

CMO360°

Chief Medical Officer Summit

The Communications Issue - Fall 2022



| What Chief Medical Officers Need to Know About Communications

| How to Build a Medical Affairs Strategy

| Use Cases for Social Media for Biotechs

| Differentiating Your Company and Differentiating Your Asset

Welcome Letter

Welcome to the **CMO360°** Fall 2022 newsletter.

This issue focuses on the role of the Chief Medical Officer in communications with different audiences. Through interviews with CMOs, a Chief Corporate Affairs Officer and a CRO founder, we explore how to build a communications strategy, tailoring your message to different audiences, best practices in medical affairs, communicating through conventional and social media and how to prepare for and deliver news when you have weak or negative data.

Enjoy reading.

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Chief Medical Officer 360°

The Conference Forum
1430 Broadway
Suite 1207
New York, NY 10018
(646)-350-2580

Andrew Goldstein

CMO Conference Producer
and Editor

Valerie Bowling

Executive Director

Meredith Sands

Executive Director
Strategic Partnership

Allyson Adams

Senior Marketing Manager

Call For Suggestions

If you are interested in contributing to a future newsletter, please contact andrew@tcflc.org

From a Communications Expert: How CMOs Can Support the Communications Strategy

Karla MacDonald, is the Chief Corporate Affairs Officer of Entrada Therapeutics. She was previously VP, Communications & Patient Advocacy of Ipsen and Executive Director, Head of International Communications and Executive Director, Head of Global R&D Communications of Merck.

Can you speak about your Communications experience?

I've worked across the biopharmaceutical industry with companies ranging from small, private biotech to large pharma. I've spent the majority of my career at Merck leading communications for the R&D division and then international communications across their ex-US markets as well as their corporate social responsibility investments. In doing so, I got to be involved in all aspects of a global company – from the incredible potential of strong R&D, to the challenges of regulatory and commercialization across different markets.

After Merck, I joined Ipsen to help expand their North American presence. I had the opportunity to establish their communications and patient advocacy functions, which was just absolutely remarkable. The patient advocacy work really helped to underscore the importance of listening to and really taking the time to understand patient and caregiver needs and then sharing them back with the company in a way that can impact the way that we are developing therapies – and even more broadly, running the business. You really need the patient perspective at the table and when it happens, it's amazing to see how everyone thinks differently. About a year ago, I joined Entrada and I'm excited to leverage my past experiences to convey Entrada's vision of developing and delivering a new class of medicines to treat devastating diseases utilizing our EEV platform.

How do you think about Communications?

I was always interested in social dynamics and understanding how people tick. Communications is a natural extension of that interest. To communicate effectively, you have to really understand the audience with whom you want to communicate and share the information in a way that can be received and understood.



I've been in the biotech industry for more than 20 years; the entire time has been in a version of corporate affairs: investor relations, corporate communications, patient advocacy and government affairs. And they all share a common set of skills – I call it my toolbox. You need to be able to learn about and understand different audiences, clearly share a credible and authentic story, and actively manage your relationships – both inside and outside of the organization. As leaders, we are representing our companies (at all times), and we need to really understand and feel comfortable talking about its culture, values, strategy and progress. It's our role to bring it all together.

How is the communications strategy different between large pharma and emerging biotech?

It's more about scope and the importance of prioritization. I went from Merck (with approximately 70,000 employees) and Ipsen (with approximately 7,000 employees) where I had significant size teams to Entrada where I'm a team of one. And when I started at Entrada, there were about 70 of us. Obviously, I can't do everything as quickly as I'd want to do it. So, there is a lot of prioritization that needs to happen. And that all starts with the mission and strategy: Why are we communicating, to whom, and what's the purpose? And importantly, how does it advance our strategy? That clarity enables me to really focus on those activities that will have the greatest impact for patients and our company.

One of the things I really like about small companies is that it's easier to be authentic. Strong communications and strong cultures happen when you are authentic and are hitting the right tones. In a small – and especially pre-commercial – space, there is an opportunity to be more rapid and less formal because you don't need to go through the big company review process. While review processes are critical, small companies have a bit more flexibility and that leads to the messages coming

out more closely to their original intention. My goal is for people to feel that there is an actual person behind every message (rather than a review team).

How do you determine tone and project authenticity based on your audience?

The key to great communications is to start with a great organizational story, a great culture and a great leadership team. Then you look at how you can best share those attributes authentically with your audiences. There have been situations in my career where people were hoping for a specific result from communications. But if your organization doesn't have a strong vision or strategy or if you can't project those attributes appropriately, the communications will always fall short.

“Nowadays, people aren't sitting around waiting for a press release. They are looking to engage with leaders authentically.”

How can CMOs best support the communications colleagues?

There is “big C” Communications and “little c” communications. Big C Communications are managed or governed by the communications professionals in an organization. Those are the larger stories sharing corporate milestones or developing brand awareness or brand identity. Those are managed centrally, and we will look to the CMO for thought leadership. That could be panels and presentations, quotes for press releases or corporate materials and participation in social media. What makes a strong difference with the CMO is when they also focus on small c communications. That includes the work they do with their natural networks and social media. Nowadays, people aren't sitting around waiting for a press release. They are looking to engage with leaders authentically.

It's important for CMOs to have a presence both inside and outside their companies. From inside their companies, how are you building engagement with your employees? Are you making sure the organization understands the role of the CMO and their departments? I recommend that leaders have what I call a “walking around deck.” A short deck of maybe five slides that helps to explain what you do and how you and your team support the mission and advance the strategy. This could include: an overview of the CMOs function, your team, and how you link together with other functions within

the company, as well as groups outside the company. It's important to find opportunities to stay visible and relevant. This could include sharing your perspective on company progress or external industry changes/advances with internal teams. While everyone at the company is responsible for being patient-centric, the CMO has an additional responsibility to bring that unique patient or physician/KOL experience. Also, since COVID, I think employees look to their CMO to provide leadership in talking about employee health and mental health.

The advice is somewhat similar around external communications. You should seek out opportunities to share your perspective on company progress, therapeutic advances, or external industry changes/advances with external audiences. CMOs should think about whether they are participating on the right panels, rather than participating just to check a box. For example, can you be a real thought leader and use your experiences to uniquely inform or advance the discussion? Being active on social media is always welcomed, but it's not a one and done activity. It has to be nurtured to create a following. People are looking to leaders to be authentic and bring new perspectives about their areas of expertise and their leadership.

At Ipsen you were responsible for both communications and patient advocacy. Can you speak to the overlap of those roles?

I loved doing patient advocacy at Ipsen because I think everyone in a company should be a patient advocate. We become advocates both by learning about the specific patient populations we serve as well as through our own experiences as patients. This should lead us to better thinking about how we discover and develop drugs. Patient advocacy is about inclusion and storytelling. It's about bringing the patient voice to our community and taking action based on what we learn.

The communications role is highly strategic and interwoven throughout the fiber of a company. A good communications person isn't just sitting in a particular swim lane and writing content. A good communications person sits at the strategic table and helps make decisions by understanding legal, finance, HR issues, clinical, basic research and manufacturing in order to tell the company story and manage the external brand. Being responsible for patient advocacy means that I bring that perspective to the strategic table.

The other piece is that, as a company, we need to listen to and learn from patients. We also need to be aware of the patient as part of the audience. Oftentimes, press releases are focused on an investor audience. But patients are also reading press releases. We need to

write press releases that are accessible to non-investor audiences and also satisfy patient expectations. We need to balance the need to talk with investors about the potential power of our technologies with the awareness that patients are looking to our industry for hope. When the communications person is heavily involved in patient advocacy, it gives an opportunity to prioritize that audience within the fiber of the organization.

It sounds like there is a lot more blurring of lines between audiences.

Absolutely. When you go to an investor conference, there are non-investors attending. When you go to a scientific conference, there are patient advocates and investors. And when you go to patient advocacy meetings you will meet other scientists and investors. You can't segment audiences the way you could ten years ago. We need to look at our activities much more holistically.

The other part that you can't segment anymore is internal versus external. In the "olden days," if you wrote an internal communication, only your employees would see it. Now you have to assume that anything you share internally will be shared externally. Likewise, posting externally on LinkedIn, for example, might be more effective in getting the attention of your colleagues than sending an email to their inbox.

How do you package a message differently based on the medium?

For the CMO of a public company, you need to be aware that everybody is listening to everything you say. As a result, you need to be careful not to share information that has not been publicly disclosed. I recommend CMOs check in with their communications colleagues to make sure they are aware of what is already in the public domain and understand what is appropriate to share. And, when communications are being developed you're helping inform them. For example, when we go to scientific meetings, we gather our teams to go over what the conference is about, the audience, the data we're presenting, and how to reply to anticipated questions.

In your experience, how can CMOs differentiate their companies or assets from the rest of the market?

Your strategy needs to differentiate you. If your corporate strategy can't differentiate you, your CMO won't be able to. You need to communicate based on what's there. The CMO has to demonstrate that they understand the

patient, prescriber and KOL perspectives. And they need to bring unique contributions to the discussion as a result of those relationships or interactions.

It is quite common for us to meet with an investor or analyst and they ask us very specific questions about how patients respond or feel about a technology. As CMO, you need a solid grasp on the patient experience, the market potential, and the competitive landscape, including the data. There is a bit of an overlap between the CMO and CSO in terms of your ability to understand the fundamental science behind your programs. Understanding the market determinants is also important.

Where and how can CMOs learn to communicate more effectively?

On your LinkedIn or Twitter feeds, find CMOs or leaders you think communicate effectively and follow them. Try to create some diversity in your social media feed. At one point I looked through my social media feed and it included a lot of people like me, which was great because I was staying in touch with folks I knew, but I wasn't learning and growing. Since then, I've made a deliberate attempt to follow many more patients, disability activists, Black physicians and leaders, people from Indigenous communities and thought leaders from the LGBTQ+ community. This has challenged my approach to communication and has helped to educate me on issues impacting communities that I may not be a part of.

If you are a CMO, spend some time with your corporate communications person. Share your team's objectives to see how they weave together. There is a lot of overlap and opportunity, especially as the CMO is the key contact with KOLs. Maybe we can leverage those KOLs internally to talk with our employees and externally as we share our science with others.

Anything else?

Don't be afraid to be a thought leader. You are in a unique position as a leader and physician in the biotech industry. Don't be afraid of social media. It is a very powerful tool to create better access and understanding of what we do. ●

What CMOs Need To Know About Social Media

Austin Chiang, MD, MPH, is the Chief Medical Officer of Medtronic GI. He is also the Director, Endoscopic Bariatric Program and Chief Medical Social Media Officer at Thomas Jefferson University Hospitals.



Can you speak about your story and relationship with social media?

I have always been a fan of social media. Facebook launched in my freshman year in college. It was a great way to connect with people and reach a broad audience. About a decade ago, I recognized that there were patients coming into the hospital due to misinformation that they were getting through conventional or social media. I spent some time at ABC news trying to understand how conventional news outlets vetted medical news before broadcasting them. At the time, ABC hosted weekly Twitter chats about various health topics. That is when I recognized that there were people using social media to learn medical information. I then made the conscious decision to put myself out there as somebody trained in gastroenterology who could speak to some of the subjects with more accuracy.

From there I migrated onto Instagram and other platforms and tried to adapt my voice to each platform and its culture with the goal to be an accurate source of health information. Ultimately, that led to forming the Association for Healthcare Social Media, which educates health professionals on how to use the platforms effectively and responsibly, especially as physicians are held to a different standard online to other people.

What should biotech CMOs know about social media? What are the use cases?

It really depends on the goals of the company and how comfortable the company is with making its employees into spokespeople. Since joining Medtronic, I have recognized that there are many more restrictions working at a publicly traded medical device company. For example, FDA regulations about how you present

information online. I'm not sure that an individual CMO would be able to advertise or recruit for studies or promote products directly. I think of it as sharing my own personal experience to elevate brand identity and awareness. For example, my joining Medtronic can present as the company being innovative and willing to adopt fresh ideas.

We recently started a dedicated Medtronic Gastrointestinal twitter account that is very much targeted toward gastroenterologists, many of whom are key opinion leaders and key customers. I don't want to think of it as something that's necessarily promotional, but it's certainly a way to get our messaging out there for people who might not want to read via email or don't have the time to search online.

How would you advise a CMO to build a social media presence and strategy from scratch?

Number one is definitely reviewing with your regulatory and legal colleagues first. Then, working with colleagues in marketing and communications. I think it really depends on the goals of the company and your goals as a CMO. If you're expected to be both public-facing and strategic, or you're trying to be more public-facing, patient-facing or customer-facing, then it would be appropriate.

First, identify your purpose and who you are trying to speak to. That defines which platforms you should use. For example, if you are looking for physicians, it's important to understand that many physicians are not necessarily on LinkedIn. They may be on Twitter. Whether you are trying to reach more experienced or younger physicians can also determine which platforms to approach. You also need to identify your own strengths.

If you are comfortable on camera or have certain editing skills, YouTube or TikTok may be more appropriate.

It's very important to put yourself in the shoes of the viewer – whether they are a customer, physician or patient – to ensure that what you are sharing won't offend. If you are sharing a recent use case of a product with a patient's story, make sure there is appropriate consent and that your sharing doesn't inadvertently reveal someone's identity. Ultimately, social media has to be social. It is rarely a one-sided street. You need to respond and react to your audience.

Can you share examples of your experience on social media?

To start with the positive, there are people who have followed me for a very long time and have gotten to know me and develop a type of loyalty. Some of them tell me about times they encouraged family members to change behaviors or get screened for cancer.

On the negative side what stands out is a video I made talking about weight loss. I went to the supermarket and showed foods that have more calories than you may think. I was trying to be educational. The video was flooded with negative comments calling the video triggering to people with eating disorders. I actually went back to my dietician colleagues and asked if I had done something wrong in the video, like not following specific guidelines about how to convey these kinds of messages. You need to be sensitive when speaking about certain things and be careful about wording.

How do you bridge the gap between communicating complex science in the short form of social media?

It's tough because you want to provide enough context. It takes a lot of practice to distill these topics down to a single point or concept, but it also matters which platform you are using. If you are on YouTube, you have 10-20 minutes to explain something. But on TikTok you get about 3 minutes and on Twitter you have 280 characters. You need to trim things down.

You also don't necessarily need to present the whole picture. One of the nice things about social media is that you can refer people to more information. Again, I would make sure you put yourself in the audiences' shoes to determine what level to speak to. For example, if I'm on TikTok and my audience is the general public, getting rid of the medical jargon and focusing on a single concept.

“I would encourage CMOs to start with one platform that has the best chances to be high yield for your needs.”

How do you think about who you are speaking to based on the platform?

It depends. Take Twitter, for instance. You have both physicians and non-physicians from all age groups there. But the algorithm works in such a way that if you speak to a certain audience, over time, those people will find you, especially as they engage with your content and share it.

Generally speaking, you find the highest number of physicians on Twitter out of all the social media platforms. Instagram has a bit of a younger and more general crowd. TikTok is also younger and more general. LinkedIn is still largely professional and may be more relevant to biopharma and medtech. If you're looking to talk about how wonderful your company is and exciting initiatives to attract people from the R&D world then LinkedIn might be more appropriate than a more physician-based audience on Twitter. At the same time, if you're looking to elevate your general brand identity and showcase your products, pushing that message out to consumers directly on Instagram or TikTok may be more appropriate.

It's easy to think you have something for each of these platforms and audiences but I would encourage CMOs to start with one platform that has the best chances to be high yield for your needs.

What were the biggest surprises you experienced as an influencer?

The visibility has been more than I could have imagined. I was an early adopter for these major platforms, which is why I was able to cultivate a following more easily. As soon as I joined Medtronic, people associated my name with the company and came to me with questions and ideas. We actually sent out the press release about my joining the company two days before one of our major conferences which led to a lot of attention at the conference.

There are also unanticipated pitfalls to having a dedicated social media following. There have been imposter accounts and people who have used my photos to sell products or scam people or do all sorts of weird things. You need to be careful about what you say because it can be used against you now or in the future. Especially

now at Medtronic, I've been careful about adding another layer of review before putting anything out there.

The other surprising thing is that despite social media having been around for two decades, it's still relatively new. It's taken us a while to understand its potential impact on health and healthcare. Now we realize – especially after the pandemic – how messaging on social media impacts public health and health education.

Dr Vivek Murthy recently tweeted about your work advocating for the LGBTQ+ community and promoting public health. How do you see your responsibility as someone visible on social media in comparison to your responsibility as a CMO?

I felt responsible to talk about those issues even before my Medtronic role. I constantly ask myself what I should be doing with social media now that I've become a CMO.

I feel like a big part of my role is really bridging the gap between physicians and industry. I've taken it upon myself to use these platforms to talk about my experience working at Medtronic and what physicians don't usually think about, like what medical device companies do from a regulatory perspective, medical affairs or business development. I feel responsible to share my experience especially with the younger generation of physicians, many of whom are entrepreneurial and innovative and have these ideas in the future of having hybrid careers.

I think that's also made me think more about how I advocate. I am still going to talk about disease states and public health issues around gastroenterology. I definitely feel a sense of personal responsibility to speak about LGBTQ+ health because representation matters. As someone who is in multiple minority groups, if I don't speak up about these things, I don't know who will.

Coming up on your one-year anniversary as CMO, is there anything you wish you knew about the role a year ago?

I would have told myself to try to understand what was going on outside my bubble. I was fairly insulated in my academic health system. Now that I'm here, I understand so much more about how our health system works, what the entire landscape of gastroenterology is about and how all the pieces come together to bring a device to market and bring innovation to the patient.

Anything else?

I have a love/hate relationship with social media because it's time consuming and mentally taxing to be on these platforms sometimes. There is a lot of positive and negative stimulation which makes it easy to give up. I think people see a snapshot of my social media presence now but don't necessarily understand it's been built up over years.

Working in a hospital, you're limited to the people you can see on your schedule. On social media, you can impact more people. I have always wanted to have a population-level impact, which is why I got into medical social media. The same drive brought me to my current CMO role: translating that desire to reach a greater number of people with messaging into impacting many more lives through innovation and developing products. ●

“It's very important to put yourself in the shoes of the viewer – whether they are a customer, physician or patient.”

Communicating Authentically as a CMO

Margaret Koziel, MD, is the Chief Medical Officer of Axcella. She previously held roles of increasing responsibility in Clinical Development with Novartis, Vertex Pharmaceuticals and Kaleido Biosciences.



What does your day-to-day look like as the CMO of Axcella?

It is a combination of internal-facing and external-facing work. Most of us who have become CMOs have done so through rising through clinical development where there is some external work like communicating scientific results and working with patient groups. The focus definitely shifts to more of a balance between working with your internal teams and communicating to the outside world what your company is doing.

My day can be anything from working with one of my direct reports on clinical trial recruitment, or questions about medical involvement to supervising individuals working on clinical pharmacology. It is my job to help them understand where their studies fall in the grand scheme of things. I also work on processes to ensure we grow efficiently, as well as communicating with investors, patient groups and physicians. My day is constantly varied, which is great.

How do you sell your science to different audiences?

You start off by knowing your audience. What are they most curious about? What would they like to know? What is their background? Who is this individual? While this is somewhat easier to understand with someone who is inside the organization, it is particularly important to gather this information when you are dealing with somebody outside the organization. For example, understanding the professional expertise of an investor – whether scientific or business development – can help get a sense of what their questions might be and how to prepare.

It is helpful to phrase language in a way you think they can understand. For example, determining what medical terms to use and how deeply to dive into medical

complexities versus explaining concepts based on your audience's scientific background. I have seen people assume that internally other colleagues understand an acronym or concept but that is not necessarily the case.

It is always incumbent on us to communicate the excitement we feel. For me it is easy because I am excited about the science at Axcella. One of the advantages of our platform is the potential for safety. People often focus on the efficacy side and they either forget to talk about the safety side or try to work around it. We have the advantage that we can do both. We can show both positive clinical data and talk about the potential safety in a way that is compelling.

How does your background as a physician and a CMO impact the way you communicate?

Part of the benefit of my professional career is that I have worked with so many audiences. I have been a practicing physician and seen patients in the clinic so I can understand and translate those stories to other audiences. I ran a federally-funded laboratory, so I have worked with scientific experts and am comfortable with that language. I have worked with investors so I can communicate investor concerns with internal audiences. Sometimes, my role is to translate technical jargon into a language that is comfortable for the audience and sometimes it is to help one group see things from a perspective that they may not have appreciated.

Axcella has recently shifted into developing a therapy for Long-COVID. Can you talk about the communication strategy around that shift?

One of the important features of Long-COVID is that it is a disease first and foremost led by the patient experience. Patients were the ones who identified and started raising this to the attention of providers,

researchers and the government. It is a good reminder that we always have to listen to the patients first.

One of the challenges is the fact that we are all learning about COVID collectively and Long-COVID specifically. This is a field in rapid flux because we learn something new on almost a daily basis. In a more established therapeutic space there may be a lot of developments and people working on it but you are not discovering new underlying science and clinical needs on a daily basis, as we are with Long-COVID. As Stephen Hoge of Moderna has said, in drug development terms, there is fast and there is COVID fast. Being a part of this rapidly evolving area is a fun challenge. Patients need us to work as quickly as possible to bring them potential therapies.

Any other lessons learned from that recent shift or other recent communications?

It is a challenge to communicate rapidly evolving science. Sometimes we are challenged by people saying, "You told me something three months ago and now it has changed," and we need to communicate that we have learned something new. As the field evolves, you need to be flexible in your thinking and communicate in a way that is both accurate and confident. Whatever therapeutic area you are in, at some point somebody will discover something with critical importance to what you are doing and you need to be able to adapt.

How does one prepare for and/or communicate weak or negative data?

It is important to gather everybody and try to understand where we are. Negative data can mean we did not enroll our trial on time or it did not read out as we thought, so it is important that everyone involved in communicating has a thorough understanding and alignment around the reason for the negative data and to reflect on how it will play out. Everybody on a team has a slightly different expertise and can speak to different audiences.

Internally, it is important to try to be as objective as possible and not to do finger pointing. It is fine to do an after-action item review but not in the midst of communicating results. The instant that people start to point fingers it removes any kind of psychological safety from the working environment and then you will never get an honest answer ever again. While there are circumstances where specific people make a major mistake, you need to focus on engineering the system and putting up guardrails internally to prevent repeats. The focus should be on how we got here and how we can do better next time.

Has your communication strategy shifted as the industry has gone from a bull to bear market?

It is still incumbent on me to communicate the excitement: why we believe what we are doing is important. There is only so much I can do as an individual about the overall bear market. I can explain why we think our opportunities are timely and important. I focus on what I can say and how I can frame our company as being in the best position to move forward.

What most surprised you about the CMO role? What is your advice to would-be CMOs?

I've had some very good mentors who prepared me well so I knew what to expect. Given my background, the biggest jump for me was the communication to external investors. In preparation, I looked for opportunities to start practicing that in lower stakes settings. I would advise VPs to look for these opportunities to interact with investors or go to investor conferences to hear their questions and think about how you would communicate with them.

If you are joining a new company as a CMO, you should think about the resources in your scope. As someone promoted to CMO internally, I had a good sense of the strengths and gaps and what needs to be built immediately versus later. If you are coming into a new company, you should ask: What are you going to lead and build in the company? Who is there to support you? You really need to do your homework on the company and be aware, especially in biotech, that you may need to step into roles outside of the scope of a traditional CMO, such as leading clinical operations or medical affairs if that support has not been built into the company. Think about diversifying your skill sets and who you know who could help you as an advisor or consultant. ●

"Sometimes my role is to translate technical jargon into a language that is comfortable for the audience and sometimes it is to help one group see things from a perspective that they may not have appreciated."

Service Provider Perspective: Investing in Upfront Communication for an Effective Relationship

Joseph Arcangelo is the Co-founder and Managing Partner of inSection Group. Mr Arcangelo speaks about how CMOs can effectively communicate with potential development partners.



How can CMOs effectively communicate their needs to service providers?

It is important the CMO is included in the creation of tangible and collaborative goals, objectives and KPIs. While the decision to partner with an outsourcing organization may begin with the sales representative or business development person, a CMO needs an alignment with someone from the service provider who will value the asset as much as they do. In so doing, when any problem should arise (and they seem to always do) solutions can be developed quickly and with unified thought.

“When you can embed and integrate the right people, the discussion of the realities of any project becomes a joint effort amongst credible experts. And frequently when that occurs, a phenomenon of what was seemingly impossible to consider, actually gets completed within the preferred timeline.”

What does ideal communication between a biotech and a service provider look like to you?

The initial, and subsequent early, conversations are pivotal. But as the time goes on, your conversations do not have to be as frequent; you should only need

to do check-ins. Since we assume the accountability to uphold our promises to our clients, all future communications should be nothing more than a review of what has been completed.

Our goal will always be to provide reliable assistance to the CMO, not to give them more work. It therefore becomes imperative that our communication is frequent, candid and authentic. It makes sense, and creates efficiencies, when we are all on the same page and we are delivering on what is expected.

How do you negotiate with a biotech around timelines and setting expectations?

Biotechs, especially the younger developing ones, have aggressive timelines almost to the point where they are unrealistic. While the operational people and CMO know it, the VCs and Board members don't necessarily see that reality.

Rather than negotiate, I would suggest we integrate, ensuring that we, the service provider, is not holding up the progress. As a service provider, we can fully control our side of the execution of a contract or agreement, we can control the initiation of the required resources and their level of experience and talent, we can choose to be nimble and responsive to work within the goals of the proposed timelines and projected KPIs among other controllable facets of our service offering. When you can embed and integrate the right people, the discussion of the realities of any project becomes a joint effort amongst credible experts. And frequently when that occurs, a phenomenon of what was seemingly impossible to consider, actually gets completed within the preferred timeline.

How do you develop a relationship of trust between the external inSeption person and the internal biotech team members?

Trust is built on a litany of little things. In my opinion, each of these “little” things are rooted in repeatedly doing what you say you are going to do. Trust is built, over time, and it starts with the personal attributes of any individual and the quality of their values. From there, you add in their knowledge, capability, experience and commitment to service, and you have the basic foundations of trust.

Yet, it even goes far beyond that. Everyone on a study, especially within emerging organizations, must assume responsibility and accountability for completing their role, for “authoring” their work, and valuing the asset.

What we have found, to have all of these facets converge successfully, the individual must be excited about the science behind the asset. Once they express true passion for the science, they just “do what they do.” As explained by one of our CMO clients: “Whenever I utilized inSeption, their people wake up in the morning, put on my uniform, wear my name tag, and work with the same passion, drive, goal and timelines as we do. Then, when they are finished for the day and take off our uniform, there is an inSeption undershirt underneath.”

Simply, the people who we provide to our clients have the experience, capability, knowledge, wherewithal and personal accountability and responsibility to do what they do well. Otherwise it doesn’t work.

Have you ever said no to a client because that passion wasn’t there or they didn’t communicate effectively?

Yes. I have a client who continually changes the responsibilities of one of my employees almost daily and it is causing this highly qualified individual to lose faith in the client’s understanding of what they are doing. So we are going to walk away.

There was another company that reached out to us for a phase III study and the individual who was heading up the study is a business operations person with no past clinical experience. They are not scientifically qualified to make decisions on how to manage that study so they should probably work with a bigger CRO who can help them while they manage the financing.

“If the asset has a high possibility of curing disease or helping patients with an illness, we are interested. If it is a “me too” drug, it will be difficult for us to find the right resources because the people who work for us are excited by the science.”

As a service provider, what makes a biotech attractive to want to partner with?

An organization driven by their platform and science to make a difference in the world for the patients that we serve fits very well with our model. It is that simple. We have an unwavering understanding that we’re working on a scientific experiment on a fellow human. If the asset has a high possibility of curing disease or helping patients with an illness, we are interested. If it is a “me too” drug, it will be difficult for us to find the right resources because the people who work for us are excited by the science.

Anything else?

When you surround yourself with people driven by the science who hold a personal accountability and responsibility for their job, you gain efficiency, gain time and save money. You communicate effectively to solve problems and can achieve great things for patients.

We are bound together, and rally around, a quote from Walt Disney: “It’s kind of fun to do the impossible.” ●



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A CMO Perspective on Tailoring Communications For Different Audiences

Deyaa Adib, MD, is the Chief Medical Officer of Triumvira Immunologics. He previously held roles of increasing responsibility with Aventis, Sanofi, Astellas Pharma, Baxalta, ARIAD, Bellicum, KSQ and Epizyme.



Tell us about your role as chief medical officer of Triumvira?

I am a medical oncologist by training and I've been in the industry for 25 years. I worked on bringing seven different molecules in oncology development through registration, and then spent the last seven years in the targeted and cell therapy space. We at Triumvira focus on solid tumors and are looking to break the code and create success that resembles what we have seen in the hematologic malignancies over the last eight years.

What is the communications aspect like in your CMO role?

Communication is an extremely important aspect of the CMO role. Part of the responsibilities of the CMO is building teams and communicating with senior leadership and the board of directors, as well as speaking with investors for financing and going to road shows. I find it most useful and efficient to prepare by understanding what type of audience I am speaking to. To start at the high level, I ask myself whether this audience is internal or external. What is the objective of the communication? That provides me with a clear, solid understanding of what I am trying to achieve and how to tailor the discussion towards that goal.

Being prepared is extremely important. Whether internally or externally you need to do your homework by looking at the data and the competitive landscape as well as recent development programs of other developers in the space and their results. Essentially, you need to be well aware of your surroundings and know what differences give your molecule distinction over others.

Can you give me an example of how you would tailor a message to different audiences?

Before speaking to a Key Opinion Leader, I need to gather and be on top of the knowledge of the indications, standards of care and development in the field in order to convince them of the merits of my strategy or technology. They may be called upon to consult on other development programs so I need to be prepared to share the differentiating factors between Triumvira's therapy versus others. This way the KOLs will realize that our development program is unique and worth their time for exploration and advice. That is very critical.

In terms of talking to investors, in addition to what I've shared about KOLs – full knowledge of our technology and differentiating factors – I also need to speak to them about our target indication, our patient segment, size of the patient population, competition for that patient population and what stage we are up to compared with competitors all in order to give them the opportunity to think about the value potential of our technology. I want them to see the potential return on investment to get them excited and participate in multiple rounds of financing. The best way to hold a fruitful conversation with investors is to be prepared with differentiating factors and numbers. Numbers means patients, patient segment in the first indication, and follow-on indications. You do not want to be locked into a box for one approval in one specific indication. It is very important for them to hear my thoughts about the follow-on indication as a way to build value over an extended duration and get excited about the financing opportunity.

What about when interacting with patients?

If I am working with patients or advocacy groups, I need to show them how well the therapy is differentiated in terms of efficacy, safety, quality of life, accessibility, and feasibility to be applied on a large scale in order to reach patients efficiently and at a reasonable cost.

What about medical affairs?

Medical affairs is a completely different ballgame. Medical affairs focuses on increasing the level of awareness once you are approaching registration or launching. When that happens you need to compete with other technologies in the field by explaining about the therapy, clinical trial results and the impact on the label. While for KOL outreach you are targeting a limited number of people, medical affairs has you trying to reach as many physicians as possible, academics as well as community-based physicians who treat high patient volumes. To that end you are designing educational material and conducting large-scale symposia at major meetings and conferences to get the largest possible segment of physician audiences who will prescribe your therapy.

What are some key ways to differentiate, especially when you are in a crowded field like oncology?

The mechanism of action is the most important. You need to understand the mechanism of action and be able to communicate it succinctly and clearly. You need to make it communicable so that your audience can understand and even further communicate about your technology to other groups. If you get more complex or detailed people may get lost and your message can be lost in translation. In addition to explaining the uniqueness of your technology, you need to share the pros and cons. Compared to other technologies out there, what problems does my technology resolve? You also need to be able to explain your patient population: Is it a large clinical impact or a tiny and unique population?

The more knowledge I have about the competitive landscape, the better. Every therapy has its pros and cons. Maybe it is quality of life or acuteness versus chronicity, for example. By understanding this, I can tell our company's story and explain how our technology can resolve those issues or avoid problems associated with other available therapies. While generally Business Development does this kind of work, the CMO, as medical lead of the company, should get deeply involved especially when it comes to analyzing the clinical data of competitors and knowing how to poke holes.

How do you align with your team when going out to communicate?

The most important element is preparation. If we are going out to communicate as a team, we need to divide the work and decide who will present the different sections of the pitch deck and who will answer which questions. Scenario planning. For example, the commercial opportunity should come from the CEO or the Chief Commercial Officer. The clinical data should come from the CMO and so on.

What is your advice for a new CMO on preparing to communicate scientific information effectively?

If you are a first time CMO, you need to have listened to or attended some kind of communication interactions with KOLs, investors and other potential audiences. There is no institution that teaches CMOs how to do their jobs. If you have not participated in a meeting with investors, board members, a potential partner or something to prepare for your role, you are not ready for the CMO role.

In preparation for your first CMO role, you need to attach yourself to someone who has done it before. That way you can see how they prepare for their talks, slide decks, strategic thinking, and how they divide the work among other senior leadership. You can see how they communicate to investors and what kind of questions they answer versus when someone else on the leadership team answers. From there, I would advise these would-be CMOs to talk to investors, potential development partners, advocacy groups, patients and board members. That is how you learn. And then the person you have attached yourself to can coach you and share their knowledge and make introductions.

What important piece of advice would you give to CMOs from your many years of experience in communicating science?

It is important to be concise, direct and to the point. Do not exhaust your audience with too many details. You may lose them. Prepare key messages. When you present, save one slide at the end of each section that delivers key messages. It will collect the focus of your audience back in case you have lost it during your presentation. ●

Building an Effective Medical Affairs Strategy

John Yee, MD, MPH, is the Chief Medical Officer of Sobi - North America. He's held roles of increasing responsibility with Genzyme (now Sanofi), AstraZeneca, Intarcia Therapeutics, Vertex Pharmaceuticals and Flexion Therapeutics.



Can you talk about your role as CMO of Sobi - North America?

My scope includes our field medical team, brand medical directors, medical information, medical communications, medical operations, pharmacovigilance, patient advocacy and regulatory affairs for the US and Canada. There is an incredible variety of different things I get to be involved in, including working on upcoming or ongoing studies, developing franchise plans and collaborating with marketing and market access colleagues. I also play an important role as an enterprise-wide leader, and member of our North America Leadership Team.

What do CMOs need to know about Medical Affairs?

It requires one to speak and understand the language and culture of our scientific colleagues as well as our commercial colleagues. Medical Affairs functions as the bridge that connects those two ends of the organization to each other. But the most important role of Medical Affairs is engaging and interacting with key external stakeholders including healthcare providers, key opinion leaders, patient organizations and policy makers, including payors and professional organizations and societies.

The common thread to keep in mind regarding engagement with any of these internal or external stakeholders is that they are involved in making or influencing decisions that will affect patients, either on the individual or population level. We want to ensure that these decisions are based on the best available medical and scientific evidence.

How does one build a strong Medical Affairs strategy?

I conceptualize it as a series of interconnected steps. The first step is about understanding: What are the unmet medical needs? What are the unanswered scientific questions? What is the problem that we're trying to solve? Based on that understanding you can take the second step, which is to determine how to generate the evidence to answer those questions or generate the education to address those needs.

But that evidence we generate or education or information we develop is only as good as the third step, which is communicating that evidence, education and information to the relevant stakeholders in a form and language that they can understand and use. That includes the outbound communication through our MSL team, publications and medical education programs. But communication is always a two-way exchange and in the process of communicating outwards you still spend a lot of effort asking questions and listening. The fourth step is gathering the medical insights to understand the remaining unanswered scientific questions and unmet medical needs to begin another cycle of understanding, generating, communicating and gathering.

How early should a company start thinking about Medical Affairs?

Ideally, Medical Affairs gets involved early with internal stakeholders to inform the pre-clinical and clinical development strategy. Early decisions in any program should be made in consideration of real-world patient and provider perspectives. Timing of engagement with external stakeholders depends on the nature of

the drug, the nature of the disease, and the nature of the specialties involved in caring for patients with that disease. It depends on the current state of education and knowledge among clinicians, and how well-developed are the existing patterns of clinical diagnosis and referral between specialties.

Field medical teams may get formed and begin to engage with the medical and scientific community as early as 3-4 years before product launch, especially in situations where there is a lack of education or when there aren't well-formed pathways for diagnosis and referral. In other cases, where those things already exist, the medical team may be formed more like 18-24 months prior to a product launch. Of course, it doesn't end with the product launch because many of those needs extend throughout the entire life cycle of a drug and so that work continues not only through the launch period but well beyond into the lifecycle management phase of the product.

Is there a specific indication you think about when you say that 3-4 years in advance versus an indication that is 18-24 months in advance?

In situations where a drug might be addressing a disease that has no existing treatment options available, you may need to get started earlier. Also, in cases where a disease is rare or ultra-rare when there is a low level of awareness and education about the disease itself, you need to get started earlier. In those situations, there may be no effective treatments available or the pathways for diagnosis, referral and treatment are not well formed. In that case, establishing those connections and understanding which centers have expertise or diagnostic capabilities takes more time and you need to get started earlier.

In other cases where the relevant clinical communities are well developed, either because there are already many other treatment options available or the disease is more common and there is a high level of awareness and education and well-developed pathways for diagnosis and referral, less time is needed. In all cases, it is essential to identify and engage with the key medical and scientific experts in the field to understand their ideas, beliefs, research, and practices.

Those are some of the variables that might determine when you should start to build out. Also, it is not totally binary. It's often more like the slope of the ramp. You might start out early with a couple of medical team members to do some of the early discovery and landscape assessment and then ramp up the size of the team as you get closer to the expected approval and launch.

How does the strategy or role of medical affairs change post-launch or post-commercialization?

The medical team plays a critical role in every product launch and throughout the product lifecycle. That is done in tandem to whatever the commercial team is already doing, by addressing any and all scientific and educational needs and questions that arise inevitably during any product launch. It also naturally extends beyond that, because, depending on the mechanism of action, many drugs may have potential utility or value in other disease states. The role of Medical Affairs then is to identify those unmet needs or unanswered scientific questions and then find ways to find answers to those questions, which may be through additional company-sponsored clinical trials or supporting investigator-sponsored research or some hybrid of the two.

“Medical Affairs is sometimes viewed narrowly as only a reactive support function to help the commercial team rather than as a strategic business partner that can help guide not only medical strategy but the overall company strategy.”

What common mistakes do companies make in the realm of Medical Affairs?

Companies sometimes wait too long. They may fail to include Medical Affairs perspectives in key decisions made during pre-clinical and early clinical development. They may also underestimate the amount of time it takes to get ready prior to approval which can hamper the success of a new product launch.

The other mistake that can happen is not fully understanding or appreciating the value or the scope of what the medical team can offer. Medical Affairs is sometimes viewed narrowly as only a reactive support function to help the commercial team rather than as a strategic business partner that can help guide not only medical strategy but the overall company strategy. This is especially true either when the disease is complex or the drug is complex or both.

How has Medical Affairs been affected by the pandemic?

Much of the impact of the pandemic for the medical team is similar to colleagues in other functions. One of the things that has become very clear is that we can do much of our work virtually. In some ways, there are advantages to virtual meetings as they expand the ability to interact while avoiding the need to spend lots of time and money traveling. In cases where there are existing relationships and partnerships, that can work very effectively. But at the same time, I think there will always be a need for in-person interactions.

There are definitely additional interactions that are more effective when we can meet face-to-face: like one-on-one interactions with KOLs, or advisory board meetings or scientific congresses. While we have done those virtually, they aren't the same. I expect that as we go forward we will never go back to things the way things entirely were before the pandemic. We will still live in this hybrid world for the foreseeable future and that is probably a net benefit for individuals and for companies.

Anything else?

Many of us came out of clinical practice or academia and now work in this biopharma industry for for-profit companies. It's important for all of us to remember that the best way to uphold our fiduciary obligation to our shareholders is by upholding our ethical obligation to our patients. When I first joined Genzyme, our CEO, Henri Termeer often reminded us that what's good for patients is good for business.

As a CMO, it is an important part of my role to represent that voice of the patient within the company, and to make sure that the patients' perspectives and interests are always kept front and center as we make and execute our key decisions throughout a product's lifecycle, from early development through the post-approval period. ●

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