

White Paper

Meeting Your Patient Advocacy Mission

Achieving meaningful engagement with patients and caregivers

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Introduction

Patient advocacy organizations play an essential role in supporting patients throughout their care journey and serve as a crucial bridge between the patient community and other stakeholders, such as researchers, healthcare providers, and policymakers.

The patient experience is a valuable source of information that can influence and guide the development of treatments, interventions, and healthcare policies. Patient organizations serve as advocates for patients' needs and preferences, ensuring that these factors are considered in decision-making processes. Their insights and expertise contribute to the development of patient-centered care models, improved treatment outcomes, and the overall advancement of the clinical industry.

The opportunity for patient organizations to take a more active role in clinical care and research decision-making is continuing to increase with regulations such as the [21st Century Cures Act](#), and a series of draft guidances released by the U.S. Federal Food & Drug Administration (FDA); including the use of [real-world evidence and registry data](#) in regulatory submissions and [patient-centered drug development](#) program to incorporate the patient voice. However, these opportunities also bring increased responsibility for patient organizations to provide representative and holistic patient insights and data, which cannot be captured without the patient and caregiver voice.



This paper outlines some of the ways patient organizations can consider adjusting their approaches and initiatives to best meet patients and caregivers where they are to improve outcomes and support those with lived experiences. Through the process of engaging with their valued constituency, active listening, continuous collection and review of perspectives and feedback, and creating meaningful communication sharing with these individuals, patient organizations can ensure that their initiatives, programs, and priorities are in line with what's most pressing for their main constituents and that barriers to engagement are being addressed in doing so.

Patient organizations aiming to undertake ambitious patient initiatives and achieve the goals of growing their reach and building ongoing engagement with their affected communities must not only seek input from patients and their families but also establish and nurture

a strong connection with them to gain comprehensive insights into their motivations and barriers to engagement. By gaining a deep understanding of patient and caregiver perspectives within the framework of their individual experiences, organizations can assume a pivotal role in advocating for and effectively conveying the significance of incorporating patient voices to other community stakeholders, including the industry and research community. This approach will not only foster patient and caregiver engagement by providing ongoing received value and ensuring their continued involvement with the organization but also drive patient-centered treatment developments.

The barriers patients and caregivers face are multifaceted and reflect a long-standing systemic approach that has not prioritized their unique needs. Listed below are just a sample of the various sources of burden that may hinder patient engagement.



Barriers to patient and caregiver engagement

Common barriers to engagement in clinical research

One of the numerous barriers to patient engagement that is commonly expressed is geographical accessibility to clinical trial sites. Oftentimes, clinical trial sites are located far from where the patient population resides, meaning the patient and their support network are forced to travel long distances if they want to participate. In addition to the distance barrier, the time and energy it takes to manage their disease can stretch resources unmanageably thin. It takes considerable time to keep up with routine clinical visits, complete lab work, receive necessary medicine, and deal with insurance providers to get basic care covered. If the patient is able to maintain employment or is a primary caregiver at home, there is the added difficulty of building travel time into their day — along with weighing the costs and benefits of participating. These burdens extend beyond the patients themselves to their caregivers, partners, and families as well.

Another issue that may impede a patient's ability to participate is that some trials have inclusion criteria that require patients to stop their regular treatment for several weeks before they can start a trial. Depending on the disease symptoms, this would require several weeks away from work and assistance in managing basic daily activities, which isn't feasible for many patients. This reality means that some people will never have the option to participate in a trial which leads to a misrepresentation of study findings and can pose a significant amount of emotional and physical distress on the patients and their caregivers.

In contrast, some patients may not know they are eligible for a clinical trial. This may be due to a lack of communication from their clinical care team about their options or the clinician's lack of awareness about the available resources. Unfortunately, in some instances trial options might not be discussed because it could require a patient go elsewhere for care. Therefore, even if a patient is eager to participate, they may not be getting the information or guidance to do so.

For patients who can get into a clinical trial, they may face several potential barriers. For example, there are instances when the trial is discontinued before the study's conclusion or delayed for indefinite periods. This can be especially difficult for patients with a limited number of years to live with the disease if they do not get into a trial, so waiting two-plus years to see if the trial will get rescheduled is a significant burden. Another example is if a patient can successfully participate in a trial, there is no standardized process for reporting findings to the patient once data analysis is complete. This leaves patients unsure about the value of their participation, what the outcomes were, and may decrease their desire to engage in future trials due to lack of clarity and not feeling fulfilled by their time donated.

Lastly, patients are often burdened by having to duplicate their efforts when providing their data and insights to multiple, disparate stakeholders, including healthcare providers, researchers, and patient registries. This repetitive task consumes a significant amount of time and effort, adding to the already complex and challenging journey of managing their health. Patients often find themselves having to navigate various systems and platforms, manually entering their information, which can be frustrating and time-consuming.

INSIGHTS FOR PATIENT ORGANIZATIONS FOR OVERCOMING BARRIERS TO CLINICAL RESEARCH ENGAGEMENT

As patient organizations develop initiatives to address these known barriers and improve patient engagement in clinical research, it will be important to learn about the unique concerns of the patients and caregivers in order to provide the relevant information to address their needs. This outreach should be coupled with a dedicated focus on the compilation of information resources about how the organization can reduce any given burden and all the factors that may come into play pre- and post-participation.

Cultural and educational barriers for patients

Cultural, educational, and technology literacy pose their own unique barriers to clinical trial participation and clinical care. Understanding the technical details of the clinical research process can be challenging for the majority of patients, especially when it comes to navigating the intricacies of technology. It is important for patient organizations to make a dedicated effort to translate clinical research information into a language that people without medical education can understand, while also addressing the technological aspects involved.

In addition to the inherent complexities of clinical research, patients may face challenges related to technology literacy. Many clinical trials and care delivery rely on digital platforms, electronic health records, and telemedicine services, which can be unfamiliar territory for some patients. Lack of familiarity with and or access to technology and the internet can hinder their ability to access and participate in clinical trials or receive care effectively. Patient organizations should recognize this barrier by providing additional support and resources to help patients overcome technology-related challenges.

Furthermore, language barriers can exacerbate the issue, as English may not be a language the patient is fluent in. It is crucial to ensure that educational materials and information about clinical trials and care navigation are available in the patient's native language and presented at a reading and comprehension level that meets their needs. Patient organizations should strive to bridge the language gap and ensure that all individuals, regardless of their language and reading proficiency, have access to vital information about their clinical care.

Additional cultural barriers, such as the comfort level discussing personal medical information, prior or perceived potential mistreatment by the healthcare system, and socio-economic status, also play a significant role in hindering clinical trial participation. Some patients may have concerns about how participating in a clinical trial and how genetic test

results are leveraged and could impact their future healthcare coverage, employment opportunities, and other unknown factors. The coverage and protections available can vary based on the country and region in which the patient resides, further complicating the decision to participate.

Moreover, socio-economic status can act as a barrier to clinical trial participation and care options, particularly in cases where preventative procedures for heritable diseases are involved. Patients may face obstacles in obtaining access to these procedures due to clinicians' assumptions about their health status and the general lack of urgency and prejudice surrounding patient employment and income status. The cost associated with preventative care for inherited genes can be prohibitively high, and instead of helping patients find the necessary resources to cover expenses, some clinicians advise patients to delay testing and subsequent treatments until they are financially stable. This directive can result in an indefinite postponement of preventative care and diagnosis, ultimately leading to poor health outcomes.

To address these barriers, it is crucial for patient organizations to engage in open discussions with patients and caregivers as they are navigating their care journey and decision making. This additionally highlights the opportunity for patient organizations to prioritize patient support services. Understanding and acknowledging these concerns is a critical first step towards developing initiatives that advocate for patients and caregivers. By recognizing the barriers presented by cultural, education, and technology literacy, patient organizations can work towards exploring motivating factors that will guide the next phase of engagement and act as champions for patients and caregivers in external initiatives.

Motivators for engaging in research and sharing data and insights

While there are existing barriers to engagement, there are also numerous motivating factors to take into consideration that encourage those with a lived experience to participate in research and patient data initiatives. There is motivation among the patient community to share personal medical data for various reasons. For example, patients want to contribute to the understanding and knowledge of their disease to help enable research developments and improve clinical care options. Another is that many people with rare and chronic diseases know others who have suffered and died from the same disease. Therefore, patients hope that by donating their data or participating in research, current and future generations of people with the disease will not have to go through similar experiences.

When it comes to sharing data, reducing burden on patients and caregivers and minimizing duplicative efforts is paramount. Providing an enjoyable experience and showing the value of donated data back to the contributor are table stakes when addressing motivations. There are times when researchers have specific goals for the information they want to gather from patients. However, one of the factors that may cause patients to be hesitant to share data is that the researchers' requests often focus solely on negative experiences instead of their resilience. Not only do patients rarely have knowledge of research processes to ensure they provide a full, holistic picture of their experience, these siloed efforts can lead to administrative redundancy when only a small portion of data is requested, and it doesn't tap into the entire lived experience journey or coordinate with broader data collection efforts for a condition or disease.

Another key consideration for engagement is that after a patient participates in a clinical trial, they are often left in the dark regarding the trial's status. They may not know the trial's results or how their



contribution helped improve patient outcomes, which can lead them to feeling their efforts were fruitless. Understanding the impact and benefits of their participation in patient organization-led initiatives is a strong motivator for patients, making it important for patient organizations to follow up with patients and caregivers and keep an open line of communication. When patients understand their impact and continue to see the value of their involvement, they are motivated to maintain engagement, building trust and value with the advocacy organization.

There are a variety of opportunities for patient organizations to empower patients and facilitate a more streamlined experience that will promote motivating factors. These include reducing the duplication of collection efforts, ensuring researchers obtain resilience factors when collecting the patient story, and relaying the impact of patient contributions to treatment developments. Patient organizations can achieve this through patient data initiatives that are collaborative and by providing patients with resources to help them navigate their encounters with providers — ensuring there are no gaps in their disease history and communication approaches to best advocate for themselves.

How technology supports engagement initiatives

While the COVID-19 pandemic introduced some complications to patient data collection, the closure of clinical trial sites ultimately drove the adoption of virtual approaches to data collection and care delivery. Patient data collected from smartphone apps, patient registries, wearables, online communities and social media provide a 360-degree view of the true impact of disease and treatments on patients. Research sponsors and industry regulators have since re-evaluated the role that patient-generated data can play in capturing a more comprehensive view of their experience both in and outside the clinic to improve outcomes. As a result, patients are better positioned as partners across the continuum of research, rather than subjects to be studied.

Incorporating technology into patient care and engagement strategies is an essential aspect of improving outcomes and accessibility. It enables productive patient interaction, can reduce the burdens patients and caregivers face, and positively impacts patient care by enhancing ease of access. However, it is crucial to recognize that there is no one-size-fits-all solution, and technology must align with constituent preferences while remaining accessible and easy to navigate.

While technology can automate processes and alleviate burdens for patients, caregivers, and organizations, it should complement rather than replace the power of human interaction with the patient organization. It serves as a tool to support and enhance the care experience. By leveraging technology, patient organizations can provide streamlined education resources, automate the maintenance of up-to-date health records, and create more opportunities for patient and caregiver engagement at various times and touchpoints that best meet their needs.



Furthermore, technology can facilitate the development of online communities where patients can connect, learn from one another, and engage in meaningful ways. These virtual communities foster a sense of belonging and empower patients to participate beyond their initial diagnosis and treatment. By leveraging the collective knowledge and experiences of others within the community, patients can gain valuable insights and support.

Patient organizations play a vital role in creating and facilitating digital platforms for their community, guiding patients through the digital platforms, addressing concerns, and ensuring that patients feel supported throughout their journey. The combination of human interaction and technological advancements creates a comprehensive approach that enhances patient care and engagement, all while providing value to the patient.

Bringing it together: Approaches and initiatives for patient organization to best engage patients and caregivers

Patient engagement in research and patient data initiatives is influenced by both barriers and motivating factors. While there are existing barriers to engagement, such as limited access to clinical trials, lack of trial awareness and education, navigating challenges in donating patient health data, cultural and technological literacy gaps, mistrust of the health system, discomfort with medical information, and socio-economic circumstances, there are also numerous motivating factors to consider. At the same time, individuals with lived experiences are motivated to participate in research and share personal medical data for various reasons. Patients have a strong desire to contribute to the overall understanding and knowledge of their disease, enabling research developments and improving

clinical care options. Additionally, many patients with rare and chronic diseases have witnessed the suffering and loss of others with the same condition. By donating their data, patients hope to prevent future generations from experiencing similar hardships. These motivating factors highlight the importance of addressing barriers and creating and fostering an environment that empowers patients to actively contribute to research and patient data initiatives, facilitating advancements in healthcare and improving outcomes for individuals with diverse medical conditions. By providing value to patients that effectively address key motivators, organizations will increase consistent engagement with their organization, data sharing, and clinical care, which will lead to expanded reach.

BEST PRACTICES FOR ACHIEVING MEANINGFUL ENGAGEMENT WITH PATIENTS AND CAREGIVERS

- **Incorporate your constituents into decisions** being made for your patients and community, and follow up to let them know what came from the efforts
- **Provide meaningful feedback** so they know their time, effort, and information was valuable
- **Anticipate the changes that come with life-altering medication.** As chances of living longer increase, there is greater need for support systems for life events (e.g., financial planning and retirement)
- **Ensure you strive for fair and uniform care** despite location, socio-economic background, ethnicity, scientific knowledge (e.g., access to clinical trials, the best information on the disease, treatments, and support)
- **Technology has changed our lives.** Incorporate technology into patient care and healthy patient interaction. The potential is huge for positive steps in patient care
- **Engage with authenticity as much as possible**
- **Communicate back to patients and caregivers how their contributions are part of something bigger** that is going to do good and make a difference

Patient organizations have the opportunity to play a pivotal role in advocating for patients to help reduce burden that has hindered engagement in both research and clinical care. This can include providing meaningful feedback to patients, acknowledging the time, efforts, and information they have shared and demonstrating that their contributions are valued and valuable. Organizations can also provide patient support services that facilitate interaction and enhance communication, access to information, and education that is easy to understand for each patient population. This can include the utilization of knowledge about the patients' clinical care and disease history, and their key concerns to provide guidance on how to effectively engage in discussions with their providers. Through the development of these educational resources and programs, organizations can enhance patients' understanding of their disease, treatment options, and available support services. In turn, patient organizations can promote effective engagement with the patient community and expand their reach in the community.



Another important role patient organizations have is the ability to serve as a conduit, convener, and collaborator among different stakeholders and the patient communities. Part of this role is providing feedback on trial results, whenever possible, including trial outcomes, insights, and advancements to patients and caregivers. By sharing this information, they can foster a sense of trust among the community and demonstrate the value of patient engagement with the organization. In addition, they can convene and collaborate with researchers, healthcare providers, and other stakeholders to guarantee patient needs are addressed and integrated into initiatives on both a micro and macro level. However, for organizations to successfully fulfill this role, patients must be involved in the decision-making process and be kept apprised of the progress achieved on their behalf.

In striving for fair and uniform care, despite location, socio-economic background, ethnicity, and scientific knowledge, patient organizations can support efforts to eliminate disparities in access to clinical trials, disease information, treatments, and services. Partly driven by federal regulatory support for the use real-world data, researchers and sponsors increasingly recognize the importance of capturing the comprehensive and representative patient data that registries can provide. **By leveraging their technology and connection to the lived experience community, patient organizations can further facilitate collaboration among stakeholders and position patients as partners in decision-making.** Furthermore, technology capabilities can help reduce burden on both patients and stakeholders that previously hindered joint approaches. For example, organizations that help streamline the data collection process to ensure that patients' efforts in sharing their health data are maximized. By reducing duplication of data collection, organization can make sure researchers obtain the complete patient story and incorporate both the challenges and resilience factors. Beyond the research settings, technology can help increase accessibility and provide an online community where patients can connect, learn, and engage meaningfully.



Patient organizations can provide crucial services and support to their community that have the potential to make a long-term impact, such as participating in the changes that come with life-altering medications. As patients with chronic illnesses experience improved health and increased life expectancy, they may face new challenges and transitions in various areas of life. Patient organizations can support patients by providing resources and guidance for financial planning, retirement, and reentering the workforce. **By proactively addressing these issues, organizations empower patients to navigate life after receiving new therapies and ensure they have the necessary support systems in place.**

Patient organizations play a vital role in engaging patients authentically and effectively communicating the valuable outcomes of their contributions to the

larger patient community. Addressing barriers and leveraging on factors to engagement will allow organizations to promote patients' ability to take an active role in research developments and clinical care outcomes. By valuing patient input, providing support services, and facilitating collaboration, organizations can create an environment that empowers patients, fosters trust, and drives advancements in healthcare. Through their initiatives and inclusive approaches, patient organizations have the opportunity to enhance accessibility, reduce burden, and provide a community for patients that will promote engagement at every stage of their disease journey. Lastly, patient organizations can serve as valued contributors to stakeholder decision-making that will ultimately lead to the success of the patient-centric approach.

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About the author



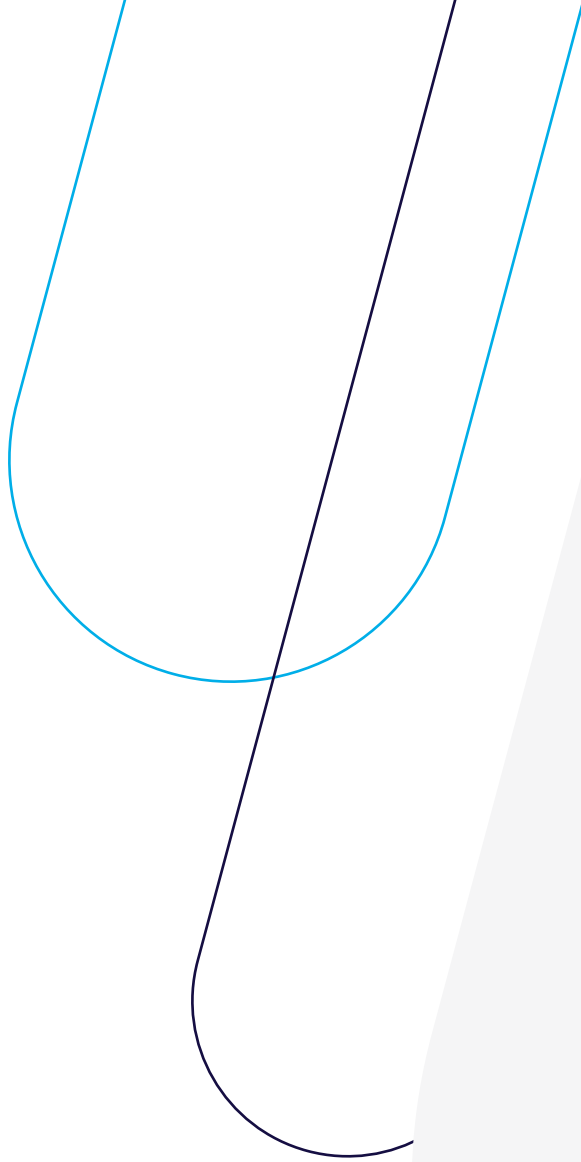
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Alexandra leads strategic client relationships with patient advocacy organizations and has been with IQVIA since January 2021. She has extensive background in patient advocacy and is a patient and caregiver advocate herself. She is passionate about working together to improve outcomes for patients while supporting the family and caregiver unit, and ensuring patient needs are addressed across stakeholder groups and in bringing therapies to market. Alex leverages her insights and knowledge to strategize

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Prior to joining IQVIA, she spent over six years leading industry relations and engagement for an oncology patient advocacy organization. While there, Alex worked closely on their Scientific & Medical Initiatives, raised funds to drive progress, and represented the patient voice for industry-hosted initiatives. She has spent over a decade in philanthropic leadership roles and is immediate past chair of her local hospital's cancer institute board. Alex received a BA in Psychology from Southern Methodist University. She is based in the Los Angeles area.



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