WHITE PAPER

A patient-centricity framework for medical affairs

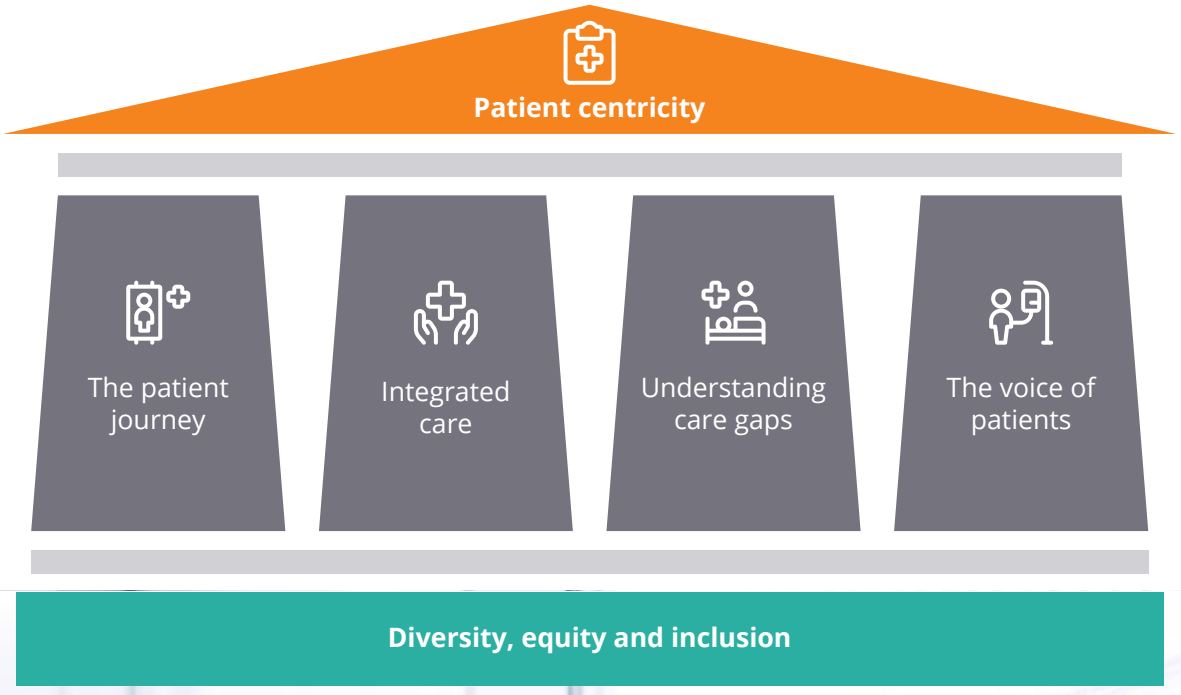
Four pillars for improving patient outcomes

By Sunil John and guest author Richard Swank

Patient centricity is an increasingly important part of the healthcare ecosystem and medical affairs teams are playing a critical role in helping improve patient outcomes. At ZS, we're using a patient-centricity framework (see Figure 1) that's comprised of four pillars: the patient journey, integrated care, understanding care gaps and the voice of patients. This framework can help medical affairs teams decide where to proactively intervene, so they can help patients and healthcare professionals (HCPs), while working within an organization's broader goals. After reviewing and considering the framework, organizations can use a model (see Figure 4) to assess their own patient-centricity maturity.

FIGURE 1

The 4 pillars of the ZS medical affairs patient-centricity framework



The patient journey

An evolution in the way medical affairs views the patient journey is needed. We recognize the patient journey as having four key markers:

- The patient notices symptoms or is made aware of asymptomatic disorders, such as hypertension or dyslipidemia
- The patient meets with healthcare providers who can determine a diagnosis
- A treatment path is chosen and the patient is treated
- The patient pursues post-treatment care

Every step or decision point in the patient journey can have an impact on the patient's overall well-being and recovery. Patients often undergo distress when moving from one phase to the other—they're overwhelmed with information and struggle with cost issues and speaking up about their treatment choices. Charting out the patient journey can help identify critical touch points and needed decisions.

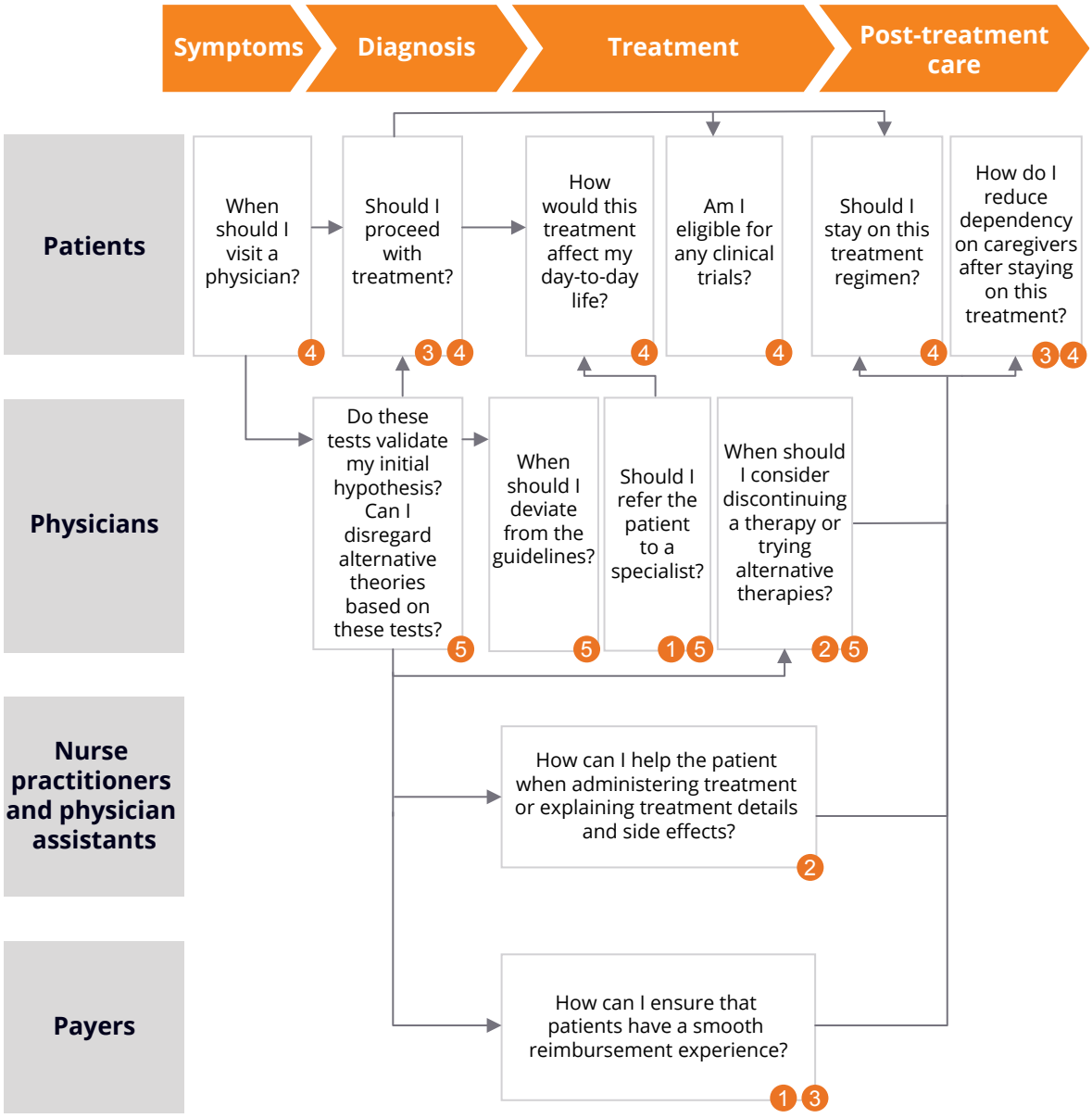
These touch points present medical affairs with the opportunity to intervene in an effort to drive positive outcomes and help reduce delays and drop-offs. One way they have often contributed is helping stakeholders and patients make informed decisions during the treatment phase by providing them with scientific information.

The key stakeholders in a standard patient journey include physicians, nurse practitioners, physician assistants, payers and others (see Figure 2). As patients interact with these stakeholders at these touch points, medical affairs can curate and provide timely education (see Figure 3), while connecting with the right stakeholders to ensure an optimal and positive experience for patients. This is why it's important for medical affairs to understand each of these touch points. This will also ensure that medical affairs stakeholders are aware of their role, enabling them to provide the right scientific information at each step in the process.

It's helpful to bifurcate medical affairs objectives into varied buckets to understand which category a decision-making point falls into. For example, the fourth objective in Figures 2 and 3 calls for more patient-friendly education and the creation of materials that encourage and amplify the patient voice and awareness. Similarly, the fifth objective calls for providing unbiased scientific information. By analyzing each decision-making point and determining what information or intervention is needed, medical affairs can play a significant role in patients' well-being and in their overall path to treatment. Focusing on the patient journey can improve access to care and reduce time to treatment.

FIGURE 2

Key decision points in the patient journey

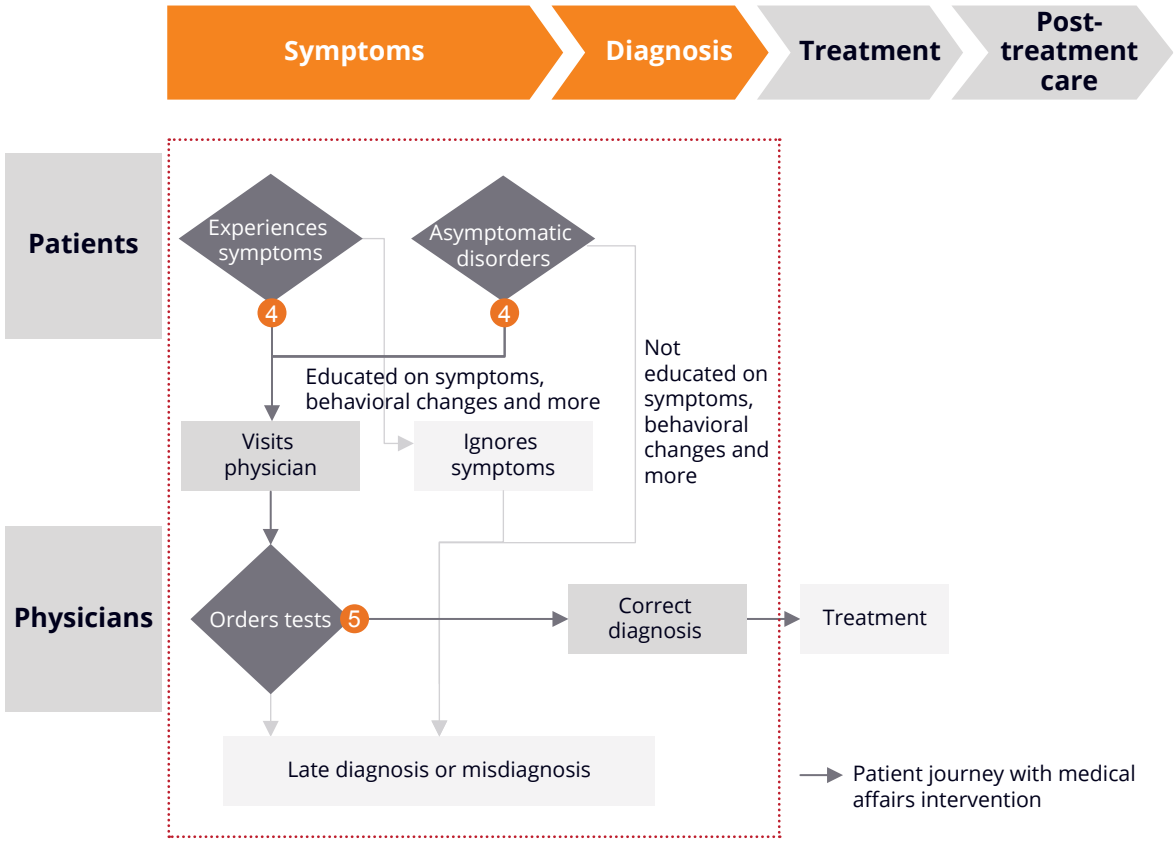


Medical affairs objectives:

1. Facilitate easier transitions and coordination of care
2. Consistency in administration through patient-oriented medical education
3. Connect to the right people and provide the right coverage information at the right time
4. Encourage active role of patients in treatment decisions via patient-friendly education, support, advocacy and more
5. Provide unbiased scientific information via effective channels

FIGURE 3

Key decision points in a patient journey with medical affairs intervention



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Integrated care

The U.S. healthcare system's shift toward patient-centered models has highlighted the need for better integration and coordination of care. This is partly due to policymakers' focus on population health, health outcomes and addressing care gaps, especially in areas where social and economic factors tend to hinder access.

Over time, healthcare systems have shifted from a horizontal integration model to a vertical one. In a horizontal model, organizations integrate with other organizations that provide similar services, such as multihospital systems or multispecialty practices. But in a vertical integration model, organizations integrate with other organizations that offer different services, functions or levels of care. These can include hospitals, primary care physicians, specialists, payers and other providers.

While the types of integration models and their goals vary, at a broader level, integrated delivery networks (IDNs) aim to avoid unnecessary duplication of care, streamline health information, share accountability, improve quality and reduce costs. They do this by delivering the right care, in the right settings, at the right time. Comparative observations around integrated care strategies versus nonintegrated care has found that the former is associated with enhanced quality outcomes for patients, which can help reduce transition times and prevent hospitalizations. IDNs are also more likely to use evidence-based care and better manage care for chronic conditions, particularly if they are affiliated with health plan providers.

IDNs are playing an increasingly important role in clinical and economic decision-making. While pharmaceutical organizations recognize the need to collaborate and engage with IDNs, the industry is not yet fully equipped to manage this shift. A single nationwide engagement strategy or field deployment tactic isn't viable, as field teams require different skills and competencies to effectively engage with diverse IDN members with varying needs that depend on geography and institutional operations. These differences require flexible and agile medical affairs engagement strategies, incorporating a deep understanding of local integrated models and objectives. Traditionally, interactions between medical science liaisons (MSLs) and key opinion leaders (KOLs) have been tactical and therapy-area focused, without touching upon patient needs or overall population health. Moving forward, key account engagement should focus on strategy and establishing partnerships that enhance individual and combined offerings, assuring improved outcomes for patients.

Medical affairs also must expand beyond its current role, as medical science liaisons increasingly need to engage with prioritized IDNs and institutions that are structurally and experientially advanced. Engaging with these potential key accounts requires a tailored approach that considers the diverse needs of stakeholders within an institution, its key decision-makers and where the value of medical affairs intervention resides. The creation and deployment of medical account management (MAM) and other field-facing institutional roles—such as account medical advisors, medical managed care directors or scientific account leads—are crucial to address the needs of organized and integrated providers

that are uniquely positioned to assess and respond to specific needs of the local patient population. Vertical networks that integrate primary care providers, specialists, payers and other stakeholders can help medical affairs holistically understand issues around access, patient education, adherence and more. These networks are equipped with a useful and novel lens, enabling them to identify aggregated trends and outcomes for patients in a specific region. They can also address challenges arising from social drivers of health (SDOH) and region-specific risk factors. Field medical teams engaging with these networks play an integral role in sharing these unique insights with their organization.

Additionally, strategically placing MAM roles at different therapy areas and levels meets key organizational imperatives including:

- Serving as a field medical expert to create a strategic and ongoing professional alliance with key payer and provider organizations
- Aligning product, therapeutic area and disease-state strategies with scientific and medical objectives in regional and national accounts
- Developing cross-functional collaborations with the commercial account to drive a seamless and integrated institution engagement plan to execution

Understanding care gaps

From evidence generation to stakeholder education on disease state awareness, pharma organizations conduct extensive research and implement numerous initiatives before launching a product. Still, positive patient outcomes can be challenging (Figure 1 is a simple representation of a standard patient journey). The disconnect between different touch points in the treatment journey or unconscious bias in the decision-making process, for example, can lead to care gaps. These can vary based on the therapy area, disease prevalence, region, as well as other internal and external factors. Commonly observed care gaps include:

Late-stage diagnosis: Patients may be diagnosed late for a number of reasons. These include not noticing symptoms early in the disease progression, physicians not ordering correct tests or the absence of diagnostic tests for early detection—especially in oncology and the rare disease space.

Low treatment adherence and persistence: Many patients do not adhere to and even drop off their treatment regimen. Reasons for this are diverse and can include the patient experiencing unpleasant side effects or not seeing their health improve.

Differential outcomes: A lack of sufficient diversity in clinical trials can lead to different patient cohorts experiencing varied outcomes while undergoing the same treatment. For example, the efficacy of a treatment might vary between people from diverse backgrounds.

Poor access: Inequitable access to quality healthcare and treatment is evident across many regions, with disparities stemming from SDOH factors such as race, income, educational background and working conditions.

The current engagement model employed in most pharmaceutical organizations keeps physicians at the center. While this certainly helps address unmet HCP needs, it's also important to understand and identify hot spots with high disease incidence and lower access to care. With this information, medical affairs can redefine its customer engagement strategy and deployment model. In addition, emerging roles like virtual MSLs can help engage HCPs who live in remote areas, for example. Medical affairs can also collaborate with patient advocacy groups (PAGs) and physicians to assist in recruiting diverse clinical trial participants and designing inclusive trials.

Many organizations have started leveraging data from claims and electronic health records (EHRs) to identify treatment patterns and care gaps and help map the patient journey. Using this data to identify care gaps can enable medical affairs to quantify to internal stakeholders why targeted interventions are needed. With that said, it's important to involve the legal and regulatory teams in the early stages to ensure data usage and compliance standards are met throughout the process. Organizations can use claims and EHR data to:

- Evaluate the screening and testing landscape by determining if hospitals and institutions are ordering the necessary tests for diagnosis
- Measure adherence and persistence by analyzing patient-level data over the course of the treatment regimen, while also identifying points of discontinuation
- Understand standards of care across regions based on SDOH factors, so that medical affairs can intervene to reduce care gaps

The voice of patients

Medical affairs has long advocated for patients taking an active role in the decision-making and treatment process. Achieving this at a greater scale could enable medical affairs to improve patient centricity by better understanding patient challenges and areas where they need support. Pharma companies increasingly recognize that treatment and product success is elevated when drug development is centered around patient outcomes, with analysis of patient data and understanding unmet patient needs driving the rapid identification of new target molecules and indications.

Many organizations, especially commercial teams, use aggregated patient insights to inform their strategies and implement initiatives that better support patients. However, across the industry, there isn't a dedicated formal process to periodically capture these outcomes and integrate them into therapy innovation or advancement. Instead, companies heavily depend on PAGs to enhance the visibility of patient experience and needs, and to leverage patient-centric approaches at the therapy's launch.

We recommend organizations pursue a recurrent, insight-gathering solution that can help understand patient perspectives. For instance, a voice of the patient survey can enable organizations to understand patient pain points, reasons for drop-off, cost burdens, challenges around disease management and more. It could also help pharma organizations discover when patients need more assistance. Additionally, organizations can gauge how pharma-developed patient education materials, support programs and other initiatives are benefiting patients, as they aim to close care gaps.

Accessing insights like these makes it easier to identify various socioeconomic factors that drive the treatment experience for different patient cohorts. Information about what is effective and ineffective can inspire action from organizations that want to include the patient perspective in all their services, from drug development and clinical trial design to making and providing support beyond medication.

Medical affairs teams are particularly well placed to listen to the patient voice and elevate patient centricity in an organization's external and internal medical strategies. They can help assess gaps in education and awareness, while identifying specific hurdles and key reasons for low treatment adherence and persistence. Field medical teams can provide training and educational resources to help HCPs translate complex scientific content and R&D data into simple language that resonates with patients—this is why it's vital to focus on materials and information that physicians use while interacting with patients. Medical affairs can also play an integral role in addressing patient challenges around costs and coverage, with the goal of minimizing cost burdens. One way they can do this is by working across corporate functions to facilitate co-pay assistance programs and collaborate with payers to ensure access to medicines is not a persistent barrier.

Moreover, feedback from voice of patient surveys can be summarized at a patient profile level to help generate programs that tackle health inequalities and improve access and

payment support assistance for underserved and disadvantaged populations. The value-driven impact from leveraging patient stories in developing programs that consider holistic outcomes is significant and differs from traditional methods of analyzing patient data that focus on the capture of physiological outcomes. Sentiment analysis, combined with the review of patient and clinical registries, can potentially predict risks, challenges and clinical outcomes, while identifying touch points for medical affairs to intervene.

Given the early involvement of medical affairs in the product life cycle, they can also ensure patient perspectives are included in preliminary phases of drug development and clinical trial design. Furthermore, medical affairs can assign metrics and track utilization and implications. An example of this is the development of a patient-reported outcome as an endpoint in a clinical trial.

Given organizations' dependence on PAGs, medical affairs should consider deploying field-facing PAG liaisons who are strategically engaged across the product life cycle. These liaisons can further refine trial protocol designs, assist in patient recruitment efforts and help develop necessary educational materials. Building close partnerships and alliances with key PAGs can shift perceptions around treatment paradigms and increase adherence.

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Evaluating your organization's patient-centric maturity

Organizations can become more patient-centric by designing solutions that generate insights, track the patient journey, collaborate with integrated health networks, address care gaps and listen to the patient voice regularly. The foundation for achieving patient centricity through the four pillars of this framework converges on the diversity, equity and inclusion of all patients. It's evident that problems around patient access, adherence, drop-offs and other gaps in care are magnified among socially and economically disadvantaged communities. To put patients first, we need to ensure SDOH is at the core of our solutions and approaches.

The first step to improving patient centricity is to assess your organization's maturity. This maturity model can help you assess how your organization can improve its strategies and implement key actions to achieve patient-centricity excellence.

FIGURE 4

Patient-centricity maturity model

	Nascent	Evolving	Best-in-class
The patient journey	• Capturing limited portions of the patient journey, with most focus on the treatment phase	• Capturing the patient journey, but organization is unsure of appropriate points for medical affairs intervention	• Mapping the patient journey from symptom presentation to post-treatment care, with key decision points in place • Gathering insights around gaps and barriers, while identifying appropriate points for medical affairs intervention
Integrated care	• Identifying institutional and key accounts • Installing engagement strategies at an account level	• Developing a field medical role for key account engagement	• Strategically placing field medical affairs roles for key account engagement • Integrating field insights into organizational medical strategy
Understanding care gaps	• Identifying care gaps across regions • Learning about specific patient cohorts and how medical affairs can intervene	• Identifying regions with prevalent care gaps and building strategies to address them	• Identifying regions with prevalent care gaps and linking to SDOH factors and medical affairs needs • Using insights to close gaps
The voice of patients	• Capturing limited portions of the patient voice • Interacting with patient advocacy groups to understand the patient perspective—though poor integration with medical affairs is often observed	• Capturing patient voice regularly • Developing actionable items to be integrated into launch strategy and clinical trials	• Integrating patient voice throughout the product life cycle • Incorporating insights from the patient voice in medical affairs plans and initiatives

Whether your organization is nascent, best-in-class or somewhere in between, now is the time to leverage this patient-centric framework. Placing patients at the center can deliver a win for all parties, from patients to physicians to pharma companies.

Sunil John has been with ZS for more than 13 years and co-leads the firm's global medical affairs practice. He has authored several articles and provided perspectives on various medical affairs issues such as reinventing the go-to-market strategy for medical affairs, future customer engagement models and using data to define customer centricity and assess field medical teams. For the last seven years, Sunil has focused exclusively on global medical affairs across field medical, medical excellence, medical information and medical education. He also helps emerging and large pharma, biotech and medtech clients extensively with business strategy, launch planning and organizational design. Sunil assists with outcome-based KPIs, frameworks for patient centricity, digital strategy and roadmapping for medical affairs, medical insights and omnichannel engagements.

Richard Swank, Ph.D., has more than 20 years of experience leading medical affairs teams across molecule and product life cycles, developing medical brand strategies and fusing scientific expertise with business acumen. He is the former head of the U.S. MSL organization and the global field medical excellence team at Amgen. He has helped MSL teams launch product portfolios in more than seven therapeutic areas and has expertise in post-acquisition team integration and navigating joint ventures with industry partners. Richard also has expertise in medical capabilities, managing medical science liaisons, HEOR liaisons, medical information call centers and global field medical excellence teams. He is the founder and principal of the medical affairs consulting firm Scientific Engagement LLC.

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