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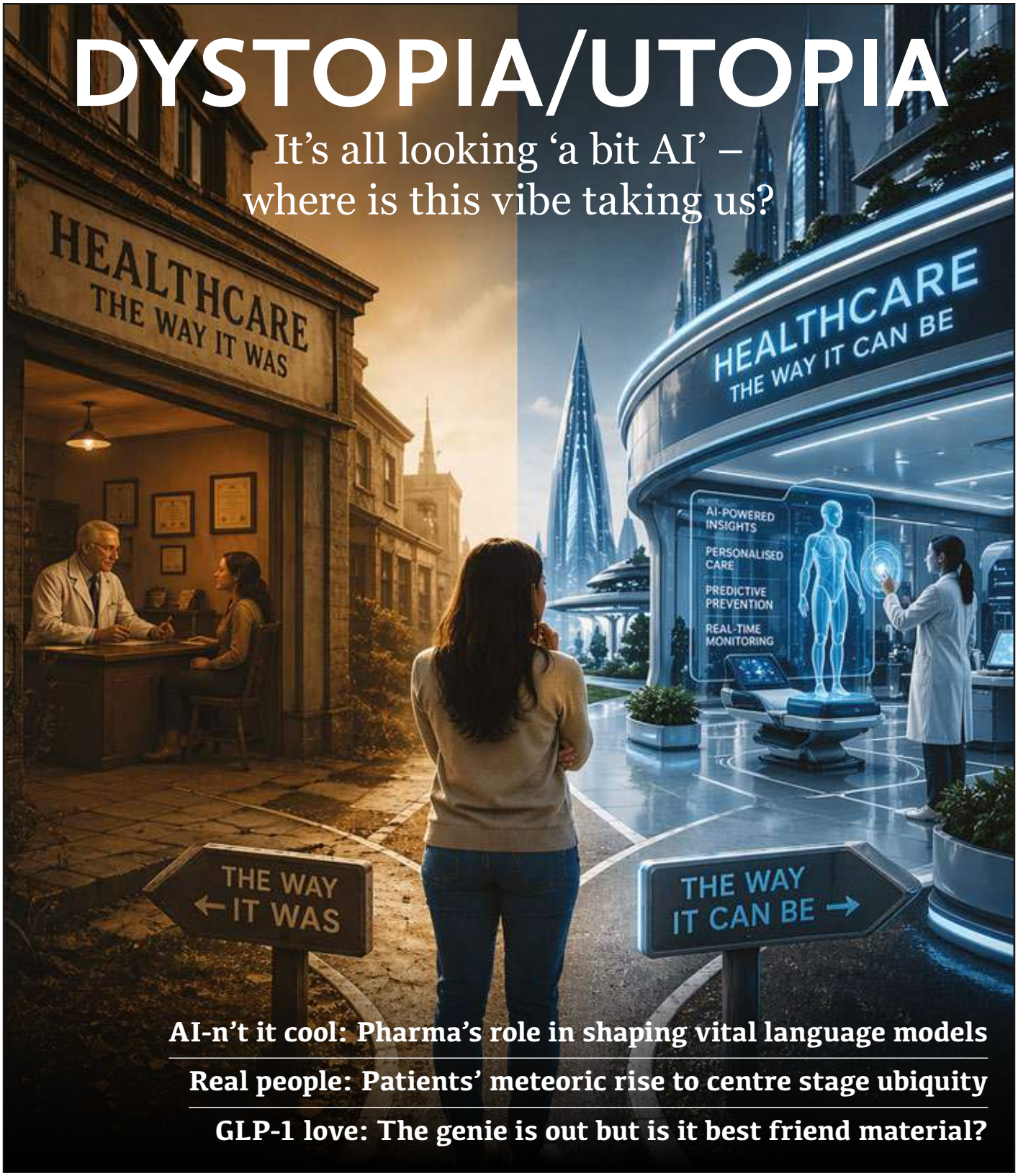

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The opioid in the room

In politics and in pharma, as in life itself, the forbidden fruit of instant gratification is ubiquitous and, even knowing about the acridity beneath its shallow veneer, we so often make ourselves oblivious to its deadly presence.

Our eyes are seduced – they start rotating like kaleidoscopic spiralled lollies at a hypnotic fairground – and, at that crucial moment, all we can see is colour such as no palette has ever hosted before.

Opting for the radiance of the moment rather than the clarity of consequence happens when people are convinced by economic ignition or deafening applause or an untouchable conviction in themselves to make decisions.

And these judgements unfold in a portal that exists outside common knowledge, involving things that are embarrassingly obvious to literally everyone else.

But the forbidden fruit starts to rot at extraordinary speed. The primrose path that Peter Mandelson and Keir Starmer skipped down is now a burnt-out wasteland dotted with dystopian signs that hint at the horror.

Pharma has its own history. Opioids, without due care, can quickly emerge as the Mandelson of the medicine cabinet. A way to 'get in there', appear to expunge the pain, before becoming seemingly indispensable.

Life sciences wider history shows that a positive legacy happens when you don't get distracted by a low-hanging crowd-pleaser but when data, trials and patients combine to big up life in a way that inspires delight not disdain.

Enjoy the mag,

John Pinching
editor

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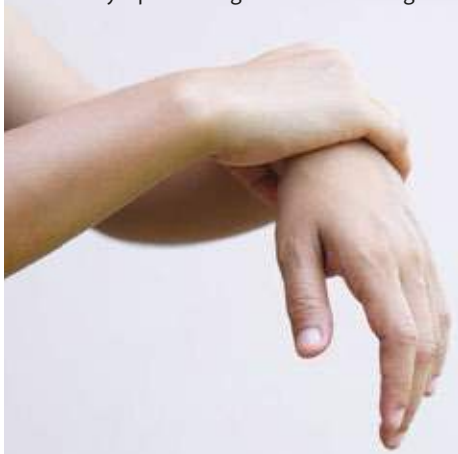
Kygevvi approved in Europe as first treatment for TK2d

UCB has received European Commission approval for Kygevvi, the first and only authorised treatment for thymidine kinase 2 deficiency, an ultra-rare and life-threatening mitochondrial condition marked by progressive muscle weakness.

The decision covers paediatric and adult patients with genetically confirmed TK2d whose symptoms began at or before age 12.



Announcing the approval, UCB said Kygevvi is a 2g doxecitine/2g doxribtimine powder for oral solution and represents the first therapy available in the European Union beyond supportive care. The company noted that TK2d places a significant burden on patients and families due to its severe and progressive nature.

Donatello Crocetta, Chief Medical Officer at UCB, said: "The European Commission's approval of KYGEVVI marks a historic milestone for the TK2d community. For the first time, people across Europe living with this ultra-rare, life-threatening mitochondrial disease have access to an approved treatment beyond supportive care.

"KYGEVVI is designed to support mitochondrial DNA maintenance in skeletal muscle, addressing a key biological driver of TK2d. We are deeply grateful to the patients, families, advocates, investigators and clinical trial teams whose partnership, trust and resilience made this achievement possible."

Caterina Garone, Associate Professor of Medical Genetics at the University of Bologna, said: "TK2d has a profound impact on people living with the condition and their families and, until now, they have faced a heavy burden of unmet treatment need with incredible resilience."

The approval is supported by pooled data from two studies in patients with symptom onset at or before age 12. The trials assessed motor milestones, ventilatory and feeding support and survival. According to the data, Kygevvi was well tolerated, with the most common adverse reactions being diarrhoea, vomiting and abdominal pain.

Across the studies, 26 of 31 patients regained one or more motor milestones after starting treatment. Changes in ventilatory and feeding support also suggested clinical benefit, with some patients discontinuing support after initiation of therapy.

Tozorakimab shows significant benefit in two major COPD trials

Positive high-level results from the phase 3 OBERON and TITANIA trials indicate that tozorakimab achieved statistically significant and clinically meaningful reductions in the annualised rate of moderate-to-severe COPD exacerbations compared with placebo.

The findings applied both to the primary population of former smokers and to the overall population, which included former and current smokers, with patients spanning all blood eosinophil counts and all stages of lung function severity. According to the data, tozorakimab was generally well tolerated with a favourable safety profile.

Tozorakimab is described as a potential first-in-class monoclonal antibody targeting interleukin-33, uniquely inhibiting signalling of both the reduced and oxidised forms of IL-33. The approach aims to reduce inflammation and disrupt the cycle of mucus dysfunction that contributes to COPD worsening.

In both trials, patients continued to experience exacerbations despite inhaled standard of care and received either tozorakimab 300mg or placebo once every four weeks on top of their existing treatment.

COPD affects nearly 400 million people worldwide and remains the third leading cause of death globally. Even with inhaled standard of care, more than half of patients continue to experience exacerbations, increasing the risk of cardiopulmonary events and mortality.

Frank Sciurba, Professor of Pulmonary and Critical Care Medicine at the University of Pittsburgh and Chief Investigator of the LUNA programme, said: "These trial results

suggest that targeting the IL-33 pathway with tozorakimab delivers meaningful clinical benefit in a trial representing a broad COPD population, independent of smoking status and eosinophilic levels.

"COPD has long been a difficult-to-treat disease with inherent heterogeneity and significant unmet need, with up to half of patients worldwide at risk of exacerbations, hospitalisations, cardiopulmonary events and death — underscoring the importance of these results for advancing COPD science."

Oxford BioTherapeutics in collaboration with Bristol Myers Squibb

Oxford BioTherapeutics has entered a multi-year collaboration with Bristol Myers Squibb to discover and develop novel T-cell engager therapies for solid tumours, marking the company's third major pharma partnership in 12 months.

The agreement will see OBT apply its OGAP-Verify discovery and validation platform to identify tumour-selective targets and generate next-generation T-cell engager molecules.

The company will also design and deliver development candidates, reflecting its expansion into a fully integrated discovery and preclinical development organisation. BMS will lead subsequent research, development and commercialisation.

Under the terms of the deal, OBT will receive an upfront payment inclusive of research funding, along with potential milestone payments and royalties on commercialised products. Financial details were not disclosed.

The collaboration follows partnerships signed with GSK and Roche in 2025, reinforcing growing industry confidence in OBT's platform.

Christian Rohlff, Chief Executive Officer of OBT, said: "Collaborating with Bristol Myers Squibb, a global leader in oncology, represents an important milestone for OBT and underscores the momentum behind our partnerships with leading pharmaceutical companies."

He added: "This new partnership builds on the proven strength of our platform to identify and validate highly differentiated, tumour-selective targets and reflects the growing confidence in our ability to translate that science into development-ready therapeutic candidates.

"By combining OGAP-Verify's discovery and validation capabilities with Bristol Myers Squibb's expertise in translating oncology innovation into clinical and commercial outcomes, we are confident that together we can advance a new generation of innovative cancer therapies that have the potential to make a meaningful difference for patients."

DNA Script signs distribution agreements with Gencell, BMS and Biostream

Providing automated, in-house and on demand oligonucleotide production in only a few hours, the SYNTAX platform will be distributed across Latin American by Gencell and in South Korea by BMS, with customers in Japan to be supported by Biostream.

Each of the companies distributing SYNTAX will provide local access to DNA synthesis without a reliance on overseas manufacturing, through established regional networks, shifting the current centralised supply chains to local DNA production.

Iwabuchi Takeshi, President of BioStream, said: "This partnership strengthens our ability to deliver advanced life sciences technologies throughout Japan, helping customers reduce dependence on overseas synthesis and long delivery timelines."

While oligonucleotides are a critical input for a wide range of applications, researchers who are located far away from large-scale synthesis centres can experience long delivery times or logistical constraints, leading to project delays.

Dukhyun Lim, Vice President of Bio-Medical Science, BMS, said: "SYNTAX offers researchers greater control and speed in

oligonucleotide production, enabling increased independence and control over project workflows, and we are pleased to support its availability in South Korea."

The aim of the expansion is to broaden the global use of SYNTAX to allow researchers who are far from the oligonucleotide production hubs in Europe and the US to access DNA faster and more reliably.

Kainova expands DT 7012 trial into Europe

Kainova Therapeutics has dosed the first patient in the European expansion of its DOMISOL phase 1/2 trial of DT 7012, a Treg-depleting anti-CCR8 antibody, marking a key step in the company's global development strategy.

The study, which began in Australia in October 2025, is now enrolling patients at leading oncology centres in France, including Hôpitaux Universitaires de Strasbourg, Institut Gustave Roussy in Paris and Institut Bergonié Bordeaux.

The programme is being led by early-phase investigators Dr Lauriane Eberst, Professor Antoine Italiano and Dr Maxime Brunet.

Professor Antoine Italiano, Head of Precision Medicine at Institut Gustave Roussy, said: "This study brings together strong clinical expertise and advanced translational capabilities, creating an important opportunity to explore how targeted Treg depletion may translate into meaningful benefit for patients with advanced solid tumours. DT 7012 offers a novel, differentiated approach to precisely address CCR8 biology and reshape the tumour microenvironment."

Dr Jean Marie Cuillerot, Chief Medical Officer at Kainova Therapeutics, explained: "Dosing of the first patient in Europe marks an important step in the clinical maturation of our flagship programme, DT 7012.

"The DOMISOL study has been designed to generate a comprehensive clinical and biological profile for DT 7012 across both monotherapy and combination settings, including paired biopsies to directly assess the intra-tumoral Treg depletion. These data will be essential to inform dose selection and support the next phases of development."

Amgen reports positive phase 3 results for subcutaneous TEPEZZA

Amgen has announced positive topline findings from a phase 3 study evaluating a subcutaneous formulation of Tepezza in adults with moderate-to-severe active thyroid eye disease (TED).

The company said the on-body injector version delivered efficacy comparable to the intravenous formulation, which is currently the only approved treatment for the condition.

The phase 3 trial met its primary endpoint, with a statistically significant and clinically meaningful proptosis response rate of 76.7 percent at week 24 compared with 19.6 percent for placebo. Mean proptosis reduction reached 3.17 mm, exceeding the threshold regarded as clinically meaningful.

Jay Bradner, executive vice president of Research and Development at Amgen, said: "These results extend and support the best-in-class efficacy of TEPEZZA for people living with thyroid eye disease, now with subcutaneous administration delivering IV-level efficacy."

He added: "With a well-understood mechanism and established impact in the clinic, we can evolve how the medicine is delivered to potentially reach even more patients through a more convenient subcutaneous option."

The study also demonstrated statistically significant improvements across several secondary endpoints, including overall responder rate, Clinical Activity Score of 0 or 1, diplopia measures and the Graves' Ophthalmopathy Quality of Life appearance subscale. A numerical trend favouring Tepezza was observed in the visual functioning subscale, although this did not reach statistical significance.

HOT & NOT

Johnson & Johnson has announced a landmark regulatory decision that will allow people living with multiple myeloma to administer the subcutaneous formulation of daratumumab themselves, or have it given by a caregiver, from the fifth dose.

The Committee for Medicinal Products for Human Use has approved a Type II variation to the medicine's labelling, making it the first oncology injectable in Europe cleared for self-administration.

Viridian Therapeutics has announced encouraging topline results from its REVEAL-1 phase 3 clinical trial evaluating elegrobart in patients with active thyroid eye disease.

The study tested two subcutaneous dosing schedules – every four weeks and every eight weeks – against placebo. According to the company, both regimens achieved clinically meaningful improvements in proptosis, with responder rates of 54% and 63% respectively, compared with 18 percent for placebo at week 24.

Positive high-level results from the phase 3 OBERON and TITANIA trials indicate that **AstraZeneca's** tozorakimab achieved statistically significant and clinically meaningful reductions in the annualised rate of moderate-to-severe COPD exacerbations compared with placebo.

The findings applied both to the primary population of former smokers and to the overall population, which included former and current smokers, with patients spanning all blood eosinophil counts and all stages of lung function severity.

FDA approves new high-dose Spinraza regimen for SMA

Biogen has received approval from the US Food and Drug Administration for a new high-dose regimen of Spinraza for the treatment of spinal muscular atrophy (SMA).

The company said the regimen, which includes 50mg and 28mg doses, was designed to deliver a higher concentration of the drug during both loading and maintenance phases.

The approval is based on data from the phase 2/3 Devote study, which evaluated the efficacy and safety of the high-dose regimen in both treatment-naïve patients and those previously treated with Spinraza.

The company said the new regimen will be available in the United States in the coming weeks and is already approved in the European Union, Switzerland and Japan.

Richard Finkel, director of the Center for Experimental Neurotherapeutics at St Jude Children's Research Hospital, said: "Optimising the dose of nusinersen builds on a therapy that we already know can change lives.

"The high-dose regimen demonstrated meaningful clinical benefit while maintaining a well-characterised safety profile." He added: "I believe high-dose Spinraza will play an important role in the future of SMA care."

The Devote study showed that treatment-naïve infants receiving the high dose experienced statistically significant improvements in motor function compared with a prespecified matched sham group. Biogen said the safety profile was generally consistent with the known safety of the low-dose regimen.

Cure Parkinson's convenes expert panel to assess funding call

Cure Parkinson's has announced the formation of a new evaluation panel to review applications submitted to its recent £2 million funding call for projects investigating combination therapies for Parkinson's. The panel will meet in April, with final funding decisions expected in May.

The charity said proposals include both preclinical and clinical studies testing rationally designed treatment combinations. The panel will assess whether the projects are scientifically robust, aligned with Cure Parkinson's mission and capable of generating results that matter to the Parkinson's community.

To ensure rigorous evaluation, the group brings together expertise in drug discovery, statistics, pharmacology and clinical trials.

Chaired by Professor Fiona Ducotterd, Chief Scientific Officer of the Alzheimer's Research UK UCL Drug Discovery Institute, the panel includes academics, industry specialists, clinicians and people with Parkinson's. Members are Ian Reynolds, Kevin McFarthing, Kalpana Merchant, Dave Weiner, Peter Debiaso, Caroline Williams-Gray, James Wason, Sue Learned, Jérémie Nsengimana, Camille Carroll and Michele Hu.

Combination therapies use two or more active treatments that may target different pathways or enhance each other's effects. They are already used to manage Parkinson's symptoms, such as co-careldopa, which combines levodopa and carbidopa. Cure Parkinson's said it hopes to encourage further research into whether such approaches could also modify the course of the disease.

CatalYm has dosed the first patient in its global GDFATHER-HCC-01 study, a phase 2b trial evaluating visugromab in combination with chemoimmunotherapy for people with unresectable or metastatic hepatocellular carcinoma who have progressed after first-line anti-PD-(L)1 therapy.

The study will test visugromab alongside nivolumab and the tyrosine kinase inhibitor lenvatinib. It begins with an open-label safety run-in to confirm the recommended dose for expansion.

Recent **NHS** setbacks include rising waiting lists, renewed strike action by junior doctors and warnings from hospital leaders that services are becoming increasingly unsafe. Financial pressures have deepened, with several Trusts reporting severe budget gaps and delays to planned upgrades.

Emergency departments continue to miss key targets, and staff shortages are worsening morale. Critics say the system is struggling to recover, leaving patients facing longer delays and reduced access to care.

Responding to the news that the BMA Resident Doctors Committee has rejected the government's offer and called for six days of strike action, **NHS Confederation's** Rory Deighton, said:

"These strikes not only cause appointments to be cancelled and patients to have to wait longer for tests, treatment and surgery, but also cost up to £300m each time – money that would be better spent on patient care. They also undermine the capacity NHS leaders and their teams have to modernise and transform services."

Crossroads

Patients are missing strategy – pharma must seize the day

For decades, pharmaceuticals have operated as functional interventions in a patient's journey.

A prescription is issued, instructions are followed and outcomes are measured clinically. The relationship is transactional: diagnose; treat; move on.

But that model is breaking down.

Patients are no longer passive participants in their care. Trust in the system is breaking down. They are actively seeking information, experimenting with treatments and, crucially, making decisions outside of clinical advice.

Platforms like TikTok have become informal health advisors, where millions of users share personal protocols, miracle cures and medication hacks. Anecdotal advice spreads faster than peer-reviewed evidence.

From a traditional healthcare perspective, this is concerning. From a consumer behaviour perspective, it is entirely predictable.

Behaviours such as micro-dosing Ozempic signal something deeper than non-compliance, they signal adaptation. Patients are not rejecting medicine; they are trying to make it work for their lives.

The uncomfortable truth for pharma is this: when patients turn to influencers over institutions, it is rarely because they prefer misinformation. It is because they are missing something essential from the system itself. This represents both a risk and a significant opportunity.

Trust in healthcare has traditionally been institutional. It has been built through clinical authority, regulation and evidence. But this has never been transparent to the consumers, and now they want more.

Patients now compare healthcare to every other service they use – retail, fintech, hospitality. They expect clarity, responsiveness, personalisation and ongoing support.

In this context, pharma's historic distance from the end user becomes a liability. The industry has optimised for safety, efficacy and distribution but not for relationships.

There are exceptions of course. Pfizer's consumer strategy around Viagra demonstrated that brand, education and direct engagement can drive both uptake and loyalty. But these examples remain the minority.

More recently, Novo Nordisk has invested heavily in patient support ecosystems around GLP-1 therapies such as Wegovy.

Haleon, a spin-out of GSK, is building direct consumer health brands with educational and behavioural components.

Digital health platforms like Hims & Hers Health are redefining the experience by combining prescription access with ongoing support, content and subscription models.

These models move beyond the product itself. They begin to address the surrounding experience. However, most still stop short of delivering what patients are clearly asking for: a structured, adaptive strategy for managing their condition.

This becomes particularly evident in chronic conditions such as diabetes, obesity, depression, endometriosis and chronic pain, where outcomes are not determined by a single intervention but by sustained behavioural and lifestyle change over time.

In these contexts, treatment exists on two planes – short-term interventions (medication, symptom relief, acute care) and long-term outcomes (behaviour change, lifestyle adaptation, prevention).

Pharma has historically excelled at the former. It has largely outsourced the latter.

Patients are told what to take, but not always how to live with their condition in a way that leads to meaningful, sustained improvement.

Guidance around nutrition, movement, stress and adherence is often generic or fragmented, or deprioritised due to time constraints in clinical settings and fear of regulation.

The rapid adoption of GLP-1 therapies provides a glimpse into what comes next. These drugs are clinically effective in driving weight loss, but their long-term success is not pharmacological alone.

> **'Patients are not rejecting medicine, they are trying to make it work for their lives'**

Patients must adapt diet, activity and behaviours to sustain outcomes. Without this, discontinuation often leads to regression.

What is emerging around these therapies in the private health sector is telling: companion apps; coaching services; nutrition guidance; behavioural tracking. The race is on. In other words, an ecosystem, not just a product.

Novo Nordisk has begun investing in these supporting layers, but the most aggressive moves are coming from outside traditional pharma.

The commercial implication is significant. The winning model will not be the molecule alone, but the system around it. The provider that helps patients achieve sustained outcomes, not just initial results, will capture long-term value.

Look at start-ups like Aide Health entering the market.

How does pharma enter this space successfully?

With human-centred design.

It starts from a simple premise: design for how people actually behave, not how we would like them to behave. The reality is people are time-poor, behaviour change is difficult to sustain, motivation fluctuates and information overload leads to paralysis.


HEALTHCARE
THE WAY IT WAS
HEALTHCARE
THE WAY IT CAN BE
AI-POWERED INSIGHTS
PERSONALISED CARE
PREDICTIVE PREVENTION
REAL-TIME MONITORING
THE WAY ← IT WAS
THE WAY IT CAN BE →

Telling patients to 'eat better' or 'exercise more' is not a strategy. It is an aspiration.

What patients need is clarity (what matters most now), prioritisation (what to focus on first), feedback (whether what they are doing is working) and adaptation (how to adjust based on results).

In other words, they need a roadmap that shows where they are, where they are headed and how to get there.

Patients are already generating vast amounts of health data – symptoms, side effects, lifestyle changes and outcomes. Today, much of this data is lost, fragmented across apps or never captured at all.

If integrated responsibly, this data could improve individual patient outcomes through personalisation, generate real-world evidence at scale and inform future treatment development. This requires a shift from designing for patients to designing with them.

Co-designed health plans where patients actively contribute data, feedback and preferences enable systems that evolve in real time.

Advances in AI make it increasingly feasible to translate this data into actionable insights at scale, and pathways to regulatory approval (SAMD) are now achievable in six-month timeframes.

'The winning model will not be the molecule alone, but the system around it'

This is not about replacing clinical guidance. It is about extending it, in a way that consumers feel valued. Building trust where there is none.

For pharma, this represents a strategic choice: remain a product provider within a fragmented ecosystem or become an orchestrator of outcomes.

This is not just a patient experience issue. It is a market opportunity. According to McKinsey Health Institute, closing the women's health gap alone could unlock $1 trillion in global economic value annually by 2040.

This figure is not driven by new drugs alone, but by better outcomes – reducing time spent in poor health, improving productivity and addressing systemic gaps in care.

Women currently spend 25% more of their lives in poor health than men, highlighting both unmet need and underinvestment.

The implication is clear: value will increasingly be created not just through innovation in treatment, but through innovation in delivery, experience and long-term outcomes. In other words, strategy at scale.

This is not just a direct-to-consumer strategy. HCPs are increasingly looking for solutions that help them achieve their targets – fewer hospital readmissions, reduced disease progression, lower reliance on costly procedures, improved long-term patient stability.

Their buying decisions are vested in improved adherence, services that support behaviour change, provide visibility into patient progress and reduce long-term intervention costs.

The pharmaceutical partner that can support these goals through integrated services, not just products, becomes significantly more valuable.

For commercial and digital leaders in pharma, the implications are clear. The competitive advantage is shifting from product efficacy alone to experience and outcomes over time.

This means asking different questions; how do we go beyond prescriptions and information to provide support services that achieve long-term outcomes? How do we build trust in a landscape where alternative sources of information are thriving?

The answer is not more content. It is better-designed systems.

Patients are not missing motivation; they are missing structure outside the GP surgery. They want to feel in control of their health, to understand what is working and to see progress over time.

In the absence of this, they will continue to experiment, sometimes successfully, often not. They are trying to build strategies for their health without the tools, frameworks or feedback loops to do so effectively.

If pharma does not step into this space, others will. ▲

Polly Thompson is Customer Strategy Director at B33 Design

Patients please – bedside bullet points

1. In the early 1900s, most patients were treated at home, not in hospitals, and family members provided the majority of care

2. The average hospital stay in the 1920s was more than three weeks, compared with just a few days today

3. Before antibiotics became widely available in the 1940s, minor infections were among the leading causes of death for patients of all ages

4. The introduction of penicillin in 1942 transformed patient survival, reducing deaths from bacterial infections by more than 80% within a decade

5. In the 1950s, patients were rarely told their diagnosis directly, especially in cases of cancer, as doctors believed disclosure would cause harm

6. The first patient controlled analgesia pumps in the 1970s marked a major shift towards patient autonomy in managing pain

7. The rise of patient advocacy groups in the 1980s, particularly during the HIV/AIDS crisis, reshaped global health policy and accelerated drug approvals

8. By the 1990s, the internet had become a primary source of health information, fundamentally changing how patients prepared for consultations

9. The 21st century saw the emergence of patients as data generators, with wearables and apps producing continuous health information for the first time

10. Today's patients make more independent health decisions than any generation before them, often blending clinical advice with digital, social and behavioural inputs.

laboratory news

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Pharma chameleon

The digital maturity gap – how AI is reshaping pharma operations

As AI rapidly matures, it is not simply accelerating innovation – it is exposing the true digital readiness of organisations across the pharma sector.

Digital transformation has become critical to operational resilience, regulatory confidence and competitive advantage in pharma. For some, AI is a catalyst for scale and insight. For others, it highlights fragmented systems, weak data foundations and decision-making blind spots.

As adoption accelerates, the digital maturity gap is becoming more visible in everyday operations – from compliance to supply chain and R&D – making digital maturity a defining factor in performance and control.

The digital and AI shifts reshaping pharma

Digital capability is now a prerequisite for transformation across the pharma value chain, with core platforms expected to operate as connected ecosystems rather than standalone tools.

For organisations that have done the foundational work, AI amplifies this shift – turning clean, integrated data into predictive insights, automation and accelerated decision-making. But the inverse is equally true. AI also exposes weak foundations, amplifying poor data quality and increasing risk for organisations with weak digital foundations.

This widening maturity gap demonstrates how leaders are separating from followers, not through isolated pilots, but through sustained, enterprise-wide capability building. AI is no longer a future differentiator; it is the lens through which digital maturity is being measured today.

AI's value in pharma emerges most clearly when applied within connected, well-governed environments, enhancing core systems for better decision-making and risk management at scale.

In compliance, AI enables a shift from reactive to predictive quality in environments where strong data integrity, traceability and validation practices meet emerging regulatory expectations, such as the draft EU GMP Annex 22.

In R&D, AI accelerates insight generation and informed prioritisation, dependent on harmonised and traceable data across systems.

In supply chains, it strengthens forecasting and reliability but relies on consistent master data and processes.

In each case, AI does not remove the need for strong operational discipline – it reinforces it. The organisations realising value are those that view AI as an extension of their digital backbone, not a shortcut around it.

Practical opportunities to close the maturity gap

1. Strengthening compliance and quality

AI can transform quality management by moving from reactive responses to predictive control. To do so responsibly, organisations must prioritise data integrity, standardised processes, clear data ownership and validation practices aligned to AI guidance

2. Accelerating R&D and insight generation

AI has the potential to restructure R&D timelines rather than just trimming them. By scanning vast data sets, AI can pinpoint new therapeutic targets, predict toxicity early and optimise trials, reducing costly late stage failures. Success depends on harmonised, high quality data and clear ownership, often starting with a robust data readiness assessment

3. Building supply chain resilience

AI-enabled demand sensing, risk prediction and scenario modelling can improve reliability across internal and CMO networks. These capabilities depend on trusted data and standardised processes across the end-to-end supply chain

4. Enhancing go-to-market and customer engagement

AI supports more personalised engagement across commercial and medical functions when customer, product and regulatory data are aligned. Strong governance remains critical to ensure traceability, content control and compliance.

Turning the maturity gap into an advantage

AI represents one of the most powerful catalysts for change in pharma – but only for organisations prepared to use it responsibly.

Leaders who view AI as a business transformation, rather than isolated innovation, will be best positioned to turn AI into a source of sustained advantage.

Those that do not risk falling further behind in an industry where speed, trust and precision are increasingly non-negotiable. ▲

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Risky business

The rise of GLP-1 drugs – why faster progress won't fix pharma's challenges

Time to market drives billions in value but fragmented systems create hidden risks.

The pharmaceutical industry has never been slow, but the arrival of blockbuster GLP-1 drugs has accelerated its pace to a new extreme.

For companies developing these diabetes and obesity treatments, even a single week's delay in reaching the market can translate into millions in missed revenue.

Under this pressure, manufacturers are being forced to rethink how they operate. Speed is no longer just one performance metric among many – it has become central to the entire business model, reshaping how the industry approaches production from the ground up.

Move fast or fall behind

Drug patents last 20 years. Roughly half that time is consumed by clinical trials and regulatory approvals before the first commercial batch is ever produced.

Once a patent expires, products typically lose around 90 percent of their value within six months.

Every delay at the manufacturing stage permanently erodes value that can never be recovered.

This is why, when capacity is constrained, companies rush to build plants quickly and instinctively avoid anything that looks like a large, disruptive IT programme. The objective is to produce compliant product – as fast as possible.

The 'fat jabs' boom

In a GLP-1 market, this pressure is amplified. For example, take Lilly's Mounjaro and Zepbound. With annual combined revenues of $36.5 billion, the drugs generate roughly $100 million per day.

Launching just two weeks earlier adds billions in value. Few capital decisions in pharma can match that return.

In the US alone, around $600 billion worth of new pharmaceutical facilities is expected over the next five years, driven by government incentives, geopolitical pressure to onshore production and the rise of GLP-1 drugs alongside personalised medicine.

Speed to market dominates every decision. This means compliance responsibility is increasingly pushed onto suppliers and contract manufacturers to accelerate timelines.

The speed dilemma

To move quickly, many companies are buying skid-based manufacturing units – modular, pre-assembled systems – that arrive pre-qualified. It is an effective way to compress project schedules, but it fragments data ownership.

Instead of one coherent operational system, companies end up with dozens. Engineering data, process data, quality data and production records reside in different environments, owned by different vendors.

It is not uncommon to see 25 or more systems supporting a single product. The industry as a whole has been slow to move beyond isolated use cases to more holistic digital transformation.

This fragmentation exists largely because there are no industry-wide standard data models or exchange structures, with each supplier solving immediate project needs. It is also partly due to the challenges of introducing new digital tools in such a heavily regulated industry.

But here's the rub: fragmented data makes it harder to analyse performance holistically, identify bottlenecks and improve processes.

'Speed is no longer just one performance metric among many – it has become central to the entire business model'

It also makes regulatory review more manual, more error-prone and more expensive, precisely when volumes are ramping up.

Using AI where it counts

Much of the public conversation around AI in pharma focuses on discovery. However, in practice, the most impactful applications today sit much closer to manufacturing.

Many pharma companies rely on multiple contract manufacturing organisations (CMOs) and contract development and manufacturing organisations (CDMOs) to meet GLP-1 demand. Each batch generates extensive documentation, often PDFs, that must be reviewed for compliance.

In many organisations, this review is still manual. Teams extract KPIs, temperatures, limits and deviations by hand and re-enter them into spreadsheets. It is slow, labour-intensive and risky.

AI can change this through rule-based, narrowly scoped applications that extract and validate data automatically. Instead of humans transcribing information, AI systems surface exceptions, flag deviations and accelerate review cycles.

The pattern extends to other applications, such as predictive maintenance that reduces unplanned downtime during high-volume GLP-1 campaigns.

The common thread is specificity. The AI that works in pharma is narrow, transparent and designed to augment human judgement rather than replace it.

Keeping up with regulations

In Europe, Annex 11 and the forthcoming updates to Annex 22 provide early signals of how regulators are thinking about AI in regulated manufacturing environments.

The emphasis is not on banning AI but on ensuring transparency and accountability, particularly for GxP decisions that affect product quality or patient safety.

Three requirements are emerging as non-negotiable:

Traceability: Every AI-generated output must be traceable to its inputs, training data and model version.

Explainability: Black-box models are unacceptable for GxP decisions.

If an AI recommends a process adjustment or supports batch release, the logic must be interpretable by domain experts and auditable by inspectors.

Human oversight: AI can assist, but it cannot autonomously make decisions that affect product quality or patient safety. A qualified person must review, validate and take accountability for the outcome.

These design constraints separate credible industrial AI from research prototypes. AI that cannot be explained, validated or audited will struggle to move beyond pilot phases. AI designed with regulation in mind will not.

Importance of data

Successful AI integration also depends on reliable operational data. Organisations must check that data is FAIR:

- Findable: Operators and analysts need to locate relevant data easily using standardised metadata and identifiers
- Accessible: Data must be securely accessible, enabling sharing within and across teams while maintaining compliance with GxP and ISO standards
- Interoperable: Data should be formatted and structured so different systems can understand and use it, breaking down silos
- Reusable: Data must be well documented and trustworthy enough to be reused in new experiments or AI models without regeneration.

By leveraging this operational data, medicines can reach the market faster while maintaining safety and quality.

Maintaining accountability when outsourcing

CMOs and CDMOs are indispensable partners in scaling production quickly. But outsourcing does not transfer accountability.

If a company's name is on the box, it remains legally responsible for what is inside it.

That responsibility extends to data integrity, auditability and regulatory compliance, regardless of where manufacturing takes place.

Without data continuity across internal operations and external partners, companies risk losing control precisely when scrutiny is greatest.

The non-negotiables

The lesson from GLP-1 is that speed must become sustainable.

The companies that come out on top will not simply be those that get to market fastest. They will be those that deploy capital projects intelligently, maintain data continuity across R&D, manufacturing and supply chains, and use AI to make faster, better-informed decisions.

That means treating data interoperability as a capital project requirement and deploying AI where it eliminates manual reconciliation – batch record review and deviation detection – without introducing new compliance risks.

It also means setting contractual requirements for how CDMOs structure and deliver batch data, pushing for real-time access to critical process parameters rather than PDF exports.

Most critically, it means assigning accountability for end-to-end data architecture. In many pharma organisations, IT owns systems, quality owns compliance and operations owns production, but no one owns the data architecture that allows them to work as one.

That needs to change.

In a GLP-1 world, speed has become a defining advantage. But the real test is whether such momentum can be sustained under scrutiny.

Success will depend on balancing rapid execution with long-term resilience; manufacturers must ensure progress holds up not only through the next quarterly earnings cycle but also under the weight of regulatory review and ongoing market expectations. ▲

GLP-1 to 10 – fun facts

1. They were never originally designed for weight loss GLP-1 receptor agonists were developed for type 2 diabetes because they stimulate insulin release, suppress glucagon and slow gastric emptying. The dramatic weight loss effect was initially a secondary observation in clinical trials

2. They reshape appetite signalling in the brain GLP-1s do not simply reduce hunger; they modulate reward pathways in the hypothalamus and mesolimbic system. This means people often report reduced cravings, lower impulsive eating and less emotional eating, not just smaller portions

3. They slow stomach emptying – but only temporarily Early in treatment, gastric emptying slows significantly, contributing to early satiety. Over time, this effect diminishes as the body adapts, but the central appetite effects remain strong

4. They may influence addiction pathways Emerging research suggests GLP-1 drugs may reduce addictive behaviours, including alcohol and nicotine use. This is because GLP-1 receptors are present in dopamine-driven reward circuits. Several trials are now exploring this directly

5. They dramatically reduce cardiovascular risk Beyond weight loss and glucose control, GLP-1s have shown robust reductions in major cardiovascular events. This makes them one of the few metabolic drugs with proven heart protective benefits

6. They are transforming supply chains and manufacturing Demand for GLP-1s is so intense that it is reshaping global pharmaceutical capacity. Billions are being invested in new facilities, and companies are adopting modular, rapid-build manufacturing to keep up with demand

7. They may alter the future of bariatric surgery Some surgeons report declining referrals as GLP-1s become more widely used. While surgery remains more effective for extreme obesity, GLP-1s are shifting the treatment landscape and prompting new hybrid care models

8. They are being studied for conditions far beyond diabetes and obesity Trials are under way for heart failure, fatty liver disease, Alzheimer's disease, Parkinson's disease and even polycystic ovary syndrome. Because GLP-1 receptors are found throughout the body, the therapeutic potential is unusually broad

9. They are creating new economic and societal ripple effects From reduced food consumption to changing airline weight load calculations, GLP-1s are influencing sectors far outside healthcare. Analysts predict long-term shifts in retail, insurance and public health spending

10. They are not all the same – and the next generation will be far more powerful Dual and triple agonists (GLP-1/GIP, GLP-1/glucagon and beyond) are already showing greater weight loss and metabolic improvements than current drugs. The field is moving quickly towards multi-pathway metabolic therapies.

Thomas McCarthy is Industry Principal, Life Sciences at AVEVA

Seize the way

From listening to action – turning medical insights into patient impact

Biopharma has never generated more data, more innovation or more scientific exchange.

Yet despite being one of the most valuable assets for improving patient outcomes, medical insights from the field remain underused.

The industry is facing a structural paradox. Breakthrough therapies are becoming more complex and targeted, but bringing them to market is slower, more expensive and more uncertain. Up to 90% of medicines that enter clinical development never reach the market.

In this environment, being able to understand real-world clinical need early and continuously is more than a competitive advantage, it is a necessity.

Medical affairs are at the centre of this opportunity. Through scientific exchange with key opinion leaders (KOLs), medical science liaisons (MSLs) capture frontline clinical insights that inform medical strategy, ensuring a therapy meets real-world patient needs.

"As you prepare for launch, medical insights become especially valuable – helping to shape medical strategy, refine scientific communications and guide overall impact in the field," says Kristina Kipp, regional medical director at BridgeBio.

But today, there is a clear gap between what the field hears and what the organisation acts on.

The cost of not listening

KOLs are not reluctant to engage. On the contrary, Veeva research shows they are highly willing to contribute.

Almost all are open to sharing their perspectives and most are comfortable being associated with the insights they provide.

Yet they believe only 30% of their input is ever used.

That gap represents far more than process inefficiency. It is lost intelligence on unmet medical need, evidence gaps, education requirements, trial recruitment barriers and access challenges, all of which directly influence patient care and therapy adoption.

At the same time, biopharma leaders recognise the strategic importance of insights but despite significant investment in digital initiatives, rate their own insight maturity as only average.

Technology has accelerated insight identification, but execution has not kept pace. Insight capture remains inconsistent; analysis is often slow and fragmented across systems and many organisations still struggle to identify and act on meaningful patterns at scale.

What should be a continuous flow of intelligence is frequently reduced to isolated data points, making it difficult to prioritise what matters or respond in time.

For many field teams, this creates a growing sense of frustration.

As one executive director of global field medical excellence at a large biopharma explains, "We hear from the field all the time: it's like a dark hole.

"I'm throwing my insights into the CRM, and does anyone even look at them? Is anyone doing anything with them?"

From insight to impact

For years, the industry has focused on scaling insight capture. The next phase is about operationalising insight to impact.

Three structural barriers consistently prevent this:

1. Unclear ownership once insights are shared
2. Limited cross-functional flow beyond medical affairs
3. No systematic way to track outcomes.

When accountability is diffused, even the most important medical themes arrive too late, lack follow-through or fail to influence decision-making.

Field teams feel this acutely; they contribute intelligence without visibility into whether it changes anything.

Closing the listening gap therefore requires a new operating model that enables biopharma to act on what they learn.

> **'As you prepare for launch, medical insights become especially valuable – helping to shape medical strategy and refine scientific communications'**

Scaling insight into action with AI and medical themes

Artificial intelligence is transforming what is possible in the insight life cycle. Many organisations have taken the first step with homegrown tools to support insight capture and basic summarisation.

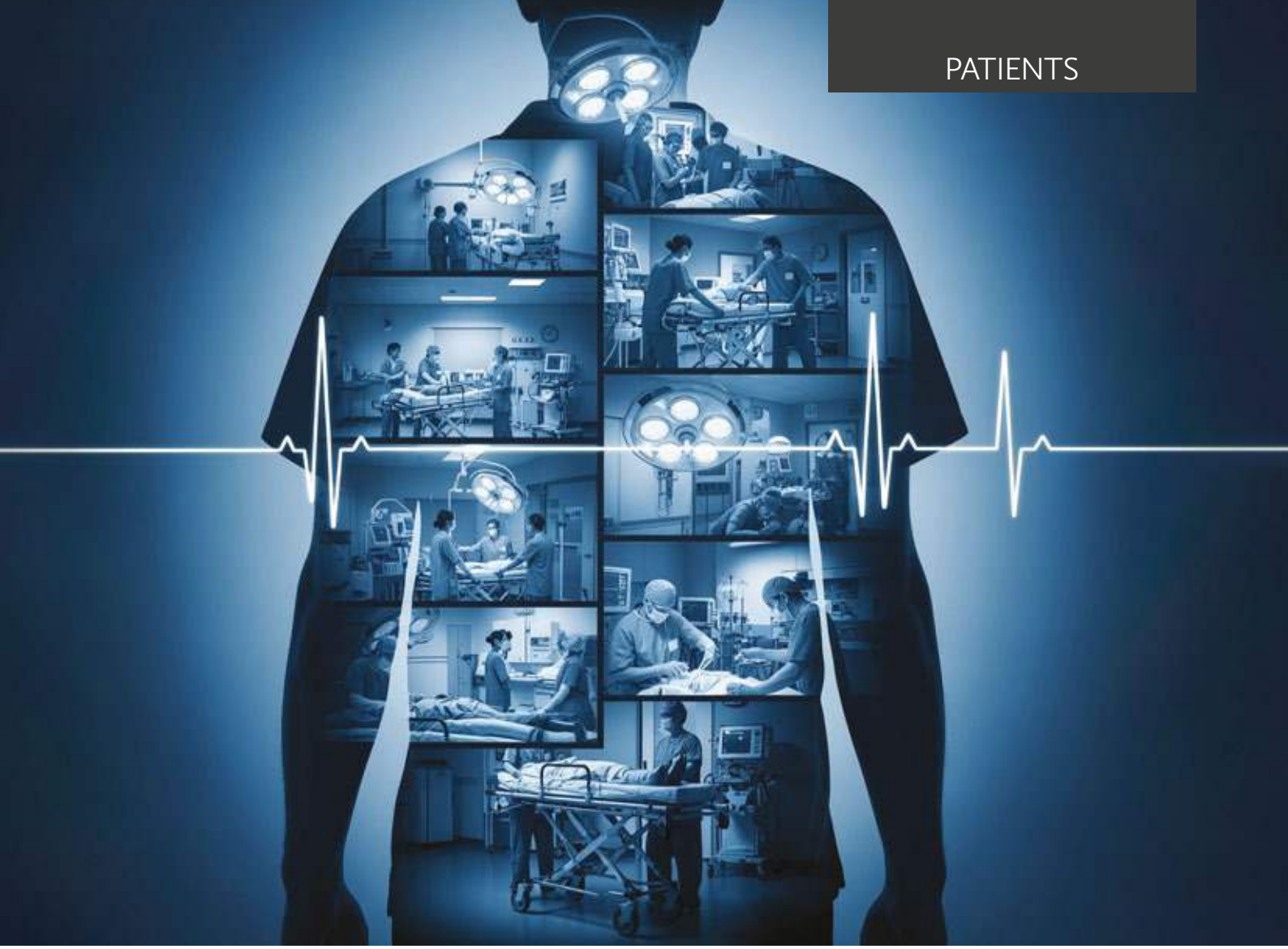
While these reduce manual effort, they are often difficult to scale, fragmented across systems and struggle to keep pace with rapid AI innovation. As the volume and complexity of field intelligence grow, static models and periodic analysis quickly become a bottleneck.

The next phase is the continuous analysis of large volumes of interactions and real-time detection of emerging medical themes. This is the shift from processing individual insights to understanding the patterns that sit behind them.

Medical themes are what turn data into direction. By aggregating insights into clear, evidence-based signals, they enable teams to separate signal from noise, prioritise what is urgent and present a coherent strategic narrative to leadership.

They make it possible to identify risks and act on opportunities earlier. Advanced solutions already combine AI with human oversight to proactively identify medical themes across thousands of insights in real time.

This changes organisational speed.



But fast insight identification alone does not create impact. As the ability to detect themes improves, the constraint shifts to decision-making, governance and cross-functional execution.

The companies that lead are those that embed these insights into how strategy is set and acted upon, connecting what they hear directly to what they do.

A company-wide framework for insight activation

Leading organisations are moving towards a standardised, enterprise-wide approach built on four principles:

1. **Define a single, shared insights process** Start by aligning on what constitutes an insight, how it is prioritised and how it moves from the field to decision-makers. This must involve the teams that collect insights and those that act on them
2. **Assign clear accountability for action** Insights create value only when someone is responsible for activating them. Medical affairs is uniquely positioned to lead this follow-through and ensure scientific intelligence informs strategy across functions
3. **Enable global visibility and learning** A unified source of truth allows organisations to detect cross-regional patterns, apply learnings at scale and respond consistently to emerging medical need
4. **Close the loop with KOLs** Scientific exchange is a dialogue, not a transaction. Providing feedback on how insights are used strengthens trust, improves future engagements and raises the quality of intelligence captured.

Demonstrating the value of medical affairs

Linking insights to measurable outcomes is becoming the defining leadership challenge for medical affairs.

When organisations can show how field intelligence accelerates patient access, improves evidence generation, optimises launches and shapes clinical practice, medical affairs moves from a supporting function to a strategic driver of patient impact.

This is the real significance of closing the insights gap. It is about elevating the role of medical affairs in the enterprise and ensuring that the voice of the clinician directly influences how therapies are developed, launched and used.

Path forward

Success depends on access to the right data, connected and activated through a faster, clearer path from insight to decision to outcome.

That requires a company-wide commitment to standardise processes, scale AI-enabled analysis with industry solutions, empower cross-functional accountability and establish an impact-tracking framework.

Biopharmas that make this shift will not only improve internal alignment, they will shorten the distance between scientific innovation and the patients who need it.

And in a world where most medicines never reach the market, the ability to listen and act may be the most important capability biopharma can build. ▲

Manuel Möller is Vice President, Veeva Insights Strategy at Veeva Systems

Real time

Making partnership working business as usual

Partnership working is having a moment, again. National strategy increasingly frames collaboration across the NHS, industry, HealthTech and the voluntary sector as essential to delivering better outcomes and accelerating innovation.

Yet for all the rhetoric, partnership working still too often sits in the 'nice to do' category, with strategy struggling to translate into real-world collaboration.

Something crystallised for me when chairing the 2026 Excellence in Healthcare Partnerships (EHP) Awards networking panel entitled 'from plan to partnership'.

The conversation wasn't short of ambition; what stood out was the shared recognition that we won't unlock the full value of partnership working until it becomes routine, and part of the fabric of how we operate as a healthcare system, rather than an add-on dependent on exceptional individuals or one-off opportunities.

What follows are my reflections on the mindset, culture and leadership required to make that shift real, what gets in the way, and a practical path forward.

Why 'business as usual' matters

When partnership working is treated as optional, it competes with everything else: operational pressures; financial constraints; organisational priorities, and the sheer cognitive load of running services and delivering targets.

Collaboration becomes something teams squeeze in around 'real work', rather than a route to achieving it.

And that's the irony. The biggest challenges in healthcare – prevention, inequalities, adoption of innovation, redesign of pathways – are cross-boundary by nature. They are not solvable through siloed effort.

Making partnership working business as usual is not a cultural nice-to-have; it is an operating requirement for modern healthcare. But if we want this to be standard practice, we need to stop treating partnership as a virtue statement and start treating it as a discipline.

Mindset: from suspicion to shared intent

The first shift is psychological. Partnership working still carries an undercurrent of uncertainty, sometimes around motives, sometimes around value, sometimes around risk.

This affects both sides. NHS teams may worry about perceived commercial influence or unintended consequences. Industry teams may worry about unclear pathways to engagement, inconsistent decision-making or partnerships that are welcomed in principle but blocked in process.

This is where 'business as usual' begins: moving from a default stance of suspicion to a default stance of shared intent without being naïve about boundaries.

One of my strongest takeaways is the need for a more mature narrative. Partnership working is neither inherently 'good' nor inherently 'risky'. Its value depends on whether it is designed with the right fundamentals: shared purpose, clear governance, transparency and a focus on outcomes.

When mindset shifts, the starting point changes. Rather than asking 'Should we partner?', leaders start asking: 'What outcomes are we trying to deliver, and who needs to be at the table to deliver them?'

Culture: trust is built, not declared

If mindset is the catalyst, culture is the container. Many partnerships fail not because the concept is wrong, but because the day-to-day culture doesn't support collaboration.

Trust is often invoked as the missing ingredient, but trust isn't a sentiment, it's a set of experiences over time.

From my perspective, trust is built through three cultural behaviours:

1. Transparency about motivations and constraints.

When organisations are explicit about what they need, what they can offer and what they cannot do, partnerships become less performative and more durable

2. Respect for complementary value.
Partnerships succeed when each party recognises what the other brings, whether that is insight, infrastructure, clinical leadership, implementation capability, data expertise or reach. This is not 'everyone does everything'; it is purposeful contribution

3. A culture that allows early truth-telling.
High-quality collaboration requires being able to surface tensions early about priorities, evidence, timelines or resources without triggering defensiveness. When truth-telling is punished, issues stay hidden until they become failures.

Culture is also shaped by what organisations reward. If the system celebrates speed, compliance and organisational performance in isolation but not collaboration and shared outcomes, then partnership working will remain brittle.

Leadership: from sponsorship to stewardship

Leadership is the single biggest differentiator between partnership-working as a one-off and partnership working as the norm.

Many leaders are supportive of collaboration in principle. Fewer practise what I would call stewardship: actively shaping the conditions for partnerships to succeed, not simply approving them.

Stewardship looks like:

- Holding a consistent line on purpose and outcomes, particularly when pressure mounts and compromises become tempting. Purpose and outcomes are often the first things to slip
- Creating clarity on governance and decision rights. Partnerships stall when it is unclear who decides what, how risk is managed and how accountability is shared. Robust governance should enable progress, not paralyse it
- Backing collaboration with resource and permission. If partnership working is 'business as usual', it should be resourced accordingly through time, roles, capability and a clear mandate.

The other leadership behaviour that matters is modelling. Leaders set the tone for how partners are treated, how disagreement is handled and whether outcomes trump organisational ego.

What gets in the way (and why it persists)

If we know partnership working is needed, why is it still not routine? In my view, five barriers show up repeatedly:

1. Misaligned incentives. Organisations remain accountable for their own metrics first, system outcomes second. This makes collaboration feel risky even when it is sensible
2. Unclear or heavy governance. Too little governance creates anxiety; too much creates inertia. Getting the balance right is a recurring challenge
3. Over-reliance on individual champions. Partnerships that depend on personal relationships are vulnerable to role changes, organisational restructuring and shifting priorities
4. Evidence debates that start too late. Too many partnerships begin with enthusiasm and only later ask: 'How will we measure success?'
5. A lack of shared learning. When examples of great partnership working aren't visible, uncertainty flourishes. People default to caution because they can't easily point to credible, comparable successes.

A workable path to 'business as usual' partnership

So, what would it take to move from aspiration to default? I believe a pragmatic pathway has four steps: simple enough to repeat; strong enough to scale.

1. Start with a shared purpose linked to population need.
Partnerships should begin with the 'why' that matters to patients and communities, not with a solution looking for a problem

2. Agree outcomes and measures early and keep them visible.
If partners cannot articulate what success looks like (and how it will be evidenced), confidence and momentum drop. 'Measurable outcomes' must be designed in, not retrofitted

3. Build proportionate governance that enables pace.
Governance should make partnership work safer and faster, not slower. Clarity on decision-making, data use, transparency and accountability reduces perceived risk and supports trust

4. Invest in the connective tissue: capability and brokerage.
Partnership working requires skills: facilitation; stakeholder alignment; systems thinking and often negotiation across different cultures and incentives. It also frequently benefits from a neutral convener who can translate between NHS realities and industry constraints, and keep discussions anchored in shared purpose.

That's why I'm optimistic. There is growing recognition that successful partnership is not accidental, it is built. And organisations with deep understanding of both NHS and industry contexts are increasingly being used to broker the early conversations that turn intent into practical collaboration.

Why recognition matters: making partnership visible and credible

If we want partnership working to become routine, we need to make success visible because visibility builds confidence, and confidence increases adoption.

This is where a platform like the Excellence in Healthcare Partnerships (EHP) Awards plays a meaningful role. The programme was created to provide a dedicated space to celebrate and showcase partnership working across sectors, something that has historically been diluted within broader awards focused on other aspects of healthcare delivery.

As we move into the EHP Awards 2027 programme (with entries opening May 2026), the opportunity is not only to recognise excellence, but to share what good looks like practically and credibly, so more organisations feel able to adopt partnership working with confidence.

Because ultimately, making partnership working business as usual is not about producing more strategy documents. It is about changing how we behave: how we lead; how we make decisions; how we measure success and how we work together across boundaries to deliver better outcomes.

If we can embed that shift in mindset, culture, leadership and a clear operating model, partnership working stops being exceptional. It becomes expected. And that is when its value becomes undeniable. ▲

Roshani Perera is Commercial & Operations Director at Visions4Health. Please contact Roshani Perera if you want to find out more about the EHP Awards 2027 or if you need support in getting a partnership working project off the ground: roshani@visions4health.com

The engagement paradox

HCPs and patients are not asking for AI. So why is pharma so determined to give it to them?

There is a growing disconnect between what the industry is offering in terms of digital customer experience and what clinicians actually value.

While pharma invests heavily in AI technologies, many healthcare professionals (HCPs) are quietly disengaging from the digital platforms already available to them.

This is not resistance to innovation but a response to experiences that still require too much effort for too little return.

HCPs and patients are not asking for AI from pharma. They are asking for faster access to relevant, trustworthy information with less effort.

Digital engagement is well established, with recent research showing that 69% interact with pharma digitally on a weekly basis, yet 65% say they have reduced or stopped engaging with a company due to poor digital experiences.

When HCPs are not engaging, the assumption from pharma is typically that platforms need to be more personalised, more dynamic or more intelligent. From that perspective, AI becomes an obvious next step.

However, this risks solving the wrong problem.

When clinicians describe what they want from a digital platform, the responses are grounded in practical outcomes: content relevance to their speciality and patients; utility in supporting real clinical tasks; usability that reduces friction and saves time.

These are the factors that determine whether digital content earns attention or is filtered out. AI only enters the picture when it helps meet those needs more efficiently.

The lack of usefulness is what is causing HCPs to disengage, rather than the lack of platform sophistication.

Pattern worth highlighting

In recent conversations with a pharmaceutical company exploring innovation opportunities, one pattern stood out early on. The discussion moved quickly from understanding unmet needs with a broad scope to identifying only those areas where AI could be applied.

What was striking was not the ambition but the sequencing. Insight gathering and opportunity definition were compressed, while disproportionate weight was given to AI-led solutions, regardless of their fit with the underlying problem.

This is becoming a familiar dynamic. AI has become the easiest way to signal innovation internally, but in prioritising visible innovation, there is a risk that the less visible, but arguably more important, work of improving everyday experiences for clinicians continues to be overlooked.

The consequences are already clear. 58% of HCPs find most pharma digital content repetitive or irrelevant, while 52% say communications are too promotional and not useful enough.

These factors directly influence whether digital interactions are considered worth the time, and if AI is applied without addressing this fundamental requirement, AI-enabled experiences will only propagate these issues, driving HCPs away.

When pharma digital does not deliver, clinicians adapt, seeking out alternative sources that better respect their time. Open platforms, peer networks and, increasingly, general-purpose AI tools are part of everyday practice.

This mirrors broader consumer behaviour, where AI is used to reduce effort in daily tasks, from search to content consumption. These tools are unlikely to be more accurate or more compliant, but they are easier to use.

> ‘The opportunity for pharma lies in deploying AI to reduce the time and effort required to access and process information’

This shift matters because it reframes competition. Pharma companies are no longer competing only with others in the industry for attention, they are competing with any tool that helps clinicians achieve their goals more efficiently.

Where AI can genuinely help

Given that the most common uses of AI amongst HCPs are searching and summarising scientific literature and handling administrative tasks, adoption is clearly driven by utility and pragmatism.

Therefore, the opportunity for pharma lies in deploying AI to reduce the time and effort required to access and process information, rather than building complex clinical solutions.

Summarisation is a clear example. The volume of new evidence continues to grow, and keeping up is a persistent challenge, with nearly half of clinicians reporting they do not have enough time to read or engage with digital pharma content.

AI can help by surfacing key findings, highlighting relevance and allowing time-poor clinicians to decide where to focus their attention.

Search is another area where improvement is overdue. Many pharma platforms still force users to navigate rather than find. AI-enabled search, based on natural language queries, has the potential to connect intent with relevant content far more efficiently.

An extension of this would be to deploy agentic AI to support task completion, reducing the number of steps required to answer a clinical question by connecting related content and guiding clinicians through complex information.

Used well, this shifts the experience from friction to flow.

Fundamentals still apply

Adding AI to an already weak experience does not solve underlying problems. Improving utility or navigation means nothing if content lacks relevance or credibility.

If access barriers remain, AI becomes another layer within an inefficient system.

Considering where clinicians are currently wasting effort, and how friction could be reduced, shifts the focus from innovation to experience. Where AI has the potential to augment or enhance experiences, the fundamentals need to be in place for it to deliver.

High-quality content, structured data, clear taxonomy and consistent governance are not optional, but many pharma companies experience structural issues in these areas.

Content strategies are shaped by brand priorities rather than user needs, digital ecosystems are fragmented and governance slows iteration.

Rather than removing these constraints, AI makes them more visible. There is a significant risk that the HCP experience could deteriorate, further reducing engagement, if these issues are not addressed.

Effort is a commercial issue

Pharma digital does not have an innovation problem. It has an effort problem, with direct commercial implications.

Platforms that reduce effort are used repeatedly, building familiarity and preference over time, while high-effort experiences push clinicians elsewhere. Once those behaviours shift, they are difficult to reverse.

AI will accelerate this dynamic. Not because it transforms the experience, but because it makes the difference between good and poor experiences more obvious.

Part of the challenge is how digital platforms are still positioned internally. Many are treated as repositories for information, structured around brand or content ownership rather than clinical use. In that model, value is limited to what is published.

When platforms are designed around the experiences of HCPs, and how they interact with both information and people, the role changes. They become environments that support tasks, decisions and conversations.

This is where value is created, not in the volume of content, but in how effectively it can be used.

Applied carefully, AI can reduce the time it takes to access information, improving clarity and engagement at the point of need and supporting clinicians in navigating increasing complexity.

But its value depends on the quality of the experience it sits within, and AI for its own sake should not be the starting point. ▲

Rob Verheul is CEO at Graphite Digital

Kylie's greatest hits

Building trust with patient organisations in the misinformation era

Hello, welcome back! This month I'm delighted to introduce the first in a series of conversations I've held with the crème de la crème of pharma comms leaders, and there's no one better to kick us off than Kylie Cuff.

Kylie currently holds the role of Global Communications (Vaccines) at GSK, which means she's immersed in a market that's up against huge change and complex challenges.

We spoke about how her team has been adapting and responding, and she shared some sound advice on how to co-create behaviour change campaigns that strike the right chord with patients.

A veteran comms leader, Kylie moved across to healthcare five years ago during the post-pandemic boom. She brought a fresh perspective on the particular quirks of our sector, telling me she was immediately struck by the tension between, the industry's need to be reactive and innovative, and on the other, a cautious approach to disrupting established processes.

I'm sure many readers will relate to Kylie's observation that approval procedures can unintentionally iron out the novel edges of an idea, leaving it looking like everything else.

But this fate is not inevitable. To avoid the gradual shrinking of your best plans, Kylie stressed that we have to be both bold and rigorous. This means bringing in our internal allies early in the creative process.

When they understand the vision from the start, we can use data and early feedback to show them how a new approach stays compliant while being far more effective than the older, more established ways of doing things.

Our conversation then turned to how quickly the patient information journey has changed. We all know that trust is under pressure, and the clinician-first hierarchy is no longer a given. Many people now consult LLMs, TikTok or Reddit before they ever speak to a healthcare professional – and before they even ask Google.

That shift changes what effective pharma comms looks like. Kylie stressed that we now have to think about content in the round – not only its accuracy and clarity, but whether it can be found and reused by LLMs without being distorted. In short, if we are not designing for discoverability across channels, formats and plain language, we're now leaving too much of the health narrative to chance.

That is one of the reasons why Kylie is such a strong advocate for building proper partnerships with patient organisations. Insights from these groups are essential to keep pharma campaigns grounded in lived experience and relevant to the people we are trying to reach. But for that collaboration to add real value, it needs to be treated as a long-term, mutually beneficial relationship, not a one-off request or a badge-and-logo exercise.

Kylie's practical advice is to bring patient partners in while the campaign is still taking shape. Share more context and plans than you normally would and be clear about what you are trying to achieve. Then ask what success looks like for them and make space for their input to influence the work.

My conversation with Kylie covered many of the same themes I've discussed with dozens of comms leaders over the past few months, but her measured optimism, pragmatism and commitment to pursuing work that will meaningfully improve patients' lives are what shone through.

I was left reflecting that, in 2026, audience trust is won through the details. It comes from information that is easy to find and understand, relationships with patient organisations that are built for the long haul (and feel mutually beneficial), and campaigns with enough substance to survive the complexities of the real world.

Working like that inside a regulated system takes patience and a fair bit of stamina, but now we know how it can be done! ▲

Jess Farmery is Senior Account Director, Health at Lexington Communications

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SUSAR coated

By 2028, near instant safety case processing could make 7 day SUSAR timelines obsolete

The conversation about AI in pharmacovigilance has typically focused on automating individual steps in the case processing workflow.

A greater opportunity lies in broader, more autonomous signal management, which could transform the speed of ICSR processing from days to minutes.

For all the attention on AI's potential to streamline operational processes in pharmacovigilance, such as case processing, the more transformative opportunity is in making signal management more autonomous.

If safety case processing could be automated to the point of near instant completion, with structured data available to signal detection teams as soon as a case is received rather than days later, the entire downstream workflow would change.

Signal detection would move from periodic to continuous. The seven day Suspected Unexpected Serious Adverse Reaction reporting timeline would feel archaic.

Meanwhile safety scientists, freed from the routine burden of data management via a signals agent that could remove much of the collation and analysis, would be able to devote their time to signal validation.

The technology components to make this possible – automated case intake, AI-assisted coding and medical review, continuous quality review – are in some cases already available or in active development.

All that is needed now is the organisational confidence to deploy them at scale.

Regulatory expectation

Regulators have already set expectations around continuous benefit-risk monitoring.

While there have been advances in applying AI to safety signal work, including smarter disproportionality analysis, natural language processing of literature and machine learning across large data sets, real transformation in turnaround speed demands greater operationalisation of AI.

If cases could be processed automatically – extracted, coded, medically reviewed, quality reviewed and entered into a safety database within hours of receipt – signal detection teams would no longer work from snapshots. They would have access to current, structured data as standard.

The monthly listing cycle would become unnecessary. With cases reaching health authority databases more promptly, the regulatory picture would improve in parallel.

The noise problem

Greater data availability does not automatically translate into better signal intelligence.

The proliferation of sources has made the analytical task harder. Internal data sets are supplemented by external data from real-world evidence, literature, electronic health records and regulatory databases such as FAERS and EudraVigilance.

Current sequential, manual workflows were not designed for cross-analysing these data sets rapidly. More sources mean more noise, more duplication and greater potential for distortion.

The scale of ICSR replication alone is notable. A study of seven major pharma companies by TransCelerate BioPharma found a mean of three submissions per case version across 2.5 million case versions, with a significant proportion reaching ten or more health authority recipients.

Media attention also affects reporting rates, as seen in the surge in GLP-1 receptor agonist reports and the spike in COVID vaccine reports during 2021. Increasingly, the signals that matter are being buried.

This is where next-level AI comes in, alleviating pressure on human teams via assisted filtering. Trained models can distinguish genuine patterns from reporting artefacts, surface the cases most likely to represent true signals and direct expert attention accordingly.

The safety scientist's job becomes one of evaluating signals that have already been prioritised and contextualised.

Rethinking human experts

Anxiety exists around removing humans from case processing, but such concerns assume that current human performance is reliable and consistent.

Manual case processing is subject to fatigue, inconsistent interpretation and declining QC effectiveness as volumes rise.

An automated system with continuous, 100% quality coverage – and a governance layer that flags drift and enables systematic retraining – offers a marked improvement. If quality issues arise, retraining a model is far simpler than retraining hundreds of processors. AI-powered action is also more readily auditable.

The dilemma about reducing reliance on internal teams has been resolved before. When PV functions began outsourcing case processing in the late 1990s and early 2000s, similar concerns were raised.

The industry developed governance frameworks, audit processes and confidence levels, and moved on.

Replacing outsourced human processing with AI is structurally the same journey. This is not about autonomous pharmacovigilance.

The goal is augmented PV, with human expertise reserved for interpreting evidence, exercising clinical judgement, communicating risk, and engaging with regulators and healthcare providers.

What 2028 could reasonably look like

The building blocks for this next level of improvement – automated ICSR processing, agentic AI capabilities including intelligent coding agents, continuous quality review layers, cross-domain data integration and AI-assisted signal prioritisation – exist now or are in active development.

All that is needed is the willingness to connect these capabilities, supported by governance frameworks that allow organisations to stand behind the output with regulatory confidence.

Within a couple of years, organisations could be operating with near instant case processing.

Signal detection could run on current data rather than periodic listings, and safety scientists could spend most of their time on analysis and decision-making rather than data management.

The seven-day SUSAR timeline, currently a regulatory baseline rather than an ambition, would become a ceiling. For products reaching market after exposure in only a few hundred patients, earlier detection means faster mitigation and earlier decisions on discontinuation where necessary.

EMA's 2030 vision for PV sets an expectation around real-time decision-making.

Organisations that get ahead will not only be more efficient, they will detect safety risks earlier, protect more patients and cultivate regulatory trust, while avoiding the need to explain at inspection why they are still running monthly listings in a real time world. ▲

Lucinda Smith is Chief Safety Product Officer at ArisGlobal

Smooth operators

AI strengthens scalability in mid-sized pharma while preserving control

Mid-size pharmaceutical companies operate in one of the most complex environments in healthcare.

They pursue innovative therapies with the agility of smaller organisations yet face the same regulatory expectations, documentation standards and inspection scrutiny as global pharmaceutical giants.

These organisations must navigate the complex path of ambitious growth strategies supported by limited infrastructure and expanding pipelines while meeting regulators' requests for transparency.

When regulatory strategy and clinical development fall out of sync, progress stalls. During this hiatus, teams can lose valuable time reconciling data across disparate systems and legacy technology stacks.

Compliance gaps emerge not from negligence but from fragmented systems and disconnected workflows. The business imperative is clear: mid-size pharma organisations must have access to scalable development models that strengthen execution without sacrificing agility.

For regulatory strategy and clinical development to stay connected, organisations must adopt a more proactive approach. This includes developing inspection-ready environments where documentation, review and accountability all take priority.

With this stance, reactive compliance practices such as late-stage documentation review can be retired for good.

From fragmented execution to integrated strategy

The traditional approach to growth by mid-size companies included layering point solutions onto existing workflows.

This meant onboarding additional staff to manage peaks in workload or deploying advanced tools to bridge gaps in either regulatory or clinical operations.

While this approach succeeds in providing short-term relief, it comes at the price of introducing new silos, increasing handoffs and reducing visibility across the product life cycle.

Over time, disconnected systems make it harder to maintain a clear view of programme status, forcing teams to track manual workflows instead of receiving real-time insights.

At a time when pipelines are expanding, this breakdown in coordination can hinder decision-making and increase the likelihood of inconsistencies across submissions.

An updated, integrated model provides a clearer and more sustainable path forward. When clinical development, regulatory strategy and life cycle management operate within a coordinated framework, mid-sized organisations can reduce friction and accelerate decision-making.

When layers of information are structured, connected and accessible across different functions, teams can respond to regulatory inquiries quickly, establish a consistent standard and reduce the number of errors that often emerge when systems operate in isolation.

Organisation-wide alignment ensures that regulatory strategies and clinical design are approached proactively, reducing costly rework and shortening submission timelines.

Regulatory complexity is a strategic business risk

Globally, no two regulatory markets are the same and they are always evolving. However, the one constant that both mid-sized and large pharmaceutical organisations can rely on is the expectation to submit comprehensive documentation, maintain transparent data governance and ensure consistent life cycle management.

Everything from labelling updates to chemistry manufacturing and controls variations to renewals and marketing authorisation transfers must be thoroughly documented and requires disciplined oversight.

These expectations continue to rise as regulatory authorities place stronger emphasis on data integrity and traceability of information being reviewed and approved throughout the life cycle.

Today's clinical research organisations must be prepared to show not only the path to how these decisions were made but also who made them.

When strategic functions operate across fragmented environments, teams spend valuable time and resources reconciling records instead of advancing programmes. Now, when done on a global scale, each additional indication or geographic expansion compounds complexity.

Eventually, operations become so hindered that submissions are delayed, compliance risks increase dramatically and commercialisation opportunities are lost.

Instead of treating regulatory operations as an administrative burden, forward-thinking organisations view them as a competitive advantage. By investing in real-time regulatory intelligence, structured submission planning and coordinated life cycle management, these organisations can develop workflows and therapies on the foundation of inspection readiness.

In the event of an audit, disruptions can be effectively mitigated, teams are better positioned with health authorities and enterprise value is protected.

Organisations that operate with this level of readiness are also better equipped to adapt to sudden changes in requirements. To achieve this, they are building their processes with consistent data, standardised review models and clear governance rather than manual workarounds.

‘For regulatory strategy and clinical development to stay connected, organisations must adopt a more proactive approach’

AI as an operational force multiplier

Another modern asset for mid-sized pharmaceutical organisations is the investment in and growth of artificial intelligence. When developed and integrated with intent, AI augments research teams and enhances regulatory and clinical workflows without requiring massive infrastructure expansion.

It is estimated that 40% of an organisation’s capacity could be freed up as agentic AI enhances or automates routine or knowledge-based tasks. Mid-size organisations typically see impact in three areas:

- Regulatory and clinical authoring: AI-assisted drafting accelerates document preparation while subject-matter experts retain control over review and final approval
- Regulatory intelligence and planning: by ingesting and analysing volumes of historical agency feedback, machine learning models can anticipate questions and mitigate risk earlier in development
- Operational transparency: integrated data environments improve visibility across clinical, regulatory and commercial functions, which reduces silos and enhances collaboration.

However, to ensure that AI investments are fully realised, they must be established with robust governance guard rails. These guard rails are developed by experienced regulatory professionals, include the review of outputs and ensure alignment with evolving regional standards.

By merging intelligent automation with regimented governance, organisations can create accelerated lanes of efficiency without compromising accountability.

Preserving agility while building scale

Mid-sized pharmaceutical companies do not need to replicate the infrastructure of large pharma teams to compete effectively. What they need are models that are scalable without diluting the agility they are known for.

Leveraging integrated development frameworks in conjunction with AI-empowered workflows allows mid-sized pharma teams to break into new markets, build out their pipelines and manage complex life cycles without breaking budgets.

This balanced approach allows teams to focus on valuable outcomes instead of administrative reconciliation. From a leadership perspective, organisations can scale programmes confidently while maintaining fiscal discipline.

Most importantly, it supports faster access to therapies that improve patient outcomes.

Execution with precision is what the pharmaceutical landscape thrives on. By replacing fragmentation with coordination and embedding intelligence into everyday workflows, pharmaceutical companies transform operational risk into strategic advantage. ▲

Michelle Gyzen is Senior Director of Strategic Regulatory Solutions at IQVIA

Short-changed

Counting the cost of pharma's unsustainable change management burden

Post-approval life cycle change management is one of pharmaceutical operations' most consequential yet most neglected disciplines.

As change volumes soar and experienced teams thin out, Megha Sinha of Kamet Consulting Group illustrates why systematic action is imperative now.

Every product in a marketed pharmaceutical portfolio exists in a state of continuous post-approval change.

Corporate structures alter, manufacturing sites move, suppliers change and formulations evolve, necessitating a range of regulatory updates and changes to product labelling internationally.

The post-approval life cycle change management challenge is substantial and growing. A large pharma company might easily have to assess several thousand changes each year, at least half of which will require regulatory submissions, with extensive implications for country-level filings worldwide.

A single site transfer could involve regulatory affairs, supply chain, quality, manufacturing, labelling, commercial, legal, pharmacovigilance and IT. Where scores of countries are affected, each with different submission categories and review timelines, a full global approval for a single change might take as long as three–five years.

That is assuming everything is still coordinated, as is commonly the case, via spreadsheets, email and weekly status calls. The systems most companies rely on to manage such changes have barely evolved in two decades.

That inefficient life cycle change management presents as friction rather than a crisis should not detract from the urgency to address it.

Although missed deadlines can be absorbed, budget overruns rationalised and supply gaps patched via expedited shipments and the heroics of stretched affiliate teams, collectively these situations erode operational performance and consume resources.

They can also create costly risk that may not be apparent until much further down the line.

Converging pressures

There are a number of reasons why current practices are both unsustainable and untenable now.

Levels of M&A activity, divestitures and portfolio reshaping in recent years have given rise to years of downstream work, transferring marketing authorisations, switching sites, rebranding products and updating labelling across up to 100 countries, which is still tying up regulatory operations today.

In parallel, supply chain restructuring is accelerating as companies nearshore and reshore manufacturing in response to geopolitical risk and the US BIOSECURE Act.

Each facility move, CDMO switch or new production line triggers a fresh cascade of post-approval changes. A single API site transfer might generate three–five separate submission categories per country.

Each industry sub-sector brings its own challenges. In biologics, any manufacturing process change, whether a scale-up, a supplier switch or a modification to upstream cell culture, triggers comparability obligations that do not apply for small molecules.

Demonstrating equivalence in efficacy, safety and quality attributes takes months. If testing surfaces unexpected differences, a standard variation can escalate into a major filing requiring clinical bridging data, adding one to two years to the approval timeline across every affected market.

'AI tools are available that can encode practitioner expertise, compute cross-functional dependencies and flag risks'

Cell and gene therapies face the most acute version of this challenge. For autologous CAR-T products, the manufacturing process is, in effect, the patient, a personalised chain of custody where any process change carries risks beyond those associated with conventional drugs.

Costs are mounting

Puzzlingly, many life cycle changes are initiated without any clear assessment of whether they make financial sense, because of a lack of end-to-end visibility of the wider ramifications.

Manufacturing might propose a cost-saving initiative, such as a supplier switch, process optimisation or site consolidation, with projected savings that look compelling on paper.

Yet once regulatory fees across scores of countries, artwork updates, dual production runs, stock write-offs and two–three years of execution time are factored in, the actual cost may cancel out or exceed the intended savings.

In effect, cost-saving projects that would not survive a fully informed business case are given the green light.

The problems only emerge later. In the case of one large-scale site transfer across more than 50 markets, a missed grace-period deadline in a single strict market created a supply gap lasting weeks, with revenue at risk in the millions, despite the submission having been approved on time.

The failure was one of coordination. The supply chain and regulatory teams were working from different timelines, so no-one spotted the gap until buffer stock could no longer be rebuilt.

In another case, involving a divestiture, the transfer of MAH status across more than 80 countries, without a unified view of country-level requirements, led to inconsistent filings, rejected submissions and a remediation programme that took more than two years and cost millions to resolve.

The issue in both cases was that no single person or system had the full operational picture.

Reinvention offered by AI

There are well-established reasons why life cycle change management has not been systematically addressed up to now, including the fact that the process falls between functions, with the result that no single leader is accountable end to end.

The undertaking is difficult to standardise too, because every change is different and the complexity across product types, countries and regulatory pathways is considerable. It has not helped that the relevant expertise has resided with individuals rather than in formal systems.

Senior regulatory operations professionals 'just know', for example, that certain health authorities will not accept a new variation while a prior one remains under review, or that some markets require double-legalisation adding weeks to any timeline.

When those people retire, as is happening increasingly now, that knowledge is lost.

Companies need to guard against these risks now by looking to the role that the latest technology can play. AI tools are available that can encode practitioner expertise, compute cross-functional dependencies, flag risks before they materialise and provide an aggregate view across concurrent change programmes.

This makes it possible to instantly identify where the same product is affected by multiple simultaneous changes, where submissions can be bundled, where timelines conflict and, crucially, where total implementation cost is likely to exceed projected savings.

Without a smarter approach, the life cycle change management problem will not resolve itself. This is about acting systematically, building structured regulatory intelligence, establishing genuine cross-functional governance and connecting planning to execution in a single unified view.

The companies that do this will find that they are able to execute changes more swiftly, spend less and protect supply continuity more reliably.

Life cycle change management may not seem strategically exciting, but it underpins the commercial life of every marketed product in every portfolio, making it one of pharma's most consequential, not to mention most directly addressable, operational challenges today. ▲

Megha Sinha is founder and CEO at Kamet Consulting Group

Crazy maze phase

Who's really in charge in the NHS? Navigating a disrupted system

There is a deceptively simple question at the heart of the English NHS – and one that frequently baffles pharma clients at HSJ Information: who is actually in charge?

For much of its history, the answer, while never perfectly clear, followed a recognisable chain of command. Ministers set direction, NHS England managed the system, commissioners commissioned and providers delivered.

For those seeking to work with the NHS, including pharma, the task was to understand that hierarchy and engage with it.

In the shadow of the NHS' 10 year plan and the power carousel it set in motion, that clarity is fading.

In its place is something more diffuse: a system of shared, negotiated authority in which power depends on context. And while recent reforms promise simplification, they are also reshaping where control really sits.

It is that dull sounding but ineffably important word: governance. The practical reality that determines who makes decisions, and ultimately how, where and whether medicines are adopted.

If you are trying to find the right people to engage, this is a commercially vital reality. This article is about stakeholder mapping it all.

The return of the centre

During the 2010s, the organising idea of the NHS was distance from government. NHS England operated at arm's length, providing a buffer between political priorities and operational delivery. That settlement has now shifted.

The direction of travel is back towards central control. This month, NHS England was officially absorbed into the Department of Health and Social Care, which is now more directly engaged in operational priorities. National bodies are taking a firmer grip on performance and finance. This reflects a political reality: when waiting lists rise or cancer targets are missed, accountability ultimately sits with ministers.

The result is a system that is more directly steered from the centre, with less tolerance for local variation. But that does not mean control is straightforward. Instead, it is being exercised through new layers.

Stealthy rise of NHS regions

If there is a tier that best captures this rather cloudy sense of operational authority, it is NHS regions.

Often overlooked, regional teams have become the de facto performance managers of the system. They sit between the centre and local systems, overseeing both providers and Integrated Care Boards, monitoring delivery and intervening where performance falters.

This matters to pharma because performance management is power over your customers. Regions may not commission services or hold budgets in the traditional sense, but they increasingly shape which priorities dominate locally, where attention and resource are directed, and how strictly national expectations are enforced.

In effect, regions form a shadow hierarchy, less visible than national bodies but highly influential in determining system behaviour.

For companies seeking to understand adoption and uptake, this layer is easy to miss and increasingly important.

ICBs – central to everything

Integrated Care Boards were designed to be the linchpin of a more collaborative NHS: system leaders bringing organisations together; shifting care upstream and improving population health.

That ambition remains. But the conditions in which ICBs operate have changed significantly.

> **'Regions may not hold budgets, but their grip on performance increasingly determines which priorities dominate locally'**

Their responsibilities are still extensive: delivering financial balance across systems; planning and redesigning services; forging links with local government; implementing national priorities such as elective recovery and cancer performance overseeing primary care developing neighbourhood health models, and managing medicines optimisation and formularies.

Taken together, this is a formidable agenda. Yet ICBs are being asked to deliver it while facing tightening running cost envelopes, headcount reductions, and a shifting role within the system.

They need pharma's immediate help to get a grip on therapy areas, prevention, and more efficient patient pathways.

Shrinking and shifting workforce

Alongside these expectations, ICBs are dealing with significant internal churn.

Headcount reductions are being driven by cost-saving requirements. At the same time, staff turnover is high, as roles evolve, teams are restructured and experienced leaders move on. Recruitment is often slower, and vacancies are not always backfilled.

Crucially, this is not limited to ICBs that are formally merging or clustering. Even relatively stable systems are seeing portfolios reshaped, teams reorganised and institutional memory eroded.

This has direct implications for delivery. A system that depends heavily on relationships between commissioners, providers, primary care and local authorities relies on continuity. When teams are in flux, those relationships must constantly be rebuilt.

At the very moment ICBs are expected to provide system leadership, many are losing the people who understand how the system actually works. So tracking who can make a difference becomes extra challenging.

Responsibility without full control

This creates a deeper structural tension. ICBs are accountable for outcomes, finance and integration. But many of the levers required to deliver those outcomes sit elsewhere.

Providers control service delivery and workforce. Regions oversee performance and can intervene. National bodies set priorities and funding constraints.

ICBs therefore operate in a space where responsibility is clear, but authority is shared.

They are expected to think like system leaders, act like commissioners and deliver like operators, while increasingly being resourced like coordinators. You could say their role is stretching rather than shrinking.

For all the structural change, one fact remains constant: NHS Trusts are where care is actually delivered.

They employ the workforce, run the services and make the operational decisions that determine patient experience. No system architecture alters that fundamental reality.

However, Trusts are now subject to tighter oversight than in previous years. Regional performance management, combined with national expectations, means autonomy is more constrained. Financial pressures further limit room for manoeuvre.

The result is a system in which Trusts hold operational power, regions hold performance authority and ICBs attempt to align the two.

Neighbourhood health

Alongside these shifts, policy continues to emphasise care closer to home. Primary Care Networks and neighbourhood health models are positioned as the future of prevention and integration.

The ambition is clear. What the structures will eventually look like is less so. Originally the grand plan was to have 150 new 'Neighbourhood Health Centres' by 2030. Sounds cool, right? Shiny new buildings that can treat all manner of complaints closer to home.

And yet: HSJ recently ran a story revealing how, in order to be designated a 'Neighbourhood Health Centre', you just need to be a GP practice with a community team. Isn't that pretty much all of them?

It is fair to say that the neighbourhood health agenda is a work in progress. PCNs do not hold budgets or statutory authority. ICBs remain responsible for primary care performance. The contractual process for how neighbourhood health providers will be financed is still being worked out.

Fortunately for pharma, our Audience Access team at HSJ has been closely monitoring developments on the ground and gathering cutting-edge data on where the new wave of providers will be and who will run them. But until the whole sector goes properly live on a national footing, this is a watch this space.

Funding, incentives and medicines

In the NHS, structure tells only part of the story. Funding and incentives are often the more reliable guide to where power lies.

For the pharmaceutical sector, this layered model is particularly visible.

Access to medicines is shaped by national clinical and cost-effectiveness frameworks, ICB level affordability decisions, local formulary choices and then clinical judgement at the point of care.

No single actor is in control. Instead, decisions emerge from interaction between layers, each with different priorities.

Formularies illustrate this clearly. While national guidance sets direction, ICBs interpret it in the context of budgets; committees determine inclusion, and clinicians ultimately prescribe.

In practice, this means that variation persists, and not as a failure of the system, but as a function of how it is designed.

What this means for pharma

For pharma, the implication is clear: there is no longer a single 'customer' in the NHS.

Engagement strategies built around a single decision-making centre are increasingly misaligned with reality. Success depends more on understanding how different layers interact in specific systems.

ICBs remain pivotal, particularly for formulary decisions, pathway design and medicines optimisation. But they are operating under pressure, with stretched teams and competing priorities. Engagement must reflect this: targeted; relevant and timed to align with system pressures.

Regions, while less visible, are increasingly influential. Their role in performance management means that therapies aligned to regional priorities, whether in cancer, elective recovery, or prevention, are more likely to gain traction.

At the same time, place and neighbourhood structures are emerging as interesting future customers, particularly in more mature systems. Here, earlier engagement in pathway design may be possible, but the landscape is uneven and evolving.

A data problem

One consequence of this uneven model is that understanding the NHS has become as much a data challenge as a structural one.

I have been hawking NHS national organisational charts for 20 years and I know now that it is not enough. What matters is who actually influences decisions within systems, how stable those stakeholders are and how priorities are shifting over time.

In a context of high churn, particularly within ICBs, static stakeholder maps quickly become outdated. Roles evolve, responsibilities shift and informal influence can be as important as formal authority.

The same is increasingly true at neighbourhood level. As systems develop new models of care, customer landscapes are becoming more granular, more dynamic and harder to track.

Our pharma clients for data and CRM are already responding to this reality, building increasingly detailed, continuously updated pictures of stakeholders, decision-making forums, and local priorities.

The ability to track these changes in near real time is becoming a prerequisite for effective engagement rather than a competitive advantage.

Power, visibility, challenges

For pharma, this creates a new kind of access challenge, depending less on engaging a single decision-maker and more on understanding how decisions are distributed, identifying where influence actually sits within systems and aligning with priorities at multiple levels simultaneously.

The organisations that succeed will be those that can track stakeholder change as it happens, understand local system dynamics, not just national policy, and engage across layers, from system leadership to neighbourhood delivery.

Because in today's NHS, access is no longer about knocking on the right door, but knowing which doors matter, how they connect and when multiple people have the key. I think I have stretched this metaphor enough. ▲

Oli Hudson is Content Director at HSJ Information

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■ Vygon UK has appointed **Dale Keegan** as its new general manager, following a decade with the company and a period of record commercial performance.

Dale, who joined the Swindon-based manufacturer in 2016, previously served as chief financial officer and a board member, working across finance, operations and commercial teams to support steady growth and deliver a record turnover in 2024.

In his new role, he will lead the strategic and operational direction of the UK business. His remit includes setting priorities, overseeing commercial performance, identifying future growth opportunities and guiding the company's 100-strong workforce.

He will also ensure the organisation continues to meet high standards of quality, compliance and sustainability, while remaining aligned with the wider Vygon Group.

Reflecting on the appointment, Dale said: "Having been part of the Vygon UK family for many years, it's a real privilege to take on this challenge."

He added: "What excites me most is the opportunity to pursue our mission: to help clinicians deliver the best possible outcomes for their patients through our complete portfolio and comprehensive expertise."

He highlighted recent progress in expanding into new markets, noting: "There is a growing need for innovative and high-quality medical devices, and we've made some fantastic progress breaking into new markets recently."

Vygon Chief Executive Officer Ludovic Richard-Vitton added: "We congratulate Dale Keegan on his promotion. His strong industry knowledge and leadership skills will help us enter a new phase of growth and innovation in the UK market."

Christy Shafer

Christine Mikail

Movers of the Month

■ Neurogene has expanded its senior leadership team with the appointment of **Christy Shafer** as Chief Commercial Officer and **Christine Mikail** to its board of directors, as the company advances NGN-401, its gene therapy candidate for Rett syndrome, towards later-stage development.

The clinical-stage biotech, which focuses on genetic medicines for rare neurological diseases, said the appointments bring deep commercial, strategic and operational expertise.

Announcing the changes, Rachel McMinn, Founder and Chief Executive Officer of Neurogene, said: "With the addition of Christy Shafer to Neurogene's experienced executive team, we welcome a proven commercial leader with deep expertise in building organisations and executing rare neurological disease product launches to guide our commercial strategy and launch readiness for NGN-401, our gene therapy product for Rett syndrome."

She added: "Christine Mikail has deep strategic, financial, transactional and operational expertise, along with a rigorous understanding of Neurogene's business and long-term objectives. Her perspective and judgment will strengthen the board as Neurogene continues to advance NGN-401 and prepares for its next phase of growth."

Christine has already played a key role in shaping the company's long-term strategy and strengthening its financial foundation. She said: "I am honoured to join Neurogene's board of directors at this important stage in the company's evolution. I look forward to contributing my experience and perspective to Neurogene's long-term strategy as a member of the board."

Christy brings more than 20 years of commercial leadership experience, most recently serving as Senior Vice President and General Manager, North America, at Avidity Biosciences.

Her previous roles include Chief Commercial Officer at Marinus Pharmaceuticals, where she led the launch of Ztalmy, and senior commercial positions at Alexion Pharmaceuticals, Pacira Pharmaceuticals and Sanofi Biosurgery.

Commenting on her appointment, she said: "Neurogene's differentiated approach to gene therapy represents a meaningful opportunity to transform outcomes for patients with devastating neurological diseases.

"I am thrilled to join this team at this inflection point and look forward to partnering across the organisation to help deliver the capabilities, strategy, and infrastructure needed to support a successful launch and commercialisation of NGN-401, if approved."

■ Omron has appointed **Virendra Shelar** as Executive Officer, President and CEO of Omron Europe. He will be based at the company's European headquarters in Hoofddorp, the Netherlands.

Virendra brings more than 25 years of experience in the high-tech sector, spanning leadership development, business transformation and global operations.

Since joining Omron in 2014, he has held senior roles including President of the Omron Management Center Asia Pacific, General Manager of the Global HR Strategy Department, Chairman of the Omron Management Center Europe, and Senior General Manager of Global Business Operations and Services within the Industrial Automation business.

Throughout his time at the company, he has played a central role in business strategy formation, organisation transformation, leadership development and driving sustainability and digital transformation.

Commenting on his appointment, Virendra said: "I am honoured to take on this responsibility. Europe is a region of tremendous strategic importance and home to world-class manufacturing, deep engineering expertise and customers who demand the very best in automation solutions.

He added: "I look forward to working closely with our teams, partners and customers to accelerate our growth, drive innovation, and contribute to a more sustainable and resilient industrial future. Together, we will build on the strong foundation that has been established and move forward with energy and purpose."

■ Asgard Therapeutics has appointed **Prof Dr Wolfram Brugger** as Chief Medical Officer, strengthening its leadership team as the company prepares to transition into a clinical-stage biotech.

Wolfram has participated in more than 130 phase 1–3 oncology trials across multiple cancer types and modalities, including solid tumours.

Announcing the appointment, Cristiana Pires, Co-founder and Chief Executive Officer of Asgard Therapeutics, said: "Strengthening our leadership team with Wolfram, who is such a highly experienced clinical trials expert and practising medical oncologist, is a privilege and we are excited to welcome him on board."

Wolfram said: "I've always been driven by bringing new modalities to patients, and I am excited to be developing a 'personalised off-the-shelf' immunotherapy which has great potential to help patients with a wide variety of cancers.

"Asgard's in vivo cell reprogramming technology has transformative potential, and the preclinical proof-of-concept data, both published and upcoming data to be presented at key scientific conferences, is highly convincing."

Wolfram joins from Autolus Therapeutics, where he led the global clinical development of AUTO1, an autologous CD19 CAR-T therapy approved by the FDA in 2024 for relapsed or refractory B-cell acute lymphoblastic leukaemia and granted conditional approval by the EMA and MHRA in 2025.

His previous roles include leading global clinical development programmes at MorphoSys and serving as global medical lead at AstraZeneca for phase 1 and early phase 2 oncology trials.

■ B. Braun UK has appointed **Craig Cannings** as its new Managing Director, following Michael Parden's transition to the role of CEO of B. Braun North America.

Craig will oversee all UK operations, covering the company's portfolio of medical devices, pharmaceutical products, digital health solutions and clinical services. He will also continue to advance B. Braun's sustainability agenda and its contribution to improving patient care across the country.

He joined the organisation in 2010 and has since played a central role in its development. He became Head of UK Group Finance in 2016 before progressing to Finance Director, helping steer the business through significant transformation and sustained growth over more than a decade.

His appointment reflects both his strong track record and the company's commitment to developing internal talent.

A proud Yorkshireman from Rotherham, Craig is known for his people-first leadership style and his focus on building strong, values-driven teams. He said: "I am honoured to take on the role of Managing Director, it means a great deal to lead an organisation with such deep roots in Sheffield and the wider region."

He added: "We have a clear mission to continue improving lives across the UK. I'm excited to champion our culture, support our brilliant teams, and continue strengthening our impact across UK healthcare."

Roman Kübler, SVP Sales Region Western Europe, B. Braun Group, said: "Michael's transition and Craig's appointment reflect the strength of leadership within B. Braun."

Human racing

The modernisation imperative in clinical data analysis and regulatory submission

In life sciences, delays in clinical development have real consequences.

Patients are waiting for therapies that could extend or improve their lives. Every delay has real consequences – not just for organisations but for patients and the progress of science itself.

Yet there are still avoidable delays, many of which stem from outdated IT infrastructure that is ill-equipped for the complexity of drug development and delivery today.

Clinical teams are often well aware of the limitations of legacy systems. Slow and clunky, the technology has not kept pace with multi-stakeholder collaboration, nor can it process the bigger and more diverse data sets from decentralised and hybrid trials and real-world and biomarker data.

Studies suggest that data points collected in phase 3 protocols quadrupled between 2012 and 2020 – a figure that will have grown further since and will continue to do so as our data capture capabilities grow.

We have reached a tipping point where organisations can no longer innovate safely at speed without a modern analytics environment.

Speed, scalability, compliance

To address these challenges, organisations are increasingly turning to modern, cloud-native analytics platforms.

A validated, cloud-native platform gives teams the speed and scalability to innovate, allowing them to deploy AI and machine learning models and remove limitations on current data processing capabilities.

However, speed in clinical development is often perceived to be at odds with compliance.

The speed these platforms offer does not compromise compliance – in fact, it strengthens it. Emerging capabilities such as agentic AI can autonomously detect protocol deviations, helping to de-risk the complex clinical trials process.

A modern analytics environment is designed to promote confidence in regulatory submissions by supporting clear audit trails, data traceability, role-based access and adherence to CDISC standards.

By reducing manual processes and improving transparency, these capabilities enable faster, more confident submissions rather than slowing them down.

Despite these advantages, acknowledging the limitations of legacy systems is one thing but nervousness about upending existing software and data migration remains a barrier to innovation.

Operationally, it is seen as a risky and resource-intensive task, where data quality, integrity and traceability must be maintained and any downtime minimised.

While this perception persists, the greater risk now lies in maintaining environments that cannot support the demands of modern clinical development.

But modern migration projects do not need to be fraught with challenges. With the right platform, it is possible to simplify the process while improving data quality and governance.

Once implemented, a modern platform provides a central global repository for teams to access data, which supports collaboration and best practices and reduces duplication.

Barriers between sponsors, CROs and regulatory bodies are broken down, while no-code/low-code capabilities empower teams to create their own AI models within strictly governed frameworks, further driving innovation.

Its open architecture and readiness for AI and machine learning, including emerging capabilities such as AI agents and copilots, allow organisations to scale innovation in a controlled and compliant way.

Modernisation is non-negotiable

The question is no longer whether to modernise but how to do so responsibly, at speed and at scale.

Most cloud-native analytics platforms are scalable, user-friendly and collaborative by design, especially compared to outdated proprietary systems. That alone can improve data analysis and develop efficient processes for regulatory submission.

However, what is critical in life sciences is that this architecture comes with an inbuilt data governance framework that not only promotes but enforces best practices. When these foundations are in place, speed is no longer a trade-off – it becomes an inevitable outcome of better systems. ▲

Patrick Homer is Advisory Life Sciences Leader at SAS

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