

White Paper

Planning to Engage: A Holistic Approach to Patient Inclusion

IQVIA's Patient Engagement Framework supports comprehensive and consistent assessment and planning for the inclusion of patient needs and preferences

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Introduction

Patient centricity is a concept that has gained increasing currency in recent years. To meet the demands of evolving healthcare systems, the pharmaceutical industry seeks to place patient needs at the heart of strategic decision making across the entire pharma value chain.

This is only truly possible if patients, their carers and loved ones, patient advocates, regulatory authorities and policy makers, healthcare professionals, and pharmaceutical companies have a common language to discuss issues and needs. In addition, patients' voices

need to be amplified and heard, rather than merely inferred. With IQVIA's Patient Engagement Framework, we propose a structured approach to creating this language to ensure the patient's voice is heard at all stages of the decision-making process.

The impetus towards patient centricity and inclusion

The COVID-19 pandemic and its aftermath has made achieving consistent patient focus more urgent than ever. It's also highlighted shortcomings of existing approaches which often fall short of true inclusion of the patient point of view.



*fewer patients
post-pandemic¹*

The pandemic and post-pandemic environment have had a significant impact on the length and complexity of many patients' journeys to effective diagnosis and treatment. As a result, some patients present later and potentially in more advanced stages of disease. The pool of available patients for certain therapies, often the most recently launched ones, has also shrunk. In an IQVIA study, oncologists and haematologists across the U.S., UK, and the EU Top 4 countries reported that they are still seeing on average 23% fewer patients than before the pandemic¹. They also reported delays

in treatment as well as lower numbers of diagnoses. Inevitably, this has consequences for care outcomes and created a backlog of untreated or undertreated patients who now must be reached. At the same time, treatments have been switched to more remote options where possible, and immune-compromised patients and their loved ones face new challenges. Of the oncologists surveyed by IQVIA, 43% reported that they are adjusting treatment protocols where possible to introduce oral cancer medications.

Outside the pandemic dynamics, there are also other mid- and long-term developments increasing the importance of a patient-inclusive approach. This includes the rise of individualized medicine which necessitates closer involvement of patients, as well as overall better treatment options for rare and complex diseases, including ones which are self- or home-administrable. Tied in with this is the rise of healthcare digitalization which enables patients to self-monitor at home and communicate with their HCPs remotely. Even clinical trials are moving out of hospitals and research facilities, and closer to patients' homes in the form of decentralized or hybrid trials. An IQVIA survey found that a hybrid trial setup appeals to a majority of patients and that patients expect flexibility and remote options when participating in trials².



PATIENT INCLUSION AS KEY TO BETTER TRIAL PERFORMANCE

The clinical trial landscape is getting ever more crowded, and therefore demand for trial participants is increasing. At the same time, there is a trend towards geographic concentration. In 2021, the U.S., Europe, Japan, and China hosted 73% of clinical trials while accounting for 86% of global pharmaceutical sales. Essentially, pharmaceutical companies situate a considerable proportion of their trials in their primary commercial markets³. Add to this the shift in R&D activity towards specialty care and rare diseases — as well as a trend towards more complex inclusion and exclusion criteria — and identifying, recruiting and retaining eligible patients becomes increasingly challenging.

It is therefore not surprising that under-enrolment is a significant factor in the overall decreasing trial performance⁴.

Early and persistent engagement with patients and patient organizations can be an effective way to improve trial recruitment. This is achieved by establishing rapport with potentially eligible patients early on and by incorporating patient needs and preferences into the trial design.

These can include endpoints, but also the trial setup and execution. Understanding the profile of “real-world” patients can help define realistic inclusion and exclusion criteria. Ongoing patient engagement can also serve to establish and maintain patients’ trust in the trial process.

The Clinical Trials Transformation Initiative found that both research sponsors and patient organizations agree⁵ that patient group engagement can be a highly effective and efficient way of improving trial performance. The key is giving patient organizations the opportunity to provide input into the trial design and support participant recruitment and retention.

PATIENT INCLUSION AS KEY TO IMPROVING LAUNCH PERFORMANCE

Innovative medicines launched post pandemic do not seem to be reaching their full potential. To improve launch performance, especially with shrinking target patient populations, early patient engagement can help to establish trust and demand.

Innovative medicines launched post pandemic do not seem to be reaching their full potential.

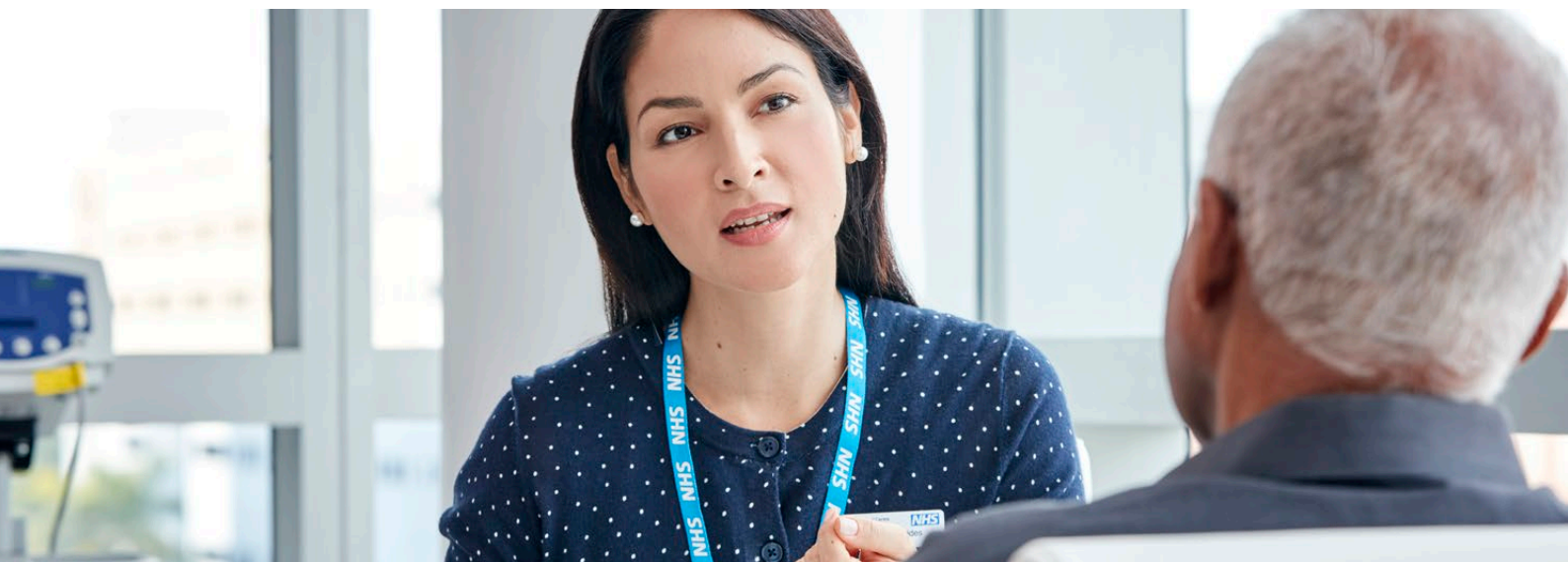
As the most recent IQVIA white paper on launch performance shows, average sales for all post-pandemic launches at the six months after launch mark are down by 19% compared to pre-pandemic benchmarks. The most recent cohort of launches for which six months' worth of sales data are available performs even worse. Here, average sales after six months are 42% below pre-pandemic figures⁶.

A major contributing factor to this underperformance is the disruption of patient journeys by the pandemic, which has resulted in a backlog of patients who remain undiagnosed or whose HCPs are reluctant

to switch them to newer therapies without a face-to-face consultation. Conversely, the relatively few outstanding launches are largely orphan or specialty medicines in areas of high unmet need, and with well-defined and pre-identified patient populations. The other group of successful launches are consumer-driven medicines in the U.S., such as the oral migraine therapies Nurtec and Ubrelvy.

While we may expect the disruption to patient journeys to ease in the post-pandemic era, the trend towards specialty care and rare diseases — and therefore smaller patient cohorts as well as more individualized treatment paths — will continue. The same applies to the increasing role of personalized therapies such as CAR-T cell therapies. In the major developed markets, spending on specialty medicines is expected to account for 60% of overall spend by 2026, while treating about 2-3% of the patient population⁷. A strong patient pipeline established pre-launch will therefore remain a crucial factor for achieving launch success.

It is also important to bear in mind that due to shorter innovation cycles and the need to precisely time launches and pre-launch activity, trial underperformance has a direct impact on overall product revenue, as does initial launch performance. Pharma companies should therefore move towards treating the entire product lifecycle, from R&D through launch to post-LoE, as an interdependent process with stages that must interact seamlessly to minimize time to market and maximize the profitable life of the product. They should also regard early and persistent patient engagement as a necessary investment to ensure product success throughout all lifecycle stages.



REGULATORS PUSH FOR MORE PATIENT ENGAGEMENT

Regulatory agencies are also keen to promote early and persistent patient engagement. The Food and Drug Administration has issued a series of guidances on patient-focused drug development to encourage incorporating the patient's voice in drug development and evaluation⁸. Similarly, the European Medicines Agency has established a framework for engaging patients and patient organizations throughout the regulatory process and for incorporating patient experience data into the evaluation of new medicines⁹. The Medicines and Healthcare products Regulatory Agency, meanwhile, has launched a pilot program to ensure patient involvement in the clinical development process by requesting evidence of patient engagement for all submissions for new medicines and new indications. While this is not yet requested for clinical trial applications, the MHRA will document evidence of patient involvement here, too¹⁰.

Regulators' emphasis on patient involvement is an important signal to the pharmaceutical industry since while patients are the ultimate recipients of new medicines, approval and reimbursement decisions rest with the respective authorities.

WHY "PATIENT CENTRICITY" ALONE IS NOT ENOUGH

Patient centrality as a term and concept has seen a meteoric rise in recent years as the momentum towards more patient involvement has taken hold and has been given an additional push by the COVID-19 pandemic. Pharma companies have revamped their structural model to shift their focus to a more direct understanding of patients. Many companies have issued vision statements to this effect and patient engagement projects have been launched and patient affairs departments created.

While shifting the focus towards patients' needs and preferences is a necessary and welcome development, the term "patient centrality" risks becoming a victim of its own success. There is at times an inflationary usage which covers a wide range of approaches and does not always include direct patient engagement. Often, when talking about patient centrality, what is actually meant is imagining and inferring patients' needs and preferences, thereby running the risk of missing the mark. Companies also miss out on the benefits of genuine direct patient engagement outlined above.

Another pattern often found is that companies implement patient engagement programs but do so for only some aspects of the value chain. Pfizer, for instance, found on reviewing their patient centrality strategy that they were doing well in patient education and advocacy, but lacking in clinical development and health equity¹¹. Other organizations, if they took a closer look, would most likely come to similar conclusions.

Figure 1: Regulators' initiatives to increase patient engagement



The rationale for the concept of the Patient Engagement Framework

To fully embrace and reap the benefits of patient centricity, a complete, 360-degree view of the fundamental components of patient-centered asset strategies, clinical trial design, pre-launch planning and patient support programs from the perspective of patients is needed.

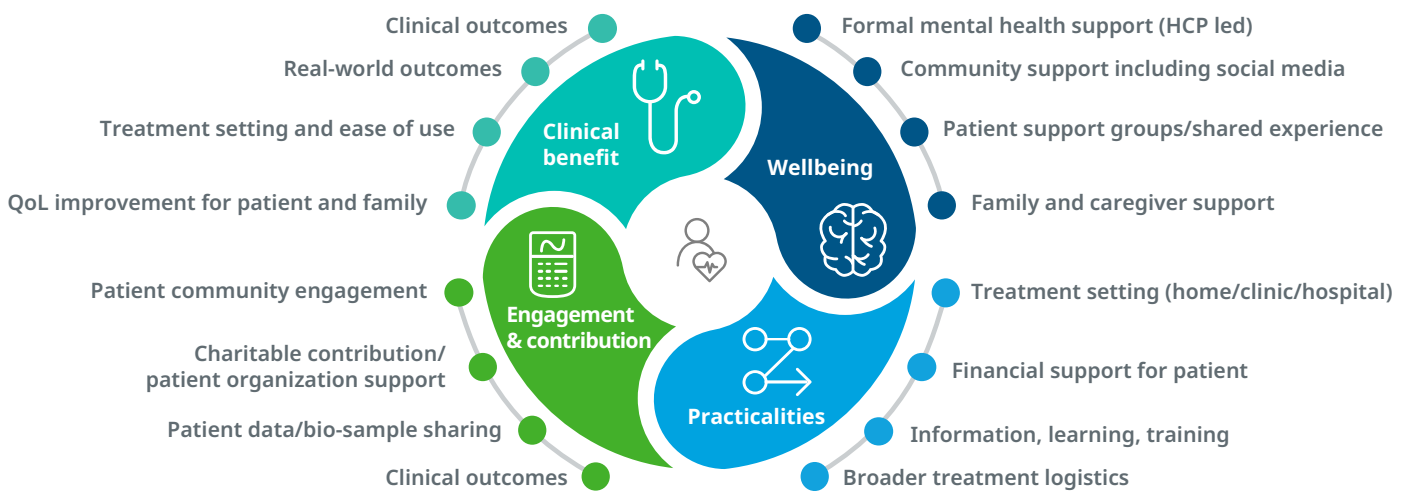
It is vital that this view includes direct input from patients and patient organizations to ensure it reflects a true understanding of the patient perspective. This in turn necessitates a common framework and language as foundation for effective communication between all stakeholders.

To meet this need, IQVIA has collaborated with patient organizations and the pharmaceutical industry to create such a framework designed to support comprehensive and consistent assessment and planning for the inclusion of patient needs and preferences through end-to-end strategic drug delivery.

The Patient Engagement Framework: defining fundamental categories and roles of patient engagement

The Patient Engagement Framework is intended to be used as a reference point by pharmaceutical companies in the development and positioning of therapies, by HCPs, by patients, their families and loved ones, by patient organizations, and by regulators and policy makers. It provides a comprehensive conceptual outline of the fundamental categories and roles of engaging with patients' needs and preferences and lays the groundwork for a common understanding and a common language which bridges the communication gaps between the various actors in the healthcare ecosystem.

Figure 2: IQVIA's Patient Engagement Framework



The framework proposes four distinct sections focusing on clinical benefit, wellbeing, practicalities, and engagement and contribution.

CLINICAL BENEFIT: UNDERSTANDING PATIENTS' EXPECTATIONS, DISEASE AND THERAPY BURDEN, AND PREFERRED OUTCOMES

Clinical benefit centers around understanding patients' clinical expectations, disease and therapy burden, and preferred outcomes. The overarching goal is to achieve quality of life improvements that are meaningful to patients and their families. This can be done by reducing the burden of disease, the burden of therapy on the patient's social life, employment, finances, education and travel, and the impact on loved ones, family, and carers.

The other categories in this section support and contribute to this overarching goal. Clinical outcomes cover measurable changes in health, function, and quality of life as prioritized by patients and caregivers. This includes ensuring study endpoints and clinical outcomes are aligned with those considered most important by patients and caregivers.

For real-world outcomes, the focus must be on enabling patients and patient organizations to access real-world data and studies to understand, outcomes in a language patients can easily understand, and give patients the opportunity to participate in real-world studies and contribute to research via patient-friendly platforms.

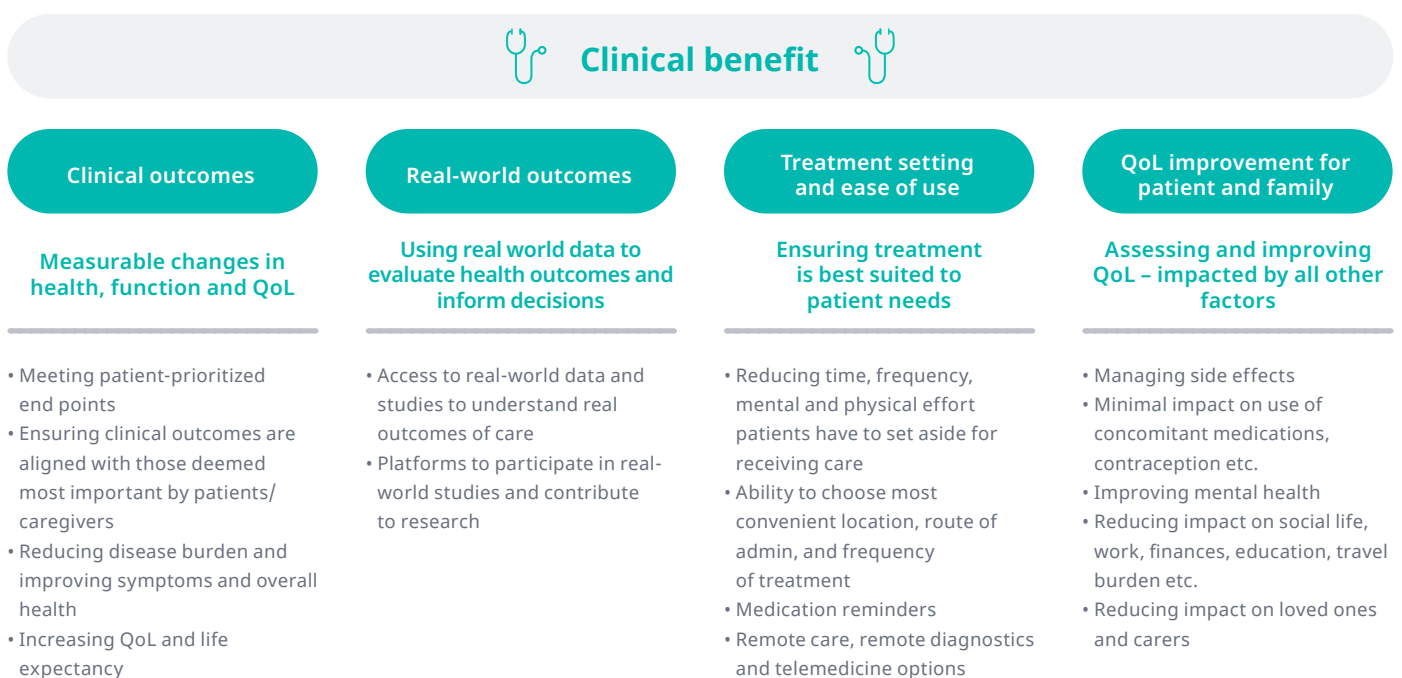
Ease of use of treatment and setting of treatment is key to ensuring patient adherence and also plays an important role in motivating patients to participate in clinical trials. Ease of use includes:

- Aspects related to on-site treatment such as the option to choose convenient locations.
- Routes of administration.
- Frequency of treatment.
- Medication adherence reminders in a patient-preferred format.
- Remote care and diagnostics options — e.g. don't overcomplicate digital solutions for people who may not have regular internet access or who are digital immigrants at best.

In the post-pandemic healthcare environment, ease of use in the form of self or home administration has gained in importance since patients may want to minimize exposure and health systems want to reduce the burden on facilities.

The overarching goal is to reduce time, frequency, and mental and physical effort patients have to set aside for receiving care, in a manner that is manageable by patients and caregivers.

Figure 3: Clinical benefit of the Patient Engagement Framework



EMOTIONAL AND SOCIAL WELLBEING: SUPPORT TO BUILD A HEALTHY MINDSET

This section focusses on providing patients, their families, and their caregivers with support to build and maintain a healthy mindset and covers aspects outside the immediate medical care.

Ensuring emotional and social wellbeing encompasses a range of measures, some of which are provided by healthcare professionals and are part of the immediate healthcare system. Others incorporate the wider community, often in a more informal setting and are led by patients and/or their loved ones.

These measures include HCP-led mental health support during and after treatment, such as access to counselling for patients and caregivers, access to specifically tailored support groups, and signposting to patient and carer communities and external sources of support. In order to meet different logistic and personal needs and preferences, these support options should, whenever possible, be available face-to-face or remotely, and it is essential that they are available quickly and without long wait times since patients' needs tend to be immediate.

In addition to more structured, HCP-led support systems, informal support systems led by patients or their loved ones are important for establishing a sense of community. These too can and should be available face-to-face or online, such as online platforms where patients and carers can share stories, seek and give peer support, and seek advice with a degree of anonymity. Equally important are face-to-face events like community meetups, conferences, or holiday gatherings.

It has already been mentioned that wellbeing support must be available not only for patients but also caregivers. Specifically tailored support systems for those around the patient — caregivers as well as family members who are not directly involved in day-to-day care — are also needed. Dealing with a loved one's illness can be harrowing, and family members need to understand what to expect and where to find support. Educational pamphlets, videos, and websites on how family members can seek support, support the patient, and support themselves can be a great help. Equally needed are more individualized options such as hotlines and online chats, and individual consultation times. All these options must be easy to access and use language geared to the targeted group.

Figure 4: Emotional and social wellbeing



PRACTICALITIES: DEALING WITH THE INTERSECTION OF TREATMENT AND DAY-TO-DAY LIVING

This section of the Patient Engagement Framework involves aspects related to enabling patients to manage their day-to-day lives by adjusting treatment settings and providing support for finances, informational needs, and broader treatment settings. This is not only essential to patients' and their families' social and emotional wellbeing, it is also a crucial factor for ensuring treatment success, especially with chronic, life-altering, and life-threatening conditions.

Issues to consider range from ensuring access to treatment and continuity of care across settings and specialties, to financial support for meeting treatment and associated costs, providing information about the disease and treatment, and support for daily activities like nurse care, long-term care, and end-of-life planning.

Access to treatment and continuity of care across settings and specialties can make or break therapeutic success. Access to care is not limited to the first point of care in a clinic, doctor's practice, or hospital, but also transitioning to another care provider or care setting. It also includes access to suitable, patient-preferred diagnostic methods as well as to remote healthcare and virtual consultations, and, crucially, access to

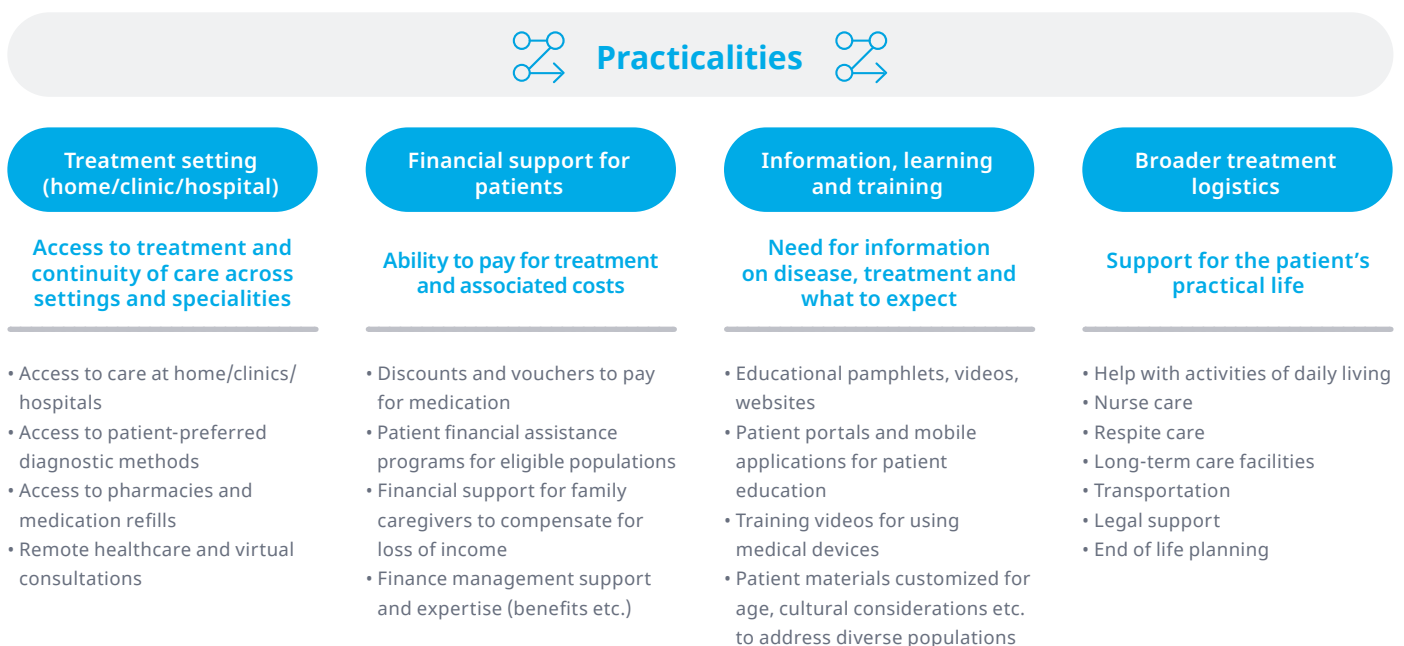
pharmacies and medication refills. Especially if patients relocate or change HCPs for another reason, continuity of care can become a challenge.

Financial support is intended to ensure patients' ability to pay for treatment and associated costs. It therefore not only entails discounts and vouchers to pay for medication not covered by health insurance, but also wider financial assistance programs for eligible populations. This can also include support for family caregivers to compensate for loss of income if a leave of absence from work has to be taken or hours reduced.

Practicalities also include meeting patients' needs for information about their disease, treatment, and what to expect, although there is also some overlap with the section covering wellbeing.

Also needed is support for patients' and their caregivers' practical life, including broader treatment logistics. These range from help with day-to-day activities to transportation needs, in-home nurse care, respite care, long-term care at home or in care facilities, legal support, and end-of-life planning. This support has become even more important in the post-pandemic environment where patient journeys have been disrupted and made more virtual.

Figure 5: Practicalities



ENGAGEMENT AND CONTRIBUTION: HELPING PATIENTS TO GAIN AGENCY

This final section is concerned with patients' need to feel part of a community of people with shared experiences and their desire to participate in trials, and thereby gaining agency in shaping current and future treatment.

To achieve this, patient communities must be engaged to ensure patients, as experts on their conditions, are involved in decisions affecting the evolution of treatments, such as designing treatment pathways, defining clinical endpoints, and understanding and prioritizing unmet needs.

The support of charitable organizations and patient organizations also has a significant role to play in this, both so patients can benefit from strong support by these organizations, and so that charities can act as an intermediary between patients and the pharmaceutical industry to enable transparent, ethical collaboration in the interest of the patient community.

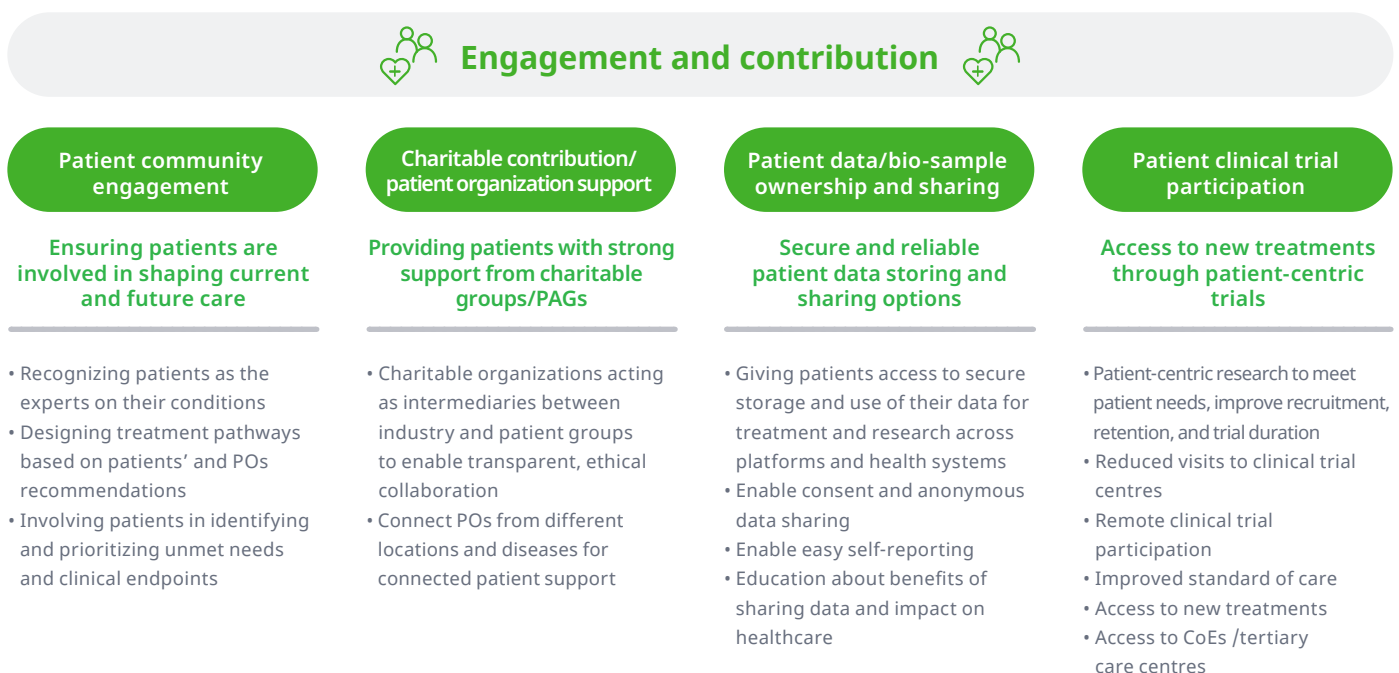
Encouraging patient participation in research for future treatments is another major aspect of engagement and contribution. This encompasses giving patients access to new treatments through trials developed around patients' needs to improve recruitment and retention

and achieve faster completion. Patient-centric trial design can include practicalities like reduced visits to trial centers and remote trial participation, but also clinical aspects like prioritizing patient-identified unmet needs and relevant endpoints.

Research participation is also fostered and enabled by giving patients ownership and opportunities for sharing their data and bio samples for research purposes. Patients must have access to safe and secure storage and use of their data for treatment and research purposes across platforms and health systems, as well as the ability to provide consent and share data anonymously. It is also important that patients understand the benefits of sharing their data and the potential impact on healthcare.

In short, engagement and contribution are about the needs and aspirations of patients but also members of the wider society to become involved and make a difference.

Figure 6: Engagement and Contribution





The Patient Engagement Framework benefits all healthcare stakeholders

THE FRAMEWORK WILL HELP THE PHARMACEUTICAL INDUSTRY TO CONSIDER PATIENT NEEDS AT ALL STAGES

The framework provides a concept for a structured approach to identifying gaps and optimizing patient centric initiatives. It is designed to be used by chief patient officers, patient engagement and patient advocacy leads, asset planners, medical affairs, and brand teams to ensure an integrated, comprehensive approach to patient engagement across the entire organization and along all stages of the value chain.

Consistent reference to the framework will help ensure that all stakeholders utilise a common language and understanding of the needs patients have and the issues they face. It will result in improved strategic planning for patient engagement driven by a better understanding of patient issues. This starts right from the point of planning clinical development and trial protocols, which should incorporate input from patients, their loved ones, and patient organizations at the beginning of the planning process. It will also enable implementation of more effective execution on patient support, education, and advocacy programs as a result of better communication. Last but not least, it will support performance and impact evaluation to ensure continuous learning and growth for all actors involved in developing new therapies and bringing them to the patients.

If used consistently, the Patient Engagement Framework is a valuable tool to ensure patient needs are at the heart of all strategic decisions along the pharma value chain.

FOR PATIENTS AND PATIENT ORGANIZATIONS, THE FRAMEWORK WILL AID IN FINDING A COMMON LANGUAGE WITH INDUSTRY AND POLICY MAKERS

In the face of the increased focus on patient centricity across the healthcare industry, patient organizations have evolved and expanded their role. They now routinely interact with the industry to advocate for the integration of the patient perspective into all stages of the medicine lifecycle through conferences, summits, expert panels and standing committees in addition to sponsoring research themselves. At the same time, they are also involved with regulatory bodies to advise on patient-focused drug development including PROs and patient-focused endpoints. Patient organizations also represent patient interests in health technology assessments, approvals, and reimbursement decisions.

Individual patients also interact with the industry and regulatory bodies in these roles; the EMA for instance explicitly calls for patients to serve not just as representatives of their community or a patient organization, but also as individual experts¹².

In their role as intermediaries and advocates interacting with the industry, regulatory bodies, and of course patients themselves, patient organizations will benefit from adopting the Patient Engagement Framework to ensure all aspects relevant to patients' lives are taken into consideration and to find a common language with industry representatives and policy makers.

REGULATORS AND POLICY MAKERS CAN USE THE FRAMEWORK TO ENSURE PATIENT PRIORITIES INFORM THEIR DECISIONS

Regulatory authorities not only place increasing importance on incorporating the patient perspective into the drug development process, they also interact directly with patient organizations as well as individual patients and include patient representatives in the decision-making process. From the point of view of healthcare efficiency, this is an important step since

Putting patient preferences and needs at the center can be expected to improve adherence and as a result outcomes, thereby ensuring that healthcare resources are employed efficiently.

In times of increasingly tight healthcare budgets, this will matter even more.

Adopting the Patient Engagement Framework will facilitate the interaction between regulators and patients and patient organizations on the one hand and industry representatives on the other. It will also help to ensure the conversation includes aspects that may be very relevant to patients' daily lives with a direct impact on therapeutic success, but may not be in the usual frame of reference for regulators and policy makers.

Concluding thoughts

The need for patient centricity and greater patient involvement has been recognized for a while now and pharmaceutical companies have responded by creating dedicated functions and elevating the issue on their agendas. Regulators, too, are placing increasing importance on patient inclusion. Patient organizations in turn have grown in influence and sophistication. The rise of social media and digital health technologies has greatly enhanced the ability of certain groups of patients to contribute their voice to key debates on care, policy and access.

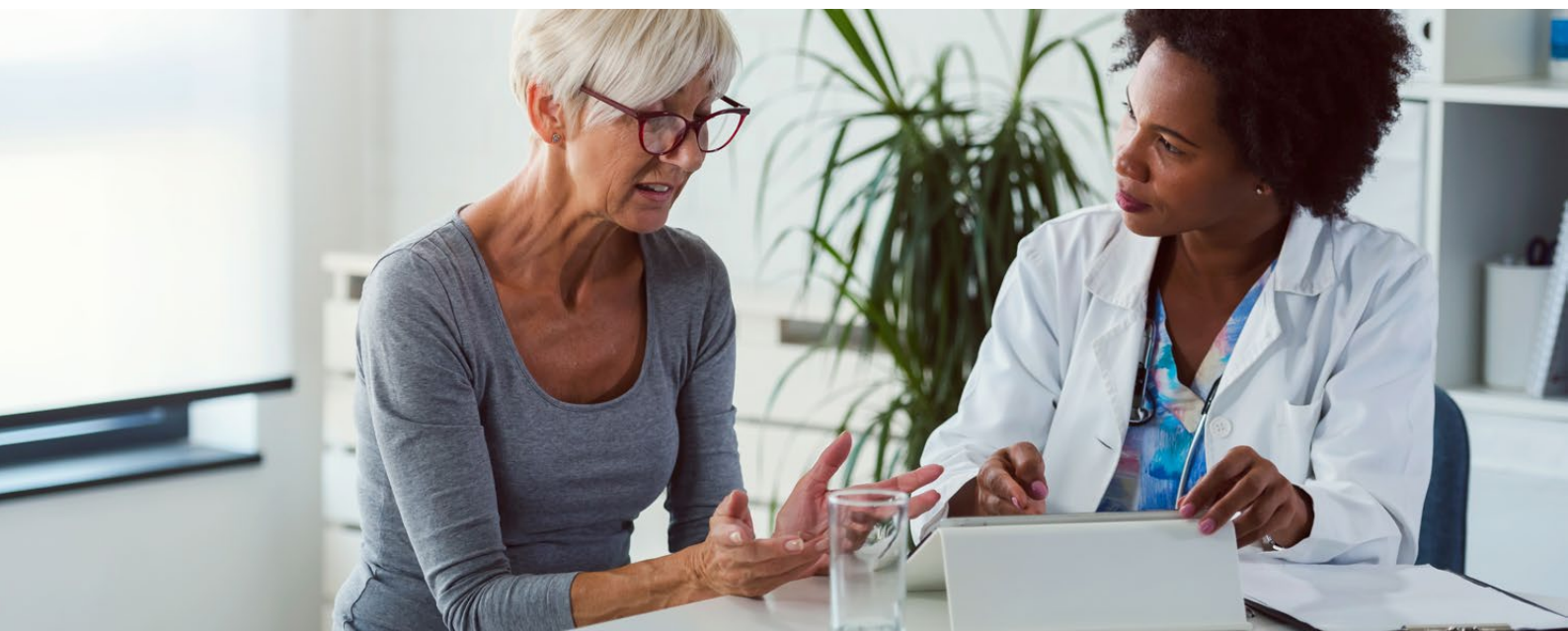
But while progress has been made, there is still much to do. Often patient focus stops short of actual patient involvement, and not all patient issues are given the level of attention they should command. In addition, not all patient voices are heard in the same way, sometimes due to lack of digital access, or because they are socially disadvantaged. The Patient Engagement Framework is IQVIA's initiative to address this by providing a conceptual foundation.

Post-pandemic, healthcare systems are under continued stress and will remain so for the foreseeable future, with direct consequences for patient care. In this environment, the Patient Engagement Framework serves the further, urgent role of reflecting patient experience and needs in the context of severely stretched healthcare systems and thereby providing indicators for effective resource allocation. If we want healthcare systems to be able to withstand the strain and provide the best possible care to the largest number of patients, the next step in the ongoing debate and in the application of the Patient Engagement Framework must be not just patient support and engagement, but health system support and engagement.



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Meike Madelung is a Senior Consultant with the EMEA Thought Leadership team and based in Frankfurt, Germany. She develops and present insights and analyses on a range of key topics based on IQVIA's data assets and expertise. Areas of interest include clinical trial optimization, the immunology product landscape, and patient-level data.

Meike has been with IQVIA for over fifteen years in a variety of roles both in London, UK and in Frankfurt, Germany. She has expertise in RX and Consumer Health data and markets both at the national and international level.

Meike holds an MA from the University of Bonn, Germany and an MBA from Royal Holloway, University of London.



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Sarah is focused on developing and executing innovative solutions in collecting the customer and patient voice to best meet client needs. For example, combining different sources of data (primary and secondary) to generate a more robust source of evidence of clinical behaviours and through the application of advanced approaches, such as Artificial Intelligence to identify patterns and predict changes. Also identifying 'why' particular characteristics exist in the market, and developing strategies of how to change behaviours, for example through the application of behavioural science frameworks.



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