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UK COVID-19 infections lowest since last October

Health officials have predicted a sharp increase in COVID-19 and flu cases this winter

COVID-19 rates by nation for the end of August are one in 70 in England, or in 95 in Wales, one in 50 in Northern Ireland, and one in 50 in Scotland.

The ONS has reported that COVID-19 infections in the UK have fallen to their lowest level since last October. Fewer than a million people had the virus in the final week of August – about 1 in 70, down from 1 in 15 in mid-July.

Cases are decreasing in England and Wales, but are staying constant in Northern Ireland and Scotland. Millions of the most vulnerable are currently being offered booster jabs. Health experts have predicted that there will be a sharp increase in COVID-19 and flu infections ahead of this winter. Anyone who is eligible for another booster vaccine is being urged to receive theirs.

The autumn booster campaign has begun across most of the UK, and care home residents are being vaccinated first. Those aged 50 and over will be invited over the coming weeks. Many people will receive one of two recently-updated vaccines which target the Omicron variant, alongside the original virus.

Approximately 944,700 people in the UK had coronavirus in the week ending 28 August, according to the ONS, which is down from 1.1 million the week before. This is the lowest since October 2021, although infections also fell below a million in late May and early June this year.

Despite this fall in cases – hospital admissions are still rising in some regions. The seven-day total of COVID-19 admissions in South West England fell to 292 on September 4, but climbed by 22% in just six days to 365 on September 12. The region was hit the hardest by the three earlier waves of 2022. However, admissions of

Routine hospital care postponed due to national bank holiday

Cancer treatments and eye surgeries among operations postponed

Opinions have been divided as thousand of NHS operations and appointments were cancelled or postponed due to Queen Elizabeth II's state funeral, on Monday 19 September. Some patients have cancelled their own appointments, where others have complained of the disruption.

According to the independent global media platform openDemocracy, the announcement of the last-minute bank holiday saw doctors being advised to reschedule 'non-urgent procedures and appointments' such as replacement

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surgeries, eye surgery, maternity checks, and cancer treatments. Emergency and 'time-sensitive' treatment continued, but in some places on a reduced timetable.

Imperial College Healthcare, which runs five hospitals in London, said it had "decided on balance it is best to postpone much of the planned care that was due to take place."

Prior to the bank holiday, Professor Philip Banfield, of the British Medical Association, said: "There remains confusion over what NHS services will be provided in hospitals. NHS England must urgently clarify their advice about the services they are expected to provide and how they will be resourced to do so."

While the main reason for most hospitals closing is out of respect for the funeral, another problem was the unexpected need for new childcare arrangements due to schools being closed.

A pregnant woman speaking to *The Independent* commented that she received a text from her hospital saying that due to "unforeseen circumstances" her appointment had been cancelled and a new date would be "rescheduled shortly." She said, "I'm really disappointed. Yes, it's a routine scan, but that's another week or two until I'm seen and wondering whether my baby is healthy – which means quite a lot of anxiety, sitting, and waiting."

Future Focus

Ypsomed and Sidekick seek digital solution to self-injection anxiety

A partnership between Ypsomed and Sidekick Health aims to tackle self-injection anxiety among patients with chronic conditions.

Patients who need to regularly inject themselves can often experience needle anxiety and worry that they may not be able to carry out the procedure correctly each time, which can reduce compliance. With Sidekick, Ypsomed intends to adopt a digital approach to combat this problem, through the development of a molecule specifically targeted towards patients with chronic conditions who need to self-inject therapies on a regular basis.

Gulli Arnason, Chief Marketing and Communications Officer at Sidekick, says, "A wide range of independent research shows that there is a risk of patients using their injection devices incorrectly."

He told Pharmaphorum: "The collaboration is all about putting patients first. We will be jointly co-developing […] a clinical grade piece of software that supports patients during their injection routine [to provide] guidance, positive habit building and negative habit breaking, adherence optimisation, as well as fear and anxiety of needle reduction."

Sidekick's digital therapeutics (DTx) platform is based on gamified health apps which help patients modify behaviours and adhere to therapy. It is already being used by pharma companies to support specific drug therapies in areas such as atopic dermatitis and breast cancer.

The new partnership sets up a drug therapy-agnostic use for the DTx, applicable to any therapy that makes use of self-injection devices, such as Ypsomed's YpsoMate pen injector.

According to Arnason, in the future, Ypsomed's smart auto injectors "will be offered to patients pre-integrated into Sidekick DTx, enabling us to offer a fully integrated and seamless patient experience, helping patients tackle some of the most complex diseases in the world."

Contents

Words from the Editor

The UK has undoubtedly experienced a wave of political and cultural change in recent weeks. We have seen a new Prime Minister assume leadership of the country, at the peak of one of the greatest economic crises in British history. On the 8 September, we also witnessed the tragic passing of Queen Elizabeth II, the news of which has reverberated across the globe. Our thoughts are with the Royal Family at this difficult time.

At a time of great need, the healthcare and pharma landscape continues to go at full throttle. Pfizer has revealed data showing that the Respiratory Syncytial Virus (RSV) vaccine is effective in older patients, burgeoning hopes for a first bivalent RSV vaccine candidate. China has approved the world's first inhaled COVID-19 vaccine for emergency use, pioneering the potential use of needle-free products in the country and elsewhere.

As we transition out of summer and into the colder months, COVID-19 vaccine uptake in the UK is once again resuming urgency. Health officials are predicting a spike in COVID-19 and flu cases this autumn and winter, and millions across England and Scotland have been invited for their booster jab, with the elderly and most vulnerable individuals being prioritised. If eligible, be sure to receive vaccines for both to ensure maximum protection against severe disease – in accordance with expert advice.

That's all from me, for now. We hope you enjoy reading our October issue. As usual – feel free to give us a follow on Twitter @Pharmafocus for regular exciting polls and the chance to have your say.

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Millions invited for COVID-19 booster jabs in England and Scotland

Health experts are encouraging those eligible to receive their autumn jab

Millions of people have been invited for their autumn COVID-19 booster jab in England and Scotland as of Monday 5 September, and care home residents will be the first to receive this vaccine.

Health officials are predicting a spike in COVID-19 and flu cases this autumn and winter, and are urging those eligible to receive vaccines for both, to ensure maximum protection against severe disease.

The UK's MHRA announced on Saturday 3 September that it had approved a second "bivalent" COVID-19 vaccine from Pfizer/BioNTech, for people aged 12 and over.

However, there is not enough of Moderna's "bivalent vaccine" to protect everyone aged over 50, so health experts say that people should take whichever booster they are offered. These vaccines will also be used in the spring.

The groups who qualify for an autumn booster are adults aged 50 and over, people aged 5 to 49 with health conditions that put them at higher risk – including pregnant women, care home staff, frontline health and social care workers, carers aged 16 to 49 – and household contacts of people with weakened immune systems.

Wales has already started offering COVID-19 boosters to care home residents and staff. In Northern Ireland, the vaccine rollout began on 19 September, targeting the same groups.

NHS England CEO Amanda Pritchard called on people "to get the newly approved, next generation COVID-19 vaccine when invited to do so, as well as your annual flu jab, to ensure you have maximum protection".

Genetically modified herpes virus delivers one-two punch against advanced cancers

This presents a new treatment option or some patients with advanced cancers

A new genetically engineered virus has delivered a one-two punch against advanced cancers in initial findings from a Phase I trial. Scientists found that RP2 – a modified version of the herpes simplex virus – showed signs of effectiveness in a quarter of patients with a range of advanced cancers.

The early findings were presented at the European Society for Medical Oncology Congress (ESMO) on Saturday, and suggest cancer-killing viruses could potentially offer hope to patients where other forms of immunotherapy have not worked.

Researchers from The Institute of Cancer Research, London, and the Royal Marsden NHS Foundation Trust, assessed the cancer-killing virus on its own in nine patients, and, in combination with the immunotherapy nivolumab, in an initial 30 patients in the ongoing Phase I trial.

The early-stage study, sponsored by the drug's manufacturer Replimune, is testing the safety and dosage of RP2, as well as evaluating its ability to shrink tumours.

The genetically-engineered RP2 virus, which is injected directly into the tumours, is designed to have a dual action against tumours. It multiplies inside cancer cells to burst them from within, and also blocks a protein known as CTLA-4 – which releases the brakes on the immune system and increases its ability to kill cancer cells.

Study leader Professor Kevin Harrington, Professor of Biological Cancer Therapies at The Institute of Cancer Research, London, and Consultant Oncologist at The Royal Marsden NHS Foundation Trust, said: "Our study shows that a genetically engineered, cancer-killing virus can deliver a one-two punch against tumours – directly destroying cancer cells from within while also calling in the immune system against them.

"It is rare to see such good response rates in early-stage clinical trials, as their primary aim is to test treatment safety and they involve patients with very advanced cancers for whom current treatments have stopped working.

"Our initial trial findings suggest that a genetically engineered form of the herpes virus could potentially become a new treatment option for some patients with advanced cancers – including those who haven't responded to other forms of immunotherapy. I am keen to see if we continue to see benefits as we treat increased numbers of patients."

Landmark partnership to improve Scotland's health

This collaboration will give patients tools to engage with their health services

A collaboration between the NHS, academia, and industry partners has been launched to improve the general health of the population and expand clinical research, to co-create NHS Scotland transformation through large scale programmes.

This partnership has the potential to change clinical practice, improve patient outcomes, and reduce waiting times, with an initial focus on long term conditions and priorities set by the Scottish Government.

NHS Golden Jubilee's national Centre for Sustainable Delivery, NHS Greater Glasgow & Clyde, University of Glasgow, AstraZeneca UK, and Lenus Health have signed a Memorandum of Understanding (MOU) to enable large-scale clinical trials and studies in Scotland, among other goals.

The expansion of clinical research will promote the profile of Scotland and change clinical practice around the world. Close collaboration between the NHS, academia, and other industry partners is anticipated to create many opportunities to expand the Scottish economy.

Professor Julie Brittenden, NHS Greater Glasgow and Clyde's Director of Research and Innovation said: "We are already seeing great success in our COVID-19 recovery, with a growth in the number of transformative studies involving novel medicines, devices, digital enabled technologies and artificial intelligence.

"This collaboration further adds to the opportunity to undertake high quality research and innovation projects such as OPERA, which will directly impact on and improve patient-centred care."

Paul McGinness, CEO, Lenus Health said: "As the exclusive digital partner of this unique agreement, we are delighted to be part of a new way of working that will enable innovations to be developed and implemented rapidly at scale in Scotland and across the NHS.

"Through our work supporting patients to manage long-term conditions using virtual care and AI platforms, we have seen first-hand how it can reduce waiting lists and prevent readmissions.

"By joining up data across clinical pathways and giving patients tools to engage with their health services, providers can significantly improve outcomes and enable more personalised healthcare.

"Not only will this agreement help expand these benefits at scale, but the commitment to the Scottish digital health and artificial intelligence ecosystem will also be beneficial to the local economy by encouraging investment in the technology sector and generating jobs."

SMC accepts Jazz Pharmaceuticals' Sativex for multiple sclerosis patients

Around 130,000 people in the UK have MS

Sativex, also known as nabiximols, has been accepted by the SMC for use by NHS Scotland, as a treatment to improve symptoms in adult patients with moderate-to-severe spasticity due to multiple sclerosis (MS).

The treatment will also be available to individuals who have not responded adequately to other anticonvulsant medications, and who show clinically significant improvement in seizure-related symptoms during the initial treatment trial.

Sativex is a complex plant-based formula which contains the major cannabinoids THC and CBD, as well as specific secondary cannabinoids and other non-cannabis ingredients. The decision recommends making nabiximols available for routine reimbursement across Scotland, making it the second UK nation to do so, following the recommendation by NICE for England in 2019.

In 2010, nabiximols was also approved by the MHRA for use as a treatment of spasticity due to MS. The therapy was first approved by Health Canada in 2005, and has since been approved in 2019 countries under the trade name Sativex.

MS is a chronic neurological condition, characterised by the progressive and disabling loss of sensory and motor nervous system function, most commonly diagnosed between the ages of 20 and 40. It is estimated that 130,000 people in the UK have MS, with an estimated 16,000 people with MS in Scotland.

"This is an important decision from SMC and an exciting development for patients and their families who have been affected by this hard-to-treat condition," commented Samantha Pearce, Senior Vice President at Jazz Pharmaceuticals.

"We are pleased that SMC has recognised Sativex's evidence base. This underscores the importance of randomised clinical trials and regulatory approval in providing access to cannabis-based medicines for patients in need."

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Round-up

EMA approves first adapted COVID-19 booster vaccines

The CHMP has recommended authorising two vaccines adapted to provide broader protection against COVID-19. Comirnaty Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.1 are for use in people aged 12 years and above who have received at least primary vaccination against COVID-19.

These vaccines are adapted to better fight the circulating variants of SARS-CoV-2. Adapted vaccines can broaden protection against different variants, and are therefore expected to help maintain optimal protection against COVID-19, as the virus continues to evolve.

The ECDC and EMA have issued a joint statement, stating that: "Exposing the immune system to contemporary versions of the virus so that it learns and recognises subsequent variants is key for building up a broader immune response."

EMA issues positive feedback to Destiny Pharma on antibiotic treatment

Destiny Pharma has received positive feedback from the EMA regarding the proposed Phase III development programme of its new antibiotic treatment.

The EMA has declared that a single, final-stage study of NTCD-M3, the group's lead clinical candidate for the prevention of the recurrence of infections caused by toxic strains of the gut bacteria, would be sufficient for it to file a marketing authorisation application.

The group added that the EMA has also endorsed a new capsule formulation of the drug, currently in development with an aim to treat the recurrence of Clostridioides difficile (CDI).

Roche agrees to buy Good Therapeutics

Good's IL-2 receptor plays an important role in regulating lymphocytes

The Swiss pharma group has agreed to buy Seattle-based biotech Good Therapeutics and its preclinical-stage PD-1 regulated IL-2 receptor agonist programme for $250 million upfront, with undisclosed milestone payments on offer tied to development, regulatory, and commercial objectives.

Roche's activity in this area is represented by RG6279, an anti-PD01 antibody fused to an engineered, variant form of IL-2, which is currently in Phase I clinical testing. These drugs are designed to eliminate tumours by stimulating a local immune response with IL-2 via natural killer cells and cytotoxic T cells, and removing a brake on the immune system by blocking PD-1. Good's lead drug is due to start clinical testing next year.

IL-2 is one of the key cytokines with pleiotropic effects on the immune system. It has been approved for the treatment of metastatic renal cell carcinoma and metastatic melanoma. Recent progress has been made in understanding IL-2's role in regulating lymphocytes, which has led to exciting new directions for cancer immunotherapy.

A recombinant form of IL-2 has been used as a therapeutic for melanoma and renal cell carcinoma (RCC) for many years, under the Proleukin (aldesleukin) name. This has led many developers to find drugs that can retain the cancer-fighting properties of the cytokine but avoid its toxicity, which is mediated through the IL-2 alpha receptor – according to Pharma Phorum.

Baby sticky tape skin test could predict risk of eczema

A team of scientists from the University of Copenhagen, Denmark have designed a sticky tape skin test which could help predict if young babies are likely to develop bad eczema, according to BBC News.

The team used the test on a group of two-month-olds to painlessly collect and then examine skin cell samples. They found detectable immune biomarker changes in the cells that were linked with future eczema risk. They suggest that babies at high risk may benefit from early treatment with skin creams to avoid painful flare-ups.

The infants with elevated levels of Thymus and Activation-Regulated Chemokine in their skin cells were found to be more than twice as likely to develop atopic eczema by the age of two, compared to the other babies in the study.

Dr Anne-Sofie Halling from the Bispebjerg Hospital at the University of Copenhagen said: "To our knowledge, this is the first to show that non-invasively collected skin biomarkers can be used to predict the subsequent onset and severity of paediatric atopic eczema."

"It is also at this age we were able to identify both immune and lipid biomarkers that predicted the development of atopic eczema."

"Our findings of predictive immune and lipid biomarkers collected at two months of age will help identify children at highest risk of atopic eczema using a non-invasive and painless method, so future preventive strategies can target these children only and prevent cases of this common disease that so many children are suffering from."

Eczema causes the skin to become itchy, dry, and sore. This condition affects about one in five children in the UK. The most common type is called atopic eczema, which often develops alongside other allergy-related conditions, such as hay fever and asthma. Severe eczema can have a detrimental impact on quality of life, and there is no cure for the condition.

Yeast cells engineered to fight cancer

A team of scientists at the Technical University of Denmark have genetically engineered yeast to recreate vinblastine, an anti-cancer drug which was in short supply between 2019-2021. It is hoped this breakthrough will pave the way to creating more synthetic anti-cancer drugs.

Vinblastine belongs to the monoterpene indole alkaloids (MIAs) category, a biologically active group which is known to be useful for fighting an array of diseases. However, they are highly complex, meaning they are difficult to produce synthetically.

The scientists did 56 genetic edits to programme the 31-step biosynthetic pathway into baker's yeast. This genetic engineering produced vindoline and catharanthine, which was then purified and coupled to make vinblastine. More work will be needed to scale the production, however the researchers believe that the yeast cells could be used to produce over 3000 naturally-occurring MIAs and millions of new-to-nature analogues in the future.

Michael Krogh Jensen, a senior researcher at DTU and one of the corresponding authors, commented: "In this project, we were looking for new ways of manufacturing complex chemistry essential for human health, although the technology may also be useful in agriculture and material sciences. Biotechnology offers something exciting because chemical synthesis is difficult to scale, and natural resources are finite. We believe a third approach is needed: fermentation or whole-cell manufacturing. The assembly lines known from nature are plugged into microbial cells and allow the cells to produce some of these complex chemicals."

Other molecules that cell factories can now produce include potential drugs for cancer, malaria, and Parkinson's disease.

Measles outbreak in Zimbabwe kills almost 700 children

Zimbabwe's Cabinet has now launched a mass vaccination campaign

A measles outbreak in Zimbabwe has now killed nearly 700 children in a rapidly accelerating flare-up of the deadly disease.

According to *The Telegraph*, health officials have expressed alarm at the speed of the spread and high fatality rate of the outbreak, which has seen the death toll jump by dozens each day.

By September 4, measles deaths had reached 698, according to Zimbabwe's health ministry, up from less than a quarter of that a fortnight earlier. Officials reported that 37 children died on September 1 alone.

Dr Johannes Marisa, the president of the Medical and Dental Private Practitioners of Zimbabwe Association, told *The Associated Press* that the government may need to force children to be vaccinated.

He said: "Because of the resistance, education may not be enough, so the government should also consider using coercive measures to ensure that no one is allowed to refuse vaccination for their children."

He urged the government to "consider enacting legislation that makes vaccination against killer diseases such as measles mandatory".

Measles is one of the world's most contagious diseases, with a reproduction (R) rate as high as 18 – compared to an R rate of between 2 and 3 for the original strain of COVID-19.

The virus causes fever, coughing, and a rash, and in some cases, it can cause potentially fatal complications. These include blindness, brain swelling, severe diarrhoea and dehydration, ear infections, and even severe respiratory infections such as pneumonia.

Zimbabwe's Cabinet has invoked a law used to respond to disasters to deal with the outbreak, and has launched a mass vaccination campaign, which aims to target two million children who are under five years old.

IMFINZI (durvalumab) approved for advanced biliary cancer treatment in the US

Approval could transform care for patients

AstraZeneca's IMFINZI (durvulumab) has been approved in the US for the treament of adult patients with locally advanced or metastatic biliary tract cancer (BTC) in combination with chemotherapy (gemcitabine plus cisplatin).

This FDA approval was based on the results from the TOPAZ-1 Phase III trial. In an interim analysis of TOPAZ-1, IMFINZI plus chemotherapy reduced the risk of death by 20% versus chemotherapy alone.

BTC is a group of rare and aggressive cancers that occur in the bile ducts and gallbladder. Roughly 23,000 peope in the US are diagnosed with BTC each year. These patients have a poor prognosis, with only approximately 5-15% of patients with BTC surviving five years.

Aiwu Ruth He, MD, PhD, Associate Professor of Medicine, and a lead investigator in the TOPAZ-1 Phase III trial, said: "This approval represents a major step forward for patients with advanced biliary tract cancer, who urgently need new, well-tolerated, and effective treatment options after more than a decade of limited innovation. The combination of durvalumab and chemotherapy should become a new standard of care in this setting, having demonstrated significantly improved survival for these patients who have historically faced a poor prognosis."

Dave Fredrickson, Executive Vice President, Oncology Business Unit, AstraZeneca, said: "For the first time, patients in the US with advanced biliary tract cancer have an immunotherapy-based treatment option that meaningfully extends survival and is well-tolerated. This approval for IMFINZI and chemotherapy advances our ambition to challenge treatment expectations and transform care for patients with gastrointestinal cancers with high unmet need."

Round-up

Anthos Therapeutics' stroke treatment receives FDA fast track designation

The FDA has granted fast track designation for the investigation of abelacimab for the prevention of stroke and systemic embolism in patients with atrial fibrillation (AF).

"Although there have been important advances in anticoagulation treatment in the last 60 years, there remains a need for new agents that protect patients from having a stroke while offering a lower risk of bleeding than currently available anticoagulants. This is especially true for the elderly, patients with renal or hepatic impairment, and those with a prior history of bleeding," said Peter Kowey, professor of Medicine and Clinical Pharmacology at Sidney Kimmel Medical College at Thomas Jefferson University, US.

"Factor XI inhibitors have the potential to uncouple the processes that lead to thrombosis from those that are involved in creating normal clots. By doing so, the hope is that this new class of anticoagulants will be at least as effective as current treatments – and have an enhanced safety profile. An alternative administration method and less frequent dosing will facilitate the care of patients who, for a variety of reasons, struggle with daily pill taking."

FDA approves Fresenius Kabi's biosimilar stimufend

The FDA has approved Fresenius Kabi's biosimilar Stimufend (pegfilgrastim – fpgk), marking the first approved US biosimilar. This provides an accessible, high-quality treatment option for US cancer patients undergoing chemotherapy to reduce the incidence of infection as manifested by febrile neutropenia.

"This is a strategic milestone for Fresenius Kabi in one of the most important and fast-growing markets for biopharmaceuticals," said Michael Sen, CEO of Fresenius Kabi and designated CEO of Fresenius. "The company consequently expands its presence and position in the highly attractive US biosimilars marketplace in line with Vision 2026."

The company's pegfilgrastim biosimilar is a supportive care medicine for patients with non-myeloid cancer. It stimulates the growth of certain white blood cells, which are essential to prevent or fight infections, a common

China approves world's first inhaled COVID-19 vaccine for emergency use

China has become the first country to approve an inhaled COVID-19 vaccine, paving the way for potential use of the needle-free product in the country.

CanSino Biologics said in a statement that China's medicines regulatory board had approved the inhaled dose for emergency use as a booster vaccine. The product is known as Convidecia Air, and it delivers a vaccine dose through a puff of air from a nebuliser that is then inhaled by mouth.

CanSino's injected vaccine is already in use in China, and has been approved in a handful of other countries.

According to a database maintained by WHO, CanSino's product is one of two specifically 'inhaled' vaccines that had reached clinical phase development, as a number of companies worldwide consider innovative ways to deliver COVID-19 protection via the nose and mouth.

Over 70 Chinese cities have now been placed under full or partial COVID-19 lockdown since late August, which has impacted over 300 million people. A low vaccination rate among the elderly is a medical reaon used by Chinese authorities to justify the ongoing disease control measures.

CanSino's Convidecia vaccine is similar to the J&J and Oxford AstraZeneca vaccines. It uses a harmless virus, called an adenovirus, to ferry instructions for making COVID-19's spike proteins into cells so the body can create antibodies against them.

None of CanSino's products have currently been authorised for use in the US, but WHO listed the injected version of Convidecia for emergency use earlier this year.

Half of global health care facilities lack basic hygiene services

Half of healthcare facilities worldwide lack basic hygiene services, without water and soap or alcohol-based hand rub where patients receive care and in toilet facilities, according to the latest Joint Monitoring Programme report by WHO and UNICEF.

Around 3.85 billion people use these facilities, putting them at greater risk of infection, including 688 million people who receive care at facilities with no hygiene services at all.

"Hygiene facilities and practices in health care settings are non-negotiable. Their improvement is essential to pandemic recovery, prevention, and preparedness. Hygiene in health care facilities cannot be secured without increasing investments in basic measures, which include safe water, clean toilets, and safely managed healthcare waste," aid Dr Maria Neira, WHO Director, Department of Environment, Climate Change and Health. "I encourage Member States to step up their efforts to implement their 2019 World Health Assembly commitment to strengthen water, sanitation, and hygiene (WASH) services in health care facilities, and to monitor these efforts."

"If health care providers don't have access to a hygiene service, patients don't have a healthcare facility," said Kelly Ann Naylor, UNICEF Director of WASH and Climate, Environment, Energy, and Disaster Risk Reduction (CEE). "Hospitals and clinics without safe water and basic hygiene and sanitation services are a potential death trap for pregnant mothers, newborns, and children. Every year, around 670,000 newborns lose their lives to sepsis. This is a travesty – even more so as their deaths are preventable."

The report details that contaminated hands and environments play a significant role in pathogen transmission in healthcare facilities and in the spread of antimicrobial resistance.

Iveric Bio announces positive topline data from Phase III trial into geographic atrophy

IVERIC bio has announced positive topline results from GATHER2, the company's second Phase III trial of Zimura (avacintcaptad pegol), a novel investigational complement C5 inhibitor for the treatment of geographic atrophy (GA).

GATHER2 met its prespecified primary endpoint of mean rate of growth (slope) in GA area at 12 months, with statistical significance and a favourable safety profile.

Zimura is an investigational drug – a novel complement C5 protein inhibitor, not currently approved in any country. Overactivity of the complement system and the C5 protein are suspected to play a critical role in the development and growth of scarring and vision loss associated with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Through blocking the activity of C5, Zimura may decrease activity of the complement system, which causes the degeneration of retinal cells, and potentially slow the progression of GA.

Age-related macular degeneration (AMD) is the major cause of moderate and severe loss of central vision in ageing adults, affecting both eyes in the majority of patients. Geographic atrophy, the advanced stage of AMD, leads to further irreversible loss of vision in these patients.

"We are thrilled to see for the first time an investigational therapy with a statistically significant reduction in the rate of GA progression at the 12-month primary endpoint across two Phase III clinical trials," stated Glenn P Sblendorio, CEO of Iveric Bio. "The results from GATHER1 and GATHER2 and our Special Protocol Assessment with the FDA provide the basis for an NDA, which we are planning to submit by the end of first quarter of 2023. We look forward to engaging with the FDA throughout the review process. I want to thank the many patients, physicians, and their staffs for their participation in the Zimura clinical program along with the employees of Iveric Bio for their dedication to achieve this important milestone."

University of California develops new technology to create CAR T cells

A new system has been developed at UCSF which uses CRISPR-Cas9 gene editing to re-engineer large quantities of cells for therapeutic applications.

A paper published in Nature Biotechnology both describes and shows how the new technology can be used to create CAR T cells, which could potentially help treat multiple myeloma – a blood cancer – as well as rewrite gene sequences predisposed to rare and inherited immune disorders.

The approach inserts notably long DNA sequences efficiently to precise areas of a genome cell, without using the typical viral delivery system.

CRISPR-Cas9 has historically been used as a basic research tool. It edits genes inside living cells, turning them off, deleting them, replacing them if a gene is mutated, or boosting cancer-fighting activity. In order to do this, viral vectors – the inactive shells of viruses – are used to carry the DNA into the gene.

Clinical trials have started where CRISPR-Cas9 has been used to generate living cell therapies. However, progress has been thwarted due to safety concerns surrounding the manufacture of bulk amounts of clinical-grade viral vectors, as well as the inability of the researchers to completely control the insertion of the viral vector.

The recent study modified CRISPR-Cas9 so that viral vectors weren't needed by using both single-stranded and double-stranded DNA.

"One of our goals for many years has been to put lengthy DNA instructions into a targeted site in the genome in a way that doesn't depend on viral vectors. This is a huge step toward the next generation of safe and effective cell therapies," stated Alex Marson, MD, PhD, Director of the Gladstone-UCSF Institute of Genomic Immunology, and senior author of the study.

Triall Partners with Mayo Clinic to show potential for blockchain technology

Triall, a blockchain provider, has joined forces with Mayo Clinic to highlight the use of blockchain technology within clinical trial design and management of study data.

Triall's eClinical platform will be used to support all main trial activities, such as data capture, document management, study monitoring, and eConsent. This will begin with a two-year pulmonary arterial hypertension trial which will include ten research sites, and over 500 patients, across the US. eClinical enables existing third-party clinical trial software providers to connect to Triall's blockchain.

The collaboration aims to highlight how Triall's Verifiable Proof Application Programming Interface (API) can be used to create unchangeable blockchain-registered audit trails, which span from a trial's start-up, all the way to post-study.

The median cost of a clinical trial in the US is estimated to be around $19 million, with approval rates for new chemical or biologic entities being around 10-20% from the preclinical phase to finish.

"We are very excited to further our collaboration with Mayo Clinic and the team of Dr Chris McLeod. It is wonderful to work with some of the thought leaders within Mayo Clinic and we are confident our collaboration will pave the way towards further innovation and enhanced quality in clinical development, utilising the strengths of blockchain technology where these truly add value," commented Hadil Es-Sbai, Cofounder and CEO of Triall.

The initial pulmonary arterial hypertension trial is set to begin in September.

Pfizer finds RSV vaccine is effective in older patients

Data from a Phase III clinical trial has shown that the Respiratory Syncytial Virus (RSV) vaccine is 85.7% effective when administered to patients 60 years and older, burgeoning hopes for a first bivalent RSV vaccine candidate.

The Phase III RENOIR study is a global, randomised, double-blind, placebo-controlled trial designed to assess the efficacy, immunogenicity, and safety of a single dose of RSVpreF in adults over 60. Approximately 37,000 patients have been enrolled, with enrolment continuing in the Southern Hemisphere of up to 40,000 patients.

An external Data Monitoring Committee conducted an interim analysis of the study, where they assessed the vaccine's protection levels against RSV-associated lower respiratory tract illness (LRTI-RSV), defined by two or more symptoms, and the primary endpoint of LRTI-RSV, defined by three or more symptoms. For the weaker strain, the efficacy was 66.7%, however the vaccine efficacy against the more serious strain was 85.7%. No safety concerns regarding the investigational vaccine were recorded.

Annaliesa Anderson, Senior Vice President and Chief Scientific Officer of Vaccine Research and Development at Pfizer commented, "We are delighted that this first bivalent RSV vaccine candidate, RSVpreF, was observed to be efficacious in our clinical trial against this disease, which is associated with high levels of morbidity and mortality in older adults."

In March, RSVpreF was awarded Breakthrough Therapy Designation by the FDA for the prevention of RSV-associated lower respiratory tract disease caused by RSV in babies aged from birth to six months, by active immunisation of pregnant women.

Merck supports Orna's development of oRNA vaccine and therapeutics programmes

Merck will fund company with $150 million upfront

A collaboration effort has been agreed between Merck Research Laboratories (MSD) and Orna Therapeutics to discover, develop, and commercialise programmes of engineered circular (oRNA) therapies, in areas including infectious diseases and oncology.

The deal includes Merck funding Orna with $150 million upfront, with a possible $3.5 billion in development, regulatory, and sales milestones, as well as royalties on approved products. Merck will also invest $100 million of equity in Orna's recently-completed Series B financing round.

Orna will retain its rights to its oRNA-LNP (lipid nanoparticle) technology platform. oRNA molecules have been shown to have greater stability *in vivo* than linear mRNA, and can produce larger qualities of therapeutic proteins.

"This broad strategic collaboration brings together Merck's significant expertise in nucleic acid biology, clinical development, and manufacturing with Orna's compelling circular RNA technology to explore the opportunity to develop a new generation of potential vaccines and therapeutics," stated Fiona Marshall, Senior VP and Head of Discovery, Preclinical, and Translational Medicine at Merck.

Tom Barnes, CEO of Orna, added, "We are thrilled to collaborate with Merck, a company committed to breakthrough science, which has recognised the potential our platform can bring to patients. Our oRNA technology plus novel delivery solutions are designed to unlock the full potential of RNA in therapeutics and vaccines."

Kelai Pharmaceutical partners with Nutrasource to support drug development into natural compounds

US-based Kelai Pharmaceutical has hired Canada-based full-service contract research organisation (CRO), Nutrasource Pharmaceutical and Nutraceutical Providers, to assist with their early-stage drug growth programme, where they hope to establish drug candidates from botanical crops to develop prescribed drugs.

"Navigating the regulatory pathway for a new drug is no simple task. Kelai is happy to have an FDA regulatory partner with significant expertise in both natural compounds and pharmaceuticals to support us in plotting this course. This will let us be laser-focused on the most important tasks – minimising our risk and optimising our efforts from the earliest stages of development," notes Dr. Jacqueline Jacques, CEO of Kelai Pharmaceutical.

Working with botanicals in a pharmaceutical capacity opens up many opportunities, due to the fact that botanicals start out as complex endogenous compounds. Many aspects of the plant might therefore produce the eventual drug candidate. However, this also makes it a fraught task as, although the medicinal properties of a plant may be well-known, they have not been used in a pharmaceutical context.

William Rowe, President and CEO of Nutrasource commented, "Nutrasource's long-standing strategic positions in both nutrition and pharmaceutical scientific solutions were key factors in Kelai's decision-making process. We are delighted to be serving Dr Jacques and her team in this capacity, bringing cutting edge botanicals and related technology down the pharmaceutical pathway."

Pfizer buys Global Blood Therapeutics for $5.4 billion

Both drugs have received orphan drug designation from the FDA

Global Blood Therapeutics (GBT), a rare disease pharmaceutical company, has been bought by Pfizer for $5.4 billion in cash. The purchase will give Pfizer ownership of Oxbryta, a sickle cell disease-fighting drug which generated $195 million in 2021, with Pfizer expecting an increase in profits when it's introduced to the global market.

The acquisition is hoped to enhance Pfizer's presence in Rare Haematology, starting with sickle cell disease, by bringing knowledge and a leading portfolio to the table. Albert Bourla, Chairman and CEO of Pfizer stated:

"Sickle cell disease is the most common inherited blood disorder, and it disproportionately affects people of African descent. We are excited to welcome GBT colleagues into Pfizer and to work together to transform the lives of patients, as we have long sought to address the needs of this underserved community. The deep market knowledge, and scientific and clinical capabilities we have built over three decades in rare haematology will enable us to accelerate innovation for the sickle cell disease community, and bring these treatments to patients as quickly as possible."

GBT also has an extensive pipeline which includes several drugs to treat rare haematological conditions. GBT601 is an oral, once-daily, next-generation sickle haemoglobin (HbS) polymerisation inhibitor in Phase II of a three Phase trial. It is hoped to improve patients suffering from haemolysis and vaso-occlusive crisis (VOC). Another drug in the pipeline is inclacumab, a fully human monoclonal antibody-targeting P-selectin currently being evaluated in two Phase III clinical trials as a potential quarterly treatment for VOCs. Both drugs have received Orphan Drug and Rare Pediatric Disease Designations from the FDA.

SpectrumX upgrades facilities to kickstart clinical trial programme

SpectrumX have announced recent changes to their state-of-the-art production facility in Knutsford, Cheshire. This has paved the way towards the production of its drug substance, SPC-069, for clinical trials, according to Proactive Investors.

The upgrades to the facility included an ISO Class 8 Cleanroom, which includes a best-in-class air purification, ventilation, and pressure-cascade system to prevent air contaminants during manufacturing processes.

Other facilities that have been added include a dedicated quality control room and a microbiology laboratory, which tests all raw materials, key manufacturing steps, and finished cosmetic and biocide products. SpectrumX can now begin preparations for a clinical trial programme to take its novel respiratory treatment, SPX-001, to market.

Ben Hibbert, SpectrumX's operations director, said: "We are delighted our Knutsford facility now meets the standards required for the production of a pharmaceutical drug substance - in our case, SPC-069.

"To achieve this, we installed equipment across the facility and introduced new operating procedures. This is a significant step for the business as it allows us to kickstart our clinical trial programme. We now have the right environment to create and distribute our full range of hypochlorous acid products, which we believe will be game-changers in the market."

Manufacturing in the UK provides SpectrumX with supply chain and production facilities which are not available when shipping product from California.

Takeda splashes €300 million to expand plasma-derived therapy production site

The site aims to cut 40% of its greenhouse gas emissions by 2025

Takeda has announced that it is investing nearly 300 million euros to build a new production facility for plasma-derived therapies, and a new warehouse, at its existing Lessines site in Belgium.

The new facility will be self-sufficient in electricity as part of the company's commitment to have net zero carbon emissions by 2030. It will also feature a water recycling system that will cut freshwater consumption by 90% before 2023. The new warehouse will have net zero greenhouse gas emissions.

The Lessines sites and its 1,200 employees currently produce plasma-based therapies that can anually treat more than 300,000 patients with rare and chronic diseases like hereditary angioedema.

The details remain thin, but the new plant will have higher output and will be "even more data and digital driven" than the existing Lessines facility said Thomas Wozniewski, Takeda's global manufacturing and supply officer, in a statement.

In 2021, Takeda unveiled a plan to more than double its manufacturing space at its Thousand Oaks, California, site, which develops rare disease treatments. The new California plant will feature automation, robotics, and digitisation to minimise human errors. The entire site aims to cut 40% of its greenhouse gas emissions by 2025, starting with a solar project.

Biovac produces first Pfizer COVID-19 vaccine doses

South Africa's Biovac has made its first batch of the mRNA shot. The company finished its first doses at its facility in Cape Town, according to Bloomberg.

Before Biovac begins its next production batch, the first set of shots will be evaluated by the South African Health Regulatory Products Authority, said CEO Morena Makhoana. Subsequent doses are set to be sold commercially, starting next year.

Biovac, which is partly owned by the government, is now on an expansion spree and expects to employ as many as 584 people at the end of this year, Bloomberg reports.

Vaccine makers have faced scrutiny throughout the pandemic for not investing more time and effort to supply doses to low- and middle-income countries. Many of the top vaccine producers responded by pledging manufacturing investments and securing deals with local partners to boost supply.

Moderna has said that it will invest $500 million in building a 'state-of-the-art' mRNA facility in Kenya to produce up to 500 million vaccine doses a year. Johnson & Johnson has also made moves towards African manufacturing. The company has enlisted Aspen Pharmacare to produce and sell its vaccine in Africa.

JRS Pharma plans $18 million manufacturing expansion in Cedar Rapids

The Cedar Rapids City Council will be sponsoring JRS Pharma's application for state financial assistance to help expand its manufacturing operations in southwest Cedar Rapids, according to Corridor Business.

JRS Pharma is planning a 9,200-square-foot expansion of its manufacturing facility, including related site improvements, machinery, and equipment. The project comprises an $18 million capital investment which will result in the creation of 18 new jobs, all of which will meet the state's current High Quality Jobs wage threshold of $24.40 per hour.

JRS Pharma will receive a ten-year, declining scale tax exemption on new property value generated by the project, in accordance with the Urban Revitalisation Plan for the area. The incentive will provide an estimated exemption of $462,000 in total property taxes over the ten year period.

JRS is a manufacturer of excipients (inactive substances that serve as the vehicle or medium for a drug or other active sbstance) for the global health science industry. The company's products include high functionality excipients, binders, disintegrants, lubricants, functional fillers, thickeners, stabilisers, carriers, and coatings.

Pharmaceutical companies record year-low of robotics hiring in August 2022

17.1% of companies were recruiting in August 2022, compared to 19.6% the same time last year

Latest figures from GlobalData show the proportion of pharmaceutical companies who are hiring for robotics-related roles is dropping.

In August 2022, 17.1% of companies included in the analysis were recruiting for at least one robotics position, compared to 19.6% the year before. In the month previous, July 2022, the rate was 20.2%.

However, analysis of the date by Data Journalism Team shows that "pharmaceutical companies are currently hiring for robotics jobs at a higher rate than the average for all companies within GlobalData's job analytics database."

The same was seen in the medical hiring field, with 38.2% in August 2021 compared to 36.8% in August 2022.

GlobalData has highlighted robotics as a major element in the future of pharmaceutical production, stating that companies who "excel and invest in these areas now are thought to be better prepared for the future business landscape and better equipped to survive unforeseen challenges."

Robotics are used in the pharmaceutical industry for a variety of reasons, mainly focusing on dispensing, sorting, kit assembly, light machine-tending, and packing. According to Pharmaceutical Technology, robots are being redefined as 'physically embodied artificial intelligence agents', due to the acceleration of technology in the field. PT's data tracker also shows a steady increase in robotics-related deals within the pharma sector, furthering GlobalData's claim that robotics are the future of pharma.

Brainomix and Bridge Biotherapeutics enter AI partnership

Brainomix – the AI-powered MedTech solutions company – and Bridge Biotherapeutics, a clinical-stage biotechnology company focused on developing novel drugs for cancer, fibrosis, and inflammation, have announced a new partnership.

The collaboration will deliver quantitative imaging biomarker analysis within the Phase II study of novel autotaxin inhibitor BBT-877, which has been designed to evaluate the safety, tolerability, and efficacy in idiopathic pulmonary fibrosis (IPF). Under the partnership, Brainomix will leverage its e-ILD technology – automated AI software – which has been trained to process high-resolution chest CT data in patients with interstitial lung diseases, including IPF and other conditions that cause progressive pulmonary fibrosis.

Clinical trials in IPF commonly rely on serial physiological measurement of forced vital capacity as trial endpoints, which can be highly variable from day-to-day for any individual patient. Meanwhile, automated AI-powered quantitative imaging has the potential to significantly improve trial design, improve the chances of identifying a positive treatment response, and accelerate the translation of new treatments into clinical practice. Using proprietary and patented objective imaging biomarkers – and tracking changes over time – Brainomix will provide Bridge Biotherapeutics with valuable insights and additional data on the efficacy and mechanism of action of biomarker BBT-877.

"We are very pleased to announce this partnership with Bridge Biotherapeutics, where our existing technology platform and expertise will be leveraged to deliver objective assessment of the efficacy of BBT-877 in IPF. AI-powered imaging is becoming an increasingly critical component of studies in IPF and more broadly non-IPF interstitial lung diseases, where it has the potential to improve trial insights, and to complement existing trial methodology and endpoints," explained Dr Peter George, medical director at Brainomix.

Agnes Jung, head of project management at Bridge Biotherapeutics, added: "We believe that the partnership with Brainomix will enable us to generate supplemental efficacy data from our clinical study on IPF patients based on their combined imaging technology and expertise. We expect to gain further insights with regard to earlier prediction of treatment response in patients, as the partnership goes on." The partnership will also build upon Brainomix's existing offering to pharmaceutical and medtech partners, where development and deployment of AI-powered biomarkers generate value during clinical development, and can foster broader adoption of existing and new therapies.

BioInnovation Institute reveals new cohort entering Venture

The group consists of nine ventures, plus two corporate-sponsored innovation projects from Novo Nordisk – all aligned with BioInnovation Institute's (BII) focus on developing scientific healthcare initiatives.

Designed to help build research-based ideas with high-growth commercial potential into viable start-ups, BII's 12-month Venture Lab programme supports business acceleration, scientific and team development, while providing a convertible loan of €500,000, plus access to labs and offices at BII's entrepreneurial ecosystem in the centre of Copenhagen.

In becoming a part of the Venture Lab programme, the early-stage companies also get an opportunity to apply for an add-on opportunity of up to €1.3m through BII's new Venture House programme.

The start-up companies include: HHC Medical, which is developing a technology platform based on electroporation; HEKA VR, which uses virtual reality to provide a new type of immersive therapy for schizophrenia patients, and Fimmcyte, which is developing the first disease-modifying treatment for endometriosis.

Bobby Soni, Chief Business Officer at BII, said: "We are delighted to announce the next cohort of start-ups accepted onto our Venture Lab programme, and we look forward to supporting them with the many aspects of development needed to deliver first-in-class science that will positively impact global health and the environment.

"Furthermore, we are thrilled to present two strong innovation projects from Novo Nordisk, and look forward to helping these projects progress by offering our Venture Lab programme as a platform for innovation."

Since its inception in 2018, BII has supported 62 start-ups and projects.

DiME reveals digital measures for treatment of atopic dermatitis

These resources offer a blueprint for future development of digital endpoints

The Digital Medicine Society (DiME) has released a new set of open-access resources to advance the use of nocturnal scratch in the treatment of atopic dermatitis (AD), according to Pharma Phorum.

Nocturnal scratch aims to offer "new ways of measuring night-time scratching, using new digital tools to improve measurement of this distressing facet of AD."

Kerry Capozza, Founder and Executive Director of Global Parents for Eczema Research explains, "There's no easy solution, unless the eczema can be treated and brought under control".

As it stands, no new medical product has been approved on the basis of a digital endpoint. DiMe has collaborated with founding partners Abbvie, Janssen, Novartis, Pfizer, and UCB, along with project collaborators Advancing Innovation in Dermatology, Almirall, Eli Lilly, GSK, Leo Pharma, and Sanofi. DiMe hopes nocturnal scratch will enact a shift in understanding, leading to industry alignment and acceptance.

Nocturnal scratch's widespread implementation aims to establish a firmer digital groundwork for future clinical research, technology development, and reimbursement decisions in the dermatological field, therefore improving the lives of AD patients and caregivers.

The open-access resources were developed over a period of nine months, based on a mixed-methods study and comprehensive literature review, a series of workshops and focus groups with payers, as well as meeting with regulators.

It is anticipated that this will serve as a "blueprint for the broader development and deployment of digital endpoints in medical product development."

Novo Nordisk and Microsoft join forces to further R&D using AI

The collaboration will advance Novo Nordisk's AI capabilities

Under the strategic partnership, Microsoft's computational services, Cloud, and artificial intelligence (AI) will be combined with Novo Nordisk's drug discovery, development, and data science expertise.

AI models developed in the partnership will be used for a variety of use cases, with two initial ones already underway, and also be used to detect new targets and validate disease biomarkers. A use case focuses on automated summerisation and information assessment for obtaining new scientific insights from sources such as patents, scientific reports, literature, and discussion forums. It can also be used to develop models that forecast an individual's atherosclerosis development risk.

Novo Nordisk Digital Science & Innovation Senior Vice-President Lars Fogh Iversen said: "We are very excited about this new partnership that allows us to work closely together with key experts from Microsoft as we look to expand our digital science and AI capabilities. Together, we are on a path to enable faster and scaled use of AI in drug discovery, ultimately leading to more breakthrough innovations, and efficiency gain, to better serve the needs of patients."

"The collaboration with Novo Nordisk is a great opportunity for us to collectively advance the state-of-the-art of AI itself and apply it in a way that amplifies the creativity of human experts. To achieve this ambition, AI needs to learn from every type of information that subject matter experts find valuable, and that requires the type of close interaction between multiple disciplines we see in this partnership," stated Vijay Mital, Corporate Vice President, AI Architecture and Strategy in Microsoft's technology and research division.

Mind Matters: How AI is evolving research into Parkinson's

In the last decade, AI has taken the field of neurology by storm. It has particularly revolutionised the way that Parkinson's is diagnosed, researched, and managed. Lina Adams explores the technological advances that are underway as researchers aim to understood more about Parkinson's pathology.

Artificial intelligence (AI) is now more ubiquitous in healthcare and pharma than ever before, and the magnitude of its role cannot be understated. From areas ranging from data management, to GP consultations, AI has drastically simplified processes that were once laborious.

In the past decade alone, AI has revolutionised how the field of neurology is researched and understood, and has paved the way for numerous critical developments. For example, AI can now diagnose stroke from CT/MRI scans, detect seizures before an attack, and classify neurodegenerative diseases based on gait and handwriting.

Parkinson's is the second most common degenerative neurological disorder, after Alzheimer's disease, and is estimated to affect one percent of the population over the age of 60. This can have a significant impact on one's quality of life, and can present challenges to their loved ones as well. There is an ongoing need to improve treatment and care, implement strategies for prevention, and enhance research into the disease, to keep patients at the fore and ensure they are receiving the care they need.

In Parkinson's research, artificial intelligence has manifested in the form of genetic sequencing, which has allowed for rapid sequencing of DNA base pairs, and has revolutionised how Parkinson's is researched and understood. AI has drastically cut the time and costs associated with identifying genes involved with PD, and will continue to play an instrumental role.

Whilst much has been discovered in the past decade, the many complexities and nuances of the disease mean there is still a long way to go in identifying PD-related genes and the cellular processes they support.

The distant past

Advances in AI have led to revelations about the Parkinson's pathology, in turn improving treatments for the condition which are tailored to the individual. A significant breakthrough

in genetic sequencing has been NeuroX, which was the first DNA chip able to identify genetic variants in a person's genome to determine any risk for developing a number of late-onset neurodegenerative diseases, including PD. The chip was developed as a result of a 2011 NINDS workshop, in a joint venture between the NIH National Institute of Neurological Disorders and Stroke, and investigators at the NIH National Institute on Aging.[1]

AI has helped scientists discover that inherited PD has been found to be associated with mutations in a number of genes, including SNCA, LRRK2, PARK2, PARK7, and PINK1. The SNCA gene provides instructions for making the protein alpha-synuclein, which is normally found in the brain as well as other tissues in the body. Studies have shown that alpha-synuclein plays a pivotal role in maintaining an adequate supply of synaptic vesicles in presynaptic terminals. It may also be involved in the movement of structures called microtubules, which help cells maintain their shape.

Current developments

Many companies are using the benefits of AI to explore Parkinson's, in areas ranging from diagnosis, to disease progression, to treatment. MIT researchers have developed a sensor which they say can help track Parkinson's patients' breathing while they sleep. Tracking is completely contact-free, and the device alerts caregivers to any progression of the patient's condition. The device emits radio waves, and captures their reflection to read small changes in its immediate environment.[2]

This study has explored the link between Parkinson's and breathing, and the disease is usually diagnosed by a more subjective examination of muscle stiffness, slowness, or tremors. This approach could also be used to help advance the development of new and innovative therapies for Parkinson's – through making it easier to see when a treatment is working, according to the researchers.

Professor Dina Katabi, Principle Investigator at the University's AI-focused Jameel Clinic, commented: "Some medical studies have shown that respiratory symptoms manifest years before motor symptoms, meaning that breathing attributes could be promising for risk assessment prior to Parkinson's diagnosis."[2]

Koneksa is another company exploring how AI can predict Parkinson's disease progression. The company is studying how digitally-collected data points could potentially be used to plot out how an individual's case of Parkinson's will advance over time. Researchers aim to identify which data points, collected by a smartwatch or other digital device, can be used to predict and model Parkinson's progression. As Koneksa founder and CEO, Chris Benko, states: "There are no current diagnostics to detect progression in early PD or in the prodromal (pre-diagnostic) stage, and identifying any predictive digital biomarkers would be a meaningful addition for patients and physicians."[3]

As it stands, treatments for Parkinson's focus on controlling symptoms, and there is currently no cure available. This highlights the importance of using AI in drug discovery, which

could accelerate the path to a permanent cure.

BenevolentAI, Europe's largest private AI company, is collaborating with Parkinson's UK and The Cure Parkinson's Trust (CPT), two UK charities, to repurpose at least three existing drugs, and identify two novel drug targets to treat Parkinson's disease. According to Labiotech: "BenevolentAI's software uses a computational method known as a 'five-layer neural network' to develop models that can predict the blood-brain barrier penetration and other properties of potential drug candidates. The software's judgment is continuously updated and improved using machine learning algorithms and feedback from experienced biomedical users."[4]

The ongoing development of digital biomarkers is also playing an important role in the diagnosis of Parkinson's. In the USA, the FDA has approved the use of brain imaging technology to detect dopamine transporters (DaT), an indicator of dopamine neurons, to help evaluate adults with suspected Parkinson's. The DaT scan uses an iodine-based radioactive chemical, along with single-photon emission computed tomography (SPECT, imaging involving blood flow to tissue), to determine whether there has been a loss of dopamine-producing neurons in a person's brain. However, as it stands, DaTscan cannot diagnose PD, and cannot accurately discern PD from other disorders that involve a loss of dopamine neurons.

According to researchers in neurology, a high-priority goal is to develop a PET imaging agent which can show alpha-synuclein accumulation in the brain. Alpha-synuclein accumulation in the brain can currently only be confirmed by an autopsy. AI has enhanced all aspects of the PET imaging chain, and is continuing to do so; the ability to detect the protein with an imaging technology in a living person would allow physicians to track the severity of alpha-synuclein accumulation over time, as well as help gauge the success or failure of therapies aimed at reducing alpha-synuclein levels. This would be a turning point in accelerating drug development.

Brain Barriers

When it comes to healthcare, cybersecurity is a prominent issue as patient data can contain very sensitive, personally identifiable information. AI plays a critical role in assisting with breach prevention by proactively searching and identifying previously unkown malware signatures. Patients need to feel secure in providing data to healthcare companies. In order to mitigate the risk of cyber attacks, organisations must ensure they hire sufficient specialised security personnel to properly manage and oversee cybersecurity operations. It is important to use reputable cloud service providers which offer continuous security monitoring and incident response, as they can quickly identify security issues and apply patches.

However, there is the inevitable risk that pharma companies can become over-reliant on AI, which can take away the human aspect of Parkinson's research. Companies should approach the adoption of AI with caution, and should prioritise successful implementation and management of AI, to make critical, real-time decisions where automation cannot resolve a cybersecurity issue.

What's next?

Whilst the field of neurology is complex and nuanced, AI has undoubtedly been a gamechanger in simplifying the processes of diagnosis, research, and treatment. For the foreseeable future – until a cure for PD is discovered – researchers hope to improve patients' quality of life with medications, which can be identified using the capabilities of AI. Although there is still a long way to go, the digital advancements that have been made in the realm of diagnosis and care have completely shifted the way that PD is understood.

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Digital platforms and the world of oncology

Pharmafocus speaks to Eoin O'Carroll, cofounder and CEO of oncology platform ONCOAssist, about the importance of digital platforms in this complex and ever-evolving field

Pharmafocus: What motivated you to develop ONCOAssist, and how can digital platforms such as this benefit the oncology landscape?

Eoin O'Carroll: I started ONCOAssist with my business partner, as a result of doing a Master's in Electronic Business in University College Cork in Ireland. As part of that, we had to create an online business. His brother at the time was a trainee oncologist and we asked him what issues he had found in hospital settings. The main problem for him was getting access to veterinary clinical information. One particular tool we worked on during that project went very well, and as a result of that, we just saw there was a niche, and there was limited access to that tool. We also saw that there was quite a variety of tools and information that were not available in the oncology field at the point of care, so we wanted to create a mobile application that can quickly be opened and can give you all the information that you need. We thought that it would be a great opportunity to make those tools available to the oncology community globally, both oncologists and oncology nurses. The way that digital platforms like this have benefitted the oncology landscape has been two-fold over the last number of years. It has sped up the process of getting the information and allowing the community access to clinically valid information, because ONCOAssist is classified as a medical device. Secondly, we've been able to provide the information to low-to-middle income countries. The app is totally free globally, but the ability for those clinicians and nurses in the low-to-middle income countries to get the same quality information as those in high income countries has been a great benefit.

What areas of healthcare alongside oncology still require advanced digital transformation?

All areas could benefit from digitalisation, because of the ability to open up your mobile phone and get access to valid information. Being trusted and validated is probably the most essential part of what we provide. That can be applicable to cardiology, various surgeries, and other areas of specialty. We've also seen that in haematology, and we're working on that area as well because it's closely aligned with oncology. We haven't gotten into other areas because oncology is such a big area and we have that wealth of experience, but there are opportunities in so many other areas in healthcare.

What are the main challenges involved in the widespread adoption of medical technology?

Over the last three years, adoption has been quite slow. We have been around for over 10 years now and we thought we would be a lot further along in terms of digital adoption. The industry is very cautious about the adoption of clinically valid tools; they'll ask "Is this software clinically valid?" and "Can it be used safely in a hospital setting?" This is especially difficult for startup companies – a lot of the big players are developing their own software, and the smaller companies might find it quite difficult to build up trust that has already been established in the community.

I suppose the biggest challenge would be the difficulty in adapting in the clinical pathway, and within hospitals itself. Over the years, we've been using a range of tools within ONCOAssist that have many points in the clinical pathway, and clinicians have been able to use it at various points within that. The systems and pathways that are currently in hospital settings are very rigorous, and they're very defined. A lot of clinicians are already happy with the pathways that they have, and bringing in digital tools that they might not be as digitally savvy in using means that there is a fear of the unknown.

Whilst COVID-19 was obviously detrimental to the healthcare industry in a lot of ways – in what way was it a catalyst for digital transformation?

From a digital perspective, it allowed the whole industry to become conscious of those new digital pathways in terms of presenting information, and allowing physicians to interact with their patients. The restrictive nature of COVID-19 made it difficult for patients and physicians to keep in contact with each other. Telehealth was probably the most prominent digital technology that was brought into the industry as a result of COVID-19, and it had a very good impact in terms of allowing the industry to take on a new way of managing patients, as opposed to pre-COVID-19 where those solutions weren't there. There was a pushback because the face-to-face nature of meeting patients is always a necessity, but COVID-19 has allowed physicians to be a bit more comfortable with the digital nature of telehealth.

Clinicians have also benefitted from patient monitoring tools (in terms of wearables) and feeding that back into the hospital networks. That's starting to kind of go in the right direction as well. It's benefitting in the long run, in terms of digital trends and allowing patients to record their own information and give it to doctors.

From an informative drug information standpoint, we have found within ONCOAssist that we've been able to work with pharmaceutical companies a lot more to bring digital content to oncologists that would benefit them in ways that they haven't done before. Bringing them information about new indications, or new ways of administering the drugs that are available to patients, is very helpful as well. The pharmaceutical industry can become a bit more tech-savvy as well, to allow that information to be sent back to the physician, and benefit them as well.

What are the advantages of healthcare tracking in patient care?

I think the big benefit is that it's bringing a whole new element in terms of patient monitoring, as patients are meeting their doctors and nurses on a two-to-three week basis. However, there's no understanding of how that patient is performing when they're away from the hospital. That's kind of been a gap in the healthcare industry, in terms of the patient's improvement and how they're performing at home. This has allowed physicians and nurses to be able to intervene at earlier stages if a patient is feeling unwell, in terms of who's on a certain prescription or certain certain medication. Those alerts, through ePros and ePro solutions, can be brought back to the patient.

For the patients and their own healthcare, it also allows multiple ways of monitoring their own health, for example their breathing or their heart rate. It's been quite vital.

Another advantage is the overall data trends and the ability to capture these trends of how patients are doing away from home. All these data sets are now becoming available in terms of patients and how they're reacting to drugs at home, how their activity is improving, if their medications had any side effects, if they are improving or disapproving as a result of taking a medication, or if a medication had an overall side effect that we were not aware of. All of these elements are becoming available, and these trends are starting to come on board in terms of these these new insights that we never had before. We're very much in the early stages of tracking this data and finding these overall trends, but it's very exciting in terms of the possibilities and what we might find in terms of the overall aspect of improving patient's lifestyle.

Move of the month

STORM Therapeutics appoints Dr Jerry McMahon as CEO

Dr Jerry McMahon has been appointed CEO for STORM Therapeutics as it transitions into a clinical-stage company with a pipeline of products targeting RNA modifying enzymes.

STORM Therapeutics is a biotechnology company specialising in discovering and developing novel small molecule therapies targeting RNA modification enzymes for oncology and other diseases. Dr McMahon has more than 30 years' experience in biotechnology leadership, scientific innovation, creative deal-making, and financing experience with expertise in a broad range of diseases, and a specialty in oncology therapeutics.

Dr Jerry McMahon stated, "STORM is well positioned to fulfil its ambition of becoming the global leader in the field of RME. STORM's first-in-class clinical candidate STC-15, an orally-bioavailable, highly selective METTL3 inhibitor, is on schedule to start initial clinical studies in solid tumours in 2022, and will be the first-ever RME inhibitor molecule to enter clinical development. I look forward to guiding STORM through future growth, capitalising on our world leading RME drug discovery experience, advancing programs into the clinic, and building the pipeline which was recently validated with a significant partner in oncology."

Lytix Biopharma recruits Stephen Worsley as Chief Business Officer

Norwegian immune-oncology company Lytix has announced the appointment of Stephen Worsley as Chief Business Officer.

Stephen Worsley is a pharmaceutical executive with over 25 years of knowledge in business development in the biopharmaceutical and drug discovery/development market. As a business development executive, Worsley has led negotiation of transformative and award-winning technology and product partnerships for leading therapeutics companies.

Lytix Biopharma is a clinical-stage biotech company developing novel cancer immunotherapies, an area within cancer therapy which is aimed at activating the patient's immune system to fight cancer. The company's technology is based on pioneering research in 'host defence peptides'.

Øystein Rekdal, CEO of Lytix said, "As we plan for continued progress to reach several important milestones in our development programs at Lytix, we are excited to welcome Stephen Worsley to our management team at Lytix Biopharma. His extensive experience in business development where he has led various strategic partnerships, acquisitions, equity investments, clinical collaborations, and out licensing transactions, will play a central role as we advance our exciting pipeline of immuno-activating drugs for cancer through further clinical development and towards market, with several potential partnering opportunities along the way."

Katharine Knobil joins Pliant Therapeutics' Board of Directors

Pliant Therapeutics has appointed Katharine Knobil to its Board of Directors.

Speaking of Katharine's appointment, Bernard Coulie, MD, PhD, President and CEO of Pliant stated: "I would like to extend a warm welcome to Kate, whose global clinical development and strategic leadership experience, including her training as a pulmonologist, aligns perfectly with Pliant as we evolve into a late-stage biotechnology company. I look forward to working with Kate, and believe she will provide valuable perspectives as we continue to execute on our strategy of making a difference in the lives of patients impacted by fibrotic diseases."

Pliant Therapeutics is a clinical stage biopharmaceutical company which focuses on discovering and developing novel therapies for fibrosis. In addition to clinical stage programmes, Pliant currently has two preclinical programmes targeting oncology and muscular dystrophies.

Dr Katharine Knobil is an accomplished pharmaceutical executive who brings over 20 years of clinical development and medical affairs expertise.

Valeo Pharma appoints Kyle Steiger to role of Senior Vice-President and CEO

Valeo Pharma is a pharmaceutical company dedicated to the commercialisation of innovative prescription products in Canada, with a focus on respirology/allergy, opthamology, and other products.

Kyle Steiger is a pharmaceutical industry veteran whose work experience includes specialty pharma, biologics, primary care, medical devices, over-the-counter, health policy, and market access. He spent nearly 20 years at Novartis Canada in various executive positions, including franchise Head of Hematology, Vice President of Primary Care, and most recently, Vice President of Opthamology.

Karl Steiger said, "We have the right set of innovative products, the right team of people and appropriate corporate structure to deliver on our ambitious corporate objectives. I am thrilled to be joining the company at such an exciting time, and look forward to help accelerating our growth, profitability, and industry leadership ambitions."

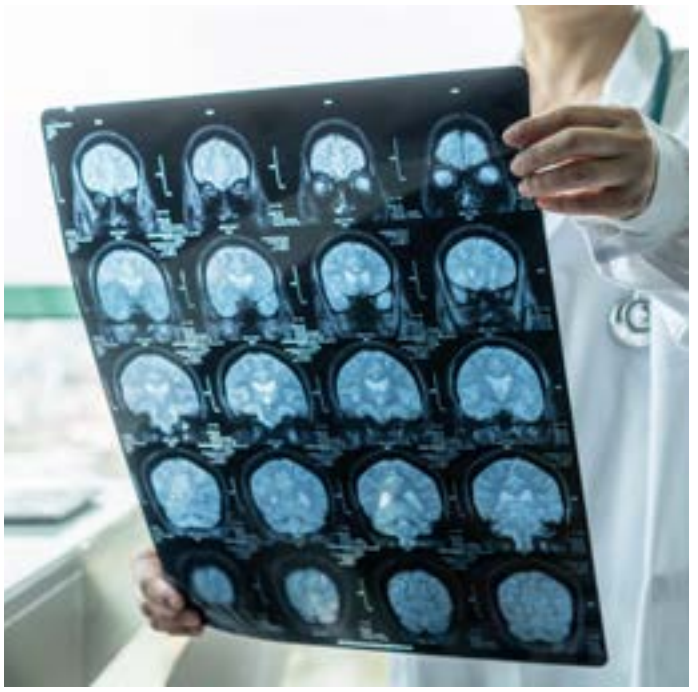
NervGen Pharma appoints Dr Matvey Lukashev as Vice President of Research

NervGen is a clinical stage biotech company dedicated to developing innovative solutions for the treatment of nervous system damage. They have appointed Matvey Lukashev, PhD, as the company's Vice President of Research and Preclinical Development.

Paul Brennan, President and CEO of NervGen said, "We are delighted to welcome Dr Lukashev to our team. Matvey will lead an important evolution at NervGen as we emphasise the development of our lead drug candidate, NVG-291, beyond our initial formulation and core indications, and build a pipeline of additional proprietary compounds that address nervous system repair. Matvey has over 20 years of industry experience in discovery and translational research, including 14 years at Biogen where he led target and drug discovery, as well as translational research programs in several therapeutic areas and was responsible for translational research supporting the clinical development of Tecfidera, a multiple sclerosis therapy that reached annual sales over $4 billion. Most recently, Matvey was at the ALS Therapy Development Institute in Massachusetts where he built and led the Augie's Quest Translational Research Center. This experience puts Matvey in an excellent position to lead our research and preclinical development efforts."

5 neurological phenomenons

1.) Aphantasia
Aphantasia is the inability to create mental images. People with aphantasia do not mentally visualise pictures of familiar objects, places, or people. This condition can actually impact other senses as well, and some aphantasics can experience multisensory aphantasia – meaning they cannot hear or imagine sounds either. There is still limited research into the condition, but it is believed that only roughly between 1-3% of people have aphantasia.



2.) Synaesthesia
Synaesthesia is a phenomenon in which stimulation of one sensory or cognitive pathway (such as hearing) leads to automatic, involuntary experiences in a second sensory or cognitive pathway (such as sight). Researchers are still unsure about the commonality of the condition, but it is estimated that it affects between 3-5% of the global population.

3.) Locked-in syndrome
Locked-in syndrome (LIS) is a condition in which a patient is aware but is unable to move or communicate verbally due to paralysis of almost all voluntary muscles in the body, except for vertical eye movements and blinking. In the US, this disease is estimated to afflict fewer than one thousand people.

4.) Astasia-Abasia
Astasia-abasia denotes the inability to stand due to a lack of motor coordination. The term 'astasia' means an inability to stand, and 'abasia' refers to the inability to walk properly. In this condition, individuals can exhibit unusual movements, such as swaying violently in various directions. This condition occurs in 5-15% of treated chronic pain patients. Although some patients can recover very quickly, most patients will experiene recurrence within the first one year.

5.) Anosognia
Anosognia is a phenomenon in which an individual is unaware of having a disability, due to an underlying physical or psychological disorder, which can result from physical trauma to the brain. Doctors estimate that 40% of people with bipolar disorder and 50% of those with schizophrenia have anosognia. A person with this condition can advance their quality of life through entering an intensive mental health programme, consisting of medication therapy, CBT, and coping skills training.

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Recent ONS statistics reveal COVID-19 rates are at their lowest since October. In light of this - are you more/less concerned about coronavirus than you were one year ago?

More – 33%
Less – 67%

Were you/anyone you know affected by NHS cancellations on the National Bank Holiday Monday?

Yes – 10%
No – 90%

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