Medical Affairs' Data-Driven Rise to Prominence

By Pratap Khedkar

As the pharmaceutical industry continues to stack up scientific breakthroughs, there's a growing need for experts within pharma organizations who can articulate deep disease knowledge, link clinical results to outcomes, and demonstrate product value. As luck would have it, a small department that's well suited to the task has steadily been building its capabilities and expanding its reach into new areas. Medical affairs, once a little-known entity, is making its mark on the industry, but if leveraged properly, its impact could be even greater.

Consider the current state of pharma: Data is the new organizational currency. The level of scientific complexity within pharma portfolios is increasing. Pharma reps' access to their physician customers continues to decrease, and new customer and stakeholder groups are gaining influence over purchase decisions. The list goes on, but suffice it to say that, as dynamics continue to shift within the pharma industry, there's an opportunity for medical affairs teams to step up and play a data-driven, collaborative role between development and commercial—and beyond.

To gain a better understanding of what medical affairs teams are accomplishing—and what's holding them back—I reached out to my colleagues Sarah Jarvis and Dean Hakanson, leaders in the medical affairs space at ZS, for their perspectives. Here's an excerpt from our conversation.

Q: Medical affairs has advanced, at least in the physicians' eyes, in terms of credibility and value, and is maybe even becoming more important than commercial. What has driven this enormous change in the profile, importance and impact of medical affairs?

SARAH JARVIS: It's the customers—the doctors, in particular—who are driving this trend. The complexity of new products coming to market and the need to have an open and non-promotional dialogue with someone that they can really trust is driving a lot of the growth. Medical science liaisons (MSLs) are the field force in medical. They're still getting 30 to 45 minutes with their physician customers, and many of these physicians are KOLs and often top investigators. Compare that to commercial roles, which usually just get a handful of minutes with the doctors, maybe.

DEAN HAKANSON: Another key is that medical affairs can help an organization's development arm overcome two hurdles to patient access. The first is the regulatory hurdle that everyone thinks of and the second hurdle is reimbursement, which is often poorly addressed due to its complexity. Medical affairs now has a huge role in providing strategic input to early trial design to the development organization, ensuring the creation of a data package for phases I to III that is clinically meaningful and in line with payers' needs, while simultaneously tackling that first hurdle for approval.

Medical directors must prioritize the insights gathered in the field by MSLs, interactions with global KOLs and competency with published literature in order to drive early- and late-phase data generation strategies. They're also helping to overcome the reimbursement hurdle by running late-phase trials and evidence-generation activities within medical that address data gaps. This includes phase IIIb to IV clinical trials, investigator-initiated trials and real-world evidence.

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Q: From your perspective, is medical affairs frequently being seen as a link between R&D and commercial? Are the people in medical affairs in most pharma companies equipped to take on the challenge, or do you think that it's going to be a bit of a tough ask?

SJ: Medical affairs should absolutely be viewed this way but often still isn't. Medical plays a key role in bringing information back to development and coordinating appropriately with commercial in the field with customers. But in many organizations, compliance concerns have created huge firewalls within these groups that make any collaboration, but especially medical-commercial collaboration, difficult at best.

DH: Compliance must be respected but not used as an excuse to silo. Companies are often fearful of regulatory repercussions and eschew collaboration altogether. But unclear siloes are riskier than informed collaboration.

There are a couple of companies that are looking at structural ways to overcome that fear factor and cultivate a collaborative spirit across the development, medical and commercial organizations. To encourage appropriate collaboration at all levels, an organization's leadership needs to drive this change. Companies must continuously assess compliance policies and provide training throughout the organization, not just the management team. It's too easy to hide behind "compliance walls" when teams and managers don't understand the policies and guidelines that affect collaboration.

SJ: I completely agree, Dean. On top of that, external pressures are set up against them. We've worked with more than 75 different medical affairs clients and see this across the industry. There's a true fear around the optics of what they do because those in field medical live day in and day out in the gray space of off-label discussion. That, by definition, is their job. People want to do the right thing, and they are doing the right thing in almost all cases, but they're so worried about what could be seen as doing the wrong thing that, understandably, the easy way out is to say no to almost all collaborations—especially with commercial.

Can the individuals within medical affairs actually be the right people to make this change? That's a tougher question to answer because I see such variability in leadership within medical affairs. Some have both the clinical and business acumen needed to make it work. Others don't.

DH: Typically, in small companies, the job becomes easier because everyone is accountable. And it may seem small, but it's

not "someone from commercial." It's Joe from across the hall. It becomes easier because it's more personal and those boundaries are easier to break down. Taking the time to "get to know each other" and understand challenges faced by other people in the company opens staff up to collaboration and reveals opportunities to help each other that were unknown prior to real discussion. When cross-functional teams understand the challenges of their colleagues, we now recognize that these teams have become "bilingual."

Q: For someone in medical affairs, is business acumen the ability to work with a cross-functional team? Is it the ability to understand what a doctor community needs? What exactly would "business acumen" mean in this context?

DH: Business acumen here means the ability to lead organizations, both internally in a cross-functional, collaborative way and externally to meet customers' needs. Many medical affairs leaders can lead large organizations, but those who struggle to build a culture of collaboration aren't "bilingual" and often are too academic in their approach. Developing similar skill sets across various functions of the organization—especially the development and commercial teams— nurtures mutual respect, and helps individuals make decisions that enhance collaboration and productivity. For example, executive-level communication skills and knowing how to have influence when you're not in a position of authority are important components of advanced business acumen regardless of your role.

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For collaborative initiatives to have a lasting foothold, senior leadership must be willing to be involved in the initiatives and make significant changes to the organization. One way to do that would be to create clear, shared objectives for the teams, providing a unifying goal that fosters collaboration. This type of "enterprise" thinking enables siloes to be reduced and engenders a sense of commitment to the broader organization.

Q: A large part of this job is coordination, meaning that medical affairs has to coordinate to some extent with commercial, even though there are risks there, and with development. Thinking about the profile of workers who are typically hired for medical affairs roles, is it time for a change? Does HR need to take a fresh look at who is best suited, and do we need slightly different competencies, not just deep expertise?

SJ: It's definitely a sensitive topic. The three key elements that you want in field MSLs are the same three key elements that you need internally (though they vary slightly): scientific acumen, communication and business acumen. The first absolutely is scientific acumen. In the field, these folks are going toe to toe with true thought leaders, and they're getting 30+ minutes with them in each interaction. They have to be able to go deep on the science.

DH: And in the headquarters, leaders are driving evidence generation, which is the content for MSLs to communicate and to meet the regulatory and reimbursement hurdles to achieve patient access. Rigorous scientific acumen is table stakes. In fact, many of the leaders in medical actually come from academia or clinical research as investigators. However, to achieve a competitive advantage, medical directors must go beyond the table stakes of scientific rigor and possess the industry knowledge that's essential for an "integrated product strategy."

SJ: Exactly. On top of the strong scientific acumen, those in field roles have to be able to communicate all of that deep science, figure out their customers and tailor their messages appropriately to build meaningful relationships and gather customer insights. They can't have the same conversation with an integrated delivery network decision maker and a key opinion leader.

DH: In-house medical leadership must also recruit, hire and develop credible, industry-expert physicians who can drive corporate objectives through successful collaboration. They need to be able to communicate with cross-functional colleagues, as well as KOLs, in ways that create value.

The third big piece is business acumen. We talked about it before, but in the field, it's all about customer centricity. Field medical leadership is placing newfound importance on this skill. Our latest medical affairs outlook report found that nearly a quarter of all training time in 2018 was spent on customer centricity initiatives.

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SJ: That's right! The problem is that if you think about those three areas and core skills, it's difficult to find someone who's really good at all of those things. There's an opportunity for the industry to consider rewriting the medical playbook with more of a partnership mindset.

Q: Another thing that we're seeing is a talent shortage. You've mentioned to me in the past that some companies are hiring MSLs on a part-time basis, which may or may not lead to eventual employment. Where is this trend going in the long term?

SJ: There has been huge growth in field medical. The problem is that if you read any job description for an MSL, there is almost always a requirement of three to five years of experience working as an MSL! Well, that quickly becomes a dwindling pool of people just jumping from company to company, so what we're seeing is a bit of a "star war" around gaining talent in the field medical role, and the result has been a big increase in salaries for MSLs.

A recent article showed that MSLs are now the highest-paid non-executive role in pharma, and in our own outlook report from 2018, we found that it takes an average of four to six months just to hire MSLs. We've seen that grow in two different ways.

One is the contract field forces. Companies like The Medical Affairs Company and Syneos Health have contract MSL teams. That's one way, and the other is the Accreditation Council for Medical Affairs, which is trying to establish accreditation for MSLs. In the future, it may well become the norm that there's a standard beyond just having an M.D., Ph.D. or Pharm.D.

Q: As medical affairs teams continue to adapt to the changing needs of a complex healthcare climate, how have field medical roles changed in response?

DH: When we talk about field medical, there are two primary roles: One is the traditional MSL, and the other—which certainly all big companies have, but they almost always have different titles—is essentially an MSL who goes out to payers. They're meeting with different audiences and engaging in a different way. Payer MSL teams typically are cross-portfolio and focused on the overall value of the product, whereas traditional MSLs are therapeutic-area-based and focused on KOL customers who rely on them for access to unbiased product information— whether it's on- or off-label. From a scale perspective, if you have 100 MSLs, you probably have somewhere south of 10 payer MSLs.

One recent trend is to upskill all MSLs to be able to communicate value. This trend is driven by KOLs adopting a similar definition of value as the payers. The spectrum of data includes not just pivotal clinical trials for regulatory needs but more data relevant to the practice of medicine. How do RWE and health outcomes play into clinical guidelines? Patient-reported outcomes are key to patient centricity and physician adoption. Healthcare financing is top of mind for KOLs and comparative effectiveness, becomes a

driving force. KOL adoption of newly launched products is a powerful lever for patient access, which requires all MSLs to understand and communicate a broad spectrum of data.

Q: What does the medical affairs function look like in five to seven years? Is it very different? How will it be perceived by the rest of the healthcare system and the doctors?

SJ: You want us to get our crystal balls out, huh? In all seriousness, predicting what this will look like a decade in the future is hard, but there's a real need for a center of excellence type of approach, especially for customer engagement in the medical affairs space. One example that I always give our clients is, if you ask me for the weather in Uganda, I can give it to you in under a minute, right? I'm just going to pick up my phone and ask Siri, and I'll get you an answer. That kind of immediacy is coming to medical affairs. The notion of what I would call the traditional, old-fashioned approach of customer engagement from a medical perspective of, you go to the thought leader, things get published, it takes months and months, maybe you present at a conference and then all of the information trickles down to customers—I think that approach is going away.

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There are a few key roles within medical affairs that customers are engaging with: One is the field medical, the person going out to your customers. Another is the call center. Most companies call it med info where, whether you're a payer, physician, caretaker or somebody from a patient advocacy group, you can call in to the company and get your questions answered either immediately from an FAQ or within a certain specified time, usually under 48 hours, depending on the complexity of the questions. I do think that dynamic is going to go away in the next five years. There won't be separate field medical and internal question-takers. With technology, those groups can just merge.

I also think that they're going to continue to grow because, again, that notion of information trickling down from thought leaders, people aren't going to wait for that. The younger generation of doctors is embracing the model of the MSL as an information source, saying, "I just text my MSL when I need something immediately."

DH: So true. The other key role is the in-house medical director who supports KOLs, trials sites and patient advocacy efforts in collaboration with the MSLs. These groups often engage medical directors to help define the details of protocol development or what is clinically meaningful. At the same time, clinical trials' focus on patient centricity will continue to accelerate. I believe that the in-house medical director role is going to transform, and that the growth and expectations of medical will only continue to increase. As the healthcare ecosystem evolves, the demand for a broader spectrum of data and assessment of value will require medical directors to innovate.

Q: Any sort of wild speculation on the future of medical affairs? Will it completely supersede and eclipse commercial in important ways a decade from now?

SJ: I do feel that medical affairs, especially from a customer engagement standpoint, is going to remain a key player in the industry along with commercial. I really don't see med affairs taking over commercial because we've certainly seen that sales plays a key role, and I think that they're both doing very different things. However, the ratio of field medical to commercial roles may change, with an increase in medical affairs.

The other piece is on that evidence generation side in the future. I'm not sure that I'm seeing it yet, but I would certainly hope that med affairs becomes the innovation engine for the industry, right? This could be where the really cool, cutting-edge things in clinical trials get tried, and there could be this mentality of "fast fails" in med affairs. Med affairs teams will have to find ways to do that, especially increasing the sophistication of the support from both a business operations and a technology perspective.

Technology could be the reason for medical affairs' rise to prominence. If artificial intelligence takes hold as expected, it will bring big changes to how healthcare stakeholders interact with each other and with the end users. If an algorithm is making, or at least strongly suggesting, decisions at the treatment level, physicians will need to adjust their approach, and there are sure to be implications for pharma's commercial model. With algorithms making some of the decisions, it becomes extremely critical for pharmaceutical organizations to generate, interpret and communicate evidence because that's what the algorithms will be based on.

Perhaps I'm painting a picture of a futuristic dystopia, but I think that evidence generation becomes vital because that's the only way that pharma organizations will get to influence how purchase and treatment decisions are made. If that sort of world comes into being, it's likely that pharma's commercial teams would be challenged, and things like medical affairs, things like the people who can actually communicate in value terms and in economic terms to payers, would come to the fore. Data and real-world evidence would be the de facto language of pharma organizations' interactions both internally and externally, and medical affairs already knows how to speak it.

About the Experts

Pratap Khedkar is a managing principal in ZS's Philadelphia office, and leads the firm's global pharmaceuticals and data science practices. He has advised many biopharmaceutical and healthcare companies on a wide range of business issues including commercial strategy, customer-centric marketing, market access, sales compensation and advanced analytics. A recognized healthcare industry expert, Pratap regularly contributes his insights to publications including The Wall Street Journal, Bloomberg Businessweek, Business Insider, Fortune, Medical Marketing & Media, NPR, Pharmaceutical Executive and others.

Sarah Jarvis is a principal in ZS's San Francisco office and leads the medical affairs consulting space. Sarah has worked in the healthcare space for more than 20 years, and currently helps medical affairs clients bring business- and customer-oriented solutions to teams across medical affairs organizations. Before joining ZS, she worked at Genentech as a market planning manager for approved products in the pre-launch phase and throughout their life cycle. Sarah holds a B.A. from Princeton University and an MBA from London Business School.

Dean Hakanson is a principal in ZS's San Diego office, and serves on the R&D leadership team. Dean provides medical affairs clients with strategic input on product development, stakeholder advocacy, communications, continuing medical education and more. He has 20 years of biopharma industry experience and spent eight years working as a full-time, board-certified physician in a clinical practice. Dean has a B.S. in cellular physiology from the University of Denver and an M.D. from the University of Colorado School of Medicine.

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