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pharmaphorum deepdive

December 2020

Deep Dive: Patients & Partnerships

If there's one silver lining from COVID-19, it's that the pandemic has brought the need for patient-centric transformation into sharp relief – and it's likely the industry will come out the other end with a better understanding of this than ever before.

As this issue's title suggests, patient centricity is about more than just talking points and marketing strategies – it requires companies to truly listen to, engage with and partner with the people they serve, and in putting this month's *Deep Dive* together it's been great to see that so many pharma firms are now taking this to heart.

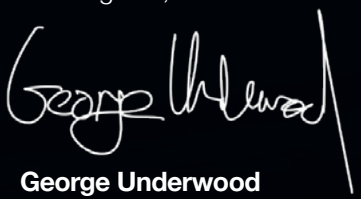
Not only that, but we are seeing patient insights being considered at every stage of a product's lifecycle, from product design to clinical trials and even post-marketing patient services. In this issue you can read expert viewpoints from across the industry on how pharma can optimise its patient engagement at all these stages.

The next step is to figure out how we can make these changes stick over the next few years – but after listening to this month's interviewees I think it's fair to say that pharma has never been in a better position to do just that.

I hope you're all staying safe in these unpredictable times!

I hope you enjoy the issue.

Kind regards,



George Underwood
Editor, *Deep Dive*

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R&D in 2021

- Digital transformation in clinical trials
- Raising awareness of rare diseases
- How specialised commissioning is evolving

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Finding agility in unprecedented times

Nicole Farmer, general manager, UK & Ireland at Sanofi Genzyme, tells us how the company aimed for agile adaptation during COVID-19, and how these lessons are driving patient centricity going forward.

2020 has been a watershed year for every company in the industry – and for Nicole Farmer, general manager for the UK & Ireland at Sanofi Genzyme, that meant moving into a pharma leadership role at a time when things couldn't be more uncertain.

Nevertheless, Farmer – who was appointed in May at the height of COVID-19 – says that her main goals when coming into the company hadn't changed due to the pandemic.

These goals were: creating an environment where people have the courage to be proactive and not wait to be told what to do; pushing beyond current limitations; and keeping customers and patients at the heart of why Sanofi does what it does.

Luckily, the company has found ways to keep working towards these objectives despite COVID disruption – proving that big pharma companies can be more adaptive than outside observers might expect.

On the patient side of things, for example, there were many decisions the company had to take quickly in order to help and protect their health during lockdown. Some patients' monthly home deliveries were switched to three-monthly to reduce resources and minimise their contact with others, and Sanofi also increased its home blood-taking services to free up hospital resources and help shield patients.

Meanwhile, the company worked closely with the NHS and private healthcare providers, particularly for oncology medicines to explore locations that would enable people with cancer to continue with their treatments in a safe place.

"Undoubtedly, the pandemic has changed a lot of things," Farmer says. "It has comforted us to know we do have the ability to be agile, we do have the ability to make quick bold decisions, and we do have the ability to reinvent how we meet customer and patient needs. It has shown us the art of the possible, which we now need to incorporate into our normal working standards."

A collaborative roadmap

This is a philosophy the company hopes to see implemented across the industry in the future.

Sanofi is part of the alliance with the ABPI and other healthcare organisations supporting the Life Sciences Recovery Roadmap – a commitment from the industry to fight COVID-19, support patients and build a more resilient healthcare sector in the UK.

In particular, Farmer says Sanofi is working to improve access to the medicines that cancer patients desperately need – and she wants to see this level of dialogue between pharma, the government and the NHS continue after the pandemic.

"Serving patients' needs and delivering them the best possible treatment is at the core of both the NHS and the pharmaceutical industry's work, so it's disappointing sometimes to feel we sit on opposite sides of the table."

"We should continue working closely together, bringing synergy and innovation to the healthcare sector."

Farmer adds that a key consideration for future discussions to aid patient centricity will be improving reimbursement systems.

"It's a thorny subject, but for me, working in speciality care and across a number of rare diseases, I feel that we need to have another look at how we assess the value that medicines bring and how medicines are approved in the UK, especially when serving ultra-small populations."

"We need to get to a point where no disease is seen as too small to treat."

She says that progress is being made, but there is still quite some way to go.

"The NICE methods review will be particularly important for patients with rare diseases and Sanofi is actively participating in the discussion to ensure more flexibility in the review framework."

"With Brexit, the MHRA has a great opportunity to fast-track licences ahead of EMEA, enabling us to start collecting real world evidence to shape access in the rest of Europe, so more people can benefit. However, there is no point racing ahead with a licence if reimbursement is not forthcoming."

Another key goal for the company when it comes to patients is to further improve support around adherence.

Starting on any new treatment can be challenging, as there can be initial side effects which are difficult to deal with. Finding better ways to support our patients through this time is essential, in order for people to gain the longer-term benefits.

Meanwhile, Farmer adds that Sanofi is aiming to boost data gathering for products in real world settings, which can inform and shape understanding of patient responses and hopefully enable better decision making.

"Data play an enormous role in providing useable insights that mean we can be more patient-focused, particularly when it comes to personalisation. Digital technologies that continue to support both HCPs and patients to manage their conditions more effectively and provide access to key information in a timely manner will be important."

In fact, Sanofi's recently-launched app to monitor skin conditions takes this idea of dual support literally, with versions for both patients and HCPs.

"The HCP version makes it a lot easier for them to measure the extent and severity of their patients' skin conditions," Farmer explains.

She adds that it is important to recognise that patients, patient groups and healthcare professionals are the "true experts", and to listen to their unique insights into what types of resources and solutions will be most valuable to people with the disease.

"We need to do this from beginning to end, during research and development, clinical trial design and drug delivery, as well as disease education, awareness and management, and ongoing support services."

The balance of digital

Often this drive requires pharma to look outside the industry at sectors with more mature digital transformation – and earlier this year, Sanofi appointed a dedicated chief digital officer, Arnaud Robert, with a background in consumer, omnichannel experience, including platform technology, big data and front-end digital experience.

His brief, Farmer says, is to drive Sanofi's digital, data and technology strategy in order to improve the company's offering to healthcare professionals and patients.

Internally, the company wants to ensure that teams are fully briefed on any new digital technology rolled out in the organisation.

This includes video conferencing tools, which Sanofi had already rolled out across the organisation before the pandemic hit, in order to encourage more collaborative working.

However, as the pandemic drew on, the company actually aimed to reduce employees' reliance on such technologies.

"We proactively supported wellbeing and moved away from video conferences, encouraging more walk-and-talk phone calls," Farmer explains.

"When possible, we have met for socially distanced walking meetings, and we reopened our office to enable those who would benefit from being there to come into a COVID-safe work environment.

"Video conference tools have been a great help, but I think now we over-use them, and as a consequence people are spending many hours a day looking at their screens. We want to actively encourage people to think whether they really need to view a screen, or whether a phone call whilst walking would be better."

Likewise, Farmer feels that companies will need to think carefully about the wider changes they want to keep post-COVID and which ones they want to discard.

"We needed to adopt new ways of working through necessity at first, but now I see many of them being embraced to support efficiency. COVID-19 adaptation has accelerated some great changes, but also had some negative impacts too. There are some things we will keep and some things where we will return to our older ways of working."

"One of my great learnings is to see how agile Sanofi can be, how quickly we can adapt to the changing needs of our patients, our customers and our people. That agility is certainly something I want us to hold on to."

About the interviewee

Nicole is currently the general manager for Sanofi Genzyme UK&IE, the specialty business unit of Sanofi. She joined Sanofi Genzyme in 2016 as head of the MS franchise, where she continued to build on the success of Lemtrada and develop Aubagio further. She then moved on to lead the MS franchise for Europe for two years before returning to the UK&IE business in her new role, in May 2020. Before joining Sanofi Genzyme, Nicole spent two years with Baxter, where she led the spin-out of the bioscience business to form Baxalta, where she was the UK managing director. Prior to this, Nicole spent 26 years at Bayer.

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.

‘No going back’ for clinical trials after COVID

Trial sites have adapted swiftly to the restrictions of COVID-19, and patients have seen many knock-on benefits as a result. The next step is ensuring the industry does not regress to old ways of working once the pandemic is over, say Karen McIntyre and Allyson Small.

COVID-19 has changed everything for clinical trials – but in most cases these are changes that were well overdue.

“For years and years, the industry has debated the practicalities and safety of decentralising clinical trials, using telemedicine, and where study activities should take place,” says Karen McIntyre, executive director, global lead Catalyst Program & site relationships at Syneos Health. “We were always having these discussions, but nothing moved forward.”

When the pandemic hit, regulators around the world rapidly updated their guidelines to reflect the realities of conducting trials amidst lockdowns and social distancing mandates.

“For example, drugs are now able to be delivered directly to patients to allow for a clinical trial visit to take place remotely,” says McIntyre.

“These changes didn’t necessarily need to involve advanced technology – we just had to adapt the way we worked.”

She says that sites quickly rose to the occasion.

“We really saw sites’ commitment and dedication come to the fore. They adapted quickly and were incredibly flexible, and rapidly became confident that, yes, they can continue to work effectively and safely with patients in the new normal.”

McIntyre had first-hand experience with just how effective alternate ways of interacting with patients can be when her husband presented with shingles just days after lockdown began

"Normally, we would phone our GP surgery in the morning to try and get an appointment. In the likely event that we couldn't get an appointment that day, we'd have to phone again the next day, and the next, until we're finally able to see a doctor.

"This time, though, I just took a photograph of my husband, emailed it to the doctor and got a phone call 11 minutes later to say that there was a prescription at the chemist."

Now, she says, the industry is wondering why it was ever afraid of change.

"These approaches have all worked, and they've made clinical trials much more inclusive. Everything has changed, and I think that there's no going back."

Diversity and access

One change McIntyre has seen is that the industry has stopped focusing on the challenges of implementing new clinical trial technologies and is now looking at what sites already have and what they need going forward.

She adds, though, that the industry has to be wary of imposing technology on sites.

"One size won't fit all. Technology that works for a large academic hospital won't necessarily be optimal for a dedicated research site. The industry also needs to think long-term – don't make technology for one specific study, but technology that can be reused for multiple trials."

A huge boon of adaptations like remote monitoring is they make patient access to trials wider than ever before.

"Most people live hours away from their nearest clinical research centre – and for people with rare diseases it might even be in another country," says Allyson Small, COO at the Society for Clinical Research Sites. "If you are working full time, or have a family to look after, that means you're prohibited from being included in many studies.

"Having flexibility therefore means that clinical studies can be much more diverse, allowing researchers to bring in patients from all over the country or even the world."

She notes, though, that it will be important to ensure patients have as many options as possible for how they participate in trials – for example, many patients still value human interaction above anything else and are keen to get back to their trial sites. For this reason, Small and McIntyre say hybrid trials are likely to be the dominant format in the future.

Similarly, many patients also have safety concerns with remote trials, and making sure that all patients feel safe outside of a typical trial setting has been a key task for sites.

"Before COVID-19, a term that was being bandied about a lot was 'siteless trials' – but really you can never have a siteless trial, because you will always need clinical oversight," says McIntyre. "It's not just about bricks and mortar, it's about being able to conduct these procedures safely, and sites are just as important for remote and decentralised trials as for traditional trials. I think people realise that now – I haven't heard anyone use that terminology in months now."

A pledge for progress

It's too early to say whether regulators will want to keep more flexible rules in place once the risk of the pandemic is gone – especially when each regulator is different, and this has been a worldwide phenomenon. But McIntyre says the industry's opinion on the matter couldn't be clearer.

"Everybody you talk to will have different opinions, but overwhelmingly, the industry response has been that there is no going back.

"We have learned that we can reduce the timelines of study start-up and increase diversity of participants, and that there are multiple ways we can collect safety data and get investigation products to patients. It's been amazing to see the collaborations that have driven that.

"We need to keep progressing and not regress back to endless discussions and debates. We've learned that it can work, that we can stop thinking that a clinical trial site is a place – rather, a clinical trial site is an activity."

To this end several companies have come together to support the #NoGoingBack movement launched by Signant Health – which is asking people from the industry to pledge to keep clinical trials moving forward into this bold, patient-centric future and not let progress slip away.

The movement's charter asks signatories to honour the lessons the industry has learned – namely that patients deserve and want flexible options for trial participation, that the industry can adapt faster than it thought it could, that collaboration between competitors is needed for acceleration, and that pharma has an "unparalleled opportunity" to make huge improvements in drug development.

"We need to keep this acceleration in technology adoption and new ways of working moving forward," says Small, who is one of the campaign's chairpeople. "It was amazing to see everyone, from sponsors to CROs and sites, rallying together at the beginning of the pandemic to share experience and ensure clinical trials could continue to serve patients, and we want to make sure that effort wasn't in vain.

"If we do that, we can move away from a 'one size fits all' approach to trials. Every patient is different, and to have one protocol with no flexibility adds unnecessary challenges to sites."

McIntyre adds: "So far everything we've done has been through protocol deviations, and now we're asking for regulators to work with the industry to create protocols that will allow for those flexibilities and are inbuilt into the clinical trial process."

She believes this goal is eminently possible.

"I think regulators are seeing the benefits. We've proven that we can do this. Never before in my career have so many people from all levels come to ask me what's happening with the sites. That shows there's a real drive here, and now we just need to make sure that sticks."

About the interviewees

Karen McIntyre is executive director, global lead Catalyst Program & site relationships at Syneos Health. Karen brings almost three decades of industry experience in a variety of therapeutic areas including cardiovascular and metabolic disorder, women's health, neuroscience and infectious diseases in phase II through phase IV clinical trials. With a special interest in site support Karen has been involved in the development of Site Support Management tools with the goal to improve quality, transparency and compliance across investigative sites since 2005. Karen is also an active member of National Research Ethics Committee, Scotland.

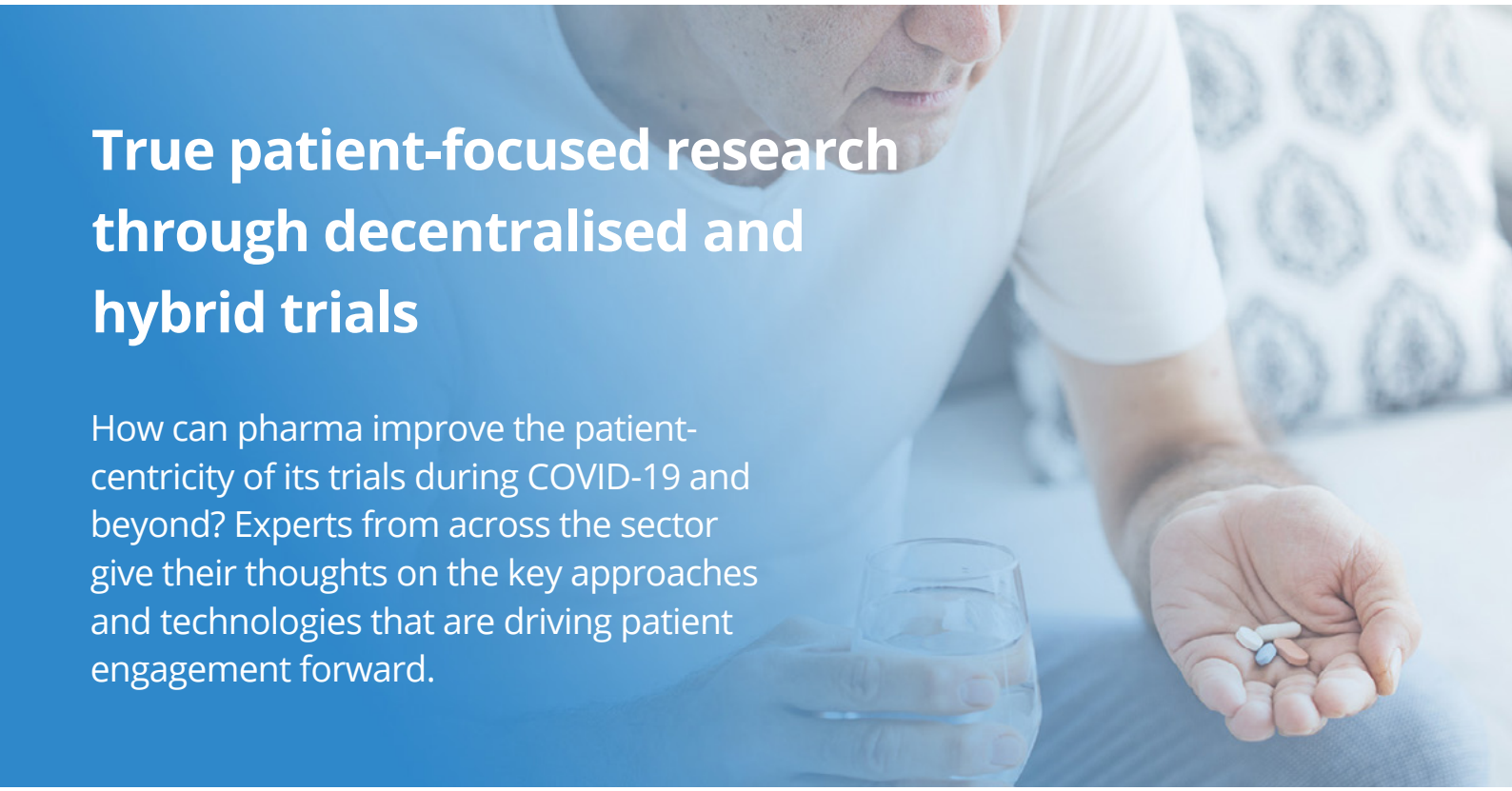
Allyson Small is chief operating officer of the Society for Clinical Research Sites (SCRS). With nearly 20 years of experience working in the healthcare industry, Small joined the SCRS team in 2013. She plays an integral role in strategic growth, developing key partnerships, and increasing global membership by 80%. Small also oversees all development and production of four International Summits. Small is a champion for creating a voice for clinical research sites across the globe and assuring site sustainability.

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.

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.



True patient-focused research through decentralised and hybrid trials

How can pharma improve the patient-centricity of its trials during COVID-19 and beyond? Experts from across the sector give their thoughts on the key approaches and technologies that are driving patient engagement forward.

With COVID-19 presenting new barriers to running and recruiting for clinical trials, making studies patient-centric is more important now than ever before.

According to one analysis, conducted by Global Data, approximately 67% of trial disruptions during the early stages of the pandemic were due to the suspension of enrolment, followed by the delayed start of planned trials at 18.4% and slow enrolment at 14.4%.

Ensuring that trials are easy to access and don't overly burden the patient is essential amidst these potential disruptions – but a truly patient-centric trial has benefits beyond enrolment.

Trials that are engaging and easy to partake in can lead to higher adherence, higher satisfaction, improved data quality and overall performance, and can even give participants a more positive view of the sponsor company in terms of their commitment to bring new treatments to patients.

Patient centricity has been an area of growing interest to the industry for a while now, however many are still trying to figure out what this means, and how it can be operationalised (including study design), for the benefit of the patient and the industry as a whole.

Defining and understanding patient centricity

Earlier this year ICON invited distinguished speakers to participate in a panel discussion on patient centricity, based on their global experience and varying stakeholder positions in the industry to gain further understanding on this key topic.

The panel's patient advocate representative was Avril Daly, vice president of EURORDIS and CEO of Retina International Clinical. Meanwhile, Professor Orla Hardiman – consultant neurologist, professor of neurology, at Trinity College Dublin and consultant neurologist at Beaumont Hospital – gave a clinical investigator's perspective, and Dr Anthony Yanni, senior vice president of patient centricity at Astellas, brought a pharma executive's view to the table.

The speakers discussed the key aspects that can help make trials truly patient-centric, and their insights provide some strong guidelines for what sponsors should be considering that could potentially support keeping trials on track in these difficult times.

Generally speaking, patient participation in clinical trials has long been below where pharma would like it to be. In a 2019 survey analysing the barriers to cancer clinical trial participation, more than 75% of patients cited structural and clinical barriers as the reason for non-participation. Other statistics show us that no more than 3% of patients participate in trials.

Avril Daly suggested that there's a job of education to be done by patient communities to keep up to date with medical developments and ensure they understand the implications and the requirements for those clinical trials. Patients, in general, are attracted to clinical trials because of the prospect of face time with the clinical experts.

"Nevertheless," Daly said, "There is, unfortunately, still a lot of negativity around trial participation... there's a guinea pig attitude... We need to provide communications that balance positive patient clinical trial experience and the potential to save lives with realistic education about the risks of failure."

Likewise, Professor Hardiman said that she believes that clinicians need to be engaged more fully and to be educated about the benefits of trials. It has been her experience in neurology particularly that patient participation in trials corresponds to the enthusiasm of the clinician.

Patient engagement

Even with ease of access, though, keeping patients engaged in a trial can still be a challenge – with patient drop-out in studies often being as high as 30%.

Dr Anthony Yanni said that overcoming this challenge requires using patient insights to understand the trial burden on patients and caregivers. Basic solutions include avoiding collecting unnecessary data, helping patients get to the site and recognising that the patient burden extends to a burden to family and caregivers.

"If we don't understand what it is like to be in the exam room with patients, we are missing a core part of the patient experience," he said.

Professor Hardiman said that trials should never cost the patient or caregiver, and the logistics for reimbursement should be seamless.

Engaging the patient throughout the journey for improved outcomes

Hardiman also underlined the importance of the clinical team using their "soft skills" to be able to communicate with the patient, to boost trust in the process and help patients feel part of something that is of value not just for themselves or the community but for society. In her opinion the best results are achieved when everyone plays their part in creating a real connection between the patient and the overall objective of the study.

Daly added that ongoing communication with the patient was critical, even during "quiet times" when data is being collected. She said that checking in with patients regularly can prevent an information vacuum, which runs the risk of fostering cynicism or a negative reaction to the trial experience.

Another area of consideration discussed when thinking about how best to engage patients was the importance of cultural difference. Dr Yanni cautioned: "You can't apply what you know about a patient in Nebraska to a patient in Beijing. The healthcare delivery systems are completely different, as are expectations. There are even cultural differences regarding patients' interest in treatment."

Decentralised and hybrid trials

Of course, there are all kinds of new barriers to patient access and engagement when social distancing and lockdown measures are in place across the world – and, as a result, the COVID-19 pandemic has accelerated the use of patient centric solutions to ease the burden of patient participation, in particular in-home visits for patient assessment.

The concept of decentralised and hybrid trials has been around for a while, but the execution, technology and compliance issues are still evolving – and even months into COVID-19 there is still a huge variety of approaches being deployed.

EB McLindon, senior vice president, sites, patients and decentralised solutions at ICON, tells pharmaphorum that for any decentralised or hybrid trial solution, creating an ecosystem that supports the patient is key to collecting quality, valuable data.

"At the onset of the pandemic there were two key areas of focus – patient safety and access to clinical research data at the site level," he says.

"In many cases, this had to be accomplished by converting traditional study conduct (i.e. monitoring source documents at the site) to a more decentralised approach with the support of the regulatory authorities.

"Many pharma companies immediately engaged mobile research nurses to conduct in-home patient follow-up or wellness checks to support patient safety. Although mobile nursing has been available in the industry since 2003, there was a tremendous uptick in interest and deployment. Protocols and study operations were amended to allow for the nurse to deliver investigational products to the patient's home."

Another solution to assist with patient safety that was less widely utilised, but deployed nonetheless, was telemedicine. In some cases, this solution was coupled with mobile research nursing.

"During the initial outbreak of the pandemic, many sites were open but were not permitting onsite data monitoring. In other words, oversight and management of study conduct was very limited. In response, industry implemented many remote monitoring tools and processes to support the gathering and evaluation of valuable research data.

"As we look to the future, we anticipate more utilisation of a risk-based quality management approach and remote monitoring for data review. It is probably too early to see if these solutions, among others, are fully adopted to support reducing the site and patient burden on future studies regardless of emergency conditions."

McLindon adds, though, that sponsors are more open to decentralised trials as a way of making trials more resilient in challenging times – although actual levels of adoption will depend on factors like endpoints under consideration, overall study design, investigational product safety profile, patient profile, and regional regulatory acceptance of decentralised technologies and processes.

> "Many pharma companies are seeking ways to make their studies more resilient and minimise future disruptions. To that end, we see strong movement from a traditional site-based approach to a more hybrid trial approach – incorporating aspects of decentralised solutions (technology, process, techniques) rather than an adjusted attitude to go fully decentralised."

Likewise, a CTTI study found that the majority of respondents (76%) – with a median age of 61 years – reported they would prefer to participate in a decentralised study using mobile devices over traditional ones, citing greater convenience and fewer in person visits.

Respondents reported they were willing to use a variety of technologies – including mobile apps, wearable devices, and ingestible sensors – provided they were comfortable, convenient, and easy to use.

In 2019, ICON conducted its own patient survey on decentralised trials and, as with other research, found most of the respondents were interested in having decentralised solutions included in their clinical trial experience.

ICON is now conducting a follow-up survey in Q4 2020, and McLindon says he expects patients' desire for decentralised solutions to have increased.

The potential of wearables

A recent ICON whitepaper highlighted connected devices in particular as an example of a tool that can help decentralise trials, facilitate patient access to studies and boost engagement.

The rise in using connected devices is owed in part to the popularity of wearables in the general public, such as Apple watches and Fitbit devices. In parallel, there has been an emergence of "over the counter" medical grade devices and sensors that were designed with the patient in mind, meaning they are easy to use, and have good connectivity and simple data flows.

These devices also have the benefit of being able to monitor daily life activities, such as the ability to go shopping or walk upstairs and see how therapies affect these aspects of patients' lives.

This allows sponsors to select measures that are more meaningful to patients – which has long been a goal of companies looking to improve the patient centricity of their trials.

This is particularly important in areas such as rare disease and disease of the central nervous system, where traditional outcomes assessments are generally accepted as not being sufficiently sensitive.

Similarly, cardiovascular clinical trials that use digital health technologies can provide continuous assessment of the quantity and intensity of activity throughout a patient's day, creating a clinically important digital endpoint for heart failure.

In fact, in an ICON webinar survey included in the whitepaper, 17% of attendees found patients living with cardiovascular indications to most benefit from novel digital endpoints.

Providing options

McLindon concludes that it's important to provide study participants with as many options as possible in order to reduce patient burden.

"We need to be able to make a patient's participation in research no different than their standard of care journey – we need to be able to present clinical research as a care option that mirrors their current care options.

"Prior to the pandemic, we witnessed how home-based patient visits increased patient satisfaction, compliance, and retention. By offering patients options to participate in research, we increase the patient catchment area and provide more access to research for a diverse population.

"Innovations will continue to help evolve the overall trial process and further enhance the patient and site experience even after COVID-19," he says, adding that he believes more patient-centric study designs are "here to stay".

For more insights into best practice for patient-centred clinical trials, read the full Patient Centricity panel report, featuring more comments from all participants and data from ICON's own research.

For further reading see the Digital Endpoints whitepaper, or take a look at ICON's report on Agile Clinical Monitoring.

About the interviewee

EB McLindon is senior vice president, patient, site & decentralised solutions at ICON. Since joining ICON, EB has driven the development of the company's site and patient strategy and led a large team of functions in the delivery of solutions including; Accellacare, ICON's global clinical research site network, Symphony, ICON's in-home health provider, patient recruitment and retention services and FIRECREST digital solutions. He is currently providing consultancy to help sponsors realise the potential of decentralised trials by developing the infrastructure, technology and operational framework for success. Previously EB had a key role in the development of Accelovance, a CRO that owns and operates clinical research sites.

About ICON

ICON plc is a global provider of outsourced drug and device development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations. The company specialises in the strategic development, management and analysis of programmes that support clinical development – from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON employed approximately 15,250 employees in 94 locations in 40 countries as of 30 September, 2020. Further information is available at www.iconplc.com.

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medidata

How patient insights are changing trial solutions

Patients have been asking for patient-centric trial solutions for years – the industry just hasn't been listening. That's according to Medidata's Anthony Costello, who was bringing patient feedback into product design long before COVID-19. He tells us what insights pharma has been missing out on and how they can be harnessed to build better solutions.

COVID-19 might have forced the industry to leave behind its reticence around remote and decentralised trials, but according to Anthony Costello, senior vice president of mobile health at Medidata, this reticence wouldn't have existed in the first place had the industry been genuinely listening to patients.

"Patients have not been saying anything new during COVID-19, but the difference is that the industry has woken up and started paying attention," he says.

"Patients have long wanted more and better technology to use in studies so that they don't have to visit sites so often, but the industry has been very reluctant to go in that direction."

The pandemic, he says, has forced many parts of the sector to treat patient-centricity as more than "lip service".

"Until now the industry has been listening to patients in an obligatory way, but not much action has resulted from what those patients are saying. Everyone had the right talking points about how they wanted to design studies that lowered patient burden, but very few clinical trials actually implemented patient-friendly technology and protocol designs.

"A year and a half ago most clinical research teams would have snubbed their nose at the idea that they would cancel site visits and do them via video instead, but now it's what everybody wants to do."

Trial burden is not a new concern for patients – health problems and the necessities of everyday life have always been barriers to participation, and better tools and technologies were already important for reducing these barriers before lockdowns forced industry-wide adoption.

Costello's team at Medidata had been hearing this through the company's Patient Insights Program for some time, and in using these insights to help build trial solutions Costello has seen how impactful the right patient feedback can be.

Patient insights

The Patient Insights Program aims to dig deep into what Medidata can do to make their protocol and technology designs better for patients.

When doing this, Costello says it is important to seek out and engage with as broad a range of patients as possible.

"We bring in everyone from cancer patients that have been on nine or ten clinical trials all the way to patients that have never been on a trial but are concerned about how they work," he says.

The backbone of the programme is patient workshops where the company gathers insights through discussions with patients and industry experts. They then use that input to influence future product design. The workshops are run eight to ten times a year, with each one being focused on a particular theme.

"We go deep into each topic then publish our learnings to the group," says Costello. "Everyone who was there has a chance to digest the findings and possibly revisit them in a future workshop.

"Everything that we learn in the workshops goes directly back into the technology that we're trying to build."

Of course, one challenge of this methodology is that it can produce a huge range of qualitative data.

"It isn't magic – often we'll get as many opinions as we have people in the room," says Costello. "We'll try and get deep engagement on every possible solution, and then it's our job to go away and find a solution that works best.

"We make appropriate trade-offs and build the product as best as we can with all the inputs in mind – but the Insights Program is designed so that we can circle back to the patients that helped us design it once we are ready to launch. We call that a 'patient acceptance test'; the patients will literally sign off that the product is acceptable, in their opinion, to go to market. Any problems they still have are documented and put into roadmaps for future consideration."

Costello says the most important consideration for a patient insights programme like this is to maintain fluidity.

"If we don't get something exactly right the first time, we'll continue developing it using an agile methodology to make it better."

Although in the past Medidata has designed products before bringing in patient insights, or has brought in these insights to improve pre-existing technology, the company has started building software from scratch with patient teams – such as the company's patient portal myMedidata.

Costello says that, in myMedidata's case, this meant spending hours "agonising over" even the simplest functions to make sure they were optimised for patients.

"For example, we spent a lot of time looking at the journey through an account creation screen. That's not something most of us would think about when getting a new piece of software, but patients have to worry about how accounts might link into their health records.

"We asked what we should put on the screen to tell patients how their information is going to be used, and when we should even ask them to create an account. Should it be on the very first screen, where they might not be comfortable yet, or do we guide them through an information screen first? Should you have one information screen or multiple screens? Should those link to other resources to read, or should there be a video instead?"

Similar considerations surrounded how consent forms should be structured, and what font sizes or colour schemes should be used.

"These are all things that matter so much to patients, who might not be experts in technology but are still going to have to look at the software every day for the 18 months they're on a trial. It really is critical to get these things right for them."

The team also sought feedback on how questionnaires, which are a huge part of the software's experience, should be structured.

"It might seem rudimentary, but we find lots of different opinions among patients," Costello says. "Some will want one question per screen in a large font size that's easy to read. Others say that having to go through multiple screens would drive them crazy.

"It also depends on the device you're using – it makes more sense to have one question per screen on a smartphone, for example.

"Sometimes we have to make trade-offs, but we also aim to build software with as much choice and flexibility as possible."

With more and more mobile data capture technologies emerging, a broader goal for the design of myMedidata was to bring multiple functionalities together into a single portal for patients, allowing them to do away with having extra devices or multiple apps with different logins to remember.

"We built myMedidata to be accessible from any kind of device," says Costello. "It also has the same authentication requirements as the rest of the Medidata platform.

"If you're on myMedidata with a single username and password, you can see every feature that you need for that study, and you can also see every other study you've ever done on our platform."

Like with other products, Medidata hopes to continuously roll out updates to myMedidata as more patient feedback comes in.

"We're getting constant feedback right now on what features are important to customers and why," says Costello. "That includes building more registry capabilities to facilitate large COVID-19 trials that are happening."

Although the rest of the industry may have been slow in taking patient insights on board, Costello believes that the pandemic has helped pharma realise what they've been missing out on, and he hopes that these kinds of insights can be filtered into development across the sector.

"Patients are not saying anything different to what they've always said," he says, "but the industry is listening in a very different way now."

About the interviewee

Anthony Costello, senior vice president, patient cloud, Medidata

After beginning his clinical research career at Genentech 20 years ago, Anthony Costello has gone on to co-found several clinical trials technology start-up companies including Nextrials (acquired by PRA Health Sciences) and Mytrus (acquired by Medidata). Over his career, he has focused on disruptive and innovative technology that can simplify clinical trials for patients, sites and sponsors. He has been selected as one of the PharmaVoice Top 100 Most Inspiring People in Clinical Research, has served as chairman of the Board for the Society for Clinical Data Management and is currently a member of the editorial advisory board for Applied Clinical Trials magazine. He is a frequent author and presenter on topics related to the efficient use of technology in clinical research.

About Medidata

medidata

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences, creating hope for millions of patients by helping to generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimise risk, and optimise outcomes.

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.

accenture

Boosting the impact of patient services

New research from Accenture has revealed that adoption of patient support services hasn't improved since 2015 despite increasing pharma investment. The company's Jennifer Spada tells us how companies can boost awareness of their programmes to improve patient outcomes.

As part of its drive towards patient centricity, the pharma industry has increasingly been building patient support programmes that can offer beyond-the-pill services to patients. The market for patient engagement solutions was worth $8.8 billion in 2017 and is projected to reach $18.68 billion in 2022, an annual growth rate of 16.2%.

These programmes can help guide a patient through complex information about diagnosis and treatment choices, or aid them with information on the medical and financial aspects of care, and also include day-to-day care management such as medication reminders, symptom monitoring, and nursing support.

Research has shown that when patients utilise these services, adherence increases, quality of life improves, hospitalisations and ER visits are reduced, and survival rates rise.

For example, one study looked at lung cancer patients using a smartphone app to monitor 13 common symptoms. This allowed the care team to monitor patients remotely and intervene when needed, which resulted in a seven-month overall survival benefit and reduced hospitalisations.

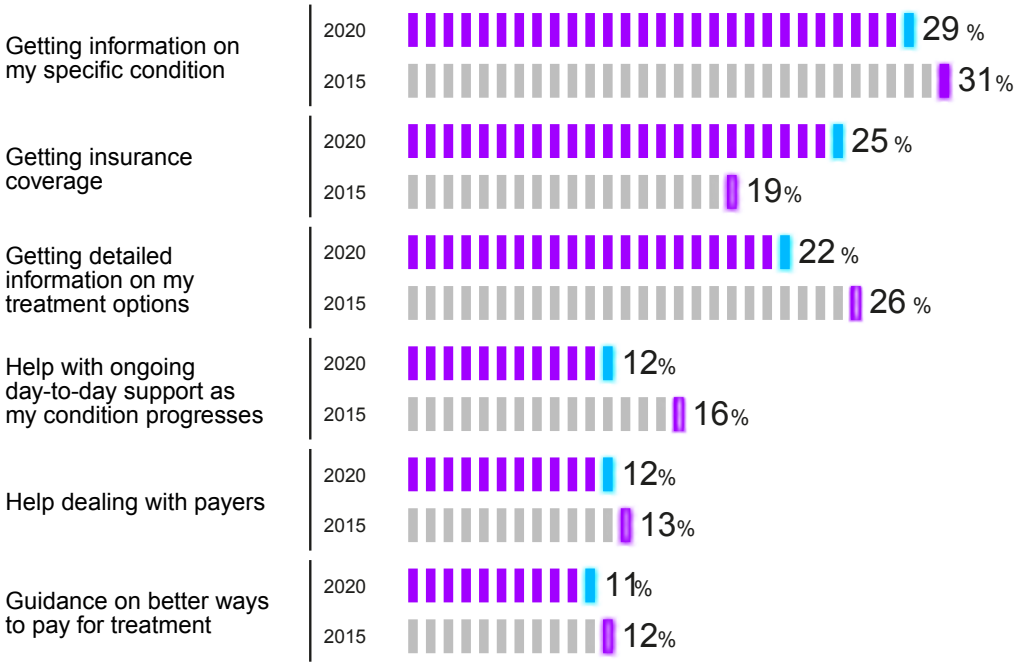
Meanwhile, asthma patients using an inhaler sensor and GPS were able to understand and avoid environmental triggers – with a 78% reduction in rescue inhaler use and 48% more symptom-free days – and diabetes patients using a patient portal, especially those with multiple chronic conditions, had fewer emergency room visits and hospital stays.

But a new survey from Accenture has shown that these services are failing to reach as many patients as they could be – even at a time when COVID-19 means patients are finding far more channels through which to get medical information and are more confident about managing their own health.

Back in 2015, the company's report 'Patient Services, Pharma's best kept secret' found that patient awareness of these services was low, dampening wider adoption. On average, less than one out of five patients (19%) were aware of the services available to them, and awareness was low across all therapeutic areas, ranging from 18% for bone, lung and heart conditions to a slightly higher 21% for cancer and immune diseases.

Now, five years later, the 2020 follow-up patient services survey – 'Move the Needle: Amplifying the signal for patient services' – has found that levels of awareness and adoption have not changed significantly (see figure 1). In fact, just 16% of the 12,000 patients surveyed were aware of any service.

Fig. 1: Percent of patients aware of each service



Patient awareness was highest for information services and lowest for financial support, such as help dealing with payers and guidance on payment options.

And while 80% of patients surveyed rated the services they used as valuable or extremely valuable, this did not translate into increased adoption or awareness.

Jennifer Spada, a managing director leading Accenture's patient research, says that the results came as a surprise to the survey team.

"None of us expected to see no change at all, especially when pharma has increased its investment in these services, understands the patient journey better and has improved capabilities to access data compared to five years ago."

As a result, the team looked into what factors might be holding the adoption of patient services back, and have published their recommendations alongside the survey results.

Simplifying patient service offerings

One of Accenture's key findings was that the landscape for patient services is extremely fragmented, with too many individual services available for HCPs and patients to keep track of. As the report puts it, "the signal is getting lost" for patients.

"The increase in specialty products over the last five years has led to an increase in tailored patient services," Spada explains. "Many of these are branded and drug-specific, and very few of these are integrated into an end-to-end programme."

Despite the ongoing growth in investment in patient services, much of this has been into new, individual services rather than cohesive, above-brand programmes.

"If you look in any oncology periodical, for example, there will be a page full of advertisements for all the patient services available to cancer patients. There's so many of them that it's hard for both patients and HCPs to sift through."

This means pharma companies should strive to make their services easy to understand.

"We believe that by simplifying offerings, and presenting them as part of a cohesive programme rather than as independent solutions, companies can make it easier for patients and physicians to understand and access the support needed," Spada says.

"One solution could be to look for synergies across a portfolio or across a therapeutic area and offering above-brand services that cover several drugs."

For example, she says that companies could offer all their oncology patient services under one umbrella programme.

"Doing this all above brand creates the simplicity needed to drive awareness and adoption of a programme and more easily communicate it to physicians. It also allows companies to tailor the support needed for each patient, because they have a variety of therapies and indications within their portfolio."

The report concludes this point by saying that pharma should "design patient services for value", building them as a structural element of holistic care that improves patient outcomes, rather than as an "occasional safety net".

Orienting communication around value

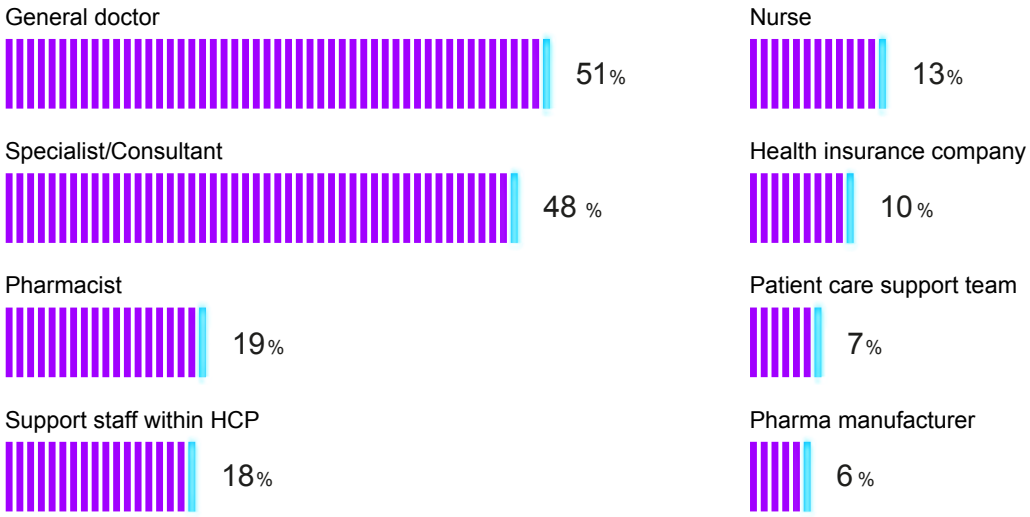
The report's second recommendation is for pharma to improve communication of these services, creating a "surround sound" approach to amplify their messages.

"Companies need to clearly and consistently deliver concise, evidence-based messages to HCPs and patients about what services are offered, and specifically about the value they're expected to create for patients," Spada says.

"You really need to make sure that communications with physicians are simple, clear and convenient so that they can provide the appropriate information and recommendations to their patients."

Accenture's survey shows that HCPs are the preferred source of prescription, medical and patient services information for patients (see figure 2) – so Spada adds that it is important to coordinate with doctors to make sure these communications get through to end-users.

Figure 2: Percent of patients who said these sources provided the best information regarding the treatment prescribed for their condition (multiple selections allowed)



Harnessing new channels

The results also show that community support groups, pharma company websites and social media are the most popular sources consulted by patients during treatment after doctors. In fact, all three of these channels saw their usage rise over the last five years, perhaps partly due to COVID-19 (see figure 3).

Spada says pharma should use these channels to help "augment and complement" the patient services recommendations that HCPs give.

"There are opportunities for online chats, video conference software and other digital technologies to act as additional communication channels with patients, and to allow more ways for patients to receive the support and services that they need for their treatment journey.

"We're recommending that companies select multiple channels to augment their messages," she adds. "Our survey has shown that COVID-19 has shifted patients towards greater adoption of digital technology, and it's critical that pharma invests in establishing these capabilities."

Forty-four percent of patients said they have had more virtual conversations with HCPs and 37% have used telemedicine more since COVID-19. Meanwhile, 39% said they have found far more ways to get information and help during the crisis, and 43% of patients said the crisis has proven to them that they can do a lot more to manage their condition themselves.

Figure 3: Top sources consulted by patients during treatment

	2015	2020
My doctor	56%	57%
Community support groups	45%	51%
Pharma company websites	36%	44%
Social Media	33%	40%

Furthermore, when asked about the use of patient services during the pandemic, 84% of patients said that the services they used – such as remote monitoring and payment support – were valuable or extremely valuable.

The report adds that this increased openness to the use of technology in the management and delivery of care could be a "game-changer" for patient services, but the biggest barrier remains low patient awareness of these digital tools. Just 13% of patients surveyed said they were aware of services such as remote monitoring and patient portals.

"There's a huge opportunity here if pharma companies can both communicate and offer their services through these channels," Spada says.

Because of this, another of the report's recommendations is that pharma companies need to make sure their services are part of the "daily mix" for patients and HCPs.

"We live in a liquid world with smartphones and screens everywhere, so you need to make sure that the communication and interaction with these services happens within technologies that are already in use," says Spada.

"Services shouldn't be something extra outside of an HCP or patient's daily activities; they should be integrated within those activities."

One example of this could be integrating patient service offerings into electronic medical record systems, so that when a drug is prescribed the relevant services are listed on the doctor's screen.

No silver bullet

Nevertheless, patient services can be as varied as the therapy areas they are related to or the patients using them – and Spada says that, ultimately, every pharma company is going to have to find their own answer.

"There's no silver bullet," she says, "but the recommendations we've set forth in the report are going to be some of the key components."

Spada notes that none of these recommendations involve completely reimagining patient services – rather, companies need to "refine the model" into something more service- and outcomes-oriented.

"Our hypothesis is that the current model has reached its limit, but if we can simplify offerings, better articulate the value of services, communicate more effectively, and leverage relevant technologies, then in five years we could have almost all patients using patient services to manage their treatments.

"It will take a lot of hard work to do that, but if pharma is able to achieve this we could see massive benefits to cost of care, health outcomes and overall quality of life for patients."

The views and opinions expressed in this document are meant to stimulate thought and discussion. As each business has unique requirements and objectives, these ideas should not be viewed as professional advice with respect to the business.

About the interviewee

Jennifer Spada is a managing director at Accenture's Life Sciences Practice, leading the Intelligent Launch offering. She has significant experience in the pharmaceutical industry across both commercial strategy and marketing roles in both primary care and specialty markets. Jen has built launch strategies and execution plans for more than 15 new products and indications.

About Accenture

Accenture is a leading global professional services company, providing a broad range of services in strategy and consulting, interactive, technology and operations, with digital capabilities across all of these services. We combine unmatched experience and specialised capabilities across more than 40 industries — powered by the world's largest network of Advanced Technology and Intelligent Operations centres. With 509,000 people serving clients in more than 120 countries, Accenture brings continuous innovation to help clients improve their performance and create lasting value across their enterprises. Visit us at www.accenture.com

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.

3 practical steps for improving patient support

Research Partnership's Emilie Braund and Harrison Gaiger dig down into the top insights pharma companies can harness to make their patient support programmes as powerful as possible.

The pandemic has undoubtedly disrupted the healthcare landscape and amplified the complex factors that influence and shape patient journeys. Findings from our recently published whitepaper '*Free thinking: The impact of COVID-19 on chronic disease management and the implications for pharma marketing*' revealed that, in the spring of 2020, two thirds of physicians across Europe felt patient management was severely impacted as a result of COVID-19. Remarkably, global health systems have evolved quickly in an attempt to adapt to the crisis and great strides have been made to continue providing patients with the information and care they need. In our research, 89% of physicians across Europe reported replacing face-to-face consultations with virtual consultations during the first wave of the pandemic. However, in some additional research we conducted with healthcare professionals, over two thirds across both the US and EU feel patients are still in need of additional support to help manage their condition.

Patient support programmes (PSPs) can play an integral role in providing such assistance. Well-developed PSPs offer a number of opportunities to improve disease management, optimise treatment pathways and deliver better patient outcomes. Our research found the following patient needs being fulfilled by effective PSPs:

- Adherence and compliance
- General education on condition
- Help with self-care
- Advice for a healthy lifestyle
- Advice on own treatment management
- Psychological support

In the future, the requirement for greater beyond-the-pill support is only going to increase and personalised care which ensures patients' individual needs are satisfied will be a key priority for healthcare providers over the next decade. Our research found 61% of HCPs think that, in light of the global pandemic, the need for PSPs has increased. Unfortunately, awareness of the range of programmes available to patients and their caregivers is reportedly low and so they are often not being used to their full potential. According to our research, only half of physicians (56%) believe that programmes developed by pharmaceutical companies are currently helpful at improving patient outcomes.

So, how can manufacturers develop their PSPs to be more effective?

1. Understand patient needs

Pharmaceutical companies need to anchor their approach to PSPs to the needs of the patient. By engaging with patients from the outset – the earlier the better in the product lifecycle – and honing in on what it is they actually need at each stage of their healthcare journey, manufacturers will gain valuable insights they can take forward into the development stage.

The pandemic may have brought about changes in the patient journey, such as changes to treatment pathways, which will need to be investigated or reviewed. Whilst some changes may be here to stay, others may only occur during this particular period.

Manufacturers also need to go beyond patients to understand the support structure around them. Complement the patient perspective by taking a 360-degree approach, building an understanding of close family members, caregivers and patient organisations. Doing this will identify the many different inflection points along the patient journey that have the greatest negative impact on treatment outcomes.

We would recommend you build your understanding using a range of methodologies including observation, listening and activity. For example, we conducted research with a company who wanted to get a strong understanding of patients with MDD (Major Depressive Disorder). We used a combination of social media listening and multi-stakeholder research with patients, caregivers, psychologists, KOLs, and advocacy group representatives to understand the patient journey for specific forms of MDD from a wider range of perspectives. We invited patients to participate in a number of activities including journals and art collages in order to understand the emotional impact of their illness. The insights from the research were highly impactful and helped the company build a deep understanding of patient needs, frustrations and behaviours.

2. Develop user-friendly programmes

It's important to remember that each patient's journey feels unique to them and they will engage in their own healthcare differently to others using a range of channels. For digital support tools, such as portals, websites, smartphone apps, and wearables, the design and delivery of a PSP needs to take into account the digital literacy of the patient. For that reason, optimise the user experience by designing patient-centric, user-friendly programmes that will cater for patients with varying degrees of familiarity using these technologies.

Conducting UX research enables pharmaceutical companies to understand patient behaviours, needs, and motivations for engaging with digital assets through observation techniques and task analysis and is key for driving long-term engagement with PSPs. Recently, we worked with a pharma client who wanted to relaunch a website to help educate, support and provide resources for patients. In order to encourage engagement and optimise the website's user experience, they required a better understanding of the patient's perspective including how they search for healthcare information and navigate resources. Through rigorous UX research we evaluated and discovered the optimal site content, organisation, navigation and nomenclature. We identified areas for improvement and were able to advise how best to refine the website in order to satisfy the user experience.

As well as digital literacy, bear in mind other forms of literacy and understanding. Use language that patients use in describing their illness and terminology that the patient can understand. Deliver support in formats that patients are most comfortable engaging with, ideally with a mix of on and offline channels.

3. Engage with physicians

Physicians often act as the gatekeepers to PSPs. Along with nurses and, to some extent, pharmacists, they're the ones who will inform patients about the range of services that are available and will help enrol them in programmes to help manage their disease. So, when developing a PSP, it's critical to consider what's in it for them and include them within your research. By understanding the needs and priorities of HCPs, you're much more likely to develop a programme that achieves their buy-in. In addition, depending on the nature of the support programme, consider collecting the perspective of payers, influencers or key decision makers at the hospital or administrative level, as their endorsement will be critical, especially if the PSP needs to demonstrate beneficial outcomes.

We recently conducted a three-phase study in COPD, initially with a small number of individual patient and caregiver interviews to understand current support mechanisms, needs and priorities. Focus groups with patients and caregivers followed, whereby patients were able to share their experiences and debate new ideas and channels for a PSP. Potential PSP outputs from these groups were then tested with physicians and nurses. This iterative approach gave our client a 360-degree understanding of the market, enabling them to develop a PSP that both best addressed patient needs and guaranteed physician buy-in.

Designing, delivering and measuring the success of a patient support programme can be challenging, and requires many different considerations, but it must be a top priority for all pharma companies. There is a significant opportunity to improve the patient experience and quality of life, increase adherence and improve outcomes through these programmes – but this can only be achieved by gathering deep insights to understand the people who will be using them.

About PSP Enhance

Using our knowledge and extensive experience in this area, we have developed a market research approach called PSP Enhance to help maximise the value of patient support programmes. From exploring needs and testing concepts to monitoring success post-launch, if you're considering how to enhance your programmes, we will work with you to support the development, delivery and usage of your PSPs.

Find out more about PSP Enhance

About the authors

Emilie Braund, director at Research Partnership, is based at the company's London office. She has over 15 years of experience in international healthcare research. In this time Emilie has built up expertise in a wide range of methodologies across many therapy areas including auto-immune, oncology, and diabetes.

Harrison Gaiger, marketing manager at Research Partnership, has almost 10 years of experience in B2B marketing and healthcare market research. During this time, he has written articles for a number of leading publications.

About Research Partnership

Research Partnership is the largest independent healthcare market research and consulting agency in the world. We collaborate with clients from the global pharmaceutical, medtech and biotech industries, providing research intelligence and strategic recommendations that elevate healthcare brands and power their success.

Enabling new models of care: pursuing pharma's partnership potential

There is a huge, ongoing shift in how health and wellness is approached in the UK, and the changes will have important implications for NHS-industry partnerships.

Transformative change is coming to the NHS and is set to radically alter how the UK's health service cares for people at a population level.

The NHS Long Term Plan signposted this change, with its emphasis on preventative health, and the forthcoming expansion of the Integrated Care Systems programme continues this direction of travel on a path towards the long-cherished hope of joining up health and social care.

As new approaches to healthcare attainment take hold there will be some degree of uncertainty among pharmaceutical companies about where they fit into the new structures and the holistic care they seek to provide.

But they're not the only stakeholders working to map out how to enable new models of care and what their role should be.

Lee Outhwaite is finance lead for the Derbyshire Sustainability and Transformation Partnership (STP), as well as serving as director of finance for the Chesterfield Royal Hospital NHS Foundation Trust.

"Traditional approaches to partnership need to be innovated," he says. "There's a growing realisation that there are boundaries between some of the silos we've had that were not serving the interests of patients particularly well.

"The NHS currently is agonising over how to make its own partnership working better and I don't think we've got a monopoly on the truth of good partnership working in the NHS."

New ideas about healthcare attainment

Meanwhile, new ideas are emerging about how to help more of the population to reach a place of 'good health', and these are being led by a desire for more person-centred and value-based models of healthcare.

This sees the sector "transcending the concepts of primary and secondary care" and "creating a more porous boundary for information sharing between healthcare and social care for local governments", as Outhwaite notes.

In the NHS' Integrated Care Systems, for example, NHS organisations, in partnership with local councils, charities, community groups and others, take collective responsibility for managing resources, delivering NHS standards and improving the health of the population they serve. So far there are 18 such systems, but more are on the way as the NHS aims to have every area of England covered by an Integrated Care System by April 2021.

Through collaborations like this, Outhwaite says, NHS Trusts can optimise the resources they already have at their disposal and make the flow of patients into healthcare settings as efficient as it can be.

They also allow systems to make more nuanced decisions at a local level, taking into account variations in different regions, towns, or even neighbourhoods – all of which can have a level of autonomy and self-sufficiency with how they are able to care for populations.

One reason for this is that health outcomes can often vary greatly between different parts of a region due to factors like socio-economic groups.

"Taking Derbyshire as an example, we've found that the most poverty-stricken fifth of the local population is massively overrepresented in the care system," says Outhwaite. "But in a traditional system we would have had a blanket approach and would provide the exact same services to every economic group."

He says that some of the traditional NHS access pathways might look quite different if care could be considered in a much more granular way – which would in turn bring systems much closer to offering truly personalised care.

Of course, this will also require a rethink of how healthcare is financed – and Stephen Jowett, IQVIA's UK director of applied insights, explains that as integrated care becomes more commonplace, it could shift in traditional division between those that commission services and those that deliver them.

"Within the world of integrated care, you have to look at pooling the pot of money and spending it in a way that is best suited for the specific population you serve – not just giving a set amount to healthcare and a set amount to social care, etc.

"That allows you to harness the autonomy these organisations can have to care specifically for the needs of their local populations."

The potential of healthcare partnerships

These changes in approaches to healthcare provision will have important implications for the kinds of partnerships that pharmaceutical companies will need to bring to the table, and these may well be outside their usual ways of thinking.

"Integrated care systems have a responsibility to look at how they're caring for their population through a different lens, and that means the component parts of a patient's care journey don't necessarily sit just within a healthcare setting – they will venture into areas like social care and education," says Jowett.

"Pharma will need to start looking at collaborations in those areas if it wants to help holistically develop new systems that act at a subpopulation level to enable better outcomes."

Jowett says there is also a broader role for pharma in helping the NHS make all these new processes work smoothly.

"The NHS is typically very focused on the big challenges it faces day-in, day-out. Even before COVID-19, for example, the backlog of elective work was already an issue, and there's always going to be an element of prioritisation within the health service as it considers what it can justifiably focus on with the resources it has at its disposal.

"If pharma is able to take the expertise and innovation it demonstrates in specific areas – areas it may be more knowledgeable about than the health service – then the industry can potentially start to build capacity for the NHS to work in new ways.

"There is also the potential here for the NHS to look at innovations from pharma that it might not have considered before under a traditional care system, but are better suited to achieving more holistic goals – such as using information to address care inequalities by enabling wider and faster access to clinical research and innovative treatments, or optimising the diagnostic pathway.

"Historically the siloed care settings have created barriers to rapidly scaling innovative ideas or adopting the new ways of working needed for them to succeed. This can make it hard going when trying to bring the right people together who can help push things forward. Hopefully as care management becomes more integrated the case for change can be made from a perspective of commonly shared goals too, and as a result transforming the opportunity for partnerships that are intended from the start to enable change to take place at pace and scale."

Optimising healthcare data to transform care

A key connective tissue that will help these new types of partnerships to thrive and create more granular, personalised care will be smart uses of technology, analytics and data science. With the right tech and safeguards to protect individual privacy, systems can encourage and enable patients to better manage their own health, lowering the burden on healthcare resources and allowing for a more seamless journey through healthcare systems, as well as bringing us closer to truly person-centred care.

"We always talk about clinical decision support being something that clinicians use, but today we're almost moving towards 'citizen decision support' as we enrich data that helps us understand ourselves better via technologies such as wearables and smart devices so we can make small changes that can in the long run have a big impact on our health and wellbeing," says Jowett. "Technology could soon guide patients in an active way."

He notes technologies like AI powered chatbots are already helping people manage their symptoms without needing to interact with healthcare professionals. "That makes them more engaged and activated in their own care, which can lead to better adherence and ultimately better outcomes."

As technological engagement increases it provides vital opportunities for improving patient care, as Roche UK's partnerships lead Jessica O'Neill explains.

"The combination of meaningful health data, advanced analytics, and digital technologies are critical to enhancing personalised care. From enabling diagnosis and faster access to treatment to monitoring for early signs of progression, these tools are key to improving outcomes and ultimately people's lives."

This was particularly in evidence, Jessica says, during COVID-19's acute phase. "During the pandemic the NHS has been able to collate, analyse and visualise large volumes of data. This has helped better understand how the virus is progressing and target local strategies that are important in combating it. This acceleration in the use of health data may provide further opportunity for industry and health system partnership."

Having worked on enabling and leading healthcare partnerships at IQVIA, Jowett has seen that by bringing together data from different settings, systems can start to be more focused on which elements of the pathway will have the biggest impact for the largest part of the population.

"The parts of the country that have invested time, effort and resources into bringing together integrated data to support integrated care objectives have the foundations to see more success sooner," he says.

"If we can bring technology and data together and see which actions will drive the best improvement, we can make sure we provide those services in a format that can truly engage patients."

"Such partnerships are about helping the NHS have more informed choices in an evidenced way," adds Outhwaite. "In fact, I think in the future the value pharma can bring to the NHS will be less in the products it sells and more in the information it can provide."

Looking to the future

Although Jowett and Outhwaite say that the NHS' reorganisation around systems to care for populations is "well under way", there are many important steps that still need to be taken.

"It's going to be interesting to see what integrated care actually comes to mean in practice," Jowett says. "Even among people who work within this realm there's often a misconception that these are actually integrated commissioning systems that are being set up to manage financial elements of the NHS in a different way."

He says that IQVIA is actively working to help facilitate innovative partnership approaches, bolstering them with a focus on reducing confusion about the torrent of changes that are happening across the NHS.

"We need to make sure people are aware of what these changes are actually aiming to deliver," Jowett says. "Once we improve people's understanding and show them what these systems are going to enable, they'll be better able to work towards achieving greater population care."

Meanwhile, Outhwaite notes that to provide "legitimacy" to these new structures there needs to be legislation to back them up.

"That can help remove some of the barriers to partnership working that exist between statutory organisations such as commissioning bodies, primary care provision, and Trusts," he says.

Nevertheless, he says there is a "genuine belief" from the sector that this new level of partnership working is "here to stay".

"We know it will be more clinically cost-effective, and we have the evidence to show that working in an integrated way leads to better outcomes both in terms of the quality-of-service delivery and the cost of delivery."

With the right partnerships between healthcare, social care and industry, the entire sector will be able to support patients across their healthcare journey – from better diagnosis and greater access to innovative medicines, to improved treatment pathways and, ultimately, better outcomes.

About the interviewees

Stephen Jowett, director, Applied Insights UK & Ireland, IQVIA

Stephen leads IQVIA's Applied Insights business in the UK&I. These teams are dedicated to helping pharma and NHS clients to understand the practical barriers that exist to improving treatment access and patient outcomes via experts in market access strategy, advanced analytics and service transformation. Since the turn of the century Stephen has been immersed in technologically enabled change aligned to continuous improvement at the front-line of care, firstly within the NHS itself, the services division of Dell Technologies through to the Expert Practices team at Unipart.

Lee Outhwaite, director of financing and contracting, Chesterfield Royal Hospital NHS Foundation Trust

Lee joined Chesterfield Royal Hospital in August 2017. His role covers Finance, Procurement, Estates and Facilities, ICT and the Chesterfield Royal Hospital Charity. He also is the director of Finance for Joined Up Care Derbyshire (the Derbyshire STP). Lee has worked in the NHS since 1993, in a number of finance roles. He sits on the Council of the Chartered Institute of Public Finance and Accountancy and is Vice Chair of their Health and Social Care Faculty Board.

Lee is a Trustee of the Healthcare Financial Management Association (HFMA) and sits on the awarding body of HFMA's qualification Policy and Research committee. In addition, he is also currently pursuing a Professional Doctorate at Keele University, in their Public Policy and Management faculty.

Dr Jessica O'Neill, partnerships and personalised health lead, Roche in the UK

Jess leads the Partnerships team for Roche UK, focused on working together with stakeholders across the UK healthcare system with a common aim to improve patient outcomes. Jess holds a PhD in translational neuropharmacology from University College London, and previously worked in strategy consulting supporting collaboration between industry and global health systems to ensure innovative technologies are utilised to their full potential.

About the author

Dominic Tyer is a journalist and editor specialising in the pharmaceutical and healthcare industries. He is currently pharmaphorum's interim managing editor and is also creative and editorial director at the company's specialist healthcare content consultancy pharmaphorum connect.

Connect with Dominic on LinkedIn or Twitter

About IQVIA

IQVIA is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. Powered by the IQVIA CORE™, IQVIA delivers unique and actionable insights at the intersection of large-scale analytics, transformative technology and extensive domain expertise, as well as execution capabilities. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 68,000 employees worldwide.

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Evidera | PPD

A collaborative approach to greater diversity in clinical trials

The need for diversity in clinical trial populations has been a topic of discussion across regulators and the industry in general for decades. Despite the introduction of US policies, beginning with the 1993 National Institutes of Health (NIH) Revitalization Act which called for the inclusion of more women and communities of colour in clinical trials, clinical trial data has remained largely based on healthier Caucasian subjects with minimal representation from minorities (African American, Latinx, Asian, Native Americans), the elderly, young, and those with co-morbidities.

To encourage more of a focus on clinically relevant populations, the US Food and Drug Administration (FDA) recently released "Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry" to increase participant access to clinical trials and the enrolment of underrepresented populations to ensure clinical trial data reflects the population most likely to use the drug if approved[1]. The guidance encourages sponsors to remove overly restrictive and legacy exclusions, broaden protocol eligibility criteria, and improve trial recruitment practices so trial data is clinically relevant for the end user.

Historical performance data, like that provided in FDA Drug Trials Snapshots, has shown that using traditional recruitment practices by themselves does not enhance the diversity of clinical trial populations. Fundamental barriers and deeply rooted mistrust of medical research motives among communities of colour require a more thoughtful and deliberate approach to participant outreach. PPD has seen recent successes in the recruitment of more clinically relevant trial populations through the implementation of patient-centered trial solutions designed to address the most common barriers to clinical trial participation among these diverse patient populations – mainly trust, understanding, awareness, access, time, and cost, especially when delivered in collaboration with organisations focused on communities of colour and community leaders to ensure optimal receptivity.

The issue of diversity in clinical trials spans all indications and geographies, though it is a bigger concern in the US due to the variability in healthcare, and health status, as a result of race, ethnicity, age, and social determinants. This has been further exacerbated by the COVID-19 crisis, which has forced many of these topics into the public spotlight with the development of vaccines and treatments providing hope of a return to normalcy. As the US moves closer to having approved vaccines and treatments for COVID-19, there is consensus that the data supporting regulatory approval must demonstrate safety and efficacy for representative populations that would receive the vaccine or treatment when approved. The disproportionate impact the pandemic has had on African Americans, Latinx, the elderly, and those with co-morbidities underscores the need for sufficient representation of these populations in the development of COVID-19 vaccines and treatments to ensure the data collected is relevant for the larger US population when approved.

To put this in perspective, US Census Bureau data from 2019 and the Centers for Disease Control (CDC) data through October 2020 show that African Americans make up 13.4% of the US population but represent 17.4% of COVID-19 cases and 21.0% of COVID-19 related deaths. Similarly, the Latinx population represents 18.5% of the US population but 29.4% of the COVID-19 cases and 17.4% of the COVID-19 related deaths[2]. With African Americans and Latinx populations experiencing higher incidences of COVID-19 positive cases and deaths, one might expect higher representation from these groups in current COVID-19 trials, which was not initially the case. Clearly, in order to ensure a clinical trial population represents the population of interest, a more thoughtful and deliberate approach to recruiting a truly representative sample is required to ensure optimal clinically relevant safety and efficacy data.

Effective implementation of diversity and inclusion in clinical trial populations requires a collaborative and holistic approach, as well as a willingness to learn from past experiences. Leveraging patient-centric solutions combined with data and technology collaborations is critical. At PPD, recent successes and working with highly motivated external partners have been important tools in framing best practices to help us reach and enrol more diverse trial populations into the studies we are conducting.

Leveraging data and technology

Building an effective and diverse recruitment strategy starts with understanding the profile and demographics of the target population. Who are the end users of the drug if approved?

Using a combination of data sources and subject engagement practices can help understand the nuances of the participants being sought for enrolment. Again, referring back to the COVID-19 example where there is a disproportionate impact on African Americans, Latinx, and elderly populations, recruitment strategies need to include a higher percentage of volunteers from these groups.

At PPD, we leverage data to support site and patient recruitment strategies to help us identify the right sites or intentionally place sites in areas ideally suited to support enrolment of the target population. Through AES, a business of PPD providing site and patient recruitment services, we are able to leverage a database of fully identified and pre-consented subjects, 10 million of whom have provided self-identified race/ethnicity information, to reach individuals from diverse populations with trials who have already demonstrated a willingness to participate. In addition, protocol optimisation and/or virtualising clinical trial design can significantly broaden eligibility and access for participants leading to faster recruitment with greater diversity in clinical trial populations. Experience has shown that incorporating a decentralised trial design can deliver 30-60% of participants from underserved communities versus the 2-10% seen in traditional trials[3,4].

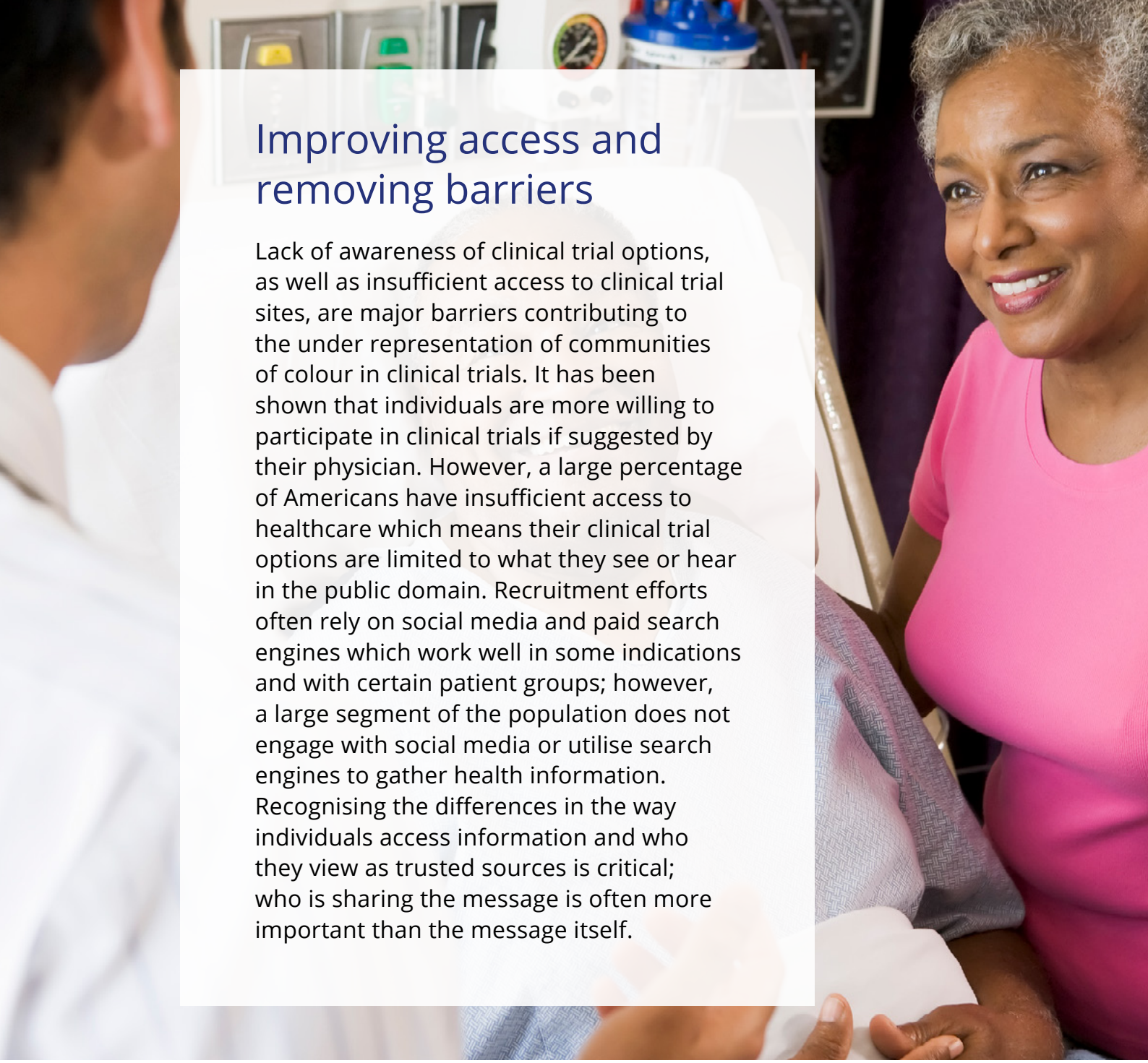
Building trust while increasing awareness and understanding

Traditional social determinants of health equity are wrought with bias and a historical lack of applied ethics. In order to successfully bolster more diverse participation in clinical trials we must first acknowledge the role history plays in the mistrust – if not outright distrust – of those populations when approached about participating in a clinical trial.

Certain communities of colour remain sceptical about promoting participation within their communities when social contracts such as the Tuskegee Syphilis Experiment and Havasupai Diabetes Project are still top of mind. Thus, any meaningful collaboration within the African American, Native American, and Latinx communities must balance this history with the need for diverse representation in clinical trials. This balance will require age-relevant and culturally competent educational materials to reverse the lack of health literacy that exists, an effort to engage with community leaders to foster greater awareness and to build trust, and an openness to study design. Over one-third of the adult population in the US is unable to understand and navigate the healthcare system adequately to make educated healthcare decisions or act upon a physician's instructions[5]. Half the population cannot read above 8th grade level, yet most health resources are written at an 11th grade level, often with little regard for readability scoring metrics or the importance of visual design[6]. These statistics, and others, have led to delays in recruitment, trial leakage, and underrepresentation among key segments of the population.

PPD has partnered with Jumo Health, a private company that focuses on health literacy, to create customised patient recruitment and retention materials that foster greater understanding of clinical trials and study specifics using videos and other visual aids to reinforce the written word. Jumo Health uses experts in the development of educational resources that reflect the target population to ensure potential participants can see their likeness in the materials presented, and provides age-appropriate, culturally sensitive materials in multiple languages that explain the "core four": 1) clinical trials; 2) the specific medical condition; 3) informed consent; and 4) the study protocol. Resources are prepared by age cohort, written by doctors, and have the added benefit of peer review. The range of media includes comic books, animations, and videos to name a few.

In providing insight for this article, Kevin Aniskovich, CEO of Jumo Health states, "We can successfully engage, build the required trust, and enrol a diverse population by focusing on the 'core four.' We educate through storytelling – words matter, but stories of hope and inspiration can motivate. This can be anything from ensuring Henrietta Lacks is widely known, to activating participants to share their experiences." Jumo Health has collaborated with a variety of stakeholders that leverage existing community action networks focused around specific indications and communities of subjects, most recently in connection with the Operation Warp Speed efforts that seek to find therapeutic treatments and vaccines to treat COVID-19. Examples of Jumo Health's work in action are available at RiseAboveCOVID.org.

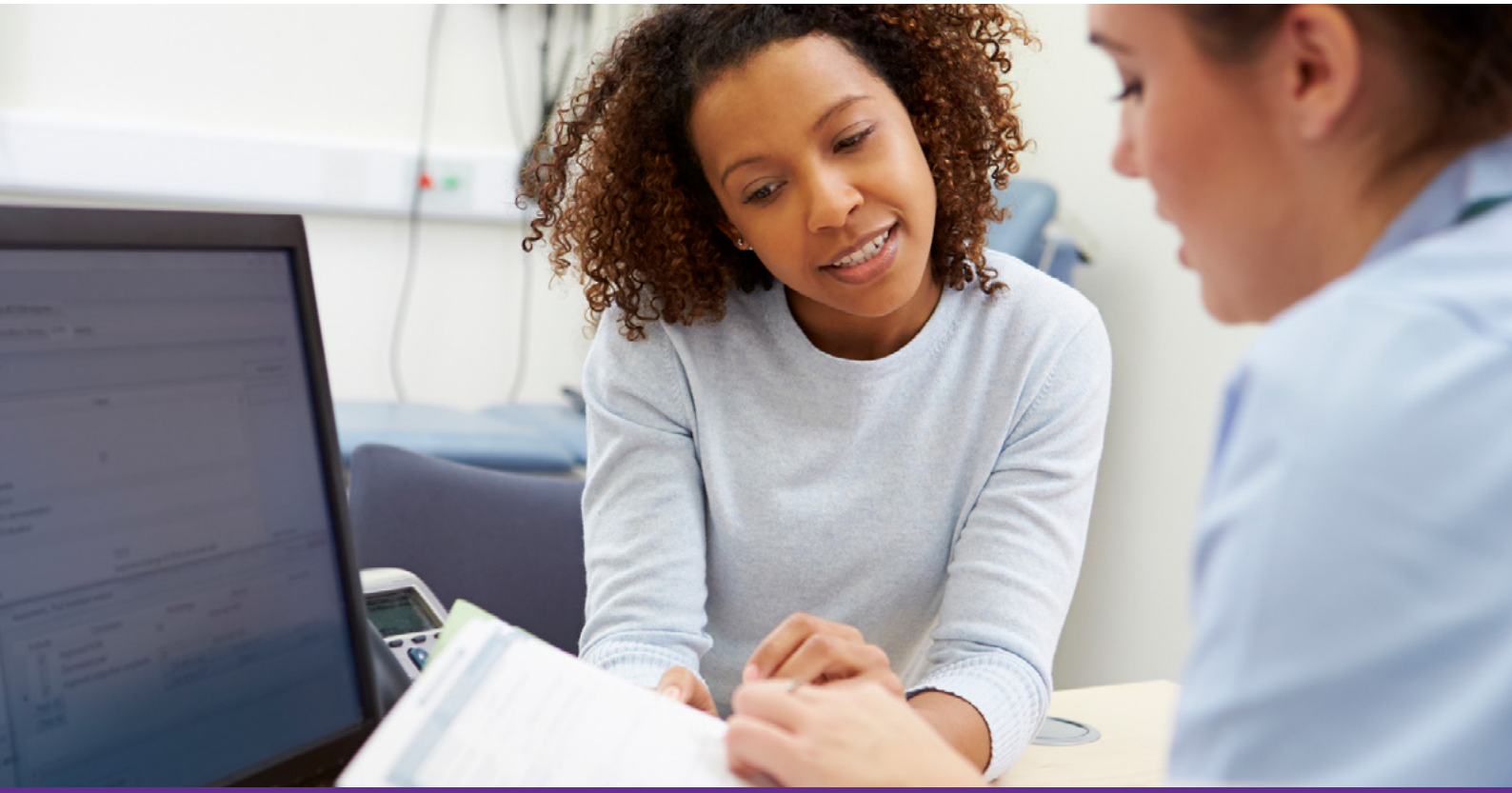


Improving access and removing barriers

Lack of awareness of clinical trial options, as well as insufficient access to clinical trial sites, are major barriers contributing to the under representation of communities of colour in clinical trials. It has been shown that individuals are more willing to participate in clinical trials if suggested by their physician. However, a large percentage of Americans have insufficient access to healthcare which means their clinical trial options are limited to what they see or hear in the public domain. Recruitment efforts often rely on social media and paid search engines which work well in some indications and with certain patient groups; however, a large segment of the population does not engage with social media or utilise search engines to gather health information. Recognising the differences in the way individuals access information and who they view as trusted sources is critical; who is sharing the message is often more important than the message itself.

Collaborating with organisations like ClinArk can help create greater awareness of clinical trial options among underserved groups through community engagement. ClinArk is a minority-owned organisation, dedicated to helping all communities gain access to clinical trials through a grass-roots approach to building trust within underserved communities. “We know the importance of building trust in the community before running your clinical trial. We work with advocacy groups and interact with community leaders and trusted organisations to help drive greater awareness of clinical trials,” said Adam Brown, founder and CEO of ClinArk, in a discussion about this article. “When ClinArk takes on a project, we involve the community in everything we do. We hire staff from the communities we serve which is important because we are creating opportunities for individuals that may never otherwise hear about clinical research.” In doing so, ClinArk contributes both to the diversity of clinical trial participants, as well as diversity in the clinical trial workforce.

There are many socioeconomic factors that are more prevalent among communities of colour and create barriers to clinical trial participation. Removing as many of these barriers as possible is important to improve diverse patient participation in clinical trials. Incorporating home healthcare options and providing transportation and reimbursement are all solutions that minimise the burden of trial participation. Additional considerations should include asking sites to offer after-hours appointments to minimise time away from work, patient stipends to compensate for time and childcare, and offering concierge services to personally assist participants in navigating the complexities of clinical trials, foster ongoing engagement, and improve retention.



Partnering with best-in-class providers can make the difference in deploying integrated, patient-centric solutions that make it easier for all individuals to participate in clinical trials, but critically important to certain subsets of the population. We have a deeper appreciation of barriers to achieving greater diversity in clinical trials through our own experiences as well as from our collaborations with stakeholders, community leaders, motivated advocates, and expert organisations. Recent success will only help us to continue to evolve best practices, as well as grow our network of experts to support education and awareness, build trust, and enable greater access to clinical trials. We are committed to making clinical trials as care options more accessible to all individuals which will drive more diversity in enrolment, as well as ensure safety and efficacy data are clinically relevant.

I would like to acknowledge Kevin Aniskovich, CEO of Jumo Health, for his professional insights and review of this article.

About the author

As vice president of patient-centered trials at Evidera, a PPD business, Rhonda Henry leads the group responsible for providing customised patient-centric strategies to engage, recruit, and retain diverse trial populations throughout the life of a clinical trial, as well as enhancing the patient experience. As part of the Patient-Centered Research team, Rhonda works with key stakeholders internally and externally to bring the voice of the patient into drug development, as well as make it easier for both sites and patients to participate in clinical research. As a breast cancer survivor, creating greater access to clinical trials and removing potential barriers to participation for all individuals remains a key area of focus for Rhonda and her team. Currently, Rhonda leads a cross-company advisory board aimed at engaging with patients and caregivers as partners in the clinical research process. She is a board member for two non-profit organisations, the Carousel Center and Flunk Cancer and was named by PharmaVoice as one of 2020's 100 most inspiring individuals in the industry.

About Evidera

Evidera, a PPD business, is a leading provider of evidence-based solutions to demonstrate the real-world effectiveness, safety, and value of biopharmaceutical and biotechnology products. We help companies generate the evidence needed to optimise the market access and commercial potential of their products.

We provide integrated and tailored scientific expertise and global operational capabilities. Our offerings include interventional studies, real-world evidence, data analytics, patient-centered research, epidemiological studies, modelling and simulation, literature reviews and evidence synthesis, market access consulting and communications, and medical writing. Our staff has contributed to hundreds of payer/regulatory submissions and has published more than 2,400 peer-reviewed articles.

To learn more, visit evidera.com.

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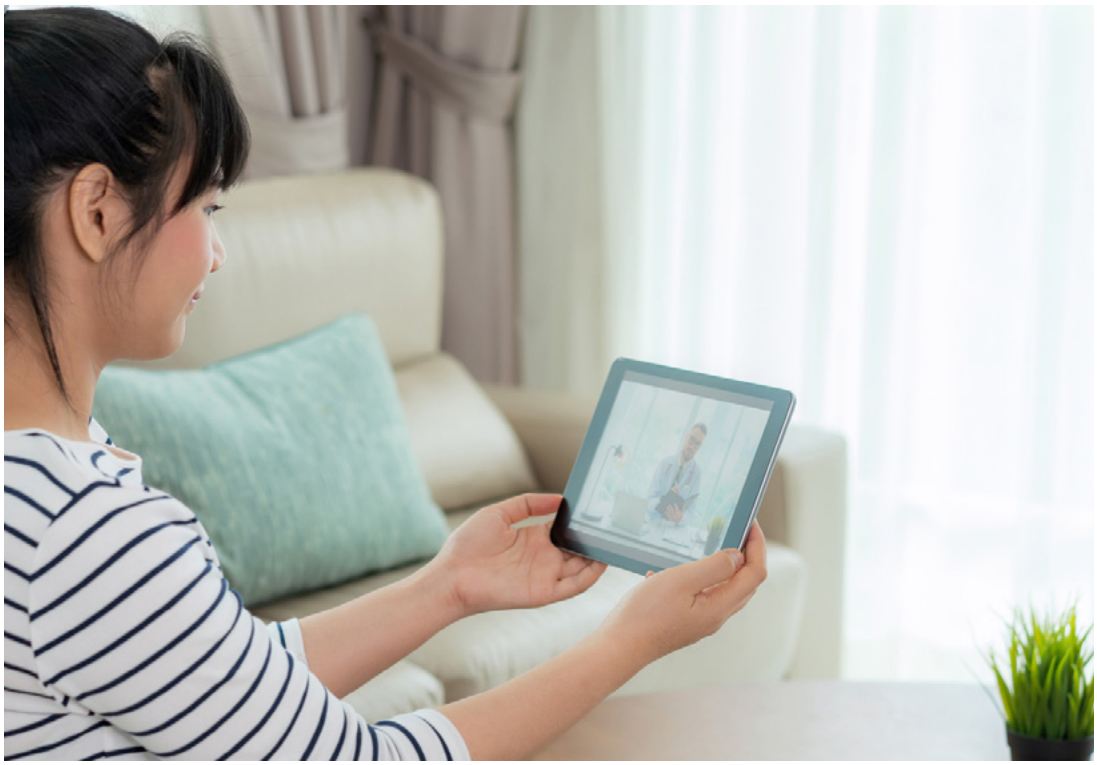
Patient journeys in the era of COVID-19

OPEN Health's Richard Jones and Sumira Riaz assess the pandemic's implications for understanding patients' experiences and how the pharma industry can support them.



It's impossible not to view healthcare in 2020 through the lens of the current global pandemic and COVID-19 is certainly set to cast a long shadow over patient needs and engagement.

Even when the virus is tamed, and recent advances with vaccines are grounds for much optimism, the huge societal and healthcare changes that we've seen take place this year will undoubtedly have left their mark in all sorts of altered, and new, approaches.

The way in which patients make their way through the healthcare system has shifted enormously, bringing disruption to the patient experience. COVID-19 has driven massive uptake of different types of digital support and interventions, most notably with telehealth.

Patients are now being trained remotely on the use of subcutaneous injections rather than nurses having to go to patients' homes, and telehealth is also being used more commonly now for treatment reviews and routine appointments that don't require face-to-face visits or any kind of inspections.

The rising adoption of digital technology is producing a significant and fundamental increase in the digital patient journey, and that's going to continue.

As more and more data emerges about the impact of COVID-19 and how patients, and healthcare professionals, are managing during the pandemic, there is sure to be more to learn about how patient journeys are changing. For now, here are three standout lessons for patient journeys in the era of COVID-19.

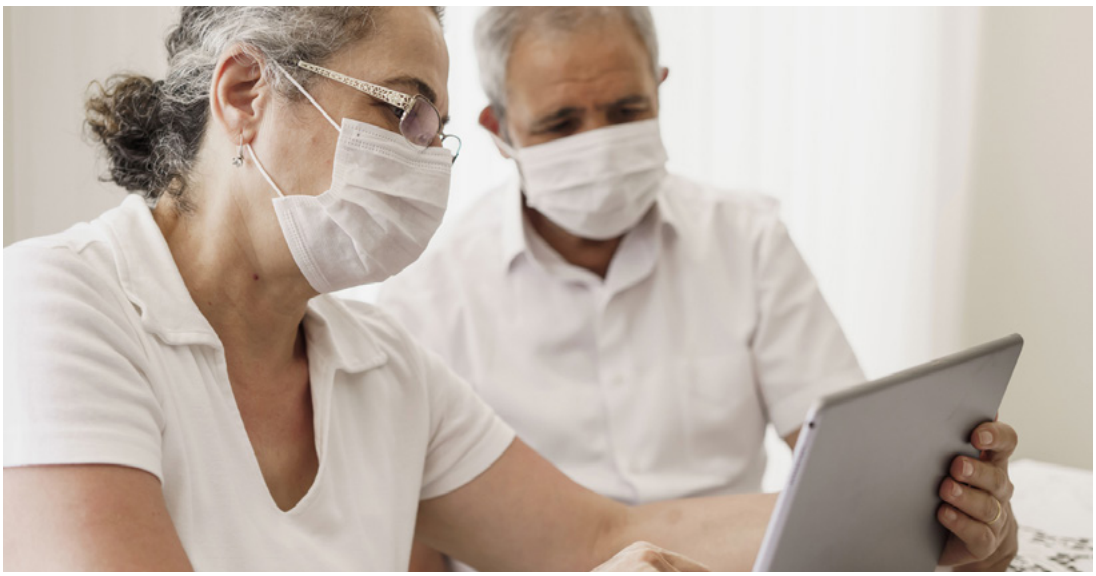
Lesson 1: Take a patient-centric approach

As patients are increasingly involved in their healthcare decisions they have become empowered and informed data-driven advocates of their own health. A patient-centric approach starts with patients being involved with defining the unmet need and acknowledges that they are experts in their disease.

So, when creating a patient journey it's important to take a 'mixed-method' approach, that combines both qualitative and quantitative insights.

Quantitative data tends to align naturally around the clinical transactional process and allows pharma companies to identify what patients' clinical steps will be, while qualitative research brings forth the narrative story from patients as well as from healthcare professionals.

There is a lot to be learnt from the qualitative data in particular, whether it comes from market research, interviews with patients and healthcare professionals, literature reviews or social listening. Once gathered, it provides a foundation for the understanding that's needed to start to develop traditional and digital journeys.



From there digital patient personas can be created around the different profiles or personas of patients that are involved in a digital journey, and that can be immensely useful for building a picture of patients, their behaviours, the information channels that they use and the support that they need.

However, to achieve a rich understanding of the patient journey it's necessary to move beyond research and approach it from both a clinical and an emotional perspective. We try and identify the journey that the patient takes during their disease progression and clearly understand and identify where the touchpoints and areas of unmet need for support exist.

This requires a very collaborative process, working closely with patients and patient advocacy groups, to help populate the journey. It is always illuminating when you 'stress test' where the touch points are, what support is currently provided, who patients talk to, who they turn to for support and what additional support needs they have. This sort of approach has proved to work really well in a multi-numbered group where you might be co-creating with four to eight patients, patient advocates or carers. From there, a really rich picture begins to emerge of the true challenges that patients face as they navigate a particular disease course.

The co-creation element of this work is absolutely fundamental. However much research and analysis is done, it's not until companies talk to patients who are living with a particular condition that they can truly get a rich understanding of the patient journey. It's only by working with patients, carers and patient groups that the really insightful touch points along the journey begin to be revealed.

Furthermore, the importance of developing personalised patient journeys cannot be overstated. Assumptions are often made that a patient with a certain disease will require a standard set of information to help them feel more educated or empowered, but all of our needs are so very different from those of our neighbours, and this individualisation must be brought into pharma's work on patient journeys.

One-size-fits-all is not a suitable approach for patient journeys, where companies should be looking for types of services that can be adaptable for different patients. There's a fine balance to be struck around wanting to empower patients through the use of digital interventions and supporting more traditional approaches. For some patients, the additional control of tasks such as scheduling will be welcomed, but others will certainly need to regularly see their doctor and absolutely rely on the face-to-face support and real human contact those appointments bring.

Lesson 2: Combine traditional and digital patient journeys

To fully understand the patient journey, traditional and digital journeys must be combined. Digital patient journeys are an increasingly important way of approaching this subject, but they are also just one channel.

Pharma companies might typically view the patient journey in terms of being solely a transactional clinical journey that seeks to try and understand the pathway of a patient moving through a healthcare system. But a more up-to-date approach would be one that seeks to create non-traditional journeys that layer traditional best-practice journeys with the psychological-emotional experience of a patient.

Today's patient journeys are about far more than which doctor or pharmacist a patient sees. They're about the impact different touchpoints have on an individual. For example, what barriers exist for a patient to even get to the pharmacy?

Particularly now, with all of the huge environmental changes that COVID-19, with its social distancing, lockdowns and other restrictions, has brought, achieving a holistic perspective on patient journeys is vital. The healthcare landscape has seen huge levels of digital transformation and the rise in digital interventions that can support patients and physicians, such as telehealth, has been striking.

Looking at the UK as an example, the NHS has rapidly adopted digital technology in the wake of the pandemic as COVID-19 forced significant changes upon the way health services were delivered. The drive to free up hospital capacity and reduce infection transmission risks in NHS settings saw a surge in remote health services. Primary care was quickly refocused, wherever possible, on remote appointments, and patient uptake of services such as the NHS App and e-prescriptions. The scale of these changes, and the incredible pace at which they have occurred, have massive implications for the patient journey.

The pandemic has forced the healthcare sector to find, and adapt to, digital health solutions that can support patients and their families. It's enabling fundamental shifts in the way patients and health systems engage, suggesting that things like a two-hour drive to see a doctor might not always be necessary. The changes that we've seen put in place, and the acceleration of existing digital solutions, are building a new type of healthcare environment, one that is probably going to be maintained and sustained for a long time.

Lesson 3: Map the patient journey

The reliance on digital media to engage, provide healthcare information and support patients through the COVID-19 pandemic and beyond means that it is increasingly important to understand and map the digital patient journey.

Pharma companies need to understand patients' interactions with the digital world, the nature of which means that data should have a primary role in mapping the patient journey.

Data can show whether people are disengaging or engaging with healthcare services and how HCPs and other stakeholders can intervene to support patients to find a way to continue their journey.

A number of the elements required to construct a patient journey can all too easily be invisible, but where patients are perhaps unable to really express how an experience is for them, data can definitely interpret disengagement and engagement as well.

The beauty of digital patient journeys is that most of the data required to fill it in is out there in one form or another. Following an evidence-based process for building patient journeys offers a structured way of looking at the available digital data that's already out there from patients. This can be bolstered by using approaches such as social listening and online landscaping to better understand where patients are going in a digital world for their information and advice.

Developing a patient journey map is hugely valuable and requires a holistic approach that brings together the digital journey and the traditional clinical journey so that clinical and emotional perspectives can be most effectively combined.

It's so important to have both sides of the story and to be able to understand the impact that it has on an individual's healthcare and their clinical experience, whether that's within the healthcare setting or external from it. How patients are at home and at work, for example, must be taken into account if pharmaceutical companies are to best support patients in a holistic approach beyond the medicine.

Applied learning

The way that healthcare systems, and patients too, have been forced to respond to the COVID-19 emergency has fundamentally changed the patient journey.

It is, therefore, vital that pharma companies understand the totality of the new touchpoints that digital health – and traditional healthcare – create and apply these learnings, and the lessons above, to tackling areas of unmet need for patient support.

In doing so this will ultimately allow pharma companies to develop better interventions for patients, support healthcare professionals and improve patient outcomes. In the era of COVID-19, there has never been a better time to take a patient centric approach with patient journeys.

About the authors

Richard Jones, managing director, patient engagement, OPEN Health

Richard is a highly successful, commercially astute leader and problem solver with a proven track record in senior roles in the pharmaceutical industry and healthcare agencies. Richard combines 20 years' commercial pharmaceuticals knowledge from GSK, AstraZeneca and Pfizer with 10 years' specialist agency experience. This unrivalled pedigree enables Richard to quickly understand his clients' business and offer innovative, differentiated and effective solutions. A senior executive, comfortable at operating strategically, above practice and respected by C-level customers. Richard has a passion for crystallising issues on patient engagement and developing innovative and effective solutions.

Dr Sumira Riaz, head of health psychology and research, OPEN Health

Sumira is a Chartered Psychologist, Registered Health Psychologist, Cognitive Behavioural Therapist. She has 16 years of experience working within the NHS, charity sector and healthcare agencies. Sumira is also part of the chronic pain team at the Royal National Orthopaedic Hospital, previously at Milton Keynes University Hospital. Here she works with patients diagnosed with pain and other mental health conditions such as depression and anxiety. Trained in Cognitive Behavioural Therapy, Sumira has accumulated 500+ clinical hours and understands the difficulties faced by people experiencing mental health and the complicated pathways when accessing help and support.

About OPEN Health

OPEN Health is a family of expert practices working in partnership to drive positive change in medical communications and market access, globally. Our journey began with a vision to improve **the lives of patients worldwide**. This vision has become a reality with the integration of experts from Pharmerit and Peloton Advantage to create a new unique entity equipped to be a global leader in HEOR, market access, advertising, medical communications, and digital services. Together, we have grown to over 700 people in 15 locations across 6 countries including the United States, United Kingdom, Netherlands, Germany, India and China.

What makes us unique is our **deeply** integrated practices that work collaboratively to bring the strategic and technical expertise needed to be a solid partner to our clients. Combined with our **broad** scope of therapeutic expertise, we produce results and solutions that are of the highest quality. OPEN Health prides itself on having a highly skilled, diverse and **connected** team working across the globe to deliver truly innovative and best-in-class solutions. This has resulted in long-term, flexible partnerships that span across multiple brands and therapy areas.

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Patient partnerships: putting relevance into relationships

There are perhaps two ways to look at 2020 – on the surface, it has been a year of pandemic health catastrophe, on a deeper level it has been a year where we finally acknowledged the fragility of health partnerships and the importance of good relationships between the pharmaceutical industry and the patients it serves.

‘New normal’ – on warp-speed

In the past decade, industry has been moving away from a transactional engagement model and towards one more based on collaboration and conversation. We arrived into 2020 with the vision and enthusiasm that a new decade offers to find that as a sector committed to a collective global health endeavour, we suddenly had to work much more openly and cohesively to problem-solve for people infected with coronavirus and to help to shield people with chronic conditions rendered even more vulnerable to the impact of reduced access to treatment and supportive care. That endeavour became essential; it became necessary to build partnerships that are not defined by the volume of the interactions but instead by the value that each interaction brings to all of the stakeholders.

Value over volume

At NexGen we have always focused on bridging new partnerships between patient groups and pharma experts. Our role is to facilitate common ground so that patients’ voices and needs are expressed to the right people within pharma and that the right people within pharma are equipped to ‘actively listen’ to those needs.

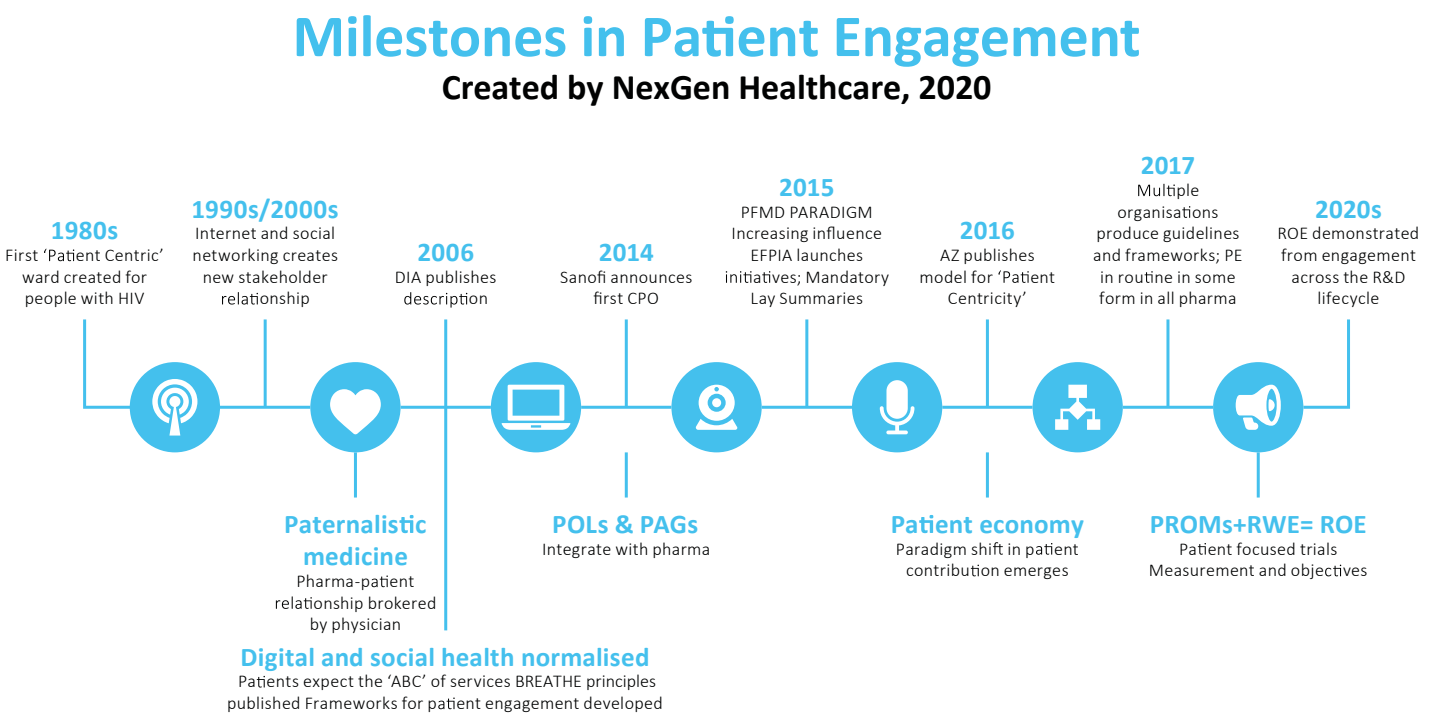
"What happens when effective patient engagement becomes the Standard of Care?" – *Kish, 2012*

Superficially, that might seem a little puerile – after all, opinion leaders should be adept in expressing their opinions and pharma experts should be eager to hear what leaders have to say. But the reality is that very little communication is verbal, and opinions are formed within milliseconds of meeting someone new (the subconscious is primed for survival – can I trust this person?) – so a 'virtual visual' through the default to online meetings due to COVID could have hindered us all in the 'business' of building patient engagement partnerships.

Fortunately, the concept of 'value over volume' (in both senses of the word – numbers and loudness) has been fermenting into the patient engagement organisational psyche for several years (see Figure 1 for an overview of milestones in pharma-patient partnerships).

Pharma has invested significantly in creating 'active listening' research and infodemiology platforms and integrating the insights from those across all aspects of the pharma development pipeline. This has naturally extended to the provision of patient platforms and services that enable the value of the patient voice to be heard. Even the quiet ones!

Figure 1. Chronology of building enduring pharma-patient relationships of relevance



"Can you imagine if a drug* reduced the need to go to the hospital by this amount? Again, it would be considered malpractice not to use it" – *Kish, 2012*

*comparing standard use of statins to standard use of a care programme of patient engagement in a Kaiser study of coordinated cardiac care, which demonstrated coordinated care patients have an 88 percent reduced risk of dying of a cardiac-related cause when enrolled compared to those not in the programme

Putting relevance into relationships

In 2012, Leonard Kish, a health information technology consultant, postulated that "patient engagement is the blockbuster drug of the century". As such, it would be reasonable to assume that all patient engagement and partnership programmes would be underpinned by a strong development strategy and appropriate investment. After all a blockbuster drug doesn't make it through the R&D pipeline without a concerted company-wide collaboration. Surprisingly, the data from the progression of this particular blockbuster drug has been slow to emerge.

This has been a catch-22 for everyone working in pharma-patient engagement. Partnerships simply don't develop nor do they deepen without investment efforts (time, knowledge of impact and money) but until partnerships are proven to work, securing investment is difficult. Where to begin to ratify the relevance of relationships?

This year we launched an initiative to help our clients build such internal relevance for ratification. Under the heading 'Peer2Peer' we were supported by industry leaders in patient engagement who not only signed up to the collaboration to share cases studies and examples of good practices but our partner colleagues in pharma agreed to a series of 'Fireside Chat' interviews in which they were completely candid about the obstacles to secure internal buy-in to patient engagement programmes.

In every conversation, the relevance of the insights gained from strong patient partnerships to improve multiple business objectives for pharma was highlighted. Furthermore, two Peer2Peer workshops reviewed the evidence emerging to be able to demonstrate ROI from patient partnerships. Further consultation with individual Peer2Peer members and with patient partners was able to generate a summary of the business relevance of patient partnerships as directly improving all aspects of the following:

- Finessing R&D priorities
- Product and service design
- Patient engagement as a unique commodity/therapy
- Stakeholder interactions
- Product approval and access
- Pharma's role in global healthcare infrastructures
- Global sustainability efforts
- Improving organisational psyche.

Specifically, the 'ROI' of patient partnerships translates into actual business relevance according to two pivotal studies:

1. Compared with an investment of $100,000 in patient engagement, the NPV and ENPV increases can exceed 500-fold the investment (Levitan, 2018)

2. One-year cost savings from these provisions of patient services and interventions were $153,800 with an ROI of 14.79x. (Brixner et al, 2019).

This is a 'relevance' equivalent to accelerating a pre-phase 2 product launch by 2½ years, 22% lower discontinuation rate, 29% higher adherence and 35% reduction disease-related medical costs. As a return on investment – these are compelling figures for any pharma CSO, CMO and CFO.

Partnerships require persuasion

Although it may be coarse news to patients, the 'real world experience' is also a harsh truth inside pharma walls. Any patient partnerships that lack a business, clinical or real-world relevance return are simply redundant to pharma. Tough times call for tough decisions and honest partnerships run on trust. As we enter a post-pandemic world, therefore, we will all need to keep facilitating partnerships that generate insights for both patients and for pharma because both the medical and the business needs need to be heard and understood. The psychology of persuasion applies here. In 1958, Krugman asserted that it takes three 'exposures' to information to spark awareness, curiosity and a decision; Miller's Rule of Action says consumers need to hear a message seven times before considering purchase. And Smith claims it took 20 exposures to a message before buying a product.

On repeat therefore – patient relationships need to be relevant to pharma based on the insights they provide. And those insights need to inform patient-partner strategy that will deliver better products, services and healthcare solutions for the continuing business of medicine.

About NexGen Healthcare Communications

NexGen Healthcare Communications provides medical communications that create value for clients, healthcare professionals and patients.

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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Medscape EDUCATION GLOBAL

COVID-19 – Delivering a pandemic of change to digital medical education

As the world of medicine continues to deal with the impact of the COVID-19 pandemic, clinicians are moving to digital solutions. Adrian Duncan dives into research into the power of digital communication to see how they could be most effectively used to improve public health.

Even as some locations move forward in their reopening plans, the shift to digital events and virtual education options are expected to continue far into the future. The move to digital by clinicians looks more than temporary – 93% of physicians expect to use digital tools for clinical-decision support, and 90% of clinicians expect to use digital learning solutions to the same or a greater extent even after the COVID-19 crisis passes.[1]

A major change in the medical community has been the transformation of live conferences and events into virtual events. A majority of physicians (60%) expect that they will not attend live meetings for more than one year, and 64% of physicians say they are likely to participate in an online version of a national meeting.[2]

While this switch presents a change to how clinicians are accustomed to learning and staying current on practice guidelines, there are new opportunities realised with the shift to virtual conferences. With virtual, many of the barriers that clinicians faced with conference attendance — cost, travel, time away from practice — are less of a factor in participation. Virtual events provide an increased level of convenience and accessibility.

The big downside for many with the switch to virtual events is the lack of one-to-one interactions with peers. However, while face-to-face peer interaction is reduced, virtual platforms can provide a chance to interact with clinicians beyond the usual geographic boundaries and core specialties. The inclusion of interactive tools and collaborative opportunities to foster that connection and network can really elevate the congress experience for global attendees.

Digital CME

In the same way that events are moving to digital, clinicians are embracing digital certified Continuing Medical Education (CME) as well. Seventy-four percent of physicians agree that online CME is more important for clinical practice during the COVID-19 pandemic than it was previously.[2] Digital CME is powerful in its ability to be flexible and accessible in a way that allows clinicians to learn on their own terms and incorporate education into their busy practice schedules.

"CME is the most trusted form of information for healthcare professionals due to its rigorous learning and content design," says Christina Hoffman, group vice president of quality and strategy at Medscape Education. "Physicians also value digital education because it is flexible and accessible, allowing them to learn in their own time and in their preferred format (online, video, audio, mobile, etc.), and to fit education into their busy practice schedule.

"It has the specific ability to provide 'just in time' learning — a feature unique to digital platforms. Digital CME is available when and where physicians need it, providing them with the education that is most relevant to their practice.

"This is even more in the spotlight in our current environment as live education options are limited, and research shows this will continue after the COVID-19 pandemic is well in hand."

The power of digital CME

Digital education has the potential for strong reach and accessibility, but what is the effectiveness of digital education solutions on the learner and ultimately, patient outcomes? A 2020 peer-reviewed study published in collaboration with the FDA sought to investigate the power of such digital education to positively impact public health.

The study examines the efficacy of targeted short form messaging and CME aimed at reducing overprescribing of fluoroquinolone antibiotics.

In 2014, five percent of all fluoroquinolone prescriptions in the United States were given for conditions for which no antibiotics are indicated, and 20% were given for conditions for which fluoroquinolones are not recommended in first-line therapy, including 6.3 million for sinusitis and UTIs and 1.6 million for viral respiratory tract infections and bronchitis, where the risks to the patient outweighed the benefits of the medication.

This is particularly concerning because fluoroquinolones are associated with a range of disabling and potentially irreversible adverse reactions, including tendonitis, peripheral neuropathy, suicidal thoughts, decreases in blood sugar and attendant risk for coma.

The researchers recognised this gap in physician knowledge around proper treatment and saw an opportunity for better communication and education. Traditional forms of physician feedback that include showing clinician behaviours are consistent with what their peers are doing seemed to only provide moderate effects.

The large study examined nearly 24,000 high prescribers of fluoroquinolones and divided 11,774 into 3 treatment groups to evaluate and measure the efficacy of targeted short form messaging and CME aimed at reducing their overprescribing of these antibiotics.

Group 1 received short-form targeted messaging only (n = 8,895). A second group received CME activity only (n = 1,756) and a third group received both short-form targeted messaging and CME (n = 1,123). A case-matched control group was also included (n = 11,774) and results were stated against that comparator population.

Hoffman, who was one of the study authors, says that to deliver these messages, the researchers followed the best practices of short form content delivered to a specific audience.

"The messages needed to be concise, read in as little as two minutes, and not require a time-consuming amount of critical thinking," she says. "Short form messages are typically 400-600 words long. We tested short form messages in email, as well as in web and mobile alerts, to select the most effective messages to use in the study and compared these to the impact of CME."

So how effective were these different digital communication strategies? In fact, all three approaches were effective, with targeted short-form messages and CME each resulting in a statistically significant reduction in new prescription volume versus control. And combining targeted short-form messages with CME yielded the greatest percentage of test HCPs with reduced prescribing (80.1%) versus controls.

"Studies have shown that multifaceted approaches are most likely to be effective in behaviour change, and our study matched this result, in that the combination of targeted short form messages and education was the most effective," says Hoffman.

"Although not directly linked to outcomes measures for new prescription volume, we observed that targeted short form messages with subject lines addressing personal fluoroquinolone prescribing were opened at slightly higher rates than targeted short form messages with a subject line addressing general fluoroquinolone safety data only.

"This result may suggest that feedback on personal prescribing had a somewhat greater effect on physician engagement than safety data alone and, by extension, was more likely to lead HCPs to education that may influence prescribing behaviour."

She adds that these techniques are broadly applicable for any matter that addresses public health concerns. The study authors have discussed the possibility of using such education in areas as varied as undertreatment of MDD, elevated blood pressure, dyslipidemia, low testosterone as well as inappropriate treatment seen with controlled substances.

"We also see some cases where anticoagulants aren't being used when patients could benefit, and this could be an intervention to make sure patients get the treatment," Hoffman says.

"One major area where we would see potential to use these interventions is in the prescribing of opioids, and how we could impact the path to addiction. It is not about getting clinicians to stop using opioids, but about how we can educate them on how to prescribe safely to the benefit of patients and their families."

She adds "The results of the study also suggest that targeted short-form messages paired with online CME could be a viable and COVID-safe alternative to other prescribing management tactics that may be more time-consuming or costly for a health system, particularly during the current health crisis."

With increased physician use of digital education looking increasingly likely to be a lasting legacy of the pandemic, now is surely the time to leverage evidence based approaches that have measurable and significant outcomes, whether they be advances in knowledge, competence or confidence, or go beyond with a deliverable impact on prescribing practice.

About Medscape

Medscape is the leading provider of digital continuing medical education (CME) worldwide.[5] As an alternative to in-person events, Medscape Education provides a variety of digital live education solutions, including Virtual Symposia: livestreamed virtual events where expert faculty present on multispecialty topics. Virtual Symposia events have the potential to reach a large, engaged, global audience by being accessible and interactive, and providing the content that clinician learners seek.

As a trusted learning partner for the medical community with proven ability to deliver education that makes an impact, Medscape Education is committed to providing digital CME to learners where, when, and how they want to learn.

About the author

Adrian Duncan is group vice president & head of global education at WebMD and Medscape Global. He manages all aspects of the Medscape Medical Education business outside of the United States.

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How pharma needs to change for the era of digital health

Experts from Healthware Group explore how companies can rebuild their approach to digital from the ground up for the benefit of patients.

Digital is not just a nice-to-have for pharma companies – it's a necessity for ensuring that patients have the best possible outcomes in modern healthcare systems.

With digital tools and techniques being able to improve almost every aspect of a pharma company's business, from R&D to sales, there's no excuse for not implementing digital transformation at every level – and that's not even mentioning new opportunities for life science firms to produce digital products that can complement or even replace traditional medicines.

Roberto Ascione, founder and CEO of Healthware, says that this landscape means that companies like his need to expand to be "communicators, connectors and builders" all at once – and this is a philosophy he has built up within Healthware over the last two and a half decades.

"When it comes to being communicators, we are communicators of disease information, which allows us to empower people to treat and cope with their conditions," he says. "We are also communicators of digital tools, which allow us to empower physicians as well, and communicators of innovation, through which we can energise innovators to build these tools.

"But we also need to be communicators of ideas. We need to take thought leadership seriously, because by communicating ideas we let them flow into the ecosystem, which generates a drive for transformation.

"This is why we want to hear from people and bring people together. That energy really fuels growth and change, and in doing so we need to constantly modernise what we communicate and how we provoke the change that will drive things forward."

healthware

Communicators, Connectors, Builders of Future Health

Far-reaching expertise

We represent, through the Intouch Group joint venture, one of the largest independent global players in the sector with a combined team of over 1,300 people and a strong international presence with offices in New York, Boston, Kansas City, Chicago, San Francisco, San Diego, London, Cologne, Milan, Rome, Salerno, Helsinki and Mumbai.

Clients

For more than 20 years, we have successfully been driving excellence in digital transformation for over 50 clients across more than 30 countries and 60+ brands.

Our health innovation ecosystem

We enjoy close relationships with the most successful accelerators, incubators and innovation hot spots globally, ensuring a constant flow of new ideas and opportunities tailored to the needs of our clients.

At the same time we love to connect and foster networking between all stakeholders whether large global life sciences companies or smart emerging start-ups.

Born digital, forward looking, fully integrated

We work at the intersection of industry digital transformation and digital health by providing a novel, integrated solution to existing and emerging stakeholders combining **marketing**, **communications**, **media and technology** capabilities with **innovation consultancy** and a vertical **corporate venture** arm.

- Advisory & Digital Transformation
- Content Factory
- Corporate Venturing
- Digital Health Consultancy
- HCP Engagement & Media Management
- Innovation Consultancy
- Marketing & Communications Agency
- Patients Experience
- Technology & Digital Agency

Therapeutic focus

Experienced in a wide range of therapeutic areas across life sciences and medical devices.

Our mission – an integrated healthcare service partner fueled by innovation

We are on the side of those companies that have understood the extent and potential of digital health transformation. We believe that technology and innovation are the main catalysts in today's healthcare revolution, and strive to unleash their power to improve health outcomes while delivering transformational business results for our clients.

By being 'connectors', Ascione says, Healthware can join dots that don't mean much on their own but can add up to something much greater.

"By connecting physicians and patients to each other and to relevant platforms, we can work towards the goal of always connecting the right targets to the right solutions. That is a massive gap in the healthcare sector at the moment.

"Similarly, by connecting people and forming communities we can give people in this space a sense of belonging and help them share ideas.

"In digital health, no one can do this alone."

He adds that the sense of being 'builders' is something close to his heart, because when he started Healthware 24 years ago the company was initially focused on building software.

"As well as building brands, building software is still a core part of what we do. But now we are starting to build companies in collaboration with great founding teams that we can complement.

"This is very transformational for our industry, because it moves a company like us from the role of helping products get to market to a company that is becoming a part of those products."

The opportunities inherent in this widespread transformation are obviously immense for pharma and service companies alike – but for the benefits to reach as many patients as possible, pharma companies need to ensure digital is deeply rooted in their organisations, not just built on an ad-hoc basis.

"Pharma needs to not just build on historic models but start to challenge the fundamental way these models operate," says Dr Paul Tunnah, chief content officer at Healthware Group. "You can see echoes of this in the approval of the Pfizer/BioNTech COVID vaccine – that was approved far quicker than anyone could have expected a year ago, because there was a real drive to rethink that process from the ground up with speed in mind."

Ariel Salmang, managing director of Healthware's Intouch International joint venture, says that pharma's current digital drive is being influenced by two key trends.

"The first is that there is a general shift towards a more consumer-based approach to information. In the past pharma has mostly just pushed information to stakeholders, but that push model has evolved into a mindset where people expect to be engaged with rather than lectured to.

"We're now seeing a demand for the creation of strong customer experiences."

The second trend, Salmang says, is that there is a global shift to outcomes-based healthcare and reimbursement, and the pressure on pharma to support that model has increased dramatically.

"Physicians are under pressure themselves to align their prescribing habits to a more financially viable model. They no longer want pharma to just give them information – they also want to be provided with the tools they need to meet these new demands."

Luckily, Salmang says, pharma is generally aware that business as usual is no longer sustainable.

"Many pharma companies have been hiring from outside the sector and have already tested many new technologies, new approaches, and new ways of going to market. Now they need to make sure they demonstrate consistency in these approaches and are committing to change on a broader scale.

"Companies are now looking for help in making their pilots grow and moving from a 'let's give it a try' approach to fundamentally changing how they do business."

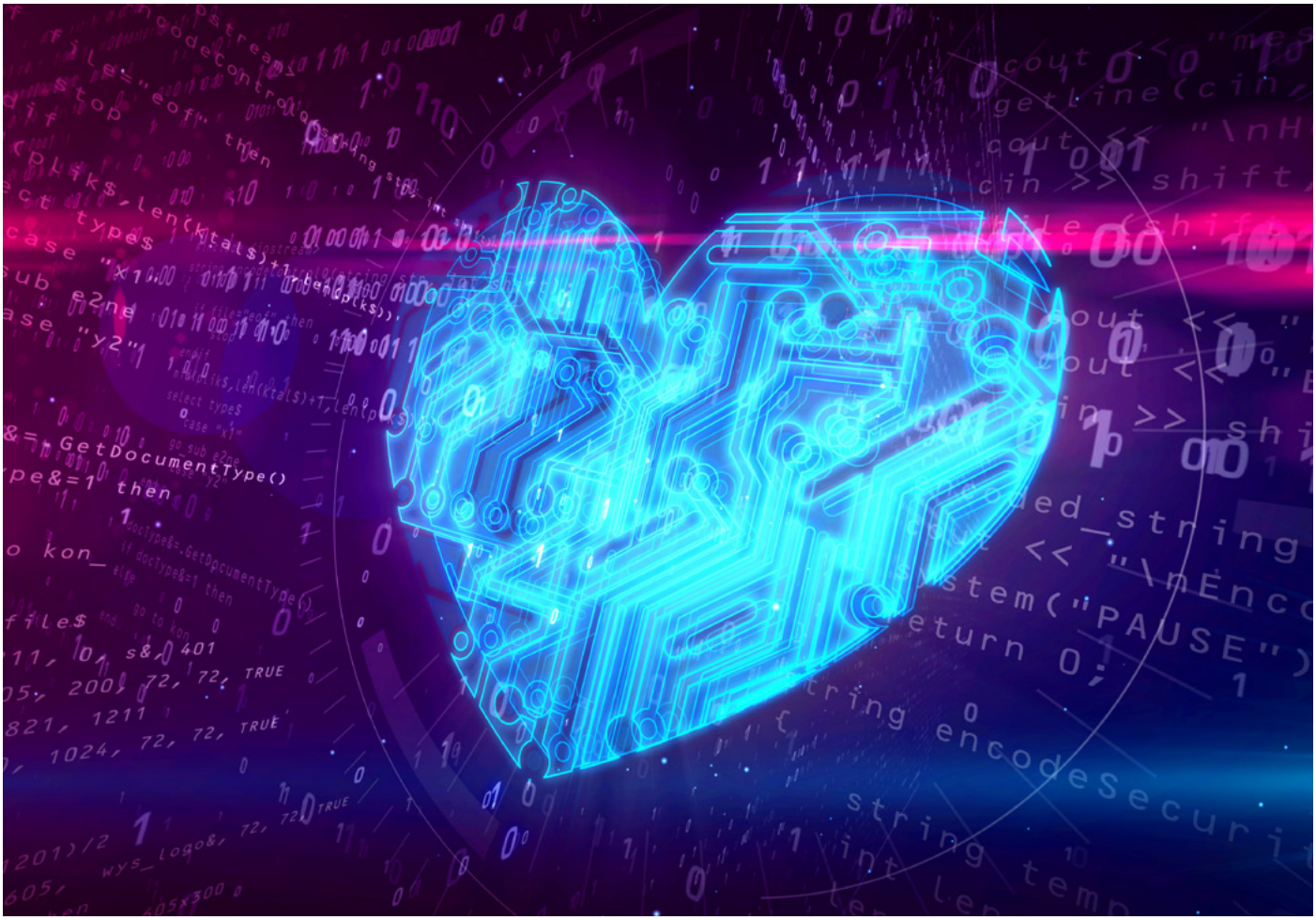
Within this environment, companies that support pharma with digital expertise are finding that they can bring a fresh perspective to the industry and play a key role in affecting long-term change.

Kristin Milburn is Healthware Group's New York-based global head of digital health partnerships. She says that the company has broadened out its model from providing more expected traditional agency services. These have been augmented by an offering of consultancy solutions that help clients to stay abreast of new trends, and provided them with the necessary strategic support to operate within them.

"One area which we've seen a lot more interest from our clients is around getting up to speed on the telehealth landscape," she says. "We've approached this in several different ways: providing landscape analyses of the field, helping educate physicians on how to leverage telehealth, and strategising on tools to support those efforts overall."

Milburn notes that the industry is facing an era where digital transformation is not static – rather, it will keep changing as technologies improve and will require constant strategic evolution and adoption.

Meanwhile, she says, we are approaching a stage where life science companies might have digital therapeutic pipelines alongside their molecular pipelines – and at some point there may not even be a distinction between the two.



"Clients vary in their readiness in this area, and as technologies evolve they need to stay competitive," she adds. "It's a continuous process to help clients adapt to these changes at scale and across geographies.

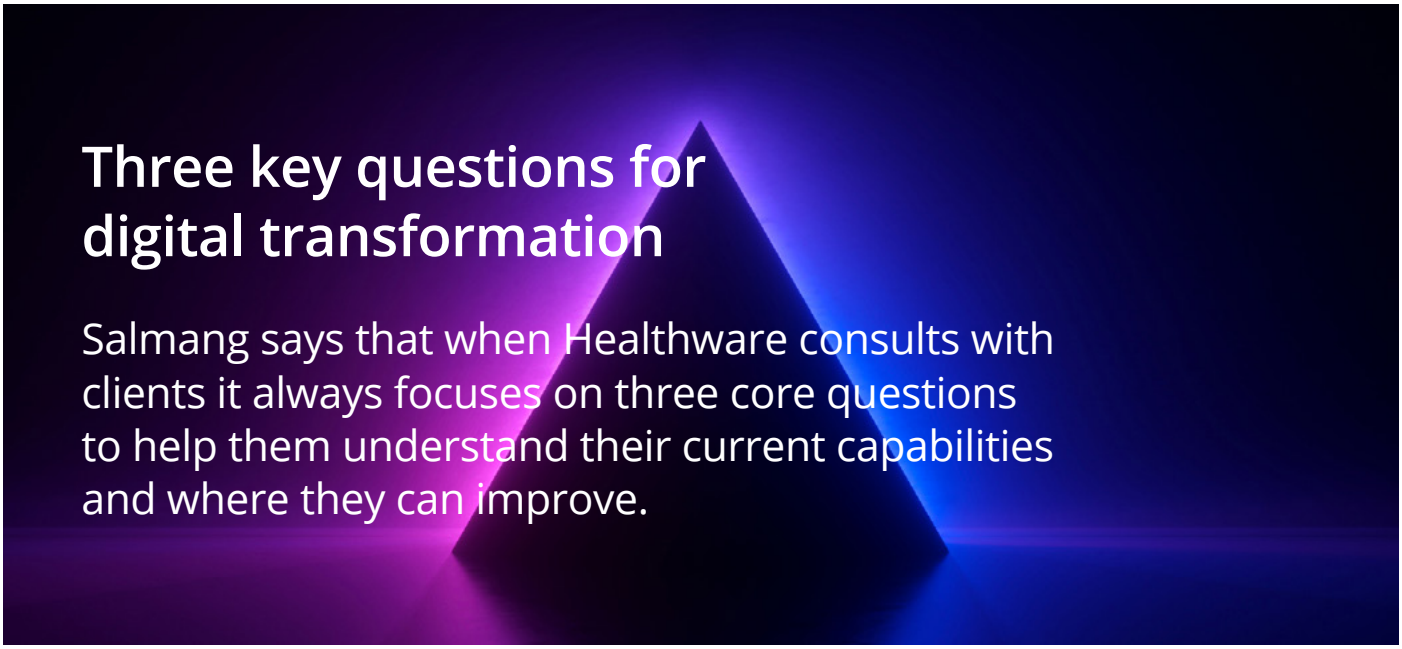
"When it comes to digital health tools, I'd say clients are at an early stage in their adoption. However, patients seem eager and willing to adopt these kinds of solutions and are doing so, so pharma needs to keep up."

Salmang says that Healthware has found the best way to get companies to change is through "a lot of honesty".

"Bringing in new technology is easy, but changing the way people work requires both a mind shift and a cultural shift across the entire organisation, and that in turn requires companies to be honest about what they can and can't do well.

"Agile working is probably the best example of this. A lot of pharmaceutical companies are adopting agile ways of working, but if you convert your marketing and sales organisations to agile but not your procurement, regulatory, medical and legal teams, you're creating new barriers.

"Digital transformation needs to be pervasive to people, processes and culture. That can be the most challenging thing to achieve in any pharmaceutical environment."



Three key questions for digital transformation

Salmang says that when Healthware consults with clients it always focuses on three core questions to help them understand their current capabilities and where they can improve.

"First there's the 'What?', which involves understanding what the status quo is, where the operational roadblocks are, what is available and what isn't being used properly," he says.

"Then we look at the 'So what?', which is the contextual layer. Take a look at the different tools and approaches employed across your markets and ask what they are doing for you as an organisation. What suffers and what benefits because of them?

"Then our key deliverable is the 'Now what?': How do we solve this situation? How do we move forward? What are the very specific next steps, both short-, mid- and long-term that can make transformation happen in a sustainable way?"

Salmang emphasises that these steps can be applied even when a company believes it is mature in its digital transformation.

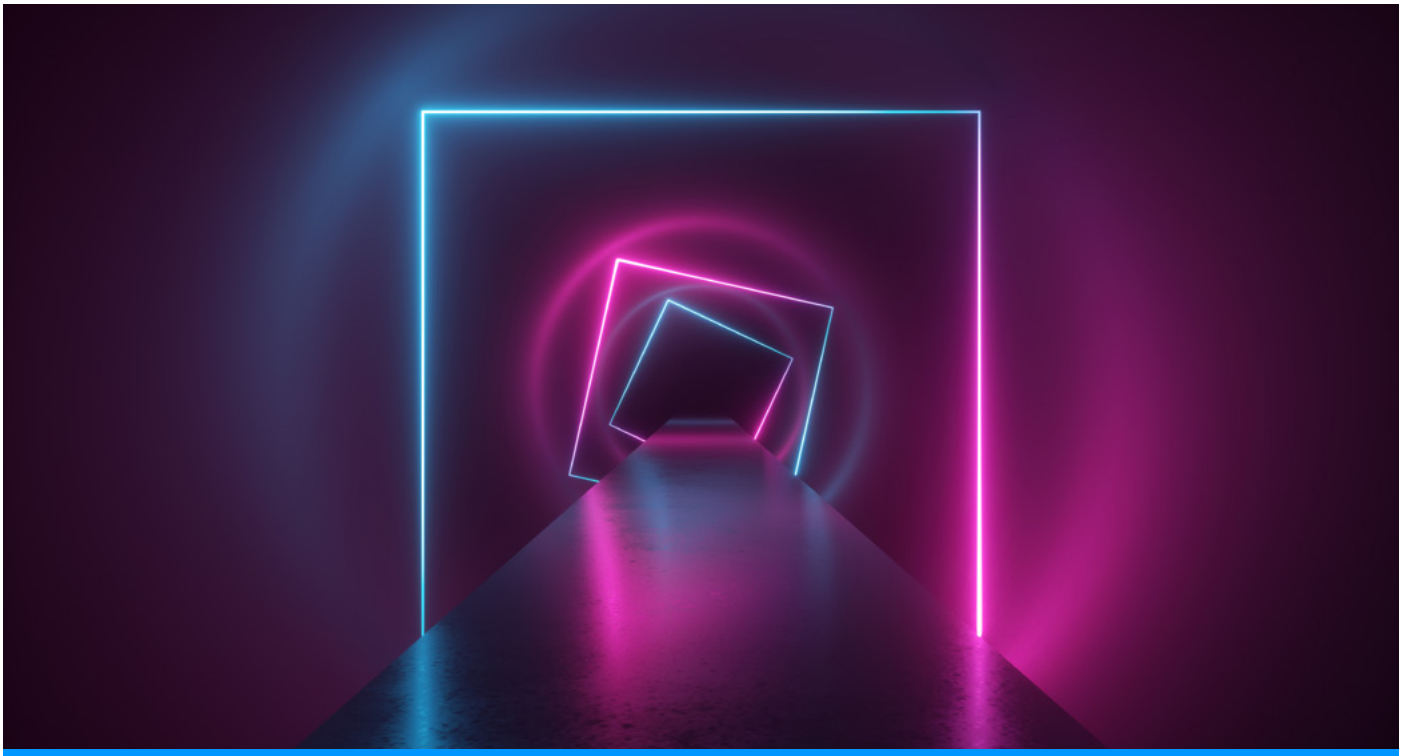
> "The fundamental truth of digital is that there is no steady state. You have to keep iterating and innovating. That means also challenging your own status quo continuously. 'What? So what? Now what?' needs to become a cycle that you're applying regularly."

A common roadblock within the industry occurs when companies approach digital with the same mindset with which they approach drug development and product launches.

"Pharma has always been told it needs absolute safety, absolute tolerability and absolute efficacy," Salmang says. "Nobody would dream of launching a drug that is unfinished. Everything pharma does is built around the principle of getting it absolutely right before launch.

"The digital world doesn't work that way, and the successful digital pharma companies are those that understand that 'good enough' is all you need to get a project through the door, as long as you don't stop there and continue to improve it."

Salmang says this is something Healthware is now implementing at an operational level within a number of different sized pharma companies.



"In an agile company you need to define the minimum viable product that allows you to go to market, see if it works, learn from that first engagement, then come back and define the next iteration. That cycle should never stop."

He re-emphasises that there is a strong recognition of this need within pharma companies, and rarely does an organisation push back against such suggestions from Healthware – but it can take time to turn that early optimism into a transformation plan and set it up.

"This is where we need to support our clients by setting a roadmap that delivers change at a sustainable speed rather than overwhelming people," he says.

"We also need to be mindful that business has to continue while the company changes. It's not like Formula 1 where you pull into the pit lane, very quickly refuel and change the tyres then start racing again. It's more like refuelling a fighter jet in mid-air – we have to keep two planes aloft while transferring petrol from one to the other."

A digital reshaping of the health ecosystem

Salmang also sees a wider role for companies like Healthware in ensuring that digital is embedded and considered at every level of the sector. When digital becomes a core part of pharma and healthcare, future transformations can happen much more smoothly.

Patients and physicians alike have reacted extremely positively to the flexibility and convenience presented by pharma's embrace of digital and remote solutions during COVID-19, and are pushing for these innovations to stick around once the pandemic ends. Meanwhile, the acceptance of digital therapeutics continues to grow, changing the ways physicians think about treating patients.

This will mandate a much more data-driven and transparent relationship between healthcare providers and patients. This will be especially pertinent as the use of electronic health records becomes more widespread and more patient data flows into the system, to be collected from digital tools and processed by AI programmes.

"All that brings with it a need for governance and a review of data privacy standards," says Salmang.

"This shift is going to become something that entirely reshapes the fibre of the health ecosystem. We recognised very early on that the evolution of the digital world was going to impact pharma, and that it couldn't stay in a Wild West scenario forever – it needed to grow up and be formalised.

"Because of that, we work with regulators, policymakers and ecosystems to establish confident, documentable, and agreeable standards."

Similarly, Healthware believes it is important to ensure that digital innovations don't remain as isolated pilots but are integrated into industry frameworks from the very beginning of their development.

"One key piece of advice we always give clients is to make sure digital pilots are being run in-house, not in separate offices off-campus," says Salmang. "If companies want to eventually transition this into business-as-usual they need everyone who is tasked with safeguarding the integrity of the business at the table.

"It took a few years of being in constant dialogue with these functions, but we're now seeing established standards for digital. We live in a regulated industry, so having all the stakeholders in the dialogue at the table is a driver of innovation, not a roadblock."

Similarly, a key factor for success is the long-term commitment required to truly make digital work for an organisation. In fact, Salmang notes that the idea of digital making everything faster is largely a misconception.

"It can actually make things take longer because it breaks the mould of established business. It's also not necessarily going to yield a result from day one.

"Digital transformation needs to be factored into a company's commercial perspective, with an understanding that it's not a short-term investment with immediate yield but a major long-term investment into generating efficiencies."

This needs a recalibration of thinking because, as Dr Tunnah notes, companies are often under short-term financial pressure. "This can drive them to focus on the commercial aspects of digital. But that creates a risk that areas that need longer-term thinking – such as how digital might accelerate R&D processes – will get left behind.

"The industry needs the right leaders, ones who have that long-term view as well as the ability to structure companies, so that the individuals who can drive that change have the space and the time to do so and are not just worried about the next quarterly financial results."

Listening to the digital ecosystem

Working in the health innovation ecosystem in this way requires companies like Healthware to make sure they are aware of how the life science, digital health and health insurance sectors might evolve in the near future and adapt accordingly.

Dr Tunnah says that building connections within this environment is key.

"We've made connectivity part of the lifeblood of Healthware by being involved in events like Frontiers Health, as well as making sure our portfolio has publication assets.

"If you're working in this space you need to be having conversations every day that aren't just to do with projects, but that help you keep up-to-date with what's happening with digital health investors, med tech companies, insurers, innovation teams and pharma.

"It's easy to think everybody does that, but actually finding the time to keep connected in a market that's moving as quickly as this one can be difficult for a lot of companies."

That comes back to the idea of Healthware being 'connectors' as well as 'communicators' and 'builders', and Ascione says that all three of these considerations must feed into one another for companies to realise the potential power of digital in improving people's health.

"The ultimate goal of digital health is to humanise care by filling the gap between the needs of healthcare and the access to it – by helping patients receive the appropriate care at the speed, the price and the location they need.

"If we are able to help solve these problems we can not only improve the 'care' part of 'healthcare', but also improve health for patients across the world."

About the interviewees

Roberto Ascione, CEO and founder, Healthware Group

Roberto is active in the digital health ecosystem in various advisor capacities, both in Europe and in the US, to companies, start-ups and investors. Among others, he has been recognised as Decade's Best Industry Leader by Health 2.0 Conference – 10 Year Global Retrospective Award in 2016, nominated Transformational Leader at the 2017 PM360 ELITE Awards and named among the 100 Most Inspiring People by PharmaVOICE in 2017. He is a founding member of the Digital Therapeutics Alliance, past president of the Health Tech Summit and is chairman at Frontiers Health.

Kristin Milburn, global head of digital partnerships, Healthware Group

Kristin has held leadership roles in strategy/planning and client engagement at various digital firms with numerous Fortune 100 pharmaceutical and technology clients. After launching her own digital shop and rising through the ranks on the agency side, Kristin jumped to the client side and joined the newly formed unit at Novartis called Digital Medicines in 2015. In that role, she looked to make transversal connections from other industries and find diverse partners from all corners of the healthcare ecosystem and beyond to help accelerate the experimentation and adoption of new digital health solutions to improve the lives of patients.

Ariel Salmang, managing director, Intouch International

Ariel has over 20 years of providing impactful digital strategies and implementation across multiple industries, from media and FMCG to telecommunications and healthcare, where he has spent the last 10+ years focusing on the digital evolution of pharma companies and the creation of impactful digital brands and sales drivers. His healthcare experience includes local, regional and pan-regional projects across the US, Europe, Asia Pacific, and LATAM.

Dr Paul Tunnah, chief content officer & managing director UK, Healthware Group

Dr Paul Tunnah founded pharmaphorum in 2009, which combines industry leading publications with a specialist strategy and content marketing/communications consultancy. 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. In June 2020, he became chief content officer for Healthware Group, a next-generation integrated consulting group that operates at the intersection of the transformation of commercial operations and digital health, offering a unique range of services combining design, strategy, communication and innovation with technology and corporate venturing. Connect with Dr Tunnah on LinkedIn or Twitter.

About Healthware Group

healthware

Healthware is a next-generation integrated consulting group that for more than 20 years has been offering large companies and start-ups in the life sciences and insurance sectors a unique set of services and expertise in strategic consulting, communication, technology and innovation to drive the digital transformation of health.

Founded in Italy, it is led by CEO and founder Roberto Ascione, an international entrepreneur and opinion leader with 20 years of experience in marketing and communication, business process transformation and innovation applied to health.

Healthware, together with its joint venture partner Intouch Group, represents one of the largest independent global players in the sector with a combined team of over 1,300 people and a strong international presence with offices in New York, Boston, Kansas City, Chicago, San Francisco, San Diego, London, Cologne, Milan, Rome, Salerno, Helsinki and Mumbai.

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