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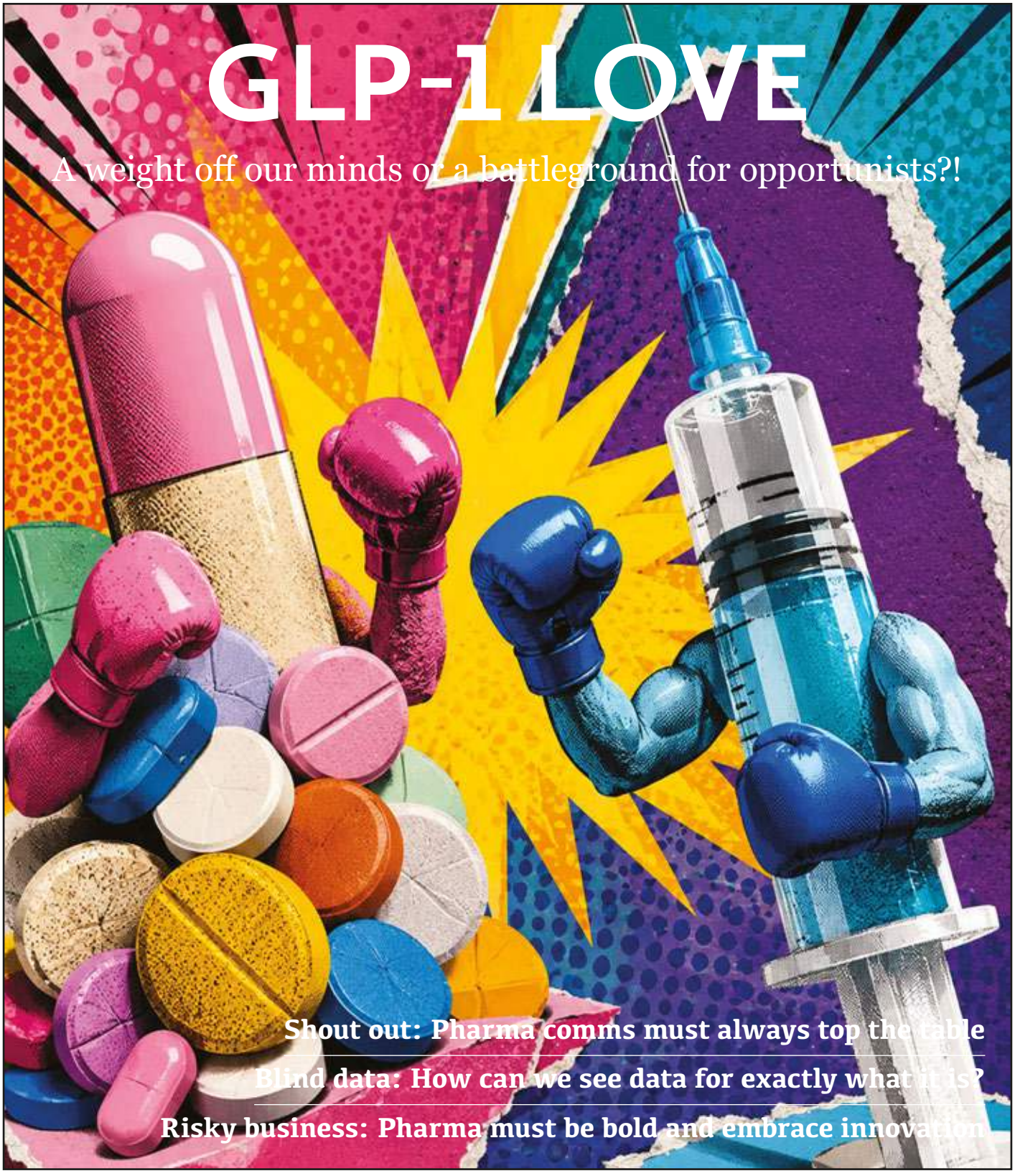
KICKSTARTING HEALTHCARE CONVERSATIONS



GLP-1 LOVE

A weight off our minds or a battleground for opportunists?!

Shout out: Pharma comms must always top the table

Blind data: How can we see data for exactly what it is?

Risky business: Pharma must be bold and embrace innovation

PharmaTimes Media Ltd,
Mansard House, Church Road
Little Bookham, Surrey, KT23 3JG
Tel: +44 (0)20 7240 6999
www.pharmatimes.com
Twitter: @PharmaTimes

MAGAZINE

John Pinching / editor
john.pinching@pharmatimes.com
Michelle Legrand / sales manager
michelle.legrand@pharmatimes.com

COMPETITIONS

Luci Sargood / business manager
luci.sargood@pharmatimes.com
Michelle Legrand / sales manager
michelle.legrand@pharmatimes.com
James Tansill / Marketing Executive
james.tansill@pharmatimes.com

PMGROUP

Tara Lovegrove / business director
tara.lovegrove@pharmatimes.com
Iona Everson / group managing editor
iona.everson@pharmatimes.com
Karl Equi / executive director
karl.equi@pharmatimes.com

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Missed the motivator?

Recently, someone found a Mars Bar from the early 90s during a routine hoarding clear-out.

After years of complaining that our intergalactic snack had been exponentially reducing in size, had we really misremembered its hitherto gargantuan form? We had not. It took three people to remove the item of historical confectionary from the scene.

Nowadays, the Mars Bar cannot be seen by the naked eye. Its PR team issued a possibly AI-generated statement about 'customer demand'.

This is yet another episode in the long history of 'human motivation'.

Indeed, after two years of dilly-dallying with AI we must hold the largest possible metaphorical magnifying glass up to what exactly is motivating it.

The other day I witnessed a chilling video. Not an AI video, but a video in which people who work in the AI ecosystem had attempted to train AI robot to 'do the laundry'. The hopeless bot failed horribly, but the most disturbing aspect was the reaction of the human beings. They were laughing because their disasterous creation couldn't even pick up a pair of pants.

Are AI people – in Silicon Valley or China or Milton Keynes or wherever – interested in eliminating the truly tedious things or is it easier to monetise our insatiable appetite for image manipulation, slop video production and really unhelpful customer service waffle?

We are told that AI can be used as a force for good or evil. It could be capable of destroying everything, even David Attenborough, or it could cure all known illnesses.

Either way, we must never trade our innate ability to challenge things, just because our new toy makes rubbish jumble sale posters.

Keep it real,

John Pinching
editor

@PharmaTimes

linkedin.com/company/pharmatimes

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NHS backs delayed-release treatment for cystinosis

NHS England has recommended delayed-release mercaptamine bitartrate for routine commissioning for eligible patients aged one year and above with nephropathic cystinosis.

The decision provides access to an additional cystine-depleting therapy that can be taken twice daily rather than the four-times-daily schedule required for the currently commissioned immediate-release formulation.

Nephropathic cystinosis affects around 1 in 100,000 to 200,000 live births, with roughly 200 people living with the condition in the UK. Two to three new cases are diagnosed each year.

David Game, Consultant Nephrologist and Clinical Lead for the Delayed-Release Mercaptamine Policy Proposal, said: "We welcome NHS England's decision to routinely commission delayed-release mercaptamine bitartrate for eligible people with nephropathic cystinosis."

He added: "Nephropathic cystinosis is a lifelong condition, and this decision marks an important milestone for the cystinosis community in England."

Care for people with nephropathic cystinosis is often complex and demanding for patients and families. With treatment options previously limited and requiring multiple daily doses, the twice-daily regimen may help reduce disruption to daily routines, improve adherence, delay complications and support quality of life.

Around 150 patients are expected to be eligible under NHS England's new commissioning policy. The condition is caused by the accumulation of cystine within cells, leading to tissue and organ damage, particularly in the eyes and kidneys.

David Garzón, Senior Director, Rare Diseases at Chiesi UK and Ireland, explained: "This is an important milestone for the nephropathic cystinosis community in England, providing an additional treatment option for these patients with a twice-daily dosing regimen."

Delayed-release mercaptamine bitartrate is approved across the UK and Europe, including France, Italy, Germany and Ireland. Following NHS England's decision, the medicine is now routinely available across all UK nations for eligible patients meeting local criteria.

BeOne Medicines secures UK innovation passport for HCC therapy

BeOne Medicines has been awarded an Innovation Passport for its investigational bispecific antibody BGB-B2033, marking a significant step in the company's plans to advance new treatment options for hepatocellular carcinoma.

The designation provides entry to the UK's Innovative Licensing and Access Pathway, intended to speed development and patient access for therapies targeting life-threatening or seriously debilitating conditions.

London-based BeOne Medicines said the Medicines and Healthcare products Regulatory Agency granted the passport for BGB-B2033, which targets GPC3 and 4-1BB and is being developed for patients with advanced or metastatic hepatocellular carcinoma.

James Harris, Interim General Manager, BeOne Medicines UK & Ireland Ltd., said: "Patients with hepatocellular carcinoma continue to face a poor prognosis, underscoring the urgent need for new treatment options.

"We believe BGB-B2033 has the potential to make a meaningful difference for this patient population, and we welcome the opportunity to participate in the Innovative Licensing and Access Pathway, which promotes early collaboration with UK health authorities to accelerate patient access.

"We look forward to working closely with the MHRA and ILAP Partners as we advance the development of this investigational medicine."

The Innovation Passport enables developers to work with ILAP Partners throughout medical development and may provide access to regulatory and development tools that support timely patient access.

Mission Therapeutics divests MTX652 to Dimerix in $292 million deal

Mission Therapeutics has agreed to divest its phase 2-ready acute kidney injury candidate MTX652 to Australian renal specialist Dimerix Limited in a deal worth up to US$292 million in upfront and milestone payments, alongside potential double-digit tiered royalties on global net sales.

The Cambridge-based biotech said the transaction validates its USP30 platform and will provide non-dilutive capital to accelerate MTX325, its lead CNS programme currently in phase 1 development for Parkinson's disease.

Mission described MTX652 as a first-in-class and best-in-class selective USP30 inhibitor designed to promote the removal of dysfunctional mitochondria. The asset will now be advanced by Dimerix for initial development in acute kidney injury.

Dr Anker Lundemose, Executive Director at Mission Therapeutics, said: "MTX652 has demonstrated a compelling clinical profile in phase 1 development completed by Mission Therapeutics to date.

"There is a substantial unmet need for novel efficacious therapies for acute kidney diseases and MTX652 represents a unique step forward for patients with these conditions. Dimerix's deep domain focus on renal disease and their proven operational expertise make them an excellent partner to further the development and commercialisation of this important drug."

He added: "This transaction provides an expedited path to patients for MTX652. It also strengthens Mission's financial position, which will enable us to accelerate development of our lead CNS-focused asset MTX325."

Dr Nina Webster, CEO & Managing Director at Dimerix, explained: "MTX652 represents an exciting and differentiated novel compound, and the acquisition of a phase 2-ready programme in acute kidney

disease represents an important step in executing our strategy to expand our renal pipeline."

She continued: "This asset is highly complementary to our phase 3 FSGS programme and broadens our development footprint across the kidney disease continuum, from acute injury through to chronic disease."

Jasper Therapeutics merges with Kira Pharmaceuticals

Jasper Therapeutics has completed its all-stock acquisition of Kira Pharmaceuticals, creating a combined business focused on developing biologic agents for a wide range of immunologically-driven conditions.

The deal is accompanied by a $132 million private placement co-led by Affinity Asset Advisors and Ikarian Capital, with participation from multiple life sciences investors and Mirador Therapeutics.

The financing, alongside an out-licensing agreement with Mirador worth $12 million upon signing, is expected to fund operations through the second half of 2028. The company will continue to trade on Nasdaq under the ticker JSPR.

The combined pipeline includes KP-104, a dual-complement inhibitor being developed for paroxysmal nocturnal haemoglobinuria and renal disorders; briquilimab, an anti-KIT antibody for transplant and immunologic indications; and KP-701, a dual-acting monoclonal antibody for autoantibody-mediated diseases.

Jasper expects to reach several clinical milestones over the coming years, including KP-104 phase 2 results, an end-of-phase 2 FDA meeting to support a potential phase 3 study, advancement of briquilimab in Severe Combined Immunodeficiency to a pre-Biologics License Application meeting, and first-in-human data for KP-701.

Jeet Mahal, President and Chief Executive Officer of Jasper, said: "We are pleased to announce this transaction with Kira following a thorough evaluation of strategic alternatives.

"Kira has built a truly differentiated complement portfolio that includes dual MOA beyond single-pathway agents and long-acting complement inhibitors, reflecting the quality of their science and the deep expertise of their team."

He added: "We are excited by the robust pipeline that this transaction creates, and are looking forward to advancing these important medicines for patients."

Patrick Crutcher, formerly Chairman of the Board of Kira, said: "Today's announcement marks a transformative step for the product candidates that Kira has developed. As we advance as part of Jasper, our mission is to develop biologic agents designed to improve outcomes in patients suffering from numerous immunologically driven disorders."

Postmenopausal study highlights oral anabolic potential

Entera Bio has announced that post hoc findings from its phase 2 trial of EB613, an oral PTH(1-34) tablet, have been chosen for two presentations at the ASBMR 2026 annual meeting in Boston.

The data includes a plenary poster, one of the highest-ranked categories selected by the ASBMR committee.

EB613 is in development as the first oral anabolic tablet for osteoporosis. The phase 2 study enrolled 161 postmenopausal women with low bone mass or osteoporosis and randomised them to placebo or four EB613 dose levels for six months.

Entera plans a single, randomised, double-blind, placebo-controlled phase 3 trial involving around 750 postmenopausal women to support a potential New Drug Application. A post hoc sensitivity analysis examined how baseline T-score severity influenced EB613's effects on bone mineral density and bone turnover markers at six months.

Tripto-Shkolnik explained: "EB613 produced rapid dose-proportional increases in biochemical markers of bone formation and reductions in markers of bone resorption."

He added: "The effects on trabecular and cortical bone suggest that bone strengthening and fracture resistance may occur rapidly with EB613."

The company noted that EB613 increased lumbar spine, total hip and femoral neck BMD, with 3D-DXA analysis showing improvements in integral volumetric BMD, trabecular volumetric BMD, cortical thickness and cortical surface BMD.

Oblenio doses first patients in phase 1a autoimmune trial

Oblenio has begun dosing patients in its phase 1a first-in-human trial of LBL-051, a tri-specific T cell engager designed to deplete both B cells and plasma cells in refractory autoimmune diseases.

The company said the therapy aims to deliver a durable immune system reset with the potential for sustained drug-free remission.

The open-label, multicentre study is enrolling patients across multiple autoimmune indications and uses subcutaneous dosing to assess safety, tolerability, clinical response, B cell and plasma cell depletion and selected biomarkers.

Ricardo Grieshaber-Bouyer, Professor of Clinical Systems Immunology and Head of the Clinical Trial Unit at FAU Erlangen-Nürnberg and Principal Investigator, said: "LBL-051 preclinical data have shown complete depletion of both B and plasma cells through dual targeting of CD19 and BCMA, with minimal cytokine release.

"These data support LBL-051's potential to achieve full B lineage immune reset consistently, which may outperform the results from approaches using a single B cell target."

He added: "The Paul Ehrlich Institute (PEI) has allowed us to pioneer a highly innovative, first-in-human, dose escalation trial design

which enables rapid and thoughtful evaluation of this off-the-shelf therapeutic approach, while prioritising patient safety, in a range of autoimmune diseases."

HOT & NOT

Qnovia has secured a worldwide exclusive licence to a new antimicrobial peptide developed at the University of Virginia, marking its move into a second therapeutic area alongside its smoking cessation programme.

The peptide, known as D8, uses a mechanism distinct from conventional antibiotics and has shown activity against multidrug-resistant bacterial pathogens and biodefence threat agents. Early laboratory and animal testing indicates potential across respiratory, bloodstream, skin and soft-tissue infections.

Sanofi has received European Commission approval to extend the indication of MenQuadfi to infants from six weeks of age, broadening access to protection against invasive meningococcal disease caused by serogroups A, C, W and Y.

The vaccine had previously been authorised in the EU for individuals aged 12 months and older. Invasive meningococcal disease is a rapidly progressing bacterial infection that can lead to death within 24 hours of symptom onset.

Polpharma Biologics has announced that the FDA and EMA have accepted for review the BLA and MAA for PB016, a proposed vedolizumab biosimilar to Entyvio for intravenous use in adults with moderately to severely active ulcerative colitis and Crohn's disease. The acceptances mark major milestones in the company's development programme and reinforce its commitment to expanding access to affordable biologic medicines.

Parsortix study shows promise for ADC target detection

CellBxHealth has announced the publication of an independent, peer-reviewed study demonstrating that its Parsortix platform can detect antibody-drug conjugate targets on circulating tumour cells taken from patients with triple-negative breast cancer and epithelial ovarian cancer.

The study was conducted by researchers at Trinity College Dublin and St James's Hospital, Dublin.

They used the Parsortix system to isolate circulating tumour cells from blood samples taken from patients with metastatic triple-negative breast cancer and advanced epithelial ovarian cancer.

The researchers showed that clinically relevant antibody-drug conjugate targets could be detected on Parsortix-enriched circulating tumour cells.

Key findings included detection of TROP-2, the target of the approved antibody-drug conjugate sacituzumab govitecan, on circulating tumour cells from triple-negative breast cancer patients. Importantly, this included cells with low EpCAM expression, a surface marker relied upon by conventional circulating tumour cell platforms.

The study also showed that FRα, the target of the approved antibody-drug conjugate mirvetuximab soravtansine, was detectable on circulating tumour cells from all three ovarian cancer patients assessed. PD-L1, an immune checkpoint marker relevant to combination immunotherapy strategies, was detectable alongside TROP-2 on the same circulating tumour cells.

A key result was the detection of antibody-drug conjugate targets on circulating tumour cells with low EpCAM expression. This is particularly relevant in aggressive cancers such as triple-negative breast cancer.

Vista trial begins dosing in precision cancer vaccine study

Infinitopes has dosed the first patient with ITOP1, its lead investigational therapeutic cancer vaccine, marking the first clinical evaluation of the company's Precision Immunomics platform.

The approach combines immunopeptidomic antigen discovery with engineered viral vector technologies to identify naturally presented tumour antigens capable of generating durable anti-tumour T-cell responses.

The VISTA study is a multicentre, randomised, double-blind, placebo-controlled phase 1/2a trial conducted with the University of Oxford. It will evaluate ITOP1 in patients with newly diagnosed, surgically resectable oesophageal and gastro-oesophageal junction adenocarcinoma.

Unlike post-surgical vaccination strategies, VISTA investigates treatment while the primary tumour remains in situ, aiming to determine whether earlier immune priming can generate stronger anti-tumour responses.

Current standard of care for resectable disease consists of neoadjuvant FLOT / durvalumab chemoimmunotherapy, surgery and adjuvant chemoimmunotherapy. In VISTA, ITOP1 is administered between chemoimmunotherapy and surgery, both before and after oesophagectomy, allowing investigators to assess vaccine-induced immune responses throughout first-line treatment.

Professor Mark Middleton, Chief Investigator of the VISTA trial, said: "The first patient dosed in VISTA is an important landmark for our programme and for the wider field of therapeutic cancer vaccines. The neoadjuvant setting provides a fantastic opportunity to study immune responses while the patient's primary tumour is still there."

Lexeo Therapeutics has secured Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA for LX2020, its investigational AAV-based gene therapy for PKP2 arrhythmogenic cardiomyopathy.

The decision follows interim clinical data from the ongoing HEROIC-PKP2 phase 1/2 trial.

The company said LX2020 now holds RMAT, Orphan Drug and Fast Track designations, strengthening its regulatory position as development continues.

NHS England continues to face significant pressures, with waiting lists still above seven million and cancer targets routinely missed. A&E departments report severe overcrowding, long ambulance delays and rising corridor care.

Staffing shortages persist across nursing, mental health and primary care, contributing to burnout and service disruption. Financial deficits are widening, while maternity and mental health services remain under scrutiny following multiple safety investigations.

NICE has not recommended lecanemab for routine NHS use in Alzheimer's disease, citing uncertainty over long-term clinical benefit and its very high cost. The decision represents one of the year's most high-profile negative appraisals, leaving patients without access to the therapy through standard NHS commissioning.

Word of mouth

Oral semaglutide signals new phase for obesity treatment in the UK

The UK approval of once-daily oral Wegovy is a significant moment for obesity treatment. For the first time, patients can access semaglutide for chronic weight management without using an injection, widening the range of formulations available and potentially removing a genuine barrier for people with needle anxiety.

Yet the arrival of a tablet should not be mistaken for the arrival of an effortless treatment pathway.

Oral semaglutide may feel familiar, but its clinical use is unusually dependent on careful administration and patient understanding. That dependence stems from the formulation challenge. Enabling a peptide medicine, which would ordinarily be broken down in the gastrointestinal tract, to be absorbed orally is an impressive pharmaceutical achievement.

However, the conditions required to support that absorption also bring strict administration requirements and a different set of adherence challenges. For some patients, incorporating those requirements into an established routine may be straightforward. For others, existing medication schedules, shift work or caring responsibilities could make consistent use more difficult.

The weekly injection avoids many of those daily decisions, meaning the assumption that tablets are inherently more convenient will not hold for every patient.

Oral Wegovy therefore expands choice rather than establishing a universally simpler route of treatment. Its clinical value will depend on appropriate patient selection, clear counselling and ongoing monitoring, with formulation decisions based on how safely and consistently each patient is likely to use the medicine.

From trial efficacy to real-world use

The evidence underpinning the drug's real-world use is encouraging. In OASIS 4, people taking 25mg of oral semaglutide once a day lost an average of 13.6% of their body weight over 64 weeks, compared with 2.2% among those taking a placebo.

Stomach and digestive side effects were the most common, a result in line with the established safety profile of semaglutide. The question now is how closely these outcomes will be replicated in routine practice, where treatment persistence and correct administration will be less tightly controlled.

The expansion of formulation choice is clinically useful, but it also places greater emphasis on treatment selection. Oral and injectable semaglutide are not directly interchangeable, and differences in administration, absorption and dosing frequency mean the most appropriate option will vary between patients. This becomes particularly important when considering a switch from one formulation to another.

Achieving comparable outcomes in practice will depend on more than making the tablet available. Patients will need to be prescribed the formulation they are most likely to use safely and consistently, supported by clear counselling and ongoing monitoring.

Switching requires clinical judgement

This need for individualised treatment selection comes at a time of heightened regulatory scrutiny of pharmacy-led weight-management services.

In April 2026, the General Pharmaceutical Council called for stronger clinical governance, risk assessment, documentation and follow-up across the sector.

Oral semaglutide adds another consideration to those responsibilities. Prescribers must assess whether patients can realistically follow the administration regimen, investigate suboptimal response before changing treatment and document why any switch is clinically appropriate.

> **'A needle-free formulation does not reduce the need for individual assessment, continued monitoring and planning'**

Dose strengths across oral and injectable semaglutide cannot be compared numerically. Oral semaglutide has lower and more variable bioavailability, and the effect of switching between formulations cannot easily be predicted. Although patients receiving 2.4mg injectable semaglutide once weekly can transition to the 25mg daily tablet, the availability of an approved pathway does not make switching a routine decision.

For a patient who is responding well to injectable treatment and tolerating it, convenience alone may not provide sufficient reason to change formulation. Any switch should follow a review of treatment response, adverse effects, concomitant medicines, patient preference and the likelihood that the oral regimen can be followed consistently.

A changing counterfeit risk

The introduction of an oral product may also change the illicit market for GLP-1 medicines in the UK.

The MHRA has repeatedly warned about falsified and illegally supplied weight-management products that may be contaminated, incorrectly dosed or contain ingredients that are not disclosed on the packaging.

Until now, much of the public concern around illicit GLP-1 supply has centred on injectable products.

Tablets are a more familiar and less intimidating dosage form, which may make unauthorised products appear more credible or lower-risk than an unverified injection. As demand grows for a needle-free option, illicit sellers may exploit that familiarity by presenting unlicensed tablets as simple, convenient equivalents to the authorised medicine.

The wider concern is that this could make prescription weight-management treatment feel more like a frictionless retail purchase.

Oral semaglutide may come in a familiar format, but it remains a prescription-only medicine with an established adverse-effect profile, specific administration requirements and a need for appropriate clinical assessment, gradual dose escalation and ongoing follow-up.

Widening choice

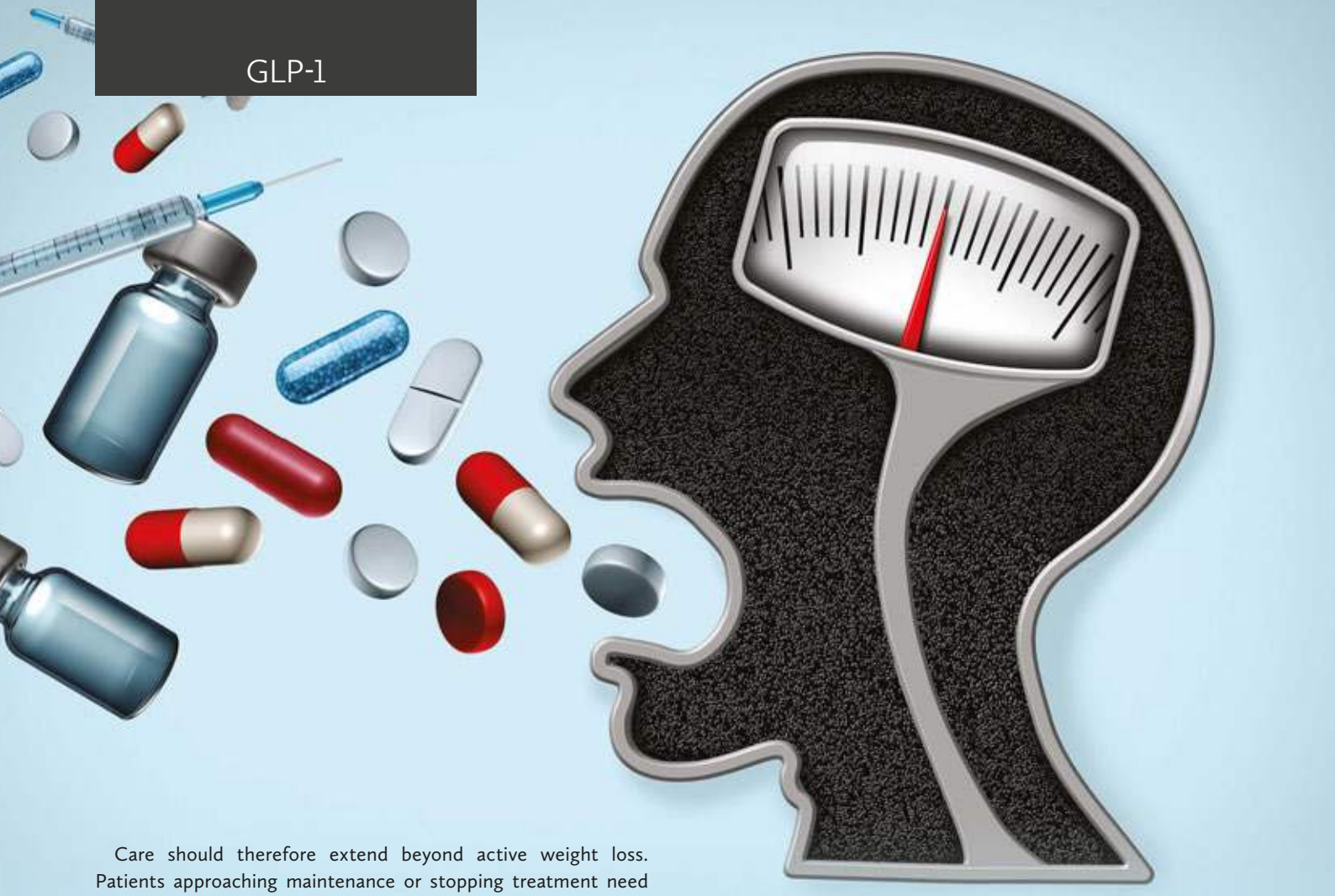
At Oushk Pharmacy, our experience supporting patients has shown that formulation preference is only one part of treatment selection.

Medical history, concomitant medicines, daily routine, previous treatment response and the ability to follow the administration requirements all influence whether a weekly injection or daily tablet is appropriate.

The decision should sit within an individualised care plan, with pharmacist-led monitoring and access to clinical support when treatment response, tolerability or a patient's circumstances change.

Suitability should also be considered across the full treatment pathway, rather than only at the point of prescribing. Appetite reduction and gastrointestinal issues may make it harder for some patients to meet their nutritional and hydration needs.

Dose adjustment, treatment interruption or discontinuation may introduce further challenges that require clinical and practical support.



Care should therefore extend beyond active weight loss. Patients approaching maintenance or stopping treatment need a personalised plan, continued clinical oversight and appropriate nutrition and well-being guidance to support long-term weight management.

While oral Wegovy widens treatment choice, its value will depend on the care surrounding it. A needle-free formulation may suit some patients well, but it does not reduce the need for individual assessment, continued monitoring and long-term planning.

Future of weight management

Oral Wegovy is an important step forward for the industry, because it gives eligible patients another licensed treatment option and may remove the barrier of injections for some. Its real impact, however, will be seen in routine practice, where treatment has to fit around existing medicines, work, family life and established habits.

The sector should avoid presenting the tablet as a simpler version of injectable semaglutide. It brings a different set of practical and clinical considerations, and patients will still need careful assessment, clear counselling and ongoing follow-up.

The future of obesity treatment will not be shaped by the number of formulations available alone. Progress will come from matching each patient to the right treatment and supporting them with appropriate monitoring, nutritional advice and realistic maintenance planning.

Oral semaglutide will widen choice, but it will not be right for everyone. Its success will depend on keeping clinical judgement at the centre of care as the market becomes more competitive, more convenient and more visible to the public.

That is how pharmaceutical innovation can lead to safer treatment and more sustainable outcomes in UK weight-management care. ▲

Pill behaviour – is the weight over?

1. Weight loss pills work in different ways, including appetite suppression, delayed gastric emptying and changes to nutrient absorption
2. Most prescription options are intended for people with obesity or overweight with related health risks, not for cosmetic use
3. GLP-1-based tablets, such as oral semaglutide, require strict administration rules to ensure proper absorption
4. Some medicines can cause gastrointestinal side effects, including nausea, constipation or diarrhoea
5. Treatment effectiveness depends heavily on adherence, correct dosing and consistent daily use
6. Weight loss pills are usually part of a wider plan that includes nutrition, physical activity and behavioural support
7. Many products sold online without a prescription may be falsified, contaminated or incorrectly dosed
8. Some medicines interact with existing prescriptions, meaning clinical assessment is essential before starting treatment
9. Stopping treatment suddenly can lead to weight regain, so dose changes should be supervised
10. Prescription weight loss pills require ongoing monitoring to assess response, tolerability and long-term suitability.

Hira Malik is Superintendent Pharmacist and Co-founder of Oushk Pharmacy

Connected trials

Addressing study complexity by meeting clinical trial sites where they are

Clinical trials are becoming increasingly complex. In a 2023 survey, 70% of investigative site staff said conducting studies had become more difficult over the previous five years.

For sponsors, this shows up as delayed decisions, duplicated effort and reduced visibility across their studies.

The challenge is rarely a lack of information. More often, it stems from fragmented processes, disconnected systems and limited access to operational insights at critical decision points.

Many study challenges can be traced back to decisions made during planning and start-up. A small issue introduced early can remain hidden until it becomes a costly delay later in the trial.

While organisations often focus on improving individual processes, lasting improvements require a more connected approach that links study planning, site selection and study conduct.

A central theme of a recent discussion between clinical research leaders from ICON, Advarra and the site community was how sponsors, CROs and technology partners can better align study delivery with the operational realities of research sites.

Research sites operate within established workflows, technologies and resource constraints. Yet they are frequently asked to learn new systems, duplicate data entry or adapt to sponsor-specific processes.

These additional requirements can increase administrative burden and divert attention from what matters most: delivering studies and caring for patients.

In practical terms, this means aligning trial delivery with the technologies and operational patterns already supporting site performance. Rather than asking sites to change the way they work, sponsors and CROs can create stronger collaboration by connecting to existing workflows and enabling information to move more efficiently between stakeholders.

A connected approach starts with better operational intelligence. Understanding site capabilities, performance trends and operational realities earlier in study planning can help sponsors make more informed protocol, feasibility and site selection decisions.

Connected approach to study delivery

Access to these insights enables teams to identify potential risks sooner, improve planning and strengthen site engagement before studies begin. However, intelligence alone is not enough. Its value depends on how effectively information can flow across the broader study ecosystem.

Through its partnership with Advarra, ICON is helping create a more connected operating environment for sponsors, CROs and sites.

Rather than introducing additional standalone systems, study delivery can be connected to technologies many sites already use. Advarra's site CTMS, eISF and eSource solutions support more than 50,000 investigators worldwide, including researchers at 90 of the top 125 academic medical centres, 90% of NCI-designated cancer centres and many leading site networks.

Through Advarra Study Collaboration, information can flow securely between site systems and ICON workflows, creating greater transparency while reducing duplication. The result is a shared operational view across study stakeholders.

Oversight improves, administrative burden is reduced and issues can be identified before they affect recruitment, timelines or study performance.

While there is no single solution to the challenges facing modern clinical trials, greater connectivity and better use of operational intelligence represent important steps forward.

As sponsors, CROs and sites continue to explore new ways of working together, aligning study delivery with site workflows and operational realities can be an effective way to improve collaboration and support more efficient study delivery. ▲

Learn more at iconplc.com/connectedmodel

Brian Mallon is Executive Vice President, Site & Patient Solutions at ICON plc

Role with it

Why clinicians have a vital part to play in guiding patients through the next phase of obesity care

The introduction of oral GLP-1 medicines, alongside growing awareness of injectable treatments such as Wegovy and Mounjaro, means patients now have more choice than ever before. Demand for the pills has increased by 350% since the launch in July.

That's undoubtedly positive, but it has also created a new challenge – increasingly, patients are asking whether they should switch, which option is 'best', or whether what they've seen online is actually true.

As clinicians, we're no longer simply helping patients access treatment. We're helping them navigate an increasingly complex landscape where headlines, social media and anecdotal experiences often sit alongside clinical evidence. Our role in providing clear, personalised guidance has never been more important.

Making complex decisions

For many patients, the prospect of a tablet rather than a weekly injection is appealing. Some are understandably anxious about needles, while others see tablets as a more convenient option that may fit more easily into everyday life. However, greater choice can also create misconceptions.

'Patients may wonder whether they can simply swap between treatments, or even combine them to improve results'

One of the most common assumptions is that a tablet is somehow a 'lighter' or less effective version of an injectable treatment. In reality, oral semaglutide contains the same active ingredient as the Wegovy injection.

The difference lies in how the medicine is delivered and absorbed, meaning it has different dosing requirements rather than different levels of effectiveness.

Patients may wonder whether they can simply swap between treatments, or even combine them to improve results.

These are understandable questions, but they reinforce why treatment decisions should always be clinician-led. Switching isn't simply replacing one prescription with another; it requires careful assessment of an individual's treatment history, current dose, tolerability, lifestyle and wider health needs.

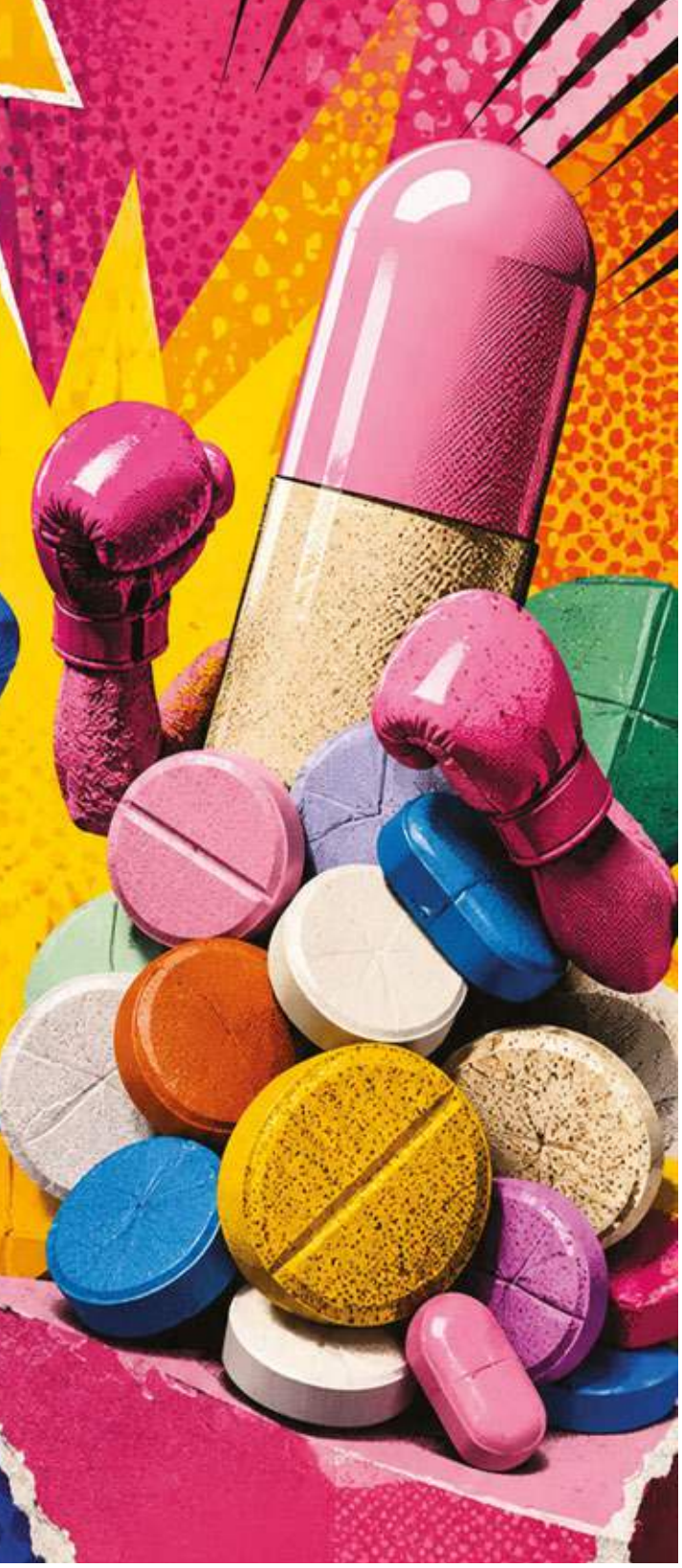
From weight loss to weight health

One of the most interesting developments we've seen over the past year is that patients are increasingly considering how treatment fits into everyday life, rather than focusing solely on the number on the scales.

Recent research conducted found that considerations around day-to-day feasibility are playing an increasingly important role in treatment decisions. More than four in ten people (41%) using GLP-1 medicines said they worry about keeping medication at the correct temperature while travelling, while 37% are concerned about taking injection pens through airport security.

More than half said they would consider pausing treatment during a holiday, often because they want to enjoy food and drink more freely or are concerned about side effects affecting their trip.

These findings highlight something clinicians are increasingly seeing in practice. Patients aren't simply asking whether a medicine works; they're asking how it fits around family holidays, shift work, business travel, social occasions and daily routines.



Convenience should not outweigh suitability

It's easy to see why oral treatments generate excitement because for someone who travels frequently or finds injections intimidating, removing needles and refrigeration requirements may appear to solve several practical challenges.

However, convenience should not come at the expense of choosing the most clinically appropriate treatment.

Unlike weekly injections, oral semaglutide requires a consistent daily routine. It must be taken on an empty stomach with a small amount of water, before waiting at least 30 minutes before eating, drinking anything other than water or taking other medication. For some patients, that's entirely manageable.

For others – particularly shift workers, those with unpredictable mornings or individuals taking multiple medicines – it may prove considerably more challenging than a weekly injection.

This is why conversations about adherence are becoming just as important as conversations about efficacy. The best treatment is rarely the one that appears most convenient on paper; it's the one a patient can realistically and safely incorporate into his or her everyday life over the long term.

How to make the switch

As more oral therapies become available, it's natural that some patients will want to explore changing treatment. But switching should never be viewed as a straightforward consumer choice.

Clinicians need to assess how well a patient is responding to his or her current medication, whether side effects are well managed, whether weight-loss goals are being achieved and whether there are practical reasons why another treatment may be more appropriate.

It's also important to reinforce that oral and injectable GLP-1 medicines should not be used together. Patients should never decide independently to overlap treatments or change dosing schedules without clinical advice. As awareness grows, ensuring patients understand these principles will become increasingly important.

Alongside this, expectation management remains essential. Patients may experience a temporary return of appetite or 'food noise' during a transition, while differences in absorption can mean treatment feels different even when the active ingredient is the same. Setting realistic expectations helps patients remain confident and engaged throughout the process.

Clinician's role is evolving

As weight loss medicines become more established, I believe the role of healthcare professionals is evolving alongside them.

Our responsibility extends beyond selecting an appropriate medicine. Increasingly, we're helping patients interpret conflicting information, challenge misconceptions and understand how treatment fits into their wider lives.

Whether discussing travel plans, morning routines, side-effect management or the practicalities of switching, these conversations are becoming just as valuable as the prescription itself.

The next generation of obesity treatments will almost certainly bring even more choice. Additional oral medicines, combination therapies and new mechanisms of action are already progressing through development. That is an exciting prospect for patients and clinicians alike.

More options, more questions

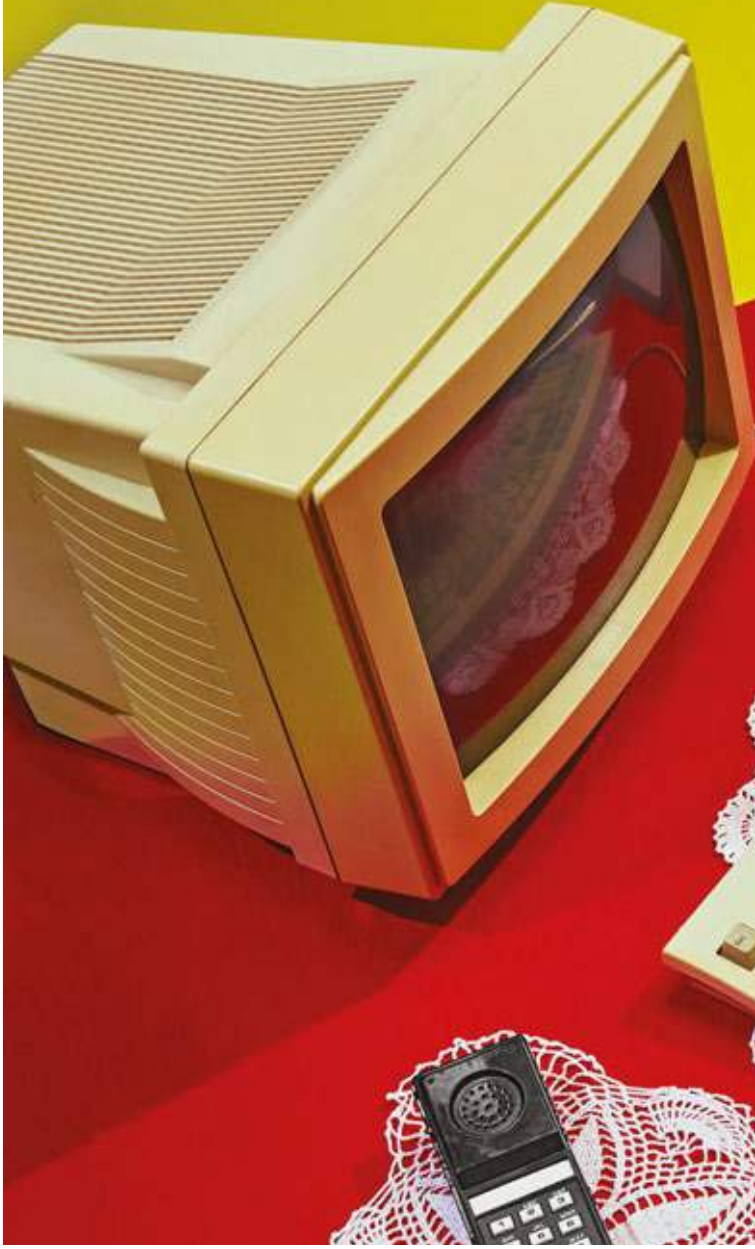
Success in obesity care won't simply be measured by how many treatments become available. It will depend on whether patients receive the personalised support needed to choose the right treatment for them, understand how to use it safely and remain engaged over the long term.

Choice is a welcome step forward, but informed choice is what ultimately leads to better outcomes. As clinicians, that's where our expertise has never mattered more. ▲

Andre da Silva is a Superintendent Pharmacist at CheqUp

Top table

Why communications strategy should never be an afterthought



'Hi, this project/product/partnership is going live next week – can you do some comms?'

All comms people dread this email. They do not dread it because they cannot work to tight deadlines, as they thrive on them. They dread it because by the time a project is close to fruition, the best comms opportunities have often already passed by.

This time, I talk to Syeda Hasnain, Head of Communications at Merck UK & Ireland, on what truly embedded communications looks like in a pharma company – and why it matters.

The importance of bringing comms in early was the first point Syeda wanted to make during our conversation. She was clear that communications deliver the most value when it is embedded from the beginning. It helps shape thinking as projects, risks and priorities are still taking form.

That perspective is informed by an unusual route into pharma. Syeda has spent most of her career in public sector communications, moving through government and health system roles before joining Merck three years ago.

The shift into industry meant she had to adapt quickly to a very different commercial environment. She reflected on the long process of getting to grips with these complexities as a steep learning curve.

'Communications works best when it is integrated into the business and never bolted on at the end'

However, for Syeda, becoming confident on the commercials as a communications leader is central to whether the function gets heard. If comms is going to earn a place in early strategic conversations, the team must understand what those conversations are about.

These include business priorities, supply realities, operational constraints and the language leadership teams use when decisions are being made.

Without that grounding, it is far harder to spot where communications input could sharpen a plan, mitigate a risk, or uncover an opportunity. Rather than accepting a knowledge gap, Syeda decided to do something practical about it. After returning from maternity leave last year, she took on a secondment in the commercial team to immerse herself in that world.

She did not become an expert overnight, but she did develop a much stronger sense of how the Merck business works. She also learned the opportunities for the comms function to add value. The lesson was that if you want to influence the direction of the business, you have to understand the business in the round.

What I found especially interesting was Syeda's approach to getting communications into the room. Part of it is process, which means making sure communications is built into workflows around launches, planning and emerging issues. Part of it is personal, involving showing up, asking to observe meetings and being curious enough to ask the obvious questions.

She described it as being 'nosy', but in practice it is a disciplined way of making sure comms is close enough to the action to be useful. That matters because one of the traps communications professionals can fall into is defining too narrowly what counts as a comms issue. Syeda's view is much broader.

Colleagues discussing operations, planning, supply or leadership decisions may not immediately see a reputational angle. However, that does not mean one is not there. Comms leaders should not wait to be invited only when something is visibly external-facing.

They should be close enough to the business to see where narratives, risks and opportunities are taking shape long before they surface publicly. That same confidence shapes her view of leadership under pressure. Having worked in high-intensity public sector media roles, Syeda is used to fast-moving, high-profile situations.

She believes good communications leadership is often less about dramatic intervention than about calm. When an issue breaks or

the stakes rise, people look to comms for judgement. If the comms lead appears uncertain or panicked, confidence evaporates quickly.

The real value, she suggested, lies in being the steady voice in the room. This means being clear about the risk, clear about the plan and calm enough to help others move forward. Our conversation also turned to agency relationships.

These are now a major part of many in-house pharma comms roles, particularly in lean teams. It was one of the most useful points in the conversation because many communications leaders inherit responsibility for agencies without ever being taught how to manage those relationships well.

Syeda works closely with external partners and her advice on making those relationships successful was, thankfully, straightforward.

The best collaborative work comes when you build relationships that are open, friendly and transparent from the outset.

That means a clear statement of work, a proper kick-off, shared context at the beginning and giving feedback early enough to change direction before time and budget are wasted. She also spoke about the need for more diversity in pharma communications leadership.

This matters because the voices in the room directly impact whose perspective is represented. It also affects how well communications teams reflect the audiences they are trying to reach. It is short-sighted for businesses to undervalue the importance of diversity in their comms recruitment and talent pipelines.

Looking ahead, Syeda sees the communications role continuing to shift away from pure content production. It is moving further towards strategic leadership. As AI makes it easier for teams across the business to create content themselves, the distinctive value of communications changes.

It becomes more about being the function that holds the narrative together. Someone still needs to understand the brand, the messaging, the culture and the wider reputational context. Someone still needs to decide what matters, what lands and what does not.

Someone needs to be nosy and make sense of the disparate information they uncover. That was the thread running through our conversation. Whether she was talking about commercial understanding, early involvement, crisis leadership or agency management, Syeda kept returning to a core point.

She noted that communications works best when it is integrated into the business and never bolted on at the end. For comms leaders working to earn influence in 2026, that feels like a useful challenge. ▲

Jess Farmery is Senior Account Director, Health at Lexington Communications

Time to heal

Wound care – reducing variation, preventing complications and supporting care closer to home

In 2018, the yearly amount that wound care cost the NHS was estimated at £8.3 billion. That is worth ten years of the UK's flood defences; it is the cost of running London's police service, fire service and entire transport system combined.

It is equivalent to the whole of the UK's foreign aid budget and its energy department. It is also, almost certainly, an underestimate.

Since 2018, pressure on the NHS has increased dramatically, with waiting lists remaining near record levels. For wound care in particular, this is a problem because chronic wound treatment relies on fast diagnoses to secure quick recovery.

If diagnosis takes longer than four weeks, the chance of a patient recovering within three months falls from 54% to just 17%. After twelve weeks, fewer than half of patients will recover within a year.

'Up to a third of people with wounds live with multiple comorbidities, compounding the mental and physical impact'

With the health burden therefore likely increasing, the true cost of wound care is probably in excess of £10 billion, and may even be well beyond that. Across Europe, an estimated 7.4 to 14.9 million people live with chronic wounds, consuming up to 4% of total healthcare expenditure.

This huge economic cost should not distract us from the human price that wounds exact on people's lives. Roughly 3.8 million people in the UK live with some type of wound.

Up to a third may live with multiple comorbidities, compounding the mental and physical impact on their lives. And this impact is sobering.

At least 30% of those with chronic wounds experience symptoms of depression and anxiety, and limb amputations necessitated by wounds have five-year mortality rates of 40–70%. Wounds, like many health conditions, also harm an individual's chance of staying in work.

For those suffering from leg ulcers alone, four working days are lost to managing and treating their condition. At a time when economic inactivity due to illness in the UK is near record levels, it matters to all of us that these individuals stay in the workforce.

Why variation and workforce shortages are worsening outcomes

But why are the economic and individual impacts of wounds so damaging? Partly because wound care too often exists in-between services rather than within a coordinated pathway.

It spans primary, secondary and social care settings. As patients move between these settings, healthcare professionals' knowledge and skill does not always move with them.

Variation in the treatments provided to patients serves to further break up that pathway. While the UK does not lack standardised guidelines for wound treatments, the implementation of these across Trusts and ICBs varies, with significant local differences in available products like dressings.

Past analysis of community nursing has revealed that local practice is more often dictated by environmental and financial constraints than evidence base. With that variation, district nursing teams face delays procuring specific products, delaying patients' healing and straining nursing resources.

And those nursing resources are already seriously stretched. Since 2009, the number of nurses working in the NHS has dropped by 43%.

With wound care accounting for the majority of community nursing time, it is best placed to suffer from this fall. This brings us to a second reason for the current state of wound care.

It is a clinical area overwhelmingly delivered by community nurses, district nurses, as well as those outside the NHS, like care home staff. But there are severe shortages in professionals able to treat wounds, and among those that can, there is large variation in skill and knowledge across the country.

Across the entire NHS, leaving rates for healthcare professionals averaged 10.1%. For district nurses, a staggering one in four left their role between 2023 and 2024.

Further, when adjusted for growing patient demand, the reduction in community nurses since 2009 becomes 55%. This long-term decline has left gaps in competency across the country.

One study conducted across Northern England found 'marked variations in care' in that region alone. The 2023 Wound Care Workforce Framework attempted to resolve this variation by providing a standardised, tiered system of competencies for those treating wounds.

Indeed, training for generalists can deliver significant benefits for patients. A Danish study found just six hours of training delivered a significant increase in wound care knowledge for nurses.

Nonetheless, without a targeted workforce plan and a significant increase in retention and training, staff shortages in wound care will likely exist for years.

How innovation and system reform can transform wound care

This is why HealthTech can make such a huge difference to wound care. Innovations in advanced wound care products are mostly incremental rather than transformative, but can provide real benefits if measured by value across the whole patient pathway.

Increases in the wear time of dressings significantly reduce the frequency of mandatory dressing changes, alleviating the burden on district nursing teams. Adopting AI and digital clinical decision-support tools could help reduce the variations in local workforce knowledge, standardising assessment, prompting earlier referral and supporting care closer to home.

Digitised record-keeping can allow the objective tracking of wound progression, ensuring that interventions are driven by clinical evidence rather than regional financial constraints or procurement delays. All these examples, and there are many more, contribute to the three shifts laid out in the Ten-Year Health Plan last year.

They prevent expensive complications, support the shift from analogue to digital and bolster community care badly affected by years of cuts.

For these products to reach the patients who need them, though, supply and reimbursement mechanisms, particularly through Part IX of the Drug Tariff, need to move beyond lowest acquisition cost towards a genuine assessment of whole-life system value.

Closer alignment is needed between the National Wound Care Strategy Programme, NHS Supply Chain, Integrated Care Boards and local procurement teams, so that national guidance translates into consistent local formularies rather than more variation.

Real-world evidence, alongside patient-reported outcomes, should be given equal standing to randomised trial data when innovations are assessed, recognising that randomised control trials are rarely well suited to the incremental product improvements common in wound care. And funding for the adoption and spread of innovation that has already proven its worth needs the same protection afforded to research funding, so that products are not lost at the point of scaling up.

None of this requires new money earmarked for wound care alone; it just requires a shift in how the system procures the innovation already available to it.

Wound care rarely attracts the headlines, yet the cost to the NHS and the impact on patients make it an area that deserves far greater recognition and focus. ▲

Owain Prescott is Market Access Executive at ABHI

Fortune favours the brave

Rediscovering an appetite for risk – funding and fuelling biotech innovation

Over the past decade, both biotech and pharma have increasingly seen a tendency to research, fund and develop products that largely could be considered 'variations on a theme', or more particularly, a few, highly developed but low-risk areas of focus.

This has not only locked venture and development capital into a limited number of funding targets – the so-called 'target herding' effect.More worryingly, it also discourages exactly the kinds of risk-taking that usually lets American firms to stay on the cutting-edge of research and retain their global competitive advantage. As the Chinese government continues to grow its direct and indirect subsidies for drug research, the need to be forward-thinking only increases.

There are three significant factors impeding biotech risk-taking – they must be understood to be counteracted.

First and foremost is capital concentration. As drug development costs have continued to escalate in accordance with Eroom's Law, the market has responded by concentrating capital in fewer start-ups.

Moreover, biotech investment firms themselves have been shrinking in size and growing in size. All of this tends to concentrate drug development decision-making in the hands of fewer hands. This is a recipe for groupthink.

Shift towards finance backgrounds

Moreover, from anecdotal reports it seems that many more of these decision-makers tend to come from finance backgrounds, which favours an investment approach rather than science or medicine.

This might be expected to yield decisions that are more focused on mitigating the kinds of risks that can be captured in spreadsheets rather than bold scientific or medical intuition.

In some ways, it is evocative of the 'financialisation' transformations of General Electric (under Jack Welch) or Boeing (under Harry Stonecipher).

Both transitions involved a cultural transformation from proud engineering pedigree to financial modelling and near-term financial returns, to disastrous effect. The engineering-first mission of SpaceX offers an obvious contemporary counterpoint.

A second issue is the phenomenon of target herding – the increasing tendency of both big pharma and biotech investors to concentrate investment in fewer and fewer disease targets.

Given the high and rising cost of clinical failure, it's perhaps understandable that financial decision-makers might seek to reduce perceived clinical and scientific risk by going after biologic targets that other groups have already proven to work.

However, this creates a sort of tragedy of the commons: rather than reducing a programme's overall financial risk, it instead converts it from scientific risk into commercialisation risk by increasing post-approval competitive pressures.

Recent examples include COVID-19 vaccines, TL1A antibodies for IBD, and GLP-1 analogue drugs for obesity. While the payouts for early adopters can be significant, companies often double down on what they consider to be proven positions in the market rather than assessing if the markets are saturated.

The sheer number of competing statins and arthritis drugs helps to illustrate this issue. Companies are more inclined to create permutations on existing products than to truly innovate.

> **'There are three significant factors impeding biotech risk-taking – they must be understood to be counteracted'**

Lipitor, seventh to market in the 1990s but the ultimate winner in the statins race, is often cited to justify this strategy, so there are reasonable arguments in favour (particularly for the fastest moving and best funded groups).

Changing timelines

But the commoditisation of most aspects of drug development and the lengthening of development timelines mean that the world of drug development is very different now, 30 years later.

Data shows that even first-in-class drugs have shorter average remaining patent life at launch, and the time to non-generic market entry by a competing molecule against the same target has shrunk to just 3 years.

Worse is coming with the biotech Cambrian explosion of innovation happening in China now. The astonishing speed and creativity of this new competitive ecosystem is likely to further compress competitive timelines, at least for the well-worn therapeutic modalities and targets.

The third major issue is an increasing reluctance to invest into breakthrough delivery vehicles and other transformative technologies and shifts. One of the most noteworthy examples is mRNA vaccine technology, which, prior to COVID-19, struggled for recognition and funding.

As is often the case, caution asserts itself in being willing to assess the actual risk/reward on truly breakthrough systems. If the expedited funding and approval of a pandemic had not been available, the technology might still be struggling.

Founders responding to challenges

Biotech founders are responding to these challenges in a variety of ways. Most important is to think clearly and holistically about all forms of programmatic risk – including market size and saturation risk – not just scientific and biology risk.

Biopharma productivity researcher Mike Rea has been advocating exactly this view for years, and we ourselves have written about the need for more rigorous modelling. Just as importantly is to think more creatively about the potential for transformative platforms and markets.

This is the path pursued by companies like Lumen Bioscience in two ways: a foundational biomanufacturing platform technology that unlocks new therapeutic modalities (oral biologics), that in turn unlocks larger, more valuable markets (preventive biologics drugs).

A third strategy is best illustrated by a big pharma: Eli Lilly. In a wide-ranging podcast interview, Lilly CEO David Ricks explained how Lilly came to offer its best-selling GLP-1 analogue drugs directly to consumers over the internet.

In a surprising passage he notes that Lilly now sells more to cash-paying customers over its LillyDirect portal 'than our insured business in new patient starts, and more than all of Wegovy.' This consumerisation and globalisation of biopharmaceuticals arguably began with COVID-19 but has exploded with the GLP-1 phenomenon, and is likely to change the industry beyond all recognition in the coming years.

Putting these three new strategies together yields a compelling alternative: products made on novel platforms (protected by novel IP) that are designed to prevent disease and selected and purchased directly by patients themselves (even if still gate-kept by physicians) at a price affordable to a far larger pool of patients around the world.

The path forward for the industry

From this perspective, the current disruption facing biopharma and its investors may in fact be the best thing to happen in decades: far from the highs of COVID-19, biopharma is now almost as widely loathed as the legal profession. It's likely that the government drug price-setting rules of the 2022 Inflation Reduction Act may be only the first of a series of political reactions.

Finding ways to make more affordable medicines that help everyone (worldwide) live better lives might be the best thing for the industry's social contract. Pharma and biotech innovation does not need to 'break the bank' or be especially high risk to provide real, lasting returns.

But it does fundamentally need to involve real innovation and risk assessment in its products. China has raised the bar for US and European biotech firms, and they're unlikely to rise to this challenge by relying on derivative products in crowded target areas with diminishing returns.

Forward-thinking involves both assessing the market as well as effective cost management. The time is right for US firms and investors to seize their innovation advantages. ▲

Kevin Klowden is a global economist and strategist, and fellow at the Milken Institute, an economic think tank. Brian Finrow is co-founder and CEO of Lumen Bioscience, a clinical-stage biotechnology company in Seattle.

Visions4Health

Evolution

Future-ready pharma teams: building knowledge and capability to navigate a changing NHS

Healthcare is evolving faster than ever. NHS reforms continue to reshape commissioning, integrated care systems are maturing and expectations of industry are changing.

Success is no longer measured solely by product expertise, promotional excellence or a compelling brand message.

Increasingly, it depends on understanding the health system, engaging customers in the context of their priorities and building partnerships that create measurable value for patients, services and the NHS.

For pharmaceutical and HealthTech companies, this creates a significant capability challenge. Customer-facing teams are operating in a more complex environment, where decision-making is increasingly system-led, priorities are shaped by population health and stakeholders expect industry to bring more than product information.

'Customer-facing teams need practical, real-world learning that translates system change into confident, credible action'

They need partners who understand NHS pressures, can contribute to service improvement and can work transparently towards shared outcomes.

Periodic policy updates are no longer enough. Sales, marketing, market access and medical teams need practical, real-world learning that translates system change into confident, credible action.

That is why we have launched the Visions4Health Learning Lab, powered by Networks4Health.

The Learning Lab helps life sciences companies navigate this changing environment by combining expert insight, practical capability building and access to the people shaping today's NHS. Powered by our Networks4Health community, every programme is informed by firsthand experience from across the health system.

Rather than delivering traditional training, it creates tailored, on-demand learning experiences that help teams understand what is changing, why it matters and how to respond in ways that strengthen customer engagement.

Two critical learning priorities

The Learning Lab is built around two complementary priorities that help teams move from transactional engagement to transformational partnership:

Knowledge uplift - Healthcare policy, NHS structures and commissioning arrangements continue to evolve at pace. Integrated Care Boards have matured into strategic commissioners, responsibilities continue to shift across systems and Place, and new approaches to prevention, neighbourhood working, pathway redesign and service transformation are emerging.

For many organisations, keeping field, marketing, market access, medical and leadership teams up to date is difficult. Our Knowledge Uplift programmes provide timely, practical learning through live panel discussions, podcasts, webinars and tailored briefings.

They help teams understand the latest reforms, policy developments, commissioning structures and system priorities, with a focus on what those changes mean in practice: how decisions are made, where priorities sit, what pressures customers face, and how industry can engage in ways that feel relevant, credible and aligned to NHS needs.

Skills uplift - Alongside NHS reform, expectations of industry engagement have evolved. Health system leaders are looking for partners who can support service improvement, contribute to shared priorities and help improve patient outcomes. That requires a different set of capabilities.

The Learning Lab delivers skills-based workshops that help teams develop the mindset, behaviours and confidence needed for successful partnership working.

From collaborative and joint working principles through to stakeholder engagement, systems leadership and outcomes-focused conversations, our programmes equip participants to have richer, more strategic discussions with NHS customers.

For sales and marketing teams, this means connecting brand objectives with system priorities in a responsible, compliant and meaningful way.

It means knowing when a conversation needs to move beyond product features and into pathway barriers, implementation challenges, service capacity, health inequalities or measurable outcomes, and building confidence to contribute to partnership opportunities grounded in mutual value.

Learning powered by real-world expertise

What makes the Visions4Health Learning Lab different is the people behind it. Powered by Networks4Health, our community of more than 350 healthcare professionals in clinical and non-clinical roles, we bring together diverse health system experts who contribute directly to programme design and delivery.

This ensures every learning experience is grounded in current insight and reflects the realities of today's NHS. Participants gain authentic perspectives that challenge thinking, build confidence and bridge the gap between theory and practice.

Visions4Health also brings a distinctive perspective as a recognised thought leader in healthcare partnership working.

Through our role in shaping and championing the Excellence in Healthcare Partnerships Awards, we have seen what strong partnership working looks like in practice: shared purpose, trust, transparency, measurable impact, and a commitment to improving outcomes for patients and the system.

That experience informs how we help industry teams build the knowledge and capabilities required for the next generation of NHS–industry relationships.

Investing in future-ready teams

As the healthcare landscape continues to evolve, organisations that invest in both system understanding and partnership capability will be best placed to succeed.

The Visions4Health Learning Lab, powered by Networks4Health, offers flexible, tailored programmes designed around organisational priorities helping teams stay ahead of NHS reform, strengthen collaborative working capabilities, align brand strategies with system priorities, or prepare leaders for the future of healthcare partnerships.

Let's talk

In a world where relationships, collaboration and shared value increasingly define success, learning cannot stand still.

If you would like to find out how the Visions4Health Learning Lab could help your teams build the knowledge, confidence and capability to thrive in the changing NHS-industry landscape, please contact us at info@visions4health.com or via the contact form on our website visions4health.com ▲

Roshani Perera is Commercial and Operations Director at Visions4Health

Future proof

Mad World Summit 2026 – where the future of workplace well-being takes centre stage

From AI and financial well-being to leadership, inclusion and sustainable performance, the challenges facing today's employers are more complex than ever.

As workplace expectations continue to evolve, organisations are looking beyond well-being initiatives and asking a bigger question: how do we build cultures where people and businesses can thrive together?

These are the conversations taking centre stage at the MAD World Summit 2026, the UK's leading event dedicated to workplace culture, health and well-being.

Now entering an exciting new chapter under the ownership of PMGroup Worldwide Ltd, the summit continues to bring together senior leaders from HR, Benefits, Occupational Health, Learning & Development, DE&I, Communications and the wider business community for a day of practical insight, collaboration and shared learning.

Returning to Convene, 155 Bishopsgate in the heart of London, the MAD World Summit 2026 builds on the momentum of last year's hugely successful event.

Widely praised by attendees for its exceptional setting, seamless experience and vibrant atmosphere, the venue once again provides the ideal backdrop for meaningful discussion and connection.

World in motion

Taking place on Thursday 26 November 2026, this year's summit promises to deliver another standout gathering for forward-thinking employers committed to shaping the future of workplace well-being.

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

Among this year's headline speakers is Dame Carol Black, whose pioneering work has helped shape the UK's approach to workplace health, alongside digital well-being expert Petra Velzeboer, who will explore the impact of AI, constant connectivity and technology on human performance.

Other speakers include Simon Blake OBE, CEO of Stonewall, Susan Gee, Head of Occupational Health & Well-being at Yorkshire Water Services, Lauren Lunniss of BNP Paribas, Jamie Broadley from Serco Group plc and Rosie Ellis from Aon, bringing together perspectives from across business, healthcare and public policy.

The programme balances strategic leadership discussions with practical workshops covering burnout prevention, financial well-being, psychosocial risk, men's mental health, neurodiversity, early careers, line manager capability and supporting frontline and shift-based workforces.

Throughout the day, delegates will hear real-world case studies, take part in facilitated discussions and leave with practical ideas they can apply within their own organisations.

Networking also plays a central role, with a hosted breakfast, exhibition, one-to-one meetings and an evening reception creating opportunities to connect with peers, industry experts and leading solution providers.

As organisations continue to navigate rapid workplace change, the MAD World Summit remains focused on one clear objective: helping leaders turn conversation into meaningful action.

Whether delegates are developing a new well-being strategy or strengthening an existing one, the event offers the evidence, inspiration and connections needed to create healthier, more resilient workplaces. ▲

Event content by PharmaTimes

Cell story

AI methods for regulator-ready real-world evidence in NSCLC

Lung cancer as a disease group is the leading cause of cancer incidence and mortality worldwide, according to World Health Organization data. Non-small cell lung cancer (NSCLC) makes up the majority of lung cancer incidence and treatments depend on the specific clinical factors and molecular biomarkers associated with the disease and its subtype.

This means, in short, that treatment is highly personalised.

Traditional clinical trials continue to define standards of care, yet they do not always capture the diversity and pace of real clinical practice. Real-world data (RWD) offers a complementary lens, capturing how patients are diagnosed, treated and managed outside controlled settings.

Artificial intelligence and machine learning (AI/ML) offer a powerful opportunity to extract insights from messy, complex RWD if applied with the right structure to produce credible, reproducible evidence.

Turning data into evidence

Real-world data in NSCLC includes electronic health records, disease registries and genomic testing results. These sources hold rich information on biomarkers such as EGFR, ALK, KRAS and PD-L1, which increasingly guide treatment selection.

AI can integrate this data at scale to detect patient subgroup patterns, predict treatment response outcomes and support more personalised therapies.

For example, AI might predict which patients respond better to a certain drug based on their genetic markers and history.

However, regulators and health technology assessment frameworks from the FDA, NICE and ISPOR/ISPE expect pre-specified study designs, transparent reporting of methods and assumptions, and demonstrable reproducibility.

Without clear, rigorous frameworks, AI tools may produce results that are unreliable or difficult to interpret or reproduce.

The AI/ML framework

A robust approach to applying AI in NSCLC real-world data rests on five core principles.

Table 1. Illustrative evaluation components for AI/ML applications in NSCLC real-world data

Evaluation domain	Illustrative considerations	Purpose in the framework
Clinical relevance	Biomarkers, clinical characteristics, and endpoints aligned with NSCLC treatment decisions	To ensure the framework reflects clinically meaningful use cases
Data fitness-for-purpose	Source documentation, variable definitions, completeness, and missingness	To assess whether RWD are suitable for the proposed application
Analytic considerations	Confounding assessment, handling of missing data, and selection bias considerations	To show how analytic validity would be addressed
Model development	Prespecified predictors, outcomes, and candidate AI/ML methods	To outline a structured and transparent development approach
Performance assessment	Discrimination and calibration measures relevant to decision support	To illustrate how model performance could be evaluated

Table 1 is illustrative and intended to summarize key evaluation components and methodological considerations within the proposed framework; it does not present empirical results from a conducted analysis.
AI, artificial intelligence; ML, machine learning; NSCLC, non–small-cell lung cancer; RWD, real-world data.

Pre-specification of analyses: define cohorts, variables and endpoints before analysis begins. This aligns with trial-like discipline and reduces analytical bias.

Data provenance and quality: document data sources, curation steps and validation checks. Confidence in outputs depends on clarity at input.

Bias mitigation: Apply methods to address confounding and missing data. This ensures that observed effects reflect true clinical relationships rather than artefacts.

Model development and validation: use established algorithms such as gradient boosting or regularised regression with rigorous internal validation. Prioritise interpretability to support clinical trust.

Transparent reporting: provide detailed documentation of workflows, diagnostics and performance metrics. This enables independent verification and reuse.

Together, these elements align with established frameworks from regulatory and methodological bodies, creating a common language for evidence generation. Potential outputs include discrimination and calibration metrics, model diagnostics and visualisations showing how clinical and biomarker data could inform treatment stratification.

From models to meaningful insights

When applied within this structure, AI models can achieve strong performance. Metrics such as discrimination and calibration demonstrate their ability to both distinguish outcomes and reflect real-world probabilities.

Integrated visualisations and diagnostics help translate complex outputs into clinically meaningful insights, showing how biomarker profiles and patient characteristics interact to influence treatment outcomes.

AI-enabled real-world evidence reflects broader patient populations and adapts to evolving standards of care. AI/ML RWE allows pharmaceutical sponsors to complement and refine evidence strategies across the product life cycle and demonstrate value in diverse populations.

A rigorous methodology allows AI to turn messy real-world NSCLC data into regulator-ready evidence that helps doctors choose the right treatment for the right patient. ▲

Nathalie A Waser is Principal ICON Insights, Evidence & Value, Ankit Pahwa is MS Lead Epidemiologist ICON Insights, Banaz Al-khalidi is Senior Epidemiologist ICON Insights, Evidence & Value

New build

The NHS commissioning map is being redrawn – is your engagement strategy keeping up?

The NHS commissioning map is being redrawn once again. For those working to engage with the NHS, the challenge is not simply learning the new organisational topography, it is about evolving how you engage to stay part of the conversation.

The changes we're seeing to healthcare commissioning in England are top to bottom: NHS England (NHSE) is being brought into the Department of Health and Social Care (DHSC); Offices for Pan-Integrated Care Board Commissioning (OPICs) are emerging as regional hubs for commissioning services at scale; Integrated Care Boards (ICBs) are evolving into strategic commissioners alongside clustering and reducing budgets by half; providers are being given greater autonomy; and greater focus and resources are being devolved to Place and Neighbourhood.

The result is not simply a new organisational chart. It is a shift in where decisions are made, how they are made and who is involved in making them. This is perhaps reinforced most clearly in the establishment of 'No.10 North' and a new prime minister focused on promoting the idea of Place.

So, if the commissioning world is changing once again, is your engagement strategy keeping up?

What these changes might look like in practice

Let's look at how OPICs, as new entities, and ICBs as strategic commissioners, might reshape the landscape.

OPICs have emerged as a necessity to manage the delegation of specialised commissioning from national to local, ensuring there is appropriate expertise in place to continue the effective commissioning of these services.

Delegated services are set to include vaccinations, most screening services, and health and justice services, among others. Importantly, OPICs are intended to support commissioning 'at scale' across ICBs to improve patient outcomes.

While in one sense OPICs might simplify industry engagement to a degree, i.e. decisions would cover multiple ICBs, in practice there is a series of potential hurdles to navigate.

To take one example: how will 'top-down' commissioned services that span ICBs map against 'bottom-up' commissioned services at Place and Neighbourhood level within ICBs? OPICs will also be directly accountable to DHSC for those services that will remain commissioned at a national level, so how does that intersect with local decision-making?

At the same time, we have ICBs now focused on strategic commissioning, with fewer resources at their direct disposal.

While keeping one eye firmly focused on the needs of local populations, ICB leaders will also potentially be exposed to far more direct scrutiny from Ministers than before with NHSE and its regional teams gone. This exposure could bring into focus the interventions that will shift the dial for local populations.

For industry, strategic commissioning means a potential reframing of how conditions are considered. It requires a focus on understanding population need, setting priorities, and commissioning services around the desired outcomes. So, for example, respiratory or cardiometabolic conditions aren't pathways in isolation, but become priorities around neighbourhood health or health inequalities.

And rather than being involved in the depths of delivery, the ICB is there to create the conditions to deliver, explore contracting models and direct resources. There may no longer be one obvious 'payer' or one obvious decision-maker with which to engage.

The future model is emerging at different speeds

The formal architecture is changing, but the reality on the ground will not change uniformly across England.

ICBs such as SouthEast and SouthWest London are already working under joint leadership, and the South London Office of Specialised Services (SLOSS) helps to align work across four specialist providers and both ICBs to support pathway transformation in areas such as cardiac, blood-borne viruses, neuroscience and sickle cell disease.

> **'Life sciences can offer evidence, data and insight, but the strongest partnerships begin with the NHS's priorities'**

With OPICs on the horizon, localities may be preoccupied with how that is going to change roles and responsibilities again, creating further uncertainty.

South Yorkshire ICB is an example of an ICB on the other side of a restructure, which now has a more streamlined focus on neighbourhood health, health inequalities, prevention and productivity among other areas.

As the ICB now focuses on the vision, the role of partnerships is increasingly important to delivery with a local emphasis on strengthening collaboration, aligning priorities and 'moving from project-based working towards more consistent collective delivery across organisations and places.'

For industry, this creates a fundamental distinction between understanding the theory of the new NHS and understanding how the new NHS is actually operating in a particular location. The policy architecture is the starting point, but local intelligence is what makes it useful.

What this means for industry field-based engagement

Here are few guiding principles that could support your thinking:

Firstly, to help navigate the pathway or problem at hand, ask yourself: 'Who is shaping the problem, who has the authority to act, who controls the resources and who needs to be involved in implementation?' The answer may involve several organisations and several levels of the system.

Secondly, understand where the local system actually is in its transformation journey. Do not assume that every ICB, Place or OPIC is at the same stage of development. Some may be looking for a flagship initiative. Others may be seeking practical support to implement an agreed direction. Public board papers can give you a helpful steer.

Thirdly, understand the local 'worry list'. What is currently keeping NHS leaders awake at night? Is it financial sustainability, waiting lists, workforce capacity, variation in care, hospital demand, implementation of a new pathway or delivering the shift towards prevention and care closer to home?

This may be more important than knowing the formal title of the person you are meeting, so keep your networks warm.

A strong engagement conversation should therefore begin with curiosity. What is the local system trying to achieve? What is getting in the way? Where is there a gap between ambition and delivery? Only then should industry consider where its evidence, expertise, medicines or technologies might contribute.

Life sciences have a great deal to offer these conversations: evidence; data; experience of implementation; and insight into how innovations have supported change in other systems, but the strongest partnerships will begin with the NHS's priorities rather than the industry's organisational chart.

Stay curious – the dust might not settle

The healthcare commissioning world is changing once again and it's not over yet. Whilst this can create confusion, change is also an opportunity. What are those partnership forums where you could get involved early to really understand the challenges and potential solutions? If industry isn't already being consulted, why not?

Staying curious to local needs and having a more dynamic approach to local stakeholder engagement could help you stay on the front foot and evolve alongside the system, rather than waiting for the NHS to re-engage with you.

The one bit of certainty we may have is a continued emphasis on localism from the new prime minister.

Andy Burnham's experience of health devolution in Greater Manchester has provided a prominent example of the argument that decisions about health and public services can be more effective when taken closer to the communities they affect.

'Manchesterism' continues to make the political argument that local progress is best delivered by local leadership.

While the innovation offered by life sciences may not have changed, how you communicate this and to whom has. Although you may need to adapt to the new environment, this could be as much of an opportunity as it is a challenge.

Investing in a dynamic understanding of the subnational commissioning landscape could be the key to unlocking an engagement approach fit for the next ten years. ▲

Jonny Savage is Head of Client Services at Visions4Health

Building the future of clinical research around the patients it serves

Clinical research is entering a new era: advances in methodological approaches, the growing integration of real-world evidence, and strengthened patient engagement are reshaping the drug development landscape.[1]

As the field continues to evolve, an important challenge has emerged: does the evidence we generate truly reflect the populations these medicines are intended to serve? Across industry, regulators and the wider research ecosystem, there is growing recognition that answering this question will be central to the next chapter of clinical research.[2,3,4]

At UCB, this commitment has shaped our approach to evidence generation for more than a decade. We have intentionally included the needs of special patient populations such as women of childbearing age from the earliest stages of development.

The future of clinical research is not only about broadening diverse participation in studies. It is about purposefully designing evidence generation from the onset to address the needs of diverse patient populations so that the evidence generated is relevant and meaningful throughout every stage of life.[2,3,4] We call this 'Start Early.'

Although women of childbearing age, children and the elderly have distinct physiological, developmental and life-stage needs, they share a common challenge: evidence relevant to their care is often not readily available when critical healthcare decisions are being made.[2,3,4,5]

Some examples of these data lags are significant; it takes between five and ten years for data on medicine use during pregnancy and breastfeeding to be incorporated into product labels.[6] In paediatrics, medicines are approved for use around eight years after adult approval on average.[7] And although our ageing population represent a growing proportion of healthcare needs,[8] they remain substantially under-represented in clinical trials.[9]

The reasons behind the lack of evidence extends beyond scientific complexity. They also reflect how clinical research has traditionally been designed.[5] Addressing them requires changing the narrative from the very beginning.

That means engaging with patients earlier, designing studies that capture outcomes that matter most to them, partnering with regulators throughout development and generating evidence that combines clinical trials, real-world evidence, and patient-reported outcomes.[10,11] Ultimately, this is about generating evidence that reflects scientific rigour and relevance to real-world practice.

At UCB, our decade of experience advancing evidence generation for women of childbearing age living with chronic diseases has demonstrated what is possible when we start early and reinforce that patients are best protected through research, not from it.

As we look to the future, we are building on those learnings to strengthen our approach to ensure that children and the elderly are considered earlier in development and supported by evidence that reflects their unique needs.

One thing we learned: no single organisation can close these evidence gaps alone. Building a more representative evidence base requires collaboration between industry, patient organisations, regulators, researchers, healthcare professionals, and most importantly, patients themselves.

Ultimately, the future of clinical research will be defined not only by scientific innovation but also by our ability to design more inclusive research, generating the right data at the right time, and ensuring every patient has access to the data they deserve. ▲

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Marie Teil is Global Head, Special Patient Populations - Women of Childbearing Age, Pediatric, Elderly at UCB

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Risk assessment

Early digital diagnostics are transforming liver care by enabling proactive detection and prevention

Chronic liver disease is a silent, global epidemic. But as metabolic conditions continue to rise, integrating digital diagnostics into routine blood work is unlocking the power of early, proactive intervention, shifting the healthcare paradigm from reactive treatment to lifelong prevention.

Liver disease is no longer a niche health issue. It is a growing public health challenge affecting an estimated 1.5 billion people worldwide and placing increasing pressure on healthcare systems.

Yet despite advances in our understanding of disease risk and progression, too many patients are still being diagnosed only after significant and often irreversible liver damage has already occurred.

The scale of the problem is difficult to ignore. Metabolic dysfunction-associated steatotic liver disease (MASLD), formerly known as non-alcoholic fatty liver disease, is estimated to affect around 38% of the global population.

In the UK alone, approximately one in four adults are believed to be living with the condition, making it the most common form of chronic liver disease.

This marks a significant shift in the liver disease landscape. Historically, liver disease was viewed primarily through the lens of alcohol-related harm. While alcohol remains an important contributor, today's burden is increasingly driven by rising rates of obesity, type 2 diabetes and wider metabolic ill health.

'Liver disease is a growing public health challenge affecting an estimated 1.5 billion people worldwide'

As these conditions become more common, so too does the number of people at risk of developing progressive liver disease.

The consequences are already becoming visible. Between 2004 and 2022, MASLD diagnoses and advanced liver disease outcomes nearly tripled in England. Premature liver disease deaths have increased by 42% since 2001, reaching almost 11,000 deaths in 2023.

The economic burden is also substantial, with diagnosed MASLD estimated to cost between £2.3 billion and £4.2 billion in the UK alone.

Yet one of the greatest challenges is that liver disease often develops silently. Patients can feel entirely well while fibrosis advances over many years.

By the time symptoms emerge, the opportunity for earlier intervention may already have passed, allowing disease to progress towards cirrhosis, liver failure or hepatocellular carcinoma, the most common form of liver cancer and the third leading cause of cancer-related death worldwide.

This is the challenge at the heart of modern liver care. We know far more than ever before about who is at risk and how disease progresses.

But that knowledge has not always translated into consistently earlier diagnosis.

The question facing healthcare systems today is not simply how we manage advanced disease. It is what becomes possible when we identify risk sooner.

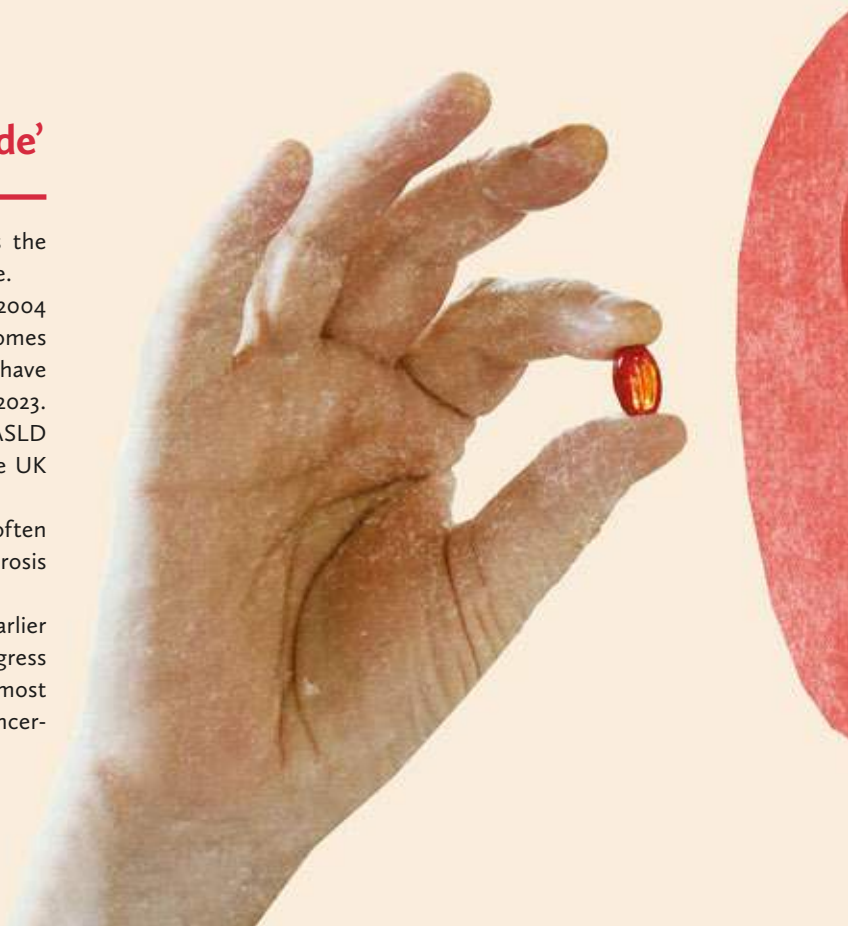
The power of proactive detection

This represents the critical diagnostics gap at the heart of modern liver care: the patients most at risk are already interacting regularly with our healthcare system, yet because early-stage disease develops silently without symptoms, we miss the crucial window to intervene.

For patients, this can fundamentally change the treatment journey. A diagnosis made after irreversible damage has occurred can mean fewer options and more complex management.

By contrast, identifying risk earlier can create opportunities for intervention before significant liver injury develops.

The challenge becomes even more pressing when viewed through the lens of modern metabolic health. People living with obesity, type 2 diabetes, insulin resistance and cardiovascular disease often interact regularly with healthcare services.



They attend clinics, undergo routine blood tests and receive ongoing monitoring for other aspects of their health. Yet liver disease can still go undetected.

Too often, these crucial moments are missed, because healthcare delivery remains largely reactive rather than proactive.

But by shifting our approach, we can begin to use the routine health data we already collect to build a digital safety net, flagging liver risk before physical symptoms ever emerge.

As new therapies continue to become available, timing is becoming increasingly important. Earlier identification has the potential to fundamentally change a patient's trajectory, creating opportunities for lifestyle modification, management of underlying metabolic risk factors, closer monitoring and more timely intervention.

A new understanding of risk

Our understanding of liver disease has evolved considerably over the last decade. Increasingly, liver health cannot be viewed in isolation from wider cardiometabolic health.

MASLD frequently coexists with obesity, type 2 diabetes, hypertension and cardiovascular disease. In many cases, these conditions are part of the same underlying metabolic picture.

This matters because it changes where we look for opportunities to identify patients at risk of liver disease, as they are no longer found exclusively within hepatology services.

They may be seen in primary care, diabetes clinics, cardiovascular pathways and weight-management programmes. Liver health therefore becomes relevant across a much broader section of healthcare than was once assumed.

At the same time, alcohol-related liver disease remains an important and potentially under-recognised contributor to overall burden.

Recent clinical studies utilising blood-based alcohol biomarkers reveal that alcohol-related cases are vastly under-reported by patients due to social stigma.

In reality, the true burden of these conditions is nearly twice as high as patient records suggest.

This means clinicians are often managing patient risk unaware of the dual metabolic and alcohol-related factors at play.

Taken together, these trends reinforce a central reality: there are likely to be more patients at risk than healthcare systems currently identify.

But they also point to a significant opportunity.

Risk factors are often visible long before symptoms develop. Clinical information already exists. Patients are frequently already present within healthcare pathways.

The challenge is connecting those dots in a consistent and scalable way.

Activating silent data

If earlier diagnosis creates new opportunities for patients, the next question is how healthcare systems can make earlier identification a reality.

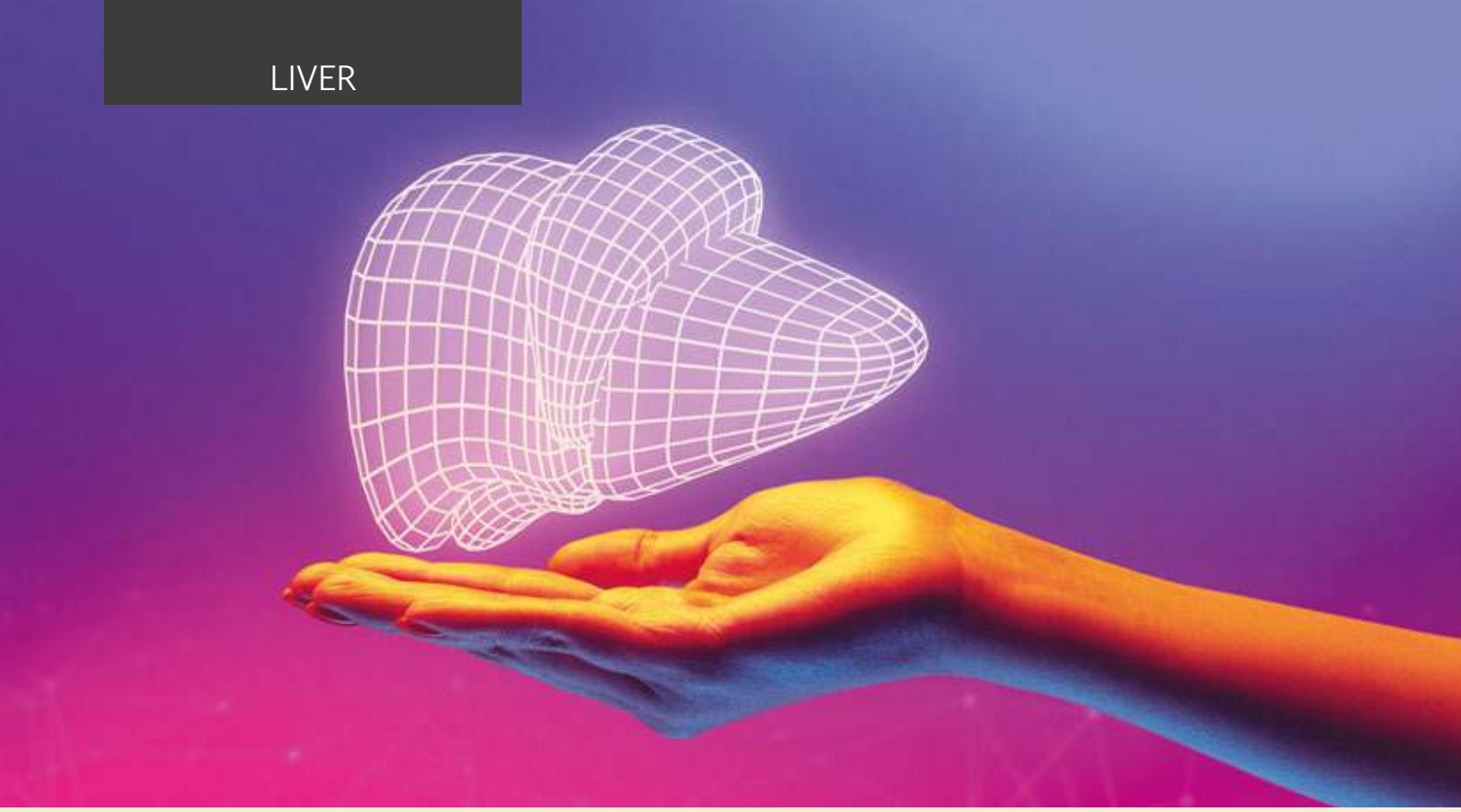
This is where risk stratification is attracting growing attention.

Every day, laboratories generate vast amounts of clinical information through routine testing. Within that data may be important indicators of liver disease risk.

Historically, however, translating those signals into actionable insight has not always been straightforward.

The challenge is not simply collecting more data. It is making better use of data that already exists.

Many healthcare systems continue to face growing demand, workforce pressures and finite resources. Any approach to earlier diagnosis must therefore be both scalable and practical.



Increasingly, there is interest in tools that can help identify risk more consistently, support clinical decision-making and reduce variation in how patients are assessed.

Importantly, these approaches are not intended to replace clinical judgement. Rather, they are designed to support it by helping clinicians recognise patterns that may warrant further investigation.

The goal is simple: ensuring more patients receive the right assessment at the right time.

Done effectively, this has the potential to improve patient outcomes while also supporting more efficient use of healthcare resources.

The algorithm advantage

One of the most significant developments in recent years has been the growing use of digital diagnostics and clinical decision-support tools.

Validated algorithms are increasingly being used to interpret routine clinical and laboratory data, helping clinicians identify patients who may benefit from further assessment and supporting decisions around referral and ongoing management.

For us at Roche Diagnostics, this thinking has driven the development of our Liver Disease Panel, including LiverPRO, which analyses as few as three to nine standard, routinely collected laboratory markers such as age, cholesterol and platelet count to assess fibrosis risk.

Such digital tools can automatically support primary care clinicians in assessing risk without requiring extra clinical visits.

When we look at the clinical and economic outcomes of this approach, the results are profound.

Using a sequential clinical pathway such as LiverPRO, followed by transient elastography, achieves a 94% specificity rate, resulting in 71% fewer unnecessary referrals compared to the traditional, age-adjusted FIB-4 Index.

Substituting FIB-4 with LiverPRO can potentially reduce the number of false-positive referrals by 3.4 times.

For healthcare systems facing unprecedented resource constraints, this clinical efficiency translates directly to vital economic relief.

Implementing this digital pathway demonstrates a 43% reduction in total screening costs and a 29% lower cost per detected case, dropping from around £3,250 to £2,300.

More importantly, it achieves an estimated 76% reduction in referrals, freeing up vital specialist capacity, while securing a 65% reduction in missed advanced fibrosis cases.

This means we are finally able to optimise both referral accuracy and patient safety.

Earlier changes everything

A diagnosis isn't the beginning of a patient's story, it is the moment the story changes.

When we shift from a reactive healthcare model to one of early detection, entirely different possibilities emerge.

By catching risk early, the clinical conversation shifts from managing late-stage disease to active clinical empowerment.

The prescription is no longer an eventual liver transplant, it is a proactive lifestyle intervention, a timely change in diet or the leveraging of dual-metabolic therapies.

We don't just save the liver, we alter the trajectory of the patient's entire metabolic, cardiovascular and diabetic health as well.

For clinicians, it can support more informed decision-making and help ensure specialist attention is directed where it is most needed.

For healthcare systems, it offers the potential to reduce avoidable complications, improve referral pathways and make better use of finite resources.

As liver disease prevalence continues to rise, the challenge is no longer simply recognising the scale of the problem.

It is ensuring that patients are identified early enough to benefit from the interventions and support already available.

Replacing the fear of a late-stage diagnosis with the opportunity for early prevention is not just a future vision. It is happening today.

Because when we know earlier, everything changes. ▲

Lee Lehman-Becker is SVP, Head of Digital Health Products at Roche Diagnostics

Joy of competing!

Who's in, who's winning and what's next

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.

1. The countdown is on – closes 17 September

- Marketer of the Year: 30+ years strong and still the gold standard. You get live scenario challenges, expert mentoring and an unfiltered look at how your strategic thinking stacks up
- Communications Awards: For the campaigns that actually cut through the noise. High-visibility, rigorous judging, zero fluff.

2. The big collaboration focus – closes 9 October

- Excellence in Healthcare Partnerships (EHP) Awards: after a standout debut, the EHPs are back to champion genuine healthcare collaboration. If you've built a bridge between industry, tech, or clinical care that actually delivered outcomes, put it forward.

3. The home straight

- Clinical Researcher of the Year – The Americas: entries are closed, and the pressure is on. Join us on 19 October as finalists go head-to-head on Finals Day, followed by the highly anticipated awards ceremony that evening.

4. On the radar

- Nursing Industry Excellence Awards: opening very soon. Start gathering your entries and nominations for the teams and individual leaders driving clinical care forward
- International Clinical Researcher of the Year – that's a wrap for 2026 after a brilliant finals day. Rest up, 2027 entries open shortly. Search 'pharmatimes awards results' for full 2026 results & roll of honour.

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

Leap of fAIth

What does CIOMS XIV mean for operationalised AI use in pharmacovigilance?

With AI now embedded in day-to-day pharmacovigilance, most drug safety operations have moved beyond considerations about whether a system can be validated for its intended use.

The bigger test comes further down the line, once inputs vary and models have been updated, at which point organisations still need to show the system remains safe and properly governed.

Here, ArisGlobal's Jason Bryant reflects on the implications for pharma organisations now operationalising AI use in a PV context, drawing on a recent podcast discussion with Denny Lorenz, an active member of the CIOMS XIV working group.

The Council for International Organizations of Medical Sciences (CIOMS) Working Group XIV AI in Pharmacovigilance report is a landmark piece of work. The international guidance, published in December 2025, is a comprehensive global consensus-based report on using artificial intelligence in drug safety.

Its detailed framework provides a structured approach for integrating AI and machine learning into PV without compromising patient safety or human accountability. Its publication confirms that the age of AI-driven pharmacovigilance has properly arrived, though the guidance itself has been a long time in the making.

The CIOMS Working Group first convened in Geneva back in May 2022 – about six months before OpenAI launched ChatGPT to the public, picking up a million users in five days, then around 100 million within a couple of months. Before that, the guidance had been built around organisations training their own machine learning models on proprietary data.

The mainstream arrival of GenAI in the form of pre-trained, general-purpose models necessitated a return to the drawing board. The Working Group rewrote most of the guidance. This settled on seven principles for the safe, accountable use of AI in pharmacovigilance, rather than serving as specific advice wedded to a particular technology.

Its principles-based approach is one of the main reasons the published advice feels so current, with widespread applicability.

But what of the plumbing – the operational detail that turns those principles into something a PV department can run day to day? This came up as a possible omission during a formal public consultation pre-publication, resulting in more detail on how the framework interoperates with the quality and regulatory frameworks organisations already work within.

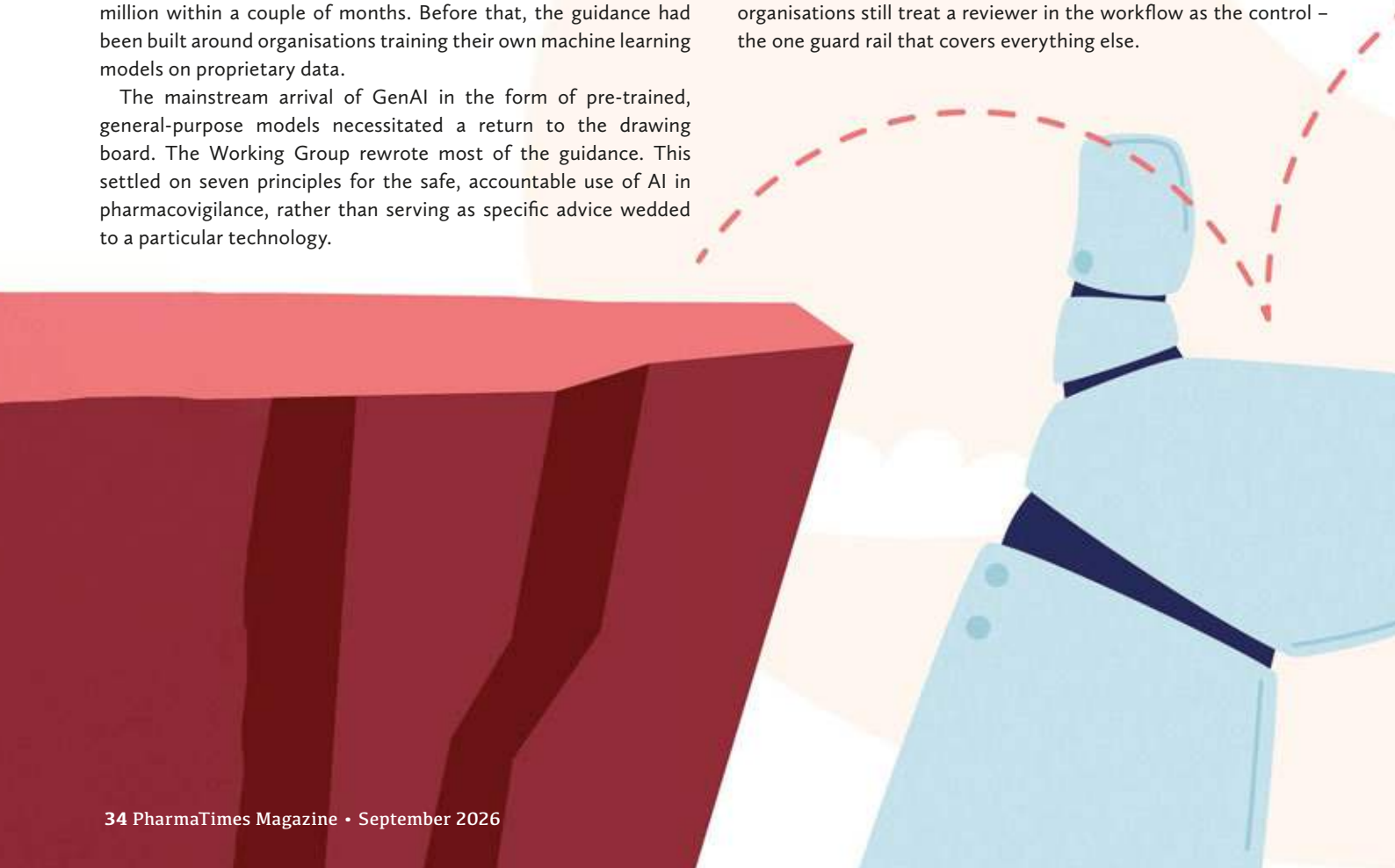
The published guidance is also more specific on life cycle and on governance, and clearer about what counts as practical evidence, so that these factors aren't left to guesswork.

Risk sets the scale for everything else

Because it ties everything else together, the principle of taking a risk-based approach to AI use tops the guidance list.

This is about determining how much validation evidence, monitoring and documentation is needed, and how this requirement should scale – based on what's actually at stake if something goes wrong in each scenario (rather than indiscriminately applying excessive measures, which could undermine the efficiency benefits AI is meant to deliver).

Human oversight is where this risk-based logic breaks down most often, something the guidance hasn't changed. Too many organisations still treat a reviewer in the workflow as the control – the one guard rail that covers everything else.



But the guidance treats oversight as one control among several, not a stand-in for the rest. A reviewer can check every single case without the PV system master file being documented, data privacy being addressed, or performance metrics existing to show whether that reviewer is actually catching what matters.

Human oversight only counts as evidence for a risk-based approach if the reviewer's own judgement is being measured too.

Ongoing performance monitoring lies within a further principle – validity and robustness – separate from watching the reviewer. Since an AI system's inputs vary case by case, and a model that appears unchanged may have a new prompt or a discrete version update behind it, validating it once at launch isn't enough.

Accountability for the safety judgement remains with a qualified PV professional throughout.

How the governance grid works

To aid accessibility and application, the report sets out a governance grid to test whether a use case is ready for production. The grid works less like a pass-or-fail checklist and more like a diagnostic.

Is there a documented risk assessment, for instance, and what about a described oversight process? Is there a governance structure that's revisited, rather than signed off once? A use case doesn't need every box ticked to move forward.

A pilot still running on a limited case set is fine, provided the gaps are known and being worked on.

The CIOMS Working Group's toughest disagreement during its deliberations, by most accounts, wasn't about any of the seven principles but rather timing – around the point at which a PV subject matter expert (SME) should join a project.

Some members wanted SME involvement kept to a formal sign-off at production; others pushed for input from the conceptual phase, alongside vendors from day one.

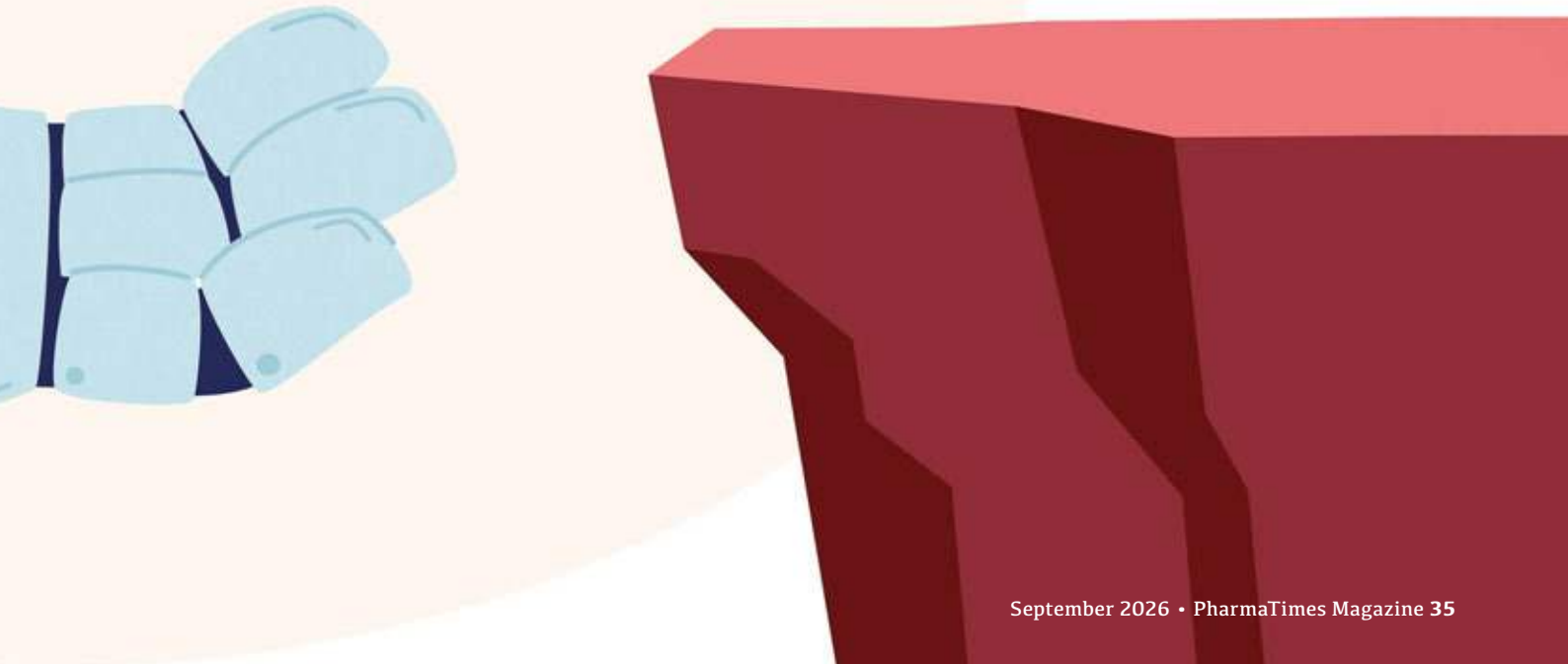
The guidance builds early involvement into the governance grid, on the basis that an SME who understands a model's limitations before it is built will produce a better-informed risk assessment.

Full field-by-field review won't be the default forever. A year of reliable data on a given field should be enough to justify checking only the low-confidence extractions and waving the rest through. Regulators haven't yet said whether they'll accept that in practice, though.

One early signal already exists in what regulators are doing elsewhere. The EMA and FDA published their own ten joint principles for AI across the medicines life cycle in January 2026, and the overlap with the work of CIOMS XIV is no coincidence – it all reflects the same shift.

The question of whether AI can be trusted isn't a one-off test, or something with a static answer. It will resurface every year, with each new model version – which is what governance now needs to be built around. ▲

Jason Bryant is General Manager, AI platforms at ArisGlobal



■ DFE Pharma has named **Khatera Alawi** as Global Director Human Resources. She also becomes part of the company's Leadership Team, bringing more than 20 years of international HR experience across pharmaceutical and consumer goods sectors.

Khatera previously held a dual global and local HR leadership role at UCB Pharma, serving as Global HR Business Partner for R&D and HR Director Germany. She supported innovation-focused business areas while shaping people and talent strategies across both global and local operations.

Across her career, Khatera has led HR functions, driven transformation programmes and strengthened talent management, performance and organisational effectiveness.

She is known for combining strategic HR leadership with practical execution to support organisations through change and build high-performing teams. Her work has contributed to sustainable business growth in international environments.

Dr Sven Abend, CEO of DFE Pharma, said: "Alawi's appointment reinforces our ambition to further strengthen a people-centric, high-performance culture, grounded in our values of 'Respect always' and 'Better every day'."

He added: "Her leadership approach reflects these principles in action by creating an environment where people feel valued and heard, while helping teams continuously improve how they work, collaborate and grow."

■ Pace has appointed **Andrew Fenny** as President of Pace Life Sciences to lead the division into its next phase of strategic growth. The company said he will focus on expanding support and capacity for pharmaceutical and biotech clients across the development cycle.

Pharmaceutical and biotechnology organisations continue to face pressure to accelerate development timelines and navigate scientific and regulatory complexity while managing rising costs. Pace Life Sciences aims to help customers address these challenges through seamless service, scientific certainty and comprehensive solutions.

Fenny brings more than two decades of experience across the CDMO and pharmaceutical sectors. He joins Pace Life Sciences from SK Pharmteco, where he served as Chief Commercial Officer. Before that, he worked for Fujifilm Diosynth Biotechnologies as Chief Business Officer.

His background spans commercial strategy, business development, integrated operations and client experience.

Ken Beyer, CEO at Pace, said: "Andy joins Pace at a time when our customers need more than results. They need a partner who can help them navigate complex regulatory pathways and challenging market conditions."

He added: "Andy's leadership and expertise will help us deliver the certainty companies need at every stage of the product life cycle because every phase drives programmes closer to patients waiting on treatments that change lives."

Mover of the Month

■ Elevara Medicines has appointed **Dr Mai-Britt Zocca** as CEO, effective 1 July 2026. She succeeds founder Emma Tinsley, who will remain on the Board as a Non-Executive Director.

Emma Tinsley, outgoing CEO, said: "Mai-Britt is an exceptional biotechnology leader."

She continued: "She combines deep scientific understanding with extensive operational and public company experience, and has successfully built organisations through exactly the stage Elevara is now entering."

Mai-Britt previously founded and led IO Biotech, advancing its pipeline from phase 1 through multiple phase 2 trials and into a pivotal global phase 3 study. She also founded a biotechnology venture focused on repurposing small molecules for cancer and neurodegenerative diseases.

Her earlier roles include senior leadership positions at Danish Biotech and Danish Chamber of Commerce, as well as posts supporting innovation and life science start-ups. She holds an MSc in Biochemistry and a PhD in Medicine from the University of Copenhagen and National Cancer Institute, NIH.

Mai-Britt said: "What attracted me to Elevara was not only the differentiated science behind ELV001, but also the outstanding work that Emma and the team have already accomplished."

She added: "The confidence demonstrated by the company's experienced investor base further strengthened my conviction that ELV001 represents a unique opportunity."

■ Lucid Group has announced that **Eric Muller** has joined the agency as Chief Executive Officer. He succeeds CEO and original DiD Agency founder Rick Sannem, who will transition to Strategic Advisor to the Board.

This leadership change comes as Lucid Group continues to expand its global footprint and reflects a deliberate step to assemble the talent needed to drive the company's next phase of growth. The agency said the move strengthens its ability to translate complex science into real-world impact.

Dr Rod MacKenzie, CMG, Chair of the Lucid Group Board, said: "Lucid works across the full arc of product commercialisation, from the earliest stages of clinical development to market launch and on through to loss of exclusivity. Eric understands how hard it can be for great science to break through but also how to commercialise healthcare at scale."

Eric explained: "Healthcare is entering a new era, driven by extraordinary advances in science, data and technology. Clients increasingly need a partner that turns complexity into clarity and impact by bringing together scientific expertise, creativity and strategy, along with the power of data and AI."

He added: "That is the future of healthcare marketing, and it is where Lucid is positioned to lead. I am a builder at heart, and I came to Lucid to build a business that helps clinicians, patients and caregivers make better decisions about the things that matter most."

■ Simris Group has appointed **Professor Andreas Pahl** as Chief Executive Officer of its Berlin-based subsidiary, Simris Biologics. He begins immediately and will oversee advancement of the company's Microcystin platform while shaping future development programmes in line with Board strategy.

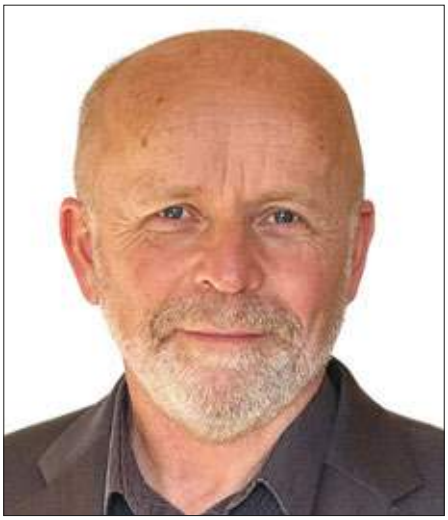
Andreas brings more than 25 years of experience across drug discovery, translational science, clinical development and corporate leadership. He previously served as Chief Executive Officer of Heidelberg Pharma, having earlier held the role of Chief Scientific Officer.

During his tenure, he helped build the business into a leading ADC developer and advanced its amanitin-based ADC platform into the clinic. The platform was successfully validated in a phase 1 study.

Jonathan Royce, Chairman of the Board at Simris Biologics, said: "Professor Pahl brings deep scientific expertise, extensive ADC development experience and a strong track record in naturally derived payloads. He understands both the science and the challenges of building an ADC company."

Andreas said: "Simris has built a strong scientific foundation and developed a differentiated approach to ADC payload discovery."

He explained: "ADCs continue to reshape cancer treatment, and I believe the Company is well positioned to build on its progress and create significant value from its technology for the benefit of patients and its shareholders."



■ Symeres and Axxam have appointed **Dr Russell Thomas** as Chief Scientific Officer to drive their joint collaboration, combining the complementary R&D services of both organisations into an integrated discovery and development offering.

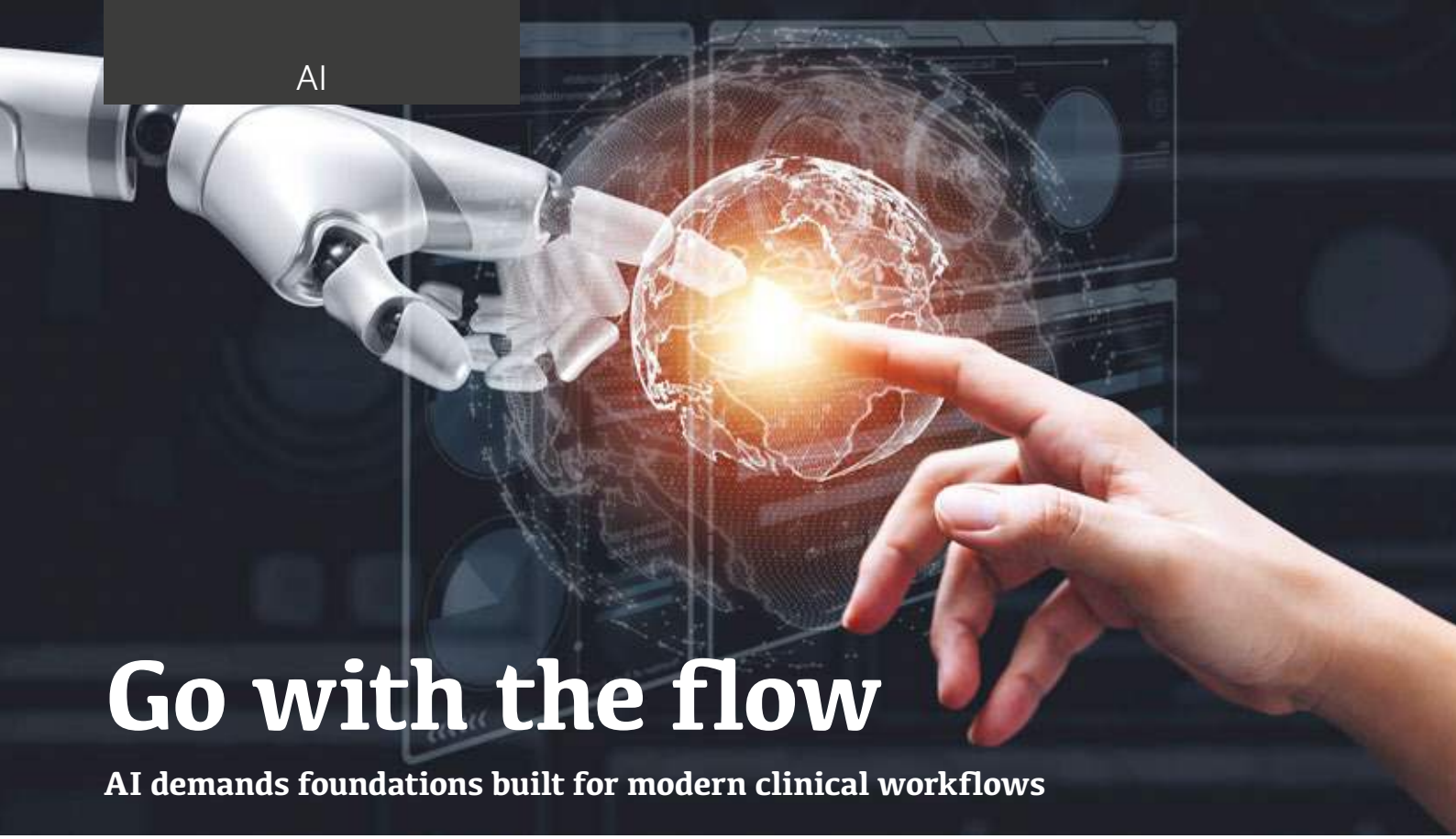
As CSO, Russell will help shape and execute scientific strategy while working closely with scientific and commercial teams across Symeres and Axxam. His remit includes supporting integrated client solutions, connecting scientific capabilities and identifying opportunities to strengthen combined discovery and development services. Demand for partners able to link scientific support across the drug discovery and development continuum continues to grow.

The collaboration will give customers integrated access to scientific expertise, established R&D platforms and long-standing teams across Europe and the US. It brings together the scientific depth, specialist capabilities and practical delivery mindset of both organisations.

Russell returns to Symeres after a year supporting biotech and biomaterials companies. His previous roles include positions at GSK, Evotec, Siena Biotech and Proteros.

"Returning as Chief Scientific Officer feels very exciting as it connects two parts of a story," said Russell.

He added: "Having spent important parts of my career at both Symeres and Axxam, I'm excited to help bring together expert-led complementary science, strong transatlantic teams and a shared mindset to support partners and projects in a truly integrated way."



Go with the flow

AI demands foundations built for modern clinical workflows

A few years ago, conversations about AI in clinical development were speculative, aspirational and cautious. The debate was mostly about when AI would change how clinical data is analysed, and by how much.

That debate is largely settled. The when is now, and the how much is turning out to be substantial.

Large language models are already speeding up regulatory document preparation and adverse event review. Digital twins are modelling patient populations to inform adaptive trial designs. Synthetic data is filling gaps in real-world data sets and supporting decentralised trials that would not otherwise have the numbers to proceed.

These are not proof-of-concept demonstrations. They are operational realities at leading organisations today.

Statistical computing environments built in the previous decade were designed for a particular paradigm: structured data sets; pre-specified analyses, and validated outputs following established templates.

That paradigm still matters. Regulatory submissions continue to demand rigorous, reproducible analysis.

The problem is that AI workflows behave nothing like it. They are iterative rather than linear. They draw on large, often unstructured data sets. They need computational resources that scale on demand.

And they produce outputs that must be explainable and auditable to regulators still developing their own guidance on AI.

An environment that was not designed for this cannot absorb it by adding a module.

Retrofit AI into a traditional environment and you tend to end up with something that is neither one thing nor the other. Not agile enough for AI, because the underlying architecture fights the iterative, compute-hungry, unstructured nature of the work.

Not clean enough for submission, because the AI capabilities bolted on around the edges sit outside the validated, traceable core the regulator expects to see.

This is the trap. A half-modernised environment often costs more than either alternative, because you are maintaining two paradigms at once and reconciling them by hand.

Analysts step outside the governed system to do the AI work, then step back in to make it submission-ready. Every handoff is a point where lineage can break and reproducibility can weaken, thinning the audit trail.

It is a familiar pattern in regulated industries. The real risk is rarely the old system everyone knows is old. It is the partial upgrade that looks modern on the surface and hides its gaps.

Built in, not bolted on

The alternative is an environment where AI is integrated from the foundation rather than fitted around it.

That means generative AI, agents, digital twins and synthetic data supported natively, and, critically, in a way that stays transparent and explainable. Explainability is not optional in clinical research.

Any output that influences a regulatory decision has to be traceable, auditable and defensible under scrutiny.

It also means supporting the languages this work is actually built in. Most machine learning and generative AI tooling lives in the Python and R ecosystems, and an environment that supports them inside a governed framework is one analysts never have to leave.

When AI and validation share the same foundation, the handoffs disappear, and with them the gaps.

The return on getting this right is not linear. It compounds. An organisation that can accelerate early-phase design with synthetic data, ease the load on safety teams with AI-assisted adverse event review and compress document preparation with language models is not saving time on isolated tasks.

It is shortening the end-to-end timeline across every trial, every phase, every submission.

That matters beyond efficiency. Every day of delay in bringing a therapy to market carries a financial and a human cost.

Every day recovered is a day closer to a patient who needs the treatment. ▲

Kurt Kaliebe is VP Americas Life Sciences and US Healthcare at SAS

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General enquiries : Luci Sargood | Luci.Sargood@pharmatimes.com | T: +44(0)7974198468
Sponsorship queries : Michelle Legrand | michelle.legrand@pharmatimes.com | T: +44(0)7474933019