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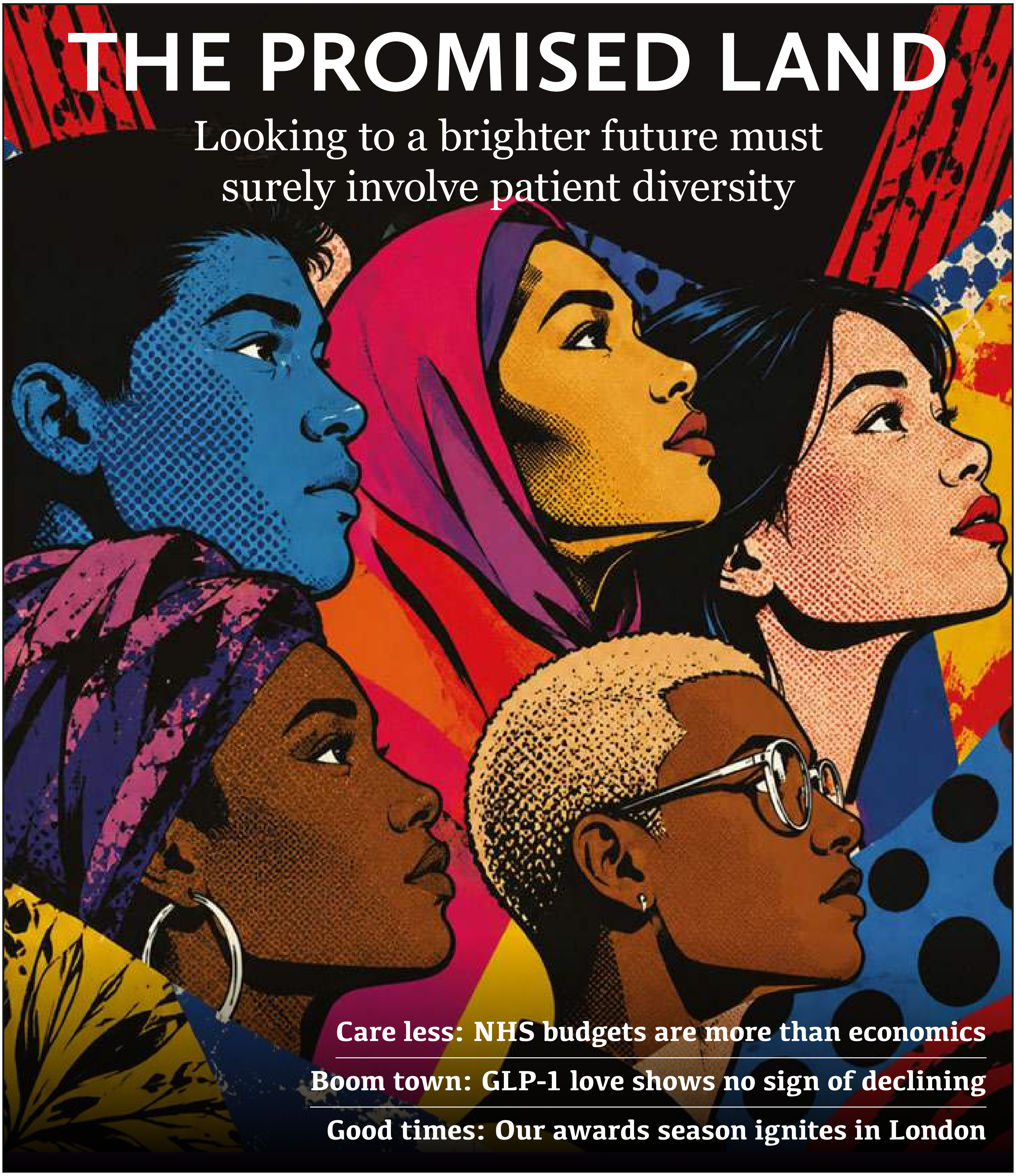

THE PROMISED LAND

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Good times: Our awards season ignites in London

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Nothing to Keir (except Keir itself)

As a writer and as someone who is duty bound to occasionally make precise reference to the bill payer at 10 Downing Street, the use of square brackets, with a last-moment instruction to drop in the 'correct' leader of this country is become absurdly common.

Even when that name is duly inserted, there is no guarantee that the name will be correct when the reader's eyes and brain process his or her credentials.

For years square brackets have existed in the shadows and, yet, through an embarrassing set of democratic and, indeed, non-democratic circumstances they have become the de facto kings of punctuation, even if they never see the light of day.

As editors, we drag square brackets from the suite of lesser-spotted keyboard characters with discombobulating regularity.

And it's not a task any of us relish. [Liz Truss] is not an insertion I would wish on my worst enemy. No, not even [Nigel Farage]. The truth is that all this dirt-digging and tittle-tattle, and the installation of a revolving door at the Prime Minister's residence has consequences for pharma.

10 Downing Streeting is by no means a guarantee. The position he vacated in order to chase the poisoned chalice caused unwanted turbulence throughout the healthcare system. [Insert something here about waiting times, dentistry and surgery being forgotten in the whirlwind of posturing and chaos.]

Enjoy the mag,

John Pinching
editor

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Smart People

Myomaker Bio unveils lab-grown human muscle platform to transform drug testing

A UK biotech company has launched what it describes as a world-first platform of lab-grown human muscle designed to give drug developers earlier, more accurate insights into how new medicines will behave in patients.

Myomaker Bio, a spin-out from Loughborough University, is scaling its bioengineered human muscle technology to support pharmaceutical and biotech companies seeking faster and more reliable preclinical testing without the need for animal studies.

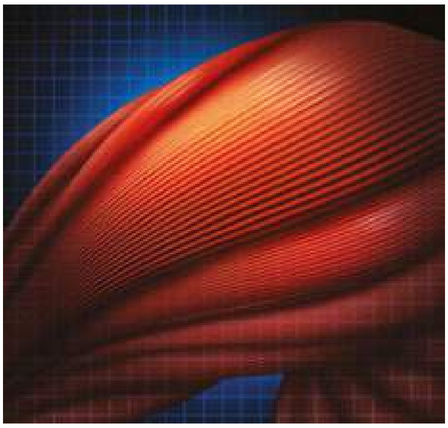
Its team of scientists and researchers, described as world-leaders in muscle biology, has created human muscle tissues and organs that replicate the structure and function of real skeletal muscle.

The platforms allow researchers to study human muscle biology, injury, regeneration and drug response in a controlled laboratory setting. According to the company, they offer a more predictive way to assess how medicines will perform before entering clinical trial.

Professor Mark Lewis, who co-founded Myomaker Bio and recently left the University to become full-time CEO, said: "Drug development remains slow, expensive and heavily dependent on animal testing, which doesn't always predict human outcomes. Our human muscle platforms are designed to bridge that gap.

"As pharmaceutical companies search for more effective and ethical research models, human tissue platforms such as ours could transform the preclinical testing landscape.

"By recreating human muscle biology in the laboratory, we can give drug developers a far more accurate way to evaluate medicines earlier in the development process. Ultimately, this means safer treatments reaching patients faster while reducing the need for animal testing."



Now based in London laboratory facilities, the company is preparing for rapid scale-up after securing £325,000 investment from SFC Capital to accelerate development and commercialisation. The funding will support expansion of its scientific team, increased production of its muscle models and deeper partnerships with global drug developers.

Pulsesight reports positive phase 1 data for PST-611 in dry AMD

PulseSight Therapeutics has unveiled positive phase 1 results for PST-611, its non-viral gene therapy candidate for dry age-related macular degeneration (AMD) with geographic atrophy (GA), following a podium presentation at ARVO 2026.

The first-in-human study, PST-611-CT1, assessed two ascending dose levels of PST-611 in six patients across Paris and Grenoble, with a 16-week follow-up. Investigators reported that the trial met its primary and secondary objectives, with the therapy demonstrating excellent safety and tolerability.

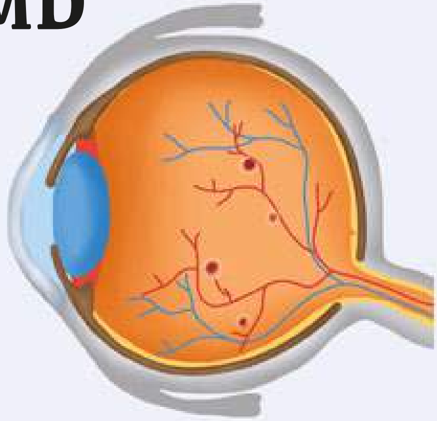
Most ocular adverse events were mild, two were moderate and no intraocular inflammation, treatment-emergent serious adverse events or suspected unexpected serious adverse reactions were observed. Best corrected visual acuity remained stable throughout.

Although not designed to measure efficacy, the study generated encouraging early signals. Patients spontaneously reported functional improvements in vision, while anatomical assessments suggested inflections in GA lesion growth. In one participant, the effect persisted beyond the trial's follow-up period.

Presenting the findings, Professor Francine Behar-Cohen said: "Geographic atrophy is a progressive, sight-threatening disease with no effective treatment currently available in Europe – the unmet medical need is real and urgent.

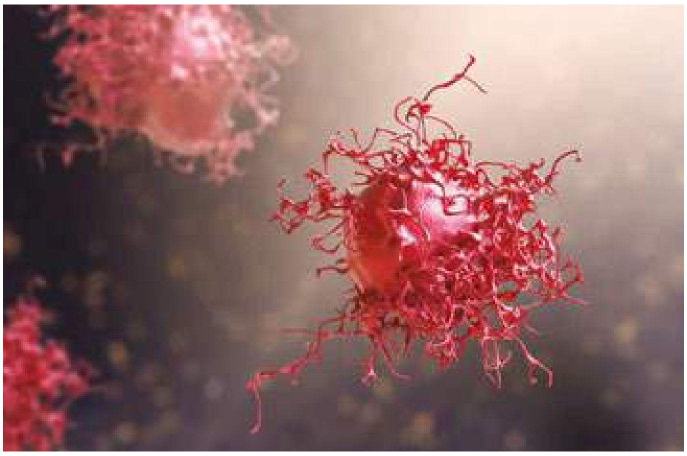
"These phase 1 results are therefore particularly meaningful. PST-611 demonstrated excellent tolerability, which is fundamental when treating patients with a chronic condition.

She added: "What makes these results stand out are the early efficacy signals we observed, both anatomically and functionally. I look forward to the phase 2a trial, which will allow us to confirm the therapeutic potential of PST-611 over a longer follow-up and in a larger group of patients."



Judith Greciet, PulseSight's chief executive officer, said: "We are thrilled by the outcome of our first-in-human study of PST-611. The trial met its primary objective with an excellent safety profile and went beyond our expectations – we observed early functional and anatomical efficacy signals, notably spontaneous reports from several participants of noteworthy vision improvements, after a single dose and just four months of follow-up."

CelLBxHealth partners with AdventHealth on CTC-based monitoring



CelLBxHealth has entered a collaboration with AdventHealth for the use of its Parsortix circulating tumour cell (CTC) platform in two multicentre studies designed to advance minimally invasive cancer monitoring.

AdventHealth is one of the largest faith-based health systems in the US, providing a broad clinical network for real-world evaluation.

The studies, ACTION and SUNRISE, will isolate and analyse circulating tumour cells from blood samples to assess treatment response and tumour biology without the need for invasive biopsies.

Researchers will use the platform for both enumeration and PD-L1 characterisation, offering real-time insight into how tumours evolve during therapy.

ACTION is an NIH-funded trial enrolling 219 patients to examine how different levels of aerobic exercise influence chemotherapy tolerability in colon cancer.

SUNRISE, due to begin in July 2026, will recruit 120 patients with gastrointestinal and lung cancers to evaluate whether remotely delivered exercise interventions can improve chemotherapy tolerance and quality of life.

Across both studies, CTC analysis will serve as a novel correlative endpoint, supporting efforts to understand how behavioural interventions and treatment regimens shape tumour dynamics.

A key aim is to bring advanced cancer monitoring closer to patients' homes. With most US cancer care delivered in community settings, combining remote interventions with simple blood-based diagnostics could reduce travel, lessen patient burden and enable continuous monitoring regardless of geography.

The approach also seeks to address entrenched health inequalities that limit access to specialist oncology services.

AdventHealth's national footprint provides a strong platform to scale these technologies in routine practice.

For CelLBxHealth, the collaboration represents a significant commercial opportunity to validate and expand adoption of the Parsortix platform across a major integrated health system, supporting broader use of liquid biopsy in everyday oncology care.

MHRA to open new Northern Ireland hub to strengthen life sciences collaboration

The MHRA is establishing a new hub in Northern Ireland to support the region's fast-growing life sciences sector, in a move announced on 13 May 2026. Hosted by Invest Northern Ireland, the hub is intended to strengthen collaboration between the regulator and local healthcare, academic and industry partners.

Northern Ireland is home to around 250 life sciences businesses, supporting 18,000 jobs and contributing £1.1 billion to the economy.

The new Belfast base will allow local organisations to book in-person sessions with MHRA technical experts on areas including innovation pathways and clinical investigations, with signposting to further regulatory support across the product development pipeline. The MHRA said this direct access will help accelerate clinical research and the development of new therapies.

The hub follows a series of stakeholder liaison events launched at the HIRANI Health Tech Spring Conference in April 2026, and builds on commitments made after the MHRA Board meeting held in Belfast in November 2025. Work is already under way to expand use of the Yellow Card scheme across Northern Ireland to strengthen safety surveillance.

Professor Anthony Harnden, MHRA Chair, said: "One of my priorities since becoming chair has been to ensure the MHRA is a regulator for all nations with an increased presence and engagement with our partners and stakeholders across the UK."

Professor Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland, said: "The establishment of an MHRA hub in Northern Ireland, hosted by Invest NI, reflects the strong collaborative relationship and sustained engagement between Northern Ireland agencies and the MHRA in recent months."

Microbiotica reports positive results for MB097 in advanced melanoma

Microbiotica has announced positive findings from its phase 1b MELODY-1 trial of MB097, an oral precision microbiome co-therapy being developed for advanced melanoma.

The study met all primary and secondary objectives, with the company reporting that MB097 was safely combined with pembrolizumab and showed encouraging early signs of efficacy in a population with primary resistance to anti-PD-1 therapy.

The international trial enrolled 41 patients across the UK, France, Italy and Spain. Participants received MB097 alongside pembrolizumab for up to six months, with half also given vancomycin preconditioning to assess whether it improved bacterial engraftment.

Microbiotica said the nine-strain bacterial consortium demonstrated robust engraftment, particularly in those receiving vancomycin.

Dr Pippa Corrie, National Co-ordinating Investigator for the study, said: “There is increasing evidence that the microbiome plays a crucial role in patients’ response to immune checkpoint inhibitors. Clinical benefit has been reported with faecal microbiota transplantations (FMT), while MB097 capsules taken orally each day affords an easy and reproducible way of modifying the microbiome.

She added: “The MELODY-1 study results show that MB097 is well tolerated, with encouraging early signs of efficacy in a very difficult-to-treat metastatic melanoma patient population with primary resistance to anti-PD-1 based immunotherapy, in whom there is a significant unmet need.”

Novo Nordisk data shows oral semaglutide delivers weight loss in phase 3 trial

Novo Nordisk has presented new sub-analyses from the phase 3 OASIS 4 trial at ECO2026, showing that oral semaglutide 25mg tablets delivered substantial weight loss and improvements in mobility for adults living with obesity compared with placebo.

The company reported that 28.8% of adults taking semaglutide tablets were early responders, defined as losing at least 10% of body weight by week 16. This group achieved 13.2% weight loss at week 16 and an average of 21.6% by week 64.

Those who did not meet early response criteria still recorded 11.5% weight loss by week 64, meaning both groups achieved clinically meaningful reductions.

Professor Partha Kar, Consultant Diabetes & Endocrinology, Portsmouth, said: “Obesity management isn’t a one-size-fits-all process. It’s nuanced, and individual responses can differ quite markedly.”

A separate analysis showed that 77.3% of people with poor physical function at baseline experienced clinically meaningful improvements in mobility and bodily pain scores when taking semaglutide tablets, compared with 42.9% on placebo. Weight loss in this group was similar to that seen across the overall treatment arm.

HOT & NOT

The **Scottish Medicines Consortium** has recommended the reimbursement of enfortumab vedotin with pembrolizumab for adults with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy.

Astellas Pharma said the decision means doctors and patients in Scotland will be able to access a treatment that substantially increases overall survival through the NHS.

Calla Lily Clinical Care has dosed the first patients in its Freedom clinical trial, a NIHR-funded study evaluating the company’s Callavid intravaginal drug-delivery platform for women with luteal phase insufficiency.

The condition, in which progesterone levels may be too low to sustain early pregnancy, is associated with infertility and

Poolbeg Pharma has received formal notification that its patent covering the use of p38 MAPK inhibitors, including POLB 001, for the prevention of cancer immunotherapy-induced cytokine release syndrome (CRS) has been granted in Canada.

The decision marks the second national grant within the company’s oncology-focused CRS patent family, following approval in Australia.

UCB and Cancer Research UK form expanded alliance to advance cancer therapies

UCB has entered a new multi-project strategic alliance with Cancer Research UK and its innovation arm, Cancer Research Horizons, aiming to accelerate the development of novel oncology candidates by combining complementary scientific and clinical strengths.

The agreement builds on a collaboration announced in 2023 between UCB and Cancer Research UK's Centre for Drug Development, which has already advanced two antibody drug candidates into ongoing clinical trials across UK and European sites.

The expanded alliance now incorporates earlier stage discovery and preclinical programmes, with UCB drawing on Cancer Research UK's oncology expertise, access to leading investigators and extensive drug development capabilities.

Under the new framework, Cancer Research UK's Centre for Drug Development and Cancer Research Horizons' Therapeutic Innovation teams will work with UCB to progress selected therapeutics from research through to early clinical development.

For each project entering the alliance, the Centre for Drug Development will design, prepare, sponsor and run a phase 1/2 clinical trial. UCB has nominated two additional projects from its internal pipeline to join the partnership.

Research and development costs will be shared, with UCB retaining exclusive rights to further develop and commercialise all programmes. Cancer Research Horizons will receive undisclosed milestone and royalty payments tied to downstream progress.

MimiVax and Roswell Park open trial of SurVaxM for neuroendocrine tumours

A new phase 2 clinical trial has opened at Roswell Park Comprehensive Cancer Center to evaluate the cancer vaccine SurVaxM in combination with temozolomide for patients with progressing metastatic neuroendocrine tumours.

The study, sponsored jointly by MimiVax and Roswell Park, is led by principal investigator Dr Jasmeet Kaur.

The trial will compare temozolomide plus SurVaxM with temozolomide alone in patients whose disease continues to advance. SurVaxM is a peptide vaccine designed to stimulate an immune response against survivin, a protein expressed in many tumour types.

Earlier phase 1 findings showed the vaccine was well tolerated in neuroendocrine tumour patients and produced measurable clinical benefit with elevated antibody responses.

Michael Ciesielski, CEO and co-founder of MimiVax, said: "This phase 2 trial is the result of years of careful, collaborative science between MimiVax, Roswell Park Comprehensive Cancer Center and the neuroendocrine tumour community. NET patients deserve more options, and we are excited to see if SurVaxM can become a new treatment for them."

Neuroendocrine tumours arise from hormone-producing cells, most commonly in the gastrointestinal tract and lungs.

Although many grow slowly, metastatic disease carries a poor prognosis and treatment options are limited once first-line therapy fails. Immunotherapy has shown little benefit in this setting, increasing interest in new immunologic targets such as survival.

Enterprise Therapeutics has reported that its phase 2 trial of ETD001, an investigational inhaled epithelial sodium channel blocker, met its primary efficacy outcome in people with cystic fibrosis who do not benefit from CFTR modulators.

The study showed clinically meaningful improvements in lung function over 28 days compared with placebo.

Health authorities are monitoring a new cluster of **Ebola** cases after infections were confirmed in a remote region, prompting rapid deployment of surveillance teams and emergency medical support.

Vaccination of contacts and frontline workers is under way, alongside efforts to trace potential transmission chains. Officials say the situation remains contained but fragile, with limited healthcare access and population movement posing challenges.

NHS dentistry in the UK remains under severe strain, with new data showing millions of people unable to secure an NHS appointment.

Many practices report they cannot take on new NHS patients because the current contract makes it financially unsustainable, leading to widespread closures or shifts to private care. The British Dental Association warns the service is at breaking point, with long waits, rising unmet need and growing regional 'dental deserts' across England.

A design for life

Why more inclusive protocols and recruitment strategies are essential

Clinical trials are evolving in response to growing expectations around diversity, accessibility and patient-centricity.

Improving diversity in clinical trials can help generate more representative evidence and strengthen confidence in treatment performance across different patient groups. However, building study populations that reflect real-world patients remains a significant challenge.

In this article, Julie Massicotte, Senior Director, Regulatory Affairs at Indero, explores how sponsors can address these issues earlier in the trial life cycle through more inclusive protocol design, patient-focused recruitment strategies and stronger statistical planning.

Clinical trials are the foundation of evidence-based medicine, generating the data needed to evaluate the safety and efficacy of new therapies before they reach patients.

However, many studies still struggle to enrol participants who accurately reflect the populations seen in routine clinical practice. Meanwhile, regulators are placing growing emphasis on diversity and inclusion, increasing pressure on sponsors to generate scientifically robust evidence across broader patient populations.

Achieving this requires more than wider recruitment campaigns alone. Protocol design, statistical strategy, site selection and patient engagement all play important roles in determining whether a trial can successfully recruit and retain a representative patient population.

Considerations around accessibility, participation burden and operational feasibility must therefore be incorporated as early as possible in study planning.

Moving beyond traditional recruitment models

Historically, clinical trials have often struggled to recruit participants from under-represented populations.

Geographic limitations, financial pressures, limited access to specialist research centres and mistrust of pharmaceutical research can all discourage participation. At the same time, restrictive inclusion and exclusion criteria may unintentionally exclude real-world patients with common comorbidities, limiting how well trial results reflect routine clinical practice.

These challenges are particularly significant because disease presentation, treatment response and adverse event profiles can vary between patient populations.

In dermatology, for example, conditions such as atopic dermatitis, acne and melanoma may present differently across skin tones, potentially affecting diagnosis, endpoint assessment and treatment outcomes.

Factors such as Fitzpatrick skin type and endpoint assessments training must therefore be considered during protocol planning to ensure that efficacy and safety data accurately reflect a broader patient population.

Regulatory agencies are increasingly addressing this issue, with the FDA, EMA, MHRA and HRA all emphasising the importance of improving participant diversity and embedding inclusion strategies into study planning.

The EU Clinical Trial Regulation also encourages sponsors to justify non-representative enrolment approaches and consider broader accessibility during protocol development.

In the UK, new MHRA regulations that came into force on 28 April 2026 introduced further guidance to help researchers embed the patient voice into the design and conduct of trials.

Similarly, the US FDA finalised its guidance on enhancing participation in clinical trials in December 2025. The final guidance provides recommendations to increase enrolment of representative populations by considering both demographic and non-demographic characteristics.

These growing regulatory expectations are also driving industry groups and professional bodies to develop guidance that helps sponsors integrate patient feedback and reduce participant burden in protocol design.

Designing protocols with patient realities in mind

Feedback from all interested parties is highlighting that excessive site visits, complex assessment schedules, lengthy procedures and unrealistic expectations can create substantial burdens for participants and sites alike.

These can be particularly significant in long-term conditions such as rheumatological diseases, where chronic symptoms, comorbidities and complex treatment histories may affect patients' ability or willingness to enrol in trials.

Most immune-mediated inflammatory dermatological and rheumatological diseases also appear during working and childbearing years, meaning intensive trial schedules heavily disrupt professional and family responsibilities.

In addition, rheumatology patients often experience severe pain and active inflammation, particularly during the screening period and first few weeks of a trial. This severely reduces their physical independence, meaning they may need a caregiver or companion to travel to and attend site visits.

Factors such as realistic visit schedules, travel support and caregiver involvement are therefore playing an important role in encouraging both recruitment and retention.

Even scientifically robust protocols may struggle operationally if they fail to reflect the realities of patients' daily lives.

While planning study designs, sponsors should consider logistical and participant-related factors that may create barriers to trial participation. Engaging with patients, investigators and site teams during protocol development can help sponsors identify these practical barriers before studies begin.

Improving representation also requires inclusion strategies to be integrated into protocol development from the start.

This includes carefully reviewing eligibility criteria to ensure exclusions are scientifically justified, as well as evaluating recruitment targets and stratification approaches that allow broader representation across demographic and clinical variables.

As these examples illustrate, sponsors must also consider non-clinical factors that may affect participation within different patient groups, including transportation difficulties, work commitments, language access, digital accessibility, socioeconomic factors and cultural sensitivities.

Clear communication remains equally important, particularly for informed consent forms, protocol summaries, study instructions and retention strategies. Using accessible language and offering information in multiple formats can help patients better understand trial expectations and build trust in the research process.

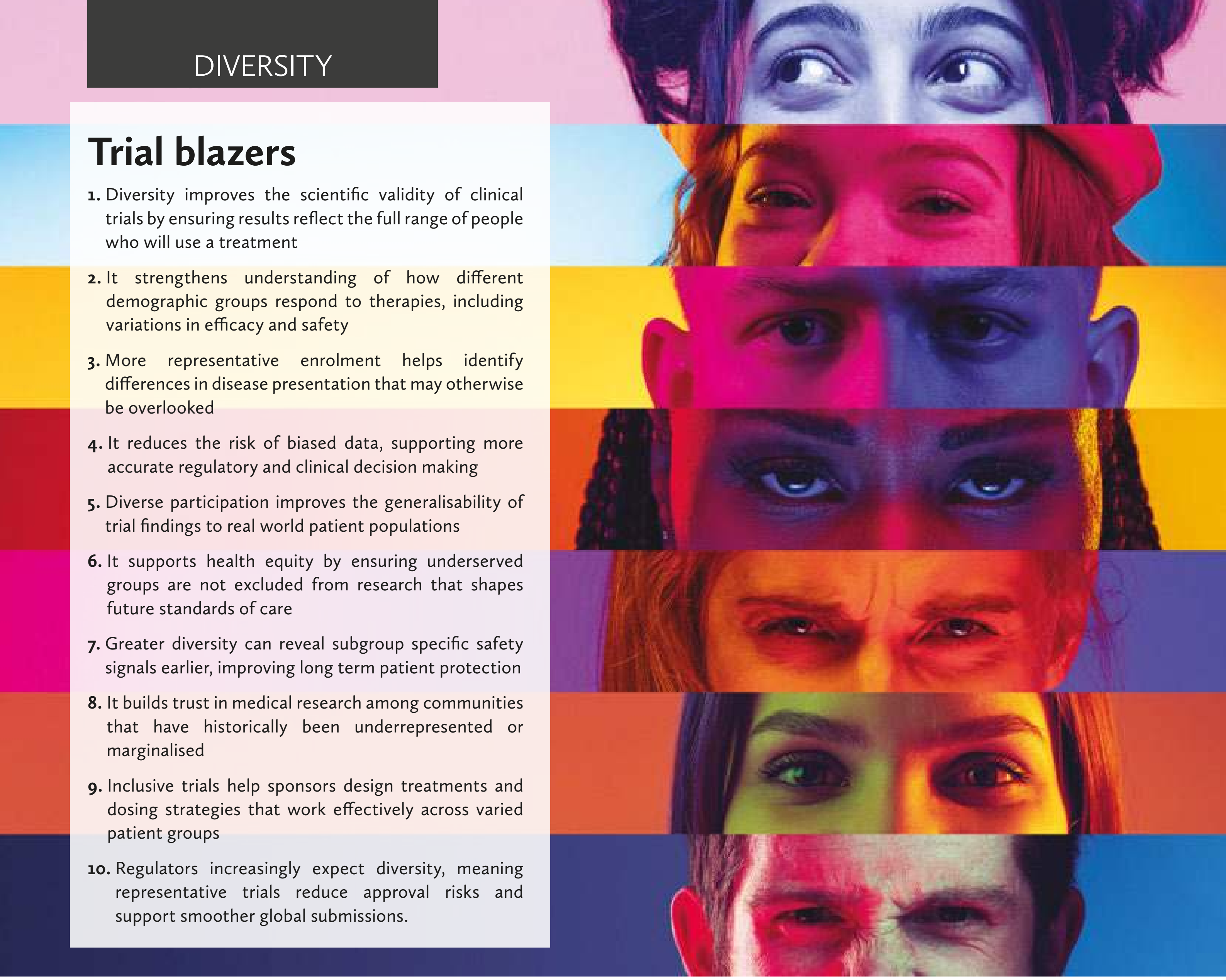
Flexible trial models are also helping to reduce participation barriers. Hybrid and decentralised approaches that incorporate remote monitoring, digital reporting tools and virtual visits can reduce the need for frequent travel and improve accessibility for patients in rural or underserved communities.

While fully decentralised models may not be appropriate in every therapeutic area, particularly where subjective or imaging-based assessments are required, incorporating flexibility wherever possible can improve recruitment and retention.

The growing importance of statistical clarity

As trial designs become more adaptive, integrated and patient-centred, the need for methodological precision grows accordingly.

The estimand framework, formalised through ICH E9(R1), addresses this directly by requiring sponsors to articulate exactly what treatment effect a trial intends to measure before data is collected.



Trial blazers

1. Diversity improves the scientific validity of clinical trials by ensuring results reflect the full range of people who will use a treatment
2. It strengthens understanding of how different demographic groups respond to therapies, including variations in efficacy and safety
3. More representative enrolment helps identify differences in disease presentation that may otherwise be overlooked
4. It reduces the risk of biased data, supporting more accurate regulatory and clinical decision making
5. Diverse participation improves the generalisability of trial findings to real world patient populations
6. It supports health equity by ensuring underserved groups are not excluded from research that shapes future standards of care
7. Greater diversity can reveal subgroup specific safety signals earlier, improving long term patient protection
8. It builds trust in medical research among communities that have historically been underrepresented or marginalised
9. Inclusive trials help sponsors design treatments and dosing strategies that work effectively across varied patient groups
10. Regulators increasingly expect diversity, meaning representative trials reduce approval risks and support smoother global submissions.

This means specifying the target population, the clinical endpoint, the summary measure, the treatment condition of interest and, critically, how intercurrent events such as treatment discontinuation, use of rescue medication or treatment switching will be reflected in the analysis.

This discipline is especially consequential in flexible designs, where divergent patient trajectories and treatment pathways are not exceptions but expected features of the data.

The estimands framework forces these decisions into early protocol development rather than leaving them to the analysis stage, reducing post hoc ambiguity and strengthening the interpretability and regulatory defensibility of trial results.

Equally important, the framework demands cross functional engagement.

Defining intercurrent events and selecting appropriate strategies for handling them is not a purely statistical exercise. It requires communication between clinicians, biostatisticians, medical experts, regulatory strategists and operational leads, who all contribute to identifying relevant intercurrent events and determining how they should be managed.

This synergistic approach helps ensure that protocols remain both scientifically robust and operationally feasible.

Collaboration will define the future of inclusive trials

More complex trial designs, broader inclusion expectations and rising operational demands are making protocol development far more cross functional.

Sponsors can no longer approach trial planning as a purely scientific exercise conducted in isolation. Successful studies now require integration of scientific and medical expertise, operational planning, statistical strategy and patient insight from the earliest stages of development.

Specialised CRO partners are becoming increasingly important in this environment, particularly for complex or adaptive study designs in areas such as dermatology and rheumatology.

These partners help sponsors balance flexibility with scientific control, identify operational risks early and develop recruitment approaches that allow broader inclusion without compromising study quality.

Ultimately, designing clinical trials that reflect real world populations goes beyond meeting regulatory expectations.

More representative research improves confidence in clinical evidence, strengthens understanding of treatment performance across patient groups and enables better long term healthcare outcomes. ▲

Julie Massicotte is the Senior Director, Regulatory Affairs at Indero

Trial blazing!

How AI and real-world data are closing the clinical trial diversity gap

Despite regulatory uncertainty around the US Food and Drug Administration's Diversity Action Plans (DAPs), most trial sponsors remain firmly committed to building more representative studies.

The missing piece has not been intent; it has been the operational tools to act on it at scale.

AI and real-world data (RWD) are now providing exactly that.

Clinical trial diversity has long sat at the intersection of scientific necessity, ethical obligation and commercial pragmatism.

For decades, the argument was clear: trials that fail to enrol populations reflective of the real-world patient community yield data that generalises poorly; labels that restrict prescribing and outcomes that underserve the most vulnerable.

Yet progress has been frustratingly slow. This is beginning to change, and the catalyst is not solely regulatory pressure.

A revolution in artificial intelligence (AI) and RWD is giving trial sponsors the operational capability to move diversity from a box-ticking exercise to a core component of trial strategy.

Regulatory backdrop: ambiguous but not absent

The FDA's June 2024 draft guidance on Diversity Action Plans (DAPs) set out clear expectations: studies should specify enrolment goals disaggregated by race, ethnicity, sex and age.

The legal basis, the Food and Drug Omnibus Reform Act (FDORA), is established.

What remains uncertain is the timing of final guidance, and with it the 180-day implementation clock.

In practice, this ambiguity has created a split market.

Large pharmaceutical companies have largely absorbed DAPs into standard operating procedures, treating them as a scientific baseline rather than a compliance obligation.

Many have public diversity commitments and track enrolment demographics as a standard metric alongside efficacy endpoints.

Biotechs present a more complex picture.

Many are focused on rare diseases and niche populations where diversity obligations interact uncomfortably with finite funding runways.

The instinct to find the fastest path to market, for shareholders and for patients, can create genuine tension with broader enrolment goals.

Yet the penalty for getting this wrong can be severe, and it is not confined to biotechs.

One company recently received approval for a pivotal phase 3 therapy but with a label restricted to the narrow population it had enrolled.

Expanding that label will require entirely new trials, costing hundreds of millions of dollars and years of delay that could have been avoided with more thoughtful enrolment from the outset.

The business case for diversity in clinical trials is no longer theoretical.

A restricted label is not just a scientific failure; it is a commercial one.

Against this backdrop, the lull in US regulatory enforcement should not be read as permission to pause.

It is an opportunity to build the right foundations, and AI and RWD are making that task considerably more achievable.

AI and RWD revolution

The phrase 'AI and real-world data' risks becoming a catch-all that obscures more than it reveals.

In the context of clinical trial diversity, these tools address specific, well-defined operational challenges across the trial life cycle.

It is worth being precise about where they add value.

1. Feasibility modelling and protocol design

The most common failure mode in diversity planning is leaving it too late.

By the time a protocol is finalised and a site network activated, the parameters that determine who can be enrolled are largely fixed.

Retrospective fixes, such as protocol amendments, site additions and targeted outreach, are expensive, slow and often insufficient.

> 'Clinical trial diversity has long sat at the intersection of scientific necessity, ethical obligation and commercial pragmatism'

AI-powered feasibility tools change this by integrating patient-availability data from the outset.

Drawing on large-scale RWD – including electronic health records (EHR), insurance claims, laboratory data and disease registries – these platforms can model the likely patient pool for a given indication across geographies, demographics and site networks before a single patient is screened.

Critically, they can stress-test inclusion and exclusion (I/E) criteria against real-world patient populations.

Many I/E criteria that appear clinically reasonable in isolation turn out to disproportionately exclude specific demographic groups: patients with comorbidities more prevalent in certain ethnic populations, or age thresholds that inadvertently exclude the elderly.

AI can surface these trade-offs, allowing protocol teams to make informed decisions about where scientific rigour is genuinely required and where criteria can be broadened without compromising data quality.

In one example, a sponsor identified that proposed I/E constraints were excluding a significant portion of eligible patients from under-represented groups.

Protocol amendments made before study initiation increased the predicted enrolment rate by 10% or 20% and broadened the eligible participant base, changes that would have been far more costly to implement mid-trial.

- AI-powered feasibility tools can simulate enrolment scenarios by demographic group before protocol lock
- I/E criteria analysis identifies exclusionary parameters that may not be scientifically necessary
- Geographic modelling highlights where under-represented populations exist but are not being reached by proposed site networks
- Early intervention is substantially cheaper than mid-trial protocol amendments.

2. Site selection and investigator networks

Site selection has historically been driven by a familiar shortlist: high-enrolling sites with experienced investigators; existing infrastructure and established prior site-sponsor relationships.

The result is a network that reflects the demographics of its past patients rather than the demographics needed for the trial at hand.

RWD is enabling a fundamentally different approach.

By analysing patient population data at the site level (including the demographic composition of the catchment population, disease prevalence, standard of care patterns and historical enrolment performance), sponsors can identify sites that serve under represented communities and have the patient pool to support diverse enrolment.

AI adds a further layer by integrating social determinants of health (SDOH) data: transport access; insurance status; language prevalence and community health infrastructure.

A site in a demographically diverse urban area may be poorly served by public transport, making it effectively inaccessible to the very patients it serves.

These factors, invisible in traditional site selection databases, become legible through SDOH analysis.

The output is not just a ranked list of sites, but a diversity-stratified network, one designed from the start to reach the patient populations that matter scientifically and commercially.

Site selection built on historical enrolment performance perpetuates demographic bias.

RWD-driven selection can break that cycle.

3. Patient identification and real-time matching

Even the most thoughtfully designed trial and carefully selected site network will underperform if patient identification remains slow, inefficient and demographically skewed.

This is where the combination of AI and RWD is perhaps most transformative.

Every day, billions of data points enter healthcare systems, such as EHR entries, lab results, prescription claims and imaging records.

Historically, the latency in these data streams meant that analyses were retrospective, often months behind clinical reality.

That latency is collapsing. Near-real-time querying of RWD is now possible, enabling clinical teams to identify potentially eligible patients as they enter the healthcare system rather than waiting for periodic data pulls.

AI supercharges this capability in two important ways.

First, it can parse unstructured data (clinical notes, discharge summaries, referral letters) that contain highly relevant patient history but have historically been inaccessible to systematic analysis.

Natural language processing (NLP) models can extract and match this information against I/E criteria at scale, dramatically expanding the pool of identifiable candidates.

Second, AI can apply matching algorithms that are expressly calibrated to surface patients from under represented groups.

These algorithms flag candidates who meet eligibility criteria but might not appear in structured query results because their conditions are recorded differently, their healthcare interactions are less frequent or their demographic characteristics are under represented in training data.

This is not about lowering the scientific bar; it is about removing the invisible filters that have always existed in manual identification processes.

The results are measurable. In one deployment, RWD triggers drove 64% of randomised patients across 25 sites within a four-month recruitment period, accelerating timelines by two months.

Critically, real-time matching reached patients who would otherwise have gone unidentified, reducing screen fail rates, and reducing burden on site staff.

- NLP models extract eligibility-relevant information from unstructured clinical notes at scale
- Real-time RWD querying identifies eligible patients as they enter the healthcare system
- Matching algorithms fine-tuned for demographic diversity surface under represented candidates
- Targeted physician outreach and referral pathways convert identified patients to screened candidates
- Reduced screen fail rates and site burden improve the economics of diversity-focused enrolment.

4. Patient engagement and reducing systemic barriers

Identifying patients is not the same as enrolling them.

Underrepresented populations face well-documented barriers to trial participation: distrust of the medical establishment; practical obstacles such as time off work and transport; language and health literacy challenges, and a lack of community-level awareness that trials are even an option.

AI and digital health tools are increasingly being deployed to address these barriers directly.

AI-driven patient engagement platforms can deliver personalised, culturally appropriate communications in the patient's preferred language, with messaging adjusted to the specific concerns of different demographic communities.

Digital consent processes, remote monitoring capabilities and decentralised trial elements can reduce the burden of participation, making enrolment viable for patients who would have been excluded by the practical demands of traditional site-based trials.

These tools do not replace the community engagement and trust-building work that is essential for reaching underserved populations.

But they provide the infrastructure that makes such outreach scalable and sustainable across a global trial network.

Two principles that apply regardless of company size

The operational reality for a top ten pharmaceutical company looks very different from that of a Series B start-up.

But the underlying principles that make AI and RWD effective for diversity are size-agnostic.

Two stand out. The sponsors who have made the most consistent progress on trial diversity share one characteristic: they begin the work before protocol finalisation.

Feasibility assessments that incorporate real-world demographic data allow teams to set realistic enrolment goals, identify gaps in the site network and design protocols that do not inadvertently exclude the patients they most need to enrol.

This is not just good practice for diversity.

It is good trial design.

Early feasibility work consistently reduces mid-trial amendments, improves enrolment velocity and produces data that is more generalisable and therefore more commercially valuable.

Meet patients where they are

Once a trial is operational, the opportunity to influence diversity outcomes does not end.

Real-time RWD and AI-powered matching allow clinical teams to continuously identify and engage eligible patients throughout the recruitment period.

This is particularly valuable for reaching patients who interact with healthcare systems infrequently or who are served by sites outside the traditional network.

The combination of digital outreach, community-level engagement infrastructure and real-time data creates a recruitment model that is responsive to the actual distribution of patients, not just the distribution of historically active trial sites.

What sponsors should do now

The regulatory environment will clarify in time.

In the interim, sponsors that invest in building AI and RWD capabilities for diversity will be better positioned on multiple dimensions: scientifically; commercially and ethically.

The practical steps are well defined:

- Integrate RWD-based demographic feasibility analysis into protocol development as standard, before I/E criteria are finalised
- Audit site selection processes for demographic bias and incorporate SDOH data into network design
- Deploy AI-powered patient identification tools explicitly calibrated to surface under represented populations

- Invest in decentralised and hybrid trial elements that reduce practical barriers to participation
- Engage community-level partners and patient advocacy organisations early; digital tools amplify human relationships, they do not replace them
- Track diversity metrics as a standard enrolment KPI, reported alongside efficacy and safety data.

Closing thoughts

There is a strong scientific and moral consensus that the pharmaceutical industry needs to move forward on diversity, in clinical trials and in patient care.

This is occurring independently of regulation. The tools to act on that consensus at scale now exist and are proven in deployment. The choice for sponsors is not whether to address diversity, but when and how.

Those that build the right data infrastructure and AI capabilities now will find that the challenge of diverse enrolment becomes, over time, not a burden to be managed but a competitive advantage to be leveraged.

And for the patients at the heart of this initiative, those who have historically been excluded from the trials that determine how their conditions are treated, the stakes could not be higher. ▲

This article is based on research and industry experience supporting clinical trial sponsors on diversity strategy.
Suzanne Caruso is General Manager & Executive Vice President, Clinical & Strategic Intelligence at Norstella
Daniel Chancellor is VP of Thought Leadership at Norstella
Claire Riches is VP of Clinical Solutions at Citeline
Fenwick Eckhardt is Associate Director, Solution Consulting Operations at Citeline

Five alive: The points of difference

Accurate efficacy and safety data: different demographic groups metabolise medicines differently due to genetic variation, enzyme levels and metabolic rates, so diverse trials ensure a drug's safety and effectiveness are understood across the full population who will use it

Identification of group-specific side effects: some adverse reactions occur more often or more severely in certain genetic or ethnic groups, and broad representation helps researchers detect these risks early

Optimal dosage calibration: a one-size-fits-all dose can cause under-dosing or toxicity in some sub-populations, so diverse participation allows more precise dosing based on factors such as body composition, age and biological sex

Better understanding of disease variations: many conditions present differently or carry different risk burdens across demographics, meaning diverse trials reveal insights that support tailored clinical understanding

Reduction of health disparities: underserved communities often face higher disease burdens but lower research representation, and inclusive trials help ensure medical advances address the needs of these populations.

Happy pills

In conversation with Ivanna Rosendal – why pharma comms needs a sense of humour

Hello pharma comms friends. I've got a truly brilliant conversation lined up for you this month – all the way from Copenhagen, Denmark.

I'm sure we can all agree this sector can take itself just a little too seriously, and the odd laugh certainly wouldn't go amiss.

One person has really taken the mission to inject levity and human connection into pharma to heart: Ivanna Rosendal, a long-time life sciences podcaster and newly trained stand-up comic.

When she's not landing perfect one-liners on stage, Ivanna is Vice President of Business Digitalisation at Ascendis Pharma, a global biopharma company based in Copenhagen.

She describes her day job as helping teams get medicines from early research towards market with less friction: through better ways of working smarter use of tech and, crucially, clearer human-to-human communication.

And humour, she argues, is one of the fastest ways to get to that clarity.

Take that

Ivanna trained as a behavioural economist, drawn to one deceptively simple question: how do you get large groups of people to make good decisions.

She started out in digital marketing for software companies, then moved into consulting at a firm optimising clinical trials. That took her to Switzerland for five years, fixing everything from cross-department collaboration to process and technology roll outs.

What she learned was that what slows down drug development often isn't the science or the regulations – it's behaviour.

"I kept seeing different manifestations of what was essentially people problems," she says. "And it inspired me to keep attempting to bring the human back to the centre of my communications, as a tool to unlock transformation."

That insight pushed her to pursue a new skill set.

"Besides my day job, for many years I've been an improv comedian," she tells me. "And quite recently I've taken up stand-up comedy."

Partly because it's liberating and creative, but also because she thinks play is serious business in an industry that can feel allergic to it.

"When we're communicating about pharma, we tend to make it so dry and so serious that it loses personal significance," Rosendal says.

Her antidote is to look for the game in the conversation: metaphor, a relatable truism, the everyday hook that makes a complex topic stick.

She's been testing that approach on a life sciences podcast she's run for four years, recently revamped to be more playful.

The result: the audience has widened from people deeply invested in the niche to listeners who simply want to understand how the system works.

Analyse this

One recent episode tackled innovation: big pharma behaving less like a single product machine and more like a venture capitalist, building a portfolio by acquiring and funding smaller biotechs.

Rather than disappearing into deal jargon, they explored it through a restaurant metaphor – because everyone understands menus, risk and why you don't want to bet the whole business on one dish.

And then there's the stand up.

This year her schedule is full of industry events where she'll do "no presentations – just jokes". The first set is (at the time we speak) two weeks away, and she's already on draft five.

"The test audience laughed in all the right places," she assures me, with relief.

Her logic is practical. If you can laugh at the problems you're facing at work, she argues, they seem smaller – and therefore more solvable.

She's already seen it translate back into the day job. Having written pharma specific material about "the industry's dysfunctions", she now finds herself meeting those same dysfunctions at work and, as she puts it, "serving the joke".

People laugh, the tension drops, and suddenly you've got a shared summary of the problem – and permission to try something different.

There's a familiar objection here: isn't humour risky in a field that deals with life and death issues.

Rosendal's view is that a good joke is proof you've understood the system well enough to distil it.

"To write a good joke about pharma, you really do need to understand what you're talking about – and you need to make your audience understand and relate to it too," she says. The laugh isn't the point; the clarity is.

So, what's her advice for comms professionals who want to bring more lightness into serious work.

Start with analogy.

"Whatever problem you're trying to describe, what's an analogy that an everyday person could understand," she suggests. Shopping, the bus, a bad restaurant booking system – anything that makes the behaviour of a molecule, a process or an organisation feel recognisably human.

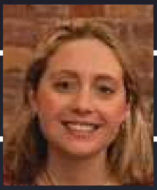
That kind of playful reframing, she says, is often what unlocks a line that's both accurate and genuinely engaging.

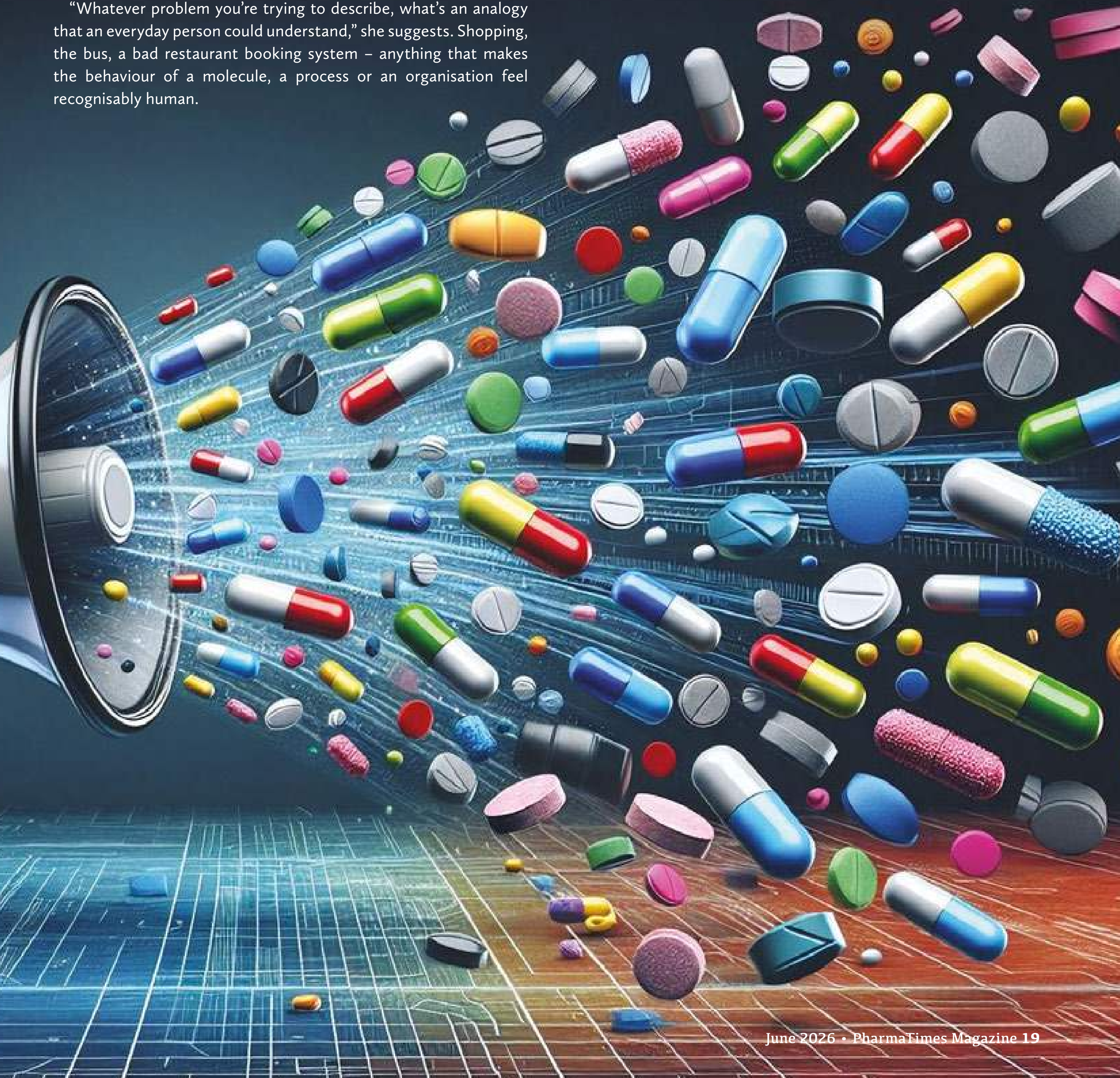
And if you want the shortcut.

"Take an improv or stand-up class,' she says. 'I can absolutely recommend it."

In an industry that can take itself very seriously, a little well-placed laughter might be less of a distraction – and more of a route back to the human point of it all. ▲

Jess Farmery is Senior Account Director,
Health at Lexington Communications





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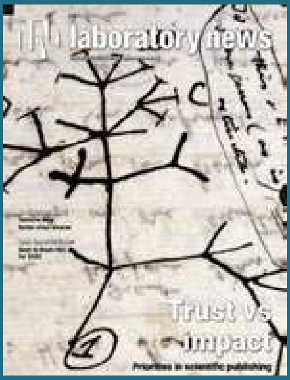
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Trust vs impact
Priorities in scientific publishing

Triumph of the heart

A Night of Excellence – the 2026 PharmaTimes International Clinical Researcher of the Year Awards. Editor John Pinching reports

The prestigious Royal Lancaster Hotel in London once again played host to the crown jewel of the clinical operations calendar – the PharmaTimes International Clinical Researcher of the Year Awards.

Bringing together industry titans, pioneering researchers and dedicated teams from across the globe, the event – in the time-honoured tradition – celebrated excellence, innovation and dedication in clinical research.

Against the backdrop of a rapidly evolving clinical trial landscape, this year's ceremony felt particularly electric – fizzing with the intoxication of possibility.

Needless to say, this was further lifted by the reassuring tones of the Alan Dedicoat; voice of the balls and peerless pharma linguist. This year he was joined by broadcaster, journalist and author Babita Sharma.

As usual the awards marked the culmination of a rigorous process designed to challenge the brightest minds and teams in the sector.

As the names were revealed the decibel level grew to new, uncharted heights. These celebrations were the joyful choruses of people who operate in serious, life-transforming arenas.

A chance to reflect and revel in a job well done is infrequent in our industry and it was a reminder that beyond the heavy science was humanity and heart. And this was a triumph of the heart (in some cases, quite literally).

Perhaps what makes these awards so unique is the profound learning and development opportunities, and the prospects they create for the future.

Beyond the trophy, every finalist walked away with invaluable qualitative and quantitative feedback from the independent judging panel. This feedback serves as a critical benchmark for personal growth and a powerful catalyst for career progression.

After decades of shaping careers, the International Clinical Researcher of the Year Awards continues to set the standard – recognising the people behind the products and highlighting the symbiotic link between science and society.

> **‘These celebrations were the joyful choruses of people who operate in serious, life-transforming arenas’**

For the complete results search ‘2026 pharmatimes clinical awards’

ROLL OF HONOUR – FOLLOWING THE DINNERS, IT WAS TIME FOR THE WINNERS

Aspiring and Junior Clinical Research Associate
Gold: Josephine Kisato – PPD
Silver: Carlota Cabeza – Parexel
Bronze: Mikołaj Rojek – PPD

Clinical Research Associate
Gold: Lydia Johnston – Syneos Health
Silver: Tryphosa Mitoko – PPD
Bronze: Jessica Cilliers – PPD

Clinical Trial Administrator
Gold: Leah Williams – Panthera BioPartners
Silver: Ian Lee – Fortrea
Bronze: Svjetlana Novkovic – Worldwide Clinical Trials

Clinical Project Manager
Gold: Luke Johnson – Syneos Health
Silver: Kirstyn Warren – Evestia Clinical
Bronze: Lara Faraj – Parexel

Start Up Individual
Gold: Livia Nicoleta Capatina – Fortrea
Silver: Myriam Grim – Worldwide Clinical Trials
Bronze: Marta Rzadkosz – Worldwide Clinical Trials
Christoph Werner – PPD

Team Leader
Gold: Kereen McDairmant – IQVIA
Silver: Zoe Kingston Griffiths – IQVIA
Bronze: Gavin Phan – Precision for Medicine

Innovation in Clinical Trial Design and Conduct
Gold: Holly Shaw – Evinova
Silver: Maja Omiecińska – AstraZeneca
Bronze: Valentina Rashkova – Freelancer

Clinical Research Team
Gold: PPD
Christina El Khawand
Amalia Leonard
Pavlos Papadopoulos
Joséphine Parisot
Sandra Sembo Backonly
Silver: Caidya
Gaelle Bernier
Liliana Golanska
Kevin Hughes
Katarzyna Kalisiak
Charline Moreau
Bronze: PPD
Ruth Deschepper
Renata Prieschl Teixeira
Sandi Somo
Siobhan Waiting

Start Up Team
Gold: Premier Research
Andrea Canazzo
Cristina Fernandez
Virginie Morbitzer
Silver: Fortrea
Clare Campbell Cooper
Elisa Di Nunzio
Anne Hage Hulsmann
Hristina Petrova
Vladimir Stranski
Bronze: Worldwide Clinical Trials
Minh Le
Simone Lee
Ranga Siriwardhana

Clinical Research Company of the Year
Winner: PPD

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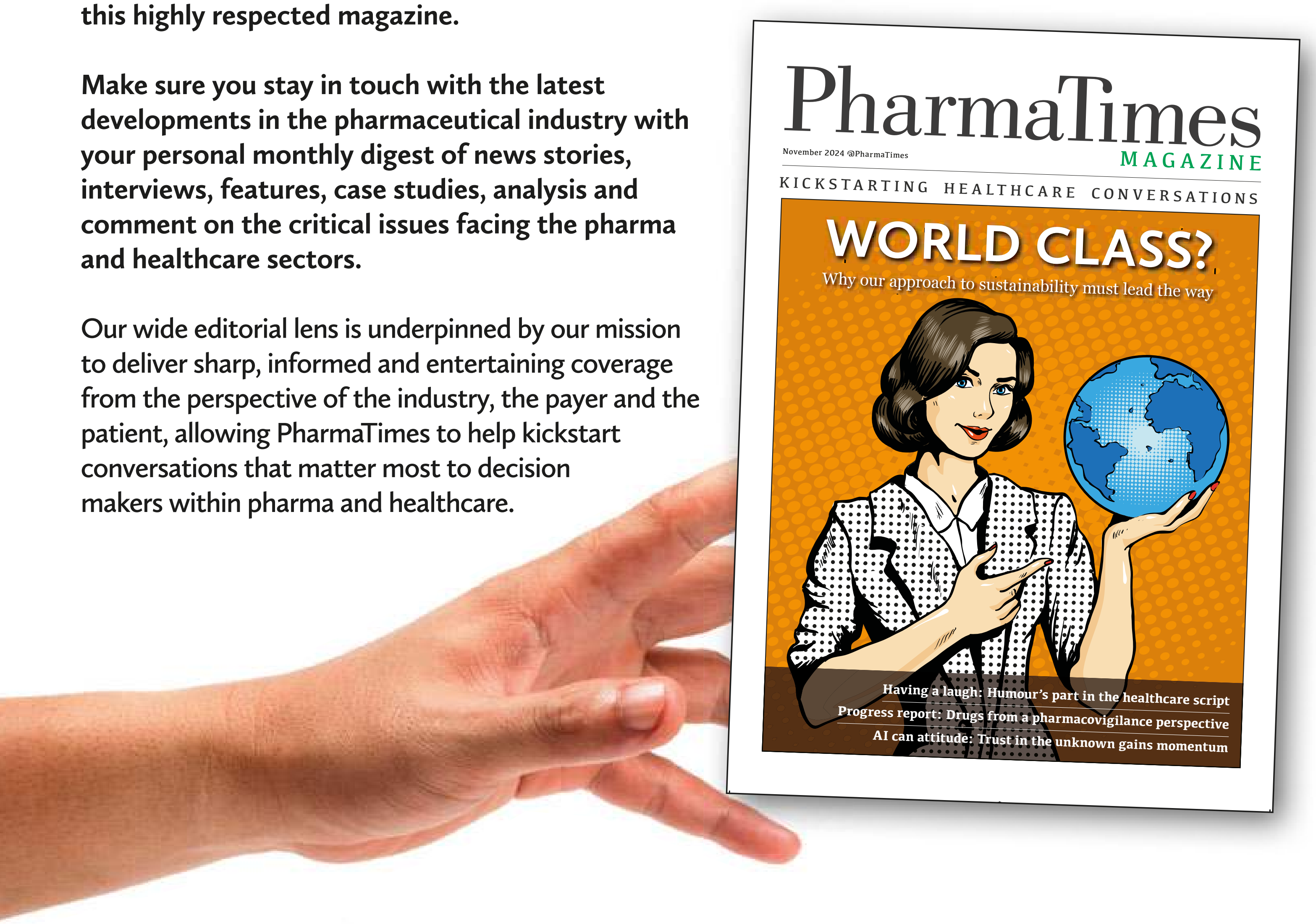

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How we roll

The NHS cannot govern medicines through a single budget line

South East London's published figures show a wider problem for integrated care boards: the medicines line that is easiest to spot is not the same as the full cross-setting medicines economy leaders are being asked to manage.

Medicines are one of the NHS's most powerful strategic levers, but leaders are often not looking at the same number when they talk about medicines spend.

In South East London, the ICB's 2024/25 annual report shows £254.336 million of prescribing costs and £53.281 million of pharmaceutical services, a visible medicines facing line of £307.617 million.

Yet the ICB's April 2026 board paper describes medicines as a budget of about £850 million across the system, with £256 million in primary care prescribing and £594 million in hospital spend, and around £300 million directly commissioned or managed by the ICB.

NHSBSA then offers a third cross-setting, ICB level view again, using a different methodology.

None of those lenses are necessarily wrong. The problem begins when one of them is treated as if it were the whole operating reality.

Different numbers, different purposes

That matters because annual accounts, board papers and national data sets are built for different purposes.

Annual accounts are there to present audited cost lines. Board papers are there to support management judgement and decision-making. National data sets are there to provide attributed visibility and comparison across systems.

All three matter. But leadership weakens when the easiest figure to find becomes the default figure for governance, especially in an area as operationally complex as medicines.

This is no longer a narrow pharmacy issue. South East London's own board paper describes medicines as one of the NHS's largest, most volatile and most influential system levers.

It says that creating headroom for new NICE approved innovation depends on delivering £22–£25 million of medicines efficiencies in 2026/27, underpinned by aligned commissioning, finance and planning.

It also makes the broader strategic point: moving from cost to value improves outcomes and system productivity. That is the language of pathway redesign, operational performance and strategic commissioning, not just of procurement.

Why framing really matters

Once medicines are understood in that way, narrow framing becomes dangerous. A visible line of £307.6 million can make medicines look like a contained budget issue.

A wider system view of around £850 million makes them look like what they really are: a cross-setting challenge touching primary care, hospitals, specialised services, neighbourhood delivery, workforce, safety, prevention and innovation adoption.

The denominator changes what feels material, which opportunities attract senior attention and who is expected to act. That is not semantics. It shapes management behaviour.

This is not an accusation of bad accounting. Nor is it a claim that a national attributed data set is somehow 'truer' than local audited accounts.

NHSBSA is explicit that its Prescribing Costs in Hospitals and the Community release covers medicines, appliances, dressings and medical devices, combines different cost measures across settings and cannot be used as a final figure for total NHS cost.

That caveat should not weaken the argument; it should sharpen it. The point is precisely that cross-setting medicines governance is currently spread across several legitimate but partial official views. Leaders still have to reconcile them.

> ‘A wider system view makes medicines look like a cross-setting challenge touching every part of care’

Strategic pressure increases

The timing makes this more than a technical irritation. NHS England’s draft Model ICB Blueprint said integrated care boards were expected to move towards strategic commissioning and cut operating costs by roughly 50% to an £18.76 per head envelope.

NHS England’s later 2025/26 pay awards guidance raised that envelope to £19.00 per head but kept the same direction of travel. Separate NHS England guidance also set out mergers and boundary changes taking effect from 1 April 2026.

In other words, systems are being asked to think more strategically with less management slack. In that environment, fragmented visibility is not a reporting curiosity. It becomes an execution risk.

South East London is a useful case study precisely because this is not a story about an obviously weak system.

NHS England’s 2024/25 annual assessment said the ICB had demonstrated a robust approach to governance and management, with effective structures and positive partner feedback.

At the same time, South East London’s digital strategy openly states that there is no ICS-wide single digital solution to support multi-organisational care teams.

That combination matters. It suggests the issue is structural, not personal. Even relatively mature systems can still end up managing medicines through multiple official views and disconnected operational environments.

South East London’s own medicines paper is also instructive about what good looks like. It points to strategic commissioning pharmacy leadership, population health management using prescribing and outcomes data, stronger contractual levers and financial accountability for medicines value and safety, and greater investment in data and analytics.

That is the right ambition. But it also exposes the scale of the challenge.

To get there, systems need more than descriptive reporting. They need one shared cross-setting operating frame for medicines, one that makes it clear which figure is being used for which decision and why.

What needs to change

So, what should follow? Not another round of abstract rhetoric about optimisation.

What integrated care boards need is a disciplined cross-setting medicines view brought routinely into executive and board discussion, with each number clearly labelled for what it is: an audited ICB cost line, a wider local management view or a national attributed view with methodological limits.

They also need medicines priorities judged consistently against patient benefit, unwarranted variation, affordability and practical deliverability, with joint ownership across pharmacy, finance and commissioning.

That is not glamorous. But it is what serious governance now requires.

The deeper lesson is simple. Public reporting and operational management are not the same thing.

Annual accounts matter. Board papers matter. National data sets matter. But no single lens is enough on its own in a cross-setting NHS.

South East London’s published material shows both sides of the truth: serious strategic intent, but also a genuinely difficult denominator problem.

Until the service addresses that more explicitly, it will keep describing medicines as one of its biggest levers while still governing them through several different windows at once. ▲

Varun Cruz is Founder of NEUVIOR

New balancing

Beyond GLP-1 – the next wave of obesity drugs and the rise of retatrutide

The landscape of weight loss management is rapidly shifting beyond the initial dominance of Ozempic and Wegovy, leading to the emergence of next-generation treatments.

Among these new weight loss treatments is retatrutide, developed by Eli Lilly. Retatrutide has been positioned as a potential 'new wave' therapy with initial clinical data suggesting superior weight loss results compared with Wegovy.

The growing popularity of GLP-1 receptor agonists will have a significant impact on the pharmaceutical sector with commercial and IP considerations becoming just as important as clinical efficacy.

Retatrutide and the 'triple G' effect

Retatrutide, a synthetic 39-amino acid peptide, is an investigational weight loss medication, which is currently undergoing phase 3 clinical trials.

Unlike semaglutide (Ozempic/Wegovy), which targets a single receptor (GLP-1), or tirzepatide (Mounjaro/Zepbound), a dual agonist for GLP-1 and GIP receptors, retatrutide goes one step further and acts as a triple agonist targeting GLP-1, GIP and glucagon receptors.

Retatrutide therefore builds on existing incretin-based therapies and signals a shift in obesity drug development by simultaneously targeting multiple hormone receptors.

This 'triple G' effect is thought to lead to a more comprehensive and powerful metabolic response, resulting in higher weight loss, improved metabolic outcomes and increased energy expenditure.

Initial results from retatrutide's first phase 3 trial (TRIUMPH-4) showed an average weight loss of 28.7% at 68 weeks on the highest dose (12 mg).

In comparison, results from Wegovy's high dose (semaglutide 7.2 mg) phase 3b STEP UP trial achieved 20.7% weight loss at 72 weeks.

Patent protection and market exclusivity

The emergence of next-generation drug candidates such as retatrutide demonstrates that there is still an appetite to drive innovation within this increasingly crowded space.

This is not surprising when the global market size for GLP-1 analogues in 2024 was valued at $54.8 billion and is estimated to reach $268.4 billion by 2030.

With such high stakes at play, and with more companies hoping to capitalise on the success of recent obesity drugs, a key strategy for market leaders such as Novo Nordisk and Eli Lilly to retain dominance and competitive advantage will, in part, rely on having a strong IP and patent portfolio surrounding these therapies.

Although patent protection for semaglutide in the US, UK and many parts of Europe is likely to last until 2031 and beyond, this is not the case for all jurisdictions.

Core patents for semaglutide have already expired or lapsed in countries such as India, Canada, China, Brazil, South Africa and Turkey.

This means that in the coming years we are likely to see a surge of generic competition for earlier generation weight loss drugs such as Wegovy. Therefore, having a robust IP strategy in place to protect the pipeline of potential drugs will be crucial for any company.

For retatrutide, Eli Lilly's core patents covering the compound appear to have been filed in 2018. Any granted patents directed to retatrutide will likely provide Eli Lilly with exclusivity at least until 2038, blocking potential generic entry for this new peptide.

> 'Initial results from retatrutide's first phase 3 trial showed an average weight loss of 28.7% at 68 weeks on the highest dose'

We will also undoubtedly see 'patent thickets' being employed by filing multiple secondary patents directed to methods of manufacture, formulations, patient groups, dosage regimens and related indications to extend market exclusivity beyond the core compound patents.

Such strategic protection of potential new pipelines could see market leaders like Novo Nordisk and Eli Lilly continue to dominate this space for years to come.

The next generation of obesity therapies

There is no doubt that the GLP-1 landscape has significantly evolved in the last few years, from the early days of single hormone agonists like semaglutide to multi-hormone agonists of today such as tirzepatide and retatrutide.

But what advancements are likely to shape the future of obesity drugs?

For existing drugs, we are likely to see developments designed for easier and more convenient administration. Initial forms of Wegovy and retatrutide were formulated as once-weekly injections.

However, we are already seeing the emergence of oral dosage forms such as oral semaglutide and orforglipron (Foundayo), which come as daily oral pills providing alternatives to weekly injections.

We could also see more combination therapies being developed to reduce side effect profiles and achieve more efficient or synergistic results than can be accomplished with monotherapies.

CagriSema is a fixed-dose combination of semaglutide and cagrilintide (a long-acting amylin receptor agonist). A new 68-week trial found that weekly injections with CagriSema resulted in greater weight loss (up to 14.2%) compared with 10.2% for semaglutide (Wegovy).

Another combination therapy comprising semaglutide and bimagrumab, an investigational antibody targeting type II activin receptors, has been reported to provide significant fat loss while preserving lean mass.

Challenges facing the obesity treatment market

Beyond efficacy alone, as the obesity treatment market continues to grow and competition intensifies, there will likely be an increasing focus on accessibility, affordability and long-term patient adherence.

As healthcare systems continue to evaluate the financial impact of obesity-related conditions, there will be increasing pressure on pharmaceutical companies to demonstrate both clinical effectiveness and wider economic and societal benefits.

This may include evidence relating to type 2 diabetes prevention, cardiovascular health and reductions in healthcare costs associated with obesity-related illnesses.

Additionally, regulatory scrutiny surrounding safety, side effect management and appropriate patient use is expected to increase as treatments become more widely adopted. Greater pressure may also fall on manufacturers to address supply chain capacity and ensure reliable global availability as demand for obesity therapies continues to grow.

For more progressive companies, we may see more AI-driven drug R&D being utilised, which could shorten the preclinical phase significantly and lead to more rapid target identification, virtual screening and toxicity predictions.

The integration of AI in R&D, coupled with synthetic biological systems that mimic metabolic processes and the monitoring of digital biomarkers, could also allow weight management to become more effective, accessible and personalised. ▲

Yumi Kato is Senior Associate at Reddie & Grose

Time travel

How agentic AI is shifting data management from time-consuming investigation to confident confirmation

AI is reshaping clinical data management (DM), moving the industry away from time-consuming, inefficient processes and towards continuous, intelligent oversight.

Agentic AI can transform one of the most resource-intensive workflows in clinical data management – manual listing review.

Manual listing review is complex, time-consuming and judgement based. Inefficient processes result in a high investigation burden, review bottlenecks, limited scalability and the introduction of greater risk into clinical data management.

Validated agentic AI offers the opportunity to shift DM work from laborious investigation to confident confirmation, improving data quality while accelerating query cycles and timelines.

> ‘Evidence-backed findings also reduce subjective interpretation and variability, leading to a higher percentage of queries being accepted’

It empowers DM teams to identify true discrepancies; surface supporting evidence and translate findings directly into action.

In this article we explore the limitations of the current manual listing review life cycle, outline the benefits of using agentic AI in manual listing review and discuss the regulatory compliance that must be in place.

Limitations of current review processes

Manual listing review remains one of the largest consumers of skilled DM capacity, with low precision and high wasted effort.

This results in lost capacity, slow query cycles and timeline risk, highlighting the need for solutions that provide measurable impact on DM.

Yet traditional solutions are failing to overcome these challenges.

Instead of focusing on depth, EDC-native approaches – which are not designed for cross-domain expertise – prioritise platform breadth and simple edit checks. This leaves the majority of judgement-based reconciliation untouched.

Similarly, classic machine learning approaches are optimised for breadth, dashboards or retrospective insights rather than giving sponsors full control and validated precision.

Outsourcing shifts the effort of manual listing review but fails to tackle the inefficiency, while also reducing sponsor visibility and control over data quality decisions. This limits real-time data visibility and threatens consistent decision logic.

Possibilities of agentic AI

Success in a pressurised DM environment requires strategic thinking about where AI can be applied most effectively.

Agentic AI combines LLMs, machine learning and natural language processing to pursue complex goals with limited supervision.

It is better suited to the complex, judgement-based data checks required for DM than EDC edit checks, broad analytics platforms, CRO-led processes, internal builds or solutions relying on machine learning alone.

In DM, agentic AI can unlock capacity, improve data quality and enable faster execution without changing workflows, ownership or regulatory posture. This removes AI governance friction and protects sponsor control.

Agentic AI should no longer be viewed as an experimental add-on. Instead, sponsors and regulators should recognise it as an increasingly essential element of infrastructure for demonstrating data integrity and accelerating submission readiness – a collaborator rather than a tool.

Unlocking capacity

In contrast to manual review, which results in around 40% precision, agentic AI can identify true discrepancies with 80% or more precision, eliminating time spent on non-issues.

This allows a higher proportion of DM effort to shift to confirmation and high-value analysis, unlocking measurable capacity without increasing staff headcount.

Auto-generated, editable query text enables faster progression from discrepancy identification to query submission and reduces back-and-forth with sites due to clearer, evidence-backed queries.

This results in shorter overall query cycle time with less rework and a focus on execution speed and quality, not just detection.

Evidence-backed findings also reduce subjective interpretation and variability, leading to a higher percentage of queries being accepted on the first pass and fewer rejections, clarifications or rework cycles.

By applying standardised decision logic consistently across studies and teams, agentic AI improves consistency in how judgement-based issues are raised.

Reduced critical-path risk

Late-stage listing backlogs threaten database lock and lead to last-minute cleaning marathons.

By focusing on the 60–70% of manual effort that is cross-domain and high variance, agentic AI offers a depth-first approach that concentrates effort where delays are most likely to occur.

This results in fewer listing review bottlenecks, earlier identification of high-risk discrepancies that could delay database lock and increased predictability in late-stage data cleaning.

Audit-ready execution

AI adoption fails without regulatory clarity. Any system must be transparent, auditable, defendable and 21 CFR Part 11 compliant.

There must be full traceability from signal to evidence to action to outcome, with documented reasoning for all AI-assisted outputs.

Restricting agentic AI models to read-only access can also ensure no data modification or imputation risk is introduced.

Developing these solutions internally requires multi-year R&D investment and ongoing maintenance, with a high risk of never reaching production-grade precision.

Instead, sponsors should look for immediately usable, validated capability backed by a proven scenario library developed and tested in real studies.

Final analysis

Intelligent query detection that combines agentic AI with precision monitoring and adaptive scenarios reduces wasted effort while maintaining sponsor control and regulatory clarity.

It eliminates manual investigation at scale by automating the most time-consuming parts of clinical data review, improves data quality and accelerates query cycles with reliable, evidence-backed findings that adapt as studies change.

When used correctly, agentic AI delivers automation without risk, combining regulatory-ready auditability with full transparency and control.

Organisations that embrace agentic automation early will see dramatic reductions in manual review burden. ▲

Varun Cruz is Founder of Neuvior

The wild west

When it comes to probiotics science has outpaced the rules

If you walk into any pharmacy today, you will find shelves full of probiotic products making confident promises about gut health, immunity and well-being. It's like the wild west out there!

Yet depending on the country, those products may be regulated as foods, supplements, drugs or something in between, and the strain listed on the label may or may not tell healthcare professionals and consumers what that bacterium will do inside the body.

The probiotic market is booming, at $76.59 billion in 2025 and projected to reach $114.95 billion by 2030, and the science underpinning it has advanced dramatically. However, the regulatory frameworks governing probiotic quality have not kept pace.

The result is a fragmented system that leaves consumers confused, clinicians uncertain and scientifically rigorous companies competing alongside products that may not meet even basic standards of transparency or evidence.

Without a common language

The problem starts with a basic question: what does 'probiotic' legally mean? The FAO and WHO definition, 'live microorganisms that, when administered in adequate amounts, confer a health benefit on the host', has existed since 2001, but global regulation remains inconsistent.

In the United States, probiotics are largely regulated as dietary supplements or food ingredients.

In the European Union, the word 'probiotic' is effectively banned on food labels because only one health claim has met the European Food Safety Authority's evidentiary threshold – the link between live yoghurt cultures and improved lactose digestion, approved in 2010 – leaving the broader probiotic category without regulatory legitimacy on European packaging.

Canada has its own monograph, Japan another framework, while China, India and Southeast Asian markets have developed separate criteria.

This has led to a fragmented marketplace where the same strain can be marketed as a clinically validated health product in one country and a generic food ingredient in another. For companies investing in proper clinical trials, strain characterisation and transparent communication, this patchwork is deeply frustrating.

For consumers, it is confusing. And for healthcare professionals, it creates uncertainty around what evidence they can trust. The Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses is now discussing harmonised international probiotic guidelines, recognising that inconsistent standards enable misuse of the term and the sale of non-compliant products. That conversation is important, but it is overdue.

Not all created equal

Here is where the science gets both exciting and humbling. Two products could carry the same genus and species name on their labels, say Bacillus clausii, and yet behave in completely different ways inside the human gut.

The research is unequivocal on this: probiotic efficacy is both strain-specific and indication-specific.

A strain shown to prevent antibiotic-associated diarrhoea may have no measurable effect on irritable bowel syndrome. Another strain may influence immune markers in healthy adults but offer little value for microbiome recovery after chemotherapy.

A useful way to think about this is the human analogy: we are all Homo sapiens, yet no one would assume that any two people have the same abilities or roles. One person may be an elite athlete, another a software engineer, another a teacher.

All share the same species classification, but their skills, physiology and responses to training or environment differ widely. Probiotic strains work in a similar way: the shared species name tells you very little about what a specific strain is actually capable of doing.

This matters clinically. When healthcare professionals recommend a 'probiotic' without identifying a strain supported by evidence for a specific condition, they are often working with incomplete information. Not because the evidence does not exist, but because current regulations rarely require that evidence to appear clearly on the label.

Dose is another major issue. In many markets, manufacturers are not required to guarantee viable bacterial counts at the end of shelf life.

Independent analyses of commercial products have found discrepancies between label claims and actual viable counts, with some products containing far fewer colony-forming units than advertised or strains that do not fully match their label descriptions.

An analysis from the International Scientific Association for Probiotics and Prebiotics found that 45% of retail dietary supplement products did not provide strain designations, while a similar proportion failed to guarantee potency through end of shelf life.

That is not a minor quality control issue. It is a structural weakness in the market.

Paying the price

Consumers are the most immediate losers. They spend significant amounts on products that may not contain the strains or doses listed on the label. They make decisions based on claims that are often difficult to independently verify.

When probiotics fail to deliver, many consumers conclude that probiotics as a category do not work, rather than recognising that the specific product lacked the evidence to support its claims.

Healthcare professionals face a different challenge. Interest in probiotics is growing rapidly among patients, and the evidence base for certain well-characterised strains is increasingly credible, but because regulation does not consistently link products to supporting evidence, recommending probiotics confidently is harder than it should be.

As a result, clinicians often fall into two extremes: broad generalisations that 'probiotics are good for gut health' or blanket dismissal of the category altogether. Neither approach serves patients well.

Researchers have repeatedly identified this heterogeneity as a major barrier to drawing reliable clinical conclusions. Ultimately, this is not simply a data analysis problem. It is a problem of standards and transparency.

When products with fundamentally different strains, evidence bases and clinical effects are grouped under the same broad ‘probiotic’ label, confusion becomes inevitable.

Three steps forward

The encouraging news is that the scientific tools already exist. The challenge is applying them consistently.

First, strain-level identification should be a minimum requirement. A label stating only the name of the species, like ‘Bacillus clausii’, tells clinicians and consumers very little. A full strain designation, including genus, species and alphanumeric strain code, provides meaningful information and allows evidence to be properly assessed.

Codex discussions already recognise molecular strain typing as a baseline standard. For manufacturers investing seriously in strain characterisation, this is simply a matter of transparency.

Second, health claims should be tied directly to the strain and dose on the label. If a product claims a clinical benefit, that claim should be supported by studies using the same strain at the same dose.

Not a related species, not a similar formulation, but the actual product being sold. This principle already underpins pharmaceutical and medical-device regulation. There is little justification for applying a lower evidentiary standard to probiotic health claims.

Third, the industry and local regulatory authorities should support global harmonisation while also raising standards. International alignment through bodies such as Codex Alimentarius would improve clarity for consumers, clinicians and manufacturers alike, but progress should not depend entirely on regulators.

Industry organisations, alongside responsible manufacturers, can adopt stronger standards now: clear strain identification; verified dose stability; transparent evidence and claims linked directly to published trials. Companies investing in rigorous science should not be competing on equal footing with products that do not meet even basic scientific standards.

Stakes are higher

Probiotics sit at the centre of one of the most promising areas of modern health research. Advances in microbiome science are opening new possibilities across immunity, metabolic health, gastrointestinal disease and even neurological conditions.

Still, that potential will only translate into meaningful public health benefit if products are trustworthy. It is not about calling for all probiotics to be regulated like pharmaceuticals, but about establishing a common scientific language, meaningful labelling standards and evidence requirements that reflect the sophistication of the science itself.

The microbiome does not recognise regulatory borders. It is time for our standards to stop acting as though it does. ▲

Denis Guyonnet is a scientist at Opella

Twin ambitions

A new vision and the digitalisation of clinical trial design

A single poorly designed clinical trial can cost pharmaceutical companies hundreds of millions of pounds, years of development time or, in some cases, prevent a new treatment from ever reaching patients.

'Virtual twins' aim to prevent avoidable trial failures by allowing sponsors to test, refine and optimise trial designs before they begin. This reduces risk, accelerates timelines and supports innovation across the pharmaceutical ecosystem.

The concept of a virtual twin is rooted in product life cycle management, historically used to design complex products such as aircraft.

Previously, development required building physical prototypes for testing, with limited ability to pressure test designs early. In aviation, for example, testing a newly designed plane required building it first – an expensive and time-consuming process.

Virtual twins transformed this by creating sufficiently rich in silico models, enabling testing and visualisation before production.

Similarly, a virtual twin in clinical research is a digital model of an entire trial. It allows earlier testing of design choices, such as patient numbers or visit schedules, rather than discovering preventable causes of delay, cost or failure once the trial is underway.

How virtual twins work

The power of virtual twins rests on sophisticated data architecture with two essential components.

First, the underlying data structure contains all the information needed to run a clinical trial. What patients need to be enrolled? What materials are required? What skills are needed? How will data be collected and processed?

Many parameters are coupled. If an endpoint is adjusted, it affects activities, data collection, cost, operational complexity and participant burden. A virtual twin shows how changing one parameter affects the whole trial.

Second, these models are underpinned by historical data from hundreds of thousands of trials across many therapeutic areas.

In a lung cancer trial, for example, the system recognises that endpoints relate to tumour growth, implying specific imaging requirements.

Sponsors know the cost and burden of CT scans and can use this to understand trial expense or how design choices may affect enrolment and retention. Historical data helps designers build real-world expectations and configure processes more quickly.

On a practical level, the benefits of virtualisation in clinical trials are threefold.

First, trial designers can pressure test every design decision. This helps identify and mitigate challenges that could harm participants or risk trial success before they materialise.

Second, virtual twins democratise trial design. Traditionally, only the designer had a holistic view. Virtualisation allows more stakeholders – patient groups, clinical teams and others – to input on feasibility, objectives and regulatory acceptability. This strengthens design and helps identify challenges earlier.

Third, virtual twins streamline document management and change control. Traditional methods require manual drafting and updating of every component. Virtual twins automate this, reducing administrative burden and lowering the risk of human error.

> **'Virtual twins allow trial designers to pressure test every decision before it reaches patients'**

Given that a single failed trial can terminate a drug's development, the overarching benefit is the ability to design more efficient trials that are more likely to succeed.

There are examples in pancreatic, lung and lymphoma trials where bold design choices, enabled by virtual twins, have shortened timelines and delivered measurable efficiency gains.

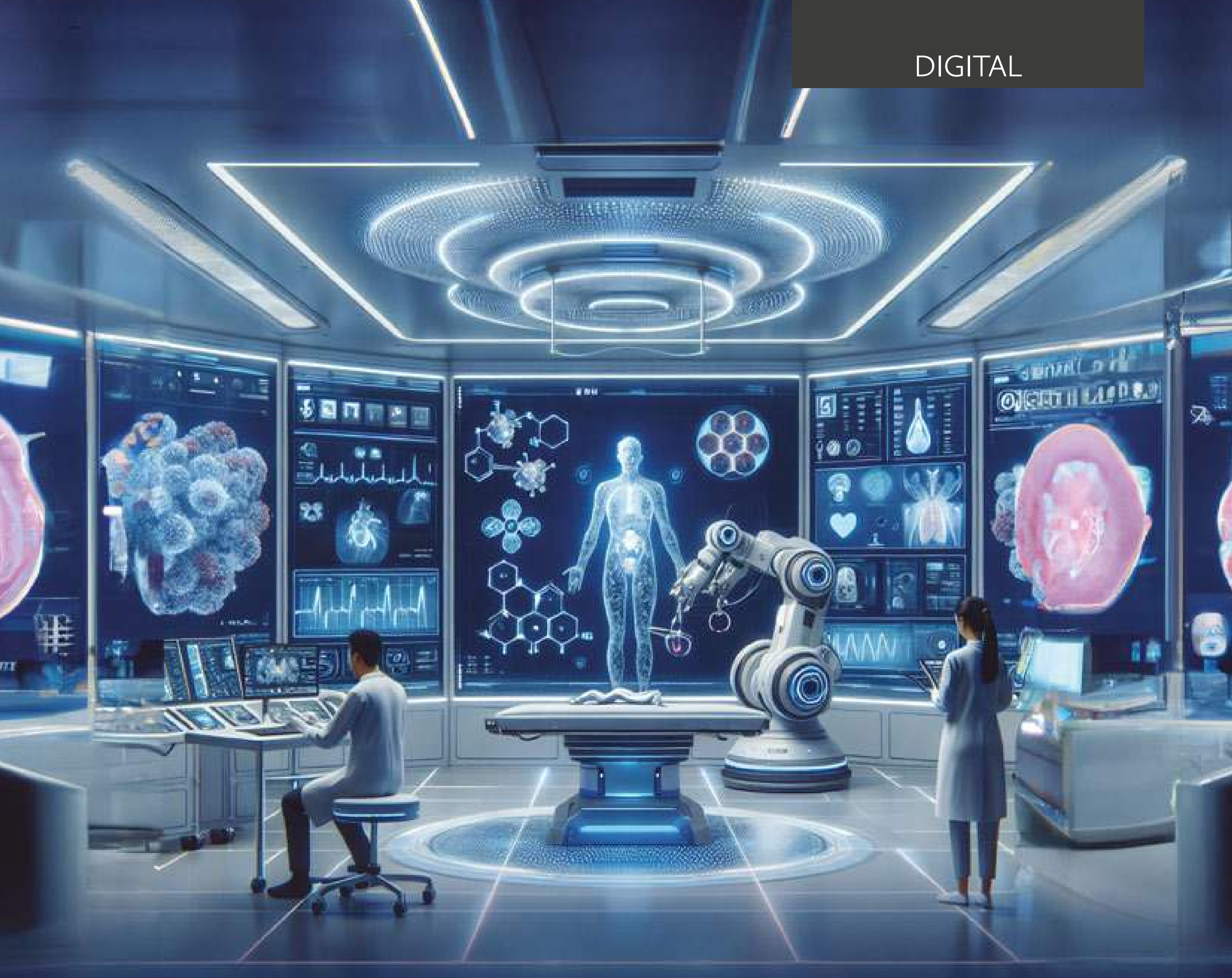
Centring the patient experience

While the above advantages benefit patients indirectly, perhaps the most profound impact lies in optimising the patient experience.

Because systems contain historical data and linkages, virtual twins help sponsors design trials that are easier to enrol in, more likely to achieve compliance and less prone to drop-outs. This includes considering visit frequency, procedures, discomfort, inconvenience and protocol adherence challenges.

This can generate actionable recommendations, such as consolidating clinic visits or incorporating wearables to collect data at home.

There is a growing desire to embed patient perspectives throughout trial design. Virtual twins allow designers to incorporate patient advocate recommendations directly, translating insights into concrete design modifications.



Looking ahead five to ten years, the capabilities and value of virtual twins will expand. Drug development is inherently complex, with countless potential failure points.

AI-powered virtual twins can identify where a drug is likely to fail before it happens. Future systems may run millions of simulations at once, identifying the pathway with the highest chance of success. In this scenario, virtual twins will further strengthen and accelerate drug development.

The emergence of virtual twins fundamentally shifts how clinical trials are conceived, designed and executed. By enabling comprehensive pre-production testing, democratising design collaboration, automating documentation and optimising patient experience, virtual twins address challenges that have constrained clinical research for decades.

The adoption of digital innovation during clinical research has the potential to unlock further innovation across the drug development life cycle, bringing life-saving treatments to patients sooner. ▲

Josh Hartman is Senior Vice President for Platform AI at Medidata

I believe in clinicals – future of our trials

1. Trials will become fully simulation-led
Virtual modelling and AI-driven scenario testing will allow sponsors to refine protocols, logistics and endpoints before first patient in, reducing preventable failures and shortening timelines

2. Patient experience will shape design from the outset
Future trials will be built around real-world burden modelling, behavioural data and patient-generated insights, making protocols more feasible, less intrusive and more representative

3. Hybrid and decentralised models will become the norm
Digital tools, remote monitoring and home-based data collection will allow trials to blend site visits with virtual participation, improving enrolment and retention while reducing operational friction

4. Documentation and governance will be increasingly automated
AI-supported systems will generate, update and reconcile protocols, schedules and operational documents in real time, reducing administrative load and improving regulatory readiness

5. Trial design will become a continuous, adaptive process
Instead of static protocols, future trials will use real-time data to adjust recruitment strategies, visit schedules or operational assumptions, creating more resilient and responsive study designs.

■ Symeres has appointed Dr **Henning Steinhagen** as its new Chief Executive Officer as the company prepares for its next phase of strategic growth.

He succeeds Guillaume Jetten, who has led the organisation through a period of expansion and transformation, strengthening its operational and scientific foundations.

The leadership change follows a planned transition designed to support Symeres' evolution into a fully integrated transatlantic partner.

The company now brings together more than 500 scientists across nine global sites, with multidisciplinary expertise spanning chemistry, biology, ADME-tox and CMC. Henning's scientific background and commercial experience are expected to support further growth as the organisation scales its services and market presence.

In his new role, Henning will focus on advancing the company's vision of being a partner from discovery through development, centred on its integrated 'One Symeres' platform.

This approach underpins strategic partnerships across biotech and pharma and aligns with the company's reputation for scientific depth.

Henning said: "I was drawn to Symeres because of its unique capabilities and legacy in delivering and supporting biopharma from inception to IND." He added: "The team brings together deep scientific depth and a way of working that is genuinely collaborative and responsive."

■ Opella has strengthened its global commercial organisation with the appointment of **Victoria Tiffin** as Chief Sales Officer, a newly created role that will see her lead the global sales function and join the company's executive committee.

Her remit includes scaling commercial execution, deepening customer partnerships and unlocking growth across international markets.

Victoria brings more than 25 years of international experience in the fast-moving consumer goods sector. She joins from Procter & Gamble, where she led the $6.5bn global grooming division, driving business turnarounds, expanding premium portfolios and accelerating direct-to-consumer capabilities. Her leadership track record spans commercial discipline, transformation at scale and the development of high-performing sales organisations.

At Opella, Victoria will work closely with local commercial teams, brands, e-commerce and marketing to identify opportunities to drive growth and bring the company's brands closer to consumers worldwide.

Victoria said: "I am excited to join Opella at such a pivotal moment. Winning in today's environment starts with truly understanding consumers and acting with speed and precision. Together with our teams and partners, we will raise the bar on execution and make our brands more accessible, relevant, and impactful in every market."

Mover of the Month

■ AbbVie has appointed **Kelly Sanderson Schrems** as its new UK vice president and general manager, taking responsibility for the company's strategy, commercial performance and partnerships across the region.

The appointment marks a significant leadership transition for the organisation as it continues to expand its presence in immunology, oncology, neuroscience and other therapeutic areas.

According to the company, Kelly brings extensive experience in global and regional leadership roles, having worked across multiple markets and functions during her career. She will oversee AbbVie's UK operations, including its commercial teams, strategic planning and engagement with NHS partners, industry bodies and patient organisations.

Kelly said: "I am honoured to take on this role and to work alongside such a talented team." She added: "AbbVie has a strong legacy of innovation and partnership in the UK, and I look forward to building on that foundation to help improve outcomes for patients."

She explained that the company remains committed to collaborating with healthcare partners to address unmet needs and support sustainable access to medicines. "Together with our partners, we can help ensure that patients receive the treatments they need at the right time," she said.

■ Ardena has expanded its executive team with the appointments of **Ben Ash** as chief financial officer and **Henny Zijlstra** as chief commercial officer, strengthening its leadership as the company continues to scale its global operations and commercial reach.

Ben joins Ardena with more than 20 years of finance leadership experience across publicly listed and privately held pharmaceutical companies in the UK and US. He most recently served as chief financial officer at Essential Pharma, and previously held senior finance roles at PTC Therapeutics and Shire.

At Ardena, Ben will lead financial strategy to support scalable growth and disciplined international expansion, working closely with the chief information officer to advance the company's digitisation road map.

Henny Zijlstra brings extensive commercial leadership experience within the pharmaceutical and CDMO sectors, having held senior roles at Lonza and most recently Adragos.

At Ardena, Henny will lead the commercial organisation across business development and marketing, with a focus on elevating brand presence, accelerating go-to-market strategy, broadening customer engagement and increasing visibility of Ardena's capabilities in complex molecules, nanotechnology, drug conjugates and bioanalysis.


Ben Ash


Henny Zijlstra

Ben said: "Ardena has a very strong operational foundation and a uniquely differentiated scientific offering. I am very excited to join the company, and I look forward to supporting its next phase of international growth, and enabling rapid, scalable expansion."

Henny added: "Ardena is at an exciting stage in its growth journey, with a strong reputation among biotech innovators, deep scientific expertise and a growing international platform, including its recent expansion in the US. That creates a unique opportunity to build stronger brand recognition and commercial leadership in the drug development space."

■ AstronauTx has expanded its senior team with the appointment of **Michelle Mellion** as chief medical officer, bringing more than 20 years of neurology, clinical development and translational expertise as the company prepares to move its lead programmes into clinical development.

The company has also appointed **Deb Gouveia** as Vice President, Clinical Operations and Development Strategy to further strengthen its clinical capabilities.

Michelle is an experienced neurologist and clinical development leader with a track record of advancing therapies for neurological and rare diseases, including neuromuscular conditions.

She previously served as chief medical officer at PepGen and EveryONE Medicines, where she led clinical development for oligonucleotide therapeutics and individualised medicines for ultra-rare disorders.

Earlier roles at Biogen, Vertex Pharmaceuticals and Fulcrum Therapeutics saw her contribute to programmes in remyelination, pain and facioscapulohumeral muscular dystrophy.

In her new role, Michelle will lead clinical strategy and development activities, working closely with the executive team to progress AstronauTx's pipeline.

Meanwhile, Deb brings more than 25 years of experience building and leading clinical operations, regulatory, quality and development functions across emerging biotechnology companies.

Jane Rhodes, Chief Executive Officer at AstronauTx, said: "Michelle's appointment marks an important milestone for AstronauTx. Her track record in advancing therapies for neurological and rare diseases aligns strongly with our ambition to develop transformative treatments targeting sleep architecture.

"As we build out our clinical capabilities and progress our pipeline, the appointments of Michelle and Deb strengthen the expertise driving our transition into clinical stage development."

Michelle added: "AstronauTx represents a rare opportunity to help define an entirely new therapeutic category at the intersection of sleep biology and neurodegenerative disease.


Michelle Mellion

"The Company's innovative approach to leveraging slow-wave sleep modulation as a potential disease-modifying strategy is both scientifically compelling and strategically differentiated, and I am excited to work with the team to advance these programmes into clinical development."

Results business

The traceability gap in modern clinical development

Confidence in clinical evidence depends on being able to reproduce how a result was generated. Increasingly, that is where modern clinical development begins to struggle.

The industry has spent years modernising for speed and scale. Clinical environments are now more distributed, data sources more diverse and analytical workflows harder to govern.

Decentralised trials, real-world evidence, biomarker integration, cloud infrastructure and multi-language analytical environments have all expanded what development teams can do. They have also made traceability significantly harder to maintain.

The problem often surfaces at the worst possible moment: during inspection preparation or regulatory submission review. Teams are forced to manually reconstruct which data sets, code versions and analytical steps produced a given result.

In some cases, the evidence exists, but the lineage behind it is fragmented across systems, vendors and environments. That operational model is becoming more difficult to defend.

Regulators are placing greater emphasis on traceability, reproducibility and data integrity across the full life cycle of clinical evidence. Recent FDA initiatives around AI credibility in drug development reflect a broader expectation that sponsors must be able to demonstrate not only what a model produced, but how that output was generated, validated and governed.

The same direction is visible in European guidance on computerised systems and electronic data in clinical trials, which places strong emphasis on auditability, metadata integrity and life cycle oversight across distributed environments.

Taken together, the message is becoming difficult to ignore. Confidence in evidence no longer depends solely on generating results. It depends on proving, continuously, how those results were produced.

Complexity

The challenge is no longer just scale. It is structural.

Clinical workflows now span multiple partners, platforms and programming environments. Data may move between sponsors, CROs, cloud systems and specialist analytical tools before reaching a submission package. At each stage, there are opportunities for lineage to become harder to reconstruct.

Historically, many organisations have managed this through retrospective documentation and manual reconciliation. That approach becomes fragile as environments grow more distributed and analytical methods more dynamic.

AI raises the bar further. Probabilistic outputs from large language models and adaptive systems challenge assumptions about reproducibility that regulators have traditionally relied upon.

If an output cannot be consistently reproduced or its provenance clearly explained, confidence in the result quickly weakens.

This does not mean AI has no place in clinical development. Far from it. But it does mean governance foundations can no longer be treated as secondary implementation concerns. Increasingly, traceability is what makes AI outputs operationally and regulatorily credible in the first place.

Traceability

The industry needs to move from retrospective audit reconstruction towards traceability by design.

That means lineage capture becomes part of the workflow itself rather than an exercise conducted later under pressure. Data transformations, code versions, metadata changes and analytical outputs should remain continuously attributable across the life cycle of a study.

In practice, this requires more than adding another oversight layer. It depends on analytical environments designed to maintain traceability natively across increasingly complex workflows.

Importantly, traceability by design is not about slowing development down. In many cases, it reduces operational friction because teams spend less time manually reconciling evidence across fragmented systems.

Modernisation only becomes meaningful when evidence remains explainable under scrutiny.

The industry has largely framed modernisation around speed, scalability and AI readiness. The harder question is whether organisations can continuously prove how their evidence was generated.

In modern clinical development, that may become the defining standard regulators care about most. ▲

Robertson Williams is Health and Life Sciences Product Lead at SAS

The PharmaTimes Communications Awards 2026 are open for entry

The PharmaTimes Communications Awards have returned for 2026, set to once again celebrate the exceptional achievements of communications professionals within the healthcare sector. This prestigious competition serves as a vital platform for recognising exceptional work in healthcare communications. We are delighted to announce that the 2026 competition is now open for entries!

Entry Closes
17th September 2026
Singles Virtual Finals Day
29th September 2026
Team Virtual Finals Day
1st October 2026
Awards Ceremony
12th November 2026

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CLINICAL
RESEARCHER
OF THE YEAR
THE AMERICAS

Open for entry

The PharmaTimes Clinical Researcher of the Year – The Americas 2026 is Open for Entry

The awards have returned for 2026, continuing to identify and celebrate exceptional talent among clinical researchers throughout the Americas. This competition has become a cornerstone for learning and development over the past 16 years, engaging clinical researchers from pharmaceutical companies, CROs, and investigator sites across the Americas.

How the competition works:

- **Stage 1:** Multiple Choice Questionnaire (MCQ) – February 2026 – July 31st 2026. Individual entrants complete an open-book, untimed online MCQ. For team entries, team leads complete an online entry form, but team members don't need to complete the MCQ.

- **Stage 2:** Clinical Challenge (Written Essay Submission) – February 2026 – July 31st 2026. Candidates who score over 70% in stage 1 write an essay based on category-specific competencies, with a 1,000-word limit (1,500 for teams). Teams submit one essay per team.

- **Stage 3:** The Finals Day- October 19th 2026. The highest scorers from Stage 2 compete in person, completing challenges and presenting to judging panels. Feedback is given to help improve performance.

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