Pharmafocus
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New treatment to increase chances of successful kidney transplant
The treatment, made by Hansa Biopharma, has been recommended by NICE for people awaiting a kidney transplant, page 5

Type 2 diabetes may speed up cognitive decline and brain ageing
Researchers have found that among older people with Type 2 diabetes, the brain appears to age at an accelerated rate, page 9

Smart technology can reduce risk of asthma attacks and prevent deaths
Research from the University of Auckland has found that smart technology could halve risk of asthma attacks, page 12

New cancer drug trial achieves 100% remission

The immunotherapy drug saw 12 rectal cancer patients entering remission over six months

An experimental cancer drug appears to have cured every single patient involved in a small clinical trial, based in the US.

The 12 rectal cancer patients entered remission after taking dostarlimab over a six-month period, according to a study published in *The New England Journal of Medicine*. The trial was sponsored by GSK.

Dostarlimab is an immunotherapy drug, used in the treatment of endometrial cancer, but this was the first clinical investigation into whether it could be effective against rectal cancer tumours. The drug works by unmasking cancer cells, allowing the immune system to identify and destroy them.

In the trial, the 12 patients received dostarlimab every three weeks for six months. This treatment was to be followed by standard chemoradiotherapy and surgery. However, six months after the patients stopped taking the medication, their cancer had vanished, and was undetectable in all physical exams such as endoscopy, positron emission tomography (PET), or MRI scans. This is the first time that an experimental drug has been able to completely eliminate cancer cells.

When the patients were examined after treatment, they were all found to be in remission. According to the paper, all 12 had a "clinical complete response, with no evidence of tumour on magnetic resonance imaging". None of the patients has needed further treatment, and also did not show any significant side effects.

Though the trial shows a great deal of promise for cancer patients, its small scale means that further studies are needed to draw conclusions about dostarlimab as a treatment.

"This is the first time this has happened in the history of cancer," Dr Luis Diaz, one of the lead authors of the paper and an oncologist at the Memorial Sloan Kettering Cancer Centre in New York, US, told *The New York Times*.

Dr Hanna Sanoff, of the University of North Carolina, US, who was not involved in the research, said the study was "small but compelling".

"These results are cause for great optimism," Sanoff wrote in an editorial accompanying the paper, adding that the research had "provided what may be an early glimpse of a revolutionary treatment shift". However, Sanoff warned that "such an approach cannot yet supplant our current curative treatment approach", adding that it remains unclear whether the patients are cured.

Researchers uncover origins of Black Death

An ancestor of the Black Death has been located in the Tian Shan region of Kyrgyzstan

An international team has linked spikes in deaths at cemeteries in Kyrgyzstan in the 1300s to the start of the plague pandemic. Ancient DNA from bubonic plague victims, buried in cemeteries on the Silk Road trade route in Central Asia, has pinpointed the area in northern Kyrgyzstan.

The Black Death killed tens of millions of people in the mid-14th century, and, between 1346 and 1353, killed up to 60% of the populace in Western Europe, and 50% in the Middle East. Dr Philip Slavin, one of the historians who helped with the discovery, also described the "unaccountable number" of individuals who died in the Caucasus, Iran, and Central Asia. The research was published in *Nature*.

"Our study puts to rest one of the biggest and most fascinating questions in history, and determines when and where the single most notorious and infamous killer of humans began," shared Slavin.

The researchers noticed a significant rise in burials near Lake Issyk Kul, in the Tian Shan region of Kyrgyzstan,

▶ *Continues on page 2*

continued from page 1

from 1338-1339.

"We have basically located the origin in time and space, which is really remarkable," said Professor Johannes Krause, at the Max Planck Institute for Evolutionary Anthropology in Leipzig. "We found not only the ancestor of the Black Death, but the ancestor of the majority of the plague strains that are circulating in the world today."

The researchers shared that they retrieved ancient DNA traces of the Yersina pestis plague bacterium (Y pestis) from the teeth of three women who died in 1338-1339. The earliest documented deaths of the plague were in 1346.

The researchers reconstructed the pathogen's genome, revealing that this strain gave rise to the strain of the Black Death that caused millions of deaths across Europe and Asia. Further, the strain is also the ancestor to most plague strains existing today. This was a sign, Professor Krause shared, of an explosion in Y pestis diversity, shortly before the Black Death.

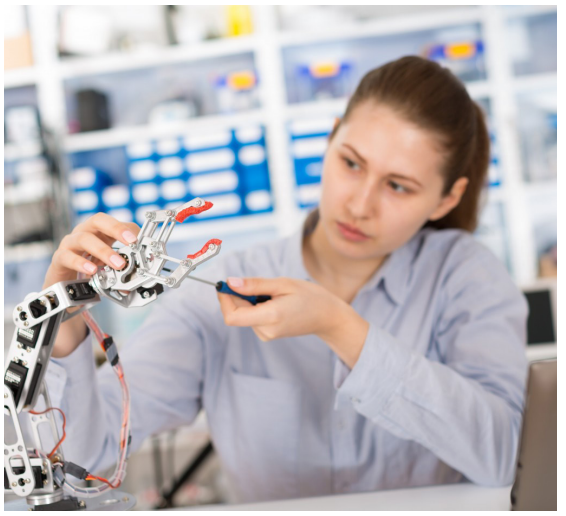
Michael Knapp, associate professor at New

Zealand's University of Otago, underlined some limitations of the research, however, including small sample size.

Inscriptions on some of the tombstones mentioned the cause of death as "mawtānā", the Syriac language term for "pestilence".

Future Focus

Researchers create Transformer-style robot that travels through body to cure disease



The technology carries payloads directly to the relevant site and is controlled by magnets

Scientists at Northwestern University have created a Transformer-style robot that travels through the human body to cure diseases. The tiny machine is controlled by magnets, carrying payloads directly to a tumour, blood clot, or infection. Set to revolutionise medicine, the 'millibot' may even come to replace pills or intravenous injections that can cause life-threatening side effects.

The researchers designed this robot crab while experimenting with mechanisms to control robots, without the need for any onboard electricity or hydraulic parts. Their movement instead relies on a metal alloy that can change shape with heat, and can then return to its original position afterwards.

According to BBC Science Focus magazine, the robots were created by engineers Professor John Rogers, Professor Yonggang Huang, and their PhD students. The devices are less than a millimeter wide, and are small enough to move around arteries and veins in the body in search of blockages. The crab's design was initially a flat sheet of a plastic polymer, with the body, legs, and chelae (or pincers) cut out. The engineers then lay the metal alloy on top of each part that they wanted to move.

The team then bent the 2D structure into a 3D robot, and its metal joints were able to remember its original flat shape.

The mechanism brings us closer to medical robots which are able to clear clogged arteries from within, or able to find and destroy cancerous tumours inside the body. However, Professor Rogers has said that the robots are not currently suitable for use in the body: "Our robots are operating in a terrestrial mode: they're walking on solid surface. But most biomedical applications will probably be in a fluid environment, where you'll need swimmers."

Contents

Words from the Editor

Hello again, *Pharmafocus* readers!

Thanks for tuning in – and welcome back to another issue.

We've got a particularly exciting issue for you this month, with *Lina Adams* and I joining forces to create a collaborative feature, providing a roundup of the recent Veeva R&D and Quality Summit we attended in Zürich. We touch upon many facets of R&D, including digital trials, end-to-end technology, data security, and patient centricity, and share insights from a number of the summit's Keynote speakers.

In terms of news, we've got some further updates on monkeypox, as well as the exciting and recently published research into the origins of the Black Death. Looking more at infectious diseases, moving from medieval to modern, we've also got insights into the importance of testing in the midst of a pandemic, from industry expert Paul Davis, GADx.

There's also the exciting news that a US cancer drug trial has appeared to achieve 100% remission in its patients. Turn to the front page to find out more about the small cancer trial, which appears to have cured every patient involved.

There's more lined up, too – hear about the stigmas of chronic kidney disease in our Patient Experience this month, or turn to our back page to look at some promising areas of research in diabetes.

Join us next time for our September issue of the magazine, and enjoy your summers!

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Hundreds of thousands to benefit from new heart attack and stroke preventative

The treatment will reduce the risk of around 425,000 of cardiovascular events

NICE has published final draft guidance for the use of icosapent ethyl in reducing the risk of cardiovascular events, such as heart attacks and strokes. The treatment has been recommended for use in adults who have raised levels of a specific type of blood fat called triglycerides.

Triglycerides form the body's main source of energy, and are essential for good health. However, too much in your blood can indicate a higher risk of cardiovascular events. It can also cause damage to arteries in organs such as the brain, heart, kidneys, and eyes.

Helen Knight, interim director of medicines evaluation at NICE, commented: "Icosapent ethyl is the first licensed treatment of its kind for people who are at risk of heart attacks and strokes despite well-controlled LDL cholesterol because they have raised blood fats. And although lifestyle changes, including diet and exercise, can help to reduce their risk, these may not work for everyone."

The recommendation means that around 425,000 people could now benefit from the first licensed treatment shown to reduce the risk of heart attacks and strokes in people with controlled low-density lipoprotein cholesterol (LDL-C, which is also sometimes referred to as "bad" cholesterol), who are taking a statin and who have raised levels of triglycerides.

Knight continued: "We have worked closely with the company to identify the population most likely to gain the greatest benefit from icosapent ethyl, striking a balance between effectiveness and the best use of public funding, delivering maximum value to the taxpayer."

Clinical trial evidence suggests that for people with raised triglycerides who have LDL-C levels controlled by statins, and who have cardiovascular disease, icosapent ethyl (also called Vazkepa and made by Amarin) reduces their risk of cardiovascular events by over a quarter, compared with placebos.

UK COVID-19 expert: Monkeypox requires 'substantial public health response'

Cases have been told to avoid physical contact and keep at least one metre away from others

Sir Andrew Pollard, who helped develop the Oxford AstraZeneca vaccine, has shared that the tropical virus outbreak does not pose the same threat as COVID-19, but that monkeypox does still require a "substantial public health response."

There are currently nearly 350 confirmed cases of the virus in England.

Pollard warned that actions are still needed to contain the disease.

UKHSA has additionally released new guidance advising households where someone has been infected to sleep and eat in separate rooms, and if possible, to use separate bathrooms.

The agency shared: "Where the use of a separate room isn't possible, cases should avoid physical contact and keep at least three steps (one metre) away from all household members. It is particularly important that they avoid close contact with young children, pregnant women, and immunosuppressed people as they may be at higher risk of serious illness."

London remains the epicentre of the virus outbreak, which has now almost reached 40 countries.

Dr Susan Hopkins, chief medical advisor at UKHSA commented: "Self-isolation is an important measure for protecting others from monkeypox. Staying at home and doing all we can to avoid close contact with other people in the household will prevent the spread of this virus. We know that self-isolation is not easy for some so it's important that people ask for support if needed."

People with monkeypox have been told they should not end their isolation until 72 hours have passed without a high temperature, all lesions have scabbed over and a fresh layer of skin has formed, and no new lesions have formed in the previous 48 hours.

The UK has recorded the most cases in the ever-growing worldwide cluster, followed by Spain (199), Portugal (166) and Canada (100).

£4bn NHS COVID-19 PPE to be burned as unusable, watchdog shares

Personal protective equipment (PPE) worth £4bn bought early in the pandemic to stop NHS staff being infected with COVID-19 is to be burned because it is unusable, a report has revealed.

The House of Commons Public Accounts Committee, a parliamentary watchdog on public spending, has accused the Department of Health and Social Care (DHSC) for England of wasting £4bn of taxpayers' money on unusable personal protective equipment in the first year of the COVID-19 pandemic, and of planning to burn much of it to "generate power."

"The story of PPE purchasing is perhaps the most shameful episode in the UK Government response to the pandemic," said Meg Hillier, the committee's chair. "At the start of the pandemic health service and social service staff were left to risk their own and their families' lives due to the lack of basic PPE.

"In a desperate bid to catch up, the government splurged huge amounts of money, paying obscenely inflated prices and payments to middlemen in a chaotic rush during which they chucked out even the most cursory due diligence."

The DHSC has so much unneeded PPE that it has appointed two commercial waste firms to help it dispose of 15,000 pallets a month "via a combination of recycling and burning to generate power", the Guardian shared.

The committee has stated that the department lost 75% of the £12bn spent on PPE to inflated prices and kit that did not meet requirements. This includes the £4bn worth that will not be used by the NHS and will be disposed of.

Further, 25% of the PPE contracts are now in dispute, the committee shared. One such contract was for 3.5 billion gloves, of which there are allegations against the manufacturer of modern slavery.

The DHSC disputed some of the findings. A spokesperson commented: "A number of these claims are misleading, including the claims that we are burning £4bn of unusable PPE and that there is no clear disposal strategy for excess PPE.

"In the face of an unpredictable and dangerous virus, we make no apology for procuring too much PPE rather than too little, and only 3% of the PPE we procured was unusable in any context."

Leaked data reveals NHS will miss target for 50,000 nurses by 2024

As many as 8.5% of nurses may leave in 2024, according to projected figures

The Independent reported that Boris Johnson's key manifesto pledge to add 50,000 NHS nurses to the workforce by 2024. The publication shared that the government could miss its target by over 10,000, according to leaked NHS modelling.

Johnson's manifesto pledge had already drawn accusations of deceit as early as 2019, as the plan was revealed to include 18,500 existing nurses, who the government hoped to persuade to remain in the workforce. The pledge also included 50 million more GP surgery appointments a year.

However, the leaked data from NHS England projects that tens of thousands of nurses are expected to leave the NHS in the next two years. The leak arrives in spite of claims from Sajid Javid, Health Secretary, that in April the government was on track to meet the election promise. The Independent, however, has described the "snowball effect" of staff quitting. "Increased burnout and fatigue" due to high pressure and demands on NHS staff may lead to as many as 8.5% of nurses leaving in 2024, according to some forecast figures.

Further, leading think tanks told the publication that even if the government met its target of 50,000 nurses, the numbers may still not be enough to cope with future public demands of the NHS.

Pat Cullen, General Secretary and CEO of the Royal College of Nursing (RCN), said: "Last year alone, more than 25,000 registered nurses left the profession in the UK – a sharp rise from 2020-21. Retaining experienced staff is a major challenge for ministers.

"Official figures from the NHS only weeks ago showed that the number of unfilled nursing jobs is rising, not falling. Ministerial boasts sound increasingly hollow.

"The government has not been transparent about how it calculates its figures, and ministers are burying their heads in the sand when it comes to the scale of the nursing workforce crisis – patient safety is at risk."

£4.25 million grant for UK-wide effort to end motor neuron disease

The devastating neurodegenerative disease affects the brain and spinal cord

A group of charities and government research organisations have awarded £4.25 million in the form of a research grant, to enable motor neuron disease (MND) experts at six UK universities to begin a collaboration to end MND.

The 'MND Collaborative Partnership' will work together to find solutions addressing the problems that currently stand in the way of contemporary MND research.

"Our goal is to discover meaningful MND treatments within years, not decades," said Professor Ammar Al-Chalabi, co-director of the research programme, Professor of Neurology and Complex Disease Genetics at King's College London, and Director of King's MND Care and Research Centre. "This landmark funding will bring the UK's major MND research centres together for the first time in a coordinated national effort to find a cure. We now have a much better understanding of MND, so we must take this opportunity to accelerate development of new treatments and work together to move this knowledge into the clinic and help people affected by this devastating disease."

MND is also known as amyotrophic lateral sclerosis (ALS), and is a devastating neurodegenerative disease, affecting the brain and spinal cord. Those living with ALS progressively lose nearly all voluntary movement, and require complex care. Around half of people diagnosed with the condition die within two years.

Six people are diagnosed with MND every day in the UK, and the condition affects around 330,000 across the world. One in every 300 will develop MND. Members of the UK-wide MND research partnership will work together and pool their expertise over three years.

This effort will include developing better tests to measure MND progression, also allowing doctors to compare different drugs, support people to take part in clinical trials more easily, and to develop more robust lab tests and models of disease, to enable scientists to test theories about the disease, and a pipeline of potential therapeutic agents that could ultimately be used as MND treatments.

Currently, the only licensed drug for MND in the UK has a modest effect on extending life. However, no treatments are currently available that can substantially modify disease or cure the condition.

Polio virus detected in sewage from North and East London

Traces of the polio virus have been found during a routine sewage inspection in London. The UKHSA has consequently declared a national incident, and an investigation is now underway to protect the public, who are being urged to ensure they are up to date with their polio vaccines.

Over the past four months, the UKHSA has found the polio virus in samples collected from the Beckton sewage works, which serves a population of around four million in North and East London. Officials believe there has been some spread between closely linked individuals in the area, most likely between extended family members.

Among those particularly urged to update their polio vaccines are the parents of young children who may have missed an immunisation opportunity.

Dr Vanessa Saliba, Consultant Epidemiologist at UKHSA said: "Vaccine-derived poliovirus has the potential to spread, particularly in communities where vaccine uptake is lower. On rare occasions, it can cause paralysis in people who are not fully vaccinated, so if you or your child are not up to date with your polio vaccinations, it's important you contact your GP to catch up, or if unsure check your Red Book."

As part of routine surveillance, it is common for up to three 'vaccine-like' polioviruses to be detected each year in UK sewage samples, the government shared. However, these instances have always been one-off findings, not detected again, and the previous detections occurred when an individual vaccinated overseas with the live oral polio vaccine (OPV) returned, or travelled, to the UK. Here, traces of the vaccine-like polio virus can be 'shed'.

"We are urgently investigating to better understand the extent of this transmission, and the NHS has been asked to swiftly report any suspected cases to the UKHSA, though no cases have been reported or confirmed so far," Dr Saliba concluded.

Investigations are underway after several closely-related viruses were found in sewage samples taken between the months of February and May, 2022. The virus has continued to evolve, and is now classified as a 'vaccine-derived' poliovirus type 2 (VDPV2).

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Round-up

EMA's releases first critical medicines list for COVID-19

The EMA's Medicines Shortages Steering Group (MSSG) has now adopted the list of critical medicines for the COVID-19 public health emergency. The medicines included in the list are authorised for COVID-19, and their supply and demand will be closely monitored, aiming to identify and manage potential or actual shortages.

The MSSG was established to assist the EMA in crisis preparedness, managing medicines and medical devices in order to monitor shortages, and to ensure robust response to major events and public health emergencies. The MSSG also works to co-ordinate urgent actions on the supply of medicines within the EU.

Given the current stage of the pandemic, the published list contains all the approved vaccines and therapeutics in the EU, to prevent or treat COVID-19. It will be updated to reflect changes in the pandemic situation which may give rise to an increased risk of shortages of particular medicines, or following the authorisation of new medicines. The EMA has emphasised that the list does not replace national guidance on vaccination and the clinical management of COVID-19.

Marketing authorisation holders (MAHs) of medicines included in the list are required to regularly update EMA with relevant information, including data on potential or actual shortages and available stocks, forecasts of supply and demand.

Member States will provide regular reports on estimated demand for critical medicines at the national level. This will enable the MSSG to recommend and coordinate appropriate EU-level actions to the European Commission and EU Member States, in order to prevent or mitigate shortages of critical medicines.

Positive Phase III data released from biosimilar trial

The study aimed to determine clinical efficiency of a proposed biosimilar to Soliris

Samsung Bioepis has announced that SB12, a proposed biosimilar to Soliris (eculizumab), showed clinical equivalence in efficacy, safety, pharmacodynamics (PD), and pharmacokinetics (PK), in a Phase III trial.

The study is an ongoing randomised, double-blind, multicenter, cross-over study in 50 patients to treatment sequence I or II.

Soliris (eculizumab) is a humanised monoclonal antibody, produced in NS0 cell line by recombinant DNA technology, currently used in adults and children for the treatment of PNH and atypical haemolytic uremic syndrome (aHUS). It is also used in adults for refractory generalised myasthenia gravis (gMG), in patients who are anti-acetylcholine receptor antibody-positive.

The objective of the study was to determine clinical efficacy by evaluating the level of lactate dehydrogenase (LDH), safety, PK, PD, and the immunogenicity of SB12 and reference eculizumab (ECU). The primary endpoints were LDH level at Week 26, and time-adjusted area of under the effect curve (AUEC) of LDH from Week 14 to 36, and from Week 40 to 52.

"We are very pleased to be sharing our Phase III study of SB12, our first haematology and orphan biologic therapy, at EHA 2022," said Luke Oh, PhD, Vice President and Product Evaluation Team Leader at Samsung Bioepis. "We are fully aware that rare diseases, such as PNH, pose many unique challenges to patients and their families. We will continue our journey to transform the way biologic therapies are brought to and enhance the lives of patients, including those with rare diseases, through our pioneering and innovative use of science and technology."

UK warns of major cholera outbreak in Mariupol, Ukraine

The UK's Ministry of Defence has said that Mariupol, now controlled by Russian forces after weeks of siege and heavy bombardment, is at risk of a major cholera outbreak. "There is likely a critical shortage of medicines in Kherson, while Mariupol is at risk of a major cholera outbreak. Isolated cases of cholera have been reported since May," the UK Defence Ministry said in the latest intelligence update.

The city's exiled deputy mayor says the 100,000 people still in the city are at increasing risk of the disease.

Russia is currently struggling to provide basic public services to the population in Russian-occupied territories. Access to safe drinking water has been inconsistent, while major disruption to telephone and internet services continues.

Ukraine suffered a major cholera epidemic in 1995, and has experienced minor outbreaks since. Medical services in Mariupol are likely already near collapse: a major cholera outbreak in Mariupol will exacerbate this further.

Expressing concern over the situation, Mariupol Mayor, Vadym Boychenko, said, "Without medicine and medical care, the restoration of water supply and proper sewerage in the city will erupt epidemics."

UK defence chiefs have also said that there is likely to be a critical shortage of medicines in Kherson, another city in southern Ukraine.

Cholera is a very serious illness, which can kill within hours if left untreated. The spread of cholera is closely linked to poor sanitation facilities and unsafe drinking water, where the disease can thrive and spread. Vaccines, combined with improvements in water and sanitation, can help get cholera outbreaks under control.

Positive data from Genentech's blood cancer portfolio

Genentech, a member of the Roche Group, has presented follow-up results and subanalyses from clinical trials of its approved therapies, as well as data on investigational medicines from its broad blood cancer portfolio, at the European Hematology Association (EHA) 2022 Congress in Vienna.

Data include five-year results from the Phase III CLL14 study of fixed-duration Veclexta (venetoclax), plus Gazyva (obinutuzumab) in previously untreated chronic lymphocytic leukaemia (CLL).

After a median of 65.4 months following treatment with Venclexta plus Gazyva, results have confirmed the combination continues to be an effective fixed-duration and chemotherapy-free option for patients with previously untreated CLL and coexisting conditions.

The estimated investigator-assessed progression-free survival (PFS) rate at this follow-up was 62.6% with Venclexta plus Gazyva, and 27% with Gazyva plus chlorambucil. The estimates overall survival (OS) rate was 81.9%, versus 77%. In addition, the analysis found that 72.1% of patients in the VEnclexta plus Gazyva arm did not require another treatment for CLL in the five years following initial treatment.

The CLL14 study is being conducted in cooperation with the German CLL Study Group, headed by Michael Hallek, MD, University of Cologne.

"Blood cancers remain challenging to treat at all stages, but by improving frontline treatment options we aim to increase the likelihood of meaningful clinical outcomes for these patients," said Levi Garraway, MD, PhD, CMO and head of Global Product Development. "With these new long-term data and other studies of fixed-duration therapies in our portfolio, we are working to lessen the treatment burdens associated with long-term cancer care."

New Moderna COVID-19 vaccine five times more effective

Moderna has unveiled a new Omicron COVID-19 vaccine that it says is five times more effective at boosting antibodies compared to its previous jab. The vaccine, which would also protect against the initial Wuhan strain, may only need to be administered once a year.

The US company reported that early clinical trials showed the next-generation jab produced 9,500 units of antibody in vaccinated individuals, compared to a maximum of 1,800 units with an original booster jab.

Moderna will submit the data to regulators "in the coming weeks", and expects it to get clearance in late summer. The company has not yet requested authorisation from the FDA, though they would like to "as quickly as possible".

Paul Burton, Moderna's CMO, said: "I think for the first time we could really be looking at that potential for just once-yearly boosting, because we can get people to such a high antibody level that it will just take longer to decay."

"I think we should have good protection (against new variants) but if we had something remarkably different, we would have to pivot quickly and start producing that new vaccine."

Stephen Evans, professor of pharmacoepidemiology at the London School of Hygiene & Tropical Medicine, said: "Using different strains of virus in a single vaccine is very familiar in flu vaccines, to try and provide continuing protection when a virus is changing its characteristics, as is happening with SARS-CoV-2."

The jab must still pass regulatory tests by the MHRA, as well as being recommended by the JCVI, before it can be distributed across the UK.

Tiziana Life Sciences announces positive results with secondary progressive multiple sclerosis

A second patient has shown clinical improvements in the positron emission tomography (PET) imaging analysis, neurologic exam, and in the timed 25ft walk test, following three months of treatment with foralumab.

Thes findings are consistent with the results obtained from the first patient following three months of treatment, as previously announced in March. Foralumab – a fully human anti-CD3 monoclonal antibody – was well-tolerated, and improved clinical and PET imaging analyses.

Foralumab (formerly NI-0401) is the only entirely human anti-CD3 mAb, which shows reduced release of cytokines after IV administration in healthy volunteers, and in patients with Crohn's disease.

"We are excited about the positive clinical responses seen in 2 out of 2 SPMS patients treated so far," said Dr Kunwar Shailubhai, CEO and CSO of Tiziana Life Sciences. "Clinical data from both patients further validate our novel intranasal therapy with foralumab, which seems to overcome the blood-brain barrier to allow therapeutic action of the drug."

Dr Howard Weiner, MD, Director of the Multiple Sclerosis Program at BWH and Chairman of Tiziana's Scientific Advisory Board, commented: "We are very pleased by both the biological and clinical improvement observed in the second patient, after treatment with intranasal foralumab for three months, which provides confirmation that the intranasal dosing modulates the systemic immune response, and in turn dampens brain inflammation. It is encouraging to see the consistency of response between the first and second patient, and that the treatment was well tolerated."

"Therapies to slow progression in multiple sclerosis are much needed, as there are only a few options for non-active SPMS," added Tanuja Chitnis, MD, Principal Investigator and Professor of Neurology at Harvard Medical School (HMS) and senior neurologist at BWH and Massachusetts General Hospital. "I look forward to treating more patients under this same protocol."

Round-up

FDA approves measles vaccine

The FDA has approved Priorix for active immunisation for the prevention of measles, mumps, and rubella (MMR) in individuals 12 months of age and older.

Priorix is currently licenced in more than 100 countries worldwide, including all European countries, Canada, Australia, and New Zealand.

"Outbreaks of measles in recent years demonstrate how quickly diseases can return without widespread immunisation. Missed vaccinations during the COVID-19 pandemic makes children even more vulnerable to vaccine-preventable diseases like measles," said Temi Folaranmi, MD, Vice President and Vaccines Therapeutic Area Head, US Medical Affairs, GSK. "Making Priorix available to patients in the US will ensure healthcare professionals have more than one option for this critical vaccine as they work to catch their patients up on recommended vaccinations."

MMR are acute and highly contagious viral diseases, responsible for considerable global morbidity and mortality. In recent years, measles outbreaks have occurred in the US and globally, with more than 400,000 cases confirmed in 2019.

FDA refuses to fully review Aeglea's rare disease drug application

FDA administrators issued a refusal to file for the Aeglea BioTherapeutic's biologic, pegzilarginase, sharing the agency will not decide until the company turns over clinical data that demonstrate a treatment effect.

The therapy is for patients with arginase-1 deficiency (ARG1-D), a rare genetic disorder that can cause seizures, spasticity, and intellectual disability in untreated children.

ARG1-D is a rare recessive genetic disease that affects children, and is passed through hereditary genetics. It can lead to severe disorders if left untreated, and affects anywhere from 1 in 300,000 and 1 in 1,000,000 births.

"We intend to work collaboratively with the FDA to identify a viable path forward to demonstrate that lowering plasma arginine confers clinical benefit," said Anthony Quinn, PhD, president and CEO of Aeglea.

Malnutrition-related form of diabetes discovered

A study by researchers in New York has revealed the threat of a new form of diabetes caused by malnutrition. This is significantly different from Type 1 or 2, and should be considered a distinct form of the disease.

Patients with this form of disease are typically thin, poor teens and young adults, who rarely live over a year after diagnosis. Insulin injections do not usually help, and can even cause death from low blood sugar.

"Current scientific literature offers no guidance on managing malnutrition-related diabetes, which is rare in high-income nations but exists in more than 60 low- and middle-income countries," said study author Dr Meredith Hawkins, founding director of the Global Diabetes Institute at the Albert Einstein College of Medicine in New York City.

"The doctors in those countries read Western medical journals, so they don't learn about malnutrition-related diabetes and don't suspect it in their patients," Hawkins explained in a college news release.

"We hope our findings will increase awareness of this disease, which is so devastating to so many people, and will pave the way for effective treatment strategies."

Hawkins noted that diabetes affects 1 in 10 adults worldwide, and three-quarters of them (400 million) live in low- and middle-income countries.

"In those countries where it's been studied, the prevalence of malnutrition-related diabetes among people with diabetes is about 20%, meaning that about 80 million people may be affected worldwide."

Hawkins compared this to the "estimated 38 million people" living with HIV/AIDS in the world today, and concluded: "We clearly need to learn a lot more about malnutrition-related diabetes and how best to treat it."

COVID-19 vaccine scheme for low-income countries pushes for delivery slowdown

Leaders of the global scheme aiming to distribute COVID-19 vacacines in the world's poorest are encouraging manufacturers, including Pfizer and Moderna, to cut or slow deliveries of roughly half a billion jabs, to ensure that doses are not wasted.

COVAX, the WHO-led scheme, is asking for between 400 and 600 million fewer vaccines doses than initially contracted from six major pharma companies, according to internal documents seen by Reuters. In total, COVAX has delivered over 1.5 billion doses in the last 18 months.

"COVAX has called for manufacturers to acknowledge the global oversupply situation, and support collective efforts to meet the timing of countries' needs, and avoid unnecessary wastage," said a spokesperson for Gavi, the Vaccine Alliance, which runs the initiative alongside WHO.

"Being cognisant of local needs, we are seeking to provide pragmatic solutions to requests whenever possible," Pfizer said in a statement. Novavax said the status of its COVAX deliveries was currently 'unclear', while Moderna said it had nothing to add at this time.

66.3% of the world's population has now received at least one COVID-19 vaccine dose, but this proportion falls to 17.8% in low-income countries, according to Our World in Data.

"What is critical for the global pandemic response now is not a high volume of doses, but tailored supply and support to lower-income countries," said Gavi.

Efforts to eliminate African trypanosomiasis continue

Efforts to eliminate the disease known as African trypanosomiasis are continuing to show strong progress, according to WHO. African trypanosomiasis, also called 'sleeping sickness', is endemic in 36 sub-Saharan African countries.

The progress aligns with WHO's 2030 road map targets for the control, elimination, and eradication of neglected tropical diseases.

Human African trypanosomiasis is caused by parasites of the Trypanosoma genus. It is transmitted by infected tsetse flies, which are found in sub-Saharan Africa, and has two principle forms, known as gambiense and rhodesiense. Trypanosoma brucei gambiense accounts for around 97% of reported cases of the disease. Equatorial Guinea has now been validated by WHO as being the latest country to eliminate the gambiense form of the disease as a public health problem within its borders.

The general incidence of the gambiense form of the disease has reduced sharply this century, with 750 cases being reported in 11 endemic countries in 2021, a figure representing a 95% reduction of cases, compared to the figure of 26,095 cases in 2001.

Symptoms of African trypanosomiasis include fatigue, high fever, headaches, and muscle aches. Further, if the disease is not treated, it can cause death. People who are bitten by a tsetse fly can get the parasite which causes this disease.

Diagnosis and treatment of African trypanosomiasis is complex, and requires specifically skilled staff. There is no vaccine or medicine that prevents the disease, rather, those living in endemic regions or travelling to them can protect themselves by preventing bites from tsetse flies. This can be achieved through covering exposed skin, avoiding bushes during the day, and inspecting vehicles for flies before entering.

Those most exposed to the fly and the disease live in rural areas, and depend on agriculture, fishing, animal husbandry, or husbandry.

New genetic eye disease discovered

Researchers from the National Eye Institute (NEI), part of the National Institutes of Health, have identified a new disease that affects the macula. The new type of macular dystrophy is a cause of central vision loss.

The macula is a small part of the light-sensing retina needed for sharp, central vision. Macular dystrophies cause central visual loss, due to mutations in several genes, including ABCA4, BEST1, PRPH2, and TIMP3.

"We found it surprising that two patients had TIMP3 variants not in the mature protein, but in the short signal sequence the gene uses to 'cut' the protein from the cells. We showed these variants prevent cleavage, causing the protein to be stuck in the cell, likely leading to retinal pigment epithelium toxicity," said Bin Guan, PhD, lead author.

Rob Hufnagel, MD, PhD, senior author and director of the Ophthalmic Genomics Laboratory at NEI, elaborated: "Discovering novel disease mechanisms, even in known genes like TIMP3, may help patients that have been looking for the correct diagnosis, and will hopefully lead to new therapies for them."

NEI's Ophthalmic Genomics Laboratory gathers and manages specimens and diagnostic data from patients who have been recruited into multiple studies within the NEI clinical program, to facilitate research of rare eye diseases. This includes Sorsby Fundus Dystrophy, which causes similar symptoms to age-related macular degeneration (AMD), though it generally affects patients at a younger age.

"Affected individuals had scotomas, or blind spots, and changes in their maculas indicative of disease, but, for now, they have preserved central vision and no choroidal neovascularisation, unlike typical Sorsby Fundus Dystrophy," said Cathy Cukras, MD, PhD, a Lasker tenure-track investigator and medical retina specialist who clinically evaluated the patients.

Simple eye exam could predict heart attack risk

Researchers have found that patterns of blood vessels in the retina could help identify individuals at risk of experiencing cardiac problems, according to The Guardian.

The researchers were able to identify participants' myocardial infarction (MI) through a simple, non-invasive eye examination, combined with other information.

A heart attack, or MI, is a serious medical emergency in which the blood supply to the heart is suddenly blocked, usually by a blood clot. It is classified as a medical emergency.

The study revealed that variations in vascular patterns in the retina can imply the development of coronary heart disease. This disease is a precursor to a heart attack.

"The calculation of an individualised MI risk from those over 50 years old would seem to be appropriate," said Villaplana-Velasco. "This would enable doctors to suggest behaviours that could reduce risk, such as giving up smoking, and maintaining normal cholesterol and blood pressure."

The researchers used data from UK Biobank, a large-scale biomedical database and research resource, which contains the records of 500,000 people's medical and lifestyle records, to calculate a measure known as fractal dimension. This data was then combined in a model with factors such as age, sex, systolic blood pressure, body mass index, and smoking status.

The researchers studied those on the database who had experienced a heart attack after their retinal images had been collected. They commented that their model achieved its best predictive performance, over five years before the heart attack occurred.

Ana Villaplana-Velasco, a PhD student at the Usher and Roslin institutes at the University of Edinburgh, UK, and the presenting author of the study, shared the following insight with The Guardian: "Strikingly, we discovered that our model was able to better classify participants with low or high MI risk in UK Biobank, when compared with established models that only include demographic data. The improvement of our model was even higher if we added a score related to the genetic propensity of developing MI."

Type 2 diabetes may speed up cognitive decline and brain ageing

Researchers have found that among older people with Type 2 diabetes, the brain appears to age at an accelerated rate, according to a study published in the journal eLife. The researchers analysed data from 20,314 people from the UK Biobank between the ages of 50 and 80.

The brain appears to age at a rate of around 26% faster than normal in patients with Type 2 diabetes, the research found, comparing neurological changes in those who did and did not have Type 2 diabetes. The researchers excluded anyone with Type 1 diabetes.

While both groups saw declines in executive functions such as working memory, learning, and flexible thinking, along with declines in brain processing speed, the declines were greater, and occurred faster among those with diabetes. Executive functions declined 13% more among those with diabetes, while brain processing speed decreased 7% more than for those who did not have diabetes. This caused an earlier cognitive decline than that seen with normal aging.

Additionally, the researchers observed the most severe neurocognitive events in participants who had the longest duration of Type 2 diabetes.

"The findings are consistent with other studies in the field, and highlight the idea that metabolic disease and lifestyle factors that influence its prevalence may be important targets for reducing the burden of age-associated cognitive loss," commented Dr M Kerry O'Banion, MD, PhD, Professor of Neuroscience at the Del Monte Institute for Neuroscience at the University of Rochester, US, speaking to Medical News Today.

The researchers additionally compared their results with those form 94 published studies. The researchers analysed abstract reasoning, executive function, processing speed, reaction time, and numeric memory data. They used MRI scans to assess the atrophy of grey matter, a major component of the central nervous system, in both those living with Type 2 diabetes, and a control group.

The researchers emphasised that the findings of the study underline the importance of better diagnosis and treatment strategies, targeting the cognitive effects of Type 2 diabetes.

Eagle Pharmaceuticals completes $104 million acquisition of Acacia Pharma

The acquisition will save the Cambridge company from the threat of insolvency

Acacia Pharma shareholders have voted to accept a $104 million rescue deal by New Hearsey-based Eagle Pharmaceuticals. The move adds two US FDA approved new chemical entities, with strong patent protection, to Eagle's arsenal.

The acquisition additionally saves the Cambridge company, Acacia, from the threat of insolvency.

"The closing of this transaction is a great achievement for Eagle, both strategically and financially. The addition of the two products expands our presence in the acute care space, and we believe that our highly capable hospital-based salesforce will have great success commercialising these assets. We believe BARHEMSYS and BYFAVO represent two compelling opportunities, as both address significant unmet clinical needs," stated Scott Tarriff, President and CEO of Eagle Pharmaceuticals.

Scott Tarriff, President and CEO of Eagle Pharmaceuticals, led the rescue deal after Acacia shared that it had to find an estimated $115 million in order to break even by early in the financial year of 2025. In spite of the potential of its pipeline, the company stated it had been hit significantly by COVID-19-triggered cancellations of surgery at hospitals.

"The acquisition of Acacia Pharma should not only help improve the care of patients undergoing medical treatments, but also solidify our leadership position in the hospital and oncology space, and bring long-term value to our shareholders," concluded Tarriff.

The two FDA-approved products of Acacia are BARHEMSYS and BYFAVO. BARHEMSYS is the first and only antiemetic approved by the FDA for rescue treatment of postoperative nausea and vomiting despite prophylaxis (PONV). It is also approved for the treatment of PONV in patients who have not received prophylaxis, and for the prevention of PONV.

Eagle is a fully integrated pharmaceutical company with research and development, clinical manufacturing, and commercial expertise. Its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states.

Bristol Myers Squibb to acquire cancer drugmaker Turning Point for $4.1 billion

Bristol Myers Squibb (BMS) has announced it will acquire oncology firm Turning Point Therapeutics in a $4.1 billion merger, expected to be completed in the third quarter of 2022. The company will gain Turning Point's lead asset, repotrectinib, aiming to treat lung cancer and solid tumours.

The boards of directors for both companies unanimously approved the deal. BMS will pay $76 per share for Turning Point. The deal is set to boost BMS' oncology portfolio, which was initially expanded by the $74 billion acquisition of cancer specialists at Celgene Corporation in 2019. Turning Point focus on oncogenesis, or the process in which healthy cells turn cancerous.

"The acquisition of Turning Point Therapeutics further broadens our leading oncology franchise by adding a best-in-class, late-stage precision oncology asset. With this transaction, we are continuing our strong track record of strategic business development to further enhance our growth profile," said Giovanni Caforio, CEO at BMS.

Repotrectinib is a next-generation tyrosine kinase inhibitor (TKI), and Turning Point's lead asset. The TKI can target the cancer-causing drivers of non-small cell lung cancer (NSCLC), as well as other more advanced solid tumours. Repotrectinib has already been granted three breakthrough therapy designations from the FDA, and BMS has shared that it hopes to see the inhibitor become a "new standard" of care for individuals with ROS1-positive NSCLC in the first line setting.

"With Bristol Myers Squibb's leadership in oncology, strong commercial capabilities, and manufacturing footprint […] we will be able to harness the full potential of our precision oncology platform to advance the standard of care for cancer patients," commented Athena Countouriotis, president and CEO of Turning Point Therapeutics.

Countouriotis outlined further that, with BMS' oncology lead and manufacturing capabilities, Turning Point will be enabled to provide and reach patients diagnosed with cancer around the world.

Astorg to acquire med comms platform OPEN Health

The acquisition will aim to build on OPEN Health's leading service offerings

Astorg and Amulet Capital Partners have announced the signing of a binding agreement, through which Astorg will acquire OPEN Health. Astorg will actively support and accelerate OPEN Health's next phase of growth and innovation.

OPEN Health is a leading global provider of scientific communications and market access services to the pharmaceutical industry, established in 2011. The platform is a key partner to its customers in helping them to develop strategies for evidence generation and data communication. OPEN Health has over 1,000 employees in 15 locations and six countries, across North America, Europe, and Asia.

"We are excited to build on the momentum across our business and to continue executing with our new partners at Astorg on a shared long-term vision to bring deep scientific solutions that support our clients in driving positive health outcomes," said Rob Barker, CEO, OPEN Health. "We are grateful for the strong partnership of the Amulet team over the last three and a half years, and for all that we have accomplished in expanding our industry-leading capabilities across disciplines. We continue to be very well positioned to drive innovation and growth, and we look forward to embarking on this next chapter for OPEN Health."

Astorg will aim to build upon OPEN Health's leading service offerings, investing in the development of the business across its main existing offerings and beyond.

Ramsey Frank, President and Managing Partner of Amulet, said, "OPEN Health was built around Amulet's investment thesis in medical affairs: the current generation of drugs is fundamentally different from prior generations, and these therapies need to be brought to market with the support of high science communications and data analytics. We brought OPEN Health together very intentionally, via three acquisitions, to create a purpose-built suite of services to meet pharma's evolving needs."

REGENXBIO opens gene therapy manufacturing facility

REGENXBIO, a clinical-stage biotechnology company, has opened a $65 million Manufacturing Innovation Centre gene therapy manufacturing facility at their campus in Rockville, Maryland, US.

Located in REGENXBIO's 132,000 square foot headquarters in Rockville, Maryland, the state-of-the-art good manufacturing practice (GMP) will implement the company's NAVXpress platform suspension cell culture process.

"In-house manufacturing is a key differentiator for REGENXBIO as a leader in gene therapy," said Curran Simpson, Chief Operations and Technology Officer at REGENXBIO. "Quality manufacturing is crucial to all stages of AAV gene therapy development, and we're extremely proud of this cutting-edge facility and the experienced team we have to lead these efforts. Bringing our manufacturing in-house allows us to control the process from beginning to end, and provides flexibility to support a wide range of clinical and commercial needs."

REGENXBIO aims to improve lives through the curative potential of gene therapy. The company's NAV Technology Platform, a proprietary adeno-associated virus (AAV) gene delivery platform, consists of exclusive rights to more than 100 novel AAV vectors, including AAV7, AAV8, AAV9, and AAVrh10.

In preparation to establish end-to-end capabilities in gene therapy, from research and early development to commercial-ready manufacturing, the company has hired 200 people over the past two years.

"Launching operations at our Manufacturing Innovation Center is an important milestone in the evolution of REGENXBIO," said Kenneth T. Mills, President and CEO of REGENXBIO. "We believe our in-house manufacturing capabilities will enable us to rapidly transition production processes across the product lifecycle, and efficiently advance new AAV Therapeutics from research and early development to clinical programs to commercial readiness, and into the hands of patients who may benefit from these potential one-time administration therapies."

Seqiris completes $156 million expansion for influenza vaccine production

The pre-filled syringe line has already received FDA approval

Seqiris has announced the completion of an expansion to the company's manufacturing facility in Holly Springs, North Carolina, US, supporting the formulation and fill-finish of its cell-based influenza vaccines in pre-filled syringes for global communities.

Seqiris is a global leader in influenza prevention, and the expansion will enhance the site's ability to respond to an influenza pandemic. The expansion began in 2018, and will support over 80 additional highly skilled jobs in the Holly Springs community.

"According to the World Health Organization (WHO), seasonal influenza can lead to up to 650,000 deaths globally each year," said Steve Marlow, General Manager, Seqirus. "As one of the world's leading influenza vaccine manufacturers, we're continuously looking for opportunities to advance capabilities and support efficient, sustained supply of new and existing technologies. Today's milestone is evidence of that commitment."

The new pre-filled syringe line has received FDA approval, and will support influenza vaccine production for the 2022/23 Northern Hemisphere season and beyond. The expanded manufacturing facility and new pre-filled syringe line will allow Seqiris to increase its capacity to supply the US market with FLUCELVAX QUADRIVALENT (influenza vaccine), the first and only cell-based quadrivalent influenza vaccine in the US for individuals six months of age and older.

"As demand for differentiated influenza vaccines grows, it is paramount that we expand our manufacturing capacity," said Dave Ross, Vice President, North America Commercial Operations at Seqirus. "This new line gives us the ability to more efficiently streamline our production process, allowing us to better meet the needs of our customers and, in turn, better meet the needs of public health."

The Holly Springs manufacturing facility is the largest cell-based influenza vaccine producer in the world, and the first of its kind in the US. The facility expansion enhances the site's regular seasonal influenza vaccine production, as well as to surge production to respond to a potential influenza pandemic.

Astellas opens $100 million US-based production plant

Astellas Pharma has completed construction of $100 million gene therapy manufacturing plant located in Sanford, North Carolina, US. The facility will support clinical- and commercial-scale manufacturing of adeno-associated virus (AAV) vectors for gene therapies.

The new 135,000 square foot facility is a standalone facility expected to create 200 new jobs, Astellas shared.

"Our new manufacturing facility symbolises our company's continued dedication to the advancement of novel life-changing gene therapies for patients with severe diseases and a significant unmet need, as well as our commitment to the Sanford community," shared Mathew Pletcher, an Astellas senior vice president and division head of Gene Therapy Research and Technical Operations at Astellas Gene Therapies.

Astellas Pharma is a Japanese multinational pharmaceutical company. The company's $100 million investment in the site will support global supply chain needs, and in-house quality control testing. The move represents part of Astellas' push into gene therapies, which has also included a $120 million down payment on Xyphos.

Xyphos, an early-stage biotech, has engineered the NKG2D receptor to be inactive until it comes into contact with a bispecific, a trigger the company intends to use in CAR T therapies.

The completion of the manufacturing facility also follows a $20.5 million partnership with GO Therapeutics, to develop antibodies with high affinity to two different targets.

Speaking further on the new production plant, Pletcher continued: "This new facility is a key enabler of our mission to develop safe, effective, and transformative gene therapies as swiftly as possible. Sanford's manufacturing capabilities will allow us to produce materials for multiple programs in parallel, as opposed to in sequence, and offer commercial-scale manufacturing ability to any future approved therapies."

YouTube feature could help users find credible health information online

The feature will allow certified sources to display health source information panels on videos

YouTube has launched a new feature which will help people in the UK find credible health information online. Health source information panels will be displayed on videos which have been certified as coming from an authoritative source, according to news site Digital Health.

Garth Graham, head of YouTube Health, has said that "only health organisations with government accountability could potentially be eligible" to have their videos verified. He added that these organisations will have to "self-certify against NHS standards for creating health content," in order to have a health information panel displayed on the content.

Graham shared that the launch of the panels reflects a shift in the way people want to access health information:

"Gone are the days that people are just looking to get their information from a flyer or a billboard, people are getting information in a lot of unique ways, including from platforms like YouTube and others.

"So, we need to think about the quality of the health information, how easy it is to understand and how engaging that information is overall."

Dr Tim Ferris, Director of Transformation at NHS England and Improvement, also said: "There is something really special and different about the transmission of health information via video, than the classic 'being handed a piece of paper as a patient as you walk out' with factual information, often written in a way that is not as accessible."

Dr Ferris also said the NHS "wants to ensure that patients can access trusted content whenever and wherever they are looking online" – adding that the intention is to "expand the options and sources going forward".

Smart technology can halve the risk of asthma attacks and prevent deaths

Research from the University of Auckland, New Zealand, has found that smart technology could halve asthma patients' risk of suffering attacks and being admitted to hospital, therby preventing deaths.

During a decade-long study involving almost 15,000 patients, University of Auckland school of pharmacy senior clinical research fellow, Dr Amy Chan, worked with researchers from University College London and Queen Mary University of London to examine 50 years of research on asthma.

They found that smart technologies, including automated text messages and electronic prompts, made a significant difference in asthma control. This is expected to play a significant role in preventing unnecessary deaths.

"Digital technologies that aim to improve medication-taking can increase people taking their medication in the way it has been prescribed by 15%, and improve asthma control and quality of life," commented Dr Chan.

"Most people with asthma are hospitalised because of poor control; by having regular medication taking, it will reduce the risk."

With one in eight New Zealand adults and one in seven children taking medication for asthma, Dr Chan shared that the technologies were "life-changing" for many.

"Not only does medication-taking every day make a difference, it can save lives. The key message to digital technologies, they need to integrate it, because it does work and helps with control."

"Asthma attacks are still the main cause of loss of life from asthma and loss of quality of life.

"At the moment, we don't have any good tools that can predict when someone will have an attack."

Somerset NHS Foundation Trust uses AI to halve time in key lung cancer stage

Somerset NHS Foundation Trust has become the first in the UK to study the performance of an AI algorithm for detecting lung cancer from X-rays. The trust has been testing whether Behold.AI can help it meet its national targets for lung cancer diagnosis.

"There's been a lot of buzz about AI at radiology meetings, but there's little experience of using it in an NHS trust," shared Dr Paul Burn, Consultant Radiologist at the Trust. "We embarked on a bottom-up initiative to test the algorithm, with the aim of helping us improve our referral times."

"We have a fairly elderly patient population, which may make it harder for AI imaging solutions to be effective because of a higher incidence of abnormalities that show up on X-rays, such as scarring and calcifications," he added.

By prioritising which X-rays need urgent attention from a radiologist, the AI helped reduce the time from chest X-ray to CT scan from seven to 2.8 days, supporting the trust to meet its 28-day cancer diagnosis target. The trust also adjusted its next-day booking pathway for CT scans, the next stage in the lung cancer referral process after an X-ray.

The Trust and Behold.AI found that of the 3,794 chest X-rays reviewed by the red dot algorithm over a three-month period, the average time for a result to enter the hospital system was 16 seconds.

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Veeva la Vida: A Roundup of the R&D and Quality Summit 2022

Pharmafocus journalists Ana Ovey and Lina Adams made their way to Zurich for Veeva's annual R&D and Quality Summit 2022. Here, they describe and unveil their reflections upon the event and what was learned

Timeline

On the 8 June, we had the pleasure of joining Veeva at their 2022 Life Sciences Summit in Zurich, Switzerland. We had the chance to speak with some prominent figures in R&D, such as Steve Guise, CIO of Roche, and Paul Attridge, Director of Regulatory Affairs at Veeva, and heard about the latest developments in digital innovation, as well as the impact that these may have on research methods.

We arrived in the late afternoon on Tuesday, and made our way to a roundtable meeting with Tim Davis, Vice President of Strategy, MyVeeva for Patients at Veeva Systems, and Jim Reilly, VP, Development Cloud Strategy, who spoke on the future of digital clinical trials. Both shared insights into how technology can enable ease of data collection, and how this can enhance patient centricity. We learnt that although COVID-19 undoubtedly pushed innovation in clinical trials, there is still a great deal more work to simplify the process of R&D through increased adoption of technology, particularly in the form of an end-to-end development cloud.

The next morning, we attended the opening keynote to the Summit and were introduced to the event by Chris Moore, President of Veeva. We then attended a zone keynote by GSK, titled 'The path to regulatory transformation', in which Paul Attridge

> **The expansion of digital clinical trials is increasingly more relevant, in the midst of the ongoing conflict in Ukraine**

expressed the importance of digitalising regulatory affairs to accelerate the often-long-winded process. One of us attended another, titled 'GSK: Scaling the vault clinical platform to accelerate R&D', while the other attended a talk from Jorge Carmona Toscano, Cross Veeva Strategy Lead, 'Laying the foundations for Clinical Trials in the digital world'.

At midday, we had the opportunity to partake in a roundtable discussion with Steve Guise, who shared how internal efficiency gains can be brought out by digital transformation.

Reflections on data management by *Lina Adams*

One of the key takeaways from our time at Veeva Summit was that new data management software is pivotal in reducing the administrative burden across clinical trials. Tim Davis and Jim Reilly highlighted that today's tools are not enough to collect patient data – the research process is slowed down because the data are all passed to a research site. In last month's issue of Pharmafocus, I wrote a feature on the importance of virtual data management, in which I highlighted that electronic data capture (EDC) currently accounts for only 20-40% of all clinical data collected, and this requires an innovative data management team to ensure transparency, integrity, and quality of data.

If everyone involved in clinical trials can use a common hub, this can help trials to run more efficiently. If there is one platform available for telehealth, symptoms, e-consent, and a patient diary, this makes for a simpler and more organised system. Phase III clinical trials typically take between 24-36 months to complete; if this can be fast-tracked, then products can be shipped off to regulatory boards quicker, meaning that patients can receive them faster. Routine visits can be made virtual, and patients are encouraged to report symptoms as frequently as they can. Veeva is hoping to cut this process down to 5-6 months.

The expansion of digital clinical trials is increasingly more relevant, in the midst of the ongoing conflict in Ukraine. Veeva is offering solutions virtually to ensure that the people of Ukraine are still receiving help.

Steve Guise also emphasised that "the infrastructure for data management was not in place before the pandemic". COVID-19 forced pharma to seek out ways of providing adequate care online, and even two years after the beginning of the outbreak, retraining and reskilling IT staff is vital in an everchanging environment. Companies like Veeva have been creating a shared platform to encourage shared solutions in data management. It is also important to bring in expertise from other industries as well. However, at a time of high inflation, companies need to allocate resources carefully, as competition for funding escalates.

Richard Young, VP, Strategy, Vault CDMS, also shared some benefits of digital clinical trials that we were not previously aware of. Prior to speaking to Richard, we were under the impression that there were significant security concerns associated with electronic data collection (EDC), which may have deterred patients from participating in virtual trials. However, Richard reassured us that since EDC is anonymised, without names or any identifiers, patient data are safe and secure. They even get assigned a unique number.

Even in regulatory affairs, digitalising data management will keep patient centricity at the top of the list, as their experience needs to be optimised. Paul Attridge put it simply, "We need to improve the transfer of information." As it stands, regulatory operations are difficult to govern, and there are better ways to improve processes and data management. In addition, the process is only going to become more disconnected as agencies place greater demands on clinical trial runners to supply them with the information, and there is a lack of clarity as to how they will manage and interpret that data. Automation is, therefore, more important than ever in reducing the workload of workers in regulatory organisations, and streamlines the publishing process.

Paul Attridge also stressed the need to "harmonise, optimise, and simplify", stating that traceability and data functionality should be combined into a single platform. Veeva is not the only company who are exploring this, and as we discussed in last month's feature on the benefits of technology in data collection: platforms such as Florence eConsent also aid with participant management, allowing leaders of clinical trials to monitor the status of participants' informed consent in real time. The system can also enable remote participant identity verification, update to the latest consent versions for new protocol amendments, and distribute and track re-consenting in the same application.

Digital trials still have some notable drawbacks. For example, a patient may be asked to perform tests multiple times a day and check their vital signs themselves. This depends on getting the right kits to the right patients at the right time. Trial service providers can work with experienced providers to accelerate timelines and help deal with logistical challenges, as at-home testing requires careful logistics management, particularly for large-scale studies.

Nevertheless, virtual trials offer a more streamlined approach than traditional trials, saving valuable time by removing the necessity for in-person visits to sites, and therefore easing the burden on HCPs and improving the patient experience.

Patient centricity with *Ana Ovey*

Ensuring a better and more meaningful patient engagement, which will result in better patient outcomes and standard of care, begins in developing a new concept of a clinical trial. This was the position of Tim Davis, Vice President of Strategy at Veeva, and Jim Riley, who on Tuesday afternoon highlighted that a streamlined interface, and end-to-end development cloud, can improve pharmacovigilance, patient engagement, efficiency, and patient outcomes. The aspect of streamlining the technology involved in trials and data collection is vital, they explained, as multiple technologies cause inefficiencies at multiple stages of the trials, and translations across multiple formats.

Currently, across the board in healthcare, technologies are not integrated, with patients having to navigate multiple apps, interfaces, and platforms. There is pressure for both patient and physician to become fluent in all of these, and multiple technologies means more training for those working in healthcare. It also means translating data across different systems and platforms – all of which creates lags in giving the best possible care to the people who need it.

In our interview with them, Davis and Riley outlined that in spite of calls to do so, attempting an increased model of decentralised trial would therefore be inefficient, if we were to attempt to accomplish it through today's tooling. This was highlighted by the pandemic's impact on R&D, which necessitated a greater focus on decentralised clinical trials, and for a time required changes beyond the capacity of what digital platforms available were able to handle. The lack of streamlined technology ready for a decentralised model meant lags in both COVID-19 trials, and in non-COVID trials.

David and Riley shared that streamlined technology would reduce the amount of time it took to bring effective medicines to patients. Further, in the face of another pandemic, an end-to-end development cloud could ensure an even faster response and delivery of innovative medicines. In fact, it was put forward that using such end-to-end technology to streamline R&D could shave 2-6 months off Phase III trials – a reduction of as much as 25%.

There are drawbacks, however, such as the question of data security and ensuring strong patient engagement in remote healthcare. Patient trust is also complicated by the introduction of potential cybersecurity concerns.

However, more positive implications exist for the long-term R&D into new treatments and management of rare diseases, extending into easier genotyping and sample management. Further, the introduction of this technology allows the delivery of healthcare to conflict areas, such as cloud technology for patients in Ukraine.

We went on to interview keynote speaker, Steve Guise, CIO of Roche, who elaborated further on these themes. Describing "the digital augmentation" of medicines, Guise shared: "When we launch a medicine, often we'll have a companion diagnostics tool for testing, but increasingly, we'll also have a digital tool that will help patients monitor their disease, track outcomes, and interface with a physician, potentially. We ask, by disease area, what are the kind of functionalities that we want to bring to patients? Then there's a new arm to the business developing, which is in the space of insights. It's a small entity at the moment, which contains data and clinical decision support capabilities, and that's something that we will grow in the coming years."

Guise also underlined that the use of such technology could

reallocate resources into drug discovery, with significant implications for current global issues, such as antimicrobial resistance, rare disease treatments, and future implications for the tackling of future pandemics and emerging infectious diseases. The system can also be used to share best practices, reduce time, and reduce cost.

However, a few drawbacks exist, including the fact that a shift to cloud-based technology in healthcare would require potentially significant reskilling, and this training may also take time. Guise elaborated on other barriers to the process:

"The main barrier is to differentiate between digitisation and digitalisation. Digitisation I would describe as taking an analogue process and simply automating it with tools and technology. Digitalisation is fundamentally rethinking how we work, without the legacy mindset of how we worked in the analogue past. I'd say that's quite difficult for people who've been in the industry for their whole careers, reimagining how to do things from the ground up."

Guise pressed the importance of "reimagining those ways of working," and "challenging the status quo" when it comes to the use of tech in health R&D. The seismic shift represented by digitalisation certainly presents a challenge, as any complete restructuring would. But the pandemic revealed the disconnected nature of health data, which slowed the delivery of vital medicines, and the discovery of vaccinations to protect the globe against a new threat. Across the world, researchers and healthcare professionals, as well as members of the public, grappled for data that was streamlined. This included insights into infection rates, deaths, recovery rates, transmission, and more.

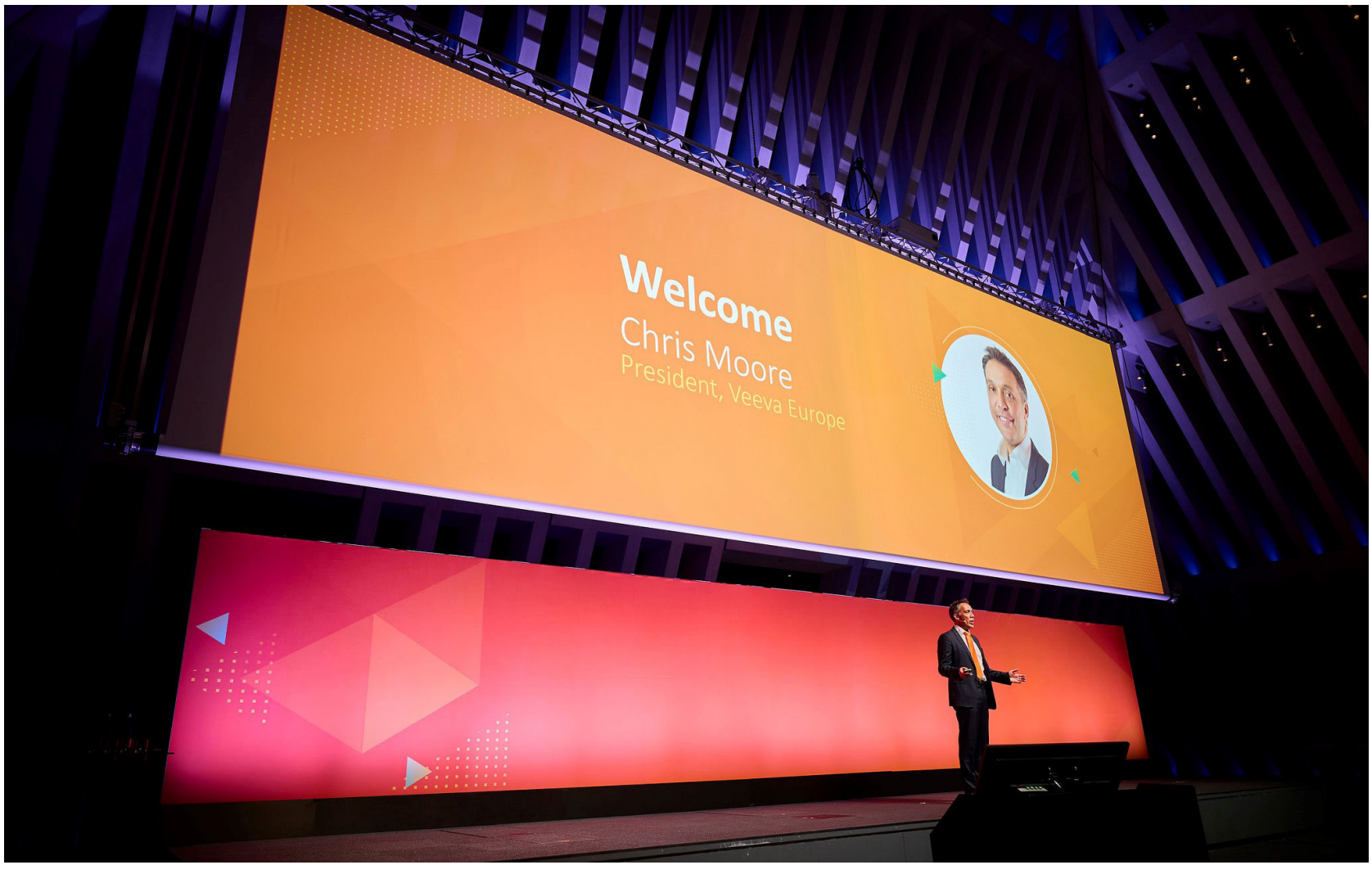
Other areas of need for a more remote and streamlined healthcare are consistently emerging, too. As highlighted by Davis and Riley in our earlier interview, the use of cloud technology in conflict areas could deliver significant results in areas of high patient need, including Ukraine and Russia: "We've worked very hard from an IT perspective to ensure that all of the systems that we make available in Ukraine and in Russia are still fully functioning and available, and they are. We run a lot of clinical trials in Ukraine, for example, that's been difficult to maintain because shipping clinical supply into the country is hindered. And of course, people are not as engaged in being part of a clinical trial as they would have been. We're trying to maintain that we continue to ship medicinal products to patients in both countries, but it's challenging. We do all that we can, and we do a lot for our employees as well. We have a big presence in Poland, and the Polish team have done a lot to help their neighbours."

Post-pandemic, there are other challenges, too. Guise shared that spending in defence, and allocation of resources, are both issues to be considered by trial designers when considering end-to-end technologies to allow for more decentralised models.

In a time of reimagining the format of R&D in a digital, decentralised age, there's clearly much to consider – even the nature and conception of clinical trials themselves. We had the privilege of hearing novel insights into an area that is under higher pressure than ever to discover and to innovate in order to bring the most efficient and effective care to patients possible. Where this idea often seems abstract and difficult to obtain, we also gained insight into what actions and changes might make it a closer reality.

Roundup

Speaking to experts in the R&D field was certainly an enlightening experience – learning firsthand about what companies like Veeva and Roche are doing to expand the digital trial network was fascinating. Each speaker at the Summit kept the patient experience at the forefront, which is vital, as the individual and their experiences can often be overlooked in the momentum of progress.



Cutting through the noise: Data science and COVID-19

Georgios Tsatsaronis, Vice President Data Science Research Content at Elsevier, illuminates the role data scientists play in the plight for new and innovative therapeutics

While artificial intelligence (AI) and machine learning (ML) have long been considered the future of research within the life science industry, real-world, impactful applications for these technologies have been limited. Like many things, this changed during the COVID-19 pandemic. The urgency that the pandemic created, coupled with advances in software and hardware, has forged the way for scientists to apply AI and deliver significant impact. Today, AI is revolutionising how data is managed and used within the life science and R&D sectors.

Data scientists play an essential role in the search for new therapeutics, and although there is an abundance of data to work with, scientific questions are becoming only more complex, while the demand for answers is becoming more urgent. To overcome the mounting pressure on research and discovery teams, the industry requires tools that can help filter and select the relevant data quickly. This is where AI and ML come in.

Keeping up with the ever-growing encyclopaedia of knowledge

In a saturated and growing data landscape, finding the relevant information to inform a discovery project can seem impossible. The timely, accurate, peer-reviewed, and efficient communication of any novel research findings is key in driving innovation. Research teams cannot be expected to read and process all the published scientific literature on a topic before setting out on their own experiments. But it is also vitally important that work is not repeated, and teams are as well-informed as possible before they undertake new projects.

Research tools need to be capable of reliably searching for and extracting only the relevant information from literature, and to provide automated results so that teams can design better-informed projects. For AI and ML tools to help, they must be able to recognise which documents are relevant. However, poorly refined models will result in unrelated papers being flagged – or worse, researchers missing out on valuable data that was mistakenly filtered out.

The COVID-19 data influx

As the research community mobilised in response to COVID-19, huge volumes of data and literature were produced in a short space of time. These resources were essential to those developing therapeutics and vaccines, but the volume and velocity of information produced made it difficult to find relevant data. As the rate of COVID-19 publications increased, so did the challenge of sifting through it.

The core needs of scientists in any area with rapidly growing amounts of data can be categorised as follows. For data to be of most value, it must be:

- Timely: Clinicians, biologists, chemists, and others interested in the data need to be able to locate answers quickly. The more time spent searching for information, the less productive researchers can be. Finding pertinent data fast can speed up treatment discovery and development times, ultimately saving lives.

- Accurate: Researchers need to be able to rely on results; inaccuracy can lead to wasted time and costs, hampering innovation, and even to potential safety issues that emerge further down the line.

- Relevant: Often, researchers come across an article that is related to their topic but has no relevance to their study. For example, an article about the financial or social impact of COVID-19 does not help those developing vaccines and treatments for the disease.

Cutting through the noise

To meet these needs, researchers need a reliable data filtration system to cut through the noise and help them locate and extract the relevant insights.

The promise of such algorithms is not limited to COVID-19. AI and ML frameworks have far-reaching potential for other diseases. While the scale of COVID-19 is anomalous, methods that facilitate more efficient literature reviews can benefit research teams working across a wide range of diseases.

Scientific literature holds the answers to researchers' questions, but thoroughly inspecting each one manually represents an insurmountable task. This hinders treatment progress, which ultimately impacts lives. It's imperative that we harness the power of evidence-based data science to overcome these challenges, and help enable timely access to answers that guide treatment decisions.

Georgios Tsatsaronis is Vice President Data Science Research Content, Elsevier

The importance of testing in the face of pandemics

Paul Davis, GADx illuminates the potential of antigen tests in fighting against future pandemics, and the importance of ensuring equal access to testing

Pharmafocus: **How might antigen tests, developed to combat COVID-19, help tackle future pandemics?**

Paul Davis: Pandemics are caused by new pathogens (or mutated versions of established pathogens) which, unexpectedly, are able to infect human beings and can easily pass from person to person. It may be that a pathogenic virus, for example, acquires a new capability (perhaps by random mutation) to establish infections in the upper respiratory tract of humans. That capability immediately opens the door to rapid spread on a global scale, as we saw in the COVID-19 pandemic. Such a virus exploits not just the cosy, welcoming environment of the human respiratory tract, but also the normal social behaviour and interactions of human beings. We gather in crowds, we face people when we talk or sing; activities which launch aerosols and larger fluid droplets into the air, ready to be breathed in by other people. In addition to this, we cough and sneeze in response to the virus infection – a behaviour in which 'my pathogens become your pathogens'.

Once the ability to infect and pass from person to person has been acquired, a pandemic is on the cards. However, there are actions we can take to limit and control the spread to try to prevent this.

Antigen tests play a key role in disease management. Simple, accurate, rapid tests must be made available, so that individuals know when they are harbouring virus loads that can infect others, and can therefore change their behaviour and social interactions, to the extent that they don't pass on their infections. Behavioural changes like self-isolation, scrupulous mask-wearing, and avoiding open coughing and sneezing in public spaces can be effective in limiting spread, and can consequently reduce the likelihood of a full-blown pandemic. A positive test, properly promoted internationally, should be a powerful incentive for anyone to keep their pathogens to themselves for the limited time in which they are contagious.

How crucial have rapid diagnostic tests been in controlling the spread of COVID-19?

Properly managed, plentiful supplies of user-friendly, accurate antigen tests, have been very important components of the overall response to COVID-19. In the early days, blanket lockdown was all we had, and that helped contain the spread, but it was not enough. Self-isolation when infection is properly diagnosed is more effective and much more acceptable.

Rapid tests have been crucial in this case, as individuals must be able to diagnose themselves easily and quickly in order to self-isolate before interacting with others. Here at GADx (formerly Mologic), daily testing of everyone proved to be highly effective, with very few infections passing on in the workplace.

However, it's difficult to determine exactly which factors have brought us to the point at which COVID-19 is in decline in many nations.

What other factors are pivotal in ensuring pandemic preparedness?

Rapid rollout of vaccinations on a global scale is one of the most important factors to ensure preparedness. However, it takes time to develop vaccines, and so it's not preventative, it's reactive. To help speed this process up, procedures, scientific networks, and pre-planned coalitions for vaccine development should be put in place, as well as planned processes for manufacture, regulatory approval, and distribution.

The same goes for diagnostic tests. The particular challenge is to develop the tests extremely quickly so that they can be deployed before the pandemic has got out of control – much quicker than was possible with COVID-19. The availability of reagents can be a limiting factor in the speed of development, and so we need high-performing antibodies to be made far quicker than has ever been possible before.

Plentiful supplies of high-quality PPE, and low-cost but efficient face masks, are also important factors, and help to ensure both virus-release and pick-up are inhibited. The challenge is to encourage the use of PPE, as populations don't normally adopt mask-wearing to anywhere near the required extent to stop a pandemic.

In his new book, 'How to Prevent the Next Pandemic', Bill Gates makes a particularly important point: It's normal, essential practice to prepare for earthquakes, plane crashes, and other sorts of natural or man-made disasters by having exercises that enable key players to work through realistic scenarios and properly prepare for when the real thing happens. Nobody has been making any plans for such preparatory exercises in pandemic preparedness.

As LFTs are no longer free of charge, what impact is this having on public health?

Again, this is very difficult to discern. It seems appropriate at this time in the UK to start relaxing a bit more, with a high proportion of vaccinations, fewer hospital admissions for COVID-19 complications, and only very rare deaths. Tests should be available to those who need them (because of availability), and they should be available at low cost, whether to the state or individuals.

What is important is that continued surveillance studies are being carried on for the foreseeable future based on antigen tests. The data from these studies are used to inform government strategy, as well as to keep the public informed about the prevalence of COVID-19.

How can we ensure equitable access to antigen tests around the world?

This is a major part of our mission, vision, and purpose. Our company has been transformed into a social enterprise, so that we can address this important challenge as our highest priority. It will need us to advance the science and technology for developing high-quality but low-cost diagnostic tests, working with partners and suppliers in other companies, institutions, and academia.

To ensure that our products are made available and used properly, we will need to engage with international agencies for procurement and distribution, organisations that can provide funding and governments that can open doors, as well as provide policies and operational support.

There are huge challenges ahead, and we can't undertake our journey alone.

Paul Davis is Co-Founder and CSO of GADx. Paul has worked in immunology for 45 years and has founded or co-founded eight bioscience businesses since 2002, with Mologic being the most prominent. As GADx's Chief Scientific Officer, Paul leads the Centre for Advanced Rapid Diagnostics (CARD), funded by the Bill & Melinda Gates Foundation. Until 2002 he was as a senior scientist at Unilever Research, leading applied immunology, and is one of the inventors of the lateral flow immunoassay.

Telemedicine driving smarter healthcare solutions in wound care

Bernard Ross, CEO of Sky, shares how telehealth solutions are the way forward, saving the NHS mass amounts of funding, and keeping patient centricity at the fore

Shortly after the first COVID-19 cases were identified in the UK, many outpatient clinics were temporarily closed or scaled back to help stop the spread of the virus. Emergency department attendance fell to 52% as fears grew of catching the virus.[1] This sudden and significant change to healthcare delivery caused telemedicine consultations to become the typical route for patients requiring non-urgent care, particularly in wound care.

During COVID-19, patients suffering with chronic wounds were consulted virtually and advised on how to best treat their condition independently at home, requiring patients to become the primary caregivers to themselves. Despite COVID-19 restrictions gradually easing around the world, the move to remote healthcare – sped up by the pandemic – has continued, as patients and healthcare professionals enjoy the convenience of remote diagnosis and care.

Measuring change in healthcare

This greater reliance on remote care is the result of a societal change that extends far beyond healthcare alone. People had to quickly adapt to entirely new circumstances when face-to-face interactions were banned. For many, this left telecommunication as the only option to keep business – and life – running as usual.

For healthcare systems, the step towards virtual care was vastly accelerated by COVID-19. Telehealth solutions and technological interventions that would have otherwise taken years to implement were rolled out in months. In wound clinics – where patients are typically above the age of 70 and are therefore considered more at-risk of developing complications with COVID-19 – minimising the spread of the virus was particularly crucial.

The burden of wound

Although most chronic wound cases are not considered life-threatening, living with chronic wounds has significant negative impacts to the quality of life of patients and those who care for them. Chronic wounds can be extremely painful, and can impede a patient's ability to walk, move, and sleep at night. In some cases, the wound may itch, puss, and release an unpleasant smell, which can cause distress, discomfort, and embarrassment for patients.[2]

This ongoing pain, combined with a lack of mobility and sleep, can lead to deteriorated mental health and further physical health consequences, such as involuntary weight loss.[3] Hard-to-heal wounds are also at risk of infection which, if left untreated, can lead to septicaemia (blood poisoning), and ultimately, the potential for limb amputation.[4]

Chronic wounds are extremely common. Venous leg ulcers, the most prevalent type of leg ulcer, account for up to 80% of all cases, and affect

approximately one in 500 people in the UK.[5] This dramatically increases with age – roughly two percent of people over the age of 80 suffer with venous leg ulcers. As our population continues to age, and comorbidities associated with wounds increase (such as obesity and diabetes), chronic wounds are likely to become a greater threat to healthcare systems.

Funding chronic wound care

The burden of wound extends far beyond the physical and mental suffering it causes patients. Chronic wounds have long been associated with significant healthcare costs, both to the healthcare systems and the patients. Treatment of chronic wounds costs the NHS approximately £5.3 billion each year, and the US more than $28 billion annually.[6,7]

These costs are relative to the intensive treatment, regular consultation, and therapy required throughout the treatment of wounds. Wounds must be cleaned and dressed by qualified medical staff, and then redressed and monitored over time to examine progress. Some wounds never heal at all, and these require regular hospital visits, consuming large portions of patients' time and money.

A study by Drew et al found that between 15 and 20% of wound costs derive from material costs, such as dressings and medical gloves, while 30-35 percent is spent on nursing time (including travel for community nurses). Patient hospitalisation accounts for more than 50 percent of the overall spend on wound care.[8] Quick diagnosis and effective care pathways are even more important in reducing the number of hospitalisations.

These costs can be further exacerbated by patient adherence and concordance to prescribed venous leg ulcer compression therapy, extending the cost and time it can take to heal an ulcer.[9] Patients can also frequently be required to travel long distances to access a specialist wound care clinic, spending a substantial amount of money to attend them.

Modernising wound care with telehealth

Incorporating telehealth into wound care delivery has the potential to significantly reduce these medical and financial burdens. In wound care, asynchronous telehealth can involve taking photographs of the wound, and tracking its progression over time.[10] These images can then be uploaded into an electronic medical record and monitored by a professional who can recommend further consultation if required. Already, this makes wound consultation more accessible for patients, and would reduce the number of unnecessary hospital trips.

Real-time telehealth involves live video calling, allowing patients to communicate directly with a medical professional from their homes. This reduces the need for nurses and patients to travel, and makes consultations quicker, cheaper, more convenient, and accessible – particularly for patients living in rural areas.

Telehealth solutions could remain deeply ingrained in wound care far beyond the aftermath of COVID-19. Research from BRC predicts that by 2030 the global telemedicine market will be worth more than $459 billion, up from the $194 billion predicted for 2023.[11] However, ensuring these changes in healthcare delivery are successful requires access to the right tools, such as video calling and subsequent Wi-Fi/cellular connectivity, and medical technology devices. Crucially, it relies on a patient's ability to manage their own medicine to much higher degrees than had previously been the case.

Technology is not limitless

Patient self-management typically involves maintaining a healthy diet, exercising regularly, managing dosages of prescriptions, or monitoring vital signs like weight and blood pressure. For wound patients, exercising to promote blood flow is not always possible, particularly for elderly patients with mobility issues. During COVID-19, many patients were also tasked with cleaning and dressing their own wounds – something which requires a level of medical knowledge and skill that should be taught by a professional to achieve optimal recovery.

Although remote consultations can be effective, they lack the ability to practically demonstrate to patients how to correctly bandage a wound. Even where patients build the knowledge base to dress a wound independently, it is possible that not enough pressure will be applied to best support recovery. For venous leg ulcers, this can have significant negative impacts on the healing process.

NICE states that: "the use [of compression bandages] calls for an expert knowledge of the elastic properties of the products, and experience in the technique of providing careful graduated compression." With patient self-management, this becomes more troublesome, and risks wounds not healing properly, or healing more slowly – in some cases doing more harm than good.

Making self-management simpler

MedTech devices are aiding the effort to make wound care more self-manageable: wearable devices that are simple to use and can be self-administered in a home setting allow patients to reduce the time spent in hospital, and take charge of their own recovery. MedTech offers solutions to issues with patient independence by speeding up recovery times, enhancing comfort during recovery, and increasing mobility.

As an example, clinical data has proven that increased blood flow to the wound surface, to enhance oxygen and nutrient delivery, can significantly help to heal leg ulcers – with wounds closing in a matter of weeks, as opposed to months, or not at all.[12] Therefore, a device that promotes blood flow could help with the closure of hard-to-heal wounds. Such devices need to be simple enough for patients to apply themselves, and come with clear and concise instructions for use. If achieved, such devices could significantly enhance the care pathway, and improve recovery in the home setting.

Remaining personal

For patients with venous leg ulcers, telehealth – if executed properly – has the potential to significantly improve healthcare systems and patient outcomes. Telemedicine is more than doctor consultations by phone or video: it means considering the entire home healing process, and ensuring patients have the ability, knowledge, and resources to be their own healthcare worker. Combining remote care with MedTech equips patients with the relevant tools to take control of their own recovery, with the support of wound specialists when required.

This could have lasting benefits for patients – reducing costs and time spent travelling, while speeding up recovery. It also gives wound specialists more opportunities to advise, diagnose, and virtually treat more patients than would otherwise be possible face-to-face. If patients can recover more quickly at home, and healthcare systems can spend less time, resources, and money on patients hospitalised with wounds, a large proportion of the significant costs associated with wound care can be reduced.

Bernard Ross is CEO of Sky

Living with Chronic Kidney Disease

Hilary Rose shares her experience of living with Chronic Kidney Disease, and sheds light on the realities of stigma, diagnosis, and daily challenges for those living with the long-term condition

Could you tell us about how you were diagnosed with CKD?

I was at work one day and I had swollen ankles, I went home and also found that my stomach was swollen. I immediately went to A&E, was admitted to the gastric ward, and believed that something was wrong with my stomach.

One day at a scheduled meeting, I was asked if a student could examine me, and I agreed. One of the students reported back to the consultant, and he said that I was a kidney patient, and not a gastric patient. I was shifted over to the Hammersmith hospital renal team.

Is there a current stigma around CKD, and if so, what is its impact?

I think more in the workplace, you may have to take time off for appointments, and have regular appointments for attending clinics, etc. The impact is depression, worry, and stress, about having to approach your manager.

Do you believe there can be an improvement in how healthcare professionals, and even politicians, approach CKD?

Yes, they need to be more compassionate about our health and lifestyle.

What are the main challenges you face in your daily life?

Coping with my energy levels, and dealing with fatigue and tiredness, can be so exhausting. This is especially true when you want to achieve a goal, and you've just got no energy to do so.

Complications for CKD include

High blood pressure

Nerve damage

Anaemia

Poor nutritional health

Weak bones

Increased risk of cardiovascular disease

What are your hopes for the future, in terms of receiving more support for CKD, and enhancing research into your condition?

I got involved with a trial on living with CKD, and it was displayed through cartoon characters. It was interesting because it showed how you can do little exercises to help cope with different issues you may be experiencing as someone living with the condition. For example, it taught us how to deal with negative feelings, by taking a deep breath and expelling it slowly.

I hope this can be recommended for all Kidney patients, not only those on haemodialysis and also for PD. Continue with research and pilot programs, home haemodialysis as a must, and have membership groups where like-minded people can share their experiences.

CKD is a long-term health condition in which the kidneys are damaged and do not function as they should. This impacts the way they filter blood and remove waste products from the body. In the UK, around 3 million people are living with CKD. Currently, over 68,000 are being treated for kidney failure, or stage 5 CKD.

CKD can worsen over time, meaning that eventually the kidneys may stop working altogether, although this is uncommon. If kidney disease worsens, wastes can build to high levels in the blood, and can make those living with the condition feel sick. If kidney disease progresses, it can mean patients require dialysis, or a kidney transplant, in order to live.

Symptoms for CKD include tiredness, trouble sleeping and concentrating, muscle cramping, shortness of breath, blood in urine, and swollen ankles, feet, or hands.

Diabetes and high blood pressure are the most common causes of CKD. However, factors such as high cholesterol, kidney infections, and blockages to the flow of urine such as recurring kidney stones or an enlarged prostate, can also raise risk of the condition.

Different causes of kidney disease may also impact the kind of treatment a patient receives. Early detection of the disease can help prevent progression of CKD into kidney failure.

Move of the month

Metrion Biosciences appoints Dr Benedetta Montagnini as Head of European Business Development

Metrion Biosciences Ltd has announced the appointment of Dr Benedetta Montagnini as Head of European Business Development. The appointment follows the recent creation of a Client Services team, as Metrion expands its operations and enhanced drug discovery capabilities internationally.

Dr Benedetta Montagnini, Head of European Business Development at Metrion Biosciences, shared: "I am delighted to be joining the team at this point in its expansion. I look forward to working with both existing and new clients, and supporting the community across Europe. I have a great respect for Metrion's strong scientific focus for ion channel drug discovery, and vision for the future development of its services."

Metrion is a specialist ion channel contract research and drug discovery company. Dr Montagnini has over 20 years' experience working within the drug discovery services environment.

DFE Pharma recruits new global HR director

DFE Pharma has appointed Marie-Louise Mans as Global Human Resources (HR) Director, joining as a member of the Leadership Team. Mans is a senior HR professional, with decades of experience with global corporates.

Speaking on her new role, Mans shared: "DFE Pharma is recognised for having some of the best people in the industry working across its portfolio and I'm really looking forward to building on this reputation and continuing to do the best for our employees.

"As a rapidly growing global excipient business, expanding across many new and exciting areas in the pharma and biopharma sectors, we have many reasons why people would like to be a part of our journey. A big part of our continuing success will be how we develop and support our teams, be that leaders, researchers or business management staff."

OxSonics appoints Dr Marianna Lalla as Chief Medical Officer

OxSonics Therapeutics has announced the appointment of Dr Marianna Lalla as CMO. Marianna, a well-respected physician with significant experience in leading clinical trials, will head the company's clinical development function to drive the development of SonoTran, in combination with multiple anti-cancer therapies.

SonoTran is designed to increase the dose and distribution of anti-cancer agents within solid tumours, thereby increasing the efficacy and reducing the toxicity of these agents.

Dr Marianna joins OxSonics from UCB, where she was the Global Clinical Development lead in Translational medicine, and responsible for the development of multiple early clinical-stage products.

Dr Marianna Lalla commented: "I'm excited to join OxSonics as it starts to generate data from the ongoing first-in-man clinical trial, and I look forward to the forthcoming initiation of further SonoTran combination clinical studies.

"There is a desperate need for new technologies to address the performance limitations of current drugs, and I believe SonoTran has the potential to overcome one of the major challenges in treating solid cancers – getting more anti-cancer therapy into the tumour tissue. Its unique mechanism of action will be of great interest to potential partners looking to increase the efficacy and therapeutic index of their candidates."

Five exciting studies on diabetes

This Diabetes Week, we thought that we would celebrate five exciting studies from this year that show promise in improving support and care for patients. Clinical trials are pivotal in helping us understand the causes of diabetes, and to develop treatments accordingly, bringing us closer to a potential cure.

1. Harvard Scientists have developed a revolutionary new treatment for diabetes

Researchers at Harvard University, University of Missouri, and the Georgia Institute of Technology, all US, have proven the successful use of a novel treatment for Type 1 diabetes. The method involves transferring insulin-producing pancreas cells, known as pancreatic islets, from a donor to a recipient, without the need for long-term immunosuppressive medicines. Their method uses technology included in a US patient filed by the University of Louisville and Georgia Tech, and has since been licenced by a commercial company with plans to pursue FDA approval for human testing.

2. Study shows that diabetes linked to malnutrition is metabolically unique

Results from a recent study suggest that individuals with a history of malnutrition suffer from a distinct type of diabetes, characterised by a defect in insulin secretion. The research team studied two groups of South Indian males, and found that their secretion failure may result from decreased beta cell mass. The researchers have posited that studying this unique form of diabetes may also improve how it is treated.

3. Portsmouth University trial to help diabetics lose weight in their sleep

Researchers at the University of Portsmouth are kickstarting a trial that will see if breathing lower amounts of oxygen (hypoxia) improves blood glucose levels. Past evidence has shown that hypoxia can reduce appetite and burn more calories in people with Type 2 diabetes. The scientists are currently looking for volunteers to investigate if sleeping in a special tent, with a lower oxygen environment, is effective at improving blood glucose control and promoting weight loss.

4. Vertex releases new data on potential cure for Type 1 diabetes

Vertex first unveiled their cell therapy, VX-880, in 2021. The treatment means that while recipients would technically still have a diagnosis of Type 1 diabetes, they may not require insulin to manage their glucose levels. In the first phase of this trial, participants were given half the expected dose of VX-880, and this dose was increased as the trial progressed. Patients with Type 1 diabetes showed an astonishing improvement in reduction of insulin dose. The FDA is currently asking for more information to support the increasing of beta cells as a treatment for diabetes, but Vertex is hoping to resolve this issue as soon as possible so they can expand their clinical trial.

5. Epigenetic markers predict complications in patients with Type 2 diabetes

A new study from Lund University, Sweden, supports the notion that patients with Type 2 diabetes should be divided into subgroups and given individualised treatment, as there are distinct epigenetic differences between groups of patients with Type 2 diabetes. An epigenetic biomarker that can predict complications at an early stage makes preventative actions more feasible. The authors now need to verify their results in other population-based cohorts.

Tweet us @Pharmafocus

Do you think we'll see a cure for diabetes in the next 20 years?

Yes – 60%
No – 40%

As digital clinical trials become more prolific, are you concerned about data security issues?

Yes – 80%
No – 20%

Follow us on Twitter to keep up to date with breaking news. Tweet us and join in with our weekly pharma polls! @Pharmafocus