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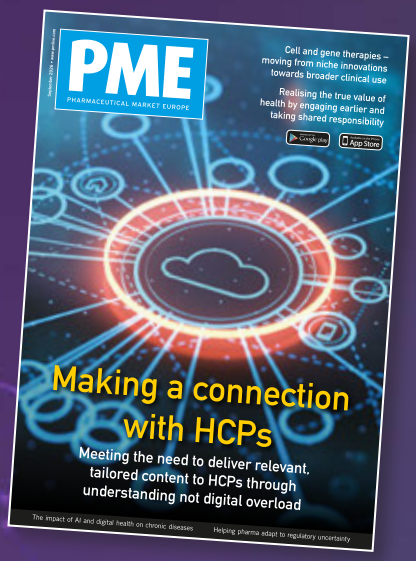

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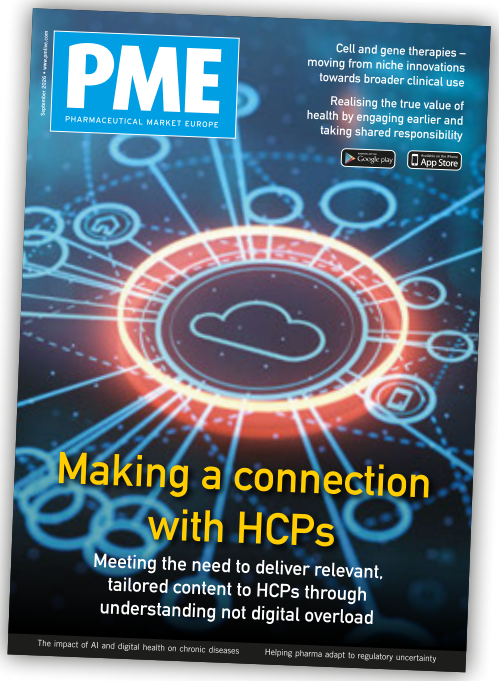

The key to strengthening engagement with HCPs

In our cover story this month, Danny Buckland looks at why strengthening engagement with HCPs needs to be done with deep understanding rather than digital overload.

As Danny says: 'Pity the HCP who now faces a clamouring queue of suitors made louder by digital strategies that should make engagement easier, but often hit like a hard-sell hailstorm. It is little wonder that most are restricting pharma team access or retreating from meetings, either face-to-face or digitally.' Read more on page 28.

In the article from J&J's Amy Grey and Nina Pinwill, the authors explain "why industry needs to engage earlier, explain value more clearly, understand service pressures and take shared responsibility for implementation".

They say: "The UK has the science, policy ambition and institutions to become a global life sciences leader [but to them] this moment feels different. Together, they explain why health is an investment, how innovation can support NHS reform and what practical action is needed to deliver its full value today." Find out more on page 16.

In the article on page 20, Professor Jacob George, Chief Medical and Scientific Officer at the MHRA looks at the "regulatory challenges of cell and gene therapies that are often developed for very small numbers of patients, and why rules that work for everyday medicines don't always work for rare or severe diseases".

The article from Ramji Vasudevan focused on why pharma needs humans at the helm of AI. As Ramji says: 'In a sector where a governance failure can cost lives as well as regulatory approval, 'a human in the loop' can no longer be viewed as a safety net. In many pharmaceutical businesses, it creates the appearance of oversight without the reality of accountability.'

Our November issue will look at rare disease clinical trials – achieving true inclusion across age, gender and disease. If you would like to make your voice heard on this topic, please get in touch at sales@pmlive.com

I hope you enjoy this issue!

Iona Everson
Group Managing Editor

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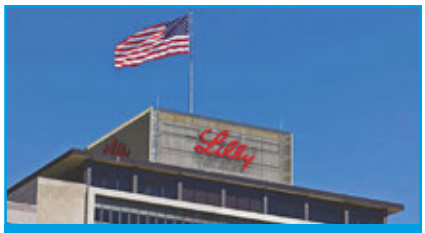

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NEWS

Lilly to acquire Merida Biosciences for $2.875bn

Eli Lilly is set to acquire Merida Biosciences, paying up to $2.875bn for the biotechnology company, which is advancing a new class of precision therapeutics for serious autoimmune and allergic diseases.

Merida's lead programme, MER511, is in phase 1 development for Graves' disease and thyroid eye disease (TED). Graves' disease affects approximately three million people in the US, and patients face elevated cardiovascular risk and mortality. Roughly 25-40% of people with Graves' disease go on to develop TED, which can cause pain, disfigurement and, in severe cases, vision loss.

While there are approved treatments for both conditions, none directly targets the autoantibodies that cause them. Because pathogenic autoantibodies drive a wide range of serious diseases, Merida's platform has potential application well beyond its lead programme.

The company's pipeline also includes MER769, a preclinical programme focused on food allergy, asthma, chronic spontaneous urticaria and other diseases driven by the antibody responsible for triggering allergic reactions, along with earlier-stage programmes in kidney diseases such as membranous nephropathy and other immune-mediated conditions. The transaction is expected to close in the fourth quarter of 2026.

FDA approves Revolution's Rasonque for pancreatic cancer

The US FDA has approved Revolution Medicines' Rasonque (daraxonrasib), a RAS inhibitor for the most common form of pancreatic cancer – delivering a new treatment option to patients with advanced pancreatic cancer.

Rasonque, a tablet taken once daily, targets multiple forms of a protein called RAS, a key driver of tumour growth in most patients with pancreatic adenocarcinoma, which arises from cells lining the ducts of the pancreas.

The approval is for the treatment of adults with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or are not candidates for multi-agent systemic therapy.

In a trial involving 500 adults with previously treated metastatic pancreatic adenocarcinoma, Rasonque improved median overall survival to 13.2 months compared to 6.7 months for standard chemotherapy.

Approximately 90-95% of the 67,000 new cases of pancreatic cancer diagnosed in the US each year are pancreatic adenocarcinoma, according to the National Cancer Institute. Despite representing roughly 3.2% of all cancer diagnoses, pancreatic adenocarcinoma accounts for a disproportionately high share of cancer deaths, owing to its typically late detection, aggressive disease course and historically limited treatment options.

J&J to pay $5.5bn to end remaining talc litigation

Johnson & Johnson has reached an agreement to end the remaining talc litigation with the plaintiff firms leading the US federal Multi-District Litigation (MDL) and related state court proceedings. The MDL Court's recent specific causation ruling confirmed the company's longstanding position that these claims lack scientific merit.

The resolution is conditioned on the express participation of at least 95% of the remaining claims, among other things. The proposed resolution follows a favourable ruling by the MDL court, and acknowledgment by plaintiffs' counsel, regarding plaintiffs' inability to prove that Johnson & Johnson's talc products caused any particular claimant's ovarian cancer ('specific causation').

The proposed resolution, with per claim payments, constitutes an efficient conclusion to the talc litigation, with Johnson & Johnson committing to pay $5.5bn. The first payment of no more than $3bn is to be made in 2027 and no additional payments are due before 2028.

Johnson & Johnson has previously settled about 95% of filed mesothelioma lawsuits, all US State consumer protection claims and all talc-supplier disputes. In 2023 the company discontinued talc-based Johnson's Baby Powder globally and separated its consumer health business, Kenvue.

Novartis announces trial results for relapsing MS

Novartis has announced positive topline results from its phase 3 REMODEL-1/-2 trials of remibrutinib in relapsing multiple sclerosis (RMS). Remibrutinib, a highly selective and potent oral Bruton's tyrosine kinase (BTK) inhibitor, demonstrated superiority versus teriflunomide in reducing annualised relapse rate (ARR) and inflammatory brain lesions with a favourable safety profile.

MS is a chronic inflammatory disease of the central nervous system characterised by myelin destruction and axonal damage in the brain, optic nerves and spinal cord. Affecting nearly three million people worldwide, it can be characterised into three main types: non-active secondary progressive (SPMS), primary progressive (PPMS) and RMS.

RMS is the most common form and includes clinically isolated syndrome (CIS), relapsing-remitting (RRMS) and active SPMS. The various forms of MS are distinguished by how the disease presents and progresses, including whether patients experience relapses, worsening disability over time or a combination of both.

The results of the REMODEL trials establish remibrutinib as a BTK inhibitor that achieved significant reductions in annualised relapse rate across two phase 3 trials in adults with relapsing multiple sclerosis (RMS).

FDA grants Fast Track status for peanut allergy immunotherapy

Aravax has received Fast Track designation from the US FDA for PVX108, an investigational immunotherapy for the treatment of peanut allergy. The company is focused on revolutionising the treatment of food allergies with next-generation, disease-modifying immunotherapies and is also developing a broader pipeline of peptide-based immunotherapies targeting additional food allergies.

PVX108 is a peptide-based immunotherapy designed to retrain the immune system to tolerate peanut proteins while minimising the risk of treatment-induced acute allergic reactions. The therapy is currently being evaluated in an international phase 2 clinical trial involving sites in the US and Australia, with topline data expected later this year.

PVX108 is a next-generation immunotherapy that uses proprietary

peptides designed to precisely retrain the immune system to tolerate peanuts while avoiding treatment-induced acute allergic reactions. Phase 2 studies of PVX108 are ongoing at clinics in the US and Australia with key data anticipated to be reported later in 2026.

People with a peanut allergy face a lifelong risk of severe allergic reactions, including anaphylaxis, and treatment options remain limited. Current management largely relies on strict allergen avoidance and emergency treatment of accidental exposures.

AstraZeneca and Daiichi Sankyo's combination therapy approved for breast cancer

AstraZeneca and Daiichi Sankyo's Enhertu (trastuzumab deruxtecan) in combination with pertuzumab has been approved in the European Union (EU) for the first-line treatment of adult patients with unresectable or metastatic HER2-positive breast cancer.

The approval by the European Commission follows the positive opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency and is based on results from the DESTINY-Breast09 phase 3 trial.

In DESTINY-Breast09, Enhertu in combination with pertuzumab reduced the risk of disease progression or death by 44% versus ataxane, trastuzumab and pertuzumab (THP) in patients with HER2-positive metastatic breast cancer who had not received prior chemotherapy or HER2-targeted therapy or had received neoadjuvant or adjuvant HER2-targeted therapy more than six months before the diagnosis of advanced or metastatic disease.

Median progression-free survival (PFS) was 40.7 months with Enhertu in combination with pertuzumab compared to 26.9 months with THP.

Following this approval in the EU, Daiichi Sankyo is due to received a milestone payment of $100m from AstraZeneca for the first-line unresectable or metastatic HER2-positive breast cancer indication.

NEWS

Pfizer and Valneva's Lyme disease vaccine candidate application validated

Pfizer and Valneva's Marketing Authorisation Application (MAA) for their Lyme disease vaccine candidate has been validated by the European Medicines Agency (EMA). The application is based on the phase 3 VALOR clinical trial, based in areas of high incidence of Lyme disease across the US, Canada and Europe and included 9,437 trial participants aged five years and older.

Lyme disease is a systemic infection caused by bacteria that are transmitted to humans by the bite of infected Ixodes ticks. It is considered the most common vector-borne illness in the northern hemisphere.

Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called erythema migrans or other non-specific symptoms like fatigue, fever, headache, mild stiff neck, muscle and joint pains) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious chronic complications affecting the skin, joints (arthritis), the heart (carditis) or the nervous system.

The Centers for Disease Control and Prevention (CDC) estimates around 476,000 people in the US are diagnosed and treated each year, with 132,000 cases reported annually in Europe.

LEO Pharma acquires rights for dersimelagon from Tanabe Pharma

LEO Pharma has agreed to acquire worldwide rights to dersimelagon from Tanabe Pharma. Dersimelagon is an oral, once-daily small MC1R agonist being developed for EPP and XLP.

EPP and XLP are rare and severe genetic diseases that cause severe sunlight-induced skin damage and can significantly limit patients' ability to spend time outdoors. Symptoms may include skin rash, swelling, redness, burning sensations and, in some cases, liver damage. Dersimelagon is designed to increase skin melanin, helping reduce sunlight penetration and protect against phototoxic reactions.

If approved, dersimelagon would represent the first oral therapy for the treatment of EPP and XLP and help address an area of significant unmet need.

Under the terms of the agreement, LEO Pharma will acquire worldwide rights to dersimelagon from Tanabe Pharma for up to $435m in upfront and near-term milestone payments together with potential down- stream milestones and tiered royalties on net sales.

Dersimelagon has been granted both US FDA Fast Track Designation and Orphan Drug Designation, and an NDA for the treatment of EPP and XLP was submitted to the US FDA for regulatory review in June 2026.

Roche's Enspryng gets Priority Review for autoimmune disease

Roche's Enspryng (satralizumab), a treatment for a rare autoimmune disease, has been given FDA Priority Review to a supplemental Biologics License Application (sBLA). The FDA is expected to make a decision on approval in MOGAD by 10 January 2027.

Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) is a rare autoimmune disease where the immune system mistakenly attacks parts of the central nervous system. It can cause sudden attacks on the optic nerves, brain and spinal cord, which can lead to vision loss, confusion, muscle weakness and disability.

MOGAD is estimated to impact 0.51 to 3.42 per 100,000 people, affecting all ages, with the symptoms that are often severe and debilitating. Relapsing MOGAD is characterised by multiple, unpredictable attacks of worsening neurological symptoms. Symptoms may not fully resolve after an attack, leading to accumulating, permanent, neurological damage, vision loss and disability.

The European Medicines Agency (EMA) has validated the application for Enspryng for MOGAD in Europe. The decision by the European Commission is expected in the third quarter of 2027. Currently, there are no approved treatment options available for MOGAD.

Sandoz announces agreement with Shanghai Henlius Biotech

Sandoz has announced a major development, manufacturing and commercialisation collaboration agreement with Shanghai Henlius Biotech. The two companies will collaborate on up to ten biosimilars, with an initial bundle of assets already agreed worth a total of up to $322m, with near-term payments associated with the initial assets that could reach up to $100.5m.

One of the initial assets under the agreement will be a proposed cetuximab biosimilar, which is in clinical development. The reference medicine, Erbitux (cetuximab), is an epidermal growth factor receptor-targeted oncology therapy used to treat selected patients with metastatic colorectal cancer and squamous cell carcinoma of the head and neck.

In addition, the collaboration also covers a proposed evolocumab biosimilar used in patients with hypercholesterolaemia and for reducing the risk of major cardiovascular events in adults at increased cardiovascular risk, and a proposed belimumab biosimilar intended for the treatment of active systemic lupus erythematosus in adults and children and active lupus nephritis in eligible patients, in addition to standard therapy. Overall, the collaboration expands Sandoz's biosimilar pipeline to 39 assets, with the potential for that to increase to up to 46.

Gilead opens new five-storey research centre in California

Gilead Sciences has opened its 182,000-square-foot Research Center at its Foster City, California headquarters, expanding capabilities in oncology, inflammation and research data science to advance medicines for some of the world's most challenging diseases.

The company currently employs approximately 11,000 people across the US, including more than 7,400 in California and nearly 4,700 in the San Francisco Bay Area. The centre marks the latest milestone in the company's $32bn investment in US research, development and manufacturing up until 2030.

Gilead marked the milestone with a ribbon-cutting ceremony attended by company leaders, scientists and government and community guests.

Designed with input from Gilead research colleagues, the five-storey centre will support approximately 325 employees, including 260 laboratory scientists. Flexible laboratory

neighbourhoods, specialised collaboration spaces and shared technology platforms will enable teams to adapt as scientific needs evolve. All-electric systems, energy-efficient design and water-saving landscaping featuring California native plants are expected to support LEED Gold certification.

The centre is one of three major Foster City projects. The other two projects include the Technical Development Center, expected to open in 2027, and the biologics facility, expected to open in 2029.

Genentech marks US manufacturing facility milestone

Genentech, a member of the Roche Group, has completed the structural framework of its new manufacturing facility in Holly Springs, North Carolina in the US.

The facility, part of Genentech's approximately $2bn investment in its first-ever US East Coast manufacturing facility, is expected to support more than 2,000 jobs, including more than 500 high-wage manufacturing roles and more than 1,500 construction jobs.

Once operational, the facility will produce next-generation treatments for metabolic conditions, such as obesity. It will incorporate advanced biomanufacturing, automation, robotics and the latest digital manufacturing technologies designed to increase production efficiency, support sustainability and strengthen Genentech's US-based supply chain.

The investment in technology includes an advanced digital twin – an AI-powered, data-driven virtual model of the manufacturing facility designed to simulate operations and test scenarios before real-world implementation. The approach improves overall reliability and minimises waste, ultimately helping critical medicines reach people faster.

The facility is part of Roche and Genentech's broader $50bn commitment to R&D and manufacturing infrastructure in the US, which currently includes 13 manufacturing sites, 15 research and development sites and approximately 25,000 employees across 24 locations in eight states.

DERMATOLOGY NEWS

FDA approves Priovant's Lisraya for dermatomyositis

The US FDA has approved Priovant Therapeutics' Lisraya (brepocitinib) tablets, the first FDA-approved oral treatment option for patients with dermatomyositis.

Dermatomyositis is a rare autoimmune disease in which the immune system attacks the muscles and skin, causing chronic inflammation, progressive muscle weakness and distinctive skin rashes. By blocking JAK pathways, which play a key role in the body's immune and inflammatory responses, Lisraya helps reduce the harmful inflammation that damages the muscles and skin, offering an effective new option for disease control.

The efficacy and safety of Lisraya were evaluated in a phase 3 study that included 241 adults randomised to receive Lisraya 30mg once daily, brepocitinib 15mg once daily or placebo for a 52-week treatment period.

The study used a standardised scoring tool that tracks changes across six areas (muscle strength, physical function, skin and other disease activity, muscle enzymes, and both physician and patient assessments of overall health) to assess how much a patient's dermatomyositis has improved. Participants showed improvements in physical function and skin disease activity and were more likely to reduce corticosteroid use by week 48.

MSD and Moderna announce potential new vaccine for melanoma

MSD (known as Merck & Co in the US and Canada) and Moderna have announced positive topline results from the phase 3 INTerpath-001 trial evaluating intismeran autogene, in combination with Keytruda (pembrolizumab), to treat patients with completely resected stage IIB-IV melanoma.

Intismeran autogene is an mRNA-based individualised neoantigen therapy (INT) designed specifically for individual patients based on the unique set of mutations within their tumours to train and activate the immune system to recognise and fight cancer.

This is the first and only combination regimen to demonstrate statistically significant and clinically meaningful improvements in recurrence-free survival (RFS) and distant metastasis-free survival (DMFS) compared to Keytruda alone for patients with resected melanoma.

Melanoma, one of the deadliest forms of skin cancer, is characterised by the uncontrolled growth of pigment-producing cells. The rates of melanoma have been rising over the past few decades, with more than 330,000 new cases diagnosed worldwide in 2022. In the US, skin cancer is one of the most common types of cancer diagnosed and melanoma accounts for a large majority of skin cancer deaths.

AbbVie's Rinvoq approved by EC for non-segmental vitiligo

AbbVie's Rinvoq has been approved by the European Commission (EC) to treat patients 12 years and older with non-segmental vitiligo (NSV). It is now the first and only systemic medication approved in the EU for NSV, the most common form of vitiligo, accounting for 84% of all cases.

Vitiligo is an unpredictable chronic autoimmune disease that can progress at any time. It is characterised by irregular white patches on the skin, resulting from the selective destruction of melanocytes – the cells responsible for skin pigmentation. Vitiligo should not be dismissed as a cosmetic disease, as its effects can be psychologically devastating, often posing a considerable burden on patients' quality of life and resulting in high rates of depression and anxiety.

The EC approval of Rinvoq is supported by data from the phase 3 Viti-Up clinical programme (M19-044). Rinvoq is also approved in the EU to treat adults and adolescents with atopic dermatitis, and adults with radiographic axial spondylarthritis, non-radiographic axial spondylarthritis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease and giant cell arteritis, and adults and adolescents with severe alopecia areata.

NICE recommends axunio's Axhidrox for severe excessive sweating

NICE National Institute for Health and Care Excellence

NICE has recommended axunio UK's glycopyrronium bromide (GPB) cream for routine NHS use in England for adults with severe primary axillary hyperhidrosis (PAHH). GPB cream is designed to block the signalling pathway that activates the sweat glands, helping to reduce excessive sweating.

Around 75,000 people in England may be eligible for treatment. In the phase 3b study, median total sweat production was significantly reduced by 65.6% following 12 weeks of treatment with GPB 1% cream compared with baseline.

Severe PAHH is characterised by excessive sweating beyond what is required for normal temperature regulation and it can have a greater impact on a patient's quality of life than other skin conditions such as atopic eczema, acne, psoriasis or rosacea.

Hyperhidrosis is estimated to affect 1-5% of the population and can have a substantial impact on daily activities, social interactions, emotional well-being and quality of life. Despite this burden, the condition remains under-recognised and under-diagnosed.

This recommendation marks an important step forward in the treatment of severe PAHH as it represents the first time NICE has evaluated and recommended a treatment option specifically for hyperhidrosis.

BriaCell advances vaccine candidate for skin cancer

BriaCell

BriaCell Therapeutics' Bria-MEL+, its personalised whole cell melanoma (skin cancer) immunotherapy vaccine candidate, has achieved a key genetic engineering milestone, advancing the programme towards clinical development.

Bria-MEL+ is a cell-based therapeutic cancer vaccine designed to harness a patient's own immune system to combat melanoma. The programme is personalised yet 'off the shelf (OTS)': a simple patient saliva test will determine which of the several premanufactured treatment cell lines will be selected for personalised treatment, avoiding the need to manufacture a unique product for each individual patient.

Bria-MEL+ is designed to activate multiple components of the immune system, including innate and adaptive immune responses, to target and destroy melanoma cells. The programme is derived from BriaCell's Bria-OTS+ cellular immunotherapy platform and is being developed using pre-manufactured cell lines selected through patient HLA matching.

The American Cancer Society estimates that approximately 112,000 new cases of melanomas will be diagnosed in the US in 2026, including about 65,400 in men and 46,600 in women. Despite major advances in treatment, melanoma remains a significant unmet medical need, with over 8,500 deaths from melanoma expected in the US in 2026.

Pfizer announces phase 3 results for non-segmental vitiligo treatment

Pfizer has announced positive topline results from two phase 3 trials evaluating the efficacy and safety of Litfulo once daily in patients with both active and stable non-segmental vitiligo (NSV) and who had a broad range of disease severity.

The studies showed significant, clinically meaningful improvements for both face and body. Based on these results, Pfizer intends to submit global regulatory filings for Litfulo as a potential new oral systemic therapy for NSV for adults.

NSV is a chronic autoimmune disease in which the immune system attacks melanin-producing cells, leading to a loss of pigment and resulting in white macules and patches on the skin/hair over time. NSV can appear at any age and in all skin types, causing depigmentation anywhere on the skin, often affecting highly visible areas such as the face, neck and hands.

While vitiligo is frequently treated as a cosmetic condition, it is a serious autoimmune disease that can have a considerable impact on patients' lives well beyond the physical symptoms. Because NSV is a chronic disease, systemic treatment options may be needed to help patients restore skin pigmentation and maintain repigmentation over time.

BRIAN D SMITH
DARWIN'S MEDICINE
ARE YOU OVER-IMITATING?

Your useless SWOT analysis is an evolutionary hangover

I laughed out loud. A Commercial Excellence Director showed me the company's strengths, weaknesses, opportunities, threats (SWOT) analysis. As with every other company I've studied or advised, it was a neat, four-box figure. "How useful do you find it?" I asked. "We call it the Silly Waste of Time, but it's in the template," he said. And from the ripple around the room, the whole team clearly thought the SWOT analysis was of no practical use.

It's not just SWOT

So here we had a team of clever, busy people spending significant time on an activity they knew to be useless. And this team and this technique were not unusual. Many marketing teams talk about the 'charade' of the annual planning process. How much of our data analysis tells us something really useful? How many patient journey maps make a difference to what we do? Does the brand's value proposition just state the obvious? The reality of corporate life is that much of it is ritualistic, like a rain dance, doing things because that's the way we do things around here, but we've forgotten quite why we do it. This has huge direct and opportunity costs. Just think what you could achieve if you spent that time and effort usefully. If we could understand the reason busy, bright people do obviously useless things, we might stand a chance of improving the situation. As usual in this column, let's turn to evolutionary science for the answer.

The over-Imitation Game

Anthropologists have long known that humans don't just imitate what others do, we imitate how it's done, even the useless parts. If we admire a firm's excellent launch execution, we copy their useful cross-functional alignment meetings, but also their useless pre-meeting meetings and overly large invitee lists. The anthropological explanation for over-imitation is that the functionally useless actions transmit norms, signal group membership and maintain cultural cohesion. Over-imitation is a cultural universal, like marriage and music, seen in every society. If something is culturally universal, you can be sure that it is deeply

imbedded in human behaviour. And once you appreciate that, it helps you tweak what you do to make it more useful.

Adapt, don't abandon

Two things are true about corporate rituals. First, they began because they once had some practical value. Second, they still have social value, oiling the way the team works together. Together, this means that abandoning the ritual might have negative, unintended consequences. It also means that if you can understand its original purpose, you can adapt it to make it useful again. My client's useless SWOT is a good example. By retaining it, they signalled they were professional strategists, adhering to norms and being rigorous. That's useful. And, if you understand that its original aim of SWOT was to tailor strategies to the firm's situation, you can adapt your SWOT process to achieve that original goal. I've seen this done in my research and the way SWOT is adapted in the best firms is a good example of turning a useless ritual into a useful process.

A better SWOT

Strategy geeks like me trace SWOT way back to Stanford Research Institute in the 1960s and, later, Heinz Weihrich's TOWS matrix in 1982. They would shudder at the way it's been corrupted into a useless four-box list. The original designers of SWOT said it must do three things. First, SWOT doesn't stand alone, it follows all other analyses, using their outputs as its inputs. Second, those inputs must be validated as objectively valid and true; they can't be opinions. Third, strengths must be aligned to opportunities and weaknesses to threats, thereby revealing what the strategy must do to be successful. If you look at the SWOT in most pharma and medtech firms, you will see they don't do these three things. But these are the useful part of SWOT. The four-box matrix, filled with vague opinions, is just ritualistic and a Silly Waste of Time. If you would like to know more about this, I can send you my longer article, 'Competing on Alignment'. Just ask.

A very human foible

SWOT is only one example of how over-imitation causes us to do useless things. It's a human foible that evolved because, in our ancestral environment, imitating was helpful to our survival. But that evolutionary hangover can go too far. To work smarter, good teams allow for that human foible and adapt, not abandon, their over-imitation.

Professor Brian D Smith is a world-recognised authority on the evolution of the life sciences industry. He welcomes questions at brian.smith@pragmedic.com. This and earlier articles are available as video and podcast at www.pragmedic.com

MIKE DIXON

THE HEAT IS ON – AND SUSTAINABILITY IS A HOT TOPIC

How agencies can embed sustainability into the way they work, lead and create value

What a summer we have had in Europe this year! Living in the UK, it's been great having days out that were not ruined by rain, being able to sit outside eating and socialising until late in the evening without having to grab a warm top and, of course, just the general well-being and happier mood that always seems to be associated with better weather. It is on track to be the hottest year on record, the meteorologists tell us. What's not to like?

Well actually, now you come to mention it, quite a bit. Wildfires raging, destroying homes and taking lives. Farmers seeing crop yields devastated. Water sources drying up with hose pipe and other water-use bans enforced due to drought conditions. Wildlife dying. Public transport systems, which have not been designed for such climates, failing – sometimes with lethal consequences. Just to pick some of the more headline-grabbing reasons.

Unless you're a diehard climate denier, this year you really can't help but start to consider more about the implications of climate change and the general health of our planet.

But what can we, as individuals or organisations, do about it when it is such a huge global issue? As the anthropologist Margaret Mead is quoted as saying: 'Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has.'

Framing the opportunity to make a difference

It's quite timely, therefore, that a new framework has been launched by the Healthcare Communications Association, providing a very practical, structured, sector-specific sustainability and ESG (environmental, social and governance) guide for healthcare communications agencies. That includes considering everything from carbon emissions and supplier relationships to employee well-being, diversity, ethics and leadership accountability.

For many agencies, sustainability may feel like yet another item on an already overcrowded to-do list. But as client expectations grow, procurement processes become more rigorous and employees increasingly want to work for responsible businesses, sustainability is rapidly becoming a core business imperative.

Many agencies are SMEs with limited budgets and no dedicated sustainability teams. That places an important responsibility on everyone within an agency. Leadership teams need to provide direction, resources and accountability. Finance departments can play a key role in gathering emissions and procurement data. Those responsible for operations can identify opportunities to improve energy efficiency and reduce waste. Others can influence suppliers and purchasing decisions. Crucially, every employee has an important contribution to make through travel choices, responsible resource use and supporting a culture that values sustainability. And, of course, to initiate the hard discussions when client requirements don't necessarily align with their own sustainability goals.

Where to start

Each agency will be at different stages of their sustainability journey. The new framework, therefore, provides multiple entry points, aligned to the organisation's progress. A good place for anybody to start is by measuring what matters. Understanding where emissions come from allows organisations to focus their efforts on the areas that will deliver the greatest impact.

Measuring an organisation's carbon footprint is typically divided into three categories:

Scope 1 emissions are the direct emissions produced by an organisation's own operations and are directly controlled. For agencies, this could include fuel used in company-owned vehicles or from the gas used to heat offices.

Scope 2 emissions are indirect emissions associated with resources purchased and used. Office electricity use is often the largest Scope 2 source for service-based organisations.

Scope 3 emissions for agencies are typically the most significant and the most challenging to measure. These include emissions generated across an organisation's value chain. These can include business travel, employee commuting, IT equipment, courier services, events, supplier operations and even digital campaign delivery.

Embedding sustainability

However, measurement alone is not enough. Agencies must also embed sustainability into decision-making. That means assigning senior ownership, reviewing ESG performance regularly, integrating sustainability considerations into procurement and assessing climate-related risks alongside other business risks. Sustainability becomes far more effective when it is woven into everyday business processes rather than treated as a separate reporting exercise.

And as already mentioned, employee well-being, diversity and inclusion, labour rights, training and ethical business conduct are all critical components of a sustainable organisation. Clients, investors and employees increasingly expect agencies to demonstrate progress in these areas, not simply reduce their carbon footprint.

Ultimately, sustainability needs to be viewed as an opportunity, rather than a burden. Agencies involved in the extensive consultation to produce the framework, identified benefits ranging from stronger client relationships and improved competitiveness to greater employee engagement and long-term resilience. Those organisations that are acting now will be far better positioned to meet future expectations and help drive positive change. The agencies that thrive over the coming decade will be those that also successfully embed sustainability into the way they work, lead and create value.

Mike Dixon is CEO of the Healthcare Communications Association and a communications consultant

MARIE LITTLE AND ALYSSA BURSTEIN
WHY STRONG DATA DOESN'T ALWAYS TRANSLATE INTO PRESCRIBING

Teams must pinpoint where the therapy offers the clearest clinical and practical value

Brand teams want to believe strong clinical data alone will convince oncologists to prescribe. But whether preparing for launch or entering a new indication, teams face crowded markets where oncologists already have treatments they know and prescribe routinely.

In these settings, even better data may be insufficient to alter entrenched prescribing patterns. A therapy may secure approval, generate awareness and demonstrate value, while oncologists default to regimens embedded in care. Familiar treatments have an advantage: prescribers know when to use them and how to manage adverse events. A new entrant, however promising, remains uncertain territory without a compelling reason to choose it.

Prescribing decisions need heuristics

Oncologists work in environments shaped by evidence, protocols, experience and habit. They manage many patients and complex pathways, leaving little scope to reassess the landscape each time. That is why decision-making shortcuts are important, especially in mature markets where existing therapies are already trusted.

Emerging assets must earn their place. Teams may invest in evidence generation, medical education and pre-launch engagement, yet fail to change practice if oncologists are unsure where the asset belongs, who it is for or when to use it.

Commercial success hinges on a clear heuristic for identifying the first appropriate patient: when I see this type of patient, this treatment should be part of the conversation.

The power of a prescribing heuristic

Broader use begins with a rule of thumb supporting quick, informed prescribing. It should make the product's role easy to recognise and recall when the right patient presents.

The first appropriate patient is the practical expression of that heuristic. Teams must pinpoint where the therapy offers the clearest clinical and practical value and where early use feels most intuitive. The most effective commercial strategies should therefore reduce uncertainty around the first prescribing decision.

Strong heuristics are grounded in the patient's clinical context and reflect the full patient and physician experience: quality of life, treatment burden, access and affordability, adverse-event management and fit within clinical practice. Patients are not interchangeable data points. When efficacy differences are modest, improved patient support, easier access pathways, reduced monitoring requirements or a better treatment experience can significantly influence prescribing behaviour. Without these realities, better-known treatments may continue to dominate.

From initial use to wider uptake

A heuristic gives oncologists confidence they are selecting the therapy for the right patient in the right clinical context. This lowers the barrier to an initial prescription by making the decision feel more intuitive and grounded. When that first experience reinforces the heuristic through the expected clinical outcome and a positive patient-physician experience, it builds confidence to prescribe again. Repeated positive experiences can strengthen the heuristic and help the therapy move from a novel option to an established choice.

This progression matters for forecasting, investment and commercial planning. Assumptions that overlook ingrained prescribing habits can overestimate adoption speed. Teams may need to model a staged trajectory, with use developing gradually before extending to a broader patient cohort.

Building the heuristic into commercial planning

Developing a prescribing heuristic should begin early and remain central throughout commercial planning. It requires coordination across commercial, medical and market access teams, and should inform positioning, segmentation, evidence generation, forecasting, field enablement and post-launch learning. During brand planning and market research, teams should test what shapes prescribing in practice.

Brand leads should ask: "When an oncologist sees a specific patient, what makes our therapy the obvious treatment to consider?" A vague or difficult-to-communicate answer may hinder adoption; a distinctive answer grounded in clinical reality makes routine use more likely.

Winning adoption starts earlier

In competitive oncology landscapes, adoption starts with a heuristic that makes the product's role clear, memorable and actionable. Defining the cue that brings the treatment to the fore for the first appropriate patient is a pivotal commercial judgement, because it sets the direction for what follows.

Teams acting too late risk reaching launch with robust evidence and high awareness, but too little influence over the first prescribing decision. Evidence gives oncologists a reason to believe. A strong heuristic turns that belief into the confidence to choose. And in the battle for adoption, that confidence often matters more than the data.

Marie Little is Client Partner and **Alyssa Burstein** is Associate Partner, both at Prescient

ALICE CHOI AND KAYHAN BINAZIR
HEART, HUMANITY AND THE WORK BEHIND THE WORDS

What makes a great healthcare communicator in an age when technology can write, analyse and create content in seconds?

As artificial intelligence continues to transform our industry, it is a question many of us are asking. Yet while the tools at our disposal are evolving rapidly, the qualities that define the best campaigns, programmes and communications remain remarkably unchanged. Behind every award-winning piece of work are people. People with ideas, passion, determination and, quite often, the patience to navigate countless rounds of feedback.

Many of us arrived in this profession by unexpected routes. Some came from academia, others from journalism, public relations, marketing or healthcare itself. What unites us is a shared purpose: helping people understand complex information and turning that understanding into action.

With over 50 years in the industry between us (yes, yikes!), we have learned that success is about far more than creating content. It is not simply the data on a slide, the words in a publication or the metrics attached to a campaign. The real value often comes from the conversations, collaborations and trust that sit behind the work. Every brief, campaign and stakeholder discussion is ultimately about people. Behind every healthcare challenge are patients, families and communities looking for answers. That is why empathy, curiosity and collaboration remain some of the most valuable qualities in our profession.

The best teams are not necessarily the ones that agree on everything. In fact, some of the best ideas emerge from respectful disagreement. What sets great teams apart is trust, mutual respect and a willingness to support one another when the pressure is on. They are the colleagues who challenge your thinking, celebrate your successes and somehow still maintain their sense of humour through files labelled 'final_FINAL_v8_ACTUAL_FINAL_THIS_TIME'.

This year has also prompted reflection on a simple idea often expressed as 'learn, earn and return'. Many of us can see a little of ourselves in each stage. We continue learning, build rewarding careers and, hopefully, find ways to give something back to the profession that has given us so much. Yet perhaps there is a fourth element that deserves equal attention: celebration.

In a profession focused on solving problems and tackling the next challenge, it is easy to move straight from one deadline to another without pausing to recognise what has been achieved. We spend so much time championing the successes of clients, brands and organisations that we sometimes forget to celebrate our own. Celebration matters because it reminds us how much effort goes into great work. Not just the final outcome, but the teamwork, resilience and creativity that made it possible. It gives us a chance to stop, reflect and appreciate what has been accomplished together.

That is also why awards matter. They are not simply about recognising campaigns. They celebrate the people behind them. Every shortlisted and winning entry represents hours of thinking, problem-solving, collaboration and commitment. More importantly, they tell stories about what can be achieved when talented people come together with a shared goal.

As AI becomes increasingly capable of generating content and streamlining processes, those human qualities become even more important. Technology can help us work faster. It can help us create. But it cannot build trust, inspire confidence or understand what truly matters to another person. Perhaps that is the real advantage we have as communicators. Beyond the messages, the campaigns and the awards, our work is ultimately about understanding people.

It is about listening, learning and creating communications that genuinely connect with the audiences we serve.

As we look ahead, our message to the healthcare communications community is simple: celebrate your achievements, champion your teams and share your stories. Whether you have delivered a standout campaign, overcome a significant challenge or made a meaningful difference to patients and communities, your work deserves recognition.

Our industry will continue to evolve. New technologies will emerge and new challenges will follow. But heart, humanity and the people behind the work will always matter most.

As we step into our roles as Co-Chairs of the Comm*uniqué* Awards, we want to champion an era that celebrates not only outstanding work, but also the people who make it happen. An era that values creativity, collaboration and genuine passion. And one that might, finally, help us work out which version of 'final_FINAL_v8_ACTUAL_FINAL_THIS_TIME' was actually the final version after all.

Alice Choi is President of Envision Medical Communications at Envision Pharma Group and **Kayhan Binazir** is Deputy Chief Operating Officer for the European Society of Clinical Microbiology and Infectious Diseases (ESCMID)

From ambition to action: realising the true value of health

Why industry needs to engage earlier, explain value more clearly, understand service pressures and take shared responsibility for implementation

By Amy Grey and Nina Pinwill

The UK has the science, policy ambition and institutions to become a global life sciences leader. Here, the authors discuss why this moment feels different. Together, they explain why health is an investment, how innovation can support NHS reform and what practical action is needed to deliver its full value today.

After decades working across UK life sciences, they have both seen no shortage of strategies, reforms and declarations of intent. Amy has spent around 25 years in pharmaceutical commercial leadership, working across areas including immunology, dermatology, gastroenterology and pulmonary arterial hypertension. Nina's career has taken her from the civil service to NICE, NHS England and the Office for Life Sciences, helping to create some of the systems through which innovative medicines are evaluated and made available.

Both have heard the UK's ambition to become a global life sciences leader before. Yet both believe this moment feels different.

Amy Grey (AG): We have always had the ambition to be a leader. Throughout my career, we have talked about the strength of our science, our universities, our research base and the NHS.

What feels different now is the alignment. We have the NHS 10 Year Health Plan, the Life Sciences Sector Plan and the National Cancer Plan all pointing towards earlier diagnosis, more personalised care and greater use of innovation. The ingredients are already here.

The opportunity now is to turn that ambition into delivery. We rank near the bottom of comparable countries for preventable and treatable mortality. It shows how much potential there is to improve people's lives if we can make the system work differently.

Nina Pinwill (NP): I agree. Having worked across NICE, NHS England, government and industry, this is the first time I can remember so many policy levers moving in broadly the same direction.

Historically, reform has tended to happen in parts. Regulation improves one process, commissioning another, service delivery another. Each part may work hard and optimise its own area, but the patient experiences the whole pathway.

'The true value of innovation is clinical, social and economic value being realised together'

What feels different now is the possibility of thinking end to end. All parts of the system can work around one shared objective – the system holding hands around a common purpose of creating healthier lives.

AG: That shared purpose matters. In any organisation, transformation becomes easier when everybody understands the mission and their role in delivering it.

The moon-landing analogy may be over-used, but it applies here. The mission was clear, and every person and function could see how their contribution connected to the outcome. In healthcare, the job is not finished when a medicine is discovered, licensed or reimbursed. It is finished when it reaches patients and improves their lives.

That is also why health should be seen as one of the smartest long-term investments a country can make. Better health improves people's lives, but it also supports workforce participation, productivity, resilience and fiscal stability. The value of health reaches far beyond healthcare budgets.

NP: And that is why becoming one of the world's leading life sciences markets is realistic. The foundations exist: excellent science, academic expertise, clinical research capability and a National Health Service able to support innovation at scale.

AG: The question is whether we choose to make it happen. Success is within our control, but it requires conviction, persistence and implementation, not another set of disconnected strategies.

When it works, patients live fulfilled lives

AG: What motivates me is hearing from patients whose lives have been transformed by treatment. There are people alive today who might not have been alive without access to a particular medicine. That is an extraordinary privilege, and it is what gets me out of bed in the morning.

The change I have seen during my career is remarkable. When I started in dermatology, treatment was largely creams, emollients and steroids. Today, targeted biologics and increasingly personalised approaches are changing what is possible for people living with chronic immune-mediated diseases.

Across gastroenterology, dermatology and rheumatology, earlier and more effective intervention can help control disease, reduce flares and, in some cases, limit irreversible progression.

But the value is not only clinical. Better disease control may allow someone to remain independent, stay in work, care for their family and avoid repeated hospital appointments or hospital-based care. Chronic conditions place significant pressure on specialist services, outpatient capacity and people's day-to-day lives. If we can support earlier diagnosis, better pathway design and more appropriate use of innovation, there is an opportunity to improve outcomes while also reducing avoidable pressure on services. A treatment that can be delivered closer to or at home, where appropriate, may make life easier for patients and support the NHS shift from hospital to community.

That is the true value of innovation – clinical, social and economic value being realised together.

Research suggests that increasing access to innovative medicines could deliver £17.9 billion in productivity gains and more than 400,000 additional years of perfect health.[1] Those numbers represent real people living healthier, fuller lives.

NP: Oncology offers another powerful example of how innovation can change not only survival, but the way people are able to live with, and beyond, cancer. Earlier in my career, we often discussed treatments that extended life by a relatively small number of months, frequently at a very advanced stage of disease.

Today, advances in diagnosis, treatment and personalised care mean that some people with cancer are living longer and, in some cases, managing their disease over a much longer period.

I still remember discussions at NICE about chronic myeloid leukaemia and the impact of treatments that enabled people to return to work and resume everyday life. That is when innovation becomes tangible. It is not simply about survival. It is about living.

But the science can only create that value when the system is ready to deliver it. In oncology, the promise of precision medicine and advanced therapies such as CAR-T depends not only on the treatment itself, but on timely access to diagnostics, biomarker testing, clinical capacity and pathways that can identify the right patients quickly and equitably.

'Research suggests that increasing access to innovative medicines could deliver £17.9bn in productivity gains'

Too often, innovation and implementation are treated as two separate stages. A medicine may be ready, but the diagnostics, workforce, commissioning arrangements or service model needed to help it reach patients may not be in place at the same pace.

That is particularly important in precision medicine. Around 48% of eligible cancer patients either do not receive biomarker testing,[2] or are unsure whether they have received it. Due to testing delays or unavailability, some patients may not be identified for the most appropriate treatment at the right time. This can affect outcomes for patients and reduce the value that innovation can deliver for the NHS.

Industry therefore has a responsibility to engage early and appropriately with the NHS, clinicians, patient organisations and other partners to understand patient needs, generate relevant evidence and support practical planning for implementation. Those conversations are most valuable when they happen early, transparently and with a shared focus on patient outcomes, system readiness and evidence-based decision-making.

Early engagement does not mean every innovation should be adopted unquestioningly. It means asking the right questions sooner: what diagnostic capacity is needed, what pathway changes are required, what evidence matters to decision-makers, and how can the system prepare so that proven innovation reaches eligible patients in a timely and equitable way?

Making access a reality

AG: Access is where innovation becomes real. I have a close friend in his 50s who appears to be living with symptoms of plaque psoriasis and is not yet receiving the specialist support he may need. For him, the issue is not whether innovation exists in theory; it is whether the pathway helps him receive appropriate care in practice.

We also see innovative medicines positioned later in treatment pathways because they are viewed primarily through a budget lens. By the time a patient receives them, some of the value of earlier intervention may have been lost.

In some therapy areas, uptake following reimbursement can still be slower or more variable than expected, reinforcing that reimbursement is only one stage in a much longer implementation process.

Innovation should not sit at the edge of the system as an additional cost. It should be embedded within care pathways as part of the solution to better outcomes and NHS sustainability.

It can also support the three shifts set out in the 10-Year Health Plan: from hospital to community, treatment to prevention and analogue to digital.

Home and community-based models can reduce pressure on hospital beds, infusion suites and outpatient capacity. Earlier treatment can help prevent progression of disease and reduce future demand.

At J&J, we see innovation and implementation as inseparable. Our role is not simply to develop medicines, but to help create the partnerships and pathways that allow them to reach patients effectively.

Scaling best practice

NP: The operational reality must be recognised too. NHS organisations are managing workforce shortages, capacity constraints, bed pressures and competing priorities every day. Even when a pilot works, sharing and scaling it can understandably move down the list.

There are many examples of excellent practice across the NHS. The challenge is maintaining focus and creating the infrastructure to spread this best practice more broadly.

Industry can help by bringing expertise, evidence and learning across the system. We can help identify bottlenecks, support pathway redesign and spread effective models so that every locality does not have to reinvent them.

AG: Too often, we behave as though every problem requires a completely new model, when excellent approaches already exist.

I recently heard about integrated dermatology and rheumatology clinics delivering more joined-up care. The question should not automatically be: 'What else can we invent?' It should be: 'How do we replicate what is already working?'

Silos are a major barrier. Different organisations own different budgets, measures and priorities, so people naturally optimise their own part rather than the whole outcome.

The multidisciplinary team is a useful model. Better decisions are made when different experts come together around the patient. We should apply that same principle to wider system reform, aligning policy, diagnostics, commissioning and service delivery from the outset.

Scaling requires shared objectives, empowered people and the freedom, time and resources to innovate. Too often, innovation depends on local determination rather than being consistently enabled by system-wide infrastructure.

NP: No single organisation has full visibility of the entire healthcare system, so no single organisation can transform it alone.

That is why the future I want to see is one where science is developed here, clinical research takes place here and UK patients benefit here. We have the foundations. Failing to capitalise on them would be a missed opportunity. Frustration comes from knowing it could be so much better. But that is also what makes the opportunity exciting.

AG: I would like the UK to move from the lower end of international outcome rankings to becoming a country others look to for best practice.

We are often very good at putting ourselves down. We describe NHS change as like turning an oil tanker, as though progress must always be slow. Sometimes those assumptions become barriers in themselves.

Industry has responsibilities too. This cannot be a conversation only about what government or the NHS should do. We must engage earlier, explain value more clearly, understand service pressures and take shared responsibility for implementation.

The job is not finished when a medicine is discovered, approved or reimbursed. It is finished when it reaches the patient and improves their life.

The UK does not need another ambition without delivery. It needs a shared mission that connects science, research, evaluation, implementation and access, with patients at the centre and practical delivery planned from the start.

The next step is clear: access, adoption and implementation must be treated as one connected agenda. By planning earlier for diagnostics, pathway capacity, workforce readiness and evidence generation, the UK can turn scientific progress into better outcomes for patients, a more sustainable NHS and a stronger life sciences environment. The opportunity is already in front of us. Our collective task is to now realise it.

References

1. ABPI (2025). 'Delivering a voluntary scheme for health and growth
2. Bell D, Bryce R, Delfino R, Godin-Heymann N, Horne J, Jäger L, Jones M, Magnell N, Sharma V, Shera D, Ratcliffe MJ, Walls K, Mughal R. Access to treatment-guiding biomarkers in the UK: surveys of cancer patients and healthcare professionals. Future Oncol. 2025 Aug;21(20):2625-2636. https://doi.org/10.1080/14796694.2025.2535098. Epub 2025 Aug 8. PMID: 40778415; PMCID: PMC12344809.

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From activity to accountability: the omnichannel metrics that pharma leadership actually acts on

By Ruzanna Martirosyan

> 'How do you prove that omnichannel is working and providing business value?'

Most pharma omnichannel programmes can tell leadership how many emails were opened. Very few can tell them whether any of it changed a behaviour, mindset or prescribing decision. That gap – between channel activity and business outcome – is the real barrier to sustained omnichannel investment.

Let's start with the questions leadership and clients are always asking – how do you prove that omnichannel is working and providing business value? And is it worth all the effort and investment?

According to McKinsey's 2026 analysis of pharma CX investment, 73% of pharma CX pilots fail to reach full deployment. In most cases the strategy was sound. The failure was that success was never properly defined and the measurement architecture to demonstrate it to leadership was never built.

Why omnichannel campaign metrics will never be enough for budget conversations

Most pharma omnichannel programmes are measured against what I call vanity metrics: activity and engagement metrics, email open rates, page views, impressions, click throughs, rep call frequency, eDetailing completion rates, etc. These metrics are real, they are trackable, but they are almost entirely unconvincing to a Chief Commercial Officer making a resource allocation decision. The question leadership asks is not: 'How many healthcare professionals (HCPs) opened the email?' It is: 'Did any of them change their prescribing behaviour?' Engagement data cannot answer that question, which is why omnichannel programmes that report only on campaign metrics level consistently struggle to secure or expand investment.

The three-tier measurement framework

Connecting omnichannel activity to commercial outcomes requires a three-tier framework:

Tier 1 – engagement quality
Not volume but relevance and depth: content consumption rate, channel preference accuracy for each HCP segment, next-best-action acceptance rate by the field force. The question is not how many interactions happened but whether they were the right interactions for the right HCP at the right moment.

Tier 2 – clinical behaviour signals
Changes in prescribing pattern in targeted segments, adoption speed, HCP-initiated contact following an omnichannel sequence, referral rate changes in supported patient populations. These signals exist in most pharma organisations. They are rarely connected to the omnichannel data that preceded them.

Tier 3 – commercial outcomes
Pipeline conversion rate, revenue per engaged HCP, market share movement in targeted specialties. Tier 3 is where the budget conversation happens. It is also where most omnichannel measurement frameworks fall short.

How to build the omnichannel accountability layer with Customer Experience Steward

Connecting all three tiers requires more than better dashboards. It requires a governance function – what I call the Customer Experience Steward: a cross-functional role with authority spanning commercial, medical and tech, responsible for building and maintaining the single HCP view, owning the measurement framework and translating the data into a commercial narrative that leadership will act on.

This role does not widely exist in pharma commercial organisations, but it should. It falls between functions – commercial does not own medical data and IT does not own strategy. The result is a complete picture of omnichannel performance that no one has at the moment.

This is not just about measurement, but about demonstrating the business value of omnichannel and creating an opportunity to embed the omnichannel thinking into the business model, rather than view it as campaign activation.

What this means in practice

Three things change when measurement architecture is built in from the start rather than bolted on at the end:

1. The budget conversation changes – leadership shifts from asking 'what did the programme reach?' to 'what did the programme move?'
2. Channel orchestration improves – when one function has visibility across all channel data, the patterns that drive prescribing decisions become visible
3. Programme design improves – because it is designed around the outcomes it needs to demonstrate, not just the channels.

Where that Customer Experience Steward role doesn't yet exist, Spectrum Science steps into it, connecting the tiers, building the measurement architecture and turning omnichannel activity into commercial momentum for your brand.

Get in touch to build your team's momentum at www.spectrumscience.com/contact/

Ruzanna Martirosyan is Executive Director, Customer Experience & Emerging Tech, Spectrum Science

Cell and gene therapies – moving from niche innovations towards broader clinical use

Looking at the regulatory challenges of cell and gene therapies for serious or life-threatening rare diseases

Professor Jacob George, Chief Medical and Scientific Officer at the MHRA, delivered the opening keynote speech at the Advanced Therapies Europe conference in Barcelona in September, on Regulatory principles shaping the future of advanced therapies and is also hosting a roundtable on Europe's ATMP rulebook reset.

Here he talks to PME about the regulatory challenges of cell and gene therapies that are often developed for very small numbers of patients, and why rules that work for everyday medicines don't always work for rare or severe diseases.

1. Cell and gene therapies are moving from niche innovations towards broader clinical use. What unique regulatory challenges do these treatments present that differ from those associated with conventional medicines?
Cell and gene therapies are different from ordinary medicines in some important ways. They're often highly complex biological products, sometimes made specifically for one patient, and how they're manufactured can matter just as much as the finished product.

These treatments are usually for serious or life-threatening conditions where there aren't many other options. They're also often developed for very small numbers of patients. That means regulators sometimes have less evidence to work with when deciding whether to approve them, compared with a typical medicine.

That's why we have to think differently about manufacturing itself. Point-of-care and modular manufacturing, where products can potentially be made much closer to the patient rather than in a traditional manufacturing facility, are still at an early stage in their development in the UK but we've had interest and enthusiasm from developers already. We have hosted some meetings, either as the MHRA or as multi-agency, with the UK Space Agency and the Civil Aviation Authority, for example, with BioOrbit, which is a good example of people who are doing amazing research in this space, working on low-gravity crystallisation of protein. We haven't yet had a formal request to use this approach, but interest from companies developing these treatments is growing fast and we expect that to increase over the next year.

Our challenge is to make sure our rules are flexible enough to support this kind of new treatment, while still giving patients and healthcare professionals (HCPs) confidence that the products reaching the market work and are safe.

2. Looking ahead, which regulatory principles will be most important in enabling the next generation of cell and gene therapies to reach patients effectively and responsibly?
One of the most important principles is proportionate regulation. Rules that work for everyday medicines don't always work for rare or severe diseases, so we look closely at the mortality and morbidity associated with the condition, whether other treatments exist, and what endpoints can meaningfully inform regulators about the efficacy and safety of the products, particularly when numbers are small.

We also need to talk to companies developing these treatments early on. Good advice given early means treatments get developed more efficiently, and it avoids later delays caused by misunderstandings about what we need to see in terms of evidence generation. Regulatory agility matters too, meaning we need to move with the science while ensuring our rules keep up with new technology without losing the public's trust.

Finally, we work closely with regulators in other countries, including in Europe, wherever that makes sense. Staying aligned avoids extra cost and delay for the companies developing these treatments. But where we can move faster and it clearly benefits patients, we will do things differently. Our approach is to stay aligned wherever we can and only go our own way when there's a good reason to.

3. As the field continues to advance at speed, how can regulators safeguard patient safety and scientific rigour while avoiding unnecessary barriers to innovation?
People sometimes think patient safety and new treatments are in conflict, but they're not. Patients only benefit from new treatments if they can trust that those treatments have been properly checked.

When we decide how much uncertainty is acceptable before approving a treatment, we look at the whole picture. How serious is the condition? Are there other treatments available? And how well can any remaining uncertainty be managed once the treatment is in use?

For some serious diseases, where there are few or no other options, we may accept more uncertainty than we would for a routine medicine. But if we do that, we need post-marketing pharmacovigilance, to keep checking the treatment is working and remains safe. Groups like Health Data Research Service UK (HDRS UK) are helping build the systems that make this kind of monitoring possible.

By combining sensible flexibility with strong pharmacovigilance, we can help patients get treatments sooner, without lowering our standards.

4. Many advanced therapies are designed for rare diseases and small patient populations. How should regulators and developers approach evidence generation when traditional clinical trial models may not always be feasible?

This is one of the hardest challenges in this field. Traditional ways of testing new medicines were designed for large numbers of patients, and that doesn't always work for rare diseases, where there might only be a handful of patients worldwide.

The answer isn't to lower our standards, but instead to think differently about what counts as good evidence. We want to work with the companies and patients in developing these treatments early on, to agree which endpoints are relevant and meaningful to regulators but also to patients and their families.

Part of that means looking at many different aspects including the underlying mechanism of how the treatment works, results from clinical trials, how it's manufactured and, increasingly, real-world evidence gathered after the treatment is approved and being used by patients.

These treatments offer real hope to patients with rare diseases who may have had few options before. The MHRA's role is to balance maintaining high standards with being pragmatic and flexible about how that evidence is gathered.

5. Patient access to advanced therapies remains a significant challenge. What are the key barriers preventing wider access and how can they be addressed?

Access depends on much more than regulatory approval alone. We're one part of a series of steps, one cog in a wheel, but I think we have a key role to play in how smoothly that whole pathway moves.

If we can provide faster scientific advice, quicker clinical trial approvals and timely marketing authorisations, that sends a clear signal to investors and developers about where it makes sense to base their work. We've worked hard over the past two to three years to speed this up and it's paying off. We've introduced regulatory flexibility through things like the UK Rare Disease Therapies Regulatory Framework and the Clinical Trials 14-day Pilot Programme. Those measures exist to show developers that we are listening and are there to support their ambitions.

But speed on our part only helps if the rest of the system can move at a similar pace. Decisions about funding and rolling out new treatments involve a lot of moving parts, and they matter just as much as our approval. That's why we've built closer links with the National Institute for Health and Care Excellence (NICE), the body that decides which treatments the NHS will fund, so these decisions can happen earlier and alongside our own work, through the new MHRA-NICE aligned pathway rather than only starting once regulatory approval is obtained.

None of this happens through regulation alone, which is exactly why conversations between industry, investors and healthcare systems at events like Advanced Therapies Europe 2026 matter as much as anything we do inside the agency.

6. Which emerging technologies or scientific advances do you think have the greatest potential to transform the field of advanced therapies over the next decade?

The ability to scale up and simplify CAR-T therapy is one area that has tremendous potential for advanced therapies to significantly impact outcomes in many cancers.

CAR-T therapy (chimeric antigen receptor T-cell therapy) works by taking a patient's own immune cells, modifying them so they can recognise and attack cancer cells, and returning them to the patient. It's already shown strong results in treating some blood cancers.

The challenge now is scale. Each treatment is currently made individually for a single patient, which makes the process complex, slow and expensive. If we can simplify manufacturing and make it more efficient, we could treat far more patients and treat them more quickly.

This matters because the science already works. What determines whether patients actually benefit is whether we can manufacture at the scale and speed needed.

Who's steering? Why pharma needs humans at the helm of AI

Understanding how AI decisions are made, who owns the outcomes and how accountability travels across partners and platforms

By Ramji Vasudevan

In a sector where a governance failure can cost lives as well as regulatory approval, 'a human in the loop' can no longer be viewed as a safety net. In many pharmaceutical businesses, it creates the appearance of oversight without the reality of accountability.

HFS Research, in partnership with Altimetrik, surveyed 505 senior executives across Global 2000 organisations, of which 68 are UK-based, to understand how AI decisions are made, who owns the outcomes and how accountability travels across partners and platforms. What the research reveals should give every leader in the pharmaceutical industry pause, because the governance gap it exposes is most dangerous where the consequences of getting it wrong are highest.

Pharma has deployed AI extensively. Across drug discovery, clinical operations, pharmacovigilance, commercial functions and beyond, intelligent systems are already making recommendations that shape consequential decisions. But deployment is not governance. And the distance between the two is widening.

The helm is empty

Only 14% of organisations surveyed said they have a clear AI strategy with defined goals and outcomes. The majority are either still developing a strategy (39%) or operating in disconnected pockets with no enterprise-wide direction (32%). Meanwhile, AI keeps moving, embedding itself into workflows, making recommendations and, in some cases, making decisions.

This pattern is visible across industries, but in pharma it carries a specific and acute risk. Too many organisations are treating strategy as a technology choice, selecting a platform provider and calling it a plan. But choosing an AI vendor is not an AI strategy. A genuine strategy requires organisations to go back to first principles: who are we, what do we exist to do and where does AI therefore fit? The organisations that demonstrate the clearest understanding of their own identity and purpose are the ones best positioned to harness AI effectively. Without that foundation, the approach becomes piecemeal.

> **'When a governance failure can cost lives as well as regulatory approval, 'a human in the loop' can no longer be viewed as a safety net'**

The consequence is that accountability becomes variable. Ownership of AI-driven outcomes shifts between functions, vendors and platforms, and no single line of sight connects a model's recommendation to the person answerable for its consequences. For pharma, where regulatory frameworks already require documented decision rights, validated processes and clear lines of accountability, this is not a theoretical concern. It is a compliance exposure that grows with every uncoordinated deployment.

The loop is hollow

In highly regulated environments, AI governance takes on an even greater level of importance. When AI contributes to a regulatory submission, a pharmacovigilance signal, a clinical trial design or a pricing decision, the ability to explain not just what the system recommended but how it arrived there is not a technical nicety. It is a requirement that existing frameworks will increasingly demand and that internal audit, regulators and, in the event of harm, courts will expect to see answered.

The problem with 'a human in the loop' as it is currently practised is that it implies review without specifying the nature, depth or authority of that review. A human may be present in the process, but are they genuinely steering, or simply watching the outputs pass through? The distinction matters enormously. As a way of thinking about it, the concept of 'a human at the helm' shifts the frame: you are still doing what you have always done, but now you are doing it with AI at your disposal. A scientist is still going to keep discovering new drugs. A laptop made that faster. AI will make it faster again. But the scientist remains at the helm.

Outright AI hallucinations may have reduced significantly, but what has replaced them may be harder to catch: misrepresentation, miscategorisation and subtle contextual errors that an untrained eye will not spot. These are not failures of the technology so much as failures of the governance model that surrounds it.

When the output looks credible and the reviewer lacks the scaffolding to interrogate it, the loop exists on paper but is hollow in practice.

Fear is a governance problem

The research identifies a reinforcing pattern that pharma organisations should recognise immediately: fear makes experimentation risky; limited experimentation prevents judgement from developing; without judgement, confidence does not form; and when confidence stays low, employees defer to AI rather than challenge it.

In pharma, the functions that most need to challenge AI outputs – medical affairs, regulatory, pharmacovigilance, clinical operations – are staffed by people with deep professional expertise. But expertise and confidence in challenging AI are not the same thing. AI's outputs have become impressively fluent and that fluency is itself a risk. When a model produces a result that looks polished and authoritative, the instinct to defer is natural, even among subject matter experts.

AI should be treated as a capable companion, not a replacement for professional judgment. It can accelerate discovery, surface patterns and handle volume at a pace no human team can match. But it does not yet possess the contextual understanding that resides in people's heads, the tacit knowledge built through years of working within a specific therapeutic area, regulatory environment or organisational culture. That knowledge does not live in documents or meeting notes alone; it exists somewhere in between. Until AI systems can access that full context – and they cannot yet – human oversight must be substantive, not ceremonial.

What humans at the helm requires

The research proposes a governance framework built from five foundations, each enabling the one above it. For pharma, each layer has a specific translation:

1. Direction means going back to first principles. A pharma company's AI strategy should begin not with the technology but with the organisation's identity: what diseases it is trying to treat; what its pipeline demands and where AI can genuinely accelerate that mission.
2. Authority means defining who has the right and the obligation to override an AI recommendation at every decision point in the value chain, from molecule selection through to commercial launch.
3. Visibility means building the infrastructure for full explainability, not just technical transparency but the ability to trace how an AI-informed decision was made, by whom and on what basis.
4. Capability means investing in the skills that allow professionals to work with AI critically rather than deferentially, developing AI-native workflows where governance is embedded, not bolted on.
5. Accountability means closing the loop: ensuring that every AI-assisted decision has a named owner; a documented rationale and a clear escalation path when something does not look right.

The question pharma cannot defer

The opportunity for pharma is not to slow AI adoption but to rewire how it is deployed. Treating AI as a bolt-on, a chat interface layered over existing processes, a dashboard enhancement or an incremental efficiency tool will deliver incremental gains. But the organisations that reimagine their workflows to be AI-native, rethinking processes from the ground up rather than optimising each existing step, are the ones that will build a genuine competitive edge. If a drug discovery process currently involves 40 steps, AI should be used to fundamentally reimagine the process as 18 or 20 steps with AI woven in from the start.

The industry's fundamental challenges are not going to change. Pharma companies will still be measured on the drugs they discover, the treatments they bring to market and the patients they reach. AI does not alter those imperatives. It raises the stakes for getting the governance right before an incident forces the issue.

Pharma has always understood that some decisions are too consequential to leave ungoverned. Patient safety, regulatory integrity and clinical credibility are not values the industry adopted under pressure. They are its foundations. The question now is whether organisations will extend that same rigour to the intelligent systems increasingly shaping those decisions or wait until a failure makes the case for them.

Ramji Vasudevan is Head of Life Sciences at Altimetrik, visit altimetrik.com

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The event takes place on Thursday 26 November 2026 in the heart of London at Convene, 155 Bishopsgate

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Chaired by Dr Amrit Singh, the programme explores the biggest issues shaping today's workplace, beginning with a data-driven look at the realities organisations are facing in 2026, before examining why well-being has become a business strategy rather than simply an employee benefit.

Among this year's headline speakers is Dame Carol Black, whose pioneering work has helped shape the UK's approach to workplace health, alongside digital well-being expert Petra Velzeboer, who will explore the impact of AI, constant connectivity and technology on human performance. Other speakers include Simon Blake OBE, CEO of Stonewall, Susan Gee, Head of Occupational Health & Well-being at Yorkshire Water Services, Lauren Lunniss of BNP Paribas, Jamie Broadley from Serco Group and Rosie Ellis from Aon, bringing together perspectives from across business, healthcare and public policy.

The programme balances strategic leadership discussions with practical workshops covering burnout prevention, financial well-being, psychosocial risk, men's mental health, neurodiversity, early careers, line manager capability, and supporting frontline and shift-based workforces. Throughout the day, delegates will hear real-world case studies, take part in facilitated discussions and leave with practical ideas they can apply within their own organisations.

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As organisations continue to navigate rapid workplace change, the MAD World Summit remains focused on one clear objective: helping leaders turn conversation into meaningful action. Whether delegates are developing a new well-being strategy or strengthening an existing one, the event offers the evidence, inspiration and connections needed to create healthier, more resilient workplaces.

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Healthcare has always been complex, but the pace of change feels greater than ever. Innovation is accelerating, AI is transforming how we work and healthcare delivery continues to evolve. In the UK alone, discussions around medicines pricing, patient access and NHS reform highlight just how interconnected healthcare decision-making has become.

As healthcare has evolved, so too has my view of leadership. It's become less about overseeing every decision and more about creating the conditions where expertise can thrive.

This year, I've spent time with our UK team in the field and at the International Society on Thrombosis and Haemostasis Congress. In both settings, the same lesson stood out: the people closest to the challenge often have the clearest understanding of what's needed.

Returning to the field, I reflected on how the role has evolved. Fifteen years ago, conversations often centred on solving a customer's immediate challenge. While those discussions still matter, increasingly, success comes from building partnerships and working together to improve patient outcomes. The expertise to navigate those conversations often sits closest to the customer – which is why empowering those teams matters more than ever.

It also reinforced a question we need to ask more often as leaders: 'How can I help and what role can I play?' Leadership doesn't always mean having the answers. It means creating the conditions for others to succeed.

That thinking is reflected in how we've evolved as an organisation. Our more integrated European operating model brings specialist knowledge closer to decision-making, with a Leadership Team focused on long-term direction, while three Management Teams combine cross-functional expertise across today's commercial, pipeline and operational priorities. Each area faces different challenges and decisions, so our choices are informed by those with the deepest understanding, rather than a single leadership group.

For me, that's what modern leadership looks like – trusting people, investing in their development and creating an environment where expertise is valued, ownership encouraged and leadership shared.

Because if the people closest to the challenge are often closest to the solution, then leaders must ensure those insights are heard, trusted and acted upon.

Mike Crosher is European Director, Portfolio & Lifecycle Management & UK General Manager at Chugai

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Strengthening engagement with HCPs needs deep understanding not digital bombardment

Closing the critical gap between HCPs' need for information and the pharma industry's ability to deliver relevant, tailored content

By Danny Buckland

Speed dating has a woeful record for successful unions, with participants feeling empty by the imperative to cram life stories and achievements into three breathless minutes.

What should be an open door to meaningful exchange can easily become a forced encounter, frantic with repetitive conversation lines that have no relevance and little chance of creating lasting connections.

Pity the healthcare professional (HCP) who now faces a clamouring queue of suitors made louder by digital strategies that should make engagement easier, but often hit like a hard-sell hailstorm. It is little wonder that most are restricting pharma team access or retreating from meetings, either face-to-face or digitally.

Research has identified a critical gap between HCPs' hunger for knowledge and learning, and the pharmaceutical industry's ability to deliver relevant, tailored content. It should be a perfect match.

A survey from Deloitte reported that the vast majority of HCPs want trusted interactions to help their decision-making and stated: 'Stakeholders want coordinated, integrated interactions with their life sciences partners, but HCPs and customers often experience redundant engagements due to poor internal communication, such as multiple visits from the same company in a week.'[1]

A 2024 study by Veeva Systems revealed that HCP engagement with field force and online channels has fallen to 53%, with 62% of those interacting with three or fewer companies.[2]

Capturing hearts

A further indicator of the challenge was raised in a British Medical Journal commentary in response to the NHS in England pledging to invest £10bn in AI to improve healthcare. It highlighted: 'Doctors have also warned that, despite the billions being put forward, the evidence base for these tools actually delivering benefits remains murky and the AI transformation must ensure there is still space for doctors to learn and grow.'[3]

'AI and its agentic qualities need to prove they have the capabilities to listen, understand and deliver tangible benefits'

To capture the hearts of HCPs and establish meaningful relationships, AI and its agentic qualities need to conquer the promise overload by proving they have the capabilities to listen, understand and deliver tangible benefits.

"Field force access has been significantly limited across all geographies, but the industry reaction of providing more emails, more outreaches and involving more teams targeting individual HCPs is counter-productive and misses the underlying needs of the profession," says Chris Moore, President, Europe Veeva Systems, a global leader in cloud software for the life sciences industry.

"HCPs want to understand new treatments and how those treatments can be applied to their patients when they are prescribing for the first time. They want answers when they need them and they want to have a relationship with those companies where they see value and where every interaction builds off the last.

"We know their time is scarce and that every interaction has to count, so the challenge is making those interactions valuable without overloading them."

A huge majority of HCPs are now digital natives who feel comfortable navigating and using innovative tools, and they are equally at ease moving to new sources if they cannot find the right content at the right time. The task of synchronising with the shifting nuances of their needs has already surpassed the capabilities of traditional call reports, observes Chris.

He highlights that, although structured picklists capture the basics of an interaction, they miss the richer detail from conversations with HCPs, such as the questions they have, their sentiment or specific barriers to treatment. This is where, he says, Veeva technology enables field teams to compliantly capture this context using voice or free text, generating 'Commercial Evidence' that helps make subsequent engagement more precise.

"Physicians do not want to talk to the industry if it's a non-value-added conversation," he says. "But if it's about new treatments that help their patients or content that educates them, gives them a voice or provides access to training, then they really want to speak to industry.

"There is a need for organisations to be more dynamic in how they interact with physicians and move away from one-size-fits-all engagement to understanding what matters to individual HCPs. This is where AI can make a real difference."

Learn and respond

Although there is a concern spectrum around AI, Veeva believes its systems can support and augment teams, using richer customer context to make human engagement more valuable. "One of the challenges is that customer engagement has traditionally been fragmented across different functions," observes Chris. "Sales might see a physician as its customer, marketing sees them as a segment and medical sees them through another lens. But ultimately, it's the same person interacting with one company.

"If you aren't working from a shared view of the customer, you don't understand the individual and you are broadcasting to them, not connecting with them. Technology can help create a more human experience where every interaction builds on another and responds to their needs."

AI is providing more opportunities for organisations to learn and respond, and Chris cites the example of a company that could not understand why prescribing rates were falling until the cause emerged through an HCP conversation with its Agentic Call Report.

"HCPs explained that they had run out of the companion diagnostic tests needed to prescribe the medicine. By quickly capturing that insight, the company was able to identify the issue and explain that there were alternative testing kits approved for use," says Chris. "Prescribing rates returned and, importantly, patients got the right treatment. This is what we mean by 'Commercial Evidence' – capturing real-world context from interactions that could otherwise go unrecorded and using it to identify and resolve barriers."

AI is hailed as the salvation for stressed healthcare systems across Europe and, providing it can satisfy clinical safety and privacy concerns, the European Commission – which introduced the European Artificial Intelligence Act to establish clear developmental guidelines – believes in its transformative capabilities. Its *Artificial Intelligence in Healthcare* paper stated: 'Advancements in AI technology present unprecedented opportunities to revolutionise healthcare, making it more effective, accessible and economically sustainable. By fostering the integration of AI through appropriate policies, we can enhance equity, improve care and ensure that new technologies, treatments and medicines benefit society at large."[4]

Trusted and relevant

Chris echoes that belief and comments: "We are on the cusp of a dramatic change. We are witnessing a real step change in the quality of information provided by large language models (LLM) and the levels of investment from the big tech platforms is unprecedented. Leaders, such as Penny Dash, chair of NHS England, have indicated the huge role AI can play in how patients and HCPs access information and guide treatment pathways.

"But you need trusted content that can be found and understood by those LLM models. You must be relevant at the point of conversation between the physician and the patient, and you've got to keep information focused on the questions HCPs and patients are actually asking.

"So, instead of static websites, you can have compliant, conversational digital experiences that give HCPs immediate answers using approved content. Those interactions may start digitally with an automated response, but they can also lead to human follow-up when that's what HCPs need.

"If HCPs are prescribing in an area for the first time, they need answers specific to their needs. The digital and human experience don't have to be separate."

He concludes: "We are using AI to make engagement more precise, rather than just creating more of it. Agentic capabilities can help us better understand what an individual HCP needs so that both digital and human interactions are more personalised. When you connect those interactions across channels, HCPs get the answers they need when they need them, helping the right medicines reach more patients."

References

1. https://www.deloitte.com/us/en/industries/life-sciences-health-care/articles/customer-engagement-strategies-pharmaceutical-industry.html
2. https://www.veeva.com/eu/resources/veeva-pulse-field-trends-report-united-kingdom-q1-2024/
3. https://pubmed.ncbi.nlm.nih.gov/42431687/
4. https://health.ec.europa.eu/ehealth-digital-health-and-care/artificial-intelligence-healthcare_en

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The impact of AI and digital health on chronic diseases

Over the past decades, advances in information technology have fundamentally transformed the management of chronic diseases, but what impact is this having on the pharma industry?

By Aleksandar Ruzicic

The economic burden of chronic conditions is immense, encompassing healthcare expenditures, productivity losses and the societal costs of premature mortality. Between 2011 and 2030, the cumulative economic losses attributable to cancer, cardiovascular disease, chronic respiratory diseases, diabetes and mental health disorders are estimated at $47tn. In addition, the global burden of lost life is projected to increase from $22.8tn in 2010 to $43.3tn by 2030.

In contrast, global healthcare spending exceeds $9tn annually, with an estimated $4-7tn directly attributable to chronic conditions. Once a chronic condition develops, it creates significant challenges for patients, healthcare providers, healthcare systems and society at large. These challenges are outlined below.

Patients:

- Patient outcomes depend heavily on patient behaviour, as success often relies on (daily) adherence to medications, healthy eating, exercise, sleep and self-monitoring
- Multiple conditions often occur together, as many patients have two or more chronic diseases (multi-morbidity), for example, diabetic patients with hypertension
- Symptoms can fluctuate with periods of stability punctuated by flare-ups or complications requiring treatment plans to be adjusted over time.

Healthcare professionals (HCPs):

- HCPs need to provide lifelong chronic disease management, as conditions such as diabetes, hypertension, heart disease and COPD cannot be cured
- Care is fragmented amongst primary care providers, multiple specialists, nurses, pharmacists and other HCPs, requiring strong coordination
- Many chronic conditions require regular measurements, such as blood pressure and blood glucose, to detect deterioration before serious complications develop.

Society and healthcare systems:

- Social and economic factors, such as care affordability, health literacy, housing and access to healthy food influence patients' ability to manage their condition
- Healthcare systems are often designed for acute care, treating short-term illnesses or emergencies, for example, in hospitals
- Complications accumulate over time, as poorly controlled chronic diseases can lead to irreversible damage, such as heart attacks, strokes, blindness and amputations.

Disease management emerged as a formal healthcare strategy for chronic conditions in the mid-1990s, building on approaches first pioneered in diabetes, the prototypical chronic disease since the 1950s. The strategy was subsequently extended to other conditions that are prevalent, costly to treat and supported by well-established clinical guidelines amenable to coordinated, long-term management, including heart failure, coronary artery disease, hypertension, asthma and chronic obstructive pulmonary disease (COPD). Over the past decades, advances in information technology have fundamentally transformed the management of chronic diseases:

- Internet era (since late 1990): access to information and communication, facilitating patient empowerment
- Mobile health era (since 2007): tools for self-management and remote monitoring, making health tracking part of daily life
- AI (since late 2010s): expansion to prediction and personalised decision support and virtual health coaching.

In the future, countries will need to address a set of critical success factors to effectively manage the growing burden of chronic diseases. This will require coordinated action across society, healthcare systems, HCPs and patients, while fully leveraging the transformative potential of information technologies.

Society and healthcare systems:

- Value-based reimbursement models: transitioning from a fee-for-service to bundled payments or capitation with financial incentives for prevention and outcomes
- Interoperable digital infrastructure: implementing unified, electronic health records that track patient data across primary care, specialist centres, hospitals, etc
- Cross-sector social integration: linking social welfare systems to healthcare networks via closed-loop referrals to address social determinants
- Continuous quality improvement: using predictive analytics and risk-stratification tools to identify high-risk populations before they experience acute complications.

'Global healthcare spending exceeds $9tn annually, with an estimated $4-7tn directly attributable to chronic conditions'

Healthcare providers:

- Multidisciplinary team care: structuring clinical practices to rely on nurses, dietitians, pharmacists and other HCPs rather than just primary care and specialty physicians
- Guideline-driven decision support: integrating evidence-based clinical protocols directly into electronic workflows to standardise treatment choices
- Proactive follow-up: establishing structured patient outreach mechanisms, such as virtual health coaches, monthly digital check-ins, telehealth triage
- Shared decision-making: communicating treatment options as collaborative trade-offs, matching clinical guidelines with patients' personal goals and values.

Patients:

- Health literacy: possessing a practical understanding of the disease trajectory, trigger points and exactly when to escalate own symptoms
- Self-management: actively using home-monitoring equipment, for example, glucometers, blood pressure cuffs and maintaining an actionable, documented self-care plan
- Medication adherence: utilising structural habits, smart pill organisers or digital notifications to maintain strict compliance with drug regimens
- Social/informal support: relying on family, friends or peer support groups to help manage emotional, physical and financial burdens of a chronic condition.

Numerous successful chronic disease management initiatives have been implemented across countries, targeting a range of conditions through diverse healthcare delivery models, payers, providers and technology solutions. Image 1 presents several examples of successful chronic disease management initiatives.

Historically, pharmaceutical executives have invested in healthcare services across the patient journey to address critical patient leakages and unlock significant growth opportunities (see Image 2, bottom box). For example, when Merck & Co launched its bisphosphonate Fosamax in the mid-1990s, the company supported the expansion of DEXA scanner availability in the US to enable earlier and more accurate diagnosis of osteoporosis patients.

A more recent example is familial hypercholesterolaemia (FH), a hereditary form of high cholesterol. Companies such as Amgen, Regeneron, Novartis and Sanofi

Image 1: Chronic disease management cases (selected examples)

Country	Chronic condition	Payer and/or provider	Technology (selected examples)	How it works
USA	Diabetes type 2	Kaiser Permanente	Electronic Health Record (EHR), patient registry, HCP alerts, remote patient monitoring	Real-time patient risk stratification based on HbA1c and BMI data, patient coordination by care managers
UK	Diabetes type 2	National Health Service	Apps to log meals, track glucose metrics, and connect patients to others entirely remotely	Connected peer groups and registered dietitians provide asynchronous behavioral coaching
Israel	Heart failure	Clalit Health Services	Internal Clalit Proactive and Preventive Intervention platform, using proprietary AI software for vocal biomarkers	Patients record a baseline & perform a brief vocal test every morning, predictive alerts of deviations (fluid accumulation)
Netherlands	Diabetes type 1	Diabeter/ Zilveren Kruis	Continous glucose monitoring, insulin pump systems and Diabeter proprietary integrated EHR/ telehealth system	10-year value-based bundled payment model, leading to exemplary clinical control (HbA1c) and less hospitalizations

have invested substantially in improving early patient identification, as an estimated 90% of individuals with FH remain undiagnosed. These initiatives reflect a broader shift towards addressing gaps in diagnosis and care pathways to expand access to appropriate treatment.

In our previous PME article, 'Valuable collection: what are the prospects for grouping complementary services around a product', we explored situations where a product with a non-differentiated clinical profile within its class can achieve a competitive advantage through value-added services that improve outcomes (see Image 2, middle box). We proposed that next-generation healthcare combination solutions – integrating complementary products and services around medicines (and devices) – have the potential to deliver superior patient outcomes, as demonstrated by emerging models in obesity management.

As AI reduces the cost and scalability barriers associated with delivering healthcare services, pharmaceutical companies may increasingly consider innovative business models that combine therapies with integrated healthcare solutions, particularly in ambulatory care settings for chronic diseases. However, such investments should be carefully targeted towards disease areas where future therapeutic innovations are unlikely to fundamentally reshape clinical practice; otherwise, substantial investments in healthcare solutions may become obsolete.

In our previous PME article, 'Digital healthcare may revolutionise management of chronic diseases, but who is going to pay for it', we highlighted the emerging business model of digital therapeutics (DTx) – evidence-based interventions designed to prevent, manage or treat medical conditions through software-based solutions that undergo review and certification by regulatory authorities. Leading pharmaceutical companies, including Otsuka Pharmaceutical, AstraZeneca, Boehringer Ingelheim and Sanofi, have been among the most active participants in the DTx space (see Image 2, top box).

'Future leaders will combine innovative therapies with value-added services that enhance patient care'

However, digital health and health technology companies have also entered this space, creating new models that integrate therapeutic interventions with scalable healthcare services. For example, Omada Health combines access to widely used anti-obesity medications with behavioural coaching and clinical weight management infrastructure through a structured, predictable cost model. As continued R&D is expected to deliver increasingly effective pharmacological treatments for obesity, pharmaceutical companies may increasingly view such digital health providers as natural partners to extend patient support, improve outcomes and enhance the overall value proposition of their therapies.

But what happens when a drug such as semaglutide (Ozempic and Wegovy) becomes generic, as is already the case in Canada (since the end of April 2026)? Following its acquisition of Live Well, a leading Canadian digital health platform focused on weight management, Hims & Hers Health launched its first international GLP-1 offering, providing generic semaglutide through a manufacturing partnership with Apotex, Canada's largest domestic pharmaceutical company. The offering combines access to the newly approved Apo-Semaglutide injection with personalised care plans, starting at CAD149 per month.

This example illustrates a potential strategic challenge for pharmaceutical companies: as therapies become more widely available and commoditised, digital health platforms and other intermediaries may increasingly control patient access, care pathways and the broader treatment experience. In the future, these players could become powerful gatekeepers between patients and pharmaceutical manufacturers.

In the long term, pharmaceutical companies can aspire to establish leadership within specific chronic conditions, as discussed in our PME article, 'Dive in: gaining long-term leadership in a therapy area can be commercially invaluable'. Future leaders in chronic disease management will be those able to demonstrate superior outcomes by combining innovative therapies with value-added services that enhance patient care.

This integrated approach could create a more resilient and differentiated business model, provided that pharmaceutical companies continue to keep pace with therapeutic innovation and evolving standards of care. Ultimately, the leading companies in a chronic condition may become the trusted, recognised brands for managing that disease – successfully combining the scientific strengths of biopharma with the patient-centric capabilities of digital health and health technology platforms.

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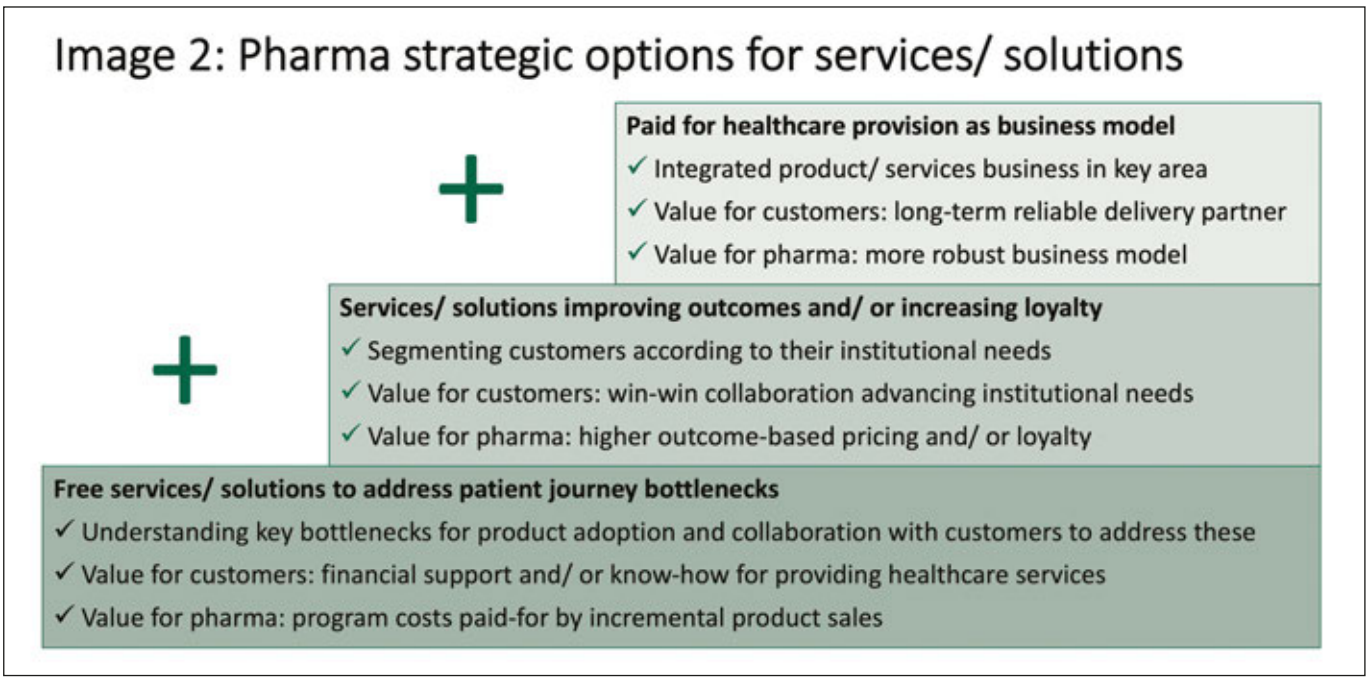
Image 2: Pharma strategic options for services/ solutions



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Regulatory complexity: the challenges of navigating the new normal

How functional service provider models are helping pharma adapt to regulatory uncertainty

By Myriam Antoun

Logistical challenges are not new in clinical research, from the high cost of developing new therapies to complexities in trial enrolment and operations. Agility and flexibility have always been important to trial design, but they are now becoming essential in the face of rising regulatory complexity. This complexity is driven by shifting global policies and increasingly divergent regional requirements, alongside a steady flow of regulatory updates. What was once a manageable operational consideration has become a significant strategic challenge for the industry. As a result, it is becoming increasingly difficult for drug developers to plan and execute clinical programmes with confidence.

The consequences are substantial, including missed development milestones, delayed regulatory submissions and downstream commercial impact. Even modest delays can carry significant financial burden, with a single day of delay in a clinical trial estimated to result in approximately $500,000 in unrealised prescription drug sales and $40,000 in direct daily costs.

Many organisations' instinct in response to this complexity has been to absorb it internally: hiring additional staff; stretching existing teams and relying heavily on institutional knowledge to bridge the gaps. However, this approach is increasingly insufficient given the pace of regulatory change. The challenge is no longer simply about capacity; it is about accessing the most appropriate specialised expertise to interpret evolving requirements, assess their impact across development programmes and respond before timelines or outcomes are affected.

As the regulatory landscape continues to evolve, a growing number of drug developers are shifting their approach. Rather than building rigid structures against uncertainty, they are prioritising flexibility, with functional service provider (FSP) models playing a central role.

From compliance function to strategic capability

For decades, regulatory affairs has primarily been viewed as a compliance function, responsible for ensuring submissions meet regulatory requirements and organisations remain aligned with evolving guidance. That model is no longer sufficient in today's environment.

Regulatory strategy has now become a core operational capability. Organisations must not only understand requirements but also anticipate change, assess its implications across development programmes and act early enough to avoid disruption. The ability to navigate regulatory complexity with speed and confidence is increasingly a competitive advantage.

Companies that do this well are better positioned to accelerate development timelines, reduce the need for late-stage remediation and avoid regulatory surprises that can delay approval or commercialisation. They are also able to make earlier, more informed decisions that improve overall programme efficiency.

FSP models are enabling this shift by embedding regulatory expertise directly within clinical development and operational teams. Rather than relying on intermittent support or overstretched internal groups, sponsors gain continuous access to specialists who monitor regulatory developments, interpret changes in context and translate them into actionable guidance.

This embedded approach allows organizations to identify risks earlier, adapt more quickly to evolving expectations and maintain momentum in increasingly complex development environments. As regulatory complexity grows, companies that treat regulatory affairs as a strategic capability, rather than a standalone function, are better positioned to bring therapies to patients faster.

The scale of the challenge

The challenge facing drug developers is not simply keeping pace with regulatory change, but understanding which changes matter and how they affect specific programmes across markets.

For global organisations, this requires continuous monitoring and interpretation of regulatory intelligence from multiple sources, including national and regional regulations, guidance updates, authority communications and industry outputs. Each of these can have implications for protocol design, submission strategy or operational execution.

Beyond monitoring, effective regulatory intelligence depends on interpretation. The impact of regulatory change varies depending on both the market and the stage of development, requiring contextual expertise that is difficult to maintain internally at scale.

Why the FSP model is well suited to this problem

The FSP model addresses regulatory complexity through a timely combination of scale, specialisation and integration that can be challenging to replicate within a single operating structure.

At the monitoring level, FSP partners maintain structured systems to track regulatory intelligence across markets. These systems capture not only headline changes but also procedural guidance, authority clarifications and regional nuances that often drive operational impact.

At the analysis level, locally based experts provide context-specific insight and, where needed, engage directly with regulatory authorities in local languages. This helps reduce misinterpretation and improves the speed and quality of decision-making.

The implementation of the EU Clinical Trials Regulation (CTR) and Clinical Trials Information System (CTIS) illustrates how

regulatory change can create periods of intense operational demand. Sponsors were required to revise established submission processes, adapt operating models and develop new expertise within relatively short timelines. For organisations managing studies across multiple countries, resource requirements often increased rapidly during the transition period as teams worked to understand new requirements, update procedures and support ongoing studies.

Once the transition activities were completed and organisations became more familiar with the new framework, those resource needs did not necessarily remain at the same level. This highlights a broader challenge in regulatory affairs: major regulatory changes can generate periods of intense activity that are difficult to predict and inefficient to support through permanent headcount alone. FSP partnerships provide the flexibility to scale specialised regulatory expertise when needed and adjust support as requirements evolve, helping sponsors navigate periods of change without overextending internal teams.

Even after implementation, the EU CTR continues to evolve as regulators and stakeholders gain experience with the framework. Variations in interpretation and evolving guidance still create complexity for sponsors running multinational studies. Access to local expertise through FSP models helps organisations respond more effectively while maintaining compliance across jurisdictions.

At the operational level, regulatory intelligence is translated into concrete updates to procedures, systems and study designs before new requirements take effect. A key advantage of the FSP model in an evolving regulatory environment is its structural flexibility. When requirements shift, resources can be scaled or redeployed quickly across geographies and programmes, helping maintain continuity and responsiveness.

This is particularly valuable for biopharma and biotech organisations that may not have the internal infrastructure to build deep regulatory capability across all markets. FSP partnerships provide access to expertise and systems that would be difficult to replicate internally.

AI and the next generation of regulatory intelligence

The application of AI and advanced analytics is beginning to reshape how regulatory intelligence is gathered and processed. The volume of regulatory data that must be monitored globally now exceeds what can be managed through manual processes alone. AI-assisted tools are enabling faster identification of relevant changes and earlier detection of emerging trends, improving how regulatory signals are translated into operational guidance.

However, identifying a regulatory update is only the first step. While AI can support the monitoring of large volumes of regulatory information and surface potentially relevant changes, determining what those changes mean in practice still requires scientific and regulatory expertise. A new guidance document or regulatory clarification may appear straightforward, but assessing its impact on ongoing studies or submission strategies often requires careful interpretation. The value lies not only in recognising that a change has occurred, but in understanding its implications and deciding how and when to respond. Access to experienced regulatory professionals through an FSP model can help sponsors translate regulatory intelligence into practical actions, while maintaining flexibility as needs evolve.

FSP partners are well positioned to integrate these capabilities into regulatory workflows in a compliant and aligned manner that reflects evolving authority expectations. For sponsors, this provides access to the efficiency gains of AI adoption without the burden of building the governance and infrastructure required to deploy it responsibly.

The human element remains essential. Regulatory intelligence, however efficiently gathered, requires expert interpretation and contextual judgment, grounded in both global requirements and local implementation practices, as well as the experience-based knowledge developed over time. The value of AI in this space lies in its ability to amplify that expertise, not replace it.

Building for what comes next

The regulatory environment facing drug developers is not temporary. Divergence across markets will persist and the pace of change is unlikely to slow. New modalities, evolving safety expectations and shifting geopolitical conditions will continue to introduce complexity.

Organisations that manage this most effectively will treat regulatory capability as a strategic asset rather than an operational burden. This requires investment in expertise and structures that support flexibility over time.

FSP models offer a proven mechanism for building that capability. By combining centralised intelligence with locally embedded expertise and scalable resources, they help organisations stay ahead of change rather than react to it.

In an environment defined by uncertainty, the ability to move quickly and decisively is no longer just an advantage. It is a requirement for sustained success.

Myriam Antoun is Functional Lead, Regulatory Affairs, PPD FSP Solutions, part of the PPD clinical research business of Thermo Fisher Scientific

Novo Nordisk

GEORGE GODFREY

Novo Nordisk has appointed **George Godfrey** as Senior Director for Medical and Regulatory in the UK. Godfrey brings over 20 years' experience at the forefront of healthcare delivery spanning clinical medicine, pharmaceutical leadership and healthcare system transformation. In this role he will lead the UK's medical and regulatory functions.

Godfrey previously served as Head of Medical for Respiratory and Immunology for AstraZeneca UK, where he led multidisciplinary medical teams. Prior to this, George spent two years in Switzerland as Regional Medical Director for Cardiovascular, Renal and Metabolism across Europe and Canada.

Before moving into the pharmaceutical industry, George worked as a trained physician in anaesthesia and intensive care medicine, experience that continues to shape his commitment to improving patient care.

Stoke Therapeutics

THOMAS MCCAULEY

Stoke Therapeutics has appointed **Thomas McCauley** as Chief Scientific Officer (CSO). McCauley has more than 25 years' experience leading high-performing R&D teams and translating early scientific discoveries into clinical programmes that have delivered new medicines to people living with severe diseases. He brings extensive expertise in developing novel technology platforms and modalities across multiple therapeutic areas, including six years at Shire where he played a key role in the late-stage development and global approvals of multiple genetic medicines for rare diseases. McCauley was most recently President and CEO of Neptune Bio, and was previously CSO at Omega Therapeutics, Macrolide Pharmaceuticals and Translate Bio, and also held roles at Inotek and Archemix.

Inventiva

CHRIS BENECCHI

Inventiva has appointed **Chris Benecchi** as Chief Operating Officer. With extensive experience in building organisations, preparing medicines for launch and integrating cross-functional operations, Benecchi brings 30 years of biopharmaceutical leadership across commercial, operational and enterprise roles. He has a track record of building organisations, preparing innovative investigational medicines for launch and leading cross-functional execution in competitive and access-challenged markets. Most recently, he served as CEO of Motric Bio (an Aditum Bio company). Prior to that, he was Chief Operating Officer, Chief Business Officer and Chief Commercial Officer at Sage Therapeutics. He also held roles at UCB, Alexion, Acorda Therapeutics, Takeda and Johnson & Johnson.

LEO Pharma

HENRIETTE MERSEBACH

LEO Pharma has elected **Henriette Mersebach** as a member of the Board of Directors. Mersebach is on the Board of Trustees of the LEO Foundation and will serve as the second board representative on LEO Pharma's Board of Directors. Mersebach has more than 20 years' experience in global drug development, R&D strategy and enterprise leadership. She most recently served as Executive Vice President, Research & Development at ALK-Abelló, where she was a member of the Executive Leadership Team and led the company's R&D and innovation strategy. Mersebach also held several senior leadership positions at Novo Nordisk, including Corporate Project Vice President for Rare Disease & Advanced Therapies and Project Vice President in Global Development.

BeOne Medicines

KANDEEPAN GANESHALINGAM

BeOne Medicines has appointed **Kandeepan Ganeshalingam** as Vice-President, Head of Medical Affairs, Europe. Leading the Medical Affairs function, Ganeshalingam will strengthen scientific leadership, evidence generation and engagement with the global oncology community. He will also be part of the European Leadership and Europe Senior Management Teams.

Ganeshalingam has more than 25 years' experience spanning clinical medicine, oncology drug development and medical affairs. Most recently, Ganeshalingam was responsible for Oncology Medical across Pfizer's International Markets, including China and Japan.

Before joining Pfizer, he served as Vice President, Head of International Medical Affairs at Seagen. He has also held senior leadership roles at MSD, Roche and CSL Vifor.

HCA

EMMA KENNY

The Healthcare Communications Association (HCA) has announced that **Emma Kenny** will be the new interim CEO, following the departure of current CEO Mike Dixon. Dixon, who over the last nine years has been instrumental in the transformation of the HCA, is retiring from the role. Kenny, who has been at the heart of healthcare communications for over 25 years, has volunteered for the HCA for many years, most recently as a member of the board. She knows the organisation well and is ideally placed to ensure seamless continuity while a permanent CEO is identified. In announcing his departure, Dixon thanked all those who had supported him over the years, adding: "I look forward to seeing the organisation continue to go from strength to strength."

NRG Therapeutics

CLAUS SUNDGREEN

NRG Therapeutics has appointed **Claus Sundgreen** as Chief Medical Officer. With over 25 years of clinical leadership with experience spanning translational medicine and all phases of clinical development, Sundgreen will lead the company's clinical development strategy. With particular expertise in ALS, he has a proven track record of advancing innovative therapies for neurodegenerative diseases and orphan diseases. Prior to joining NRG, Sundgreen held senior medical leadership positions across biotechnology and pharmaceutical companies in Europe and the United States, providing strategic and operational leadership for innovative therapeutic programmes. His earlier career included Medical Director roles at Schering Plough and Nycomed.

CNX Therapeutics

LUCY RALPH

CNX Therapeutics has announced the permanent appointment of **Lucy Ralph** as Chief People and Transformation Officer. Ralph joined CNX in May 2026 as Interim Chief People Officer. She now moves into the role on a permanent basis, with an expanded remit that adds organisational transformation to her existing People responsibilities. In this broader role, Ralph will continue to lead CNX's people function while taking on responsibility for organisational transformation. She has extensive HR leadership, transformation and private equity experience. She spent almost 14 years at Evaluate, rising to Chief Human Resources Officer in 2018. After a merger, she went on to hold the dual role of Chief Administration Officer at Norstella from 2022.

Lucid Group

ERIC MULLER

Lucid Group has appointed **Eric Muller** as Chief Executive Officer (CEO). Muller will succeed CEO, and original DiD Agency founder, Rick Sannem.

Muller's immediate priorities centre on expanding talent, client partnerships as well as data and technological capabilities. He is a highly experienced executive who has operated both commercially and in senior leadership positions across global healthcare commercialisation for more than 25 years. Most recently, Muller was Group President and Chief Operating Officer of Publicis Health and previously held roles including President of Digitas Health. He began his career at Grey Advertising in New York.

Sannem, Strategic Advisor to Lucid's Board of Directors, said: "Eric's track record as a hands-on, transformative leader makes him the right person to lead Lucid into its next chapter of growth."

Envision Pharma Group

RYAN TUBBS

Envision Pharma Group has appointed **Ryan Tubbs** as Senior Vice President, Commercial Growth. In this newly created role, Tubbs will lead the centralised Commercial Growth function spanning sales enablement, lead generation, marketing and client success. He will also help shape the company's commercial strategy and operating model to accelerate enterprise growth. Tubbs brings more than two decades of commercial and customer leadership experience across enterprise software, healthcare and life sciences, higher education, and public sector organisations. He most recently served as SVP, Customer Success, Value & Managed Services at Ellucian, leading a global post-sale organisation, driving retention, expansion and margin performance.

VML Health

SUS MISRA

VML Health has appointed **Sus Misra** as Executive Director, Data & Analytics, a new role created to put advanced analytics, AI and health data strategy at the heart of client growth. Misra will lead VML Health's global data and analytics capability, building the infrastructure, governance and AI powered capabilities to turn complex health data ecosystems into clear commercial outcomes for the agency's pharma and life sciences clients. With more than 20 years' experience in health and marketing analytics, Misra has led data and measurement strategy for pharmaceutical and medtech clients across a number of therapeutic areas. Misra joins VML Health from Havas Media, where he served as SVP, Consumer Science & Analytics. Prior to this, he held senior roles at IPG and Publicis.

Saatchi & Saatchi

PEDRO ROSA AND MAY LEEN WONG

Saatchi & Saatchi Health London has appointed **Pedro Rosa** as Executive Creative Director and **May Leen Wong** as Head of Strategy. Rosa joins from a career including VML UK and Brazil, Grey London, Mother and AlmapBBDO. He will lead creative vision and culture across the agency. May Leen Wong joins with more than two decades of global experience spanning consumer, healthcare and wellness brands. She was most recently EVP, Executive Strategy Director at Havas Health. Rosa and Wong will be responsible for partnering closely with clients and teams. They will both report directly to Katie McMorran, Group Managing Director, who said: "Pedro and May both bring international experience, outstanding track records and a relentless belief in the power of creativity."

Prescient completes integration of Uptake and Dolon under single global brand

Healthcare consultancy Prescient Healthcare Group has completed the integration of recently acquired businesses Uptake and Dolon under a single global Prescient brand, creating an organisation of more than 550 specialists supporting life sciences companies across commercial strategy, competitive intelligence, medical affairs and value, pricing and access.

The rebrand marks the final stage of integrating the three businesses following Prescient's acquisitions of Uptake and Dolon, providing clients with a single point of access to expertise spanning the pharmaceutical product life cycle.

Jason McKenna, CEO of Prescient, said: "Over the past several months, the Prescient, Dolon and Uptake teams have been working together to solve increasingly complex challenges for clients. Bringing everything together under the Prescient name reflects how the platform works today, as one integrated organisation combining specialist expertise across commercial, medical and market access disciplines."

The unified business supports pharmaceutical and biotechnology companies from early clinical development through product launch and life cycle management. Prescient said the integrated structure enables multidisciplinary teams to address

increasingly connected commercial, scientific and market access challenges facing the industry.

The evolution reflects a broader way of partnering with life sciences organisations as they face increasingly interconnected scientific, commercial, medical and market access decisions. As a strategy-to-impact partner, Prescient helps clients move from insight, to strategy, to implementation, connecting the expertise needed at each stage of an asset's journey, from early development through launch and life cycle optimisation.

The unified Prescient brand also simplifies how clients engage with the business. Rather than navigating multiple brands, clients now access one connected organisation with specialist expertise across Commercial Strategy and Planning; Competitive Strategy; Medical Affairs and Real-World Evidence; and Value, Pricing and Access

The integration follows a period of operational alignment between the three organisations and establishes a single global Prescient brand across its seven international offices.

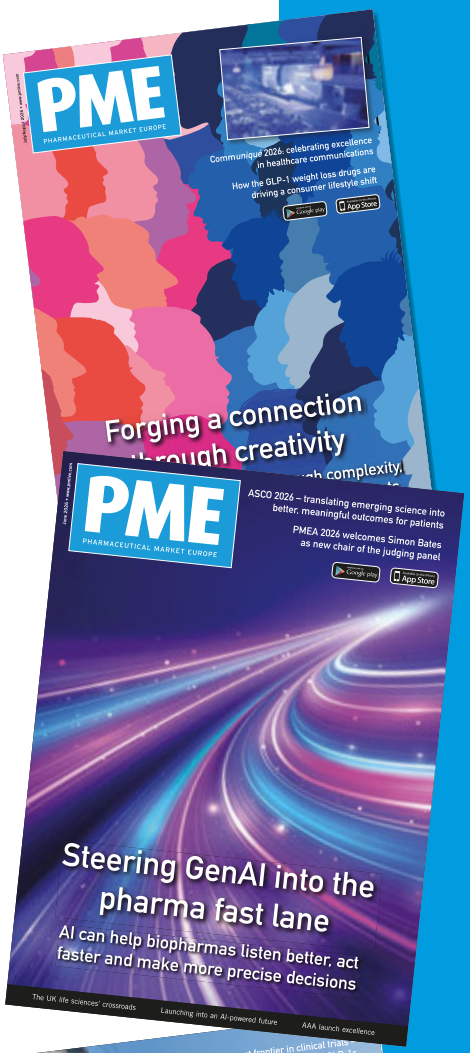
Havas Lynx expands Claire Knapp's remit to oversee Havas Lynx New York

Havas Lynx has announced that Claire Knapp, CEO of Havas Lynx UK (pictured top left), will expand her leadership remit to oversee Havas Lynx New York.

Knapp has spent more than 15 years at Havas Lynx, pioneering the agency's strategic offerings, and has held a series of leadership roles spanning strategy, innovation, client partnership and business growth. Throughout her career, she has led global, regional and local initiatives across creative and media disciplines, helping shape work across multiple therapeutic areas and advancing thought leadership on healthcare professional well-being, health misinformation, sustainability and patient-centricity. As part of her expanded remit, Knapp will be based in New York while dividing her time between the US and UK.

Dan Rubin, Group President, North America, Havas Health Network, said: "Claire's strategic vision, entrepreneurial mindset and commitment to leveraging creativity to deliver impact that matters have helped drive the agency's evolution, growth and reputation for excellence. Claire's leadership, coupled with her passion for innovation and talent development, positions Havas Lynx strongly for its next chapter."

Knapp commented: "Healthcare continues to evolve at an incredible pace, creating new opportunities for creativity, innovation and connection. I'm excited to build on the strong foundation we've created, alongside our teams around the world."



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