Market Access

Plus: delivering on the promise of treatment innovation

How do we make patient centricity a reality?

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Closing the digital expectation gap in pharma

pharmaphorum deepdive

May 2022

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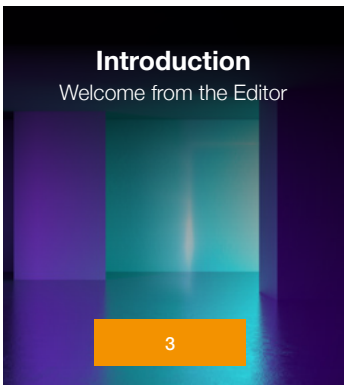
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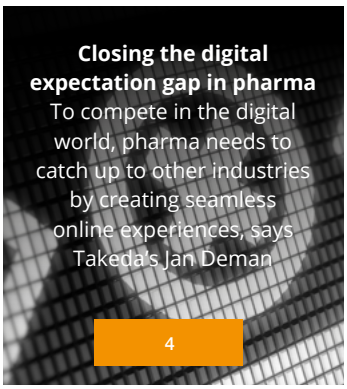
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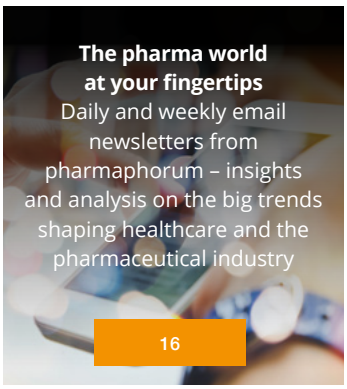
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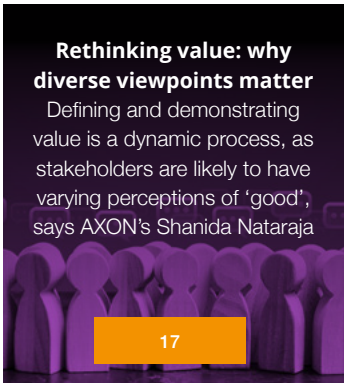
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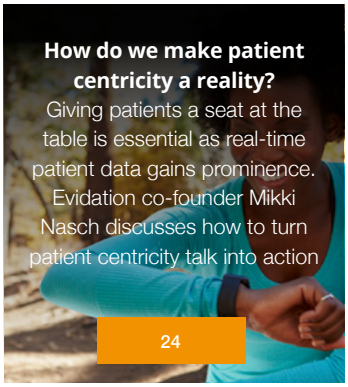
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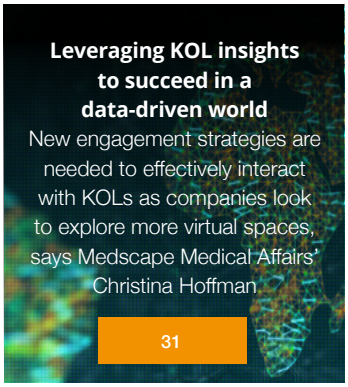
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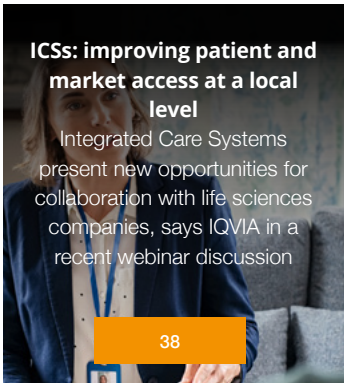
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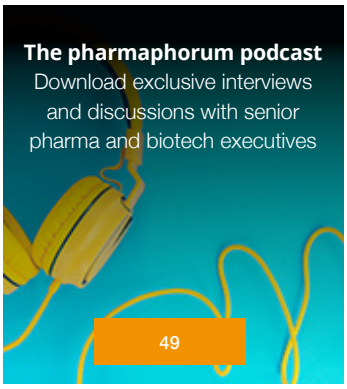
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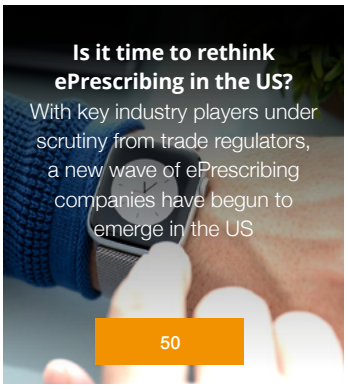
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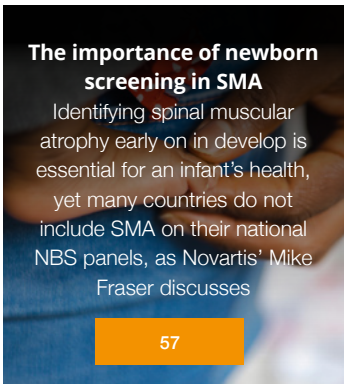
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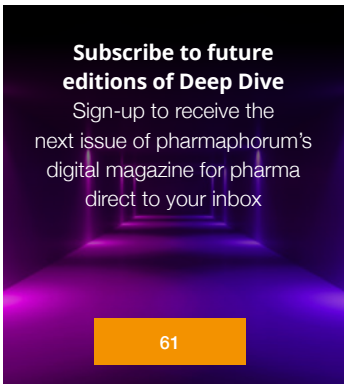
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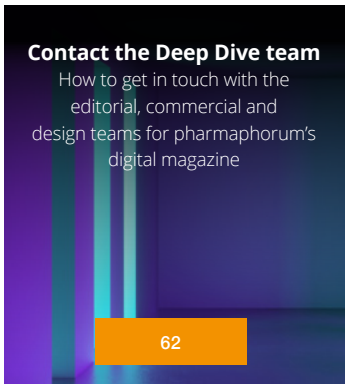
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Deep Dive: Market Access

Amid seismic changes in the healthcare landscape, both in terms of capabilities and therapeutic need, the subject of market access has become an understandably hot topic for many across the healthcare landscape.

The combined impact of COVID-19 and the accelerated adoption of digital technologies has created a perfect storm for change, with new avenues for companies to engage with consumers, healthcare providers, and patients in the digital realm, as well as traditional face-to-face interactions.

While this is certainly an exciting and innovative time for life sciences, not all of these new developments fit into the confines of traditional market access frameworks. As such, companies are thinking outside of the box to create processes that reflect the changing paradigms of modern medicine.

In this issue of Deep Dive, we take a closer look at some of the key issues and trends in market access – with experts from across the industry sharing their insight and advice to help companies navigate the hybrid environment.

Moreover, we'll also delve into the subject of diversity and inclusivity in shaping product value. As real-world data creates more opportunities for patients to play an active role in research and development, companies can use real-time information to understand value and create a permanent seat at the table for patients.

By pulling together, companies across the sector have the chance to tear down traditional market access barriers and deliver much-needed therapeutics to patients around the world.

I hope you are staying safe.

Eloise

Eloise McLennan – editor, Deep Dive

Next issue:
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Closing the digital expectation gap in pharma

Jan Deman is Takeda's head of digital customer experience for Europe and Canada. But he'd prefer not to refer to what he does as "innovation". It's a word, he says, that doesn't reflect where pharma stands in relation to larger trends.

"It's not innovation in the usual sense of the word," Deman says. "Mostly it is about catching up with what is happening outside of our industry and going back to basics to ensure a seamless customer experience."

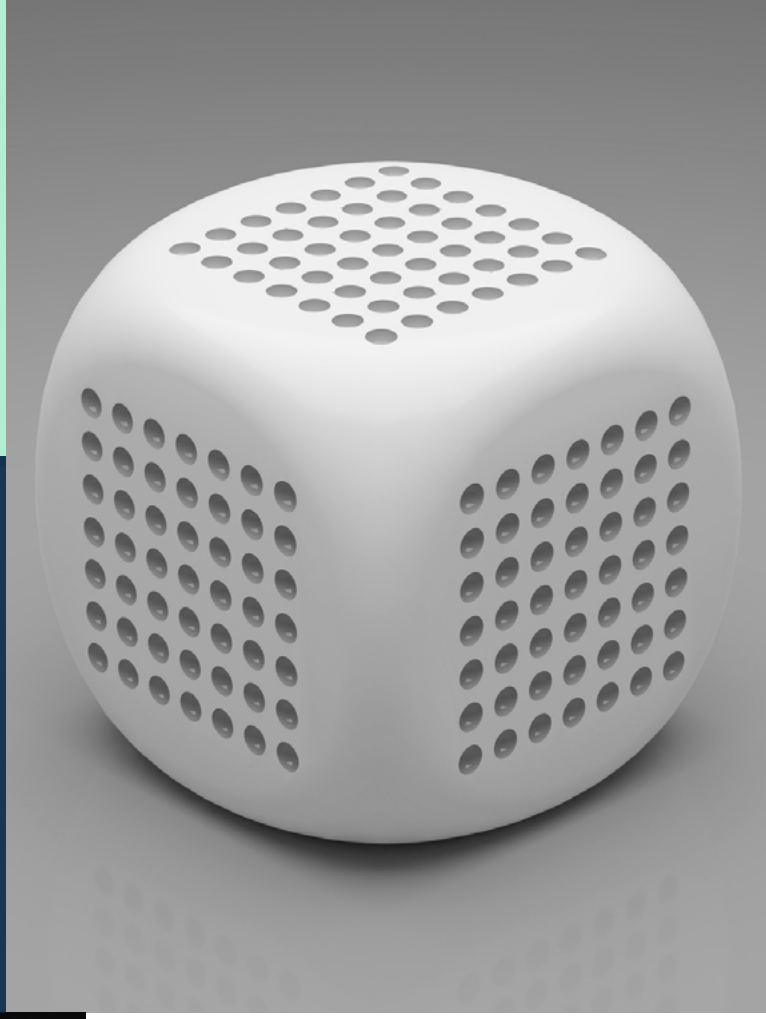
"In a world where digital technology has made it easy to book travel, order food, make restaurant reservations, do banking, submit taxes and almost any other 'everyday' transaction you can think of pharma companies have some catching up to do – specifically in the customer experience and services space," Deman says.

And this lack of progress on basic digital interactions can also hinder more ambitious innovation plays.

"If you could pick one of two things to have good customer experience, managing your health or ordering a taxi, I like to think most people would probably choose managing their health," he says. "But that's not how it works right now"

"In Pharma, many have been very focused on the sometimes more sophisticated opportunities like digital companions to therapies and innovations on the far end of the digital spectrum – which are all very necessary. However, sometimes we forget the basic digital services and more importantly how to digitally operationalise the customer experience across the whole value chain. Failing in this area risks losing or frustrating people on things that are now common digital practices in the world we all live in," he says. "To date, where the industry is still not winning is in closing the gap on the customer experience on these very small steps."

What's holding pharma back?



Why has pharma fallen behind in closing what Deman calls the digital expectation gap?

One might object that pharma is a tightly regulated, defensibly a risk-averse industry. But Deman considers those barriers – specifically in the customer experience space – to be more easily overcome than people think.

"We're not the only regulated industry in the world," he says. "And while our products are very different compared to these industries – the way customers could and expect to engage with us is not that different. The opportunity for us is how to respect appliable laws and regulations and still engage in a modern way with our stakeholders, like so many other regulated industries have succeeded to do in the past years."

In fact, pharma's defining quality – of the products it makes and the positive impact these potentially life-transforming medicines have on people's lives – should make it more, not less important to get customer experience right.

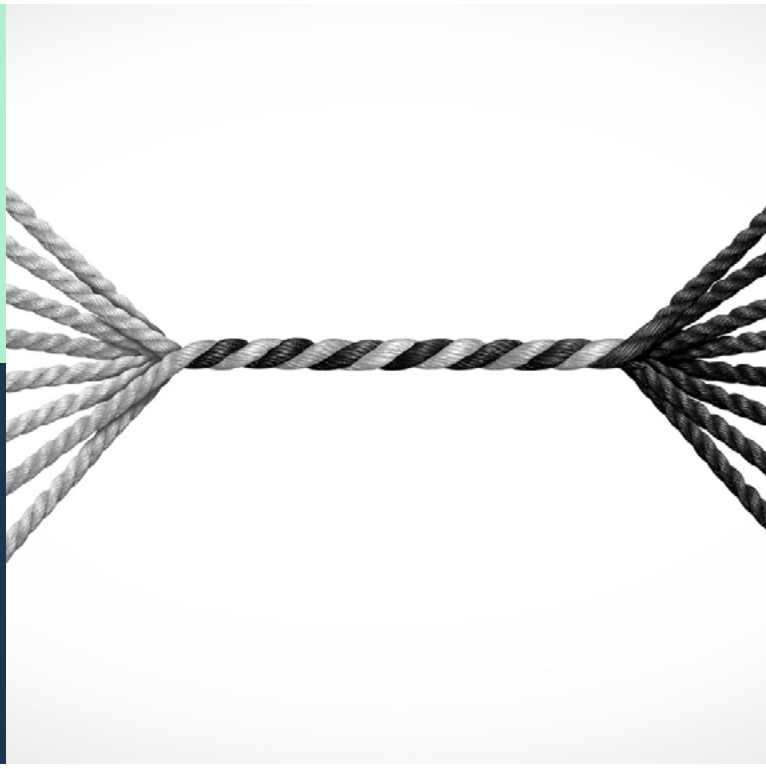
"If you could pick one of two things to have good customer experience, managing your health or ordering a taxi, I like to think most people would probably choose managing their health," he says. "But that's not how it works right now"

For another thing, pharma companies can miss the forest for the trees when they focus on comparing themselves to each other, rather than looking outward to the wider world.

"We keep benchmarking each other," he said. "But the more insightful benchmark would be comparing our digital customer experience with some common industries or even government services – specifically in this 'digital' services space."

Better benchmarks and seamless integration

Instead of comparing themselves to each other or even to others in healthcare, pharma companies should look to the tech companies that have helped create this digital status quo in the first place, Deman says.



"Take Amazon or take Apple as some of these leading examples that everybody uses. It's not because they have a great website or because they have a great app. It's because you have a great, enterprise level digital relationship with them that is cohesive independent of the touchpoint that you have. You don't have multiple logins. You don't have to give consent multiple times. It's all about truly putting your customer core and centre and thinking in an integrated way on how you approach customers – not just in one brand or in one country but across the whole enterprise value chain."

In the quest to start closing this gap, Takeda has been focusing on fundamental elements to create a seamless digital enterprise level customer relationship.

"We've created something which is called the Takeda ID, which is your digital identity with Takeda, not just for the Health Care Professional, but anybody who wants to interact digitally with Takeda," Deman explains. "So, independently of your profile any member of the public can sign-up for a Takeda-ID. Because we believe that independent of your entry point in the Takeda Digital ecosystem, you'd still use the same ID to access other functions in our digital ecosystem when a personal experience is required."

Takeda ID has seen significant uptake since its launch across the enterprise and across all functions in Takeda. It isn't a solution in and of itself, Jan says. But it's a foundation the company can build a seamless customer experience on top of.

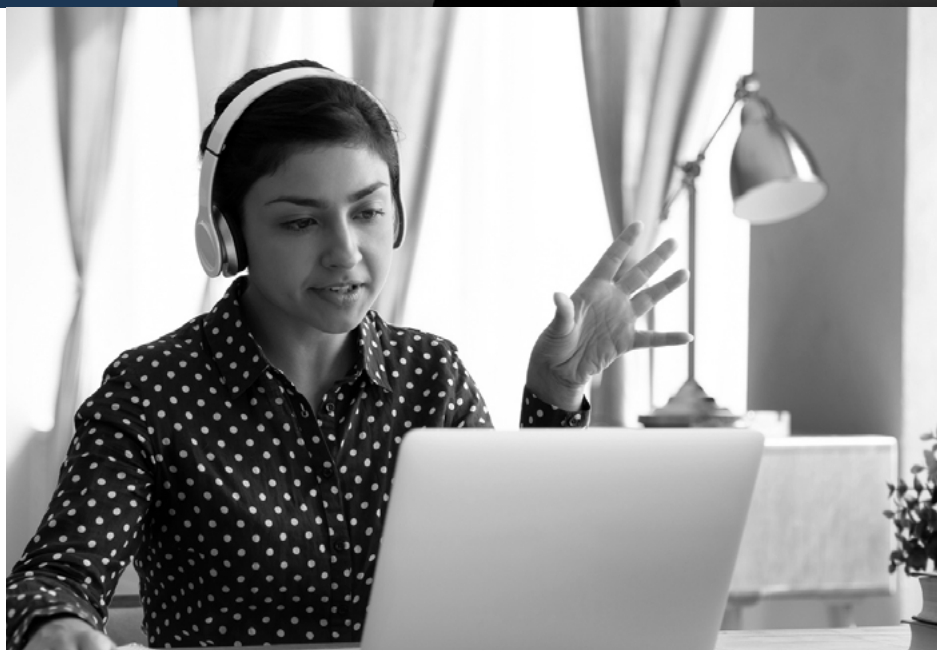
"If you do this right together with several other basic foundational digital services (like consistent consent- and preference management), our hope is that your engagement with Takeda will be smarter, it will be a much more personalised, and it will be a much more productive engagement."

Taking down the false barriers

Inside and outside his own company, Deman thinks change is not only possible, but imminently achievable and necessary in today's digital world.

"Closing the digital expectation gap, allowing us to create differentiating services, that's what I would like to achieve," Deman says. "I would like to achieve that very quickly. And I feel that we're very close to that. It's a matter of months, maybe multiple months, but definitely not decades."

If pharma is so behind in implementing these kinds of seamless online experiences, why should industry be catching up now? One piece of the answer is, of course, COVID-19.



"I think with COVID, some of the perceived barriers have all been eradicated. … All of these assumed barriers have just been taken down because they were either false, had not been revisited for the digital world we have been living in for decades., or they were not completely focused on the real question in hand, which is – 'Are we finding solutions to improve our interactions with physicians and the general public which in turn, enhance treatment and standard of care for patients? Also, the assumption that our physicians or our customers, patients and even our internal field teams would not be willing to use these services, it's all gone. I believe if the value proposition is strong and clear, then people will adapt and change."

The omnichannel future

Next steps for Takeda – and for industry more broadly – will involve creating seamless omnichannel experiences for physicians, who will be able to interact through online experiences, video calls, or more traditional interactions with field-based staff and seamlessly switch from one channel to another across the whole enterprise digital ecosystem. And this not just in one brand or in one country – but at an enterprise level.

"I think the environment has just become a lot more complex," Deman says. "Whereas in previous ways it was all about a single or few channels that you had to excel in. The more you had of that channel, the bigger your prediction of success was going to be. But that's not true anymore. At the same time, we have much more accurate knowledge of the tactics that work well and what needs tuning – thanks to the insights we can generate from the rich data we can collect and the advances in analytical capabilities."

Now, Deman says, successfully competing in the digital world will require adaptability and a solid foundation of seamlessly integrated digital capabilities. It will involve looking at our organisational structures, processes, backend technology architecture and most importantly the people capabilities we need in this new normal, as well as recognising new channels as they emerge and being smart about when and how to use them. For instance, online conferences or even virtual reality "metaverse" conferences provide new opportunities to connect with providers. But taking advantage of those opportunities is more complicated than just porting an experience from one platform to another.

"It's all about the value proposition" he said. "If we can come up with a good value proposition that is differentiating, that is easy to use and is really helping our physicians do something for their patients, whether it's the Metaverse, a real congress, an in-person scientific exchange or a phone call helping to solve a patient problem, the opportunity is in making it a frictionless and a valuable experience for all our stakeholders. It's no longer a single siloed platform that is going to do it for us."

About the interviewee

As Takeda's head of digital customer experience for Europe and Canada, Jan Deman is responsible for managing the region's IT digital CX strategy. Since 2007, he has focused on digital transformation in the pharma industry, with previous experience working in local, regional, and global leadership roles for R&D-IT, commercial-IT, commercial operations, patient services, and digital marketing at BMS, Teva, Shire, and Takeda.

About the author

Jonah Comstock, Editor-in-Chief

Jonah Comstock is a veteran health tech and digital health reporter. In addition to covering the industry for nearly a decade through articles and podcasts, he is also an oft-scene face at digital health events and on digital health Twitter.

Combination pricing: access to the future of oncology treatment relies on collaboration

Combination therapies are fast becoming the cornerstone of cancer treatment: not just in the UK, but across the world. With strong evidence to support how two or more medicines can work simultaneously to target different pathways in numerous ways, it's clear that these kinds of treatments are vital in helping to change the way people live with complex diseases like cancer.

With more than 300 active clinical trials for combination therapies in cancer currently in progress in the UK alone, we can expect that the prevalence of combination treatments will continue to increase over time, and, with that, so will our understanding of their efficacy and impact on long-term patient outcomes.

This is an incredibly exciting time for the clinical and patient community. There is increasing evidence to show that combination therapies can extend disease-free or progression-free survival for those living with certain cancers, as well as reduce the risk of tumours developing resistance to treatment. However, multiple unresolved issues around the value, assessment, pricing and funding of treatments used in combination remain.

It's no use having effective new treatments if patients aren't able to access them"

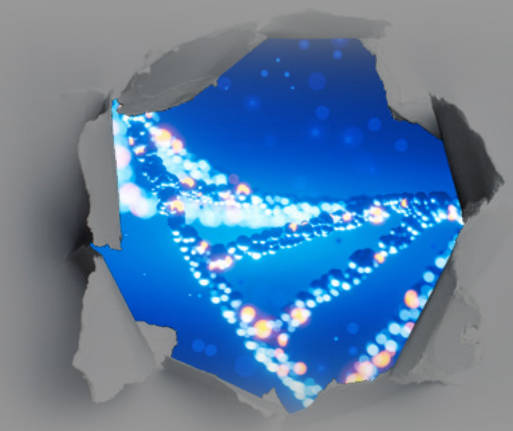
In my role as head of market access at Sanofi UK and Ireland, I strive to address challenges around matching treatment value to patient access, and I am passionate about delivering evidence to ensure patients can receive the most appropriate treatments for their condition. But the issue around pricing and reimbursement of combination therapies within the current healthcare system isn't something I – or the pharmaceutical industry – can resolve in isolation.

New frontiers for exploration

Despite the advances in research and pharmaceutical innovation in recent years, significant unmet needs in many oncology indications still exist. Sadly, the life expectancy for those living with cancer remains significantly lower than that for the general population and approximately 50% of cancer patients in England and Wales do not survive ten years with the disease.

In light of this, innovative new treatment options must be explored, and the complex therapeutic challenges presented by oncology patients must be addressed with more effective solutions.

The need for therapies involving multiple mechanisms of action is clear, as are the positive implications of new combination medicines for the cancer community. But it's no use having effective new treatments if patients aren't able to access them and innovation, too, will be halted if not met with fair and balanced long-term solutions.



The Life Science's Vision outlines the UK Government's ambition to become the best place in the world for the discovery, development and launch of new treatments, however access challenges could stand in the way of additional investment and scientific advancements. This, in turn, will be of detriment to patients or could act to delay, or even stop, availability. It's vital that we address these challenges to keep pace with future needs, solidify the UK's position as a global leader in life sciences and support patient access.

A major challenge in oncology

So, what exactly is the issue? Despite their great potential, there are long-standing challenges that restrict patient access to combination medicines.

Evidence from clinical trials regularly demonstrates how life changing combination therapies can be for those living with cancer. It can however be difficult to demonstrate the cost-effectiveness of such treatments to Health Technology Assessment (HTA) bodies due to restrictions associated with combination pricing.

Almost one third (15) of the 48 potential combination therapies that were submitted to the National Institute for Health and Care Excellence (NICE) between 2016 and 2020 were either not recommended, or were withdrawn so had their appraisal terminated. A major factor contributing to this low success rate of medicines under appraisal comes from the pressure placed on manufacturers under the current system to provide vastly discounted prices that are unsustainable in the long-term.

Further to this, combination therapies are currently evaluated as single technologies, even though they usually include treatments that are priced independently and are owned by different manufacturers. In fact, the current cost-effectiveness threshold that NICE is willing to approve medicines for use on the NHS means that, in some cases, the manufacturer of the new "add-on" therapy would have to offer the medicine at £0 to meet it.

This issue is further heightened by the effectiveness of combination therapies, meaning that patients are living longer, and therefore, the cost of the episode of care for each patient is extended. As such, it's clear that the current system for assessing an individual medicine within a combination therapy does not allow truly value-based pricing for each component of the combination therapy.

Although it may seem this could be addressed by the pharmaceutical industry practicing greater collaboration and agreeing to lower the prices of medicines within the combination, competition law currently prohibits companies from discussing commercially sensitive information.

However, it's time to realise that such conversations are necessary before therapies are submitted to NICE, in order to help provide the NHS with value for money and, ultimately, allow patients to access effective combination treatments. Intra-industry collaboration can only take us so far in achieving value for money for all: the challenges around combination policy are multi-faceted and will require a broader range of stakeholders to work together before the issue is fully resolved.

Enabling cross-sector collaboration

A number of stakeholders have submitted insightful proposals on the issue in recent years, however to-date there has been little tangible progress. We recognise this is not a new problem, nevertheless we are committed to taking the steps necessary to find a collaborative solution.

This will only work if we approach the challenge together: we need to enable cross-sector conversations between a number of key stakeholders, including payers, pharmaceutical companies and policymakers. Together, we can support positive, fair and efficient pricing and reimbursement frameworks that have the patient need at the centre.

To help the oncology community move forwards, we need to reform pricing and reimbursement systems to promote increased flexibility and recognise the total value brought by combination therapies. With combination medicines at the heart of our pipeline, it's our ambition to advance oncology treatment to create more effective therapies for a wide range of diseases, including genetically defined and hormone-dependent cancers.

To ensure these treatment combinations are able to benefit the lives of patients, we need to make sure each product in a combination is valued fairly, while promoting patient access, sustainable health system expenditure and rewarding innovation.

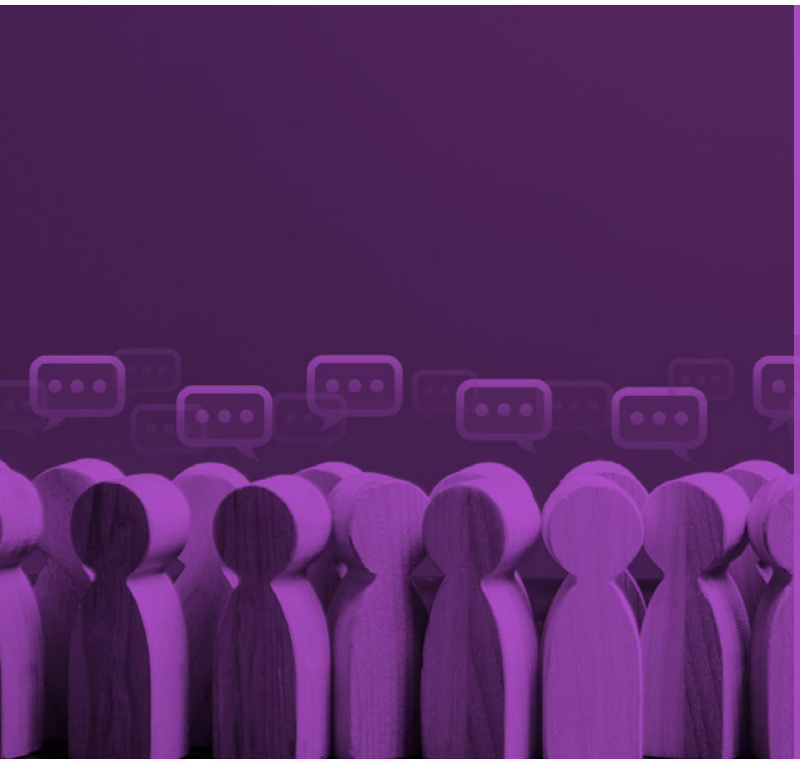
Conversations are already taking place in an attempt to initiate these changes. The pharmaceutical industry made a commitment in the 2019 Voluntary Scheme to investigate an industry side solution to enable companies to engage with one another, ahead of submitting therapies to NICE. Sanofi, along with other companies, has supported the Association of the British Pharmaceutical Industry's work to deliver this, which could mark a significant step towards a long-term solution.

For many people living with cancer, access to combination therapy options could mean better chances of survival and improved quality of life. As an industry, together with regulatory bodies and payers, we must have a united mission to provide access to appropriate treatments and put patient needs at the centre of these efforts.

As science and research continues to advance, our frameworks must adapt and shift to allow for progress and growth, to the benefit of industry, payers and, vitally, patients. We remain open to discussion on this important topic and look forward to working together with all stakeholders to make the solutions to combination policy a reality.

About the author

As head of market access for Sanofi UK and Ireland, Fleur Chandler has over 30 years of industry experience. Her passion lies in working collaboratively with key players in the wider healthcare community, as well as the NHS, to enable patient access by delivering evidence to support value, access and pricing.



Rethinking value: why diverse viewpoints matter

Value is a tricky concept to capture accurately. Given the diverse and complex world that we live in, different people will often hold contrasting views of what constitutes value.

Identifying and measuring value is a particularly interesting quandary for life sciences companies, as inevitably each of these viewpoints will interact with the industry in some way, shape or form.

Traditionally, it was relatively straightforward for companies to define the value of an intervention through the efficacy and safety results of treatments tested within the confines of a clinical trial. Payors and other decision-makers have created specific measures within different disease categories to define 'what good looks like,' when it comes to demonstrating value.

However, amid an ongoing global pandemic and surging demand for greater diversity, equity, and inclusion in healthcare, our understanding of value is changing, and life science companies are increasingly looking beyond the confines of clinical trial results for more inclusive and diverse ways to measure value.

With the availability of a plethora of healthcare data points and analytics, information can now be gathered from a variety of sources outside of the traditional trial setting, a development that has greatly increased the number of invested stakeholders across all levels of the product development lifecycle.

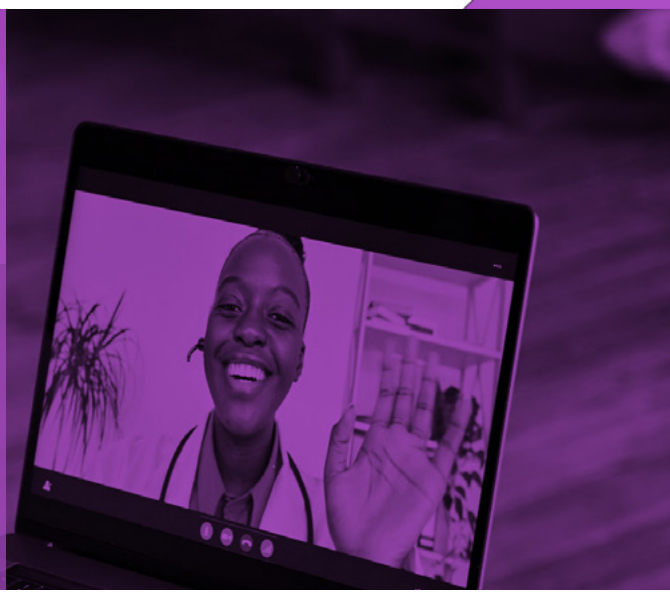
This complexity presents a significant challenge and opportunity for companies, as stakeholders are likely to have varying priorities and perceptions when it comes to defining and demonstrating a product's value.

Each key type of healthcare stakeholder perceives value through a slightly different lens. For example, for a patient, value may be gained through having extra time to spend with their loved ones, or the ability to maintain their independence. Their perspective is inevitably more humanistic, more holistic. For a physician, value is likely to be strongly linked to clinical outcomes; how will a treatment impact how long a patient lives or how well their condition is managed. For payors, value is closely tied to costs, on a population basis, and whether the resources could be better used elsewhere. Their perspective considers the whole healthcare system rather than the individual patient. It is important to take these general perceptions from theoretical discussions in the boardroom into the real world to understand the impact they may have on healthcare decision making.

"Each key type of healthcare stakeholder perceives value through a slightly different lens."

How is the concept of value changing?

The COVID-19 pandemic has changed the way that healthcare is delivered, and value is perceived differently in a number of ways.



First, digital health and telemedicine are playing an increasingly important role for many patients. In some ways, this pivot supported greater inclusivity as people did not necessarily need to take time off work to get to physicians' waiting rooms. At the same time, it has been well-evidenced that postponed routine disease monitoring and surgeries have had – and will continue to have – a negative ripple effect on timely diagnoses. Countless patients have missed out on diagnoses due to not having access to digital health interventions or not seeing healthcare providers in a timely way.

As such, the value of a new intervention needs to be assessed in the context of a mindset shift that includes the possibility of remote diagnoses, treatment, and monitoring, while at the same time, being inclusive by ensuring traditional ways of engaging with patients.

Additionally, costs relating to the pandemic have forced a reassessment of spending overall. The relative value of all interventions – COVID- and non-COVID-related – has been recalibrated to allow the system to cope with the current pressures.

While each of these contributing factors is helping to shape our changing perception of value, perhaps the most influential output of the pandemic is the emerging role of real-world evidence.

When clinical trials were delayed due to the pandemic or other pressures, real-world research has provided much-needed insights to guide regulatory approvals, access, and reimbursement discussions. The ability of real-world research to capture the value of an intervention, in a very broad sense, is one of the key reasons why it is becoming so important in healthcare decision making. We have seen an increase in regulatory submissions using real-world evidence over recent years, and this increase only accelerated because of the pandemic.

Using real-world evidence to create value stories

As real-world research brings together information from a wide array of sources, it captures a far broader definition of value than traditional clinical trials. Modern technology and communications systems have empowered researchers with access to a multitude of sources of health data, from electronic health records to data being streamed from wearable devices.

Collating data from various points of care can help to identify and understand the true patient experience, including the impact of a treatment on symptom burden, patient quality of life, treatment satisfaction, and healthcare resource use. For patients, this is an important development that means their input and experience is at the heart of determining the value of an intervention. Gaining real-world insights from clinicians is also key as the day-to-day treatment of patients can vary widely from the clinical trial setting.

Evaluating data sources is key here, as the variety and quality of data captured on the potential value of an intervention can quickly become challenging. It is becoming increasingly important to spend time upfront thinking strategically about what real-world insights are needed to demonstrate value, and what the best research approaches are to meet these needs.

Exposing disparities in care and the impact on value

In enhancing our understanding of the patient experience, real-world evidence can and is unveiling disparities in care linked to race, socio-economic background, and education.

As people from heterogenous backgrounds are likely to have varying priorities that impact how they define or perceive value in healthcare, this presents companies with an opportunity to develop value stories that demonstrate how new interventions address these individual needs and values.

The apparent disparities in both access to care, and patient outcomes from that care, should be a call to action to ensure that, when we are defining the value of a new intervention, we are inclusive, embracing diversity and acknowledging the value of the opinions and perspectives of all stakeholders. This starts with increased diversity in clinical trial recruitment, supplemented with real-world research conducted in diverse patient populations, so we can better understand the value that patients will derive from a new intervention.

This is reinforced by accessible and appropriate health information at all stages of the patient journey, inside and outside of clinical trials. It's about understanding what means the most to a representative group of patients, and how an intervention works in the context of their health beliefs and behaviours.

Demonstrating real-world value

As highlighted, patients can and should play an influential role in determining value, with insights gathered from their real-world experiences informing key decisions across healthcare. But to truly develop and foster patient trust in the value story of an intervention, diversity and inclusion are fundamental.

For example, imagine that you are trying to sell someone a car. If you don't understand what the customer values in a car, whether they are looking for something with a punchy acceleration or that helps minimise their carbon footprint, how do you know what features you're going to highlight or even what car you should be showing them?

It is important to involve patients across the stages of clinical development to truly understand their needs, especially when it comes to demonstrating value. Payors and healthcare providers should be listening to the real unmet needs that patients face with their diseases and conditions, as they are best able to vocalise what they would value the most in a new treatment approach.

Understanding patient beliefs and behaviours is a critical step towards understanding how they will perceive the value of a new intervention and in crafting a value narrative grounded in robust research that will resonate with patients and the people who care for them. We recommend not only consulting with patients prior to developing value narratives, but also involving them in testing and validating the developed value story prior to roll-out.

Capturing value across the patient journey

Of course, defining and demonstrating value is a dynamic process. As we have seen throughout the COVID-19 pandemic, perceptions of value are not set in stone and can be influenced by a variety of outside factors.

Through real-world data, companies can generate a broader evidence base to support the value of their interventions, as well as assess the beliefs and behaviours of key stakeholders. These insights can then be used to define, capture, and demonstrate value in a way that influences decision-making across all stages of the patient journey.

Expanding our understanding of value using inclusive and diverse real-world data will be increasingly important as we advance in the era of personalised medicine. Offering patients an individualised approach when decision-making is based on a population basis raises challenges. It's these very complex decisions around the relative value of a mixture of different healthcare measures in a population that will present the greatest challenge for the future, and the conversation will continue to shift towards establishing whether a new intervention is 'worth' the demonstrated value, not just its value per se.

About the author

Shanida Nataraja leads AXON's Real-World practice and oversees a global team of consultants servicing real-world mandates for a wide range of Pharma companies. Before entering the healthcare communication industry, Shanida completed a BSc and PhD in neuroscience at University College London, and two years of postdoctoral research into learning and memory at Johns Hopkins University.

During her 21 years in the healthcare communication industry, Shanida has gained experience in a wide range of health economic and outcomes research (HEOR) and market access activities, including communication support and analytical/publication planning for non-interventional research, value proposition/value story development, and evidence synthesis & literature reviews. In addition Shanida brings expertise in broader communication activities, including communication strategy and positioning workshops, market and competitor analyses, scientific story flow and key message development, advisory boards, scientific symposia, train-the-trainer and other educational programmes, and disease awareness campaigns.

About AXON

www.axon-com.com

AXON is a global healthcare communications agency that ignites change in healthcare. Through the power of life-changing communications, we contribute to medical advances that improve lives. At the core of every scientific innovation and advancement, there is a simple and compelling story to be told. We know how to tell that story, how to use the right tools to reach the right audiences at the right time, to provoke meaningful change.

We specialise in advising clients on medical affairs, clinical studies, real-world evidence, marketing, advocacy, and communications, all underpinned by insights and creative strategy. AXON has an international reach, with offices in Copenhagen, London, New York, and Toronto, and a worldwide affiliate network. Established in 2002, we have a deep heritage and expertise in healthcare strategy and communication, and we continue to learn and grow in the fast-changing healthcare sphere. AXON is proudly an AVENIR GLOBAL company.

How do we make patient centricity a reality?

For years, the subject of fostering direct connections with patients has been highlighted by notable figures across the healthcare and life sciences industries as a key feature to be explored in future strategies.

The trouble is, when it comes to turning these impassioned ideas into actionable progress, patient centricity has generally been limited to commercial teams. Moreover, while the vocal support for such inclusive measures is strong, true strategic support and economic drivers have been somewhat lacking when it comes to giving patients a seat at the table.

However, this does appear to be rapidly changing. As patients grow more aware and informed about their healthcare decisions, they are taking an increasingly proactive role in the development and focus of their treatment. Advancements in technology have facilitated access to a wealth of previously untapped information on how diseases, symptoms, and treatments behave outside of traditional clinical settings.

Demand for more patient involvement has also started to inform regulatory processes, making it increasingly important for life science companies to incorporate the patient voice in product development.

As we approach a crucial point in the journey towards patient centricity, it is time to start turning the promise of inclusion into a reality.

"Patient centricity has to start at early clinical development, move all the way through R&D, and then the body of longitudinal evidence will be right there when we're trying to understand better strategies for market access," explains Evidation co-founder Mikki Nasch. "The voice of the patient needs to be heard in that arena more than anywhere else because that's where you're going to influence the way that payers are going to view your products."

"It's very important for patients to feel not only that they've been heard, but that they're getting something of value back from sharing the input."

Utilising patient insight and between-care data

Generally speaking, the majority of patients spend more time outside of the clinical setting than in it. But, while the location may change, the existence of their condition, their symptoms and their treatment continue long after they part ways with the healthcare professional.

In the past, this left lengthy blank pages in our understanding of the true patient experience. This was just a fact of life; we had no way of accurately measuring or monitoring what happened during this between-care period. Thanks to the advent of advanced digital technologies and data analytics capabilities, that no longer needs to be the case.

As Nasch notes: "There is so much information that's happening between care and we've obviously seen the rise of real-world data in terms of wearables, apps, and tracking systems where patients can input what's happening to them between visits."

With access to a wide array of real-time information about treatment performance, side effects, and symptom severity, as well as contextual information about the patient's lifestyle and potential external influencers, physicians can now see beyond the symptoms of disease to the full human being behind them.

Between-care data can be collected through a variety of sources, such as wearables, digital apps, and electronic health records. Using these resources, physicians can monitor the progress of a patient or therapy over an extended period of days, months, or even years. But, for Nasch, collecting data is just the first piece of the puzzle. Here – as with the full patient experience – context is key.

"When we think of the data streams that get collected, it is really important to annotate that data," she explains. "I may only go once every three months to a physician for my chronic disease updates. The 90 days between visits are variable, there's seasonality, and there are all the things that could possibly create different data effects. If we don't check in occasionally with that patient and annotate all of their streaming data with what's going on, the data itself becomes a little less valuable."

Empowering patients in the research landscape

This mixture of commercial and clinical data collection is particularly important when it comes to developing patient relationships – it gives patients the opportunity to play a more active role in their healthcare decision-making.

For Nasch, answering this desire to be seen and valued should be a priority in the drive for patient partnership: "When you think of research as: 'I, the researcher, come in, expect everything from you and then there's going to be a black hole while I go through the regulatory process', that model doesn't work. It's very important for patients to feel not only that they've been heard, but that they're getting something of value back from sharing the input."

Beyond inclusion, championing the patient voice and partnering with them from an early stage, all the way through development, can provide additional benefits for companies beyond market launch. If an engaged individual values a product, their position of trust as a patient makes them well-placed to become an advocate for it.

"You have to add that value and you have to add that trust," explains Nasch "You need to activate patients so that they activate their physicians. In healthcare, we've never had to do that because it was thought: 'You're going to trust your doctor, they're going to tell you to take a specific course of action, and everything's going to be fine', but that's not true anymore."

Developing trust takes time and patience, but in healthcare, there is one particular element that should be a key consideration: respect. Patients have full, complex lives outside of the clinical setting, so overloading them with requests for information can add to their burden. This is where solutions such as technology-enabled quarantine could play an important role.

Whereas traditionally siloed departments (e.g., clinical research and market research) may have maintained separate patient registries, without any bridge between those functions or integration of the different channels, companies ran the risk of overlapping and overloading patients.

"There is a legal requirement to ensure that if a patient is in a medical study, they're not doing market research. This is a big barrier that at times is thrown up as to why companies must have two different registries," says Nasch.

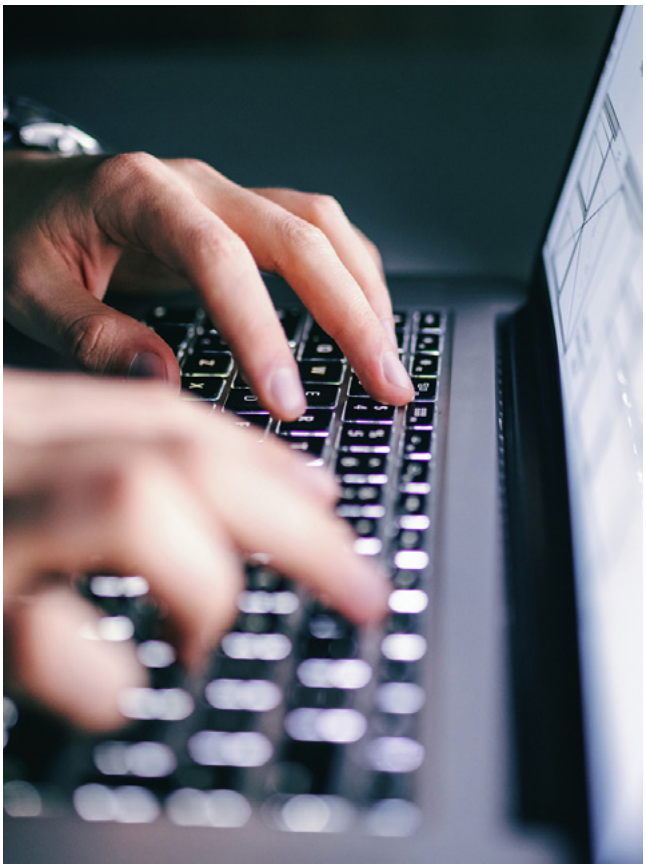
However, with a single firewalled and annotated registry, users would be able to tag patient files with notes that denote their eligibility, or unavailability for market requests.

"With their permission, we tag people," explains Nasch. "If they're in a medical study, we can tag them with an experiment tag that says, until the completion of the study, say for 90 days, this person is not available for any market research requests."

"You've effectively created a firewall that solves for the legal requirements without ever having to break the relationship with a patient."

Breaking down barriers to long-term patient relationships

While the benefits of enabling and fostering long-term relationships with patients have been discussed for many years, there are still barriers that stand in the way of realising the promise of patient centricity.



Trust is a significant challenge when it comes to data. Data privacy has been a growing issue in public discourse, exacerbated by high profile examples of data misuse and breaches of security. These instances are few and far between, with great efforts being made to ensure that data is only used for the agreed purpose.

“When we’re dealing with this data, we have to be front and centre that what we are doing is for the benefit of the patient,” she notes. “These are measures that matter to the patient, and if they choose to withdraw at any point, they should be able to. If they choose not to share information, they should be able to. That level of choice over what happens with their information, and follow-through by the company holding or using the data, is critical to gaining their trust.”

Another prominent barrier highlighted by Nasch is willpower. Changing your behaviour or working patterns is not easy, especially when you have multiple stakeholders relying on stability and results. Moving away from the siloed environment that has been created around patient registries is a notable example of this.

“Firewalls between functional areas in pharma create duplicate purchasing of the same patient access and insights,” she says. “We’re getting to the stage now where everybody’s starting to look at cost-cutting and cost containment. It’s the right time to actually rethink these engagement strategies, and technology can help address the regulatory requirements, so it may no longer be necessary to have three or more patient registries for the same therapeutic area.”

Giving patients a seat at the table

At its core, patient centricity derives from the human desire to be seen and valued as a whole person, rather than a collection of problems that need to be solved. Acknowledging this desire is only the first step in developing a workable solution that not only understands the patient experience but creates a healthcare landscape that serves both patients and industry symbiotically.

"When we think of patient centricity, we need to disconnect it a little bit from the patient services model and shift it into fully integrated engagement through the full product lifecycle, so the patient's voice is heard at every step," says Nasch.

Demonstrating value is a key example of how this could work in practice. With the aid of between-care evidence garnered from patients, pharma and biotech companies can have recorded proof as to whether a treatment meets the patients' needs and how it impacts their own personal experience. In this scenario, the absence of the patients' voice would put companies at a disadvantage, cutting off an important resource to inform strategic decision-making.

"It's the three-legged stool analogy," explains Nasch. "If value-based payments are ever to be fair, then all three entities have to be at the table. You need the patient, you need the healthcare professional, and you need pharma. We can't build a risk model with one-third of the risk not at the table. It doesn't work. It is not achievable without the patient at the table."

About the interviewee

Mikki Nasch is the co-founder and SVP of Commercial at Evidation, responsible for revenue and strategic business development. Prior to co-founding Evidation, she was the EVP of Business Development for Sense Networks, a pioneering machine learning company founded by leading scientists at MIT and Columbia. She has held executive roles at Fair Isaac and leadership positions in the incubation phase of numerous start-ups. A serial technology entrepreneur, Nasch was part of the founding team of Backweb Technologies and managed business development projects at AT&T Business Network, Europe Online, and Reuters. She is on the Advisory Committee for Goergen Institute for Data Science at the University of Rochester.

About Evidation

evidation

Evidation measures health in everyday life and enables anyone to participate in ground-breaking research and health programmes. Built upon a foundation of user privacy and control over permissioned health data, Evidation is trusted by millions of individuals – generating data with unprecedented speed, scale, and rigour. We partner with leading healthcare companies to understand health and disease outside the clinic walls.

Guided by our mission to enable and empower everyone to participate in better health outcomes, Evidation is working to bring people individualised, proactive, and accessible healthcare faster. Founded in 2012, Evidation is headquartered in California with additional offices around the globe. To learn more, visit evidation.com, email us at partner@evidation.com, or follow us on Twitter @evidation.

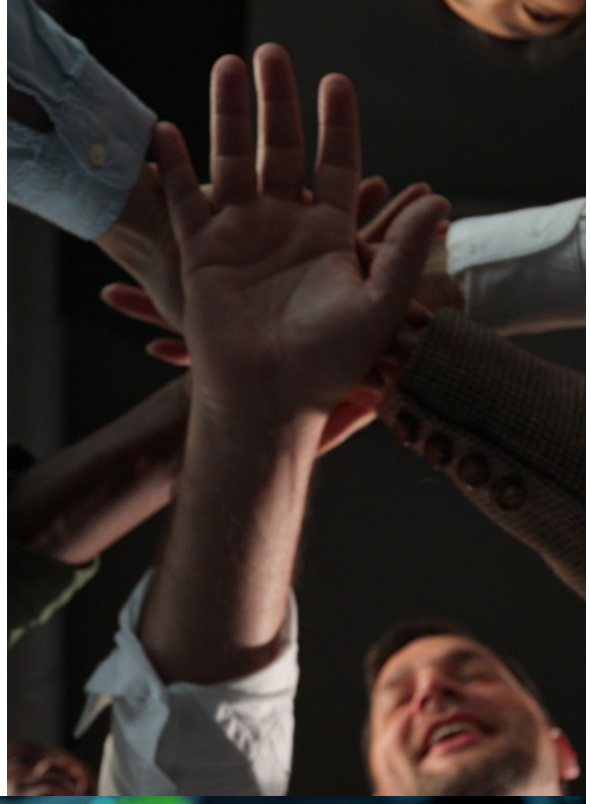
Leveraging KOL insights to succeed in a data-driven world

For years, key opinion leaders (KOLs) have held a position of authority and respect amongst those working across the life science industry, be it a result of their expertise in a specific therapeutic area, notable experience working in a particular field, or their connections with researchers, decision-makers, and patients.

In a traditional setting, where face-to-face interactions are prioritised, identifying KOLs is relatively straightforward. These influential individuals could be physicians, hospital executives, researchers, or patient advocacy group members, who have established themselves as active members of the community using vehicles such as research publications or participation at industry events to demonstrate the value of their insights.

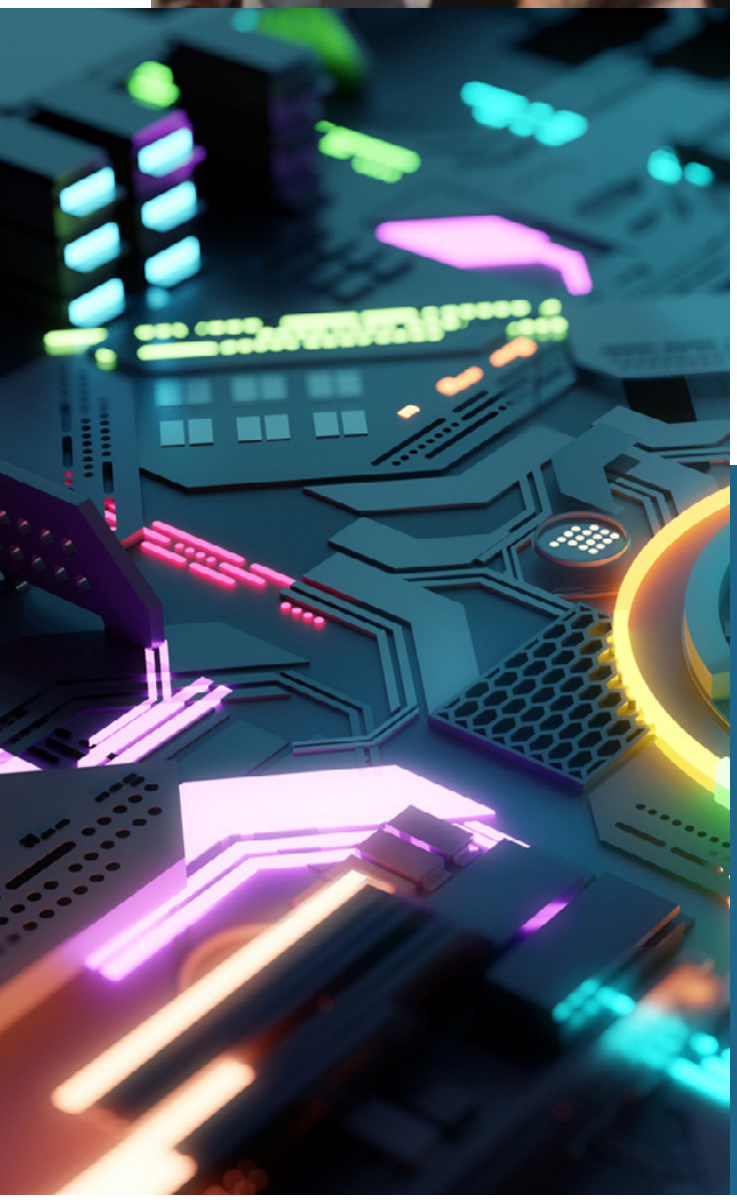
As companies move to explore more virtual spaces, new channels for KOL engagement have emerged, as has a new breed of influential figures: digital opinion leaders (DOLs). While this hybrid engagement environment may require companies to develop new engagement processes to suit different platforms, creating and fostering a positive relationship with these critical healthcare decision-makers remains an essential part of engaging with both KOLs and DOLs.

"Relationship building is at the heart of any good traditional or digital KOL plan."



"Relationship building is at the heart of any good traditional or digital KOL plan, and while the tactics may be varied, the goal is the same – to understand KOLs on a personal and professional level," explains GVP global head for Medscape Medical Affairs Christina Hoffman.

Because medical affairs often acts as a bridge between industry and the wider medical community, those working in this space are uniquely positioned to develop and maintain these relationships. However, with a variety of access points for one KOL, ensuring that any digital systems are respectfully used to enhance communications is a delicate process.



Opportunities created by digital technologies

Today's hybrid engagement environment opens the door for new methods of communication between life science companies and practitioners. This was particularly evident during the COVID-19 pandemic, as the industry rallied behind technologies to facilitate connections in lieu of face-to-face meetings. There are many benefits to be found in virtual spaces, most notably that they provide opportunities for interactions that otherwise may not have occurred due to time or location constraints.

"Most KOLs see themselves as change agents in medicine," says Hoffman. "Partnering with industry medical affairs teams allows them to amplify their position and create a powerful call to action for their clinical colleagues to follow their model."

But while there are more ways to engage with clinicians, for Hoffman it is important to remember that they too are people, who experience the same highs and lows as people outside of the clinical space. Understanding this can be valuable when developing KOL engagement strategies, as companies can tailor their plans to cut through the information overload found in virtual spaces.

"It's easier to tune out or multitask in the virtual space, which means the person is not fully paying attention to the discussion and results in less yield for the time spent," she explains. "It's a balancing act. Topics should be short with strong visuals, as opposed to lines and lines of text. Interaction check-ins also allow those watching to feel their feedback is needed and helpful."

Creating more meaningful interactions with KOLs

It's tempting to try and replicate traditional face-to-face KOL engagement strategies in this new hybrid environment, but this may not create the best end result. Whereas a physical meeting can provide opportunities for complex interactions, with professional information layered among personal details, cultural events, and general conversation, this is very difficult to achieve through digital materials, where there are limited opportunities to capture and retain the attention of the KOL.

To create meaningful engagement, it's important to recognise that clinicians need to gain something from each of their professional interactions, be it opportunities to learn new things or tools that make their lives easier. For Hoffman, identifying areas of unmet need is one avenue that can help to differentiate communications with KOLs.

"Not all KOLs have the same needs and as such it's not the same answer for all," she explains. "Industry needs to assess the unmet needs of KOLs more broadly, and maintain and share that information within their organisation so that it can be amassed and resources can be pointed toward the largest needs.

"Companies should pull alongside the KOL and glean what they can do to help improve clinical practice. If they can demonstrate the willingness to learn and help, KOLs will be very happy to partner."

What role is data playing in creating actionable KOL insights?

Due to the complex nature of hybrid engagement, sophisticated analytical tools have emerged as an important asset for medical affairs, allowing them to scrape relevant data from transcripts of traditional advisory boards. Not only does this free up valuable time to concentrate on engagement strategies, incorporating data can also help to foster an authentic two-way relationship with traditional and digital KOLs by whittling down complex subjects to ensure that the end content is high-quality, relevant, and actionable for them.

There are, of course, caveats to this. Transcripts sourced from virtual spaces are ripe with data ready to be analysed, but to truly leverage KOL insight using data, companies first have to know how to process the data provided. For Hoffman, this is where social listening can support data scraping.

"Social listening can provide an understanding of not only who says what, but who is in contact with whom," she explains. "In the digital space, we are no longer limited by traditional top-down influence cascades, rather it is more of a circular process. For example, if I'm sitting at the community level of an influence cascade, nothing stops me from getting access in the social space to an international KOL. That social dialogue is also immensely informative to the DOL's thinking and rationale."

For Hoffman, engaging with digitally-informed KOLs requires a bifurcated strategy. The first prong in this process should be to identify who the target audience is, and the key figures influencing their behaviour and decision-making processes. The second involves assessing the social environment to determine who is actively discussing issues that align with company aims and values. For example, a well-respected oncology specialist discussing the subject of breast cancer in an online forum, would be a strong KOL candidate for a company focused on breast cancer research and treatment.

Once a KOL has been identified, either in the physical world or online, the next stage of the roadmap should be to demonstrate knowledge and competence in the digital space. For Hoffman, a dedicated medical affairs social presence can be a beneficial asset here, helping to engage key players who are influencing the conversation and shape strategies that address the needs of different KOLs, from field medical to MA leadership.

"DOLs and traditional KOLs have more in common than they don't," she notes. "The biggest difference is simply the channel they use to influence. Find ways to institutionalise the knowledge gained by social scraping in CRMs for field medical to access, and of course make sure the field medical can also inform the understanding via real time discussions, either live or virtually."

Using KOL insights to drive future innovation

As has been illustrated over the past three years, those working across the industry are skilled at adapting to new working environments, finding creative and effective solutions to keep KOLs engaged and informed even in uncertain times. The growing prevalence of digital engagement provides an opportunity for medical affairs teams to showcase this ability once again, using data to inform and shape new engagement strategies that serve a wide pool of influential figures, both in person and online.

Understanding how clinicians view and interact with new engagement methods is just one area where data can play a role. With this knowledge, medical affairs teams can ensure that they are developing and maintaining a relationship with KOLs that serves both parties equally. With this foundation of trust and understanding, KOLs, both digital and traditional, are more likely to actively engage with the company, providing valuable insights that can be leveraged to drive innovation, and the adoption of new treatments.

"The relationship between industry and the KOLs who influence their business interests is a partnership," says Hoffman. "KOLs have huge amounts of information about what's really happening and, more than anything, have a pipeline into the perceptions of their colleagues that makes them an invaluable resource."

About the interviewee

Christina L. Hoffman, MS

Christina (Chris) Hoffman joined Medscape/WebMD 14 years ago to serve as a Cardiovascular strategist in education. She was promoted to Executive Director/Team Lead with business development leadership responsibility for Diabetes, Obesity and Dyslipidemia education support. She most recently served as the strategic visionary for Medscape medical education around the globe. She is now the global leader of the Medical Affairs (MA) Business unit that launched in January of 2021.

Chris has over 30 years of professional health education experience with the lay public as well as with healthcare professionals. She has accomplished this mission in a wide array of settings including; local government, non-profit health, the pharmaceutical industry and most recently with the leader of on-line medical education-Medscape. Chris has a Bachelor of Science in Biology/ Public Health from Ball State University and a Master of Science in Clinical Psychology from California State University, San Jose.

About Medscape Medical Affairs

Medscape® Medical Affairs

Medscape Medical Affairs partners with Medical Affairs teams throughout a product's lifecycle. We facilitate optimal collaboration between internal teams, physicians, and the broader medical community, connecting you directly with Medscape's five million active physician members worldwide.

ICSs: improving patient and market access at a local level

Integrated Care Systems (ICSs) – 42 partnerships of health and care organisations who will plan and deliver more joined-up services for their locality in England from 1 July 2022 – will touch on every issue that is shaping healthcare today.

"A lot of things are happening in the environment right now and all of the key issues at the national level are relevant at the sub-national – ICS – level. Whether it's the levelling up agenda, economics, social care and population health management and more, ICSs are front and centre of everything,"
Steven Ferguson, head of Market Access UK and Ireland, IQVIA.

Ferguson was joined in a pharmaphorum webinar by Uday Bose, country managing director and head of human pharma, Boehringer Ingelheim, Matthias Winker, former head of Integrated Care System Strategy, Buckinghamshire, Oxfordshire and Berkshire West and Jim McCardle, commercial director, Interface Clinical Services, IQVA. In a panel discussion moderated by Dr Paul Tunnah, chief content officer and managing director UK, Healthware, they discussed the opportunity for collaboration between ICSs and life science companies to improve patient and market access at a local level.

The Panel

Uday Bose

Jim McArdle

Steven Ferguson

Matthias Winker

Dr Paul Tunnah

Fundamental change in mindset

The move to ICSs has been ongoing since 2014 and the change that the formal adoption of ICSs brings is fundamental. "This is a significant change for how health and care services are being planned, commissioned and delivered, with a focus on collaboration rather than competition, around the health of the entire population," explained Winker.

The ICSs will operate through an Integrated Care Board (ICB) – an organisation with responsibility for NHS functions and budgets – and an Integrated Care Partnership (ICP) – a statutory committee that brings together all system partners and who will produce a health and care strategy.

Winker noted, "ICBs will have increased commissioning responsibilities [versus CCGs], particularly on specialised commissioning. We saw the intention last year from NHSE&I to delegate pharmacy, optometry and dental services to ICBs, which will happen in this financial year. More specialised commissioning services will follow in the future years, subject to decisions by NHSE&I."

The ICSs are in a position to deliver on the patient-centricity agenda because of a shift in mindset that comes with thinking about the system, not an organisation. Such system thinking can unlock more value – with the patient at the centre – than a siloed approach." We're breaking down the barriers, the mental barriers, we're not so much looking at what's best for the organisation, but what's best for the patient," explained Winker.

The priority for ICSs when they formally take on their responsibilities in July 2022 is to set out their strategies. Each ICS will have to consider the priorities for the NHS – the NHS Long Term Plan is still a key touchpoint for everyone in the NHS – but through a strategy that reflects the specifics of their local population and circumstances.

These strategies will be required reading for life sciences companies because it will enable them to see how their products and services can fit with the ambitions of each ICS. Winker explained, "We will know more by the end of this year. By December 2022, all ICSs will have their ICS strategies developed with defined priorities and approaches to meet their responsibilities. This will provide industry more certainty of the direction of travel."

A key opportunity is in how ICSs will be able to deliver uptake of medicines that are safe, effective, high quality and when approved by health technology assessment body, NICE, cost-effective too. That's because it's often at the local level that there can be challenges to overcome.

Bose explained, "you go through a rigorous process of regulatory and NICE review, but the frustration for all of us, especially for patients, is when you don't get access to those medicines. We've learnt it is very rare that the challenge that is facing the health care system is the profile of the medicine itself. The challenge is at a local level, how to bring those NICE guidelines to life."

More opportunities for collaboration with life sciences

New ICSs mean new opportunities for joint work with life sciences companies. McCardle said, "Life sciences companies can act as a system enabler, to help the ICSs with their agenda."

"Life sciences companies need to make connections with the health and social care players," Winker added.

Joint work has a long history in the NHS but the change to ICSs offers a new basis for that work in recognising the value that life sciences expertise – and their products and services – can unlock for the system, not just an organisation.

It should not be more of the same, rather the challenge was put to the life sciences industry to ensure that their offer is tailored to the ICSs. "There are many life sciences companies that already partner with the NHS and there are wonderful examples. But are these programmes of work fit for the new ICS agenda?" said McCardle.

Yet there are challenges for life sciences companies to overcome to deliver the very best joint work that offers a triple win, for patients, the system, and the company.

McCardle said, "Local knowledge is paramount for life sciences for who to engage with, where and why."

The solution is out there though. Winker pointed out, "we should not disregard our colleagues at AHSNs [Academic Health Science Networks], they have great expertise in the adoption of innovation; they should be brought in early."

A genuine opportunity for joint working will only come when there is value on offer for both the ICS and the company. It sounds obvious, but it needs to be crystal clear to all just what that value is. "Be very clear what the offer is and which particular the problems it will solve," said Winker. Bose echoes the sentiment, "life sciences companies need to be clear what their value proposition [to the ICS is]. They need to be clear what the value is not just to one organisation but the system and not just for two to three years, but the longer time horizon."

Collaboration also means just that, starting with co-design. Bose pointed out, "it's incredibly important to have the insights of patients. Their insights and their input at the design phase of pilots is incredibly important." Winker added, "bring people in early on, clinicians, local authorities, third sector, to design the product or service."

Collaboration in practice can unlock value for all partners: Oxfordshire's experience

A pilot of an enhanced NHS multidisciplinary integrated respiratory team was trialled in Oxfordshire with joint work between the Oxfordshire Clinical Commissioning Group (CCG) and Boehringer Ingelheim (BI). Respiratory illnesses were more common in the North and City areas of Oxfordshire. Chronic obstructive pulmonary disease (COPD) hospital emergency re-admissions within 30 days of discharge were also far higher than the English average and prevalence was lower than seen at the national level, prompting a pilot of an enhanced NHS multidisciplinary integrated respiratory team.

Building on the local services already available the pilot put in place a new integrated team with staff from across the community, hospital and primary care and linked in with the third sector.

Boehringer Ingelheim (BI) worked with partners to design the pilot and provided co-funding.

Just some of the benefits for patients included improvements in anxiety/depression scores as well improvements in their experience with care delivered faster closer to home and not in the hospital. Patients were also able to access support for cold and damp homes. More than two-thirds of patients in the pilot died in their preferred place of care/death.

For the NHS, the pilot allowed them to identify patients with respiratory diseases and identify improvements to the care of patients by changing the way the 'system' worked together. These flow into savings. Small sample analysis revealed that 33 per cent of patients with chronic obstructive pulmonary disease (COPD) had a CAT score improvement that could lower the use of the NHS by £1,257 to £1,837 a year. Ninety per cent of patients with asthma had a CAT score improvement that could translate to lower use of the NHS by close to £600 a year. There were fewer outpatient referrals too.

BI was able to test new concepts and build their knowledge and develop a deeper understanding of the changing NHS landscape. This knowledge can be leveraged in future joint work by BI but also the pilot could be scaled to be used nationally, enabling spread and adoption.

Life sciences companies wanting to reap the benefits of joint work in the new integrated NHS should:

- Involve and engage local stakeholders early in new pathways and agree on priority outcomes
- Share progress often with the pilot holding six-weekly board meetings and monthly implementation meetings
- Anticipate the need to respond to questions from patients, staff, local media and others
- Plan for a planning phase to ensure data accuracy and access to data as needed
- Build-in time for navigating NHS governance processes

Any organisation embarking on joint work needs to start with the end in mind. It's not enough just to run a successful pilot, that would miss the opportunity to scale up benefits across all ICSs. Bose said, "The perennial problem has been scalability. How can you take what looks good from a pilot and scale that up? There is a tremendous appetite for this."

Yet that does not mean that life sciences companies must do it all as they need to work with ICSs to understand what works. "What we can absolutely do is pilots and projects. That's incredibly important. It's a safe environment for us to test different ways to optimize the patient pathway and evaluate the impact on outcomes and efficiency," said Bose.

ICSs themselves will need to take on responsibility for a lasting legacy from such pilots. "I don't think that the life science industry can ever promise that it will provide a long-term solution, but it is about showing the art of the possible, what the system needs, and getting the ball rolling, to create a value proposition, prove it works in this ICS, but it's not their job to keep it going. It should be a business case for the NHS then," said Ferguson.

Bose also put in a request to ICSs to collaborate with life sciences companies to focus on where they can add value by focusing on the work, not navigating potentially different processes to enable joint working. "With 42 ICSs there is a risk that everybody tries to do their own thing. It's incredibly important we have consistency for the approach to joint working. If every single ICS has a different approach that will add time and complexity. There needs to be some specificity for the locality but wherever we can simplify processes to accelerate access to innovation that's important."

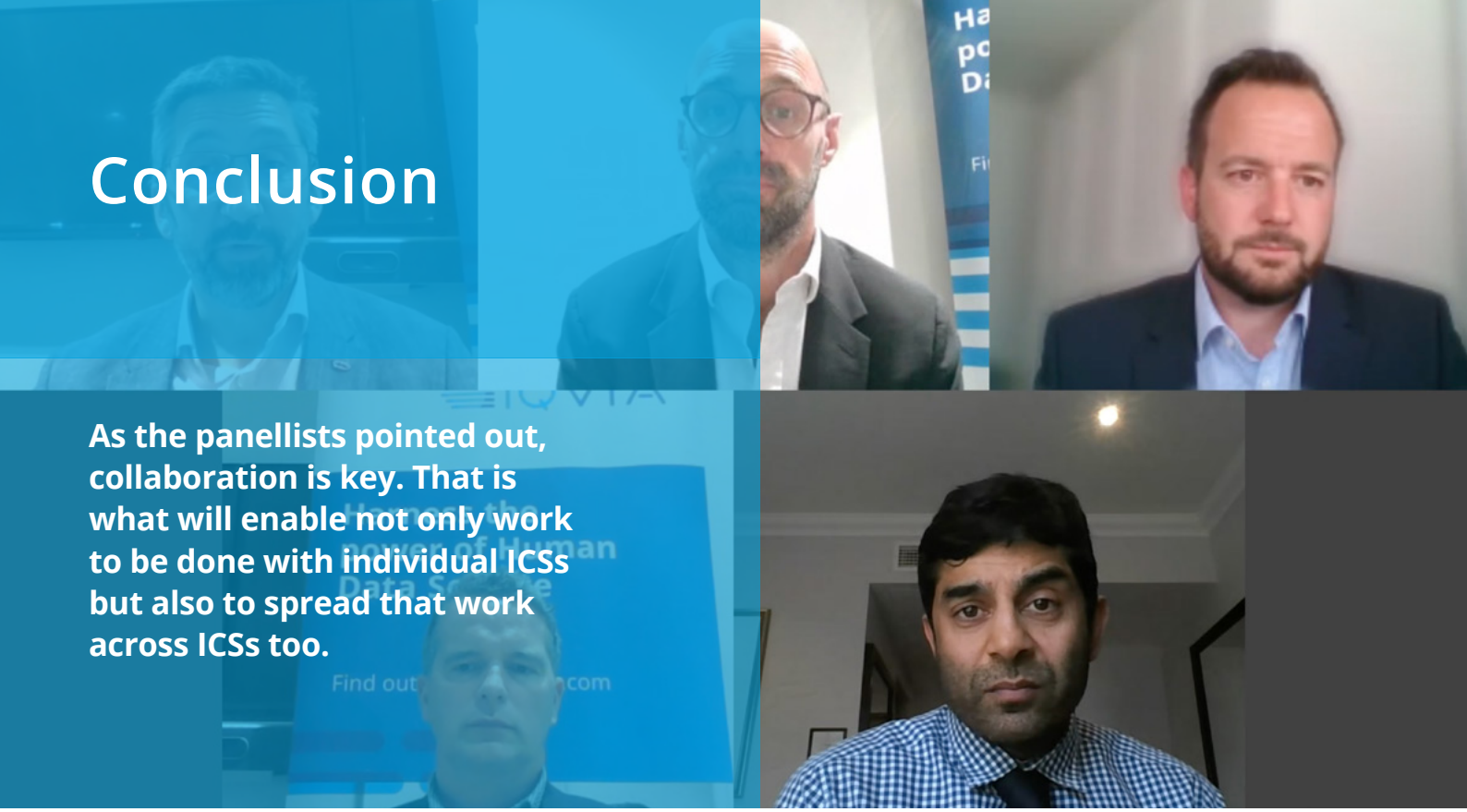
The promise of richer data

Data is an enabler for all stakeholders. For life sciences companies, data can help them to shape their offer so that it's tailored to the ICS that they are working with. Ferguson explained, "We all need to be a bit smarter and a bit more intelligent about what is going on at the local level. We need to use data and insights to understand the problem at the ICS level, which will allow us to align value propositions to the local needs."

For ICSs data is the bedrock for their work when it comes to developing strategies and commissioning. There are ambitions to improve on what's already available. Winker explained, "ICSs will be driving forward the data and digital agenda. They will be developing shared care records over the next two to three years, which will provide a much broader and more detailed picture of patients and their pathways."

The payoff from investment in data this way is not only in the depth of the data but the breadth of decisions that data can support. "We can use this [improved data] for regulatory decision making, commissioning of services, but also research and designing and monitoring interventions," Winker said.

Conclusion



As the panellists pointed out, collaboration is key. That is what will enable not only work to be done with individual ICSs but also to spread that work across ICSs too.

"Collaboration is at the core of the ICS, life sciences need to make those connections, that's absolutely crucial. We're looking for partnerships to deliver on the big challenges. Life sciences can bring their expertise from their therapy areas with expert clinicians, economists, epidemiologists and academics. They need to demonstrate their subject matter expertise and show how they can be complementary [to the expertise in the ICS]," said Winker.

Bose sees the opportunity too to help counter variation in uptake of NICE approved medicines. "There is variation in terms of how NICE guidelines are implemented. There are local interpretations of NICE guidance that can add delays. At the local level, collaboration and support is needed to bring those medicines to patients," he said.

About the panel

Uday Bose, country managing director and head of human pharma, Boehringer Ingelheim. Uday Bose is a highly experienced and successful leader in the pharmaceutical industry within the human pharma sector, with over 25 years' experience spanning general management, health economics, sales and marketing roles with National (UK/Ireland), Regional (EMEA) and Global accountability. He has significant speciality care experience, including all aspects of commercialisation for early and late stage assets including 15 launches across 6 products. Since November 2018, Uday has held the position of country managing director and head of human pharma for Boehringer Ingelheim UK & Ireland. In May 2020, Uday was appointed to the Association of the British Pharmaceutical Industry (ABPI) Board of Management. He is also Chair of the European Medicines Group.

Matthias Winker, former head of Integrated Care System strategy, Buckinghamshire, Oxfordshire and Berkshire West. Matthias is an internationally experienced professional at a senior level in the healthcare industry with a focus to create value for public and private provider organisations, commissioner, life science companies, governments and authorities. He worked in the NHS on provider corporate and clinical services strategies. In his current role, Matthias heads the strategy function of an Integrated Care System and works on the future positioning of the ICS to deliver better outcomes, improve population health and drive economic and social growth throughout the health and life sciences eco system. He holds a Master's degree in health economics and is an alumni of the Henley Business School.

Jim McArdle, commercial director, Interface Clinical Services, IQVIA. After qualifying as a pharmacist, Jim worked across many sectors of pharmacy both in the UK and internationally. In 2006, Jim joined Interface Clinical Services as commercial director, responsible for strategy and growth, and was a key factor in the success of the organisation. A passionate proponent of the role of clinical pharmacists, harnessing data to inform clinical and commissioning decisions, and patient centricity, Jim is viewed as a true innovator in healthcare. He has led on many projects designed to improve the lives and wellbeing of patients across primary and secondary care and recognizes the value in collaborative working between the NHS and life science sector to bring innovative solutions to health economies and to patients. Jim has a BSc in Pharmacy from LJMU and a Masters in Business Administration (MBA) from the University of Liverpool.

Steven Ferguson, head of Market Access UKI, IQVIA. Steven heads up IQVIAs Market Access function and brings extensive Industry experience after 25 years in the Pharma Industry, most recently from Merck where he led on Market Access across their broad portfolio.

Dr Paul Tunnah, chief content officer and managing director UK, Healthware (moderator). Alongside his work as a recognised author, speaker, moderator and industry advisor, he founded the industry-leading publication pharmaphorum in 2009. Dr Tunnah also holds a BA in Biochemistry and DPhil in Biological Sciences from Oxford University, where his work focused on identification of novel anticancer therapies.

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ICSs - an opportunity to improve Patient & Market Access at a local level

Uday Bose, Boehringer Ingelheim; Matthias Winker, NHS; Jim McArdle, IQVIA; Steven Ferguson, IQVIA; Paul Tunnah, pharmaphorum

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About the author

Leela Barham is a researcher and writer who has worked with all stakeholders across the health care system, both in the UK and internationally, on the economics of the pharmaceutical industry. Leela worked as an advisor to the Department of Health and Social Care on the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS).




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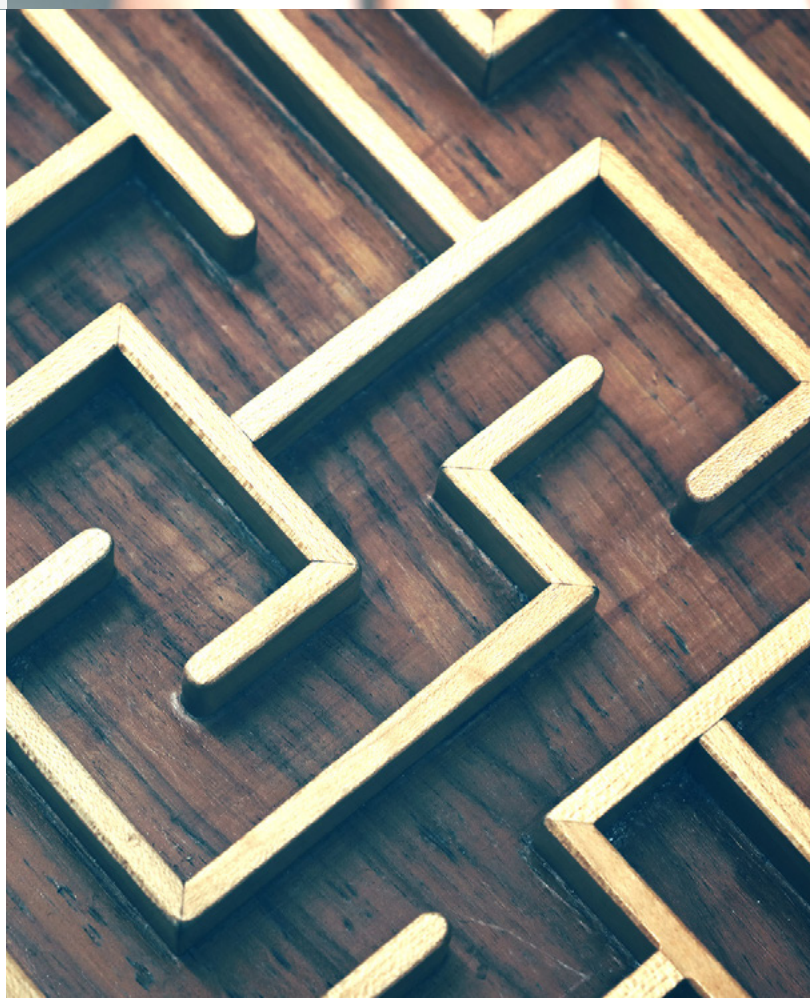
Is it time to rethink electronic prescribing in the US?

It is a fact of life that most – if not all – patients will require some form of prescription medication during their lifetime. Generally, accessing their assigned medication is relatively straightforward, as non-specialty drugs can be dispensed through various channels, including national retail chains, community retail pharmacies, and mail-order pharmacies.

But, for the select few patients that need specialty drugs, accessing a filled prescription is not quite as simple. While these medications account for a relatively small percentage of overall prescription volume, they tend to be more complex and, in many cases, far more expensive.

Over the past two decades, payers, technology experts, pharmacy benefit managers, and pharmacies have developed solutions to help improve the prescription landscape in the US, with electronic prescribing achieving almost universal adoption across the country. However, this was largely dominated by one company and, as such, practitioners had limited avenues to explore when it came to adopting new methods and processes.

With an increasing number of specialty drugs being approved by the US Food and Drug Administration, demand for a greater variety of options in the space has become louder. And both start-ups and historied companies have begun to answer the call.



One such company is First DataBank (FDB). With more than 40 years' experience providing drug knowledge, medicines optimisation and clinical decision support, in 2022, the company announced that it was entering the ePrescription market with a non-exclusive cloud-based network.

For FDB president Bob Katter and vice president of clinical network services at FDB, and general manager of FDB Vela, Lathe Bigler, the decision to expand into new territory has been a long time in the making.

"For specialty drugs, there are additional needs and a lot of that is still done very manually," explains Katter. "I think the increased demand for more sophisticated services for specialty drugs, as well as just general unease in the marketplace about not having a choice of networks are the things that made an impression on us.

"Nearly all standard prescriptions for basic eligibility, basic formulary checking, and Rx routing are digital at this point. People are almost frustrated that they still have to do manual workflows for other things, such as around specialty drugs. I think those end users are saying, 'Why doesn't this work as easily for enrolling a specialty drug for instance, as it does for just dispensing a standard medication?'."

Controversy creates market opportunities

In an industry famed for feats of lifesaving innovation mixed with significant risk, the electronic prescription space may not seem like a likely hotbed of controversy. And yet, over the past few years, progress in the market has been clouded by a high-profile anti-competitiveness lawsuit brought against one of the leading figures in e-prescriptions.

ePrescribing has been in the works for over a decade, with precursors to today's systems appearing in the late 90s. But it wasn't until 2008, one year after electronic prescribing became legal nationwide, that the industry reached the critical crossroads to advance healthcare technology adoption in pharmacy services.

Surescripts has long been an influential feature of the ePrescribing market, having developed an established national network connecting doctors, hospitals, pharmacies, and health plans since its founding in 2001. However, while the company played a fundamental role in shaping the current landscape of prescriptions in the US, it has also been the subject of significant criticism.

Perhaps the most notable controversy began in 2019 when the US Federal Trade Commission sued the company for alleged anti-competitive practices in the electronic prescribing market. The agency's complaint accuses Surescripts of engaging in a "long-running anticompetitive scheme to maintain its monopolies over two separate, complementary markets: electronic prescription routing ("routing") and eligibility".

While the company denies any wrongdoing, both sides continue to clash over what relief might be appropriate to resolve the lawsuit. And, with one of the biggest names in electronic prescribing now the target of high-profile criticism, a new wave of competitors is entering the field.

Navigating the red tape of specialty prescribing

According to IQVIA, specialty medicines will account for nearly two-thirds of launches over the next between 2019 and 2023, up from 61% in the five years prior. As a result, the specialty share of spending is forecast to rise to nearly 50% by 2023 in most developed markets.

Unlike traditional prescription medications, specialty drugs are typically higher-cost therapies that require large amounts of clinical information that must be transferred from provider to pharmacy before it comes close to reaching the patient. Consequently, the unique demands and resource-intensive processes of dispensing these medications have fuelled the rise of dedicated specialty pharmacies across the US.

While these pharmacies may provide unique training or expertise, many still rely on telephone and fax communication to relay vital information between prescriber and pharmacy. Moreover, the prescriber may not know where to send a prescription electronically, as a given drug may only be available through a limited distribution network. As a result, it takes an average of 24 days for a medication to be dispensed, leaving vulnerable patients waiting for vital treatments.

To improve efficiency and reduce the risk of human error, many specialty pharmacies have adopted online enrolment forms that providers can fill out and fax over for pharmacy staff to review. However, this approach is not infallible, as there are still multiple opportunities for mistakes to be made during manual data entry.

"Fundamentally, when we're talking about specialty drugs, we're talking about more red tape," explains Bigler. "Right now, I can go to my provider, get a prescription written if it's a standard drug, and go pick it up at the pharmacy an hour later."

"But for specialty drugs, because of the authorisation requirements prior to the patient actually receiving that prescription and the significant amount of work that goes on behind the scenes, we saw a real true pain point where applying technology, innovation, and automation could make a difference very quickly."

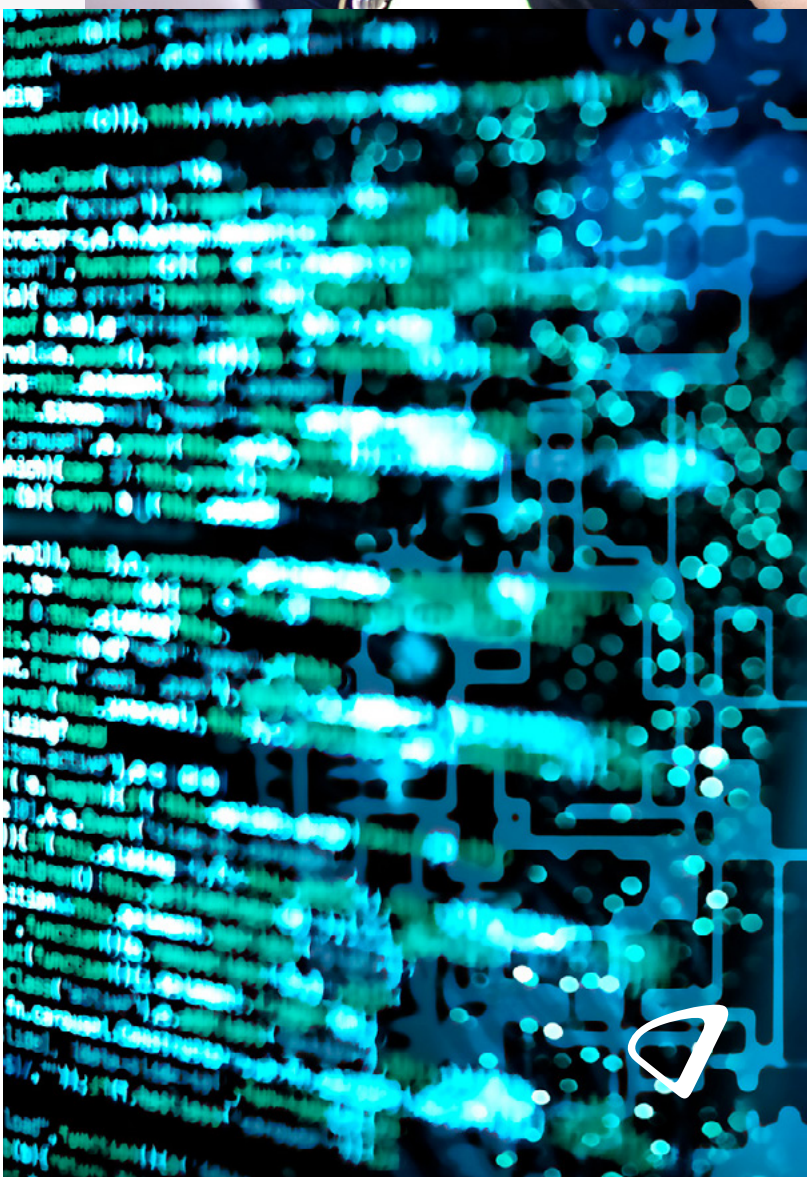
How electronic prescriptions can improve market access

As the healthcare industry looks to eliminate administrative burdens and curb unnecessary spending, reducing human error in prescribing is a particular area of interest. According to the US Government, the total cost of caring for patients with medication-associated errors exceeds $40 billion each year. Add to this the initial high price tag associated with specialty drugs and the psychological and physical experience for patients, and the overall monetary and human cost is even greater.

For patients, accessing these expensive medications is also a costly endeavour. However, whereas healthcare professionals have an insight into the wider prescribing environment, patients are often left in the dark regarding the limitations of distribution networks.

"In the US, a lot of patients go to the pharmacy and find they have a significant out-of-pocket liability and maybe the drug that the provider thought they would be filling and taking, they're not going to take because of cost considerations," explains Katter. "Bringing that transparency up right at the point for the doctor and the patient to be able to see that is critically important. That's transparency. That's part of this equation."

In a market landscape built upon sharing large amounts of complex data, interconnectivity has become a notable trend in the space. This is particularly evident in specialty medicine, as each different network can require three or four unique processes, which ultimately place a higher administrative burden on pharmacists.



"There should be more of a unified approach," says Bigler. "If you're a provider and you're just essentially doing what you do in your EHR workflow, all of the administrative requirements that flow from that: the specialty enrolment, eligibility, the formulary check, the authorisation, all that should happen in one unified step. You shouldn't have to go to three different places or a different portal to do that step, which should just really flow out of the natural workflow process."

Leveraging data to drive developments in US pharmacies

Disrupting the standard practice in any market is a challenging prospect. However, the emergence of new competitors after a period of stagnation is a positive sign that a fire has been lit underneath the ePrescribing market. With multiple innovators working to develop solutions to approach this new workflow and support different business models, the industry appears to be set to witness an influx of innovative solutions to help specialty pharmacies decrease costs, increase efficiencies, and, ultimately, improve outcomes.

For Katter, connecting multiple stakeholders across the market will be an important feature in future developments. With the insight garnered from notable industry figures, as well as the patients and practitioners set to be impacted by any changes to standard processes, companies can create a system that serves both patients and industry,

"For the network to be successful, pharmacies, pharmacy benefit managers, specialty pharmacies, not to mention the providers who use electronic health record systems – all of those different parties need to participate."

The unification is not limited to healthcare professionals. Instead, Katter foresees a central role for patients in the prescription process in a future landscape that harkens back to more patient-controlled paper-script methods.

"We think at some point in the industry, consumers will once again control their own prescriptions, most likely through a secure connection on their cell phone," he explains. "It'll be much more unified, a lot of the side workflows will be eliminated, and everybody, including the patient, will be involved."

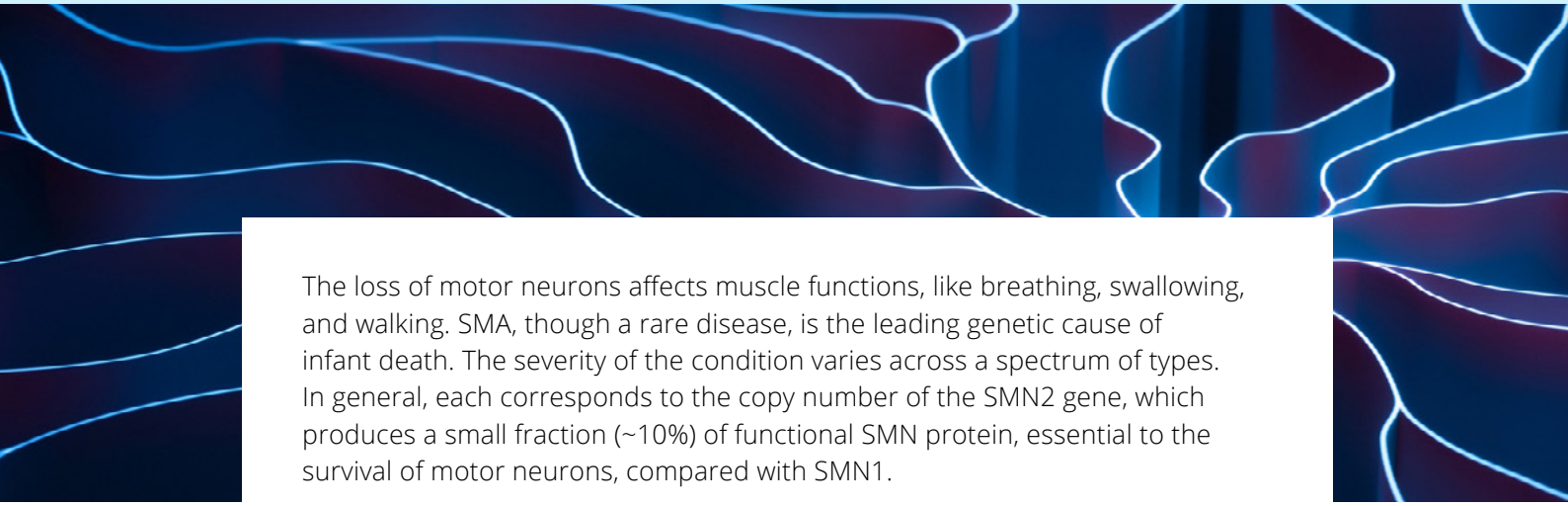
**Surescripts did not respond to multiple requests for comment*

About the author

Eloise McLennan is the editor for pharmaphorum's Deep Dive magazine. She has been a journalist and editor in the healthcare field for more than five years and has worked at several leading publications in the UK.

Time is motor neurons – the importance of newborn screening in SMA

Spinal muscular atrophy (SMA) is a devastating, genetic neuromuscular disease caused by a lack of a functional *SMN1* gene that results in the progressive and irreversible loss of motor neurons. SMA affects approximately one in 10,000 live births worldwide.



The loss of motor neurons affects muscle functions, like breathing, swallowing, and walking. SMA, though a rare disease, is the leading genetic cause of infant death. The severity of the condition varies across a spectrum of types. In general, each corresponds to the copy number of the SMN2 gene, which produces a small fraction (~10%) of functional SMN protein, essential to the survival of motor neurons, compared with SMN1.

When left untreated in its most severe forms, SMA leads to permanent ventilation or death in 90% of cases by the age of two years.

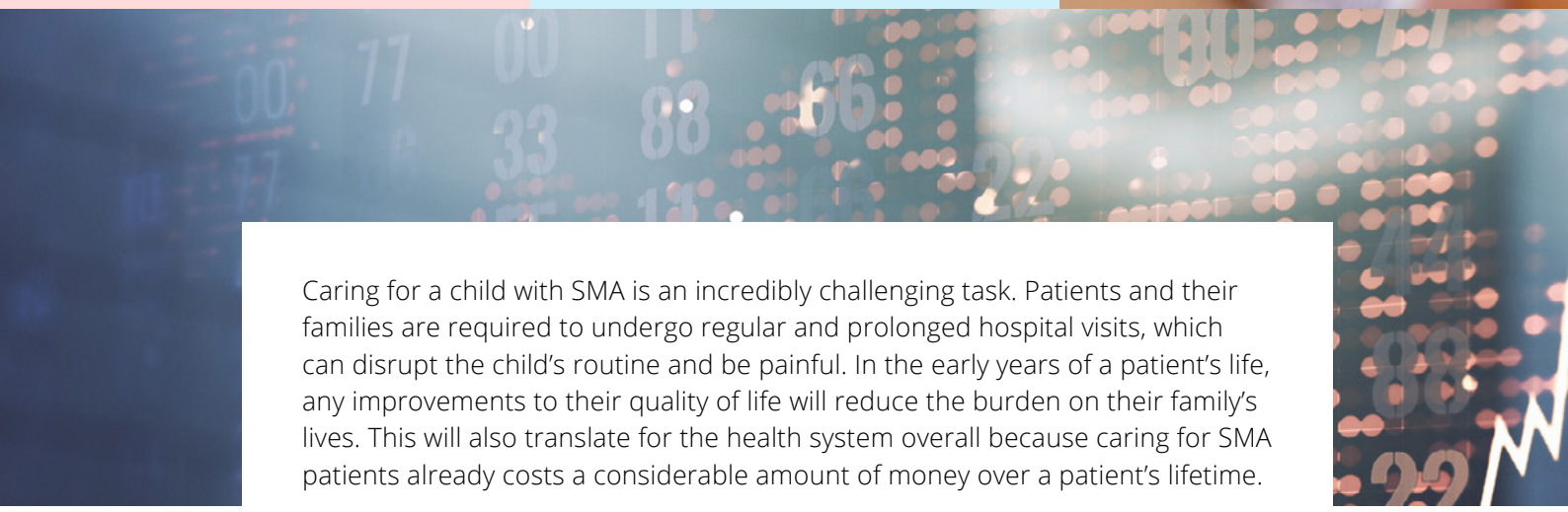
Loss of motor neurons cannot be reversed, so patients with symptoms at the time of treatment will likely require some supportive respiratory, nutritional and/or musculoskeletal care to maximise functional abilities. This is why it is so important to detect and diagnose SMA as early as possible and begin treatment with proactive supportive care.

The main challenge in diagnosing SMA is that many clinicians do not initially recognise the early signs of the disease, which leads to delays in the diagnostic journey and, as a result, in treatment. SMA is a rare disease, therefore symptoms such as poor head control or a weak cry are often subtle at first.

"Clinical data has proven that the earlier a patient is diagnosed and treated, the better the chance of a successful outcome."

Newborn screening has many benefits

The detection of treatable diseases through newborn screening allows for timely access to treatment and effective care, resulting in improved clinical outcomes. In SMA, for example, the earlier a baby is treated, the fewer motor neurons are lost irreversibly and the better the clinical outcome.



Caring for a child with SMA is an incredibly challenging task. Patients and their families are required to undergo regular and prolonged hospital visits, which can disrupt the child's routine and be painful. In the early years of a patient's life, any improvements to their quality of life will reduce the burden on their family's lives. This will also translate for the health system overall because caring for SMA patients already costs a considerable amount of money over a patient's lifetime.

By identifying patients with chronic diseases when they are newborns, chronic care costs per child can be reduced, which allows for cost savings and additional resources to be allocated to other areas of need. It is estimated that the cost of caring for a child with a genetic paediatric rare disease is between €2 million and €5.6 million over ten years, and these costs increase with age.

Newborn screening (NBS) is a test where a baby gets a "heel prick", and a drop of blood is extracted and tested for known, treatable diseases. These tests help reduce the time to diagnosis and initiation of treatment.

A recent report showed that, despite NBS for different diseases existing in many EU countries, there are significant inequities within countries as to the number and types of diseases screened. For example, in Italy, screening takes place for 48 diseases, whereas in France or Spain, only six or seven diseases are included in the national NBS panels. NBS panels are updated at a country level according to local regulations, but this happens on an irregular and inconsistent basis.

Better treatments and better outcomes

Over the last decade, research has led to three different pharmaceutical treatment options for SMA, including a one-time gene therapy. Clinical data has proven that the earlier a patient is diagnosed and treated, the better the chance of a successful outcome, including the ability to achieve motor milestones that were previously unachievable for SMA babies in the natural history of the disease.

Current standard of care guidelines also recommend a proactive multidisciplinary approach following treatment. A typical treatment route for patients with SMA incorporates neuromuscular, respiratory, nutritional, orthopaedic, growth, and bone healthcare, as well as physical therapy, occupational therapy, and speech therapy. Since each avenue of therapy has different benefits to specific extremities of SMA, it is up to the child's physician to assign an appropriate treatment route to maximise effectiveness for each individual case.

Newborn screening for SMA was added to the Recommended Uniform Screening Panel (RUSP) in the US in 2018, and now 92% of babies born in the US are screened for SMA at birth. In Europe, many countries such as Germany, Netherlands, Belgium, Czech Republic, Portugal, Norway, and Austria have added SMA to their NBS panels, as there are now effective treatments for SMA.

These countries have realised the value of being able to identify and treat these babies as early as possible. But there are still other countries, including the UK, France, Switzerland, Spain, Italy, and Greece, that have not added SMA to their national NBS panels yet. SMA Europe has launched a multidisciplinary SMA-NBS Alliance, which Novartis Gene Therapies is proud to be a part of, with the ambition to have SMA in all national NBS panels in Europe by 2025.

In summary, screening for SMA – as well as other detectable and treatable genetic diseases – is essential for realising the best possible outcomes for patients and a standard of care that lives up to the incredible new resources medicine has at its disposal.

Governments and professional organisations need to continue to work together to help ensure implementation of wider newborn screening panels with a regular and consistent framework at the national level, so that every family with a newborn baby can benefit from early diagnosis and treatment.

About the author

Mike Fraser is general manager for Europe Middle East and Africa at Novartis Gene Therapies. He has more than 20 years' experience in the pharmaceutical industry, spanning strategy, analytics, digital innovation, early drug development, brand launches and brand management.

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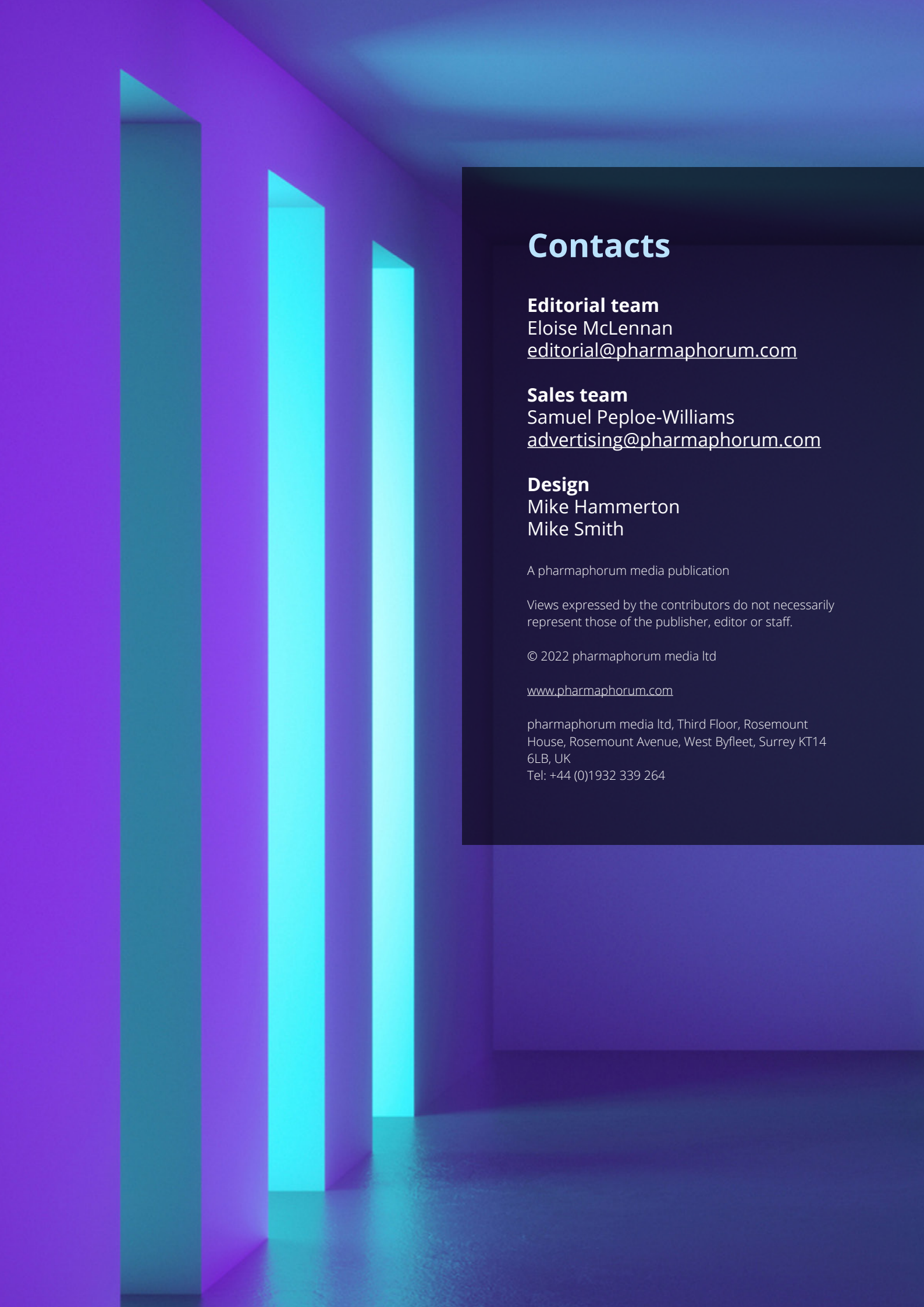

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