pharmaphorum deepdive

Communications & Commercialisation 2022

What doctors need from post-pandemic pharma comms

Achieving launch excellence in oncology

The missing pieces of the digital therapeutics puzzle

September 2022

Contents

Deep Dive: Communications and Commercialisation 2022

There is little doubt that the arrival of COVID-19 changed the game for communication and commercialisation efforts for pharmaceutical companies around the world. Cut off from tried and tested methods of engaging with stakeholders, digital and virtual solutions were thrust into the limelight as the industry proactively accelerated the adoption of technology across all levels of healthcare.

While some doubted the staying power of digital tools, as traditional face-to-face interactions resumed it was clear that the days of single-channel engagement were gone. Instead, customers, patients, and industry stakeholders saw the benefits that technology could bring to the communication and commercialisation environment.

As we slowly work to recover from the impact of COVID, companies must now work to refine the use of digital tools to drive launch excellence and address changing HCP engagement needs in a post-pandemic landscape. In this issue of Deep Dive, M3's Maxim Polyakov discusses how the pandemic has changed what HCPs need from pharma communications, Joyce Nortey and Christine Lemke examine the revolutionary impact of decentralised trials on the patient/industry connection, and Research Partnership's Tania Rodrigues questions if gene therapies for prevalent diseases in Europe are the perfect storm of economic sustainability.

Plus, we find out how pharma marketing transformed from a wild west of quackery to a well-regulated source of information, and chart the key elements of a successful oncology launch with Envision.

For all this and more, read on.

I hope you are staying safe.

Eloise

Eloise McLennan – editor, Deep Dive

Next issue:
Patients & Partnerships (October 2022)
Plus:

- Patient experience and engagement
- Improving patient care and value through co-creation

Catch up on recent issues:

Oncology – June 2022

Market Access – May 2022

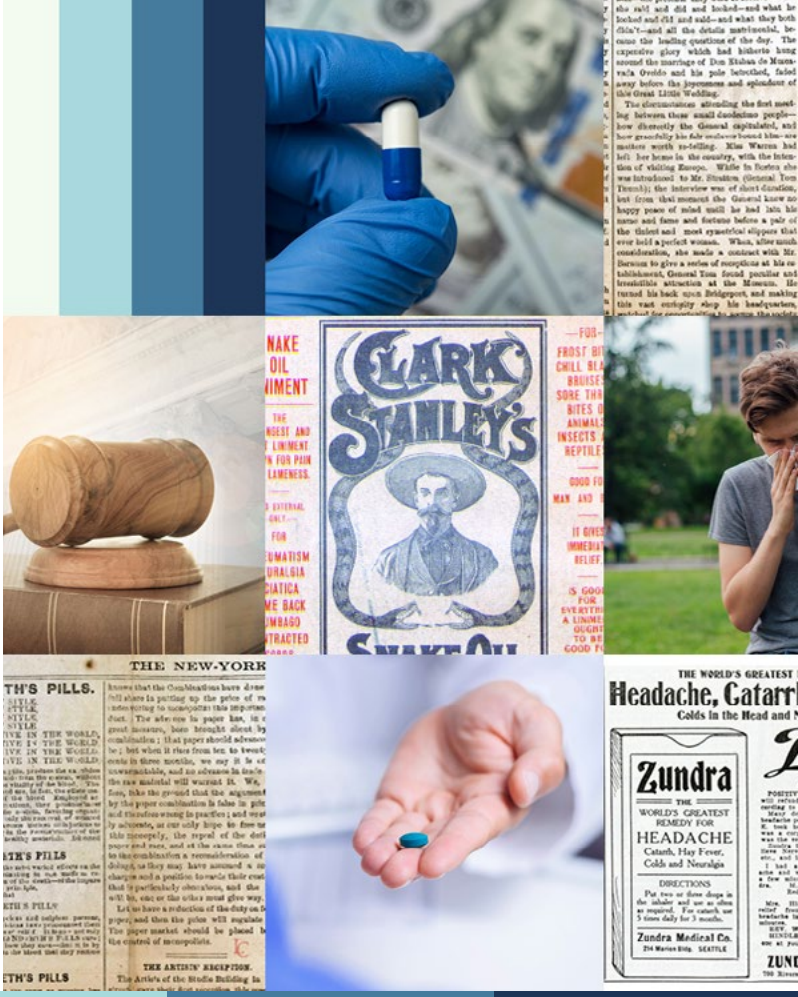
Research and Development – February 2022

Digital Health – December 2021

Inside the colourful history of pharma advertising

Pharma companies employ a variety of tactics to increase brand awareness and promote their products. While the tactics used to market prescription drugs may be controversial, today's advertising efforts are a far cry from the outlandish claims made in the early days of the pharma industry.

With each passing decade, pharma companies and regulators have worked to refine the art of marketing, adapting to new technologies and innovations to deliver creative campaigns. That is not to say that the journey has been a smooth one. So how did pharma advertising transform from a wild world of patent drug quackery to a tightly knit machine of creativity?



1868

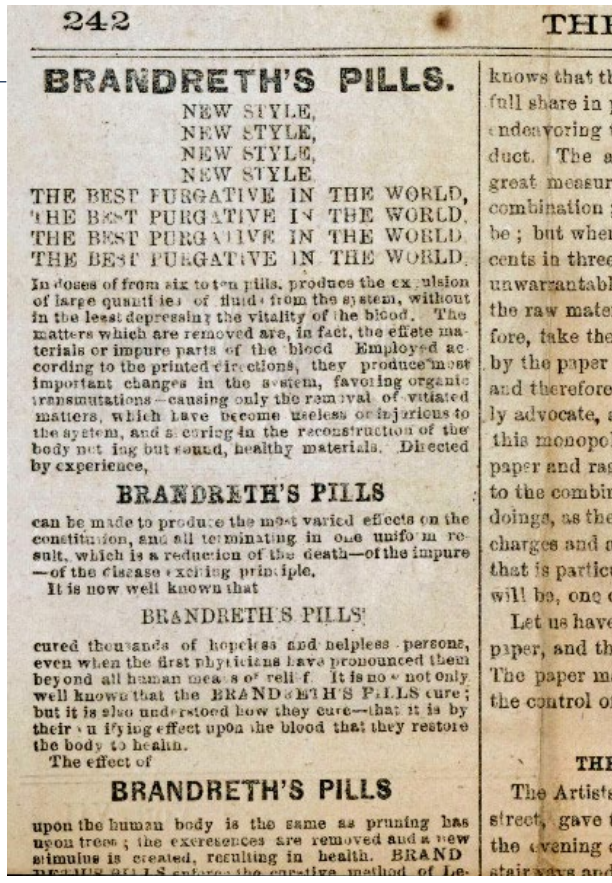
The birth of mass marketing

After assuming control of his grandfather's patent medicine business, Benjamin Brandreth ventured across the Atlantic Ocean in search of a bigger market for his now famous Vegetable Universal Pill.

In an early example of mass marketing, Brandreth was a pioneer in targeting prominent health concerns – in this case, the widespread belief that blood impurity caused various illnesses – using a distinctively literary approach to appeal to the general public.

Through the distribution of books and newspaper adverts, Brandreth positioned the pills as a purgative, claimed to be a 'cure-for-all' remedy for all ailments. Unfortunately, in reality – as with most patent medicines at the time, these miraculous assertions were unproven and often not worth the ink they were printed with.

But, despite a lack of confirmed efficacy or safety, this early example of mass marketing proved immensely influential. Soon, 'Brandreth's pills' became a household name, with esteemed authors Herman Melville and Edgar Allen Poe referencing the pills in their works.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BRANDRETH'S PILLS.

NEW STYLE,
NEW STYLE,
NEW STYLE,
NEW STYLE

THE BEST PURGATIVE IN THE WORLD,
THE BEST PURGATIVE IN THE WORLD,
THE BEST PURGATIVE IN THE WORLD,
THE BEST PURGATIVE IN THE WORLD,

In doses of from six to ten pills, produce the expulsion of large quantities of fluids from the system, without in the least depressing the vitality of the blood. The matters which are removed are, in fact, the effete materials or impure parts of the blood. Employed according to the printed directions, they produce most important changes in the system, favoring organic transmutations—causing only the removal of vitiated matters, which have become useless or injurious to the system, and securing in the reconstruction of the body not ing but sound, healthy materials. Directed by experience,

BRANDRETH'S PILLS

can be made to produce the most varied effects on the constitution, and all terminating in one uniform result, which is a reduction of the death—of the impure —of the disease exciting principle.

It is now well known that

BRANDRETH'S PILLS

cured thousands of hopeless and helpless persons, even when the first physicians have pronounced them beyond all human means of relief. It is now not only well known that the BRANDRETH'S PILLS cure; but it is also understood how they cure—that it is by their purifying effect upon the blood that they restore the body to health.

The effect of

BRANDRETH'S PILLS

upon the human body is the same as pruning has upon trees; the excrescences are removed and a new stimulus is created, resulting in health. BRAND

By AlanEisen – Own work, CC BY-SA 4.0, https://commons.wikimedia.org/w/index.php?curid=119856985

By Clark Stanley – https://www.nlm.nih.gov/exhibition/ephemera/medshow.html, attributed to:Clark Stanley's Snake Oil Liniment,True Life in the Far West,200 page pamphlet, illus.,Worcester, Massachusetts, c. 1905,23 x 14.8 cm., Public Domain, https://commons.wikimedia.org/w/index.php?curid=47338529

1890s

The rise of snake oil and quackery

Before the early 1900s, little, if any, regulation was in place to govern how drug companies (as well as any medicine-minded layman) developed, patented, and marketed their formulas. Stemming from England, where 'patents of royal favour' were granted to those who provided medicine to the Royal Family, patent medicines took the US by storm. Unlike their royal counterparts, however, most 19th-century patent medicines were not officially patented.

Although the booming industry received criticism from physicians and medical circles, demand for remedies to cure and prevent all manner of ills grew. The press stoked the popularity of patent medicines. Patent pages dedicated to advertising these concoctions – often fortified with morphine, opium, or cocaine – to adults, children, and infants became an essential source of income for newspapers at the time.

Into this wild west of 'miraculous' tonics and concoctions entered one of the most prolific examples of deceptive marketing in medicine – the snake oil salesman. Unlike the original snake oil remedy brought to the US by Chinese workers, which was rich in inflammation targeting omega-3, the knock-off imitations across the country contained ingredients deemed useless in treating any medical condition.

Having learned of the anti-inflammation benefits of rattlesnake oil, entrepreneur and famed "rattlesnake king" Clark Stanley caused a stir when he unveiled his remedy at the 1893 World's Exposition in Chicago. But, surprisingly, when investigators seized a shipment of the product in 1917, Stanley's Snake Oil was found to contain no snake oil at all, instead comprising mineral oil, a fatty oil believed to be beef fat, red pepper, and turpentine.

The term 'snake oil salesman' is now more commonly associated with fake cures and fraud than the legitimate remedy it originated from.

1905

The Great American Fraud

Towards the end of the 19th century, the tides appeared to be turning for patent medicine. Journalists had started investigating significant public health threats, including misrepresenting harmful substances as medicine.

Fed up with watching swindlers peddle unregulated and unproven 'medicines' to unsuspecting people, American journalist Samuel H Adams made his views on patent medicines clear in a publication titled "The Great American Fraud". In this series, Adams exposed the dangers posed by unregulated patent medications to the general public, explaining in plain terms why the practice could not go on.

The Great American Fraud proved to be instrumental in driving legislative changes to improve the safety and efficacy of drugs for patients across the country.

PUBLIC OPINION

COLLIER'S EXPOSÉ
OF THE
PATENT MEDICINE FRAUD

DEATH'S LABORATORY

CRIMINAL ALLIANCE OF THE NEWSPAPERS WITH FRAUD AND POISON

THE GREAT AMERICAN FRAUD

PERUNA AND THE "BRACERS"

CONSPIRACY AGAINST THE FREEDOM OF THE PRESS

LIQUOZONE

THE SUBTLE POISONS

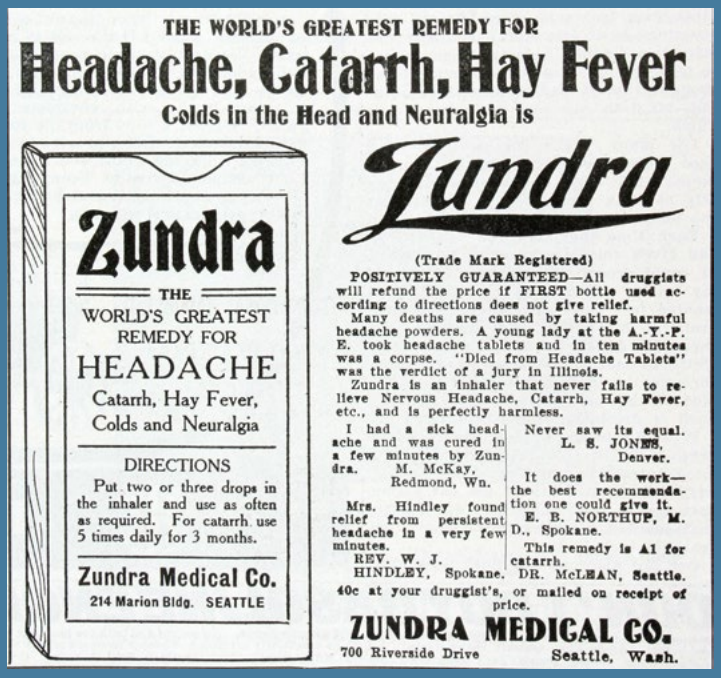
Other Articles to be Announced Later

NEWSDEALERS EVERYWHERE

Collier's
THE NATIONAL WEEKLY

TEN CENTS PER COPY

Collier's, illustration by E. W. Kemble, Public domain, via Wikimedia Commons



THE WORLD'S GREATEST REMEDY FOR
Headache, Catarrh, Hay Fever
Colds in the Head and Neuralgia is

Zundra

Zundra
THE
WORLD'S GREATEST
REMEDY FOR
HEADACHE
Catarrh, Hay Fever,
Colds and Neuralgia

DIRECTIONS
Put two or three drops in the inhaler and use as often as required. For catarrh use 5 times daily for 3 months.

Zundra Medical Co.
214 Marion Bldg. SEATTLE

(Trade Mark Registered)

POSITIVELY GUARANTEED—All druggists will refund the price if FIRST bottle used according to directions does not give relief.

Many deaths are caused by taking harmful headache powders. A young lady at the A.-Y.-P. E. took headache tablets and in ten minutes was a corpse. "Died from Headache Tablets" was the verdict of a jury in Illinois.

Zundra is an inhaler that never fails to relieve Nervous Headache, Catarrh, Hay Fever, etc., and is perfectly harmless.

I had a sick headache and was cured in a few minutes by Zundra. M. McKay, Redmond, Wn.

Never saw its equal. L. S. JONES, Denver.

Mrs. Hindley found relief from persistent headache in a very few minutes. REV. W. J. HINDLEY, Spokane.

It does the work—the best recommendation one could give it. E. B. NORTHUP, M. D., Spokane.

This remedy is A1 for catarrh. DR. McLEAN, Seattle.

40c at your druggist's, or mailed on receipt of price.

ZUNDRA MEDICAL CO.
700 Riverside Drive Seattle, Wash.

University of Washington, Public domain, via Wikimedia Commons

1906

Congress passes the Pure Food and Drug Act

The work of muckraking journalists like Adams and 'The Jungle' author Upton Sinclair pushed the US Government to take decisive action against publishing unproven medical claims. In 1906, then-President Theodore Roosevelt signed the Pure Food and Drug Act, otherwise known as the Wiley Act, into law.

Under this new legislation, the manufacture, sale, or transportation of tainted, misbranded, poisonous, or harmful foods, drugs or medicines, and liquors was now prohibited. Importantly for legitimate drugmakers, the Act stipulated that drugs had to comply with the standards of strength, quality, and purity defined in the United States Pharmacopoeia and the National Formulary. If a product contained variations from the applicable standards, it could not be sold unless the specific variations were clearly stated on the label.

In addition to increasing consumer protection efforts, the passing of the Pure Food and Drug Act also formed the cornerstone of what would become the US Food and Drug Administration (FDA).

1911-1938

Defining, and redefining, drug fraud

Not everyone was satisfied with the definitions laid out in the Pure Food and Drug Act. Specifically, although false statements as to the identity of the drug were illegal under the law, debate arose over whether or not it specifically outlawed false curative or therapeutic statements.

With adverts claiming to cure cancer still adorning newspaper pages, the US Supreme Court was called upon to clarify the issue in the United States v. Johnson case.

The court ultimately ruled in favour of publishing outlandish and exaggerated claims, as the law only banned companies from misrepresenting a drug's ingredients.

In response, Congress passed the Sherley Amendment barring false therapeutic claims on drug labelling the following year. However, there was one slight issue as regulators needed to demonstrate that the company had fraudulent intent, which is very difficult to prove.

In 1938, the passing of the Federal Food, Drug, and Cosmetic Act ended the debate over what constitutes fraud. Under this new law, drug fraud, intentional or not, was publishable by law.

Moreover, the Act gave the FDA power to regulate the drug market. Before any advertising or marketing efforts could begin, companies had to gain FDA approval.

1962

The FDA takes control

The next major milestone came in 1962, with the introduction of the Kefauver–Harris Amendment (also known as the Drug Efficacy Amendment).

In addition to requiring companies to provide proof of safety and efficacy before approval, the amendment ushered in significant changes for the pharma marketing world. Significantly, the FDA was given authority to regulate prescription drug advertising and labelling.

The amendment also prohibited drugmakers from marketing cheap generic drugs as expensive, breakthrough treatments under a new brand name.

Further stipulations were made in 1969, when the FDA published four fundamental rules to govern how pharmaceutical companies could market prescription drugs. Under the new regulations, companies were not allowed to be false or misleading, drug risks and benefits had to be described in a fair and balanced way, marketing materials were required to include facts relevant to the drug's advertised use, and companies now had to create a summary that contained all of the risks listed on the drug label.

1980s

The return of direct-to-consumer marketing

After years of regulatory reforms, the appeal of direct-to-consumer advertising had dwindled since the passing of the Pure Food and Drug Act. But in the 1980s, the combined impact of a favourable political climate and cultural changes pushed patients to pursue a more active role in medical decision-making, reigniting interest in targeting patients directly.

In 1981, Merck spearheaded the direct-to-consumer marketing movement by running a print ad that promoted its new anti-pneumococcal vaccine, Pneumovax, in Reader's Digest.

Boots Pharmaceuticals upped the ante in 1983, when it released the first direct-to-consumer TV ad for a prescription drug. Through the TV campaign, Boots Pharmaceuticals publicised the lower price of its pain relief drug Rufen - without directly referencing any specific medical benefits of the product. Within a few days, the company was sent a cease-and-desist letter by the FDA and told to pull the ad from the air.

Pfizer and Eli Lilly were also key players in the rise of modern direct-to-consumer marketing, using carefully placed adverts on television networks and radio stations to advertise medications.

Responding to the growing popularity of direct-to-consumer TV ads, in 1985, the FDA established regulatory authority over this new marketing approach. In a notice published in the Federal Register, the regulator stated that while drugmakers could air TV ads, they had to follow rigid rules for disclosing side effects and other information.

1997

Blue skies for Claritin

Presented with strict rules for disclosure and limited time constraints for TV adverts, companies quickly began exploring ways to get around the FDA's regulations.

Reminder ads and help-seeking ads offered a productive solution to the problem, as these types of adverts were not subject to the FDA's regulations. Schering-Plough's cautious and ultimately confusing television campaign for its hay fever drug Claritin was one notable example. The ad made no reference to the drug's intended use or benefits. Instead, it simply repeated the phrase "It's time for Claritin", a perplexing statement for viewers who were unsure what the product was and what it did.

While the FDA had already begun to address issues in TV regulation, experts note that the Blue Skies for Claritin campaign pushed the regulator to relax the rules on direct-to-consumer advertising on television.

As of 1997, direct-to-consumer drug ads on the radio and TV are were only required to mention the major risks of a drug and direct consumers to where they can find more information.

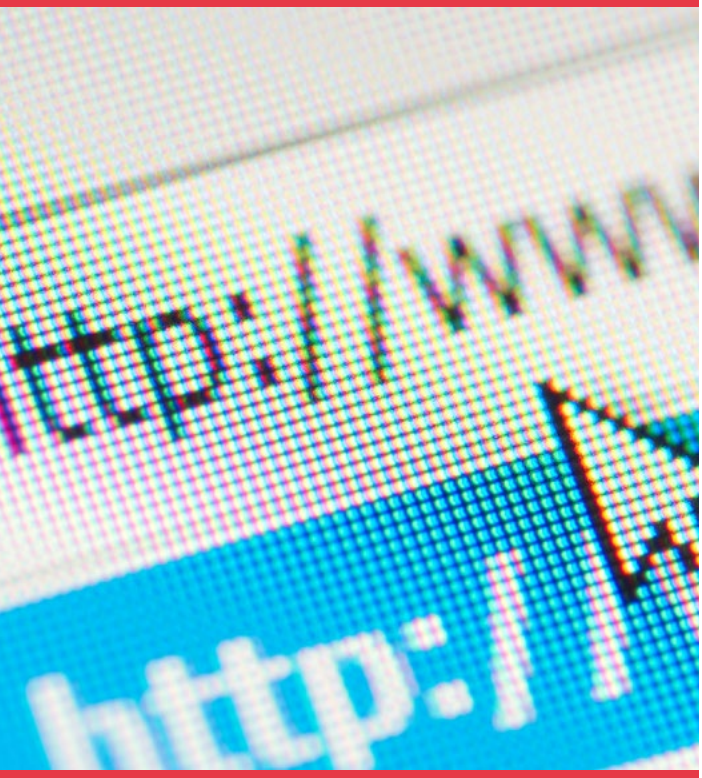
1998

Viagra launches a lifestyle movement

On the surface, former US congressman Bob Dole may have seemed like an odd choice to become the first Viagra spokesperson. But in 1998, impotence was something of a stigmatised subject. Although Pfizer had developed a strong product, in the run-up to launch, the company's marketing team realised that this perception of the condition could hinder the drug's impact and that the benefits could be overlooked in favour of cheap jokes.

With his trusted and serious reputation, Dole provided the quiet gravitas needed to position the drug as a serious product. Before Viagra even hit the market, Pfizer established a focused educational campaign to rebrand the sensitive subject of 'impotence' as erectile dysfunction.

Although the ad became a national punchline, even for Dole himself, the impact this campaign had on how drugs are marketed cannot be overlooked. Through marketing, Pfizer changed the narrative of the market it was entering. While subsequent campaigns took on a more light-hearted and jovial tone, it was this first approach that began to connect medications with lifestyle aspirations in marketing materials and acted as a springboard for the coveted celeb endorsement in future campaigns.



2000-2022

Pharma advertising heads online

Following the public introduction of the 'world wide web' in 1991, the internet became a hot commodity for companies looking to bring product marketing into consumers' homes. Undoubtedly, the internet revolutionised how people seek out and access information – including details about their personal health and medical treatments.

The potential offered by this cultural shift was not lost on pharma companies, and soon search and display adverts for prescription medications began to appear online. In 2009, the FDA sought to address the growing popularity of sponsored search engine links, which often included the name, intended use, and benefits of a drug, but not the risk and side effect information.

To police the situation, the FDA sent 14 warning letters to the pharma companies buying up these sponsored search ads, declaring that sponsored links were "misleading" and violated US regulations.

The regulator ruled that drug company–sponsored links had to include either the name of the drug or the name of the disease it was used to treat – but prohibited the use of both simultaneously.

Online pharma marketing grew steadily over the following years as companies experimented with and refined engagement approaches.

Today, marketing teams utilise a combined force of apps, social media, mobile, TV, and radio ads alongside traditional print campaigns.

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.

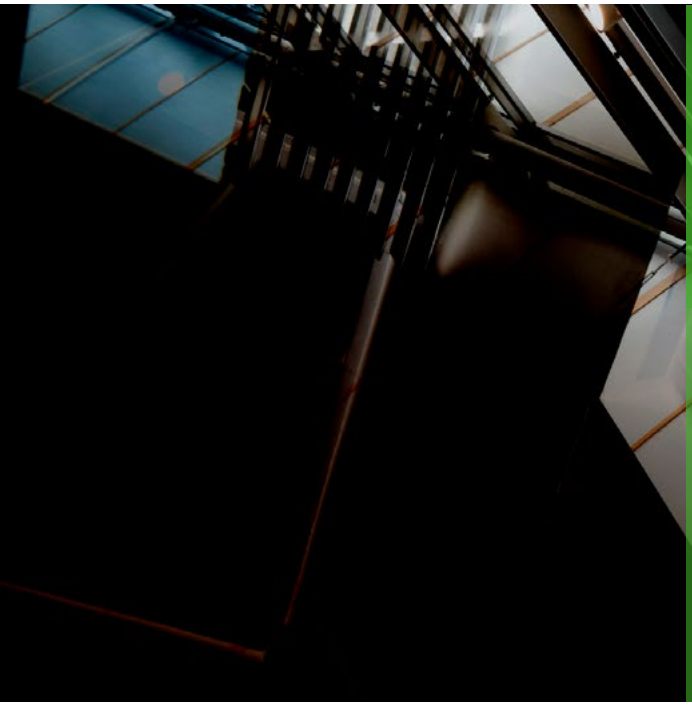
Unlocking the potential of connected commercialisation solutions

It is no secret that today's post-pandemic healthcare landscape in the UK is very different to its pre-pandemic counterpart. Driven by necessity, COVID-19 accelerated reforms that had long languished on the sidelines of healthcare agendas in the UK, ushering in a new way of working for both the NHS and UK life sciences industry on an unprecedented scale.

NHS priorities have changed amid workforce and capacity issues, technological innovations and the growing influence of Integrated Care Systems (ICSs). For life science companies, it is more important than ever to understand the market access landscape they are launching in and review how commercial and engagement strategies align with the needs of today's customers.

Preparing a cross-functional strategy with aligned priorities, activities, and recommendations across commercial, medical, and market access teams is essential if companies are to successfully cut through the noise of the modern healthcare market and connect with healthcare professionals. With connected solutions that link the priorities of each team, companies can optimise their engagement with the NHS, and ultimately ensure that patients are able to benefit from their products.

Here, IQVIA's head of commercial effectiveness Martin Fox, head of strategic market access, Steve Ferguson, engagement lead global CSMS, Elizabeth Murray, and patient and market access solution lead, Stephen How discuss the need to align value propositions with NHS priorities, the importance of connected solutions and cross-functional teams in commercialisation, and how companies can maximise marketing efforts to connect with decision-makers.



Aligning with 'multi-dimensional' NHS priorities

Communicating the value of a new innovative product or indication has long been a central feature of commercialisation strategies. However, the recent re-emergence of value-based procurement and a pivot towards system-led planning has disrupted conventional perceptions of value across the NHS.

To effectively demonstrate value in this new environment, life science companies must acknowledge this mindset shift by developing robust, evidence-based value propositions that align closely with key NHS priorities. By anchoring value propositions with the organisations' central objectives, such as the Green Agenda or workforce capacity needs post-pandemic, life science companies can target a wider array of considerations that influence drug purchasing decisions.

"You have to find a way of making your product relevant," says Ferguson. "The way to do that is to understand what the NHS is struggling with and what they're trying to achieve, and then find a way of articulating that in your product value proposition. Even if it's quite tangential, you've got to try. Otherwise, it is not going to be of any use to the NHS moving forward."

Addressing the heightened nuance of today's commissioning landscape is particularly important with the introduction of ICSs. With multiple stakeholders now involved in the process, showcasing value for different levels of the healthcare system is a priority.

"You need the national flag flying to say, 'we're reaching the high-level healthcare policy agenda items that have been set in stone'," says Fox. "Then, sub-nationally, everybody will require a slightly different version of that value. So, for example, the healthcare needs of the Northwest of England probably look different from Surrey or Central London."

This is where the NHS partnerships can be an asset for life sciences beyond product value propositions. For both Fox and Ferguson, creating trusting partnerships is an essential step for the industry. By working in collaboration with the NHS, companies can provide support beyond supply, such as preparing the system to accommodate innovative treatments.

"Companies now need to think about preparing the system to be able to use these types of technologies," explains Ferguson. "It's not just about bringing the latest innovative cancer treatment to the market. If the genomic testing required to identify the patients is not in place yet, or it is not included on the latest Test Directory, and therefore is not being financed at the moment, patient access will not happen.

"Looking at CAR-T, I think that is the blueprint for innovative medicines moving forward. It's been a big success story. Even though these treatments are expensive and single-patient manufacturing creates significant challenges, the NHS really bought into the potential of CAR-T and has worked with companies to make them available."

Enhancing communication strategies for a hybrid landscape

Of course, to successfully articulate value to stakeholders across the NHS, companies must first navigate the changing landscape of hybrid communications. Today's engagement landscape looks very different than it did before the pandemic. As such, the way life science companies communicate and connect with HCPs must also evolve to reflect the shift towards multichannel and omnichannel engagement.

To maximise the impact of both digital and in-person interactions, it is important to understand what customers need from each type of interaction.

"It is not really a case of either/or, it is about how you stitch these channels together depending on individual HCP preferences and the type of activity that is being offered to them," explains Murray. "A lot of companies are talking about having an omnichannel vision where different channels are pulled together in a seamless, connected way; but making that shift to having a truly customer-centric omnichannel approach that delivers a good customer experience is quite a jump."

Consistency and quality are two essential characteristics of good communications. Here, adopting a cross-functional approach can be productive. For example, ensuring that analysis of real-world evidence is shaped to meet the communication requirements of medical, market access, and commercial teams will address the needs of multiple decision makers.

"Sometimes, the danger is that commercial teams get involved later in the process when it gets close to commercialisation," says Fox. "The NHS is complex, and there are multiple decision-makers and stakeholders. If your engagement strategy is disconnected, there will not be a unifying message or unifying support from within the life science company in terms of providing data to all those different people."

Using insights to drive connected solutions

Achieving this vision of a seamlessly connected commercialisation process requires comprehensive insight into customer behaviour, as well as the ability to measure the effectiveness of the product and related communications.

Facilitating communication and collaboration between cross-functional teams allows life science companies to be agile in decision-making. The addition of real-world evidence (RWE) can also provide critical information about adherence and effectiveness that life science companies can use to identify potential issues or barriers to treatment.

"It is important to understand the impact of your product on the clinical service, on workforce capacity, changes in diagnostics, or follow up," says How. "The NHS frequently does not have the headroom to implement some of the pathway changes necessary for the introduction of innovative medicines. Collaboratively gaining real world evidence on the whole pathway impact is a powerful way to communicate your value proposition."

In the current healthcare ecosystem, measuring the impact of an engagement strategy is an evolving process. Omnichannel engagement is still a relatively young process in the history of modern healthcare and, as such, companies are working to assess the relative success of different channels and marketing approaches.

"It's very, very rare that companies know exactly which elements of the campaign were the most effective," explains Ferguson. "I think that's going to take time for companies to fully understand because, ultimately, we measure effectiveness on how many patients are receiving the treatment versus the number of appropriate or available patients."

Exploring the value of collaboration

At the height of the COVID-19 pandemic, the life science industry has shown just how effective a connected and united healthcare landscape can be. But to carry this vision of connection and partnership into post-pandemic plans, life science companies need to invite the whole organisation to partake in the journey from pre-launch to post-market brand planning.

"A connected solution is an integrated approach to a business problem, rather than a connected set of activities," says How. "This means understanding local issues and pressures, from clinic waiting time pressures – such as diagnostic or genomic test availability – to providing market access support in pathway development or patient activation services, such as support nurses or homecare services to facilitate access to treatment."

The key is understanding. Cross-functional teams can use industry and data insights to develop a united front of information aligned across messaging, values, and brand strategies. This foundation can then be used to understand how a product fits into the wider market access landscape, allowing teams to identify key areas of unmet need in the wider NHS ecosystem and develop a tailored communication and engagement strategy.

"The traditional industry approach has been about pushing their messages, but the pandemic has really forced companies to think a bit more about talking to the healthcare professionals on their terms," Murray concludes. "This is a journey, and it is important that communication and engagement efforts evolve to truly meet the needs of HCPs."

About the interviewees

Steve Ferguson, head of strategic market access, IQVIA

Martin Fox, head of commercial effectiveness, IQVIA

Elizabeth Murray, engagement lead global CSMS, IQVIA

Stephen How, patient and market access solution lead, IQVIA

About IQVIA

IQVIA is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialisation of innovative medical treatments that improve healthcare outcomes for patients. With approximately 77,000 employees, IQVIA conducts operations in more than 100 countries. Learn more at www.iqvia.co.uk

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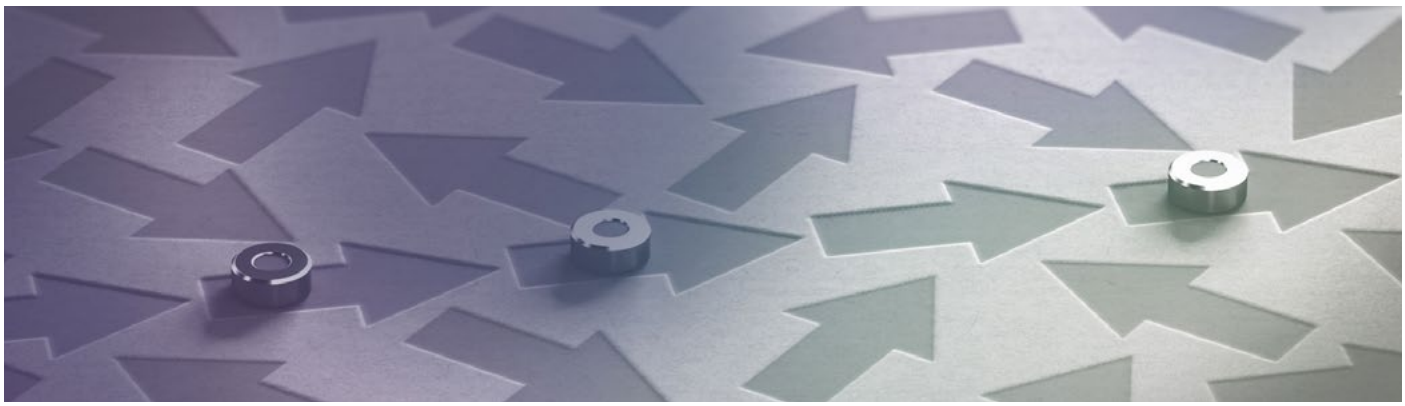
Achieving launch excellence in oncology

Any new drug launch must overcome numerous obstacles in the pursuit of success. Many of these challenges are exacerbated in oncology, where the treatment landscape rapidly evolves with novel mechanisms of actions (e.g., cell therapy, bi/tri-specific antibodies), where there are ever-changing regulatory requirements, the use of biomarkers, etc. Today's oncology launch landscape is highly saturated and competitive, cumulatively presenting significant challenges, particularly for small and emerging companies to gain traction with medical and scientific communications that inform key stakeholders about their oncology therapies.

Cutting through the noise is critical, as the volume and complexity of information has become a barrier. The treatment landscape changes rapidly, and healthcare providers (HCPs) have limited time to comprehend these large volumes of new information. It is even more challenging for patients. HCPs, patients, and payers need clear, concise, and consistent information to ensure that they are providing patients the best possible care.



Strategic planning and early investments in HCP and patient education are critical success factors for small and emerging companies launching oncology products. This is not limited to medical oncologists, patients and caregivers are increasingly involved in their care decisions, and we need to do a better job of learning from the experience gained through the clinical trials to effectively educate the differing stakeholders. When engaging the community, consider:

- Field teams, especially MSLs, need to understand practice-specific patient populations and treatment preferences to effectively engage in oncologist-specific scientific exchange. Correspondingly, resources need to be equipped with easy-to-navigate, concise communications that can be appropriately catered to the differing physician types.
- Patient advocacy and engagement are becoming more important in the oncology landscape. Understanding how patients perceive and value differing treatment options will be critical to inform communications.

Given the complexity of the externally changing environment, often internal education and terminology are not aligned within emerging organisations. Yet, overlooking a coordinated effort in these areas can result in a disjointed and confusing communication plan. A lack of internal consistency about key product messages can translate into a lack of understanding by external stakeholders. These pitfalls are avoided by establishing a foundation, through a formal scientific platform and publication strategy, which allows for idea sharing and consistency.

Planning is critical

A number of core elements underly the need for deliberate and dynamic communications to consistently convey the product's value and place in the treatment paradigm. Some of those are particularly challenging for emerging pharma, yet critical to a successful launch.

Integrated launch planning and management: This launch planning process needs to be grounded in strategic imperatives and integrated across the medical and commercial organisation. This enables the differing functions to collaboratively build upon what is planned and executed. The exercise should start with Medical Affairs in phase 2 to establish relationships with the community, followed closely by development of robust, integrated commercial plans.

Scenario planning: The plan needs to consider risk mitigation and differing outcomes in terms of the asset's registrational path (e.g., positive, neutral, sub-par). Scenario plan around the differing outcomes, including the possibility of a change in course due to competitive data and/or regulatory decisions. This will enable the organisation to pivot quickly and appropriately, enabling control of the narrative.

Advantages and challenges for small and emerging biotech companies

Highlighted through the core elements detailed above, it is easy to see potential challenges for an emerging pharma company launching in the complex oncology landscape. Large companies may have an advantage with sophisticated organisations and financial resources to support a launch. However, there are numerous benefits to be found in being a small and emerging organisation preparing for a product launch in oncology.

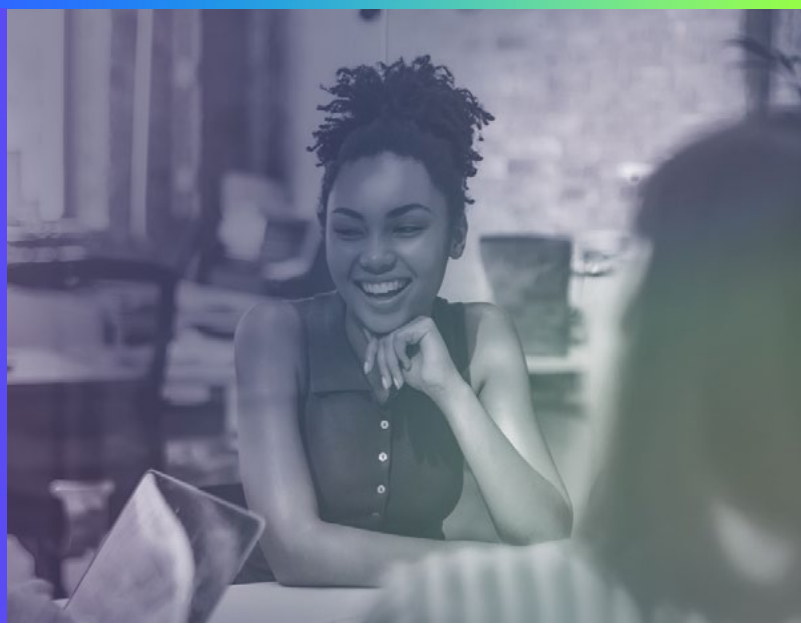
One distinct advantage that smaller companies can leverage is focus and agility. With fewer decision-makers involved in approving changes, small and emerging companies can be nimbler than their large company counterparts.

Another asset for small and emerging companies is often the company culture. Emerging biotechs are commonly fuelled by a few committed and highly skilled individuals, often with a personal connection to the oncology space. Not only does this give biotech a clear and central purpose to motivate success from, but the smaller organisation size lends well to the company's ability to pursue personal relationships with HCPs and patients starting at the leadership level.

It is important for small and emerging companies to identify what their version of success looks like early on. Success for a smaller company is likely to look quite different from success for a larger company with extensive access to funding and resources. To overcome resource limitations, these biotechs need to have focused strategies and plans alongside realistic objectives for what success looks like. This is where partnering with an established agency with experience working with small and emerging companies in oncology can be an asset.

Choosing the right agency partner

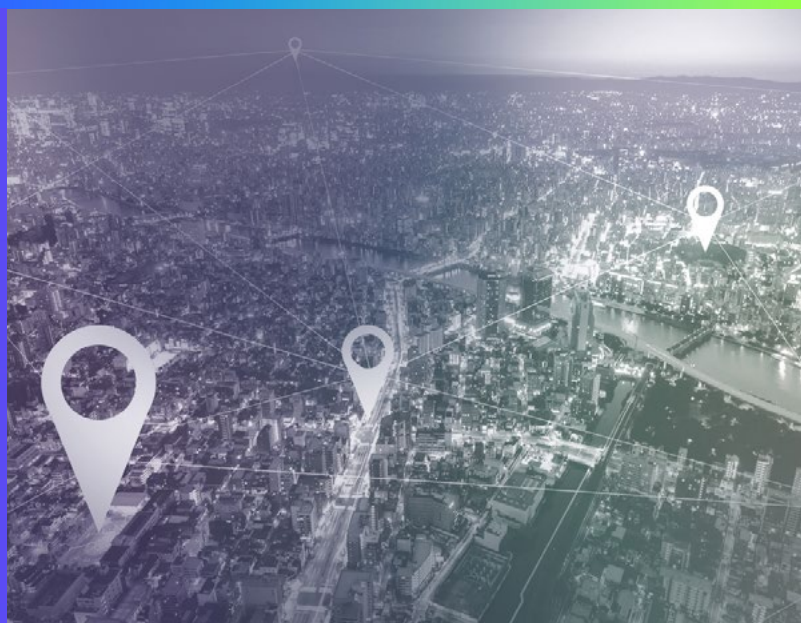
Launching a new cancer therapy is a collaborative effort. Small and emerging biotechs have limited resources, and engaging an established agency partner with knowledge and expertise across small, mid, and large pharma, can open doors to opportunities that would have been otherwise inaccessible.



This is where finding the right agency partner is critical. Assess fit, experience, and flexibility – and decide what balance is most appropriate for your launch. It is important that partners understand the dynamics a small company faces, which often include a rapidly changing market space, funding hurdles, and lifecycle development stage gates to manage.

Navigating the journey to launch excellence

The road to achieving launch excellence is not smooth or well-defined. There are numerous obstacles along the way that can threaten to upset even the most established strategies and plans.



Prepare for these challenges by thinking through the scenarios – what can happen and what will we do. This includes engaging the community in an appropriate manner, that clearly defines the benefit of the novel treatment to the differing audiences. Adapt to each change in the terrain by leveraging the flexibility and passion inherent within the small organisation and collaborating with the right partners. Each new therapy that enters the market opens more opportunities for patients to receive life-changing care and challenges scientific minds to reach a little further toward the goal of eradicating cancer.

About Envision Pharma Group

ENVISION PHARMA GROUP

Envision is a leading provider of evidence-based communication services and industry-leading technology solutions (iEnvision) that have applicability across many areas of medical affairs and related functional responsibility. Envision provides services and technology solutions to more than 90 companies, including all of the top 20 pharmaceutical companies. TwoLabs is an Envision company focused on providing integrated and customised product launch solutions for small pharma/biotech companies. We help chart the path from clinical and medical affairs to commercial for a new product launch and provide strategies for continued market viability for drugs on the market.

To find out more, visit www.envisionpharmagroup.com and www.twolabs.com.

About the authors

Angus Bromley, Two Labs

Angus has a strong healthcare-focused background with over 15 years of industry and management consulting experience. As a leader in Two Labs Strategic Consulting group, he has collaborated with clients to address strategic and operational challenges across medical and commercial organisations, including oncology focused new product planning, launch strategy and planning, and capability development.

Rachel Shemer, Envision Pharma Group

Rachel Shemer is a SVP, Medical Strategy at Alligent Medical Affairs. Working with biotech and pharma, Rachel has over 20 years' experience in marketing, brand planning, medical affairs, KOL development, and launch execution in the US and global markets. Her role serves to understand the client's long-term goals and analyse the market landscape, clinical development programmes and risk mitigation whilst working with the team to develop a go-to market strategy that contains all the necessary ingredients to support a successful launch.

Kimberly Cash, TwoLabs

Kimberly Cash is a general manager, Medical Affairs & Communications, at TwoLabs who works with BioTech/BioPharma companies to deliver strategic medical affairs tactics and impactful medical communications plans. Kimberly has led medical affairs strategy & development at small to large pharmaceutical companies for over 20 years. She has led several successful, multi-faceted product launches in the BioTech/BioPharma space and applies this expertise to guide clients through these unique challenges in the interest of improving the lives of patients.

The doctors have spoken: what physicians need from pharma comms in the post-pandemic world

In the rapidly changing field of medicine, effective communications are essential to ensuring that innovations are cascaded out across the health system.

COVID-19 rendered the primary face-to-face model of engagement obsolete. With no time to waste, the industry turned to digital means of engagement.

While the initial turmoil of the pandemic appears to have plateaued, the impact of COVID-19 is still very present in healthcare. Faced with increasing wait times and delays in patient diagnosis and treatment, many healthcare systems are struggling to cope, with ever growing pressures on doctors' time.

New research from M3 highlights the need for pharma to adapt their communication efforts to help ease the burden placed on doctors. Here, M3's Dr Maxim Polyakov and Dr Deepak Jadon, consultant rheumatologist at Cambridge University Hospitals, discuss some of the key findings of this research.

"Health systems today are under a huge amount of stress," says Polyakov. "To fit into doctors' busy diaries in a way that's most helpful for the doctor and most effective for pharma, the industry needs to change how they engage with their customers."

Understanding the current pressures on doctors

Even after the end of the COVID-19 peak, doctors are busier than ever. Backlogs and delays in health care reached record levels due to the pandemic, putting substantial pressure on already stretched healthcare systems and professionals.

Although efforts are underway to reduce the current backlog of patients and restore services to pre-pandemic levels, there is no guarantee that healthcare systems will fully recover. In a survey of 750 doctors across the UK, France, Germany, Italy, and Spain, M3 found that approximately 20% of doctors do not believe referral waiting times can be reduced to pre-COVID levels, while 40% think this is possible, but will take many months to achieve.

Without capacity in the system to accommodate all the patients who need to be seen in a timely manner, HCPs are struggling to cope under the immense pressure of heavier workloads, longer hours, and no clear end to the current situation.

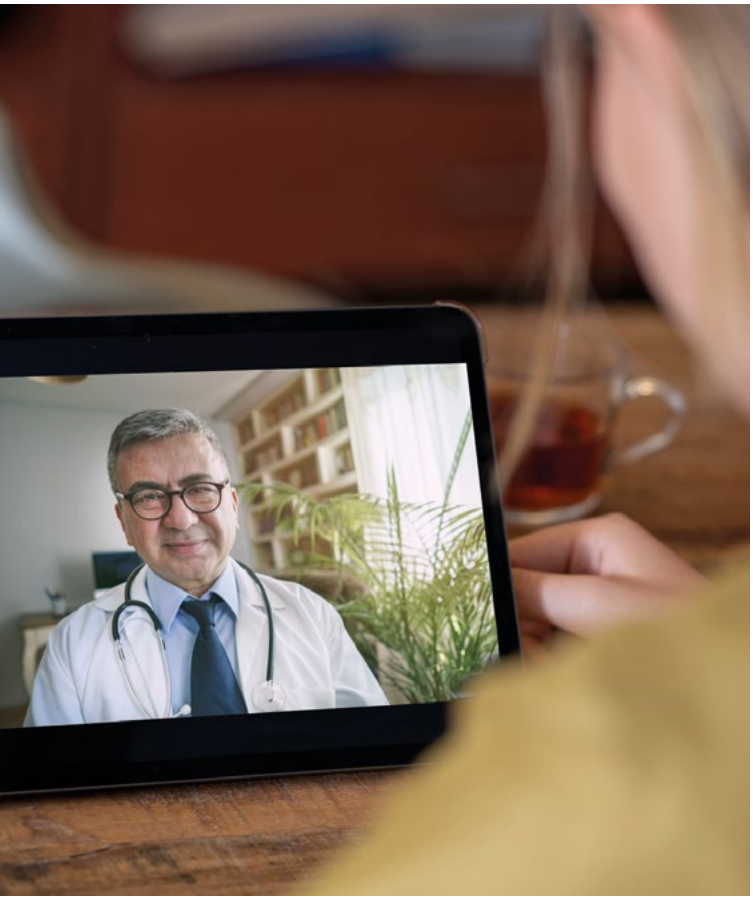
"To see 65% of doctors saying that they're having to work harder this year than before COVID-19 is shocking," says Polyakov. "At a very human level, it's important to recognise that there's been a huge cost to the healthcare profession, as doctors are still having to work harder because of staffing pressures and the huge numbers of patients who need to be seen."

The physical and mental impact of the pandemic on the European healthcare workforce is clear. Of those surveyed, 89% agreed that clinical staff where they work are more exhausted or burnt out than before the pandemic. Clinical staff are also more likely to take early retirement, take long-term sick leave, or leave medicine altogether than before COVID-19.

Across the healthcare ecosystem, stakeholders must find solutions to ease the burden on HCPs, including giving them the information, tools, and time they need to navigate this challenging period.

Permanent shifts in ways of working

Alongside the impact of COVID-19 on capacity and services, the pandemic fuelled a significant shift in the day-to-day working and communication habits of doctors. Amid lockdowns and social distancing restrictions, a surge of remote and digital approaches rose to fill the gap left by the sudden loss of face-to-face interaction. Driven by necessity, doctors rapidly worked to adapt to this stark inversion.



However, this extreme remote- and digital-only approach was never expected to last. As restrictions lifted and face-to-face interactions began to resume, a balance of hybrid engagement emerged – both in how doctors engage with patients as well as pharmaceutical companies.

As Polyakov explains, "If you consider what a doctor's day looks like now and how pharma fits into that day, it is quite different to the way it looked before COVID. For example, doctors are on the phone a lot more, they're in front of their computers, they might get online referrals that need to be reviewed. Our survey showed, for instance, that in EU5 countries, doctors will spend about double the amount of time interacting with patients remotely than they did pre-COVID.

"In effect, it's no longer just patient, ten minutes, next patient, ten minutes. It's a much more hybrid approach to working, across more modalities. To fit into that day successfully and in a way that's helpful to their customers and respectful of the pressures they are under, pharma companies need to think about how they can adapt their approach to reflect these hybrid engagement patterns."

With approximately 50% of surveyed doctors across the EU5 expecting to spend half or more of their engagement time with pharma online, about twice the level seen before the pandemic, it is evident that interest in a mixture of digital and face-to-face communications with pharmaceutical companies is here to stay.

It is a stark contrast to established pre-pandemic ways of working. Before COVID-19, doctors primarily engaged with pharma via reps, face-to-face. Now, having been introduced to systems and services that allow them to interact with industry content on their own terms, doctors are open to a wider variety of engagement options that reflect their preferences.

Consequently, the onus is on the industry to adapt, as the traditional approach to engagement is unlikely to continue to suit the individual requirements of their customers.

As Jadon explains, "If a pharma rep was going to travel from Manchester or Newcastle to come and see me, I would feel I need to give them some value for their time and offer them at least a half an hour appointment. I would therefore find it harder to find time in my diary to do so. Whereas if I'm going to do it online, I don't mind doing a ten-minute call because they're not travelling four hours to come and see me. As a result, I often prefer to engage with pharma online – it just fits better with my diary."

What do doctors want?

To realise this vision of a flexible, multi-channel engagement approach that connects with the individual preferences of today's doctors, pharma companies will have to evolve and challenge existing ways of creating and delivering content.

Today, effective communication starts with understanding your audience. For pharma companies, this requires a careful and thoughtful design of robust data-driven customer journeys that can be deployed at scale and improved over time. By tailoring communications to the needs and preferences of individuals, companies can ensure that the information is useful and accessible so that doctors will – however busy they are – want to engage with it.

"Doctors want information as long as it's new and valuable," says Polyakov. "However, the burden is on the communicator – i.e. pharma companies – to find out what is valuable to different members of their audience, and to serve them content that is as closely tailored to their needs as possible."

As Jadon explains further: "To cut through the noise and increase accessibility, it is important to address potential barriers that may deter a doctor from engaging with content. If someone sends me something for which I have to fill out yet another registration form and then remember the username and password, I'm not going to do it," he says. "Pharma need to make it as easy for me as possible to engage with them. That's the big thing."

"This is not an easy situation for marketeers," says Polyakov. "They used to have a few big channels to work through. Now, within just a few short years, they have to work across multiple, fragmented channels, all of which are important. There is also a growing expectation for personalisation, meaning they need to tailor what they do to the needs of different segments of their audience, taking into account their diverging content, format, and channel preferences – and do this at scale. Finally, all of this needs to be tracked and continuously reviewed, with insights fed into the next turn of the wheel. This is a big change to standard processes, resource allocation, and ways of working."

A key learning from the survey highlights this dynamic. When asked to select channels through which they would want to receive information before prescribing a new product for the first time, only 27% of doctor surveyed in the UK said they would want to speak to a pharmaceutical company product or medical rep.

Speaking on this, Polyakov notes: "In the UK, even in a 'new product' situation where a doctor hasn't prescribed a drug before, pharma can no longer rely on traditional rep interactions. They need to learn to use a broad range of sources to get the right information to their customers. This is a fundamental shift to how the industry used to operate."

Bridging the gap between traditional and digital engagement

For Polyakov, one important lesson to take from the study is that, during this difficult time, it's even more important for the industry to do everything it can to help doctors, including providing them with information on their terms.

This means understanding what content doctors need and want, and using the right channels to make this information accessible to them, increasing the value and impact of each interaction.

"Having realised that they can have a choice, doctors now want to engage in a way that suits them," explains Polyakov. "The ball is now in pharma's court. To play the next shot well, pharma must adapt to the current situation and implement a proper omnichannel strategy, tailored to individual customer segments and operationalised at scale; and driven by data and insights about doctors' behaviour and preferences that are derived from robust primary and secondary research."

He concludes, "This is, of course, not a trivial challenge, and will require time, resources, and expertise to get right. The good news is that, even now, there are some platforms out there that can offer this level of service to pharma."

About the interviewees

Dr Maxim Polyakov is director, strategic accounts within M3's business intelligence and research division. He is passionate about using data to drive better decisions, and ensuring that the voice and needs of patients and HCPs remain at the centre of healthcare systems.

Dr Deepak Jadon is a consultant in rheumatology and director of the Rheumatology Research Unit at Cambridge University Hospitals, UK. He leads the psoriatic arthritis service, co-leads the ankylosing spondylitis service and co-chairs multi-specialty meetings for IBD-spondyloarthritis, psoriasis-spondyloarthritis and the East of England spondyloarthritis MDT. He leads a large rheumatology research team conducting academic studies and clinical trials in rheumatology. He is a clinical researcher (associate principal investigator) in the Department of Medicine, University of Cambridge. He is director of studies at Emmanuel College, University of Cambridge.

About M3

M3 is the world's largest network of verified doctors with over six million members across many key markets; our closed and local communities of doctors are trusted by our members as places where they can reach content relevant to their profile and their geography. M3 has over 20 years' experience in building online doctor communities. These communities include Doctors.net.uk in the UK, Vidal in France and m3.com in Japan and offer clients a unique opportunity to communicate with doctors. M3 is committed to its mission to use technology to help people live longer, healthier lives and reduce costs in healthcare.

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The missing pieces of the digital therapeutics puzzle

When it comes to marketing digital therapeutics, companies can only do so much on their own until certain information infrastructure is in place, Kristin Milburn, managing director of Healthware Labs, tells pharmaphorum Deep Dive.

Over the last few years, digital therapeutics have made great strides in efficacy, regulatory approval, and even reimbursement. But the most effective digital therapeutic in the world does nothing if a patient doesn't know it exists, or a doctor doesn't know they can prescribe it.

For marketing and communications around digital therapeutics today, awareness is the watchword – pharma marketeers have to get the word out about not only their particular product, but often about the whole category of digital therapeutics.

"I would say one of the biggest challenges, assuming that there's a reimbursement pathway and you can get paid, is just awareness of these solutions," Kristin Milburn, managing director of Healthware Labs, says. "And I do think that there needs to be an industry-wide effort to help educate both patients – and maybe physicians even more to start – about what are DTx and what is available in their therapeutic area. Because until they are aware of them, they're never going to recommend them, obviously, to their patients."

Healthware Labs partners with digital health start-ups and pharma companies to encourage digital innovation in healthcare. Milburn says the need to educate around digital therapeutics isn't something that should take pharma by surprise.

"If you think about it, pharma spends a ton of money – and have since medicines were first developed – in doing market shaping and educating around specific new treatment modalities. This is no different. You can't expect to create an entirely new category of solutions without educating broadly around what those kinds of solutions are."

Still, though there may be similarities between traditional and digital therapeutics, it's the differences that create difficulty for marketing and communications around DTx – and it will take the introduction of new sales infrastructure to fully address those challenges.

Educating the physicians

As the primary prescribers, doctors are the first group that needs to be educated about digital therapeutics, and at the moment, that doesn't generally happen in formal medical education, Milburn says.

For now, pharma has to rely on the same channels it has always used to teach doctors about new therapies: a combination of key opinion leader education, digital channels, and sales reps. Though, Milburn notes, that paradigm is changing right now, even for drugs, so it likely won't look like the traditional sales force model.

There's a more pressing issue when it comes to physician education, however. Just as the user experience for patients needs to be easy for them to adopt, doctors will be more likely to prescribe something if that process is made as simple as possible – which can present a challenge for digital therapeutics.

"The doctors need to know about it," Milburn says. "They need to be able even to prescribe it. So, there needs to be some kind of integration into their workflow. And that's an area where I think there needs to be some work to develop either platforms where DTx can be distributed, or integrated within EHRs. But this notion of 'if you build it, they will come', as we all know – that's not true."

In addition to a simple workflow for prescription, Milburn says doctors need a simple way to survey the landscape of available digital therapeutics.

"How are they supposed to find out about them? Is there going to be some central place where they can look at all DTx and compare them against each other? Is it just finding out about it from their networks? I think there's no kind of standardised way for physicians to learn about this new class of therapeutics."

Reaching out to patients

Digital therapeutics marketeers need to target two audiences with awareness campaigns: physicians and patients. These efforts need to be differentiated, but can't be undertaken in siloes from one another.

"You need to educate doctors, but then, once you educate the doctors, and you start to prescribe, then the patients themselves need to understand how to use the product," she says. "The doctor's not going to be there to hold their hand and show them how to use this new thing. There's going to need to be some support on that side of things to ensure that they use it and that there's engagement with the product."

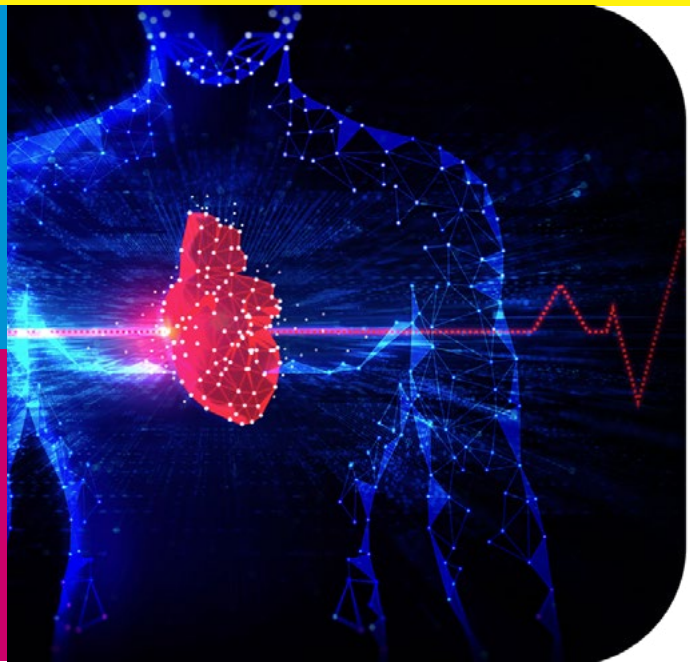
Even when selling into large groups, Milburn says, it's going to be important not to take adoption for granted.

"In the case of when it's sold into a payer or an employer, you might sell in a contract with an employer or a payer, but it doesn't automatically mean that you're going to have users," she says. "You have to do the work of getting the adoption and getting people to download it, getting people to use it."

Some of this work must be done on the front end as the digital therapeutic is developed; development needs to happen with the input of patients and an eye toward usability. Several of the most promising digital therapeutics today have an engaging form factor as a major selling point. Milburn used the example of Akili Therapeutics, which has developed a DTx for children with ADHD that takes the form of a video game.

"In the case of Akili, when they're dealing with kids especially, we all know that kids love to play games," Milburn said. "So, if you could deliver a clinically meaningful solution in the form of a game, presumably the adoption would be much higher than telling them they have to go read a book or something else that kids might not be as engaged with."

Digital therapeutics and the patient journey



Another aspect of securing patient buy-in is for doctors to engage the patient at the right point in their journey, which involves DTx makers thinking hard about when that is for their particular intervention.

"When would be the appropriate time for a conversation about leveraging a specific DTx?" Milburn asks. "Is it right when they find out they have the disease? Is it after they've used other things? I mean, I tend to believe that DTx are going to eventually become kind of first-line therapeutics."

Milburn sees DTx as first-line treatments in many cases because of their safety profile relative to drugs, as well as their scalability in cost and logistics of implementation.

One area where DTx might see strong traction is in conjunction with telemedicine, where the appeal is high for a therapy that can be delivered remotely. Another is around chronic conditions – a good example of the value of DTx as front-line treatments.

"I believe that DTx will probably be extremely helpful for chronic conditions that have a behavioral aspect to them, where we know different lifestyle interventions can really help these patients before they need to be on a drug. So that's why we saw so much activity around diabetes. I think we'll see more and more around cardiology and things like that."

Building the future of DTx

Whatever the future has in store for digital therapeutics, if they're to be widely understood, prescribed, and used, then the industry as a whole will need to step up to create the infrastructure to enable that adoption.

That will include better baseline education for physicians around DTx, established workflows for DTx prescription; established workflows for DTx prescription, and some kind of digital formularies to help make physicians aware of the DTx options available and their efficacy. On the patient side, it will require early attention paid to user experience and patient centricity to ensure that patients not only start using a therapeutic, but that they can have the sustained engagement necessary for therapeutic benefit.

In the meantime, the best thing pharma companies and DTx start-ups can do is focus on the fundamentals of good marketing and communication.

About the interviewee

Kristin Milburn, Managing Director, Healthware Labs

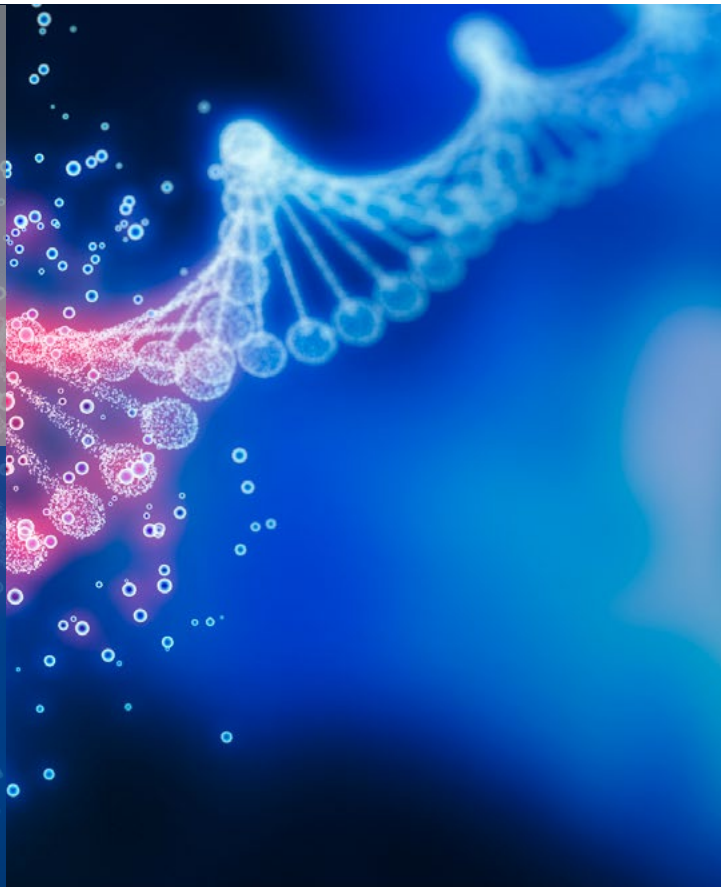
A twenty+ year veteran of digital consulting, Kristin Milburn's experience has had a consistent focus on healthcare, technology, and the intersection of the two. She is a strategic and innovative thinker, who has held leadership roles in strategy/planning and client engagement at various digital firms with numerous Fortune 100 pharmaceutical and technology clients. After launching her own digital shop and rising through the ranks on the agency side, Kristin jumped to the client side and joined the Digital Medicines team at Novartis for several years. Looking to gain experience on the start-up side, she then joined the digital mental health start-up called Headspace, helping integrate meditation and mindfulness into healthcare. Kristin is now the managing director of Healthware Labs, the digital health innovation consultancy of Healthware Group.

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-seen face at digital health events and on digital health Twitter.

Gene therapies for prevalent diseases in Europe – the perfect storm of economic sustainability?



In this article, Research Partnership reviews why the path to commercialisation for the half a dozen approvals in Europe over the last few years has not been smooth, and shares feedback gathered from our payer network on the outlook for gene therapy market access in Europe, especially considering the shift to more prevalent diseases.

In January, the Alliance for Regenerative Medicine (ARM)'s Cell and Gene State of the Industry briefing earmarked 2022 as a record year for approval of gene therapies for rare diseases. This has not transpired. As of September, only three gene therapies from the ARM list have received European Medicine Agency (EMA) approval so far, with three expected to reach the market in 2023 (see Table 1).

Table 1: EMA gene therapy approvals in 2022 and expected approvals in 2023

Brand name*	Active substance	Manufacturer	Indication	EMA final approval date/ expected date
Upstaza	eladocagene exuparvovec	PTC Therapeutics	Aromatic L-amino acid decarboxylase (AADC) deficiency	Jul 2022
Roctavian	valoctocogene roxaparvovec	BIOMARIN	Haemophilia A	Aug 2022
Lumevoq	lenadogene nolparvovec	GenSight Biologics	Leber's hereditary optic neuropathy	2023: CHMP opinion expected by Q3 2023
EtranaDez	etranacogene dezaparvovec	CSL Behring	Haemophilia B	2023: As of Mar 2022, EMA accepted for review under its accelerated assessment procedure
Vyjukek	beremagene geperpavec	Krystal	Dystrophic epidermolysis bullosa	2023: As of Aug 2022, marketing authorization application submission expected in H2 2022
Not available	OTL-103	Orchard therapeutics	Wiskott-Aldrich Syndrome	2023: As of Jan 2022, marketing authorization application submission expected in Mid-2022

*Based on a listing of the Alliance of Regenerative Medicine in Jan 2022

Developing, manufacturing, and getting a gene therapy to a patient is complex and expensive. Gene therapies are associated with a high cost of goods and require a price reflective of their curative value. For ultra-orphan and orphan diseases, the small numbers of patients who will benefit mean high prices are needed to ensure profitability and these have proven challenging to achieve.

While the industry remains active in developing advanced therapies (including gene therapies) within the rare disease space, including haematological disorders and eye disorders, there is an increasing shift from the advanced therapy sector as a whole to more prevalent diseases (see Table 2).

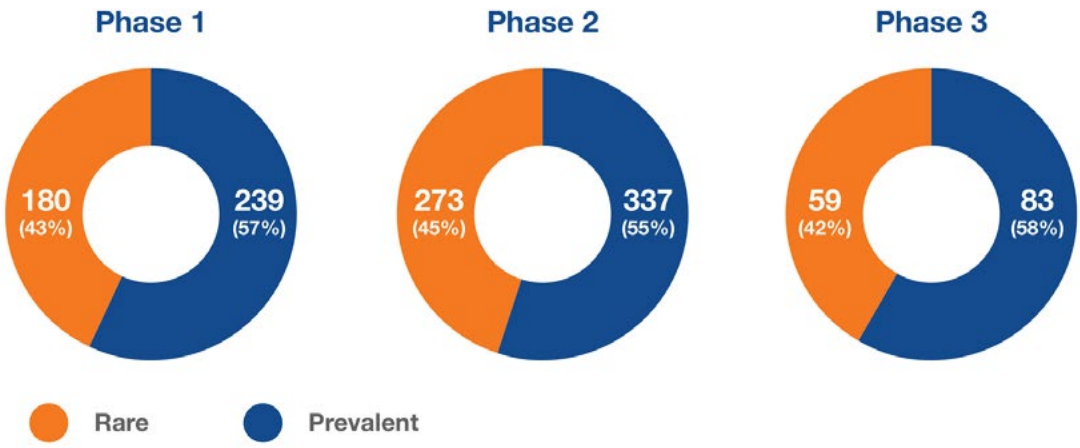
Table 2:
Clinical activity breakdown of rare versus prevalent disease indications

Rare Diseases	Prevalent Diseases
Sickle cell disease (39)	Osteoarthritis (61)
Hemophilia (28)	Diabetes & related complications (54)
Retinitis pigmentosa (26)	Parkinson's disease (21)
Amyotrophic lateral sclerosis (ALS) (15)	Critical limb ischemia (18)
Thalassemia (15)	Macular degeneration (18)
Mucopolysaccharidosis (14)	Stroke (17)
Multiple sclerosis (12)	HIV (12)
	Alzheimer's disease (10)

Source: Based on the Alliance of Regenerative Medicine 2021 Annual Report, published in Mar 2022

According to the ARM, just 59% of the 2,405 advanced therapy clinical trials (both industry and academic/government sponsored) are focused on diseases defined by ARM as 'prevalent', as outlined in Graph 1.

Graph 1: Rare versus prevalent disease breakdown for industry-sponsored trials



Source: Based on the Alliance of Regenerative Medicine 2021 Annual Report, published in Mar 2022

Bumps in the road

The latest stream of positive news regarding gene therapies has been peppered with a series of "here we go again" moments.

The economic challenges associated with commercialisation of a gene therapy for an ultra-orphan disease were once again underscored by the July 2022 decision by Italy's non-profit organisation, Telethon Foundation, about Strimvelis for Adenosine Deaminase severe combined immunodeficiency. The Foundation decided to take sole responsibility for commercialising Strimvelis after current license holder Orchard Therapeutics opted to withdraw from this programme due to lack of economic viability. Figure 1 signposts the chequered past of cell and gene therapies.

Figure 1: European marketing withdrawals of cell and gene therapies to date

The Strimvelis development follows the high-profile decision of US firm Bluebird Bio to cease operations in Europe after two years of failed discussions with reimbursement authorities over its beta thalassemia gene therapy, Zynteglo.

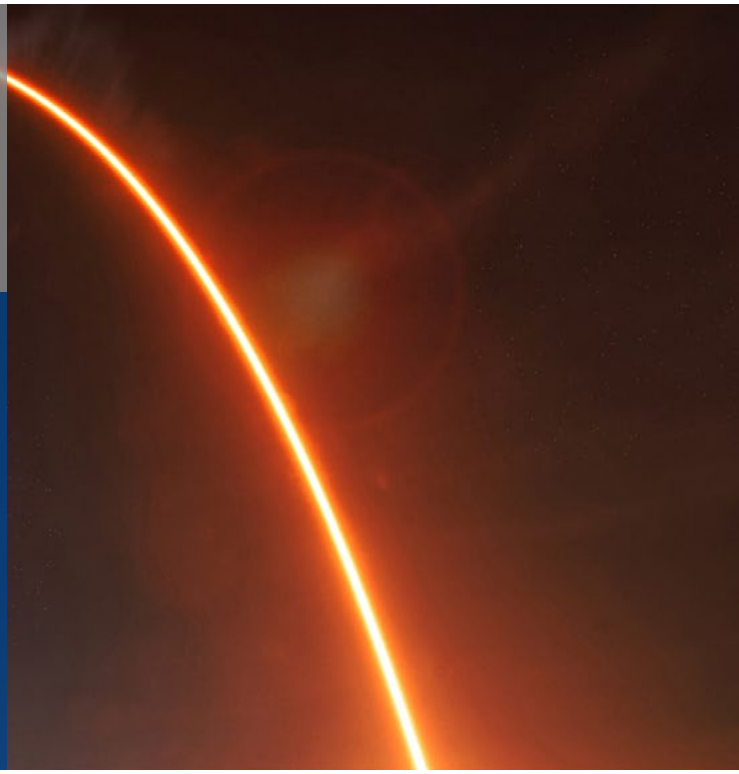
Failure to achieve appropriate value recognition for Zynteglo, and the inability to identify a commercialisation partner, led the company to also withdraw its regulatory marketing authorisation for gene therapy Skysona for cerebral adrenoleukodystrophy from Europe. Skysona was the only gene therapy approved by the EMA in 2021.

When the Telethon Foundation stepped in to 'rescue' Strimvelis, it echoed the thoughts of many developers, stating that scientific advances have not been matched by an adequate evolution of regulatory and market access processes for gene therapies, considering their unique characteristics compared to traditional drugs.

Gene therapies face a range of evidence-generation challenges, including uncertainties regarding the magnitude and duration of treatment effects, poorly defined patient populations, limitations in trial duration and size, and reliance on single-arm trials and surrogate endpoints.

The challenges associated with characterising value made us curious about HTA body and payer preparedness to deal with the imminent influx of gene therapies with an inherently high sticker price. From our global network, we reached out to seven payers with gene therapy expertise in the UK, France, Germany, Spain, and Italy to get their views.

Importance of RWE to resolve uncertainties at launch



When asked about preparedness of their country's pricing and reimbursement (P&R) systems, most of the payers we spoke to considered them to be 'somewhat prepared'. Part of this readiness related to their perception of the importance of real-world evidence (RWE) collection to resolve the evidence uncertainties at launch.

Most respondents believe that RWE is 'somewhat important', however, a French payer emphasised that this depends on the objective and the context. Haute Autorité de santé's (HAS') latest evaluations of gene therapies make requests of RWE collection as part of reassessments, including monitoring data as part of early access programmes.

"If RWE intends to overcome a too-rapid development plan, the HTA body will not be as welcoming. If [RWE] is, on purpose, providing valuable information in addition to the clinical development, it will be very much welcomed."

Payer, France

The German payer highlighted that the G-BA selects which EMA conditionally approved products and orphan drugs must be part of a mandatory RWE data collection registry. Although only expected for selected products, the registry requirement aims to help overcome the uncertainty associated with weak evidence at launch. After the first test case, Zolgensma for spinal muscular atrophy, Roctavian for haemophilia A is the next gene therapy to be subjected to a registry.

Impact of Zynteglo's European withdrawal on future P&R outcomes

Most payers surveyed expect the Zynteglo challenges to have a moderate to high negative impact on the future P&R assessment of other gene therapies.

Only three respondents, including two from France, do not expect it to have an impact. One French payer underscored that Zynteglo was granted an ASMR rating III for patients aged over 12 to less than 35 years by HAS. This meant it was in a good position to obtain a high price from CEPS until negotiations stopped due to the marketing authorisation withdrawal.

The German payer considered Zynteglo's list price of €1,575,000 as one of the main reasons for its demise. During the AMNOG's Arbitration Board process, this price could not be justified, considering its very low cost-comparator, i.e., annual blood transfusions. The Board was convened after Bluebird Bio could not agree a final reimbursement price with the National Association of Statutory Health Insurance Funds, GKV-SV. According to the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), this was not the fault of the G-BA, but the tough line taken by the GKV-SV in not recognising performance-based guarantees.

"There are gene therapies that are needed (like Zolgensma and Lumevoq [still under EMA review]) because there is a need for a therapy or a later line therapy after failure of prior lines. And there are those that are not needed, like Zynteglo, where nobody can understand, why a little less transfusion per year should be worth 1.5 million euros. This was the same with [the no longer commercialised] Glybera."

Payer, Germany

Annuity payment models are on the cards in certain jurisdictions

There has been considerable discussion about innovative payment models to better reflect the value of gene therapies, but the volume of discussion has not been matched by implementation; finding a way to truly capture their value and overcome the uncertainties remains challenging. With the influx of more gene therapies, the payers we surveyed were more open to the following models versus others outlined in Table 3: outcome-based payment (not annuity), annuity payment (outcome-based), and price volume agreements.

In Germany, outcome-based models have been used by individual sickness funds for the gene therapies commercialised so far. At the GKV-SV level, it has been more common to use one-time payment with evidence development via the mandatory registry data collection.

In both Germany and France, annuity payment models, which would allow the high upfront cost of gene therapies to be split over multiple years, could be on the cards. As of March 2022, there was debate in Germany around amending the GKV-FKG act's 2021 risk pool mechanism for high-cost therapies, which eliminates incentives for entering instalment-based payment contracts. In France, the CEPS-innovative drug industry association LEEM framework agreement of March 2021 included contractual amendments that may now split payment over several years, but they are yet to be implemented into legislation.

"Budget cap and price volume agreements already exist in France. The key evolution will be an annuity payment to take into account the long-term efficacy of gene therapies."

Payer, France

Table 3: Payers surveyed openness towards different payment model types for gene therapies

More open

Less open

Payment model	Definition
Outcome-based payment (not annuity)	A manufacturer fully or partially refunds therapy cost to the payer if an agreed outcome is not achieved
Annuity payment (outcome-based)	Payer payments for a therapy are split over a timeframe and linked to therapy performance
Price volume agreement	Price is commonly discounted stepwise at specified (confidential) volume thresholds
Budget cap	Involves a spending cap that if surpassed within a specified timeframe, could lead to a refund of excess via payback or an initial price revision
One-time payment with evidence development	Single payment followed by health technology reassessments informing future reimbursement decisions and price adjustments based on specific evidence submission at predefined times
Simple discount	Reduction to the list price

Importance of exploiting the cross-border pathway despite challenges

Apart from country market access challenges, in the ultra-orphan space in particular, manufacturers must also navigate the European Union's cross-border reimbursement pathway, whereby EU citizens have the right to access healthcare in any EU country and to be reimbursed for care by their home country.

This pathway is emerging as a key market access route for products for severe genetic and ultra-rare diseases that require specialist centres of excellence, due to complexity in patient management and needed clinical expertise. Despite Brexit, in February 2022, Orchard Therapeutics announced that patients will be able to take advantage of cross-border pathways to get access to its gene therapy Libmeldy from a UK site (one of five centres across Europe).

Despite manufacturers like Orchard using this framework, the industry does not believe it is fit for purpose. Key barriers are the complexity and the opaque discretionary approval process, particularly for products without favourable P&R outcomes in patients' home countries.

There also seems to be a need for better planning: in our research only two out of seven payers (a German and a French respondent) said their countries were very prepared to manage the pathway.

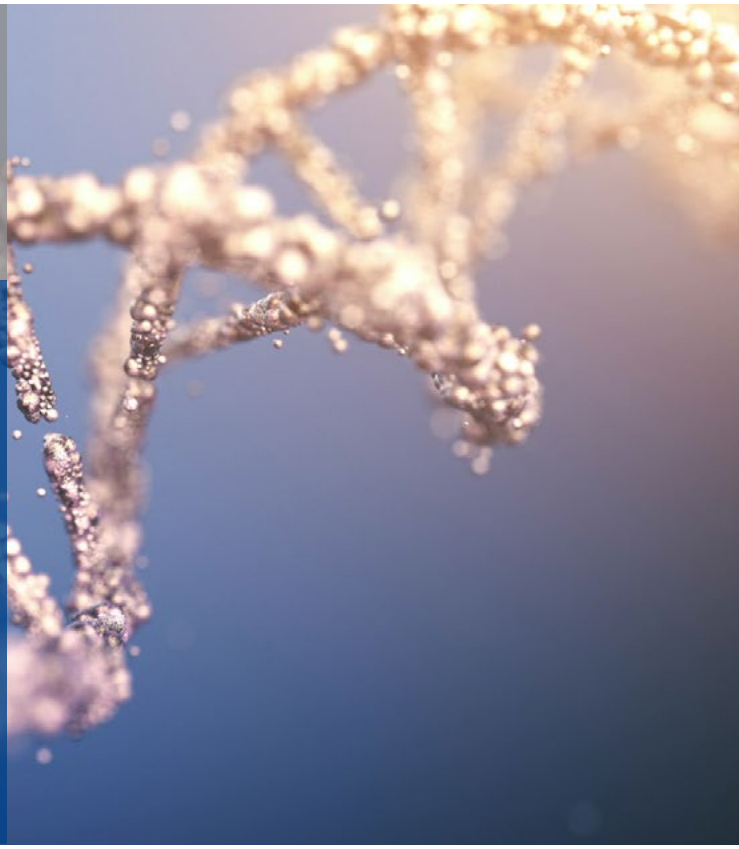
Interestingly, the payers surveyed do not expect the EU's new joint clinical assessment, which will be starting for advanced therapies in 2025, to help the cross-border pathway to realise its full potential. A French respondent emphasised that this is because P&R decisions will continue to be done nationally.

"I don't anticipate impact [of the EU's new joint clinical assessment] because it is not the conclusion and not the decision. I acknowledge that it is the basis of the decision, but each country [will] still independently decide what they want to decide."

Payer, France

Outlook and implications

In terms of the cross-country considerations, there is need for the pharmaceutical industry to continue lobbying for greater transparency and understanding to ease navigation of gene therapies for orphan diseases as an alternative market access route. Although it will be critical to prepare for the joint EU HTA for advanced therapies due in 2025, national P&R decisions will continue to dictate the commercial fate of gene therapies.



The Strimvelis case also underscores the need for a policy environment supportive of the advances made in gene therapy for rare diseases. This requires a recognition of the challenges of economics of this space, which has implications for pricing. It is important that the promise of gene therapy can be met in orphan indications although the ultimate value may reside more with indications for prevalent diseases.

In pursuing these indications, gene therapy commercialisation represents a perfect storm as the issue of economic sustainability becomes acute. Besides the potential high budget impact, the unmet needs for diseases like beta-thalassemia and haemophilia are not deemed as high versus, for example, spinal muscular atrophy where Zolgensma commanded a high price. Moreover, in these conditions the comparators are typically much lower priced.

This means that HTA bodies and payers will continue to demand more data to justify reimbursing such gene therapies. Therefore, it will be important for manufacturers to seek early feedback from these stakeholders on data requirements and expectations, as underscored by a UK respondent surveyed. This feedback should be on a range of aspects including their clinical trial design, economic modelling plans, additional data collection requirements, and suitable payment models.

"I would advise that manufacturers of gene therapies should engage in early discussions on data requirements and expectations."

Payer, Germany

To improve HTA/P&R outcomes at launch, it will be key to strengthen evidence generation plans to show potential lifetime durability of efficacy and capture additional elements of value. Commitments to longer-term ongoing submissions of post-marketing data, follow-up pivotal clinical trial data, and RWE collection can support in this regard. A direct measure of health-related quality of life in the clinical trial could also help demonstrate a quality-of-life improvement.

Continued HTA body and payer education is needed to change mindset, particularly when it comes to therapies for prevalent diseases. This would help increase willingness to pay and support with pushing for greater HTA/P&R process adaptations, whilst reducing concerns about budget impact, health system sustainability, and administrative burden.

Innovative payment models, such as outcome-based and annuity models, are potential solutions to ensure the collection of pertinent data to reduce payers' long-term uncertainty regarding these therapies' effectiveness, whilst providing a reasonable return on investment. However, the development and implementation of such models are complex. Payers could also manage affordability/budget impact concerns by spreading their costs across several years linked to outcome demonstration, but this requires greater flexibility and legislative change. All eyes are now on how Roctavian will succeed in navigating the EU P&R landscape, having just received conditional approval from the EMA.

About the author

Tania Rodrigues is a senior consultant in Research Partnership's market access division. Tania manages qualitative global market access projects in varied therapeutic areas, with a particular interest in cell and gene therapies (CGTs). Recent projects have ranged from understanding payer perceptions of the clinical value, HTA, and pricing potential of CGT product profiles, to providing guidance on key policy considerations to inform pricing, and payment model decisions in the CGT space.

About Research Partnership

Research Partnership is now a member of Inizio Advisory, the consulting business unit of Inizio, a strategic partner for health and life sciences with a full suite of medical, marketing, advisory, and engage services. As the market insights specialist of this curated group of companies, we collaborate with clients from the global pharmaceutical, medtech, and biotech industries, providing research intelligence and strategic recommendations that elevate healthcare brands and help them thrive in a complex and challenging environment.

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Company Profile: Viseven

There is no doubt that pharma has developed quite a bit regarding its digital maturity. That said, there is still much room left for growth.

Viseven has been involved in pharma marketing since 2009, providing interactive content development and cloud-based solutions for global pharmaceutical brands in over 50 countries worldwide. The marketing provider for health tech helps life sciences companies implement and execute omnichannel digital operating models and enterprise content strategy, including but not limited to modular content for more efficient engagement with healthcare professionals.

"The pharmaceutical industry and pharma marketing, in particular, are going through groundbreaking transformations. Businesses of all sizes, from small companies to big brands, have faced the need to adapt to the new rules of the game if they want to evolve and prosper," says Viseven CEO Nataliya Andriychuk.

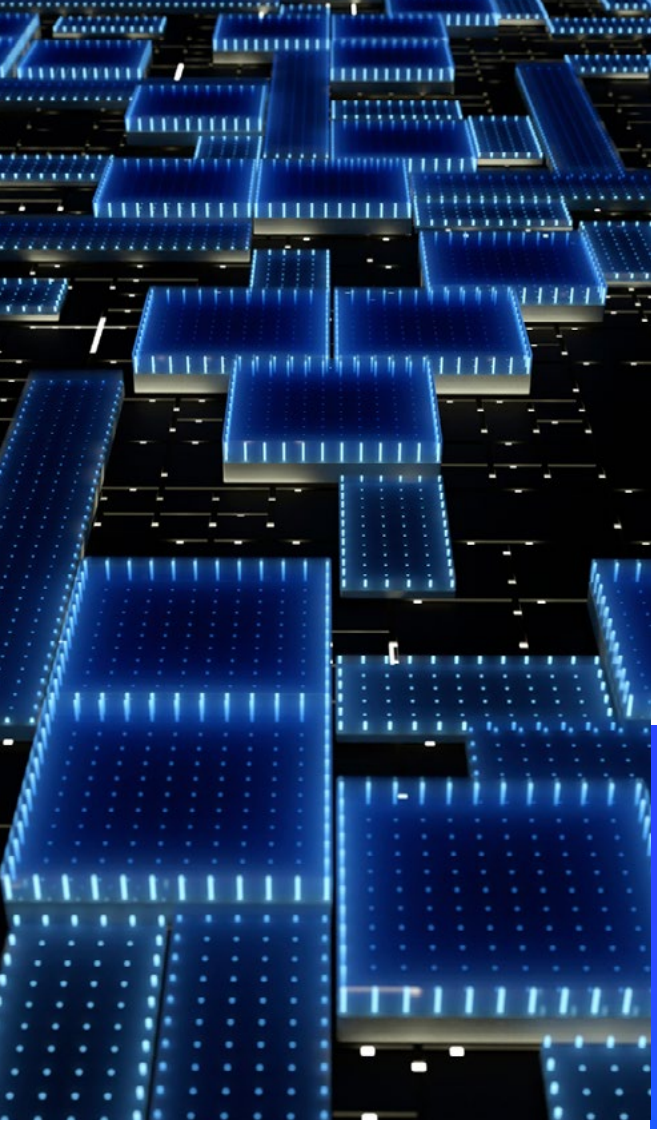
"The techniques that many pharma companies are considering for the future of marketing were revised by the Viseven team a long time ago. Now, we are looking for more ways to innovate pharma marketing and enhance our expertise with clients and partners, and I'm really excited about that."

Streamlining growth and communication efficiency with omnichannel marketing

The omnichannel approach is a hot topic among the many services and solutions that Viseven offers. Andriychuk underlines that creating a cohesive and data-driven omnichannel strategy in the age of digital personalisation is the only way for a pharma brand to engage its target audience. Listening to the client's needs and providing them with all the options that will continuously improve their communication is crucial for pharma today.

Life sciences companies have access to multiple online and non-digital channels to interact with their customers and nurture relationships with their partners. However, Nataliya Andriychuk points out that many companies still focus on a multichannel marketing approach, rather than omnichannel. Many tend to confuse the two, thinking they are the same. Omnichannel is about being cohesive, whereas multichannel offers the ability for every channel to act separately.

So, why is the omnichannel approach the better way? According to Andriychuk, another crucial advantage of switching from multichannel to omnichannel is the ability to cover the entire target audience of the pharma company at once by segmenting it into multiple groups. Developing segmentation strategies allows us to discover customers' preferences and needs, which – in its turn – leads to planning the best customer journeys.



Thinking of omnichannel approach? Do not forget about modular content

Enhancing omnichannel marketing with a modular content approach is the backbone of omnichannel communication between healthcare professionals and their audiences. Targeting multiple audiences across numerous channels requires professionals to create a lot of content, as well as a unique personal content experience for every target audience.

To meet these challenges, Viseven developed eWizard, an omnichannel content management and acceleration platform powered by the modular approach, which allows marketers to break down content into the smallest possible semantic pieces called modules.

The benefits of the modular approach for omnichannel content marketing are colossal. When creating a content campaign for a particular audience, a specialist can reuse, interchange, and customise modules in any possible combination and for the channels they need. Modular content is a real game-changer because it eliminates content duplication and frees up significant resources to spend on other marketing activities.

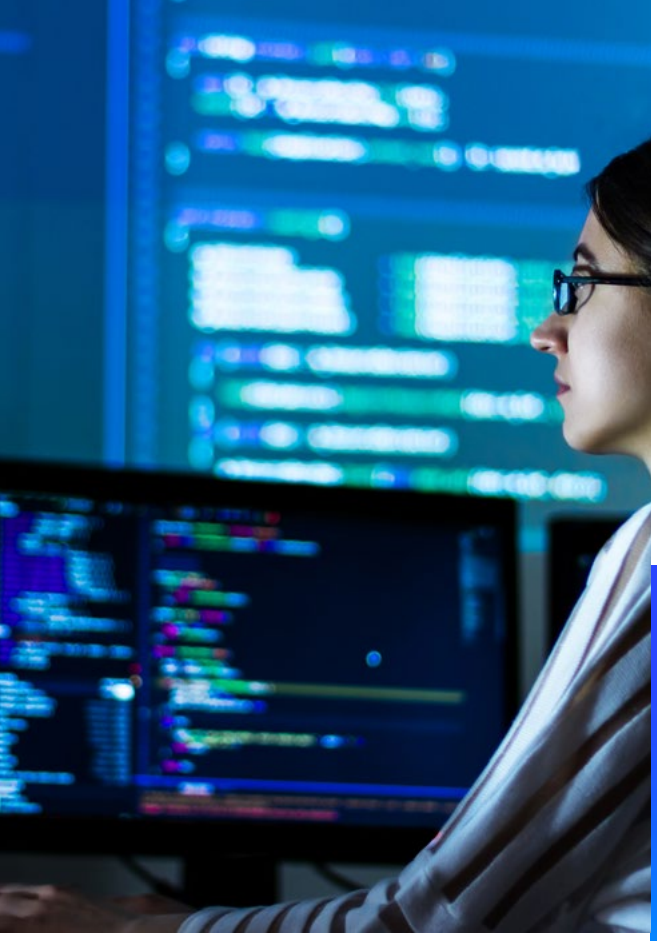
Building end-to-end engagement models with full digital content factory

Our team's experience with clients and partners over the years suggested that pharma had no content development standard and apposite content management system. The next idea after developing eWizard was to evolve a solution based on a single development standard to simplify and reduce the high costs of content production, release, and localisation.

"The world connected by digital capacities leaves no space for uncertainty. This global connection is crucial to building a secure business foundation for future growth. So, having a team around the world where every person has a remarkable vision and understanding of local specifics can boost chances of finding our customers no matter where they are on the map," says Andriychuk.

"India has become a serious player in the global digital market in the past few years. We are truly looking forward to connecting our approaches, introducing new members to our team, and ultimately saving lives by improving communication."

A digital content factory covers the entire content lifecycle with KPIs set for every channel, providing end-to-end delivery and support of services and all the digital initiatives at every customer experience stage, with more facilities for workload distribution. The factory is the collaboration of our specialists, in-house teams, and global and local agencies for handling the development and delivery.



Agility and resilience are key to success

It is no secret that the pandemic of 2019 hugely impacted all businesses, including pharma and life sciences. We had to adapt and roll with the punches, looking for new ways and approaches to communication. So, we did.

At Viseven, we implemented new ways to manage teams, staff, and offices. The remote follow-the-sun model has proven to be a success. Our teams are available to assist clients no matter where they are in the world.

Andriychuk stresses that having a game plan ahead of time, being prepared, and ensuring all processes continue to run is the key to managing a business in critical times. It is all about having an agile point of view. Adapting and showing strength are crucial to leading a successful business in pharma, regardless of the approach one chooses.

About the interviewee

As a digital marketing professional with over ten years of expertise, Nataliya Andriychuk has contributed to developing advanced digital solutions and software for clients in more than 70 global markets.

Andriychuk is also of Ukrainian background and witnessed the start of the war. However, being a global company leader, she had the hard task of balancing communication with clients and her staff, some of whom needed help relocating to safer areas. She was there at the beginning of digitalisation in life sciences and pharma marketing.

As part of her job as the CEO at Viseven, a global MarTech provider, she is bringing marketing interactions in pharma to the next level by introducing new methods to more companies.

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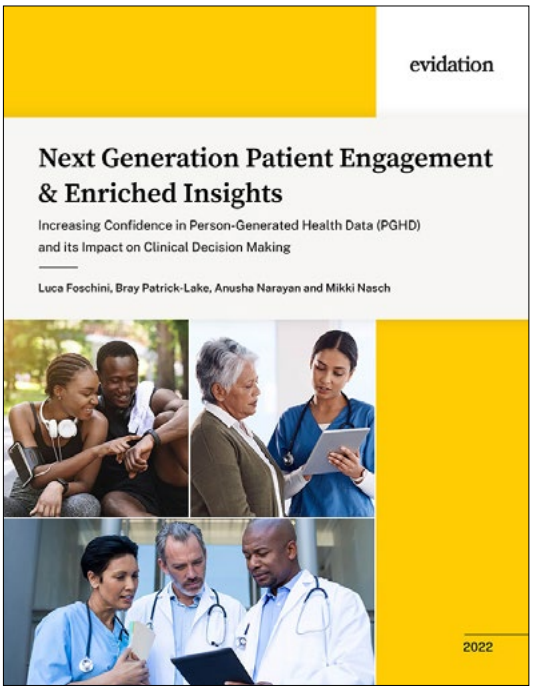

Over the last decade, PGHD and its value have become more widely recognized across clinical research and development, public health, and care delivery.

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Every scientific message has a story. Medical communications must adapt to effectively bring these to life.

Medical communications are in a state of transition. Due to the combined impact of emerging technologies, changing provider preferences, and an evolving post-pandemic world, pharma must navigate new ways to engage providers with relevant, science-driven, digital content. Delivering these materials in the proper format, however, requires a keen understanding of providers' educational needs, learning science, and creative storytelling. Francis Namouk, managing director of Healthware MedComms, a new medical communications and education division of the Healthware Group, tells us more.

No doctor wakes up in the morning asking what your brand can do for them.

That statement, coined by one of my colleagues at Healthware MedComms, summarises the changing state of communications between pharmaceutical organisations and their healthcare provider (HCP) stakeholders. Triggered both by the industry-wide digital transformation and by the impacts of the COVID-19 pandemic, HCPs' expectations for the ways they receive information from pharma partners have shifted. Where communications have historically centred on brand, providers now desire more tailored, science-driven messaging.

Navigating this shift means reframing the way pharma teams approach provider-focused content. Medical communications must be able to offer useful information to HCPs when questions arise, whether that's in the clinic with a patient or in a surgical theatre. Operationally, such a change also puts medical affairs teams and medical science liaisons – some of the leading scientific voices within pharma organisations – on the frontlines of provider communications, a responsibility traditionally held by brand and sales representatives.

When pharmaceutical leaders can proactively answer their customers' questions and become the point of reference for their future needs, they build trust that can eventually lead providers to prescribe their product. Doing so requires an understanding of the educational, scientific, and creative underpinnings of effective medical communications – and the production chops to execute them. Such expertise may not sit within the medical affairs function, but an experienced agency partner can guide pharma in the right direction.

Below, I dive deeper into the changing landscape of medical communications, and how to build successful materials that help you win with HCPs.

"Loyalty can be established when a provider is searching for the next best step in a patient's care journey, and their pharma partner has the data they need – where and when they need it most – to inform a clinical decision."

How COVID-19 shifted medical communications

Historically – and still, in many instances, today – insufficient thought has been invested in understanding providers' experience receiving high volumes of medical data. You could present for an hour to a very narrow audience – perhaps a room full of metastatic breast cancer experts – but any one of them may only be interested in ten minutes of the session. How can we help providers navigate the vast amount of available information to find what's most relevant to them?

When COVID-19 hit in 2020, pharma was forced to change their modes of engaging with HCPs. Without the possibility of in-person meetings, how could they continue to inform, educate, and build trust with providers?

As all content shifted to online formats, healthcare professionals showed us their preferences for receiving information. For example, they're interested in scientific exchange over brand, meaning they'd prefer to interact first with medical science liaisons, than with sales reps. Even under the umbrella of scientific exchange, they've shown they prefer the option of on-demand content and digital platforms. Where scientific symposia may last hours and cover a range of topics, many HCPs prefer or require bite-sized, highly tailored content which they can consume at their convenience.

This puts medical communications today in a state of transition, both towards digital transformation and toward true customer centricity. But many make the mistake of rushing to achieve short-term digital goals – for example, publishing a website or a new tech platform – rather than building a long-term, omnichannel, strategic plan that can help pharma teams build brand loyalty with customers.

In a post-COVID world, sustainable hybrid models are the key to engaging effectively with providers. While some in-person meetings have resumed, HCPs now expect tailored, digital, scientific content. Without a medical communications strategy that considers and accommodates providers' needs, pharma risks missing opportunities for relationship building with their stakeholders.

"Communications agencies can act as the 'conductor' of an effective medical communications strategy, harmonising the efforts of pharma's innovative development teams, experienced scientific leaders, and novel therapeutics into messages and formats that providers remember."

How pharma must adapt to providers' changing expectations

Pharma has also been forced to change the ways they operationalise provider engagement. Medical affairs teams are now in the drivers' seat to deliver on customer centricity, a role typically held by commercial teams, leading to some uncertainty in how best to bring scientific content to providers. If they're approaching a provider who has been effectively treating patients with the same staple drugs for years, how can they bring a novel therapy to their attention? How should they gain their trust? How do they move providers from not considering using a new treatment to adopting a new standard of care?

Successful customer engagement first requires pharma to understand providers' educational needs and gaps in their current understanding. This begins with an educational landscape assessment: what literature is available in a specific geography? What gaps or guidelines exist in the region? What content are their customers engaging with today, and is it relevant?

From there, pharma can identify stakeholders – including regional influencers or opinion leaders – and conduct one-to-one interviews to reinforce understanding of professional education gaps for providers. These interviews inform a survey, distributed across academia in the region, to take a deeper dive into the needs of their customers.

This process allows pharma to map where their stakeholders' greatest educational needs are, and where the pharma organisation should allocate resources to create useful customer materials.

In medical communications, building trust with providers means being the point of reference for critical treatment-related questions. Loyalty can be established when a provider is searching for the next best step in a patient's care journey, and their pharma partner has the data they need – where and when they need it most – to inform a clinical decision. This cycle of understanding providers' needs, then designing content to help them improve outcomes for their patients, is the key to medical communications success.

Bringing scientific stories to life

Data on a novel molecule or interesting clinical trial findings is, of course, fascinating on its own. But if it is not presented to providers in a way that resonates with them, the information may be lost among the flood of other content in a provider's inbox.

Doctors are human; they can connect to emotion evoked by effective storytelling. Creativity, then, is the medical communicator's challenge. How can we craft a message that elevates key scientific points? Should we package it in an email or in a video for social media? As the first point of engagement with customers, it's important that pharma uses engaging narratives to convey an emotion for their stakeholders.

We must also appreciate the role learning science plays in effective communications. For professional adults, knowledge is gained when new insights are delivered at the right moment and in the correct format, as opposed to the curriculum-style format we may have received during school. Such understanding must be infused into all provider-facing communications.

This capability isn't native to pharma organisations, and rightfully so, as their service is to develop and market lifesaving treatments. Communications agencies can act as the "conductor" of an effective medical communications strategy, harmonising the efforts of pharma's innovative development teams, experienced scientific leaders, and novel therapeutics into messages and formats that providers remember.

Improving the medical communications experience for HCPs

In today's digital world, doctors are overwhelmed by the volume of available data. We have an opportunity to create a better learning experience for HCPs, where they receive the information they need at the appropriate moment, and in a format that they'll respond well to. We can help them cut through the noise and focus on the most important messages.

With the expertise needed to build engaging content – specifically, creative storytelling capabilities, medical knowledge, and a deep understanding of learning science – an experienced agency partner can support pharma in designing memorable materials.

Whether via animation clips, white papers, or even TikTok videos, science and creativity can complement one another to reach providers where they are, empowering them to offer more innovative care to their patients.

About the author

Francis Namouk is a serial entrepreneur whose passion is to improve patient outcomes by focusing on creative storytelling and immersive learning experiences. He has over 15 years of medical and digital comms expertise within the life science and consumer health sector.

Francis is now Managing Director at Healthware MedComms, the medical communications and education division of the Healthware Group. He also remains Managing Director at SWM, a creative motion lab and consultancy which Francis co-founded in 2020, before it was acquired by Healthware Group the following year. SWM is focused on virtual and hybrid experiences, scientific content development, and medical education. He continues to oversee the strategic and tactical implementation of all Healthware virtual and hybrid customer engagement solutions for the Group.

About Healthware MedComms

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Healthware MedComms meets the always-on, audience centric, evidence driven demands of today's clinical environment. We support our clients with modern medical communication and education offerings that meet the needs of the contemporary clinician. We do this by partnering with our clients to reimagine scientific exchange by creatively translating new and complex science into digestible, engaging, learning experiences which healthcare professionals can adopt to improve patient outcomes.

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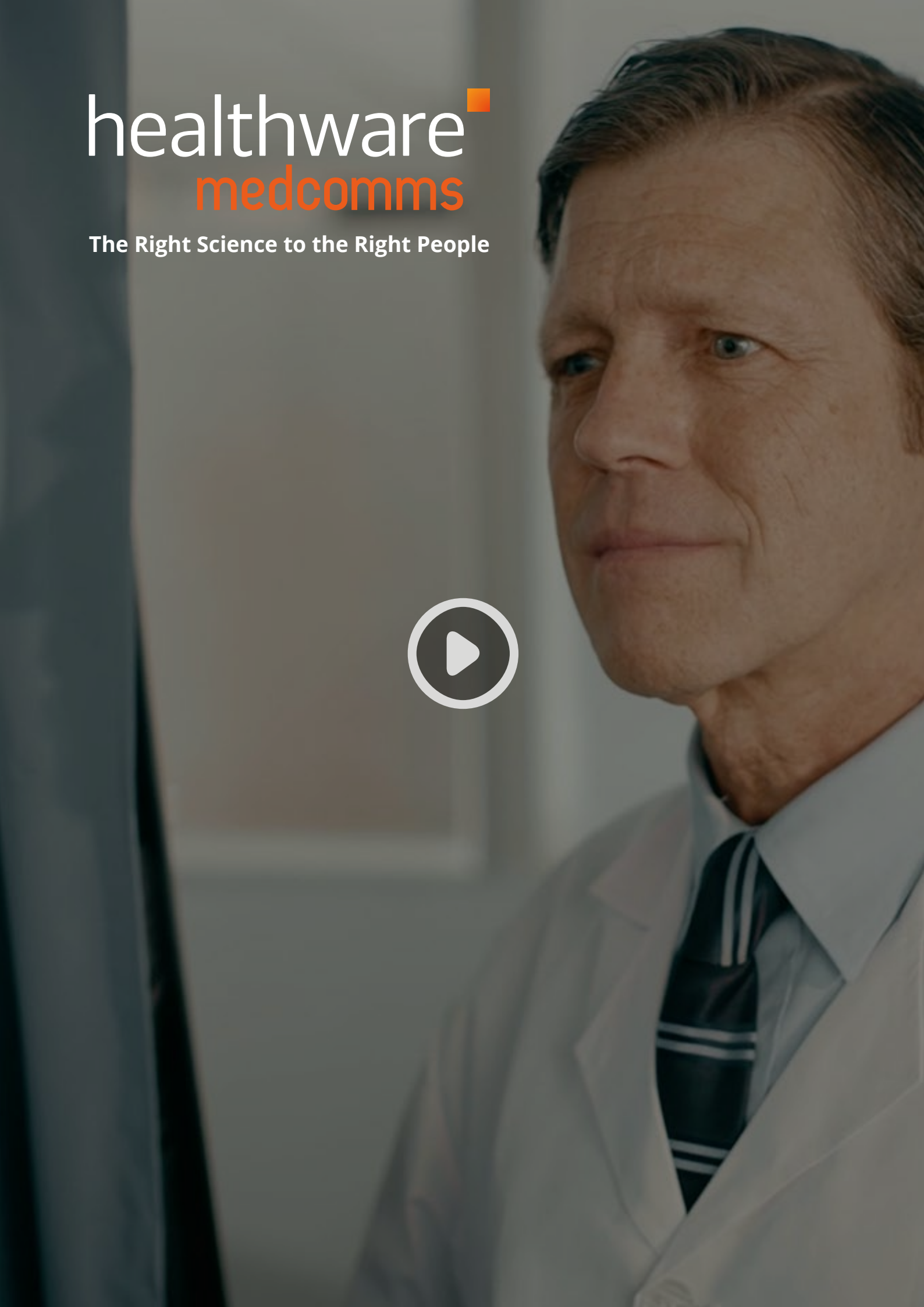
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