MAPS
FOR Medical Affairs Professionals
BY Medical Affairs Professionals

Medical® Affairs Professional Society

The FUTURE of EXTERNAL EDUCATION 2030

A position from **MAPS** on how **Medical Affairs** can OPTIMIZE industry-led and independent Medical Education for maximum VALUE and IMPACT

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OPTIMIZE industry-led and independent Medical Education for maximum VALUE and IMPACT.

Introduction

External Medical Education involves providing a variety of tools and content to healthcare professionals (HCPs), payers, and patients or caregivers aimed at closing specific knowledge, competency, or performance gaps. It encompasses several overlapping categories:

- Continuing Professional Development (CPD) includes a broad range of activities such as leadership or practice management.
- Continuing Medical Education (CME) and Continuing Education (CE) aim to provide the medical, surgical, or device knowledge or skills needed for optimal patient care.
- Performance Improvement (PI) involves evidence-based performance measures.
- Quality Improvement (QI), in response to quality concerns, will improve patient outcomes or reduce costs.

External Education should focus on providing scientifically sound education to improve medical knowledge and, ultimately, clinical practice. According to MAPS, the primary goal of Medical Education should be to enhance the recipient's understanding of a disease state and pertinent data and ensure the safe and effective usage of a product or drug delivery system or medical techniques. (1) (2)

External Education generally consists of three buckets: Firstly, Independent Medical Education (IME), which is free from Commercial influence and conducted by an independent organization and can be funded with Commercial support; secondly, company-led education which can be driven by various functions, including Medical Affairs or Commercial teams; and thirdly, collaborations between a sponsor company and medical society or other credible organizations. (3) However, it should be noted that regulators consider only two buckets; independent and non-independent. Industry can be held responsible and accountable for any External Education that is not 100% independent. (10)

Each type of External Education can support products in different phases of their life-cycle, and all should be deployed synergistically as part of an overarching strategy aimed at accomplishing organizational goals. In doing so, External Education is an important function enabling Medical Affairs to demonstrate its value as a strategic pillar within an organization.

ABOUT this WHITE PAPER

THIS WHITE PAPER AIMS to articulate a position from the MAPS organization on standards and best practices in External Education, with a particular focus on current areas in need of clarification, such as scientific exchange and cross-functional collaboration.

A MAPS roundtable workshop hosted by the External Education working group was held on March 26, 2023; the roundtable brought together leaders from External Education, Medical Communications, Field Medical, Strategy, Digital, Medical Information, Launch Excellence, Compliance, Patient Centricity, and more.

The group discussed how different functions can optimize their work processes to have the highest levels of success in External Education and scientific communication and engagement, building on the MAPS White Paper "The Future of Medical Affairs 2030." (11)

Insights from the roundtable have been collated and extended through in-depth interviews with contributors, and the main findings are laid out in the following pages. In particular:

- ✓ Current challenges and overlap between Company-led Education and Independent Medical Education
- ✓ Clarification around Evidence Dissemination, Scientific Exchange, and promotional vs. non-promotional activities and education.
- ✓ Addressing current gaps and barriers regarding Scientific Exchange and Promotion
- ✓ Distinguish between the role of Medical Affairs and Commercial functions in External Education

Introduction
(continued)

In the US, most External Medical Education funding from the pharmaceutical (pharma) industry is awarded to IME. However, in recent years, particularly with the growing impetus towards omnichannel engagement, company-led External Education has been on the rise, following trends in other regions.

In planning External Education, four core elements are essential: a Needs Assessment, instructional design, execution, and outcomes measurement. Each stage plays a critical role, starting from identifying the specific gaps or needs in knowledge or skills. This assessment then informs the development and execution of the External Education strategy. Instructional design tailors the educational content to address these gaps effectively. (4)

The execution phase involves the actual delivery of this education, followed by measuring outcomes to evaluate the impact and effectiveness of the educational program. This comprehensive approach ensures that the education provided is relevant and effective in addressing the identified needs and guides improvements or course corrections as necessary.

Regulatory Responsibilities

While the Medical Affairs function provides scientifically sound and fair balanced medical education, commercial educational offerings can be promotional in tone. Consequently, regulators may consider the intent of Medical Education when assessing it.

In the US, the FDA has jurisdiction over any promotional content—including scientific or educational activities that mention approved and pre-approved products. The FDA has issued guidance documents that allow for exceptions in scientific communication, specifically for content that is not promotional. One such exception is the 'Independence' safe harbor provided by IME. (10) This safe harbor ensures that educational materials and activities are independent and not influenced by manufacturers. Materials and activities must comply with the Accreditation Council for Continuing Medical Education (ACCME) standards to achieve independence (regardless of whether an activity is certified for credit). (3)

These standards guarantee that accredited CME meets the needs of patients and the public, is based on valid information, and remains free from commercial bias.

Figure 1. Planning starts with the known patient healthcare gaps and ends with closing the HCP performance and competency gaps needed to improve care. Source: MAPS Standards and Guidance on External Education.

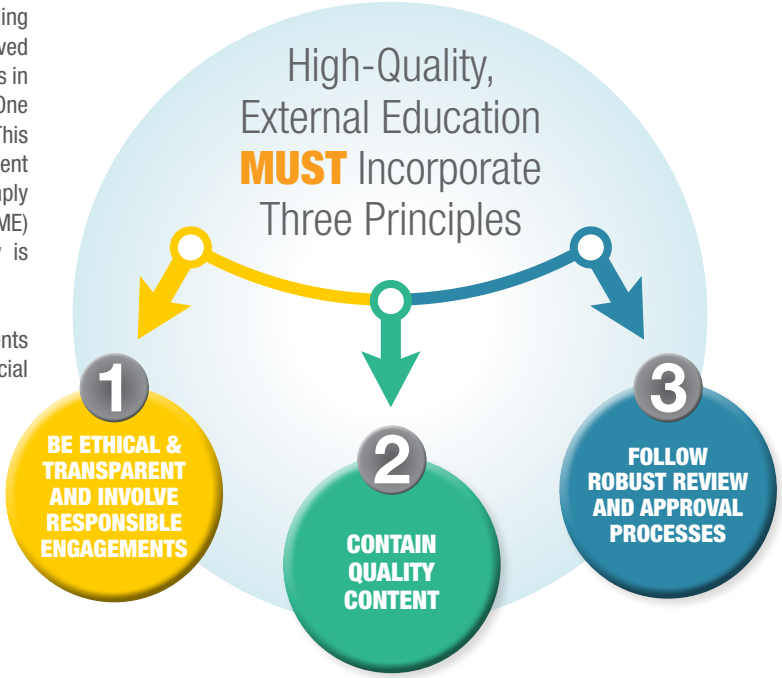


Figure 2. MAPS position on the fundamental principles of high-quality External Education. Adapted from MAPS e-Learning Module, Introduction to External Education.

Strategy and Planning

In today's omnichannel environment, Medical Affairs is poised to become—or has already become in some cases—a strategic leader within organizations. However, a major challenge remains—achieving a holistic understanding of how various Medical Affairs teams integrate their tactics. One way to do this is to create an Integrated Medical Communications Strategy & Plan (iMC S/P), as discussed in the MAPS White Paper on Integrated Medical Communications Strategy and Plan. (5)

When building a plan, bringing global and regional Medical Affairs teams together to define and separate efforts to create a coordinated education strategy is a solid starting point. Importantly, any communications regarding off-label uses or investigational products should be planned and conducted solely by Medical Affairs teams to avoid regulators inferring improper promotional intent.

Each Medical Affairs team should ideally concentrate on shared goals, with their activities harmoniously complementing each other. By synchronizing these efforts, the collective actions can advance the field at hand more efficiently, leading to improved patient outcomes, a task far more challenging if teams work in isolation. Backward planning, when properly utilized, can ensure that the end goals identified during Needs Assessment activities drive the content design for maximum effectiveness and clarity, focusing on impacting patient outcomes. It is also essential to recognize where the product or compound is in its life-cycle and identify the specific needs at that stage.

Education provided by different communication channels in Medical Affairs should be synergistic and integrated into one plan. They should not be seen as competing against one another, nor should they replace each other. Each element has its unique purpose and necessity. Moreover, they collectively fill a gap for learners, such as HCPs, addressing their specific needs and challenges.

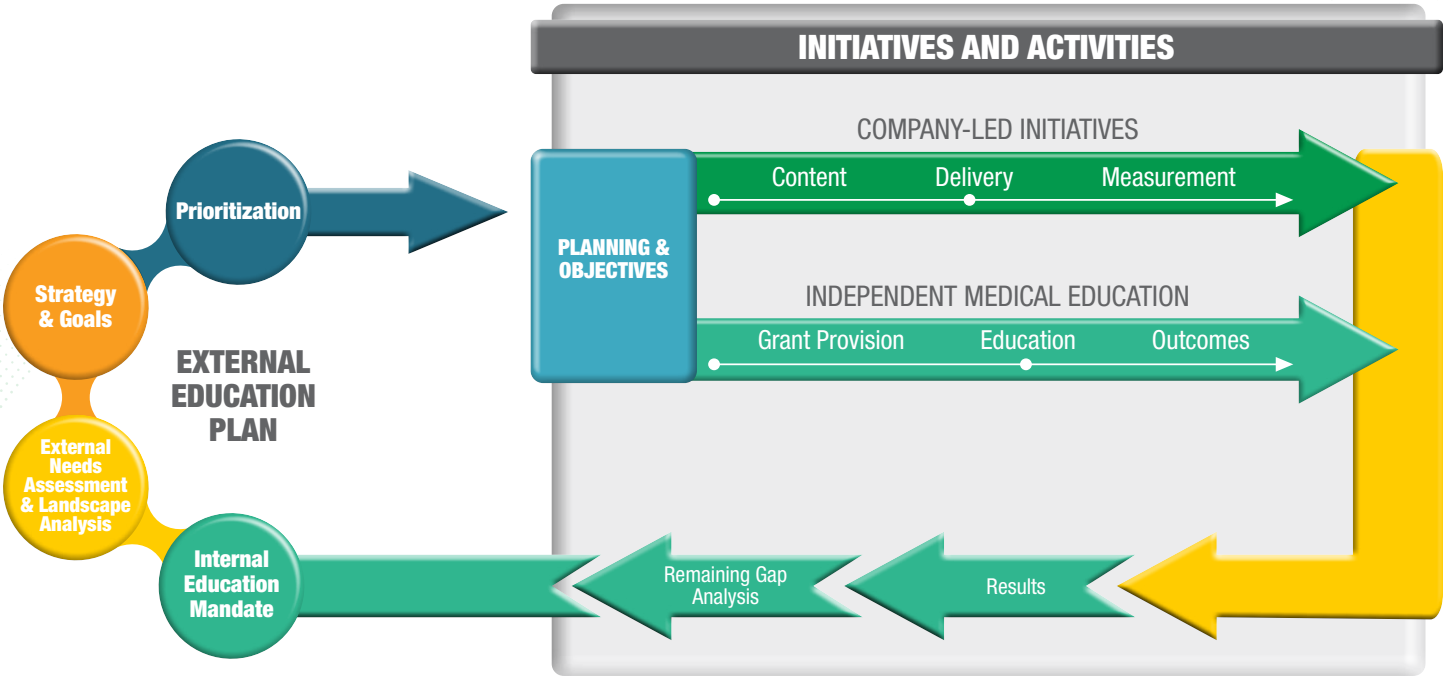


Figure 3. A framework for cohesive strategic planning of External Education. Source: Adapted from Pfizer Global Medical Grants.

Needs Assessment

Performance and competency gaps are identified through an ongoing Needs Assessment. When focused on specific performance needs and gaps, CE improves learning outcomes for HCPs and positively impacts patient care. The process of gap identification, understanding the divide between actual and ideal performance, should always be conducted with the expected outcomes or desired results in mind.

Strategy and Planning
(continued)

Gaps typically stem from deficiencies in performance (the actual behavior), competence (the requisite ability or skill), or knowledge (the necessary facts and information). Ongoing practice-based Needs Assessments and education that utilizes various relevant, interactive learning methods are essential in supporting outcome changes. Please consult the MAPS Standards and Guidance on External Education for further information.

Instructional Design

Instructional design is the practice of systematically creating instructional products and experiences that allow learners to acquire knowledge efficiently, effectively, appealingly, engagingly, and inspiringly. Instructional design includes learning formats, program design, and curriculum. Please consult the MAPS Standards and Guidance on External Education for further information.

Choosing Educational Tactics to Bridge Gaps

Currently, many Medical Affairs professionals are seeking guidance on the value of each tactic and when to use it while avoiding duplication of effort or overlap. That is where the power of iMC S/P can be fully realized by aligning and leveraging the intent and content across different communications channels. The most appropriate tactic depends mainly on the content and intent of the education. (see Table 1 on page 6)

IME

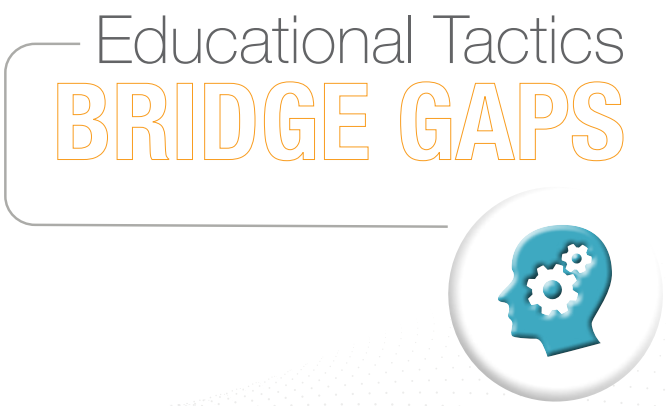
One advantage of IME is that it tends to reach more significant numbers of HCPs than company-led education, as congresses and content form part of avenues and channels that HCPs regularly use in staying up-to-date in their clinical practice. Additionally, the content is typically accredited, adhering to robust and stringent standards, and is viewed as more trustworthy by recipients due to the lack of industry influence. IME often aims to address HCP performance gaps or healthcare system quality gaps. Examples of activities include congresses, live or virtual events, self-paced learning, or QI initiatives.

Company-Led Education

Company-led education allows for direct influence over content, enabling companies to tailor their message to address specific knowledge gaps or needs. This approach is beneficial for the company, as it allows for the integration of the company's scientific narrative. Being able to direct the message enables the delivery of relevant content, which is the end goal. Aims might include improving patient outcomes by improving specific competencies, knowledge, or performance gaps. Content might include therapeutic areas, disease states, and investigational compounds within the pipeline. Many companies review and approve these as promotional programs, meaning that most programs are limited to on-label information.

Examples of activities include satellite symposia at congresses, webinars, scientific standalone meetings, surgical and procedural training labs, surgical techniques and management of complications, and educational videos or infographics (see Figure 2 for more details).

Regulatory and compliance frameworks within an organization are essential components of the content creation process. Many companies are currently focusing on creating omnichannel-friendly regulatory and compliance approaches, which allow for modular content, reduce the duplication of effort, and increase efficient and more standardized content production for company-led scientific and educational content.



Strategy and Planning
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Question

What is a key strategic consideration in terms of External Education that you think should be addressed by an organization?

CO-AUTHOR CORNER

A. *"Overall, the biggest challenge is coming to a place where we can understand how all the Medical Affairs teams and communication channels fit together like puzzle pieces so that there is an overarching strategy and vision from a Medical Affairs perspective. Any given team should really be aiming at one North Star with our efforts aligning so that we're doing different things that are complementary to each other, not duplicative with each other or contrary to each other either. That way we're all aligned and moving an area forward, as opposed to teams working in silos."*

Sue Ellen Touma
Director, Global Medical Education, Regeneron

A. *"Over the last three years or so, company-led education has become more relevant and present in the US. In many other parts of the world, company-led education has been utilized more heavily for many years. I would like to clarify how IME and company-led education work synergistically together to ensure the strategies of the Medical Affairs teams are supported adequately and fit into the life-cycle planning of a product or portfolio within an organization."*

Kirtida Pandya
Ex. Director, Medical Services and Operations, Sandoz

A. *"The life-cycle of the product plays an important role in what the educational needs are and the strategy. The education tactics are synergistic rather than competitive, because they each have their own purpose of serving the need of the product within the life-cycle as well as that they're fulfilling a gap for the healthcare professional."*

Patricia Jassak
Independent Consultant, Strategic Excellence and Insights, Inc.

A. *"How can you target the right content to the right customer at the right cadence on the right channel? You're trying to tailor the information that is being served or the education provided to each respective healthcare professional, while also partnering with sources of authority, like medical societies."*

Jean-Jacques Murama
AVP, Global Medical Affairs Omnichannel & Independent Education, Lilly

A. *"Each company has a core strength in terms of their technology and knowledge about specific disease areas and mechanisms of action for their products. This is a depth of knowledge that IME providers often can't contend with, because of the depth of knowledge within the company. I think we as an industry could do a much better service to the community if we focus more on company-led Medical Education initiatives where we have the depth of knowledge and leave more generalized Medical Education to IME providers, where they could potentially source subject matter experts from the community itself."*

Neha Shah
Sr. Director, Digital Medical Affairs, Moderna

A. *"There's a lot of up-skilling required for people developing materials for pharma companies, because the digital space is different. There are things like targeting that seemed very promotional historically. But in the digital space, there are medically appropriate ways to target audiences. Medical reviews and requirements are different from promotional review requirements, but our audiences only see one company. If Commercial colleagues are on the same channel as medical teams, and we're all producing pieces at volume, the regulatory authorities have concerns. So, there are new requirements that you have to be responsible for coordinating activities with your Commercial colleagues."*

Jennifer Ghith
Sr. Director, Generative AI Content Team Lead, Pfizer Inc.

Strategy and Planning
(continued)

EXTERNAL EDUCATION OVERVIEW

	NON-INDEPENDENT/HIGH LEVEL OF INFLUENCE					INDEPENDENT/NO INFLUENCE
	INDUSTRY-LED		COLLABORATIONS/SUPPORT FOR SOCIETIES		INDEPENDENT MEDICAL EDUCATION	
	COMMERCIALLY LED	MEDICALLY LED	MEDICAL SPONSORSHIPS	COLLABORATIONS OR PARTNERSHIPS	CONTINUING MEDICAL EDUCATION	FELLOWSHIPS OR YOUNG INVESTIGATOR AWARD
INTENT	Promotional	Non-promotional (disease-state)/science driven promotion (brand-aligned)	Non-promotional	Non-promotional	Non-promotional	Non-promotional
CONTENT FOCUS	Disease state, on-label treatment	Medical Education that addresses knowledge, competency, or performance gaps, including pipeline, therapeutic, or disease state to improve patient outcomes	Research-based or scientific	Research or addressing healthcare challenges	Addresses HCP performance gaps or healthcare system quality gaps to improve patient outcomes	Building healthcare capacity/specialist training
INDUSTRY PROACTIVELY IDENTIFIES THE PROVIDER	Yes	Yes/no	Not applicable	Yes/no	No; however, a call for grants or a request for proposal may also be utilized	No
ACCREDITATION	Non-accredited	Non-accredited in pharma/ sometimes CE-accredited (device/outside the US)	Non-accredited	Mostly non-accredited	Accredited/non-accredited	Not applicable
PROGRAM APPROVAL PROCESS	As directed by internal company policy. Usually includes compliance/ governance, medical, legal; may be at local, regional and global levels. Requires content approval	As directed by internal company policy. Usually includes compliance/governance, medical, legal; may be at local, regional and global levels. Requires content approval	As directed by internal company policy and/or appropriate governance requirements, which may vary (e.g., review committee, non-promotional review)	Appropriate governance and transparency requirements as directed by company policy and partner company/society policy. May require content approval	Grant review committee Many organizations allow delegation of authority to grant managers to approve grants under a specified amount	Grant review committee
FACULTY SELECTION	Company with/without external provider	Company with/without external provider (medical communications agency) Company-selected external steering committees	Determined by external organization/society	Scientific steering committee of partner/society with/without company input	Grant requestor/ educational provider/Medical Education and Communication Company	Universities/societies
EXAMPLES	Product presentations for meetings and events, speaker trainings, promotional speaker meetings, product/ innovation theaters at congresses, ad campaigns, journal advertorials, unmet needs disease-state campaign (unique to asset to be promoted)	Satellite symposia at congresses, webinars, scientific stand-alone meetings, review publication on disease burden, mechanism of disease video, disease website for HCPs providing overview of patient unmet needs, educational video series or infographics	Disease-state think tank associated with a professional society Sponsorship of medical society or international congress (e.g., gold, silver, or bronze)	Collaboration/partnership with a professional society on an educational event or asset. May involve more than one industry partner Preceptorships with an academic Medical Center of Excellence	Live/virtual or enduring activities, (QI) initiatives	Graduate Medical Education (GME) approved Fellowships Young Investigator Scholarships

Table 1. External Education Overview for Industry-Led Education and IME. Source: MAPS Standards and Guidance.

Strategy and Planning
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ALIGNING EXTERNAL EDUCATION

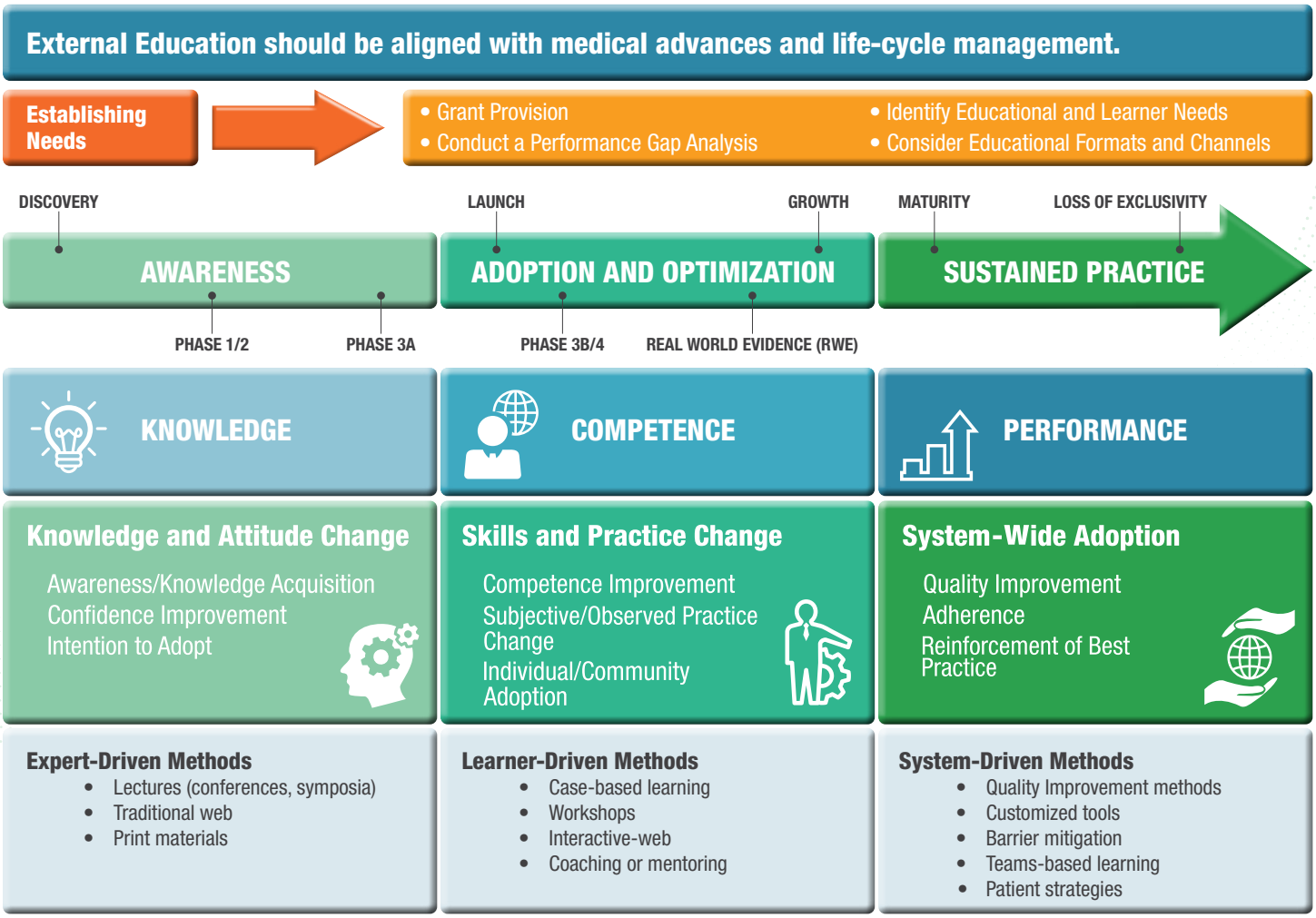

Figure 4. How to elect External Education tactics according to product life-cycle stage. Source: MAPS e-Learning Module Introduction to External Education. Source: MAPS e-Learning Module 3. (24)

Reinforcement of Best Practice

Evolving Compliance Considerations

Defining Medical Affairs and Commercial Roles

Industry colleagues are particularly focused on understanding the distinction between Medical and Commercial communications. This is partly driven by time-pressured HCPs seeking more scientific value from their engagements with pharma and Medical Technology (MedTech) companies. At times, they prefer peer-to-peer interactions, such as scientific exchange with Medical Science Liasions (MSLs) or Medical Affairs professionals, instead of traditional meetings with sales reps.

Despite Commercial teams still receiving the bulk of communications budgets, HCPs' preference for Scientific Exchange with Medical Affairs colleagues has resulted in emerging trends across the industry. These include an increase in the number of MSLs partly because many healthcare organizations are limiting sales reps' access to clinicians. Additionally, Commercial teams are working to incorporate meaningful value-added offerings, such as educational materials, to engage busy HCPs under elevated time pressures, especially since the COVID-19 pandemic.

One such trend has been that disease awareness education has become increasingly the remit of Medical Affairs, whereas traditionally, it fell to marketing. Subsequently, there is a need to clarify what is permissible for Medical Affairs professionals to discuss instead of Commercial colleagues.

This includes discerning the boundaries within Medical Affairs communications, such as differentiating between product-specific education and disease-related information and whether these topics can be addressed concurrently. FDA guidance informs us that disease awareness communications are communications disseminated to consumers or HCPs that discuss a particular disease or health condition but do not mention any specific drug or device. They also do not make any representation or suggestion concerning a particular drug or device. (6)

Much of the existing uncertainty stems from varying perceptions of risk. If there were clearer distinctions and guidelines regarding what constitutes branded versus unbranded content, promotional versus non-promotional material, and the appropriate combination of these elements, it would assist the industry in determining what can and cannot be communicated and what the guardrails are regarding review and approval of such content. Enhanced clarity in these areas would help not only in compliance but also in strategizing effective communication methods within the industry.

CO-AUTHOR CORNER

Question

Can you define which areas of External Education you feel lack clear guidance or need some clarification to aid execution?

A. *"A Working Body across the industry consisting of legal and compliance individuals focusing on Medical Education challenges would be very helpful—not only from a medical perspective but also a Commercial one. We could focus on company-led scientific education of external stakeholders and consider FDA guidelines to create a more specific framework."*

Neha Shah, Sr. Director
Digital Medical Affairs, Moderna

A. *"One of the key challenges that we have is that the FDA guidance in terms of Scientific Exchange is vague. The guidance can be interpreted in numerous ways in practice; for example, are we able to support scientific discussion on new evidence at congresses in person or online? We have had to rely on our legal and regulatory team to help us define guardrails, based on case law and discussions with the FDA so that we are protected in our procedures."*

Jean-Jacques Murama
AVP, Global Medical Affairs Omnichannel & Independent Education, Lilly

A. *"Historically, marketing has been doing disease awareness education campaigns. Now, Medical Affairs and marketing are kind of all in the same pot looking for ways to consistently provide value and are both doing disease awareness education. Medical Affairs is not only viewed as more scientific from an external user's point of view, but it is more scientific. So how do we split that out and separate it?"*

Patricia Jassak
Independent Consultant, Strategic Excellence and Insights, Inc.

A. *"Within Medical Affairs, clarity is needed on how External Education differs from other activities and engagements led by other Medical Affairs functions, such as Medical Information, Medical Communications, Publications, or MSLs in the field. For example, are MSLs providing External Education or engaging in scientific exchange?"*

Jennifer Ghith
Sr. Director, Generative AI Content Team Lead, Pfizer Inc.

Evolving Compliance Considerations
(continued)

Compliant Cross-Functional Collaboration in an Omnichannel World

Cross-functional planning has become essential to ensure adherence to regulatory and compliance requirements and carefully observe the growing potential for overlap between Commercial and Medical Affairs, thereby remaining compliant. The more activities are integrated, the more challenging it becomes to convince regulatory bodies like the FDA or the Department of Justice of their distinctiveness.

This is especially important when it comes to activities that Medical Affairs should deal with alone, according to Jessica Ringel, a partner at King & Spalding law firm specializing in FDA regulations. She advises clients to be aware that regulators assess organizational activity as a whole rather than the activities of isolated functions, teams, or activities.

If Commercial and Medical Affairs teams are using the same communication channel, producing a large volume of content, it could lead to regulatory concerns due to the creation of an "echo chamber" effect.

"If you're communicating off-label uses, such as different dosing regimens—if we're talking about pharma—or an emerging procedure—if we're talking about devices—even if the Medical Affairs department is leading the communications, a regulatory agency such as the FDA may still look at the activity skeptically," says Ringel, explaining that a regulator will consider the totality of activities from across an organization to determine whether to deem the intent behind communications on an off-label topic as promotional or non-promotional.

This necessitates new responsibilities, such as coordinating with Commercial counterparts. It is essential to ensure that when one team is active on a channel, the other is not. It may be necessary to decide to use only a specific channel that the other team does not use, leading to strategic discussions. The level of coordination between Commercial and Medical remains an area of risk, and each company may choose to set different limitations.

ASK A LIFE SCIENCES LAWYER

Q. What do you see as the most important compliance elements for pharma, MedTech, or biotech companies to consider when approaching External Education?

A. *"Coordination between Commercial and Medical Affairs is increasing. Be aware that everything will be viewed by regulators as a constellation of activities, and they will look at that larger context, but at the same time, they can also cherry pick."*

Q. How do you define Scientific Exchange?

A. *"Scientific Exchange is advancing scientific knowledge and discussion by disseminating scientific findings or information that is not intended to drive or create product demand or sales. Often, Scientific Exchange might talk about off-label uses and emerging data or techniques that haven't yet been through the regulatory pathway. So, to track the effectiveness of scientific exchange, you might show a decrease in questions or queries on a topic or a decrease in adverse events."*

Q. What advice would you give for conducting off-label communications?

A. *"If Medical Affairs is conducting communications on off-label uses or techniques, a regulator may still be skeptical and question whether activities are truly separate if Commercial and Medical colleagues regularly work together, for example, if an MSL and a sales rep work together on sales calls. Working together and coordination is fine when everything's on-label, but when you're doing something that is more appropriately in the purview of Medical Affairs, it's harder to claim independence when half the time functions are actually working together."*

Q. Why is it important not to work in silos, but to be aware of off-label communications across teams?

A. *"One activity from one team alone might look innocuous, but when compiled together with other activities from other teams, a number of small, insignificant activities to the regulator looks like a concerted effort to drive off-label sales."*

Jessica Ringel, Partner, King & Spalding LLP

Evolving Compliance Considerations
(continued)

"It's important that we don't silo ourselves so that we don't miss anything," says Jennifer Ghith, member of the MAPS Digital Working Group and Senior Director, Generative AI Content Team Lead at Pfizer, Inc. "If we continue to operate the way we have in the past," explains Ghith, "we risk being on a channel where Commercial messaging is occurring, and your customers don't see the difference between Commercial- and Medical Affairs—driven content—and neither do the regulatory authorities."

Jennifer Ghith
Sr. Director, Generative AI Content Team Lead, Pfizer Inc.

Overview of Off-Label Communication Safe Harbors

The FDA recognizes the importance of being able to communicate non-promotional information about unapproved uses of existing therapies that have not yet been through the regulatory pathway. New draft guidance from the FDA on disseminating scientific information, revised and published in October 2023, has expanded to cover industry-produced presentations of scientific data from published reprints and independent clinical practice resources. This scope goes beyond its initial focus on distributing scientific or medical journal articles, reference texts, and clinical practice guidelines. Additionally, it features an updated format, including questions and answers. However, uncertainty and challenges remain.

FDA guidance details various "Safe Harbors" under which the dissemination of scientific information will be considered non-promotional:

1. Off-label and pre-approval communications with payers

FDA guidance finalized in 2018 permits communications with payers and purchasing decision-makers regarding off-label uses of marketed products and for investigational drugs and devices not yet approved for Commercial sale but expected to be within approximately six months, in recognition of payers' and purchasers' need to plan for coverage and purchasing far in advance of regulatory authorization. Significant delays can ensue if discussions with committees are postponed until FDA approval or clearance is granted. This results in the inability to provide these drugs or devices to patients immediately upon approval or clearance due to the lengthy procedural lead times these committees face. Thus, this guidance permits earlier communications with decision-makers about investigational drugs or devices and off-label uses of drugs and devices already on the market. (7)

2. Handling unsolicited requests for information about off-label usage

The FDA's guidance emphasizes the importance of properly managing unsolicited inquiries from doctors regarding off-label product use. It focuses on ensuring these inquiries are genuinely unsolicited to prevent companies from subtly promoting products. Organizations can respond if a request is unsolicited, but the guidance specifies that Medical, not Commercial, teams should prepare responses. These responses must be factual and non-promotional, and directly address the specific question asked. The FDA distinguishes between private (e.g., during sales visits or via direct communication) and public (e.g., social media, symposia) inquiries, advising that public questions be redirected to private channels for response. This approach aims to ensure that reactive dissemination of off-label information does not create a new intended use for the drug or device and to maintain the integrity of information dissemination. (8)

3. Disseminating scientific information on unapproved uses of cleared/approved products

Examples include peer-reviewed scientific journal reprints and clinical references. As mentioned, in October 2023, the FDA revised the draft guidance on distributing scientific information on unapproved uses, expanding communications beyond scientific reprints to include how an organization presents and disseminates off-label information from reprints. Company representatives can actively distribute references and company-generated presentations of information from within the scientific references, provided they adhere to specific criteria for selecting suitable reprints and publications. The presented information must be based on solid, peer-reviewed science and comply with numerous other rules. Furthermore, there are guidelines on presenting this information, such as including the FDA-approved label and information regarding conclusions from other studies that are contrary to, or cast doubt on, the presented information. (9)

4. Off-label and pre-approval IME content

Regardless of whether an IME session focuses on off-label or investigational uses of an organization's drug or device or discusses a disease state that includes off-label or investigational treatments, the creators of IME may approach the manufacturer for funding through an educational grant. According to guidance, an organization can financially support such a session and be listed as a Commercial supporter. However, the Commercial supporter must maintain complete independence from the IME's content and organization beyond providing funds. This means a manufacturer must not be involved in selecting speakers or any aspect of planning and implementation—these responsibilities fall to the IME provider. Additionally, the company must not review or influence the educational materials, such as slides. Adhering to these guidelines ensures that the organization's involvement is limited to financial support and does not cross into inappropriate off-label promotion, per FDA regulations. (10)

Evolving Compliance Considerations
(continued)

"Each Medical Affairs function within a company will be involved in different aspects of HCP omnichannel engagement, aligned with various strategic priorities of the company. For example, the aim of evidence dissemination is to maximize the distribution of the company's scientific information, which indirectly can lead to HCP knowledge and self-learning. However, the purpose of External Education activities (company-led or independently supported) is to improve the knowledge and skills of HCPs, instill an attitude belief that will enable a behavior change, and enhance clinical practice to positively impact the patient outcomes, beyond the assets of a company."

Kirtida Pandya
Ex. Director, Medical Services and Operations, Sandoz

Company Strategic Priorities: Evidence Dissemination, Scientific Exchange, and Education

Medical Affairs teams are adept at integrating distinct facets of scientific discourse, including clinical and Commercial topics, into a unified discussion. They often lead these discussions, which can take various forms, establishing Medical Affairs as key facilitators in driving Scientific Exchange and dialogues. While Medical Affairs takes the lead, Commercial teams and other departments may also participate in scientific discussions with HCPs, especially on topics that are within the approved product use (on-label) or during advisory boards, where there is a chance to explore broader topics like new ideas, study results and impact, and products.

Each Medical Affairs function within a company partakes in differing aspects of HCP omnichannel engagement, tailored to align with the organization's strategic priorities. The goal of External Education activities—whether led by the company or supported independently—is to enhance the knowledge and skills of HCPs, instill attitudes and beliefs that foster behavioral change, and elevate clinical practice, ultimately benefiting patient outcomes beyond the confines of the company's assets.

In today's rapidly evolving information landscape, where new data constantly emerge, it is essential to develop processes and tools to monitor such data continuously. This approach demands a more agile and responsive strategy to keep pace with the continuously changing data landscape. It enables frequent updating and refining of scientific narratives to reflect the most recent information.

Evidence dissemination could be considered the first step in communicating scientific information, intending to build awareness and knowledge. The channels involved include publications, medical communications with HCPs, and medical information disseminated widely through journals, congresses, social media posts, and websites.

Scientific Exchange encompasses an active, unbiased dialogue and exchange of medical information, with an overarching goal beyond merely clarifying and answering queries. It aims to foster a deep understanding and build confidence among interested parties in specific scientific information. This is achieved through education and training, encompassing discussions on disease states, pathophysiology, procedural and surgical techniques, complications, best practices, and guidelines.

Active channels that provide an opportunity for recipients to ask questions and engage in dialogue, such as during training with an educator in real time, symposia, webinars, and MSL-led events, but could also include emails triggered by medical requests for information, interactive educational apps, or information on pipeline investigational compounds.

Notably, regulators consider the number of programs when assessing whether communications can be classed as Scientific Exchange and will also evaluate whether communication is too frequent or no longer "novel."

External Education could be considered the training and content needed to enable HCPs to gain and use new skills within clinical practice and share or advocate for them within their respective care teams, as shown in Figure 5.

ORCHESTRATING Omnichannel Engagement

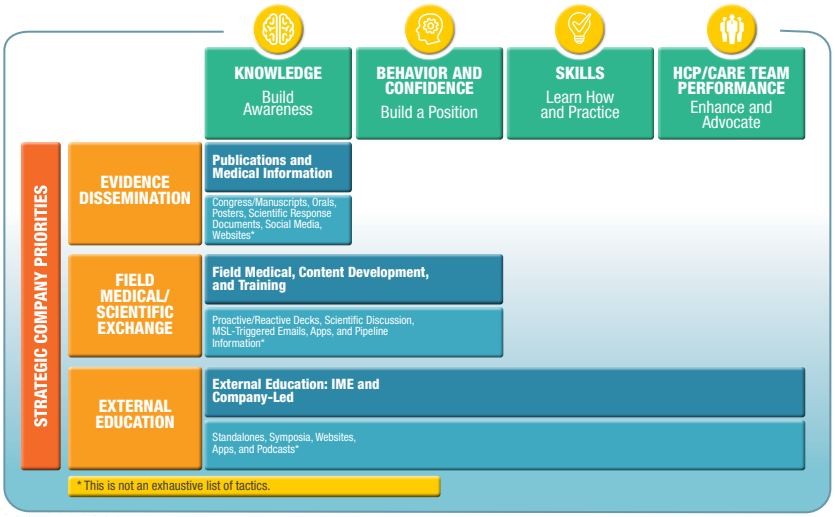

Figure 5. Aligning company strategic priorities with the gaps, tactics, and accountability across Medical Affairs teams.

Avoiding Duplicity and Budgeting

"When omnichannel engagement is orchestrated optimally, all stakeholders will have a seamless and focused experience, aligned with their learning needs and preferences."

Kirtida Pandya
Ex. Director, Medical Services and Operations, Sandoz

Duplication of effort is currently an issue for many organizations among Medical Affairs teams, including External Education teams. IME and company-led teams often overlap resources rather than producing complementary education or leveraging existing resources.

Intentional and early communication between cross-functional teams is critical to ensuring work is complementary rather than overlapping and relevant content can be leveraged as needed. By discussing and aligning educational strategies, the competition for budget allocation can be alleviated, and better value in terms of impact can be offered to the organization. To avoid duplication of effort, an overarching integrated Medical Communications strategy is needed, in which Medical Affairs functions ladder up to create complementary plans to achieve an overarching goal.

Leveraging Modular Content

Although not specific to educational activities, developing efficient global and local content creation processes, such as leveraging modular content, can prevent reinvention of the wheel by multiple teams. Content such as slide decks, courses, and websites and any other educational materials can be created more efficiently with optimized budgets. As shown in Figure 6, modular content processes allow scientific exchange information, website content and External Education content to be produced more efficiently. Pre-approved global content can be housed centrally and adapted by local teams for use on multiple platforms and channels with higher quality and consistency.

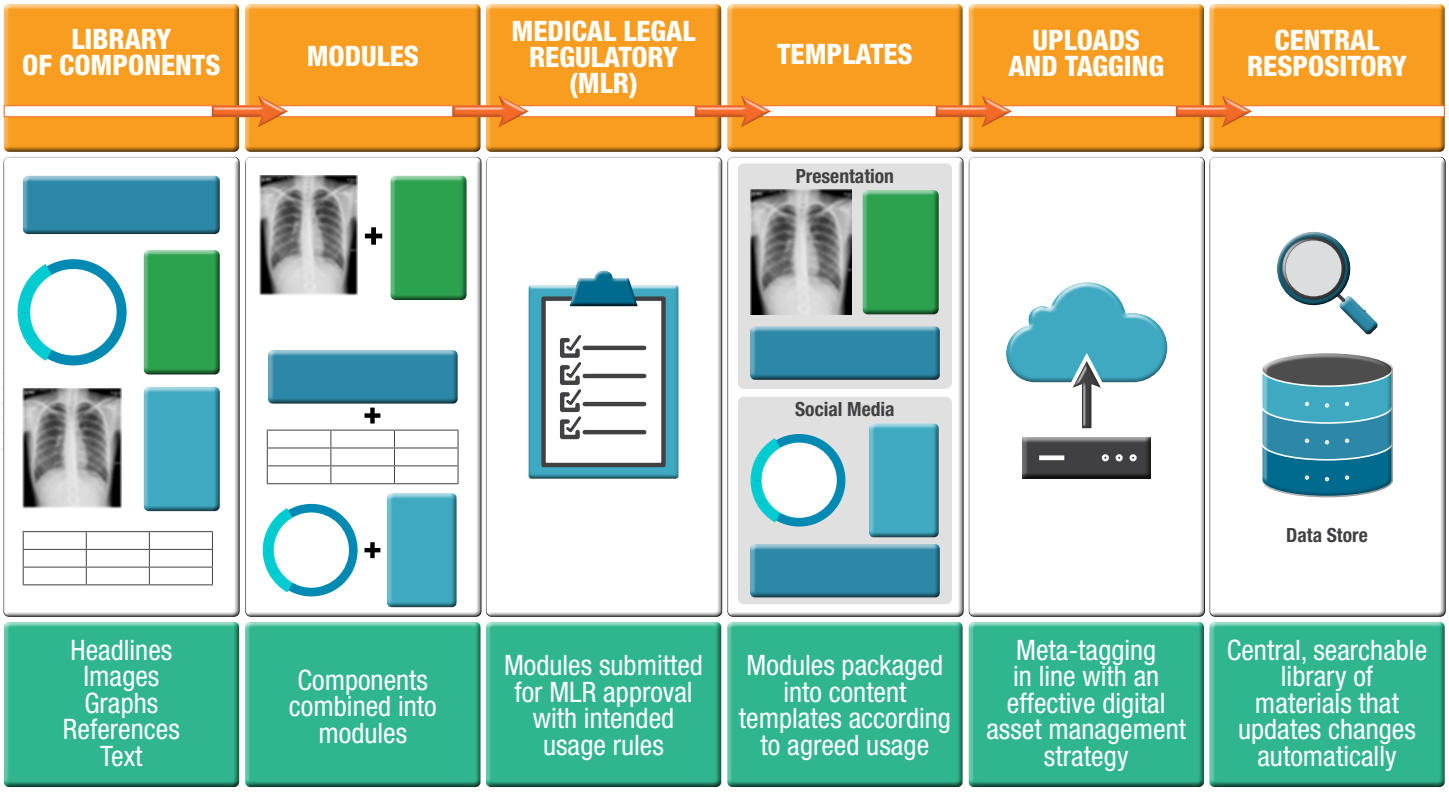

Figure 6. Illustration of how modular content is created, approved, and housed. Source: MAPS White Paper "Modular Content in Medical Affairs: The Foundation of Omnichannel Engagement."

Avoiding Duplicity and Budgeting (continued)

Question

How can you maximize efficiency and impact from your budget allocation among Medical Affairs teams?

CO-AUTHOR CORNER

A. *"To minimize duplication of effort between IME teams and company-led education teams, be more intentional and opening a two-way conversation about what you're doing and doing it earlier. So that way you don't get to the point where you realize 'Oh, we've done very similar things in very similar places.'"*

Sue Ellen Touma
Director, Global Medical Education, Regeneron

A. *"We separate our omnichannel and Medical Education budget, so we can be more agile with company-led Medical Education. We pivot faster as we see trends in terms of what people want to learn about much more quickly than IME. IME looks at trends that are more locked in earlier in the year, but company-led Medical Education is more dynamic. We are a small, growing company and so how we do things changes very rapidly from month to month. Our functions change rapidly and there are fewer stakeholders to begin with that are involved in everything, from the Medical Education strategy to Commercial strategy and clinical strategy. It's more harmonious that way."*

Neha Shah
Sr. Director, Digital Medical Affairs, Moderna

A. *"To make best use of our budget, we use baseline metrics to check who is showing up. We put out a webinar with content aimed at anesthesia providers and found that it was attracting the wrong audience who were showing up to get credits but were not really interested in the content. We cut back our webinar budget and reallocated it to things that made more sense."*

Kerry Tomlin
Sr. Director, Medical Affairs, Ceribell, Inc.

"We pivot faster as we see trends in terms of what people want to learn about ..."

MAXIMIZE
Efficiency **and** Impact

Tracking Effectiveness and Impact

External Education must be agile to meet the needs of HCPs and the evolving healthcare landscape. Tracking the effectiveness and impact of activities through either quantitative or qualitative measures can help External Education continuously evolve to address those needs. Outcome measures should aim to give a holistic view of performance to help identify continued gaps and determine future educational efforts.

Various models to assess educational programs are being used across the industry, such as Moore's Model shown below, which shows how outcome measures for External Education can work together or be ranked in terms of how directly they correlate with patient and community health measures. Data from across the organization can be utilized, potentially encompassing a wide range of perspectives, including Field Medical data on the number of queries or misconceptions being documented or the number of Medical Information queries on a specific topic.

Ideally, the impact of External Education should be based on community and patient outcome measures or performance or quality improvement within healthcare settings, which can be informed by epidemiological data, electronic medical records (EMR) data, or other data from patient care settings. Realistically, however, this is not always possible for pragmatic and financial reasons, and many organizations continue to focus on measuring competence levels, knowledge, satisfaction, and participation.

To achieve the highest levels of outcome, teams should consider implementing or supporting QI initiatives alongside educational programs. It is essential to tackle practice-based barriers that hinder the adoption of new advances, not just to enhance knowledge and understanding.

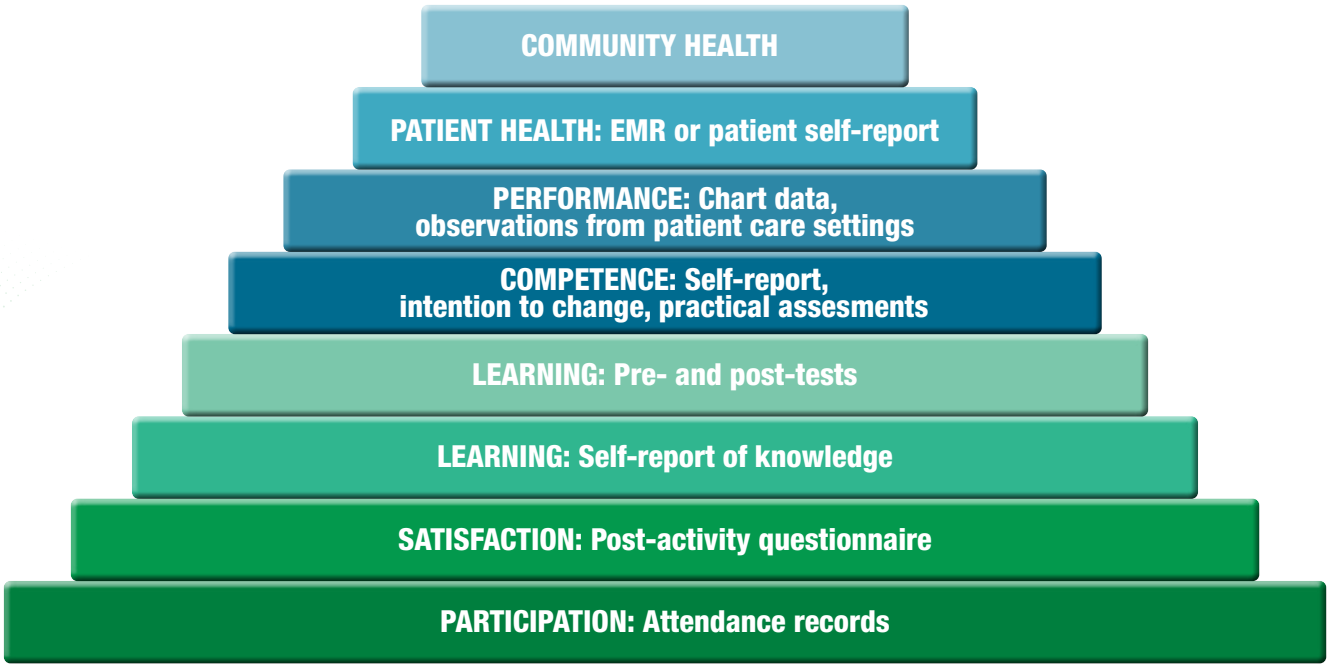

Figure 7. Moore's Model is a framework for assessing outcome measures that are used to assess education. Source: Moore DE Jr, Green JS, Gallis HA. Journal of Continuing Education of Health Professionals. 2009:29(1):1-15.

Tracking Effectiveness and Impact (continued)

When considering Medical Affairs strategies as a whole, aligning Key Performance Indicators (KPIs) used in External Education with those used by the other teams could help better understand how activities combine. Some Publications teams within Medical Affairs have developed composite scores of metrics; offering a more holistic view, using historical data to benchmark previous efforts and identify successful strategies and tactics to reuse or hone, and aligning measurements could allow for more accurate assessments and demonstration of value.

Modern technologies allow tracking sentiment, engagement duration, and specific interactions with educational materials at conferences or other channels. For instance, it is possible to follow which parts of a poster or program attendees focus on and for how long and the duration spent viewing a particular video.

Recipient Evaluation and Feedback

Standardized customer satisfaction tools, such as the Net Promoter Score (NPS), are used to gauge customers' likelihood to recommend or be satisfied with a company, product, or service. They are an example of a tool that can be used to gather recipient feedback on External Education.

Without a standardized approach for measuring the impact of industry-led Medical Education, the content below illustrates an example of how one company approaches impact scores. The HCP Impact Score measures the average satisfaction of HCPs attending a Medical Education activity. The HCP Impact Score was crafted from a combination of the NPS and the Net Engagement Score (NES).

Core HCP Impact Score Questions

1. How well did this education improve your knowledge?
2. How likely are you to apply the knowledge from this educational program to your clinical practice?
3. How likely are you to recommend this educational offering to a peer?
4. Did the program meet the stated educational objectives?

How to calculate and interpret

- Each question has a response scale of 0 to 10 (based on literature on the NPS and NES)
- Determine the average of all responses for each question
- Determine the aggregated average to define the overall HCP Impact Score
- HCP Impact Score of ≥ 7 demonstrates the HCPs felt the education was valuable
- A lower score means the approach used should be reviewed and reassessed

Question

How do you measure impact of educational materials?

CO-AUTHOR CORNER

A. *"I would suggest we think about impact, reach, and engagement more holistically and not view our channel metrics or our metrics from the field or engagements in silos. We have a lot of data from a lot of materials. Field Medical, publications, publication enhancements, digitally disseminated non-curated content, metrics on whether our publications enter into guidelines, and so on. There are Medical only social media handles where people go only for education. As Medical Affairs, we can pull in impact measures from many sources to create amalgamations of a number of different metrics and gain more holistic measures of impact from our coordinated activities."*

Jennifer Ghith
Sr. Director, Generative AI Content Team Lead, Pfizer Inc.

A. *"We test learning on the way into educational sessions or modules and on the way out. We also ask for self-assessed confidence and competence ratings and ask about their intent to adopt new technologies or change the way they practice."*

Kerry Tomlin
Sr. Director, Medical Affairs, Ceribell, Inc.

"... gain more holistic measures of impact ..."

Medical Devices Spotlight

External Education programs for Medical Devices tend to focus on the safe and effective use of technologies and typically encompass both a knowledge component and a skills acquisition component. With the differing contexts in which education is needed, educational tools and techniques can be varied, novel, and creative. These include live surgery sessions, virtual and augmented reality, gamification, simulation, and cadavers or anatomical models to teach procedural and surgical techniques.

Education is often company-led and can be influenced by the specific function conducting it. When organized by Commercial teams, it is often part of an overarching organization-wide marketing strategy. However, if conducted by Medical Affairs teams, education may be part of a non-promotional Medical Affairs strategy that is not tied to marketing. This depends on the company's structure and where the education team sits within the organization.

Audiences are composed of end users of a device in a clinical practice setting—including allied health professionals—such as nurses, respiratory therapists, and paramedics—physicians, and technicians. While educational activities aim to enhance professional knowledge and skill, it is important to note that most Medical Device industry-sponsored education does not receive CME or CE credits or accreditation.

Challenge: Commercial Strategies Overlook Medical Input

Device organizations face significant challenges in scientific communication, mainly because Medical Affairs is not always seen as a strategic partner. This oversight can lead to suboptimal strategies by Commercial teams who may overlook the necessity of Medical and scientific input. It is crucial to reiterate that Scientific Exchange can only be conducted by Medical Affairs. However, on-label scientific communication can be conducted by either the Commercial or Medical Affairs organizations.

Additionally, creating effective communication strategies for technologies designed for specific use cases can be challenging, particularly when focusing on educating about the problem the device addresses. Furthermore, devices vary in complexity, and some can have simple use cases. The organizational strategy, at times, may be based on market size rather than the significance of the clinical use case, which can subsequently make education challenging.

Advice: Establishing a system incorporating frequent internal cross-functional meetings can help ensure that diverse perspectives are included during planning. If Medical Affairs teams are not initially part of Commercial discussions around education, proactively forming a forum around Medical Affairs activities and inviting the Commercial team to participate in the planning can help foster a more collaborative approach. Actively seeking the Commercial team's input ensures they become more engaged with the project and the Medical Affairs team, potentially leading to reciprocal inclusion in strategy sessions and Commercial projects.

However, exercising caution and discernment in this collaborative process is essential. Commercial teams should not be involved in Scientific Exchange activities intended for HCPs, emphasizing the need to carefully evaluate the nature of Medical Affairs activities before soliciting Commercial input.

Challenge: Defining Promotion and Non-Promotion

Distinguishing between promotional and non-promotional educational activities presents a complex challenge for medical device educators. This complexity is heightened by device-specific regulations that allow Commercial and sales staff—unlike their counterparts in pharmaceutical therapies—to provide practical training on device usage during clinical procedures, reducing the demand for more comprehensive Medical Education programs.

Promotional activities are typically characterized by marketing efforts aimed at increasing product sales. In contrast, non-promotional or Scientific Exchange activities focus on disseminating scientific and medical information without direct Commercial intent and can include data on investigational products or use cases. For the medical device sector, the conditions under which training by Commercial teams is permissible often appear bewildering, requiring a nuanced understanding of when such training crosses from an educational to a promotional activity and when it necessitates direct involvement from Medical Affairs to ensure compliance and integrity.

Advice: As detailed in the overview of safe harbors above, FDA guidelines allow off-label information to be discussed under various circumstances. Also relevant for device companies are reprints and data on off-label usage, unsolicited requests for information about off-label usage, IME, and communications with payers.

Medical Devices Spotlight (continued)

Challenge: Significant Workforce Changes Since COVID-19

The device education landscape is evolving to address the needs of all clinician levels, not just physicians. In the US, the COVID-19 pandemic has increased the number of "floater nurses" and per-diem mid-level providers who must adapt to various hospital wards and unfamiliar technologies. Previously, nurses specialized in specific areas, like ICU or general care, but now they often find themselves in different settings without prior training on the technology used there. This shift poses a significant challenge for medical device companies, as they must now ensure that these versatile yet temporarily placed HCPs have the appropriate training to use their devices safely and effectively.

Advice: To accommodate the changing workforce, there is a growing need for quick, accessible training methods, such as short instructional videos on cell phones. Unlike in-depth webinars, educational events, and device-specific procedural/surgical skills training, these resources provide essential, immediate information time-efficiently, enabling nurse and mid-level providers to quickly adapt to new environments and technologies. This shift reflects the necessity to adapt newer ways of utilizing educational and training resources for a more dynamic and versatile clinician group than before.

QUICKLY ADAPT to new Environments and Technologies

Medical Devices Spotlight (continued)

Device-Specific-Dialogue on **DYNAMIC TOPICS**

MedTech Talk

Commercial and Medical Affairs roles and responsibilities

"One of the bigger challenges in scientific communications for device organizations is that Medical Affairs as a function is not recognized by Commercial as a strategic partner—I know pharma still has a way to go there too. In devices, there's often an attitude amongst Commercial that they can get by without Medical input, creating strategies which could have been better had they consulted Medical Affairs, which can be stressful."

Kerry Tomlin, Sr. Director, Medical Affairs, Ceribell, Inc.

"We should think of education through a clinical and scientific lens in the MedTech industry. I find that healthcare professionals prefer to be engaged with scientific dialogue and discussions on pathophysiology, disease state, and procedural and surgical techniques Physicians really want to dive in and understand how a particular medical device or technology can solve a particular clinical challenge and improve the outcomes of their patients. Medical Affairs professionals are oftentimes uniquely positioned to lead these discussions due to their scientific and clinical backgrounds and experiences."

Stuart Hart, Chief Medical Officer, Integra Life Sciences

Solutions and best practices for execution

"We create an operating mechanism that requires regular meetings to bring cross-functional voices to the table. When we create an asset [in Medical Affairs] as part of a Medical Education program that the Commercial team are involved in, we ask the Commercial team to give us their input. They then feel more invested in the asset and your team, and they start to bring you into their work too. So, if we're not invited to the Commercial table, we create our own table and bring them in. If you can be more collaborative in the very early stages, they tend to be more invested. Even if they are not being super collaborative, it starts to bridge the gap."

Kerry Tomlin, Sr. Director, Medical Affairs, Ceribell, Inc.

Measuring impact of education

"Effectiveness of Medical Education can be tracked without relating it back to ROI. For example, if there were a certain rise in, for example, procedure-related adverse events, and an effort was made to educate HCPs on procedural technique and subsequently those adverse events decreased, that would demonstrate effectiveness of the training. Also, a decrease in the request for repeat training, for example, if you have an implant and you have surgeons requesting refresher training, that can indicate that the education wasn't very effective and can be a prompt to improve your educational content, so that you see fewer repeats of second or third training sessions."

Jessica Ringel, Partner, King & Spalding LLP

"It is important to assess whether the education and training program that was provided to the HCP had a real impact on the way they treat their patients and if these changes improved outcomes. HCPs are constantly pressured for time, so understanding whether the education and training program provided real value for the HCP is essential so that these programs can be continually updated and improved to maximize the HCP's time and the impact on their clinical practice."

Stuart Hart, Chief Medical Officer, Integra Life Sciences

"The good thing about monitors and ventilators is they record real-world data on clinical use, and in some circumstances to ensure compliance, we can use that to measure impact of training. For example, at a clinical study site with a in an ongoing research relationship, we could potentially access and upload de-identified data from those devices."

Kerry Tomlin, Sr. Director, Medical Affairs, Ceribell, Inc.

"... be more collaborative in the very early stages ..."

Future

In External Education, there will always be the need for educational activities from pharma and medical device companies because the scientific and medical environment is rapidly changing. While data and information will be readily accessible, learners will continue to have unperceived needs and are not always aware of their own knowledge and practice gaps.

External Education will need to be agile to respond to drastic changes occurring within the healthcare system, such as a need for more industry-led short-form educational content suitable for convenient access. One example is to meet the needs of mobile HCPs, such as floater nurses, who may be sent to any ward at any time to increase patient treatment capacity—a consideration that has become increasingly prevalent since the COVID-19 pandemic.

Additionally, omnichannel engagement systems are poised to advance rapidly, incorporating innovative technologies and channels such as educational platforms that employ AI recommender systems such as Next Best Action engines and other forms of automation. As this evolution unfolds, coordination between industry-led education from Medical Affairs and the Commercial function will continue to develop and require careful consideration, regulatory guidance, and more defined metrics. This will be particularly important as Medical Affairs demonstrates its strategic position at the center of clinical development and commercialization efforts over the next decade. (11)

As generative AI becomes an integral part of content generation, there is likely to be a proliferation of content from some teams that manage to streamline processes to enable rapid and compliant content production. Clarification will be needed to ensure high-quality, accurate content without copyright issues, whether the content is created internally or by external providers.

It is widely accepted that HCPs and external stakeholders view each organization as a single entity rather than as separate functions. As such, various Medical Affairs teams, ranging from External Education to Field Medical teams, may become increasingly relied on to provide scientific, objective, unbiased, peer-to-peer engagement that offers optimal value to time-pressed clinicians.

Finally, medical societies are becoming increasingly involved in education, developing robust online educational platforms to align with their in-person education and training programs. They are also increasingly dependent on industry support to underwrite the cost of these programs. This type of platform may increasingly provide the industry with an approach to help deliver credible independent educational offerings to HCPs without the regulatory risks associated with industry-led educational programs.

"The future of Medical Education is customer-centric—designing channels and content around what customers need. In the near-term future, we are focusing on measuring the value and impact of our efforts and then designing for the future based on those insights."

Neha Shah, Sr. Director
Digital Medical Affairs, Moderna

Conclusion

In conclusion, the External Medical Education landscape is undergoing notable change, with new, streamlined methodologies, regulatory guidelines, and implementation strategies being developed. This White Paper underlines how Medical Affairs teams can facilitate a holistic External Education strategy to improve learning outcomes and patient care.

Key regulatory obligations, such as shifting industry trends around acceptable Scientific Exchange and compliance issues, including the differentiation between Medical and Commercial communications and cross-functional collaboration, underline the need for comprehensive and thoughtful strategic planning. Within these changing scenarios, Medical Affairs professionals must adapt their approach to remain compliant and optimize the impact of their industry-led and independent Medical Education initiatives.

Duplication of efforts, particularly in resource allocation, remains a significant challenge. To counter this, it is essential for teams to intentionally engage in early communication and collectively work towards achieving overarching goals. Furthermore, tracking the effectiveness and impact of External Education activities through quantitative or qualitative measures is essential for adaptability. The alignment of KPIs can provide important insights into overall strategies, guide future efforts, and ensure optimal value delivery.

As we look forward, Medical Affairs teams should continue to strive for an integrated education strategy focusing on shared goals. The ongoing evolution of the External Education landscape requires continuous adaptation, transparent compliance practices, strategic planning, and tracking effectiveness for better learning outcomes and value delivery.

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MAPS transforms Medical Affairs organizations and Medical Affairs professionals globally by speaking as the single voice of the Medical Affairs profession, defining the current and future practice of Medical Affairs, and being the global community for Medical Affairs professionals. Furthermore, we leverage collective thought leadership to train the next generation of Medical Affairs leaders by tapping into the collective experience and best practices of Medical Affairs peers globally.

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