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Defining the Course & Navigating the Finish Line

**Why life sciences companies need
medical affairs in today's highly competitive
pharmaceutical landscape**

Introduction

Authored by Zipher Medical Affairs Co., LLC now part of Lumanity

Despite the significant education and experience of Medical Affairs Professionals, their value is often questioned – likely because the business objective and impact of Medical Affairs teams are unclear. Their colleagues in Regulatory, R&D, and even Commercial have defined quantitative and milestone-driven goals, making it easier to track outcomes and measure their contribution toward business objectives. The Medical Affairs goal is not as well defined and outcomes are described in terms of tactical wins – the number of engagements, publications, or insights collected – it’s a struggle to communicate their deep connection to an overall strategic goal and how each member of the medical team contributes. This challenge can limit the effectiveness of the team and their ability to stand as a strategic partner within the company.

Imagine a rowing team in which each crew member understands their position and the role that they play, but they don’t know how to navigate the course or when – or if – they have crossed the finish line. Although individual focus, motivation, and energy may exist, would the value of this team be known? How would they synchronize actions and navigate to the finish? That’s the conundrum Medical Affairs teams face when their goal is undefined.

Would the situation change if we define the goal and clarify the finish line?



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Medical Affairs Strategy
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Medical Affairs is responsible for ensuring patient access to the company’s approved medicines by enabling informed decisions by providers, payors, and patients.

Defining the role of Medical Affairs as focused on patient access may seem controversial. Within Pharma, “access” is often associated with commercial roles dedicated to price and reimbursement. But the landscape is changing – medicine is more complex and barriers to access are expanding. Clinical guidelines, reimbursement pathways, and growing consumerism all influence access to

medicine. There is a greater demand for data and transparency to help providers, payors, and patients make informed decisions ensuring everyone wins.

Just as a coxswain provides information, motivation, and encouragement to their crew, Medical Affairs generates evidence, develops a clear narrative, and delivers the information directly to the key decision makers who can remove those barriers to access. By advocating for their crew in the midst of a moving landscape, helping them navigate, and communicating constantly, Medical Affairs is the force that propels movement in the right direction for patients.



Enabling informed decisions

While it is simple to say that the business objective for Medical Affairs is... ensuring patient access to the company's approved medicines by enabling informed decisions by providers, payors, and patients... it's true meaning is a bit more complicated.

In order to visualize how this business objective is achieved and value is recognized, we must consider both the internal and external perspective of the

Medical Affairs role and grasp how and when these intersect. Access doesn't begin at commercialization. It begins with clinical development as decisions are made that will define the regulatory pathways and eventually influence commercialization. Medical Affairs strategic leadership is part of this journey through the product life cycle from clinical development to a patient receiving therapy.

Internal leadership

Real-world vision to enhance and accelerate integration into the clinic

The pharmaceutical and biotech industry needs Medical Affairs to deliver insights and inform internal decision makers regarding if and how an investigational drug will fit the therapeutic landscape and have a differentiated value proposition. The Medical Affairs role is to anticipate and understand the barriers that may impede future access and communicate internally to help guide development and portfolio decisions. When engaged by their cross-functional partners early in the process, their knowledge can inform development and regulatory efforts and potentially accelerate integration of a new drug into clinical practice.

Scientific insight to support study enrollment

An effective Medical Affairs team can recognize obstacles, understand enrollment challenges, and develop plans to help clinical operations achieve their goals. Through consistent site engagement, the Medical Affairs team can help inform

potential investigators of the study rationale and design and inspire excitement for the study. Enrollment is essential for future approval and consequently a foundational need for the organization to accomplish their business objectives.

Data generation to fill information gaps and facilitate clinical decisions

Given the fact that regulatory studies typically fail to provide a complete clinical picture of real-world practice, Medical Affairs plays a critical role in identifying data gaps that may limit clinical utilization. Early exposure to the development and regulatory strategy allows Medical Affairs to properly plan for additional data needs. The timing of real-world studies, secondary analyses, and the release of the associated data become critical components to launch. Medical Affairs teams need to identify potential challenges to clinical utilization early, as well as provide action needed to support studies and create research programs— all of which will facilitate more effective clinical decision-making to guide appropriate patient access.

External leadership

Medical Affairs is the team that has the ability to analyze, translate, and communicate complex scientific and medical information in an objective and unbiased manner to a variety of decision makers. Stakeholders expect to engage

with medically trained personnel, and they demand data customized to their needs. These expectations speak to the strategic depth required by Medical Affairs and the importance of assessing the quality of interactions with decision makers.

At the provider level

The Healthcare Provider Team is a complex ecosystem made up of academic physicians/researchers, community physicians, allied health professionals, and nurse practitioners who participate in treatment decisions. Although channels of delivery and the context may be different for each stakeholder, they each require knowledge of clinical data, and a clear understanding of where these data fit in the therapeutic landscape, as well as the appropriate patient to benefit with the most manageable side effect profile.

The evidence to support this knowledge comes from regulatory studies, post marketing studies, and real-world evidence generated over many years. If the data are not available at the right time, a significant barrier to access will form.

A valued Medical Affairs Team is integral in the development of evidence and the communication of data. They maintain close

relationships with the frontline clinical team and understand their needs, concerns, and expectations. With that knowledge and a focus on coordinated research efforts, Medical Affairs can potentially prevent Provider barriers.

Because the lead time from study concept to data availability can be lengthy, these coordinated efforts should occur early in the development process to address current and future challenges and opportunities. The resulting evidence will supplement approval data and provide both Thought Leaders and Clinical Experts with the information they need to shape guidelines and pathways and allow healthcare providers to make informed and personalized clinical decisions for their patients.



Valued medical affairs team

- Recognizes the unique data needs of each member of the Provided Team
- Focuses on audience-specific communication of data
- Times delivery to align with the need

The influencers of informed decisions

Clinical Practice Guidelines set the standard of care for therapy through a 'systematic review of evidence and an assessment of the benefits and harms of alternative care options.'¹ Professional societies, provider groups, and research organizations develop and implement clinical care guidelines to promote evidence-based treatment for various disease processes. The attributed level of evidence and placement in the guidelines can have a significant effect on the utilization and reimbursement of a new therapy. Medical must have the data available and published to align with the timing for review and release of new guidelines.

Clinical Pathways and Formularies provide detail consistent with the local structure, systems, and time frames necessary to utilize the practice guidelines consistently and appropriately.² Pathways are tools with the ultimate goal of reducing unnecessary variations in care and costs. Clinical pathways are a way for physicians to lead improvements in quality of care and decrease the need to reduce reimbursement

through step edits and prior authorization. Lack of placement or poor placement on a pathway also reduces access for patients. Medical Affairs must develop and execute a multi-step educational process to deepen the understanding of the clinical treatment gap and show how the medicine uniquely fills the clinical need.

Patient-Physician Relationship is the foundation of all decision-making. Physicians must understand the treatment, so they can assess clinical benefit while also evaluating the social and personal needs of the patient. Consideration of the patient's co-morbidities and concomitant medications, combined with a growing volume of data, make decision-making more complex. Medical Affairs must consolidate and streamline, bringing only pertinent, fair balanced, and meaningful information to the attention of providers. This enables physicians to more readily talk with patients about how the drug profile may or may not fit their personal and clinical needs.



¹ AAFP Clinical Practice Guideline Manual. AAFP website. <https://www.aafp.org/patient-care/clinical-recommendations/cpg-manual.html>. Accessed May 4, 2020. ² Rotter T, Kinsman L, James E, et al. Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs. Cochrane Database Syst Rev. 2010;(3):CD006632. Published 2010 Mar 17. doi:10.1002/14651858.CD006632.pub2

Enabling access

At the patient level

A dynamic set of challenges is a defining characteristic of any contest or race. The condition of the team, the weather on race day, and the unexpected moves by the competition require a coxswain to be on guard, focused, and ready to act to a changing landscape. Regardless of the barriers impacting patients, Medical Affairs has a responsibility to support ease of access. Though not directly communicating with patients, the team must:

- Improve understanding of the disease state
- Raise awareness of therapeutic options
- Improve medication adherence

As more patients are taking healthcare into their own hands, they are going to make an increasing number of decisions for themselves. If that is true, then Medical Affairs must develop a strategy with that in mind. Medical Affairs can serve to improve health literacy toward better health outcomes.

A successful Medical Affairs team will engage with Advocacy groups, support patient education programs, and even

gamify learning and adherence with mobile applications. Each of these intersects with the need for evidence-based communications while further promoting engagement and education for patients. If the role of Medical Affairs is to ensure patient access by enabling informed decisions, then it is clear that Medical Affairs must work diligently with clinical care teams and advocacy groups so that patients fully understand their options for care.

Another focus for Medical Affairs is patient enrollment in trials. Medical Affairs teams do not talk with patients directly, but rather help clinical teams know what studies are available to their populations. Equally important to study awareness is guidance from Medical Affairs to socialize that research such that it reaches specific populations in the recruitment effort and ensures understanding of the value and medical benefits of participating. The ability to accelerate enrollment creates a greater potential for patients to have rapid access to new medicine.

Health literacy

Patient barrier to access

A great deal of research has been done to understand barriers to medication access for patients beyond cost and physician recommendations.³

Health literacy impacts the patient's perceived need for therapy, decision to seek help, ability to adjudicate the prescription, and finally, the capacity to adhere to the medication.⁴ Therefore, education is a key component to removing barriers that might prevent patients from realizing the full benefit of treatment.

3. Access to Care: Development of a Medication Access Framework for Quality Measurement. Pharmacy Quality Alliance website. <https://pqa.memberclicks.net/assets/Research/PQA-Access-to-Care-Report.pdf>. Accessed May 4, 2020. 4. Zullig LL. Engaging Patients to Optimize Medication Adherence. NEJM Catalyst Innovations in Care Delivery. 2017 May 14. <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0489>. Accessed May 4, 2020.

At the payor level

In understanding a payor's role, Medical Affairs can often determine motivating factors for coverage and address payor concerns before progress and access are adversely affected. The Medical Affairs team should be working closely with the Market Access team to strengthen the value proposition. Knowing the driving force and criteria for decision making can support the ability of Medical Affairs to help address issues related to insurance benefit design, coverage or no coverage, and publicly funded vs. private or commercial plans well in advance of product launch. The Medical Affairs team must recognize gaps in the data that are important to payors early in development and construct a health economic outcomes research strategy to address these payor needs.

While national payors author the rules for reimbursement, they often require supporting data to address the safety of the product. Medical Affairs is essential in supporting safe and cost-effective delivery by providing scientific evidence-based support.

Regional payors may not own or direct formulary assignment, but can be equally

influential if budget constraints or politics drive their decisions. Locally, Medical Affairs teams need to be familiar with the committees, administrators, and pharmacists who are likely more focused on their localized systems and deliver data corresponding to the localized need.

In each payor case, the requirement for supportive data is growing. With the help of Medical Affairs, agreements between payors and pharma companies are now being negotiated earlier so that approved treatments and products can be offered as soon as brands arrive in the marketplace. The ability of Medical Affairs to interface with payors early on, at every level, can accelerate adoption of treatments and help to educate influencers who are focused on delivering quality healthcare to patients.

Through payor presentations, advisory boards, and research presentations, Medical Affairs can validate the science behind the methods and provide actionable insights on reimbursement issues, which in turn, promotes clinical, population-centric, evidence-based discussions with stakeholders.

Figure 1
Informed decision making requires



Source: Lumanity analysis

Medical Affairs in the stern

Steering also means adequately synchronizing the effort.

The timing for strategy and execution of a Medical Affairs plan is similar to a cox's plan for a regatta. If it is not perfectly synchronized, the coordination of a program can suffer, and it becomes impossible to fluidly and consistently navigate the course. By maintaining a consistent role throughout

the lifecycle of a drug, Medical Affairs can aptly steer a team to better outcomes.

The role of Medical Affairs is also at the stern throughout the lifecycle of a drug. As a coxswain is not a rower in the race, they still maintain an equally important and arguably, more critical position. Behind every action, they direct the effort and help the team harness and achieve its potential.

Figure 2
Medical Affairs in the stern



Source: Lumanity analysis

Leading with strategy

To develop an effective strategy and promote patient-focused outcomes and informed decision making for all, the Medical Affairs team must understand the influencing factors from the start. Being responsible to lead the communication of that strategic plan requires them to collect insights early and report them, reflecting pertinence to each audience, in a timely way.

Prioritizing situation analysis helps Medical Affairs determine the uniqueness of each medicine in context of the needs and the perceived needs of each patient population and Provider. Following that, the careful

review of data, landscape conditions, and the competition can provide information to further strengthen the organization's ability to navigate toward their business objectives.

Weaving those pieces together while also considering safety, efficacy, and convenience helps Medical Affairs to create a compelling narrative which defines the medical needs, opportunities, and potential challenges of the market. Furthermore, that process and resulting information builds the clarity needed for Medical Affairs to prioritize defining tactics for how their goals will be accomplished.

Advancing with strong tactical execution

Scientific exchange, insight/knowledge collection, data generation, and scientific communication programs are the core functions of any Medical Affairs team. Individually, these tactics can create a considerable amount of information and consume a tremendous amount of effort. However, when programs are built around a strategy focused on the business purpose of Medical Affairs – which is to ensure that key decision makers have the information needed to make informed decisions about patient care – then the framework is in place to prioritize needs and resources. Cross-functional, integrated programs executed with this goal and entire team in mind, will rapidly advance the business objective and help establish an insight-driven culture.

As a coxswain must constantly survey and balance the needs of – the rowers, the landscape and the timing – so must Medical Affairs commit to harmonizing the internal and external functions which impact development, delivery, and access.

Scientific exchange

Medical Science Liaisons and Medical Directors engage with clinical experts, advocacy groups, payors, and medical societies to share data, discuss strategy, and participate in a dialogue which provides both parties with valuable knowledge.

These experts who engage with pharma expect to learn more about the rationale for study designs, gain a deep knowledge

of the data, and engage in an objective, balanced, and unbiased conversation about the strengths and weaknesses of the data. Medical Affairs professionals must understand how the data are interpreted within the current and evolving landscape and assess the real-world implications. Medical Affairs professionals not only participate in dialogue but, through active listening, gain actionable insights and knowledge from the experts that may influence future data generation or communications strategy.

The insights generated and the communications shared during scientific exchange accelerate the transfer of information to break down barriers to access.

Medical communications

Barriers fall when data in peer-reviewed publications support changes in clinical practice. Exposure to such information is amplified through channels to reach providers, patients and payors.

Interpretation of data, the timing and flow of data release, and the scientific narrative that is supported by the published data is an essential component of any successful pharmaceutical launch. The conversion of these data into communications designed for each audience and delivered by Medical Affairs can make or break the success of a new therapy. These communications, as well as Medical Information call center activities, are venues to educate and gain additional insights.

Data and evidence generation

The continuous development of evidence is essential to ensure proper information is available for decision makers.

As the therapeutic landscape has become more complex for most disease states, the data generated through regulatory studies is merely a starting point. The gaps in the data must be rapidly filled through Medical Affairs studies (Phase IV, collaborative trials) or analyses. Otherwise, the lack of data and knowledge can lead to delays in the integration of a new medicine into clinical practice.

The Medical Affairs team is responsible for providing insights to help prioritize the objectives of secondary analysis of

regulatory studies, designing studies to satisfy post-marketing commitments, and learning how to manage toxicity. Their role goes even deeper with the development of early access programs and real-world data collection through registries and retrospective database analyses. The medical team builds collaborative studies to expand signal detection for future use and oversees the areas of interest for Investigator Sponsored Studies (ISS). The objective is to fill knowledge gaps in order to eliminate barriers to use and potentially discover clinical signals that could further guide clinical development.

Collaborative effort

Achieving medical excellence

Just as on any sports team, the players in the Medical Affairs arena must share a common goal, know their positions, rehearse their roles, and practice as a coordinated and collaborative group – focused on a clear objective.

This effort requires a deep knowledge of scientific methodology as well as the ability to analyze, interpret, simplify, and communicate data from many sources. The team needs to quickly fill evidence gaps that could limit decision-making efforts at any level. Their effort is rewarded when patients have immediate access to a new therapy upon regulatory approval.

Medical Directors

Charged with providing strategic leadership to the entire medical team, the Medical Directors engage cross-functional partners, drive medical understanding internally, interpret insights from engagements with Key Thought Leaders, and lead strategic planning and tactical execution. Their role requires them to not only have the strong clinical and scientific depth of knowledge, but to also have the vision and forethought to grasp the potential evolution of the therapeutic landscape. Medical Directors guide the development and execution

of data generation plans that will deliver the evidence to meet the needs of the providers, patients and payors.

Critical skills and capabilities:

Leadership and facilitation, strategic and analytic thinking, decision making, data analytics, professional communications, business knowledge, operations and time management.

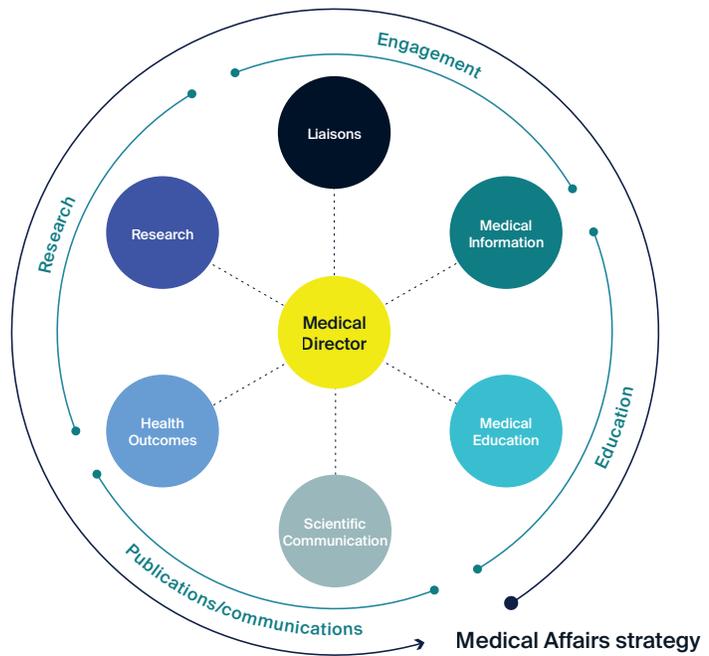
Medical Science Liaisons

Forming the external face and the voice of Medical Affairs, Medical Science Liaisons are the scouts building relationships. While participating in scientific exchange, they serve as a portal for thought leaders to the company and observe/identify critical information that will impact the company. The field-based team provides the “boots on the ground” perspective of the healthcare decisions makers, the competitive landscape, the data needs, and the detailed knowledge of access challenges. Their ability to assess and communicate their learning can be a game changer for the medical team.

Critical skills and capabilities:

Scientific competence, analytical knowledge, active listening, strategic thinking, professional communications, relationship management, business sense, and initiative.

Figure 3
Medical Affairs strategy



Source: Lumanity analysis | Copyright © 2019-2020 Zipher Medical Affairs Co., LLC, a Lumanity business

Scientific publications

Responsible for shaping the scientific narrative and determining the communications strategy and the channels for delivery, these communication professionals define how to display and interpret data while working closely with thought leaders who will communicate the data through publications and presentations. Often this role is under appreciated due to heavy focus on deliverables and project management. However, this team spends an extensive amount of time with Key Thought Leaders and is on the front lines of defining the medical messages used by the entire company.

Critical skills and capabilities:

Scientific competence, analytical knowledge, relationship management, project management, leadership, strategic thinking, professional communications, and initiative.

Health economic and outcomes research (HEOR)

While regulatory studies set the foundation for agency approval, the value of the medicine is established by combining knowledge of the development data with real-world studies to measure performance under real-life circumstances. The HEOR, also known as the Value Evidence Generation Team, has the knowledge and expertise of big data and executes real-world studies through registries or databases. HEOR has its greatest success when they begin planning early and work closely with the Medical Directors to understand the unique barriers effecting each medicine.

Critical skills and capabilities:

Analytical knowledge, database comprehension, business acumen, strategic thinking, project management, and scientific/ medical communications.

Medical information

Patients and providers expect rapid responses to their queries. Medical Information is the portal to live, real-time information through their customer service focused function in Medical Affairs. The Medical Information professionals are charged with anticipating potential questions and preparing response letters as well as rapidly researching and preparing responses to questions. Historically, providers (HCPs or pharmacists) reach out to the medical information call center while the patient is in the examining room. How quickly, concisely, and thoroughly the call center responds may have a direct influence on patient access to the medicine. Today even patients are reaching out and expecting answers.

Critical skills and capabilities:

Clinical knowledge, strong written communication skills, regulatory training, customer service focus.

Independent medical education (IME)

While IME is awarded through grants and no longer an activity executed by Medical Affairs, it remains an important function that must be integrated in Medical Affairs planning. Formal, certificate-based education is still a major source of information for providers and online education is a growing source of information

for patients and caregivers. The timing to initiate disease state education should align with clinical development planning because it may influence enrollment in trials. In addition, IME/CME provides a strong independent source of information to support clinical decision making. When considering the timing of this education, it should take place such that it aligns with the release of key publications or presentations at congresses to assure up-to-date education for providers, patients and payors.

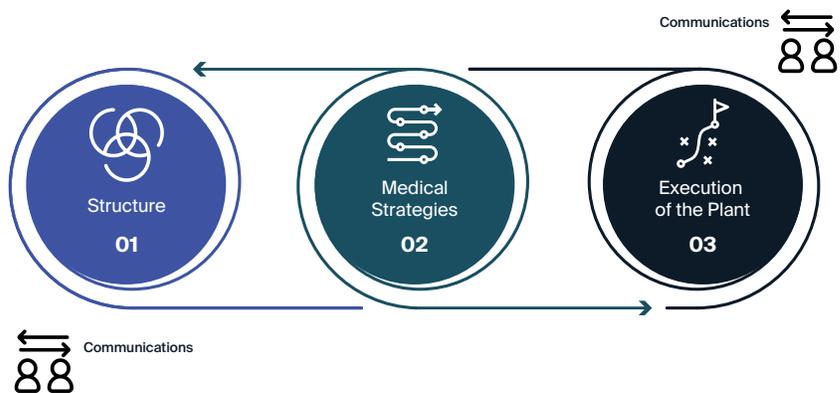
Critical skills and capabilities:

Business acumen, strategic thinking, knowledge of adult learning, operations and project management skills.

Medical Affairs team members collectively have a deep understanding of disease state, market landscape, compliance and safety issues, internal and external stakeholders needs, and health care systems in general.

This cross-functional understanding uniquely positions them to take the lead in establishing an early strategic plan to meet the demands of new therapies. Their clinical and operational expertise as real-world data drivers who hold insight into the needs of both internal and external stakeholders is invaluable to organizations competing in the current Pharma market. Their cross-functional collaboration is key to driving medical launch success.

Figure 4
Integration of tactics



Source: Lumanity analysis

Setting a course for success

Clinical evidence continues to drive the differentiation of drugs and optimal positioning on formularies, pathways, and in clinical practice guidelines. Medical Affairs must demonstrate assertive leadership in lobbying to redefine their strategic identity within pharmaceutical and biotechnology organizations to navigate and advance the field and maintain patient focus.

It is a fact that there is only one chance to launch effectively. It may require us to think differently about the traditional role of Medical Affairs. In order to balance the demands of all essential pillars, Medical Affairs needs to be at the forefront — focused on their business objective — not just to disseminate information outwardly but, equally to collect, assess, and distribute meaningful information as a strategic partner to the development effort and the commercialization process.

Despite potential barriers, they must fight for the right to enter early, communicate often with meaningful and relevant data to

drive team efforts toward patient access as the win. Value is a data-driven endpoint dependent upon the communication of scientific evidence and the delivery of information tailored to each stakeholder.

As in any race, valuable lessons are learned in defeat. The team must identify where the crew and coxswain could have handled situations better. And, as a team continues to practice together, they begin to understand that the best way to perform is with informed direction and consistency, through mastering the skills of the sport, and then perfecting implementation in real-world pressure-filled situations.

Creating and delivering clinical evidence is like treading water in the race, unless the information is rooted with meaning and relevance to an audience primed to receive it, nothing happens. The goal is always the same, Medical Affairs must strive to ensure access by providing the right information to the right patient at the right time.

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Today it is rare for a drug to enter a market with an empty therapeutic landscape. To succeed you must know the landscape, think through the needs of each stakeholder, understand reimbursement issues and make sure the right data are available. The current business model has not quite adjusted to the speed of change in the current market. Medical Affairs has to step in earlier and strategize for better outcomes and quicker access.

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Summary

The intended purpose of Medical Affairs is to provide data and knowledge to inform decision making and allow patients access to effective drugs in a timely way with minimal side effects. We must elevate the Medical Affairs role to a strategic partner similar to the coxswain, poised at the stern, to set the course and successfully navigate in the right direction for patients.

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real-world insights and evidence that powers successful commercialization and empowers patients, providers, payers, and regulators to take timely and decisive action.

Contact us to learn more about how Lumanity can support your unique challenge.

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