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Withnail and AI

When placed in an artificial reality, not totally dissimilar to the film sets that have defined his career, Richard E. Grant's ubiquitous pretence shuddered to a crunching halt, among a cast of mainly D grade 'personalities'.

What was it about this contrived stage that burst the banks of his storied theatricality? Drama is Richard E. Grant's territory. Staying within the wingspan-range of Richard E. Grant is what Richard E. Grant does. And, yet, amid a completely unchallenging environment of bozos he spontaneously exploded into an uncharacteristic display of 'honesty'.

But what do we actually know about thespian Richard E. Grant, beyond him being a privately educated, hopelessly posh, aristocratic Englishman? Well, for a start, he's not called Richard E. Grant, he did not attend Eton, he is not aristocratic and is not from England. But let's not get bogged down in details!

What has this got do with the modern clinical trials landscape, I hear you ask? Well, when it comes to clinical trials it is important to get bogged down in details. Swathes of patient data, in volumes beyond our comprehension, are being generated, processed and regurgitated in a concentrated melting pot of super-charged enlightenment.

As AI emerges as a force within the currency and calculation clinical trials, its ability to establish the faithful data, while discarding (or in some cases including) amusing flights of fancy, such as blurting out that you're 'a traitor', will be crucial in a bid to control the datasphere.

And, in a game where the rules are always changing, control may be all we have left. Losing it doesn't bear thinking about. Just ask Richard.



John Pinching
editor

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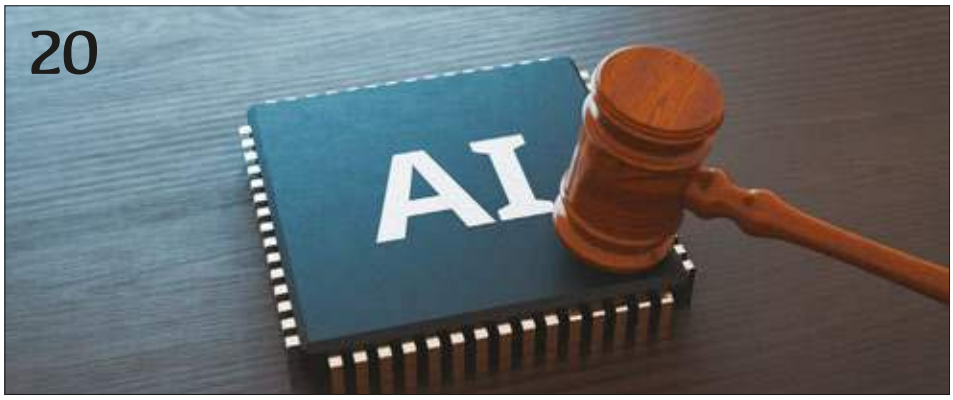
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RougeTx launches with $58 million series A financing for HHT therapy

RougeTx has launched with a $58 million Series A financing to advance RTX-001, a potential once-daily oral treatment designed to restore blood vessel stability in HHT (hereditary haemorrhagic telangiectasia).

The round was co-led by BGV, Angelini Ventures and Kurma Partners, with participation from Epidarex Capital, Vesalius Biocapital Partners, ROM Utrecht Region, p53 Invest and Kerna Ventures.

The funding will support RTX-001 as it progresses towards first-in-human development. HHT is the second most common inherited bleeding disorder, caused by abnormal blood vessel formation known as AVMs.

These can lead to recurrent nose and gastrointestinal bleeding, iron deficiency, chronic anaemia and serious complications affecting major organs. There are currently no approved therapies for HHT.

Andrew Lightfoot, Chief Executive Officer at RougeTx, said: "RTX-001 is designed to stabilise fragile blood vessels by restoring pericyte attachment. The data we have generated for RTX-001 gives us a strong foundation as we move toward the clinic. This financing also allows us to explore where the same biology may impact other vascular diseases."



Franck Lebrin, Co-Founder and Scientific Advisor at RougeTx, remarked: "RougeTx represents the culmination of more than 20 years of research, initially at Inserm and over the past decade in my laboratory at Leiden University Medical Center. I am excited by the opportunity to bring a novel treatment to the HHT community."

RougeTx's periSCOPE platform is designed to expand the pipeline beyond HHT, identifying new treatment opportunities in diseases driven by vascular instability and supporting development of small-molecule therapies based on shared underlying biology.

Laverock unveils new in vivo programmes in oncology

Laverock Therapeutics has announced new in vivo programmes spanning CAR-T and genetic medicine, expanding its therapeutic pipeline beyond ex vivo cell therapies.

The company said the move strengthens its ability to tackle major challenges in oncology and genetic disease. Its programmable gene control platform enables tunable and multiplex control of endogenous targets and transgenic payloads.

The technology has already been validated in several cell therapy applications, including armoured autologous T cells and iPSC-derived macrophages targeting solid tumours. Laverock said its in vivo programmes will improve efficacy, safety, accessibility and scalability for CAR-T, while supporting development across high unmet-need indications in genetic medicine.

Solid tumours represent 90% of cancer cases, and the company believes its platform is well suited to overcoming the inhibitory factors of the tumour micro-environment.

In genetic medicine, Laverock will use in vivo gene silencing through direct delivery of gene editing tools. This approach aims to support therapy development for nervous system disorders and metabolic disease.

The company said its technology is differentiated by its ability to control multiple targets or pathways simultaneously with precision and context-specific gene expression.

David Venables, CEO of Laverock Therapeutics, said: "Building on our success in developing ex vivo therapeutics, we are extremely excited to announce the launch of our in vivo programmes, and realise the benefits these cutting-edge technologies can bring to patients."



He added: "This area is highly innovative, and our platform can provide a key element to realising its potential."

Laverock said industry interest is growing in therapies that can be delivered directly to patients while maintaining precision and safety. The company has several technology partnerships and is open to new collaborations.

Bespak and SNBL agree global access deal for FDA-approved nasal device

Bespak has signed an MOU with SNBL to provide immediate and exclusive global access to SNBL's proprietary nasal dry powder delivery device for developers of novel intranasal therapies.

The agreement strengthens Bespak's nasal drug delivery offering, which now spans liquid, soft mist and dry powder products from early development through to commercial supply.

The device will be marketed as the Air Pump Unit Dose Intranasal Powder device. It is single-use, compact and easy to carry, delivering powder intranasally from a drug-containing nozzle attached to a simple user-activated air pump. It does not require patients to coordinate breathing during administration.

Nasal drug delivery is attracting growing interest for CNS and systemic routes, with potential applications in pain, neurological conditions, degenerative diseases and vaccines.

SNBL's device, approved as part of Satsuma Pharmaceuticals' Atzumi migraine treatment in April 2025, is one of only three FDA-approved dry powder nasal devices available. Bespak is the chosen contract manufacturer for filling and assembly of Atzumi, offering customers a faster and lower-risk route to approval in the US and other regulated markets.

Chris Hirst, CEO of Bespak, said: "Nasal drug delivery is entering an exciting new era, with developers looking for solutions that can deliver next-generation therapies effectively while also meeting patients' needs for greater convenience and ease of use.

"Our agreement with SNBL strengthens Bespak's ability to respond to that need, bringing together an FDA-approved dry powder nasal device with our capabilities in formulation, development and commercial manufacturing. Our ambition is to help our customers unlock the potential of nasal delivery and bring more nasal drug breakthroughs to patients."



NHS Blood and Transplant partners with Northwest Biotherapeutics

Northwest Biotherapeutics and NHS Blood and Transplant have agreed a collaboration to support production of DCVax-L, a personalised immunotherapy for solid tumour cancers. The partnership will begin in Leeds and Oxford, with plans to extend services across England.

DCVax-L uses a patient's own immune system to recognise and attack cancer. Each treatment is manufactured individually using immune cells collected from the patient and material from the tumour.

Under the agreement, NHS Blood and Transplant will provide specialist services to collect and process patients' immune cells for DCVax-L manufacturing. This includes leukapheresis, an established procedure that collects specific white blood cells while returning remaining blood components to the body, alongside specialist cell processing and handling delivered by Cellular and Molecular Therapies teams.

Working with Northwest Biotherapeutics and Advent Bioservices, NHS Blood and Transplant will help strengthen UK infrastructure supporting DCVax-L production.

The organisations are also exploring opportunities to expand the collaboration across NHS Blood and Transplant's network of specialist facilities. This could reduce the distances patients and families need to travel.



Linda Powers, CEO of Northwest Biotherapeutics, said: "NHSBT's impressive expertise and facilities for advanced therapies are at the forefront of the field.

"We are very excited about collaborating with them on our DCVax-L personalised immune therapies for cancer. We believe NHSBT's capabilities can significantly enhance the scale-up and accessibility of DCVax-L."

MINT study results strengthen real-world evidence for mogamulizumab

Kyowa Kirin International has announced final results from the German MINT study evaluating mogamulizumab in patients with MF and SS. Presented at the EORTC-CLTG Annual Meeting 2026, the findings represent one of the largest real-world evaluations of the therapy in Germany and add to evidence supporting its use in routine practice.

MINT was a company-sponsored, multi-centric, non-interventional real-world study across 18 centres. It assessed outcomes in a broad patient population, including clinically relevant subgroups such as LCT and fMF, and stratified by disease stage and MAR status.

MF and SS are forms of CTCL, a type of non-Hodgkin's lymphoma that manifests on the skin. Symptoms can include persistent rashes, changes in skin colour and plaques or tumours. These visible symptoms can significantly affect patients' quality of life.

Professor Chalid Assaf, Director of the Department of Dermatology and Venereology, Helios Klinikum Krefeld, said: "For patients living with mycosis fungoides and Sézary syndrome, understanding how treatments perform outside the controlled setting of clinical trials is critically important.

"The final MINT results demonstrate meaningful clinical outcomes across a broad patient population treated in routine practice and highlight the value of collaborative real-world research in helping clinicians make informed treatment decisions."



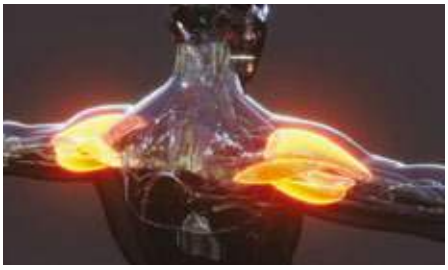
Atrogi reports human data showing muscle gains with ATR-258

Atrogi has announced positive human data for ATR-258, its first-in-class oral GRK2-biased β2-adrenergic modulator designed to improve muscle function and body composition.

In an eight-week investigator-initiated study in 13 overweight or obese adults, the therapy was well tolerated and associated with an approximately 13% mean improvement in lower-extremity muscle power. Participants also saw statistically significant reductions in fat mass and increases in lean mass.

The open-label, single-arm trial, led by Professor Morten Hostrup, evaluated three ascending dose levels of ATR-258. Treatment resulted in a mean 1.1 kg reduction in fat mass and a 0.8 kg increase in lean mass. Atrogi said the profile highlights the therapy's potential in metabolic and muscle-related diseases with high unmet need.

Professor Tore Bengtsson, Chief Scientific Officer and Founder of Atrogi, said: "These first clinical data give us important confidence that our approach is translating. To see fat loss alongside an increase in lean muscle mass and improvement in muscle function represents a truly differentiated profile, and is highly encouraging."



He added: "Beyond muscle-sparing weight loss, we believe this mechanism also warrants investigation in sarcopenia and rare diseases marked by substantial muscle loss and weakness."

The findings build on a landmark *Cell* publication from 2025, which established Atrogi's GRK2-biased signalling approach and detailed first-in-human safety data from a 69-subject phase 1 trial. The new results provide first human proof-of-mechanism and

HOT & NOT

NICE has issued final draft guidance recommending Tryngolza (olezarsen) for adults in England and Wales with genetically confirmed familial chylomicronaemia syndrome, but only when response to diet and conventional triglyceride-lowering treatments has been inadequate.

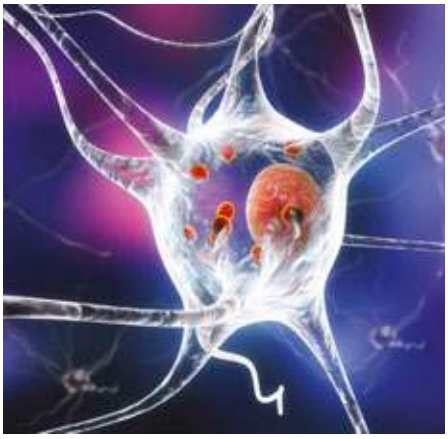
FCS is an ultra-rare inherited lipid disorder marked by severe hypertriglyceridaemia and a high risk of acute pancreatitis. The condition can lead to severe abdominal pain, hospitalisation, permanent organ dysfunction and death.

Alnylam has welcomed a Scottish Medicines Consortium decision to accept vutrisiran for adults with ATTR-CM, enabling eligible patients to access AMVUTTRA through NHS Scotland. The therapy is the first long-acting disease-modifying option to target the underlying biology of the condition.

Vutrisiran is administered as a subcutaneous injection every three months and delivers rapid, sustained knockdown of transthyretin proteins, observed from six weeks and persisting up to 30 months.

Galderma has announced new NEMLUVIO data to be presented at Fall Clinical 2026, including a post-hoc analysis from the ARCADIA LTE study showing that most adults and adolescents aged 12 and older who responded at week 16 maintained deep and lasting improvements in skin lesions and itch for up to three years. The findings add to growing evidence supporting long-term efficacy in moderate-to-severe atopic dermatitis.

Lundbeck presents phase 1b data for Parkinson's disease therapy



Lundbeck has reported results from an open-label phase 1b trial evaluating Lu AF28996, an investigational oral prodrug of a D1-like/D2-like dopamine receptor agonist, in people with advanced Parkinson's disease whose motor symptoms remained suboptimally controlled despite optimised non-invasive treatment. The findings are being presented at MDS 2026 in Seoul.

Parkinson's disease involves progressive degeneration of dopamine-producing neurons. Many people develop motor complications over time, including fluctuations between Good ON-time and OFF-time, and treatment-related dyskinesia.

Existing options for advanced disease often require invasive procedures or continuous drug delivery, highlighting the need for effective non-invasive approaches.

Tarek Samad, Executive Vice President and Head of Research & Development at Lundbeck, said: "Many people with advanced Parkinson's disease continue to experience motor fluctuations and dyskinesia that can significantly affect daily life.

"We are encouraged by the phase Ib results with Lu AF28996, including the improvements observed alongside substantial reductions in levodopa dose. With the DARE2 phase 2 trial now underway, we are taking the next step in evaluating its potential in a larger, randomised and controlled study."

In part B of the trial, 34 participants received Lu AF28996 twice daily for six weeks, with 25 continuing for an optional 12-week extension. Most treatment-emergent adverse events were mild, with no unexpected safety signals. The most common events were nausea, dizziness and fall.

SMC accepts AQUIPTA for eligible migraine patients in Scotland



AbbVie has announced that the SMC has accepted AQUIPTA (atogepant) for acute migraine treatment in adults, only if at least two triptans were previously tried without sufficient effect, or triptans were contraindicated or not tolerated, and NSAIDs and paracetamol were also tried but did not work well enough. Suitable patients can now be prescribed atogepant for acute use within NHS Scotland.

The acceptance follows NICE's recommendation published on June 30, 2026 and the MHRA's marketing authorisation granted on April 22, 2026. Migraine affects around 600,000 adults in Scotland and is the second leading global cause of years lived with disability among people aged 15 to 49 years.

Migraine is widely misunderstood as merely a headache. Symptoms include recurrent moderate-to-severe throbbing head pain, nausea, vomiting and sensitivity to light and sound. The condition can disrupt daily life and prevent people from carrying out everyday activities. It also carries a considerable emotional burden, with many people reporting stigma and dismissal of their symptoms.

Rob Music, CEO at the Migraine Trust, said: "Access to appropriate migraine care can be seriously inconsistent, creating a postcode lottery. We know that many people with migraine struggle to access the treatments they need or had to face long waits to see a specialist before finding the option that works best for them."

Mums whose babies developed life-threatening sepsis and meningitis from group B Streptococcus are urging pregnant women to join a new vaccine study.

The BEATRIX study, supported by the **NIHR** and sponsored by **Pfizer**, is the first large-scale phase 3 vaccine trial for GBS. Researchers from the NHS and UK universities, alongside international partners, aim to prevent avoidable infant deaths and stillbirths.

GBS is the leading cause of life-threatening infection in newborns, causing sepsis, pneumonia and meningitis.

A new **Royal College of Nursing** report warns that patients are being harmed daily due to severe nurse shortages across England's NHS.

Trusts are reporting hundreds of 'red flag' safety incidents each month, including delayed pain relief, missed vital-sign checks and postponed essential medication. The analysis suggests the NHS is short of around 55,000 registered nurses.

A government-commissioned inquiry warns the **NHS** is heading for 'system failures' as demand for ADHD, autism and wider mental health care surges. The review found soaring distress across all age groups, years-long waits for assessment, and rising overdiagnosis risks. Experts say the system cannot cope.



Burnham ambition

Fifth member of The Smiths attempts to write a compelling chorus

So, Andy Burnham's NHS – what does this Prime Minister mean for pharma?

With prevention, integration and devolution at the heart of his political philosophy, Andy Burnham brings an unusually developed vision of healthcare to Downing Street. But will his brand of 'business-friendly socialism' deliver for the pharmaceutical industry?

In June 2009, I found myself in a press huddle with Andy Burnham, newly installed as Health Secretary in Gordon Brown's government. He looked about 16, had been in the job for barely a week, and after I got over quite how big his eyes were, I asked him what his overriding priority would be. His answer was immediate: prevention.

Seventeen years later, Burnham is Prime Minister, and remarkably little has changed. Prevention has become the organising principle of his political philosophy, extending beyond healthcare into housing, education, employment and welfare.

At my training company Life Science Access Academy, our clients are asking us how to prepare for the future. Well, it may well involve a thorough understanding of this word, prevention, in healthcare. For only prevention, in its widest sense, will ultimately reduce the inexorable demand on the NHS.

For Britain's pharmaceutical industry, understanding this philosophy may be the key to understanding the next three years of NHS policy – and potentially considerably longer.

The Manchester model

But first, a little more about the man. Burnham is unusual among prime ministers in having both run the Department of Health and spent nearly a decade developing his own approach to public service reform.

As Mayor of Greater Manchester between 2017 and 2026, he championed 'Manchesterism': a blend of devolution, public service integration, economic development and active government.



‘Companies demonstrating how their medicines support earlier diagnosis or keep people economically active will speak Burnham’s language’

Its central proposition is that Whitehall’s departmental boundaries frequently obstruct progress. Poor housing produces ill health. Ill health reduces employment and productivity. Inadequate social care causes hospital admissions and delayed discharges. These interconnected problems require coordinated solutions.

Greater Manchester’s experiment in health and social care devolution enabled some of these ideas to be tested. Its achievements have been mixed but encouraging, with research identifying improvements in life expectancy, well-being and some indicators of health inequality, although obesity and emergency care pressures remain stubborn.

Burnham’s ambition is now to apply this approach nationally.

Prevention, in this worldview, extends beyond vaccinations, screening and healthy lifestyles. It means intervening earlier across health, care and social policy – including with medicines, digital and device interventions – rather than paying considerably more to address the consequences later.

This is entirely consistent with the three shifts underpinning the existing 10 Year Health Plan: hospital to community, analogue to digital, and sickness to prevention. Burnham has inherited a programme that, philosophically at least, he might have written himself.

Friend or foe of pharma?

The pharmaceutical industry might reasonably wonder whether a politician associated with public ownership, state intervention and democratic socialism will prove sympathetic to its commercial interests.

The evidence suggests a nuanced answer.

Burnham has characterised his economic philosophy as ‘business-friendly socialism’, and Greater Manchester’s development depended heavily upon partnerships with private investors.

Life sciences were among its important growth sectors, with the city region developing a substantial innovation ecosystem connecting universities, NHS organisations, technology companies and pharmaceutical manufacturers.

Health Innovation Manchester, established in 2017, embodies the collaboration Burnham favours: connecting industry and research with local health service needs.

He is neither instinctively hostile to private enterprise nor an enthusiast for outsourcing public services. Burnham appears comfortable with businesses generating profits through innovation and investment, while remaining sceptical about private interests extracting value from essential public services.

For pharma, that suggests opportunity accompanied by expectations.

Companies demonstrating how their medicines prevent deterioration, reduce hospitalisation, support earlier diagnosis or keep people economically active will find themselves speaking Burnham’s language.

The proposition that a treatment deserves NHS funding simply because it is innovative may prove less persuasive.

And prevention should not be confused with cheap interventions. Effective medicines for obesity, cardiovascular disease, diabetes and other chronic conditions could become central to his agenda, particularly where benefits extend beyond conventional clinical endpoints.

The commercial realities

There is, however, considerable difference between being pro-life sciences and pro-pharmaceutical pricing.

The UK-US pharmaceuticals agreement has already committed Britain to higher spending on innovative medicines, changes to NICE’s cost-effectiveness thresholds and a more favourable commercial environment.

The successor to the current voluntary pricing agreement, due in January 2029, will test Burnham’s relationship with industry.

His government must reconcile commitments to pharmaceutical investment with NHS financial constraints. Manufacturers seeking improved returns will face competing demands from social care, community services, workforce investment and hospital recovery.

There is also tension between national efforts to accelerate medicines access and Burnham’s enthusiasm for devolution.

The developing Single National Formulary, for example, seeks to reduce unwarranted geographical prescribing variation. But a more locally empowered NHS raises questions about who controls implementation, prescribing priorities and resources.

Burnham must balance local autonomy with national consistency.

Ultimately, the industry's most productive argument may be economic: that effective medicines adoption contributes to a healthier workforce, reduced demand for expensive services, and improved productivity.

Why Yvette Cooper?

Burnham's appointment of Yvette Cooper as Health and Social Care Secretary was revealing.

Cooper – your classic 'safe pair of hands' – is among Labour's most experienced political operators, having held senior government positions including at the Treasury, Home Office and Foreign Office. She also served as a junior health minister between 1999 and 2002, contributing to the first NHS Cancer Plan.

Her appointment provides political authority to a portfolio undergoing major structural change.

It suggests Burnham has little interest in making healthcare a one-man operation.

Cooper's unlikely to approach the brief as a campaigning outsider seeking wholesale transformation. She is more plausibly a disciplined, detail-oriented administrator focused on performance, accountability and implementation.

Her initial priorities reinforce that impression: maternity safety, social care, mental health and operational pressures.

Above all, Cooper's appointment appears designed to give social care the prominence Burnham believes it has lacked.

She has the experience to challenge the Treasury, coordinate colleagues and manage conflicts accompanying reform.

For pharma, she may prove a demanding rather than ideological interlocutor: interested in evidence, deliverability and demonstrable benefits, but operating within a government whose ambitions extend beyond medicines policy.

The big-ticket agenda

The most consequential development may be Burnham's determination to confront the long-standing failure to reform social care.

His proposed National Care Service, announced in September, would ultimately introduce free personal care for older people, supported by changes to the state pension settlement. Baroness Casey's commission is expected to report in summer 2027, with implementation envisaged during the next Parliament.

This is politically ambitious and financially hazardous, but consistent with Burnham's belief that health and social care cannot operate separately.

Meanwhile, the Health Bill progressing through Parliament will reshape NHS governance.

Its central measure is the abolition of NHS England, transferring responsibilities to DHSC and integrated care boards. Other provisions include enabling a single patient record, changing patient safety arrangements and giving local NHS organisations greater flexibility.

The legislation also envisages closer relationships between ICBs and elected regional leadership, including mayoral representation.

This expresses Burnham's belief that democratic accountability and devolution should play greater roles in public services.

Yet the Bill highlights a contradiction. Abolishing NHS England concentrates authority in ministers' hands, potentially increasing central control while government promises local autonomy.

Resolving that tension will be critical.

Alongside structural reform, Burnham must sustain improvements in waiting times, cancer services, urgent care, mental health and patient safety while delivering neighbourhood health services.

The pitfalls

Burnham's greatest difficulty may be that his preferred reforms require investment now to produce savings much later.

Prevention is attractive but financially awkward. Funding community services, early intervention and social care while maintaining hospital capacity creates substantial transitional costs.

There is no guarantee reduced acute demand will materialise quickly enough to release resources.

Devolution brings complications too. Greater Manchester benefited from distinctive political leadership, institutional relationships and civic identity. Reproducing its model across England, where local government capacity and NHS relationships differ, will not be straightforward.

And NHS structural change has an unfortunate tendency to consume the managerial attention required for actual improvement.

Abolishing NHS England is particularly formidable, with responsibilities, staff and accountability arrangements requiring reorganisation.

These obstacles could frustrate even a prime minister deeply committed to reform.

The 2029 question

Yet Burnham has one significant advantage: an increasingly credible prospect of winning the next general election.

Recent polling suggests Labour has recovered ground under his leadership, with Burnham retaining stronger personal ratings than his principal opponents. Victory in 2029 is far from guaranteed, but increasingly plausible.

A renewed mandate would radically improve the prospects for the 10 Year Health Plan.

Without one, Burnham may spend his premiership laying foundations that a successor could abandon. With another parliamentary term, he would have time to implement social care reform, develop neighbourhood health services and demonstrate whether prevention genuinely reduces NHS demand.

That would give Pharma a coherent policy direction stretching into the 2030s.

But it would demand a different relationship with government: less narrowly focused on individual product pricing and reimbursement, and more concerned with contributions to population health, prevention, service transformation and economic growth.

I remember that young Health Secretary's answer in 2009 because it was unequivocal. Prevention was a priority then, and remains so today. The difference is that Andy Burnham now has an opportunity to make it the organising principle in healthcare.

Whether the NHS – and the pharmaceutical industry – can adapt to that ambition may define his premiership. ▲

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Go to accessacademy.cloud



Supporting heart patients between appointments

For Alice, support was needed long after she left the consultation room

Like many patients living with a heart or circulatory condition, some of Alice’s biggest questions emerged after the appointment.

Questions about understanding her diagnosis, navigating treatment options, adapting to lifestyle changes and making sense of what comes next.

Healthcare professionals play a vital role in supporting patients through these challenges, but many concerns arise between appointments. Access to trusted information, reassurance and guidance during this time can help patients better understand their condition, feel more confident managing their health and engage more effectively with their care.

At British Heart Foundation (BHF), our Information & Support services are designed to complement the care patients receive from healthcare professionals and the NHS. Our aim is to help people better understand their condition, build confidence in managing their health and access emotional support throughout their journey.

A key part of our offer is BHF’s Heart Helpline. Staffed by experienced cardiac nurses, the service provides a trusted source of support for anyone affected by cardiovascular disease.

Whether someone has questions following a diagnosis, wants to better understand a treatment plan, is preparing for an upcoming appointment or is supporting a family member.

Importantly, the Heart Helpline exists for concerns that do not always fit into a clinical appointment and may arise days, weeks or even months later. These might relate to everyday life, recovery, managing a condition, understanding symptoms or simply seeking reassurance.

While the Helpline does not replace clinical care, it can act as an extension of the support healthcare professionals provide.

Alongside the Heart Helpline, BHF provides a wide range of information on cardiovascular conditions, treatments and healthy lifestyle changes. Available online and in print, these resources can support conversations with patients and provide trusted information they can refer to once they leave the consultation room.

The BHF Online Community, HealthUnlocked, also offers opportunities for people to connect with others who have shared similar experiences, creating valuable peer support alongside professional guidance.

Alice’s experience shows the difference trusted information, support and reassurance can make alongside clinical care, helping people feel supported when questions arise between appointments.

Support your patients beyond the consultation room

Heart Helpline | Heart Health info | Online Community

Find out more about BHF Information & Support
Search **“BHF Healthcare professionals”**

The great escape

Diabetes care: The technology has transformed. Now access must catch up

Few areas of healthcare demonstrate the transformative potential of HealthTech quite as clearly as diabetes. Over the past 50 years, advances in diagnostics, monitoring and insulin delivery have fundamentally changed how people manage the condition.

What once required repeated finger-prick tests, handwritten records and careful calculations can increasingly be managed through connected devices that monitor glucose levels continuously and, in some cases, automatically adjust insulin delivery.

For people living with diabetes, these developments offer something far more valuable than technological convenience. They provide greater freedom, confidence and control over a condition that requires attention every day.

For the NHS, they offer opportunities to prevent complications, reduce avoidable hospital attendances and make better use of already stretched clinical resources.

Yet, despite this progress, access to diabetes technology remains inconsistent across the country. While the UK has established care pathways and has made important commitments to funding innovation, the availability of approved technology does not necessarily translate into access for patients.

Regional differences in funding, workforce capacity and implementation mean that people who could benefit from the same technology do not always have the same opportunity to receive it.

This is increasingly the challenge facing our industry. We have technologies capable of transforming diabetes care. The question is whether the healthcare system can deliver them consistently, sustainably and equitably.

From finger-prick testing to the artificial pancreas

The evolution of diabetes technology is a remarkable example of how successive innovations can fundamentally change the experience of living with a long-term condition.

The introduction of home blood-glucose monitoring in the 1980s, followed by its wider adoption during the 1980s and 1990s, marked an important turning point in diabetes care. For the first time, people could routinely monitor their own glucose levels and make more informed decisions about their diet, lifestyle and treatment.

Over subsequent decades, digital devices made it possible to store readings and identify trends, giving patients and clinicians a more complete picture of how glucose levels changed throughout the day.

Continuous glucose monitoring represented another significant advance. Small wearable sensors, connected to smartphones and other devices, can now collect glucose data throughout the day and night, reducing reliance on repeated finger-prick testing and providing a much clearer picture of glucose fluctuations.

More recently, hybrid closed-loop systems have taken this a step further by connecting continuous glucose monitors with insulin pumps.

Sometimes described as an artificial pancreas, these systems use algorithms to automatically adjust insulin delivery in response to changing glucose levels, although users still need to manage certain aspects of their treatment.

For eligible people with type 1 diabetes, the benefits can be substantial. Better glucose management can reduce the risk of hypoglycaemia and other complications, while giving individuals greater flexibility in their daily lives.

Fewer severe episodes also mean fewer potentially avoidable emergency attendances, creating benefits for patients and the wider healthcare system.

This progress illustrates something important about HealthTech innovation. Transformative improvements do not always come from a single breakthrough. They frequently emerge through successive developments in diagnostics, medical devices, digital technology and medicines, brought together to address a clinical need.

Diabetes is a particularly powerful example of what can be achieved when these different areas of innovation work together.

Innovation is only valuable if patients can access it

The challenge is that technological progress has not been matched by equally consistent adoption across the NHS.

Hybrid closed-loop systems provide a useful example. National funding has helped support their introduction in England, following positive NICE guidance and considerable work by clinical leaders, including Professor Partha Kar OBE. This represents an important commitment to making innovative diabetes technology available to eligible patients.

However, national funding does not automatically guarantee local access. Uptake varies between regions, and the ability of individual services to introduce these technologies depends on considerably more than the availability of devices.

Patients need training, ongoing support and access to healthcare professionals who understand the technology. Clinical teams need the capacity to identify eligible patients, introduce new systems and provide assistance when problems arise.

Industry already plays an important role in supporting this process through education, technical assistance and collaboration with NHS services.

Where these arrangements are well established, technology can be integrated more effectively into routine care.

Where they are not, patients may experience delays or miss out altogether.

This creates a particularly concerning situation for people living in less advantaged communities. If access depends on the capacity and resources of individual services, there is a risk that innovation reinforces existing health inequalities, rather than helping to address them.



There is also the question of long-term funding. The current national funding arrangements for hybrid closed-loop technology are time-limited, raising important questions about how Integrated Care Boards will support existing users and newly eligible patients in the future.

For people who have already experienced the benefits of these systems, continuity of access matters enormously. Introducing a technology that transforms someone's ability to manage his or her condition, only to leave uncertainty over its future availability, is not a sustainable approach to care.

These challenges are not unique to diabetes. Across HealthTech, we repeatedly encounter situations in which regulatory approval, positive clinical guidance and demonstrated patient benefit are not enough to secure consistent adoption.

This is why the conversation needs to move beyond the technology itself and towards the funding, infrastructure and service arrangements required to make it work.

Making better use of the data we already collect

There is another significant opportunity that has yet to be fully realised: the enormous amount of information generated by modern diabetes technologies.

Continuous glucose monitors and connected insulin-delivery systems can provide detailed information about an individual's condition. However, different manufacturers operate different digital platforms, and interoperability between these systems remains a challenge.

For healthcare professionals managing large groups of patients, this fragmentation can make it difficult to bring information together and identify those who may need additional support.

Improving interoperability could fundamentally change how diabetes services operate.

Rather than relying primarily on scheduled appointments and retrospective assessments, clinicians could potentially use integrated data to identify patients whose glucose management is deteriorating and intervene before more serious complications develop.

It could also support more effective remote monitoring, allowing people to manage their condition at home while ensuring that healthcare professionals retain appropriate oversight.

This is particularly relevant to the NHS's ambition to shift towards prevention and deliver more care closer to home. Diabetes technology already generates much of the information needed to support more proactive management. The challenge is making that information accessible and useful across different services and systems.

The opportunity extends beyond people already diagnosed with diabetes. Earlier identification of people at risk of developing type 2 diabetes, combined with appropriate lifestyle interventions and ongoing monitoring, could help delay or prevent the progression of the condition.

However, technology must be supported by appropriate clinical pathways, evidence and professional oversight. Collecting more data is not an end in itself. Its value lies in enabling better decisions, earlier intervention and improved outcomes.

A shared responsibility for industry and the NHS

The HealthTech industry has an important role in addressing these challenges, but progress will require collaboration rather than individual companies working in isolation.

Through ABHI's Diabetes Group, we are bringing companies together to identify common barriers to procurement, funding and implementation. While companies continue to compete and drive improvements in their technologies, they share a common interest in ensuring that effective innovations reach the patients who need them.

That means working with national policymakers, NHS leaders, clinicians, healthcare professionals and commissioners to identify where implementation is falling short and what practical changes are required.

It also means recognising that successful adoption involves more than purchasing equipment. Training, clinical capacity, technical support and long-term funding all need to be considered alongside the initial cost of a device.

There is considerable potential for further innovation. Improvements in sensor technology could eventually make monitoring less intrusive and allow devices to remain in place for longer. Advances in connected systems may further reduce the daily burden of managing diabetes.

Longer-term developments in regenerative medicine could open entirely new approaches to treatment.

These are exciting possibilities, but they should not distract us from the opportunity immediately in front of us.

We already have technologies that can make a meaningful difference to people's lives. We have established clinical pathways, positive guidance and examples of successful implementation. What we need now is a more consistent approach to translating those advantages into everyday care.

Ultimately, the measure of progress in diabetes care should not simply be how sophisticated our technology becomes. It should be whether people living with diabetes can access the right support and treatment, regardless of their postcode or socioeconomic circumstances.

The evolution of diabetes technology demonstrates what our industry can achieve through sustained innovation. The next challenge is ensuring that the benefits of that innovation are available to everyone who needs them. ▲

Ravi Chana is Executive Director, Diagnostics at ABHI





Every drop counts

How central laboratory strategies are transforming paediatric clinical trials

Paediatric clinical trials are among the most challenging studies to conduct in drug development.

Researchers must generate robust safety, efficacy and biomarker data while working within strict physiological, ethical and operational constraints. Unlike adults, children have limited circulating blood volume, rapidly changing physiology and heightened sensitivity to invasive procedures.

As a result, trial designs that rely on conventional adult sampling approaches are often impractical in paediatric populations. These realities are driving a shift towards laboratory strategies designed around the needs of children rather than adapted from adult research.

Blood collection remains one of the most significant challenges. A sample volume that appears modest in an adult can represent a meaningful proportion of total blood volume in a neonate or young child. Regulatory guidance in the United States and Europe emphasises minimising blood collection and carefully managing cumulative blood loss during research participation.

In Europe, research-related blood loss is generally recommended not to exceed 1% of total blood volume at a single time point and 3% over four weeks. These restrictions require clinical teams to maximise the scientific value obtained from every specimen collected.

Increasingly, central laboratories are becoming involved much earlier in protocol development to address these constraints. Rather than serving solely as testing providers, laboratory experts can evaluate blood-volume requirements, model cumulative sampling burdens across study visits and assess whether planned analyses are truly necessary.

Early collaboration allows study teams to optimise sampling schedules, reduce unnecessary testing and identify feasibility risks before a protocol is finalised. This is particularly important in paediatric programmes, where operational challenges can quickly become participant burdens.

Innovation

Technological innovation is also expanding what is possible in paediatric research. Low-volume collection tubes, qualified for a range of laboratory tests, enable investigators to obtain required data using substantially smaller blood draws than traditional approaches.

Advances in microsampling have created additional opportunities. Capillary collection technologies and other minimally invasive sampling approaches may reduce reliance on venepuncture, potentially improving participant experience while supporting studies that require frequent monitoring.

These methods also offer potential advantages for decentralised and remote trial models, although analytical validation remains essential to confirm suitability for specific assays and study endpoints.

However, reducing collection volume is only part of the solution. Equally important is ensuring that each sample yields the maximum possible information. Sample-sparing laboratory workflows are therefore becoming increasingly valuable.

Strategies such as reflex testing, assay miniaturisation, platform consolidation and analyte prioritisation can help reduce sample consumption while maintaining analytical integrity. Preventing sample loss is also critical.

In paediatric studies, redraws resulting from haemolysis, clotting, processing errors or insufficient volume can create additional burden for participants and caregivers while jeopardising protocol compliance and data completeness. Robust collection, handling and quality-management procedures help minimise these risks.

As global paediatric trials become more complex, harmonised laboratory processes are gaining importance. Validating assays across multiple regions and reducing the need for sample splitting or intercontinental shipment can help preserve limited specimen volumes while maintaining consistency of results.

Looking ahead, digital planning tools and protocol-modelling technologies may further enhance trial feasibility by helping teams predict blood-volume requirements and evaluate alternative sampling strategies before studies begin.

Ultimately, successful paediatric trials depend on more than innovative technologies alone. They require integrated planning that balances scientific objectives with the realities of conducting research in children.

By combining thoughtful protocol design, low-volume sampling technologies, sample-conserving workflows and harmonised analytical processes, the clinical research community is finding new ways to generate high-quality data while reducing burden on young participants and their families. In paediatric research, every drop truly counts. ▲

Megan O'Shaughnessy is Scientific Affairs Specialist at ICON

Basic instinct

Should pharma communicators stop trying to make science 'simple'?

In pharma communications, translating complex science into a 'simple' narrative is often treated as an essential skill. But finding the right kind of simplicity for the right audience is anything but simple.

Does it mean shorter sentences? Fewer technical terms? One clean message that everyone can remember? And how do we know when we have struck the elusive balance between accessibility and accuracy?

To mull over this topic, I spoke to Simone Jendsch-Dowe, who leads European oncology communications at Daiichi Sankyo, a global pharma company based in Japan. She describes her job as "making complex science understandable, relevant and meaningful without stripping away the uncertainty, nuance or limitations".

However, she was quick to explain that, although patients, healthcare professionals and journalists need accessible information, a tidier headline should "never come at the expense of accuracy".

Her instinct to translate – rather than oversimplify – was shaped outside of the pharma bubble. Simone's first taste of working life was as a local newspaper intern, sent out on a scooter to meet people, ask questions and report on the stories shaping life in the town.

She went on to study American cultural history and communications while working for newspapers and radio stations, before moving into agency PR across consumer electronics, food and drink, and other fast-moving consumer sectors.

Asking the questions experts forget

She later applied for a role at Daiichi Sankyo without, by her own account, entirely knowing what she was applying for. Nearly ten years later, she has watched its European oncology business swell from just 30 people into a huge, complex and increasingly global organisation.

She has shifted gear from corporate and internal communications into product communications, which necessitated some speedy learning about treatment lines, patient populations, data milestones and that unique rhythm of a medical congress.

As she settled into her years in oncology, Simone became increasingly confident about where her strengths should be played in. She realised that, although communicators need enough scientific understanding to translate responsibly, their value does not lie in impersonating the medical expert in the room.

Their role is to ask the questions an expert may no longer think to ask: what does the data actually mean? What is genuinely new? Why should anyone care?

Senior comms leaders should make space for those questions, including the ones that feel embarrassingly basic. If a communicator cannot follow the explanation, there is a fair chance much of the intended audience will struggle too. Asking for clarity – and then asking for more – is evidence that comms is doing exactly the job it was brought in to do.

However, that all-important accuracy depends on keeping every message tied to robust evidence. Simone explained how she had become used to a consumer style of communications that aimed to create preference and influence behaviour. She needed to unlearn that very quickly in healthcare, where responsibilities are covered by professional communications codes and verbal nuance matters hugely.

Pressure to secure attention can still tempt teams to inflate an announcement beyond what the evidence supports. But words such as 'statistically significant' and 'clinically relevant' are not interchangeable decorations, and not every development is transformational.



Some are useful, encouraging or simply worth noting. Simone's advice reminded me of a parent's dinnertime refrain 'if you do not have anything to say, be quiet'. It may not delight a content calendar, but audiences notice when every update is presented as a breakthrough and they eventually stop believing any of them.

Building narratives that work globally

As Daiichi Sankyo's oncology business has grown, Simone's role has also become more about connecting the internal dots.

When medical affairs consider the data, commercial colleagues look at the wider business, market access brings a country-by-country view and affiliates understand what will and will not land locally, it is communications that helps the organisation connect and make sense of those perspectives. Simone and her team find the stories that can hold them together and keep information moving between teams.

So, what are Simone's words of wisdom for comms peers with ambitions of success in a multinational leadership role?

Firstly, she wants to be clear that regional comms teams cannot build an effective narrative centrally and drop it onto markets from a great height. Instead, Simone's advice is to involve local teams early, co-create the messages and allow sensible exceptions where audiences or contexts differ.

Online consistency has become more important as AI systems increasingly draw on published content, but consistency should not be justification for copy-and-paste execution everywhere.

Secondly, Simone urges comms leaders to invest in scientific literacy but not to ask teams to masquerade as scientists. Reward the person who challenges an overclaim rather than the person who finds a shinier adjective.

Bring markets and patient-facing colleagues into the work before the narrative is fixed. Treat internal connection as a strategic communications task rather than something to be delegated. And occasionally give everyone permission not to publish something.

Finally, remember that complexity is only a communications problem when nobody has done the work to understand it.

The communicator's craft is to learn enough, keep asking until the meaning is clear and explain it without hiding the evidence or uncertainty underneath. That requires curiosity, judgement and respect for the science – grounds for hope that AI will not be taking over our jobs any time soon. ▲

Jess Farmery is Senior Account Director, Health at Lexington Communications



Sharp focus

Who is responsible for monitoring AI medical devices following market authorisation?

The UK, the EU and the US have each spent 2026 moving more of their oversight of medical AI out of the approval process and into real-world use.

For pharma companies moving into AI, that brings conditional authorisation and post-market monitoring duties that could benefit patients and developers alike, but only if the monitoring is properly enforced and funded.

An AI model that performed well in testing at one hospital will not necessarily perform as well at another. Different data environments and a different patient mix can degrade a model's performance because the data and metadata it now sees may not match the data it learned from. That decline can go unnoticed for months.

Medical device regulation was designed around a single point of assessment, after which a product was expected to behave the same way for years.

That assumption was generous for software even before machine learning arrived, and it does not hold for AI at all. Regulators on both sides of the Atlantic have spent this year acknowledging as much, and their answers matter to pharma as much as to device makers.

Drug developers are moving into AI through companion diagnostics and clinical decision tools, whether they build them in-house or bring them in through acquisitions and partnerships.

The model the regulators are moving towards, with conditional authorisation followed by real-world monitoring, will look familiar to medicines, but for AI the obligations land in different places and on different people.

A life cycle view from the UK

In September, the National Commission into the Regulation of AI in Healthcare, set up by the MHRA, published a 119-page report containing 44 recommendations. Its central finding is that the UK framework was designed for static products assessed once, whereas AI products are updated frequently and can perform differently from one data setting to the next.

The commission wants oversight to run across the whole life of a product, from development through deployment and into real-world monitoring.

Among its more eye-catching proposals is staged authorisation, which the MHRA has compared to L-plates for learner drivers. A new model would be cleared for use within a controlled scope and allowed to expand as real-world evidence accumulates.

It would also replace pre-agreed lists of future software updates with defined boundaries within which a model can be adapted.

Around 77% of public respondents to the commission felt the current framework was somewhat or too loose, while 65% of industry respondents described it as somewhat or too restrictive, and 77% of healthcare professionals called for significant reform or a complete overhaul.

Both sides are pointing at the same imbalance with heavy scrutiny before launch and very little afterwards. A manufacturer can face a lengthy round of documentation for a significant software update, while the hospital using the same product may have no routine way of checking whether it still performs as it did at approval.

Europe buys time

The EU AI Act would have applied its high-risk obligations to AI-enabled medical devices from August 2027. Under the Digital Omnibus agreed this year, that date has moved to 2 August 2028, largely because the EU-wide technical standards that manufacturers would use to show they comply with the Act have not yet been written.

The amended law also lets the European Commission limit specific AI Act requirements where the Medical Devices Regulation (MDR) or In Vitro Diagnostic Regulation already impose equivalent obligations, answering years of complaints about overlapping conformity regimes.

> **'When an AI tool flags a possible abnormality on a scan, the radiologist checking could be swayed by that flag, particularly under time pressure'**

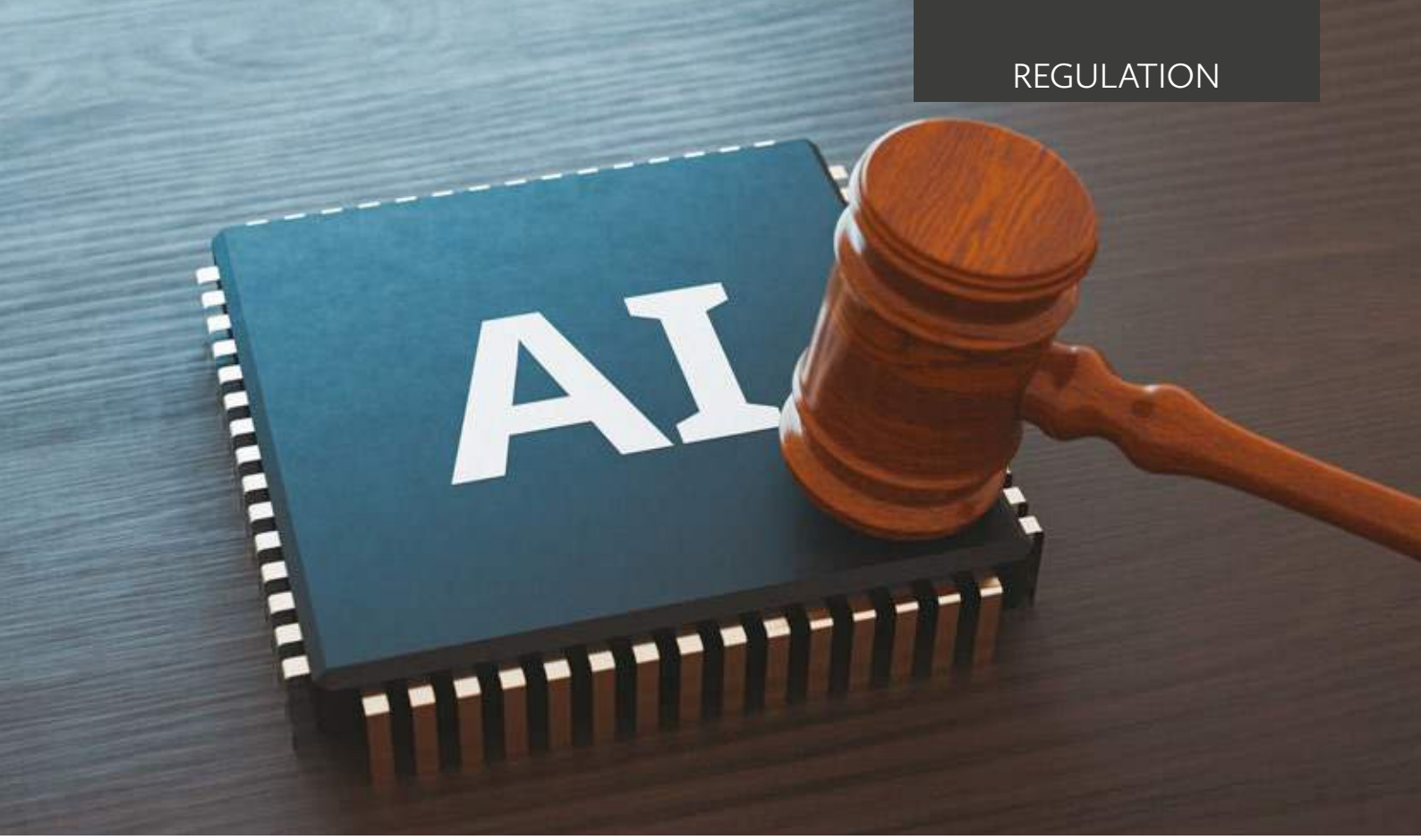
The underlying requirements are unchanged, though, and manufacturers will be building Quality Systems against standards that are still being drafted, with a real risk of rework once the final versions are published.

For patients, the delay means AI-enabled devices will keep reaching the EU market under the MDR alone, without the AI Act's specific requirements on training data quality, bias and human oversight, so the gap the UK commission identified stays open in Europe until 2028.

The American approach to change

The FDA's list of AI-enabled devices authorised for the US market had passed 1,450 by early 2026.

To cope with software that keeps changing after clearance, the agency finalised guidance at the end of 2024 on Predetermined Change Control Plans (PCCPs), which let a manufacturer agree in advance the modifications it intends to make and how it will validate them.



Draft guidance published a month later, and not yet finalised, looks further into the life of a device, asking manufacturers to consider transparency and bias from development through to decommissioning, including evidence that a device benefits all the groups it is meant to serve, and inviting comment on post-market performance monitoring plans.

The agency has been less willing to let those plans replace scrutiny before launch. When a radiology AI developer asked the FDA to exempt several types of imaging AI from 510(k) clearance, provided the manufacturer already held a clearance and ran a robust post-market plan, it refused in April and confirmed the decision in a Federal Register order in September.

Its clinical decision support guidance, finalised in January 2026, draws the boundary from the other side, setting out which software falls outside device regulation altogether.

Who carries the risk?

Most AI medical devices depend on a clinician to check their outputs, which moves much of the risk out of the product and onto the people using it.

When an AI tool flags a possible abnormality on a scan, the radiologist checking could be swayed by that flag, particularly under time pressure, a problem known as automation bias. Intended-purpose statements are often clear that outputs should not be relied upon without clinician judgment.

The National Commission found that under the existing negligence framework, claims are disproportionately likely to land on healthcare professionals and providers, creating what it calls 'liability sinks' in which frontline staff carry responsibility for AI failures they had little power to prevent. It wants contracts between manufacturers and providers to allocate every risk control explicitly, while accepting that wider legal reform will take longer.

A growing share of healthcare AI products is built on a small number of general-purpose foundation models, most of them owned outside the UK.

An update pushed by a model developer on another continent could alter the behaviour of a triage tool in a UK hospital without anyone in the regulatory chain being told, which is why the commission wants manufacturers to declare these dependencies and developers to be able to share technical detail confidentially with the MHRA.

Some of the most widely used AI sits outside the device framework altogether. Around a fifth of UK GPs surveyed for *BMJ Health & Care Informatics* said they had used generative AI tools such as ChatGPT in their work, in some cases to suggest diagnoses, and life cycle regulation can only monitor products that enter it.

Who pays for the monitoring?

Staged authorisation spares developers from anticipating every conceivable risk before a single patient has used a product, and gives patients a system that keeps checking performance after launch.

Life cycle regulation only works, however, if somebody pays for the life cycle. Continuous monitoring needs data pipelines and clinical safety officers with time to review incidents, and while manufacturers will carry part of that cost, a significant share falls on the organisations deploying the technology.

The government has said it accepts the commission's recommendations, and its cross-government response, which has yet to be published, should make clear whether hospitals will be given the funding and staff to monitor AI tools once they are in use.

If that funding does not materialise, hospitals will have nobody to collect the evidence the UK and EU approach relies on, and clinicians will go on carrying the risk when an AI tool gets something wrong. ▲

Dr Hugh Harvey is Managing Director at Hardian Health

Channelling discovery

Jelena Mann is Professor of Epigenetics at Newcastle University and the co-founder and former CEO of FibroFind, where she serves as non-executive director

Throughout her career, Jelena has combined deep biological understanding with commercial clarity to identify structural limitations in traditional approaches and position practical solutions that advance fibrosis and epigenetics.

Jelena played a central role in building FibroFind into a commercially focused business, establishing its scientific foundations and translating early insight into a scalable platform. Under her leadership, the company progressed from concept to a globally recognised partner to the world's leading pharmaceutical companies.

Journey from academic scientist to founder and CEO

I never intended to become a CEO. I spent my career as an academic scientist studying fibrosis along with the four founders.

Together, we had accumulated more than 100 years of research but shared a persistent frustration. However interesting our discoveries, we had no model that could tell us with confidence whether they would translate into patients.

That led us to develop a bioreactor capable of keeping precision-cut slices of healthy and diseased human tissue alive outside the body for prolonged periods, allowing potential therapies to be tested in the biological setting they were intended to treat.

We built it to answer our own scientific questions, but pharmaceutical companies became interested in testing their compounds, which led to further development.

Eventually, demand outgrew what we could deliver in an academic setting. In 2019, we founded FibroFind and I became CEO. It was never a planned career transition. I simply followed the science until it led me from running an academic research group to running a company.

Challenges of turning scientific research into a commercial proposition

I quickly learned that scientific value and commercial value are not the same. A technology may be innovative but that tells you surprisingly little about whether somebody will use it to make real decisions.

We were fortunate to spend several years operating within Newcastle University before establishing FibroFind, which allowed pharmaceutical scientists to bring us compounds and test whether the model answered commercial questions.

We stopped solely focusing on experiments we found scientifically interesting and started understanding what information drug developers need before progressing a molecule. It taught us that reproducibility matters as much as novelty. If an experiment contributes to a drug development decision, the client needs confidence in the underlying biology, how the tissue is sourced, how the study is performed and how the data is interpreted. Commercialisation is less about selling the science than learning how to deliver it reliably.

Why promising preclinical research does not always translate into clinical success

Preclinical models have contributed enormously to medicine but every model is an approximation of the target disease. Human disease exists within a complicated biological environment involving different cell types, tissue architecture, genetics, age, disease severity and treatment history, which is difficult to reproduce experimentally.

A drug can perform beautifully in a model and disappoint in patients, not because the experiment was badly conducted but because the biology that determined the clinical response was simply not present.

> 'I simply followed the science until it led me from running an academic research group to running a company'

This is why I became interested in studying medicines in viable human tissue, particularly tissue with established disease. When developing a treatment for fibrotic lung, kidney or liver disease, it is logical to ask how that drug behaves in the corresponding fibrotic tissue before moving into patients.

It will never tell you everything that will happen clinically but it can provide valuable evidence in the transition from promising experimental biology to a potential medicine.

How human-relevant models can strengthen decision-making during drug discovery

The important word is not human but relevant. A cell growing in a dish is human but it is not operating within the complex cellular neighbourhood of its original organ.

Precision-cut tissue slices are thin sections of viable human organ that preserve multiple cell types and much of their natural three-dimensional organisation, allowing researchers to study a potential medicine in something considerably closer to the biological environment it will eventually encounter in a patient.

The ability to work with diseased tissue is particularly interesting. Rather than creating an experimental approximation of fibrosis, inflammation or another pathology, a candidate can be tested in tissue in which that disease has already developed naturally in a person.

The question then becomes wonderfully simple: what does your drug do in the tissue you want to treat? That does not replace animal studies, cell systems or clinical trials but it can add highly relevant human evidence when there is still time to make a different development decision.

What you have learned from building and scaling a science-led life sciences business

Building FibroFind taught me that science-led companies succeed or fail on much more than the science. In the beginning, we did virtually everything ourselves, from experiments and client reports to tissue logistics and cleaning freezers. This meant we understood every part of the business. As the company grew, that model had to evolve. Processes replaced individual knowledge, automation replaced repetitive manual work and we had to recruit people who were better than us at particular jobs and trust them to do them.

I learnt that scientific credibility and commercial credibility have to be earned separately. A strong publication record may persuade somebody to have the first conversation with you but it will not necessarily persuade them to come back.

That depends on whether you deliver what you promised, whether the data withstands scrutiny and how you behave when something does not go according to plan. In science-led businesses, you cannot promise certainty but you can promise rigour, transparency and accountability.

Experience as a female scientist, founder and leader in the sector

I have never thought of myself as a female scientist, founder or leader. I am a scientist who founded and led a company and being a woman is incidental to that.

To me, it is like asking whether having blue eyes has affected my career in science. It has not. I expect to be judged on the quality of my work, the decisions I make and what I deliver and I would not want it any other way.

That is not to suggest that other women have not encountered barriers because of their sex or that inequalities do not exist because clearly, they do. It is simply not the lens through which I have viewed my own career.

Perhaps genuine equality is reached when that becomes completely unremarkable: when a woman building and leading a successful scientific company requires no more explanation than a man doing exactly the same thing. ▲



AI together now

Four realities reshaping HCP engagement strategies

Biopharma commercial strategies have historically relied heavily on internal data, analysing past interactions to predict future outcomes.

For years, field execution has been driven almost exclusively by internal CRM databases, a methodology equivalent to navigating a busy highway by staring only at your own rearview mirror. As healthcare systems grow increasingly complex, relying on internal historical data is a competitive risk.

In the meantime, commercial leaders now have access to a wide range of data points, both internal and external, which can be harnessed by AI to give field organisations a distinct competitive edge.

The key challenge, however, is ensuring these vast streams of information do not simply translate into noise but instead deliver the high-impact insights needed to drive precise decision-making.

To orchestrate customer engagement and power AI effectively, commercial leaders must see the entire market landscape – not just their own data – through clean, high-value data signals.

When we speak with commercial leaders across the industry, four realities consistently emerge that teams must address to stay competitive.

1. Tightening HCP access and fast-changing preferences require a dynamic approach

The reality facing modern commercial teams is stark. First, overall physician access continues to tighten: just 45% of HCPs are accessible to biopharmas, down from 60% in 2022. Furthermore, roughly half of those accessible physicians now limit their face-to-face engagement to three or fewer biopharma companies.

Second, beneath this restricted access, we have also observed shifting HCP engagement preferences. By analysing aggregated engagement data across 80% of industry CRM data, we see a clear trend: HCPs constantly change their channel preference.

Every 90 days, roughly half of HCPs in the top five EU countries change their interaction level or preferred way of engaging. An HCP who met with a field rep every week last quarter might suddenly switch to virtual-only contact, or the HCP might stop taking visits altogether. Over a 16-month period, nearly 30% of top-tier target prescribers drift into lower engagement tiers or drop off field schedules completely.

The underlying cause of this shift stems from changing clinic operational pressures, local administrative burdens and personal communication habits. When healthcare systems adjust their policies or when clinical reality for the dominant patient group changes, the HCPs' willingness to engage with commercial teams changes quickly.

To keep up with this trend of changing channel preferences, biopharmas need to move from sourcing static lists to a more dynamic approach. This will help direct field capacity towards the HCPs who are actually open to engaging via the right channels.

2. Reliance on CRM data alone leaves blind spots for AI

Faced with a shrinking window of opportunity and rapidly shifting HCP habits, commercial organisations are rushing to deploy AI workflows designed to orchestrate in-person visits, emails and virtual channels in real time.

However, an AI engine is only as smart as the data fuelling it. When AI feeds solely on internal CRM logs, targeting remains limited to internal knowledge.

> 'HCPs constantly change their channel preference, with half shifting their engagement behaviour every 90 days'

Internal CRM records show where field teams have already been, but they cannot show where an HCP is actively engaging across the broader industry. An AI algorithm relying exclusively on internal history will continue suggesting rep visits to an HCP who has quietly closed his or her doors to a brand, while ignoring a high-volume prescriber who is accessible and actively meeting with competitors.

Whether navigating the fragmented payer landscape in the US or strict country-level access policies across Europe, AI requires macro-level visibility into total industry activity, share of voice and real-time channel preferences to deliver true predictive precision.

Without this total-market context, even the most sophisticated AI engines simply automate outdated, reactive field behaviour.

3. Industry data reveals high-value prescribers your competitors may already see

When biopharmas fuel their orchestration engine with industry-wide HCP access data, field strategy fundamentally shifts from reactive to predictive. Macro-level transparency allows AI to pinpoint high-value prescribers who are actively engaging with the broader market but remain unreached by a specific brand.

For one top 20 biopharma company, this market clarity identified over 600 new high-value, highly accessible targets, unlocking a $9 million annualised sales uplift and an immediate 9x ROI.



Industry access data exposes critical visibility gaps regarding HCP accessibility:

- Clinicians labelled as 'no-access' in an internal CRM are frequently opening doors to competitors
- Across major markets, database churn is substantial; for example, from Q4 2025 to Q1 2026, the database of HCPs across the EU5 grew by 14.7% and decreased by 15.7%.

Without external market signals, field teams miss these new market entrants and misjudge HCP availability based on outdated internal history.

4. Engagement trends vary significantly across regions and specialties

The availability of broader industry data points gives far deeper context into changing HCP habits and preferences and precisely how fast those changes happen.

By analysing industry HCP access data, we have quantified 'HCP drift', measuring how frequently physicians change their engagement preferences with biopharma companies over time.

How quickly habits shift varies significantly depending on geography and therapeutic area. In fast-moving markets like the UK, nearly two-thirds of HCPs (64.6%) change their meeting frequency every three months due to health system workload shifts.

France sees a similar amount of movement, with 57.9% of HCPs shifting availability quarterly. Germany, Italy and the US maintain a steady baseline where roughly half of all HCPs change visit habits every 90 days.

Specialty dynamics vary as well. Primary care settings like retail pharmacy (54.6% drift) and general practice (44% drift) experience rapid rotations in availability as clinic workload demands change. Specialists like cardiologists (32.7%) keep much more predictable schedules over long periods.

In fast-changing markets or high-turnover specialties, updating target lists once a year is not frequent enough. Yearly updates mean field teams waste time chasing HCPs whose availability changed months ago.

Addressing the commercial blind spots

In hindsight, the biopharma companies succeeding with AI and omnichannel today are not necessarily the ones who had the largest budgets; they are the ones leveraging data and insights to fuel decision-making and stay agile in an ever-changing industry.

When 52% of HCP engagement tiers shift every 90 days, static annual target lists are no longer a viable foundation.

By integrating industry-wide HCP access data and real-time engagement drift metrics, biopharma companies can stop navigating by their own historical footprints and begin executing against the actual market landscape.

It is the fundamental difference between guessing your next tactical move and executing a winning commercial strategy. ▲

Marc Krüger is Director of HCP Access Strategy at Veeva Systems

Bot now?

The ability to explain AI's reasoning cannot be a proxy for safety in governance frameworks

Qinecsa's Beena Wood sets out other critical provisions that need to be designed into intelligently automated PV systems, and adapted by use case and associated risk profile, for an AI-based PV system to be deemed trustworthy and 'safe' – both at the outset and over time.

While large swathes of the life sciences industry have enthusiastically bought into what next generations of AI technology appear to offer them, they now need to double down on what will make AI-optimised systems safe and compliant. That's if they want to avoid exposing themselves to avoidable risk in a pharmacovigilance context.

Looking beyond explainability (an AI-enabled system's ability to evidence its reasoning) is an important part of this. Justifying how a conclusion was reached does not prevent error or ensuing harm.

Recognising this, regulators have made clear that they will not tolerate errors arising from vigilance failures linked to AI. AI governance in a PV setting now needs to be multilayered, adapted to the given use case and reviewed and honed over time.

MHRA in the UK, the US FDA and the EU's EMA all now refer to the need for governance and trust to be risk-based and proportionate, focused around outcomes and context of use. Meanwhile validation should not be a one-time activity, given how quickly needs and capabilities can change.

PV technology vendors are already on the case, but not so much pharma companies' procurement teams. That is, they are often looking for reassurance in the wrong places. Automation bias, where organisations or functions deploy AI and blindly trust its output, is problematic, certainly, and regulators are toughening their stance on such over-reliance.

In April 2026, the FDA issued its first-ever warning letter to explicitly cite over-reliance on AI as a violation, after a company (Purolea) used AI to generate compliance documents without human review and then attributed a missed regulatory requirement to the AI not having flagged it.

To avoid such scenarios, pharma companies need to be reassured not only that a system can explain its reasoning, but also that an AI-supported system will fail 'safely' if something goes wrong (such as by triggering alerts and prompting human checks).

In the future, inspectors will want to see operational evidence of what happens in practice in an organisation – that is, whether an AI system has followed the designated SOPs, not just that expectations have been documented.

Recommended selection criteria

Going forwards, a vetting framework for pharma companies procuring AI systems for PV should ideally seek to determine that the data feeding the system is verified and trustworthy, while the system reasons only in the context relevant to that specific decision.

It should also confirm that the AI system operates within the organisation's own rules, and governance for this use case has been shaped around its specific risk.

Oversight should be calibrated to that particular risk and 'designed in' ahead of time. Assurance should hold up continuously across the whole life cycle, and the organisation should be able to produce operational evidence that the system has followed its SOPs if an inspector asks.

> 'Justifying how a conclusion was reached does not prevent error – regulators will not tolerate vigilance failures linked to AI'

The way that the risk profile and controls will need to vary according to what the use case touches and where it comes in the PV life cycle, meanwhile, is usefully illustrated by the relative needs of case intake versus signal detection and evidence building.

In the former scenario, the primary risk is source and context (does the incoming data accurately reflect a single reported event, correctly triaged for seriousness and causality?).

When it comes to signal detection and evidence building, on the other hand, data is being pulled together across multiple sources and contexts – e.g. in building a disproportionality trend or cumulative evidence across cases, potentially for onward review by a safety review committee.

The stakes here are structurally different. A single case processed incorrectly is a serious error affecting one case. Incomplete scoping or provenance of the underlying data could mean missing an entire signal, with farther-reaching implications.



An additional, related risk concerns what is feeding the decision to escalate or close a case: i.e. whether the statistics, trends and supporting cases shown to a reviewer are being reliably calculated from real data, or derived from an AI-generated summary (this may be plausible yet inaccurate).

Staying alert

Governance needs to be adapted to the identified risk profile rather than be applied uniformly, including considerations around how much an AI-enhanced system is allowed to do without human review.

For the most consequential decisions, it may be that AI judgement needs to be removed altogether – either by requiring human sign-off before anything proceeds (so that the AI capability is never permitted to act on its own initiative), or by handling the decision using a fixed rule.

A further factor to look out for is 'automation complacency'. Take the scenario of a reviewer required to oversee 100 cases a day that have been processed by AI. After a while, the responsible individual is unlikely to be actively reviewing them, but rather rubber-stamping them. Companies will need to mitigate for that, if only by restating personal accountability, or monitoring for throughput of human checks that is unfeasibly quick.

Continuous monitoring capabilities should ideally include detection and flagging when a normally active data source has gone quiet, and of possible contradictions between sources – for instance, a patient reporting no concomitant medication against an HCP report vs. contradictory lab data (which could have a bearing on the causality assessment).

Evidence generation should be built into the way that an AI-based system operates day to day, if PV leads are to have real confidence in the reliability and trustworthiness of their systems.

Layering in all of the appropriate governance measures, and reviewing and adapting them over time, has to be the way to go now.

Only with a comprehensive and adaptable approach to governance will fears around AI 'going rogue' be calmed and the full spectrum of AI benefits be elicited. ▲

Beena Wood is Chief Product Officer at Qinecsa

Game changing

How pharmacies can stand out in the TikTok Shop supplements market



TikTok Shop has transformed how people discover and buy supplements. A product can go from a recommendation in a 20-second video to a purchase in only a few taps – often before people have had time to consider whether it is appropriate for them or what it can realistically achieve.

This has made wellness products more visible and accessible, which is not necessarily a bad thing. Social media can help people start conversations about health concerns they may previously have kept private, including fatigue, digestive issues, hair changes, nutrient deficiencies and weight management.

It can also introduce people to products and ingredients they may not have otherwise considered.

The challenge is that the speed of discovery can encourage people to make health decisions at the same speed. A compelling personal story, a before-and-after image or a popular creator's endorsement can feel more persuasive than measured information about dosage, evidence, suitability and potential limitations.

The fact that a supplement is popular does not mean it is the right product for every person watching.

What needs to be considered

Supplements are often presented online as simple additions to a routine, but they can sit alongside much more complex health circumstances. Someone may be taking prescription medicine, managing a long-term condition, pregnant or breastfeeding or experiencing symptoms that need medical assessment rather than a product recommendation.

Even when a supplement is appropriate, it is important that people understand what it is designed to support and its limitations in providing a quick fix for wider lifestyle or health concerns.

This is where clinically led businesses have an opportunity to offer something different. TikTok Shop allows pharmacies to reach consumers as they discover new wellness products, but their role should go beyond encouraging a purchase.

Product listings and supporting videos can explain what a supplement is intended to support, who should seek advice before using it and what it can realistically achieve.

Short, accessible videos can answer common questions about ingredients, suitability and realistic expectations, while directing viewers towards fuller guidance or professional advice before they buy.

In an increasingly competitive market, this also offers a way to stand out. Rather than competing solely through viral trends or influencer endorsements, clinically led brands can make qualified expertise visible through clear, evidence-based advice and access to professional support.

A short video cannot cover every consideration, but it can help someone understand what to check and where to find reliable information.

> 'Patient feedback should be considered alongside clinical evidence and robust product development'

Building trust through transparency

Trust is built through clarity and transparency about what a product contains, why an ingredient has been included, who it may be suitable for and where its limits lie.

The need for clearer information was reflected in a 2025 *Which* survey of 2,514 adults, which found that 52% of supplement users considered available information confusing, yet only 37% had consulted a healthcare professional before starting a supplement.

This points to a clear gap between the ease of discovering and purchasing products online and consumers' ability to judge whether they are appropriate for their individual needs, existing medication or wider health concerns. This creates clear space for clinically led brands to offer expert insight and practical guidance.

Building trust also means being honest when a concern is unlikely to be resolved through supplementation alone. Responsible communication should make people feel more informed, reducing unnecessary anxiety and avoiding the implication that they need a growing list of products to be healthy.

Guiding product development

Listening to patient feedback can reveal where people feel unsupported and what questions they repeatedly have. It can also highlight where education is needed.

For example, if patients consistently ask about fatigue, it is important to explain that this can have many causes and should not automatically be treated with a supplement. If people are unsure how a product fits alongside medication or a prescribed weight-management treatment, that should prompt clearer guidance and access to professional advice.

Patient feedback should be considered alongside clinical evidence and robust product development, helping keep innovation focused on genuine needs. Pharmacies, including Oushk Pharmacy, can bring questions raised by patients into this process.



In weight-management care, for example, recurring questions about nutrition and maintaining healthy routines can point to where clearer guidance or further product development may be useful. This helps keep the focus on patient needs rather than short-lived wellness trends.

This is particularly relevant as supplements become more closely connected with wider well-being and weight-management conversations. Weight loss medicines are used alongside dietary and lifestyle advice, but people's nutritional needs vary.

Some may have questions about protein or hydration; a clinician can assess whether additional support is needed and whether a supplement is appropriate. Advice should keep balanced, food-first nutrition and appropriate clinical care at its centre, rather than present supplements as a routine need.

People should be able to understand why a supplement has been formulated, what role it could play in their wider health routine and when further advice may be needed, particularly if they are trying to make sense of conflicting information.

This is particularly important in a fast-moving market where commercial messaging and genuine health education can be difficult to distinguish.

Informed choices in a fast-moving market

TikTok Shop is unlikely to slow down the relationship between wellness content and consumer purchasing.

The responsibility therefore lies with brands and healthcare professionals to make sure speed does not come at the expense of understanding. Consumers deserve products developed with their real experiences in mind, alongside information that helps them make considered choices. This means being transparent about ingredients and intended use and resisting exaggerated claims.

The future of the supplements market should be about building long-term trust through quality, transparency and products that respond to the issues people genuinely face.

For clinically led businesses, TikTok Shop offers a chance to bring evidence-informed education to consumers at the point of discovery.

When patient insight shapes product development and professional guidance accompanies social commerce, pharmacies can stand out by helping people make informed decisions. ▲

Hira Malik is Superintendent and Co-founder at Oushk Pharmacy

Yes brainer

Getting rare disease drugs past the brain's self-defence mechanism

The blood-brain barrier (BBB) is the brain's self-defence mechanism, keeping out bacteria and viruses but allowing in vital nutrients; unfortunately, it also blocks a very high per cent of drugs designed to treat neurological conditions.

Neurological diseases affect the central and peripheral nervous system, which includes the brain, spinal cord and nerves.

Here, we discuss current approaches to delivering drugs into the central nervous system (CNS), focusing on the specific challenges for key therapies like gene-silencing drugs that aim to treat rare neurological diseases. Almost half of the 8,000-10,000 known rare conditions are neurological.

The language surrounding novel approaches to CNS drug delivery can sometimes seem dramatic; there is talk of smuggling, piggybacking and Trojan horses. But however they are described, they are all designed to help alleviate the suffering caused by these predominantly severely debilitating diseases.

The BBB routinely blocks large or water-soluble molecules, but it is less strict about lipid compounds, which do not dissolve in water. Depending on your perspective, this is either good or bad – alcohol, nicotine and caffeine are lipid-soluble, so they slip seamlessly through – which is why you feel the buzz of a coffee or beer almost instantly.

Thicker than water

The CNS, like all major organs, requires a huge, constant supply of blood, which it receives via the carotid and vertebral arteries, delivering oxygen, nutrients, vitamins and hormones to every cell while removing harmful by-products such as carbon dioxide.

The brain needs about 20% of the body's total oxygen consumption and is very sensitive to oxygen depletion, starting to lose cells within minutes when deprived.

Oxygen crosses the BBB via simple passive diffusion straight through the lipid membranes of endothelial cells, simply because an oxygen molecule is very small and lipid-soluble. Lipids are fatty, organic compounds that do not dissolve in water.

Stop right there

The endothelium is a one-cell-thick layer that lines the interior surface of blood vessels and the heart; the cells are tightly packed, leaving no gaps for large or water-soluble substances. The BBB prevents roughly 98% of small-molecule drugs and nearly 100% of large-molecule or protein-based therapeutics from passing. Only tiny, highly fat-soluble molecules can easily pass by slipping directly through the cell membranes.

And if something unexpected or unwanted, like pesticides and pollutants ingested through food or water, or excess steroid hormones such as cortisol or progesterone, does make it through, then special proteins actively eject it back out into the bloodstream.

Some drugs are chemically engineered to 'piggyback' on natural carrier systems that transport essential nutrients like glucose or amino acids into the brain, but nature already knows about such tricks; viruses like HIV infect white blood cells, certain types of which the BBB lets through to patrol the brain – the pathogens ride inside them like a Trojan horse.

Ways and means

The most frequently adopted mechanism for crossing the barrier is known as receptor-mediated transcytosis (RMT), which moves molecules across a cell layer by binding to cell-surface receptors.

For complex, large therapeutics like monoclonal antibodies and gene therapies, RMT is the primary and most successful strategy. The drug is attached to a ligand or antibody that binds to receptors on the surface of endothelial cells. Ligands are molecules that bind to a larger biomolecule, such as a receptor protein.

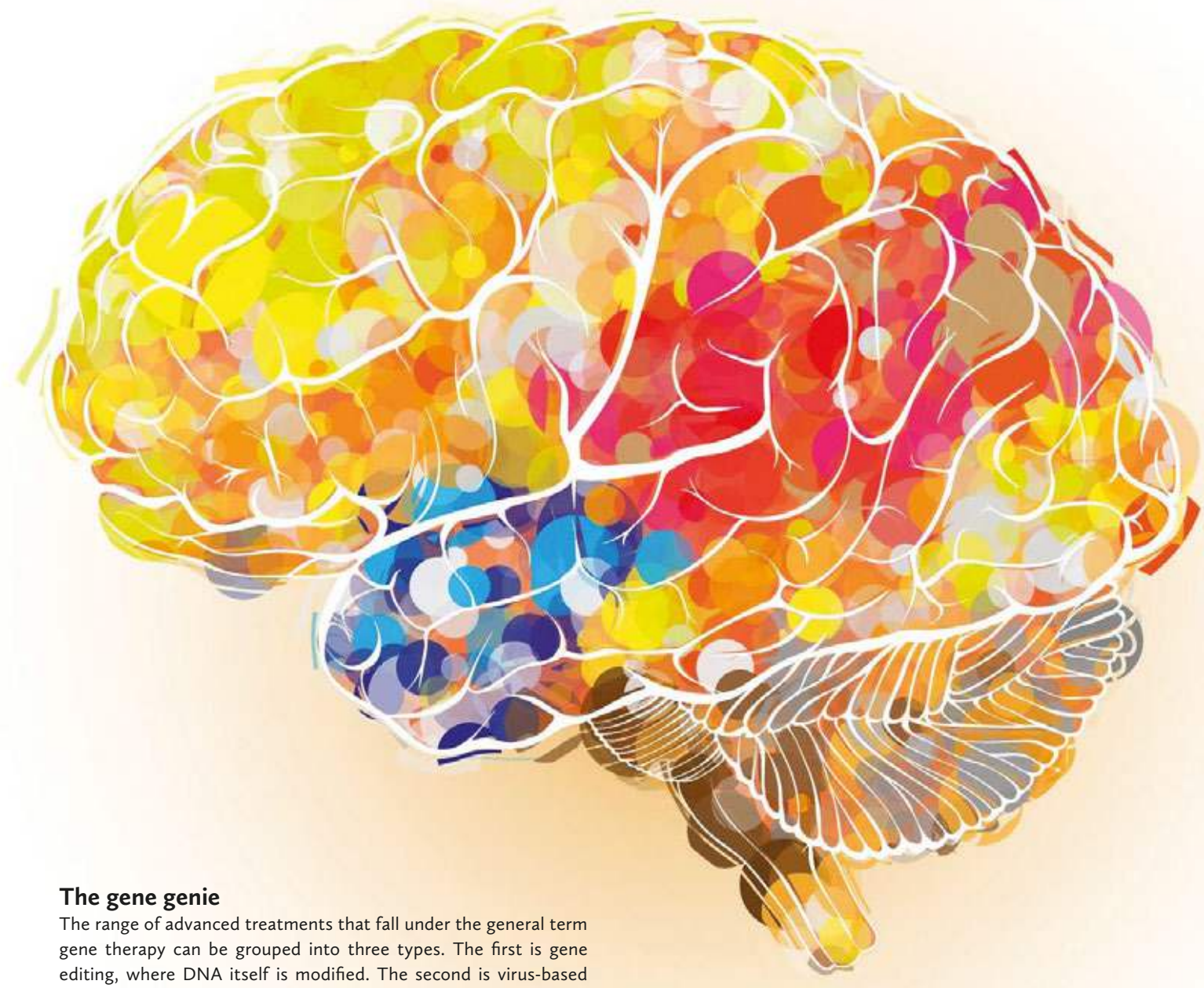
> **'Recent advances in genomics, biology and computing have given us the understanding and ability to design drugs'**

When ligands bind to receptors on bloodstream-side endothelial cells it triggers a process called endocytosis, in which the cell engulfs the receptor, the ligand and anything else attached. These are captured in a vesicle that moves through the inside of the cell to the CNS side, releasing its cargo out of the cell and into the CNS. The best-known example is the transferrin receptor, which transports iron into the brain.

Most success has been achieved by using antibodies as ligands to ferry an attached drug across the barrier. Researchers are also testing antibodies that can not only trigger RMT but also bind to targets once inside the brain. One such antibody, called trontinemab, is in phase 3 clinical trials for treating Alzheimer's disease.

For smaller molecules, lipid nanoparticles are being developed to ferry gene-based therapeutics, such as antisense oligonucleotides (ASOs), into the brain. Another approach uses ultrasound waves.

By injecting tiny gas bubbles into the bloodstream and exposing them to ultrasound waves, the bubbles vibrate and gently push the tightly packed barrier cells apart for a few hours, letting medication slide through.



The gene genie

The range of advanced treatments that fall under the general term gene therapy can be grouped into three types. The first is gene editing, where DNA itself is modified. The second is virus-based therapy, where working versions of faulty genes are delivered directly into affected areas. The third is gene silencing, where mutated genes are prevented from producing their associated toxic proteins; critically, the gene itself is untouched.

In general, gene silencing causes fewer side effects and is highly suitable for monogenic diseases, those caused by a single-gene mutation. ASOs are a key gene-silencing technology, but they are large and cannot naturally pass through the BBB.

The current clinical standard for delivering ASOs into the CNS is injection directly into the cerebrospinal fluid (CSF), but ASOs are large molecules and cannot efficiently cross the BBB on their own. As noted above, they are quickly cleared by the liver and kidneys when delivered intravenously.

So advanced delivery strategies have been developed to allow intravenous (IV) or subcutaneous ASO administration, including the use of transferrin receptors to trigger endocytosis and get those drugs into the CNS.

Final analysis

The blood-brain barrier is one of evolution's greatest achievements, protecting the brain from harmful, blood-borne substances while allowing in necessary supplies of the good stuff.

But neurological diseases are a huge global health challenge, one that cannot easily be addressed by conventional drugs, administered orally or intravenously, that are carried in the blood.

Recent advances in genomics, biology and computing have given us the understanding and ability to design drugs, and methods of delivering those drugs, that circumvent in one way or another the brain's self-defence mechanism. This is especially important for those living with rare diseases, almost all of which have major neurological impacts.

Beyond the challenges of getting drugs into the brain, these patients have further problems with physical drug delivery mechanisms; for key therapies like gene-silencing drugs, today's default approach of injecting directly into the spinal fluid is both risky and uncomfortable.

New and rapidly emerging approaches, based on piggybacking, smuggling and Trojan horses, are making IV-based solutions once more feasible and cost-effective – very good news for those living with a rare disease. ▲

Dan Williams is CEO at SynaptixBio

PharmaTimes

INTERNATIONAL CLINICAL RESEARCHER OF THE YEAR

The 2027 competition is Open for Entry







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Good times!

Competitions corner: finals, deadlines & what's coming up

Let's skip the corporate fluff: competition season isn't just about putting another trophy in the reception cabinet.

It's about stress-testing your strategy, getting honest feedback from industry legends and knowing exactly where you stand against the competition.

Here is your monthly check on what's open, what's closing and what to watch.

Looking ahead to the big celebrations

Marketer of the Year: Entries may be closed, but the competition is far from over. Finalists will put their strategic thinking, creativity and marketing expertise to the test before joining us for the PharmaTimes Awards evening on 12 November.

Communications Awards: The entries are in and the finalists are preparing to showcase their communications expertise. The finals and judging will culminate in the PharmaTimes Awards evening on 12 November alongside Marketer of the Year.

Excellence in Healthcare Partnerships (EHP) Awards: Entries are now closed and the judging process is underway. Following a standout debut, the EHP Awards will culminate in an evening celebrating the partnerships delivering meaningful outcomes for patients, healthcare organisations and industry on 4 February 2027.

Ready for your next challenge?

International Clinical Researcher of the Year: The search is now underway for the next generation of clinical research excellence. With categories recognising outstanding individual and team performance, entries are now open. Start preparing your entry and put your expertise in the spotlight.

Celebrating clinical research excellence

Clinical Researcher of the Year – The Americas: The awards evening took place on 19 October, celebrating the outstanding achievements, expertise and contributions of clinical researchers across the Americas. The event brought together finalists and industry professionals to recognise excellence and honour the individuals and teams helping to advance clinical research.

Start preparing your entry

Nursing Industry Excellence Awards: Entries and nominations will be opening soon. Now is the time to start thinking about the individuals, teams and achievements that deserve to be recognised across the nursing and healthcare community.

Think your team has what it takes? Don't leave it to the final hour, head to the PharmaTimes Competitions Portal to kick off your entry today.





Research for a hero!

A celebration of skill, spirit and scientific swagger at the 2026 Clinical Researcher of the Year Awards – The Americas. John Pinching reports

Clinical research may generally run on precision, protocol and relentless problem-solving, but once a year it is fuelled by pure, unapologetic joy (with a pinch of data-driven ecstasy).

Indeed, the eleventh 2026 Clinical Researcher of the Year – The Americas finals and gala unfolded at the Sheraton Imperial Hotel in North Carolina, amid wild celebrations.

This year's finalists arrived not as quiet operators behind the scenes, but as heroic ambassadors for a profession that keeps global healthcare moving. After months of assessments, scenario challenges and scrutiny from the Executive Steering Group, the best of the best stepped forward.

The categories reflected the breadth of modern clinical operations: Clinical Programmer, Data Management & Biostatistics, Clinical Research Co-ordinator, Clinical Trial Administrator, Clinical Trial Manager, Decentralised Solutions Individual of the Year, Novice CRA and Intermediate CRA.

The mood throughout the day was familiar to anyone who has been involved in any of our PharmaTimes Awards – a unique blend of competitive focus and genuine camaraderie. Finalists swapped stories from sites, shared hard-won wisdom and compared the dizzying quirks of working across time zones, all while navigating a steady flow of coffee, adrenaline and, finally, deafening applause.

By the time the gala began, our clinical crews were ready to show exactly why they had rocked up in outfits they had never or rarely worn before! It wasn't just an awards ceremony; it was a reminder that clinical research is delivered by real humans with real passion. And, now more than ever, that seemed very appropriate.

Ultimately, the 2026 event didn't simply recognise excellence – it honoured the resilience, creativity and determination that define clinical researchers everywhere. And yet again, it showed that when this community comes together, it doesn't just transform science, it takes it to a whole new level. ▲









WALK OF FAME

Clinical Programmer, Data Management & Biostatistics
Gold – Nancy Monterrubio López, PPD™ clinical research business of Thermo Fisher Scientific

Clinical Research Co-ordinator
Gold – Parker Shoaf, The University of North Carolina at Chapel Hill School of Medicine

Clinical Trial Administrator
Gold – Julia Lourdes Rotelle, Worldwide Clinical Trials

Clinical Trial Manager
Gold – Casey Wagner, Linical

Decentralised Solutions Individual of the Year
Gold – Alexis Kelly, PPD™ clinical research business of Thermo Fisher Scientific

Novice CRA
Gold – Bethany Ostermann, PPD™ clinical research business of Thermo Fisher Scientific

Intermediate CRA
Gold – Poornima Gopalan, CTI Clinical Trials

For complete list of USCROY winners please search 'pharmatimes uscroy winners'











■ Brunelcare has appointed **Bruce Moore** as its new Chair of Trustees, effective from 1 November. He succeeds Graham Russell, who is stepping down for health reasons after holding the position since July 2023.

Bruce is Chief Executive of Housing 21, a national not-for-profit provider of retirement living and extra care housing, a role he has held since 2013. His career includes senior leadership positions at Hanover Housing Group, Wolverhampton Homes and Anchor Trust. He has also served on the Boards of several housing associations and charities.

Bruce brings extensive experience and a longstanding connection to Brunelcare, having previously served as a trustee almost 20 years ago.

Bruce Moore said: "I am thrilled to be joining Brunelcare to help lead the organisation through its next chapter as Chair. Having previously served as a trustee for the charity almost twenty years ago, I am looking forward to returning in this new role."

"I have long admired the work of Brunelcare and the positive difference it makes to the thousands of people it provides care and support for every day. I look forward to working closely with the Board, Executive Team and colleagues across Brunelcare to uphold its vision of later living that makes the most of every moment."

As Chair, Bruce will work closely with Brunelcare's leadership team to drive forward its Strategy for 2024–2030. The strategy focuses on delivering great customer service, making homes fit for the future, providing tailored care and support and ensuring Brunelcare is a great place to work and thrive.



■ Populate, the place management platform owned by mixed-use developer Socius, has appointed **Dr Angela Kukula** as Director of Science and Innovation. She was previously Chief Executive of MedCity and Director of Life Sciences at London & Partners, where she championed London's life sciences sector internationally.

Her earlier career included roles as Commercial Director at Chelsea and Westminster Hospital NHS Foundation Trust and positions at the Institute of Cancer Research focused on commercialisation and business growth. She has played a central role in connecting growing companies with investors, research institutions and healthcare partners.

In her new role Angela will expand Populate's offer in the science and technology sectors. She will advise property owners, research institutions and corporate occupiers on creating ecosystems, commercial partnerships and campus infrastructure that support innovation.

One of her first projects will be the London Cancer Hub. Populate is working with Socius and Aviva Capital Partners, alongside the Institute of Cancer Research and Royal Marsden NHS Foundation Trust, to enhance the campus environment and bring together researchers, clinicians, oncology companies and investors.

Angela explained: "In my career to date I have focused on building the networks and partnerships that enable innovation and growth to happen. At Populate I will take this a step further and help to curate and manage physical places that make collaboration seamless and create a real commercial advantage for businesses."



Mover of the Month

■ Nuclera has appointed **Carl Raimond** as Chief Executive Officer as the company advances its proprietary protein technologies across key life-sciences workflows.

Co-founder and former CEO Dr Michael Chen has transitioned to the role of Chief Scientific and Business Officer, continuing to guide scientific strategy while supporting market development and strategic partnerships.

The leadership change marks a new phase in Nuclera's evolution, building on more than a decade of work in cell-free protein synthesis, digital microfluidics and protein production.

The combination of Carl's experience scaling life-sciences businesses with Michael's scientific leadership will support Nuclera as it expands adoption of its platform across priority applications.

Nuclera is applying its cell-free protein synthesis and digital microfluidics capabilities to accelerate protein science. Current focus areas include full-length IgG antibody screening, challenging membrane protein synthesis and soluble protein expression.

Carl joins Nuclera from Thermo Fisher Scientific, where he served as President of Proteomic Sciences following its acquisition of Olink Proteomics. He previously served as President of Olink Proteomics, helping lead the company through its $3.1 billion acquisition. His earlier career includes senior roles at PerkinElmer, Agilent Technologies and Affymetrix.



■ Numab Therapeutics has appointed **Dr Rajesh Chopra** as Chief Scientific Officer as the company continues to advance its proprietary pipeline of multispecific antibodies in immunology and oncology.

Rajesh brings nearly four decades of experience across oncology, immunology, translational medicine and drug development, with senior roles at Prologue Medicines, Apple Tree Partners, AstraZeneca, Celgene and The Institute of Cancer Research in London.

Across his career he has contributed to the discovery and development of innovative therapies from early research through regulatory approval. His experience spans scientific leadership, portfolio strategy and the progression of complex biologics through key development stages.

The appointment strengthens Numab's scientific capabilities as it advances its multispecific antibody pipeline, including NM81, a trispecific antibody for inflammatory bowel disease designed with best-in-class potential.

Numab's integrated discovery and engineering platform combines its proprietary λ-Cap, λ-Stealth and MATCH technologies with advanced Fc engineering, enabling modular design of differentiated multispecific antibodies.

Rajesh's background in oncology, immunology and translational medicine will support Numab's broader pipeline of programmes across immunology, inflammation and oncology. His leadership is expected to help accelerate the development of multispecific therapeutics with improved precision and clinical impact.



■ Pharmanovia has appointed **Dr Béchir Ben Hadj Yahia** as Global Head of Medical Affairs as the company expands its presence in specialty oncology. Based in Paris, he will lead Pharmanovia's global medical organisation, shaping medical strategy and overseeing its execution across the portfolio with in-market teams.

Béchir is an MD, PhD with more than 20 years of experience across healthcare, public health and global oncology. He spent almost ten years at Roche in senior medical roles specialising in oncology, working on more than ten oncology assets and contributing to five major launches.

Before entering the pharmaceutical industry, he pursued a clinical-academic career at university hospitals in Paris and Lille. He also served as an adviser to the French Ministry of Health's High Council for Public Health and the French National Cancer Institute, giving him direct insight into public health decision-making.

Dr Stephen Deacon, Chief Scientific Officer, said: "Béchir combines medical rigour, deep oncology expertise and a rare understanding of how medicines are evaluated and adopted. As our portfolio grows, Medical Affairs will be central to the value we create for clinicians and partners alike, and Béchir is the right person to make that happen. We are delighted to welcome him."

Béchir added: "In specialty medicine, value is created long before launch and sustained long after it. Medical Affairs sits at the heart of that journey, connecting science, clinical practice and the needs of healthcare systems."



■ BioDuro has appointed **Dr Greg Makara** as Senior Vice President Lead Discovery Chemistry as the company strengthens its early-phase drug discovery capabilities. In this role he will lead the expansion of BioDuro's computational chemistry, AI and lead discovery functions and further integrate computational approaches across the company's early drug discovery platform.

Greg brings more than two decades of experience in drug discovery and chemistry leadership across pharmaceutical, biotechnology and technology companies. His background spans library development, hit-to-lead and lead optimisation, computer-aided drug discovery and AI-assisted drug discovery.

In his new role Greg will work across the discovery organisation to support lead discovery projects and expand the use of computational approaches including molecular modelling, structure-based drug design, fragment-based discovery, virtual screening, molecular design and compound prioritisation.

"These capabilities will complement BioDuro's experimental chemistry, biology and DMPK expertise to help clients accelerate hit identification, lead generation and optimisation while making more informed decisions throughout early drug discovery," said Dr Armin Spura, CEO of BioDuro.

Greg added: "BioDuro has built a strong foundation in chemistry, biology, DMPK, and integrated drug discovery, and I am excited to help further connect these capabilities with computational and medicinal chemistry."

The data day

Where trustworthy evidence begins in the AI ecosystem



Clinical data is the most valuable asset in drug development. Preparing it is still one of the most manual stages of the entire process.

Before trial data can feed a submission, it has to be converted into the standardised format that regulators review. The work is skilled but repetitive, and anyone in clinical data management or statistical programming could describe it in detail. Few expect it to change. It has been filed, quietly, under the cost of doing business.

That trade-off is no longer necessary. AI, applied with experts firmly in control, can now take on the heaviest part of the work without loosening the rigour regulators expect. The clearest gains are at the very start of the pipeline, where trustworthy evidence begins.

Data arrives from electronic data capture systems, laboratories, devices and research partners, each in its own format. The target is the Study Data Tabulation Model, or SDTM, the industry standard that gives trial data a common structure for regulatory review.

The conversion is painstaking. Someone has to work out, variable by variable, where each piece of source data belongs, then write and check the code that moves it there. On a single study, that source-to-target mapping can take weeks of skilled effort. When a protocol amendment lands or a late data transfer arrives, the rework begins and timelines can start to slip.

It also resists scale, at a time when each trial draws on more data from more sources. More studies have simply meant more people doing more mapping. And because the work is so manual, it drifts: the same lab test can be mapped differently by different teams or vendors, and hard-won knowledge rarely carries over to the next study.

This is where AI changes the economics, and where many experienced practitioners grow wary. Regulated data is no place for tools nobody can inspect, and that scepticism is healthy.

The answer is to keep experts in charge. In a human-in-the-loop model, AI proposes the mappings and generates the transformation code, and specialists review and approve it, adjusting where needed, before anything is used. The AI does the repetitive groundwork but people make the decisions, and every decision can be seen and checked.

Nobody is arguing for fewer statistical programmers. The point is to move their time from repetitive mapping to the complex derivations and judgement calls that genuinely need them.

The starting line

Much of the conversation about clinical data integrity focuses on the finishing line: proving how results were produced and getting submissions right.

Both depend on what happens here first. SDTM feeds the analysis data sets, tables and figures that eventually reach a regulator, so a weakness at the start travels all the way through, and so does a delay.

Speeding up one step only helps if the chain stays connected. Inside a validated, governed environment, versioning and auditability are part of the work from the outset. SAS Clinical Data Transformation, where AI recommends mappings and generates code for experts to review, is one example of where the industry is heading.

The bigger shift is in how clinical data is seen. For too long it has been treated as plumbing. Its quality and speed shape how quickly a programme learns and how confidently it can go to regulators, which makes transforming it a strategic decision, not a matter for the back office.

Clinical data begins with the patients and volunteers who give their time and trust to a trial. It is patients, too, who gain most when that data moves faster without losing its integrity. That is what gets therapies to them sooner. ▲

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