Getting new tech onto the NHS

VR meets Al

Digital Health Innovation 2020

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deepdive

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Research Partnership's Vicki Newlove explores research into digital change during COVID-19 to find out what business questions pharma needs to address to succeed with innovations



A new dawn for clinical trial management

It's time for pharma to take a 360-degree view of its clinical trial data and step into the future with near real-time study management



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Deep Dive: Digital Health Innovation 2020

Most of the digital health experts we spoke to for this issue of Deep Dive made one thing clear – with the future constantly in flux, it's important that pharma companies remain adaptable and innovative. If they can do that, there are myriad opportunities to thrive even amongst the confusion of COVID-19.

In this issue we hone in on some of the tech that is set to change healthcare forever – including VR, Al and digital therapeutics – and look at how pharma can best harness them.

We also examine how the pandemic is affecting digital sales, patient support programmes and HCP consultations, and speak to some exciting digital start-ups that are bringing new ways of managing health into systems like the NHS – who tells us how small companies can overcome the challenges of these complex environments.

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

I hope you enjoy the issue.

Kind regards,

George Underwood

Editor, Deep Dive, Communications 2020

Next issue:

Patients & Partnerships

- 2020 in review & predictions for 2021
- · Boosting clinical trial recruitment
- Overcoming low adoption of patient support services

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The key elements driving the success of digital health

Ahead of Frontiers Health 2020, steering committee members Roberto Ascione and Paul Tunnah from Healthware give us their thoughts on the trends driving the bright future of digital health.



It might be easy to think of pharma and healthcare as conservative industries, but the reality is that digital health is now far further along than we predicted it would have been 10 years ago – or even one year ago.

Much of this is, of course, down to COVID-19 – but it's clear that digital health was already on the up and up long before the pandemic hit.

When the industry first started talking about digital health, we were really talking about 'beyond the pill' strategies, which mostly included things like apps to boost adherence and patient support programmes.

Now, though, what we are seeing is true digital health, which does encompass beyond the pill, but also focuses much more on digital therapeutics – including digital devices that are complementing medicines directly for therapeutic benefit (rather than just adjacent factors like adherence), as well as digital interventions which are themselves therapeutic.





No one could have predicted ten years ago that the sector would develop as quickly as it has. In fact, ten years ago we were really just on the first wave of digital health, and the first wave of what we might call 'personal diagnostics'. The iPhone hadn't been around for long at that stage; it wasn't collecting the kind of data we are able to collect now with more advanced smartphones and devices like Fitbit.

Back then, no one thought digital health could become so diverse, or that there would be much investment in it at all. And nobody thought it would transform medicine, and for the first time enable a true emphasis on preventative care.

Trends in the market

When we look at the kinds of digital health products that are now coming to market, we can see a few key trends.

The smart digital health companies are the ones who are now treating product development like they would medicine development. They understand that they need to have clinical evidence of efficacy, safety, and cost effectiveness.

That's a critical factor, because even a good digital therapeutic is going to struggle to gain traction if it doesn't present strong evidence for doctors to feel comfortable prescribing it, and if it doesn't save health systems enough money to justify the case for reimbursement.



Likewise, health systems themselves also need to be ready for, or at least open to, upcoming innovations. These factors combined are arguably what made it difficult for Proteus Digital Health, an early (perhaps even ahead of its time) company pioneering digital medicine for adherence management through 'connected pills', to gain traction, despite the rich evidence the company had available.

A second trend is that companies are becoming more conscious of the fact that digital should not get in the way of, or try to replace, the doctor-patient relationship.

We can now be confident that technologies like Al will not replace doctors – rather, a combination of the two is a much better option.

That's not to say there aren't some digital health devices that can have benefits on their own, but there's a real trend towards products that also have the ability to connect the patient to an individual for direct engagement.

Examples include Healios, a UK application for treating mental health disorders, and mySugr, a diabetes management app that was acquired by Roche – both of which link patients to medical professionals for advice and intervention in novel ways.



In other words, many devices are now closing the loop between patients and physicians, rather than replacing this interaction.

Similarly, the ability to link patient data to clinicians is becoming a key feature for many devices, and there are several companies focused on collecting real-world evidence (RWE) in this way. If companies build large real-world evidence databases, looking at patient outcomes, that will in turn start to shape the positioning for the products themselves.



Short term versus long term

The industry needs to remember, though, that there are still many pitfalls to avoid when building digital capabilities - and being cognizant of these challenges is often what makes for a truly successful digital strategy.

Like many sectors, pharma and healthcare must wrestle with a balance of short-term and long-term goals for digital health. Big companies often face pressure to deliver immediate value for shareholders, which, understandably, drives a shortterm focus within digital. This results in their digital projects mostly being focused on commercial considerations, such as how these tools can boost sales force effectiveness or internal operational effectiveness.

That challenge ties into a second one, which is that digital is an incredibly broad terminology, and it is applied in the industry in countless ways.

It can refer to using digital for commercial benefits, to accelerating R&D, or innovating with the way we diagnose and treat disease, among many other definitions.

Some companies have created a challenge for themselves by grouping all these areas together under the massive umbrella of 'digital pharma'. And when it is grouped together like this under roles such as a chief digital officer, these people have a lot of pressure to focus on the more immediate, commercial side, even though investing in aspects such as digital transformation in R&D is likely to lead to longer-lasting benefits.

There are also external challenges common to all companies. For example, it's still not easy to integrate digital products with global markets and healthcare systems, because they're all trying to adapt to this rapidly changing landscape as well.





We have to remember that these are systems that were built to cope with the development cycles of medicines and devices, which take longer to come to market than digital tools – and although they can certainly assess digital tools in a similar way to traditional products, many health systems and regulatory authorities don't yet have the expertise to do that.

Luckily, we are starting to see a lot of investment by regulators such as the FDA in personnel that come from a digital health background and understand the area. We're also seeing pathways for reimbursement being developed, such as Germany's ruling last year about reimbursement for digital health products.

That said, there's still enormous variation across the world, and familiar challenges such as IP protection will remain.

It's also important to remember that there are many markets where you can't get access to the whole healthcare system. The UK is a good example of this, where you have a number of different regions, such as Clinical Commissioning Groups (CCGs) and hospital Trusts. Because of that, the adoption of innovation tends to be quite fragmented, which can slow uptake.



How to be successful in digital health

But what actually makes for a successful digital health company? First and foremost, there needs to be a clear product or solution that meets a genuine need within a patient or pre-patient population. It can't just be a gimmick.

When you have that good idea, you need the right management team and the right personnel to bring that idea to life. Having an idea is quite easy – making it happen is much harder.



There also needs to be a good investment approach and a good finance system in place.

All that needs to be allied with the right technology execution, because it's important to get the product developed efficiently and onto the market to generate the right data to support your business case, which is driven by at-scale adoption and engagement of the user's base with the product.

Finally, like a lot of things in digital, you need the ability to pivot when necessary and take a slightly different route based on the evidence that you're seeing.

A positive future

This year's Frontiers Health is going to be more important than ever, and in the run-up to the conference we've seen that, despite all the challenges of COVID-19, the pandemic has actually had a very positive impact on the digital health landscape.

A lot of the digital companies we're talking to as part of the conference could have had their applications in more widespread use years ago – but sometimes the key barrier to adopting these products is simply behaviour change. As human beings, we're creatures of habit - we like to do things the way we've always done them, and it takes a big push to make us change that. That's what COVID has done.

We'd like that to be the key message people take away from the conference – that things are really looking up for the sector, with rapid acceleration of behaviour change and investment around digital.

Stakeholders are starting to see that digital health is not just some interesting, innovative curiosity on the sidelines of medicine - digital health is now a core part of healthcare, and it's here to stay.





About Frontiers Health



Frontiers Health has emerged over the last years as one of the premier global events on digital health and innovation in healthcare. In the last five years, the conference has turned into a unique platform for deal making, networking and learning in the industry and has been repeatedly defined as "a home to the digital health ecosystem", gathering thousands of innovators, leaders and key players from the health industry each year in Berlin and in other locations across the world.

The format of the 2020 edition will combine online global streaming together with offline events and activities held at Local Hubs in multiple locations such as Italy, Germany, Finland, Malta, Spain, Switzerland and USA – all of which will also be streamed globally.

The conference will be dedicated to digital health innovation in the context of the 'new normal', focusing on telemedicine, digital therapies, breakthrough technologies, patient-centricity, healthcare transformation, investments and ecosystem development.

The programme will start at 2:00 pm CET on both days with plenary sessions (talks and panels) and parallel break-out sessions (masterclass, workshop, deep-dive formats) in pure Frontiers style.

The iconic Start-up Discovery sessions have also moved online opening more opportunities to connect with both earlier-stage and more established digital health start-ups.

About the authors



Roberto Ascione is the CEO and founder of the Healthware Group. He 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 he is chairman at Frontiers Health.



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.



A "pivotal moment" for digital health adoption

Former chief digital officer for the NHS, Juliet Bauer, is now applying her experience to the private sector through video consultation firm Livi. She shares her thoughts on how well the NHS is integrating digital health and what the public and private sectors can do to further boost adoption.



Bauer's path to working in the NHS began when she spent many months in the care of the health service with a highly risky pregnancy and an extremely premature baby in NICU.

"I was hugely grateful for the brilliant care I received whilst in hospital – but I could also see the huge potential for digital to improve patient access and efficiencies

Bauer wanted to utilise her first-hand patient perspective and experience in digital transformation to drive positive, long-term change.

During her time as chief digital officer, she led the strategy for digital services for NHS England – which forms part of the organisation's Long Term Plan.

Leading a large team, her role was to overhaul the organisation's patient-facing digital service like NHS.uk and innovate the system so patients could access and interact with services seamlessly across both digital channels and physical settings.

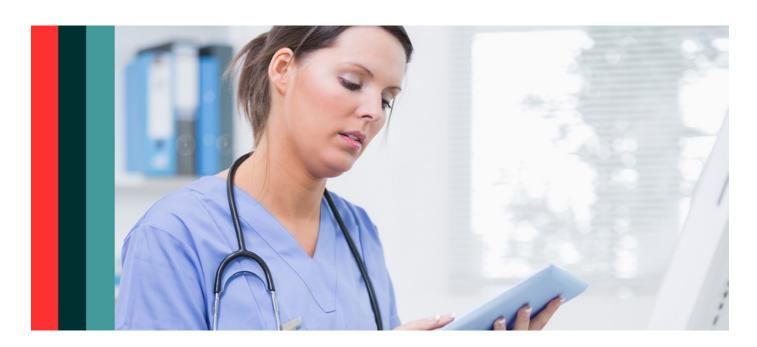
She says this meant engaging with developers inside and outside of the healthcare system on delivering "meaningful and personalised health", to ensure patients received the best possible care – whilst also ensuring the NHS was achieving these targets in a sustainable and efficient manner.

"When I joined the NHS, my main goal was to provide a more patient centred service such as the NHS app," she says.





"Like most organisations, the NHS definitely had room to increase its digital capacities. Despite this, it was clear that the NHS was willing to embrace technology to improve the overall patient experience. I was lucky that I was working with an experienced team who helped implement innovative approaches to enhance the role of digital across the NHS."



She says the NHS' willingness to embrace technology is driven by a similar understanding that private companies like Livi have – that transformation can only come through scale.

"That being said, there is also a mutual understanding that this approach must be scaled appropriately," she adds.



A meeting of sectors

In early 2019, Bauer moved to Swedish digital health company Livi (known as Kry in the Nordics), which provides video consultation services to connect patients with GPs, and is Europe's largest digital healthcare provider.

Through its tools, the company aims to boost access, reduce waiting times and add capacity to healthcare systems.

The company is now also looking to expand its digital pathways to include urgent care and mental health services.

"Looking back, it was a big decision for me to leave the NHS and join Livi, and one that I didn't take lightly," Bauer says. "Moving over to the private sector gave me the opportunity to bring the patient and system insights I gained to a company that was driving innovative and rapid change.

"Leading change and digital transformation at an organisation like the NHS was certainly a challenge at times. Nonetheless I gained a deep understanding of digital's potential to transform the way we access and deliver healthcare. My role was to show how it is an essential component in driving innovation – this is definitely something I have been able to bring to Livi.



"I also hoped I could bring the sentiment that underpins the NHS - the drive to provide patients with first class care - and make sure that Livi was enhancing the services available to individuals across the UK."

Bauer says she also hopes her experience in the public sector will help Livi thrive in a time when closer collaboration between public healthcare and private companies is becoming key to driving digital innovation.



"One of the key things I take from my time at the NHS is that for companies like Livi to deliver high quality digital healthcare, which ensures patients of all backgrounds have access, you have to be willing to collaborate with the entire system, and be willing to constantly find new solutions.

"Technology is the enabler in ensuring both patient access and cost efficiencies, but this only works when you work in partnership – as opposed to in competition – with the NHS. After transitioning to my role at Livi my belief in this approach was strengthened and now I consider partnership as a crucial element of securing long term success for the company.

"After all, our approaches work in tandem – we both believe in patient-centric care, high standards for clinicians and ensuring patient access."

The time is now for digital health

Bauer says she believes the NHS is improving its digital capacities every year – but despite significant progress over the years, the COVID-19 pandemic has highlighted some of the major hurdles that the health service needs to overcome when it comes to digital, especially regarding healthcare inequalities and variations in access.

The reality, she says, is that patient access to high quality digital healthcare is still dependent on where you live – and COVID-19 has only further exposed the urgent need to address this.

Bauer says the pandemic is a "pivotal moment" for digital healthcare transformation, which has not only accelerated adoption but also changed the kinds of people who are using these tools – for example, Livi's demand tripled during the pandemic and 55% of its patients are now over the age of 50.

But Bauer says this will only work long-term if applied at scale and through system-change.

"Digital healthcare is not a sticking plaster, but a whole new way for patients to access high quality care.

"For some patients with chronic illnesses, it is neither safe nor desirable to go to a physical setting for care which they can receive; for others, they are finding it difficult to book a GP appointment in the first place – recent polling shows that 53% are finding it harder to book an appointment these days.



"Clinicians are under increased pressure in terms of their capacity, and many – such as older doctors or those with health conditions themselves - have to ensure they can practice safely as well. Nine percent of all single person practices in England are run by doctors who are high at risk from COVID. Digital can be part of the solution for all of this."

While healthcare systems have naturally moved to a remote-led service in response to the pandemic, Bauer says that in the future she'd like to see digital being used across the NHS as a "front door" to effectively triage patients across the whole of England.

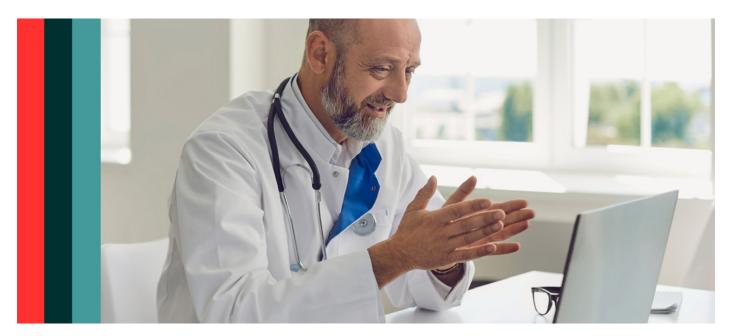
"I'd love to see system-wide change where patients are treated at a time and place of their choosing, by the right type of clinician – making their experience better, and ensuring efficiency of resources for the individual clinician and across healthcare.

"As well as this, the healthcare industry should have the confidence to go beyond just primary care with digital."

Livi itself is trying to push for a more seamless, integrated digital journey for patients in the NHS, by joining up its platforms beyond primary care – including urgent care, mental health or integrating with 111.

Bauer says that mental health in particular is an area where she wants to see digital tools having a greater impact.

"Mental health is a significant challenge for the NHS right now. The coronavirus outbreak and ensuing lockdown has had a significant impact on almost all aspects of our day-to-day lives. We're facing a growing mental health crisis across the UK as many patients often do not feel able to access mental health services, and as a consequence we saw a 20% drop in the absolute number of mental health meetings from March to April overall – despite an obvious increase in demand. Furthermore, we also saw a 36% drop in mental health meetings from men, from March to April 2020, a specific challenge in and of itself.





"During that time digital consultations have proved a highly effective way to ensure patients can quickly access specialist mental health care."

She again stresses the importance of partnership between different sectors in helping digital health to address these issues - for example, Livi has launched a pilot with mental health service Let's Talk Hull to ensure vulnerable patients can more easily access mental health care.

Like many, Bauer says she believes that digital will be the preferred choice for many patients, clinicians and the wider system in the future.

"When combined with physical care, digital will create healthier patients, and a healthier NHS. Digital will enable the NHS to overcome challenges that are currently deeply embedded in the organisation's every day operations.

"Ultimately, organisations like Livi are helping to address the fundamental issues healthcare systems all over the world are struggling with, such as ageing populations, long queues, rising costs and better provision of mental health care.

"We can't stand still. Digital can unlock full scale benefits for patients, doctors and the wider health system and I am proud to be a part of this work."

About the interviewee



About the author



George Underwood is a senior member of the pharmaphorum to this at Pharmafocus. He is a trained journalist, with a degree from



What will the digital health ecosystem look like post-COVID?

COVID-19 has turned the world on its head and healthcare systems have had to respond rapidly to match the sudden changes created by lockdown. Digital health had already been building a presence before the pandemic, but the tools it offers have been essential to counter the disruption caused by the coronavirus, reports Richard Staines.

COVID-19 isn't going away any time soon but when, and if, this crisis subsides the healthcare systems that are left behind will have changed radically.

While the pandemic has been a global tragedy it has also forced health systems to rethink the way they operate in order to minimise risks to both patients and healthcare staff.

the pandemic and digital health has







With no end in sight to the pandemic either, investors are confident that this demand will be maintained.

According to a new report from Mercom Capital, Telehealth attracted \$1.7 billion in investment in the first half of the year, followed by analytics, which got \$826 billion. mHealth apps got \$794 billion, followed by clinical decision support tools (\$545 million) and healthcare booking (\$326 million).

Telehealth

The delivery of health services remotely, telehealth has taken off during the pandemic. It was already becoming established before coronavirus took hold, but the technology has become commonplace as health clinics seek to keep patients and healthcare staff safe.

One of the reasons why the technology has become successful is that it has the support of patients.

As reported by pharmaphorum, a study by Accenture found that most patients who switched to virtual tools like video calls, online chat and apps would continue using the technology to talk to their doctors once the crisis abates.

The survey of 2,700 cancer, heart disease and immunology patients from around the world found that nine out of 10 using remote services felt their quality of care was as good or better than with conventional services.





But according to one analysis it's not altogether clear whether telehealth will remain popular in healthcare systems once the pandemic is over.

The analysis by the Peterson Center on Healthcare and Kaiser Family Foundation said that telehealth spending had bucked an overall downward trend on healthcare spend in the US.

But the <u>analysis</u> noted that the reimbursement policies currently propping up the spend on telehealth have sunset dates.

Without the support of the federal government's funding measures it's entirely possible that the trend towards telehealth will reverse.

But patient demand could be enough to ensure that telehealth retains its popularity as the decade matures and the COVID threat recedes.

Mobile health

Smartphones are increasingly becoming part of peoples' lives and the pressures of COVID-19 have meant that mobile apps have played an increasing role in healthcare.

Apps have been used with varying degrees of success to help countries in their efforts to control the disease.

South Korea was one country that embraced track and trace technology, using a highly sophisticated tracking system that monitored each person's movements and alerted them if they had come into contact with an infected person.

A similar tracking and tracing scheme in the UK has not been nearly as effective, partly because this version of the app is not nearly as intrusive due to concerns over privacy.





Another use of phones has been to monitor patients' overall wellbeing during the pandemic when visits to clinics and doctors' surgeries are considered impractical or unsafe

Tools such as Careology in the UK allow doctors to monitor COVID-19 patients' vital signs remotely and alert them to a deterioration.

This technology, which is already available on iOS, sets a precedent for use of similar apps once the pandemic is over for patients with other conditions.

Digital therapeutics

Digital therapeutics (DTx) – apps or programs that are backed by clinical data to show their safety and efficacy – have been flourishing since the start of the pandemic.

The technology was already gaining traction in a range of conditions, although mental health is the area where most of the benefits have been seen.

The sector was already forecast to grow before the start of the pandemic but DTx now look even more appealing, given they can produce an effect similar to a drug but at lower cost.

There has already been huge investment in pharma and biotech since the pandemic began and DTx have seen an upswing in their fortunes.





While nothing can be taken for granted in these uncertain times,

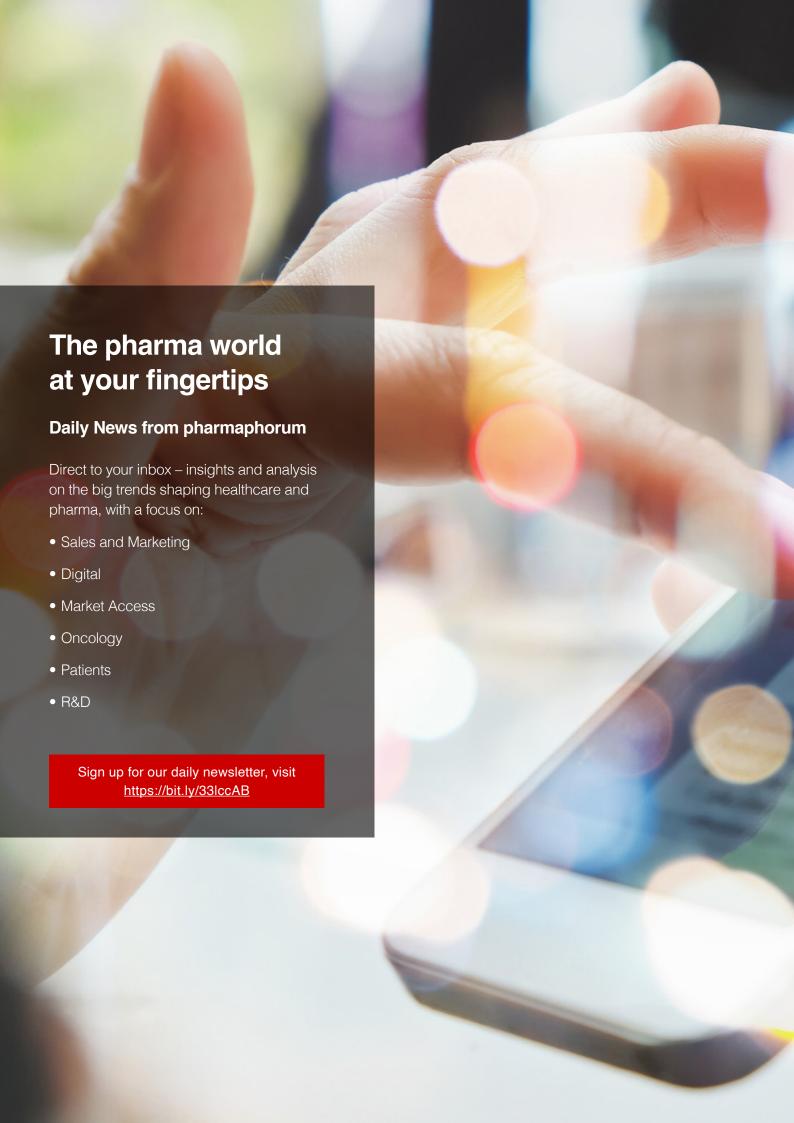
About the author



Richard Staines is senior reporter at pharmaphorum. He has been a journalist since the 1990s and has written for websites, newspapers and magazines. He has always had an interest in health, and has been focusing on the pharma industry since 2010, interviewing industry leaders and covering stories on topics including regulation, mergers and acquisitions, and the latest clinical developments.









Germany's digital health changes will boost digital therapeutics in Europe

Digital therapeutics are gaining momentum worldwide and offer developers, including pharma, both a huge opportunity and a stimulating market access challenge, say Olaf Schoeman and Emanuele Arcà.



The last 12 months have shone a spotlight on digital transformation in Europe's healthcare systems, with all the signs pointing to digital therapeutics (DTx) moving ever more into the healthcare mainstream.

Germany is spearheading these advances, particularly with its 2019 changes on national digital health reimbursement. The country will provide further momentum during its presidency of the Council of the European Union (EU), which runs from July until December 2020 and will see it work closely with the succeeding presidencies of Portugal and Slovenia. The countries have agreed a 'trio programme' to identify issues that would benefit from a fluid transition from one EU member state's presidency to the next to form an 18-month agenda, with progress in digital health one of the highlights of their plans.

While we would not expect digital therapeutics to replace pharmaceuticals themselves, they could bring huge complementary benefits to patients and prescribers and, in doing so, could bring pharmaceutical companies perhaps as much value as the medicines they traditionally produce.

There's also considerable interest in digital therapeutics from payers, thanks to the way that these digital interventions can provide more data and evidence for treatments as they work to improve the health or quality of life of patients. The approaches and requirements for reimbursement and pricing of this new type of intervention are currently being developed on a country-by-country basis, leading to a non-uniform landscape. For pharmaceutical companies this all adds up to a stimulating market access challenge.



Digital health changes in Germany

Implemented by the German Ministry of Health in December 2019, the Digital Healthcare Act (DGV) has captured a lot of people's imagination as a signpost to the future of health technology. It stipulates that digital health applications should now be considered to be medical products and, as such, can be prescribed by doctors as well as reimbursed by the country's statutory health insurance funds

The Act means that Germany is the first country to enable the reimbursement and prescription of digital therapeutics on a national level. Before the legal changes, digital therapeutics were reimbursed on a case-by-case basis in Germany; now, the country's new legislation puts a framework into place for evaluating the evidence and pricing negotiations for the whole statutory health insurance system.

In addition to the important implications that these changes have for those in the pharma industry involved in market access and health economics outcomes research (HEOR), the changes demonstrate a clear intent on the part of the German authorities to make the country a frontrunner in innovation and to allow patients access to these novel interventions. Certainly, taken as a whole, the legislation is a big step forward for creating a new market and stimulating innovation in the entire healthcare market.

However, although the groundwork for change in Germany has been laid, there's still some uncertainty about the detailed implications of the legislation and how it is actually put into practice. It was a very lean legislation process with the intent to learn as the system matures and, where needed, update the DGV, the associated Digital Health Applications Ordinance (DiGAV) developed by the Federal Ministry of Health, and/ or the Guide for Manufacturers developed by the Federal Institute for Drugs and Medical Devices.

Nevertheless, these changes have drawn huge interest, as seen by the strong international attendance at the recent Digital International Health Summit, which drew some 1,500 attendees from more than 20 countries. So, there's this huge interest from across the marketplace in what is happening in Germany and the indications are that it's going to have quite a wide geographic influence, as other countries try to learn from the German approach.





They may have different healthcare systems and alternative approaches to pricing and reimbursement, but we would certainly expect other countries to look to the approach Germany is taking and see how they might adapt and implement it within their own markets.

Furthermore, as noted in our recent Digital Therapeutics Landscape in Europe white paper, Germany isn't the only European country pushing forwards the digital health agenda – the UK is also on the front line of digital transformation in healthcare. Recently formed bodies like NHS Digital and innovation body NHSX are helping to accelerate the digital transformation of healthcare in the UK and integrated within these efforts is the country's framework for digital therapeutics.



However, there are important differences that pharma should note between the drivers behind efforts in the UK and Germany to advance the digitalisation of their healthcare systems. In Germany there appears to be a strong political desire to stimulate innovation and bring novel healthcare solutions to the patient, while in the UK it seems to be more about efficiency drivers leading the process on a more 'administrative' level.





COVID and healthcare's digital transformation

Even before COVID-19 upended societies and healthcare, and thrust technology even further into the spotlight as people adapted to social distancing measures, the use of digital health was following an upward trajectory. Countries across Europe were looking to learn from the experiences of their neighbours and the pandemic has necessarily heightened interest in digital health.

Amid the tremendous pressures that healthcare systems have faced during 2020 there is a real sense of urgency about using digital health technologies like digital therapeutics in the most effective way.

One of the effects of the COVID-19 pandemic, and there will be many for historians to choose from, is the way that it has finally streamlined thinking and processes that have been discussed for years. In this way we would note the huge progress made in areas like telemedicine or the drive to implement effective new approaches in many different disease areas. COVID-19 has shown how fragile healthcare systems' primary and secondary prevention is, and boosting the digitalisation of health will be one way to strengthen our existing structures.



Within pharma we also see various companies starting to collaborate with the tech start-ups developing digital therapeutics and as awareness of this area grows so too will the industry's willingness to invest in these new types of products and the companies that work on them.

COVID-19 has also brought additional attention to public investments from different countries and from an EU perspective. The EU's existing digitalisation agenda has been reinforced with a stronger focus on health and healthcare, with EU4Health set to provide €9.4 billion of funding to EU countries, health organisations and NGOs to bolster efforts in areas such as digital transformation. The proposed programme is the EU's response to COVID-19 and is set, in funding terms, to be the bloc's largest ever set of health activities as the union seeks to strengthen health systems so that they can face future epidemics and the long-term challenges they could bring.

Many of the efforts in digital transformation were already in progress before COVID-19 hit, but the sense of momentum that the pandemic has given them cannot be overstated.

At the moment the European marketplace for digital therapeutics remains very fragmented, and even in Germany there are some questions over what evidence will be required as the framework evolves and matures.

Many aspects of Germany's 2019 Digital Healthcare Act remain unclear, and we would highlight areas such as how it will treat structured integration across healthcare practices, exclusivity issues and patent/intellectual property rights as areas to watch for further development. Moreover, as the first wave of reimbursement submissions for digital therapeutics have now resulted in the listing of the first DTx in the DiGA directory, the next important milestone to watch will be the outcome of the first price negotiations.



Once those first negotiations are finished we can start to build an understanding of what sort of prices one can expect from digital therapeutics. However, what is valid now might no longer be valid in six months, and what is valid then, might no longer be valid in 18 months as it concerns a learning system or iterative framework. There will continue to be new developments and the processes and requirements will evolve, which is something that pharma really needs to stay up-to-date on. As part of that, market access and HEOR executives should expect, plan for, and raise awareness internally about changes in the market - both in Germany and, as they begin to catch up, other European countries.



To start to anticipate change companies will need to understand the marketplace and its stakeholders, including patients, healthcare professionals and payers. In Germany, there are two or three large insurance companies who are very much pushing digitalisation, while some of the country's other healthcare insurers are proving to be somewhat slower when it comes to digital health adoption. The same holds true for physicians, where some physicians are interested in understanding the benefits of DTx and providing novel treatments to patients, whereas others are more cautious about the effectiveness, safety and data security of DTx. Finally, patients generally are keen to adopt new technologies to improve their health and care, in particular if they have been involved in the development, either directly or indirectly through patient associations.



There may be some in the industry who view these developments with a certain amount of suspicion, perhaps fearing that digital interventions could replace pharmaceutical treatments, but we would not see them as a threat to the industry.

After all, pharmaceutical companies know the markets, have the connections and know the patients, prescribers and payers far better than any start-up - they also have the resources to invest in new innovative products. If the Googles, Apples and IBMs of this world can move from the tech space to healthcare, why shouldn't a pharmaceutical company, at least partially, be able to transform itself into a tech company?

We already see data science and life science becoming ever more intertwined. As many new drugs enter the market with very specific, and usually very small, patient populations, the evidence available at market entry can often be very small. One of the consequences of this has been a rise in the demand for risk-sharing agreements, and these can only be successful for the industry in the long-term if companies are able to generate sufficient data to prove the case for their products to payers.

Ultimately, digital therapeutics offer an important opportunity to add value in addition to pharmaceuticals and (non-digital) medical devices, given the difference in treatment modality, but also through direct outcomes data collection.

To learn more about how digital health is changing in Europe, and the market access and HEOR implications of these advances, download the <u>Digital Therapeutics Landscape in Europe</u> white paper



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Digital therapeutics: Why human psychology is key to adoption

The healthcare system is running at its limits in many countries worldwide. One reason is the growing demand for healthcare, largely driven by the rise of chronic diseases. COVID-19 has further underscored just how stretched the system is today. Is there any solution to the twin challenge of managing costs while extending capacity?



We believe that digital technologies are an important part of the answer. Although still in early stages, it is poised for broader adoption thanks to recent technological advances. While digital won't help solve all the problems in our healthcare system, it will significantly contribute to easing the cost and capacity burden.

One particularly promising area in this context is digital therapeutics. Based on the analysis of individual patient data, patients receive personalised medical recommendations – through an app or a digital platform – without the need for physician intervention. Digital therapeutics can help patients stick to treatment plans and/or better understand what triggers critical situations. Digital therapeutics are already available for different indications including diabetes or asthma and are being developed in many other areas as well.



The 'therapeutic alliance'

Unfortunately, most patients stop using these solutions after only a short time even though the benefits are often obvious. But to achieve true value in the system, sustained adoption is pivotal.

A major obstacle is the psychology of the patient. Most digital therapeutic solutions are essentially self-management tools that require the patient to consistently add his or her data and follow the suggested actions. Without high levels of self-discipline and motivation, patients often lose interest. Thus, we need to focus on how we can improve sustained patient engagement with these digital therapeutics.

Let's take a closer look at the relationship between the physician and patient. According to Accenture Research, trusted healthcare professionals ranked highest in motivating consumers to take a more active role in managing their health¹. How is this trust created and why do patients stay engaged with the instructions they receive from a physician? According to leading behaviour psychologists we have interviewed, one key concept explaining the bond between patient and doctor is 'therapeutic alliance'.

This concept, which was already described forty years ago by Bordin et al², seeks to explain why and how this bond is established. Evidence from various studies shows that a strong therapeutic alliance does positively influence treatment outcomes³.



Four key factors contribute to a high-quality therapeutic alliance from a patient's perspective:

- **1. Relatedness:** The patient and physician connect on an emotional level; the patient has the feeling that the physician really cares
- **2. Agreement on goals:** The patient and physician jointly agree on and support the outcomes they want to achieve
- **3. Agreement on interventions:** The patient and physician jointly agree on the necessary steps to achieve this goal
- **4. Perception of competence and ability to help:** The patient sees the physician as a qualified authority who, based on his professional experience and knowledge, will make appropriate treatment decisions.



What does this mean for the development of digital therapeutics? By their very nature, digital tools cannot build emotional bonds with patients. However, the four factors outlined above can be replicated in digital solutions in various ways:



- 1. Relatedness: Instead of asking for entering and providing data alone, the digital therapeutics solution must communicate with the patient in an engaging and personalised way. For example, personalised messages and motivational feedback via a chatbot help the patient overcome challenges and continue the digital therapy
- **2. Agreement on goals:** The digital therapeutic needs to highlight the defined goals to the patient in a comprehensive and relatable way back to the patient. The goals are personalised to the context of the patient based on, for example, a survey
- 3. Agreement on interventions: The proposed interventions must always be linked back to the agreed goals. It is important that patients understand how cause and effect are connected. This link needs to be constantly reinforced along the treatment journey
- 4. Perception of competence and ability to help: The patient needs to believe the app is trustworthy. There are different ways to drive this trust; one way is for a physician to endorse or prescribe the digital therapeutic, another is having a trusted organisation, such as a leading health institution, being visibly involved in the development of the solution.

The hybrid model: digital meets human

Today, most digital therapeutics do not manage to effectively apply these concepts of replicating the human component and thus struggle to create a strong therapeutic alliance. But without this 'human touch', digital therapeutics struggle to sustain engagement with patients, especially as many patients still don't trust diagnosis and treatments determined by an intelligent machine or artificial intelligence – as a recent Accenture study revealed4.

A promising approach to overcome this is to combine both digital and human in a hybrid model for digital therapeutic solutions. This can be achieved by designing regular human touchpoints with a doctor or a nurse when certain milestones are either achieved or missed based on the data from the digital solution. The role of the healthcare professional is to assess and feedback the therapeutic progress and give personal coaching and additional advice to the patient based on data from the digital tool. This reinforces the health actions already recommended by the digital therapeutic solution.





One successful realisation of such a hybrid model is Migraine Care from Novartis. The programme focuses on helping migraine patients better manage their condition through a combination of a mobile app and human health professional. This allows users to keep track of their symptoms and actions. The healthcare professional has access to the data from the app and can therefore base recommendations on these insights. This provides a highly personalised and emotional experience with individual objectives and actions for the patient instead of the more general advice a user would receive from standard migraine apps.

The Migraine Care team, led by Leonhard Schaetz from Novartis, published results of a six-month study that demonstrate the therapeutic value of such a hybrid model5. More than two out of three participants completed the programme and the number of working days lost due to migraines was reduced by almost two thirds. Participants said they were encouraged by their personal conversations with the nurse and therefore felt an obligation to follow the recommended care plan. These conversations not only focused on recommending specific actions – based on the personal data on their wellbeing and symptoms they had entered into the app – but also left enough room to discuss symptoms more generally and establish an emotional bond.

We expect more of these solutions, which combine the strengths of digital technology and human interaction, coming to market in the next years. A similar hybrid approach is used by Liva Healthcare, which has developed an app for learning healthy lifestyle habits in connection with a personalised coaching programme. The solution focuses on patients with or at risk of getting chronic diseases. While the app is built for daily interaction and tracking health habits, users also have access to a human health coach through the Liva platform.

Hybrid digital solutions provide an effective way to emphasise the 'human touch' at key moments in the therapy where patient behaviour can be influenced. In the (distant) future, the human touch can increasingly be provided by a virtual health assistant powered by Al. But the speed of this happening depends on the developments in the field of machine learning and neural networks which are still at early stages.

The hybrid human-digital approach is a great way to build trust in digital therapeutics solutions today. With this approach, we can create truly meaningful solutions that not only engage patients in the long term but also lead to sustainable changes in their health outcomes. This should increase adoption and help to free up capacity and bring down costs in the healthcare system.

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Navigating the NHS as a digital start-up

We speak to finalists from the Greater Manchester Future of Health accelerator to find out how digital small companies face in bringing their technologies into the NHS.

Right now the NHS is embracing digital to an extent no one could have foreseen a year ago – but that doesn't mean it's a smooth journey for digital health start-ups looking to gain traction in the health service.

"COVID has forced the NHS to change, but so far most of the implemented digital innovations have been low-hanging fruit such as video consultations," says Rory Cameron, CEO and co-founder at diabetes risk management app Gendius. "Adoption of new tech is still a real challenge."



He says that part of the problem is that standards of care are rapidly changing, and it is therefore difficult for companies to prove their concept.

"The NHS is certainly open to the idea of greater digital adoption - but CCGs often get caught up with various issues that stop them moving forward with new technology.

"Often you'll need to do a pilot to demonstrate the platform works, where the product is provided for free, but at

the same time CCGs will be asking how much you want to charge once the pilot is over. You can't justify a cost until you have supporting evidence, and you can't get that evidence until you do a pilot, so you get caught in a vicious circle where nothing can get approved.



"It would be better if CCGs accepted that sometimes they need to take the risk on a pilot, as long as their hearts are in the right place and the patients are able to make an informed decision about whether they want to take part."

Many Trust and CCGs, as well as pharma companies working in the UK, are aware of these problems. and several digital accelerators have been set up around the UK to help start-ups get their innovations into the health service.

One such initiative is the Greater Manchester Future of Health Challenge – which Gendius was a finalist for.

The accelerator programme was launched last year, with 15 start-ups chosen, and was run by UP Ventures and delivered in partnership with Novartis, Push Doctor, Google, The Landing, MediaCityUK, Salford Royal NHS Foundation Trust, Salford Digital, Apadmi and Health Innovation Manchester – who had support and funding from the UK Office of Life Science and the European Regional Development Fund.



The programme provided multi-faceted support to help finalists launch their technologies into an NHS setting, ranging from mentoring, investment, networking, office space and access to a range of commercial and healthcare masterclasses.

"The programme was a fantastic example of how we can tackle the healthcare challenges of the 21st century by working together towards a collective mission and embracing innovations in data and digital," says Rosalind Way, head of strategic partnerships at Novartis.

"We all have a shared interest in ensuring our NHS can continue to provide sustainable healthcare, and partnerships like the Future of Health Challenge create new possibilities to improve the health of people in the UK, provide better experiences for patients and find smart ways of working together to build a health and care system fit for the future."



Richard Deed, associate commercial director at Health Innovation Manchester, says there were two key criteria the programme was looking for in start-ups who applied.

The first was whether the innovation actually addressed a problem for the Greater Manchester health system.

"You can have a great piece of tech, but if it doesn't actually address what the system really needs, it's not going to get any traction," he says. "Going to a cash-strapped NHS with a product in an area that no one is paying for at the moment is never going to work."

The second factor was the company itself.



"We were looking for a mix of a good idea and good people. It doesn't matter how small the company is, we wanted people who were going to go the extra mile, to take on board what the system is saying and be flexible enough to respond to that.

"The success of an innovation is probably 40% to do with the idea and technology and 60% to do with the people."

As partners of the programme, Novartis were also involved in the selection process.

"Many pharma companies like Novartis are looking to go beyond providing solutions as pills or devices, and are now also asking where they can intervene and assist with delivering and improving pathways of care," says Deed.

"Novartis were looking for innovations that could help achieve that - either by coming into an existing pathway of care or disrupting them and offering another way of delivering that care."

> Once the finalists were selected, Health Innovation Manchester's role was to help them understand the landscape of the NHS.

"A lot of innovators think the NHS is one organisation," says Deed, "but actually it's multifaceted. Hospitals and clinical commissioning groups are all working in slightly different ways. We needed to explain that there's no one front door to go to, no one person that can actually answer all of your problems."



Return on investment

It was also important to teach the companies how to demonstrate return on investment and show how their innovation will be addressing pain points in the system.

"Even if you've got a great innovation, if you can't demonstrate a return on investment nobody is going to pay for it," says Deed.

Lara Mott, CEO and co-founder of finalist ImproveWell – which helps hospitals gather feedback for improving their ways of working – says that her company took this advice and built an 'impact calculator' on their website, based on their own evidence and academic research.

"People can enter the size of their workforce onto the calculator and see what our tool can do for their organisation," she says. "It's been a great conversation starter."

Mott says the programme was also helpful for honing the company's approach to customer experience.

"It was great to have lessons on how to do a great job in your customers' eyes – looking at the basics from the private sector and how you can bring those principles into your own company."

ImproveWell was co-founded by Mott and her childhood friend Dr Na'eem Ahmed. Dr Ahmed's original concept was a junior doctor feedback app – the idea being that those on the frontline are best placed to identify areas for improvement.

"It's now developed into an app for everybody regardless of role or background to get involved in improving their workplace, staff experience, and ultimately the quality of patient care," says Mott.

Users can set up a working group, and contribute feedback to an ideas hub. The app has a poll survey function, as well as a 'sentiment tracker' which helps people understand what contributes to a good day at work.

"Users might want to ask employees if they've had a good day, and they can share the reasons behind their answer," says Mott.

"With the combination of those three feedback systems, different colleagues can get involved in sharing real-time feedback to address known challenges, and also uncover issues that haven't previously been identified."

ImproveWell found itself in the right place at the right time when the COVID-19 pandemic hit – with the tool ready to use, they were able to mobilise in just a couple of days to help the emergency Nightingale hospitals in London and Cardiff.



Mott says that real-time feedback and rapid learning were particularly helpful for these new, temporary hospitals.

"They were really focused on listening to staff, understanding what had gone well that day and where it could be improved, and then making those changes the following day."

Data and diabetes

Meanwhile, for Gendius a key benefit of the programme was the help in gathering data to create the algorithms for their diabetes management app.

"Through the work on the programme, we managed to get Oldham CCG involved," Cameron says, "and Dr Angela Paisley at Salford Royal NHS Foundation Trust has taken the clinical lead on our AI development project, which is fantastic.



"The programme also gave us some great advice on how to pitch well – for example we were taught in that session that what you really need to articulate isn't what you already have but what your aspirations are."

Cameron and co-founder Chris Genders had worked in pharma for some time before founding Gendius. When Genders was diagnosed with diabetes at age 50, he assumed, having worked in healthcare, that he would find it straightforward to deal with.

However, he found it very difficult, and five years after his diagnosis he developed a foot ulcer that took 12 weeks to heal.

Based on that experience, Genders and Cameron developed a tool that would make it easier for diabetes patients to understand what they need to do to avoid complications.

"If you google 'diabetes' now, you get millions of results, and while on one hand it's great to have lots of information to hand it can also be overwhelming," says Cameron.

"We could see we needed to do something to help empower and educate people with diabetes, and an app seemed like the natural solution."



The app takes a user's clinical history and uses algorithms to predict their risk of complications. It then gives them clinically validated hints and tips each day around the areas where they're at highest risk of complications, with the aim to prevent those complications from happening.

The app is also connected to over 150 different WiFi and Bluetooth and app-enabled devices, such blood pressure cuffs, WiFi scales, and blood glucose meters.

Gendius is also aiming to integrate with electronic medical records.



"We want it to be as easy as possible for users to pull data in," Cameron says.

With the COVID-19 pandemic in full swing, Gendius has been looking into whether they can leverage their platform to stratify groups by risk – as diabetes patients are thought to be particularly vulnerable to the disease.

"The app could show diabetes patients exactly how much risk COVID poses to them, allowing them to plan their lives accordingly."

The future of health

Despite accelerators like the Future of Health programme and partnerships between the NHS and pharma helping many start-ups, Deed, Mott and Cameron all acknowledge that there is still a long way to go to make it easy for health innovations as a whole to make an impact on the health service.

"The NHS has done a good job with digital during COVID-19, considering the circumstances," says Deed. "It's been great to see resource and support flowing into that area, for example with national initiatives around remote consultation. I think we will see more of that in the future.

"But that's not to say that the NHS is wonderfully digital now. There's also a much bigger undercurrent relating to existing digital architecture, particularly the use of data and digital health records. Using electronic health records much more effectively and efficiently will lead to better healthcare for all, but the health service is not quite there yet."

Mott adds that other challenges for small businesses remain.

"We've been very lucky with the strong NHS partnerships we've had – and word of mouth can't be underestimated. We focussed on doing a really good job for one customer, so that they would hopefully talk positively about us to other systems.



"I really believe that the NHS wants to adopt digital technologies, but if I put myself in their shoes, I can see that there's a lot to choose from."

Mott says that to show the NHS that your innovation is the right choice, you need an evidence base, and you need to make sure that taking on the product is as low a risk as possible for the buyer.

"You need to make sure you're up to the standards of a digital supplier to the NHS, your cybersecurity needs to be good, your data policies need to be good, you need to be obviously solving a problem, and you need to communicate that well," she adds.

"If you execute all of those hurdles and build a track record of delivery and credibility, it's much easier. It's a challenging market, but I think it's a very receptive place if you are actually doing a good job at addressing an unmet need."

About the author



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bruntwood SciTech

Building the infrastructure for successful digital health start-ups

2020 might go down as the year digital health truly began to boom - but to continue thriving, health tech start-ups will need a strong support network and an environment that fosters innovation.



With advanced tech becoming ubiquitous, healthcare stakeholders finally embracing digital, and patients rapidly shifting their preferences, there has arguably never been a better time to be a digital health start-up.

Dr Kath Mackay, managing director of Bruntwood SciTech's Alderley Park – the UK's largest single-site life science campus – says there are many positive signs for the sector.

"There's a lot of investment in life science and digital health. Private and public stakeholders are keen to fund these companies, and many firms are growing. People are embracing digital technologies like never before, and awareness has never been so high."

But Mackay cautions that while 2020 has been a boom year for digital tech, the sector will still need support in order to continue that into 2021.

"There might be longer-term issues with funding, especially as many of these digital companies are SMEs. They're going to need some fuel in 2021, and we must ensure this is forthcoming.

"That has to be considered in government spending reviews. If we want to continue this digital transformation, there has to be investment."



Mackay, who previously worked in Innovate UK, notes that much of the company growth she has seen before and during the pandemic has been driven by dedicated government investment in health programmes through initiatives such as the Digital Health Technology Catalyst.

"Initiatives like that can give a targeted boost to companies working in the field. It's not just about money – the connections you acquire through that funding are also important. Quite often these schemes are a tool for much larger and more strategic relationships with the NHS, often linking innovators with potential first customers.

"This is important because the NHS is a huge asset in adopting new technologies, as well as in generating data that goes back to the innovators."

As such, Mackay says that the digital companies that are seeing the most success at the moment are those with meaningful partnerships and collaborations with the health service. In fact, Chris Genders, director and co-founder of diabetes management app Gendius (see Navigating the NHS as a digital start-up) who are based at Alderley Park's Glasshouse, says that while the NHS makes a huge amount of noise about tech, it can still be incredibly difficult for small digital companies to get any traction in the health service without these connections.



"CCGs are often still rooted in a pharma mindset – e.g. wanting to see randomised clinical trials and health economic outcomes. But that isn't necessarily how small health companies work best."



Meanwhile, Richard Westman, founder of employee wellbeing platform Kaido, based at Bruntwood SciTech's Innovation Birmingham campus, says his company decided early on to work with both the private and public sector in order to lower the risks inherent in a small healthcare business.

"When we started, the initial plan wasn't to be in workplace wellbeing at all," says Westman. "It was to have a consumer application that public health would procure. We quickly realised that was far too ambitious for a small business."



Westman founded Kaido in 2016 following a career in professional sport. He wanted to help more people proactively look after their physical and mental health and was fascinated with how technology and data could provide new and more personalised opportunities for population health management.

The Kaido Insights platform uses big data and professional health expertise to empower individuals and businesses to better understand their health, specifically through its 'Health and Wellbeing Challenges' that help teams make small positive steps in their health.

"I'll never forget the day that the commercial director at the AHSN said to me, 'If you're coming into this expecting the NHS to buy you or your service outright, that's not going to happen any time soon'," Westman says. "That learning quickly pivoted us to always have the NHS in our sights, but to also have a private side to our business model."

"The NHS is very fragmented," adds Mackay. "It's not one organisation, and it's not like everyone is knocking on the same door in Whitehall. Although challenging, this can often be a benefit for companies trying to tap in.

"Because of the various routes in, digital start-ups need good connections to their local NHS and local clinical population. Reaching out to your local Academic Health Science Network (AHSN) is key – as is contacting other organisations like Innovate UK and the Knowledge Transfer Network.

"It's not a perfect solution, but those organisations are specifically set up as the honest broker between industry and the public sector. They can help you navigate the system and make those connections.

The right environment for digital start-ups

Mackay says that this is why innovation districts like those in the Bruntwood SciTech network have decided to offer more to companies than just a space to work.

"Our companies are going to be successful if we help them make those connections," she says. "Because of that, we invest heavily in business support in each of our regions – from Manchester and Leeds, to Cheshire, Liverpool and Birmingham – and we have people on the ground in every campus nurturing those relationships on behalf of the customer."



For example, the AHSN Health Innovation Manchester is headquartered at Bruntwood SciTech's Citylabs campus, but also has a satellite office at their Alderley Park campus in Cheshire. Likewise, the West Midlands AHSN is based at its Innovation Birmingham campus. What's more, the company's Citylabs Campus in Manchester is a joint venture between the University of Manchester and the Manchester NHS Foundation Trust.

Bruntwood SciTech also offers training to digital companies to help them develop a business proposition and pitch it, as well as providing links to funding, with venture funds on-site.

"It's our role as operators of science and technology campuses to try and understand what companies need in order to grow, and provide that for them," Mackay explains.

As an example, Gendius met and secured funding from venture capital firm Catapult Ventures through its connections at Alderley Park.



"We wouldn't have achieved that without the Park's network, and without having people there who liked what we were doing and seemed to almost adopt us," says Genders.

When Gendius joined Alderley Park, they were one of the only digital health companies on the site.

"We were a bit of an odd creature at the zoo, but that didn't get in the way of people introducing us to their contacts. There were a lot of people buzzing around and pointing us in the right direction. That's the beauty of the dynamics at these kinds of places – the people that inhabit the sites really make a difference."

Since then, Bruntwood SciTech has opened Glasshouse – a tech hub at Alderley Park which now hosts 27 companies employing 300 people, and, perhaps in a sign of the promise of digital health in these times, has continued to grow despite COVID-19.

Mackay says that what really interests her is the "grey space" in the middle of life science and tech, which she hopes Bruntwood SciTech can foster through having both kinds of companies coexisting.





"That space is due to be a huge growth area. As life science companies grow in scale, they're going to be learning a lot from what's happening in the tech sector. We already have companies at Alderley Park who are working on artificial intelligence and various other data-driven approaches, so having people from the tech sector working beside them is going to be incredibly helpful.

"Added to this, we've recently announced our plans to develop Birmingham Health Innovation Campus (BHIC), in partnership with University of Birmingham. The campus will provide a world class hub for companies working in medtech, biopharma and precision medicine and bring together leading clinical and academic institutions. Digital health is at the core of our strategy and BHIC will also house the University of Birmingham's Precision Health Technologies Accelerator, providing colocated companies with direct access to clinical trials and research capabilities."

Meanwhile, Kaido's Westman says there are both structured and unstructured benefits to working in such an environment - not least the fact that NHS Global Digital Exemplars University Hospitals Birmingham Foundation Trust and the Birmingham and Solihull Mental Health Foundation Trust are both situated in the city.

"Particularly when you're selling into the NHS, which is actually quite a niche market, getting to know people in the sector through these networks and building confidence with them can be incredibly valuable," he says.



"It's also helpful to meet other tech companies that have all faced the same issues as you have in their journeys and are able to share learnings."

He adds that being at a campus like Innovation Birmingham can help "professionalise" a digital startup by giving it an office space to call home.

Through the Serendip open innovation programme at Innovation Birmingham, supported by West Midlands AHSN, Kaido was able to raise £150,000 in grant funds and gain access to its first clients.

"The first three NHS Trusts that ran Kaido were introduced to us through this programme, and some of the people we met in the NHS have since become consultants for the company. As someone who knew relatively little and had never founded a company before, that has been incredibly useful."



Evidence-based digital health

The right environment is essential for digital start-ups to get a strong footing in the healthcare sector – but once they graduate from incubators, there are still many other factors that can determine levels of success.

When asked what advice he'd give to people starting a digital health company, Genders says it's important to acknowledge that it will be a "long road".

"It's not just a question of writing an app. It's becoming increasingly important to have evidence that the product actually works.

"There are thousands of apps available in diabetes alone. You've really got to be different to stand out from the crowd, and to do that you need endorsement from people in the clinical or academic space who get what you're doing and back you."

He adds: "Over the next couple of years, digital health is going to become a clinical evidence-based space. If you haven't got evidence that stands up to scrutiny, you won't even get on the app stores – the doors will be slammed shut, because as technology gets more sophisticated there's a real danger of doing harm to people."

Genders adds that businesses also increasingly need to have a "scalable, unique" proposition.

"It's no good being a me-too in this sector. You've got to be brave, and you've got to go out and test the product and get people to tell you some harsh truths about whether it is actually solving a problem."

Westman concurs that a start-up's business proposition should focus on the specific niche problem they're trying to solve, but he notes that this doesn't necessarily mean every product needs to reinvent the wheel.

"I think at Kaido we probably came in thinking we were going to do that – but in reality, we've gone into an existing market and just tried to do it better than everyone else. That's enough to be successful."

Likewise, he says that waiting to create the "perfect product" before launching can only hold you back.

"If you wait for that you'll never get it launched and you'll never be able to get feedback from people who are actually using it."

All said, though, Westman is keen to encourage anyone who might have an idea for a digital start-up to give it a go.





"It's great to do it while you're young and have fewer commitments that might increase the risks of launching a business," he says.



"Over the next five to ten years I think we'll see some real success stories in digital health that will encourage more people to take the jump."

Likewise, Mackay says there is a lot to be optimistic about in the sector going forward.

"Public stakeholders want to invest in life science and digital health companies as part of their COVID recovery plans, because those companies are weathering the storm at the moment," she says.

"That stresses the importance of having strong connectivity with the broader sector and investors and working somewhere with sector experts who can help build those connections."

About the interviewees



Chris Genders is the co-founder and director of Gendius. As a diabetic, Chris had the idea to set up a business that would help people focus on their areas of highest risk. An experienced sales director within the pharmaceutical industry, Chris brings an understanding of what it is like to have diabetes and a view of how this can be improved – created from his own experience but also from working in the pharmaceutical diabetes area for many years with healthcare professionals and other people with diabetes.





Dr Kath Mackay is managing director of Bruntwood SciTech - Alderley Park, home to the UK's largest single-site life science campus and award-winning tech hub, Glasshouse. Her responsibilities include stimulating new business ventures and managing further development of the Park. Mackay joined Alderley Park in 2019 from Innovate UK. In her most recent role there, Mackay was director for ageing society, health and nutrition, and part of the executive management team.



Rich Westman is the CEO and founder of Birmingham-based digital health company Kaido. Kaido supports businesses to make health and wellbeing an integral part of their culture, and works with clients such as Transport for London, KPMG, and the NHS. Prior to founding Kaido, Rich worked as a sport scientist, supporting professional athletes from Worcester Warriors, Leicester Tigers and the LTA with their fitness and conditioning. In 2019, Rich was the Technology and Innovation category winner at the Birmingham Young Professional of the Year (BYPY) awards.

About Bruntwood SciTech

Bruntwood SciTech is the UK's leading developer of innovation districts, creating the environments and ecosystems for science and technology businesses to form, scale and grow.

A 50:50 joint venture between leading property company Bruntwood and Legal & General, Bruntwood SciTech provides high quality office and laboratory space and tailored business support, offering unrivalled access to finance, talent and markets, an extensive clinical, academic and public partner network and a sector-specialist community of over 500 companies.

Bruntwood SciTech has a portfolio of over 1.8m sq ft including Alderley Park in Cheshire, Platform in Leeds, Innovation Birmingham, a cluster in the heart of Manchester's Oxford Road Corridor innovation district, Manchester Science Park, Citylabs 1.0 & 2.0 part of the Manchester University NHS Foundation Trust (MFT) campus and Circle Square – a joint venture with Vita Group and a development pipeline of 850,000 sq ft which includes Birmingham Health Innovation Campus.



EPG HEALTH



Two decades of digital: the changing habits of pharma and HCPs

When Chris Cooper of EPG Health launched his 'European Prescriber Guide' software twenty years ago, he was among a select few taking digital in pharma seriously. Since then he has seen the industry slowly come to embrace every aspect of digital. He tells pharmaphorum how pharma can learn from the past to enter an innovative future.

"I always knew pharma was notoriously slow to adopt change," Cooper says when asked about the unexpected digital changes he has seen in the industry over his career, "but I never thought 20 years ago that change would take this long in digital!"

Luckily, he says, the industry has now got to a stage where it is starting to think beyond just clicks and impressions and is treating doctors as consumers of valuable and relevant information – and there has been no better time for pharma to harness this to make their content more impactful than ever.

This is a path Cooper has been on for some time, though, and he was somewhat ahead of the curve when, in 2000, he founded the European Prescriber Guide, which aimed to give up-to-date prescribing information to HCPs via a software application.





Now the company, known today as EPG Health, is providing its offering through the website Medthority using cutting edge tech to hyperpersonalise content for HCPs and provide information in a variety of formats.

A gap in the market



When Cooper started EPG Health, the digital landscape was very different.

"Market level affiliates would often be far more innovative with the use of digital on a tactical level – however, at a regional level, having conversations about how digital could be used as part of a multichannel strategy was extremely difficult.

"There were some exceptions to the rule – a handful of thought leaders emerged throughout the noughties, and the industry started to pay attention. People like Len Starnes formerly of Schering and Bayer, and Kay Wesley formerly of AstraZeneca.



"Those and others like them were catalysts for change in their businesses, and the sector. I didn't always agree with everything they and others said (and made no secret of it), but did agree with the direction of travel, and continue to have huge respect for their contribution to our sector, and digital in particular."



Unfortunately, Cooper says, thought leaders like these tended to be exceptions to the rule at that time, and meaningful conversations about what digital could do rarely happened at a strategic level, but instead remained "a pitch" at brand/tactical level.

"Consequently, projects would often have a 'one off' feel about them, rather than forming part of a wider strategy," he says.

Since then, Cooper says, the industry has shifted its focus away from digital promotional activity and towards educational digital programmes.

"While some pharma companies are still quite internally siloed in their approach, we have seen, over the past few years, more clients with internal joined-up thinking around digital projects. We have seen a move from pure marketing-driven initiatives to multi-stakeholder involvement – including medical, marketing, and digital teams.



"We're also starting to see longer term commitment to projects, with regular content updates, evolving goals, and a focus on activities that help build and sustain HCP engagement over time."

> As pharma's comfort with digital has increased, so too has HCPs' – but rather than making it easier to reach them in higher numbers, Cooper says this has led to more difficulties due to the vast range and volume of competing sources available to them.

> "They are now using multiple devices and channels at home and at work," he says. "They are always 'connected' but have become more selective, choosing where, when and how to access content. This means we have had to become much more creative, flexible and adaptable to their needs."



Because of this, pharma needs to start creating <u>content that specifically works for digital platforms</u>, rather than just putting existing, channel-agnostic content online.

"HCPs consume highlights when they lack time, and therefore need quick access to key messages, short videos, intuitive instruction and interactive content – but they still require long-form scientific content for when they want to deep dive into the detail.

"We need to provide options to cater for the personal needs and preferences of individuals."

From software to website



Like most companies, EPG Health has had to adapt to changing times to keep ahead of what HCPs want to see from pharma's digital engagement – and its origins lie in Cooper spotting a gap in the market when digital was still in its infancy.

Doctors at that time were only able to access prescribing information through disparate forms of media, such as annual books or manuals, Excel spreadsheets circulated by email, and a handful of websites.

"Information was typically out of date by the time it was published and would often be published only once a year. This is all before the actual content and the variance in its nature and substance across the various media was even considered."

Cooper says pharma at that time could best be described as "experimental" in the digital space – there was a lot of interest (and some investment), but few if any constants or strategies to encompass that.

"The rate with which new treatments or revisions to existing treatments came far outpaced the cadence of updates to the existing sources of information on prescription medicines.



"I felt an opportunity might exist to provide pure digital publishing solutions that could link pharma clients with doctors and other healthcare professionals in near real time."

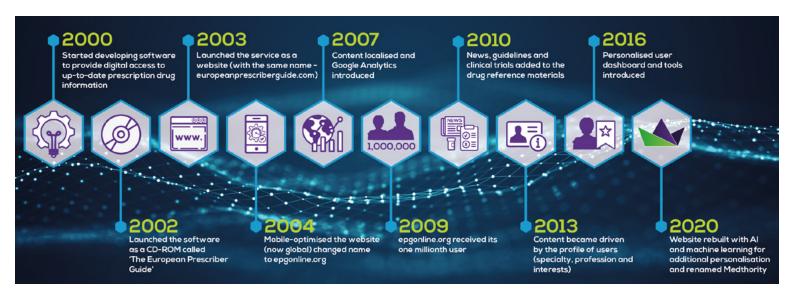


Cooper's solution was to create a software application (delivered on a CD-ROM) that would allow users to browse available treatments for various conditions and diseases, and for those same users to be exposed to a form of interactive self-directed learning – sponsored by pharma companies - called 'Knowledge Centres'.

"The software could periodically connect with a central server to pass back a log file detailing which product the user had viewed and what their search behaviour had been."

The software was called 'The European Prescriber Guide', which became the 'EPG' in 'EPG Health' and launched in early 2002. With the rapid growth of internet access, the company was able to go online in 2003, simultaneously going from a predominantly European audience to a global one.

Since then, EPG has continued to evolve its offering based on advances in digital tech, and while Cooper's goal to ease the discovery of medical information for HCPs has remained the same the way the company delivers this has changed significantly (see image below).



Now, 17 years later, the company's current website, Medthority, is still adapting content based on HCPs' use habits, but is starting to do so through the use of machine learning and advanced AI analytics – and like many in the industry, Cooper believes AI is likely to play an increasingly important part in the digital channel.

"It allows us to show doctors content that will interest them, is not repetitive and is logical based on their prior behaviours, or the behaviours of similar users," he says. "It's similar to how Amazon will show you items you or others like you might be interested in."

Using AI like this, he says, drives very significant change in the way, depth and frequency with which HCPs interact with digital content, and will ultimately help pharma companies adopt a more personalised approach to digital engagement.



"If we can break down the central premise (i.e. the benefits of and argument for) a treatment into its constituent parts – a series of key messages – we can use the technology to expose doctors to as many of those arguments as possible, and also put them front and centre of the user experience."

In general, Cooper adds that pharma should focus more on both the true power and potential of the technology (and how to plan and use it), as well as accelerated and deeper multichannel integration of digital channel capability across all communications, involving reps, MSLs, scientific meetings, third party platforms, social and email channels to effectively get their message heard – thoughts that have been backed up by EPG Health's own research (outlined in a whitepaper <u>Accomplish</u> Meaningful Engagement Online).



Digital renaissance

Cooper says that his business has been fortunate to both survive and thrive through years of ups and downs in the industry's relationship with digital.

"These times could roughly be subdivided into a near decade long period where many of our own customers were not quite getting what it was we did (but knowing it was important enough to buy it); then a renaissance where digital became part of the lexicon; to a third age of industry revolution where we – with thanks to our customers – have been able to invest in and harness the kind of technology I once only dreamt of."

He adds: "We could not have done that without pharma, or the many who have believed in what we do and the driving vision along the way.

"There has been a cultural change in the role digital plays, and the sense that – finally – the significance of digital overpowers the 'new car smell' of the tech that has come and gone, and will continue to come and go."



He says that the industry needs to work much harder now than it did ten, or even five years ago to achieve digital engagement excellence.

"It is much more complicated and resource heavy than it was. While our technology played a large part in defining our business for two decades, we came to realise that our business and its transformation was about so much more than just the technology.



"In fact, our digital transformation was evolving so fast that our technology could not keep pace, and we had to accept that we could no longer develop and maintain it in-house. To stay ahead, we decided to outsource and use PaaS with AI, machine learning and data handling that would allow us to grow and meet future digital demands and behaviour of HCPs."

This has allowed EPG Health to focus on other important components of transformation that don't relate specifically to the technology.

"This includes introducing the right personnel, structure and processes to help us work effectively with evolving technology and our multi-stakeholder customer teams, including optimising content for digital consumption, multichannel integration, virtual events, etc."



On the up and up



Cooper says that he still sees the industry facing many challenges in its digital engagement (see the top 10 challenges) – and one area in particular where more work still needs to be done is bringing understanding and true digital expertise into pharma and unifying that expertise into multidisciplinary customer teams at a tactical level.

"Having knowledge of the technologies, the capability of the technology, and the nuanced nature of digital work would hugely benefit customer teams, how they invest, and what return on investment they secure.



"Often, it feels that this competency is left to chance at strategic level by the customer organisation, with the corporate organisation gambling that the protagonists in their tactical teams have that knowledge, or that vendors like us will fill the gaps."

Cooper says that although many customer team leaders are adept and knowledgeable in terms of what digital does in broad strokes, even today he sees a continuing focus on numbers of impressions and not enough focus on quality of engagement metrics, such as behaviour change and how many strategic targets were reached with the key educational messages.



"If a digital project is not thought through, planned and executed properly – in all regards from the key educational messages, the way those are presented for consumption, and how that consumption is measured etc. - then we are left with an overly-simplistic measure of ROI.

"In fairness, that is where we ourselves were perhaps 10 years ago, but today it is simply not good enough, and dramatically underestimates the potential that can be unleashed by leveraging the right expertise, domain knowledge (from the customer and our own teams), and the technology - all combined and working in concert.



"The capability to understand engagement and behavior change is here now, and we need to get past basics such as volume of X user reached and look at how people engage, react and what they do next."

He adds that it is key for companies to know their strengths and weaknesses.

"The ambition and will is there for pharma, but digital transformation involves a rapid and unified company-wide journey. That's really difficult, and often there are too many obstacles to overcome, projects take too long, cost too much and will eventually be abandoned without external support.

"This might be solved by outsourcing, as we found."

Nevertheless, Cooper remains optimistic about the future of digital in pharma.

"The industry is far better aligned with digital now than it has been at any point in my career. Most – if not all – of our customers are digitally native. That was not the case 20 or even ten years ago, and it makes a huge difference.

"Talking to customers today who expect (and are used to consuming) best-in-class digital in their everyday life – and so recognise 'good' for themselves – has been one of the key drivers behind the change we have seen, in particular in the last five years. Digital now sits front and centre for many customer teams."



About the interviewee



Chris Cooper

Chris Cooper is the founder and chief executive of EPG Health. He has 30 years' experience in digital, 20 of which are in the health sector. In that time, he has grown a digital business and led the evolution of its medical website for healthcare professionals, including the technology, content, commercial offering and people. He has been a consultant to pharma, workshop leader and advisory board members on digital marketing. He is currently looking for investment to grow the business further.

About EPG Health and Medthority



EPG Health is the publisher of Medthority, an independent medical website for healthcare professionals (HCPs). Supporting modern digital behaviour and preferences, Medthority provides a trusted learning environment with convenient access to content that drives better treatment decisions and patient outcomes. With an actionable reach of over a million HCPs globally, EPG Health provides pharmaceutical companies with an integrated toolset to reach and engage target audiences with Key Educational Messages (KEMs) while measuring the outcomes.

For more information visit www.epghealth.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.





Thriving in COVID-19 with flexible marketing strategies

Pharma sales is set to change forever. To keep afloat in the current climate, teams need to embrace flexibility and remember that traditional content won't work in new contexts, say experts from Syneos Health.

Selling in a socially-distanced world is about more than simply taking conversations online it requires a wholesale change in how sales teams operate and the kinds of content they use.



Ian Dorrian, president of Syneos Health Communications Europe, says COVID-19 has driven "unprecedented disruption" in pharma's interactions with its customers.

"There's no case study for this situation; we need to embrace risk and define a new normal.

"Every company has two choices: either they've got to lead change, and define a new normal, or see what others do and then play catch up forever."

He says that at the beginning of the pandemic, Syneos Health had to quickly figure out how to adapt its own large sales force it runs for clients to the new normal.

"Ultimately, patients still depend on those processes to bring new drugs to the market quickly. For them, speed is everything".

"We just couldn't stand still. We still wanted to leverage customer intimacy in a way that only a sales representative can, but we had to find a different way of doing it."



Physicians themselves have demonstrated some major behaviour shifts over the course of the pandemic. Data from Veeva shows that whilst only a couple of thousand calls were made using its remote detailing platform in January, those numbers had rocketed to 80,000 per month by June.

"We also see that the average call duration for remote details this year has been around 19 minutes – compared to around two minutes in face to face meetings," says Alex Brock, managing director, omnichannel & digital Europe at Syneos Health.

"Reps have traditionally been trained to deliver content in a couple of minutes, but now they're having to sustain in-depth, detail oriented scientific conversations for much longer.

"Many are finding that they don't actually have the tools or depth of information to do that."

What this shows, Brock says, is that adapting to this 'new normal' is about more than just flipping from one channel to another.

"When you change channels, you also change the context of usage, which means people will interact with you in a different way."

Every new channel is a new opportunity



The differences between virtual conferences and in-person meetings is a prime example of this.

"Many virtual conferences opted to use platforms that basically presented a virtual exhibition hall, complete with images of exhibition booths," says Brock.

"It's familiar and therefore somewhat comforting, but there's a fundamental difference in the way that a physician interacts with that versus a physical congress. A physician might spend three or four days at a physical conference, passing each booth dozens of times, and eventually stopping when they have a free minute.

"No physician is ever going to spend three days on a congress website. The context in which somebody interacts with that is completely different."

Brock notes that content from virtual conferences will potentially be hosted online for months. This means that congresses are no longer focused bouts of activity – now, they are campaigns.



"Your campaign might not even need to sit on the congress website," says Andreas Reinbolz, managing director of Syneos Health Communications Germany. "Maybe the website is just a placeholder for information that sits somewhere else. That gives you more control to shape interactions in the way you want."

He adds: "Any permission given at a conference is always a deal with someone. For example, at a physical conference, the email follow up on a scientific conversation and some coffee at the booth might be considered enough value in exchange for their email address.

"When we can't talk to someone over a cup of coffee anymore, what's the new value that we provide? Why should a physician allow you to contact them? Surely not for three advertising key messages. Now the quality and the value of the content and interactions are becoming the critical elements.

"We need to look at how we transfer the singular interaction from a congress or a sales rep into something that's more a continuum of communications."

The changing role of reps



Not only, then, is the role of the rep changing to be more sciencefocused, but reps are also moving away from delivering short 'soundbite' messages to having more of a content management, value-provision role.

"In the past reps did everything," says Brock. "Now some of the more transactional tasks, like inviting a customer to an event, have been automated.



"The more collaborative, problem-solving, relationship building roles in a face-to-face scenario can't be automated. We shouldn't think of this dynamic as taking anything away from the rep; instead, it is freeing them up to do more of the tasks that really make a difference."

Syneos Health has learnt from its own sales force that having fewer calls with more depth is becoming an increasingly successful tactic.

The company has also found that "smart targeting" of high-value customers can allow for greater depth of interaction.

"Previously we might have said that there's digital on one side and the rep on the other, with nothing in between," says Reinbolz, "but the reality is that reps are increasingly using digital channels and tools to help manage content and provide valuable interactions."

One such tool Syneos Health has developed in response to the pandemic is RepCast – which allows for engaging socially-distanced discussions with a physician in a face-to-face environment.

The platform 'beams' content from the rep's device to an HCP's phone. This allows the rep to drive content and stay in control of the narrative even when sitting far apart from the physician.

Other useful tools might include smartpasses, which allow quick, simple ongoing HCP engagement through a smartphone's digital wallet; hybrid detailer aids for face-to-face and remote use; and chatbots that can provide product support to patients or physicians.

Flexibility



Ultimately, this means that reps and their companies need to be more flexible than ever. Teams can no longer write a sales plan in October then not look at it again until the following year. Rather, these plans need to become living documents.

"There's always new data coming out," says Reinbolz, "and you need to be able to adjust messages as you go."



"When faced with uncertainty, it can be easier, and feel safer, to stick with what you know. But there's no such thing as a COVID-safe marketing strategy. You've got to leave your comfort zone and think about what you can do to be recognised by physicians for what you stand for, using different tools and content elements."

He says that being able to connect expertise in clinical studies, publication writing, congresses and sales operations is key – and this has allowed Syneos Health in particular to embrace flexibility during the pandemic.

The riskiest thing a sales team can do in the current situation, he adds, is to continue working in the same way they were before the pandemic.

"People often pretend it's just a matter of media mix. I've even seen people say that three emails equal a rep visit.

"That's not serving clients very well. What we think is really helping clients is looking at things more strategically, and from an agile perspective – asking how you can be flexible, how you can have conversations in different channels, and ultimately how you can provide value to your customers, especially in light of COVID-19 and the challenges it poses.

"If the conversation's happening on that level, it gets a lot more powerful – and then the channel is just a way of transmitting that value. If you haven't sorted out the value conversation, the channel discussion will not help you."

About the interviewees



Andreas Reinbolz leads the German team of Syneos Health Communications across advertising, PR and medical communications. His scientific background as a biologist combined with long standing expertise in strategic communication planning and his creative approach fuel German and international healthcare brands.





Ian Dorrian is the European regional president for Syneos Health Communications, leading a team of over 250 communications professionals working across advertising, medical communications and public relations to deliver a wide variety of global omnichannel customer experiences. He has consistently worked in the life science sector for over 30 years; both in-house and in major holding company service agencies.



Alex Brock leads omnichannel and digital across Syneos Health in Europe, and runs the central digital team based in the London HQ. He has worked at Syneos Health for the past seven years, overseeing the evolution of digital insight, strategy and optimisation across the EU business. Prior to this he has worked in various insight and digital strategy roles in healthcare and consumer sectors over the past 14 years.

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.



VR, COVID and ensuring safety with cutting-edge tech

Not too long ago virtual reality (VR) tech might have seemed like a dream, but now it's being harnessed by the healthcare industry for a wide variety of purposes, and during COVID-19 has helped educate physicians when real-world training isn't feasible.



Commercial VR is still a relatively fresh prospect, but already the pharma and healthcare industries have caught onto the hype and are exploring the myriad ways this tech could be used to improve patient outcomes.

That's not to say VR is widespread in the sector – far from it – but the readiness to adopt such a new technology from even big pharma firms is somewhat surprising considering how conservative the industry has been in the past.





<u>Novartis</u>, for example, has used the tech to help researchers improve the molecular makeup of a drug, by allowing them to view these structures at a larger size and in a more "natural" 3D view. Similarly, <u>Pfizer</u> is using the technology to allow researchers to visualise and virtually explore the human body at a molecular level. One recent <u>study</u> even explored how VR could be used to analyse drug candidates that target the main protease of the SARS-CoV-2 virus behind COVID-19.

Some companies are also exploring the possibility of using VR to meet other people in a <u>virtual space</u> in lieu of in-person conferences, or to give doctors and researchers a <u>vivid experience</u> of what it's like to live with difficult conditions such as Alzheimer's.

Meanwhile, in marketing, augmented reality (AR) and VR tech offers several advantages, including ensuring effective communication by providing immersive experiences, assisting sales representatives to give quick and appealing product illustrations, and enabling individuals to assess the impact of various treatment options, through product demonstrations or the use of 'virtual clinics'.

According to one report, estimates suggest that more than 60% of consumers feel more engaged with a brand that offers them a VR experience; likewise, a similar percentage of US-based physicians are inclined to use such solutions for education and training purposes.

It's easy to see why, then, the global AR and VR is expected to reach <u>\$10.82 billion</u> by 2025.

"Although these technologies are still relatively new, the extent of their usage in the healthcare and pharma sectors is growing at a rapid pace," says Dr Alexander Young, former trauma and orthopaedic surgeon turned founder of VR firm Virti.

"Now platforms are integrating VR, AR, and Al technology to develop cloud-based immersive training platforms providing education to physicians and patients remotely, accessible on any smart device or headset.

"Sophisticated updates to the software and hardware are constantly being developed and released."

Young adds that in the UK, several NHS Hospital Trusts are "enthusiastically" investing in VR and AR tech, as are industry-leading pharma companies – and he has seen similar enthusiasm coming from the US.

VR in the fight against COVID-19

Earlier this year Virti and its VR HCP training platform won funding from NHSX's TechForce19 challenge in its search for tools to help with the COVID-19 crisis.

"A common challenge encountered by HCPs is that, during a traditional medical education programme, it's difficult to obtain high-quality practical experience," explains Young. "Owing to constraints of time, space and opportunity, often these students encounter critical situations for the first time when they are in a position of responsibility – and that can be extremely stressful.



"VR is just like performing the procedure in real life, but there is zero risk. This means that all the learners have the same access to high-quality training, driving down medical error."

During the pandemic, Virti has been utilised by healthcare providers to produce simulations that train hospital staff in key skills like donning and doffing PPE, navigating unfamiliar wards, and the use of ventilators (see a video demonstration here).

"We often hear it said that nothing can beat an in-person training session, but independent research has actually proven that, with the right tools, quite the opposite is true," Young adds.

A study carried out as part of the TechForce19 challenge showed that, in the health and social care sector, training with immersive VR technology improved understanding of infection control measures by 76% and improved knowledge retention of crucial health and safety guidelines by 230%.

"This is most likely because as humans, we learn best by doing, not by listening, watching or reading," says Young. "Traditional face-to-face or book-based training can be disengaging and far removed from the realities of using the skills.

"In contrast, when participants train using an AR or VR platform, they have the opportunity to In addition, by integrating AI tools, the students can each receive personalised, objective feedback on their performance, rather than relying on off-hand comments.

"We know that students who train with these platforms don't only come out of the process with more refined skills, but they also hold onto their knowledge and their confidence for a longer period of time after the training has been completed."





Additional applications for the technology during COVID include delivering patient education remotely when in-person consultations are challenging.

"With telehealth and remote consultation being rapidly adopted during COVID-19, many physicians have reported anxiety around maintaining rapport and delivering difficult diagnoses over telephone or video consultations," Young says.

"VR is excellent at 'soft skills' training, allowing HCPs to be immersed in emotive virtual role-plays that simulate real-life situations."

And with many patients unable to leave their homes VR can be used to transport them to new locations and reduce social isolation, Young notes.

Clinical challenges

As VR becomes more commonplace in healthcare, questions will invariably arise as to when we may see VR become a viable technology for clinical use.

Some clinical uses have already been tested – according to a <u>study</u> published in *Pharmacy* and *Therapeutics*, VR has shown benefits in treating pain associated with a variety of physical and psychological illnesses, as well as anxiety and phobia disorders.

However, using such a new technology in clinical trials comes with a whole host of challenges.

The study notes that trials involving VR often suffer from poor study design, thanks to factors like sample sizes, lack of control groups, varying technical standards for VR tools (which change rapidly as the tech evolves), and a lack of consideration of economic feasibility (VR tech currently being fairly expensive).

As such, there is also currently a lack of data regarding long-term effects of using the technology for patients.

In 2018, an international working group of VR experts met in response to these concerns to standardise and create best practices for VR clinical research.

The committee members described the current state of clinical VR research as the "Wild West" with a "lack of clear guidelines and standards", with studies often focused "more on the tech rather than the theories behind it".

They expressed concern that much of the current research is "merely descriptive" in nature, often insufficiently powered, focused on small case reports and retrospective analyses, and often does not employ experimental designs.

The report released by the committee listed several standards for all levels of VR trials that aim to make them as robust as RCTs for drugs and other medical devices.





In particular, the report noted that it was vital to include the patient's voice "early and often" in the development of VR treatments – as well as the voice of providers.

"The committee believes that the more attuned a development team is to the specific perspective and needs of patients, the more likely they are to design meaningful VR treatments," the report says.

They identified three key principles that are fundamental for developing "desirable, feasible and viable" VR treatments and promote empathy, team collaboration, and continuous user feedback – inspiration through empathising; ideation through team collaboration; and prototyping through continuous user feedback.

"The committee believes that the use of these principles allows development teams to better identify users' needs, incorporate user feedback, and institute rapid cycle improvements that generate more relevant products at lower cost," the report says.



VR meets Al

Looking into the future of the technology itself, Young says the integration of AI tech into VR devices is likely to become an "industry gold standard".

"It's now clear just how powerful these technologies can be in combination, and we are just beginning to see how AI is going to underpin so many different facets of the business and the healthcare landscape over the coming years."

Young believes VR will become the norm in several areas, such as helping surgeons prepare for complicated operations with Al-embedded virtual practice tools, new employees being assessed via Al-enhanced virtual exercises, and top salespeople working on refining their skills based on algorithm-derived feedback.

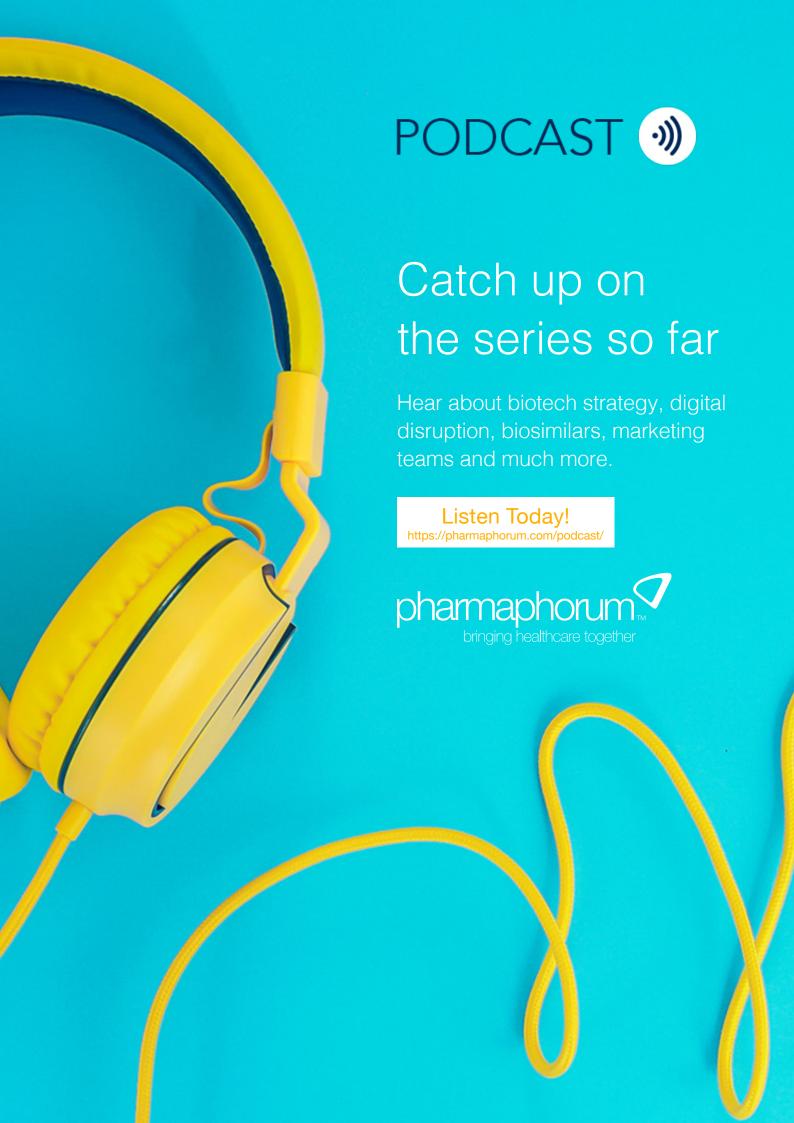
"Now that remote conferencing and learning seem set to continue for the foreseeable future, there's no sign of a slowdown in the adoption of VR and AR technology."

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 innovations booming during **COVID** and how to adopt them successfully

Research Partnership's Vicki Newlove explores research into digital change during COVID-19 to find out what business questions pharma needs to address to succeed with innovations.

Pharma companies are facing a confusing and uncertain future, and no one can say how the industry might look in a year's time, or what the balance of digital and physical working might be. Even those companies that responded well to the pandemic and quickly embraced digital can't know how long restrictions will last, and many are still revising their strategies and figuring out how best to position their digital offerings.

The companies that will thrive are those who gather insights into how COVID is impacting the patient journey and physicians' behaviour and adapt accordingly. This will allow them to put robust, long-term strategies into place.

Our own research has shown marked shifts towards digitisation in the industry. For example, findings from our Therapy Watch report 'Free thinking: The impact of COVID-19 on chronic disease management and the implications for pharma marketing' show that 89% of physicians across the EU5 report replacing face-to-face consultations with virtual consultations during the pandemic.

This article will focus on three key areas where we expect to see accelerated innovation: new product development, digital communications, and 'around the pill' support. We have also identified some key strategies companies need to put in place to ensure they are successful in these areas.



New product development

Pharma was already seeing a slew of innovative product developments before the pandemic, and COVID has done nothing to slow the industry's digital adoption.

One such development is the employment of artificial intelligence (AI) in the delivery of healthcare provision. AI technology has multiple uses but in particular we have seen it working alongside physicians to help minimise human error – for example by detecting early signs of disease or predicting treatment outcomes – thus optimising the patient experience.

While many patients and physicians are keen to embrace AI, just as many are wary of it. Some physicians don't think AI can replace their years of practice knowledge, and don't like having less control over what happens to their patients. To overcome hurdles like this in product adoption, we use behavioural economic theory in the research, design and analysis we do at Research Partnership.



First, we need to understand the person's current behaviours, attitudes and beliefs, and the biases or heuristics that might be driving certains beliefs or behaviours. Then we look for ways to encourage a new behaviour.

We apply the EAST behaviour change framework – which proposes that for a new behaviour to be adopted, it needs to be Easy, Attractive, Social, and Timely. For example, one barrier to adopting a new product might be that the doctor simply doesn't want to learn a new technology. The EAST framework would suggest that we need to demonstrate that the product is easy to use and will free up their time. It can be difficult to uncover the biases that are driving perceptions or behaviours, so we use projective techniques to delve deeper into the doctor's psyche. By understanding behaviour and demonstrating how to effect change, we can help our clients improve the physician and patient experience.



Communication

Similarly, the use of digital communication tools (e.g. e-detail and telemedicine) has increased during the pandemic. The advantage of these tools is that they can be personalised based on an individual's preferences and behaviours, and we can enhance their usage by profiling the customers adopting them.

In our market research, we may help clients profile customers in terms of their receptiveness to using digital forms of communication, or identify the aspects of the communication that are most relevant to them.

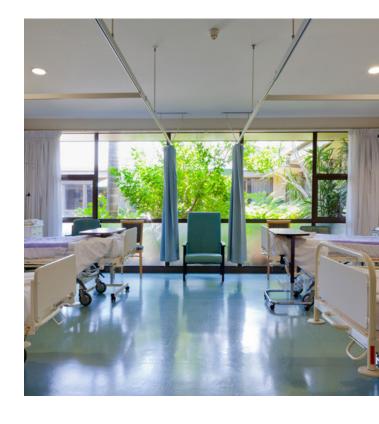


This will allow, for example, a physician to have a much more personalised experience of an e-detail if the information shown can be targeted to their preferences. Or, by understanding individual patient receptiveness to digital communication, our clients can help physicians optimise how they communicate with their patients.

Around-the-pill

Around-the-pill patient services such as wearables and apps have become more important over the course of the pandemic, as a consequence of the restrictions on faceto-face interactions. As before, it is important to profile patients so you can ensure that the digital offerings you're developing are being given to people who are going to benefit the most from them. For example, it's better to recommend a disease management app to someone who has already shown high engagement with their disease, such as by participating in online patient groups. You can then also educate physicians to recommend that digital product for a specific patient type.

As well as a boom in around-the-pill tech, we're also seeing digital patient support programmes (PSPs) become more commonplace, as clients look for new ways to support patients outside of traditional doctor-led interactions.





Therapy Watch research has found that the steep rise in telemedicine has had some knock-on effects on the patient journey. Patients are not presenting as early as they should be, either because they're scared to go to the hospital or because their appointments have been cancelled. Combined with doctors being less confident about managing complex treatments without regular in-person interactions, this means patients aren't getting the same treatment offerings that they might have had pre-COVID. Our clients are therefore having to rethink and re-research the patient journey and understand at what points in the new pathway around-the-pill offerings would work best.

PSPs can help to take the pressure off doctors – but companies must be aware of how such programmes might function differently in a COVID-19 world. As with other facets of pandemic business, gathering insights is key to this. We offer an evaluation service called PSP Enhance, where we gather information on patient unmet needs and get insights from all stakeholders, including physicians, upfront, to ensure clients design PSPs that have the best potential out of the gate.

User experience

The common throughline here is that user experience needs to be the prime consideration for all digital offerings. It's all very well rethinking your strategy and implementing digital offerings, but they must be useful and relevant for customers. A lot of ideas on paper end up lacking when translated into a digital product.

This can be small things like making sure that the most relevant information for the user is on the front screen of an app, or that a device is measuring what is most important to the patient or physician.



That's why user experience research is key – and that research needs to happen as early in the development process as possible.

At Research Partnership's User Experience division, we collect feedback on both live digital assets and those in the design phase and help our clients to identify optimal site content, organisation and navigation



An agile future

Keeping abreast of market research insights has the broader benefit of allowing companies to think on their feet and react quickly to changes in the situation. Agile working is only going to become more and more important as the pandemic progresses.

Digital offerings that were already growing in popularity before the pandemic, like AI, are likely to stick around, as their benefits have been shown to outweigh people's concerns. What is more uncertain is whether the technologies that were forced into the limelight by circumstance – such as telemedicine and e-details – will remain popular post-COVID.

Every individual patient journey is different, and every patient will have varying degrees of success with digital tools. We've certainly heard from both physicians and patients that they're not 100% comfortable with never seeing each other face-to-face.



Most likely, we will be looking at a hybrid world that combines digital and physical interactions – but it's almost impossible to say at the moment what the balance will end up being. In the meantime, companies need to remain aware of the latest market research insights, and researchers like us need to make sure our research programmes are addressing ever-changing business questions from our clients.



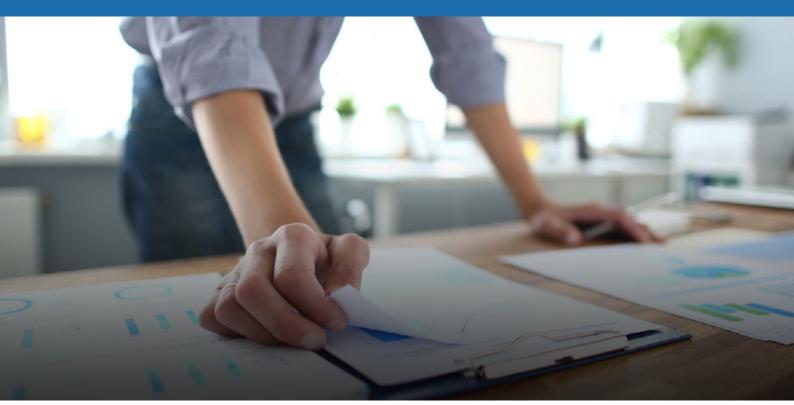
About the author



Vicki Newlove, associate director at Research Partnership, holds a degree in Sociology and Research Methods. She has 13 years of healthcare market research experience, and during this time has worked with key pharma industry clients across a range of therapy areas and using a variety of insight driven methodologies. Recently, she has worked on several research pieces helping her clients to assess the drivers, barriers and opportunities for digital assets.

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.





A new dawn for clinical trial management

It's time for pharma to take a 360-degree view of its clinical trial data and step into the future with near real-time study management.

The pharmaceutical industry faces an important inflection point in its approach to clinical trials and it's one that COVID-19 has thrown into even sharper relief.



The last great change for studies was the advent in the early 2000s of electronic data capture (EDC). At the time there was a significant amount of resistance to EDC, but now it's rare to hear about the collection of trial results using paper in all but the occasional single site investigator study.

Now, the major advance that's available to pharmaceutical companies is in the amount and range of data they have access to and how it can be applied to the risk-based monitoring and remote monitoring of studies.

Joseph Goodgame, Remarque Systems' chief technology officer and co-founder, explains what's driving this shift: "Technology is barrelling along at a super-fast pace in all aspects of our life and patients have an expectation that technology is available to them, whether it's by ePROs (electronic patient reported outcomes), telemedicine visits or other tech advances."



Geographic market

Based in the US, supporting the biopharmaceutical industry globally

Clients

17+ sponsors, CROs, and ACROs including large pharma, mid-size pharma and biotech organisations use our platform to support over 100+ trials to date

Year Established

2015

Core areas of expertise

Real Time Monitoring, RBOM, Dashboard Metrics, Machine Learning. Study Start-Up, CTMS

Our mission

To provide the industry with the first fully integrated workflow system to design, deploy, and manage clinical trials – one, single integrated solution that connects clinical trial data together, centralising all data sources, without the complexity of using multiple separate components. Remarque Systems improves operational performance of a clinical trial through the following:

- · Process optimisation
- Increased visibility
- · Rapid communications
- Improved quality





The current situation with COVID-19 has driven a huge amount of digital transformation across healthcare, and that's certainly proving to be true for clinical trials.

"The pandemic has escalated these changes within pharmaceutical companies, because the old model of a patient going to a site and having all of their data collected at that site, and then a clinical monitor going out and checking the data at that site has become less valuable in the current climate," Goodgame says.

A need for clinical trials innovation

Many of these transformative technologies had already begun making clinical trials more efficient and patient-centric before COVID-19 hit and are likely to have a lasting impact after the pandemic.



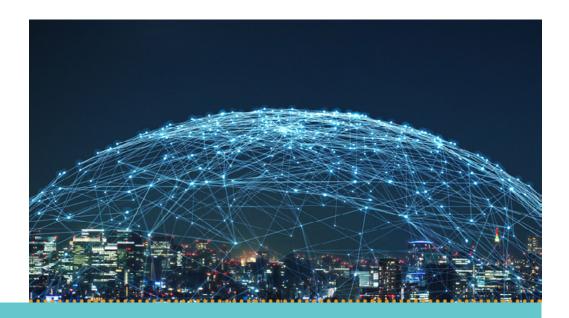


This includes telemedicine tools that support decentralised trials, remote monitoring technologies and machine learning tech that enables more timely review and analysis of large datasets leading to identification of potential issues and anomalies much earlier in the process.

But, despite the justified excitement surrounding clinical trial evolution, there are still a number of barriers preventing sponsors from fully embracing these technologies.

Remarque's solutions service director Kristin Mauri notes, for example, that there are few incentives for the industry to change from a regulatory perspective.

"Agencies across the globe have put out a lot of regulations and recommendations around how to use technology to do things differently, but they're not actually auditing companies against them, so there's no consequences for sticking with the old way of doing things.





"That mindset is very challenging. Until the industry moves towards training and building up that skillset, it's going to be slow in moving forward. It requires a lot of evangelising to show people that this is the right way to look at data."

This data problem also points to a wider issue with drug development, Mauri says.

"People do things the way they've always done them because it's proven to work and because trials are so expensive. There's a lot of pressure on teams to just get through the process and doing anything new can be intimidating because they then feel as if they don't have control and can't meet deadlines."

Finally, most current trial management platforms were not designed with these advances in mind, and the landscape has evolved so rapidly that many have struggled to keep up.

"The way clinical trials are executed is going to fundamentally change over the next few years, but legacy systems were not designed to be able to evolve with that," says Mauri. "Companies need a foundational platform that's able to take them into the future as we move towards things like decentralised and patient-centric trials. What's out there today is not built to do that."

A better way to manage clinical trials

For this reason, Goodgame says, Remarque Systems has been careful to design its own clinical trial operating platform with change in mind.

"We've spent five years honing this platform to a point that it can cope with the current changes to clinical trials. It's not a quick fix; it's like back in 1998 when Jeff Bezos said Amazon was going to be a data company. It was a big decision we made way in advance of when the industry actually started leveraging these capabilities.

"That was a quite risky move for us as a young start-up company. We could have taken the solid, well-established approach, but we decided to do things differently."

In practice, this means the company has had to focus on being as flexible as possible.

"What's unusual about our platform is that you can use it as-is with traditional trial methods, or you can have a completely decentralised trial with telemedicine tech, etc," says Michael Arlotto, president and co-founder at Remarque. "Once they upskill their data literacy and get comfortable with the system, all of the data capture methods and technologies behind it will look the same to the end-user."



Arlotto and Goodgame founded Remarque in 2015 based on the idea, as Arlotto puts it, that "there had to be a better way to manage clinical trials".

"We had both worked at a large global CRO in the past, and while there it felt like we were always a few steps behind the trials. We never had the ability to manage studies in real-time or near real-time as data flowed into the system. It always depended on data being transferred a month later, or even a quarter later.



"Meanwhile, trial managers could only look at the data if they created a general data warehouse and then used business intelligence tools on top of it. Because of that, the data was rather old by the time it went through all of the manipulations. You weren't looking at data flowing directly from the site, the patient or the labs."

Arlotto and Goodgame wanted to find a way to give clinical trial managers visibility on data in real-time.

"We wanted to see data from studies at a patient level, at a site level, and at a study level. We wanted to see all the available data - not just the data from electronic data capture systems, clinical trial management systems or laboratory systems, but all of the data in a consolidated manner. That would allow people to clearly see what was going on with that patient, that site, or that clinical trial."



They also wanted to create a platform where trial managers could manage, monitor and mitigate risk within one system – aligning with the concept of risk-based monitoring that was just starting to take off at the time. Remarque aimed to be a provider of solutions for risk-based monitoring of all forms, including remote, central, medical and on-site, in-process analytics, and continuous development for data quality improvement.

"We wanted the system to be able to pull data from multiple sources and expose it to the end-user in a meaningful way," says Arlotto.

"We also added in the ability to use the TransCelerate Risk Assessment Characterization Tool (RACT). Through that we can manage every possible risk, identify data points that are associated with it, and suggest mitigation strategies when a risk is detected. We wanted users to be able to act on any risks they saw in the system."



Machine learning algorithms allow a degree of automation and can flag potential issues much earlier in the trial process – and, as pharma has often found out, knowing whether a trial needs to be stopped or altered early on can save companies enormous amounts of money by avoiding drugs that won't ever make it through the pipeline.

Arlotto notes that there are also more nuanced situations where real-time data can save pharma time and money.

"In studies with complex protocols you can make sure you avoid redundancies. For example, if you only need to give six people the 10-milligram dose, but three sites are recruiting at the same time, you may end up with more patients than you need.



"If there is an issue at the site and you have to lose patients, it's best to lose them while the enrolment is still going on than to lose them when the study is finished."



The company also added a business processing workflow system into the platform – if a user sees an issue in the system, it can be assigned to a named individual to resolve, with the entire process captured in a trial audit for regulatory purposes.

The result is what the founders describe as "the first fully integrated workflow system to design, deploy, and manage clinical trials – one, single integrated solution that connects clinical trial data together, centralising all data sources, without the complexity of using multiple separate components".

Arlotto and Goodgame say that the advantage to the user is speed of implementation, ease of connecting data together and cost efficiency.



"We think that's going to be important in the future as clinical trials evolve, and people start to use things like wearables or telemedicine. There needs to be a system that can still consolidate all of that information into one place, and help you act upon it."

Since its founding, Remarque has been consistently adding new functions to its software, such as dashboarding and business intelligence – as well as the ability to generate monitoring reports directly out of the system, linking those to action item letters that go to a site, and integrating that with an electronic trial master log.

Goodgame notes that many of these innovations, such as dashboards, visualisations and machine learning, are changes that other industries had already embraced.

"We wanted to say to pharma, biotech and device companies that they didn't have to stick with legacy platforms that were designed 20 years ago and don't integrate or give visibility on data."

Optimising the customer experience

The company has retained a sense of agility and "thirst for innovation" and these, Goodgame says, have played a vital role in underpinning its drive to improve clinical trials for pharmaceutical companies.



"We make sure we develop using an agile methodology. That allows us to be very mindful of different customers as they come in. After all, every customer has different approaches, skillsets, and teams.

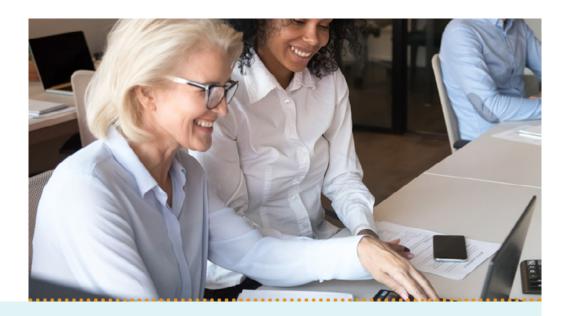
"We have everything from customers with absolutely no experience in managing a trial through to customers who absolutely lead the way in defining risk-based monitoring methodologies."



As such, Goodgame says it's been important to also apply that agile mindset to Remarque's customer engagement team in order to optimise the customer experience. This is particularly notable with change management, an important area if data literacy upskilling and teams are to be supported to get the most out of the platform.

He says: "The customer engagement team can speak to the company to understand the situation and adapt accordingly. It's a consultative approach to customer experience. We want to make sure these consultants are highly knowledgeable about how the drug development process works. That knowledge is really important when you're a small group."

The company has also added a layer of account management to govern relationships and ensure that the customer gets as much benefit out of the software as possible.



"We want to, over time, help them take these bite-sized pieces of the product, and grow and expand them," says Mauri. "As we've said, they can easily use the system with traditional methodologies, but our account management strategy is really meant to help guide people into the future of how trials will be executed."

That idea of guiding pharma into the future is a key part of why Arlotto and Goodgame founded the business in the first place.

Goodgame explains: "One of the reasons I joined the life sciences industry in 2003 was that I felt the whole industry had a backwards approach to managing data. I don't think it was necessarily intentional - but everything used to be done on paper, and when new technology came along it was just used to repeat the same manual processes on a different platform. Most other industries had moved way beyond that."



He says that the industry is still "a long way behind" on using data.

"But this industry can leverage learnings and approaches that have been honed in other strictly regulated industries and leapfrog ahead. Change is happening a lot quicker than is normal in pharma and I anticipate that things are going to evolve quite drastically in the next couple of years."

In the meantime, Remarque is keen to show that even a small company can bring great benefits to pharma by staying ahead of the curve in these developments, while giving the industry greater visibility of more types of data, taking an agile approach to development and facilitating risk-based monitoring.

If pharma can embrace these evolutions, then efficient, decentralised and patient-centric trials will no longer be a pipedream, but a core pillar of the industry's work.

About the interviewees



Michael Arlotto

Michael Arlotto is president and co-founder of Remarque Systems. Michael is an industry leader who understands the key business drivers to generate value, with more than 25 years of scientific investment and operational experience in pharmaceutical, biotechnology, pharmaceutical service, and healthcare IT industry.



Joseph Goodgame

Joseph Goodgame is the co-founder and chief technology officer of Remarque Systems and has worked extensively in the data and information space for over 20 years. He has been recognised in Computer World for his cutting-edge work on building a patient analysis framework across over 60 million patients, and named on a number of patent applications for new and novel analysis methods.





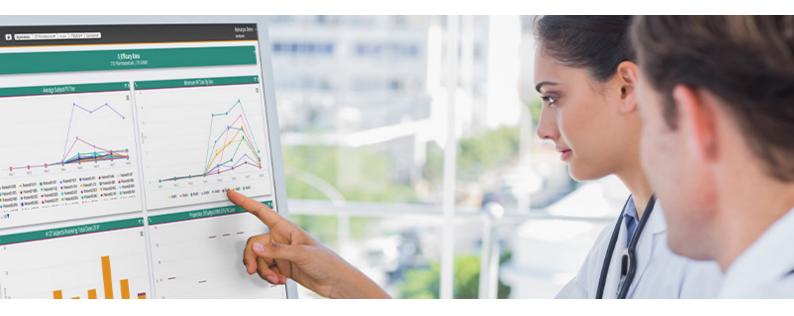
Kristin Mauri

About Remarque Systems



Remarque is a clinical trial data company that enables researchers to use data from any source, on one platform. Remarque provides real-time visualizations and risk alerts to study sponsors and contract research organizations (CROs) to enable data-driven decisions.

For further information, visit <u>remarquesystems.com</u>





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