Patient Engagement

Exclusive interview with Astellas' new head of patient centricity Dr Anthony Yanni

Successful patient co-creation

Preparing for the digital journey

pharmaphorum deepdive

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Deep Dive: Patient Engagement

Even in just the last five years the growth of patient-centric pharma has been phenomenal – especially for a traditionally conservative, slow-moving industry.

Few would deny there is still a long way to go before the industry can truly claim to have mastered patient engagement, but I certainly feel like it's made the transition from being a vague hope to a tangible part of every company's business – as demonstrated by the number of success stories in this issue of Deep Dive.

First up we have an exclusive interview with Anthony Yanni, Astellas' new head of patient centricity (a role that would have been unheard of five years ago), about his vision for integrating the patient voice into the company.

Elsewhere, MS patient advocate Trishna Bharadia tells us how she worked with Merck to develop a truly patient-centred event, and we take a look at how online patient communities can be used to identify unmet need – so long as analysts remember that patients don't discuss their conditions in pharmaceutical terms!

Experts from Syneos Health run through the best ways to improve trial recruitment through patient engagement; Krystallia Pantiri from Pharmerit explains how patient involvement with HTA groups needs to evolve; and Emma Sutcliffe from Nexgen Healthcare Communications gives her views on the future of the area.

And since digital is such a key part of patient engagement, we also speak to Sandoz's digital guru Andre Heeg about his views on the area, while experts from S3 Connected Health look at how companies can improve adoption of digital health solutions.

I hope you enjoy the issue.

Kind regards,

George Underwood
Editor, Deep Dive

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Patient-partnered drug discovery: vision or reality?

pharmaphorum's Paul Tunnah talks to Anthony Yanni, newly appointed senior vice president & global head of patient centricity, Astellas, about why partnering with patients is the cornerstone for change throughout the drug development lifecycle – from early discovery through to market. Here he reveals how, in his new role, he will use this defining principle to reshape the very foundations of the organisation

What do you think when you read the words 'patient centricity'?

While few can dispute the inherent sense behind pharma shouting about patient centricity from the rooftops, this sentiment has – until now – lacked authenticity and many companies have failed to define how having a patient-first focus is either commercially beneficial or sustainable.

Now, however, enlightened companies are waking up to the reality that 'nice to have' has become 'must have' and are putting patient centricity firmly front and centre of their future vision and strategy.

"Understanding patients' hopes, values and expectations in the real world helps us contextualise our approach from a business perspective and ensures we address the entirety of the patient need beyond the medicine."

"The evolution for me began eight years ago," says Yanni. "At that time, there was minimal engagement with patients and a lack of clarity around how patients can have a positive impact in medicines discovery, research and development. Eight years on and there is robust effort regarding patient engagement."

As a recent arrival to Northbrook, Chicago, where Astellas' US headquarters and some of its global functions are located, Yanni has been tasked with leading the organisation's global patient centricity strategy following a long-held role as global head, patient insights, solutions and outcomes at Sanofi Medical in New Jersey. It was during his time there that Yanni led the creation of one of the first systems to integrate patient and clinician perspectives and deploy this knowledge in prioritising early research and development portfolios.

From an organisational perspective, Yanni notes, placing patient centricity at the heart of the business means focusing in on the patient as a valued partner throughout the drug development continuum.

But how does this ethos showcase itself day-to-day? "Patient centricity will be embedded into all core disciplines and workflow – from initial engagement, to insight gathering and R&D decision-making," says Yanni. "It means instilling these values across all functions of the organisation to acknowledge every employee's importance in helping bring new and clinically meaningful medicines to patients.

Making sense of patient centricity

- Patient advocacy, whether through advocacy groups or individuals, is all about working collaboratively to shape the environment, for example through disease awareness or policy change, to support better outcomes
- Patient experience is the focus on truly understanding every aspect of what it's like to live with a specific condition – in terms of diagnosis, treatment, medical and emotional support, information and technology
- Patient engagement is about how and where you interact directly with the patient to improve that experience, often also necessitating advocacy, either through additional interventions beyond the pill or direct input/co-creation of solutions
- Patient centricity includes them all – and all have a role to play

Where next for patient centricity? Check out Paul Tunnah's recent blogs on pharmaphorum.com here and here

"In this context, and for Astellas, patient centricity becomes our core: integrating deep understanding and insight and utilising this knowledge in the research and development of new medicines."

The next step, says Yanni, is to move from listening to action; to connect patient learnings and insight to the infrastructure changes that will transform the way medicines are developed.

Putting the patient first

Without doubt, patient centricity has become somewhat of an overused phrase in pharma. Consequently, stakeholders have become cautious and – in some quarters – downright sceptical that organisations are living and breathing the patient-first approach.

"Yet, patients and practitioners don't make treatment decisions based on science alone," Yanni observes. "They make decisions based on how the science delivers clinically meaningful benefits to them."

With this in mind, understanding the patient need, their insights, values and expectations and weaving this into both the scientific discovery process and expected real-world application of new interventions is critical. "Providing the insights and the expectations of patients and practitioners to teams from discovery, for instance, provides a valuable roadmap and supports decision-making across the spectrum," Yanni explains.

Understanding the patient journey

Like every good story, we need to start at the beginning. We need to delve into and truly understand the patient journey whether we are in discovery phase or in the real-world setting, Yanni adds. "Understanding patients' hopes, values and expectations in the real world helps us contextualise our approach from a business perspective and ensures we address the entirety of the patient need beyond the medicine.

"The common thread throughout the product lifecycle is – and has to be – the patient," he stresses, "but each stage and stakeholder is associated with a different method of engagement, understanding, integration and impact within the developmental cycle."

However, there is equal danger in connecting a larger opinion to an individual patient as in connecting an individual patient's experience to a broader group, says Yanni. In contrast, having a broader perspective using multiple modalities – whether it's individual interviews, panel interviews or Real World Data – provides robust insight over time. There should, he says, be linkage in the same way we shepherd a new drug through a process: we should be capturing, engaging and partnering along that same continuum.

Smart communication and sharing of information are also equally important. "A critical part in my view of enlightenment," Yanni observes, "is to develop best practice that allows us to explore the commonalities that exist for patients across therapeutic areas. This would allow us to better relate to our patients and utilise that information in our internal processes to avoid reinventing activities every time we engage and, indeed, replicating past failures. It is as important to learn from where things go wrong as it is from our successes."

A laser focus on outcomes

Ultimately, of course, it is outcomes where the laser focus ends for all stakeholders in the healthcare ecosystem, whether they are payer, practitioner or regulator. For industry, however, it becomes about aligning the requirements of these multiple stakeholders to ensure outcomes are translated into a meaningful benefit for patients.

"We want innovative medicines that have meaningful impact and meaningful outcomes. The question we're facing in the industry is how to best make the transition from this understanding and alignment into operational processes that are able to impact decision-making in a responsive and robust way."

But what do we mean by outcomes? And how do you bridge the gap between what is a good outcome for the patient, with what is a good outcome for a physician, or payer or pharma?

To Yanni, it takes collaboration, patience and an ability to create processes and the right vehicles to deliver on insights and inform decisions. "It's never going to be black and white; it's never going to be simple," he adds. "In fact, the more successful we are at engaging and integrating knowledge earlier on in the process, the more complex it will be."

For pharma, we need to understand what outcomes are important to patients so we can prioritise our path to success based on what patients and practitioners are telling us. Then we need to understand how we work with regulators to better align our understanding and measure outcomes in a meaningful way using mutually validated tools.

Any lack of alignment in this process, Yanni stresses, creates an obstacle for patient access to medicines.

Not all headlines and bright lights

Without doubt, the depth of the vision Yanni has for Astellas will require hard work and commitment. “It requires an openness to change and an ability to share best practices. So, when we look at impacting the work we do, infrastructure change will be key moving forward.

“In terms of patient centricity, we’re just beginning the upslope in making this knowledge and understanding actionable. That’s not exciting, but it’s necessary. In the midst of all that change – not all of it is headline – but that’s what we should be talking about moving forward.”

So, what does the future look like for patient centricity at Astellas?

First, Yanni is building a framework and infrastructure that supports engagement with patients, care partners and healthcare practitioners throughout the lifecycle strategy, whether that is discovery research or late development.

Second, this will allow it to make those critical business and organisational decisions early on to adapt and refine its approach based on what patients need and healthcare systems can support.

“Everyone agrees that engaging patients and developing sustainable relationships is essential for future success. The next step is how to integrate those insights into the drug development decision-making process in an industry that, ten years ago, didn’t involve the patient or the practitioner’s perspective. Then, internally, building on an internal culture where the patient continues to be our primary motivation. The two are inherently connected,” Yanni adds, “because if you create change before you create the message, it fails. It is critically important to deliver on what we’re promising, both internally and externally.”

So, as the hype around patient centricity subsides – and pharma’s rush to cover itself in glitter wanes – defining precisely how this ethos contributes not only to improved innovation, access to medicines and patient outcomes, but to commercial benefits for pharma, is critically important. And having this deep understanding of how carefully planned patient centricity is good for the industry, health systems and patients is key to a sustainable future.

About Astellas

Astellas Pharma US is an afiliate of Tokyo-based Astellas Pharma, a top 25 global pharmaceutical research company. Astellas is committed to turning innovative science into medical solutions that bring value and hope to patients and their families. Keeping our focus on addressing unmet medical needs and conducting our business with ethics and integrity enables us to improve the health of people throughout the Americas and around the world.

About the Author

Dr Paul Tunnah founded pharmaphorum in 2009, which is a content and communications company offering industry leading publications (www.pharmaphorum.com) and a strategic consultancy (www.pharmaphorumconnect.com). He is a recognised author, speaker and industry advisor on content marketing, communications and digital innovation, having worked with many of the world's leading pharmaceutical companies and the broader ecosystem of healthcare organisations.

Connect with Dr Tunnah at Linkedin or email paul.tunnah@pharmaphorum.com.

True pharma-patient co-creation

A recent MS patient group forum hosted by Merck KGaA demonstrates the power of true co-creation with patients.

This year saw Merck KGaA host its third patient group forum at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) congress in Sweden.

But this forum had a key difference from previous years – it was developed entirely in collaboration with multiple sclerosis (MS) patient advocate Trishna Bharadia.

Bharadia says that this affected every aspect of the forum's design, and resulted in a resounding success that Merck hopes to replicate in the future.

Family planning and MS

This year, the theme for the forum was family planning and MS.

"There's a big unmet need for more information on this topic," says Bharadia. "At the moment people aren't necessarily able to make an informed decision about whether they should have children or not. And it's not just about the person who has MS – it's also potentially about their partners as well."

There were three parts to the event. First was a panel discussion, guided by the questions from attendees and featuring a diverse group of panellists – a neurologist, a representative from the Multiple Sclerosis Association of America (MSAA), a mother who has MS, and a representative from Shift.ms, an online patient community that has produced a series of videos about family planning and MS.

The second part was a roundtable discussion, based around some of the themes and issues that were brought up by the panel.

Then there was a period of networking so that attendees had the opportunity to talk to people from all over the world who are involved in MS patient advocacy.

“One of the aims was to give the patient groups and patient advocates the space to share best practice,” says Bharadia. “For example, the neurologist’s hospital actually caters for women who are planning to have a family and who have MS. There are joint clinics run with the obstetrician-gynaecology department. That isn’t what’s happening in the vast majority of places. Most of the time, if you fall pregnant and you have MS, neurologists basically say, ‘I’ll see you in nine months or when you stop breastfeeding’.”

Bharadia says that much of this was influenced by Merck choosing to involve her as an MS patient in the development of the forum.

“I co-led on the development of the project, and that included everything from how the actual event was put together and what the components of the event were, to who was going to be best suited to be on the panel and what representations we needed.

“I also consulted on the language that was used throughout the event and in the invitations. I made a real push that we shouldn’t be using the word ‘patient’. We referred to ‘people affected by MS’ instead, because that not only encompasses the person with MS, but also the people around them.”

Bharadia also gave input for the setup of each component of the event.

“For example, I suggested that we needed to have a designated notetaker who wasn’t somebody participating in the roundtable, so that the delegates – the patient advocates and patient group representatives – weren’t worrying about also having to take notes to feedback into the post-event report.

“Often, when I’ve been to events, somebody who is actually on the roundtable is designated as the notetaker. They then end up worrying more about taking the notes than actually listening and being able to contribute to the discussion.”

The aim, she says, was to make the event “as patient-focussed as possible”.

“To be perfectly honest, the only way to do that is to have somebody who is used to going to these kinds of events, knows what kind of issues can come up, and is knowledgeable about the way in which we could get the best out of the event and the delegates involved.”

A positive change

This focus seems to have paid off – Bharadia says that the feedback they’ve received has been “overwhelmingly positive”.

“The fact that the delegates could see that I had been involved in the development of the event, and that I was a visible presence at the event itself, really set the tone for the whole event. It felt like it was an event for them. If somebody who has intimate knowledge of living with MS was there, up on stage, it wasn’t a company event that was being held for other people. It was being done with us.”

Despite pharma’s supposed enthusiasm towards patient engagement, Bharadia notes that it is still rare to see this kind of co-creation within the industry.

“If they do have adequate involvement, it tends to be towards the end of a project, where they’ve already created something and they’re just asking patient groups what they think of it.

“A lot of the time, even if you want to give them constructive criticism, part of you is wondering how much they’re actually going to change if they’re asking about something that has already been developed.

“It’s starting to change, and I’m starting to see more companies recognising the value of getting patients involved much earlier, but the industry definitely still isn’t there.”

Trishna says she would also like to see a recognition that there are different levels of patient advocates.

“There are some who are very highly skilled, and have a lot of experience in this type of thing. They understand the industry and its restrictions.

“It shouldn’t be a case of just getting any old patient who happens to have the condition. It needs to be the right type of patient, because otherwise you’re not really going to be able to progress in a less-frustrating way.

“Even with this forum, there were compliance issues that we needed to overcome. Somebody who isn’t knowledgeable about the way that compliance works would have found it very frustrating, and might not have been able to give input in the correct way.”

For example, as with all events like this the panellists at the forum were not allowed to talk about specific drugs.

“That’s probably one of the biggest issues when it comes to family planning and MS, but because of compliance we weren’t able to talk about it. Somebody who doesn’t understand the way the pharmaceutical industry works might have turned around and said, ‘Well, that’s just silly. It’s such a big issue, and we should talk about it anyway’.”

Bharadia wants pharma to know that many patients themselves are keen to be involved in these kinds of projects if companies are ready to reach out to them – although actual levels of engagement willingness will vary between patients.

“I know lots of people who wouldn’t be comfortable going up on stage and publicly talking about their own journey with family planning and MS. That’s one of the reasons why we produced a post-event report, so we can reach as many people as possible.”

Thanks to the success of the event, Merck is hoping that from now on any of their events involving patients will be developed in collaboration with an advocate.

“It shows a real commitment for a company to have done this,” says Bharadia. “It wasn’t easy; it never is when you’re doing things for the first time. You need to have buy-in from people internally. That makes it much easier to make things like this happen. And it’s really great to be able to see a company actually taking on board things that I’m saying.

“It just makes sense to have patients involved right from the very beginning. That’s what true co-creation is.”

About the Interviewee

Trishna Bharadia is a multi-award winning health advocate and patient engagement champion who lives with several conditions, including multiple sclerosis. She was diagnosed with MS in 2008, aged 28, and since then has worked to put the patient voice into every stage of the healthcare journey. She collaborates with industry, the third sector, clinicians and individuals living with chronic illness. Her work includes writing, content/literature review, consultancy, media outreach and speaker services. She regularly works across disease areas, on topics as diverse as digital health, disease awareness, patient engagement, health literacy and engagement with BAME communities.

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Learning from online patient peer support groups

Online patient communities have become a staple part of the healthcare landscape in recent years, presenting the sector with ever greater opportunities to identify, understand and tackle unmet need.

The importance of peer support across long-term conditions cannot be overestimated, and the internet has enabled groups of patients to come together like never before.

Millions of people around the world have sought solace in the ability to share their stories, learn from each other and simply talk to someone who understands what they are going through.

The value of this is well documented. Various reports have highlighted that peer support can reduce isolation, boost education and help people to manage their own health, improving overall outcomes.

Monica St Claire, product lead for insights at Inspire, an online patient forum networking platform, says: “People often turn to online and patient communities to be able to vent some of the emotions, challenges, struggles and feelings that they just don’t have a space for offline.”

This, she added is crystallised for those living with rare diseases, who often have no other way of finding people who faces the same issues as them.

“Rare-disease patients and caregivers have access to so few people, often including their healthcare providers, who really understand their situation and can offer clinical or practical advice.

“That’s not to say that you don’t see people build friendships in non-rare disease communities, but I think there is a deeper connection in rare diseases. They rely on each other a lot more.”

Valuable insights window

Through these communities, advocacy groups, industry players and policy makers alike have access to a ready-made cohort of informed and engaged patients.

"Data seems like a cold harsh word in this context, because we are talking about the lives and challenges of people living with a health condition and their caregivers," says St Claire, who leads Inspire's internal market research division. "But really it's about understanding people's experiences and their needs."

By hosting communities from across therapy areas, Inspire has the English language's largest database of patient-generated healthcare content.

The team can use this information to "connect the dots" and truly understand community members' values and concerns – the things that are "bubbling under the surface and keeping people up at night", St Claire says.

Camaraderie and cooperation

Of course, every situation is different, but the Inspire team have spotted some general commonalities across therapy areas.

"It's often driven by the community wanting to share, and a lot of the interaction is driven by questions," explains St Claire.

The requested information is often disease or treatment related, but it can also be practical advice such as signposting to products or services that can help improve daily living.

St Claire says there is a "real camaraderie and cooperative nature" on display in online patient communities, particularly in rare disease networks.

"It is present on other healthcare-patient support groups and communities, but it's so palpable when it comes to rare diseases They are much more concentrated to smaller groups, and they are trying to help each other because they know that their situation is different from pretty much everyone else. They know that they have to stick together."

On a quest for information

There is an overarching thirst for information within patient communities, whether they are hosted via platforms such as Inspire or are general social media-based groups.

It means that members are often more than happy to participate in projects and surveys that add to the knowledge base.

Inspire, for instance, has “incredible engagement” from people who want to share their stories and experiences, but that relationship must be reciprocal, St Claire believes.

“By virtue of why they have come to the site, to find and share information, they want to provide their answers and share their experiences. And if we send out a survey to our community, they want to see the result.

“We say to industry partners that if they want to come to our site, engage with and gather intelligence from our members, then we need to inform them of the outcomes.”

Despite the communities’ willingness to share, surveys and interviews are not the sole route to knowledge, and other avenues should be considered first.

Listen and learn

Social listening, or looking for patterns in what people share online, should be the first step to any patient-focused research project, according to St Claire. This part of the process, she explains, can usually answer between 60-80% of a client’s questions.

“We use that organic patient activity as a foundation before we do interviews or a survey. It saves time, because you then don’t need to ask as many questions, but you are also able to expand the scope and know how to best use the time you have with patients.

“This is our full-time job, but patients have lives and if they commit to giving us 30, 40 or 60 minutes of their time, let’s not waste it. Let’s be respectful of it.”

Speaking the same language

Investigators also need to be aware of disparities in language and lexicons – patients will rarely use staple industry phrases such as "unmet need", for example.

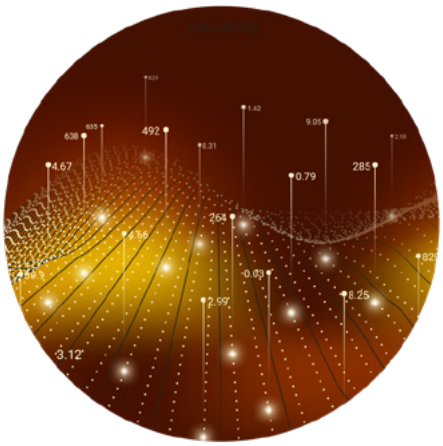
St Claire says: "Every once in a while, you get lucky and have a patient or caregiver say: 'You know what would be really great? If we had X, Y or Z'. Unfortunately, unmet needs are not always packaged like that.

"Our clients always want to know: 'What are the unmet needs? How can we do this? How can we support that?' But one of the challenges of working with unstructured, authentic patient data is they don't use words like 'unmet needs'."

Much of Inspire's insights work is about bridging the gap between these two different worlds so that clients can "speak the same language" as patients.

"To discover unmet needs, we go through a lot of data and notice patterns in the different stories and experiences that indicate a similar underlying need," says St Claire.

"The value in analysing these conversations and interactions is that it shows you what is really important to patients and caregivers."



Ensuring access

Being able to put these insights into context is paramount to being able to utilise them effectively, she went on.

"A client could do tons of research, and really have a firm understanding of what it is patients and caregivers want and need, and of how they feel and talk. They can use this to develop the most incredible and resonating patient support.

"But if you don't know where patients are in the network or on their pathway, how they engage or where they get their information from, it's an 'if a tree falls in the woods' situation. It's not only about producing that impactful, relevant support, it's about making sure people can access that."

The growing popularity of online communities is indicative of an unmet need in itself, so "digital-first" isn't necessarily the best ethos, she says.

"Sometimes, industry partners are overly focused on digital, rather than the fact that these patients are online in the first place because they struggle to access the support they need offline," she says, adding that having a great handle on patient experience was not enough by itself.

"The sweet spot is knowing where these patients are, knowing what they need, and being able to provide that in a way they can access it."

Industry's learning curve

Traditionally, industry has been cautious over the use of social media and unsupervised patient and caregiver discussion. This has been due, in part, to a fear of being associated with misinformation.

St Claire says that balancing the line between moderating content and protecting the autonomy of online communities is a concern, but that the benefits far outweigh the risks.

"Patients and caregivers are doing the best that they can, but with varying levels of health literacy, we do sometimes encounter misinformation."

Inspire's forums are overseen by moderators who remove potentially dangerous content, but we also need to give the audience the credit they deserve, she says.

"These patients have to become so sharp and thorough in trying to uncover the information that they need that they become very attuned to what are credible and non-credible sources, studies and physicians. They become more discerning when it comes to information."

Ultimately, the horse has bolted in terms of online health information, meaning the days of industry shying away from social media and online patient forums have no choice but to be over, St Claire says.

"Patients are already going online. Industry, in general, has realised that this is happening and that they need to understand it.

"I think as more people go online, the industry will become more comfortable, fluid, flexible, and efficient at engaging with them there."

Her hope, she adds, is that better use of this valuable insights window will enable the healthcare sector to create clearer paths to the high quality, relevant information that people so desperately need.

About the Author

Amanda Barrell is a health and medical education journalist, editor and copywriter. She has worked on projects for pharma, charities and agencies, and has written extensively for patients, healthcare professionals and the general public.

Boosting trial recruitment through patient engagement

Improving clinical trial recruitment has long been a priority for pharma, but despite having a plethora of new innovations at their disposal, along with a sincere commitment to patient centricity, the industry still struggles to get patients engaged with trials.

Working at Syneos Health has allowed Clare Grace, VP site and patient access, Syneos Health Clinical Solutions, and Olivia Hunt, associate director of PR, Syneos Health Commercial Solutions, to get a broad view on what makes for a successful recruitment strategy by bringing together learnings and experience from both sides of the organisation to help inform and engage the patient. We spoke to them to find out where the biggest opportunities lie.

It should be clear to pharma companies by now that there is no silver-bullet solution to trial recruitment difficulties, but Hunt says that one of the most important issues to tackle is awareness of clinical trials – which remains low among the public.

“There’s also a real misunderstanding of clinical trials in the public perception,” she adds. “Even when people do know about them, they often misunderstand what they are, what they’re for and how safe they are. They tend to base their views on sensationalised media stories, when in fact patient safety is at the forefront of the entire process.”

Even when people are aware of and understand clinical trials, pharma needs to find ways to encourage them to participate.

"That's quite challenging," Grace says. "We often hear from patients that they'd love to take part in research, but they just can't find the message. Or if they find the message, the questionnaire is so complex and so restricted that they can't actually participate.

"Don't underestimate the power of simple but effective communication. It doesn't have to be too complex, it doesn't have to be too expensive, but you need to make sure your patients really understand what you're doing and why."

There's a simple solution to these problems – asking patients themselves what would make clinical trials and related communications more accessible to them. Pharma has traditionally not fully embraced this opportunity, though.

Hunt says: "I think there's a myth out there that patient engagement methods are stale and, from a recruitment perspective, are a luxury – that if you pick the right sites you don't need patient recruitment and engagement activity on your study. But the environment is too competitive for that to be the case."

Luckily, the industry is making progress – Syneos Health has seen several companies starting to embrace early engagement.

Getting patient focus groups involved at an early stage of development can help pharma to home in on their target profile and develop endpoints that are more meaningful to patients.

"We've seen quite a few of our clients partnering more closely with patients right from the very beginning," says Hunt, "from protocol development with key advocacy groups, to making sure that all recruitment materials are clear, helpful, have the right level of detail and answer the questions people are asking.

"That really helps to educate and increase awareness amongst the patient groups' members as well. They can provide great strategic counsel all the way through the clinical trial process, from development to the recruitment stage and beyond."

Roadblocks to patient engagement

But Grace says that despite the "explosion" in patient engagement activities Syneos has been involved in, it can be hard to measure if more patients are actually getting involved in studies, as there are several other factors at play.

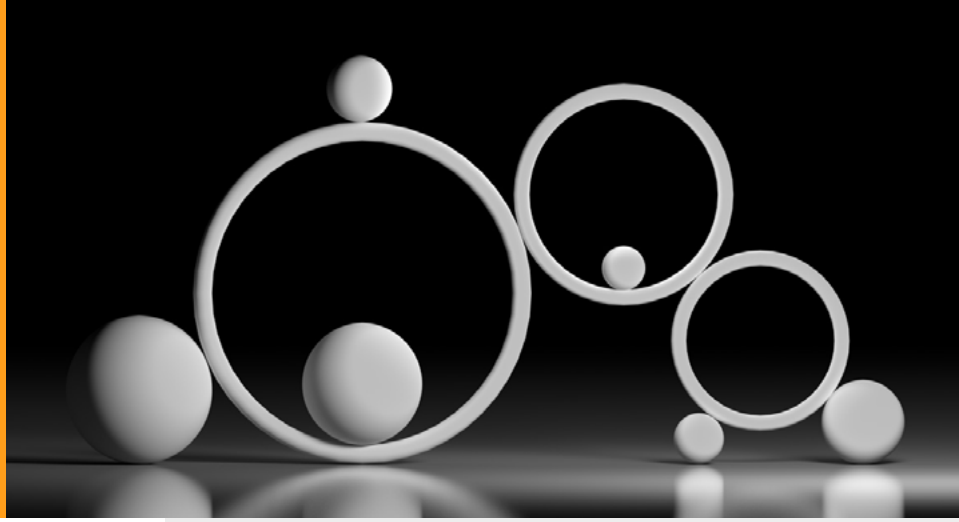
"For example, protocols are becoming a lot more restrictive," she says. "We now understand the diversity of diseases and their biomarkers, and how they affect different populations, a lot better. This means we're segmenting the patient population more than ever, and even if we get more people interested in clinical trials, we're going to be looking for a much more specific group."

Meanwhile, Hunt notes that patients themselves can sometimes find patient centricity a difficult concept to accept, as it tends to forget that the patient is a person.

"Patient centricity often focuses on the condition, which isn't necessarily wrong, but patients want to be known for more than just their illness," she says.

"Supporting them and their families is key when it comes to recruitment. There always needs to be a balance of scientific excellence and empathetic communications within clinical trials.

“That’s something pharma is still struggling with, but if we can get that balance right, that’s when patient engagement will truly improve.”



Grace says that “global consistency and local execution” is key to this.

“Even in a global trial you need to remember that different patients in different age and geographic groups require different things. For example, in a protocol with patients aged 18-65, a parent in their mid-30s is going to have totally different needs from somebody who is in their 60s and retired.

“The person in their 60s might have a more traditional relationship with their HCP and value face-to-face contact, but someone in their 30s with a child might value time flexibility, and a virtual visit over Skype might be better suited for them.

“There’s no one-size-fits-all approach for any patient population. It’s about being flexible.”

Syneos Health has gained several insights on how to adapt on a patient-by-patient basis like this by working on clinical trials in rare diseases – where populations are very small, keen to engage, and often have very specific needs.

“Something that has worked really well for us in rare diseases is patient journey mapping,” says Hunt. “This involves us looking at where patients go for information, what they’re saying, how they’re feeling, and where they go to for help.

“Other disease areas could see a benefit in doing similar exercises. It allows you to look at the unmet needs of that patient group so you can tailor how you speak to them, what kind of voice you’re using, and what channels you’re using in the messaging.

“It gives you true insight into the challenges patients face, and can ensure that you’ve got the right solutions for the right populations.”

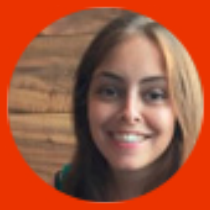
But Grace notes that rare disease populations tend to be incredibly motivated and have a very different level of engagement to that of other patients.

“That often doesn’t translate across to other disease areas. Flying patients halfway around the world, for example, is not going to work in more common indications. On the other hand, techniques like virtual visits might be more appropriate there than they would be in rare diseases.”

There’s perhaps no easy answer to the recruitment problem, but the clear common thread is the importance of keeping the patient in mind at every step, and designing every facet of a trial with your specific population in mind. At the end of the day, trials are a collaboration with people with a disease, and pharma companies won’t get very far if they don’t understand them.

As Grace points out, “If you don’t understand your patients, you can’t be patient centric.”

About the Interviewees

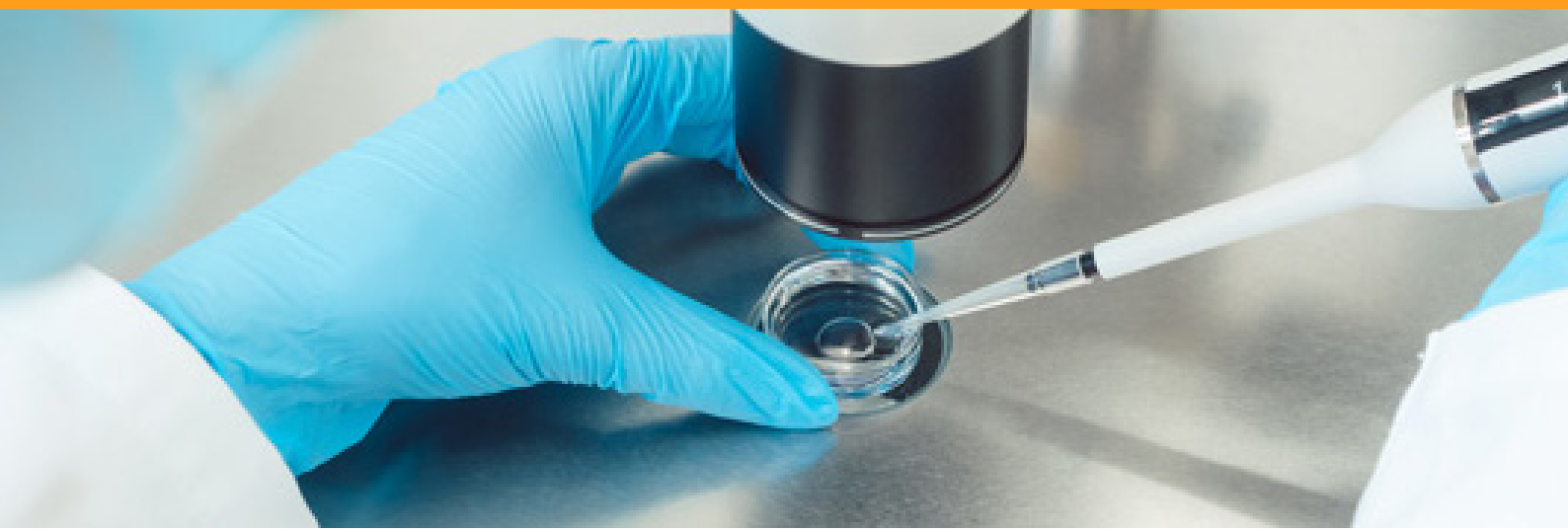


Olivia Hunt leads clinical trial recruitment and communications within Syneos Health Communications UK, ranging from early phase cell therapy to phase III Alzheimer's research. Before Syneos Health, Olivia worked within patient recruitment at Langland and the NHS. With over ten years' experience, Olivia has extensive knowledge of advertising and public relations in both the pharmaceutical and NHS sectors.

Clare Grace brings nearly two decades of strategic global leadership expertise to her role, including a unique blend of academic, pharmaceutical, biotech and CRO industry experience. She joined Syneos Health from PPD where she held several senior leadership roles, including most recently senior director and head of global site intelligence. Clare holds a PhD in Molecular Oncology from the University of Manchester Institute of Science and Technology and a bachelor's degree in applied biochemistry from Liverpool John Moores University.

About Syneos Health

Syneos Health is the only fully integrated biopharmaceutical solutions organisation. The company, including a contract research organisation (CRO) and contract commercial organisation (CCO), is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry-leading companies – INC Research and inVentiv Health – it brings together approximately 24,000 clinical and commercial minds to help its biopharmaceutical customers shorten the distance from lab to life. Learn more at syneoshealth.com



S3 Connected Health

Designing digital solutions that drive adoption

If any digital patient solution is to have an impact, adoption by its intended end users is critical. Securing adoption might sound simple, but isn't easy, and requires careful work during the design and development process, as S3 Connected Health's David Mulligan and Sinéad Ní Mhurchadha explain.

There has been a proliferation of digital patient solutions over recent years, but average user numbers and overall adoption rates are often low.

In a recent survey of more than 1,000 UK clinicians, just 36% said their patients are currently using digital products like diabetes management systems and health-tracking wearables.

However, the NHS staff themselves were overwhelmingly in favour of more use of data-driven technology, with 76% saying they thought it would lead to more accurate monitoring of symptoms and better management of conditions.

Meanwhile, patients are embracing new technology where they perceive it to offer clear value in their care, as can be seen in the general support for video consultations with doctors for minor ailments and ongoing conditions.

So, what's holding digital patient solutions back? S3 Connected Health's head of consulting David Mulligan says that a focus on user experience (UX) and user interface (UI), while necessary, has come at the expense of analysing what drives acceptance by the key stakeholders and motivates them to adopt the solution.

"It's important for life science companies to understand who the users and stakeholders of their solution are, be they HCPs, patients, payors or providers, and analyse those factors that will influence them to adopt a solution," he adds.

One of the reasons why this may not have been done to date is due to a certain amount of confusion around the term 'adoption' and what aspect of it pharmaceutical companies should focus on.

Defining adoption

There are two sides to adoption. Firstly, there's a solution's initial acceptance and uptake, and then there's sustaining its usage and patient engagement over time.

Speaking to Mulligan, it's clear that these different elements have different problems that come at different time points within development and require different analysis.

This article will define adoption as the initial acceptance and uptake of a digital patient solution, acknowledging that ongoing engagement and sustained use is a different problem which needs to be examined separately.

Planning for adoption through the design process

Looked at from this perspective, Mulligan says it's entirely possible for pharmaceutical companies to understand, analyse and successfully plan for the adoption of a new digital patient solution.

"Leveraging behavioural science and analysing a user's capability to use a digital solution, the motivations they may have to use it, and the external opportunities that can influence whether it is available to them, can lead to solutions that not only drive adoption but have an impact on care delivery and healthcare outcomes," he says.

But it would be a mistake to assume that the process of securing adoption for a digital patient solution starts at its launch; it has to be planned for throughout the design and development process.

To do this, companies need to define the health behaviour challenge they face and identify a high-level solution that could address it. From there it is essential to analyse the factors that could affect a solution's adoption, an understanding of which requires the application of behavioural science principles, says Sinéad Ní Mhurchadha, senior consultant in behavioural science at S3 Connected Health.

"The COM-B model of behaviour is often used to drive the design of a solution in terms of affecting change in a particular health behaviour. It can also be used to understand the behaviour of adoption of a solution and it can be analysed per user/stakeholder. For example, the COM-B components affecting a healthcare professional's decision to use a solution may be different to that of the patient."

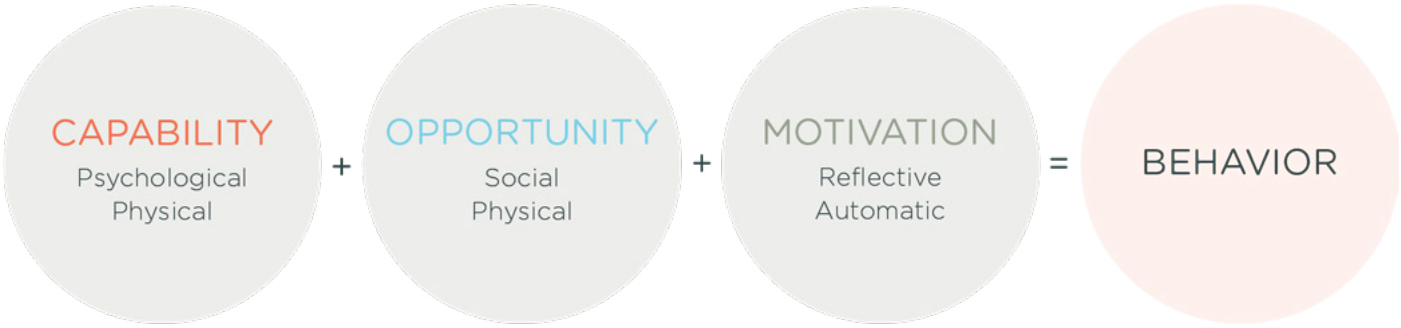
COM-B stands for Capability, Opportunity, Motivation and Behaviour. Applying the COM-B model to a healthcare professional's adoption of a solution from the outset, could identify that:

- **Capability:** The HCP needs digital literacy skills to use the solution
- **Opportunity:** The health service will not endorse the use of the solution
- **Motivation:** HCPs have considerable concerns about privacy of sensitive information

If these types of barriers are not addressed when designing and launching the solution, they can present considerable barriers to adoption of the solution.

The model can also be used to address the factors that may impact a patient's adoption of a solution; identified through patient experience mapping techniques.

"Patients must also perceive value in the solution and see that it addresses a need, and they must have the health literacy skills to adopt the solution. They may also need to consider whether they can afford it, if it's self-funded and if it's reimbursed by the healthcare system or even accessible," Ní Mhurchadha says.



Gaining adoption

Once pharmaceutical companies have solid plans in place, ensuring adoption of a digital patient solution still requires many other considerations to be taken into account, as Ni Mhurchadha explains.

"When you think of adoption, there are different drivers and barriers to face and each need to be considered in relation to all aspects of the problem, which is complicated and time-consuming – and probably the reason why it has been avoided in the past."

In addition to embedding behavioural science techniques into the overall design process, companies should also decide upon the 'core adoptable solution' they can produce. Mulligan explains this idea as "the true intrinsic piece of value that a solution will deliver to make a difference". It is the core of a solution, upon which future iterations can be built and scaled.

With those two aspects addressed, companies can look to solve further adoption problems that users and other stakeholders may experience by designing enrolment, training and ongoing support strategies.

"To do this, companies must engage with users and stakeholders early, and often, to truly understand the factors that are affecting adoption, and then follow through with the same early adopter users to test the propositions being designed and remove any barriers to adoption that are identified," Mulligan says.

Placing pharma's focus on adoption to improve patient outcomes

Digital patient solutions have often suffered in the past from a blind spot when it comes to adoption, partly because it's an undoubtedly complicated challenge to address, but also because it's easy to lean on assumptions about what drives behaviour, rather than applying academic theory to it.

To truly bring about change, pharmaceutical companies need to focus on both patients' needs and those of HCPs. Only by considering both of these perspectives can firms understand what will have an impact on the likelihood of adoption for any new digital patient solution.

It is all too easy for digital patient solutions to be designed and launched without paying due attention to the very real adoption challenges they will face. Though these are by no means insurmountable, they require pharmaceutical companies to have a clear focus on a solution's initial acceptance and uptake, addressing the different drivers and barriers they will face, and underpinning their efforts with an appropriate use of behavioural science principles.

COMING SOON

Register here for early access to the upcoming whitepaper from S3 Connected Health, 'Digital patient solutions: the secret to delivering and securing adoption', which will be released in January 2020.

Request Whitepaper

About the Interviewees

Sinéad Ní Mhurchadha a senior consultant in behavioural science at S3 Connected Health and a chartered psychologist with the British Psychological Society and the Psychological Society of Ireland. She completed a BA in psychology at University College Dublin, an MSc in health psychology at University College London and a PhD in psychology at Dublin City University.

With extensive experience in the health and pharmaceutical industry, Sinéad has successfully led the research, design and creation of many global, regional and local patient-support solutions and healthcare-professional initiatives across a range of conditions. Her work includes primary research, patient experience mapping and solution design. Sinéad is driven to support patients living with chronic illness and to make real-world, long lasting changes that benefit their lives.

David Mulligan is head of consulting at S3 Connected Health. He and his team use behavioural analysis, patient journey mapping and data-driven insights to understand the needs of patients, clinicians and providers to inform the conception, design and delivery of tailor-made digital health solutions.

With a strong background in hardware and software development, David has worked for Philips and ResMed in scientific hardware and software R&D and was previously director of consumer product development for Europe at Microsoft. In recent years his focus has moved towards improving patient outcomes through patient engagement and empowerment, leveraging the opportunities which mobile, device and cloud technologies offer. David has a passion for developing creative and innovative solutions to large challenging problems.

About S3 Connected Health

S3 Connected Health provide digital therapy management and patient engagement solutions that empower patient self-management and provide real-world evidence to support access, reimbursement and value-based care.

S3 Connected Health

Using behavioural analysis, patient journey mapping and data-driven insights, their multi-disciplinary team understands the needs of patients, clinicians and providers to create, launch and operate scalable, secure and regulatory compliant digital health solutions.

With over 17 years' experience, they have delivered award-winning solutions in over 50 countries across 20 therapy areas, including neurology, immunology, endocrinology, dermatology, respiratory, cardiology and oncology.

Shaping the patient-centric evolution of HTA in Europe

Patient engagement is one of the most important drivers for improving healthcare delivery but, as Krystallia Pantiri explains, approaches by European health technology assessment (HTA) bodies vary

Patients, their families and caregivers are increasingly being recognised as therapeutic area experts, given their day-to-day hands-on experiences with their respective conditions. Underpinned by the ever-greater availability of online medical information, patients are becoming more involved in, and engaged with, their healthcare.

Many patients have a clear desire to contribute to the drug development process. The same holds true for involvement with HTA activities, with many efforts undertaken by patient associations, advocacy groups and HTA agencies in Europe to facilitate this.

Alongside these efforts, there are opportunities for the pharmaceutical and medical device industry to help bring the patient voice into HTA discussions. Incorporating patients' insights on the value an intervention could provide in a particular therapeutic area may help improve patient benefit and fulfil the unmet need.

"The ultimate aim for pharmaceutical companies is that patients have access to treatment. Market authorisation is the first step of the process, but it doesn't ensure that the patient will be able to access a treatment. Access follows from reimbursement decisions made by HTA agencies," says Krystallia Pantiri, a research consultant at Pharmerit International, a consultancy with groups specifically focused on market access and patient-centred outcomes.

She adds: "Cooperating with patients during the HTA process and exchanging knowledge with them helps companies to focus on patients' needs."

Patient engagement in HTA

To dig deeper into how pharmaceutical companies can best engage with patients, Pharmerit recently undertook a qualitative study on the European landscape of patient engagement in HTAs.

Commissioned by the European Federation of Neurological Associations (EFNA), the project sought to explore the HTA processes in place, and these processes' impact, from the perspectives of patients and HTA members/experts.

Building on the findings from literature for the UK, Germany, and France, Pharmerit conducted a series of patient and HTA stakeholder telephone interviews from the three countries, each of which have distinct patient engagement models.

"In Europe now, countries vary greatly in the degree of patient engagement in HTA. In the three big markets (i.e. the UK, Germany and France), patients have a lot of opportunities to interact with the HTA bodies," Pantiri explains. "These interactions include drafting reports on certain evidence, or participating in the scoping process and guidance development."

In the UK, patients can attend HTA meetings held by the National Institute for Health and Care Excellence (NICE). If they disagree with the decisions taken by NICE, patients can appeal against them, but they cannot directly vote for or against those decisions.

Patients in Germany don't have voting rights for reimbursement decisions. The Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) does publish assessment reports on the Gemeinsamer Bundesausschuss (G-BA) website and requests input via a public session. However, patient associations are very rarely approached by IQWiG.

In contrast, patient voting rights are present in France and its HTA body, Haute Autorité de Santé (HAS), publishes details of its future assessment plans. However, France's seeming transparency can still present a challenge to patient associations, because the onus is put on them to check what kinds of assessments are happening and when.

When patients do not have a voice at the voting stage, they are treated unequally to the rest of the stakeholders, potentially undermining efforts for meaningful patient engagement in HTA.

Pharma's challenges in facilitating patient engagement in HTA

A common issue in the UK, French and German systems is that there is often misalignment between formal HTA process and real-world practices. Across countries, patient and expert feedback highlights four areas for improvement in meaningful patient engagement to facilitate better integration of the patient perspective in HTA decision-making: shared purpose among the stakeholders, representativeness of the stakeholders, transparency in communication and capacity and capability for engagement.

Pantiri explains: "HTA authorities expect patients to generate evidence not available from other sources, help interpret the existing data and provide feedback on data relevance rather than replicating the evidence that somebody else has produced. Patient associations, on the other hand, want to impact the decisions and to make sure that their perspectives are heard. So patients' focus is on being able to attend assessment meetings, vote on their decisions and be seen as equal to the rest of the stakeholders."

In addition to a lack of shared purpose, there can also be an issue if the patients present in assessment meetings are not wholly representative of individuals with the specific disease being discussed. When this occurs, an opportunity is missed to understand the comprehensive experience of the condition.

HTA processes themselves can hinder patient engagement, perhaps through a lack of transparency in communication and documentation. For instance, NICE provides very detailed formal procedures and guidance for people who want to get involved and provide input to its assessments but without feedback to the patients on how their input is subsequently used.

Pantiri says: "They welcome the input but there is no mechanism to check if it was taken into account in any part of the process. Even if the input wasn't useful, if NICE doesn't give feedback to the patient associations that took the effort to get involved, they won't know where they need to improve.

"It's really important for patients to understand what is expected from them so that they can provide more relevant evidence and actually impact decisions."

From a pharmaceutical perspective, companies need to be aware that patients often lack the skills or resources to navigate HTA processes and contribute effectively. "Many also face problems of sustainability – their volunteers engage in HTA without financial support and it takes time away from their home life, work or family engagement," Pantiri notes.

To some extent, the solution to these problems is a financial one. "Without funding, patients are left with few opportunities to mobilise resources and organise information in a way that will reach the level of the rest of the stakeholders. In the end, the better the quality of information, the more likely it is that their evidence will be taken into account," Pantiri says.

These challenges are then accentuated by Europe's scattered HTA landscape, which requires pharmaceutical companies to tailor their approaches to patient engagement in HTA on a country-by-country basis.

Maximising patient engagement in HTA

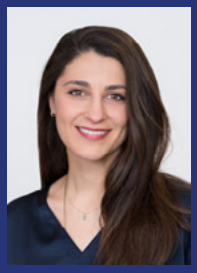
Pharmaceutical companies can help maximise the effectiveness of their future patient engagement efforts within HTA in Europe. Starting with engaging patient associations earlier in the process – i.e. phase III trial design at the latest – can ensure that the endpoints captured in a clinical trial are relevant to the patients and reflect the comprehensive experiences of the condition.

"It is important to share knowledge and agree on quality standards in order to support the implementation of engagement practices and then to allocate resources to sustain change over time," Pantiri recommends.

There are many different ways that pharmaceutical companies can involve patients at different phases of a product's development, such as consultation interviews on the design of clinical trials, entry and exit interviews in trials, concept elicitation interviews to understand a patient's journey with the disease and treatment, and cognitive interviews to evaluate and refine outcomes measurement tools based on patient input. The key thing here, Pantiri says, is to ensure that activities are relevant and meaningful to patients.

She concludes: "It's very important that you have conversations with the patients to see if your outcomes are indeed aligned with patients' actual experiences."

About the Interviewee



Krystallia Pantiri is a research consultant in strategic market access and patient-centered outcomes, located in Pharmerit's Rotterdam office, in the Netherlands. Her all-round experience includes (systematic) literature reviews to inform network meta-analyses, global value dossiers and HTA/reimbursement dossiers, patient/stakeholder engagement, preference studies and qualitative patient reported outcomes (PRO) research. Disease areas she has worked in include vaccines, inflammatory disease, respiratory diseases, oncology, hematology, neurological disorders and orphan diseases.

About Pharmerit International

Pharmerit International is a global, premier health economics and outcomes research (HEOR) consultancy with 20 years of experience supporting pharmaceutical, biotechnology, and medical device organisations in health economics and outcomes research (HEOR) and market access worldwide. Pharmerit delivers quality research across four multi-disciplinary Centres of Excellence, Modelling & Meta-Analysis, Patient-Centred Outcomes, Real-World Evidence, and Strategic Market Access. Pharmerit recently announced that it will be merging with the OPEN Health Group. The combined entity will have approximately 700 people, 15 offices, and representation across three continents. The consolidation of publications, medical communications, HEOR, RWE, and market access creates a unique entity equipped to be a leading global HEOR and Medical Affairs Consultancy.

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SANDOZ A Novartis Division

Preparing for the digital journey

Fresh off his appearance at this year's Frontiers Health conference, we sat down with Sandoz's head of digital Andre Heeg to get his views on where digital pharma is heading and how companies can make sure they always keep the patient in mind during this transformation

Are there any particular areas of pharma that you think are lacking in digital adoption? Why might it be important to harness digital in these areas?

We are definitely in the middle of a pharma digital revolution. While we are not ready to claim victory – YET – digital is already making our business way smarter and more focused than we've ever been previously.

There are five areas where digital can and is making a significant impact. These are:

1. Predictive forecasting and planning
2. Waste out – automation and simplification
3. Data visualisation and insights
4. Digitised marketing and selling
5. Culture change and training

We are collecting reams of data every day. Visualising and transforming the data into usable information – that makes a difference for how quickly patients get their medicines and at what cost. For our over-burdened healthcare systems every minute counts.

As a generics company Sandoz obviously has a focus on getting patients access to medicines – how do you think digital can help you facilitate that?

We are looking across our business and applying a digital mindset across every part of the value chain including how we innovate, operate, create medicines, and sell. It is not just about collecting data, but about taking that data and turning it into usable information that helps us get smarter, faster – taking waste out of the system and speeding up how quickly we are able to get medicines to customers, and from customers to patients.

Is it safe to say that pharma is still behind the times in terms of digital adoption compared to other sectors? Or have things improved in recent years?

With great examples coming from other industries – for example Amazon, Berkshire Hathaway and JPMorgan Chase creating Haven Healthcare to provide better healthcare management to their employees – it can seem like traditional healthcare companies are lagging behind in terms of digitalisation.

Let me reassure you though, healthcare data and digital transformation is really a thing.

Data is collected on a daily basis, giving insights on everything from markets, patients, and our own processes to pipeline – both the molecules we are developing and the products we want to put on the market. And across Novartis, we continue to integrate artificial intelligence, predictive decision-making, analytics and automation to improve internal processes and make them as efficient, and cutting-edge as possible.

Do you envision pharma being overtaken by big digital companies like Amazon/Google in the healthcare sector if they don't embrace change? If so, is there anything they can do to avoid this?

We are a learning versus knowing culture. It is important to look at Amazon and Google and drool a bit to see how they have harnessed data in an incredibly powerful way.

Great examples across all industries help to fuel our own desire to do better. We are exploring partnerships with younger companies or start-ups, academia, and think tanks in order to get exposure to new ideas and learn. Last year, we entered a partnership with UnternehmerTUM and their applied AI team, which is a think tank associated with the Technical University of Munich. The partnership was about advancing our thinking and working on applying artificial intelligence to solve business challenges. Most recently, we also hacked five of our employee-voted business challenges during the weekend of November 8-10 with leading minds in digital along with our Sandoz employees. Agile teams developed prototypes and most importantly we learnt and flexed our ability to solve big problems quickly and efficiently.

We are looking to join forces with pioneers in this field in order to digitise everything from how we innovate, operate, create medicines, and sell.

Are there any digital pitfalls pharma companies can easily fall into? How do you avoid them?

Before joining Sandoz, I asked myself a lot of really important questions. Things like: Is the company ready for this type of digital change? What are the expectations of the digital agenda? How do you get stuff done in such a big company? Will I be held up in too many unnecessary or cumbersome processes? I was particularly worried about that last question.

After joining, I learned that sometimes within a large matrixed company, you do get held up by the size of the beast. But, what makes the difference for me is the sheer number of really high quality people who I get to work with every day. It is incredible. They taught me how to navigate, ways to get things done working within the system, how to collaborate, and join forces. That is something I already take away now as a big win.

Do you think there will come a point when pharma stops referring to 'digital' as a separate entity and has it naturally embedded in every part of the business? How close are we to that?

I have set a personal challenge to get Sandoz – and the industry – to a place where we no longer need a digital function, because digital is so fundamental to everything we do that everybody just does it.

We have to break out of dated ways of thinking and organising ourselves, and start doing things in a totally new, "connected" way. This digital mindset has to drive everything from how we innovate, operate, create medicines, and sell.

And that includes our attitudes to partnering and collaboration, because the "we-know-best" approach to innovation just won't cut it in the new convergent world. We are moving more toward a space where our traditional capabilities need to complement others' high-tech know-how, and vice versa.

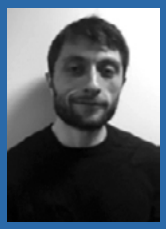
What's an unexpected or little-known aspect of digital healthcare you're interested in seeing develop?

There is a lot of **start-up DNA** within Sandoz. It would be interesting to apply this pioneering mindset to data responsibility. With data comes a lot of opportunity but also a very big responsibility. We all know that there is a lot of value in mining data and making smart algorithms to drive decisions. On the other hand, you have the need and the requirement for data privacy – no one wants their data to be exposed. It is not 100% clear how this will play out. What we know for certain is that we will have to work with regulators and all involved parties. But what is very clear is that we have to keep patients' interests in mind in order not to compromise any aspects of their privacy.

About the Interviewee

Andre is an experienced start-up executive, business and sales manager, leader, and strategist. He is an expert in inside and field sales management, pharmaceutical and medical products marketing and sales, commercial strategy planning, and healthcare topics. Andre joined Sandoz in June 2018 from his role as CSO at Thermondo GmbH, an integrated energy company.

About the Author



George Underwood is a senior member of the pharmaphorum editorial team, having previously worked at PharmaTimes and prior to this at Pharmafocus. He is a trained journalist, with a degree from Bournemouth University and current specialisms that include R&D, digital and M&A.

About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercialising novel, affordable approaches that address unmet medical need. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2018 sales of $9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

SANDOZ A Novartis Division

Digital therapeutics grow up

Back in January, pharmaphorum caught up with the Syneos Health team to discuss their experience and insights into the emerging category of digital therapeutics (DTx), and the use of software-based services to deliver preventative, management, or treatment interventions to patients either as a monotherapy or as an adjunct to a pharmacological treatment.

While a number of key challenges were identified, not least from a pharma perspective, the challenges of traditionally slow-moving product development processes needing to adjust to the swifter more agile world of rapid software development and distribution, and their perspective on this aspect of pharma's future was largely positive.

Much of this positivity was driven by the apparent early successes of some well-known DTx poster-children, best personified by Pear Therapeutics reSET for treating opioid use disorder.

Not only did Pear's solution provide a uniquely modern approach to a uniquely modern epidemic, but its 12-week programme of digitally delivered cognitive behavioural therapy shot through FDA approval supported by robust claims of improving clinical outcomes. As a result, the company inked a highly publicised headline deal with Novartis' Sandoz to partner on commercialisation and development, with reSET intended to work hand-in-hand with therapy on buprenorphine.

Now, however, that co-promotion deal has come to an end, inevitably placing the topic of pharma's role in the DTx market – particularly in the shortterm – back into the spotlight.

Duncan Arbour, SVP innovation at Syneos Health is sanguine about what could easily be seen as a reversal of expectations for the sector. "I think our point a year ago was very much that forward-looking pharma companies, those already committed to a digital future, no longer had their heads in the sand around the potential of DTx – and the Sandoz deal was a key marker of this.

"But what we're seeing now isn't those heads going back into the sand – it's more a case of those heads looking around a little wide-eyed and dazzled, not yet able to see a clear short-term horizon for a new and potentially challenging treatment class."

In many ways, the horizon Arbour describes is obscured by something of a perfect storm. Firstly, there's the wider context of social, political and economic uncertainty around the future of industry-wide pricing, reimbursement and access in general (clouds that will remain at least until we're well over the other side of Brexit and a 2020 US election). And for DTx specifically there's also the recognition that despite some early successes for the category, widespread adoption for any one treatment in the category is still far from being achieved.

Syneos Health asset strategist Skye Hodson is quick to frame this current situation: "Yes, the DTx market is clearly still at a fragmented, subscale experimentation phase, but that's not the same as being unhealthy."

Rather, to Hodson it's just a well-known station on the track of mainstreaming any new technology: "You can see parallels with any new technology, it's like the William Gibson quote: 'The future is already here, it's just unevenly distributed.'"

And in the bigger picture, this change in direction for Pear and Sandoz doesn't signify any real changes for the wider DTx opportunity. It's still an area tipped to reach a value of more than $7.8bn by 2025 with a compound annual growth rate of 20.5%. Neither has this divorce appeared to throw Pear off course. The company is still moving forwards with new partnerships and ventures that will see it expand its offer beyond the DTx heartland of CNS into areas such as inflammatory and gastrointestinal conditions.

But what might the cold feet on the Sandoz side of things mean for pharma's DTx approach going forwards?

For Syneos Health's EU head of digital Alex Brock, this bump in the road reflects a familiar problem that the industry has been grappling with for years as it tries to understand that 'digital' is a mindset as much as it is a series of technologies.

"It's a cliché, I know, but there's an epic gulf between the old Silicon Valley mantra of 'move fast and break things', and the conventional but entirely appropriate healthcare approach of 'move slowly and take care'. But if you're wholehearted about being focused on your patients then you have to be equally wholehearted in recognising and responding to the inevitability of a patient preference for interventions that can be delivered through their personal digital devices. In terms of healthcare technology, you could argue that daily insulin syringes are more likely to go away than smartphones in the next 20 years."

While this doesn't necessarily suggest that medicines manufacturers should be looking to enter into DTx co-promoted partnerships in the Pear/Sandoz mould just as this original template comes to an end, Brock is however clear on the need for industry not to lose its focus on continuing to hire the right digital talent to support these initiatives in the future.

"It's great that we've seen senior leaders come into the industry from non-healthcare leaders like Sainsbury's and Walmart, but these companies also need to make sure that they're making similar hires for roles that are more operational and on the ground. A strategic partnership to set a vision is one thing – but delivering practically on its promise is another, and it requires a whole new set of smarts."

If anything, what the end of the Pear/Sandoz partnership highlights is a tension between the models of small DTx start-ups and big pharma's incumbents. The former are looking to pharma for funding and partnerships as the fastest possible route to scale via access to marketing and sales support; but traditional players will always be preoccupied with protection of core business and investor returns, to which it's hard to see DTx as a significant contributor in the immediate future.

Nevertheless, the Syneos Health team sees the last 12 months as a period of significant progress for the sector.

Hodson is quick to point to a raft of developments in the US that may point to a new and necessary paradigm for reimbursement – a critical roadblock to committed investment thus far.

"So far, even some digital therapeutics which have had regulatory approval for a while have still struggled for reimbursement outside of trials. But now we're seeing things like a digital formulary from Express Scripts, and an announcement from the pharmacy benefit manager (PBM) at Caremark of a platform for validating digital health apps so that payers can more easily review and select effective solutions for their plans. And for solutions that incorporate remote monitoring, there has finally been the introduction of CMS codes allowing physicians to code their time."

Europe is following suit, notes Alex Brock. "People often think of Europe, particularly outside the UK, as lagging behind the US. But France and Germany were trailblazers in this area, with Servier's roll out of the Deprexis programme on prescription for depression before people were even using the term 'DTx'.

"People talk about our health minister Matt Hancock as a digital evangelist, but our German team are always reminding me that his equivalent over there, Jens Spahn, is equally progressive. There's draft legislation out there right now which could see the establishment of a new registry of digital health solutions, even allowing ones which get approved to gain market access and reimbursement without full supporting evidence, as long as they can generate it within the next twelve months."

France, notes Brock, has similarly introduced its own MyHealth 2022 bill which also includes ePrescriptions and guidance on certification and prescribing of digital health apps.

So it has been an eventful year for an emerging sector, but what can we expect in 2020? Arbour believes it may be the year that we actually see the impact of patient wants and needs shaping the market. "You don't hear a lot about patients and patient experience in the current DTx conversation, but it's their adoption – or not – of new healthcare tools that will see the sector stand or fall. I don't believe in the line that 'patients are just like consumers in other sectors', but I do believe that one place in which they always have consumer-level expectations is with the experiences they have on their smartphones. And what consumers need from DTx more than a route to prescription and reimbursement is a brand they can trust that delivers an exceptional experience.

"I wouldn't be at all surprised if we saw a successful global smartphone health super brand like Headspace or Calm – both big names in mindfulness – move explicitly into the DTx space in the near future and replace newer start-ups with no brand recognition as the focus of pharma partnership activity across a host of therapy areas where co-morbidities include anxiety, stress or even physical pain."

While there remains a fair amount of uncertainty in the DTx space, history demonstrates that the industry's cautious embrace of digital possibilities is very much business as usual. This is something to be very much expected of any technology that has such transformative potential for patients and the healthcare sector and shouldn't be a cause for pessimism. The industry and the public's appetite for DTx is clear, and the organisations that make a concerted effort to understand, embrace and evangelise for it stand to make a huge impact on patients' lives.

About Syneos Health

Syneos Health is the only fully integrated biopharmaceutical solutions organisation. The company, including a contract research organisation (CRO) and contract commercial organisation (CCO), is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry-leading companies – INC Research and inVentiv Health – it brings together approximately 24,000 clinical and commercial minds to help its biopharmaceutical customers shorten the distance from lab to life. Learn more at syneoshealth.com

About the Authors

Skye Hodson, a Syneos One asset strategy director at Syneos Health, has seven years of multi-sector experience that has seen him not only shape strategies but also ensure their successful implementation. He specialises in supporting the commercialisation of new and disruptive innovation, working across healthcare systems and the lifecycle of assets, with a particular focus on digital strategies and digital therapeutics.

Alex Brock leads digital for communications across Syneos Health Europe, and runs the central digital team based in our London HQ.

He has worked at Syneos Health for the past seven years, overseeing the evolution of digital insight, strategy and optimisation across the business. Prior to this he has worked in various insight and digital strategy roles in healthcare and consumer sections over the past 14 years.

Duncan Arbour works in the Innovation team within Syneos Health Communications. He has been with Syneos Health for the last seven years and has had an exclusive focus on life sciences for the last 12. Prior to healthcare, Duncan spent a decade in senior strategy roles for some of Europe's leading digital agencies including DigitasLBi and Syzygy, leading projects for clients in sectors including financial services, automotive and government.

Engaging the empowered patient

Success requires addressing behaviour from the individual's perspective, as well as a socio-cultural and environmental context, says Andy Stankus, Kantar's general manager, Health Division

To improve the value of healthcare solutions, we must better understand the empowered person living with a condition and how that person proactively manages that condition in their daily life. What's more, in today's evolving healthcare world, it's all about health outcomes. The shift from products to outcomes is being driven by a variety of factors, including globalisation, demographic changes, healthcare reforms, health IT advances, and an insatiable appetite for value-centricity.

In our research, we've found that it's best to address behaviour from the perspective of not only the individual, but also from a socio-cultural and environmental context. The result is unique insights and a complete picture of the person that fosters significant advances for improving real-world outcomes.

The many faces of healthcare consumers

There is a pressing need in healthcare for greater insight into the many faces of today's diverse healthcare consumers. That means we must develop and leverage strategies to gain a deep understanding of the healthcare ecosystem and the healthcare consumer as a complete person.

These strategies must incorporate three factors:

Experience – First, start by always listening to the voice of the healthcare consumer, as this is the best source for gathering an individual's experience regarding their condition or overall wellness. Primary research is a great way to collect the details of their thoughts and emotions in a stated and derived way. Additionally, qualitative interviews, quantitative surveys, social media listening and other patient information sources provide rich opportunities to truly hear the voice of the complete person.

Evidence – Next, we must contextualise any new findings through evidence. Observational healthcare studies contain crucial evidence about patient behaviours. Work on patient engagement can also include clinical research and real-world outcomes portfolios, activity and biometric monitoring work, non-interventional studies, linked and fused clinical data (claims & EHR), and epidemiology and ethnographic studies.

Expertise – Finally, you must integrate all of this research to create new and transformational insights. In-depth expertise and knowledge about behavioural science allows for the interpretation of behaviours based on proven explanations of motivation.

Truly understanding a disease burden, the healthcare consumer journey, or behaviour of your specific segment compared to the general population or relevant cohorts is only attainable through data from healthcare consumers themselves.

Elements that support your clinical decisions and expose the dynamics of the marketplace throughout the product lifecycle include: primary research (qualitative and quantitative research); patient reported outcomes; social media listening; benefit-risk preference studies; activity and biometric monitoring; ethnographic studies, which allow researchers to observe 'natural' behaviours and witness first-hand the impact of the context in which behaviours take place; clinical and non-interventional studies that demonstrate the true value of medicines to all stakeholders; real-world and outcomes research; real-world data, including claims data, electronic health records and disease registries for performing market and scientific research; and epidemiology studies.

Medicine adherence and ‘patient modes’

To drive better medicine adherence and improve patient health, life science companies and pharmaceutical manufacturers need to place greater emphasis on the individual person’s health journey and acquire a better understanding of ‘patient modes’.

Modes, which are a relatively new concept in healthcare, describe the mindset that a patient is in at a particular point in time, and are part of everyone’s experience as a human being. And while everyone experiences modes in different ways, there’s a universal connection in that we all move through these modes in a fluid manner throughout the day, week, month and year.

By understanding which modes lead to better outcomes, life science companies can help people reach their goals of living better, healthier lives. Kantar’s qualitative research suggests there is a connection between patient modes and adherence, as certain modes may lead to a greater likelihood of adherence while others tend to cause people to drop off from taking their medications. By allowing a patient to set their own health goals, modes may help industry stakeholders, including pharmaceutical marketers and patients, take action for getting back into modes that lead to better adherence or avoid getting into modes that tend to cause poor adherence in the first place.

We believe that adherence improvement is driven by three forces:

1. Seeing personal results and improvements, as defined by the individual, is the strongest motivator of a given behaviour.

2. Employing digital technology that enables the use of advanced techniques to better understand what modes people go through, which modes are helpful and harmful, how to predict which modes are likely to be experienced in the near future, and how to interact with people to create ongoing, impactful communications that are specifically tailored to individuals.

3. Defining goals, including those around adherence, that are set by individuals, not a marketing team.

Finally, we believe a marketing team's number one job is to help people achieve their goals. This includes making changes and adjustments to activities based on the individuals' feedback about how to best interact and help them. Leveraging the benefits of patient modes is a key part of this equation, as they help life science and pharmaceutical companies provide the support that patients need to live healthier lives – either through better clinical outcomes, increased happiness, greater self-esteem or other key measures.

The drivers of health outcomes

In order for life science and pharmaceutical companies to optimise patient research needs and commercial opportunities, they'll need to do a better job in their relationship with the healthcare consumer. By getting to the core of the healthcare consumer and the stakeholder's experience, as well as their interactions within the healthcare ecosystem, we can truly understand all of the drivers of health outcomes and translate this knowledge into actionable insights for improving health around the world.

About the Author

Andy Stankus has more than 22 years of healthcare industry experience across global and emerging markets. Andy publishes research at international conferences. His work focuses on various therapeutic areas, including autoimmune, cardiovascular, CNS, dermatological, gastrointestinal, infectious disease, and metabolic, as well as topics such as patients' attitudinal behaviour, health outcomes, clinically linked insights, and disease-specific cultural differences.

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Welcome to ‘Generation R’ for the next decade of patient engagement

Relationship recrudescence; inertia, cynicism and complacency must not prevail, says Nexgen Healthcare Communications’ Emma Sutcliffe

“Are patients too close to industry?” was a comment at a recent meeting that had me reaching in fury for my ‘interactive keypad’ in response. This recrudescent pantomime- casting of pharma-as-villain was disappointing. However, it was not surprising, as there is still reluctance to invest comprehensively in patient engagement programmes that fully engage patients from the R&D get-go, which leads to such inevitable archetyping.

You would be forgiven for thinking that given the plethora of reports, events and multi-stakeholder organisations publishing guidelines that ‘good patient relationship practices’ are routine and that the cynicism shrouding industry-patient partnerships is the ‘ghost of Christmas past’. Indeed, it would be reasonable to assume that the relationship between most pharma and patient organisations is now a great one; underpinned by trust, measured by collaboration, linked with a common language. However, inertia to turn relationship ambition into practice still prevails in many companies that can frustrate and undermine the success of longer-term partnerships. Scratch away at the superficial claim ‘we put patients at the heart of all that we do’ and what does that mean, every day, in every pharma company away from the glare of the conference spotlights?

Pharma still needs to breathe ‘real life’ into patient engagement

As head of patient engagement at Nexgen Healthcare I’ve transferred some twenty five years experience as a medical writer into shaping the services that the agency offers. Alongside great colleagues – ex pharma executives, respected healthcare marketeers and social health practitioners – we share a common goal: to bridge the gap between pharma and patients and bring them as close together as possible to encourage common understanding and shared objectives. Initially we developed the ‘BREATHE’ principles to enable pharma to look at the life of a patient through the patient’s eyes (Fig 1). This evolved into the Halogen Audit – a seven domain audit to establish PE infrastructures across an organisation from early R&D through to long-term services. We’ve been delighted to work with many progressive and determined clients who trust us to turn their intentions for patient engagement into reality.

Boost the patient experience not boast about a product

Real world patient needs not the homogenous sanitisation of the clinical trial

Empathy/entertainment using the right language and allowing for emotional participation

Action-oriented engagement allows patients to contribute beyond their scientific ‘limits’

Trust transactions are the core equity for long-standing relationships

Help patients with the everyday impact of the condition on their lives

Earned respect is reciprocal; step up and provide the ‘ABC of engagement’

nexGEN healthcare communications

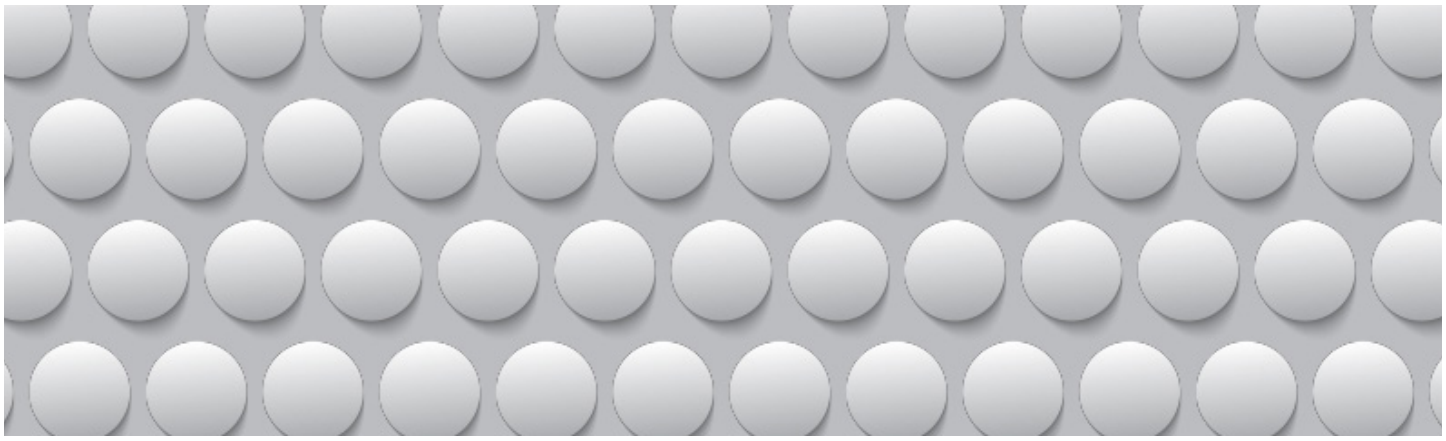
At times, we've had to battle with those clients to ensure that 'patient centricity' truly gets the attention and budget it deserves and needs within their organisation. The opportunity to become complacent and to tick-box items such as 'a patient journey' or 'a patient advisory board' as being enough to satiate a sense of 'good patient engagement' needs to be guarded against. For one, it is nowhere near 'enough' to a patient being courted by Google, Amazon and the consumer lifestyle companies who are enthralling them with data and digital solutions to only be 'used' by pharma when it seems to suit pharma.

Furthermore, minimising a patient's life to being a 'journey' bores patients and borders on the offensive. There is no pleasant destination in the everyday chore of living with a chronic condition. This type of language and attitude is increasingly faecetious to patients. There is a lot more to be done to keep industry alert to the growing expectations of patients to be 'treated' with, and to, full lifestyle support programmes that they can pick and personalise.

Patients want 'Citizen Science' camaraderie with pharma; specifically they want multi-pharma collaborations through research and lifestyle platforms and pharma needs to upskill their data architecture and investment in collaborative platforms accordingly.

Inertia undermines intention

Irritatingly, the excuses for inertia in patient engagement have started to creep back into our practices. Industry and PO partnerships remain delicate and where some areas of engagement strive forward; others struggle to take the right steps. To understand this hesitancy, we went through case-studies and dissected the interviews from more than 40 pharmaceutical/biotech companies and POs/Patient Opinion Leaders who have participated in the Halogen audits. We also launched a social media campaign; "Lingo Bingo" inviting all experts to help us to identify pockets of inertia (Figure 2).



From this project, we are starting to see that the most frequent excuses for inertia in patient engagement can be segmented as follows:

1. Compliance concerns regarding promotion versus discussion of product data

"I'm not allowed to talk to patients"

"We can't promote our products to patients"

"It's too risky"

2. Ineffective reimbursement systems

"We can't pay patients to come to our meetings"

"We don't have a protocol for this"

"I don't have any budget"

3. Reluctance to perceive patients as experts

"It's more important that we understand the disease"

"We can't invest in patient engagement until we get phase 2 data"

"We've done patient journey mapping"

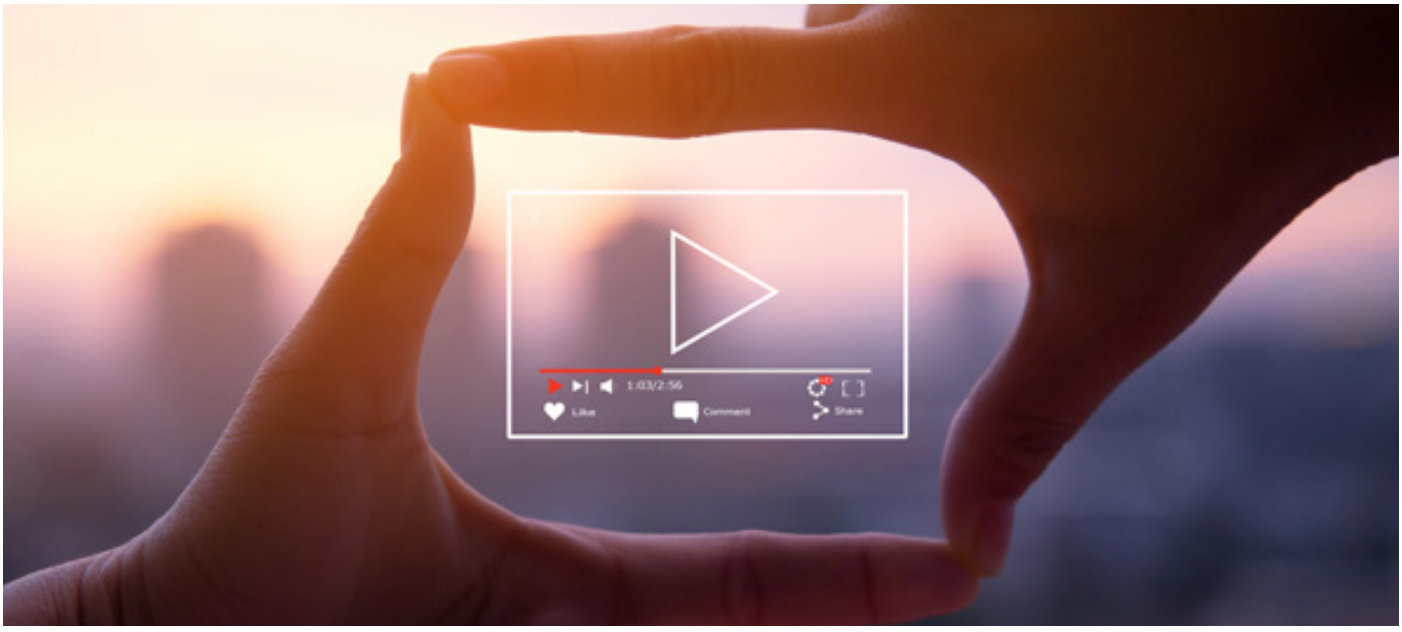
The corollary of this is how patients misinterpret or don't understand the internal pressures that pharma executives face during drug research and development. The main criticisms iterated during the 'Lingo Bingo' campaign included:

- "My condition affects me every day; not just when your latest data comes out"
- "It's always the same people invited to the meetings with pharma"
- "Pharma say 'talk to us' but it takes too long to get answers"
- "Keep me in the loop; don't make me run in your process circles."

The most frequent complaint was; "So you can pay a 'doctor expert' for their time, but you can't pay me to tell you about my experience?".

Ruthless relationships ahead

Trite as it is to use the new decade to push the message of a clearer '2020 Vision' about patient engagement; as a sector we do need clarity about what's next. That necessitates identification of the inertia and calling time on the excuses for poor or stagnant patient engagement as the initial 'LingoBingo' exercise has done. Pharma companies have moved towards perceiving – and paying – patients as subject experts in their own right and to removing the red-tape and procedural obstacles around product information and promotion. Recognising that patient experts are the collective conscience of the pharmaceutical industry should be the impetus to create more mature, collaborative partnerships.



Hyperfocus is a deterrent to innovation and pharma needs to keep looking at the big picture to avoid becoming entangled in compliance minutiae; patients will use social channels and work with Google, Amazon, Facebook and Apple as the 'GAFA generation' and if pharma fails to collaborate by not streamlining patient engagement processes, then their reputational 'we know the diseases' advantage will become bleating into an echo chamber as increasingly super-connected and customer focused groups 'know the people'.

Patients 'love' digital workflows and connected devices to create frictionless interactions that look at a clinical trial from a patient-informed perspective. This co-creation in the clinical trial setting will move the needle on patient engagement; creating new imperatives for recruitment where virtual trials can save time, money and still be of necessary quality. Clinical agility is the key to accelerating innovation for patients and a 'start-up- entrepreneurial mentality will need to be developed which will be an epiphany for how to re-purpose patient engagement in the clinical trial process. This Ux design approach in drug development will be about inviting patients to be a guest in an existing product trial or create their own. It is scalable, adaptable and meaningful to patients.

Finally, pharma must adjust mindsets ready for "Generation R' – the rise of the young and the ruthless. 'Young Persons Advisory Group' (YPAG) involve patients, parents and caregivers in clinical trial design as partners are on the increase. Spokespeople from 'LiverpoolGenerationR' recently dominated a pharma patient engagement summit with their confidence that "as a young persons' group we are ruthless – there is nothing that we won't say and we will question it". It is clear that there will be no more excuses for avoiding co-creation; this is evident with confirmation from the FDA who have stated that that patient engagement is about to stop being optional. As such, we have to ensure systemic patient input in the entire product lifecycle.

When it comes to patient engagement for the new decade, companies must take the robust position of "this is the right thing to do and POs want us to do it". Overall, there is no time and no space for inertia in patient engagement. It is now big business for big pharma – the actual professional business of patient centricity.

About the Author

Emma Sutcliffe has been a medical writer and leader in patient engagement since 1995. Emma is head of patient engagement at NexGen Healthcare Communications and a lecturer in patient engagement and social and public health at the University of Cambridge.

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