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Turning Insight into Action: The Expanding Role of Medical Affairs

#### Dr. Birnholz:

Coming to you from the Medical Affairs Professional Society's Annual Meeting in Denver, Colorado, this is ReachMD *MAPSChats*. I'm Dr. Matt Birnholz. I have the pleasure of being joined by Dr. Michael DeLuca. He's Executive Vice President of Global Medical Affairs and Medical Information for EVERSANA, which is an integrated commercial services platform.

Mike, welcome to you.

#### Dr. DeLuca:

Thanks for having me.

#### Dr. Birnholz:

Yeah, it's great to have you. The first question out of the gate I have to ask you—your title is so unique to me, having this executive role around global medical affairs as well as medical information. Can you just help describe how that came about?

#### Dr. DeLuca:

Yeah, definitely. My background has largely been working at various pharmaceutical companies. Prior to joining EVERSANA, I worked at Esperion Therapeutics, Alexion Pharmaceuticals, and Sanofi Pharmaceuticals. I've been largely in the global medical information space. But as my role evolved over time, it also involved taking over med affairs operations, med comms, and supporting medical, legal, regulatory review. So throughout my career it's expanded, but it's always had a core function within med info.

I joined EVERSANA about five years ago to take over and help lead the global medical information contact center function, but also to build out additional services and support. For us, we do support around medical, legal, regulatory review and medical content development. We do some digital medical affairs solutions, like medical portals for clients. And then we also do medical affairs staff augmentation. So we have some clients that say, "Hey, I need an expert for X number of months in a certain area," and we help with that too.

So it's a broad scope, but we still have a concentrated focus in the med info space. And a lot of our clients are med info clients. But then it's the same thing; their scope has changed, and they need other support. So it kind of blends across different functions within the med affairs realm.

#### Dr. Birnholz:

Yeah. It sounds like in a way, your team and your colleagues need to be the handyman of all things medical affairs for these teams because you never know where it's going to adjust.

#### Dr. DeLuca:

Yeah, exactly. And we have team members who are definitely very focused and hyperconcentrated in certain areas, so they know that's where their expertise is. But then we do need folks that are the jack of all trades. And I think you see that too, even with med affairs companies and different pharma organizations, where they have the medical affairs excellence and operations, and they have to have a broad understanding across the organization so they can help execute the strategy too. And obviously, we're a service provider, so we're usually helping on the execution side of things.

#### Dr. Birnholz:

Yeah, that makes sense. And I imagine in order to provide some of those services, you need to have a network that is miles deep.

#### Dr. DeLuca:

Yeah, exactly. That's been a big piece of it too. Obviously, we are primarily all FTEs, and we're hiring and keeping full-time staff. But it's the same thing. We do work with a wide network of consultants too, who help us fulfill the needs of what our clients are looking for. We could have them request anything, but sometimes they're really looking for someone very specific with the right experience who could come in and help them. Sometimes they have something going on in medical leave, or they have someone take a new assignment, or they have turnover and change, or companies go through restructurings, mergers, and acquisitions, and then there's some gaps. And sometimes that gap is helping them to prepare for a new launch or just helping to fill an empty spot.

So we help them with that too. But it does require that network because it's not like you can just bring someone new in who hasn't done that exact job. You need to find someone who has that right experience and could also fit into that company's culture and therapeutic area. So networking becomes a big part of it.

**Dr. Birnholz:**

From a clinical practitioner standpoint, this seems almost metaphorically similar to the locum tenens model for medical affairs of being able to place the right person in the right place at the right time.

**Dr. DeLuca:**

Yes, it definitely becomes that too. And we're global as well, so we have clients that we need to keep an even wider cast of network because obviously a lot of our folks are US and US-focused, or even within global functions but based in the US. But we also have European clients we support. We support LATAM. We have some folks in Japan, and we have a hub in India. Sometimes it's finding the right mix of talent for the company's perspective too. Sometimes it's the expertise, and sometimes it's also cost. So being able to source experts from a global perspective can, especially for smaller clients who can't do that, help them fill that gap in need as well.

**Dr. Birnholz:**

When I looked into your platform, it sounds like there's also a focus on launch excellence, and I'm interested in where that goes. That might be within or outside of the purview of your own role, but I'm interested in that.

**Dr. DeLuca:**

It's definitely part of it. It's part of what EVERSANA was built on. A lot of companies had started out as clinical research organizations and then expanded their services into commercialization—helping companies bring products to market—as opposed to post-marketing.

But EVERSANA was built around a concept of helping companies just commercialize and bring products to market. So across all the groups, it is around launch excellence, and that could be anything, like helping to set up field medical sales reps. We do third-party logistics and distribution, revenue management, specialty pharmacy, and patient services. We have a large marketing agency, EVERSANA INTOUCH. We have a value and evidence team. We have an EVERSANA management consulting team as well. And then all the supportive functions, and that's what we see ourselves in. But obviously there's strategy behind that too, with all our medical affairs services, med info, pharmacovigilance, and regulatory quality—so not the marketing side of things, but you need all those aspects to bring a product to market.

So it really does cover that whole gamut. And then what EVERSANA does for some clients is provide what they call “complete commercialization support.” So sometimes small clients who don't want to have to build the entire infrastructure or out-license their product can keep all the rights and use all of EVERSANA's services to bring their product to market. So they can pick and choose. But they can take the whole thing, and it helps them de-risk. Then it brings all the expertise across all the different functions together to execute that. So we definitely support those clients too. That level of expertise is needed from preparation perspective—the strategy, obviously, but also the operational execution and getting the work done to make sure that you have all the deliverables and operations in place to support the client as they bring their product to market.

**Dr. Birnholz:**

Yeah. That's interesting. And the buzzword you used in terms of “the whole gamut” makes me think of that jack-of-all-trades model in terms of the need to be dangerous in a number of different areas. Let me translate that to, as we look upon this annual conference devoted to medical affairs, you have a unique perspective in your team, where you are involved and have a stake in a number of different aspects across medical affairs, implementation, strategy, et cetera. What's your take on what you've been seeing trend-wise around this conference? The hits, the misses, the things that galvanize you, and the things that concern you.

**Dr. DeLuca:**

Yeah. I've been coming to MAPS for the last several years. Obviously, as you look at themes that have happened over the last few years too, there's been a focus on digital and omnichannel experience, and really, that's around better customer engagement and, how does medical affairs approach customer engagement and outreach? How do they improve scientific exchange? How do they increase their scientific share of voice? So that's always been a focus. Obviously the buzzword at all these meetings now is AI and how to integrate AI

into all the various services and models. That's always a consistent theme from the last couple years too.

I think a couple other areas that we see a focus too are being able to get actionable insights, not just from the field medical teams, but from all the teams—med info, sci comms, and med comms—those digital channels of engagement. How do they bring that in? How do they bring social listening in from those aspects? So those actionable insights. And then I think medical affairs is always trying to demonstrate value in impact when they can't tie it to prescriptions and to revenue. What are those measures?

So I think those four components seem to come up, and they still come up throughout these meetings, but you see a lot at these workshops and different sessions here too. A lot of it is around AI and AI implementation, really across every single function of med affairs. I don't think there's one function that's being talked about where AI can't come in and support.

**Dr. Birnholz:**

Yeah, absolutely. And I think one motive for that that I'm seeing is, obviously it's very hot buzzword in and of itself, but on the other side of things, we had some of the plenary speakers who touched upon the idea that within healthcare, the concept of outcomes is not well-defined. It is highly contested in terms of, which outcomes for which conditions and which situations? And that, in turn, impacts how we understand the concept of impact. And so AI becomes a very attractive potential set of tools to help amalgamate all these disparate sources of data to try to give us a better sense of how outcomes can be defined, how value can be defined, and how impact can be defined. What's your take? Do you have an optimistic perspective based on this, or is there cautious skepticism? Where do you fall right now based on that? And all answers are right.

**Dr. DeLuca:**

No, I agree with you. I think when you look at that and you say, "We like to tie our activities to patient outcomes," like you said, that's going to vary by disease state and by product. But also tying the activity directly to that—I don't know how easy that link is, and I think that's always been the trouble. I think you're correct, though, around where AI can come in. If you're going to look at a lot of datasets, both unstructured and structured, and try to draw some conclusions from it, the AI can help with that.

People talk about it a lot, but it's always the "how." I always say, "It makes sense, but how are you going to actually do that?" Is it claims data? What's happening through the discussion through different platforms of what HCPs are saying or how they're practicing? We always wanted to measure as groups—MSLs, med info, a lot of exchange with HCPs and KOLs, and addressing unsolicited requests for medical information. One of the things that we have always tried to gather is, is that information actually impacting clinical decision making? And sometimes it's just asking, did this information help you make a diagnosis or make a treatment decision? And sometimes that can tie into it, but it's not necessarily linked to an actual outcome. I think it's hard because you don't always know who the customer is. You don't always know what patient they're treating. So trying to get those links is not always the easiest thing.

**Dr. Birnholz:**

Yeah, not at all. And so it becomes a very attractive concept to say, "Well, you have these tools that can potentially work wonders. And by the way, we don't really know how they work. Maybe they can help us."

**Dr. DeLuca:**

Yes, and do it faster and maybe cheaper as well. And then anywhere, you can bring in operational efficiency. I think it's a focus for a lot of people these days too. Especially when you have large datasets, we're looking at where AI can come in and do that. I think it's been shown really well, even for organizations that are taking their own internal data and trying to find insights or trends—that's one area where it's internal knowledge too. It's not externally facing, so there's less risk of any compliance risk as well. I think there's areas like that. So that's where people have seen success there—how can they apply it to other data sets they may be leveraging to try to get to that further information on outcomes?

**Dr. Birnholz:**

Yeah. So, just looking at the big picture, I'm interested in what's next on the horizon for you, either with EVERIANA, or in general in the areas that you're particularly interested in?

**Dr. DeLuca:**

I mean, obviously, it's some of the same topics. We're looking at how to efficiently and compliantly bring AI and automation to the appropriate places within workflows. Obviously, we break that out into different aspects of our services and the models that we do most often. But within our contact center services, we're looking at backend support, like agent assist, sentiment analysis, analytics, and insight generation, as well as even just full transcription call summarization. All those things, AI is pretty good at it when leveraging the large language models.

So we obviously are looking at those things, but then there's customer-facing aspects of that, and we try to do it within the right confines

of what our clients are looking for and what will be compliant. But we look at things like smart, interactive voice response systems, voice bots, and chat bots, those things that can self-answer questions as well—that's one aspect of what we look at. Then on medical content development, same thing—how to bring in AI to develop the content and manage the content, how to leverage component or structured-based authoring so that we can make things more modular, translate them to different audiences faster, and manage them easier and more efficiently.

And then obviously we do a lot of support for medical, legal, regulatory review. So folks are very interested in, how do they implement AI into those processes? Once again, not to replace the medical reviewer, the legal reviewer, or a regulatory reviewer, but how do they amplify, once again, the compliance piece of the data accuracy piece? So obviously all those areas are things we're exploring as we look at what our clients are looking for. But for us, we'd like to really kick the tires on them, validate it, and make sure it's actually doing what it's supposed to be doing.

**Dr. Birnholz:**

Yeah, that seems completely rational to me, and I hope you'll treat this as a fun snapshot opportunity. I'd love to be able to follow up with you at some point down the road and ask, "Hey, what have been the workings and the not workings?" I think what you guys are looking to do across the life sciences area is really well representative of the chase that everybody's in right now, and I'd love to be able to catch up with you on that sometime.

**Dr. DeLuca:**

Yeah, definitely. And what we're seeing too is which large language model you're leveraging and how you're leveraging it. And there are differences. I think if you hear from folks that say they do it, like people complain about the consistency of the information, and the repeatability when you ask the same question; you're getting a slightly different answer. And some things shouldn't really be that different. If you're asking, "What are the most common side effects of this drug," it should be pretty straightforward. That's in the label; it's in a lot of all the promotional materials. So that shouldn't necessarily be changing all that much over time if you're asking the same exact question. There's things like that.

But then obviously, as the models have gotten better for medical and as a bunch of the large language model providers have developed medical healthcare specific models, you start to see much better outcomes from the quality of the information that's coming out of those systems, and then you're keeping it in with a closed knowledge base, not letting it go external, and keeping it to your data sets that you want to look at.

So that's where we're seeing some of the differences. And that's where, I think, testing and validation come into play.

**Dr. Birnholz:**

Fantastic. Well, Michael, thank you so much for your time. It's been a pleasure to be able to get your insights.

**Dr. DeLuca:**

Thanks again for having me.

**Dr. Birnholz:**

This has been an episode of ReachMD *MAPSChats*, and I'm Dr. Matt Birnholz. For more episodes in this series or others related to medical affairs and other topics, visit us at ReachMD.com, where you can Be Part of the Knowledge. Thanks so much for listening.