific knowledge of many other processes of the company.

Metrics assessment.

Companies have established standards to evaluate MSLs metrics. Naturally, these metrics are analyzed together, the company evaluates equally the performance of all MSLs in the region and is where they frequently find differences that could be

considered as an MSL´s inefficient development in countries where the role is hybrid because the MSLs are immersed in other processes of the company that demands more effective time outside the territory.

Some pharmaceutical companies intend to consider these functions within the MSL´s role, in this way there is a real evaluation of their work, and all other areas of the company know the scope of their role. Even in the beginning of this transformation, the pharmaceutical companies have changed the roles name to Medical Advisor or Medical Manager and the Cluster Medical Manager takes a new role as Therapeutic Area Head. In those companies, we see specific job descriptions with different requirements such as MBA studies and other skills such as communication, negotiation, soft skills, etc.

We see that the MSL´s role is not only taking greater importance, also greater amplitude and they are being customized according to each operation. I think that there are new challenges ahead for MSLs and there is still a long way to go. Changes in health systems, the demand for new scientific evidence, new therapies, changes in the assessment of healthcare technologies, and the payer´s assessment will continue to have an impact on the MSL´s role. I am fully confident that MSL´s are prepared to adapt to new company needs and at the same time keep the scientific soul that maintains us in the role.

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A Critical Evaluation of Informed Consent in Clinical Research: Opportunities for Improvement

By karolina | March 2022

The doctrine of informed consent can be little understood and followed in international clinical trials, therefore necessitating an examination of ethical and other dimensions. Arguably, informed consent provides the foundational basis for all clinical research, and also represents the right of every individual to have control and make a personal decision to accept being a volunteer in a research study, and also have to domain over personal choices in medical treatment. To exercise this right in a clinical research study, the patient or clinical research subject must receive adequate and unambiguous information to make an informed decision that will be conducive to consenting, refusing treatment, or partaking in a study (Thornton, 2000). With this right, now also codified in statute, it is therefore incumbent upon physicians and researchers to provide disclosures about the risks associated with the proposed treatment, vital in all clinical research studies involving human subjects. Palmeirim et. al, (2001) expressed a universal dilemma in a Tanzanian context, that although study participants must sign an informed consent form

(ICF), the optimal methods to convey trial-relevant information in the ICF, in low-income countries remains a challenge and an inadequacy. The process of creating awareness by clinical investigators by providing to research subjects, full information the deep level of knowledge and insight to human participants and volunteers represents the fundamentals of informed consent, with full disclosure.

Informed Consent and Challenges

The goal of clinical research is to aid discovery in drug development, however, it is mired in many difficulties, even with the best interests in mind of researchers and study participants. The process of informed consent entails patient autonomy to voluntarily participate in a trial with full awareness, knowledge, and ability to make an informed decision. However, with the copious amounts of documentation to be maintained in a study, extensive patient and other records, the overall bureaucratic process, regulations, documentation, and oversight, this process represent a complex and burdensome enterprise with many details and protocols for participants and investigators, and short timelines do not alleviate the situation as well. Nevertheless, informed consent must never be taken lightly and a sponsor and CRO must err on the side of informed decision-making by participants. In Sub-Saharan Africa, De Pretto-Lazarova et al., (2021) suggested specifying the minimum maternal age for transparency in the recruitment of children with minor mothers, the proxy decision-makers in international clinical trial guidelines would facilitate correct and transparent informed consent for children and children with minor parents.

The responsibility of IRB's, clinical researchers, and investigators, therefore, cannot display any laxity in respect of the informed consent process in the era of complexity in clinical research, with the expeditious intent and the emerging focus on biotechnology, gene, and other therapies. Laws and amendments must be fully cognizant of and complied with to the letter and spirit. For instance, the difference between consent in clinical trials of investigational medicinal products (CTIMPs) and other kinds of clinical research that are non-CTIMPs is of significance, as the Mental Capacity Act 2005 does not apply to CTIMPs (Craig, 2013). Perin et al., (2021) have called informed consent rightly, "a defining moment" where researchers must facilitate patients' comprehension of their condition and outcomes, to build trust and confidence.

With the intense scrutiny and copious FDA and regulatory stipulations, some may contend they would arguably limit discovery and business growth, however, the informed consent process cannot be less stringent in any way merely due to voluminous reporting or comprehensive processes. Meeting standards in regulatory compliant written informed consent is difficult when besieged with communicable and infectious diseases (Woods et al., 2016). Knowledge from clinical research benefits humankind where vigilance is required to ensure the choices made by patients, physicians, administrators, policymakers, and others in the clinical research enterprise is compliant with the responsible informed consent process. The inculcation of good recruitment practices and standards during the initial study startup is essential. Observance of regulatory compliance must not be construed as obstacles and impediments; rather they denote the oversight and advance planning which may help in observance of compliance, and informed consent reflects the voluntary and personal choices participants may make in participating in a clinical research study or considering otherwise. When patents, investors, decades of research, and— most importantly—patients' lives are at stake, a one-size-fits-all approach simply will not work (Goldman, 2004), and this can be said of the informed consent process, as well. Research subjects must be furnished with extraordinary detail so that they can comprehend the risks and benefits and make an informed decision in willfully partaking in a study, or abstaining.

The recommendation of this author is that the FDA Code and guidelines are a good starting point to examine the elements of Informed Consent since all research must display conformance to the regulatory agency guidelines and dictates. Critically, research studies falling under the purviews of the requirements of the FDA regulations, the informed consent documents should meet the requirements of 21 CFR 50.20 and contain the information required by each of the eight basic elements of 21 CFR 50.25(a), and each of the six elements of 21 CFR 50.25(b) that is appropriate to the study (FDA, 2016). IRBs however are the final arbiters to determine the adequacy of the information in the informed consent document.

While many IRBs have developed uniformity in documents, the customization to local cultures, languages, and dialects remains a challenge. Nevertheless, the standardization serves to provide an acceptable source of reference, that facilitates adherence and compliance with confidentiality, compensation, recording of queries to questions, and to record the voluntary nature of participation. Each investigator should comply with the local IRB requirements before submitting a study for initial review (FDA, 2016). On the surface, it appears that the different regulatory agencies are working seamlessly to advance the cause for research. In looking at the complexities involved, there seems to be a different story of fragmentation and a lack of cohesion. A common thread of lament is failure to achieve harmonization, with reasons including complacency, a maze of bureaucracy, excessive paperwork, comprising of the major reasons which run against the grain of streamlining the responsible conduct of research (Mastroianni, 2008), with informed consent signifying the vital first step in the conduct of a clinical trial.

Facilitators and Barriers in informed consent: Complexities in Clinical Research

A facilitator of informed consent is comprehensive information offered to study participants to make informed decisions. Bolcato, et a., (2014) noted that there is a responsibility in enrolling subjects in a clinical trial, for subjects to be thoroughly informed about the nature of the study, and every possible benefit and risk, so that a voluntary decision to participate is consciously made. The inadequacy of information is a barrier. The authors cite the great emphasis the Ethics Committee (EC) of the Verona University Hospital assigns to ensure the adequacy and completeness of the written information to the subjects, presenting statistics on over 101 the changes the institution saw necessary in recent IC (Informed Consent) processes. Descriptions of major differences between the interventions studied and commonly practiced usual care, as well as potential risks associated with these differences, are essential elements of adequate informed consent (Cortés-Puch, et al., 2016). The willful, or inadvertent failure to provide adequate and comprehensive information on risks and benefits to study participants, represent the major barriers to informed consent and are the facilitators and barriers that would fall under these good practices and lapses.

Some Informed Situations that have Impacted Consenting

Clinical trials are increasingly global and geographically dispersed, for good reasons of economics, a more readily available and suitable pool of research participants, however, that only exacerbates the ethical complexities and increases the potential for informed consent breaches and lapses. The focus of this component of the article is on clinical research studies, with an Indian perspective. The justification is that this is a country of over 1.3 billion people, and an ever-increasing number of clinical trials are conducted there. A country also with the highest number of pharmaceutical companies in the world. Every clinical trial must be customized to the operating environment, for we know that clinical trials will vary by country and geography. Recruitment obstacles to be overcome will include ethical, social, cultural factors, in addition to clinical strengths of researchers, and the inadequacies, relative to the geography of a study, which may pose difficulties in recruitment. The implicit trust by research subjects of their physicians and caretakers, as noted by Kaye (2021) in Uganda, featured as the motivators for participation, with laudable intent in contributing to science and discovery.

While the emphasis globally, and generally is ethically oriented, insofar as providing complete information and ensuring voluntary participation, with the efforts on harmonization of ethical tenets of informed consent, the lapses and breeches prevail. The dilemma seems more prevalent in developing countries, noting “when intentional lapses in conduct of trial hamper the ability of socially and economically disadvantaged communities in developing countries to make a free and informed decision (Agrawal, Joshi, & Shah, 2014). To counter these lapses, regulators have made compulsory the audio-video (AV) recording of informed consent, to supplement the mandatory written consent from participating subjects. The documentation and recording must also be safeguarded and securely stored, to abide by the principles of confidentiality.

Citing the record of accomplishment and current lapses, the authors point to numerous instances globally, and in India, where humans appear often subjected to undue risks and abuses, requiring increased oversight and regulations for their safety (Agrawal et al., 2014). India and the awareness of informed consent and the Hippocratic Oath principles of ‘…never do harm to anyone and physician-directed care of patients is a welcome sign, as well as the Nuremberg code and the declaration of Helsinki. It would be remiss not to mention that some researchers have found redesign of the IC as a limited psychological capacity even in stable patients to fully comply with the informed consent, as set in the Declaration of Helsinki.

Voluntary participation and the ethical tenets to ensure that patient consent is obtained in a fair and just manner, however undesirable lapses in the conduct of clinical trials have not entirely disappeared. Intentional lapses seem to stem from the exploitation of socially and economically disadvantaged communities in developing countries in the conduct of trials. The dangers in developing countries studies for interventions may pose potential to cause serious risk to patients, or those involving minors, and failure to enact ethical recruitment of participants will stymie the speed of drug development and the goal of affordable medicines, an important consideration in India (Agrawal et al., 2014). Video recording may be a step to prevent breaches and lapses in ethical conduct, while ingraining best practices represent those which aid patients in making well-considered and informed decisions, by evaluating the pros and cons.

Multiculturalism is another potential barrier in India, arising from logistical, linguistic, cultural, and other challenges. The difficulties in efforts at harmonization notwithstanding, national and international guidelines, codes, and regulations do serve to guide the ethical conduct of research involving human participants in India. The problem is compounded when applying ethical principles in obtaining informed consent in a multicultural society in India. Kulkarni (2014), expressed the challenge eloquently: “While, on the one hand, they are not to violate universally applicable ethical standards, the local culture of research participants must also be considered”, citing a strong role of Ethics Committees (ECs, over 850 registered in India) for researchers to document the informed consent process and all the relevant information in the protocol before initiation of the study, including waivers. In a multi-center study, it takes Regional Ethics Committees (RECs) to examine the informed consent (Kulkarni, 2014), which may be the solution to overcome the potential exploitation and the barriers due to cultural and other factors.

In summary, Kulkarni (2014) has listed the important issues and challenges of Informed Consent as participant-related factors, involving comprehension and translation to regional languages for the understanding of participants, where there are many vulnerable participants. Storage period of biological samples and obtaining audio-visual and online informed consent, providing post-trial access and benefits to the participants, and monitoring the process of informed consent in studies, and where applicable, a waiver of informed consent. Awareness of these challenges appears a step in the right direction to forging a path to drug development and affordable health for all in India.

The Road Ahead

Is informed consent going to be redundant in the future will be anybody's guess? Genetic mapping, molecular genetics, and developments in biomedical research and healthcare can in the future cause a revisiting of the concept of informed consent, as we know it, and possibly challenge existing perceptions and imperatives in informed consent. The informed consent concept hinges on informed decision-making based on a careful evaluation of risks and benefits, and forms as well, the underlying principles for the protection of study participants, safeguarding their privacy, and the responsible conduct of research. However, advances in genetics and biomedical research as well as new forms of decision-making in healthcare may well require a rethinking of this traditional idea (Kegley, 2004).

The author of this article calls for the preparation of IC models to be adaptable, customizable, and ready to reference with checklists to different situations. For instance, Pal et al, (2021) found value in using a validated questionnaire in testing for clinical trial comprehension and cautioned that with the increased ethical, level of detail and contentiousness in the early phase and terminally ill cancer patient clinical trials, and patient selection and participant information sheets (PIS.

The Clinical Trials Directive (CTD), adopted in 2001, aimed to change this by harmonizing all legal regulations on clinical trials applicable in the EU but nevertheless allowing national deviations in implementation into national laws through opening clauses and aspects that were left unregulated. In view of the Clinical Trials Regulation (CTR) which, according to the current status, will with high probability be applied from 2022 on, and which in future will be the legal basis for clinical trials with medicinal products in humans, applied directly in all EU member states, the necessity to take stock of the effects of the CTD was evident.

It is hoped that increased oversight and awareness may remedy the problem cited in the past, in the selection of countries for conducting clinical trials, for financial and other considerations, and legal requirements, secondarily (Schweim, et. al., 2021). Adequate information is the cornerstone of informed consent, which may not reflect future trends. To promote thought in this direction, there are recent advances in genetic science and medicine, and particularly the development of population genetics databases, and perhaps it may be not long before the notion of informed consent is laid to rest as new forms of consent emerge, such as the application of artificial intelligence in data scrutiny, with patients therefore not in the forefront of direct risk. Kegley, (2004) vociferously has the crystal ball prediction: "Old rules often cannot fit new situations, and the changing needs, knowledge, and globalization in biomedical and genetic research may demand a new ethical and legal framework for consent".

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Mentoring vs. Coaching for Field Medical

By karolina | March 2022

The MSL, as other field-based roles in the pharmaceutical industry, is one of those on which the COVID-19 pandemic had the strongest impact. The past 24 months have shown us what is required and possible in terms of adaptation. Not only in relation to the role, but also for the individual MSL. That makes it even more important moving forward that every MSL receives as much support as possible.

Flexibility and (self)development are unavoidable at this stage and the support of coaching and/or mentoring is required to aid in challenging times. Data show, in addition to an increased ability to adapt to changes and new challenges and increased self-awareness, such support can also enhance job and life satisfaction1. A long-term study by Harvard Business Review showed that effective coaching is directly proportional to the level of employee engagement3. And we know mentees perform better, are more competent, quit less often, are more self-confident, more satisfied, and more stress-resistant.2,3,4 This will in turn raise engagement and engagement has a greater impact on performance than corporate policies and perks (incentives)5!

What kind of support for personal development should you apply in which situation? To answer this question, we first need to differentiate mentoring and coaching from training (sometimes also referred to as coaching) and managing (see table 1).

While both mentoring and training depend on the industry expertise and knowledge of the mentor/trainer there is a distinct difference. The mentor will share his/her experience for the mentee to listen, learn and apply to their own situation. Whereas a trainer will provide a strict structure of Training and exercises the trainee has to go through in order to gain specific expertise or ability.

E.g., a trainer will give you a methodology on how to prepare and execute a successful negotiation. The mentor will share how he/she has successfully implemented the method, include additional nuances, and how this can help in achieving your specific goal.

In coaching the expertise and knowledge come from within the coachee brought to light by the questions asked from the coach. This is an "I help you to help yourself" tapping into the coachee's own resources: "'What do you think you need to consider to make this negotiation successful?". Whereas managing means providing clear instructions on the expected outcome and pointing out negotiation as an appropriate way to achieve this goal. In managing, you are defining tasks and required skills in accordance with the company strategy and values thereby also developing and supporting the individual to grow in their role.

	Mentoring **Stands for advising**	**Coaching** **Stands for asking**	**Trainer Coaching** **Stands for training**	**Managing** **Stands for telling**
Purpose	Supports a person's development	Supports a person's development	Supports a person's development	Supports a person's development in line with company values and strategies
Setting	Mainly 1**:**1	Mainly 1:1	Can be 1:1 or group	Can be 1:1 or group
Format	Typically involve a series of meetings, over several months	Typically involve a series of meetings, over several months	Typically involve a series of meetings, over several months	Typically involves regular meetings, on an ongoing and continuous basis
Focus	Mentoring tends to focus on longer-term topics e.g., career progression though a Mentor can also support someone in their current role	Coaching is more likely to address immediate topics related to skills and performance in the current role	Trainer coaching is more likely to address immediate topics related to skills and performance in the current role	Managing is more likely to address immediate topics related to skills and performance in the current role

Process	Mentors already have experience in the field their mentees are working in. Mentoring is all about sharing knowledge, experience and expertise	Coaches are not required to have experience in the field the coachees are working in as coaching is all about asking the right questions	Trainer coaching is about applying own experience and expertise to develop a structured, standardized process focused on imparting specific knowledge or skills	Managing is about giving directives, day to day support, measuring progress, and working toward effective project delivery
Background	Mentors are more likely to be from within the industry, but can be external	Coaches can be external	Trainer coaches are more likely to be from within the business or industry	Managers are from within the business
Value	Help you through experience sharing and providing knowledge and ideas	Help you to help yourself	Remember and practice	Help you to become better by providing solutions and implementing company values
Ownership	Mentee drives meetings	Coach drives meetings	Trainer Coach drives meetings	Manager drives meetings

Table 1: Differentiation between Mentoring, Coaching, Trainer Coaching, and Managing 7,8,9,10

For the purpose of this article, I will focus on mentoring and coaching only:

A mentor draws from his/her experience, expertise, and a network that is relevant to the development of the mentee. In this relationship, the mentor is the one with the knowledge/wisdom.

A mentor advises and guides a mentee by

- Sharing experience of how to be successful in a specific role
- Advising on how to prepare for future roles
- Introducing contacts (internal and external to the business) that may be useful to the mentee
- Providing advice on ‘how to get things done’ (navigating the business)
- Providing the bigger picture (industry trends, business strategy, etc.)

In mentoring, the learning is achieved by sharing experience and expertise and applying it to the mentee’s situation while keeping a holistic, long-term focus.

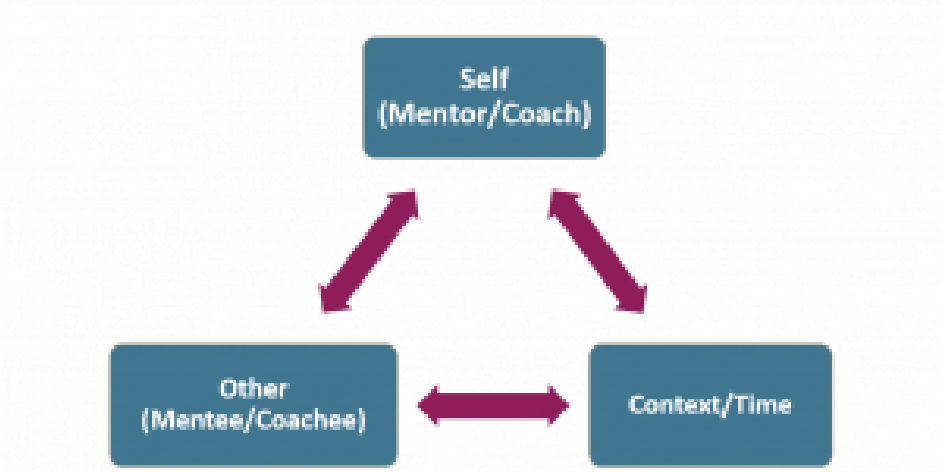
A coach has the belief that the coachee has the knowledge/wisdom required and knows they can discover solutions for themselves.

A coach

- can coach anyone on anything and does not need experience or expertise in the topic of the conversation
- uses skillful questioning, and a structured conversation, to support the coachee’s growth

In coaching, the learning is achieved by the coachee through self-reflection, self-exploration of the options, and thoughtful action.

To understand which of the two approaches are used best in a given situation there are three factors to determine:



Graph 1: Factors for consideration

Self (Mentor/Coach): Do you have experience in the MSL role and working environment and/or do you have experience/interest in the art of coaching? Are you more the "I'd like to share a story with you" kind of person, or are you rather sitting back and asking questions? If you love to share your own experience and stories, mentoring will most likely be your default position when you have to make ad-hoc decisions. In contrast, if you have no experience with the MSL role coaching is your better choice.

Other (Mentee/Coachee): Is the person you are guiding open to learning from your experience? If so, mentoring is a good option to cover short-term, but also long-term aspects. If the person is unlikely to "listen and learn", but full of golden nuggets, try applying coaching for effective revealing new skills.

Context/Time: Mentoring tends to be more informal. In case you quickly want to solve a situation, go with mentoring, as there is most likely not enough time to discover new approaches and ways of working when in a rush. Also, apply to mentor in a situation where you want the person to invest in their future by providing the bigger picture and options which may apply a bit later in their career.

If you have more time at hand, use the more formal ways of coaching to solve a repetitive topic, use coaching for long-lasting results and increased confidence in the person's own abilities.

Taking into account these three aspects will help you to identify which approach is most appropriate for the situation you are trying to enhance. Those approaches can also be mixed and, in fact, I have observed MSL leaders doing so. However, it is important to first understand and be able to differentiate the techniques you are working with in order to develop enough expertise and the ability to switch approaches in order to reach your desired outcome.

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Maja holds a Phd. in Biology. She has been working successfully in the pharmaceutical industry for 20 years now, in a variety of positions with extensive experience in Marketing and Sales, Medical and Medical Science Liaison. For more than 10 years she has dedicated her work exclusively to the role of Medical Science Liaison with personal experience as MSL, MSL team lead at country and international level as well as driving MSL excellence on a global corporate level. She is currently holding the position of Global Director of Field Medical & HCP Exchange at Merck/EMD. Maja is the founder and owner of MSL-Excellence.de, where she provides mentoring and consultancy to aspiring MSL, MSLs and MSL Leaders. As a result, she follows the development of the MSL role from a wide variety of perspectives.

The Medical Plan: Demonstrating Stakeholder Influence with MSL collected Real-World Clinical Insights

By Susan Malecha, PharmD, MBA | March 2022

The Medical Plan is a periodic, usually annual, consolidated document detailing the Medical Affairs activities to be undertaken and/or funded for a licensed product. Medical Affairs (MA) demonstrates leadership and value through this strategic planning process that aligns all Medical Affairs competencies needed to support the product and organization. The MA team navigates the complex therapeutic environment for the product, acknowledging challenges, taking advantage of opportunities, and filling scientific gaps. The Medical Science Liaison (MSL) is well-suited to provide real-world clinical insights to the comprehensive and supportive tactical plan that can provide the most impact to the stakeholders in a therapeutic space while taking the MA team closer to achieving annual goals.

The five steps to writing a medical plan are:

1. Analyze the external environment/competitive landscape
2. Look at the available internal environment (study data, safety, place in therapy, indication)
3. Perform a SWOC (Strengths, Weaknesses, Opportunities, and Challenges)
4. Develop key medical objectives

5. Add tactics after strategy, considering available budget and realistic timelines

A critical success factor for developing a solid medical plan is to include all functions in Medical Affairs and align with cross-functional partners. It is important to work with clinical development, HEOR/Market Access, publication planning while addressing/incorporating the global standpoint. Commercial and Medical can discuss/align regarding product strategies (SWOC, data gaps, strategic imperatives, etc.). However, once the strategy has been aligned and agreed upon, the translation of the strategy into the Medical Affairs tactical and operational plans needs to be developed separately.

Many teams view the Medical Plan as a static document when in reality it needs to be addressed periodically for feasibility and relevance with the ever-changing healthcare dynamic. If the plan is not reviewed and a detailed execution plan is not in place, the timelines and programs are often delayed or eliminated.

The MSL can show immense value in the Medical Plan process. Bringing real-world clinical insights can shape situational analysis, medical strategy, and resultant tactics. The role of the MSL in providing this information is vital to the success of the Medical Plan, and every MSL should be actively contributing to the plan.

When the MSL has the opportunity to contribute to the Medical Plan, the focus should be on both short and long-term strategies and tactics, keeping in mind where the indication/product is within the lifecycle. The MSL is specially equipped to bring learnings from field communication during the pandemic. This includes incorporating digital programs that broaden the reach such as social monitoring (Key Opinion Leader, KOL/Digital Opinion Leader, DOL)), virtual scientific education programs, and hybrid KOL engagement planning to name a few. The winners will be those who succeed in positioning the science, especially those who can combine and analyze data sets to ultimately improve patient outcomes. This involves the incorporation of real-world evidence, utilization of digital health and electronic medical records, and innovative ways of mining data.

The recent position paper in the Journal of Therapeutic Innovation & Regulatory Science in July 2021, “Promoting Best Practices for Medical Science Liaisons Position Statement from the APPA, IFAPP, MAPS, and MSLS,” intended to provide recommendations that will help lay the foundation for best practices for MSLs and their activities. One of the three key activities for the MSL is gathering insights. “MSLs are well-positioned to gather insights from the field that can be used to inform internal clinical development, marketing, and market access in developing their strategies. These insights may be based on expert opinion, observations of barriers in the patient journey or questions that emerge in scientific exchange.”

In today’s hybrid peri-pandemic era, MSLs have that unique ability to collect timely, relevant, and actionable insights from experienced KOLs. This is one area that the MSL can clearly demonstrate value for the Medical Plan while contributing to the science and therapeutics that will ultimately help patients.

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Susan Malecha is a results-driven versatile medical professional with a proven track record for achievement in the pharmaceutical/biotechnology industry. An accomplished author, she has lectured extensively and is called upon to present the latest developments in the areas of medical affairs for the pharmaceutical industry. Dr. Malecha is an active member of Healthcare Businesswomen’s Association (HBA), as the current President of the San Diego Chapter. She is also Vice-President, Board of Directors, Health Care Communicators of Southern California, and Board Director for California Special Projects Fund

for American Association University of Women. Earning her BS in Pharmacy from Butler University, she completed her Doctor of Pharmacy at University of Illinois at Chicago and earned her Masters of Business Administration from Keller Graduate School of Management. Dr. Malecha is a certified Etiquette Consultant and currently the Senior Director, Medical Affairs at Puma Biotechnology.

How My Post-COVID Hobby Has Taught me About KOL Relationships

By Mitch D'Rozario, Ph.D | March 2022

New Year, Same Pandemic. As the new year rolls in, I am struck by how much the pandemic has taken from us: face-to-face meetings, ability to travel, and work-life balance. On the other hand, it has taught us to be resilient, adaptive, and grateful for what we have. In addition, the pandemic has allowed me to hit the “pause” button and learn how to garden.

The Stoic philosopher Marcus Aurelius wrote, “Your mind will be like its habitual thoughts; the soul becomes dyed with the colors of its thoughts”. The lessons I was learning from gardening were seeping into how I managed my KOL interactions. In this article, I will share 4 gardening tips, I’ve learned, for successful KOL relationship management.

1. **Ensure a nutritive soil**

I learned this the hard way. When growing a garden, it is important to make sure that you have good soil. You need to make sure to have a good bed for your seeds to sprout from and be able to hold strong. Similarly, to be a successful MSL, I believe it is important to have a good company culture and a training program that allows you to function properly and support KOL relationships. Much like how good seeds may not sprout well in malnourished soil, MSLs thrive in nurturing environments

2. **Not all seeds sprout at the same rate**

Once you have a good foundation, you need to plant the seeds. However, not all seeds will germinate at the same time – some grow faster, while others are slower, some are seasonal. This is akin to an initial introduction with a KOL. Not all KOLs will be open to partnering with you for multiple reasons. Each KOL interaction is different and they may progress at different rates. From the KOLs’ perspective, ask yourself “Why you?, Why them? Why now?” These are critical questions to ask before setting the meeting agenda. Much like gardening, KOL relationship management requires patience and vigilance to ensure that the relationship, much like the seedlings, grows at their respective pace.

3. **Make sure to water the plants, but do not overwater them**

While seeds grow into plants, it is important to make sure that you water them frequently, taking precautions not to overwater

them. Similarly, as an MSL it is important to ask the KOL what cadence the KOL would like to hear from you, what is their preferred mode of communication, and ensure that you follow up appropriately. However, it is equally important not to drown them with too many requests or have an uncoordinated approach among different internal stakeholders.

4. **Be Bold with Pruning**

Pruning is an essential gardening skill to ensure healthy growth and flowering. By removing excess branching, you provide good air circulation. As an MSL, it is important to take stock of your existing interactions and see which relationships need more attention and which ones are easy to maintain. Prioritizing internal meetings is also key. Asking yourself these questions:

When Prioritizing internal meetings:

- Are there certain meetings that are optional for you?
- Are there some meetings that will be recorded that you can listen to afterward?
- Can you ask for an agenda so that you know which part of the meeting you need to attend?

When Prioritizing External meetings:

- If you are already meeting with 3 KOLs from the practice, is it possible for you to focus on a couple of KOLs?
- If the KOL has multiple research interests, would it be possible to introduce them to respective medical directors on one call to save time?
- Does this meeting need to be a F2F (face to face) or zoom, or can it be done over text?

5. **Be curious about what support will help your plants grow stronger**

Finally, one of the tips I've learned from gardening is that each plant has different needs. Some garden varieties like peas and tomatoes need trellises to support the plants to grow. A major challenge in the US healthcare system is related to healthcare disparities, as segments of our populations are affected in different ways and often do not have access to equitable clinical trials. The onus is on us in Medical Affairs to be diverse and inclusive in our clinical trial selection, but more importantly, realize that some sites may require more support than others. For example, clinical trials that require frequent visits to specific sites may place a burden on participants and the clinical trial staff. How can we be more flexible on-site visit requirements and incorporate digital health tools without additional burden on the staff/patients?

In conclusion, I hope you are finding hobbies of your own in the new year. I hope that these creative habits, the ability to make something new, allow you new perspectives and act as a buffer in times of uncertainty and ambiguity. More importantly, I am hopeful that moving forward, we can all have the best of both worlds – be back on the road for F2F (face-to-face) interactions and congresses, empowered with the new insights and perspectives we have developed during the pandemic.

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Mitch is a Malignant Hematology MSL at Genentech/Roche. In his MSL career spanning hematology and ophthalmology, Mitch has supported ocular surgical devices, microdosing implants, biologics, antibody-drug conjugates, oral inhibitors and bispecific antibodies from Phase I-IV. Mitch enjoys advocating for customers and patients, collaborating with internal colleagues, and building strategic tools to make informed business decisions and deliver urgent medical solutions. Mitch earned his PhD from

Drexel University and trained as a postdoc at Washington University School of Medicine. In a pre-COVID world, Mitch can be seen keeping pace with his two boys, Francis (2.5 years) and Miles (1 year). In a post-COVID world, he has been busy being a Montessori dad, learning how to bake, and going to OrangeTheory (while maintaining safe distance) to burn off the said baked goods.

The Emerging Need for Medical Affairs in Telemedicine

By Alec McCarthy | March 2022

Introduction

With a staggering growth rate since the onset of COVID-19, telemedicine has emerged as a primary method for HCP-to-patient interaction.[1] According to Allied Market Research, the Telemedicine Market generated $40.2 billion in 2020 and is projected to generate $431.82 billion by 2030 with an estimated 25.9% from 2021 to 2030.[2] While many larger clinics and hospitals are adopting telemedicine practices, a wide range of new telemedicine and concierge telehealth clinics are appearing. These clinics, while still offering products, are primarily growing through offered services and products.[3] Though beneficial for a variety of reasons, the sudden increase in telemedicine usage throughout the US has ushered in a need for new virtual MSLs, virtual-engaging MSL, and expanded virtual training for current MSLs to ensure adequate scientific exchange and medical education in otherwise limited person-to-person practices.

Advantages and Shortcomings of Adopting Telemedicine Practices

Many HCPs who took the leap into telemedicine are encouraged by the opportunity to see patients who could remain in the comfort of their homes during the pandemic. It also gave HCPs a new avenue to provide care for the underserved and underinsured, resulting in an overall improvement in medical equity. Anecdotally, as medical director of a clinic that began as a health optimization clinic, we transformed into a front-line clinic diagnosing new pathologies. We identified countless new diagnoses of diabetes, depression, adrenal and pituitary tumors, and many other pathologies. These patients would certainly have delayed diagnoses otherwise. Compared to my full-spectrum practice, telemedicine had a new atmosphere to acclimate to, with many advantages and barriers to providing care. The team-based approach to healthcare is especially crucial in telemedicine, largely because the “swiss cheese model” of medical errors has larger holes. The HCP is the end-stop, or the rind, in this paradigm of errors. This is particularly difficult without a nurse to provide an extra layer of support. These holes should be narrowed through the use of technology, clinic staff, and medical affairs personnel. Like any clinic, a telemedicine clinic must consist of experienced healthcare professionals, from the HCP to nurses to office staff. Close-the-loop communication and stringent documentation are vital given the difficulty of virtual handoffs.

The Role of Medical Affairs

Without question, medical affairs and MSLs are necessary for the proper function of telemedicine clinics. One distinct advantage of using telemedicine is that the MSL

and their collaborators have access to a new patient population and modality for conducting clinical trials and surveys remotely.[4] Assuming the providers have an adequate virtual clinic infrastructure, the role of the MSL would be identifying and assessing patient populations for compliance and assessing the performance of HCPs in a virtual setting. Both of these tasks require MSLs to understand how patient and HCP relationships are fostered via virtual visits. Together, the HCPs and MSLs will be able to rapidly identify and address pinch points that are deleterious for patient care. This will allow regulatory bodies and other virtual practices to ensure patient and practice compliance to best telemedicine practice guidelines.

MSLs and HCPs can also help to standardize telemedicine practice across state lines, allowing improved access to telehealth for patients in health care deserts. The MSL is invaluable for helping navigate market intel reports to help identify trends and needs. The MSL will be privy to observing an untapped patient population that can provide inspiration for investigator-initiated trials. The emerging use of HIPAA-compliant biometric data to help monitor patients remotely will bring improved trial opportunities. During the pandemic, KOL’s have certainly been open to engaging with MSL virtually. Thought leaders in telemedicine are apt to be equally receptive (Figure 2). Virtual MSLs would presumably travel significantly less, and their success would rely predominantly on their ability to communicate virtually. In the coming years, we may see a shift in virtual MSLs engaging via virtual reality.

Limitations with Telemedicine & How Medical Affairs Can Help

While there are many benefits to adopting telemedicine practices, there are also limitations to the role of medical affairs in telemedicine that can be addressed with additional training. The main barrier to success for MSLs in telemedicine is technology. There is a need to investigate the “wild west” heterogeneity of virtual infrastructure, including HIPAA compliant EHRs, televisit meeting platforms. It is more difficult to access tools such as PDMPs to study rates of adherence to filling prescriptions without these being built-in to the EHR. Another barrier that will remain is the lack of a physical exam which robs the HCP and MSLs of valuable objective data. The use of non-standard EHRs can make collecting data difficult. Despite these limitations, we hope that the medical affairs community is inspired to take the leap and improve the booming telemedicine community. For MSLs, understanding emerging trends in telemedicine will allow for prompt engagements and medical education with providers in specific therapeutic areas.

Conclusions

Telemedicine has emerged as a permanent healthcare practice, having been solidified during the onset of the COVID-19 pandemic. HCPs utilizing telemedicine practices have increased patient reach. In turn, there is a growing need for virtual MSLs to help

disseminate scientific knowledge virtually. Traditional exchanges (i.e., office visits, didactic in-person lectures, and training) may now often occur virtually and require the MSLs to be well-trained in maneuvering virtual landscapes. There may be several unique opportunities for medical affairs professionals and HCPs to conduct virtual clinical trials in the future, particularly in non-traditional patient populations. In addition, it is crucial for MSLs to ensure regulatory compliance and proper telemedicine best practices by educating clinicians who have limited in-person interactions with other HCPs.

Disclaimer Alec McCarthy is an employee of Merz Aesthetics. His views are his own and do not represent those of his employer.

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Scientific Share of Voice as KPI for Medical Activities – Key Success Factors

By karolina | March 2022

A lot has been written about the evolving role of (Field) Medical Affairs and the imperative to measure and benchmark Medical activities as a result of the increasing importance, visibility, and allocated budgets.

One of the possible KPIs that often comes up in the discussion is Scientific Share of Voice (SSoV) which basically means comparing (primarily) publications in journals and presentations at medical meetings/conferences on your own product (or therapy area/indication) with the activities of relevant competitors in a quantitative way.

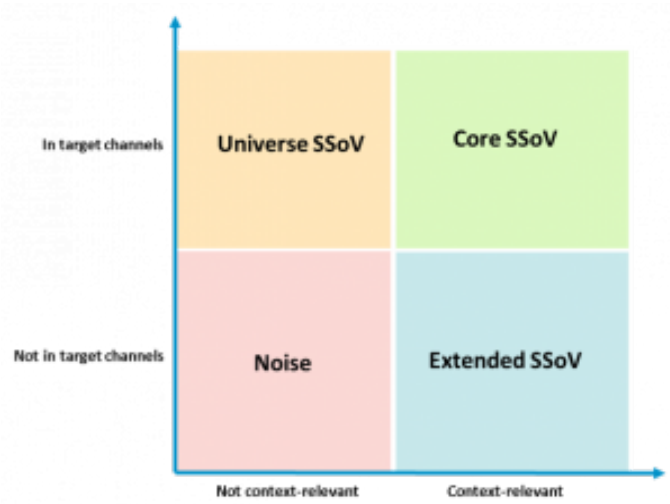
As a starting point for this article, I have conducted a little poll in my Medical Affairs network about the current and intended future use of SSoV. The results were pretty ambiguous, some companies use SSoV analysis, some consider introducing it and some don't for different reasons. One respondent for example expressed concerns with regards to a consistent methodology and another Medical Affairs Executive told me that in his company linking Medical Affairs activities to any kind of measurable output/ROI is considered as "commercial intent" and therefore not compliant. Going through all of the responses I have the impression that:

1. There is still a large unmet need to somehow quantify the effect of successful Medical Affairs work
2. It also very much depends on company culture how this need is being addressed

SSoV in the narrow sense as a measure for a company's ability to translate scientific evidence into publicly available medical information can play a role here and I would like to come back to and focus on the methodology discussion. Yes, it is pretty tricky to define the right basis for the analysis to not end up comparing apples with oranges but the following ideas can help develop an objective and relatively "noise-free" methodology framework.

Being as specific and narrow as possible in the definition of the data sources, types of activities, and competitor universe is the foundation for meaningful output, particularly in a post-launch situation where the entire community of practice has access to the product in scope and can create and disseminate scientific content.

The following illustration can serve as initial guidance:



The two dimensions are “Not/Context-relevant” and “Not/In target channels”.

“Context-relevant” means that the captured and analyzed data points (journal publications or medical congress presentations mentioning the company and/or competitor compound/s) are related to the defined scientific dissemination strategy. An example not necessarily context-related could be a research pipeline overview article for a specific indication covering the company/competitor drugs.

“In target channels” means that the data point is found in a defined journal or conference that is reaching the specific target group. An example for not in target channels could be a primary care conference with a presentation mentioning a CNS drug that is typically not prescribed by GPs.

If you want to go beyond quantitative SSoV analytics you can use the data to also look at your competitors’ communication strategy over time answering questions like:

1. How has the messaging changed over time (e.g. efficacy pre-launch to safety post-launch)?
2. What was the geographic communication strategy (e.g. which role did international/regional vs. national channels play)?
3. Which were the conferences and journals (e.g. large vs. smaller conferences)?

Although only retrospective by default, applied properly, SSoV can generate interesting insights into your competitors’ scientific dissemination strategy and help you plan your own activities fact-based.

And most importantly: only a transparent and thorough methodology ensures reliable results and buy-in from all relevant stakeholders working with SSoV analytics.

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Marcus Bergler is a globally recognized thought leader in KOL Identification, Profiling, and Network Mapping.

Before joining D2L Pharma Research Solutions as Global Vice President of Sales and Strategy in November 2017 he served as General Manager Europe for Veeva's KOL business unit (now Veeva Link) after Veeva's acquisition of Qforma's/Mederi's Global KOL business in 2014 where he was also responsible for the EU KOL and Targeting business. Prior to joining Qforma in August 2013, he was VP Sales and Marketing at Cegedim Customer Information (CCI) providing nomination-based KOL Identification and Network Mapping to major life sciences customers.

Before he accepted the CCI assignment in March 2010, Marcus held positions as Consulting Principal and Sales Team Leader at IMS Health, Germany. From January 2003 until December 2006 Marcus was responsible for the business development of Rogers Medical Intelligence Solutions, New York (now Pharmaspectra) in the German market and for selected headquarter clients, providing innovative competitive intelligence and medical education services to pharmaceutical companies.

Prior to that Marcus gained consulting experience of 10 years in the healthcare/pharmaceutical industry. Marcus holds a degree in Economics from Ludwig-Maximilians-University in Munich.

3 Challenges Faced by Medical Affairs Teams and How to Overcome These Obstacles

By karolina | March 2022

As the efforts of Medical Science Liaisons (MSLs) are becoming increasingly prevalent, it has become pivotal to understand the strategic importance of Medical Affairs within the industry. With access to healthcare professionals (HCPs) and Key Opinion Leaders (KOLs) severely curtailed during the pandemic, the expectation is that the limited time the KOL provides will be used for value addition. MSLs, with their ability to collate data for gaps in the existing clinical trials and discuss off-label topics, can provide crucial scientific value.

Commercial success is often attributed to the efforts of the sales team with little regard to correlating or backtracking success to the Medical Affairs efforts. MSL teams often lack the business intelligence (BI) and metrics to showcase the true value that transcends beyond scientific advocacy.

Common Challenges Among MSL Teams

We recently attended the 9th Annual MSL Society Conference live in Las Vegas, NV. It was one of our first in-person conferences since the start of the COVID-19 pandemic and we were relearning how to talk to people live rather than through Zoom.

As we attended panels and spoke to a lot of MSLs and Medical Affairs Professionals, we learned a lot about the daily struggles, both new and old, faced by MSLs. We brainstormed some ideas and discussed how to overcome these obstacles.

Throughout these conversations, there were three topics that seemed to come up time and time again:

1. MSLs would like to be involved earlier in the process of creating the product's marketing strategy
2. The desire to spend more time adding value rather than demonstrating the value-added to the organization
3. Capturing actionable insights

Importance of Involving the MSL Team Early in Strategy Creation

The COVID-19 pandemic has accelerated a trend already years in the making: reduced access to physicians. Both medical affairs and sales teams are getting fewer opportunities to spend time with physicians, and that means the time they do get needs to provide as much value to the physicians as possible. This is even more critical for product launches, especially for drugs with newer mechanisms of action where the market might not be as educated.

Typically, the marketing and medical affairs teams are brought in about 12-24 months in advance of the product launch. During their early interactions with HCPs, medical affairs obtain extraordinary insights that should be used as key inputs for the marketing strategy and product launch. However, there is a strong perception within the medical affairs community that the marketing and commercial teams tend to move too quickly early in the planning process, laying out the underlying strategy before medical affairs has had a chance to provide any feedback. This is not a new problem within the industry, where many product launches have been derailed because of preconceived notions of trying to reuse tactics that may have worked with another product launch.

A more progressive and effective way to approach strategy creation is by starting with medical affairs and allowing them to provide the initial insights that should inform the product's marketing strategy. Bringing the medical affairs team early into the strategic discussions after they have spoken to the KOLs could increase the probability of launch success. A study by Bain Consulting that looked at why 65% of product launches are failing to meet their forecast identified the big bang approach towards KOL development as a key contributing factor. The study recommended the use of broader physician and patient advocacy allowing to vocalize blocking and tackling for a higher degree of success.

Demonstrating the Value of the MSL Team to the Organization

It can be difficult for MSL teams to show the impact being made and quantify the value provided through the success of scientific communications and interactions. Many MSL teams report spending countless hours putting together dashboards and reports in an attempt to demonstrate their value. Time that could be better spent elsewhere, such as meeting with HCPs and KOLs. Furthermore, they are sometimes asked to do activities that they are not directly responsible for, such as facilitating meetings with clinical sites experiencing stalled clinical trial enrollment. These types of tasks are not typically in their job description and fall under Clinical Operations. MSLs find themselves facilitating tasks that benefit the overall organization's strategic goals.

This is an obstacle that has been faced by medical affairs and MSLs for as long as we can remember, and there are a few things that can be done to overcome this challenge, including:

- Creating a strategic framework and understanding key objectives

Interactions do not equal impact – let the sales team believe that fallacy. Successful medical affairs organizations are increasingly creating strategic imperatives for their organization that is informed by the organization's strategy and medical objectives. They are creating KOL engagement plans and approaching each meeting with outcomes in mind.

- Arming your MSL team with the right resources and tools

IT support for medical affairs in most organizations is anemic. The best they currently can hope for is a CRM tool like Veeva or Salesforce.com which are designed for sales teams with the mentality that interactions equal impact. This only contributes to further frustration as MSLs are now capturing insights into ill-equipped tools.

Many Med Affairs organizations that have leaders that are strategic tend to create these KOL engagement plans and manage them in Excel spreadsheets with varying degrees of success. Some are increasingly able to convenience their IT departments to help digitize this process, others are turning to specialized SaaS vendors like TikaMobile.

Making sure your medical affairs team has the right resources available to them and the right tools in place to effectively and efficiently do their job is critical. Even better if the system is created and optimized with Life Sciences organizations, and medical affairs specifically. The system should have the ability to create target KOL lists, key attributes like publications, clinical trial information, interest, etc., and tracking interactions and eMIRFs within the platform. Most platforms today have these capabilities, but also important is that the system allows you to develop a KOL engagement plan, track KOL development, and capture insights within the system.

If this platform has strong artificial intelligence (AI) capabilities, it will also have the ability to pull the data that is stored within your CRM system into actionable dashboards and reports that can be easily analyzed. This is where the systems really differ, as this will allow you to focus on adding value and spending time demonstrating that value you are adding.

Converting Interactions into actionable Insights and focusing on Outcomes

Capturing insights and acting on them consistently was identified as the biggest challenge by MSLs.

Approaching a KOL meeting with clear objectives and planning for it with clearly defined potential outcomes can be transformative. However, many organizations are not satisfied with the current processes being used to conduct meeting preparation. Most Medical Affairs professionals would agree that fewer engaging and high-quality interactions are typically more beneficial to an MSL than having many meandering interactions. But how to train the team and capture this in a repeatable way is a challenge.

This approach also has the added benefit of focusing the medical affairs team – allowing them to capture the insights with a clear idea on how they are helping with organizational imperatives. This approach makes insights more actionable.

Overcoming These Common Challenges

Although this is not an exhaustive list of all challenges faced by medical affairs teams, these are some of the most common topics you will hear being discussed at medical affairs-focused events. So, if your team is facing any (or all) of these obstacles, you are certainly not alone in your struggles. How you deal with and overcome these challenges is where companies and medical affairs teams differentiate themselves.

Are you facing these challenges? Contribute to the conversation – drop me a line at msharma at tikamobile.com.

About the author:

Manish Sharma, MBA

Manish is founder and CEO of TikaMobile, an enablement company focused on the medical affairs industry. He has a wealth of experience in medical device, pharma, and bio pharma product launches and is an expert in delivering the benefit of enterprise business intelligence to every level of the organization. He has been involved in executing and refining product launch strategies for clients in Urology, Orthopedics, Critical Care, Cardiovascular, CNS, and Oncology. His technique in converting a product launch strategy into patient, physician, and hospital centric mobile solutions have been successfully used worldwide by life sciences companies to drive higher HCP engagements.M

About TikaMobile:

TikaMobile, Inc. is leading innovations in cloud-based mobile and analytics SaaS solutions for the life sciences industry.

Dedicated to customer success, TikaMobile's real time recommendation analytics go beyond CRM to give medical affairs and field sales teams ongoing, actionable intelligence. TikaMobile's apps allow medical affairs teams to create KOL engagement plans, drive physicians on a development continuum and capture insights and outcomes. Our powerful, yet agile applications for Pharmaceutical and Medical Device organizations are easy-to-use, easy to deploy, and can accommodate companies of all sizes.

Promotability: How to Land Your Next Promotion

By karolina | March 2022

"Promotability" may be defined as one's suitability for being promoted. Is it your goal to obtain a promotion this year? If so, how suitable or promotable are you for that next step? Job-seekers and professionals often ask me what steps are necessary for advancement. I have broken my advice down to the always popular "Top 10" List. However, there is one VERY important concept to understand before starting this process. The idea of promotability requires being PROACTIVE. If you are seeking a promotion or trying to position yourself in your career, it is YOUR responsibility to make it happen. The more initiative you take, the better your chances are for future success. Consider these efforts an investment in your career and future self. TAKE ACTION.

Here are 10 things I recommend:

- **Decide what role you want next.**

The best advice is to think of this along with the terms of the title – what title or titles are you looking to pursue? Is this role in-line with your long-term goals, or will it get you to where you ultimately want to be? You also should look at this in terms of steps and what the progression may need to be. It can be tough since many people do not always know exactly what they want to do, so my advice is to seek clarity. Spend time doing research, talking to others in the industry, and seeing what aligns best with your long-term goals. What do you ultimately see yourself doing? It is important to answer this question first to set yourself on the right path.

- **Establish a timeline. How quickly do you want to get there?**

In your mind, what is the ideal time frame to make this transition into your promoted role? This requires being realistic and giving yourself ample time to get there. Be careful not to be too hard on yourself if it is taking longer than expected.

- **Update and UPGRADE your Resume/CV**.

Make sure your resume matches and aligns with the role or roles you wish to pursue. Make initial changes that show your experience and transferable skills line up well with these roles. BUT, it is likely that you may not be exactly where you need to be for this promotion. That's okay, your CV is a living, breathing document that you will improve, expand upon and update regularly to help position you for that next promotion.

- **Be VOCAL.**

Make your Manager and internal leaders aware of what your goals are so that they can help support and further develop you. It is likely that they could establish a development plan for you and offer additional responsibilities. UNLESS… you have no

intention of gaining that promotion internally. In that particular case, you still need to be vocal but with external sources.

- **Seek out mentors**.

An ideal example mentor would be someone possibly already in the role that could offer advice to help direct your course. Mentors are key and will offer insights as well as the direction you may not be able to obtain otherwise. It could be internal folks at your current company, but it could also be people outside your organization. A mentor is simply someone in a position to help you get to where you want to be. Internal, external…it may even be beneficial to have both perspectives.

1.Step up – Expand your role.

Start doing some of the things you may need to do in this role to showcase your capabilities. **For example:** A Medical Science Liaison that really wants to take the next step into an MSL Management role.

Ask yourself – what types of leadership- or management-related tasks can you add to your plate to build experience on this front? You can volunteer to get involved in hiring initiatives, volunteer to be a mentor, raise your hand for projects to assist leadership, etc. Try to grow your skills in other applicable areas (i.e. HEOR or the payer side, communications, writing/publications, conference team lead, etc.).

2. Solve Problems.

The very best way to stand out and get noticed is to be a problem-solver. Take notice of the pain points affecting leadership or your teammates. If you can offer your help and help in solving some of these problems, you will most certainly inch yourself closer to that next opportunity.

3. Network (Internally and Externally).

Spend time each week reaching out to colleagues and professionals in your space to build stronger relationships and grow your network. This should be done internally as well as externally. You never know who you may be able to help, and in turn, who you may be able to be an asset to as well.

4. Show Servant Leadership.

Find ways to “give back” to your organization and your team. Servant leadership is a philosophy built on the belief that the most effective leaders strive to serve others. Consider becoming a mentor to a younger employee or volunteer to help co-workers with their own projects. Be a trusted resource that others appreciate and rely on.

5. Showcase your GREATNESS.

What makes you great? What makes you special? What are you known for? Some may call them “core strengths;” others may see it as your personal brand. Put your best self and skills on display and others will invariably take notice. However, important to note, it is your responsibility to communicate your accomplishments in a tactful and subtle way with those that need to notice.

To conclude, increasing your promotability is simply a matter of increasing your professional visibility. Again, this is about being PROACTIVE in your career journey. It requires outreach, initiative, creativity, extra effort, and of course, communication. It is about connecting with the right people internally and externally, while also offering assistance and mentorship where needed. This is about standing out, but also being able to communicate your accomplishments in a constructive way. One of my favorite quotes is, “Slowly is the fastest way to get to where you want to be.” Keep that in mind as you plan the next phases of your career and take action each day/week/month to get there.

Good luck on your journey!

About the Author:

Tom Caravela, BA

Tom Caravela has 30 years of pharmaceutical industry experience and is the Founder and Managing Partner of The Carolan Group and Host of the MSL Talk podcast. Founded in 2002, The Carolan Group is a leading pharmaceutical and biotech search firm specializing in Medical Affairs and Medical Science Liaison recruitment. Tom is responsible for leading a team of expert recruiters and account managers in client expansions for various levels of field-based and in-house Medical Affairs professionals including Medical Science Liaisons, MSL Leaders, Managed Care/HEOR Liaisons, Medical Directors as well as various other medical and clinical affairs roles. With almost 3 decades of pharmaceutical industry experience, Tom is a frequent speaker and Medical Affairs Consultant for clients, advisory boards, and industry meetings. His strategic interests focus on hiring, retention, and career development for the field-based MSL role.

From Patient Care to Medical Science Liaison: One Physician Assistant's Journey

By karolina | March 2022

My journey as a Medical Science Liaison began about a year ago. To give you a little background of how I transitioned into this field, let me share with you my own personal story.

I want to begin by saying that I have a unique journey, and I always believe that every step we take in our life is meant to get us to wherever the next step will be. Sometimes it's hard to see that when you're in the middle of something that may not be so easy, but looking back I now understand why I was put in that place at that specific time. I say this because I *know* there are many others out there that likely have similar feelings that I share here.

Always remember that life is a journey–It's not a sprint, but a marathon.

I majored in Biochemistry in college and was originally pre-med, but during my senior year I did a thesis and I fell in love with research. I loved the molecular detail and felt I could help patients at a different level this way than through my original pre-med plans. After graduation, I attended a Ph.D. program in Molecular Medicine at Wake Forest University. I spent 5 years working on research focused on cardiac regenerative medicine. During this journey, I met the most wonderful friends, colleagues, and mentors that I *still* keep in touch with today. I gained such valuable experience and knowledge at the molecular level of science and there were many parts of this journey that I loved.

However, there was still something missing. I always had this desire for taking care of patients, and I thought that this would fulfill that for me at the research level. During my post-doctoral fellowship, I started searching for something else that would give me that patient care interaction and I discovered the physician assistant career. It sounded like exactly what I wanted. I attended Wake Forest PA program and graduated with my Masters in Medical Science and became a Certified Physician Assistant! Two weeks after taking my certification exam, I had my first child.

For those of you who are career-driven working mothers, so much emotion develops once you have children. It's extremely hard to balance the two and your perspectives change dramatically.

I have had a few jobs in the past 10 years as a PA. My first role out of PA school was in a leadership position. I was the Director of the Clinical Research Unit at Wake Forest Baptist. I led a team of nurses, lab technicians, nutritionists, clinical research

coordinators that worked together to help run the clinical trials for the academic physicians. This job was quite fulfilling but about 10 months into this role, I received a phone call from a previous mentor about an opportunity that I couldn't pass up. I had this incredible opportunity to open and run as a solo provider a family medicine practice in a small town, about 30 minutes away from any other healthcare. Within the first 2 years, we expanded exponentially. After 2 years, we hired an MD on site with me, and together we continued to take care of patients. I honestly loved my patients. I still keep in touch with many of them today.

Unfortunately, what I realized after several years as a family medicine PA was that it was wearing me down.

The 15-20 minute patient slots, SO many patients to see every day, the never-ending charting, the constant in-basket messages and so many emotions involved. I also had a second child during this time. Even though I truly loved taking care of my patients, I found that this job was taking a toll on every aspect of my life and I knew I had to make a change.

The last 2.5 years as a PA before I transitioned to this MSL position, I spent time as a PA in Cardiology. I had an amazing group I worked with. I took care of patients both in the clinic and the hospital. However, what I found is that even with this position in a specialty, although it was much more manageable than my previous family medicine position, it was still so hard as a full-time working mom. The 10-plus hour days, weekends, not really much flexibility, the charting, the stress of patient care, and a lack of advancement opportunities within the PA position.

To be honest, I have always wanted to be in medicine taking care of patients. I wanted to save lives. I wanted to be the person that takes care of everyone. It sounds cliche, but it is true. Healthcare, though, is *not* for the faint of heart. Before the pandemic, and even more so now, the healthcare industry is one of the toughest fields because there is so much emotion involved.

As I said in the beginning, I feel like every step in your life has a purpose to get you where you are supposed to be; to me my 10 years of Ph.D., research and 10 years of patient care and the people I met along the way led me to the MSL career.

My transition developed from several factors. During my Ph.D. I met one of my greatest friends, who started his career as an MSL years ago and now is one of the leaders in his company. For years, he consistently told me to consider this incredible career, but despite his recommendations, the thought of leaving medicine full time was somewhat terrifying. In addition, I'm part of a Facebook group called PA Moms where many other people express similar feelings looking for other non-clinical opportunities. I have met the most wonderful people through this group and connected with so many more on Linked In. I am *extremely* grateful to each person that took the time to share their personal story with me of how they made this transition to the MSL field.

Networking was key to my transition. Your network becomes your family.

This was how I met the most amazing manager, Leona Hamrick, DMSC, PA-C. She had just joined Biodesix and her role was to grow the Medical Affairs team. We had just connected informally a few weeks prior through LinkedIn when she messaged me about an opportunity on the East Coast. I went through the formal interview process, did the presentation in front of the company, and then she offered me the position!

My advice to those of you looking to make this transition from patient care to the MSL world is you *have* to go outside of your comfort zone. You have to build your network. Create that Linked-IN profile with the keywords. Set alerts for jobs. Get help with that resume and update it. Apply! Read Samuel Dyer's book "How to Break Into Your First Role". Attend the MSL society meeting. Join the MSL society. Read these journal articles. Listen to these MSL Talk Podcasts.

For those of you clinicians looking to be an MSL, definitely do not undervalue your experience as a clinician. You are an *excellent* candidate for these MSL positions! You have this ability to listen and understand the patient *and* the provider's perspective. You can provide great value to this role as an MSL.

My last piece of advice for those clinicians wanting to transition to the MSL field is to be patient because when the time is right it will happen.

Author:

Dawn O'Reilly, PhD, PA-C

Dawn O’Reilly is a Medical Science Liaison with Biodesix. She lives in North Carolina with her husband, 3 children, and their spunky golden retriever. She is passionate about healthy living, playing outside with her kids, and she loves to travel.

The MSL as Agent of KOL Personalization

By Jessica Wong, MBA | March 2022

The MSL role has become more strategic as the frontline agent for KOL engagement. KOL expectations have also increased in terms of what they are looking for from biopharma partnerships. The trend toward personalized engagement has accelerated significantly due to rapid digital transformation and hybrid engagement advancements in recent years across life science companies. Personalized KOL engagement is no longer a novel concept, it represents a new norm for medical affairs and MSLs. MSLs are uniquely positioned to deliver personalized medical and scientific information to KOLs. We will review relevant frameworks and capabilities for MSLs to effectively deliver personalization that aligns with each KOL's unique needs.

Personalization is all around us. Many industries that touch our daily lives have long focused on advancing people, technology, and process investment to enhance engagement experiences with each of us. In Life Science, commercial teams have steadily increased their efforts in Healthcare Professionals' (HCPs) personalization over the last decade. Medical affairs functions have also begun to consider more tailored scientific exchange with Key Opinion Leaders (KOLs) as an emerging trend.

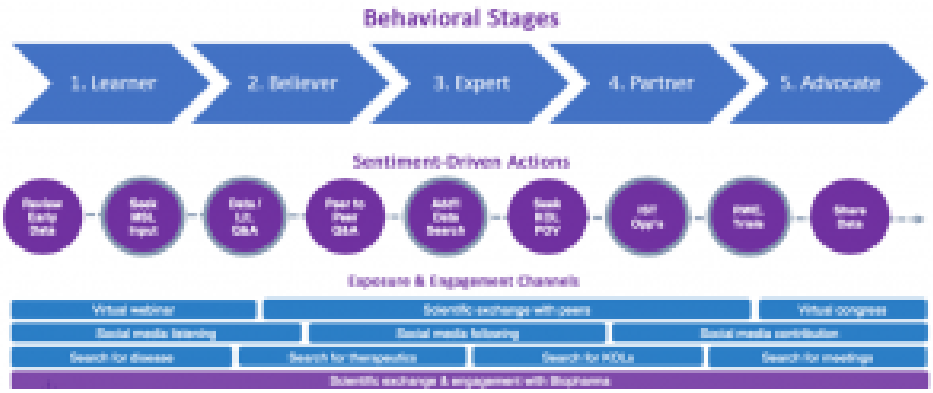
Medical Affairs and Medical Science Liaisons (MSLs) are primed to lead and execute on scientific exchange personalization with KOLs. They are the first line of contacts representing Life Science in this regard. They are coordinating across siloed functions while keeping KOLs' unique scientific needs top of mind. They must juggle everything with grace, clarity, and agility, which is a major responsibility and may require a more modern support model to supercharge critical personalized interactions effectively.

To create this new foundation for MSLs to deliver personalized scientific exchange effectively, we first need to define it. What is a personalized scientific exchange? It is the tailored delivery of scientific communication and engagement to meet the unique needs of each KOL.

Sometimes that is the outreach, or the follow-up touchpoint(s) surrounding the scientific exchange. Other times it is the exchange itself, requiring MSLs to slim down and customize from large sets of data and files down to snippets compliantly. This

allows MSLs to respond to unsolicited questions and keep convenience and timing factors in mind.

To understand what/how to personalize, let's review how the MSLs can better appreciate unique KOL needs empathetically by applying the below framework.



Source: December 2021, Alucio, Inc.

1. Who are they? Where are they along the scientific learning journey?
2. What are they doing proactively to learn and gain new knowledge? Who are they reaching out to? Do we have this information?
3. Are we there along the way as KOLs gain exposure and seek information across various channels and resources? Are these touchpoints supportive, useful, and personalized?

Once we know what it is we want to achieve with personalized KOL interactions, there are important success factors to help set up and execute these capabilities. Such factors span from individual soft skills application, customization tools, and services, to modernizing foundational support in data training and technology platforms.

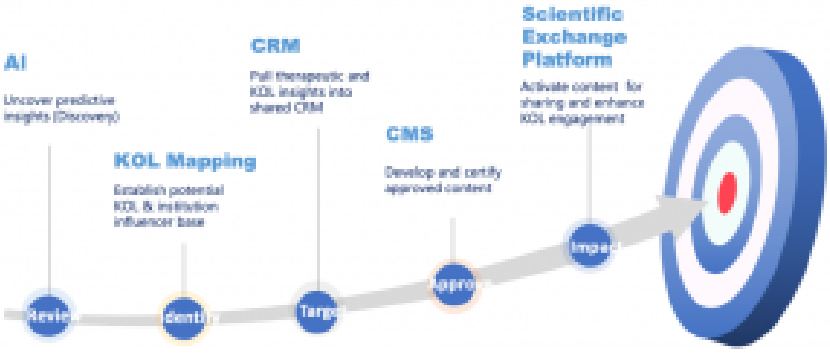
Source: December 2021, Alucio, Inc.

For each of the success factors, below is what good looks like for an empowered MSL.

1. I can easily access my KOL's behavioral stage, knowledge level, channel preferences, and scientific questions longitudinally to help me plan for the engagement.
2. I am equipped to apply active listening and an EQ lens to help observe and probe further based on their starting questions, allowing me to address them appropriately.
3. I have readily available and approved modular content pieces for external use purposes, I can assemble, present, and share with ease in a visible, compliant, and trackable manner.1
4. I can gather insights in various modes as I exchange with the KOL within the engagement platform itself without impacting my meeting rhythm. These insights are shared internally to help inform content creation strategy and market planning decisions.[1]
5. I have access to deeper training on expanded sets of content that I need to be well-versed in (or be made aware of).
6. I utilize a single, simple, easy-to-use content activation and engagement platform to facilitate scientific exchanges that are designed for me and my medical affairs team. It allows me to personalize my interactions that suit my

KOL's exact needs.[1]

Delivering on these new use cases requires a modern technology platform starting with predictive insights and KOL mapping, seamless feeds to and from enterprise CRM/CMS systems, that ultimately feed the "next-gen" scientific exchange platforms that effectively and efficiently enable personalized KOL engagement. [1]



Source: December 2021, Alucio, Inc.

In conclusion, field medical remains a critical function with growing importance given the transformations in KOL engagement and increasing personalization expectations. It's time to evolve and advance related capabilities for MSLs to be empowered to better tailor to and meet KOLs' unique needs. By investing and modernizing such capabilities, medical affairs can deliver more impactful value to itself and to the broader organization.

As an example, Alucio's flagship product, Beacon, is a multi-channel content management and HCP engagement platform built specifically for MSLs and optimized for personalized scientific exchange. It is a Medical Affairs-centric solution and has a robust analytics dashboard built-in on content use/adoption metrics by MSLs and KOLs.

Authors:

Jessica Wong, MBA

Jessica Wong is a seasoned marketer with >16 years of experience in the Biopharma industry across both US and global markets. She has held successive leadership positions and advised various organizations in launch strategy, digital health & scientific communications – in the context of product development and commercialization.

Jessica has implemented numerous mission-critical and user-centric services to enable HCP disease and therapeutic education, as well as patient treatment access/adherence support. The majority of these programs are in the oncology and rare disease areas, powered by robust digital analytics and multi-channel engagement.

Before joining Alucio, Jessica worked for Roche Pharmaceuticals, Genentech, Omnicom Advertising/Digital Agency Network, closer look digital & relationship marketing agency, and Accenture. She has an MBA in Strategy/Finance from the University of Chicago, and a BA in Economics from the University of Illinois at Urbana-Champaign.

Dave Gulezian, MBA

Dave is a successful entrepreneur with 20+ years of executive management experience in innovative, technology-based companies – including the last 15 within the life science industry. His background combines deep strategy, technology, sales, marketing, product launch, and operations expertise.

Before Alucio, Dave founded and led Viscira, a provider of digital marketing solutions and software applications for the life science industry. The company became a leader in the space, working with 22 of the top 25 pharma and biotech companies in the world. In early 2016, he led the successful acquisition of Viscira by WPP – the world's largest marketing communications company.

Dave has personally built and managed business relationships with many of the market leaders in the pharmaceutical and biotech industry, both in the US and globally, including AbbVie, Amgen, BioMarin, BMS, Exelixis, Genentech, Gilead, Jazz Pharmaceuticals, Novartis, Pfizer, and Roche.

Accelerating Medical's Digital Awakening

By karolina | March 2022

Digital maturity is essential for scientific engagement amid more complex therapies and spheres of influence.

Nearly six in 10 life sciences products hitting the market are in specialty or rare disease categories.[1] As scientific complexity grows, healthcare professionals (HCPs) and key opinion leaders (KOLs) seek science-based education via webinars, virtual medical conferences, and online journals as opposed to traditional promotional materials.

Medical teams have evolved beyond reactive sources of medical information to become health experts' trusted advisors. They're expected to distill evidence and data in meaningful ways to support better patient outcomes. Especially as new stakeholder groups emerge and the industry leans more on digital, medical teams must quickly adapt to changing needs and channels.

A new framework for scientific engagement can help teams effectively navigate today's complex, fast-changing medical landscape––spanning digital opinion leaders (DOLs), social influencers, payers, and patients. Several foundational capabilities are key to sustainable digital transformation, including customer intelligence, omnichannel engagement, and centralized medical content.

Digital's growing influence

In the last two years, there's been a significant uptake in the use of digital and multichannel engagement by medical teams, with over a quarter of a million virtual meetings hosted by Veeva's medical customers and their stakeholders. HCPs spent 40% more time in these meetings with medical reps than those with sales reps. Interestingly, 42% of those virtual meetings included three or more participants, as compared to the traditional in-person approach of a single primary traveling rep.[2]

The adoption of digital technologies is enabling medical teams to gain deeper insight into their customers' preferences and behavior patterns. They now have visibility into what's been communicated, a better understanding of which messages resonate, and which emails have higher response rates.

Personalized emails from medical teams, for instance, were opened 47% of the time, 11% higher than emails from their counterparts in commercial.[3] This increase in meaningful scientific interactions helps guide more impactful next best actions for medical science liaisons (MSLs).

“A sophisticated and integrated CRM solution is absolutely essential,” said Nick Warwick, chief medical officer at Advanz Pharma. “It helps you foster a two-way dialogue and capture valuable real-time insights from discussions in the field.”

As digital adoption continues to grow, HCPs and KOLs expect a more on-demand relationship with the pharmaceutical industry. This means shifting some focus away from activities that communicate with large audiences only through physical events or virtual congresses. Instead, value-added digital content can meet experts where they are across social and scientific channels.

Together, these dynamics expand the ecosystem of scientific influence, requiring medical teams to develop relationships with new stakeholders, embrace social media more fully, and create digital MSL roles. To stay ahead, medical teams need to advance their digital maturity and implement it as part of their ongoing engagement strategy.

Figure 1: 2021 Global Medical Engagement Trends, Veeva Pulse Metrics

Figure 2: 2021 Global Medical Engagement Trends, Veeva Pulse Metrics

A digital foundation for next-level scientific engagement

While medical teams have made great strides in digital adoption, this alone won't guarantee success. Teams need to rethink how they orchestrate scientific engagement and establish a 360-degree view of all their activities with stakeholders.

Here are five key initiatives medical organizations can implement to maximize their impact.

1. **Start with customer intelligence.** Modern data-connected platforms help MSLs navigate stakeholder networks and gain deeper insight into KOLs, emerging influencers, and their sphere of influence. This enables teams to understand experts' interest areas and preferences, helping them shape discussions around relevant treatment pathways.
2. **Develop a customer-centric, omnichannel engagement ecosystem**. KOLs and key stakeholders don't want to be flooded with medical information across all channels at once. What's more effective are timely, relevant interactions. By strategically orchestrating omnichannel engagement, medical teams can create highly personalized and seamless experiences for customers.
3. **Drive impactful business decisions with actionable insights.** Medical teams tend to rely on siloed systems. This limits information sharing between functions and tracking of scientific and customer objectives. By collecting and exchanging strategic insights across the organization, teams can better focus their resources on activities that drive results.
4. **Streamline and centralize medical content.** To ensure consistent and compliant distribution of scientific communications across channels and geographies, medical teams can adopt a single platform with which to create, review, and distribute scientific materials. Doing so brings visibility along the content supply chain and drives efficiencies that speed the delivery of information to key experts.
5. **Achieve digital excellence through transformation.** It is crucial for medical leaders to maintain a relentless focus on driving a foundation for digital excellence. This means looking holistically at the data, processes, and talent needed to increase agility and foster a digital-first mindset across medical affairs.

"When thinking about digital requirements for medical teams, it is not just about choosing a framework or system that fills a short-term need," said Warwick. "Instead, companies should ask how these new technologies and processes will complement and amplify medical teams' long-term strategy and objectives."

Medical teams that innovate and advance their digital-led strategic agendas will translate priorities into actionable plans that better meet customer needs. There's no doubt––digital will be a key enabler for elevating and demonstrating the value of medical affairs in the years ahead.

Reference

[1] "FDA Shows Sustained Support of Rare Disease Product Development During the Public Health Emergency," U.S. FDA, March 1, 2021.
[2] 2021 Global Medical Engagement Trends, Veeva Pulse Metrics
[3] 2021 Global Medical Engagement Trends, Veeva Pulse Metrics

Author:

Louisa Peacock

Louisa is the Practice Manager of Veeva's European Business Consulting group in Medical Affairs, focused on realizing value across Medical Affairs and transforming how Medical operates. She is experienced in delivering complex strategic and operating

model transformation projects. She holds a ten-year career at Accenture and EY working with Merck, BMS, AZ, Takeda, UK Department of Health, and others.

Best Practices: MSL and Commercial Partnership

By karolina | March 2022

This article is aimed to discuss some methods of developing and cultivating effective relationships with your commercial partners. I'll go through a few major topics and provide personal examples of my approach. I'll mention the disclaimer that regulations are not the same at all companies, and company-specific guidelines should be used to assist these topics.

Compliance

I wanted to tackle this topic first because it is single-handedly the biggest pain point in the medical-commercial partnership. There's no easy way around it. It exists, and we have to figure out the best way to work together compliantly. Truth be told, compliance is an ongoing conversation that should take place between the medical science liaison (MSL) and commercial representative. Every person is different based on how 'black and white' they see the guidelines, and situations are not always so clear-cut.

Any time a situation blurs the lines of compliant collaboration is the perfect opportunity to have a discussion with your representative. Examples may look something like, 'In the future, if this happens again, how would you like to have this conversation?' Or, 'Here are my expectations for how and what we can communicate. How does that align with yours?' These are completely appropriate questions to ask and will only help build trust between the rep and MSL. The goal is to communicate and set expectations to allow for mutually, beneficial relationships.

A piece of advice that I tell my representatives is anything that you are unsure of or is borderline compliant, make a phone call. Absolutely nothing in writing. No forwarding of emails. No texts or voicemails with specific information. Just a simple, 'Hey, I'd like to chat when you get a moment, call me'. That phone conversation can prevent any potential non-compliance before it happens and give the opportunity to have a discussion on expectations.

Communication

Now that we have that out of the way, let's bridge to a topic frequently mentioned already, communication. If I can think of one word to best describe communication in the MSL commercial partnership, it's 'open'. I strive to have every single rep feel comfortable and confident to talk to me at any time, about anything. During this year's plan-of-action meetings, I made the point to have this discussion with my commercial partners. I told them not to feel like they are bothering me because I feel the same way when I call 14 times a week. Now, this was a slight exaggeration, but I'm in my first year in this territory and my reps know it way better than I do. I wanted to give them the green light to always feel free to reach out, which I followed very quickly with my preferred method of communication.

Yes, you guessed it. You should communicate how you prefer to be communicated with. Have the conversation about each other's preferred method whether it's email, text, phone, or any combination. For me, I prefer to text. I'm a younger millennial and dread spur-of-the-moment phone calls. It gives me anxiety. Saying that I realize that's not the best method for those delicate situations I mentioned before. Text me first with, 'Hey, are you busy, I'd like to chat, giving me time to prepare. I told them this and they laughed, but now all text me before. Be open with how you like to communicate, and your representatives will do the same to you.

Share Insights

The last topic I want to touch on is the flowing exchange of customer-specific information that can help guide interactions. The MSL and rep should have frequent touch bases on providers within the territory when account planning and customer-specific insights can be shared. More immediate exchanges should occur after interactions if an opinion leader says something intriguing. This exchange goes both ways from an MSL to a representative and vice versa. Of course, don't forget about the first topic of compliance and ensure information exchange across medical and commercial does not go outside of your company-specific regulations. An example would be if a provider was very much interested in the safety profile of a specific product or drug class, or if a provider has had a particularly hard time with access recently. Remember, the relationship between you and

each of your representatives will be unique, so communication is key.

These three topics do not fully cover every aspect of the perfect medical commercial relationship, but they are great places to start. After utilizing these techniques and methods, I have been able to cultivate and strengthen my relationships with my representatives. Building personal relationships with your commercial representatives will create trusting, open, and compliant communication.

Author:

Matt Kolenda, PharmD, MBA, BCPS, BCCCP

My name is Matt Kolenda and I graduated from pharmacy school in 2017. Following graduation, I completed a residency at Cleveland Clinic Hillcrest Hospital and then accepted a position there afterward. I worked for 3 years as a clinical pharmacist specializing in critical care while obtaining my MBA. In May of 2021, I graduated with my MBA and started in my current role as an MSL with Janssen.

Is Your Product “Cost-Effective”?

By karolina | March 2022

How does your health technology (e.g., drug, vaccine, device, diagnostic) compare to competing alternatives in the same therapeutic area? Is it considered **cost-effective**? Cost-effectiveness focuses on maximizing health benefits for a given budget. It does *not* simply indicate the *least expensive* or the *most effective* alternative. There are 5 common scenarios where a health technology is deemed cost-effective.

Cost-Effective: 5 Scenarios

Compared to the alternatives, the new technology…

	Cost	Benefit
1.	Less	More
2.	Same	More
3.	Less	Same
4.*	More	More
5.*	Less	Less

**Trade-off: Is extra benefit worth extra expense?*

The first three scenarios are straightforward. Compared to the standard of care and other alternatives, *your* health technology may either (1) cost less with more clinical benefit, (2) cost less with the same benefit, or (3) cost the same with more benefit. The next two scenarios indicate a **trade-off**, wherein your technology may (4) cost less with less benefit, or (5) cost more with more benefit.

Understanding how trade-offs can be cost-effective is not intuitive, so consider this example. Imagine that you have a choice between buying one of two cars. Both cars are identical in every way, except one includes a seat warmer option and costs more. Is the extra benefit worth the extra cost? Or, on the flipside of the same coin, is less benefit worth the lower cost? There is no correct answer. In trade-off scenarios, the decision maker's **willingness to pay** determines which option is cost-effective. A "good value for the money" might depend on whether you live in a snowy climate or in the desert. Is the car with the seat warmer worth $5,000 more to you? What if it cost only $1,000 more? What if it cost only $5 more? Clearly, there is some point between $5 and $5,000 where most of you would pay more for more benefit, called the **willingness-to-pay threshold**.

This example illustrates two important concepts. First, when presented with the exact same cost-effectiveness data, different decision-makers (i.e., payers) can come to different conclusions because they have external considerations (e.g., budgets, population needs) that they bring to bear on the decision-making process. Second, cost-effectiveness analysis is a tool that packages and distills information from multiple sources to facilitate decision making – like using Consumer Reports data to buy a car – but does not, *cannot*, make the decision for you.

Now imagine that you are comparing two drugs: Drug A is the standard of care (**comparator**), while Drug B is new to the market and recently approved for prescribing. Let's say the *overall cost* of Drug A is $14,000, which includes the cost of a course of the drug itself, the cost of treating potential side effects, and the cost of treatment failure. Let's also say that the *overall effectiveness* of Drug A is .60, or a 60% chance of treatment success after accounting for the chance of side-effects and failure. Drug B has an *incremental* overall cost of $1,000 more (i.e., $15,000) and overall effect of .15 more (i.e., 0.75). In a real cost-effectiveness analysis, you would be sure to include all relevant comparators, perhaps also technologies C, D, E, and so on.

These cost-effectiveness results can be displayed on a graph called the **cost-effectiveness plane**. The vertical line represents overall costs, while the horizontal represents overall effectiveness. Drug A, the standard of care, is at the origin of the graph. Any health technologies plotted in the upper half of the graph are more costly than Drug A, and anything in the right half of the graph indicates more effectiveness than Drug A.

In this way, each quadrant represents one of four possible results. We can call these the northeast, southeast, southwest, and northwest quadrants. Drug B appears in the northeast quadrant because it costs more and has more effect than Drug A, representing a trade-off scenario. In which quadrant would a new technology appear if it *cost more* and was *less effective* than A? That's right, the northwest quadrant, which is called **dominated**. In this case, we would favor the standard of care, Drug A, and automatically reject any new technology that falls into the northwest quadrant.

What does it mean if a new technology falls into the southeast quadrant? Correct again! The new technology costs less and is more effective than Drug A, called **dominant**, and would be automatically accepted. If Drug B ended up in either the northwest or southeast quadrants, we can stop right there, no further analysis is needed. The decision is clear. But this rarely happens.

Most of the time, technologies fall into the trade-off quadrants, requiring further consideration. And as you have now learned, Drug B may be considered cost-effective depending on whether it is considered "good value for the money". To decide if it is a good value, it must be compared to the threshold, representing the maximum amount that the decision-maker is willing to pay.

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