Essjay Solutions Ltd Newsletter

May
2026

Sagittal Pharma
CONSULTING
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essjay
SOLUTIONS LTD

Minutes New signals detected from EU spontaneous reporting systems

EU referral procedures for safety reasons – Urgent EU procedures

Newly triggered procedures

None

Ongoing procedures

None

Procedures for finalization

None

EU referral procedures for safety reasons - other EU referral procedures

Newly triggered procedures

None

Ongoing procedures

None

Procedures for finalization

None

Re-examination procedures

None

Others

None

New signals detected from EU spontaneous reporting systems

Alprazolam (NAP); **amitriptyline hydrochloride / medazepam** (NAP); **amitriptyline / chlordiazepoxide** (NAP); **bromazepam** (NAP); **bromazepam / propantheline bromide** (NAP); **brotizolam** (NAP); **chlordiazepoxide** (NAP); **chlordiazepoxide / clidinium bromide** (NAP); **cinolazepam** (NAP); **clidinium bromide / diazepam** (NAP); **clobazam** (NAP); **cyclobarbital calcium / diazepam** (NAP); **clonazepam** (NAP); **clorazepate** (NAP); **clotiazepam** (NAP); **cloxazolam** (NAP); **delorazepam** (NAP); **diazepam** (NAP); **diazepam / gamma-amino-beta-hydroxybutyric acid** (NAP); **diazepam / isopropamide iodide** (NAP); **diazepam / octatropine methylbromide** (NAP); **diazepam / otilonium bromide** (NAP); **diazepam / sulpiride** (NAP); **diazepam / sulpiride / pyridoxine hydrochloride** (NAP); **estazolam** (NAP); **ethyl loflazepate** (NAP); **etizolam** (NAP); **flunitrazepam** (NAP); **flurazepam** (NAP); **ketazolam** (NAP); **loprazolam** (NAP); **lorazepam** (NAP); **lormetazepam** (NAP); **medazepam** (NAP); **mexazolam** (NAP); **midazolam** – BUCCOLAM (CAP), NAP; **nitrazepam** (NAP); **nordazepam** (NAP); **oxazepam** (NAP); **pinazepam** (NAP); **prazepam** (NAP); **remimazolam** – BYFAVO (CAP), NAP; **temazepam** (NAP); **tofisopam** (NAP); **triazolam** (NAP); **trimebutine maleate / medazepam** (NAP)
Scope: Signal on miscarriage associated with in utero exposure to benzodiazepines (including fixed-dose combinations)

Amoxicillin (NAP); **amoxicillin/clavulanic acid** (NAP)
Scope: Signal of encephalopathy

Dapagliflozin – EDISTRIDE (CAP); DAPAGLIFLOZIN VIATRIS (CAP); FORXIGA (CAP), NAP; **dapagliflozin / metformin** – EBYMECT (CAP), XIGDUO (CAP), NAP; **dapagliflozin / saxagliptin** – QTERN (CAP); **dapagliflozin/sitagliptin** (NAP)
Scope: Signal of lichen sclerosus

Exenatide – BYDUREON (CAP), BYETTA (CAP); **insulin icodec / semaglutide** - KYINSU (CAP); **semaglutide** – KAYSHILD (CAP), OZEMPIC (CAP), RYBELSUS (CAP), WEGOVY (CAP), WEGOVY FLEXTOUCH (CAP)
Scope: Signal of of peripheral neuropathies

Ixekizumab – TALTZ (CAP)
Scope: Signal of Behcet's syndrome

Semaglutide – OZEMPIC (CAP), RYBELSUS (CAP), WEGOVY (CAP), WEGOVY FLEX TOUCH (CAP), KAYSHILD (CAP); **insulin icodec / semaglutide** – KYINSU (CAP)
Scope: Signal of gastrointestinal volvulus

Tocilizumab – AVTOZMA (CAP); RoACTEMRA (CAP); TOCILIZUMAB STADA (CAP); TUYORY(CAP); TYENNE (CAP)
Scope: Signal of cutaneous vasculitis

Signals follow-up and prioritization

Pancreatin (NAP)
Scope: Signal of infection due to viral transmission

Variation procedure(s) resulting from signal evaluation

None

NICE recommends Genmab's Tivdak for recurrent or metastatic cervical cancer

It is estimated that 3,300 women are diagnosed with cervical cancer in the UK each year

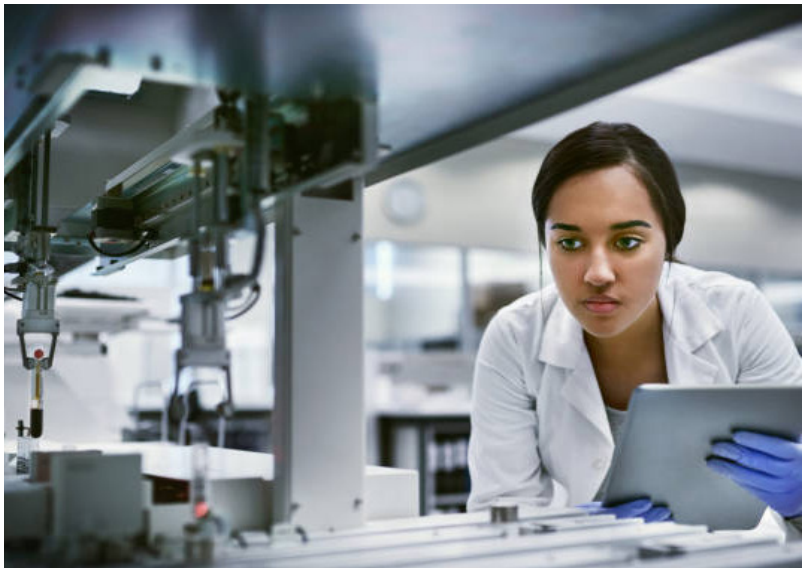
"Cervical cancer affects around 3,300 women in the UK each year, causing approximately 900 deaths"

NICE has recommended Genmab's Tivdak (tisotumab vedotin) for adults with recurrent or metastatic cervical cancer that has progressed on or after systemic therapy.

As the first antibody-drug conjugate (ADC) approved in this setting, it offers an alternative to chemotherapy where treatment options have historically been limited. Eligible patients will have immediate access via the Cancer Drugs Fund, ahead of full routine NHS funding.

Cervical cancer affects around 3,300 women in the UK each year, causing approximately 900 deaths. Up to 30% of patients whose disease initially responds to treatment experience recurrence, and outcomes for metastatic or recurrent disease remain poor.

The recommendation is based on the phase 3 innovaTV 301 trial, which compared tisotumab vedotin against chemotherapy in patients previously treated with a chemotherapy doublet, bevacizumab and, where eligible, an anti-PD-1 or anti-PD-L1 agent.



AstraZeneca's Baxfendy approved by US FDA for adults with uncontrolled hypertension

Hypertension affects more than 1.4 billion people worldwide and many patients remain uncontrolled despite multiple therapies

> *"Hypertension affects 1.4 billion people globally and remains the leading modifiable cardiovascular risk factor worldwide"*

The US FDA has approved AstraZeneca's Baxfendy (baxdrostat) for adults with hypertension whose blood pressure remains inadequately controlled on existing medications.

It is the first-in-class aldosterone synthase inhibitor (ASI), targeting hypertension by directly inhibiting aldosterone, a hormone that raises blood pressure and increases the risk of heart and kidney problems.

Approval was based on the phase 3 BaxHTN trial, in which Baxfendy achieved statistically significant and clinically meaningful reductions in systolic blood pressure at both 1mg and 2mg doses, with a good tolerability profile.

Hypertension affects 1.4 billion people globally and remains the leading modifiable cardiovascular risk factor worldwide. In the US, around 23 million patients remain uncontrolled despite taking two or more antihypertensive medicines, a population that has seen little therapeutic innovation for two decades. A near double-digit placebo-adjusted reduction in systolic blood pressure is considered clinically significant, with epidemiological data suggesting a 10mmHg decrease is associated with approximately 20% lower risk of serious cardiovascular events.

US FDA approves Taiho's Inqovi for older adults with acute myeloid leukaemia

In 2026, an estimated 22,720 people in the US will be diagnosed with AML

"The approval was based on results from the phase 2 ASCERTAIN-V study"

The US FDA has approved Taiho's Inqovi (decitabine and cedazuridine) combined with venetoclax for adults newly diagnosed with acute myeloid leukaemia (AML) who are aged 75 or over, or who cannot tolerate intensive induction chemotherapy.

This is the first all-oral combination treatment approved for this patient group, removing the need for frequent clinic visits required by injectable alternatives. The approval was based on results from the phase 2 ASCERTAIN-V study. Inqovi was previously approved in the US and Canada for myelodysplastic syndromes and chronic myelomonocytic leukaemia.

AML affects an estimated 22,720 Americans in 2026, with more than half expected to be ineligible for intensive chemotherapy due to age or poor health. Taiho says the all-oral regimen has the potential to reduce the treatment burden on patients and caregivers by limiting the need for hospital or infusion centre visits.

FDA gives Rare Paediatric Disease designation to Satellite Bio for urea cycle disorders

The mortality rates of UCDs exceeds 25%, with no curative treatment available for newborns

> *"Satellite Bio is also advancing additional liver-focused therapies for paediatric and adult liver diseases"*

Satellite Bio has received Rare Paediatric Disease (RPD) designation from the US FDA for SB-101, its investigational therapy for urea cycle disorders (UCDs), a group of rare, life-threatening genetic conditions that primarily affect infants and children.

UCDs are associated with high mortality, neurological injury and long-term cognitive impairment, with no curative treatment currently available during the first weeks of life. Current standards of care remain limited, with mortality rates exceeding 25% and around half of patients experiencing cognitive deficits.

SB-101 is a first-in-class, off-the-shelf liver therapy designed to restore essential liver function in infants with severe early-onset UCDs. Satellite Bio plans to begin a Phase 1/2 clinical trial in 2026.

According to the company, the FDA designation recognises the urgent unmet need in UCDs and supports the development of new treatment options for affected children. Satellite Bio is also advancing additional liver-focused therapies for paediatric and adult liver diseases.

GSK announces bepirovirsen's 'functional cure' data to treat chronic hepatitis B

Over 240 million people worldwide live with chronic hepatitis B

"CHB affects over 240 million people worldwide and accounts for more than half of global liver cancer cases"

GSK has reported positive phase 3 data for bepirovirsen, an investigational antisense oligonucleotide (ASO) for chronic hepatitis B (CHB), published simultaneously in the New England Journal of Medicine and presented at EASL.

Pooled data from the B-Well 1 and B-Well 2 trials showed a 19% functional cure rate in the overall study population after six months of treatment, versus zero in the placebo group. In patients with lower baseline surface antigen levels (≤1000 IU/mL representing around 45% of diagnosed CHB cases globally), the functional cure rate rose to 26%. This compares to functional cure rates of less than 1% with the current standard of care, which typically requires lifelong therapy.

Functional cure is defined as undetectable HBV DNA and hepatitis B surface antigen (HBsAg) for at least six months after stopping all treatment, indicating immune control without medication. HBsAg loss is associated with an 89% reduction in liver cancer risk and a 62% reduction in all-cause mortality. An exploratory analysis found that 49% of bepirovirsen recipients had surface antigen levels linked to improved immune control one year after treatment ended. The safety profile was consistent with prior studies, with injection site reactions and a temporary rise in a liver enzyme among the most common adverse events.

CHB affects over 240 million people worldwide and accounts for more than half of global liver cancer cases. Bepirovirsen is under priority review by the FDA with Breakthrough and Fast Track designations and is also under regulatory review in Europe, Japan and China. GSK anticipates first regulatory decisions in Q3 2026.

Cuttsy+Cuttsy launches a practical roadmap to enhance clinical trial participant experience

"The roadmap also covers post-trial communication, an often-overlooked stage that can influence long-term trust and future participation"

Cuttsy+Cuttsy has launched The Experience Gap, a practical roadmap designed to help clinical trial teams improve participant engagement, support and retention across the fu.

Patient communications agency Cuttsy+Cuttsy has launched The Experience Gap, a digital roadmap designed to help clinical trial teams improve how they engage and retain participants throughout the trial journey.

The tool responds to well-documented industry challenges: 85% of trials miss recruitment targets, dropout rates frequently exceed 20%, and gaps in participant diversity persist. The roadmap aims to address these by providing practical, moment-by-moment guidance across the full participant journey from first contact and consent through to study close rather than offering purely theoretical frameworks.

Key areas of focus include building early trust, simplifying consent, personalising engagement and anticipating disengagement before it occurs. The roadmap also covers post-trial communication, an often-overlooked stage that can influence long-term trust and future participation.

Built on behavioural science and informed by Cuttsy+Cuttsy's previous research publications, it is intended as a practical resource for site teams, sponsors and CROs looking to design more consistent, human-centred trial experiences.

AMR Bio launches with phase 3-ready antimicrobial gel targeting surgical infections

Antimicrobial resistance contributes to nearly five million deaths each year

"A phase 2b study in 124 patients undergoing open heart surgery demonstrated a 99.5% reduction in bacterial nasal carriage"

AMR Bio has launched as a clinical-stage biotechnology company focused on antimicrobial resistance (AMR), built around a platform acquired from Destiny Pharma following its administration.

Its lead asset, XF-73 Nasal, is a phase 3-ready topical antimicrobial gel applied to the nose before surgery to rapidly eliminate harmful bacteria the leading source of post-surgical infections, which cost the US healthcare system around $10 billion annually. A phase 2b study in 124 patients undergoing open heart surgery demonstrated a 99.5% reduction in bacterial nasal carriage. The gel is designed to work within a 24-hour window with no resistance risk, potentially reducing reliance on antibiotics. It holds FDA Fast Track and Qualified Infectious Disease Product (QIDP) designations and has received an Innovation Passport from the MHRA in the UK.

A second asset, XF-73 Dermal, targets severe wound and skin infections including diabetic ulcers and trauma-related wounds, in a global dermal market estimated to reach $9 billion annually.

The broader context is stark: AMR contributes to nearly five million deaths per year and, without intervention, could cause an additional ten million annually by 2050. AMR Bio's focus on prevention, stopping infections before they develop, reflects a deliberate strategic shift as existing treatments become less effective.

Regeneron agrees research collaboration with Parabilis Medicines

Regeneron will pay Parabilis $125m upfront, with up to $2.2bn in potential milestone payments and royalties

"The collaboration will explore Helicons both as standalone treatments and paired with Regeneron's antibodies to form AHCs"

Regeneron has entered a strategic research collaboration with Parabilis Medicines to develop therapeutics using Parabilis' Helicon peptide platform, with a particular focus on a novel drug class called antibody-helicon conjugates (AHCs).

Helicons are stabilised, cell-penetrating peptides that can engage intracellular protein targets including flat protein surfaces that small molecules struggle to bind making them potentially useful against historically *"undruggable"* targets. The collaboration will explore Helicons both as standalone treatments and paired with Regeneron's antibodies to form AHCs. Like antibody-drug conjugates, AHCs use antibodies to deliver a payload directly into specific target cells, with the Helicon acting as that payload to modulate intracellular proteins.

Regeneron will pay Parabilis $125 million upfront, with up to $2.2 billion in potential milestone payments and royalties.

GSK signs agreement with Protas to streamline clinical trials

The new three-year agreement builds on an existing two-year relationship

"GSK has signed a new three-year agreement with Protas, extending and expanding an existing two-year partnership"

GSK has signed a new three-year agreement with Protas, extending and expanding an existing two-year partnership.

Protas will provide scientific and operational expertise to improve the quality, speed, efficiency and accessibility of clinical trials, drawing on its experience in trial design and data-driven approaches.

The expanded collaboration will cover phase 2 and 3 trials across GSK's respiratory, immunology, inflammation, vaccines and infectious disease programmes. GSK says the partnership is part of its broader effort to accelerate its late-stage pipeline and bring new medicines to patients more quickly.

Boehringer and Immunitas agree on licensing deal for chronic inflammatory and autoimmune diseases

The agreement strengthens Boehringer Ingelheim's growing immunology pipeline

"The programme aims to provide more durable disease control by targeting disease-driving cells at sites of inflammation"

Boehringer Ingelheim and Immunitas Therapeutics have entered a global licensing agreement for a preclinical antibody programme targeting chronic inflammatory and autoimmune diseases.

Under the agreement, Boehringer Ingelheim gains worldwide rights to develop, manufacture, and commercialise the programme, which is designed to selectively target pathogenic cells driving chronic inflammation. Immunitas Therapeutics will receive an upfront payment and is eligible for up to €407.5m in development, regulatory, and commercial milestones, plus tiered royalties.

The programme aims to provide more durable disease control by targeting disease-driving cells at sites of inflammation, addressing limitations of current therapies that may lose effectiveness over time. The collaboration expands Boehringer Ingelheim's immunology pipeline and supports the development of new treatment options for chronic inflammatory and autoimmune diseases.

Where Making Health Whole began

"The core insight remains consistent: healthcare is only effective when it works in real-life contexts"

Mental health providers revealed years ago what healthcare is only now beginning to recognise: information alone does not sustain engagement.

This article explores how Mednet's heritage in mental health has shaped the foundations of Making Health Whole™.

Mental health services have long recognised that information alone does not sustain engagement. Even when treatment is clearly explained and supported with evidence, engagement can still break down if individuals feel overwhelmed, uncertain, or disconnected from their care.

At Mednet, this understanding has shaped our work for over a decade and underpins our Making Health Whole™ approach.

Our mental health experience dates to 2015, reinforcing the view that outcomes are influenced not only by treatment, but also by emotional state, confidence, and daily routine.

One of our earliest programmes, the Maintaining Adherence Programme (MAP) for people living with schizophrenia, schizoaffective disorder, and bipolar disorder, highlighted that disengagement is rarely due to a lack of information. Instead, it often reflects the lived reality of managing long-term conditions. Disconnection tends to develop gradually through missed appointments, reduced motivation, and withdrawal from support, driven by emotional fatigue and cognitive burden.

This principle has continued to guide our work across different settings, including community mental health initiatives in Ghana in 2018 and programmes delivered with the Gibraltar Health Authority in 2023. The core insight remains consistent: healthcare is only effective when it works in real-life contexts.

This approach is also embedded within Mednet's internal culture. The organisation is a certified Mindful Employer and works in partnership with Mind, supporting employee wellbeing initiatives and helping individuals return to work through programmes such as Workplace Leeds.

Today, as many organisations focus on patient engagement and whole-person care, Mednet's experience in mental health reinforces a central principle: effective healthcare design must reflect the realities of people's lives, not just their clinical condition.

LEO Pharma and Allergy UK launch 'Don't Ignore' chronic hand eczema campaign

The campaign aims to improve awareness and understanding of the condition

> *"CHE is defined as hand eczema lasting more than three months or recurring at least twice a year"*

LEO Pharma and Allergy UK have launched an out-of-home awareness campaign called *"Don't Ignore"* to raise awareness of chronic hand eczema (CHE) and encourage people to seek medical advice earlier.

The campaign is running across bus stops, billboards and petrol pumps in Leeds and parts of South London. It aims to help people with persistent or recurring hand eczema recognise their symptoms and consult a GP sooner.

CHE is defined as hand eczema lasting more than three months or recurring at least twice a year. It affects around 4.7% of people globally and is characterised by itch, pain, redness and irritation on the hands and wrists. Around 70% of those with severe CHE report difficulties with everyday activities.

The campaign's core goal is to prompt earlier diagnosis and more timely conversations with healthcare professionals.

Bristol Myers Squibb announces strategic agreement with Anthropic

The collaboration builds on more than three years of AI investment by the company

> *"BMS describes its approach as a deliberate multi-vendor strategy, drawing on the strongest available capabilities across the industry"*

Bristol Myers Squibb (BMS) has announced a strategic agreement with Anthropic to deploy Claude across its research, clinical development, manufacturing, commercial and corporate functions, giving more than 30,000 employees access to advanced AI capabilities.

The collaboration marks a shift from conversational AI tools toward agentic AI systems that can act autonomously within workflows rather than simply responding to queries. BMS is prioritising three areas: accelerating engineering through Claude Code, embedding AI agents into drug development workflows, and connecting Claude to institutional knowledge held across the company's data systems.

The agreement builds on over three years of AI investment at BMS, which has previously given employees unlimited access to frontier AI models through an internal platform. BMS describes its approach as a deliberate multi-vendor strategy, drawing on the strongest available capabilities across the industry.

The stated aim is to unlock value currently trapped in decades of data silos, enabling tasks such as generating clinical study reports, surfacing relevant internal research and identifying manufacturing issues in real time – ultimately with the goal of getting medicines to patients more quickly.

The real-world challenge pharma can't ignore: Sustained engagement

"For pharmaceutical and biotech organisations, this represents a genuine differentiator"

Breakthrough therapies do not fail because the science stops working. They fail when healthcare is not designed for the physical, emotional and mental realities shaping how people engage with treatment in everyday life.

Effective treatments often fail not because the science is flawed, but because real-life pressures cause patients to disengage before they fully benefit. Delays, missed monitoring and declining motivation are typically framed as adherence problems, but the deeper issue is that healthcare is designed around conditions rather than the people living with them.

Engagement erodes gradually. Uncertainty and information overload affect patients at diagnosis; side effects and complexity create hesitation during treatment; motivation fades when benefits are preventative or slow to feel. Everyday pressures such as work, finances, relationships, caregiving compound this. The commercial consequences are significant: declining persistence, weaker real-world outcomes and reduced health-economic value.

The piece argues that providing more information is insufficient, as it does not change behaviour. Engagement must instead be actively designed for by reducing cognitive overload, simplifying routines, building confidence and addressing emotional barriers early, in ways that reflect how people actually think and act under pressure.

For pharmaceutical and biotech organisations, this represents a genuine differentiator. As clinical claims converge, the experience of managing a condition does not. Brands that support patients through the full reality of their lives not just the treatment pathway stand to achieve stronger persistence, better real-world outcomes and improved relationships with patients, clinicians and payers.

Lilly and UNICEF collaborate to improve non-communicable disease prevention

Six-year initiative to improve NCD prevention and care for children in low- and middle-income countries

"The programme aims to reach over 30 million children and caregivers by integrating NCD care into routine health services"

Eli Lilly and Company and UNICEF USA have announced a six-year collaboration (2026–2032) to improve prevention and care for non-communicable diseases (NCDs) in children and adolescents across 21 low- and middle-income countries.

Eli Lilly is committing $50m to support UNICEF's efforts to strengthen primary healthcare systems, focusing on earlier detection, prevention, and management of conditions such as diabetes, congenital heart disease, sickle cell disease, respiratory illnesses, and childhood overweight and obesity.

The programme aims to reach over 30 million children and caregivers by integrating NCD care into routine health services, expanding community-based care, strengthening health worker training, and improving early diagnosis and long-term management within national health systems.

The initiative builds on UNICEF's existing model of embedding sustainable, system-wide approaches into national health systems, with the goal of reducing long-term health risks and improving equitable access to care in resource-limited settings.

Novartis breaks ground on US radioligand therapy site

The construction is part of the company's investment in US research and manufacturing

"The new plant is expected to be operational in 2028 and will expand the company's coast-to-coast RLT manufacturing network"

Novartis has begun construction of a 46,000 sq. ft radioligand therapy (RLT) manufacturing facility in Denton, Texas, as part of its broader $23bn investment in US manufacturing and R&D.

The site is Novartis's first in Texas and its fifth RLT production facility in the US.

The new plant is expected to be operational in 2028 and will expand the company's coast-to-coast RLT manufacturing network, supporting increased supply of personalised cancer therapies across the southern United States. It will also create new roles in bioengineering, advanced manufacturing, quality, and operations.

RLT manufacturing is highly complex and time-sensitive, with each dose individually produced and coordinated for patient administration. Novartis notes its US network already enables over 99% of doses to be delivered on the planned treatment day.

The Denton facility is part of a wider expansion programme announced in April 2025, under which Novartis is investing $23bn over five years to strengthen its US manufacturing footprint, including multiple new and expanded sites nationwide.

Amiculum joins Bionow: supporting collaboration across the life sciences sector in the North of the UK

"Amiculum is pleased to be part of this network, which supports engagement across regions where the company has an established presence"

We're delighted that Amiculum has become a member of Bionow, joining a collaborative community that plays an important role in bringing together life sciences organizations across the North of the UK.

At a time when early-stage innovation is advancing rapidly and development decisions carry long-term implications, strong regional networks such as Bionow continue to play an important role in enabling collaboration, knowledge sharing, and collective progress across the life sciences sector.

Amiculum is pleased to be part of this network, which supports engagement across regions where the company has an established presence, including Manchester, Bollington, Newcastle, and Dundee.

With a global team of around 300 employees, Amiculum works with life sciences organisations from the earliest stages of drug development, helping to establish clear, strategic foundations that support informed decision-making and enable smoother progression through key development milestones.

The company looks forward to engaging with fellow members at upcoming Bionow events, including *"Demystifying and Navigating Health Economics & Regulatory Compliance"* in Manchester, BioFocus 2026 in Newcastle next month, and the Bionow Neuroscience Conference 2026 in Sheffield this July.

Angelini Pharma to acquire Catalyst Pharmaceuticals for $4.1bn

Catalyst Pharmaceuticals is focused on novel medicines for rare diseases

"The transaction will expand Angelini Pharma's presence in rare diseases and neurological therapies, particularly in the US"

Angelini Pharma has agreed to acquire Catalyst Pharmaceuticals in a $4.1bn (€3.5bn) deal, unanimously approved by both boards and expected to close in Q3 2026, subject to regulatory approvals.

The transaction will expand Angelini Pharma's presence in rare diseases and neurological therapies, particularly in the US, by combining Catalyst's commercial-stage rare disease portfolio with Angelini's Brain Health capabilities. Following completion, the companies plan to integrate operations to build a broader rare disease platform while maintaining Angelini's core European business and its industrial base in Italy as a key production and R&D hub.

Lilly commits additional $4.5bn for US manufacturing sites

The company has also opened its first dedicated genetic medicine facility in Indiana in the US

"The funding will support expanded capabilities at Lilly Lebanon API and Lilly Lebanon Advanced Therapies"

Eli Lilly has announced a further $4.5bn investment in its Indiana manufacturing network, increasing its total capital expansion commitments in the state since 2020 to more than $21bn.

The funding will support expanded capabilities at Lilly Lebanon API and Lilly Lebanon Advanced Therapies, the company's first dedicated genetic medicine manufacturing facility. The investment is intended to support Lilly's growing pipeline and anticipated demand for its medicines, while incorporating new manufacturing technologies and process designs.

Lilly Lebanon Advanced Therapies will provide clinical and commercial production of genetic medicines, supporting a range of modalities from early-stage research through to large-scale manufacturing. The Lebanon campus will ultimately comprise three facilities: Lilly Lebanon Advanced Therapies, Lilly Lebanon API and the Lilly Medicine Foundry.

The expanded investment will also support production of key metabolic medicines, including obesity and diabetes treatments Zepbound (tirzepatide) and Mounjaro (tirzepatide), as well as Foundayo (orforglipron), Lilly's recently approved once-daily weight-loss pill, and retatrutide, an investigational therapy for obesity and cardiometabolic disease.

Lilly said the announcement reflects its continued commitment to strengthening domestic manufacturing, with total US capital expansion investments exceeding $50bn since 2020.

UCB presentation highlights impacts of epilepsy on daily life

The data underlines the consequences of disrupted sleep for patients and caregivers

"Interim survey findings in developmental and epileptic encephalopathies (DEEs) showed that more than a quarter of patients experience daily sleep disturbances"

UCB presented new data at the American Academy of Neurology Annual Meeting 2026 highlighting the wider impact of epilepsy on patients and caregivers.

Interim survey findings in developmental and epileptic encephalopathies (DEEs) showed that more than a quarter of patients experience daily sleep disturbances, which were associated with temporary losses in daily functioning and communication.

Real-world data also demonstrated the significant burden of prolonged seizures, with most patients and caregivers reporting disruption to everyday activities, alongside reduced work productivity and increased anxiety and depression. Patients experiencing prolonged seizures were found to have greater healthcare resource use, including more hospitalisations, emergency visits and ambulance callouts.

Additional analyses in Lennox-Gastaut syndrome (LGS) indicated that continued treatment with fenfluramine was associated with reduced healthcare utilisation and lower antiseizure medication burden. Among patients with 12 months of treatment data, reductions were seen in hospitalisations, emergency room visits and ambulance use, with treatment persistence rates of 73% at six months and 61% at 12 months.

UCB said the findings reinforce the substantial burden of epilepsy beyond seizure control, encompassing daily functioning, mental health and healthcare use. The company presented 21 abstracts at the meeting, with the majority focused on epilepsy and others addressing rare neurological conditions, including myasthenia gravis.

Strategies to enhance the provider and patient EAP experience

"Digital solutions, including patient portals and communication platforms, can help improve engagement, adherence and care coordination"

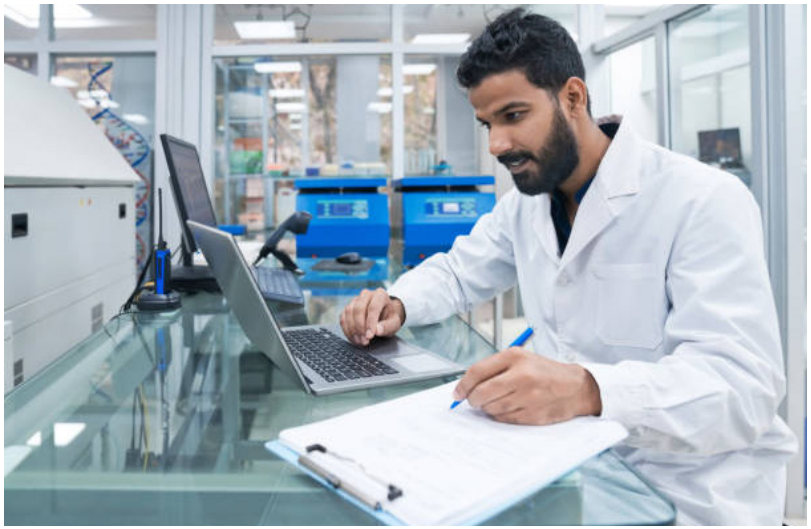
Expanded access programs (EAPs) play a multifaceted role in the drug development life cycle, serving as a critical bridge between clinical trials and commercial availability.

A new white paper from Uniphar highlights strategies for improving the experience of healthcare professionals (HCPs) and patients participating in Expanded Access Programmes (EAPs), which provide access to investigational medicines before commercial availability.

The paper emphasises the importance of raising awareness among HCPs through medical networks, congresses and transparent information resources, while ensuring compliance with regulatory requirements. Clear communication, simplified enrolment processes, dedicated support teams and digital tools are identified as key factors in facilitating patient access.

To enhance the patient experience, the authors stress the need for comprehensive educational materials, treatment continuity planning and ongoing support throughout the treatment journey. Digital solutions, including patient portals and communication platforms, can help improve engagement, adherence and care coordination.

The white paper also highlights the value of a single-provider approach to EAP management, enabling consistent communication, reduced administrative burden and more integrated patient support. According to Uniphar, successful EAPs depend on clear communication, seamless coordination and a patient-centred approach that supports stakeholders from programme initiation through to commercialisation.



Why clinical innovation doesn't translate into real-life outcomes

"According to the article, sustained engagement is a key driver of improved adherence, persistence and health outcomes"

We've made extraordinary progress in healthcare. However, outcomes depend on whether people can make treatment work in their lives.

A new thought leadership article highlights the gap between clinical innovation and real-world health outcomes, arguing that treatment success depends not only on medical advances but also on whether people can integrate care into their daily lives.

The article notes that many patients struggle to start, engage with or persist on treatment due to factors such as uncertainty, emotional fatigue, cognitive burden and lifestyle challenges, rather than a lack of information or motivation. It suggests that providing more information alone is often insufficient and can sometimes increase barriers to engagement.

The authors advocate for a shift from simply informing patients to designing healthcare around the realities of living with a condition. Through its Making Health Whole™ philosophy, the approach seeks to combine clinical expertise, behavioural insights and lived experience to better support patient decision-making, confidence and long-term engagement.

According to the article, sustained engagement is a key driver of improved adherence, persistence and health outcomes, helping patients achieve the full benefits of medical innovation.

The blind spot undermining pharma product launches – and how to eliminate it

Something critical is missing: a clear view of what's happening on the ground

> *"Once live, real-time tracking of local access dynamics allows early intervention rather than reactive course-correction"*

The piece argues that most pharmaceutical launches underperform because teams lack visibility of what is happening at a local level and by the time problems show up in sales data, it is too late to course-correct.

The core problem is that national reimbursement is treated as the finish line, when it is only the starting point. Access is determined locally, and local implementation is uneven and largely invisible. UK data illustrates this: in the first two years of VPAG, 73% of formularies failed to list NICE-recommended medicines within the mandated timeframe. The pattern is consistent across Europe; a national approval does not automatically translate into patient access. Meanwhile, evidence suggests that more than 80% of launches continue as they start, meaning the trajectory set in year one tends to persist.

The response to underperformance is typically more resource, more analysis and a refined national strategy none of which addresses the underlying blind spot.

The piece, written by ValueBase, argues that sub-national visibility is a prerequisite for launch success. Using data from comparable products, teams can anticipate where access is likely to be won or lost before launch and allocate resource accordingly. Once live, real-time tracking of local access dynamics allows early intervention rather than reactive course-correction. ValueBase positions its launch intelligence platform as the mechanism for delivering this continuous, locality-level visibility shifting launch management from reactive to proactive and enabling faster, more targeted decision-making throughout the critical first year.

Closing the last mile: translating national market access into real-world patient access in the UK

UK market access needs the right conditions nationally, along with subnational investment and delivery locally

"The piece argues that subnational access must be treated as a core strategic priority, not an afterthought"

The UK market access environment has improved markedly entering Q2 2026, driven by three developments: reforms to VPAG, the UK-US pharmaceutical arrangement, and an increase in NICE cost-effectiveness thresholds from April 2026.

NICE estimates these changes will result in three to five additional positive technology appraisals per year meaning more medicines reaching patients in areas of high unmet need.

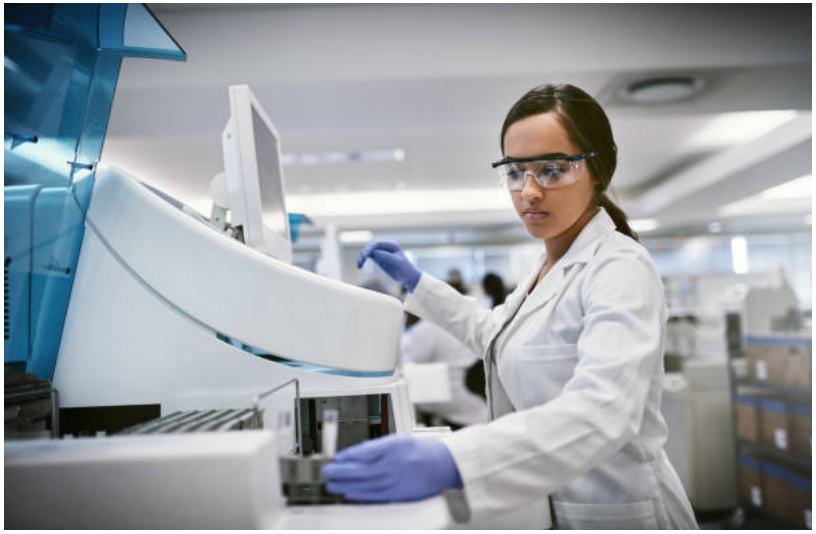
However, a positive NICE appraisal no longer equates to real-world patient access. A growing gap exists between national approval and actual prescribing, driven by NHS system constraints at the subnational level. According to EFPIA, which tracks ten factors that delay access to innovative medicines, two of five root causes relate specifically to health system constraints and subnational approval processes meaning that without addressing these, 40% of a market access strategy is effectively unplanned.

The piece argues that subnational access must be treated as a core strategic priority, not an afterthought. Effective execution should begin 24 months before launch, with teams mapping care pathways, identifying pressure points, and determining whether new diagnostics, monitoring requirements or cross-specialty input are needed. From 18 to 12 months out, advance budget notification and stakeholder mapping should be underway. At launch, the value proposition must be tailored to local system priorities including health inequalities, workforce pressures and capacity constraints.

The conclusion is that national conditions and local delivery must work in tandem. Without investment in the last mile of market access, the gains made at the national level risk failing to translate into patient outcomes.

The Ripple Effect: Why Connection is the Heart of Healthcare Leadership

> *"On mentorship, leadership is framed as a legacy. Supporting others creates a ripple effect that improves patient care across generations"*



In the fast-paced environment of clinical medicine, it is easy to focus solely on data and outcomes.

However, as Dr. Toyin Nwafor (Gilead Sciences) and Dr. Shirin Mazumder (University of Tennessee) argue in the latest Hear From Her podcast, the most transformative growth happens through connection, to our peers, our mentees, and our patients. From Proving to Improving

The piece draws on insights from healthcare leaders on leadership, listening and mentorship.

On leadership, the shift from a *"proving"* to an *"improving"* mindset is highlighted as critical requiring leaders to admit uncertainty and normalise struggle. When leaders openly acknowledge challenges, whether professional setbacks or personal difficulties, they create psychological safety for their teams to take risks.

On listening, the guests argue that effective clinicians go beyond clinical data to observe the social factors shaping a patient's life. Labels such as *"non-compliant"* often obscure practical barriers like transport or childcare. Narrative medicine asking open-ended questions to understand a patient's full situation enables treatment plans that are more realistic and individually relevant.

On mentorship, leadership is framed as a legacy. Supporting others creates a ripple effect that improves patient care across generations.

The hidden work of turning breakthroughs into outcomes

> *"The output is an integrated system of sequenced touchpoints rather than disconnected assets, with continuous learning built in to sustain engagement over time"*

The *"problem"* in healthcare comms is rarely what you say, it's whether people can act on it.

This article explains how we design whole-person engagement to turn intent into sustained behaviour.

This piece outlines Mednet's Making Health Whole approach to patient engagement, framed around a client case study.

The central argument is that effective communication must be designed around how people actually live, feel and make decisions not simply what they need to know clinically. When a client was preparing to launch into an underserved therapy area, rather than assuming uptake would follow availability, they commissioned research into the standard-of-care experience. Patients reported an emotional gap between what treatment demanded and what they could realistically manage including undisclosed distress, feeling unprepared for treatment's impact on daily life, and a disconnect between clinic reassurance and day-to-day coping.

From this, Mednet designed a support programme addressing the lived consequences of care. The approach maps decision points across the full patient journey identifying where communication gaps become psychological barriers and where trust either builds or breaks down. This informs a behavioural and creative throughline aimed at shaping belief and building confidence, rather than simply raising awareness.

The output is an integrated system of sequenced touchpoints rather than disconnected assets, with continuous learning built in to sustain engagement over time. The underlying principle is that engagement must be engineered, not assumed so that innovation delivers meaningful outcomes within the full human context of patients' lives.

Where patient insight meets strategy: measuring what truly matters

> *"For internal advocacy leaders, this means moving beyond activity metrics to evidence of influence"*

Measuring the impact of patient engagement is widely recognised as difficult outcomes are often long-term, much of the value is qualitative, and stakeholders perceive that value differently.

Comprehensive frameworks exist but can overwhelm rather than clarify.

A clearer consensus is emerging: the most meaningful measure is whether patient insights influence decisions, priorities and actions across an organisation. For internal advocacy leaders, this means moving beyond activity metrics to evidence of influence. For patients, it demonstrates that lived experience is driving genuine organisational change.

The piece argues that evaluation should move away from volume and satisfaction measures toward indicators that capture learning, decision-making and behavioural change. Crucially, measurement must be anchored to strategy mapping indicators against an organisation's specific patient engagement objectives across three complementary layers: process, outcome and impact.

Prioritisation is key. Rather than tracking everything, the recommendation is to align cross-functional teams and patient partners around a focused set of indicators that reflect strategic intent turning patient engagement from an activity into a demonstrable driver of organisational momentum.

Lilly to acquire Curevo in deal worth $1.5bn

The acquisition will help build Lilly's infectious disease portfolio

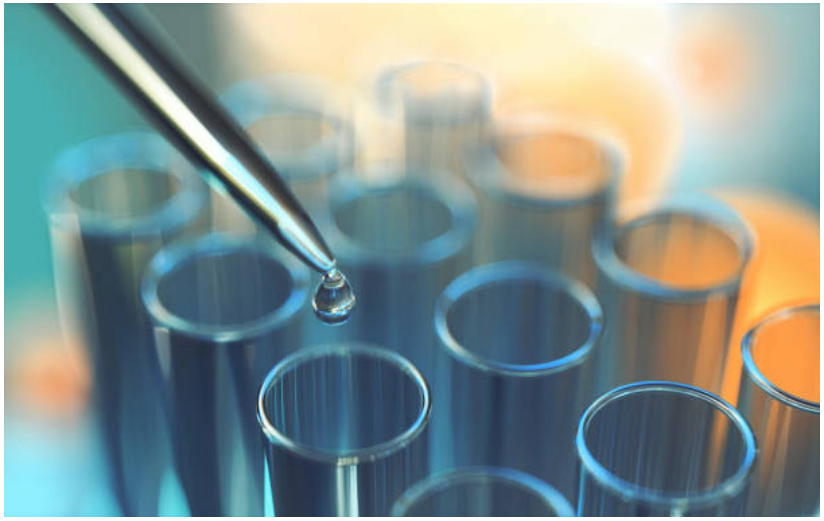
"Growing evidence links the infection to elevated stroke risk, and shingles vaccination has been associated with reduced dementia risk"

Eli Lilly has agreed to acquire Curevo, expanding its focus into infectious disease.

The deal is worth up to $1.5 billion in cash, comprising an upfront payment and a milestone-dependent payment.

Curevo's lead asset is amezosvatein, an adjuvanted subunit vaccine for shingles prevention in adults. While the current standard of care is effective, tolerability issues including fatigue, chills and injection site pain limit uptake and contribute to second-dose hesitancy. Amezosvatein was designed with a next-generation synthetic adjuvant to address this: in a phase 2 head-to-head trial, it matched the standard of care across all primary immune response endpoints while reducing those side effects by more than half.

The strategic rationale extends beyond shingles itself. Growing evidence links the infection to elevated stroke risk, and shingles vaccination has been associated with reduced dementia risk. A better-tolerated vaccine could therefore meaningfully expand vaccination rates and reduce long-term neurological consequences at a population level consistent with Lilly's broader interest in the downstream health effects of common infections.



Lilly to acquire LimmaTech Biologics and Vaccine Company in deals totalling $2.33bn

The acquisitions reinforce the company's commitment to reduce the long-term burden of serious disease

> *"LimmaTech Biologics is developing vaccines against bacterial pathogens where rising antimicrobial resistance is narrowing treatment options"*

Eli Lilly has announced two further acquisitions LimmaTech Biologics and Vaccine Company alongside its previously announced purchase of Curevo, signalling a deliberate strategic push into infectious disease prevention.

LimmaTech Biologics is developing vaccines against bacterial pathogens where rising antimicrobial resistance is narrowing treatment options, including Staphylococcus aureus, Neisseria gonorrhoeae and Chlamydia trachomatis. Its platform targets the toxins and superantigens that drive disease to generate broad, durable immune responses. The lead programme, LTB-SA7, is in phase 1 development as a vaccine against S. aureus the leading cause of surgical-site infections with a preclinical pipeline addressing additional pathogens, including those driving infertility and other long-term consequences disproportionately affecting women. Lilly will pay up to $780 million for LimmaTech.

Vaccine Company is advancing proprietary in vivo nanoparticle (IVN) technology designed to elicit durable immune responses comparable to virus-like particle vaccines, but without the associated manufacturing complexity. Its lead programme targets Epstein-Barr Virus (EBV), with a five-antigen, phase 1-ready candidate. Given growing evidence linking EBV to multiple sclerosis and several malignancies, a prophylactic vaccine could prevent not only acute infection but also serious long-term neurological and oncological consequences. Lilly will pay up to $1.55 billion for Vaccine Company.

Taken together, the three acquisitions reflect Lilly's stated aim of preventing disease at its source particularly as antimicrobial resistance makes bacterial infections increasingly difficult to treat.

LEO Pharma to acquire Replay gene therapy platform

The acquisition will advance innovation for patients with rare skin diseases

"The deal adds a herpes simplex virus (HSV)-based gene therapy platform to LEO Pharma's dermatology pipeline"

LEO Pharma has agreed to acquire Replay, a gene therapy company focused on rare genetic skin diseases, for $50m upfront plus milestone payments and tiered single-digit royalties.

The deal adds a herpes simplex virus (HSV)-based gene therapy platform to LEO Pharma's dermatology pipeline.

Replay's technology uses engineered HSV vectors to deliver large genetic payloads directly into skin cells, including a topical gel formulation for local application. Its lead candidate is in preclinical development for dystrophic epidermolysis bullosa (DEB), a rare condition that causes fragile, blistering skin and chronic wounds.

The acquisition is intended to strengthen LEO Pharma's capabilities in medical dermatology and support development of a broader rare disease dermatology franchise combining gene therapy innovation with its existing global expertise.