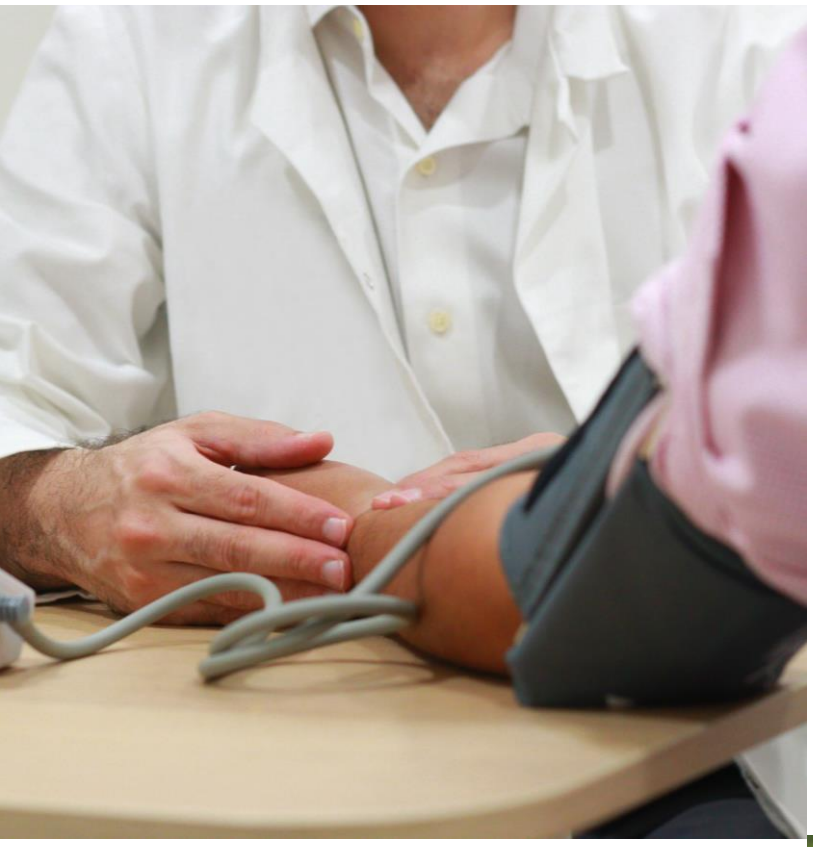
Patient over product

Improving the clinical adoption and engagement of digital health solutions starts by focusing on patient-centricity



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Co-foreword

As a practicing clinician, I would like to think that I and every other stakeholder in the healthcare ecosystem have always been patient-centric. However, the question is, "What is patient-centricity?" While we would all agree that being patient-centric means placing the patient's (and their families', too) individual needs and preferences first, definitions vary across the globe. Furthermore, in today's healthcare ecosystem, with all health systems globally facing time and resource pressures, is it reasonable to expect that we stop and ask what each of our patient's needs and preferences are? And take a completely holistic approach? I believe it is.

This position paper by PwC in collaboration with National University of Singapore's (NUS) Institute of Digital Medicine (WisDM) aims to redefine patient-centricity, in a holistic manner that involved seeking input from more than 100 individuals and across all stakeholders. By highlighting and quantifying not only the opportunities from an academic, business and clinical perspective but also the challenges faced, this paper proposes a patient-centricity framework and best practices that can be applied to digital therapeutics each step of the way, starting from conceptualisation through to commercialisation. Regardless of our role in any health system, let us all work together towards being truly patient-centric, or perhaps even better, patient-driven as a recent article I came across stated. In the words of a large hospital group CEO, "If you look after your patients, the business will look after itself."

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Asia Pacific Health Industries Leader,
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If digital health solutions (DHS) have the potential to disrupt healthcare, there is still a long journey ahead before these solutions can benefit and be used every day by clinicians, patients, and their family members. Among the numerous critical challenges that DHS need to address is the question of patient-centricity and how best to address the needs of patients to ensure that these solutions are used in a real-world environment beyond the traditional few weeks of a clinical trial. As the World Health Organisation (WHO) and numerous others have emphasised, there is a critical need for the development of DHS to meaningfully involve the patients and communities they impact, particularly concerning the applications of artificial intelligence (AI).

For this reason, using digital therapeutics (DTx) as a use case, this white paper defines what patient-centricity means, outlines effective ways to involve patients in technology development, identifies key stakeholders to engage, and presents best practices for patient-centricity. Additionally, a framework for patient-centric best practices is introduced, designed as a comprehensive tool for evaluating patient-centricity in DHS. We hope this framework will be used as a roadmap to enhance patient values of solutions by empowering patients to actively engage in their healthcare journey as equal partners.

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A focus on patient-centricity

How is patient-centricity currently defined?

Patient-centricity means prioritising patients' needs and preferences, not just when it comes to healthcare innovations but in general, too. One major way to be more patient-centric is to enhance their participation at every stage of the digital health solution (DHS) lifecycle, from inception to clinical validation and implementation. Yeoman et al. defined patient centricity as 'putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family.' It is thus crucial to emphasise patient engagement in all stages of development of DHS.

This position paper aims to present various stakeholders' perspectives and interpretations of patient-centricity, incorporating both ground-up perspectives and from existing literature. Additionally, it proposes a framework for evaluating patient-centricity in digital therapeutics (DTx) solutions.

What are the benefits of patient-centric digital health solutions?

This section explores why pursuing patient-centricity provides benefits to both patients and a broad range of stakeholders, including clinicians and healthcare systems. Two key categories of benefits stand out: Enhanced patient experience, and improved patient outcomes.

Enhanced patient experience

Patient-centricity prioritises the individual needs and preferences of patients, encouraging their active involvement in the development process of healthcare solutions. When patients are engaged in the design process, they are more likely to access online healthcare resources, participate in studies to understand their conditions better, and engage with online patient communities. Establishing the norm where patients are closely involved in healthcare research advocates for healthcare which aligns with their needs. Patient-centric care emphasises empathy, communication, and collaboration between patients and healthcare providers, resulting in a more positive and satisfying healthcare experience. The outcomes of such enhanced and personalised experiences for patients often include a greater sense of empowerment, engagement, and trust in the healthcare system to care for their unique needs. Such positive patient experiences can in turn be used to promote greater uptake of the digital health solution.

A case in point: Perx Health[1] reported a remarkable 96.8% implementation adherence using a digital therapeutics (DTx) mobile app over a six-month period. Their multicomponent adherence management intervention, incorporating reminders, educational components, incentives, gamification, and social community components, demonstrated the success of this approach in maintaining optimal medication adherence.

Improved patient outcomes

By centring on the individual needs and preferences of patients, patient-centric solutions contribute to better treatment adherence[1], reduced hospital readmissions[2,3], and overall enhanced health outcomes[4]—essential benchmarks for any healthcare solution. Moreover, we can argue that improved patient outcomes, or initial data indicating that patients are progressing positively in terms of their conditions and/or symptoms—a data-driven approach—will also bolster patient adherence.

A case in point: In the pharmaceutical industry, which faces similar challenges to digital healthcare solutions, a research report by Parexel[5] for The Economist Intelligence Unit revealed that drugs developed using patient-centric clinical trials, involving patients in design or execution, were 19% more likely to be launched successfully. Such case studies support that patient-centric methods are more likely to yield successful health innovations with superior outcomes for patients.

Why is patient-centricity important across all stakeholders?

Medical professionals

- **Increased efficacy:** Patient-centricity leads to better patient outcomes and disease management[6], rendering the efforts of medical stakeholders more effective.
- **Engagement:** Patient-centricity offers medical professionals the chance to learn from patients[7], who can be extremely knowledgeable about their own health condition(s).
- **Ethos:** Patient-centricity is a core tenet of healthcare, as patients form the driving motivation for medical professionals.

Patients

- **Personalisation:** Patient-centricity offers tailoring of the best experience for end-users, empowering patients to make informed decisions about their healthcare.
- **Cost:** Patient-centric DTx solutions, done right, can be associated with lower costs. (e.g., Sleepio users had 28% lower healthcare costs, decreasing by US$1677 on average per person[8]).
- **Engagement:** Enables patients' involvement in the research process[9], where they can provide meaningful feedback on potential DTx solutions.
- **Partnership:** Therapies and treatments are decided on in partnership with the patient, for the patient.

Regulators and developers

- **Tackling non-adherence:** When DTx solutions are patient-centric, they are more likely to be well-received by patients, thus providing a new avenue to enhance patients' health effectively and address longstanding issues of non-adherence, which can cost between US$949 and US$44,190 per person[10] annually[11].
- **Cost-effectiveness:** In drug development, early investment in patient input on drug design is more effective for recruiting and retaining patient participants, which saves downstream costs over its future development. Research has found that investing US$100,000 to gather patient input on drug design and improve participant recruitment and retention can save an estimated US$60m over the drug's lifetime[12].
- **Market demand:** Patients can be drivers of new innovations that best meet their needs which can limit market failures due to low demand.

Academics

- **Equity considerations:** Patient-centricity is crucial in academia to ensure research and healthcare innovations address diverse patient needs, experiences, and outcomes, ultimately promoting equitable access to effective treatments and improved health for all populations.
- **Real-world validity:** Much of the academic research within DTx ultimately aims to be applied to real scenarios. Patient-centricity offers a means of applying academic theories with better uptake, i.e., truly going from bench to bedside.

Survey methodology and stakeholder results

In order to determine how medical stakeholders viewed patient-centricity, in January 2024 we conducted a survey of 118 stakeholders worldwide, the majority of whom were from the Asia Pacific region. Countries represented included Australia, New Zealand, Singapore, Indonesia, Malaysia, Philippines, Thailand, Vietnam, China, India, Japan, Taiwan, United Kingdom, France, Germany, Brazil and the United States of America.

The survey was designed to capture the stakeholders' perspectives on patient-centricity. Participant responses were collected through the researchers' professional networks. Each respondent was asked to identify up to three stakeholder positions they most identified with, which was designed to acknowledge how individuals frequently contribute across various professional domains.

Digital therapeutics were used as a case study to capture the perspectives of stakeholders within the healthcare community on the concept of patient-centricity.

The proportion of stakeholder representation within our sample was as follows:

- MedTech – 39%
- Clinical providers – 31%
- Investors – 27%
- Technology providers – 27%
- Patients / Patient advocate groups – 18%
- Government agencies – 14%
- Institutes of higher learning – 12%
- Healthcare administrative staff – 9%
- Pharma – 9%
- Regulators – 3%
- Economists – 2%
- Insurers – 2%

The top five stakeholder groups represented were: (1) medical technology, (2) clinical providers, (3) investors, (4) technology providers, and (5) patients / patient advocate groups.

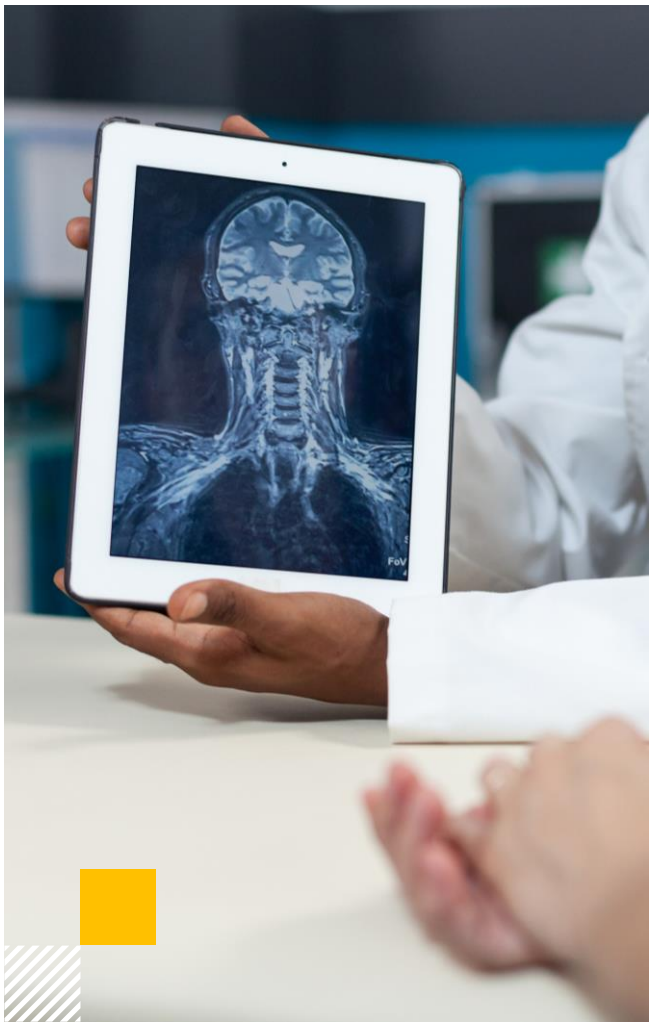
The next section summarises the key insights from the participants' responses and support the operationalisation of patient-centricity and help establish patient-centric best practices.

How did our survey respondents define patient-centricity?

Through thematic analysis of responses, seven complementary characteristics of a patient-centric solution were identified.

	Characteristics of patient-centricity	Qualifying explanation
1	**Meeting patients' needs**	Meeting patients' needs involves various approaches, such as catering to patients' technological proficiency levels, addressing genuine and unmet needs, and comprehensively understanding the patient beyond their disease parameters. Embracing a patient-centric design approach means ensuring that all aspects, from treatments to clinical trials and technology, revolve around the patient and prioritise their needs and interests.
2	**Prioritising and achieving improved patient outcomes**	Enhancing patients' quality of life, ensuring an effective intervention by producing the desired health outcome, addressing their pain points, improving their condition, and providing a clear value proposition for patients by giving them access to outcomes which improve their quality of life.
3	**Respecting patient values**	Understanding and respecting patients' personal values and preferences throughout the healthcare solution's development. Any healthcare solution should prioritise the problems which patients determine to be of highest importance and delivered in a manner which respects their personal and moral values.
4	**Providing an accessible solution**	Accessibility means ensuring that there are minimal barriers to treatment for patients, which include equitable access to technology, convenience of obtaining care, and affordability.
5	**Providing a simple and intuitive user experience**	The technology's user interface should be simple, intuitive, user-friendly, facilitate the ease of patients' access to healthcare, and be easily integrated into patients' everyday lives.
6	**Involving patients**	Actively seeking and integrating patients' input by directly engaging them as equal stakeholders in every stage of healthcare technology development. It signifies adopting a patient-driven approach towards providing healthcare solutions.
7	**Empowering patients**	Encouraging patients to take ownership over their health by providing them with the education, tools and resources they need to make informed decisions or take the initiative to manage their health. Empowerment also involves actively engaging with patient voices and making meaningful change based on their experiences.

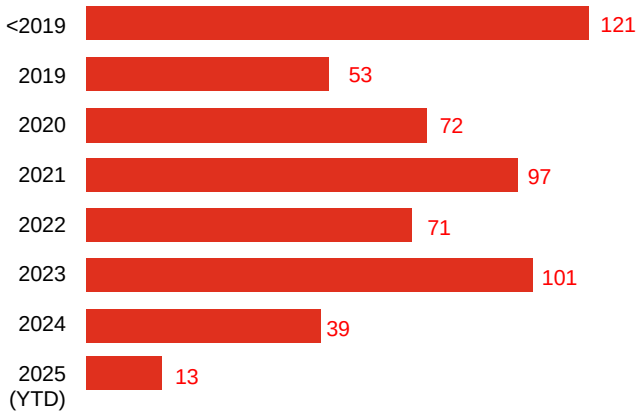
What opportunities and momentum are there for DTx?



Clinical

Number of clinical trials by DTx ventures YoY

A total of 567 clinical trials have been conducted or are currently underway by digital health ventures focusing on digital therapeutics. As of September 2024, 39 clinical trials had been logged, which was below the 101 clinical trials recorded in 2023.



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Business

US$5.66bn
2023

US$36.47bn
2032. CAGR 23%

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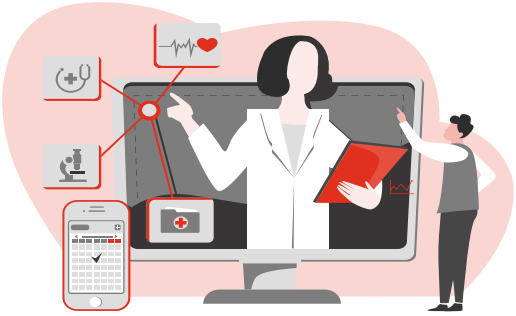
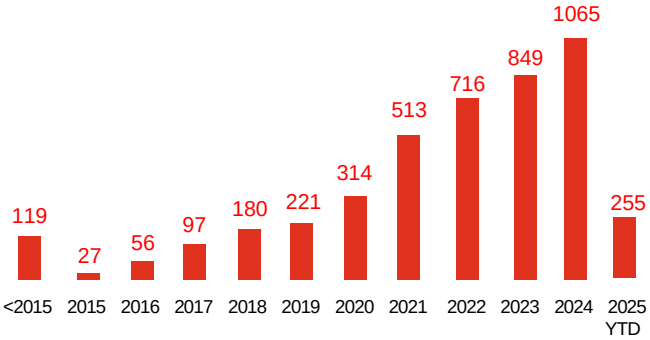


Academic

Number of scientific publication by DTx ventures YoY

More than 4,412 scientific publications were published by digital therapeutics ventures since 2010. In 2023, the annual number of publications reached 849, down 9% YoY.



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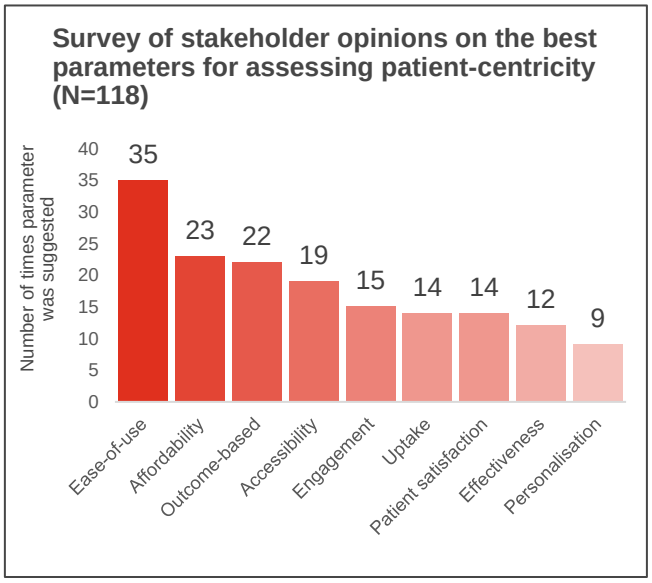
Without certainty, the observed reversal above of an increasing trend over preceding years with a decline of clinical trials and academic publications in 2024 may be reflective of uncertainties in (1) securing funding representative of investor hesitancy, and (2) navigating market access, regulatory approvals, and potential reimbursement as governments have slowly started establishing DTx-specific frameworks.

How should patient-centricity be measured?

118 participants' responses to the question of measuring patient-centricity were coded and the five most recurring points for evaluating patient-centricity in DTx solutions included (1) Ease-of-use, (2) Affordability, (3) Quality of outcomes, (4) Accessibility, and (5) Engagement. These results re-emphasise that, beyond ensuring clinical efficacy, DTx technology must engage with patients as they are. To be patient-centric, a DTx technology should remain accessible to patients regardless of their technological familiarity, financial, or social backgrounds.



How best can we involve patients in the development of DTx?

Our survey results showed that

1 Usability studies, followed by working with

2 patient advocate groups/patient ambassadors

were thought to be the best means of involving patients in DTx development over in-app feedback channels, clinical trials, patient surveys, and community patient forums.

What the results tell us

Stakeholder responses imply that patients should be actively engaged in iterative usability studies, allowing them to provide continuous feedback during the development process of DTx technologies. In contrast, clinical trials require a DTx to be sufficiently mature before undergoing medical testing with patients, which usually occurs later in the development process. There is, therefore, a gap between stakeholder opinions on when it is most beneficial to involve patients, and when patients are actually involved in DTx development. Involving patients earlier, rather than later, would provide more avenues for patient input and set the basis for more patient-centric DTx development. Moreover, existing literature suggests that patient focus groups, conducting patient advisory panels and patient advocate group involvement are initiatives with the lowest cost and highest impact on the patient, relative to other patient-centric practices[13]. A co-creation approach is needed to genuinely address the needs and preferences of its users, primarily patients and healthcare providers. Taking an interdisciplinary approach towards engaging patients and stakeholders in the concept, design and development process enhances the relevance, usability, and effectiveness of health solutions, resulting in improved patient outcomes, higher adoption rates, and ultimately, enhanced healthcare delivery.

Who should be involved in the development cycle of a patient-centric DTx?

Unsurprisingly, patients! Across the development, clinical validation and implementation stages, patients are continuously cited as the most important stakeholder to involve. The support and involvement of family members and caregivers are vital for the physical, emotional, and practical well-being of patients, contributing to better outcomes and quality of life during illness or recovery. Consequently, they should also play an integral role in the development cycle of patient-centric digital therapeutics (DTx).

Secondly, healthcare professionals with the closest contact with patients in treatment contexts are also thought of as warranting the greatest involvement in developing patient-centric DTx. 85% of survey respondents selected doctors, and 62% selected nurses as the health professionals thought to have greater involvement in the DTx development cycle compared to C-suite, healthcare administrative staff or other allied health professionals. The results from this survey corroborate with results from a previous study conducted by PwC and Singapore's National Health Innovation Centre (NHIC) that similarly found doctors' and nurses' perspectives were perceived as the most highly sought after and valuable ones.

Finally, whilst regulators are mentioned 'only' once in the top three throughout the DTx lifecycle, we would argue that early engagement with regulators is crucial for the successful development, validation, and eventual approval of DTx solutions. This ensures that they meet regulatory standards while delivering safe and effective healthcare interventions which can be easily adopted and used by the consumer at a cost-effective price. Early engagement allows developers to understand and comply with regulatory requirements from the outset, thereby reducing the risk of costly delays or rejection during the approval process. Regarding regulators, some countries have issued guidance on developing patient-centric digital measures, emphasising the importance of patient centricity. For instance, in the US, the Food and Drug Administration (FDA) has created a series of four patient-focused drug development guidance documents. These documents guide stakeholders on gathering and submitting patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decisions. While not strictly limited to digital health, many of these approaches, tools, and best practices are relevant for DTx. The FDA guidance, for example, references the 'Digital Measures That Matter' framework, which provides a hierarchical model for establishing the meaningfulness of such digital measures.

In addition to regulators, a crucial stakeholder potentially missing from our respondents' answers is the payor. The monetisation of DTx presents one of the most intricate and complex challenges organisations currently face. Engaging and consulting with payors (including insurance companies, employers, and government agencies) during the DTx development is therefore imperative. This involvement is essential for validating the solution's value proposition, ensuring market suitability, understanding reimbursement landscapes, facilitating market access, and determining the scale of adoption beyond the clinical trial.

Top three stakeholders who should be involved throughout the DTx lifecycle according to survey respondents

Development
- Patients
- Clinical providers
- Tech. providers

Clinical validation
- Patients
- Clinical providers
- Regulators

Implementation
- Patients
- Clinical providers
- Tech. providers

What are some examples of best practices in patient-centricity?

An example of involving individuals in the early technology development and testing phase. Image depicts the swallowing of a camera embedded in a pill to seek early user feedback.

In technology development

- Patient engagement
  - For example, consider MedRhythms, a US based company that utilises neurotherapeutics to aid patients with neurological diseases or injuries in enhancing their functional mobility through music. Incorporating the patient perspective into daily decision-making was at the heart of MedRhythms' inspiration in forming the first-of-its-kind Digital Therapeutics Patient Advisory Board[14], alongside the typical scientific advisory board. Patients are deeply engaged and consulted from the inception of MedRhythms' product development and consistently provide input on product innovation.
- Interdisciplinary and mixed-methods approaches
  - The Institute for Digital Medicine (WisDM) at NUS is committed to seeing its DHS implemented in real-world settings. To achieve this, their research engineers, clinicians, implementation science experts, and other professionals collaborate closely with their in-house dedicated behavioural team. Together, they conduct ongoing usability and feasibility studies, actively listening to end-users and incorporating their feedback into the requirements for improved (and more relevant) design and user engagement.
  - Mixed-methods approaches, combining quantitative and qualitative approaches, offer a comprehensive understanding of patient perspectives and help assess the generalisability of observations.

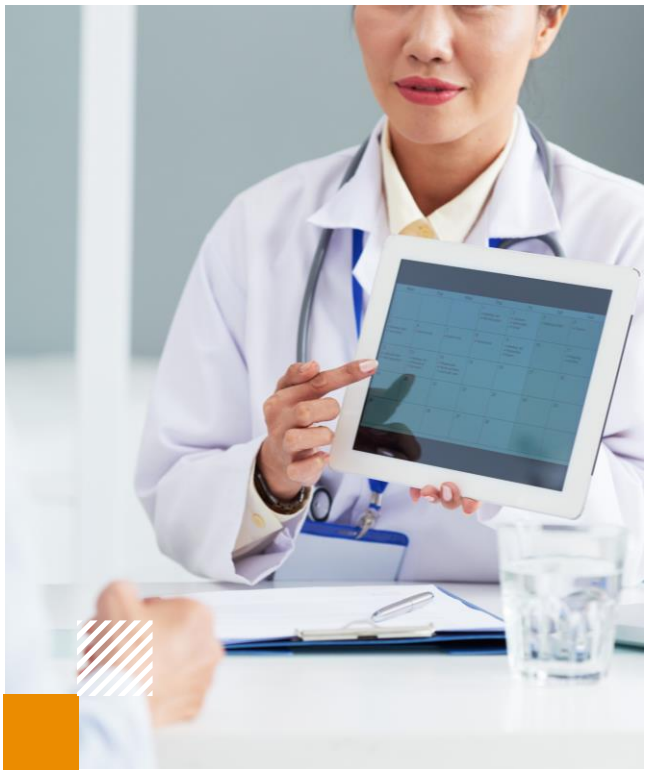
In clinical validation

- Decentralised clinical trials
  - Decentralised clinical trials are randomised control trials made patient-centric by organising trial activities around participants instead of investigator sites, increasing the convenience for participants. For example, trial activities can take place at or near participants' homes using operational approaches like telemedicine visits, directly delivering study drugs (or in this case, DTx products) to participants' homes. Decentralised clinical trials aim to increase participant engagement, retention, and recruitment, whilst decreasing barriers like the burden of travel — which may result in more diverse clinical trial samples. Accommodations need to be made to effectively engage a representative cohort of consumers.
  - For every additional 48 kilometres patients have to travel, it was found that enrolment and retention rates would decrease by 10%[15], suggesting that reducing participants' travel burden could make them more inclined to enrol, or less inclined to drop out of trials. Another pilot study suggested that decentralised clinical trials delivered 300% greater enrolment rates and higher rates of retention (89% as opposed to 69%)[16].

- Patient partner collaboration
  - The Patient-Centered Outcomes Research Institute (PCORI) in the US has established a ‘patient co-investigator’ role for their studies. These patients, often referred to as ‘non-scientists’ or ‘lived experience experts', and are not merely ‘study participants,’ they also serve as advisors, actively engaged throughout the research process from the concept stage through to implementation, by sharing their own lived experiences. This involvement helps in effectively designing new DTx solutions that are relevant and impactful.
  - A study conducted by Parry et al[17]. indicates that patients show increased engagement when provided with high-quality decision-aids. These aids enhance their comprehension of how to engage as patient-partners with clinical research, defining their priorities, and the perceived benefits vs. risks of participating in clinical trials. These decision aids serve to inform patients about clinical research, provide them with actionable opportunities to collaborate with investigators, and patients to consider their priorities, readiness (including benefits and risks), and the next steps they can take. Feedback from patients suggests that these decision aids are user-friendly, relevant and beneficial, offering knowledge and support that facilitates patient-oriented research.
  - Patients can also be involved as partners. A research study conducted by Bunka et al[18]. exemplified this practice by including two patient partners on the team responsible for modelling the standard care pathways for adult patients with major depressive disorder. These patient representatives were instrumental in challenging and verifying assumptions made by the model and were able to point out unique limitations. The study noted that the final model was stronger as a result of diversity in the modelling team, and raised new research questions based on patient partners’ lived experiences. The success of their approach in including patient partners provided the impetus for other teams to consider when modelling issues in healthcare.
  - Other key advantages of utilising patient partners include:
    - Their ability to test new DTx objectively and provide valuable feedback, ensuring new DTx is relevant and prioritised for consumers.
    - Ensuring independent and diverse perspectives are included in product development[19], evaluation and implementation, which improves access and equity to technology and healthcare.
    - Keeping DTx development companies accountable and transparent in their processes.
    - Ensuring DTx is effective for the end user and meets their needs.
    - Involving patient partners from the concept stage improves trust in new DTx, and can assist new technologies in coming to market.

In implementation

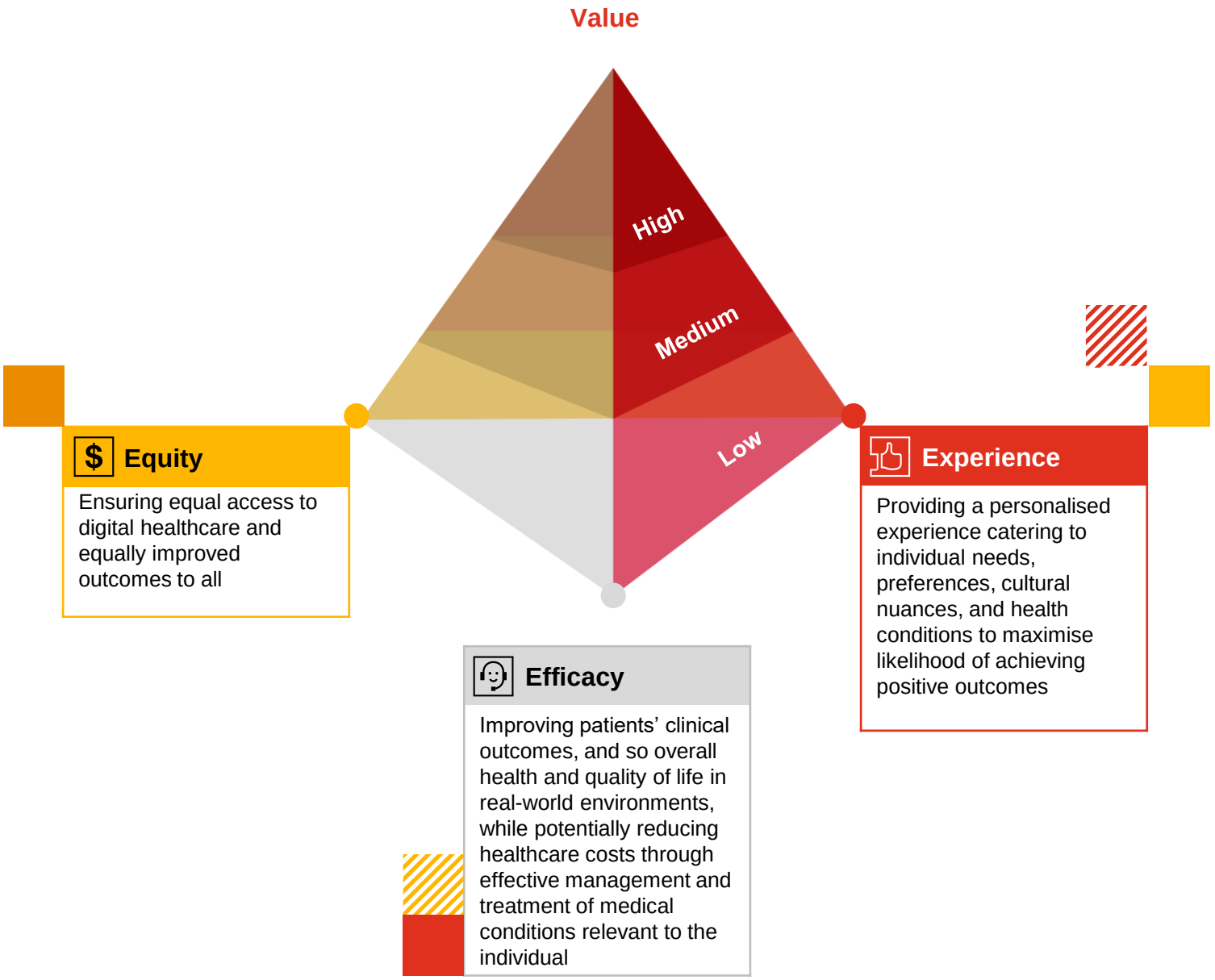
- Ensuring equal access to digital healthcare and equal outcomes
  - DTx should be designed within an equity framework, which might incorporate the considerations of several interrelated factors, such as socio-economic and cultural contexts, digital determination of health or resourcing and quality of care – to name just a few. As Hadjiat[20] (2023) highlighted, a DTx, 'can make a difference to health inequity, IF fit for purpose'.
- Ensuring accessibility and affordability of DHS
  - A patient-centric solution allows patients to access solutions comfortably and should be available for use by patients regardless of their background. Accessibility can be ensured by providing multi-language support for diverse communities, user-friendly interfaces that cater for different degrees of digital literacy, providing digital literacy programs and robust customer support. Accessibility is further enhanced through stable internet connectivity and offline functionalities. Furthermore, affordability can be ensured with cost-effective technology and insurance or welfare services coverage. These solutions can work together to ensure that patients of all backgrounds are able to interact with healthcare professionals with confidence and ease and across care pathways.



- Providing individualised support to patients
  - Welldoc, a platform that helps patients manage chronic conditions like diabetes, hypertension, heart failure and behavioural health, provides users with individualised treatment recommendations based on their activity[21]. Patients can not only access their healthcare information (e.g., weekly glucose levels), but also receive AI insights into the factors influencing their health (e.g. attributing higher glucose levels to poor medicine adherence, or dietary reasons etc.). Welldoc's AI can recognise patterns in user's behaviours and give appropriate recommendations. These trends are passed on to the patient's healthcare providers to assist in optimising care pathways.

A framework for evaluating patient-centricity in digital health solutions

Patient-centricity in health technology is about designing, developing, and implementing innovations with a primary focus on addressing patients' preferences, improving their well-being and experiences, and ensuring accessibility, affordability and ultimately, a positive impact on clinical and non-clinical outcomes. The results from our survey corroborate this definition, which provides the basis of a new and holistic definition of and framework for patient-centricity. The following patient-centric framework is designed to serve as a comprehensive tool for assessing the degree of patient-centricity, using DTx as a use case. Its primary goal is to empower DTx developers to prioritise patient-centredness throughout the design, development, and implementation phases. By leveraging this framework, developers can systematically evaluate the level of patient-centricity embedded within their innovations and utilise it as a roadmap towards achieving maximum value for the patient.



The patient-centricity framework is built around three key dimensions: Equity (Accessibility, Affordability), Experience (Education, Engagement, Empowerment, Empathy, Ease-of-use), and Efficacy (Quality and safety, Clinical trial efficacy, Effectiveness, Relevance)

How to evaluate each framework dimension for your organisation

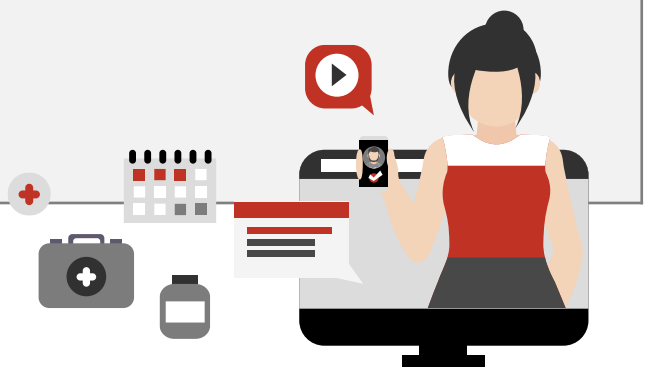
In the table below, we have taken a fictional organisation to demonstrate how the proposed patient-centric framework above can be utilised for conducting a self-assessment of your organisation and outlining a pathway towards excellence and patient-centricity. Please note that this example is not intended to be comprehensive or exhaustive in the selection of certain features, nor is it representative of any specific organisation. It is purely for illustrative purposes.

Patient-centricity (PC) framework evaluation tool

Aspects of PC (definition)	**Low** levels	**Medium** levels	**High** levels
Equity			
Accessibility The ease with which patients can physically access, and in a timely manner, the DTx.	Limited availability of the DTx across various devices, platforms, and channels restricting access not only for patients lacking specific devices, operating systems, or sufficient internet connectivity but also for patients who may lack the necessary digital health literacy to utilise such technological solutions (e.g. pilot trial with a potential commercial partner such as an insurer or employer).		Following FDA and Conformite Europeenne (CE) clearance, the DTx is now available in multiple countries, and accessible across various platforms and channels. Importantly, it ensures accessibility for all individuals, regardless of their level of digital health literacy, device preferences, or internet connectivity status.
Affordability Patients should have the economic capacity to purchase the solution, and/or it should be cost-effective for a healthcare system to justify potential reimbursements or subsidies.	In a market where individuals pay out of pocket, the cost of the DTx could be a considerable expense compared to patients' income or the available budget and resources of potential payors (e.g. more expensive than current gold standards, and/or standard of care).	Availability of (government) subsidies to lower income group users (e.g. cost neutral compared to current gold standards, and/or standard of care).	Availability of reimbursement mechanisms or complete (government) subsidy of DTx (e.g. cheaper than current gold standards and/or standard of care).

Patient-centricity framework evaluation tool (cont'd)

Aspects of PC (definition)	**Low** levels	**Medium** levels	**High** levels
Efficacy			
Quality and safety (including manufacturing) Does not cause harm to users (e.g. mechanical, electrical, and chemical safety) while ensuring data security, patient privacy, and adherence to regulatory standards.	No 'system of controls' and associated processes to provide confidence over key clinical risks in place.		A high reliability framework adopted and implemented as a precursor to any potential regulatory submissions.
Clinical trials efficacy The extent to which the DTx demonstrates clinical validity and achieves its intended health outcomes.	Expert opinions, case reports and case series.	Case control study, retrospective cohort study, prospective comparative study.	Randomised controlled trials. Beyond evaluating the DTx's performance in terms of its intended medical purpose and ensuring it does not cause adverse effects or harm to patients, post-market surveillance and monitoring of adverse events are required for maintaining clinical safety.
Real-world effectiveness Produces the desired health outcomes when implemented in real-world settings but also considers the significance of these outcomes (e.g. in weight management, a clinically significant amount of weight loss is defined as ≥5% of baseline body weight. Anything below this threshold may be considered a low level of real-world effectiveness, despite potentially high statistical significance).	DTx intervention shows effectiveness primarily in specifically defined scenarios, such as in pilot studies conducted with employers, which might lack generalisability across the wider population.	Conduct pragmatic clinical trials, which are designed to determine the effectiveness of interventions in real-world clinical settings.	Conducting an economic evaluation, which is often overlooked but critical, alongside pragmatic randomised trials is crucial for assessing the cost-effectiveness of the DTx intervention under real-world conditions.



Patient-centricity framework evaluation tool (cont'd)

Aspects of PC (definition)	**Low** levels	**Medium** levels	**High** levels
Efficacy			
Relevance Appropriateness of the DTx to patients, to address an unmet need, to the Healthcare Professionals (HCPs) to address a clinical need, but also to the health system broadly speaking and government.	Target audience research such as secondary market research on the Total Addressable Market (TAM), Serviceable Addressable Market (SAM) and Serviceable Obtainable Market (SOM), as well as of the clinical relevance and clinical benefits of the DTx intervention.		Actual user research, conducting usability studies, with a combination for example of in-depth interviews and focus group discussions. This approach aims to explore patients' interest and perspectives as well as potential challenges and concerns, in utilising DTx to support the management of their medical conditions, with the goal of enhancing overall outcomes.
Experience			
Education Process of equipping individuals with the knowledge, skills, and competencies needed to effectively navigate and utilise a DTx intervention.	DTx created with what designers presume patients would require/need.		Key considerations are given to the health literacy and digital health literacy of targeted users, identifying potential gaps and addressing them through hyper personalised, bite-sized content, interactions, and engagements.
Engagement Level of active involvement and sustained participation of individuals in using DTx to manage their health.	General engagement mechanisms that offer minimal personal interaction with the user.	Develop comprehensive personas based on previous study findings and observations, identifying key touchpoints and interactions for each patient, as well as important features to foster engagement (e.g. peer support groups and community support).	A dynamic patient engagement system uses various communication channels and touchpoints according to patient preferences and integrates these channels through omnichannel engagement.[22]

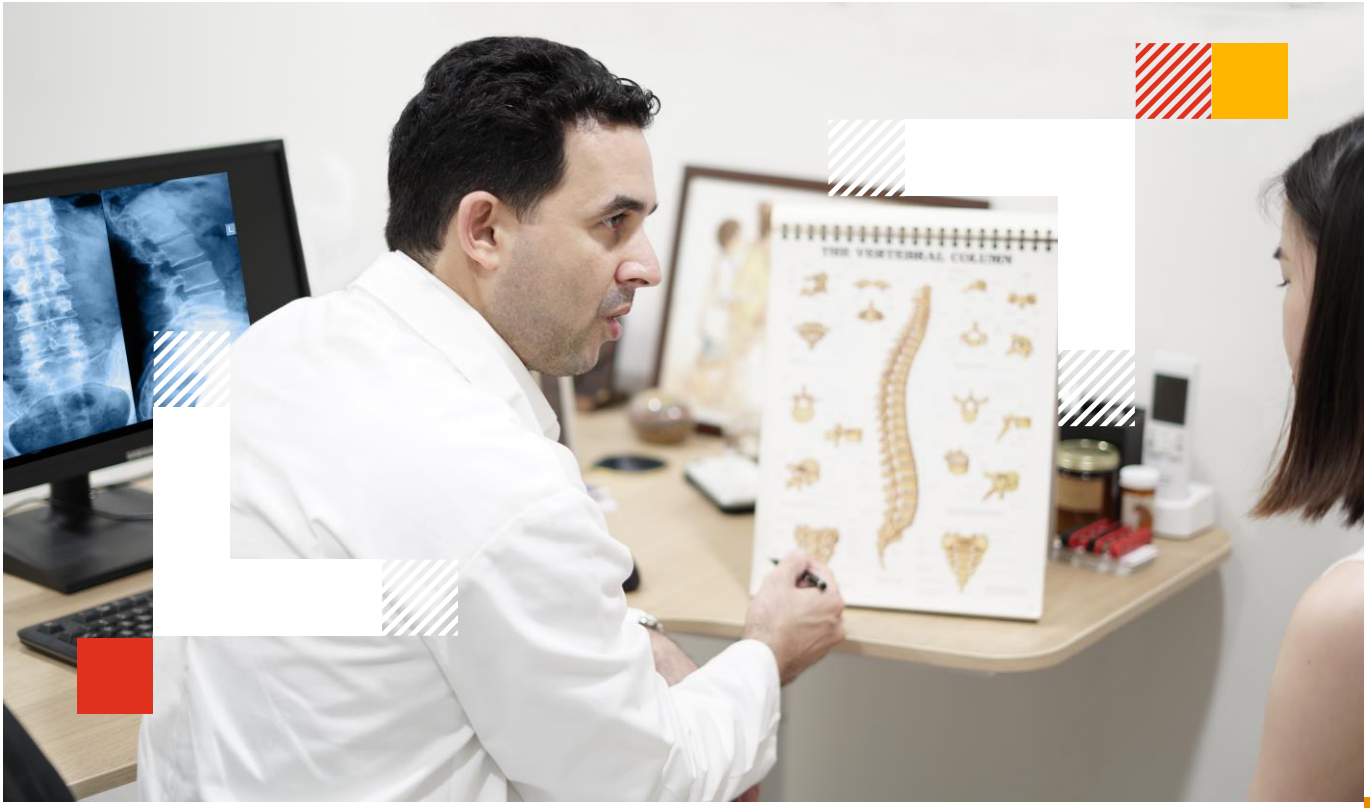
Patient-centricity framework evaluation tool (cont'd)

Aspects of PC (definition)	**Low** levels	**Medium** levels	**High** levels
Experience			
Empowerment Providing individuals with the tools, information, and resources they need to take control of their health, make informed decisions, manage their conditions effectively, and actively participate in their healthcare whilst respecting their values in how they want to receive healthcare.	Pre-determined interventions based on basic patient data (e.g. height, weight or gender), with users having minimal control and access, and/or limited ability to manage their health information or make informed decisions, often relying heavily on healthcare providers.	Users have access to essential health information and tools that support self-management and informed decision-making, such as rule-based algorithms that facilitate shared decisions (e.g. 'Would you like to fast in the morning, afternoon, or evening?').	Users have extensive control and comprehensive access to their health information and a range of tools, enabling full self-management, informed decision-making, and active participation in their healthcare (e.g. incorporating patient-reported outcome measures (PROMs), improves doctor-patient communication, promotes shared-decision making, and enables patients' quality of life concerns to be addressed). [23]
Empathy Ability to understand and address the emotional and personal experiences, needs, and concerns of users, thereby fostering a sense of trust and support.	Top-down approach with respect to information/intervention delivery.	Slight personalisation in communicating information or administering interventions to patients, targeted at a specific patient profile (but not at the individual patient level).	Use of generative artificial intelligence (GenAI) in DTx intervention to enhance empathy by providing personalised and contextually relevant interactions with users, providing compassionate and hyper personalised experiences at the individual patient level.
Ease of use How easily users can understand, and use a DTx to meet their needs without extensive training or support.	DTx involving extensive patient onboarding, including training for both patients and physicians, as well as ongoing patient support from healthcare professionals like nurses.	One-time consultation with patients to assess their requirements/needs and subsequently develop a DTx based on the collected data.	Co-created DTx with patients considering elements such as colour choice, language, convenience, and simplicity, resulting for example in user-friendly and intuitive interfaces, leading to improved DTx 'uptake'.

Recommendations for stakeholders to be enablers of patient-centricity

If you are a…	…you should consider the following:
Patient	• Learn about the potential benefits and risks associated with clinical trials, and if appropriate, join research efforts to provide detailed, valuable feedback on what aspects of a DTx are successful or unsuccessful from an end-user's perspective. • Join patient advocacy groups, patient forums or other equivalent groups and raise your concerns and perspectives when opportunities arise.
Researcher or academia	• Proactively seek advice from patient stakeholders early in the process of creating new digital health solutions, rather than asking for patient feedback retroactively. This could be done by first asking patients what pain points they experience, then co-designing a targeted digital health solution. • Actively engage patient advocates and support groups in clinical trials and other feedback channels, allowing consumers to assess whether healthcare solutions align with their lifestyle and values. Ensure these solutions are relevant, appropriate, and accessible. • Consider mixed-methods approaches, combining quantitative and qualitative approaches, which offer a comprehensive understanding of patient perspectives and help assess the generalisability of observations.
Payor	• Ensure digital health solutions reach diverse patient populations, including underserved communities, and address health disparities effectively. • Focus on solutions that emphasise outcomes that matter to patients and can be tailored to individual needs and preferences. • Move from volume-based to value-based reimbursement structures that reward solutions based on their effectiveness in improving patient outcomes.
Regulator or legislator	• Involve patients in policy development and include them in committees that evaluate and select digital health solutions for coverage. • Allow healthcare providers greater liberties to propose a research project with low-risk patient-centric DTx technologies, by reducing the bureaucratic processes or waiting times associated with obtaining regulatory approval to participate in trials. • Design specific legislative pathways for DTx technologies that have demonstrated sufficient effort to engage with patients. • Consider creating and expediting the regulatory approval and potential reimbursement of DTx through 'fast-track' processes, such as the Digital health applications (DiGA) in Germany or La prise en charge anticipée numérique (PECAN) in France.
Clinical provider, including hospital administrator	• Clinical providers should consider better understanding patients' needs and preferences based on their unique and individual circumstances. They may also wish to consider allocating allotted time to evaluating the suitability of new healthcare technologies and innovations to determine and ensure they are fit for purpose for their patients. • Consider feedback/complaints from patients, no matter how small. This will ensure a more patient-centric approach and that more DTx and other solutions are explored. • Be willing to constantly and proactively learn about promising new technologies and potentially adopt them if they are shown to significantly improve patients' treatment experiences and health outcomes. • Inculcate an environment where the opinions of all clinical stakeholders (doctors, nurses, healthcare administrative staff, C-suite etc.) are given due consideration, especially if the perspective can be used to enhance patient-centric practices.

If you are a…	…you should consider the following:
Technology provider	• Promote the cultivation of multidisciplinary skill sets within your teams. This will ensure that they have the technical expertise to develop healthcare technologies and understand how to design innovations that best meet patients' needs. • Involve patient or lived experience partners from the concept stage of new technology and iteratively throughout the technology developmental process. It is recommended that diverse patient population groups be consulted through surveys, focus groups and other consultation methods to ensure a wide range of views are represented.
Pharma, Life Sciences and MedTech	• Consider incorporating patient feedback into the research and development processes. All new technology developments and research projects have patients or people with lived experience of targeted health conditions, as members of their research or development team to ensure health outcomes are addressed. • Focus on creating intuitive, accessible interfaces that cater to diverse patient populations, including those with limited tech literacy. • Prioritise robust data protection measures and be transparent about data usage to build patient trust.
Investor	• Focus on funding healthcare technologies that have taken measurable steps toward patient-centricity, using established frameworks to evaluate their potential for maximising value to patients and their families. • Emphasise patient outcomes and engagement. Make investment decisions based on solutions that demonstrably improve patient outcomes and quality of life, while also considering key performance indicators such as user adoption rates, patient satisfaction scores, and long-term engagement. • Support evidence-based impact assessment. Allocate resources for real-world evidence studies to evaluate the actual impact of digital health solutions on patient outcomes post-launch, ensuring that investments truly deliver on their promise to improve patient care.



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