

THE POWER OF PATIENT ENGAGEMENT IN MEDTECH



How effective patient engagement provides an opportunity to drive innovation in the medical technology industry



Ongoing dialogue and engagement with patients could help to address unmet needs within many patient communities, whilst also saving MedTech organisations time, money, and resources in the long run.



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DEFINITIONS OF KEY TERMS

+ Co-creation

The collaborative development of new concepts, solutions, and products together with experts and/or stakeholders (such as patients). Co-creation is a form of collaborative innovation where ideas are shared and improved together, rather than kept to oneself.¹

+ Digital device

An electronic device that can create, generate, send, and process information, such as laptops, tablets, and smartphones.²

+ Digital health

Digital health is a broad, multidisciplinary concept that includes concepts from an intersection between technology and healthcare. Digital health includes mobile health apps, electronic health records, electronic medical records, wearable devices, and telehealth.³

+ Medical device

An instrument, apparatus, machine, or implant intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.⁴

+ MedTech

MedTech refers to every product, service, or solution using medical technology to improve people's health by preventing, diagnosing, monitoring, and treating disease.⁵

+ Patient engagement

The active, meaningful, and collaborative interaction between stakeholders across all stages of development. Where research decision-making is guided by patients' contributions as partners, recognising their specific experiences, values, and expertise.⁶

+ User testing

A technique used in the design process to evaluate a product, feature, or prototype with real users.⁷

INTRODUCTION

There is a growing awareness of the importance of patient engagement in research amongst the pharmaceutical industry, and evidence of the benefits of involving patients throughout all stages of the drug development process is increasing. But does this extend to the development of products, technologies, and devices that allow patients, families, and carers to actively support and manage their own care?

The medical technology industry—or MedTech industry as it's commonly known—is rapidly expanding, and medical devices, digital health technologies, and diagnostic solutions are now a central component of the healthcare journey. In many respects, the MedTech sector is leading the way when it comes to innovation, yet when it comes to patient engagement, there is still a need to cement patient input as a key component of the development process.⁸

Opportunity exists for the MedTech sector to draw on insights gained by the pharmaceutical industry when it comes to the best approaches for engaging patients throughout the research and development process, and utilising these learnings to enhance the development of medical devices and technologies.

This report will explore the importance of patient engagement in the development of medical devices and digital health technologies, focusing on solutions that patients interact with directly.

Drawing on experiences of companies and researchers within the MedTech sector, the report will outline some of the challenges facing the industry when it comes to patient engagement, as well as opportunities to enhance innovation. It will conclude with recommendations on how best to engage with patients in the most meaningful way for better patient outcomes.

WHY IS PATIENT ENGAGEMENT IMPORTANT FOR MEDTECH?

Nowadays, patients have more control than ever over their health. They're not just relying on care options from their doctor; they are actively choosing how they manage their health to best work with their lifestyle and to give them the best outcomes. Patients are now empowered to make decisions for themselves, and advances in MedTech have been a key enabler of this.

The ability to monitor one's own health using readily available digital health tools, such as mobile apps or wearable devices, has given patients more freedom and has increased people's knowledge of their health.

Patients are already experts through lived experience, and they now also have access to data and insights that can support them to be well-informed, active decision makers in their own care.

It would be remiss of the organisations developing medical devices, that are going to be used by patients, to not involve those very patients in the design and development process. Without the involvement of patients, they run the risk of developing devices and technologies that are not useful or relevant for the intended audience. Patient engagement is therefore a logical investment that companies should make throughout the development of a device, not only to save time, money, and resources later down the line,⁹ but also to ensure optimal solutions are created for patients.

It's important to consider patient input at all stages of development, rather than just the end-stage testing of devices. Patient engagement can be conducted in a range of ways, from an informal chat with a patient about a concept, to the day-to-day testing of a prototype. Having initial discussions with patients about different concepts can help to determine which design is most appropriate to build for that population.

As an example, in therapeutic areas like diabetes, medical devices are improving the quality of life for patients by allowing them to develop management plans tailored to their lifestyles.¹⁰ Automated tracking of blood sugar levels via continuous glucose monitoring devices gives patients immediate access to data that can be used to inform their decisions around food intake, exercise, and medication. The ability to review data over a period of time further enables patients to develop a deeper understanding of their condition. Patient engagement comes into play here, as it's important that the data presented to patients is

relevant and useful for that specific population.¹¹ Providing patients with information that does not meet their needs is not useful, and could lead to confusion or uncertainty. Furthermore, it is vital to get input from patients on the design of such devices, to ensure they are discrete and compatible with the patient's lifestyle.

There is evidence that early engagement brings value to all involved

Existing reports highlight the value that early engagement brings to the technology sector, as well as the potential risks of not involving patients in the development process. In IEEE's report 'Why software fails' they estimated 50% of rework time could have been avoided had testing been done in the early design stages.¹² Fixing errors or making software amendments is much easier and less costly during development stages, as opposed to later down the line when the device has been rolled out for large-scale user testing.

Medical device development needs patient input to determine how devices can be made as intuitive as possible for the end-users, and to help ensure the designer's vision for the product is aligned with the priorities of patients. Furthermore, if a device is not used in the 'real world' in the way it was designed to be used, this can pose safety risks — which is vital to discover early on. Testing usability in the early stages of development can also identify functions that are redundant, or that need further education or training in order to utilise them.

At worst, the lack of patient engagement can contribute to the failure of products altogether — as was the case with Exubera, an inhaled insulin. The product was positioned as a less invasive route of administration over injected insulin. However, after being approved by the United States Food and Drug Administration (FDA) in 2006, the delivery device was found to be too cumbersome for patients, meaning it was not a viable replacement for injectable insulin. In addition, concerns over the effects on pulmonary function were rising amongst physicians, leading to further apprehension about its uptake.¹³ Therefore, the pharmaceutical company behind the device, Pfizer, withdrew the drug from the market in 2007,¹⁴ costing the company \$2.8 billion. Had patients been consulted during the product development stage, the impracticalities of the device design could have been identified and steps could have been taken to modify the device to better suit patients' needs.

The benefits of patient engagement are two-fold

The following lists demonstrate some of the positive impacts for patients and industry as a result of increased patient engagement in drug development processes. Involving patients more closely in MedTech development is likely to bring the same kinds of benefits.

Patients

- + Greater potential for patients' needs to be met by healthcare providers and for products to be more relevant to them, which in turn improves outcomes
- + A sense of empowerment in making decisions to improve the health of society
- + More personalised and relevant patient interactions and products due to organisations developing a better understanding of specific patient groups
- + Improved perceptions, trust, and relationships with the healthcare industry
- + Increased awareness of the latest treatments or services available

Industry

- + Better understanding of patient needs, which leads to improved product design
- + Greater trust with patients during product development can lead to better adoption of the product in the real world
- + Patients may highlight problems with a device early on in development, which enables changes to be made earlier in the process and save the company money and resources in the long term
- + Better outcomes for the health technology assessment (HTA) process when companies can demonstrate that patients have been involved
- + Building a more trusting relationship with the FDA and other regulators, as they want to see evidence of patient engagement
- + Greater potential to avoid protocol amendments or further changes to products
- + Improved adherence and retention in patient engagement programmes

BARRIERS TO OVERCOME IN PATIENT ENGAGEMENT

At COUCH Health, we advocate for engaging with and involving patients as early as possible with our clients, particularly in the development and testing of potential new treatments and products. We know from experience that embedding patient engagement isn't easy, and our research has revealed a number of recurring challenges across the MedTech industry that are currently hindering uptake of patient engagement.

Current regulations, policies, and guidance do not offer clear direction

Guidance for engaging with patients is vital to ensure they are protected. The codes of practice outlined in policies are crucial, but are often lacking in clear direction when it comes to patient engagement. Privacy policies and GDPR regulations can be a barrier for organisations that do not have the resource to handle additional responsibilities around data collection, patient privacy, and confidentiality. For example, in small-sized MedTech companies, there may not be the means to allocate more resources in creating and managing a robust data protection framework that ensures patients' personal information is protected. Organisations could be concerned about the risks of using personal data inappropriately, which could in turn be enough to discourage organisations to involve patients altogether.

For devices, there is also uncertainty around when is the most appropriate time within the development process to involve patients, depending on the device classification.

There are stricter regulatory requirements for products classed as medical devices compared to those classed as consumer products, which not only affects the development of products, but also the claims that can be made about them during development. The implications for when and how patients should be involved, depending on the chosen pathway, are currently unclear, and more often than not, companies will err on the side of caution and choose not to involve patients at all.¹⁵

There is a need for more guidance and an opportunity for ownership in this space to hold MedTech companies accountable for conducting patient engagement activities in a safe, ethical, and meaningful way. Although guidance is limited, there are some useful resources from MedTech associations that offer guidance for MedTech organisations, such as:

- + The FDA: Patient Engagement in the Design and Conduct of Medical Device Clinical Studies
- + Medical Device Innovation Consortium: Science of Patient Input program
- + MedTech Europe: Guidance on interactions between the medical technology industry and patient organisations

Perceptions of risk discourage companies from attempting patient engagement

Feedback given by AdvaMed (the MedTech trade association) on draft FDA guidance for patient engagement suggests that the MedTech industry is nervous about working with patients. Although guidance such as the above is a welcome step, companies are still unclear on how they can involve patients whilst operating within existing regulations that are designed to protect patients against fraud, bribery, and abuse.¹⁶

In their feedback to the FDA, AdvaMed cite concerns about creating bias amongst patients, off-label promotion, and managing conflicting interests of patient advisors. These concerns need to be addressed for companies to fully understand their responsibilities in undertaking patient engagement activities.



Unless FDA clarifies the applicability of other statutory requirements... sponsors will struggle to involve patient advisors and others in the design of clinical trials.¹⁶

AdvaMed feedback on FDA draft guidance

Until these uncertainties are addressed, patient engagement may be considered too high risk, and companies will be reluctant to embrace patient engagement as part of the medical device development process. There is opportunity for the sector to work with regulatory bodies to seek clarification and develop further support and guidance.

MedTech companies are not representative of the patient populations they serve

In healthcare, we're responsible for maximising everyone's health outcomes, regardless of a patient's age, gender, ethnicity, race, sexuality, and other individual factors. However, we know that biases result in healthcare not being equitable for everyone — and the lack of workforce diversity in the MedTech sector is a contributing factor. In a 2021 survey of the world's largest MedTech companies, only 19% of the top executives were women.¹⁷ People from ethnic minority communities are also underrepresented in MedTech companies — "It's 2021 and the fact that we only have 3% of black leaders in place in medtech shows we have a long way to go [to address the diversity challenge]," comments Everett Cunningham, former CEO of GE Healthcare, US & Canada.¹⁸

Why does this matter? The result of underrepresentation at a workforce level is that systemic factors that drive health disparities are missed during development and decision making, meaning health inequities persist. Diversity is also a key driver of innovation and creativity. A workforce that better reflects the patients and communities they serve is more likely to recognise the value of involving patients in the development process.

One group, MedTech Color,¹⁹ have shared their mission to increase the representation of racial and ethnic minorities in medical device companies, and are leading the way in developing strategies and best practices across all critical aspects of the product development lifecycle. As an organisation, they aim to build a cohesive community of ethnic minority leaders in MedTech, increase the number of underrepresented executives who enter and stay in the industry, and drive thought leadership.



Lived experiences are critical to informing the development of meaningful medical technologies that address unmet needs. Thought leadership that champions the development of medical products and innovations that target the unmet needs of racial and ethnic groups can go a long way to moving us toward equitable health.²⁰

Investment in patient engagement roles is still relatively new to MedTech companies

Looking at how pharma is increasingly incorporating patient insights into the drug development cycle, it's clear that there are opportunities to do the same in the MedTech innovation loop. This will require buy-in from senior leaders and a willingness to invest resources to make engagement happen.

Although there is an overall sense of urgency around patient engagement, it appears the MedTech sector has fewer resources or capacity than their pharma industry peers.²¹ They typically have smaller teams of employees, which can make it difficult to prioritise and embrace patient input.²² This makes reaching out to diverse patient groups more challenging, and patient engagement becomes less of a priority as a result.

Organisations within the PFMD partnership²³ are working together to build and co-create patient engagement tools that aim to build companies' capabilities, to engage with patients in more meaningful and effective ways. This is a step in the right direction to improving organisations' abilities to conduct effective patient engagement.

Identifying and reaching out to the right patients can be a daunting task for companies

Some of the current reluctance to carry out patient engagement activities is in part driven by uncertainty about who to engage and how, when the appropriate time to engage is, and what is or isn't reasonable to ask patients to do. Without dedicated resources, it is also unclear who within companies these responsibilities should sit with. Finding patients to involve takes time, and managing relationships directly with patients or advocacy groups also requires expertise to carry out successfully. Patients who are invited to review prototype devices in the early stage, for example, must have their expectations managed about what their contributions might lead to, and a realistic view of the likelihood of the final product's development and approval.

The wellbeing of patients must also be considered when deciding the right time to engage. Depending on the therapy area and severity, there will be factors that could affect patients' willingness and capability to engage with companies, such as their treatment schedules, hospitalisations, or if they are undergoing late-stage treatments.

CASE STUDIES

Although MedTech companies face several challenges when it comes to patient engagement, there are real-world examples which demonstrate that the hurdles to engagement can be overcome. If carried out in the right way, patient engagement activities can have a hugely positive impact, with the potential for more efficient product development and better outcomes for patients.

COUCH Health spoke with people from three organisations with expertise in device development, clinical research, and patient engagement to learn more about opportunities for patient engagement in MedTech. The learnings from these projects can be used to guide other companies looking to work with patients more closely in the development of medical technologies.





Tristan Collins joined gaitQ as CEO in 2019. He has over 15 years' experience as an executive and entrepreneur, with a background in business strategy, early-stage technologies, and engineering. gaitQ is a medical device company based in the United Kingdom, developing a wearable smart device to improve mobility for people with Parkinson's. They are currently conducting early-stage usability testing to help inform the design of the device, which they want to be discreet and user-friendly.

Tristan provided some great examples of where patient engagement has had a direct benefit for people with Parkinson's as well as gaitQ's development programme.

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IMPROVING PRACTICALITY OF THE WEARABLE STRAP

Tristan discussed the advantages of talking to people living with Parkinson's in the early stages of device development.

"Our product designers developed a strap which attaches the gaitQ device to the wearer's leg. When speaking with people living with Parkinson's and physios who regularly interact with this community, they advised us not to use a clickable strap as they are challenging for people with Parkinson's to use."

So instead, our designers came up with a magnetic clasp to make it easier for people to take the device on and off. The community who tested the new strap provided very positive feedback and stated it was really easy to use."

Receiving patient feedback in the early stages of device development was proven to be essential, as it allowed the team to make the necessary changes easily.

REDESIGNING THE DEVICE HOLDER

Product developers don't always create the most practical product for the patient. Tristan shared an example of how patient engagement revealed a mismatch between the team's vision for the device and the needs of people with Parkinson's.

"We thought we had been really clever by designing the device holder so that you could insert the device from any side — top or bottom — we thought having this flexibility would make life easier for people using the device. However, when this concept was tested, it became clear this was not practical for people affected by Parkinson's. People were so frustrated by the product, some started to put Sellotape on the bottom of the strap as the device kept falling through.

This feedback led to a new version being developed where the device was completely encapsulated on all sides."

This is a perfect example of why patient engagement in product development is so important — getting feedback from people early on enables you to learn what does and doesn't work, so changes can be made sooner in the development process, avoiding costly changes later down the line.

PATIENT ENGAGEMENT DOESN'T HAVE TO BE COMPLICATED

Tristan discussed the importance of interacting with patients in all settings, and emphasised that engagement doesn't have to be overly complex or technical. As an example, at gaitQ they are implementing a regular coffee morning for people living with Parkinson's. In an informal setting, people can chat with like-minded individuals, as well as get involved in some product testing, where they're asked for their opinion on different ideas and concepts.

This type of informal engagement is important for not only the gaitQ team, but also the patient group, as they are able to build trust and feel that they are contributing to something important for the community.

FOLLOWING REGULATIONS CAN OFTEN BE CHALLENGING

Tristan discussed the challenges for smaller companies when it comes to navigating regulatory requirements and conducting patient engagement:

"You have to process all of the regulatory documentation that goes alongside creating a medical device, so this can be a huge burden for an early-stage company. Regulatory overhead involved in product development and understanding the nuances and the optimal approaches at any given stage of development is key to a company's success. Understanding what is and isn't okay when it comes to patient engagement can be challenging."

Regulatory guidance on how to incorporate patient engagement into the device development processes from the early stages would be beneficial, especially for small-sized companies.

gaitQ's approach demonstrates how a small-sized company can do patient engagement well, without adding too much cost or risk to the development process. The result is a product that better meets the needs of people affected by Parkinson's.



National Kidney Foundation®

David Feldman joined the National Kidney Foundation (NKF) as Medical Project Director in 2015 after a career of more than 30 years conducting pre-clinical research in cardiovascular and kidney disease in the pharmaceutical industry. David has also been involved in the development of international guidance and resources to support engagement within the pharmaceutical industry.

The NKF provides support for all people affected by kidney disease. They are the largest, most comprehensive, and longstanding patient-centric organisation dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. They enhance the lives of kidney patients and their families through action, education, and accelerating change.

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EDUCATION IS KEY

A key talking point in the interview with David was the importance of education — not only for healthcare professionals, but for patients as well:

"The company has to convince the patient that patient engagement is important. The patient has to understand how a product could benefit their life, and the lives of others with the same condition, before they would consider getting involved. And then you have to educate the company on how patient input would be beneficial when developing their product."

It's important that the benefits of getting involved in patient engagement are clearly communicated to patients, without making assumptions. Companies should make it clear why patient input is an essential part of the design process and how co-creation at the early stages will positively impact the end product.

PARTNERSHIPS WITH PATIENT ORGANISATIONS

From David's time working at the NKF, he feels that most patients are keen to get involved in patient engagement activities. He mentioned that there is an opportunity for MedTech companies to collaborate with charities and foundations, like the NKF, in order to find people to get involved in patient engagement activities.

The benefits are two-fold; the company is able to access a range of people to take part, and the foundation and patients benefit from a sense of helping to give back to the community.

It could be beneficial for start-up organisations to build up a network of people to co-create their products with, if done in the right way.

CHALLENGES WITH RECRUITING PEOPLE AT DIFFERENT STAGES OF THEIR CONDITION

Although many people are interested in getting involved in patient engagement activities, David has noticed that willingness can differ depending on how the product relates to the stage of condition an individual is at.

People who are at a late stage in their condition may not see the value in participating in patient engagement, as they may have exhausted treatment options, and may not believe there is anything that can help them.

On the other hand, people who are at an early stage of their condition, who are asymptomatic or have mild symptoms, may not see the point in getting involved if they are already managing their condition well with existing products and treatments.

This brings us back to the importance of education. Highlighting the benefits of getting patients involved at an early stage of product development can help patients feel they are contributing to something meaningful, and ensure that device development is driven by the needs of the patient community from the outset.

COMPANIES MUST PRIORITISE PATIENT ENGAGEMENT

David discussed the importance of allocating sufficient time and resource to support patient engagement activities. Although it can be a challenge for companies new to engagement to get started and commit the time, it is essential to make patient engagement a core aspect of the MedTech development process.

[Companies] should have dedicated people for patient engagement. That's the challenge for MedTech — it's making the commitment, and doing everything that is needed to meet that commitment."

For some companies, embedding patient engagement may require a change of culture. This won't happen overnight, but taking small steps towards this is key for enacting long-term change.

David's insights demonstrate the important role patient organisations play in facilitating patient engagement. Investing time and resources to build capacity for patient engagement is also key.



King's College London is an internationally renowned university delivering exceptional education and world-leading research.

Patricia Grocott, Professor of Nursing Technology Innovation; Tanya Graham, Research Fellow; and Kim Terry, Research Assistant, work at King's College London with people with vulnerable skin conditions, including Epidermolysis bullosa.

The team bring patients, carers, and families together with clinicians, academic engineers, and manufacturers to co-design medical devices that improve people's day-to-day living. In her work as a hospice nurse, Patricia saw how wound dressings were not meeting the needs of patients. This inspired her to move into academia and work with patients to co-create the solutions they actually need — not the ones that the industry thinks they need.

A number of their co-designed devices are now available on the NHS and sold internationally.

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EMPOWERMENT IS KEY

Patricia, Tanya, and Kim all highlighted the importance of empowering patients. Being involved in patient engagement activities means that patients become part-owners of the products that they are helping to create. Patients are invested in the final outcome, so it's crucial that products work for those who help to create them.

"People start to take on ownership of what's going on. It's very much an iterative process; we have to keep going back to the design team to make sure everyone is on board. It is also an empowerment process — patients are no longer the vulnerable recipients of whatever anyone wants to give them."

BALANCING SAFETY AND INNOVATION

Listening to patients is essential when it comes to developing medical devices, as they are the experts in living with their condition. However, managing expectations during patient engagement can be challenging. Any device developed must be safe, feasible, and ultimately something that can be brought to market.

The team shared details of a project they worked on, where ensuring the safety of patients and meeting patients' needs was particularly challenging.

“Different devices have different demands. For example, there is one project we did with patients who have a blistering condition of the skin, and they are very much in control of their own dressings. So, they told us they needed an alternative to bandages to hold their dressings in place, and we worked with a designer and knitwear company to develop reusable dressing retention garments.

Whereas, for the hand splint device we are working on, we need to balance the patient’s wish list with splint requirements for the complex structure of the hand. The safety of the patient absolutely has to come first. It can be a massive tension to satisfy the clinicians, who are responsible for keeping patients safe, as well as enabling patients to design devices that could be life changing for them.”

Matching requirements to achieve this with patients’ needs can be tricky, but good communication between all stakeholders helps to navigate this.

DIGITALISATION OF PATIENT ENGAGEMENT

Many industries were forced to shift from in-person to virtual-working strategies during the COVID-19 pandemic. Patient engagement was no exception. The team highlighted that patients often prefer a virtual set-up, as there are no long commutes and people can have more candid conversations when they feel relaxed in their own homes.

There is also potential to send devices out in the post to be tested from

home. This could potentially be a game-changer for start-up MedTech companies who are looking for ways to cut down the costs of patient engagement tasks, as it takes out the reimbursement of travel and the booking of room spaces. However, this does depend on the stage of development a product is at, and what type of feedback is required from the patients.

LIFE CHANGING IMPACT

The team have developed devices that have proven to be life changing for their patients. Patient engagement is at the core of ensuring devices improve quality of life.

“The conditions we work to help are very debilitating. People live in very bulky and uncomfortable bandages all through the day as their skin condition stops them from being able to touch anything. One participant who tested our novel gloves said his hands were free in the gloves and by implication, he was able to do things he was not able to do previously in bandages.”

The work done by the team at King’s College London provides a great example of the power of patient engagement, and what can be achieved when all stakeholders come together. Taking the time to understand requirements, set expectations, and provide updates along the way is key to success.

See appendix 1 for links which explore King’s College London’s patient engagement activities in more depth.

BEST PRACTICE RECOMMENDATIONS

Using advice from the experts cited in the case studies, we have developed some best practice recommendations that will enhance patient engagement in MedTech product development.

1 Invest in patient engagement as an organisation

Having someone in a dedicated patient engagement role, or a leader in the business who is driving patient engagement, opens up more resource and capacity to work with patients. It also positively affects how the company incorporates patient input with feedback from other stakeholders (e.g. clinicians, academics) and increases stages in the development process where there could be potential for patient feedback.

2 Work with patients from the early stages of development

If a product is user-tested throughout all development stages, it allows more opportunity for patients to raise any concerns they have with the product, which helps avoid costly development changes being made later down the line in development.

3 Build trust between patients and your organisation

It's important to recognise the historical and systemic factors that lead to distrust around engaging with medical research.²⁴ Having a greater awareness of the reasons behind patient mistrust allows for better engagement with patients. For example, using clear and transparent communication, as well as understanding your patient's level of health literacy, can help build trust and ultimately access to care.

4 Communicate your aims clearly and succinctly

Transparent communication will help to serve the purpose of co-creation and collaboration. Being respectful of the patient's condition, experiences, and culture is crucial. This transparency will also help to build a positive relationship with patients, by facilitating a good level of trust.

5 Be mindful of the regulatory guidance and the industry standards of working with patients, including data protection and fair market value

Though we have seen that there isn't a clear governance on patient engagement, there are principles to follow to ensure that individuals' safety, privacy, and wellbeing are maintained in any and every interaction. Whether that is related to communication or paying patients fair market value for their time. It's important to educate yourself on the guidance that does exist — reach out to the regulatory bodies directly for support so that you feel comfortable in getting started.

6 Reach out to patients where they are

Engaging with local communities and patient groups can be daunting for organisations, but it is the most effective way of reaching the relevant audiences. It's important to reach diverse groups of patients and examine the needs of the specific patient group that you are designing products for. Patient organisations and community groups are often vital contacts in this process, as they can share the message and begin those initial conversations that build trust and understanding, and also help to remove any inherent biases that are built into product development.

7 Collaborate with others to elevate the final product

When MedTech organisations bring various stakeholders together, such as patients, carers, and families, along with clinicians, academic engineers, and manufacturers, the result is a more useful product that meets the needs of patients. There is a key opportunity to partner with patient foundations and charities to optimise patient engagement within MedTech.

WHAT CAN YOU DO TO GET STARTED?

Patient engagement in your organisation doesn't have to feel overwhelming. You also don't need to do it alone — at COUCH Health, we are specialists in providing the tools and support to engage with patients at the right time in the right way.

In the meantime, here are some initial steps that you can take to help get started with your patient engagement journey.

Learn from patient engagement case studies across the pharma and MedTech sector for inspiration before getting started

There are many examples of where patient engagement has improved product and drug development. Getting inspiration from other people's work, such as the case studies from gaitQ, National Kidney Foundation, and King's College London, is a great place to start and will help you to plan your projects effectively.

Start having conversations with relevant patient organisations, local community groups, and charities and build relationships with them

Let organisations know who you are and your purpose. Often patient organisations are eager to get involved, so it's just a case of having those initial conversations to start things off. Once you're connected, there may be an opportunity to attend a regular community meeting to introduce yourself and the device you are starting to develop.

Examine the structure of your organisation and assess where patient engagement could fit into it and add value to your business

Speak to senior leaders within the business and build a case for the importance of patient engagement that can lead to a strategic plan.

Create a plan for possible touchpoints for patient engagement activities from start to finish of development

Be aware of what stages in product development you anticipate patient engagement, and to what degree. By identifying optimal touchpoints, you can factor this into your timeline and budgets and avoid any costly changes further down the line.

CONCLUSION

Patient engagement is becoming increasingly important in the design and development of medical devices. Our report has uncovered some key opportunities that MedTech organisations can utilise to involve patients in the development of devices and technologies, and ultimately create more effective outcomes.

It's clear that ongoing dialogue and engagement with patients could help to address unmet needs within many patient communities, whilst also saving MedTech organisations time, money, and resources in the long run. And although regulatory guidance can often be unclear in this field, the movement has started in the industry, and regulators are beginning to catch up. It's important to get on board with patient engagement now, as the movement continues to grow, and improve outcomes for patients and their families.

More support is becoming available for MedTech organisations in conducting patient engagement activities, and patients are keen to get involved in the process. We are seeing a shift to virtual engagement activities via online video platforms, as well as informal, low-key coffee mornings with groups in local cafes.

Patient engagement is an essential component of successful product development. Patients are experts by their lived experience, and this expertise is vital for ensuring medical technologies are high quality, fit for purpose, and meet user needs.

Incorporating patient engagement will require an investment of time and resources, but the long-term gains are sure to outweigh the short-term costs. Patient engagement isn't the future, it is the present. There is no better time to start than now.

CONTACT DETAILS

Organisations featured as case studies in this report

gaitQ:

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National Kidney Foundation:

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The King's College London team are interested in collaborating with the MedTech Industry to develop and evaluate medical devices. Please contact below if you have a product idea or patient group in mind:

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www.kcl.ac.uk/news/spotlight/creating-medical-devices-with-the-people-that-use-them

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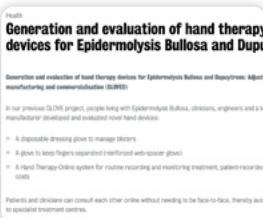
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APPENDIX



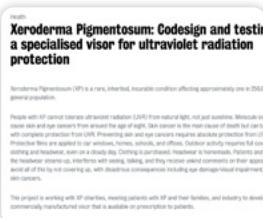
Hear from the researchers at King's College London and the patients involved in the GLOVE co-creation project to develop hand therapy devices to improve quality of life for patients:

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This article builds on the GLOVE project, and aims to advance the development of the hand splint to become more personalised for patients:

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