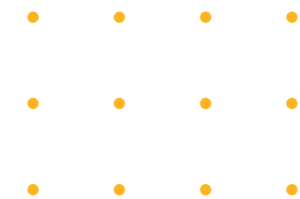




**UNLOCKING THE FUTURE
OF PATIENT PARTNERSHIPS**



OUR INTRODUCTION

Sometimes the best thing a company can do is switch the narrative. Success isn't achieved by doing things the way they've always been done. The world's most successful companies are prime examples of this. The most popular taxi service? Uber — a company with no cars. The most profitable holiday letting company? Airbnb — a company that owns no properties to let.

The narrative for patient engagement needs to switch too. Patient engagement in research and development (R&D) isn't working as it should. It's time to turn the whole process on its head.



TABLE OF CONTENTS

What is patient engagement? 4

- + Why is patient engagement important?
- + When should patient engagement be conducted?

Where does patient engagement belong in the R&D process? 7

- + How far has patient engagement come?
- + The evolution of the development process
- + A fresh take: How patient engagement could be redesigned
- + How can methods of patient engagement be integrated into the development pathway?

Defining full patient partnerships 11

- + Understanding who we're talking about in patient engagement
- + Understanding the stages of patient acceptance
- + Reaching people in the undiagnosed and dismissal stages

How the future could look 15

- + Re-structuring the clinical research day
- + Understanding the role of digital integration and education
- + Supporting patient care throughout the clinical research and beyond
- + How R&D can drive innovation in patient engagement strategies
- + How healthcare professionals can help improve diversity in clinical research

Play your part in uplifting patient engagement 22

References 23

WHAT IS PATIENT ENGAGEMENT?

Patient engagement is more than a buzzword.

Simply put, it's strategically interacting with patients to get insights into the patient experience. The patient experience could include anything, from medication side effects, to real-life impacts of disease, to the feasibility of a clinical research protocol.

We need patient engagement across all healthcare settings, particularly when designing clinical research. It's about building trustworthy and valuable relationships between pharma, biotech, MedTech, and patients and patient communities. These relationships create opportunities for equal partnerships, giving patients a voice in the product development process.

Patient engagement is the process of building the capacity of patients, families, carers, as well as healthcare providers, to facilitate and support the active involvement of patients in their own care, in order to enhance safety, quality and people-centredness of healthcare.

The World Health Organization¹

Why is patient engagement important?

Nothing about patients should be done without patients.

Sure, you could be an expert in any given research and development area. You may have studied a given disease or condition for decades, and you could know the biological mechanisms that cause the condition like the back of your hand.

But no matter how much you read, you will only ever have a baseline understanding of what it feels like to live with the disease. You will never be an expert in this area — how could you be? You have no lived experience of the condition. This is why it's so important to talk to those who do. It's vital that the patient voice has a platform to share unique and insightful perspectives, helping the industry to co-create medicines, treatments, and other forms of care that align perfectly with patient needs. On top of this, we can also use these insights to build accessible and inclusive clinical research designs.



When should patient engagement be conducted?

Simple answer: all the time.

The most optimal answer would be to conduct it continuously throughout the entire product lifecycle, but we understand this isn't always possible. You should at least try to implement patient engagement in the development process as early as possible, and certainly by phase II and III clinical studies. Ideally, you should start at the discovery stage and have an ongoing patient advisory board who consult at key milestones throughout the development process.

The possibilities for insights are truly endless.

This eBook will tell you everything you need to know about the ways patient engagement strategies can be integrated into the research and development journey.

Where you decide to implement patient engagement strategies depends on the insights you are looking to obtain.

Want to be sure that the drug or tech you're researching is going to benefit patients' lives?

Get patients involved in the discovery stage.

Want to learn how to promote equitable practices in your clinical studies, and how to make sure your studies are inclusive of all patient groups?

Talk to patients just before you design your clinical study.

Want to know how your treatment is being used in the real world?

Listen to patients' opinions and views after your product hits the market.

Want to know how to make sure your clinical studies are accessible?

Speak to patients just before you start picking study sites.

WHERE DOES PATIENT ENGAGEMENT BELONG IN THE R&D PROCESS?

How far has patient engagement come?

We can't move forward with patient engagement without looking back at how it's evolved already.

R&D pipelines have been moving in a more personalised direction for the last few decades. Medications are now developed with the aim of treating unique individuals, rather than patients as a single population. On top of this, companies are now beginning to include the patient voice in their development processes. We've seen this through an increase in patient lay summaries, transformation of patient reported outcomes (PROs) strategies, and initiatives to improve access to care — such as the newly updated legislation that mandates Medicaid must cover the costs of patient participation in clinical research in the United States.²

We are moving towards a more patient-focused version of healthcare, which is an exciting time to be involved in the industry. Patients have never been more ready to be engaged with. Not only are patients well-informed about their health and their condition, they now have a heightened awareness of the clinical research industry owing to the COVID-19 pandemic.

So, with patients in a great position to be engaged with, how can patient engagement be integrated into the R&D process?

The evolution of the development process

Integrating patient engagement into the development process isn't a new idea. In fact, extensive guidelines already exist, such as the proposed blueprint from the European Patients' Academy on Therapeutic Innovation³ showing the potential ways patient insights could be used throughout R&D.

HOW PATIENT ENGAGEMENT IS CURRENTLY BEING USED

Unfortunately, just because the guidance is there, it doesn't mean that companies use this template to its full potential. To the right are the areas where most companies use patient engagement to inform their R&D process.



A fresh take: How patient engagement could be redesigned

This is the blueprint we are proposing. We think patient engagement has a role as early as the discovery stage, where patients can advise companies on what outcomes they would like to see from a treatment.

Take a look at the opportunities for patient engagement to the right.

Determining research priorities

- Use patient and caregiver insights to identify unmet needs
- Engage with patients early to shape development

Research design and planning

- Conduct patient advisory boards and councils to shape research development

Research conduct and operations

- Engage local communities to increase diversity and inclusion
- Co-create study materials to improve recruitment and retention

Dissemination, communication, and post-approval

- Foster long-term patient and community partnerships to ensure real-world outcomes

How can methods of patient engagement be integrated into the development pathway?

There are many different ways to obtain insights from patients. However, it can be a challenge to find suitable ways of integrating all of the possible patient engagement methods to actually yield useful and actionable insights.

To help you visualise the possibilities, we've developed an example plan of how patient engagement methods could be used.



DEFINING FULL PATIENT PARTNERSHIPS

Understanding who we're talking about in patient engagement

Patient engagement has long been based on the inclusion of patients who have a prominent voice in the pharmaceutical industry through raising awareness of conditions — also known as the patient expert. But without careful consideration of other voices, patient experts can become an echo chamber — repeating the same perspectives, opinions, and insights. This isn't to say that they aren't valuable, quite the opposite. It's just that if only patient experts are listened to, the patient insights that are obtained can become skewed, biased, and restricted. There is no way that listening to the same people again and again can lead to insights that are representative of the entire patient population. So, who should we get our insights from if not patient experts?

Let's take a deeper dive into the possible avenues for patient engagement.

- 1 THE LAY PATIENT:** Patients all have their own unique thoughts and opinions to share. Getting multiple people from the patient community involved in engagement activities will enable you to explore trends across a diverse range of individuals.
- 2 CAREGIVERS:** Caregivers, including parents, can describe the knock-on impacts on a patient's ability to socialise and live, and may also be more receptive to smaller changes in symptoms than the patient themselves.
- 3 SPOUSE:** Spouses often share the patient's experiences second-hand. Spouses can share insights on patient burden, and also the burden placed upon them as a caregiver.
- 4 FRIENDS AND COLLEAGUES:** Friends and colleagues of patients can help you to understand the social impacts of a condition and how a condition may affect a patient's career, helping to build a well-rounded view of the patient experience.
- 5 CHILDREN:** If a patient is also a parent, their children can give valuable insight into the patient experience, such as how the condition affects their parent's daily activities at home, and the knock-on impact it may have on family life.

Understanding the stages of patient acceptance

There is another clear-cut flaw with our current method of patient engagement. We aren't targeting the entire patient population. Far from it, actually.

Let us explain why.

To the right is a diagram based on the Patient Health Engagement model,⁴ that shows the stages of acceptance for patients.

After receiving a diagnosis, patients may go through a process of various stages of grievances, acceptance, and action. Typically, we only target the patients in the recognition stage, disinterested stage, disengaged stage, and the activated stage. We are missing out on all of the patients in the undiagnosed and dismissal stages.

Undiagnosed stage: People in this stage are aware they may have a condition, but they are lacking a formal diagnosis from medical professionals. People in this stage can also fit into any of the stages of acceptance.

Dismissal stage:

People in this stage have a formal diagnosis, but they are dismissive of the impacts of their health condition. This group of people are unlikely to be aware of clinical research.

Recognition stage:

People in this stage have started to recognise and accept their diagnosis, and are now trying to learn to live with it. They may be unaware of the potential benefit of clinical research.

Disinterested stage:

People in this stage are aware of clinical research in their disease area, but they have concerns relating to safety, or their cultural or religious beliefs.

Disengaged stage:

People in this stage are aware that taking part in clinical research may be beneficial to them, but they are unlikely to take part due to travel, financial, or work-related burdens.

Activated stage:

People in this stage are fully aware of the benefits of clinical research, and they are prepared to take part and engage with healthcare.

Regression: Some people who take part in clinical research may drop out for various reasons. These people regress to the disengaged stage.

Reaching people in the undiagnosed and dismissal stages

The first step to reaching people in the undiagnosed or dismissal stages, is to understand why people are in these stages.

For example, it can be challenging for people with certain conditions to get a diagnosis. In the United Kingdom, waiting lists for an ADHD or autism diagnosis can be years long for adults. But this doesn't mean people in the undiagnosed stage are any less valuable as participants of clinical research. While a formal diagnosis may be mandatory for research participation, people in the undiagnosed stage could still provide in-depth insights throughout the development process through informing study design, quality of life measures, and desirable patient outcomes.

Another example could include people with cancer who must have a specific genetic mutation to take part in clinical research. While they have been diagnosed with their condition, they haven't been formally diagnosed with a specific mutation. So, studies wishing to enrol these people must include genetic testing in their screening procedure, thus providing people in the undiagnosed stage an opportunity to move up to the engaged stage. This needs to be more easily accessible and promoted as an option.

In the dismissal stages, people with conditions can be hard to reach for many intricate and complex reasons. There can be cultural barriers that prevent people from accessing the care they need.

A clear example of this would be transgender women and gay and bisexual men during the 1980s, when people with HIV and AIDS were heavily discriminated against as a result of homophobia and transphobia. Another reason people are in the dismissal stage could be from the initial shock of a diagnosis, leading to a period of denial.

People in the undiagnosed, dismissal, and disengaged stages need reliable, trustworthy, and simple educational resources to help them better understand their disease, the implications it may have on their lives, and the possibilities they have within clinical research. There are numerous ways that both biopharma and healthcare professionals can help educate patients about their conditions.

1 TAKE EDUCATION INTO THE HEALTHCARE SETTING AND DE-STIGMATISE CONDITIONS

Effective patient education must begin in the doctor's office, which must also be reflected in healthcare advertising — especially in communities at risk of experiencing stigma as a result of their condition.

2 INVEST IN SIMPLE LANGUAGE SUMMARIES OF CONDITIONS

Understanding how to convey health information succinctly and clearly is crucial for disseminating information to patient communities. To make sure your communications are inclusive, you must also consider culture and community-specific language and interpretations in your materials.

3 BE MORE OPEN TO BUILDING TRUST BETWEEN PATIENTS AND MEDICAL PROFESSIONALS

Consider how you can influence interactions so that they are more likely to result in the building of trust. One way to do this would be to speak to patient communities about their needs and how they would like to rebuild trust with the industry.

4 DO MORE THAN JUST SPONSORING ADVOCACY GROUPS BY GETTING INVOLVED IN THE DISCUSSIONS

Showing face is an important part of engaging with patients. Make sure you regularly interact with patients to get a clear understanding of their individual needs, wants, and experiences.

5 SHARE THE KNOWLEDGE GAINED FROM RESEARCH AND DEVELOPMENT IN A STRAIGHTFORWARD WAY

The interactions between patient communities and clinical research should be a two-way street. Take steps to ensure that the insights gained in R&D are shared with patient communities.

HOW THE FUTURE COULD LOOK

Re-structuring the clinical research day

We're all well-versed on the classic timetable for patients taking part in a clinical research study.

- ✓ Appointments every week.
- ✓ Numerous tests on the first day.
- ✓ Monthly check-in calls.

The list goes on. It's a wonder how we fit it all in. Except, are we really the ones who take the hit when it comes to scheduling things in?

A patient has their own life to think about. That first day where they have numerous tests to complete? They also have to fit in their meals, relaxation time, and any other life responsibilities that come calling. And what if they have children? You can add more meal planning to the mix, and the responsibility of organising childcare around appointments.

TO DO LIST

- ✓ Take the day off work
- ✓ Make sure children have their lunches and homework
- ✓ Drop off children at childcare
- ✓ Bring packed lunch
- ✓ Buy train tickets
- ✓ Walk to clinical research centre
- ✓ Attend appointment
- ✓ Have blood tests taken
- ✓ Fill out paperwork
- ✓ Reorganise any social occasions in the evening
- ✓ Pick up groceries on the way home

People within the research industry are well aware of these barriers, but we still structure study visits around what works for us as research professionals. Is this really the direction we should be going in?

Currently, a typical clinical research schedule of activities looks like a large table with many, many crosses in boxes. What if, alongside the schedule of assessments, we included a timetable of a typical patient's daily activities: populated with scheduled times for eating, sleeping, and travelling? We could say goodbye to the exhaustion by X's, and create a timetable that reflects a more realistic time schedule for patients. We could even start integrating options for research days to be conducted on weekends or in the evenings. Integrating flexibility into the time schedules for patients could go a really long way.

Ultimately, having time for downtime, sleeping, and eating are important to every single human being. So, it's even more important for those taking part in clinical research who may have low energy due to health conditions.

It's time we started viewing patients' time as valuable.



Understanding the role of digital integration and education

Digital tools and apps are all the rage these days. And this is working its way into clinical research too. Some participants will be given tablets to complete their assessments throughout the study, we routinely recruit people online using social media, and Google now plays a role in patients' research about their health conditions — think about it, how often do you google your symptoms before your go to the doctors?

However, not everyone is comfortable with using the latest technology. For example, by recruiting people for a focus group using solely digital ads, you may be missing out on vital insights from groups of people who decide not to, or struggle to use social media. In general, you need to include options that include both digital and non-digital.



A few ways you can cater for both preferences

Don't restrict yourself to just digital ads

As mentioned above, there are large groups of people who don't use social media and therefore won't be targeted by digital approaches. Successful recruitment approaches include a wide breadth of patient engagement strategies, with physical advertising in the forms of events, posters, radio ads, and more.

Be prepared to provide education prior to insight sessions

Many focus groups and insight sessions take place online now. But not everyone is well-versed in using video-calling software. Make sure you have a key person of contact that people can talk to prior to the focus group to answer any technical questions. Also, make sure this person is available during the insights sessions to solve any technical issues.

Consider how people would like to receive their information after an insight session

Typically, people who take part in insight sessions will be given a report that summarises the findings of the session, and how the insights will be used in the future. Consider if the people who took part would like this to be sent as an email attachment, or whether there are other ways they would prefer to receive updates.

Have alternative methods of collecting information

This applies to clinical research too. Try paper-based surveys that can be sent off to a physical address, or in-person interviews. There are plenty of ways to get insights without having to go through the internet.

Prioritise establishing real connections with patients

When providing information in a digital format, it can be easy to forget that your main aim isn't just to provide the right information in the right way, it's to connect with patients. Make sure that this forms the drive behind all of your patient communications, both digital and in-person.

Supporting patient care throughout clinical research and beyond

Before enrolling onto a study, patients are often provided with a wealth of support.

From medical professionals in the screening process, to patient phonelines to call for information about the study, there are plenty of people and resources to provide knowledge, understanding, and care about their condition. But when these patients sign up to take part, the support often subsides, and they are left with quick, surface-level interactions during their appointments. Not to mention when the study ends or even fails, communications with patients often grind to a swift halt.

Here are a few ways you can integrate patient support into the clinical research process:

Provide patients with resources about mental health and wellbeing

Alongside all the information given to patients during their pre-screener and enrolment onto the study, provide patients with resources to help them regulate their mental wellbeing. These resources can include blogs, articles, or handbooks to give them tips and tricks for looking after their mental health.

Have dedicated clinical research wellbeing teams on hand

Some people will prefer to talk to professionals rather than read about tips and tricks for mental wellbeing. Having someone to talk to about their worries and concerns can go a long way to providing comfort and understanding.

Create forums for patients and their families to share insights anonymously

Forums are a great way for patients to communicate their worries, needs, and also their experiences — all of which may be useful for other patients on the study. Here they can open a dialogue for communication about mental wellbeing. Consider working with local patient advocacy groups to create forums for patients and families to find and provide additional support for each other.

Outline a clear process for the end of the clinical research study

When a study ends, often patients are left with no support. Make sure to explain to patients what resources they will still have access to once the study ends. On top of this, make sure to outline what would happen if the study was to end early, providing comfort and understanding.

How R&D can drive innovation in patient engagement strategies

Changing the way new treatments are created costs money, and some companies may be wary of committing resources to methods that aren't necessarily tried and tested, especially with no guarantee of return on investment. This means innovation can often get moved to the side. However, there is a middle ground. Companies can support patient engagement innovation without investing heavily — they already have the resources they need. Many people employed in the life sciences industry are also patients themselves. Not only are they well-accustomed to typical development intricacies, but they are also experts in their own conditions too.

With both industry knowledge and personal experience of disease, these people are invaluable. We need more people with dual experience to be included in decision-making throughout organisations to help keep clinical research firmly focused on the patients' needs during every single step of the process.



How healthcare professionals can help improve diversity in clinical research

Uplifting patient engagement is one thing, but making sure that you're engaging with a diverse range of patients can be a challenge. Below are some ways that healthcare professionals can support more diverse patient engagement.

Diversify locations where research sites are based on demographic, socio-economic, and cultural diversity.

Include other community centres in research to increase the number of patients who can participate.

Provide initiatives that help improve patients' digital literacy.

Be open to innovating clinical research options that are designed around patients.

Encourage education about clinical research to be included in medical school curriculum.

Treat patient communities as equals with valuable experience.

Recruit a more diverse range of principle investigators.

Undertake cultural safety training.

PLAY YOUR PART IN UPLIFTING PATIENT ENGAGEMENT

Patient engagement can be tricky to get right. But this doesn't mean we can't try to improve the process. All in all, patients deserve to be considered experts in their condition, and their insights deserve to be highly valued and acted upon to improve the product development journey. On top of this, patients also deserve to be well-informed every step of the way.

If you would like to learn more about how patient engagement could work for your clinical research, or you want help implementing some new approaches, get in touch with us at hello@couchhealth.agency.

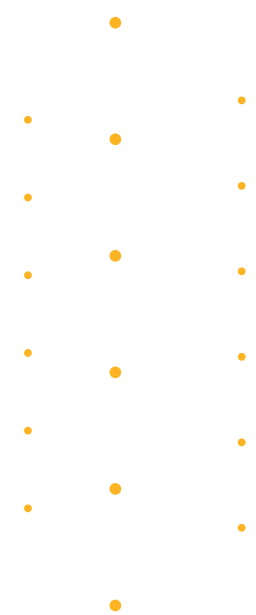
We have the expertise to help you uplift patient engagement in your research, generate more impactful insights, and build purposeful relationships with patients, helping you to create treatments that significantly improve patients' lives.



REFERENCES

1. World Health Organization. Technical series on safer primary care. 2016 [8.3.23]. Available at: <https://apps.who.int/iris/bitstream/handle/10665/252269/9789241511629-eng.pdf>
2. Samuel U. Takvorian, Carmen E. Guerra, William L. Schpero. A hidden opportunity —Medicaid’s role in supporting equitable access to clinical trials. 2021 [8.3.23]. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMp2101627>
3. EUPATI Open Classroom. Chapter 9: Patient involvement in the informed consent process. In: Trial participants: Informed consent, GCP, Patient Involvement. 2023 [8.3.23]. Available at: <https://learning.eupati.eu/mod/book/view.php?id=346&chapterid=303>
4. Guendalina Graffigna, Serena Barello, Giuseppe Riva, A. Claudio Bosio. Patient engagement: the key to redesign the exchange between the demand and supply for healthcare in the era of active ageing [internet]. IOS Press; 2014. Pages 85–95. Available from: <https://ebooks.iospress.nl/publication/37282>





COUCH Health
2nd Floor
5 Richmond Street
Manchester, M1 3HF
United Kingdom

www.couchhealth.agency



© COUCH Health, 2023. All rights reserved.