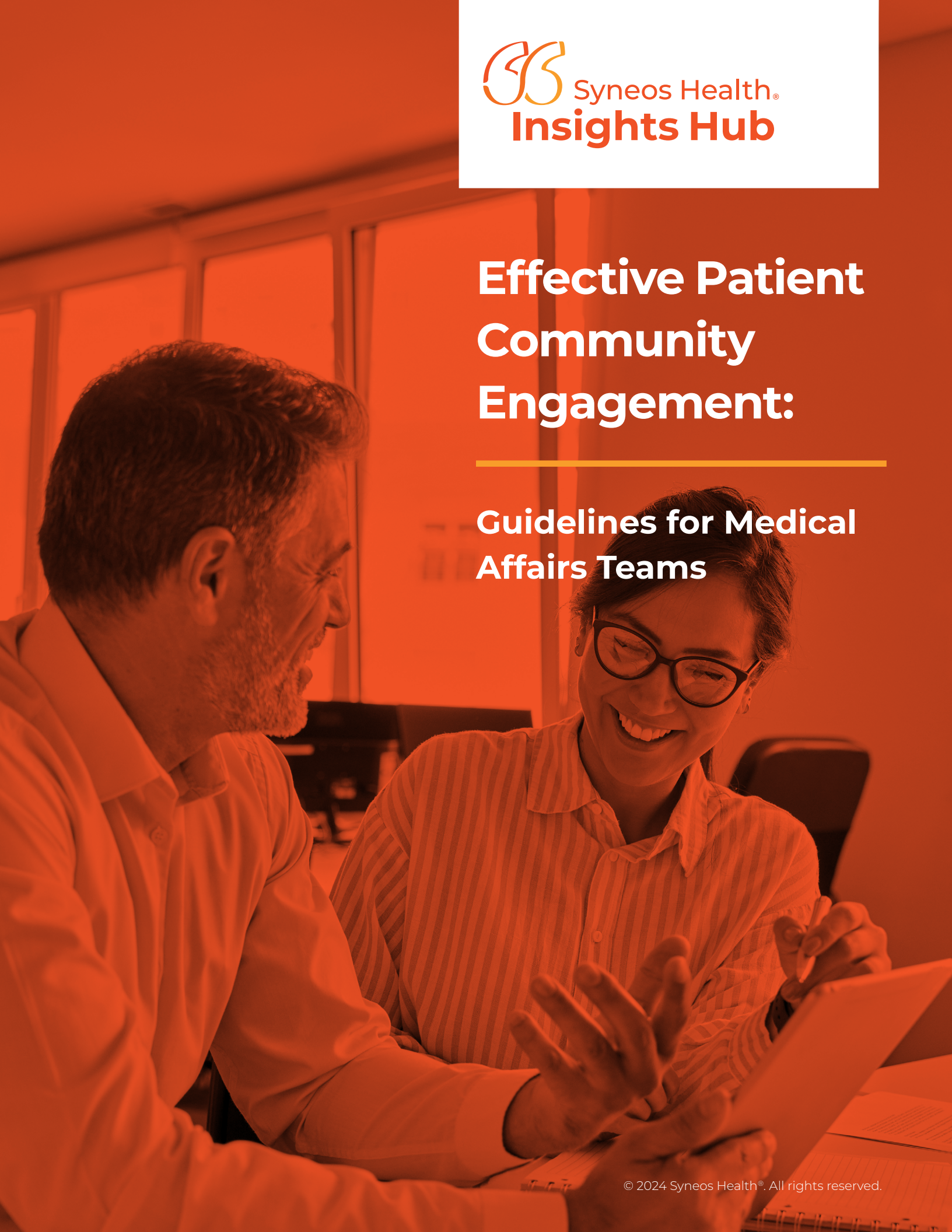
Syneos Health®
Insights Hub

Effective Patient Community Engagement:

Guidelines for Medical Affairs Teams



Introduction

In the race to deliver better treatment options to patients, drug sponsors have often waited too late in the drug development process to gather patient insights about their disease and unmet needs. As a result, therapies risk not adequately addressing what patients want. To prevent this and better deliver on patient expectations, it is essential that drug sponsors begin listening to patients early in drug development process and then incorporate the patient insights into their ongoing asset development plans.

Medical Affairs teams along with key stakeholders within the pharmaceutical industry are now being tasked with championing patient-centricity within their organizations. As Medical Affairs' involvement in drug development efforts often precedes product approval, the function is in a unique position to advocate for patient needs. They can elevate the patient voice, offering insights that stakeholders across the corporate organization can infuse into development plans.

Medical Affairs' focus on patient groups as an appropriate and vital audience is not new where such engagement has been permitted under country laws and company policy. However, the remit to bring patients' needs and concerns to light earlier in the drug development process is relatively new for Medical Affairs. Consequently, not all Medical Affairs teams may have established best practices for engaging with patient groups earlier in the asset lifecycle.

And, regardless of the timing of their involvement with patient groups, not all Medical Affairs professionals have necessarily honed the required skills for communicating effectively with patients (as opposed to healthcare professionals (HCPs)). Understanding how to effectively engage patient groups or others who may not have medical or scientific training requires a new set of skills and appropriate language for a respectful, meaningful exchange.

Here, we explain the importance of engaging with patient advocacy organizations (PAOs) in order to inform development plans, present the guiding principles for how to do so ethically, offer suggestions on how best to ensure a fruitful exchange built on respect, and make recommendations on how Medical Affairs professionals should be preparing themselves for success in this new endeavor.

Patients: A Gateway to Understanding – and Addressing Unmet Medical Needs

Today, patients are not only integral to clinical research for their participation in clinical trials, but they also provide vital, first-hand perspectives on their health-related needs, fears, and preferences. And listening to them yields a stronger joint understanding of disease and the patient journey with the goal of enhancing patient care through innovation. It provides opportunities for incorporating the patient voice into clinical trial design and support programs, supporting health equity, providing context to company dossiers, strengthening market access, and delivering better patient outcomes.

More specifically, by engaging and communicating with patient groups early in asset development, drug sponsors may:

- Ensure – from an early stage – that they are developing products that people want and need
- Speed time to market and reduce the costs associated with delays and protocol amendments
- Provide context for dossiers and datasets submitted to regulators
- Ensure that appropriate language and resources are provided to support health equity and self-advocacy
- Improve access by providing information on patient preferences and experiences sought by value assessors, health technology assessors, and policy makers
- Build trust and transparency with groups who can become allies
- Support better outcomes through more productive shared decision making between patients and their healthcare providers

For a more in-depth discussion of the value of the patient voice, see our whitepaper, "Engaging Patient Communities: The Changing Role of Medical Affairs."

A Range of Valuable Advocacy and Engagement Activities

In many pharmaceutical companies, the primary responsibility for "owning" the relationship with PAOs rests within a Patient Advocacy function. Such groups may be standalone functions, or may report into Medical Affairs, Government Affairs or Operations. In any case, when such a department exists, all PAO-related activities should be aligned and any insights gained should be communicated in a timely manner to guide medical strategy.

The need for such cross-functional coordination and teamwork is reflective of a broader dynamic within the industry that is compelling companies to adopt an integrated approach to product development planning, clinical trial execution, and launch planning. Thus, companies are seeking more integrated and synchronous ways of working that cut across the traditional Clinical, Medical Affairs, and Commercial functions and focus on collaborative efforts to guide drug development. This enhances their ability to deliver optimal treatments that may advance patient care needs and underscores the fact that everyone is working towards one objective: to deliver novel treatments that make a difference in the lives of patients who are waiting.

Toward this end, Medical Affairs teams may be asked to include patient advocacy groups and medical organizations in their regional plans. The focus of their proactive engagement with patient groups can either be to:

1. Impart up-to-date information on the evolution of research, the current treatment landscape, or the latest understanding of the disease and its progression and the care pathway; and/or
2. Listen to areas of concern regarding specific unmet needs or other insights that can be relayed to internal stakeholders.

Interactions with PAOs can take a variety of forms, as shown in Figure 1, depending on the company's strategic needs.

Figure 1: Options for Engaging with Patient Communities

Build a Strategic Approach when Engaging Patient Organizations

Conferences

- **Community Conferences** Engage directly with individuals, families, care-partners at community-targeted educational meetings
- **Professional Medical Association (PMA) Meetings** Engage with advocacy leaders at major congresses to gain insights on data impact and foster continuing communications

Partnership

- **Mutually beneficial** activities and resources that align mission and business objectives
- **Increase awareness,** build reputation, grow internal and external engagement
- Support initiatives that **improve health equity** and reach under-served communities

Education

- **Grow Health Literacy** Provide resources that address the diverse needs of all stakeholders within the community
- **Co-creation** and/or validation of content to ensure language and visuals resonate with audiences

Insights

- **Voice of the Community** Meaningful interactions and communications that helps build the Community
- Provide **actionable insights** to directly inform and shape how you do business

Culture

- **Foster Patient-First Culture** Internal North Star that institutionalizes the experience of the individual as the cornerstone of the corporate culture and provides a framework for collaboration

These options are suggested and must be reviewed by company to ensure local laws / policies permit these interactions and activities.

Additionally, Medical Affairs may listen to patient concerns passively by monitoring various social media platforms and attending conferences or support meetings where patients may share their experiences and journey to seek care or better treatments.

The topics for patient group discussions can be wide ranging and in-depth. They include:

- A sponsor's treatment approach and clinical development programs
- An overview of scientific advances
- The participants' experience with the disease and its impact on their daily lives
- Patients' expectations and motivations for participating in a clinical trial
- Comments on clinical trial design and the logistics of participation
- Patients' understanding of digital tools that may be used in a trial
- Feedback on community-facing messaging and materials

Guiding Principles

Medical Affairs professionals must, of course, adhere to company Standard Operating Procedures (SOPs) when engaging with PAOs. Beyond that, Medical Affairs teams may naturally have questions and concerns about compliance requirements with respect to their interactions with patient groups, given guardrails to guide their communications with HCPs and align them with the appropriate policies.

The details of what constitutes acceptable communications with advocacy organizations and patient communities are different by region. For example, in the US, there are no formal rules or guidance documents to direct engagement, although there are several informal, high-level recommendations published by organizations such as the Drug Information Association (DIA), the National Health Council, and others.[1] Thus, it is up to companies and PAOs to determine how they want to interact. In contrast, the EU has very specific guidance in the European Federation of Pharmaceutical Industries and Associations (EFPIA) code that impacts how the industry can engage, who can engage, and what must be reported.[2]

Notwithstanding the regional differences, there are a few constants:

01

Information presented must be factual, unbiased, and non-promotional

Companies should instruct their Medical Affairs teams to communicate with PAOs following the same principles that are established for communications with HCPs. The basic tenet is that when imparting information, Medical Affairs professionals are obligated to provide truthful, non-misleading, factual, and unbiased information in a non-promotional context. The information provided must be based on studies and analyses that are scientifically sound and provide clinically relevant information. The content may not be promotional in any way, i.e., all content that is shared with PAO must be reviewed and approved by the company to ensure neutrality, accuracy and appropriate understanding of any product or investigational data that is allowed to be shared with PAO or patient groups / patients.

02

The content must not constitute clinical advice

Clinical advice should only be provided by a HCP directly to their patients and not to or through a patient organization.

03

PAOs must remain independent in their decision making

Like HCPs, advocacy organizations must remain completely independent of pharmaceutical companies to maintain the trust of their community and to fulfil their mission. That does not preclude pharmaceutical companies from providing funding to organizations through any combination of sponsorships, grants, in-kind services, fee-for-service arrangements, and social responsibility giving. (In fact, some organizations refrain from working with contract research organizations (CROs) or other third-party research organizations hired by the industry that do not compensate them for their contributions.) To avoid any sense of indebtedness or undue influence, either party may require that such funding be provided from multiple sources.

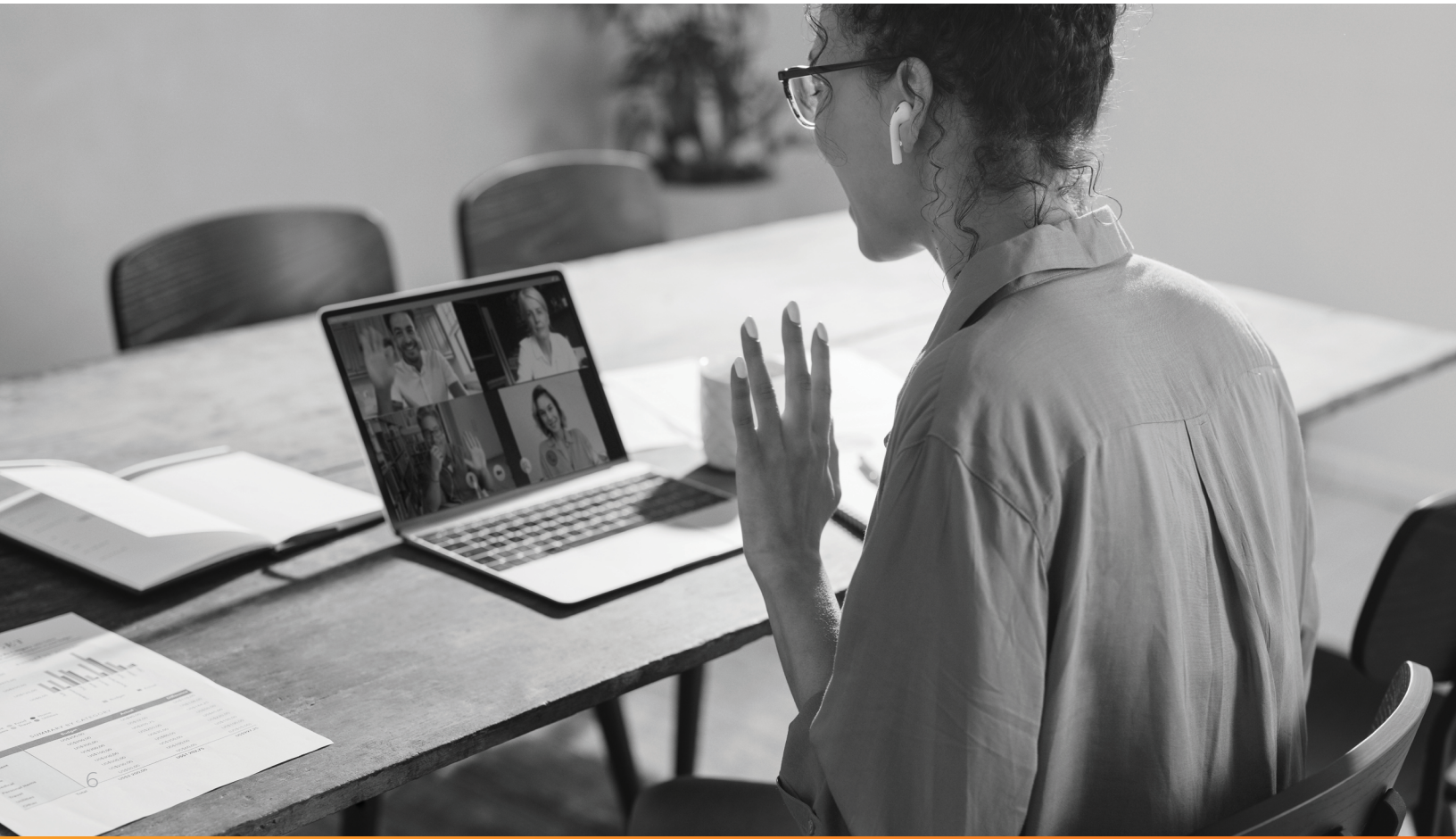
The Elements of Ethical Interactions with Patient Organizations

Mutually beneficial relationships built on trust, respect and integrity

Similar to relationships with HCPs, the best relationships with advocacy groups are built on transparency, engender trust, and become long term. Approaching interactions as a two-way dialogue rather than as a monologue is a foundational step in fostering a mutually productive, ongoing partnership. The initial step when meeting with patient groups is to use active listening to seek deeper understanding and further discuss topics based on their needs and interests.

Exchanges with PAOs should be underpinned with an understanding that what is meaningful and valuable to patient organizations is necessarily different from the information that HCPs and key opinion leaders seek from MA. Whereas clinicians are often interested in detailed scientific information, for example on the mechanism of action of a drug, we have found that patient organizations are most interested in understanding the treatment landscape and knowing how a treatment or research initiative will support their community.

Syneos Health conducted a survey in 2022 of a select group of leaders from patient advocacy organizations serving rare disease communities. Our goal was to better understand their priorities. We found that nearly three-quarters (74%) considered being involved in the development of new treatments as central to their mission. To help effectuate this, 47% of responding organizations had established programs designed to identify, train, and prepare community members to engage with researchers and clinicians to increase participation and diversity in clinical trials. Another 43% were actively considering such initiatives.



Content and objectives tailored to the specific audience

Patient communities are all unique entities; they have varying levels of expertise and differing needs for information about the disease area, treatment options, and scientific/clinical developments. Depending on their focus and mission, they may be most interested in early research, clinical trials, patient support, or education and awareness of the disease.

There may also be differences in their interest based on the characteristics of the disease – whether it is a rare or chronic disease or whether it is prevalent in children or adults, for example. In general, the more development activity there is in a disease area, the more complex the advocacy landscape will be. Members of the organization will have many interactions with the research community and will be eager for information about new discoveries, clinical trials, and research results. This is especially true in many rare and chronic disease areas where large, national organizations are well-established. They have deep knowledge in the therapeutic area and are involved in funding research and development. In fact, most have designated positions responsible for building relationships with the industry.

Similarly, when it comes to communicating with individuals, it is important to remember that they all bring different considerations and lived experiences to the exchange. While there are commonalities across individuals, the similarities cannot be assumed. We've identified five personas based on their familiarity with, and sphere of influence within, the disease area:

01 **Individual patients.** These people represent solely their own personal views, opinions, and experience with a disease.

02 **Informed patient experts.** While these people speak to their own experience, they have invested more than the average patient in understanding the disease area and treatments – perhaps by participating in clinical research, serving on an advisory board, or attending conferences, etc.

03 **Patient advocates.** Patient advocates may or may not be affiliated with a PAO, but are nevertheless able to speak on behalf of patients at large. They are influencers within the community. Their influence may be spread through writing a blog, administering an online forum, speaking at conferences, and participating in town halls.

04 **PAO representatives.** These people represent the interests and views of the PAO. They themselves might be a patient or a care partner.

05 **Care partners.** These people tend to the day-to-day needs of patients and often speak candidly about the burdens of the disease. Often, they do a great deal of research on their own into the disease area.

Although some personas may naturally be more vocal than others, it is important to interact with them all; each type of advocate can provide valuable insights to pharmaceutical companies.

Empathy and sensitivity

Medical Affairs teams should be conscious of the fact that communicating with patient communities requires more empathy and sensitivity than communicating with HCPs, given that community members are either people living with a disease/condition or their care partners, family, friends, or others with a vested interest in their wellbeing.

Empathetic listening is about actively listening with the intention of understanding others. It involves a deep understanding, placing oneself in the other's shoes, and seeing the world from their perspective. It goes beyond simply hearing another's words to grasp their frame of reference and relate to their emotions. In essence, it is a different way of approaching communication so as to truly comprehend others.

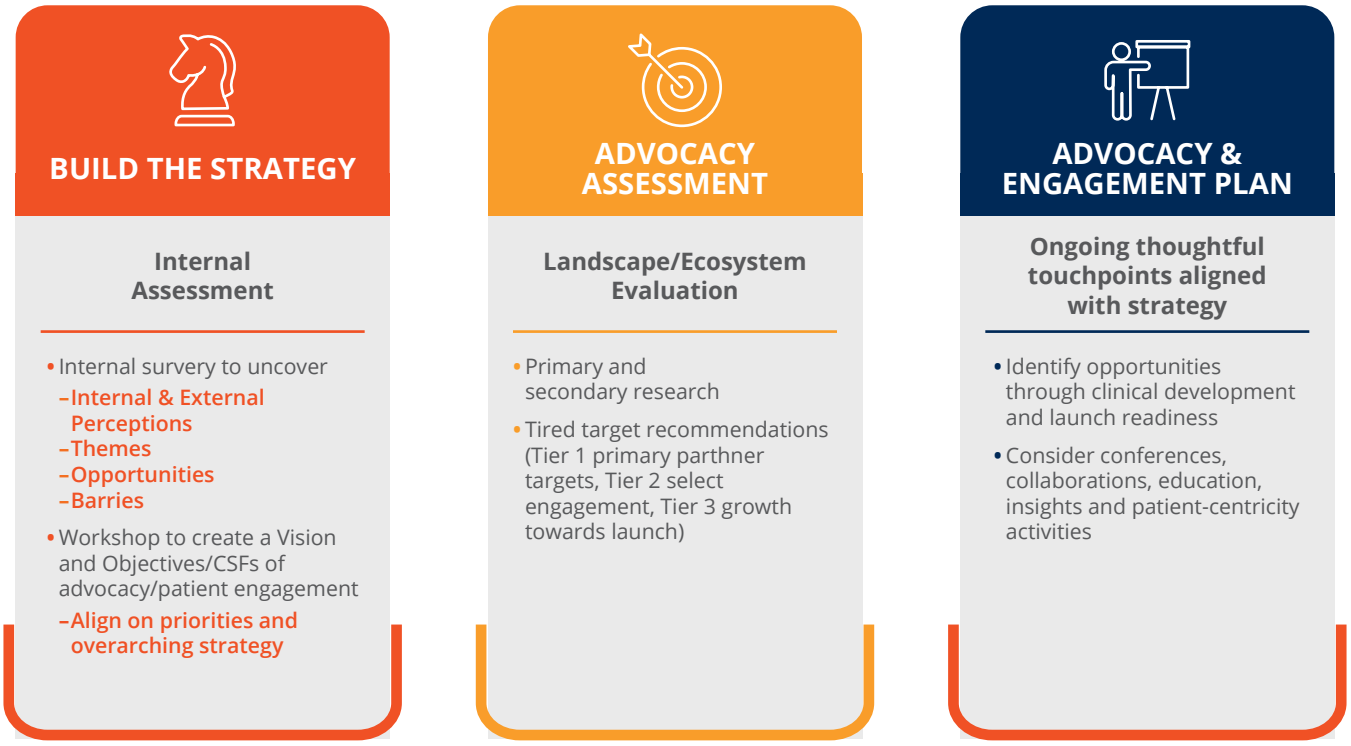
Being sensitive to the feelings and reactions of those in patient communities involves entering conversations free of assumptions, taking care to use respectful and inclusive language, and being attuned to non-verbal cues. Listening for the needs of the patient should guide the direction of all discussions.

Best Practices for Meaningful Exchanges

Build the foundational plan

Like other business initiatives, launching a program to engage with PAOs takes careful planning, as outlined in Figure 2. Companies entering a new therapeutic area should first explore their goals for Medical Affairs' interactions with PAOs and align on a strategy. They should then conduct a comprehensive advocacy landscape assessment to understand the mission and focus of large national groups, the regional groups, and any community-based organizations. Finally, they should develop an advocacy and engagement plan that aligns with the company's business objectives and supports the mission of the target organizations.

Figure 2: The Engagement Planning Process



Ensure that Medical Affairs teams have the requisite soft skills

Medical Affairs teams can often benefit from additional training in order to adapt their communication skills to patient audiences. Through this training, they should learn how to:

Follow formal guidance and informal recommendations

Training for Medical Affairs professionals should include instructions on complying with the applicable regulatory guidance in the EU and Canada, with the industry recommendations in the US, and with the company's specific policies to prevent any inadvertent infractions. This training should include coverage of the latest update to the Good Publication Practice (GPP) guidelines for publishing company-sponsored research via manuscripts, presentations, posters, abstracts, and plain-language summaries. It should emphasize the need to involve patients in various publication-related activities such as steering committees, publication planning, and authorship.

Create a conducive environment and productive process

In general, organizers of exchanges with PAOs should ensure that they are prepared for the engagement and establish a welcoming environment. The venue should accommodate any special requirements of the anticipated attendees and should be private enough to facilitate candid conversations. Information- gathering meetings with PAOs are most productive when companies have prepared their audience and ensure that participants represent many points of view and perspectives of their lived experience. We consider it a best practice to conduct a pre-meeting survey to gain early insights and to provide participants with material to read in advance. Forming a patient advisory council is one way to gather ongoing input to guide development efforts.

Conclusion

Engaging patient groups to understand patient needs and concerns at the earliest juncture in development is essential to guiding development efforts and delivering therapies that better address patient care needs – as defined by patients themselves.

Ethical interactions with PAOs are a legitimate way for pharmaceutical companies to engage with patient communities, and the practice brings us a step closer to treating the patient as an equal shareholder in drug development and commercialization.

The Medical Affairs department is uniquely positioned to infuse drug development with the voice of the patient and to share appropriate disease and scientific information with patient communities in a way that resonates with them. To be most effective in their engagement with PAOs, Medical Affairs professionals must approach interactions with an appropriate mindset, abide by ethical standards, follow best practices, and, in some cases, adopt new skills for communicating in this context.

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Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. We support a diverse, equitable and inclusive culture.

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